RECENT DEVELOPMENTS
IN MIGS

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Microinvasive glaucoma surgery (MIGS) is in its infancy compared with other surgical glaucoma options. Since the iStent Trabecular Micro-Bypass Stent (Glaukos) received FDA approval in 2012, research and development in this field has exploded. MIGS procedures use an ab interno approach, are minimally traumatic, reduce IOP at least modestly, and offer extremely high safety and rapid recovery.¹ These procedures are often positioned as the next step for patients with mild to moderate glaucoma in whom topical glaucoma medications have failed or who have a visually significant cataract and glaucoma concomitantly. As options for MIGS and other minimally invasive glaucoma procedures expand, it is important for ODs to keep abreast of the latest developments, which I review in this article.

DEVICES FOR THE TRABECULAR MESHWORK AND SCHLEMM CANAL IMPLANTS

In 2018, the FDA approved two MIGS devices for use in combination with cataract surgery for the reduction of IOP in patients with mild to moderate primary open-angle glaucoma: Hydrus Microstent (Ivantis) and iStent Inject (Glaukos). Both increase aqueous outflow by stenting the trabecular meshwork and accessing

Figure 1. View of a Hydrus Microstent via an intraoperative gonioprism immediately after device implantation.
Schlemm canal (see Implant Research Results).

Optometrists who already comanage cataract surgery patients will find the process combined with placement of either a Hydrus Microstent (Figure 1) or iStent Inject (Figure 2) to be similar but with a few additional considerations. A layered hyphema can occur with either device, but it was reported in 0.5% of patients in the HORIZON Study and none in the iStent Inject pivotal trial. Preoperatively, it is important to educate patients receiving either device that they may develop a mild, transient hyphema that may cloud their vision. The hyphema will eventually resolve at around 1 week. The transient hyphema, if not layered, will appear to be a mild anterior chamber reaction at the slit lamp.

Either implant can become obstructed. The reported incidence of device obstruction was 3.8% obstructive and 14.9% nonobstructive in the HORIZON Study and 6.2% complete or partial in the iStent Inject pivotal trial. Gonioscopy is required to visualize obstructions. If an obstruction is identified and deemed to be increasing IOP, the patient should be referred back to the surgeon for treatment options. In some cases the blockage can be removed with an Nd:YAG laser. It is important for optometrists to visualize a stent once during the first 3 months after surgery to look for obstruction and to repeat gonioscopy if unexplained disease progression or IOP elevation occurs.

Surgical Systems
Launched in 2015 and 2018, respectively, the Kahook Dual Blade (KDB; New World Medical) and Omni Surgical System (Sight Sciences) excise trabecular meshwork tissue.

The KDB allows surgeons to remove 3 clock hours of trabecular meshwork, which gives aqueous direct access to Schlemm canal and distal collector channels (Figure 3). The Omni Surgical System targets three points of resistance in the conventional outflow pathway. First, it delivers small amounts of OVD through a microcatheter to viscodilate Schlemm canal for either 180° or 360°. Second, the device excises either 180° or 360° of trabecular meshwork to allow aqueous access to Schlemm canal and distal collector channels. A third surgical option, ab interno canaloplasty (ABiC), uses a lighted catheter (iTrack, Ellex) to deliver small amounts of viscoelastic to viscodilate Schlemm canal 180° or 360°.

These procedures are indicated for patients with mild to moderate glaucoma who are pseudophakic, but all

Figure 2. The iStent Inject places two stents 3 clock hours apart. It is important to visualize the stent or stents at least once during the first 3 months after surgery for potential obstructions.
A retrospective study using the Omni Surgical System (Sight Sciences) included a total of 81 eyes undergoing a standalone Omni Surgical System procedure with nearly two-thirds of the eyes (61.7%) having undergone prior glaucoma surgery. Investigators reported an average IOP reduction of 7.3 mm Hg from a mean medicated baseline IOP of 23.7 mm Hg on 1.7 medications to a mean IOP of 15.7 mm Hg on 1.1 medications at 12 months.1

A retrospective study of the Kahook Dual Blade (KDB, New World Medical) included a total of 197 eyes with 32 eyes undergoing KDB as a standalone procedure and 165 eyes undergoing KDB combined with phacoemulsification. In the KDB alone group, a decrease in mean IOP from 20.4 mm Hg on 3.1 medications at baseline to 14.1 mm Hg on 2.3 medications occurred at 12 months. In the KDB combined with phacoemulsification group, a decrease in mean IOP from 16.7 mm Hg on 1.9 medications at baseline to 13.8 mm Hg on 1.5 medications at 12 months occurred. The incidence of an IOP spike was 10.2% at 1 week, and transient hyphema was 17.3%.2


Key Points
Hypotony is not a postoperative concern with the Hydrus Microstent, iStent Inject, Omni Surgical System, or AbiC because none of the devices or procedures bypasses the backstop pressure of 8 mm Hg to 10 mm Hg called episcleral venous pressure. In other words, episcleral venous pressure essentially serves as a safety net with these procedures.

With all five MIGS options, managing IOP in the first 3 months after surgery is critical. If a patient has achieved the target pressure established before surgery, medications may be removed one by one at IOP checks. It is important to remind patients that IOP can fluctuate during the first 3 postoperative months as the eye recovers. It is also worth reemphasizing to patients that glaucoma is a lifelong disease, that no MIGS procedure can cure it, and that regular checkups are essential.

A SUBCONJUNCTIVAL DEVICE
In 2016, the FDA approved the Xen Gel Stent (Allergan) for the treatment of patients with refractory glaucoma in whom previous surgical treatment failed and patients who have primary open-angle glaucoma or pseudoexfoliative or pigmentary glaucoma with open angles who are unresponsive to maximum tolerated medical therapy (see Putting the Xen Gel Stent to the Test).7,8 The device comes preloaded in an injector. It is implanted through a clear corneal incision using an ab interno approach (Figure 4A). The Xen shunts fluid from the anterior chamber to the subconjunctival space, forming a low-lying bleb.7,8
The most common postoperative considerations with this device are fibrosis of the bleb and hypotony. In the FDA pivotal trial, the rate of bleb needling was 32%, and hypotony occurred at a rate of 24.6%; hypotony spontaneously resolved in a majority of cases. If a patient presents with hypotony (IOP < 5 mm Hg or an IOP below which the eye does not maintain its normal shape), it is advisable to discontinue all topical glaucoma medications. The next steps are to examine the anterior chamber for iridocorneal touch and perform a fundus examination to look for choroidal effusion. If both conditions are ruled out, the patient may be monitored.

Recently, many surgeons have transitioned to ab externo placement of the Xen Gel Stent (Figure 4B). Although techniques vary, the greatest advantage of an ab externo approach is that it avoids entangling the device in sub-Tenon capsule, which can increase the rate of bleb needling.