**Sir,
Difluprednate versus prednisolone acetate for
inflammation following cataract surgery in pediatric
patients: a randomized safety and efficacy study**

We read with great interest the article by Wilson *et al.*¹ The authors must be congratulated for this randomized control study on pediatric cataract. Potential concern with the use of a highly potent steroid like difluprednate 0.05% is the possibility of intraocular pressure (IOP) elevation. In children, the ocular hypertensive response occurs more frequently and more severely than that reported in adults, and monitoring the IOP is essential in children receiving steroids in any form.² Clinically significant rise in IOP after difluprednate is seen in 50 to even 80% cases in pediatric studies.³

The current treatment regimen used by the authors is same for a neonate and a toddler, that is, four times daily. It is difficult to understand why the same frequency was used in a 10-day-old baby and a 3-year child as the inflammatory response would be much more in younger child necessitating aggressive steroid instillation. This could then have an adverse effect on the IOP even though it may control the inflammation. In such a scenario there could be a question on the safety profile of difluprednate. Our own surgical experience is that, younger the child the more frequent dosing he needs.⁴ Some of these authors who were also part of the Infant Aphakia Treatment Study (IATS) believe that the infants received more corticosteroids than the minimal protocol in their study because the surgeons felt the requirement.⁵

The technique of IOP estimation is not mentioned in the study. There are numerous factors affecting the measurement of IOP in children. Anesthetic gases lower IOP and on the other hand in an office-setting tight squeezing of the lids may increase IOP. What were the preoperative baseline IOP measurements in these children to actually comment on the raised IOP postoperatively? The cut off value of 21 mm Hg in an adult has been extrapolated to children. Since the IOP measured in children is usually lower; this cut off value may be higher for children especially neonates and infants less than 6 months. Authors have also mentioned that the IOP rise in one patient is unrelated to the treatment. We would be interested to know on how this conclusion was reached.

The global inflammation score used by the authors is a very subjective scale. Future advances in the form of a hand-held flare photometer may be a more objective and quantifiable method to monitor the inflammatory response in children.

The IATS group has recommended contact lens use as early as 1 week after surgery for aphakia correction. In the present study the authors used topical medicine over the contact lens. Although 0.05% difluprednate (Durezol ophthalmic emulsion, Alcon laboratories, Inc, Irvine, CA, USA) has sorbic acid as preservative instead of benzalkonium chloride, the statutory warning with the drug prohibits its use over the contact lens. What is the opinion of the authors in this regard?

Although difluprednate 0.05% is a welcome addition to the steroid family to curb inflammatory response after cataract surgery, it would not be wise to authenticate its safety from this study considering the more frequent and

longer dosing schedule required in infants as compared with older children.

Conflict of interest

The authors declare no conflict of interest.

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We thank Drs. Kaur and Sukhija for their interest in our article. They make several interesting and important points in their letter. They mention that difluprednate is a highly potent steroid that may cause intraocular pressure elevation. They also mention that they dose steroids more frequently than four times per day in infants and young children.

Our study was a multicenter randomized controlled trial comparing difluprednate 0.05% to prednisolone acetate 1% in children aged 0–3 years after cataract surgery.¹ The U.S. FDA requested that the study be performed on children of this age.

We personally use four times per day dosing of topical prednisolone acetate in our practices after cataract surgery in infants and children. Over the last several years, we have each adopted a four times per day dosing regardless of age and increase the frequency only in