

Update on New Glaucoma Surgical Devices

The trend toward less-invasive procedures continues.

BY ROBERT J. NOECKER, MD, MBA

Glaucoma surgery continues to evolve. Many new devices that are currently under investigation or that were recently introduced onto the market use existing physiologic pathways. These technologies are designed to increase safety and reduce surgical manipulation. A growing trend in the field of glaucoma is the development of procedures that can be performed in conjunction with cataract surgery with little additional anesthesia and minimal effects on refractive error.

WHAT IS AVAILABLE NOW

Background

Innovation in glaucoma surgery has lagged when compared with the fields of cataract and refractive surgery. Trabeculectomy remains the gold standard procedure, despite the unpredictability and risk associated with intraoperative variation and patients' healing. Glaucoma drainage devices (Baerveldt glaucoma implant [Abbott Medical Optics Inc., Santa Ana, CA], Ahmed Glaucoma Valve [New World Medical, Inc., Rancho Cucamonga, CA], and Molteno Implant [Molteno Ophthalmic Limited, Dunedin, New Zealand]) are still the most commonly used second-line surgical interventions for glaucoma. These implants have changed little during the past 30 years.

The trend toward minimally invasive glaucoma surgery (MIGS) began with the introduction of endocyclophotocoagulation (ECP), canaloplasty, ab interno trabeculotomy, and the Ex-Press Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX). All are currently available in the United States and have been in use for a number of years.

Endocyclophotocoagulation

In my hands, the results of ECP have gotten better with improvements in fiber optics and laser technology (E2 Microprobe Laser and Endoscopy System; Endo Optiks, Little Silver, NJ) as well as the development of treatment algorithms that permit more aggressive treatment (Figure 1). ECP is also the one procedure that addresses the inflow of aqueous through selective ablation of the ciliary epithelium. ECP can be used in conjunction with outflow procedures.



Figure 1. Endoscopic view of the ciliary processes. The treatment endpoint is whitening and shrinkage of the processes, which in turn reduces the amount of ciliary epithelium producing aqueous.

Canaloplasty

Canaloplasty has emerged as an effective procedure that, in my experience, lowers IOP over an extended period of time by augmenting the eye's natural outflow apparatus. Canaloplasty appears to decrease the IOP through the creation of a Descemet window and the dilation and tensioning of the trabecular meshwork. The latter step is accomplished by means of a unique microcatheter system (iTrack microcatheter; iScience Interventional, Menlo Park, CA) and the placement of a suture in Schlemm canal. Some surgeons find the procedure to be technically challenging, but the clinical data demonstrating its ability to lower IOP are compelling.¹

Ab Interno Trabeculotomy

The Trabectome (NeoMedix Corporation, Tustin, CA) is a thermal cautery device that is used to ablate a quadrant of trabecular meshwork under direct gonioscopic visualization (Figure 2). In my experience, the removal of a section of the trabecular meshwork facilitates outflow. The procedure is relatively quick and is frequently performed in conjunction with cataract surgery. It appears to lower the IOP marginally well.²

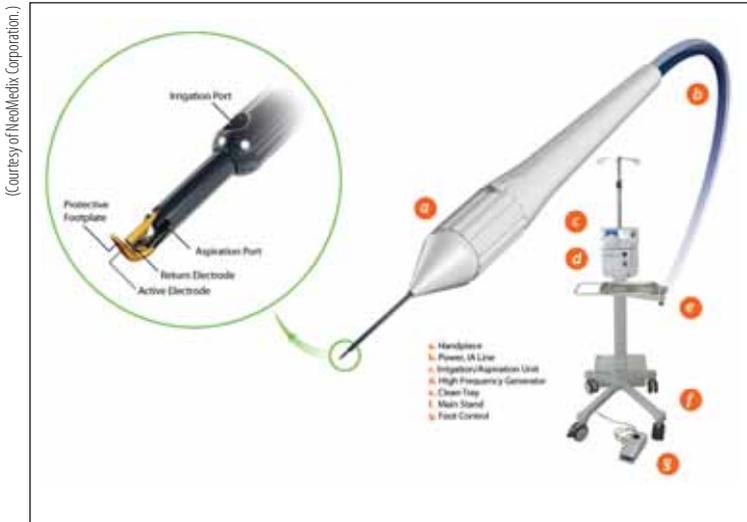


Figure 2. The Trabectome system.



Figure 3. Several hours after surgery with the Ex-Press Glaucoma Filtration Device, this patient had a visual acuity of 20/25 and minimal postoperative inflammation.

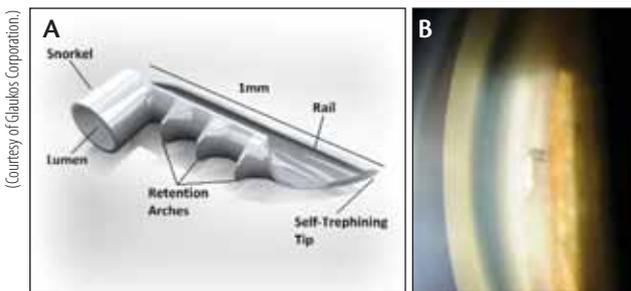


Figure 4. The iStent (A). A gonioscopic view of the implanted device (B).

Modified Filtering Surgery

I have found the Ex-Press to improve on the traditional trabeculectomy by standardizing the procedure and restricting outflow during the intraoperative and immediate postoperative periods (Figure 3). This stainless steel mini-shunt is placed under a scleral flap and makes filtering surgery more reproducible and less traumatic by eliminating the need for iridotomy and reducing the amount of tissue to cut. Postoperatively, patients' recovery appears to be faster, and the need for additional intervention seems to be lesser than after traditional trabeculectomy surgery.³

ON THE HORIZON

Several new devices are currently being evaluated in US clinical trials. These MIGS procedures can be grouped into those that improve on traditional procedures that bypass the outflow system, those that increase outflow by bypassing the trabecular meshwork, and those that lower IOP by increasing outflow through the uveoscleral pathway.

The AqueSys Implant (AqueSys, Irvine, CA) is placed in the eye via an ab interno approach to create a pathway

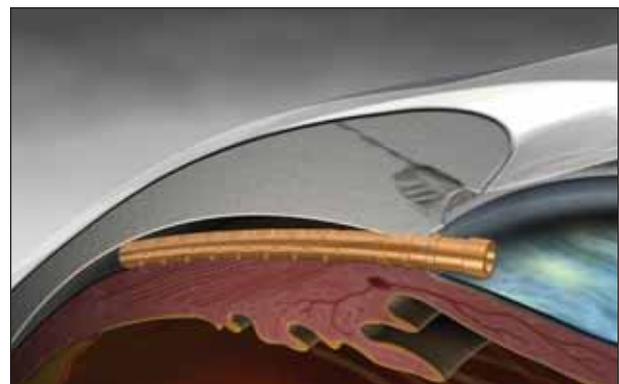


Figure 5. The CyPass Micro-Stent is placed in the supraciliary space, allowing outflow to the choroidal space.

to the subconjunctival space. The surgeon inserts a pre-loaded needle through the cornea and then passes it across the anterior chamber and into the subconjunctival space. According to the company, the implant keeps the outflow pathway open to the subconjunctival space and remains in place permanently unless it is removed.

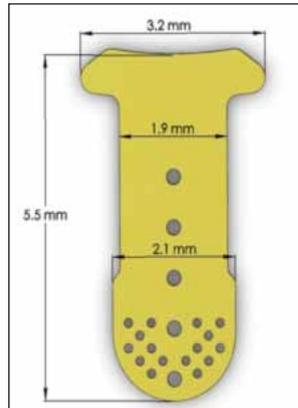
The surgeon inserts the iStent (Glaukos Corporation, Laguna Hills, CA) through a clear corneal incision into Schlemm canal under gonioscopic visualization. This small, titanium, trabecular-bypass device allows aqueous fluid to drain directly into Schlemm canal (Figure 4). Current trials are investigating the placement of more than one iStent to further lower the IOP. The device is designed for use in early-to-moderate glaucoma, frequently in combination with cataract surgery.

Similarly, the surgeon places the Hydrus intracanalicular implant (Ivantis Inc., Irvine, CA) in Schlemm canal under gonioscopic visualization. This device is larger than the

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iStent and reportedly opens more clock hours of Schlemm canal. The Hydrus may work by creating a relatively large opening through the traditional source of blocked flow and achieving a scaffolding effect within Schlemm canal. Clinical trials are evaluating the device's use alone and in conjunction with cataract surgery.



(Courtesy of Solx, Inc.)

Figure 6. The Solx Gold Shunt.

In addition, clinical trials are assessing the safety of the CyPass Micro-Stent (Transcend Medical, Menlo Park, CA) and its efficacy in lowering IOP via the suprachoroidal space (Figure 5). This microstent is inserted through a clear corneal incision and placed in the supraciliary space. It is designed to increase uveoscleral outflow. The device's implantation can be combined with cataract surgery.

Also placed in the suprachoroidal space is the Solx Gold Shunt (Solx, Inc., Waltham, MA). This 3- X 6-mm device is made of gold that is less than 0.1 mm thick and is highly biocompatible (Figure 6). Using an external approach, the surgeon inserts the shunt through a 3-mm incision in the sclera and places it in the supraciliary space. Previous glaucoma procedures failed in the study population for the device's clinical trials.

CONCLUSION

New devices hold the promise of making MIGS a reality, with its associated faster visual recovery. The FDA's approval of more of these technologies will increase ophthalmologists' ability to customize surgery to the specific physiologic deficiencies of each eye. ■

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