

Original Investigation | CLINICAL TRIAL

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

The Infant Aphakia Treatment Study Group

IMPORTANCE The efficacy and safety of primary intraocular lens (IOL) implantation during early infancy is unknown.

OBJECTIVE To compare the visual outcomes of patients optically corrected with contact lenses vs IOLs following unilateral cataract surgery during early infancy.

DESIGN, SETTING, AND PARTICIPANTS The Infant Aphakia Treatment Study is a randomized clinical trial with 5 years of follow-up that involved 114 infants with unilateral congenital cataracts at 12 sites. A traveling examiner assessed visual acuity at age 4.5 years.

INTERVENTIONS Cataract surgery with or without primary IOL implantation. Contact lenses were used to correct aphakia in patients who did not receive IOLs. Treatment was determined through random assignment.

MAIN OUTCOMES AND MEASURES HOTV optotype visual acuity at 4.5 years of age.

RESULTS The median logMAR visual acuity was not significantly different between the treated eyes in the 2 treatment groups (both, 0.90 [20/159]; $P = .54$). About 50% of treated eyes in both groups had visual acuity less than or equal to 20/200. Significantly more patients in the IOL group had at least 1 adverse event after cataract surgery (contact lens, 56%; IOL, 81%; $P = .02$). The most common adverse events in the IOL group were lens repopulation into the visual axis, pupillary membranes, and corectopia. Glaucoma/glaucoma suspect occurred in 35% of treated eyes in the contact lens group vs 28% of eyes in the IOL group ($P = .55$). Since the initial cataract surgery, significantly more patients in the IOL group have had at least 1 additional intraocular surgery (contact lens, 21%; IOL, 72%; $P < .001$).

CONCLUSIONS AND RELEVANCE There was no significant difference between the median visual acuity of operated eyes in children who underwent primary IOL implantation and those left aphakic. However, there were significantly more adverse events and additional intraoperative procedures in the IOL group. When operating on an infant younger than 7 months of age with a unilateral cataract, we recommend leaving the eye aphakic and focusing the eye with a contact lens. Primary IOL implantation should be reserved for those infants where, in the opinion of the surgeon, the cost and handling of a contact lens would be so burdensome as to result in significant periods of uncorrected aphakia.

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Intraocular lens (IOL) implantation at the time of cataract surgery is considered by many to be the standard of care for children 2 years of age or older in the United States.^{1,2} In some developing countries, IOLs are used almost exclusively as the primary optical correction for children following cataract surgery.³⁻⁵ In addition to its convenience, IOL implantation during childhood may be associated with better visual outcomes.⁶ However, when IOLs are implanted during early infancy, these potential advantages are offset by a higher incidence of intraoperative and postoperative adverse events.⁷⁻⁹ Additional intraocular surgical procedures are often required to treat these adverse events, which are associated with risks, costs, and parental stress.^{10,11} Furthermore, the rapid and somewhat unpredictable growth of infant eyes makes it difficult to select the ideal IOL power to implant.^{12,13} Although it is generally agreed that cataract surgery during early infancy is associated with the best visual outcomes,¹⁴⁻¹⁶ it remains undetermined whether primary IOL implantation is advisable in this age group.

The Infant Aphakia Treatment Study (IATS) is a multicenter, randomized clinical trial comparing cataract surgery with or without IOL implantation in infants aged 1 to 6 months with a unilateral congenital cataract. We have previously reported the design of the clinical trial, baseline findings, and clinical outcomes at age 12 months.^{7,9,10,13,17-23} Grating acuity was not significantly different between the 2 treatment groups.⁹ However, significantly more intraoperative and postoperative adverse events and additional intraocular operations occurred in the IOL group.⁷ Also, the mean cost of treatment was 38% higher in the IOL group,¹⁰ and parenting stress was higher among caregivers in the IOL group 3 months after cataract surgery.¹¹ This article reports the visual acuity outcomes using the HOTV test at age 4.5 years and the clinical findings at age 5 years by treatment group.

Methods

Supported through a cooperative agreement with the National Eye Institute of the National Institutes of Health, this study was conducted by the IATS Group at 12 clinical sites. The study design, surgical techniques, patching and optical correction regimens, evaluation methods, and patient characteristics at baseline have been reported previously.^{9,17} This study was approved by the institutional review boards at all 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) was covered by US Food and Drug Administration investigational device exemption G020021. Written informed consent was obtained from all guardians/caregivers.

Clinical Examinations

Follow-up clinical examinations were performed by an IATS-certified investigator postoperatively at 1 day, 1 week, 3 months, and then at 3 months \pm 2 weeks intervals until age 4 years to adjust the optical correction and to monitor for adverse events and then at ages 4.25, 4.5, and 5 years. Intra-

ocular pressure was assessed at either the 4.5- or 5-year examination using rebound tonometry (Icare Finland),²⁴ Tonopen (Reichert Technologies) or Goldmann applanation tonometry. At age 5 years, cycloplegic refraction and ocular alignment were assessed at distance and near using the simultaneous prism cover test followed by the prism alternate cover test. If the visual acuity was severely reduced in the treated eye, ocular alignment was assessed with the Krimsky or the Hirschberg light reflex test.

Visual Acuity Assessment

Monocular optotype acuity was assessed at age 4.5 years (window + 1 month) by a masked traveling examiner using the Amblyopia Treatment Study HOTV test.²⁵ Patients were tested wearing their best correction (updated at their last study visit 3 months earlier). Visual acuity was tested first in the aphakic/pseudophakic eye. The eye not being tested was occluded using a translucent occluder mounted in child sunglass frames (Good-Lite) to minimize the amplitude of latent nystagmus under monocular conditions. The initial testing distance was 3 m. If the child was unable to see the HOTV letters, this distance was decreased to 1 m. If the child still could not identify the letters, the Low Vision Card (Teller Acuity Card, 0.32 cy/cm) was used to test for pattern vision. If gross pattern vision was not present, the eye was assessed for light perception or no light perception following standard protocols.

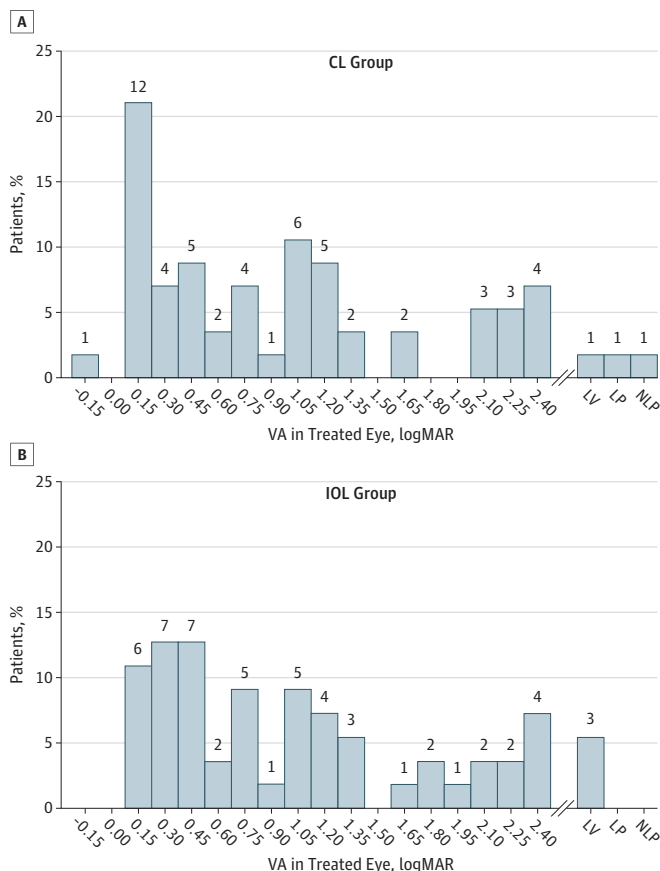
Adherence to Patching and Optical Correction

Adherence to patching and optical correction was assessed using 48-hour recall telephone interviews and 7-day diaries. Interviews were conducted every 3 months starting 3 months after surgery. Caregivers completed a 7-day patching diary 2 months after surgery and annually thereafter. Excellent adherence to patching was defined as a mean proportion of patching at least 75% of the prescribed time within five 12-month periods (<12 months of age, 12 to <24 months, 24 to <36 months, 36 to <48 months, and 48 to <60 months of age). For each period, analyses were restricted to children with at least 3 assessments.

Statistical Considerations

The visual acuities 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 low vision. The Fisher exact test was used to compare the treatment groups for the following factors: the percentage of patients experiencing adverse events, the percentage undergoing additional intraocular surgical procedures, the percentage orthophoric at distance and near, the percentage undergoing strabismus surgery, and the percentage with excellent patching. Following the intention-to-treat principle, all analyses are conducted with patients included in the treatment group to which they were randomized. All reported *P* values are 2-sided. For the primary outcome—visual acuity—a *P* value less than .05 was deemed statistically significant, whereas for all other outcomes, less than or equal to .01 was required.

Figure 1. Histograms Showing the Visual Acuity (VA) at Age 4.5 Years of the Contact Lens (CL) and Intraocular Lens (IOL) Treatment Groups



The median visual acuities were 0.90 logMAR (20/159) for both groups. The interquartile ranges for the 2 groups were CL = 0.30-1.60 (20/40-20/796) (A) and IOL = 0.40-1.73 (20/50-20/1074) (B). LP indicates light perception; LV, low vision (Teller Acuity Card); NLP, no light perception.

Table 1. Visual Acuity at Age 4.5 Years by Treatment

Visual Acuity	Treatment, No. (%)	
	Contact Lens (n = 57)	Intraocular Lens (n = 55)
20/20 to <20/40	13 (23)	6 (11)
20/40 to <20/80	9 (16)	14 (25)
20/80 to <20/200	7 (12)	8 (15)
20/200 or worse	28 (49)	27 (49)

Results

Study Population

There were 114 children enrolled in the study, with 57 randomized to each treatment group (eFigure 1 in Supplement). Three children with an exclusion criterion (eg, persistent fetal vasculature with stretching of the ciliary processes) were inappropriately enrolled in the study. Ninety-five percent of 2445 expected follow-up visits were completed. One patient in the IOL group was lost to follow-up at age 18 months. The remaining 113 patients had visual acuity assessed at age 4.5 years (mean, 4.5 years; range, 4.5-4.9 years) and a clinical examination at age 5 years (mean, 5.0 years; range, 4.7-5.4 years), with an average length of follow-up of 4.8 years (range, 4.4-5.3

years). For 110 patients (97%), the visual acuity examination was done within 36 days after age 4.5 years; the remaining 3 examinations were performed 71, 136, and 151 days after age 4.5 years. The primary end point could not be assessed in 1 patient in the IOL group secondary to developmental delay that was not associated with an exclusion criterion.

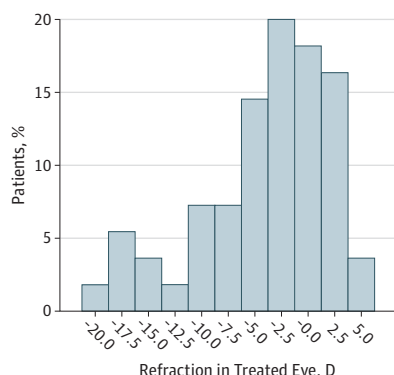
Visual Acuity

All 57 patients in the contact lens group and 55 patients in the IOL group completed visual acuity testing. The median logMAR visual acuity in the treated eyes did not differ significantly between the treatment groups (0.90 [20/159] for both groups, $P = .54$) (Figure 1 and eFigure 2 in Supplement). About 50% of treated eyes in both treatment groups had poor visual acuity ($\leq 20/200$) (Table 1). However, more than twice as many treated eyes in the contact lens group had visual acuity greater than or equal to 20/32 (contact lens, $n = 13$ [23%]; IOL, $n = 6$ [11%]). The median logMAR visual acuity in the fellow eyes did not differ between treatment groups (both, 0.1; $P = .44$).

Clinical Findings at Age 5 Years

Eight of 57 patients (14%) in the contact lens group and 14 of 56 patients (25%) in the IOL group ($P = .16$) were orthophoric at distance and had not had strabismus surgery. Eleven patients in each group were orthophoric at near (contact lens, 19%;

Figure 2. Histogram of the Spherical-Equivalent Refractive Errors at Age 5 Years of the Children Treated With Intraocular Lenses



IOL, 20%; $P = .99$). Strabismus surgery was performed on 21 patients (37%) in the contact lens group and 24 (43%) in the IOL group ($P = .57$).

The median (25th, 75th percentiles) refractive error in the treated eyes in the IOL group was -2.25 D (7.25, 0.00; range, -19.00 to $+5.00$ D) (Figure 2). The median refractive error for eyes in the IOL group without glaucoma (-1.69 D) was lower than eyes with glaucoma (-7.25 D) (eFigure 3 in Supplement). For the 3 patients who underwent an IOL exchange, the refractive error prior to the procedure was used in the analysis.

Adverse Events

By age 5 years, at least 1 adverse event had occurred in 32 eyes (56%) in the contact lens group compared with 46 (81%) in the IOL group ($P = .008$) (Table 2), the most common being lens repopulation into the visual axis, pupillary membranes, and corectopia. Only 2 eyes (4%) in the contact lens group developed lens repopulation into the visual axis and pupillary membrane and 1 (2%) corectopia, whereas in the IOL group, 23 (40%) developed lens repopulation into the visual axis and 16 (28%) developed a pupillary membrane and corectopia.

Glaucoma developed in a similar number of eyes from each group (contact lens, 9 [16%]; IOL, 11 [19%]; $P = .81$). Glaucoma suspect status developed in 11 eyes (19%) in the contact lens group and 5 (9%) in the IOL group. When these diagnoses are combined, 20 eyes (35%) in the contact lens group and 16 (28%) in the IOL group had either glaucoma or glaucoma suspect status ($P = .55$). Three patients in each group progressed from glaucoma suspect to glaucoma.

Contact lens-related adverse events occurred in 10 eyes (18%): 2 corneal ulcers, 2 corneal abrasions, 5 transient corneal opacities or a punctate keratopathy that resolved after removing the contact lens and treating with topical antibiotics, and 1 contact lens that broke while on the eye. No cultures were obtained for any of these adverse events. None of the contact lens-related adverse events resulted in central corneal scars that were judged to permanently affect visual acuity.

Additional Intraocular Surgical Procedures

Since enrollment, 12 eyes (21%) in the contact lens group required 1 or more additional intraocular surgical procedures

Table 2. Patients With Postoperative Adverse Events by Treatment Group

Adverse Event	Treatment, No. (%)	
	Contact Lens (n = 57)	Intraocular Lens (n = 57)
Lens repopulation into visual axis	2 (4)	23 (40)
Pupillary membrane	2 (4)	16 (28)
Corectopia	1 (2)	16 (28)
Glaucoma	9 (16)	11 (19)
Glaucoma suspect	11 (19)	5 (9)
Contact lens-related adverse events	10 (18)	0 (0)
Vitreous hemorrhage	2 (4)	5 (9)
Retinal hemorrhage	2 (4)	3 (5)
HypHEMA	1 (2)	4 (7)
Retained cortex	2 (4)	3 (5)
Retinal detachment	2 (4)	0 (0)
Endophthalmitis	1 (2)	0 (0)
Phthisis bulbi	1 (2)	0 (0)
Corneal edema >30 d	0 (0)	1 (2)
Wound leak/dehiscence	0 (0)	1 (2)
Intraocular lens capture	0 (0)	1 (2)
At least 1 adverse event	32 (56)	46 (81)

compared with 41 (72%) in the IOL group ($P < .001$) (Table 3). The most common additional intraocular surgery in both treatment groups was clearing visual axis opacities (contact lens, $n = 8$ [14%]; IOL, $n = 39$ [68%]). The second most common procedure was glaucoma surgery (contact lens, $n = 2$ [4%]; IOL, $n = 5$ [9%]). The number of additional intraocular surgical procedures varied from 0 to 3 in the contact lens group and 0 to 5 in the IOL group (eTable in Supplement). One eye in the IOL group underwent an IOL exchange during the first postoperative year to correct a large myopic refractive error (-10.00 D) and 2 eyes after the first postoperative year for refractive errors of -8.50 and -19.00 D. Secondary IOLs were only permitted before age 5 years if contact lens compliance failed, defined as an average of fewer than 4 hours per day wear over a period of 8 consecutive weeks. Three eyes in the contact lens group underwent secondary IOL implantation at ages 1.7, 3.2, and 4.8 years.

Adherence With Patching

All participants had at least 3 adherence assessments during year 1, decreasing to 90% in year 2, 86% in year 3, 79% in year 4, and 78% in year 5. The percentage of participants included in the adherence analyses did not differ by treatment group. Until age 1 year, the parents of more than half of the patients in each group reported that their children patched the fellow eye an average of more than 75% of prescribed hours (eFigure 4 in Supplement); this level of patching was reported to be achieved in 28% of the parents of children in the contact lens group vs 20% of those in the IOL group who reported that their child was patched at least 75% of the prescribed hours on all interviews during the first year of life and on the 3-month diary. The proportion of children reported to have excellent

Table 3. Patients With Additional Intraocular Surgical Procedures by Treatment Group

Type of Surgical Procedure ^a	Treatment, No. (%)	
	Contact Lens (n = 57)	IOL (n = 57)
Clearing visual axis opacities	8 (14)	39 (68)
Glaucoma surgery	2 (4)	5 (9)
Repair retinal detachment	2 (4)	0 (0)
Repair wound dehiscence	0 (0)	1 (2)
IOL exchange	0 (0)	3 (5)
Iridectomy/iridotomy	1 (2)	1 (2)
Lysis of vitreous wick	0 (0)	1 (2)
Secondary IOL	3 (5)	
At least 1 surgical procedure	12 (21)	41 (72)

Abbreviation: IOL, intraocular lens.

^a Multiple surgical procedures could have been done during the same episode. Examinations under anesthesia only or strabismus surgery only are not included.

patching decreased to approximately one-third during the second, third, and fourth years of life. By age 5 years, 33% of parents of children in the contact lens group reported excellent patching compared with only 15% of parents in the IOL group. However, none of these differences approached statistical significance.

Discussion

At age 4.5 years, there was no significant difference between the median optotype visual acuity in the treated eyes of children with unilateral congenital cataracts who underwent surgery during the first 6 months of life and were optically corrected with either a contact lens or an IOL. However, there were significantly more adverse events and additional intraocular surgical procedures in the IOL group.

Our results are consistent with Birch and colleagues⁶ who reported no significant difference in visual acuity at age 4 years between eyes left aphakic and treated with contact lenses (n = 5) and eyes after primary IOL implantation (n = 4) following unilateral congenital cataract surgery. However, the mean logMAR visual acuity was better in the operated eyes in their series at age 4 years (both groups, 0.44 [20/55]) than the median of the operated eyes in the IATS. Aufrata and colleagues²⁶ also reported better logMAR visual acuities at age 5 years in the treated eyes of children following unilateral cataract surgery optically corrected with contact lenses (n = 23) or IOL implantation (n = 18) (contact lens, 0.58 [20/76]; IOL, 0.43 [20/54]). There are a number of possible reasons why visual acuities may have been worse in the IATS at age 4.5 years than these 2 other studies. First, the Birch et al⁶ and Aufrata et al²⁶ studies only analyzed the visual outcomes for patients who had good to excellent patching compliance, while we analyzed the visual outcomes for all patients. Second, the length of follow-up was variable in the Aufrata et al study,²⁶ whereas all of the patients in the IATS underwent visual acuity testing between ages 4.5 to 4.9 years. Lastly, there may have been a bias

in patient selection in these other studies because they were not randomized clinical trials.

Lens repopulation into the visual axis and pupillary membranes were the most common adverse events. This adverse event occurred 10 times more often in the IOL group; most occurred during the first postoperative year.⁷ These findings are consistent with other reports of children undergoing IOL implantation during infancy.^{8,27} In aphakic eyes, the margins of the anterior and posterior capsular bag usually fuse together, preventing lens material from migrating out of the Sommer ring into the pupillary space. Whereas in pseudophakic eyes, lens material is able to migrate into the pupillary space because the IOL interferes with the fusion of the lens capsule remnants.

Glaucoma and glaucoma suspect status occurred nearly equally in the contact lens and IOL groups—20 (35%) vs 16 (28%) eyes, respectively. Haargaard et al²⁸ reported a 13% incidence of glaucoma in the treated eyes of children who underwent a lensectomy when younger than 9 months of age after 5 years of follow-up. Chak and Rahi²⁹ reported a 10% incidence of glaucoma in eyes that underwent cataract surgery at a median age of 4.5 months after a median follow-up of 6.8 years. The higher incidence of glaucoma/glaucoma suspect in our study may reflect the younger age of the patients in our series at the time of cataract surgery (median, 1.8 months) and different definitions of glaucoma and glaucoma suspect. Both the Chak and Rahi²⁹ and Haargaard et al²⁸ studies only defined eyes as having glaucoma if they received sustained medical treatment or surgery, whereas our glaucoma suspect definition included eyes with elevated intraocular pressure that had not undergone medical or surgical treatment. A longer follow-up of the cohort of patients enrolled in the IATS should allow us to better assess whether the initial surgical treatment affects the incidence of glaucoma and glaucoma suspect.^{28,30}

While the median refractive error was −2.25 D in the treated eyes in the IOL group, there was a wide range of refractive errors in these eyes at age 5 years (range, +5.00 D to −19.00 D). All pseudophakic eyes had a targeted postoperative refraction of +6 or +8 D at the time of IOL implantation.¹⁷ However, the absolute prediction error was 1.8 D and only 41% of eyes had an absolute prediction error less than or equal to 1 D.¹⁹ While the inaccuracy of achieving the targeted refractive error was a factor, our inability to accurately predict the degree of axial elongation in these eyes was the primary reason for the wide range of refractive errors at age 5 years.¹³ As expected, owing to the increased axial elongation that occurs with glaucoma in infantile eyes, pseudophakic eyes with glaucoma were more myopic than pseudophakic eyes without glaucoma.

Most patients in both treatment groups developed strabismus. Other studies have also reported a high rate of strabismus following unilateral cataract surgery during infancy.^{26,31}

On average, reported adherence to patching was slightly higher in children randomized to contact lens wear than in children with an IOL. In addition, the proportion of children having excellent adherence to patching was higher among aphakic than pseudophakic children. However, there were substantial variations in patching adherence in both groups and

none of these differences approached statistical significance. Therefore, it is unlikely that adherence to patching confounded the association between treatment and visual acuity. It should also be noted that the proportion of parents reporting that they achieved excellent adherence may not be generalizable to other populations because our study provided contact lenses, spectacles, and patches for participants at no charge and regular monitoring of adherence to these treatments may have improved compliance.³² As a result, our outcomes may reflect efficacy (benefit under ideal conditions) rather than effectiveness (benefit under usual conditions).³³

One limitation of the IATS is that the age at onset of a cataract was not ascertained. When an infant presented with a cataract, it was often unclear whether the cataract had been present since birth. We chose to use the term *congenital* cataract because it is likely that there was a lens abnormality in all of these

children since birth. However, in some cases, the lens abnormality may have been visually insignificant at birth and only later progressed to a visually significant cataract.

Conclusions

This study did not demonstrate any visual benefit from implanting an IOL at the time of unilateral cataract surgery in infants younger than 7 months of age, and the children who had IOL implantation had more adverse events and required more reoperations to clear visual axis opacities. Some families will find contact lens wear especially challenging. In such cases, the benefit of eliminating contact lens issues by implanting an IOL needs to be weighed against the drawbacks associated with early IOL implantation.

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Invited Commentary

Treatment Outcomes of Monocular Infantile Cataract at 5-Year Follow-up Work in Progress

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Management of monocular infantile cataract is time-consuming, expensive, and tries the tolerance of parents as well as the patience of their child's ophthalmologist. During the last



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2 decades, many technical problems have been overcome with treatment associated with good vision for some children. Among those innovations was the introduction of extended-wear silicone elastomer and custom rigid-gas permeable contact lenses, which were a great improvement over aphakic spectacles. Nonetheless, there are problems with aphakic contact lenses including the cost of replacement and need for frequent replacement for reasons such as refractive error change, lens loss, parental stress managing the lens, and corneal injury. These reasons have made aphakic contact lenses in infancy appear not to be the final answer.

The possibility that the one-time placement of an intraocular lens (IOL)—highly successful for older children, teens, and adults, with constant partial correction of the ametropia leading to better vision with less hassle and expense—has seemed an obvious direction for care improvement.¹ Testing this hypothesis has been the primary objective of the Infantile Aphakia Treatment Study (IATS)² in which infants with unilateral cataract younger than 6 months of age were randomized to either lensectomy with contact lens correction or IOL implantation. Earlier reports have found no difference in visual acuity and risk for glaucoma, but there has been a significantly higher number of additional intraocular surgeries required by the IOL group.³

The IATS is not just a study of infantile cataract surgery but of a system of eye care delivered during 5 years, beginning with IOL selection and surgery and including intense amblyopia therapy, refractive correction, contact lens manipulation, and additional surgery. Infants eligible for randomization in the IATS group had a normal posterior segment, no microphthalmos, and normal development. These criteria assured a reasonably homogeneous group of enrolled infants with a reasonable chance of a successful visual outcome, representing the best-case scenario for monocular infantile cataract. Thus, these outcomes do not extend to all monocular cataract or infants with bilateral cataract.

The IATS group appropriately considered visual acuity to be the primary objective. By this measure, there was no difference between contact lenses and IOLs. However, the lack of difference might obscure the fact that more than one-third of the combined cohort achieved 20/60 visual acuity or better, a marked improvement from a few decades ago. Unfortunately, each approach left about 50% of the children with

20/200 visual acuity or worse, indicating that neither of these approaches are the last word on treatment.

Treatment of the amblyopia associated with monocular cataract includes hours of occlusion. Maintenance of this treatment intensity over years is a struggle for parents and all of their children, not just the affected child. In this study, this threshold was achieved by just over 50% of families using parent-reported adherence and a study-specified target of 75% of prescribed patching hours, even during year 1. At the time of the 5-year outcome assessment, only 33% of the contact lens group and 15% of the IOL group achieved that threshold. Parent-reported adherence rates likely overestimate true compliance. New approaches to amblyopia therapy are a priority.

Development of glaucoma after infant cataract surgery in the IATS was feared. The rate of glaucoma or suspected glaucoma in the IATS group at 5 years follow-up was about 30% with no difference between treatments. The rate has more than doubled from 12% reported 1 year after surgery.⁴ The rate of glaucoma was higher than typically reported, possibly because of careful definitions used by the IATS group and the young age at surgery. The lack of a difference in rate of glaucoma between treatments needs emphasis as it has been suggested that the placement of an IOL protects against the development of glaucoma.⁵

Difficulties with management of contact lenses in this population has been one reason for placement of an IOL. About 1 in 6 eyes was reported to have at least 1 contact lens-related problem, although none were associated with any damage to the cornea affecting visual acuity. This is remarkable and is testimony to the diligence of the parents and health care teams who worked with these children.

Since the outcome report at 1 year of age,³ the single outcome measure by which the treatment approaches have differed significantly has been the rate of additional intraocular surgery. That difference remained substantial so that at 5 years follow-up, 21% of the contact lens group and 72% of the IOL group have required at least 1 such surgery. Most of these surgeries were related to the clearing of the visual axis. In addition, more patients in the IOL group required more than 1 procedure. While this difference is dramatic, it is partially offset by the expectation that some of the contact lens group will elect to undergo placement of a secondary IOL.

One purported advantage of primary IOL placement was the ability to more accurately correct the refractive error for more time during infancy than could be achieved with a contact lens and also have minimal uncorrected refractive error later in life. First, this approach is not so simple, as it has always required that children wear spectacles to fine-tune re-

fraction because of assumptions made in selecting the IOL power. The IATS investigators set a target refractive error of +6 or +8 diopters (D) with the hope for low myopia upon reaching adulthood.⁶ The investigators did fairly well achieving their target postoperative refractive error.⁷ Of concern is the variable and unpredictable evolution of refractive error observed during the subsequent 5 years. While the median refraction at 5 years follow-up for the IOL group was -2.25 D, the range was large, from -19.00 to +5.00 D, with 25% of eyes being more than -7.25 D. These data confirm the difficulty selecting an IOL based on an infant's age and axial length needed to obtain the desired refraction years in the future. Improved IOL power prediction is needed, perhaps by identifying baseline characteristics, which might be used to more accurately predict eye growth. In contrast, secondary implants placed in the eyes of the contact lens group should have far greater precision achieving the desired long-term refractive error.

Is the treatment of monocular infantile cataract worth the effort?⁸ At 5-year follow-up, the answer remains yes, but further innovation is needed to improve outcomes. The use of an IOL for infantile monocular cataract is not yet transformative. While the outcomes reported by the IATS group are not a complete success, they must be viewed in the historical context of a decidedly hopeless situation just years ago. In 2014, half of children have visual acuity better than 20/200; 20%, 20/30 or better; and 20% are orthotropic. The effort in terms of cost and time has been significant, although some children benefit for many decades.

It is my impression that no parent is prepared to understand the overwhelming impact this condition and its treatment will have on his or her family's life. The IATS allows ophthalmologists to more accurately inform parents of their treatment options along with the struggles and successes they will encounter.

ARTICLE INFORMATION

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