RECENT DEVELOPMENTS IN MIGS

Be ready to comanage patients who undergo these procedures.

BY JUSTIN SCHWEITZER, OD, FAAO

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

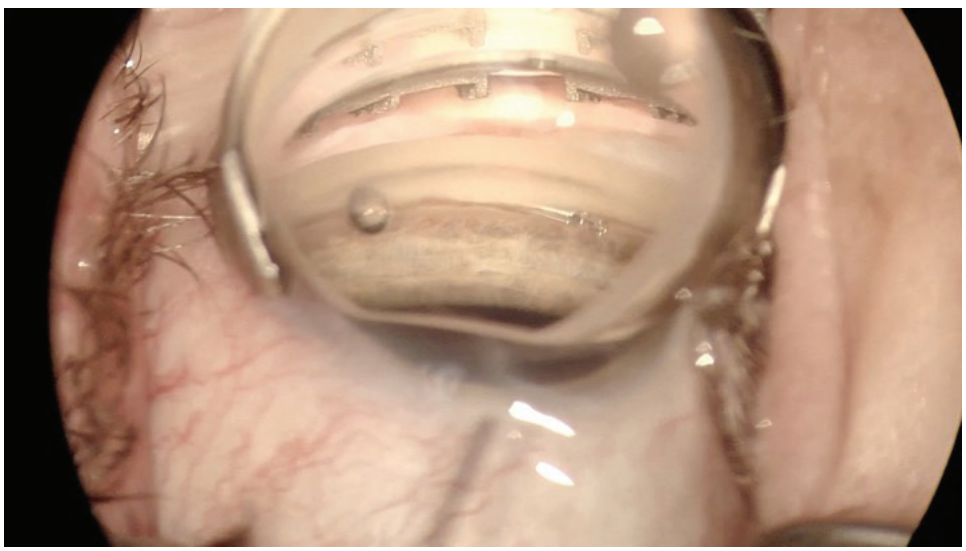

Figure 1. View of a Hydrus Microstent via an intraoperative gonioprism immediately after device implantation.

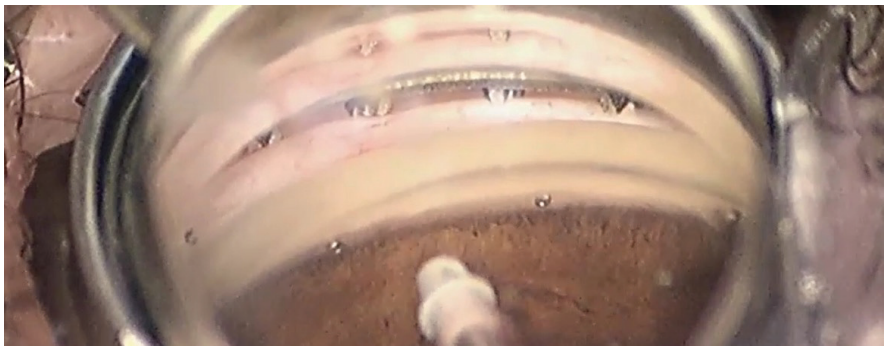

Figure 2. The iStent Inject places two stents 3 clock hours apart. It is important to visualize the stent or stents at least once during the first 3 months after surgery for potential obstructions.

IMPLANT RESEARCH RESULTS

HORIZON Study

In this study, 369 eyes underwent phacoemulsification combined with placement of a single Hydrus Microstent (Ivantis), and 187 eyes received phacoemulsification alone.[1] A significantly higher proportion of patients who underwent the combined procedure achieved a 20% reduction in unmedicated mean IOP (77.3% vs 57.8%) at 24 months. In addition, eyes in the combination group experienced a significantly greater reduction in mean unmedicated IOP at 24 months (-7.6 mm Hg vs -5.3 mm Hg).

iStent Inject Pivotal Trial

In this study, 387 eyes underwent phacoemulsification in combination with the iStent Inject procedure (Glaukos), and 118 eyes received phacoemulsification alone.[2] A significantly higher proportion of eyes that underwent the combined procedure demonstrated a 20% reduction in unmedicated mean IOP (75.8% vs 61.9%). Patients in the device group also demonstrated a greater reduction in mean unmedicated IOP from baseline at 24 months compared with patients who underwent cataract surgery alone (-7.0 mm Hg vs -5.4 mm Hg).

1. Samuelson TW, Chang, DF, Marquis R, et al; HORIZON investigators. A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: The HORIZON Study. *Ophthalmology*. 2019;126(1);29-37.
2. Samuelson TW, Sarkisian SR, Lubeck DM, et al; iStent inject Study Group. Prospective, randomized, controlled pivotal trial of an ab interno implanted trabecular micro-bypass in primary open-angle glaucoma and cataract. *Ophthalmology*. 2019;126(6);811-821.

Schlemm canal (see *Implant Research Results*).[2,3]

Optometrists who already comanage cataract surgery patients will find the process for patients undergoing that procedure 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[2] and none in the iStent Inject pivotal trial.[3] 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[2] and 6.2% complete or partial in the iStent Inject pivotal trial.[3] 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.[4-6] 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).[5,6] 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.[4]

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

RESEARCH ON THE KAHOOK DUAL BLADE AND OMNI SURGICAL SYSTEM

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]

1. Sarkisian SR, Mathews B, Ding K, Patel A, Nicek Z. 360º ab-interno trabeculotomy in refractory primary open-angle glaucoma. *Clin Ophthalmol.* 2019;13:161-168.
2. Sieck EG, Epstein RS, Kennedy JB, et al. Outcomes of Kahook Dual Blade goniotomy with and without phacoemulsification cataract extraction. *Ophthalmology Glaucoma*. 2018;1(1):75-81.

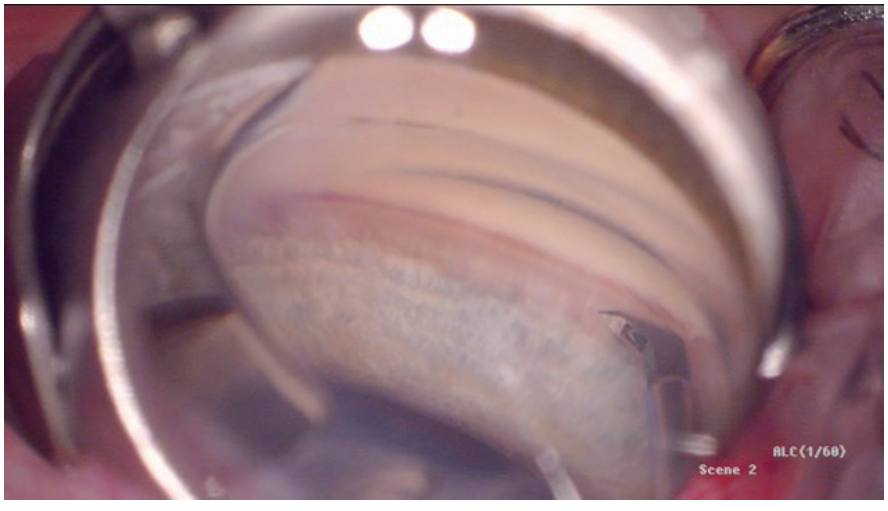

Figure 3. Surgeons use the KDB to remove 3 clock hours of trabecular meshwork to unroof Schlemm canal and allow aqueous direct access to Schlemm canal and distal collector channels.

of the procedures can be paired with cataract surgery as well (see *Research on the Kahook Dual Blade and Omni Surgical System*).

The most common postoperative consideration with these procedures is hyphema. In a recent retrospective study, 50.6% of patients had a transient hyphema after treatment with the Omni Surgical System.[4] A majority of the hyphemas were rated as mild and self-resolving. In a retrospective study involving the KDB, 17.3% of patients were noted to have hyphema, with the majority on postoperative day 1 and resolving within 7 days of presentation.[5]

Key Points

Hypotony is not a postoperative concern with the Hydrus Microstent, iStent Inject, KDB, 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]

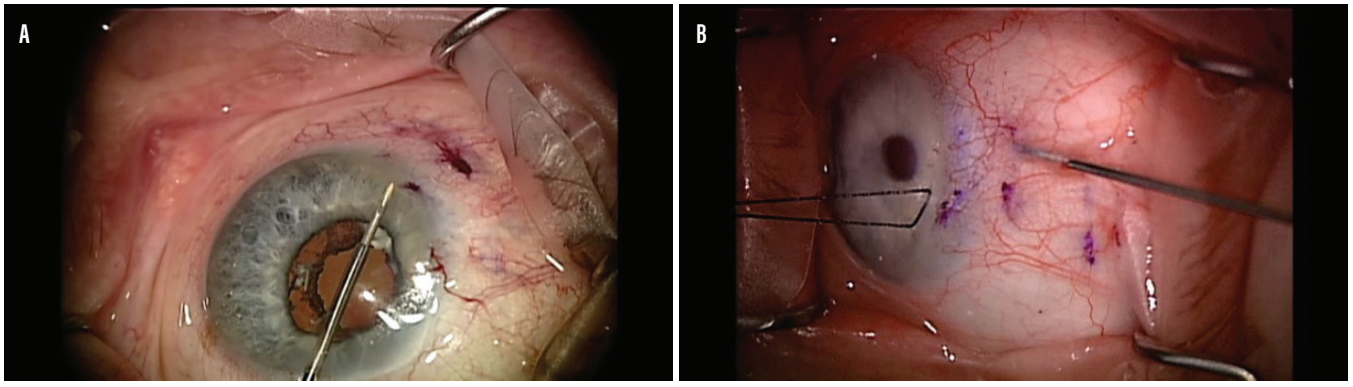

Figure 4. The Xen Gel Stent is implanted through a clear corneal incision using an ab interno approach (A). Ab externo placement of the Xen Gel Stent (B) is becoming more commonly adopted by surgeons to avoid entangling the device in sub-Tenon capsule, reducing bleb needling rates.

PUTTING THE XEN GEL STENT TO THE TEST

The pivotal trial of the Xen45 Gel Stent (Allergan) involved 65 patients (30 men and 35 women) implanted with the Xen Gel Stent device. Fifty-seven patients were diagnosed with primary open-angle glaucoma, six had pseudoexfoliative glaucoma, one had pigmentary glaucoma, and one had mixed-mechanism glaucoma. Most patients (45; 69%) had a history of cataract surgery, 41 (63%) had undergone a prior incisional glaucoma procedure, 14 (22%) had undergone prior laser trabeculoplasty without an incisional glaucoma procedure, and 10 (15%) had no prior glaucoma procedures and were not responsive to maximally tolerated medical therapy. Investigators reported a decrease in IOP from a mean baseline of 25.1 mm Hg on 3.5 medications to 15.9 mm Hg on 1.7 medications at 12 months.[1]

1. Allergan. Directions for Use for the Xen Glaucoma Treatment System. Available at: https://allergan-web-cdn-prod.azureedge.net/actavis/actavis/media/allergan-pdf-documents/labeling/xen/dfu_xen_glaucoma_treatment_system_us_feb2017.pdf. Accessed September 6, 2019.

The most common postoperative considerations with this device are fibrosis of the bleb and hypotony.[8] In the FDA pivotal trial, the rate of bleb needling to remove fibrosis was 32%, and hypotony occurred at a rate of 24.6%; hypotony spontaneously resolved in a majority of cases.[8] 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.

BE PREPARED

As the prevalence of glaucoma continues to rise across the world, the volume of MIGS and minimally invasive glaucoma procedures will increase. Optometrists must be ready to educate and manage these patients. ■

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6. Greenwood MD, Seibold LK, Radcliffe NM, et al. Goniotomy with a single-use dual blade: short-term results. *J Cataract Refract Surg*. 2017;43(9):1197-1201.
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