NEW GLAUCOMA DEVICES FOR THE ANTERIOR SEGMENT SURGEON

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. Even in the hands of fellowship training glaucoma surgeons the outcomes of trabeculectomies and tube shunts are not great. The five year results from the tube versus trabeculectomy trial have shown that 46.9% of trabeculectomies failed at five years while 29.8% of tube shunts have failed at five years. Clearly, we need improved surgical options for glaucoma. Compliance with ocular hypotensive medications is also known to be quite poor with wide compliance ranges reported in the literature. SLT and ALT play an important role to help with noncompliance and delay surgical intervention, but often the IOP lowering response is underwhelming. Given the current treatment paradigm, surgeons often find themselves in the difficult position of trying to delay surgery (because of the risks), while patients can have difficulty keeping up with the expense and challenge of taking glaucoma drops everyday. Thankfully, new minimally invasive glaucoma surgeries (MIGS) are bridging the gap for those patients with mild and moderate glaucoma who could benefit from a safe and effective surgical option.

Saheb and Ahmed MD have defined MIGS by a couple of key features:
1. Ab interno microincision.
2. Minimal trauma.
3. Efficacy.
4. High safety profile.
5. Rapid recovery.

As a new category of glaucoma surgery, MIGS has some strong advantages. The safety profile and recovery time for MIGS is quite similar to the fast recovery of cataract surgery. From the an efficacy perspective MIGS is an elegant procedure that can lower intraocular pressure, reduce dependence on medications, and slow the progression of glaucoma.

Currently only 2 FDA approved devices clearly fall into the MIGS category. The Glaukos iStent (Glaukos Corp. Laguna Hills, CA, USA) and the trabectome (Neomedics Inc. Tustin, CA, USA). 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 Glaukos iStent recently received FDA approval as the only glaucoma device ever to go through the rigorous PMA process of the FDA. Other devices were approved the the FDA 510K pathway based on approval of prior medical devices. The Glaukos iStent is a heparin coated titanium snorkel shaped device that is implanted directly into Schlemm’s canal under direct visualization with a gonioprism. The device comes preloaded on an inserter and can be performed through a sub-2 mm clear cornea incision.

The procedure is initiated by filling the anterior chamber with a cohesive viscoelastic. The second and possibly most important step of implanting a stent is obtaining good visualization of the trabecular meshwork by aligning the microscope, patient head, patient eye, and the gonioprism. Typically the surgeon operates temporally, which allows a better angle to the trabecular meshwork since the brow is not obstructing the approach. The patients 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 their 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 inserter and 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 schlemms canal. Often a small reflux of blood is observed. The stent is seated into position and the viscoelastic is removed from the eye. 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 value less than 0.001). The safety profile of the Glaukos iStent was similar to that of traditional cataract surgery.

One important consideration is how many stents will be necessary to achieve adequate IOP lowering. Of course this will depend on the needs of the individual patient, but it is clear that one stent alone will provide pressure reduction and that may adequate for most patients with mild to moderate glaucoma. In those patients who need further pressure reduction multiple stents may be necessary to achieve adequate IOP lowering.

The side effect profile and predictability of MIGS in general and the Glaukos 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.

The long term outcomes of the Glaukos iStent are still to be determined but, however the Villaobos reported results at 53.7 months with repeated results with an average follow up of 53.7 months on 19 patients showing that IOP decreased from an average of 19.4 to 16.3 and medications decreased from 1.3 to 0.8.

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’s canal. The hand piece has irrigation aspiration and an electrocautery unit that can maintain the anterior chamber while stripping the trabecular mesh work. Francis and Winarko showed that phaco-trabectome surgery in 89 eyes resulted in a decrease of IOP from 22.1 to 15.4 at one year (p < 0.01). The incidence of hyphema is a bit increased in trabectome compared to phacoemulsification alone and the long-term results still under investigation.

FUTURE DEVICES

The need for better surgical glaucoma options are evidence by the myriad of new MIGS devices currently under investigation with the FDA include multiple stents, longer intracanalicular stents, suprachoroidal stents, and subconjunctival stents which all take an ab interno approach. Investigational devices aimed targeting the trabecular meshwork include improvements to the currently available Glaukos iStent and the Hydrus canalicular scaffold (Ivantis Inc. Irvine, CA, USA). The trabecular meshwork is a good target to safely lower IOP since the approach simply bypasses the high resistance portion of the trabecular meshwork allowing aqueous to directly access schlemms canal. Since 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 10mmHG. Devices that exploit the suprachoroidal space include a stent from Glaukos and the CyPass Micro-Stent (Transcend Medical, Menlo Park, CA, USA). 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 (Aliso Viejo, CA, USA) 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.

Data from these trials will be coming quickly over 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 ourselves much easier, thus creating the first glaucoma surgical paradigm shift in decades.


