HHS Public Access

Author manuscript

Eye Contact Lens. Author manuscript; available in PMC 2018 November 01.

Published in final edited form as:

Eye Contact Lens. 2017 November ; 43(6): 352–357. doi:10.1097/ICL.0000000000000291.

The Infant Aphakia Treatment Study Contact Lens Experience to Age 5 years

Buddy Russell, C.O.M.T.[1], **Lindreth DuBois, MEd, MMSc**[1], **Michael Lynn, M.S.**[2], **Michael A. Ward, MMSc**[1], and **Scott R. Lambert, M.D**[1] **for The Infant Aphakia Treatment Study Group**[*]

[1]Department of Ophthalmology, Emory University School of Medicine, Atlanta, GA

[2]Department of Biostatistics and Bioinformatics, Rollins School of Public Health of Emory University, Atlanta, GA

Abstract

Purpose—To describe our experience treating a cohort of unilateral aphakic infants with contact lenses in the Infant Aphakia Treatment Study (IATS).

Materials and Methods—Fifty-seven of the 114 infants in the IATS were randomized to contact lens wear; all were followed until age 5 years, although a few had lapses in care. An examination under anesthesia (EUA), including keratometry, was performed at the time of enrollment and at approximately 1 year of age; keratometry was performed again at 5 years of age. A traveling examiner assessed visual acuity at approximately 1 year of age and again at 4.5 years of age.

Results—Twenty-four treated eyes (46%) wore silicone elastomer (SE) contact lenses, eleven eyes (19%) rigid gas permeable (GP) contact lenses and seventeen eyes (29%) wore both lens types during. Median logMAR visual acuity was +0.70 (IQR, +0.30 to − 1.20) in the SE group and 2.03 (IQR, +0.20 to − 2.28) in the GP group at age 4.5 years. The mean (± SD) keratometric power of the treated eyes was 46.3 ± 2.8 D at baseline, 44.6 ± 2.3 D at one year of age, and 44.3 ± 1.7D at 5 years of age. Keratometric astigmatism of treated eyes was 1.98 ± 1.37 D at baseline, 1.62 ± 0.98 D at one year of age, and 2.00 ± 1.00 D at 5 years of age. Thirteen contact lens related adverse events (AEs) occurred among 7 patients after age 1 year.

Conclusions—A cohort of infants with unilateral aphakia successfully wore contact lenses with relatively few adverse events.

Keywords

contact lens; aphakia; cataract; infant

Corresponding Author: Buddy Russell, Emory Eye Center, 1365 Clifton Rd, Atlanta, GA 30322, buddy.russell@emoryhealthcare.org, Phone: 404-778-5828, Fax: 404-778-5823.

[*]See Appendix 1

Proprietary interests: none

Introduction

The Infant Aphakia Treatment Study was designed to compare the visual outcomes in children who were 1 to 6 months of age at the time of unilateral congenital cataract surgery and were randomized to optical correction with contact lenses or an intraocular lens (IOL). Children randomized to IOL treatment had their residual refractive error corrected with spectacles. Children randomized to aphakia were treated with a contact lens. In previous publications we have shown that the visual results are comparable for these two treatments at both 1-year and 4.5 years of age, but significantly more of the infants randomized to IOL implantation required additional intraocular surgeries [1–3]. For this reason, it is recommended that infants undergoing surgery for a unilateral cataract during the first 6 months of life be left aphakic and be optically corrected with contact lenses. In this report, we describe the clinical findings of the children randomized to contact lens wear.

Materials and Methods

The Infant Aphakia Treatment Study (IATS) is a multicenter, randomized clinical trial comparing IOL and contact lens treatments after c unilateral congenital cataract surgery when 1 to 6 months of age. 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 previously [1]. The complete protocol for the IATS can be viewed online at (http://www.sph.emory.edu/IATS). 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; informed consent was obtained from a parent or legal guardian of all patients prior to randomization.

Study Design

The main inclusion criteria were a visually significant congenital cataract (≥ 3 mm central opacity) in one eye and an age of 28 days to <210 days at the time of cataract surgery. The main exclusion criteria were an acquired cataract, a corneal diameter <9 mm, a medical condition that might interfere with visual acuity testing at age 4 ½ (e.g., syndrome likely to impact cognitive development), an intraocular pressure (IOP) ≥ 25 mmHg and prematurity (<36 gestational weeks). Patients were randomized to have either an IOL placed at the time of the initial surgery or left aphakic and corrected with a contact lens. Patients were examined at 1 day, 1 week, 1 month and every three months after surgery until age 4 years; thereafter, visits were at 4.25, 4.5, and 5 years of age. A masked traveling examiner on all 114 subjects measured objective grating visual acuity at 1 year of age (±2 months) using Teller Acuity Cards (Stereo Optical, Chicago, Illinois); and on 113 subjects at 4.5 years of age using the subjective ATS-HOTV optotype system. Keratometry measurements using a hand-held instrument were obtained at the time of initial cataract surgery, at approximately 2 weeks prior to the visual acuity assessment at 1 year of age and at the 5-year visit using an IOLMaster or autorefractor. Caregiver diaries and telephone interviews obtained at regular intervals were used to assess contact lens wear.

Contact Lens Correction

Within one week following cataract surgery, patients randomized to the contact lens (CL) group were fitted with either a Silsoft (SE) (Silsoft Super Plus; Bausch & Lomb, Rochester, N.Y.) or a GP (X-Cel Specialty Contacts, Duluth, GA.) contact lens with a 2.0 D overcorrection to provide a near-point correction. The contact lens power was adjusted for infinity at approximately two years of age along with spectacle over correction with a straight top bifocal with a plus three add placed at the center of the pupil. Contact lenses were fitted in a clinical setting without sedation. The initial lens type and wearing modality used was at the discretion of the contact lens professional at each clinical site. Contact lens professionals participating in the study were certified by written examination. Patients were evaluated by both the surgeon and the IATS certified CL professional at each study visit. Contact lens parameter changes were made at these visits to optimize power and fit of the lens. A patient was deemed to have failed contact lens wear if the lens was worn for fewer than 4 hours per day on average for a period of 8 consecutive weeks as defined by the IATS study protocol. Patients who failed contact lens use underwent the implantation of a secondary IOL.

Contact Lens Fitting

Silsoft Super Plus contact lenses for pediatric aphakia (>20 diopters) are available with the following parameters: diameter, 11.3mm, base curves: 7.5 mm (45.00D), 7.7mm (43.75D), and 7.9mm (42.75D), optic zone of 7.0mm and powers ranging from +23.00D to +32.00D in 3D steps; the power closest to the target refractive error was selected. The Silsoft material has an oxygen permeability (Dk) value of 340, with oxygen transmissibility (Dk/t) of 58 at 0.61mm. [B+L, http://www.bausch.com/en_US/ecp/visioncare/product/softcontacts/silsoftplus_ecp.aspx accessed 10/07/15]. If an accurate refraction could not be obtained using retinoscopy, a 7.5mm BC/+32.0 D/11.3mm diameter Silsoft Super Plus lens was dispensed, and the lens power and fit were subsequently refined at the earliest opportunity. In cases in which a SE lens was not worn successfully, a GP contact lens was fitted, and vice versa. GP lenses were manufactured in Boston XO_2 (hexafocon B, Valeant Pharmaceuticals, Lynchberg, VA) with an oxygen permeability (Dk) of 141, and a transmissibility of 28 at a nominal center lens thickness of 0.50mm.

A custom designed and standardized set of aspheric, high plus, lenticulated diagnostic lenses were used for GP lens fitting; the fitting procedure has been previously described [4]. Application and removal training was provided to each caregiver along with a training video and written and verbal instructions that were confirmed at each study visit.

Statistical Methods

The median visual acuity at 4.5 years of age for patients wearing GP lenses was compared to that of patients wearing SE lenses 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 (low vision, light perception, no light perception). The mean keratometric power at ages 1 and 5 years and the mean change from age 1 to 5 years were compared between treated and fellow eyes using a paired t test. The mean change in keratometric power

between ages 1 and 5 years was compared between contact lens types using an independent group's t test. A p-value <0.05 was deemed statistically significant.

Results

Study Population and Type of Contact Lens

There were 114 patients enrolled in the study with 57 patients randomized to contact lens treatment for aphakia. The median age at cataract surgery of the CL group was 1.8 months (iIQR, 1.1 – 3.1 months), 32 (56%) were female, and 49 (86%) were white. Of the 57 patients, 2 had non-amblyopic NLP or LP vision shortly after surgery and did not require optical correction. Three received secondary IOLs between ages 1 and 5 years. Of the remaining 52 eyes who wore CLs, 24 (46%) were treated with SE lenses only, 11 (21%) were treated with GP lenses only, and 17 (33%) used both lens types and/or soft contact lenses at various points in time. Only 3 study sites routinely fitted GP lenses. Thirty-seven (84%) of the eyes that were first fitted with a SE lens, were fitted with a 7.5mm back optic zone radius (BOZR) and 11.3mm diameter; the remaining were fitted with a flatter base curve. One study site initially fitted 5 eyes with a flatter BC than the 7.5 mm option, Eight of the 37 (22%) eyes remained in the 7.5 base curve lenses while the remainder (78%) were-fit with flatter base curves over the course of the study. Of the children who completed the study wearing SE lenses, 14 were wearing 7.5 BC, 14 were wearing 7.7 BC, and 7 were wearing 7.9 BC. Nine of 21 children wearing powers ≤ +20 D at the end of the study were wearing the largest diameter available SE lens (12.5 mm).

Two patients were fitted with a Cooper Proclear soft lens when the required Rx decreased to +20 D.

Of the 41 patients wearing SE lenses between ages 1 – 5 years, 28 wore a lens on a continuous wear schedule (7–21 nights), 6 on a daily wear basis, 3 alternated between daily and continuous wear; the wear schedule was not documented for 4 patients. Two patients wearing SE lenses had their routine lens care (lens removal and/or exchange) performed by either the contact lens professional or the investigator at two different clinical sites. Children wearing a GP material wore a lens on a daily wear basis.

Three of the patients randomized to contact lens wear were deemed CL failures and secondary IOLs were implanted after the first visual acuity assessment at 1 year of age. In all 3 of these cases, the caregiver was unable to manage the application and removal of the CL. All three of these patients had worn SE lenses only.

Vision with Contact Lens Correction at 4.5 Years of Age

At age 4.5 years, the objective median logMAR visual acuity was +0.90 (IQR, +0.30 to −1.60). The SE subgroup median acuity was+0.70 logMAR (IQR, +0.30 to – 1.20). In the GP subgroup, median logMAR acuity was 2.03 (IQR, +0.20 to – 2.28) Figure 1. Thirty-three percent (33%) of the patients wearing GP lenses achieved 20/40 or better vision compared to twenty percent (20%) wearing SE lenses. (Table 1).

Keratometric Findings

The mean decrease (flatter) in keratometric power of the treated eye between the ages 1 and 5 year was −0.14 D ±0.8 D. The mean decrease in mean keratometric power between the age 1 and 5-year visits of the fellow eye was 0.06 ± 1.1 D. Of the 57 patients randomized to the CL group, 46 patients had K-readings at both the age 1 year EUA and the clinical exam at age 5 years. The mean (± SD) age at the age 1 year EUA 11.0± 0.4 months and 59.9 ± 0.7 months at the age 5 years clinical exam. The mean time between the two measurements was 48.9 ± 0.7 months. No significant change in mean central values between ages 1 and 5 years were found in the treated or fellow eye (Table 2).

The mean keratometric power difference at age 5 years compared to age 1 year was −0.06 ± 0.7 D,(n=35) in the SE treated eyes while those in the GP group were −0.4 ±1.0,D (n=11) (Table 3).

Corneal Astigmatism

The mean keratometric astigmatism at the age 5-year visit was 2.0 ± 1.0 D (n = 51; range, 0.36 – 4.03 D). The mean flat meridian was 43.34 ± 1.86 D, range 39.02 – 49.78). The mean steep meridian was 45.34 ± 1.60 D (range, 41.77 – 52.00). The change in mean keratometric astigmatism between 1Y and 5Y was 0.40 ± 1.28 D (range, −3.12 –3.38) (Table 4). Our data reveals 66% of treated eyes (n=51) had greater than 1.5 D of corneal astigmatism at 5 years of age. Approximately half (52%) of treated eyes had ≤ 2 D of corneal astigmatism while the balance (48%) had greater than 2 D at 5 years of age. Table 5

Adverse Events

There were 13 CL related AEs that occurred in 7 patients after the first postoperative year. Three eyes had more than one AE. With the exception of an in situ broken GP, all AEs occurred in eyes being treated with SE lenses and overnight wear. Two eyes had a corneal abrasion, six eyes had a single incidence of bacterial keratitis, two eyes had a single incidence of corneal ulcer, and three eyes were reported to have recurrent post-keratitis corneal opacities. The mean age at the time of the AE was 2 years 8 months (range, 1.1 – 4.4). None of the AEs were cultured, but those reported to be “bacterial” were based on resolution after the use of topical antibiotic medications. None of these eyes had visually significant sequelae.

Additional AEs in the contact lens group but not related directly to contact lens wear included 2 eyes with lens proliferation into the visual axis, 2 eyes with a pupillary membrane, 1 eye with corectopia, 9 eyes with glaucoma and 11 eyes that were glaucoma suspects [5]. One eye randomized to the contact lens arm of the study developed a retinal detachment in the early postoperative period and later developed phthisis bulbi resulting in no light perception vision. A second eye developed endophthalmitis postoperatively and had only light perception vision.

Discussion

Contact lenses were well tolerated by most children randomized to contact lens wear in the Infant Aphakia Treatment Study. During 5 years of follow-up, only three (5%) patients randomized to contact lens wear underwent the implantation of a secondary IOL. In contrast, in another series, 30% of aphakic children were reported to discontinue contact wear during early childhood [6]. The lower failure rate in the IATS may be because investigators were strongly encouraged to delay IOL implantation as long as possible. Protocol mandated trials of alternative CL types and/or aphakic spectacles preceded a request to the study Steering Committee for a secondary IOL. Finally, CLs were provided at no cost to children participating in the IATS thereby eliminating the cost of replacing lenses as a reason to discontinue contact lens wear. The majority of eyes in this study were fitted with SE lenses. The use of SE lenses for pediatric aphakia is well documented, and remains the lens of first choice for most pediatric contact lens professionals due to its ease of fitting, high power availability and excellent oxygen permeability [7–11]. Although the SE lens is available up to +32D powers, it is limited to 3D steps in power. Additionally, only three base curves are available with powers greater than 20 D with the steepest BC (7.5) equaling 45.00D. Nearly 90% of the eyes wearing SE lenses in our series were initially fitted with 7.5mm BCs, which was also the default BC selection [12]. Children wearing SE lenses frequently require refitting at approximately three years of age due to increased deposit formation requiring more frequent replacement [12]. This deposit formation may be related to lipid composition and lipid thickness changes and/or increased palpebral fissure size and blink rate compared to infants [13–15]. In our study, many children remained in SE lenses for the duration of the study. This may be due to lens replacements being provided by the study or to insignificant numbers of adverse events occurring despite the age of the child. Evaluating the fit of SE lenses requires the application of fluorescein and the use of a cobalt blue light source to determine alignment verses a flat or steep central pattern. The lens should have good centration and complete coverage of the cornea and limbus along with adequate tear exchange at the lens edge. Tight fitting SE lenses worn routinely overnight may cause increased risks [16]. All but one of the adverse events in our study was related to overnight wear with SE lenses. The cleaning/disinfection/changing of the lens was performed entirely by study site professionals for 2 patients. This may not be practical outside of a study of this type. Caregivers who are unwilling to perform application, removal and care of their child's contact lens may be better managed with an IOL. However, caregivers in the IATS IOL group reported higher levels of stress than those in the contact lens group 3 months after surgery [17]. The 5-year treatment mean total costs of an infant with a unilateral congenital cataract corrected optically with a CL in this study has been reported to be $25,331 with supply costs of $7728 compared to mean total costs of $27,090 and supply costs of $3204 in the IOL group [18]. While the total costs were higher in the IOL group, the higher supply costs in the CL group is an important consideration since these costs are often not covered by insurance policies.

The use of GP contact lenses for correction of infantile aphakia has been well recognized. [19–22] However, only 3 of the 12 sites fitted GP lenses on 12 eyes. The mean GP lens BC at baseline was 47.62 ±2.62D. At 12 months after surgery, the mean GP BC was 47.00

±3.50D. At age 5 years, the mean GP base curve was 44.31 D and the mean overall diameter was 9.4mm. Although our GP sample size is small, the mean values determined in our study represent the initial GP BC to be 1.62 D steeper than mean keratometric values at baseline, 1.87 D steeper at 12 months after surgery and identical (44.3 D) to the mean keratometric value at the five year visit. The contact lens practitioners fitting GP lenses made changes to the BC and diameter based on fluorescein pattern evaluations in a clinical setting. An optimally fitted GP lens should align with the central cornea and maintain centration over the visual axis. This evaluation is usually performed with a portable slit lamp, conventional slit lamp, hand held burton lamp or LED cobalt blue flashlight [23]. GP lenses require more time and expertise to fit, which is likely why they are used less often to correct pediatric aphakia. Only one AE occurred in the GP group related to a broken lens.

The visual acuity data obtained at both the 1 and 4.5 years of age fail to provide convincing evidence regarding which contact lens material is the best option for managing infantile aphakia. In the SE group, 20% of treated eyes developed acuity between 20/20 – 20/40 and 44% had acuity of 20/200 or worse. In the GP group, one third of the treated eyes had acuity of 20/20 – 20/40 while two-thirds had acuity 20/200 or worse. Although GP lenses are customizable to fully correct the refractive error, and SE lenses are limited to availability to 3D steps at +20D, there was not a significant difference in the visual outcome between the two groups possibly due to the small sample size of children wearing GP lenses.

The infant cornea is typically steeper in curvature than the adult cornea. The mean corneal curvature at birth has been reported to range from 47 to 48.50 D. [24–25]. With age, the globe’s radius enlarges and the corneal curvature flattens to an adult mean of approximately 43 D. Moore reported that the mean corneal curvature flattens at a faster rate in aphakic than in normal eyes [26]. In our cohort of eyes, both the treated and untreated eye demonstrated no changes in mean corneal curvature from 1 – 5 years of age suggesting the central corneal power is stable at 1 year of age.

Our study compared keratometric data obtained at the time of surgery to data obtained after an average of 8.5 months and again following approximately five years of contact lens wear. The mean rate of decrease in keratometric power was less in eyes that wore GP lenses (0.10 D/mo.) compared to eyes wearing SE lenses (0.22 D/mo.) from baseline to 1 year, although this difference was not statistically significant ($p = 0.15$). This insignificant difference may arise from a corneal molding effect from a relatively flat fitted SE lenses. It may also be that the GP lens prevents the cornea from flattening. The change in average central keratometric power from 1 to 5 years in the GP group was −0.4D (SD 1.0) and −0.06D (SD 0.7) in the SE group (p-value 0.23) was not statistically significant. (Table 3) This finding suggests the infant wearing a GP lens had more flattening of the central cornea in years 1–5 and that perhaps the GP lenses worn from baseline to year 1 were steeper fitting than those fitted in years 1–5. Longitudinal studies done after discontinuing GP wear may help to elucidate the effect of GP lenses on corneal curvature and the impact it may have on secondary IOL surgery outcomes.

We found that the cataractous eyes had steeper corneal curvatures than the fellow eyes at both 1 and 5 years of age. Trivedi and Wilson [27] reported that the corneas of cataractous

eyes of children with unilateral cataracts were significantly steeper than the corneas of the fellow eye at birth to six months of age. We found that on average the keratometric astigmatism for the contact lens wearing cohort decreased by 0.36 D in the first year of life [4]. This is consistent with another report that noted a reduction of astigmatism in children during the first year of life [28]. Our data demonstrates 66% of treated eyes (n=51) had greater than 1.5 D of corneal astigmatism at 5 years of age.

Contact lens professionals had the option to fit HEMA-based soft hydrogel lenses. Two eyes wore a Cooper Proclear 8.6 BC 14.2 DIA when the power required was +20 D or less. Custom designed high oxygen flux silicone hydrogel lenses are available in the US market. However, they were not FDA approved at the time of our initial study design. There were no eyes fitted with custom silicone hydrogel lenses in this study. Silicone hydrogel materials for infantile aphakia are the preferred soft material in Australia [29].

Ultraviolet radiation exposure damages the human eye, and has been reported to be associated with a variety of ocular disorders [30–32]. The aphakic eye is potentially more vulnerable to retina changes related to UV exposure since the crystalline lens filters UV light. SE contact lenses do not have UV protection, whereas GP contact lenses do. This is a theoretical advantage for GP lenses over SE lenses. However, there are no data to show whether this difference is clinically meaningful.

Summary

Contact lenses provide a safe and effective treatment for infantile unilateral aphakia and are the recommended method of correction during the first six months of life based on equal visual outcomes with primary intraocular lens implantation, but few adverse events. (3)

Acknowledgments

IATS would like to thank Valeant and X-Cel Specialty Contact lens for providing the lenses in this study at a reduced fee.

Supported by National Institutes of Health Grants U10 EY13272 and U10 EY013287 and in part by NIH Departmental Core Grant EY006360 and Research to Prevent Blindness, Inc., New York, New York

Appendix 1: The Infant Aphakia Treatment Study Group

Administrative Units and Participating Clinical Centers

Clinical Coordinating Center (Emory University): Scott R. Lambert, MD (Study Chair); Lindreth DuBois, MEd, MMSc, CO, COMT (National Coordinator)

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

Visual Acuity Testing Center (University of Alabama, Birmingham): E. Eugenie Hartmann, PhD (Director); Anna K Carrigan, MPH; Clara Edwards

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

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

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

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

Medical University of South Carolina; Charleston, South Carolina (14): M. Edward Wilson, MD; Margaret Bozic, CCRC, COA; Carol Bradham, COA, CCRC

Harvard University; Boston, Massachusetts (14): Deborah K. Vanderveen, MD; Theresa A. Mansfield, RN; Kathryn Bisceglia Miller, OD

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

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

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

Oregon Health and Science University; Portland, Oregon (9): David T Wheeler, MD; Ann U. Stout, MD; Paula Rauch, OT, CRC; Kimberly Beaudet, CO, COMT; Pam Berg, CO, COMT

Emory University; Atlanta, Georgia (9): Scott R. Lambert, MD; Amy K. Hutchinson, MD; Lindreth Dubois, MEd, MMSc, CO, COMT; Rachel Robb, MMSc, CO, COMT; Marla J. Shainberg, CO; Michael Ward, COMT; Buddy Russell, COMT

Duke University; Durham, North Carolina (8): Edward G. Buckley, MD; Sharon F. Freedman, MD; Lois Duncan, BS, CO, COMT; B.W. Phillips, FCLSA; John T. Petrowski, OD

Vanderbilt University: Nashville, Tennessee (8): David Morrison, MD; Sandy Owings COA, CCRP; Ron Biernacki, CO, COMT; Christine Franklin, COT

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

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

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

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

Medical Safety Monitor: Allen Beck, MD

References

1. Lambert SR, Buckley EG, Drews-Botsch C, et al. The infant aphakia treatment study: design and clinical measures at enrollment. Arch Ophthalmol. 2010; 128:21–7. [PubMed: 20065212]
2. Lambert SR, Buckley E, Drews-Botsch C, et al. 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. Arch Ophthalmol. 2010; 128:810–818. [PubMed: 20457949]
3. Lambert SR, Lynn MJ, Hartmann EE, DuBois L, Drews-Botsch C, Freedman SF, Plager DA, Buckley EG, Wilson ME, The Infant Aphakia Treatment Study Group. Comparison of contact lens and intraocular lens correction of monocular aphakia during infancy. A randomized clinical trial of HOTV optotype acuity at age 4.5 years and clinical findings at age 5 years. JAMA Ophthalmol. 2014; 132:676–682. [PubMed: 24604348]
4. Russell B, Ward MA, et al. The infant aphakia treatment study contact lens experience: one-year outcomes. Eye Contact Lens. 2012 Jul; 38(4):234–9. [PubMed: 22669008]
5. Plager DA, Lynn MJ, et al. Complications in the first five years following cataract surgery in infants with and without intraocular lens implantation in the infant aphakia treatment study. AJO. Nov; 2014 158(5):892–8.
6. Mittelviefhaus H, Mittelviefhaus K, Gerling J. Etiology of contact lens failure in pediatric aphakia. Indications for intraocular lenses? Ophthalmologe. 1998; 95:207–12. [PubMed: 9623255]
7. Cutler SI, Nelson LB, Calhoun JH. Extended wear contact lenses in pediatric aphakia J Pediatr Ophthalmol. Strabismus. 1985; 22:886–91.
8. Nelson LB, Cutler SI, Calhoun JH, et al. Silsoft extended wear contact lenses in pediatric aphakia. Ophthalmology. 1985; 92:1529–31. [PubMed: 4080326]
9. Levin AV, Edmunds SA, Nelson LB, et al. Extended wear contact lenses for the treatment of pediatric aphakia. Ophthalmology. 1988; 95:1107–13. [PubMed: 3231450]
10. Aasuri MK, Venkata N, Preetam P, et al. Management of pediatric aphakia with silsoft contact lenses. CLAO J. 1999; 25:209–12. [PubMed: 10555735]
11. Ozbed Z, Durak I, Berk TA. Contact lens in the correction of childhood aphakia. CLAO J. 2002; 28:28–30. [PubMed: 11838987]
12. De Brabander J, Kok JH, Nuijts RM, et al. A practical approach to and long-term results of fitting silicon contact lenses in aphakic children after congenital cataract. CLAO J. 2002; 28:31–5. [PubMed: 11842819]
13. Lawrenceson JG, Birhah R, Murphy PJ. Tear-film lipid layer morphology and corneal sensation in the development of blinking in neonates and infants. J Anat. 2005 Mar; 206(3):265–70. [PubMed: 15733299]
14. Isenberg SJ, Del Signore M, et al. The lipid layer and stability of the preocular tear film in newborns and infants. Ophthalmology. 2003 Jul; 110(7):1408–11. [PubMed: 12867400]
15. Lavezzo MM, Schellini SA, et al. Eye blink in newborn and preschool-age children. Acta Ophthalmol. 2008 May; 86(3):275–8. [PubMed: 17995981]

16. Keay L, Stapleton F, Shein O. Epidemiology of contact lens related inflammation and microbial keratitis: a 20- year perspective. Eye Contact lens. 2007 Nov; 33(6 PT 2):346–3. [PubMed: 17975418]
17. Celano M, Hartmann EE, et al. Parenting stress in the Infant Aphakia Treatment Study. Journal of Pediatric Psychology. 2013; 38(5):484–493. [PubMed: 23475835]
18. Kruger SJ, DuBois L, et al. Cost of intraocular lens versus Contact lens treatment after unilateral congenital cataract surgery in the infant aphakia treatment study at age 5 years. Ophthalmology. 2014
19. McQuaid K, Young TL. Rigid Gas Permeable Contact Lens Changes in the Aphakic Infant. CLAO J. 1998; 24:36–40. [PubMed: 9474452]
20. Amos CF, Lambert SR, Ward MA. Rigid gas permeable contact lens correction of aphakia following congenital cataract removal during infancy. J Pediatr Ophthalmol Strabismus. 1992; 29:243–5. [PubMed: 1512667]
21. Shaughnessy MP, Ellis FJ, Jeffrey AR, et al. Rigid gas-permeable contact lenses are safe and effective means of treating refractive abnormalities in the pediatric population. CLAO J. 2001; 27:195–201. [PubMed: 11725981]
22. Saltarelli DP. Hyper oxygen-permeable rigid contact lenses as an alternative for the treatment of pediatric aphakia. Eye Contact Lens. 2008; 34:84–93. [PubMed: 18327043]
23. Sindt CW. Fitting infants and young children with GP Lenses. CL Spectrum. Jan.2010
24. Inagaki Y. The rapid change of corneal curvature in the neonatal period and infancy. Arch Ophthalmol. 1986; 104:1026–7. [PubMed: 3729771]
25. Asbell PA, Chiang B, Somers ME, et al. Keratometry in children. CLAO J. 1990; 16:99–102. [PubMed: 2347079]
26. Moore BD. Mensuration data in infant eyes with unilateral congenital cataracts. Am J Optom Physiol Opt. 1987; 64:204–210. [PubMed: 3578486]
27. Triedi RH, Wilson ME. Keratometry in pediatric eyes with cataract. Arch Ophthalmol. 2008; 126:38–42. [PubMed: 18195216]
28. Mutti DO, Mitchell GL, Jones LA, et al. Refractive astigmatism and the toricity of ocular components in human infants. Optom Vis Sci. 2004; 81:753–61. [PubMed: 15557849]
29. Lindsay RG, Chi JT. Contact Lens Management of Infantile Aphakia. Clin Exp Optom. 2010; 93(1):3–14. [PubMed: 20070735]
30. Young RW. The family of sunlight-related eye diseases. Optom Vis Sci. 1994; 71:125–44. [PubMed: 8152745]
31. Ooi JL, Sharma NS, Papalkar D, et al. Ultraviolet fluorescence photography to detect early sun damage in the eyes of school-aged children. Am J Ophthalmol. 2006; 141:294–8. [PubMed: 16458683]
32. Cejkova J, Stipek S, Crovska J, et al. UV rays, the prooxident/antioxidant imbalance in the cornea and oxidative eye damage. Physiol Res. 2004; 53:1–10. [PubMed: 14984308]

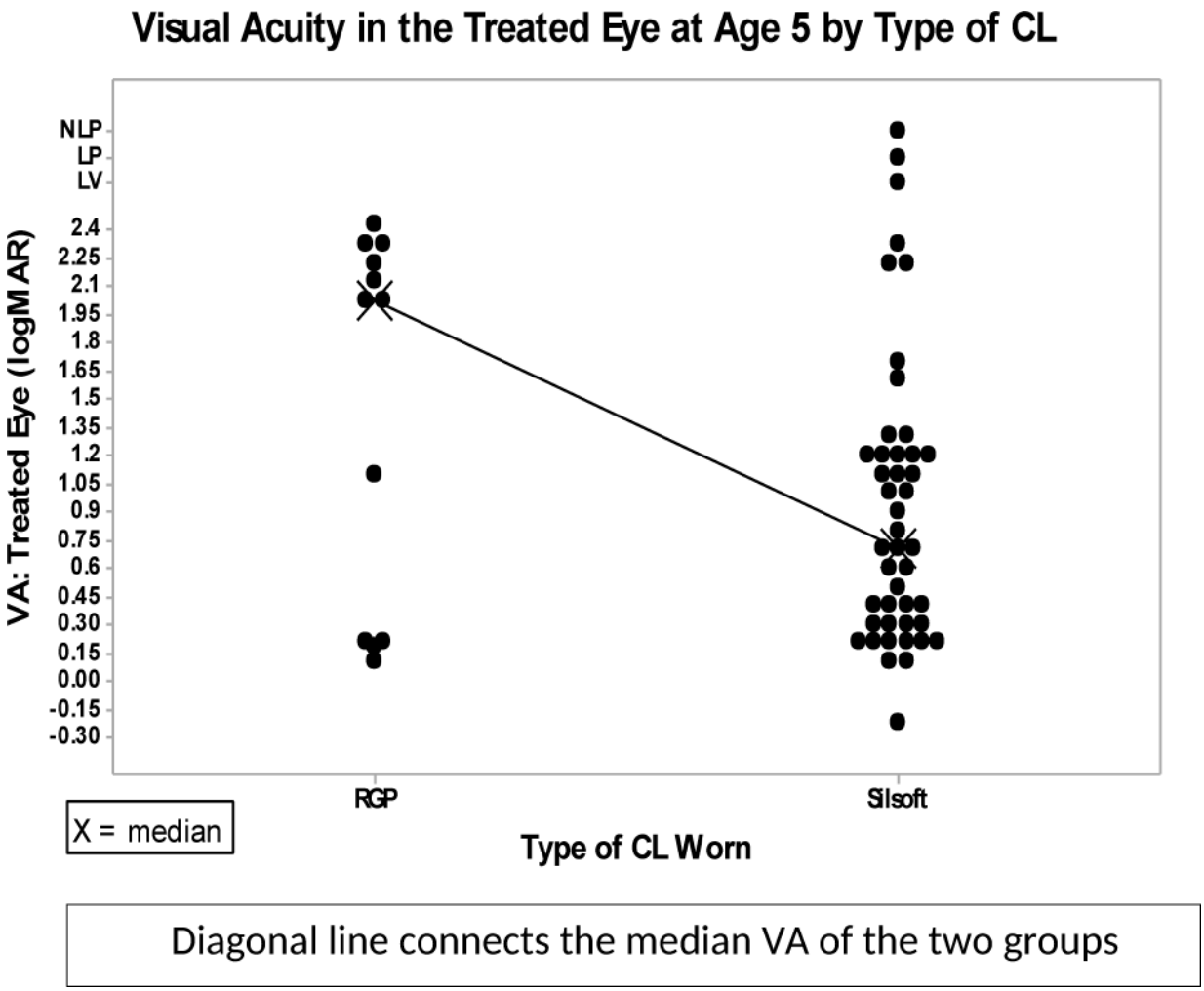

Figure 1.
Visual Acuity in the Treated Eye at Age 5 by Type of CL

Table 1

Categories of Visual Acuity at 5 year According to the Type of CL Worn

Visual Acuity	Type of CL Worn	
	RGP (n=12) n (%)	Silsoft (n=45) n (%)
20/20 to < 20/40	4 (33%)	9 (20%)
20/40 to < 20/80	0	9 (20%)
20/80 to < 20/200	0	7 (16%)
20/200 or worse	8 (67%)	20 (44%)
p-value *	**0.13**	

* The p-value for Fisher's exact test comparing the percentages in the visual acuity categories between the two groups.

LogMAR values for Snellen acuities

+0.00000	20/20
+0.30103	20/40
+0.60206	20/80
+1.00000	20/200

Table 2

Mean Central Keratometric Power (D) at 1 and 5 Years of Age for Treated and Fellow Eyes For 46 patients with Measurements at Both Age 1 and Age 5

Age	Treated Eye	Fellow Eye	Difference	p-value*	95% CI**
1 Year	44.5 (1.9)	43.5 (1.5)	1.0 (1.9)	0.001	0.4 – 1.6
5 Years	44.3 (1.7)	43.5 (1.4)	0.8 (1.9)	0.008	0.2 – 1.4
Change†	−0.14 (0.8)	0.06 (1.1)	−0.2 (1.3)	0.29	−0.6 – 0.2

Of the 57 patients randomized to the CL group, there were 46 patients who had K-readings at both the age 1 year EUA and the clinical exam at age 5 years. The mean (± SD) age at the age 1 year EUA was 11.0 ± 0.4 months and was 59.9 ± 0.7 months at the age 5 years clinical exam. The mean time between the two measurements was 48.9 ± 0.7 months.

Values are mean (standard deviation)

*The p-value for the paired t test comparing the means of the treated and fellow eyes. The difference was calculated as (Treated – Fellow).

**The 95% Confidence Interval for the difference between the means of the treated and fellow eyes.

†The change was calculated as (Age 5 – Age 1) and therefore negative values indicate a decrease in average central keratometric power.

Table 3

Change in Mean Central Keratometric Power from 1 to 5 Years of Age for Treated Eyes According to Type of CL Worn

Type of CL Worn	n	Change* in Keratometric Power (D) Mean (SD)	p-value**	Difference Between the Means of RGP and Silsoft†	
				Mean (SD)	95% CI‡
RGP	11	−0.4 (1.0)	0.23	−0.3 (0.8)	−0.9 – 0.2
Silsoft	35	−0.06 (0.7)			

*The change was calculated as (Age 5 – Age 1) and therefore negative values indicate a decrease in mean central keratometric power.

**The p-value for the independent groups t test comparing the means of the two CL groups.

†The difference between the mean changes in keratometric power of the two CL groups. The difference was calculated as (RGP – Silsoft).

‡The 95% Confidence Interval for the difference between the means of the two CL groups.

Table 4

Keratometric Astigmatism at Ages 1 and 5 Years

Age	Measure	Mean (Std Dev)	Range
1 Year (n = 52)	Astigmatism	1.62 (0.98)	0.00 – 5.00
	Steep Meridian	45.40 (2.34)	42.00 – 54.87
	Flat Meridian	43.78 (2.34)	40.25 – 53.62
5 Years (n = 51)	Astigmatism	2.00 (1.00)	0.36 – 4.03
	Steep Meridian	45.34 (1.60)	41.77 – 52.00
	Flat Meridian	43.34 (1.86)	39.02 – 49.78
Change * (n = 46)	Astigmatism	0.40 (1.28)	−3.12 – 3.38

* The change was calculated as Year 5 – Year 1 so that negative values indicate a decrease in astigmatism.

Table 5

Categories of Keratometric Astigmatism at Ages 1 and 5 Years

Keratometric Astigmatism (D)	Age	
	1 Year (n = 52) n (%)	5 Years (n = 51) n (%)
0.0 – 0.5	7 (13%)	1 (2%)
0.6 – 1.0	10 (19%)	9 (18%)
1.1 – 1.5	14 (27%)	8 (16%)
1.6 – 2.0	7 (13%)	8 (16%)
2.1 – 2.5	7 (13%)	7 (14%)
2.6 – 3.0	3 (6%)	11 (22%)
> 3.0	4 (8%)	7 (14%)