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A Randomized Clinical Trial Comparing Contact Lens to Intraocular Lens Correction of Monocular Aphakia during Infancy: HOTV Optotype Acuity at Age 4.5 Years and Clinical Findings at Age 5 years

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Dear Editor

We appreciate the interest of Sueke and Chandna in the outcomes of the Infant Aphakia Treatment Study (IATS).

The “intention-to-treat” strategy is used in randomized clinical trials to ensure that treatment groups remain similar. This strategy requires that patients are analyzed with the groups that they were originally randomized to even if they received a different treatment. One patient in our study was randomized to the IOL group, but did not undergo IOL implantation and three patients in the contact lens group received secondary IOLs. All of these patients were analyzed with the group they were originally randomized to. Missing data can also be an issue. We were fortunate that this was not a major problem in our study. Only 1 patient was lost to follow-up and all but two patients had the primary outcome, optotype visual acuity, assessed at age 4.5 years (one patient did not have data as a result of developmental delay). In contrast, patching adherence (which was not a clinical outcome) was assessed using recall telephone intervals every 3 months and a patching calendar completed by the child’s primary caregiver for one week each year. Since not all caregivers completed these calendars and some recall phone interviews were missed, there was more missing data for patching

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adherence (missing data: year 1, 10%; years 2–5, <25%) than for the other clinical outcomes.

The primary outcome of the IATS was optotype acuity at age 4 ½ years using the Amblyopia Treatment Study HOTV test. There was no difference in the visual acuity outcome between the two groups (both; median logMAR 0.90; p=.54). While it would have been interesting to have collected data for other parameters of visual function, many of the children in the IATS would have had difficulty performing these tests when age 4 ½ years.

Two patients in the contact lens group had serious visual threatening complications. We discussed these complications in detail in previous publications describing the 1 year outcomes.[,] The percent of patients with serious, vision threatening complications were not significantly different between the two group using the Fisher's exact test (contact lens group, 2/57 (3.5%); IOL group 0/57 (0.0%); p=.50).

The decision to use the visual acuity in the treated eye as the primary endpoint, rather than the difference in visual acuity between the treated and fellow eyes, was made prior to the start of the study and in consultation with the Data and Safety Monitoring Committee. The decision was based primarily on statistical considerations. The use of the interocular difference in the analysis is a form of adjusting for a postrandomization covariate in which the estimated effect on the resulting visual acuity in the treated eye when using an IOL rather than a CL is adjusted for the visual acuity in the fellow eye. Given the disadvantages of adjusting for a postrandomization covariate, particularly the possibility of introducing bias into the estimate, the decision was made to use the visual acuity in the treated eye as the primary endpoint.

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