Visual Acuity Development After the Implantation of Unilateral Intraocular Lenses in Infants and Young Children

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Purpose: Intraocular lenses (IOLs) are now being implanted in infants and children with unilateral cataracts. However, there are no prospective data on the development of visual acuity after implantation. The aim of the present study was to prospectively assess the development of acuity in infants and preschool children who received IOLs or aphakic contacts lenses (CLs) after the extraction of a unilateral cataract. ***Methods:*** Visual acuity was assessed using Teller Acuity Cards and/or crowded HOTV tests at target ages of 6 months, 1, 2, 3, and 4 years. ***Results:*** Infants who received a primary IOL after extraction of dense congenital unilateral cataract (n = 5) showed improvement from an initially low mean visual acuity of 20/170 at 6 months to 20/85 at 12 months and 20/54 at 4 years. Visual acuity in the IOL group was similar to that of children who had good-to-excellent compliance with CL wear (n = 36; 4-year visual acuity 20/50) and better than that of children who had moderate-to-poor compliance (n = 11; 4-year visual acuity 20/135). Children who received IOLs after extraction of developmental unilateral cataracts by 6 months (n = 4; 4-year visual acuity 20/55) had visual acuity development similar to those treated with CLs (n = 5; 4-year visual acuity 20/55). Children who received IOLs after extraction of developmental unilateral cataracts after 1 year of age (n = 18) had better visual acuity than children those treated with CLs (n = 4) at 4 years of age (20/40 vs. 20/135). ***Conclusion:*** IOLs and aphakic CLs support similar visual acuity development after surgery for a unilateral cataract. IOLs may support better visual acuity development when compliance with CL wear is moderate to poor or when a cataract is extracted after 1 year of age. (J AAPOS 2005; 9:527-532)

Intraocular lenses (IOLs) are now being implanted in infants and preschool children after surgery for unilateral cataracts, including dense congenital, developmental, and traumatic cataracts.[1] Although aphakic contact lenses have been used successfully for more than 25 years,[2-15] the rationale for the use of IOLs is that they provide continuous optical correction and thus may promote better visual acuity development. Certainly, compliance with aphakic contact lens wear is a problem for some patients and their parents,[8,16,17] and the blurring experienced during noncompliant episodes may limit the maturation of visual acuity. However, IOL implantation cannot completely correct aphakic refractive error throughout infancy and early childhood because of the rapid growth of the eye.[18-20] Therefore, most infants who have an IOL implanted also will need to wear a contact lens or spectacles to refine the refractive correction. The IOL will provide at least partial optical correction even when compliance problems with the spectacles or contact lenses arise. The maturation of visual acuity in infants treated for unilateral cataracts is also dependent on compliance with occlusion therapy,[8] and it is unknown whether compliance with occlusion may differ between infants who receive IOLs or aphakic contact lenses.

Currently, there is controversy, concern, and little sound medical evidence regarding a visual benefit of IOL implantation over aphakic contact lenses.[21] No prospective visual acuity development data are available to compare visual acuity outcome after IOL implantation versus aphakic contact lens correction. There is only one retrospective analysis of grating acuity of aphakic and pseudophakic infants at about 20 months of age.[22] The authors found no significant difference in grating acuity; the 12 children in the IOL group averaged approximately 1.7 logMAR lines better than the 13 children in the aphakic contact lens group. However, because the fellow eye in the IOL group was about 0.7 lines poorer on average than the fellow eye in the aphakic contact lens group, the intraocular difference in visual acuity was significantly smaller in the IOL group (approximately 2.5 lines) than in the apha-

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kic contact lens group (approximately 5 lines). The reoperation rate was significantly higher in the IOL group (83%) than in the aphakic contact lens group (23%, including one reoperation to place a secondary IOL). The aim of the present study was to prospectively assess the development of visual acuity in infants and preschool children who received IOLs or aphakic contacts lenses after the extraction of a unilateral cataract.

MATERIALS AND METHODS

Participants

Participants included 71 infants who were diagnosed with a unilateral dense congenital cataract during the first 2 weeks of life, of whom 5 received a primary IOL and 66 were fitted with an aphakic contact lens after cataract extraction. Of the 66 who received an aphakic contact lens, 15 had an IOL implanted as a secondary procedure at a later date. In addition, 31 children with developmental cataracts participated, of whom 9 developed dense cataracts during infancy and had surgery by 6 months of age (4 received IOLs and 5 received aphakic contact lenses) and 22 developed dense cataracts and had surgery after 1 year of age (18 received IOLs and 4 received aphakic contact lenses). All but one of the patients who had placement of an IOL had posterior capsulotomy and anterior vitrectomy at the time of the initial surgery. Patients were referred to the study by 10 Dallas/Fort Worth area pediatric ophthalmologists. Excluded from participation were patients with associated retinal anomalies, systemic disease, or neurological disorders. Informed consent was obtained from one or both parents before the patient's participation. This research protocol observed the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of the University of Texas Southwestern Medical Center.

Compliance With Contact Lens Wear

Compliance was assessed informally by parental report to research staff of the number of hours prescribed and asking the parent to estimate the percentage accomplished as 0%, 25%, 50%, 75%, or 90%. Compliance was categorized as good-to-excellent if 75% to 90% was reported. Compliance was categorized as poor-to-moderate if 0% to 50% was reported.

Occlusion Therapy

Patients with congenital unilateral cataracts received similar occlusion therapy whether an IOL was implanted or they were fitted with an aphakic contact lens. Typical occlusion therapy regimens prescribed by referring pediatric ophthalmologists were 50% of waking hours, alternate day occlusion, and 6 to 8 hours/day. Patients with developmental cataracts with IOL implantation and those fit with an aphakic contact lens also had similar occlusion therapy regimens. Typical occlusion therapy regimens prescribed by referring pediatric ophthalmologists for infantile onset were 50% of waking hours, alternate day occlusion, and 6-8 hours/day whereas, for later onset, 2 to 6 hours per day was more commonly prescribed.

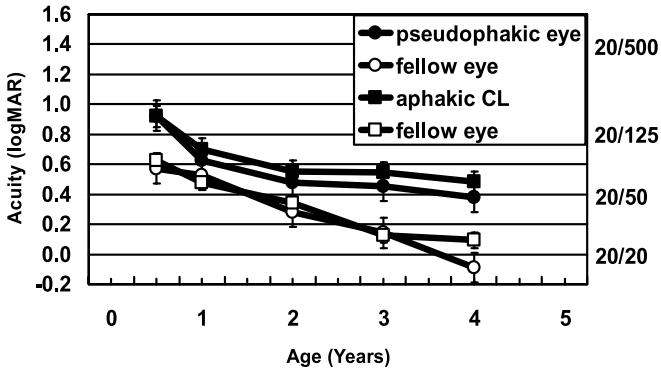

FIG 1. Visual acuity maturation for pseudophakic and fellow eyes of infants who received a primary IOL after extraction of a unilateral dense congenital cataract (n = 5). Also shown is the visual acuity maturation for a comparable cohort of infants who were fitted with an aphakic contact lens correction after extraction of a unilateral dense congenital cataract (n = 51). Error bars show ± 1 standard error of the mean.

Development of Visual Acuity

Participants were enrolled in a prospective study of visual acuity development as soon as feasible after cataract extraction, usually within 3 months. Target ages for testing visual acuity were 6 months, 1, 2, 3, and 4 years of age. Grating acuity was evaluated with Teller Acuity Cards (Stereo Optical Company, Chicago, IL), using a forced-choice staircase procedure,[23] until the child was old enough to participate in visual acuity tests using crowded HOTV optotypes presented using the EVA system developed by the Pediatric Eye Disease Investigator Group.[24] All visual acuity data were converted to a common logMAR scale before data analysis.

Data Analysis

Comparisons of mean visual acuity between treatment groups were accomplished by t-tests.

RESULTS

Primary IOLs for Unilateral Dense Congenital Cataracts

Visual acuity maturation for pseudophakic and fellow eyes of infants who received a primary IOL after extraction of a unilateral dense congenital cataract at 3.8 ± 3.1 month of age is shown in Figure 1. At 6 months of age, the mean pseudophakic eye visual acuity was 0.925 logMAR (20/170). Visual acuity in the pseudophakic eye improved rapidly to 0.628 logMAR (20/85) by 1 year of age, when it approached the visual acuity of the fellow eye (0.530 logMAR, 20/70). After 1 year of age, visual acuity of the

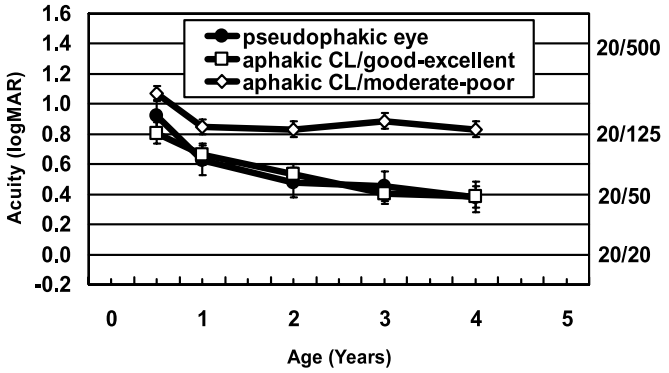

FIG 2. Visual acuity maturation of the pseudophakic eyes of infants who received a primary IOL following extraction of a unilateral dense congenital cataract (re-plotted from Figure 1). Also shown is the visual acuity maturation of two subgroups of infants who received aphakic contact lens correction, those with good-to-excellent compliance with contact lens wear (n = 36) and those with poor-to-moderate compliance with contact lens wear (n = 11). Error bars show ± 1 standard error of the mean.

pseudophakic eye failed to keep pace with the fellow eye, attaining on average 0.436 logMAR (20/55) and −0.097 logMAR (20/15), respectively, at 4 years of age. Also shown in Figure 1 is the visual acuity maturation for a comparable cohort of infants who were fitted with an aphakic contact lens correction after the extraction of a unilateral dense congenital cataract at 2.4 ± 2.6 months of age. Overall, there was no significant difference between the cohort who received a primary IOL and the cohort that received aphakic contact lens correction in the course of visual acuity maturation for either the affected eyes or the fellow eyes during the first 4 years of life (affected eyes: $0.03 < t < 1.13$, n.s. for all age groups; fellow eyes: $0.18 < t < 1.53$, n.s. for all age groups).

The compliance with aphakic contact lens wear, by parental report, was 75% or more (good-to-excellent) in 36 children (71%) and 50% or less (moderate-to-poor) in 11 children (22%). The visual acuity maturation of the pseudophakic eyes from Figure 1 is replotted in Figure 2 along with visual acuity data from the 2 subgroups of infants who received aphakic contact lens correction, those with good-to-excellent compliance with contact lens wear and those with poor-to-moderate compliance with contact lens wear. There was no significant difference between the cohort who received a primary IOL and the subgroup with good-to-excellent compliance with contact lens wear in the course of visual acuity maturation for the affected eyes ($0.22 < t < 0.71$, n.s. for all age groups). On the other hand, the cohort who received a primary IOL had significantly better visual acuity than the subgroup with moderate-to-poor compliance with contact lens wear, who attained a mean visual acuity of 0.847 logMAR (20/140) at 1 year of age and showed little improvement thereafter. By 2 years of age, mean visual acuity was significantly better in the IOL cohort than in the moderate-to-poor compliance aphakic contact lens group (2 year age group $t = 2.03$, $P < 0.03$; 3 year age group $t = 2.04$, $P < 0.03$; 4 year age group $t = 2.40$, $P < 0.02$).

Postoperative complications occurred in 60% of the IOL cohort (n = 5), including 2 operations for capsule opacification and 1 surgery for glaucoma. Postoperative complications occurred in 14% of the aphakic contact lens cohort (n = 51), including 2 surgeries for secondary membranes, 1 surgery for iris cyst, 1 vitrectomy for endophthalmitis, 2 surgeries for glaucoma, and 1 retinal detachment surgery. Fewer children in the IOL achieved stereopsis than in the aphakic contact lens cohort (0% IOL cohort, 12% aphakic contact lens cohort). The prevalence of strabismus surgery was 60% in the IOL cohort and 43% aphakic contact lens cohort).

Secondary IOLs for Unilateral Dense Congenital Cataracts

Visual acuity maturation of infants who initially received an aphakic contact lens after extraction of a unilateral dense congenital cataract but had secondary implantation of an IOL at 0.75 to 2 years of age is shown in Figure 3A. These infants start out at 6 months of age with visual acuity comparable with the cohorts who were treated with only a single mode of optical correction throughout visual development, IOL or aphakic contact lens. However, because of difficulties with contact lens compliance, these infants showed little improvement in aphakic eye visual acuity after 6 months of age, until an IOL was implanted. Visual acuity improved rapidly after IOL implantation so that, by 4 years of age, this cohort achieved a mean visual acuity of 0.549 logMAR (20/70), which was just slightly poorer than the 20/50 to 20/60 mean visual acuity that was achieved by the cohorts who were treated with only a single mode of optical correction throughout visual development (visual acuity at 4 years of age; aphakic contact lens only vs. secondary IOL $t = 0.28$, n.s.; IOL only v. secondary IOL $t = 0.69$, n.s.).

Visual acuity maturation of infants who initially received an aphakic contact lens after the extraction of a unilateral dense congenital cataract but had secondary implantation of an IOL at or after 3 years of age is shown in Figure 3B. These infants had a mean visual acuity at 6 months to 2 years of age that is comparable with the mean acuities of the cohorts who were treated with only a single mode of optical correction throughout visual development. However, at approximately 2 years of age, difficulties with contact lens compliance resulted in a drop in aphakic eye visual acuity by 3 years of age. Visual acuity improved rapidly after IOL implantation so that, by 4 years of age, this cohort achieved a mean visual acuity of 0.414 logMAR (20/50), similar to the 20/50 to 20/60 mean visual acuity that was achieved by the cohorts who were treated with only a single mode of optical correction throughout visual development (visual acuity at 4 years of age; aphakic contact lens only vs. secondary IOL $t = 0.49$,

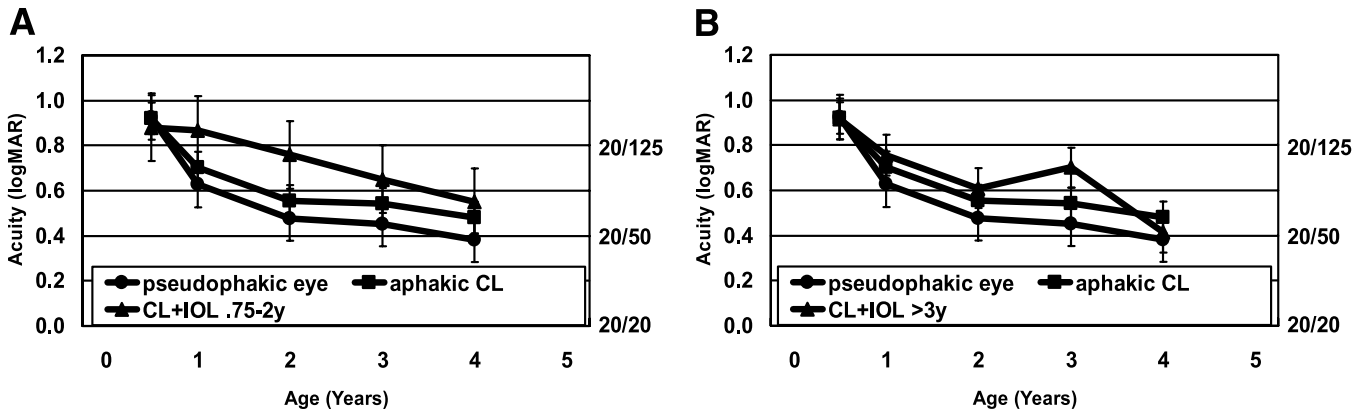

FIG 3. Visual acuity maturation of infants who initially received an aphakic contact lens after extraction of a unilateral dense congenital cataract but had secondary implantation of an IOL at 0.75 to 2 years of age (n = 7; A), or at >3 years of age (n = 8; B). Also shown is the visual acuity maturation of the affected eyes of infants who were treated with a single mode of optical correction throughout the study period, either IOL (n = 5) or aphakic contact lens (n = 51), re-plotted from Figure 1. Error bars show ± 1 standard error of the mean.

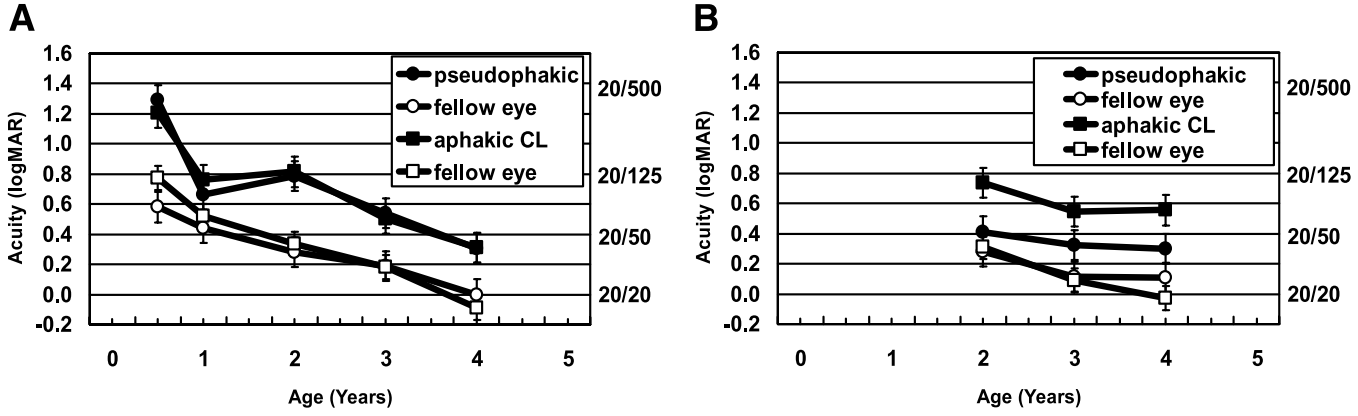

FIG 4. Visual acuity maturation for pseudophakic and fellow eyes of infants who received a primary IOL after extraction of an infantile developmental cataract by 6 months of age (n = 4; A) or at ≥1 year of age (n = 19; B). Also shown is the visual acuity maturation for comparable cohorts of infants who were fitted with an aphakic contact lens correction after the extraction of an infantile developmental cataract by 6 months of age (n = 5; A) or at ≥1 year of age (n = 4; B). Error bars show ± 1 standard error of the mean.

n.s.; IOL only vs. secondary IOL t = 0.14, n.s.). Postoperative complications occurred in 27% of the secondary IOL cohort (n = 15); all 4 of the surgeries were for glaucoma. The prevalence of strabismus surgery was 53% in this cohort.

Primary IOLs for Unilateral Developmental Cataracts

Visual acuity maturation for pseudophakic and fellow eyes of infants who received a primary IOL after extraction of an infantile developmental cataract by 6 months of age is shown in Figure 4A. At 6 months of age, the mean pseudophakic eye visual acuity was poor, 1.290 logMAR (20/390), but rapidly improved to 0.764 logMAR (20/90) by 1 year of age. The pseudophakic eye attained a mean visual acuity of 0.448 logMAR (20/55) at 4 years of age. Also shown in Figure 4A is the visual acuity maturation for a comparable cohort of infants who received aphakic contact lens correction following extraction of an infantile developmental cataract by 6 months of age. Overall, there was no significant difference in the acuities of the affected eyes between the cohort who received a primary IOL and the cohort that received aphakic contact lens correction ($0.03 < t < 0.51$, n.s. for all age groups).

Visual acuity maturation for pseudophakic and fellow eyes of infants who received a primary IOL after extraction of a developmental cataract after 1 year of age is shown in Figure 4B. At 2 years of age, the mean pseudophakic eye visual acuity was 0.431 logMAR (20/55) and showed further improvement to 0.298 logMAR (20/40) at 4 years of age. Also shown in Figure 4B is the visual acuity maturation for a comparable cohort of infants who received aphakic contact lens correction following extraction of a developmental cataract after 1 year of age. This cohort fared much more poorly than those who received an IOL, with a mean visual acuity of only 0.905 logMAR (20/160)

at 2 years of age and a mean visual acuity of 0.838 logMAR (20/135) at 4 years of age. Mean visual acuity was significantly poorer for the aphakic contact lens cohort than for the IOL cohort in all 3 age groups (2 years: $t = 2.03$, $P < 0.04$; 3 years: $t = 2.78$, $P < 0.009$; 4 years: $t = 3.43$, $P < 0.003$).

Postoperative complications occurred in 9% of the IOL cohort (n = 22), including 1 operation for capsule opacification and 1 vitrectomy for endophthalmitis. Postoperative complications occurred in 11% of the aphakic contact lens cohort (n = 9), ie, 1 surgery for glaucoma. In addition, 3 children (14%) in the IOL cohort and 4 children (44%) in the aphakic contact lens cohort had strabismus surgery.

DISCUSSION

IOLs and aphakic contact lenses support similar visual acuity development in infants and young children treated for unilateral dense congenital cataracts. Contact lenses are the most common mode of aphakic optical correction in infants because they generally are well tolerated and because the power of the aphakic contact lens can be changed frequently to keep pace with the rapidly changing refractive error of the maturing aphakic eye. The data presented here suggest that IOLs, used in conjunction with contact lenses and/or spectacles to fine tune the refractive correction, support visual acuity development similar to that observed with aphakic contact lenses.

It is well known that the development of visual acuity in infants treated for unilateral dense congenital cataracts with aphakic contact lenses will depend on both contact lens compliance and compliance with occlusion therapy. IOL implantation may minimize the problem of poor contact lens compliance as at least a partial optical correction will be in place at all times. If improving optical correction in this way is of benefit to visual acuity maturation, then IOL implantation may have an additional benefit of improving compliance with occlusion therapy. The data from the present study support this hypothesis since visual acuity development in the IOL group was better than visual acuity development when in the aphakic contact lens cohort with moderate to poor compliance.

Some infants who initially had good or excellent compliance with contact lens began to experience compliance problems between 0.75 and 2 years of age. In the present study, children who received an IOL as a secondary procedure showed rapid improvement in visual acuity. By 4 years of age, the visual acuity of the cohorts who received secondary IOLs was comparable to the visual acuity of children who were treated successfully with only a single mode of optical correction throughout visual development (IOL or aphakic contact lens).

IOLs and aphakic contact lenses also were found to support similar visual acuity development in infants and young children treated for developmental unilateral cataracts during the first 6 months of life. However, IOLs supported better visual acuity development when a developmental cataract was extracted after 1 year of age. This may reflect the difficulty of contact lens compliance when it is initiated at 1 to 3 years of age.

A limitation of this study is that the infants were not assigned randomly to IOL and aphakic contact lens treatment groups. Instead, a variety of treatment protocols resulted from referrals for participation in the study from 10 pediatric ophthalmologists with different practice patterns. Therefore, the IOL and aphakic contact lens cohorts may differ in some unknown way. In addition, other aspects of treatment (eg, the occlusion therapy dose or schedule) may have covaried with the mode of aphakic optical correction.

A second limitation of the study is that the small sample sizes limited our power to detect small differences in visual acuity outcomes between treatment groups. However, the sample sizes were sufficient to detect clinically meaningful differences in visual acuity outcomes. For the primary analysis of IOL and aphakic contact lens treatment for unilateral dense congenital cataracts, there was 90% power to detect a difference in mean visual acuity of 0.24 logMAR (2.4 lines on an eye chart). In comparing the visual acuity outcome of the IOL group to that of the good-to-excellent and poor-to-moderate compliance groups, there was 90% power to detect a difference of 0.24 and 0.29 logMAR (2.4-2.9 lines), respectively. For comparisons of visual acuity outcome of infants who had secondary IOL implantation by 2 years of age or after 3 years of age with those who were treated with only a single modality of optical correction (IOL or aphakic contact lens), there was 90% power to detect difference of 0.20-0.31 logMAR (2-3.1 lines). Comparisons for children treated for developmental cataracts with IOLs versus aphakic contact lenses had 90% power to detect differences in visual acuity outcome of 0.38 logMAR (3.8 lines) for those operated by 6 months of age and of 0.28 logMAR (2.8 lines) for those operated after 1 year of age. Overall, then, with the single exception of the early developmental cataract group, sample sizes were adequate to detect a difference in visual acuity outcome of 2-3 lines.

A third limitation of the present study is that the number of infants who received primary IOLs was too small to assess safety. While there was some suggestion of a higher rate of postoperative complications in the IOL cohort, the sample sizes are small and the patients were not randomly assigned to the two treatment groups. Serious postoperative complications occurred in both groups. The surgery required to implant an IOL is technically more difficult, and the limited data in the literature suggest that the postoperative complication rate is greater with IOLs than with aphakic contact lenses.[22,25,26] The long-term safety of an IOL in a growing eye is unknown.

Thus, although the results presented here are the first long-term prospective data that support the effectiveness of IOLs in comparison to aphakic contact lenses, a randomized trial of IOLs versus aphakic contact lenses fol-

lowing extraction of congenital and infantile unilateral cataracts is needed to provide definitive answers. The Infant Aphakia Treatment Study, which was launched in 2004, is a National Eye Institute-sponsored multi-center randomized clinical trial comparing IOL and CL correction for monocular aphakia in infants.

This study was conducted at the Retina Foundation of the Southwest.

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