Glaucoma Drainage Devices for Cataract Surgeons

Surgeons are newly excited about the prospect of treating glaucoma patients!

BY RICHARD A. LEWIS, MD

veryone wants to be a glaucoma surgeon these days—or so it seems! The dream of safely and surgically controlling IOP seems closer than ever. The allure of good diurnal pressure control without eye drops has caught the attention of the large pharmaceutical manufacturers as well as the venture capital world. One would think from all this ophthalmic media attention that an in-office outpatient surgical glaucoma cure was imminent. Although it might be closer at hand than ever before, more work remains to be done. Some of these new procedures are approved and available; others remain in clinical development.

Glaucoma surgery has not always elicited excitement. The old surgical standby, trabeculectomy, is technically straightforward but fraught with early and late postoperative complications. Innovations such as the use of mitomycin C and laser suture lysis have helped surgeons achieve greater efficacy but have not consistently provided greater safety. The unreliable nature of this century-old procedure scared off many ophthalmologists and fostered the use of polypharmacy in order to avoid surgery. For the most part, glaucoma surgery has been performed by glaucoma surgeons. This paradigm is definitely changing.

How can surgeons make sense of the "new" procedures? What is known about them? How will they fit into surgeons' practices?

MORE PROCEDURES BEING DONE

One thing is clear: the number of glaucoma procedures is increasing. Some have been "reborn" (eg, cataract surgery as a standalone procedure to lower IOP for some types of glaucoma). Others represent modifications to prevent scarring such as the Ex-Press mini glaucoma shunt (Alcon Laboratories, Inc., Forth Worth, TX).

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Still others are new and advancing through clinical trials. In fact, referring to all of the procedures as *drainage devices* is misleading. It is more accurate to define the new procedures based on the site of action (ie, transscleral, canalicular, suprachoroidal).

TRANSSCLERAL PROCEDURES

These procedures drain fluid from the anterior chamber, through the sclera, and into the subconjunctival space. The classic trabeculectomy surgery uses a Kelly punch to create a scleral hole under a superficial patch of sclera. The intraoperative application of mitomycin C decreases scarring of the conjunctiva and facilitates formation of a bleb cyst. Controlling aqueous outflow is the challenge. Too large a hole and there is hypotony; too small and the bleb collapses. The Ex-Press allows greater standardization of the hole. Meticulous closure of the conjunctival wound is necessary in all filtering surgery to prevent leaks. The key to achieving good IOP control depends on the size of the bleb or drainage area. A new device in clinical development from AgueSys (Irvine, CA) would place a delicate tube ab interno through the scleral angle to create a bleb while avoiding conjunctival manipulation and fibrosis.

Drainage devices or implants such as the Ahmed Glaucoma Valve (New World Medical, Inc., Rancho

Cucamonga, CA), Molteno Implant (Molteno Ophthalmic Ltd., Dunedin New Zealand), and Baerveldt Glaucoma Implant (Abbott Medical Optics Inc., Santa Clara, CA) work on a similar transscleral principle. A silicone tube is placed into the anterior chamber to drain to a silicone plate 8 to 10 mm back from the limbus. The size of the plate dictates the extent of the IOP reduction. Unlike the other devices, the Ahmed implant has a valve at the proximal end of the tube created that prevents the IOP from dropping too low. The Molteno and Baerveldt implants require an absorbable suture to temporarily ligate the tube until tissue fibrosis or encapsulation occurs over the plate to control outflow.

A landmark study comparing trabeculectomy versus Baerveldt tubes confirmed that both approaches successfully lower IOP over 3 years. Side effects were surprisingly high for both procedures in the short and long term. The implants are indicated when conjunctival scarring will limit formation of a bleb and in many of the secondary glaucomas.

CANALICULAR

These nonpenetrating procedures work directly in the canal of Schlemm. They mechanically alter the canal to enhance outflow without dependence on a conjunctival bleb or subconjunctival drainage. Trabeculotomy, canaloplasty (iScience Interventional, Menlo Park, CA), and Trabectome surgery (NeoMedix Corporation, Tustin, CA) are FDA approved and commercially available. The FDA's Ophthalmic Devices Panel of the Medical Devices Advisory Committee recently recommended approval of the iStent (Glaukos Corp., Laguna Hills, CA), and other devices are in clinical trials and/or waiting FDA review. These procedures require open angles and can be further differentiated by the presence or absence of a direct opening of the stent through the trabecular meshwork.

For example, the ab interno Trabectome procedure is completed with a gonio prism. An electrocautery on the tip obliterates 90° to 120° of the trabecular meshwork and thus eliminates that site of resistance to outflow. Canaloplasty, first used in 2005, does not disrupt the meshwork but enhances circumferential flow from the canal of Schlemm to the collector system.² The surgeon passes a catheter through the canal to facilitate the placement of a tensioning suture in this space. Outflow increases through the meshwork as well as through a Descemet's window. Both Trabectome surgery (data on file with NeoMedix Corporation) and canaloplasty have good efficacy data beyond 3 years (unpublished data, 2010). These nonpenetrating procedures significantly reduce the chance of hypotony-related side effects, and

they can be performed in conjunction with cataract surgery. In fact, pseudophakia seems to offer a greater chance of lowering the IOP.

SUPRACHOROIDAL

The CyPass (Transcend Medical, Menlo Park, CA) is placed ab interno in the anterior chamber angle at the iris root, with fluid directed to the suprachoroidal space. Leaving a stent in this space represents a new frontier for glaucoma surgery. Clinical trials in Europe are currently underway, and the early data appear promising.3

OTHER

Endocyclophotocoagulation (Endo Optiks, Little Silver, NJ) has been available for a number of years. Unlike earlier iterations of the procedure, no device is left in the eye. Cyclophotocoagulation is applied through an endoprobe to directly disrupt the ciliary body and reduce aqueous formation.

Ologen (Optous, Greenville, SC) is a collagen matrix used to enhance wound healing. Glaucoma surgeons are using this new material to cover sclerostomy sites in trabeculectomy as well as placing it under the superficial scleral flap in nonpenetrating surgeries.

SUMMARY

The plethora of new glaucoma surgeries has allowed glaucoma surgeons to get beyond the "one-size-fits-all approach" of trabeculectomy. No one questions that the new procedures are significantly safer than filtering surgery. What remains to be validated is long-term efficacy. If these procedures can maintain IOP levels in the low to midteens, the renaissance will continue.

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