Overview on Microinvasive Glaucoma Surgery

Where are we now?

BY REAY H. BROWN, MD

The advent of microinvasive glaucoma surgery (MIGS) has brought new excitement to glaucoma treatment. The Trabectome (NeoMedix) and the iStent Trabecular Micro-Bypass Stent (Glaukos) are the first MIGS products to become available to US glaucoma surgeons. Other MIGS devices such as the CyPass Micro-Stent (Transcend Medical) and the Hydrus (Ivantis) are currently in clinical trials. These technologies promise to transform glaucoma surgical treatment.

FIRST STEPS

The Trabectome allows surgeons to perform an ablative trabeculotomy from an internal approach and through a very small incision. Trabeculotomy with this device has demonstrated efficacy as a standalone glaucoma procedure and also when combined with cataract surgery.[1]

After more than a decade of research and clinical trials, in 2012, the iStent became the first FDA-approved MIGS device for use in combination with cataract surgery. Glaukos was very careful about the US rollout of the iStent and initially limited its availability to select glaucoma specialists and cataract surgeons. The technology is now available to all surgeons who complete the comprehensive training, including an online course and a wet lab.

CANDIDATES

As the MIGS era unfolds, one question is which patients will benefit the most from these technologies. So far, most of the devices—the iStent, the CyPass, and the Hydrus—have been studied primarily in patients with mild to moderate glaucoma. Typically, the IOP of these individuals is controlled on one or two medications. They generally do not have extensive visual field loss and none that involves fixation. The expectation is that MIGS devices will lower IOPs into the teens but that they may not achieve the ultralow or single-digit pressures needed in patients with advanced glaucomatous damage.

> "MIGS makes possible a new philosophy on treating patients with glaucoma."

PHILOSOPHICAL CHANGE

MIGS makes possible a new philosophy on treating patients with glaucoma. Historically, glaucoma surgery was reserved for patients losing vision despite maximal medical therapy. Treating it as a last resort was appropriate because of the high risks associated with trabeculectomy and tube shunt surgery. The hallmark of MIGS, however, is safety. The pivotal FDA study of the iStent concluded that implanting the device at the end of cataract surgery did not increase the risk of the procedure over that of a cataract surgery done alone.

MIGS therefore challenges ophthalmologists to consider surgery as a valid alternative to medical

FUTURE TRENDS IN DEVICES FOR MICROINVASIVE GLAUCOMA SURGERY

By E. Randy Craven, MD

Microinvasive glaucoma surgery has taken off since the iStent Trabecular Micro-Bypass (Glaukos) received FDA approval in 2012. Many companies and physicians are dedicated to increasing aqueous outflow to lower IOP via a small implant. Glaukos' iStent and iStent Inject (the latter in US clinical trials) circumvent the trabecular meshwork and inner wall of Schlemm canal to reestablish outflow. The advantages of the iStent are its smallness and its ease of insertion once the device is positioned and the surgeon has a good view. It is unknown at this time if two stents will provide a lower IOP than one, but preliminary evidence suggests that two devices and one eye drop can achieve an IOP of less than 15 mm Hg.[1]

The canal might benefit from dilation, however, and the Hydrus (Ivantis) exploits that option by dilating several clock hours of the canal after entering the eye through the trabecular meshwork. This technology is the subject of an FDA clinical trial, and several trials across the globe are evaluating the efficacy of the device. There are few published reports on the Hydrus' efficacy, but the preliminary data are promising.

The suprachoroidal and supraciliary space (the uveoscleral outflow system) is also being investigated for microinvasive glaucoma surgery. IOP values of 12 or 14 mm Hg might be achievable because of the lack of outflow resistance from the collector channels and the episcleral venous pressure. European registry data for the CyPass Micro-Stent (Transcend Medical) showed that patients with uncontrolled IOP achieved over a 35% reduction in IOP after the device's implantation.[2] The uveoscleral outflow system might also work better than the canal system in patients with obstructions to the trabecular meshwork or those who have poor vascularity and a lack of aqueous veins.

The Xen (AqueSys) implant uses a porous gel to slow the flow of aqueous in the hole the device creates. As aqueous moves into the subconjunctival space, it creates a bleb. The gel allows for a more controlled outflow. Data are not yet available, but the concept is appealing.

For now, it appears that these implants, once approved, will fit nicely into daily practice.

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treatment for mild to moderate glaucoma. For example, in the past, a patient with early glaucoma who had well-controlled pressures on one or two medications would not have been a candidate for surgical glaucoma treatment. Today, this patient and his or her surgeon could reasonably consider the placement of a MIGS device at the time of cataract surgery with the goal of reducing the patient's need for ongoing medical treatment. This is a very different strategy from performing a trabeculectomy with the goal of helping a patient with advanced glaucoma discontinue the use of three or four medications by achieving an IOP of 8 to 10 mm Hg.

Although the goals of implanting a MIGS device may appear modest compared with those for a trabeculectomy or tube shunt, these technologies may still have a major impact. Not only would the cessation of one or two medications save patients money, but it might also somewhat ease the psychological burden of a potentially blinding disease by giving patients a more consistently controlled IOP.

There have already been several suggestions for enhancing the efficacy of the iStent. Ike Ahmed, MD, has shown that placing two implants may lower IOP to a greater extent than a single iStent.[2] He has also suggested targeting the device's placement to areas

RESULTS OF CATARACT SURGERY WITH A TRABECULAR MICROBYPASS STENT

By John P. Berdahl, MD

After the FDA approved the iStent Trabecular Micro-Bypass Stent (Glaukos) in 2012, I began a study with my colleagues to evaluate the safety and effectiveness of the device in patients with open-angle glaucoma and a cataract.

Our prospective review included 168 consecutive eyes (patients' mean age, 72 years) with open-angle glaucoma and a cataract. The data we collected included IOP, number of medications, and visual acuity. We monitored IOP for spikes over 15 mm Hg.

My surgical approach is standard. I do not use acetylcholine (Miochol-E; Bausch + Lomb) or carbachol intraocular solution (Miostat; Alcon). In my experience, the device slides easily into the trabecular meshwork, after which I nudge the stent into position. Postoperatively, my patients use steroids and nonsteroidal antiinflammatory drugs for 1 month and antibiotics for 1 week. I stop glaucoma medications 1 week after surgery if the IOP is stable. If the IOP is not in an acceptable range, patients continue using glaucoma medications until their pressure stabilizes.

In the study, the mean preoperative IOP was 18.5 mm Hg. Six months postoperatively, the mean IOP was 14 mm Hg, and the average number of glaucoma medications had decreased from 1.7 to 0.8.

Pressure spikes greater than 15 mm Hg occurred in 20 eyes (12%) at different time points. Most IOP spikes happened on the first postoperative day and then again at the 1-week and 1-month visits. One patient required implantation of an Ahmed Glaucoma Valve (New World Medical).

Based on these results, I believe that combining implantation of the iStent with cataract surgery to be safe and effective, and I expect to achieve a mean reduction in IOP of about 4 mm Hg and to decrease the number of glaucoma medications a patient needs by approximately 50%. I am considering instilling a miotic agent at the time of surgery to see if it reduces the incidence or severity of IOP spikes on the first postoperative day.

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where there is more pigment in the canal, which may indicate higher aqueous outflow. Other surgeons have suggested combining the iStent with endocyclophotocoagulation in a procedure called *ICE*, which stands for iStent, cataract surgery, and endocyclophotocoagulation. There will undoubtedly be many more attempts to modify, improve, and enhance surgery with this and other MIGS devices.

CONCLUSION

Only a small minority of glaucoma patients under treatment has advanced glaucomatous disease requiring traditional filtering surgery. A vast majority of glaucoma patients has mild to moderate disease. Treatment for the latter group has always been medical, but the excellent safety profile of MIGS will make a number of them eligible for surgical treatment.

Glaucoma treatment is ripe for change. Medical therapy is often ineffective due to expense, side effects, and a terrible lack of compliance. Traditional filtration surgery is associated with too many sight-threatening complications. How far the MIGS transformation will go depends on a multitude of evolving factors—safety, efficacy, ease of use, and reimbursement. There is no doubt, however, that the MIGS era has begun. A revolution in glaucoma management may be underway. ■

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