

immediately to the nearest stroke center without obtaining any further workup themselves.⁴

VALERIE BIOUSSE
NANCY J. NEWMAN
Atlanta, Georgia, USA

FUNDING/SUPPORT: NO FUNDING OR GRANT SUPPORT. Financial Disclosures: Valerie Biousse is a consultant for Gensight Biologics (France) and received research support from the NIH/PHS (P30-EY006360), NIH (R01-NS089694), and Research to Prevent Blindness. Nancy J. Newman is a consultant for Gensight Biologics (France) and serves on the Data Safety Monitoring Board for Quark Pharmaceuticals (Israel) clinical trial, has provided expert testimony on the topic of optic disc edema, and has received research support from NIH grants (R01-NS089694, P30-EY006360) and Research to Prevent Blindness Lew R. Wasserman Merit Award. The authors attest that they meet the current ICMJE criteria for authorship.

REFERENCES

1. Lavin P, Patrylo M, Hollar M, Espaillat KB, Kirshner H, Schrag M. Stroke risk and risk factors in patients with central retinal artery occlusion. *Am J Ophthalmol* 2018;196:96–100.
 2. Hayreh SS. Do patients with retinal artery occlusion need urgent neurological evaluation? *Am J Ophthalmol* 2018;196:53–56.
 3. Arnold AC. Urgent evaluation of the patient with acute CRAO. *Am J Ophthalmol* 2018;196:xvi–xvii.
 4. Biousse V, Nahab F, Newman NJ. Management of acute retinal ischemia. Follow the guidelines! *Ophthalmology* 2018;125(10):1597–1607.
 5. Youn TS, Lavin P, Patrylo M, et al. Current treatment for central retinal artery occlusion: a national survey. *J Neurol* 2018;265(2):330–335.
 6. Olsen TW, Pulido JS, Folk JC, Hyman L, Flaxel CJ, Adelman RA. Retinal and Ophthalmic Artery Occlusions Preferred Practice Pattern®. *Ophthalmology* 2017;124(2):P120–P143.
-

Five-Year Postoperative Outcomes of Bilateral Aphakia and Pseudophakia in Children up to 2 Years of Age: A Randomized Clinical Trial



EDITOR:

WE READ WITH INTEREST THE RECENT ARTICLE BY VASAVADA and associates¹ reporting the results of their clinical trial randomizing children <2 years with bilateral cataracts to intraocular lens (IOL) implantation or aphakia. They reported a lower incidence of visual axis opacities (VAO) in the pseudophakic group than did the Infant Aphakia Treatment Study (IATS) while reporting similar visual acuities in the 2 treatment groups.² The low incidence of VAO in the Vasavada study is to be commended; however, the patient populations in these studies differed in 2 important ways that make comparison difficult. First, the median

age of the children undergoing IOL implantation was quite different: IATS = 1.8 months; Vasavada = 6.0 months. The rate of VAO is much higher after cataract surgery in children <6 months of age, even when performed by an experienced surgeon.³ Second, all patients in the IATS had unilateral cataracts, 63% of which were persistent fetal vasculature (PFV) or nuclear, whereas no patients in the Vasavada study had PFV and the number of nuclear cataracts is unknown. In particular, PFV is associated with a higher incidence of adverse events.⁴ Most patients in the Vasavada study had lamellar or total cataracts compared to <4% of the IATS patients.

Vasavada and associates reported that only 2 of 30 (6%) patients randomized to aphakia in their study wore contact lenses for >1 year. In contrast, contact lens wear averaged over 90% for the children randomized to aphakia in the IATS.⁵ Vasavada and associates attributed this difference to the fact that parents were not charged for contact lenses in the IATS and “monitoring of compliance was performed by regular home visits by trained personnel.” While it is true that contact lenses were provided at no cost to parents in the IATS, home visits were not part of the IATS protocol.²

The Vasavada protocol mandated that patients undergo an examination under anesthesia every 3 months for the first postoperative year and then every 6 months until age 5 years. Assuming that a patient undergoing cataract surgery at age 6 months returned for each examination, they would have received general anesthetics 13 times by age 5 years. Because of concerns about the neurotoxicity of general anesthesia in young children, general anesthesia was reserved for children undergoing additional surgeries in the IATS.⁶ In fact, the need for additional general anesthetics for children in the pseudophakic group was one of the primary reasons we advised against primary IOL implantation in infants unless “the cost and handling of a contact lens would be so burdensome as to result in significant periods of uncorrected aphakia.”² We congratulate Vasavada and associates on their excellent surgical outcomes in a challenging patient population and we agree that IOLs are a good option for children >6 months of age. However, for the reasons stated and for long-term refractive considerations not addressed in their paper, we still believe that it is generally better to leave infants <6 months of age aphakic after cataract surgery and to correct their aphakia with contact lenses or spectacles.

SCOTT R. LAMBERT

Stanford, California, USA

ERICK D. BOTHUN

Rochester, Minnesota, USA

DAVID A. PLAGER

Indianapolis, Indiana, USA

FUNDING/SUPPORT: SUPPORTED BY NATIONAL INSTITUTES of Health Grants U10 EY13272, U10 EY013287, UG1 EY013272, UG1 EY025553, P30 EY026877 and Research to Prevent Blindness, Inc, New York, New York, USA. Financial Disclosures: The following

authors have no financial disclosures: Scott R. Lambert, Erick D. Bothun, and David A. Plager. All authors attest that they meet the current ICMJE criteria for authorship.

REFERENCES

1. Vasavada AR, Vasavada V, Shah SK, et al. Five-year postoperative outcomes of bilateral aphakia and pseudophakia in children up to 2 years of age: a randomized clinical trial. *Am J Ophthalmol* 2018;193:33–44.
2. Infant Aphakia Treatment Study Group, Lambert SR, Lynn MJ, et al. 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(6):676–682.
3. Plager DA, Yang S, Neely D, Sprunger D, Sondhi N. Complications in the first year following cataract surgery with and without IOL in infants and older children. *J AAPOS* 2002;6(1):9–14.
4. Morrison DG, Wilson ME, Trivedi RH, Lambert SR, Lynn MJ. Infant Aphakia Treatment Study: effects of persistent fetal vasculature on outcome at 1 year of age. *J AAPOS* 2011;15(5):427–431.
5. Cromelin CH, Drews-Botsch C, Russell B, Lambert SR, Infant Aphakia Treatment Study Group. Association of contact lens adherence with visual outcome in the Infant Aphakia Treatment Study: a secondary analysis of a randomized clinical trial. *JAMA Ophthalmol* 2018;136(3):279–285.
6. Walters JL, Paule MG. Review of preclinical studies on pediatric general anesthesia-induced developmental neurotoxicity. *Neurotoxicol Teratol* 2017;60:2–23.

Five-Year Postoperative Outcomes of Bilateral Aphakia and Pseudophakia in Children up to 2 Years of Age: A Randomized Clinical Trial



WE READ WITH GREAT INTEREST THE ARTICLE BY Vasavada and associates.¹ As has been highlighted well by the authors, intraocular lens (IOL) implantation in pediatric cataract, especially when dealing with patients <2 years of age, remains a matter of concern. In this regard, this study is of paramount importance as it highlights the safety of IOL in these cases, with visual outcome comparable to the aphakia group. However, there are a few concerns, which we would like to highlight.

In any randomized controlled trial (RCT) the sample size calculation, as well as the power of the study, is crucial for interpretation and extrapolation of the results. However, we could not find a mention of the same in the manuscript.

The cut-off of intraocular pressure for diagnosis of glaucoma in this study was taken as 21 mm Hg. Although the cut-off is well established for adult patients, will it remain the same for pediatric cases?²

The authors have assessed the anterior segment inflammation based on large and small cells with the help of

slit-lamp attachment in a microscope for this study. We went through the authors' cited reference in this regard; however the criteria used for classification of small and large cells were not clear to us.³ Since this is an RCT, we believe that the criteria for classifying cells should be discussed in the methodology section, which would help the readers. Do the authors believe that the presence of cell deposit over the IOL surface always indicates inflammation? A retained viscoelastic substance can also result in deposits over the IOL surface. Also, did the authors modify the steroid regimen on the basis of examination under anesthesia (EUA) findings of cell deposits in early follow-up?

We would like to know the rationale for prescribing +16 diopter spectacles in the aphakic group in the immediate postoperative period. Wouldn't it be a better idea to perform retinoscopy of the first eye when operating the second eye for prescribing spectacles? Also, the authors state that after suture removal, glasses were prescribed for distance correction in all cases. Do they mean that the kids were corrected for distance only, without any near addition? Considering the mean age of 6 months and 8 months in the 2 groups, and the fact that children in this age group predominantly depend on near vision for most of their activities, are the authors justified in prescribing distance correction until the age of 2.5 years?

In the study, the authors have highlighted contact lens compliance well. Can the authors also comment on the spectacle compliance in the 2 groups, as aphakic children are prone to poor compliance with spectacles owing to the thick, heavy, and uncomfortable glasses? Also, the compliance with glasses is bound to change with age. Any difference in the compliance with spectacles can adversely affect the outcome of this study and can explain the cause for delayed visual rehabilitation in the aphakic group.

PRANITA SAHAY

SIDDHI GOEL

PRAFULLA K. MAHARANA

New Delhi, India

FUNDING/SUPPORT: NO FUNDING OR GRANT SUPPORT. Financial Disclosures: The following authors have no financial disclosures: Pranita Sahay, Siddhi Goel, and Prafulla K. Maharana. All authors attest that they meet the current ICMJE criteria for authorship.

REFERENCES

1. Vasavada AR, Vasavada V, Shah SK, et al. Five-year postoperative outcomes of bilateral aphakia and pseudophakia in children up to 2 years of age: a randomized clinical trial. *Am J Ophthalmol* 2018;193:33–44.
2. Jaafar MS, Kazi GA. Normal intraocular pressure in children: a comparative study of the Perkins applanation tonometer and the pneumatonometer. *J Pediatr Ophthalmol Strabismus* 1993;30(5):284–287.
3. Vasavada AR, Shastri LR, Raj SM, Ashutosh S. Cell response to AcrySof intraocular lenses in an Indian population. *J Cataract Refract Surg* 2002;28(7):1173–1181.