AMERICAN GLAUCOMA SOCIETY

Position Statement on New Glaucoma Surgical Procedures

The American Glaucoma Society (AGS) is an organization of over 700 fellowship-trained glaucoma surgeons in the United States whose mission is to promote excellence in the care of patients with glaucoma, and preserve or enhance vision by supporting glaucoma specialists and scientists through the advancement of education and research.

The AGS recognizes and supports its members who are working to advance the surgical care of glaucoma. Glaucoma filtration surgery, commonly performed as a trabeculectomy, is considered the gold-standard surgical procedure for patients who have failed medical or laser therapy, or who have advanced glaucoma because of its significant intraocular pressure lowering effect that serves to prevent further vision loss. However, glaucoma filtration surgery has been performed for over a hundred years with only minor modifications to the technique as microsurgical instruments, suture material and wound healing adjuncts became available. While often successful in lowering intraocular pressure and slowing disease progression, glaucoma filtration surgery may be associated with early and late complications such as hypotony, bleb leaks, and bleb-related infections.

In recent years, technologies have become available that seek to avoid the complications of traditional filtration surgery by accessing the eye's natural aqueous drainage pathways and enhancing them. These technologies specifically seek to avoid a filtration bleb that can be the source of infection, discomfort, and other problems. These technologies represent a shift in focus and skills, yet seek to accomplish the goal of lowering intraocular pressure sufficiently to prevent vision loss from glaucoma.

A new technology whose intraocular pressure lowering effect allows for a reduction in medications, or a reduction in the need for more advanced surgical care, or improves patient adherence to care, would provide advantages to glaucoma patients. If effective and safe, we believe that these benefits and the fact that these technologies will not have bleb-related complications would represent an "improvement in net health outcomes". In addition, some of these types of glaucoma surgical techniques still allow traditional filtration surgery to be performed in the future if necessary. The AGS supports the

development of new technologies that will allow for effective and safer surgical management of glaucoma.

The AGS is a member of the World Glaucoma Association and has reviewed and endorsed a recent publication entitled: The World Glaucoma Association Guidelines on Design and Reporting of Glaucoma Surgical Trials. Please see the World Glaucoma Association Surgical Trials paper for more in-depth discussion of conducting surgical clinical trials. http://www.icoph.org/resources/148/Guidelines-on-Design-and-Reporting-of-Glaucoma-Surgical-Trials.html

Given that traditional glaucoma filtration surgery has a well-documented literature of effectiveness and complications, the AGS has established criteria under which Case Series of new glaucoma surgical technologies may be evaluated.

CRITERIA FOR PROPER REPORTING OF CASE SERIES:

1. Case series should report on all patients undergoing a planned procedure, even if the procedure needed to be aborted.
2. Case series should have at least 1 year of follow-up on all patients reported (not just an average follow-up of 12 months).
3. Results should be reported as Kaplan-Meier or other life-table analysis and scatter plots. Definitions of success and failure should be unambiguously stated and determined a priori, and failures at any time point not censored for analysis at subsequent time points.
4. Case series results should be clearly divided into cases that underwent the investigated procedure alone, and the investigated procedure combined with cataract surgery. These two groups should not be reported together as a combined series, but should be reported separately for all outcome measures. The most useful series will be reports on the investigated procedure as a therapy with consistent procedural techniques.
5. Important outcome measures are intraocular pressure and complications. Intraocular pressure results should indicate the number of eyes requiring IOP lowering medications postoperatively at various time points, as well as the number of medications.

6. Complication detection should be explained in detail in the report and should be determined at the outset of the study to include relevant, clinically significant complications.

COMMENTS ON SURGEONS AND SUBJECTS AND OUTCOME MEASURES:

1. The AGS strongly urges all study authors and participants to fully disclose financial interests and funding for surgical trial reports.

2. The AGS recommends that a limited number of surgeons be involved in the early phase of refining a technique and teaching it to other surgeons. Once the technique is refined, at least 50 eyes should be compiled for an initial analysis. Once the procedure is disseminated and in "widespread use", an acceptable number of surgeons actively utilizing the technique might be defined as 15% of the clinical glaucoma specialists in the AGS. The AGS strongly encourages all surgeons involved in a new technology procedure to collect clinical information about their cases, in a standardized fashion.

3. Given that trabeculectomy is a relatively rare surgical procedure (only 30,000 annual cases in the Medicare population), and glaucoma drainage implants with far posterior plate reservoirs even rarer (less than 9000 annual Medicare cases), the AGS acknowledges that relatively small numbers of subjects will comprise surgical trial reports, and still be acceptable for evaluation of the technique. An acceptable number of eyes enrolled in a case series reported out to at least 12 months of a technique meant to supplant or be an alternative to trabeculectomy might be 100. An acceptable number of eyes enrolled in a case series of previously operated eyes undergoing a far posterior aqueous drainage procedure might be 50. Although power calculations may be used to alter the necessary number of eyes required to show efficacy.

4. Successful outcome elements for new intraocular pressure lowering techniques may include an increased safety profile, or improvement in patient adherence and/or comfort, or reduction in medication use, or speed or simplify recovery, postoperatively,

5. Each new procedure should be compared to an appropriate control group based on the proposed or observed efficacy and safety profile, and need not be compared to trabeculectomy. For example, surgical techniques that are known to lower the intraocular pressure by modest amounts may still allow for an improvement in health outcomes and may necessitate a more appropriate comparison than trabeculectomy.

6. Some categories of new surgical devices and techniques are utilized at the time of concomitant cataract surgery. Cataract surgery alone has been shown to lower intraocular pressure. A control group of patients with similar entry criteria undergoing cataract surgery alone may be appropriate for these technologies.

The AGS recognizes the limitations of surgical trial evaluations, but also strongly supports the investigation of new technologies to help our patients achieve effective and safe vision preservation.

Revised and Approved by the AGS Board of Directors: February 29, 2012

Approved by the AGS Board of Directors: October 23, 2009