

EDITORIAL

Comments on: Dye-Enhanced Anterior Capsulorhexis: Surgical Techniques, Guidelines, and Recommendations for Surgeons

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Dye staining of the anterior capsule is one of the most significant advances in the management of complicated cataracts. Drs. Pandey, Werner, Vroman, and Apple summarize the growing body of evidence, which demonstrates that this technique is safe and effective. Safety, however, depends on the specific dye and the formulation. Lawrence et al reported on four eyes in which intraocular methylene blue, used for capsular staining, resulted in irreversible corneal edema that eventually required corneal transplantation.¹

Horiguchi et al first described the use of 0.5% indocyanine green (ICG) to stain the anterior capsule in 1998.² In a randomized, prospective study of 20 consecutive mature white cataracts, half of which received ICG dye and half of which did not, there were no statistically significant

differences in endothelial cell loss, laser flare-cell photometry, or postoperative intraocular pressure. It is important to note that lyophilized ICG is sold and packaged with a solvent that, being intended for IV injection, is of an inappropriate pH and osmolality for the anterior chamber. For this reason, Horiguchi et al mixed the dye using BSS Plus[®] (Alcon, Ft. Worth, TX) and the supplied solvent in a ratio of nine parts to one. In 1999, Melles and coauthors published their series of 30 mature cataract patients using 0.1% trypan blue dye to stain the anterior capsule.³ There was no clinical evidence of increased inflammation, corneal endothelial impairment, or elevated intraocular pressure; however, there was no control group.

Each of these two dyes was chosen because of laboratory and animal studies supporting their

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safety. Indocyanine green was nontoxic in rabbits, and had been safely used to count cells on donor keratoplasty buttons.⁴ This was also true of trypan blue, which had been used to examine the endothelium in over 32,000 donor corneas by the Dutch National Eye Bank.³ To gain approval in Europe, a standard cytotoxicity study with cultured fibroblasts was used by Melles to evaluate four different dyes—trypan blue, ICG, methylene blue, and gentian violet. Trypan blue showed the best score with insignificant toxicity (personal communication, Gerritt Melles, Dutch Ophthalmic Research Company, Netherlands, September 2001). Since these initial reports, both of these dyes have been widely adopted worldwide. For example, trypan blue is available in 80 countries, with approximately 450,000 units sold to date. There are no published complications directly attributable to either dye.

With respect to efficacy, the benefit of improved capsule visualization is clinically very obvious. However, there has also been one randomized study that demonstrated better visualization improves the ability to complete a capsulorhexis in mature cataracts.⁵ In their paper presented at the American Academy of Oph-

thalmology annual meeting in 2001, Dada and coworkers randomized 50 eyes (10 eyes each) to capsular staining with five different agents—0.1% trypan blue, 0.001% gentian violet, 0.5% ICG, 2% fluorescein, and autologous hemocoloration. The first three dyes provided superior capsule visualization and capsulorhexis success rates with no cases of capsule tear extension. Each of the last two groups had poor visualization and a 20% extension rate.

In 2000, I reported a clinical comparison of ICG and trypan blue.⁶ Trypan blue provides a significantly darker and more intense staining of the capsule. This is particularly helpful when other factors, such as corneal edema, are present. In addition, trypan blue provides a more persistent, long-lasting staining of the anterior capsule. This greatly facilitates nuclear emulsification in mature white and brown lenses, where poor visualization makes the capsulorhexis more likely to be torn with the phaco tip or second instrument.

In the United States, there is no FDA-approved dye for capsular staining. Only ICG is available, being approved for choroidal angiography, but labeling issues preclude packaging it in a smaller, more cost-effective quantity. Un-

fortunately, randomized controlled studies large enough to demonstrate reduced complication rates in mature cataracts with capsular dye raise ethical concerns, and have been deemed too costly by the manufacturers involved. For this reason, no FDA capsular dye trial has been initiated, and trypan blue continues to be unavailable to U.S. eye surgeons and their patients.

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