Update on MIGS: Devices of the Future

Although in their infancy, these procedures may improve surgical outcomes, speed visual recovery, and offer greater safety compared with traditional filtering surgery.

BY STEVEN D. VOLD, MD

On June 25, 2012, after more than a decade of development and clinical evaluation, the iStent (Glaukos Corporation) received FDA approval for the management of mild to moderate open-angle glaucoma at the time of cataract surgery. This widely anticipated event may transform how clinicians approach glaucoma management. Previously, surgical intervention for the treatment of glaucoma was largely reserved for patients in whom both medical and laser therapy had failed. Glaucoma surgery was to be avoided unless absolutely necessary. With the iStent now available, many surgeons believe earlier surgical intervention is indicated to provide adequate glaucoma treatment in light of patients' generally poor compliance with prescribed topical therapy, the side effects of glaucoma medications, and the need for 24-hour IOP control. This article provides an overview of potential future advances in the new class of procedures known as *microinvasive glaucoma surgery* or *MIGS*.

WHAT IS MIGS?

Ike Ahmed, MD, coined the term *MIGS* several years ago. Initially, it was an acronym for minimally invasive glaucoma surgery and was generally used to describe a new class of ab interno microstent procedures. Interestingly, the use of this term exploded and was used heavily to market a wide array of glaucoma procedures, not all of them considered by glaucoma subspecialists to be minimally invasive. In fact, *MIGS* was used to describe almost all glaucoma surgeries

Figure 1. iStent Inject.

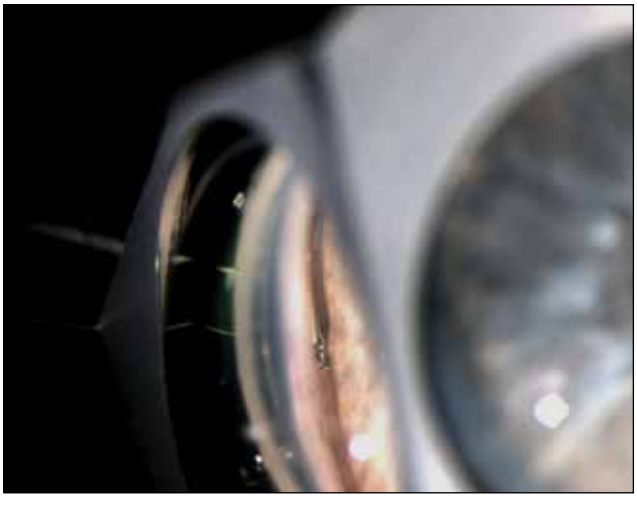


Figure 2. Hydrus.

other than trabeculectomy or tube shunt procedures, and the terminology became quite confusing.

Consequently, Dr. Ahmed and his colleague Hady Saheb, MD, published a review of this topic and clarified their thoughts on this surgical space. They redefined MIGS to represent microinvasive glaucoma surgery and assigned the following criteria to this classification of procedures:

- ab interno surgical approach
- minimal trauma to tissue
- superior safety and a low complication profile compared with traditional filtering surgery
- at least modest IOP-lowering efficacy
- rapid postoperative recovery of patients

TRABECULAR MICROBYPASS MICROSTENTS

iStent Inject

In an effort to further automate the implementation of multiple iStents in a single surgical maneuver, Glaukos Corporation began developing an injector system that uses a rivet-shaped iStent (Figure 1). Currently, this approach is the subject of both FDA clinical trials and overseas studies. One-year clinical results appear to demonstrate the ability of two iStents to lower IOP into the midteens while maintaining an impressive safety profile.[1,2]

Hydrus

The Hydrus (Ivantis, Inc.) is a 6-mm, flexible "scaffold" of Schlemm canal (Figure 2). It is composed of nitinol and is designed to re-establish aqueous flow to the collector channels. This microstent is injected into Schlemm canal through a clear corneal wound by way of an ab interno surgical approach. The Hydrus dilates and supports Schlemm canal and targets approximately 3 clock hours of the collector system. Its unique design may permit later enhancements to aqueous outflow through the application of YAG laser energy to three trabecular meshwork windows in the microstent. Early European data (on file with the company) demonstrate IOPs in the midteens at 12 months. This device is currently available in Europe and is in an FDA investigational device exemption (IDE) clinical trial in the United States.

Ab Interno Canaloplasty

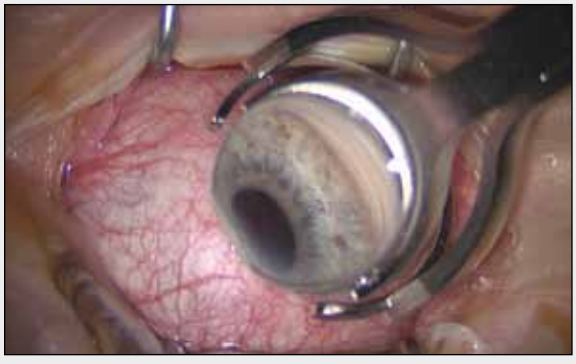
In an effort to increase surgeons' intraoperative efficiency, iScience Interventional is making a significant effort to allow them to place a 360° trabecular-suture microstent from an ab interno approach. The overall impact of this surgical approach on IOP lowering and surgeons' technique has yet to be fully determined.

A NEW GONIOLENS

For many ophthalmic surgeons, intraoperative gonioscopy represents the single most challenging acquired skill in the performance of microinvasive glaucoma surgery (MIGS). Existing direct intraoperative goniolenses used to perform ab interno angle surgery require tilting of the operating microscope and significant dexterity from the surgeon to obtain clear visualization of the anterior chamber angle. With a tilted microscope, surgeons are located farther from the patient, which requires them to alter the normal position of their surgical arm. Furthermore, inexperienced MIGS surgeons are prone to compress the cornea during gonioscopy, potentially compromising their visualization of the angle and shallowing the anterior chamber during surgery.

In an attempt to better meet surgeons' needs, I worked with Transcend Medical to develop the Transcend Vold Goniolens (Figure). This instrument combines a high-quality, floating, direct gonioprism with a stabilization ring that allows the ophthalmologist complete control of the eye throughout surgery. This new goniolens is designed to offer the following unique benefits compared to other goniolenses:

- Visualization of the iridocorneal angle in the primary phaco position with minimal adjustment of the operating microscope and patient's head
- Stabilization and control of the globe throughout surgery
- Superior visualization of the angle and maintenance of gentle contact with the cornea yet simultaneous minimization of potential corneal distortion and anterior chamber shallowing due to manual corneal compression with the goniolens
- An ambidextrous handle so that all surgeons may use a single goniolens



(Courtesy of Transcend Medical.)

Figure. Transcend Vold Goniolens.

I am optimistic that the Transcend Vold Goniolens will enhance surgeons' experiences with MIGS and thus help to optimize patients' surgical outcomes.

Figure 3. CyPass Micro-Stent.

Figure 4. iStent Supra.

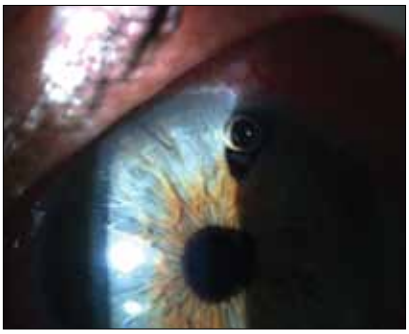


Figure 5. Aquecentesis subconjunctival microstent.

SUPRACHOROIDAL MICROSTENTS

CyPass Micro-Stent

The CyPass Micro-Stent (Transcend Medical) is a supraciliary device composed of a polyimide material (Figure 3). It has a 300-µm lumen and is 6 mm long. The device is implanted via an ab interno approach into the supraciliary space.

The preliminary results of the ongoing FDA IDE trial have been promising: a decrease in IOP of approximately 35% and a significantly reduced need for topical glaucoma medication among patients with mild to moderate open-angle glaucoma in the setting of cataract surgery. The procedure is remarkably straightforward for surgeons and has demonstrated an impressive safety profile thus far.[3,4] Completion of enrollment in the pivotal US IDE trial is targeted for the end of 2012.

iStent Supra

The design of the iStent Supra (Glaukos Corporation; Figure 4) is similar to that of the CyPass Micro-Stent. Both use the uveoscleral outflow mechanism to lower IOP. The pivotal US IDE trial of the iStent Supra just began.

Solx Gold Shunt

Although this device (Solx, Inc.; not available in the United States) has thus far been implanted from an ab externo approach, ab interno placement is now being evaluated as well.

SUBCONJUNCTIVAL APPROACH

Aquecentesis (AqueSys, Inc.) is the first ab interno subconjunctival-space technology to treat glaucoma that has been developed potentially to replace trabeculectomy as the filtration surgery of choice for glaucoma surgeons (Figure 5). This procedure uses a collagen-derived, gelatin implant that is soft and flexible when hydrated. It is noninflammatory and may mitigate the problem of an implant's migration.

The porcine tube is injected into the subconjunctival space from an ab interno approach, but its lumen rests 1 to 2 mm into the anterior chamber. The company continues to assess and refine the dimensions of this product and the surgical technique.

Early postoperative data are very encouraging: postoperative IOPs have averaged in the midteens at 1 year, and patients undergoing incisional glaucoma surgery for the first time have experienced a dramatic reduction in their need for glaucoma medication.[4] The device is currently undergoing evaluation in an FDA 510(k) protocol to assess its efficacy and safety in refractory glaucoma patients.

CONCLUSION

The advent of MIGS and the recent approval of the iStent represent potential breakthroughs in the management of glaucoma. Although these surgical procedures are in their infancy, they offer the hope of improved surgical outcomes, faster visual recovery, and greater safety than traditional filtering surgery. Further study and development of these procedures will almost certainly advance the field. ■

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1. Belovay GW, Nagi A, Chan B, et al. Using multiple trabecular micro-bypass stents in cataract patients to treat primary open-angle glaucoma. *J Cataract Refract Surg*. In press.
2. Bacharach J. Results through two years postoperative from prospective, randomized studies of second generation stents and cataract surgery in mild-moderate open-angle glaucoma. Poster presented at: American Glaucoma Society 22nd Annual Meeting; March 1, 2012; New York, NY.
3. Vold SD, Ahmed IK, Craven ER, Ianchulev S. Surgical outcomes and safety of novel supraciliary microstent. Poster presented at: ASCRS/ASOA Symposium and Congress; April 20-24, 2012; Chicago, IL.
4. Vold S. Future devices. Paper presented at: ACOS Summer Symposium; July 27, 2012; Deer Valley, UT.