Glaucoma Devices for the Anterior Segment Surgeon
New glaucoma devices have the potential to dramatically change patients’ care.
By John Berdahl, MD

Surgeons have long been accustomed to the perils of traditional glaucoma surgeries such as trabeculectomies and tube shunts. Because of the high morbidity rate associated with traditional glaucoma surgeries, many anterior segment surgeons have left these technically challenging and artful surgeries to fellowship-trained glaucoma specialists. Yet, even in the hands of these surgeons, the outcomes of trabeculectomies and tube shunts are not great. The 5-year results from the Tube Versus Trabeculectomy (TVT) Study have shown that 46.9% of trabeculectomies and 29.8% of tube shunts failed at 5 years.¹

Clearly, there is a need for improved surgical options for glaucoma management. Compliance with ocular hypotensive medications is known to be quite poor, and a wide range of compliance rates have been reported in the literature.² Laser trabeculoplasty (either selective [SLT] or argon laser [ALT]) is an option; some patients are able to reduce their medication requirements after treatment, which avoids compliance issues and may delay surgical intervention. The intraocular pressure (IOP) lowering response, however, is underwhelming.

EXPANDING TREATMENT CHOICES
In the current treatment paradigm, surgeons often find themselves in the difficult position of trying to delay surgery (because of the risks), and patients can have difficulty keeping up with the expense and challenge of taking glaucoma drops. Thankfully, new microinvasive glaucoma surgeries (MIGS) are bridging the gap for those patients with mild to moderate glaucoma who could benefit from a safe and effective surgical option (Table).

As a new category of glaucoma surgery, MIGS has strong advantages. The safety profile and recovery time for MIGS procedures is similar to that after cataract surgery.⁴ From an efficacy standpoint, MIGS is an elegant procedure that can lower IOP, reduce dependence on medications, and slow the progression of glaucoma.

Currently, two devices approved by the US and Food and Drug Administration (FDA) fall into the MIGS category: the iStent Trabecular Micro Bypass (Glaukos Corporation) and the Trabectome (ab interno trabeculotomy; NeoMedix Corporation). Some would include endoscopic cyclophotocoagulation (ECP) in the MIGS category; however others would not because of the induced trauma to the ciliary body and slower recover time.

The iStent has the distinction of being the only glaucoma device ever to go through the rigorous FDA premarket approval process (other devices were approved via the FDA 510K pathway based on approval of prior medical devices). The device is a heparin-coated, titanium, snorkel-shaped device that is implanted directly into Schlemm canal under direct visualization with a gonioprism. The company is currently investigating a version of the device available in a preloaded injector that can be performed through a sub-2.0-mm clear corneal incision.

USING THE DEVICE
The procedure is initiated by filling the anterior chamber with a cohesive viscoelastic. The second and possibly most important step of implanting an iStent is obtaining good visualization of the trabecular meshwork by aligning the microscope, the patient’s head, the patient’s eye, and the gonioprism (Figure 1). Typically, the surgeon operates temporally, which allows a better angle for approaching the trabecular meshwork, because the brow is not obstructing the approach. The patient’s head is tilted away from the surgeon about 30°, and the microscope is tilted about 30° away from the surgeon. The patient is asked to look toward his or her nose and a small amount of viscoelastic is placed on the cornea to couple with the gonioprism. The microscope, head, eye, and gonioprism are all adjusted as needed to obtain a clear view of the trabecular meshwork.

Next, the injector (with the device) is introduced through the clear corneal incision and visualized through the gonioprism. The self-trephinating stent is used to engage the trabecular meshwork and, as it moves laterally, it slides into Schlemm canal. Often, a small reflux of blood is observed; it should be noted that this observation does not constitute trauma to the eye and may be an indicator that the stent is properly positioned. After the stent is in position, the viscoelastic is removed from the eye.

One important consideration is how many stents will be necessary to achieve adequate IOP lowering. This will depend on the needs of the individual patient, however, one stent will provide pressure reduction and that may be adequate for most patients with mild to moderate glaucoma. In those patients who need further pressure reduction, multiple stents may be necessary to achieve the desired IOP-lowering efficacy.

SAFETY AND EFFICACY

The side effect profile and predictability of MIGS in general, and the iStent in particular, is favorable enough that it is reasonable to implant the stent in combination with an accommodating or toric lens to decrease the need for spectacles among these patients. There is certainly no surgical contraindication to MIGS in combination with a multifocal IOL; however, if decreased contrast sensitivity is present or may worsen in the future from glaucoma, then it is advisable to avoid a multifocal IOL which will further decrease contrast sensitivity.

In a randomized controlled multicenter clinical trial that included 240 eyes, 72% of eyes in the treatment group achieved an unmedicated IOP of 21 mmHg or less (P < .001). In this study, the safety profile of the iStent was similar to that of traditional cataract surgery.

The long-term outcomes with the device are still to be determined. Villalobos et al reported results on 19 patients with an average follow up of 53.7 months showing that IOP decreased from an average of 19.4 to 16.3 mmHg and medications used decreased from 1.3 to 0.8.

TRABECTOME

The trabectome has been available in the United States since 2004. The trabectome is a cautery electrode that can strip the trabecular meshwork in the inner wall of Schlemm canal. The handpiece has irrigation/aspiration and an electrocautery unit that can maintain the anterior chamber while stripping the trabecular meshwork. Francis and Winarko showed that phaco-trabectome surgery in 89 eyes resulted in a decrease of IOP from 22.1 to 15.4 mmHg at 1 year (P
The incidence of hyphema after trabecome is increased compared with phacoemulsification alone, and the long-term results still under investigation.

FUTURE DEVICES

The need for better surgical glaucoma options is evidenced by the myriad new MIGS devices currently under investigation, including multiple stents, longer intracanalicular stents, suprachoroidal stents, and subconjunctival stents that are all used with an ab interno approach.

Investigational devices aimed targeting the trabecular meshwork include improvements to the iStent and the Hydrus Microstent (intracanalicular scaffold; Ivantis, Inc.). The trabecular meshwork is a good target to safely lower IOP, as the approach bypasses the high resistance portion of the trabecular meshwork, thus allowing aqueous to directly access Schlemm canal. Because episcleral venous pressure will dampen the IOP-lowering response, hypotony should not occur; however it will not be possible to lower IOP below the episcleral venous pressure, which is usually around 10 mmHg.

Devices that exploit the suprachoroidal space include another stent from Glaukos, the iStent Supra and the CyPass Micro-Stent (Transcend Medical). The suprachoroidal space is a large “sink” and can absorb significant amounts of aqueous fluid. Utilizing the suprachoroidal space may allow surgeons to achieve lower IOP, but since episcleral venous pressure has been bypassed, hypotony is a possibility. The AqueSys (aquecentesis; AqueSys, Inc.) is a device that is intended to utilize the subconjunctival space by inserting a tube from the anterior chamber into a subchoroidal space without violating the conjunctiva externally. As surgeons know from trabeculectomy and tube shunts, the subconjunctival space has a tremendous ability to absorb aqueous and lower IOP dramatically. By entering the subconjunctival space through an internal approach, surgeons will be able to avoid the unpredictable individual healing of the conjunctiva. Of course, hypotony would be a risk since the backstop of episcleral venous pressure is bypassed.

CONCLUSION

Data from trials involving these devices will be forthcoming during the next few years, and glaucoma and anterior segment surgeons alike will benefit from an increased armamentarium of surgical options. The MIGS approach to glaucoma may be able to simultaneously decrease morbidity and increase compliance, thus making the lives of our patients (and our own) much easier and creating the first glaucoma surgical paradigm shift in decades.

Table:
Key features of MIGS devices
1. Ab interno microincision.
2. Minimal trauma.
3. Efficacy.
4. High safety profile.
5. Rapid recovery.
Correct patient posture is essential for visualizing the surgical field through the gonioprism.


