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# ADVANCES IN OPHTHALMOLOGY AND OPTOMETRY

# Micro-Invasive Glaucoma Surgery



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#### Keywords

- MIGS Micro-invasive glaucoma surgery Minimally invasive glaucoma surgery
- Techniques Updates Glaucoma

#### **Key points**

- Relevance of MIGS: Micro-invasive Glaucoma surgery has filled a gap in care in the management of glaucoma, allowing for earlier surgical intervention in a safe and effective manner.
- MIGS Approaches and Devices: MIGS devices and techniques have different tissue targets within the eye. Some MIGS bypass or incise the trabecular meshwork. Other devices stent open the canal of Schlemm, while others divert the flow of aqueous to the subconjunctival or suprachoroidal spaces. Cycloablative procedures also are used to lower the intraocular pressure.
- Literature Update: Recent long-term data for specific devices, randomized clinical trials, and head-to-head comparative studies are summarized.

### INTRODUCTION

Glaucoma is a chronically progressive optic neuropathy resulting in characteristic irreversible visual field depression. It is estimated that glaucoma affects almost 80 million individuals worldwide, and this number may increase to 111.8 million by 2040 [1,2]. Glaucoma currently is the leading cause of irreversible blindness worldwide. The mainstay of glaucoma treatment is lowering intraocular pressure (IOP), the only major modifiable risk factor shown to slow down progression of the disease [3]. IOP reduction can be achieved with medications, which are often the most used treatment modality, lasers,

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and surgery. Poor adherence to medications poses an increased risk for visual loss in patients with glaucoma, especially for those on multiple eyedrops [4]. In addition, some patients show progression of their glaucomatous disease despite good medication adherence.

Before the twenty-first century, the glaucoma specialist's surgical armamentarium was mostly restricted to invasive filtering trabeculectomies and tube shunt procedures, which are wrought with serious short and long-term complications that have been well-documented, and often result in failure [5]. With advancements in glaucoma surgical techniques, the role for procedural intervention earlier in the disease course is becoming increasingly common. Micro-invasive Glaucoma Surgery (MIGS) is an approach to glaucoma surgical management that affords patients with good efficacy, a high safety profile, relatively shorter surgical times, and rapid surgical recovery. MIGS are deemed less invasive and safer than traditional glaucoma filtering procedures. At a minimum, a modest reduction of IOP is the goal, and this is achieved with minimal tissue disruption often by enhancing the eye's existing anatomy [6]. There are many approaches, but generally, there is less or no conjunctival disturbance compared with traditional filtering procedures. MIGS can be performed either as a standalone procedure, or in combination with cataract surgery.

Since they have become commercially available, MIGS have increasingly filled a gap in care for patients with glaucoma. These techniques have become a standard of care for patients with glaucoma and IOP-related issues for comprehensive ophthalmologists and glaucoma specialists alike. Novel technologies and techniques provide for unique treatment modalities alternative to traditional filtering surgeries. Updated studies on MIGS are constantly emerging, allowing for better data on efficacy and real-world clinical and surgical practice.

Within this article, we provide a summary of the MIGS devices and techniques available and discuss the advances and updated research in this field. We detail the devices used, pathways targeted, short and long-term efficacies where applicable, and safety profiles. We offer summaries of current research, including studies that compare techniques head-to-head, and discuss future avenues in MIGS care.

#### SIGNIFICANCE AND CURRENT RELEVANCE

Traditional glaucoma filtering procedures have been the mainstay for glaucoma surgical management for decades. At the turn of the twenty-first century, a novel approach to glaucoma surgical management emerged: MIGS. The cardinal features of MIGS are that they are minimally invasive to the target tissue, demonstrate a modest reduction of IOP with minimal tissue disruption, provide a good safety profile, and allow for a relatively rapid recovery [6]. A vast array of patients with glaucoma can benefit from MIGS (Table 1).

There are a wide array of procedures and devices that are considered MIGS, and their mechanistic targets differ in how they achieve IOP reduction. The main mechanisms by which MIGS lower IOP are improving trabecular outflow

<b>Table 1</b> Micro-invasive glaucoma su	rgery candidates
Open-angle glaucoma • Mild • Moderate • Severe Angle closure	Medication toxicities/Intolerance/Allergy On intraocular pressure–lowering therapy and will be undergoing cataract extraction Insufficient intraocular pressure control with laser/medications Medication burden/Noncompliance
• Select cases and devices	

through the Schlemm canal, creating an alternate outflow pathway in the subconjunctival space, enhancing uveoscleral outflow in the suprachoroidal space, and ciliary body destructive procedures (Table 2).

Most aqueous humor drainage occurs via 2 pathways: the conventional trabecular outflow pathway and the unconventional uveoscleral pathway. It has been well-established that most aqueous outflow resistance is at the level

Schlemm Canal/Increase Trabecular Outflow		
Stenting	Cutting	Dilating
iStent Micro-Bypass (Glaukos) IStent <i>inject</i> (Glaukos) IStent inject W (Glaukos) Hydrus Microstent (Ivantis)	Excimer Laser Trabeculostomy Gonioscopy-assisted transluminal trabeculotomy (GATT) Kahook Dual Blade (New World Medical) TRAB 360 Trabeculotomy (SightSciences Inc) Trabectome (NeoMedix Inc) OMNI	Ab interno canaloplasty (ABiC) VISCO360 Viscosurgical System
Subconjunctival CyPass Micro-Stent (recalled) XEN Gel stent (Allergan) PRESERFLO MicroShunt (Santen) Suprachoroidal IStent SUPRA (Glaukos) MINIject (ISTAR medical) CyPass MicroStent (Alcon): Recalled Cycloablative EndoCyclophotocoagulation (ECP) High-Intensity Focused Ultrasound cyclocoagulation Micropulse diode laser		

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of the juxtacanalicular trabecular meshwork, especially in older patients [7]. Thus, most of the commercially available MIGS devices aim to lower resistance at the level of the trabecular meshwork, either by removing a portion of the trabecular meshwork or bypassing it completely to allow aqueous to access the Schlemm canal and the collector channels. The nasal quadrant is the most common surgical target in MIGS, given its easy access from the temporal clear corneal incision of cataract surgery, and this coincides with the highest concentration area of collector channels.

We provide a review of select MIGS devices and procedures and updates on their use and efficacy. First, we discuss trabecular stenting procedures. The 2 commercially available devices approved for implantation at the time of cataract surgery in the United States are the iStent Trabecular Micro-bypass stent and the Hydrus Microshunt. These enhance the flow of aqueous through the Schlemm canal and the collector channels by helping to bypass resistance at the level of the trabecular meshwork.

### IStent TRABECULAR MICRO-BYPASS STENT

The iStent Micro-bypass Stent (Glaukos Corporation, San Clemente, CA) was first implanted in the United States in 2005 and received Food and Drug Administration (FDA) approval in 2012 [8]. It was designed to create a permanent conduit for aqueous to pass directly from the anterior chamber into the Schlemm canal. The device is made of heparin-coated, non-ferromagnetic titanium. In its first-generation design, the device has an inlet or "snorkel" that connects to the implanted portion of the implant at a 90-degree angle. The implanted portion is pointed to facilitate canal entry [9]. Three retention arches help to stabilize the device in the angle. The device's dimensions are 1 mm  $\times$  0.33 mm  $\times$  120  $\mu$ m.

The second-generation iStent, known as the "iStent inject," was developed such that 2 stents are injected into the Schlemm canal. It received FDA approval in 2018. The device is made of heparin-coated titanium, just as the first generation. The design is smaller and consists of an apical head that connects to a thinner thorax and a terminal wider flange. The device is 360  $\mu$ m in length  $\times$  230  $\mu$ m in diameter. The apical head is inserted directly into the Schlemm canal. A slightly larger variant to the iStent, known as the "iStent inject W" has also been made commercially available, and its wider dimensions are thought to aid with surgical placement.

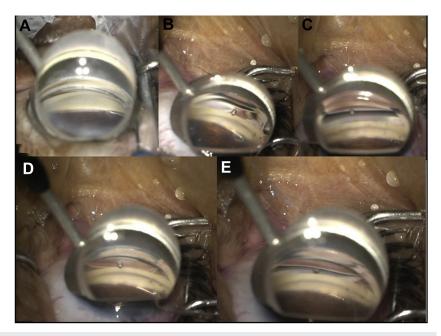
In the United States, the iStent is approved for implantation in mild-tomoderate open-angle glaucoma in combination with cataract surgery, but is approved as a standalone procedure in Europe. The ideal surgical candidate is a patient who has stable mild-to-moderate open-angle glaucoma or who is somewhat uncontrolled. As with other trabecular devices, the iStent's IOPlowering capability is limited by the episcleral venous pressure, thus after implantation, IOP would likely be no less than 8 to 9 mm Hg [7,10].

In 2011, the iStent Study Group published outcomes in IOP reduction in patients receiving first-generation iStent at the time of cataract extraction versus cataract extraction alone. The primary endpoint was an unmedicated IOP  $\leq 21$  mm Hg at 1 year. This endpoint was seen in 72% of the iStent group and 50% of the control group. In addition, the iStent group demonstrated a significant reduction in the number of hypotensive medications required to achieve equivalent IOP reduction compared with cataract extraction alone [11]. Years later, it was proposed that implanting 2 iStents would be at least as efficacious as the IOP-lowering effects of being on 2 anti-ocular hypertensive medications. This was further studied in the iStent *inject* Study Group. At the time of cataract extraction, the treatment group received 2 iStent *inject* implants versus the controls, who only underwent phacoemulsification. The primary endpoint of the study was  $\geq 20\%$  reduction in unmedicated diurnal IOP by 24 months. This was demonstrated more frequently in the treatment group than controls [12].

#### HYDRUS MICROSTENT

The Hydrus Microstent (Ivantis Inc., Irvine, CA), received FDA approval in 2018. The device is 8 mm in length and 290  $\mu$ m in diameter; 7 mm of the device is scaffolded into the angle at a curvature consistent with the natural architecture of the Schlemm canal, and this portion contains 3 windows. The inlet, which is 1 mm, resides in the anterior chamber. The device spans approximately 3 clock hours of the angle. It scaffolds the Schlemm canal to help keep it patent and bypasses the trabecular meshwork by way of stenting. The device is made of nitinol, which is a nickel-titanium alloy that has demonstrated excellent biocompatibility and has been used in vascular stenting [13]. The single-use Hydrus inserter is used to place the device. The trabecular meshwork is pierced with the distal sharp tip of the device and then dialed into the angle for approximately 3 clock hours. The inlet is then nudged into the angle so only approximately 1 mm is protruding into the anterior chamber. This can be achieved with a second instrument such as a Sinski or even the irrigation and aspiration handpiece (Fig. 1).

The HORIZON study, published in 2019, demonstrated superior efficacy in the reduction of IOP for the Hydrus Microstent when implanted at the time of cataract surgery compared with cataract surgery alone up to 24 months after implantation. This study was a multicenter, single-masked randomized controlled trial in patients who had cataracts and mild-to-moderate primary open-angle glaucoma (POAG) on 1 to 4 topical glaucoma medications. The primary endpoint was a reduction in unmedicated mean diurnal IOP by 20% or more. This was achieved in 77.3% of the Hydrus Microstent group and 57.8% of controls at 24 months. The secondary endpoint was change in mean diurnal IOP from baseline at 24 months, which favored the Hydrus group. Twentyfour-month unmedicated mean diurnal IOP was reduced by 7.6  $\pm$  4.1 mm Hg and 5.3  $\pm$  3.9 mm Hg in the Hydrus and control groups, respectively. In addition, the device was deemed to be safe, as no serious adverse events occurred in relation to its implantation and no significant differences in safety were noted between the 2 groups [13].



**Fig. 1.** Hydrus Microstent implantation into the Schlemm Canal; various stages. (A) Initial placement by engaging device into trabecular meshwork. (B, C) Device advancement into the Schlemm Canal. (D) Device deployed from injector (used Sinskey to advance to final position). (E) Final position of implant.

Three-year data from the HORIZON trial showed promising long-term efficacy and safety. At the 3-year mark, patients in the Hydrus group had stable IOP compared with controls. Seventy-three percent of Hydrus patients and 48% of controls were medication-free. Hydrus eyes also were more likely to demonstrate an IOP of  $\leq$ 18 mm Hg without medication compared with controls (56.2% vs 34.6%). No difference was seen in endothelial cell density between the 2 groups, and no significant differences in safety were noted between the 2 groups [14].

Other studies have demonstrated the efficacy of the Hydrus Microstent finding it to be superior in lowering IOP in patients with POAG compared with selective laser trabeculoplasty and canaloplasty [15].

Recently, the 5-year HORIZON data were presented at the American Glaucoma Society 2021 virtual conference. The results redemonstrated the safety and efficacy of the Hydrus, with no significant long-term differences noted compared with cataract extraction alone. A sustained decrease existed in IOP and use of hypotensive medications, and subjects were 2.8 times less likely to have repeat glaucoma surgery. There was 20% to 30% improvement in being medication-free compared with control group. No evidence occurred of statistically significant endothelial cell density difference between Hydrus and controls [16].

Another recent randomized clinical trial, the COMPARE study, performed a head-to-head comparison of the Hydrus and iStent implants as standalone treatment for mild-to-moderate open-angle glaucoma. Subjects were divided into 2 different treatment arms, either receiving 1 Hydrus Microstent, or 2 iStent Trabecular Micro-bypass devices, and were followed for 12 months. The study looked at several different parameters: IOPs, number of medications, and need for repeat glaucoma surgeries. At 12 months, the Hydrus group demonstrated a higher success in subjects attaining medication freedom, and also had greater rates of complete surgical success. In eyes that remained medication-free, the Hydrus group achieved an IOP of  $\leq 18$  mm Hg at a rate of 30.1% versus 9.3% of the iStent group. Two patients in the iStent group required further glaucoma surgery, and none in the Hydrus group. At 12 months, the Hydrus group had an elimination of 1.6 medications and the iStent group had an elimination of 1.0 medications compared with preoperative levels. A  $\geq$ 2-line decrease in best corrected visual acuity occurred in 2 eyes in the Hydrus group and 1 eye in the iStent group. Compared with prior singlecenter studies looking at standalone insertion of 2 iStent devices, data from the COMPARE trial demonstrated less of a pressure reduction effect. Prior studies demonstrated an average IOP of approximately 13 to 14 mm Hg with and without medications at 12 months, whereas IOP was shown to be higher on average at 12 months in the COMPARE trial [17].

The next set of MIGS to be discussed mainly involve incising the trabecular meshwork to remove the level of resistance of aqueous flow. Removing the trabecular meshwork allows the aqueous to access the collector channels more easily and with less resistance. The various trabecular meshwork removal MIGS vary in their techniques and in the amount of tissue excised. Unlike the implantable devices mentioned previously, the indications for usage in the United States are broader, therefore they can be used to treat forms of glaucoma other than mild-to-moderate POAG.

### GONIOTOMY-ASSISTED TRABECULOTOMY

Goniotomy-Assisted Transluminal Trabeculotomy (GATT) is a technique in which an Ab interno approach is used to incise and remove the trabecular meshwork, thus improving flow into the Schlemm canal and the collector channels. The surgical technique involves making a nasal incision in the trabecular meshwork under direct gonioscopic visualization followed by advancement of an illuminated microcatheter (iTRACK; Ellex iScience Inc., Fremont, CA) or Prolene suture circumferentially  $360^{\circ}$  around the Schlemm canal. After complete advancement, the distal end is grasped and pulled, while holding tension on the proximal end, creating a full-thickness excision of the trabecular meshwork. The first data on GATT were released in 2014. The study was a retrospective review of patients with documented various forms of open-angle glaucoma, and GATT was performed both as a standalone and in combination with cataract surgery. Results for patients with POAG at 12 months demonstrated an IOP reduction of 11.1  $\pm$  6.1 mm Hg (average of 39.8% decrease

in IOP from baseline) and subjects were on approximately 1 less hypotensive medication. For subjects with other forms of open-angle glaucoma, results also were promising with a reduction of IOP by  $19.9 \pm 10.2$  mm Hg at 12 months, and patients required 1.9 fewer hypotensive medications at this time frame. Treatment failure, which was deemed to be an IOP of 21 mm Hg or more at 2 consecutive visits, was seen in 9% of patients, and these patients required further glaucoma surgery [18]. Twenty-four-month follow-up data on GATT, released in 2018, redemonstrated efficacy of the procedure. For subjects with POAG, there was a 37.3% reduction in IOP at 24 months. For patients with other forms of open-angle glaucoma, there was an average reduction of 49.8% from baseline. Interestingly, in the subgroup of patients who underwent GATT at the time of cataract extraction, a higher rate of failure was noted and reoperation occurred after 24 months [19]. Two other studies by Grover and colleagues [20,21] have demonstrated efficacy of GATT in other forms of glaucoma, including eyes that have had previous incisional surgeries, primary congenital glaucoma, and juvenile open-angle glaucoma.

In 2021, a retrospective comparative cohort study was performed comparing trabeculectomy with mitomycin-c versus GATT in patients with open-angle glaucoma. The study included patients with different forms of open-angle glaucoma, including POAG, pseudoexfoliative, and uveitic with uncontrolled IOP despite maximal medication therapy. Success within this study was defined as a  $\geq$ 30% reduction in IOP from baseline and absolute IOP of  $\leq$ 18 mm Hg. At 18 months, subjects in the augmented trabeculectomy group displayed greater IOP reduction than those in the GATT group, with a 16.9 mm Hg reduction in the trabeculectomy group and a 11.6 mm Hg reduction in the GATT group. The average IOP at 18 months was approximately 12.4 mm Hg in the Trabeculectomy group and 15.2 mm Hg in the GATT group, which has implications for patients requiring extreme IOP reduction to control their disease. Given the parameters for success within this study, the probability of success was not statistically significantly different between the 2 groups. Also, the overall GATT success rate within this study echoes those previously reported in Grover's original studies. Within this study, as has been well-established previously, hypotony was the most common complication in post-trabeculectomy subjects, and hyphema was the most common complication of GATT [18,20]. This study also found that GATT is at least or more effective in lowering the IOP compared with other commonly performed MIGS procedures [22].

#### TRAB360 TRABECULOTOMY

The Trab360 (SightSciences) microsurgical device has a similar mechanistic surgical action compared with GATT. This device can be used in patients with open-angle glaucoma. The trabeculotomy is achieved through a disposable, nonpowered injector device, which consists of a cannula, from which a flexible nylon-like suture is injected into the Schlemm canal. The suture is advanced for 180° then pulled out of the angle, incising the trabecular meshwork, and repeated for the untreated 180° [23] (Fig. 2).

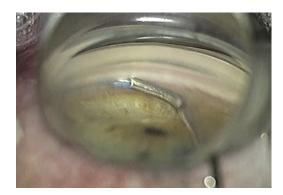


Fig. 2. Trab360 insertion.

#### TRABECTOME

The Trabectome (Neomedix Corporation, Tustin, CA) received FDA approval in 2004 for Ab interno trabeculectomy (AIT). This device combines bipolar electrocautery (550 kHz electrode) with irrigation and aspiration and is used to ablate  $30^{\circ}$  to  $180^{\circ}$  of the trabecular meshwork. According to a metaanalysis of AIT, most cases in the literature were reported on individuals with POAG followed by pseudoexfoliative open-angle glaucoma and various other secondary open-angle glaucoma subtypes. Generally, success was defined as a final IOP of  $\leq$ 21 mm Hg or a >20% decrease in IOP from baseline without further surgical intervention. Average success was deemed to occur more frequently among the studies analyzed in cases of combined phaco-AIT compared with standalone AIT. Information obtained from the Trabectome database, which has the longest available data, demonstrated success rates of 85% for phaco-AIT at 5 years and 56% for standalone AIT at 7.5 years. Seven percent of these cases required further surgical intervention. Similar to GATT, AIT does not reliably result in an IOP in the low teens, and thus may not be a substitute for more invasive filtration surgery in eyes requiring this level of IOP control. Overall, AIT lowers IOP by approximately 36% to approximately 16 mm Hg on 1 less hypotensive medication. At 2 years, average success rate is approximately 66% per the previously mentioned criteria. Similar to other trabecular-excising MIGS, hyphema is the most common complication, but generally otherwise has a good safety profile. Currently, there are no randomized controlled trials in the medical literature on AIT [24].

#### **KAHOOK DUAL BLADE**

The Kahook Dual Blade (KDB; New World Medical Inc, Rancho Cucamonga, CA) was FDA approved in 2015 for use in combination with cataract extraction and as a standalone MIGS procedure. It can be used in open and closed angles and can also be used for goniosynechialysis. This single-use device has a distal tip with 2 cutting edges. It is advanced through a clear corneal

incision and is used to incise and cleave approximately 3 to 4 clock hours of trabecular meshwork, removing a strip of trabecular meshwork, thus theoretically reducing the risk of scarring and failure (Fig. 3).

A prospective, interventional case series looked at the efficacy of KDB in combination with cataract surgery in the treatment of open-angle glaucoma. The average reduction in IOP was 26.2% with a reduction in medication usage of 50% from baseline at 12 months. The procedure was deemed to be safe with no sight-threatening complications. The most common adverse event observed was intraoperative hyphema, as with other trabecular-incising MIGS procedures [25].

The efficacy of KDB has been studied in comparison to and in combination with other MIGS procedures, including iStent and ECP [26,27]. A small retrospective study published in 2021 demonstrated that both iStent and KDB goniotomy were safe and have IOP-lowering effects, with goniotomy showing a slightly advantageous IOP reduction [26]. Izquierdo and colleagues [27] compared eyes undergoing phacoemulsification with ECP versus phacoemulsification with goniotomy and ECP and found that the tri-modal treatment was safe and more effective in reducing IOP than that of the phacoemulsification with ECP alone.

#### AB INTERNO CANALOPLASTY

Ab interno canaloplasty (AbiC) is a minimally invasive glaucoma technique in which an illuminated microcatheter (iTrack; Ellex iScience, Inc.) accesses the anterior chamber angle through a clear corneal incision, and is used to catheterize the Schlemm canal for 360°. Following this, viscoelastic is used to dilate the canal and its proximal collector channels. It has been proposed that this technique can help patients achieve IOP in the low-to-mid teens. It is thought that the Viscodilation of the Schlemm canal and the collector channels allows



Fig. 3. Kahook dual blade goniotomy. (Courtesy of New World Medical, Inc.)

for some restoration of the natural anatomic function of the angle, thus contributing to the efficacy of the procedure. AbiC can be performed in various forms of open-angle glaucoma including pseudoexfoliation, pigmentary, and in pediatric and congenital cases. Potential complications include hyphema, Descemet membrane detachment, cataract formation, IOP spikes, and hypotony [28]. The Visco360 and Omni360 devices also are used to perform AbiC and are discussed as follows.

#### VISCO360 AND OMNI

Similar to the technique described previously for AbiC, the Visco 360 device can be used to catheterize and Viscodilate the Schlemm canal. This singleuse device has a distal tip that incises the trabecular meshwork allowing a microcatheter to advance 180° through the canal. Then, viscoelastic is inserted into the Schlemm canal. This is then repeated for the remaining 180° [29].

The OMNI system uses the same handpiece as the Visco 360 but is unique in that it combines the techniques of the Visco360 and Trab360. After the device is used to catheterize and Viscodilate 180° of the Schlemm canal, a trabeculotomy is performed. This is then repeated for the remaining 180°. This technique targets 3 main mechanisms of resistance to flow: excision of the trabecular meshwork, which helps to overcome the resistance to aqueous flow, and Viscodilation of the Schlemm canal, and dilation of the collector channels. The Omni system has been shown to reduce IOP by an average of approximately 35% from baseline and can reduce medications by 25% to 50% according to retrospective studies. A recent prospective case series published in the European Journal of Ophthalmology in 2021 further investigated the effects of OMNI in patients with mild-to-moderate open-angle glaucoma as a standalone procedure and in combination with cataract extraction. This study found an IOP reduction of approximately 35% and reduction of approximately 2 medications compared with preoperative baseline at 12 months. Hyphema was the most common complication [29].

Both Visco 360 and Omni can be performed for the treatment of open-angle glaucoma and ocular hypertension. They can be performed in combination with cataract surgery or as standalone.

The next 2 devices that are discussed work by forming a subconjunctival bleb to divert aqueous and lower IOP. These techniques can be used in cases of more advanced disease contrary to the devices that target the trabecular outflow and the Schlemm canal.

## **XEN GEL STENT**

The XEN Gel stent (Allergan, an AbbVie company, Irvine, CA) received FDA approval in 2016 as a subconjunctival stent allowing aqueous to flow from the anterior chamber to the subconjunctival space. The device is a 6-mm hydrophilic tube with an inner tube ostium of 45  $\mu$ m (most commonly used size). The material is biocompatible and in contrast to the silicone material used in tube shunts, is thought to induce less of an inflammatory reaction, thus

contributing to less scarring. The tube channels through sclera, allowing for controlled flow of aqueous from the anterior chamber to the subconjunctival space. The original FDA trial for the XEN described an Ab interno approach, but it has become commonplace for the Xen to be placed both Ab interno and Ab externo depending on surgeon preference and patient selection. Some noted complications with both approaches are hypotony, choroidal effusion, and loss of Snellen visual acuity. It has been reported that the Ab externo approach has similar safety and efficacy to Ab interno approach [30].

#### PRESERFLO

The PRESERFLO Microshunt (Santen Inc., Miami, FL) is a subconjunctival MIGS device that is awaiting FDA approval. It was previously known as the InnFocus MicroShunt. The device is 8.5 mm in length with a 79-µm lumen. It is composed of an inert and biocompatible material. It is designed to be placed from an Ab externo approach and is used in conjunction with 0.4 mg/mL of Mitomycin-C. The procedure involves making a 6- to 8-mm conjunctival peritomy to form a fornix-based subconjunctival and tenon's flap in the superotemporal quadrant. Mitomycin-C then is injected underneath the flap for approximately 3 minutes and washed out. Then, 3 mm posterior to the limbus, a triangular scleral pocket is made. A 25 to 27g needle then is used to transect the sclera in this area to enter the anterior chamber. Forceps then are used to insert the shunt into the anterior chamber. The fins of the shunt are tucked into the scleral pocket. The distal end is observed for droplet formation. The conjunctiva and tenons are closed [31].

A recent single-center, nonrandomized, single-armed interventional clinical study evaluated the safety and efficacy of the device in patients with POAG up to 5 years. Subjects achieved a mean IOP reduction of 46.7% from baseline and 61.1% of subjects were medication-free. Adverse events associated with PRESERFLO Microshunt placement were similar to that of prior 3-year data and included device to iris touch, transient hypotony, flat anterior chamber, hyphema, and bleb-related complications. No cases of chronic hypotony or endophthalmitis were noted [31].

#### SUMMARY

MIGS has allowed for a renaissance in glaucoma management. A wide range of techniques and devices give the glaucoma surgeon a diverse armamentarium to deal with this complex and often recalcitrant disease process. The paradigm of glaucoma treatment is prevention, as we are all too familiar with its irreversible and blinding effects. Delaying the need for medications helps with delaying glaucoma-disease progression. Adherence to therapy is a known issue for many patients and accelerates optic nerve damage. Patient quality of life can be adversely affected by medications, which can place a large cost burden and often result in ocular surface irritation. Offering MIGS to patients earlier in their disease course can lower their medication burden and allow eye surgeons to get ahead of disease progression.

In the past, the necessity of MIGS in combination with cataract surgery has been called into question, but data from randomized clinical trials have continued to support the use of MIGS in combination with cataract surgery, showing significant decreases in IOP that are sustained.

Traditional glaucoma surgeries require very close postoperative management, are more prone to severe adverse outcomes, and require longer operative times. These features limit their use for many comprehensive ophthalmologists. MIGS has many benefits for surgeons and patients alike. Techniques are relatively straightforward, allowing both comprehensive ophthalmologists and glaucoma specialists to offer surgical intervention to more patients. Outcomes are safe and effective, surgical times are relatively short, and patients often have immediate improvements in IOP in the early postoperative period in addition to similar visual acuity outcomes when combined with cataract surgery.

With the recall of certain MIGS devices, such as the Cypass Micro-stent, due to accelerated endothelial cell loss, evaluating the safety of other MIGS devices is an important goal for the glaucoma community. Thankfully, no other commercially available MIGS devices have been shown to contribute to accelerated endothelial cell loss compared with cataract surgery alone. Accelerated endothelial cell loss has been associated with tube shunts and trabeculectomies in prior studies [32,33].

Current available research and data on the various available MIGS techniques and devices argues for their safety, effectiveness, and role in the management of glaucoma. Further investigational studies, specifically randomized clinical trials, are needed to further substantiate the safety and efficacy of various MIGS. Long-term data is needed to assess efficacy and safety over time.

It is an exciting time to be a glaucoma surgeon. MIGS has filled a gap in glaucoma care, and with advances in techniques and devices, we have hope that our ability to care for patients with glaucoma will only improve in the future.

## **CLINICS CARE POINTS**

- MIGS allows for surgical diversification in the care of patients with glaucoma.
- Angle-based surgery is a relatively newer surgical technique with distinct technical challenges. Given the differences among MIGS techniques, each can present a unique surgical challenge and learning curve.
- The wide array of MIGS devices and approaches can lead to confusion regarding appropriate surgical management of glaucoma.
- With appropriate research, preparation, and selection, MIGS can be a safe and effective approach to the surgical management of glaucoma, saving patients from more invasive surgeries, which are well known for short-term and long-term complications.

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#### Disclosure

The authors have nothing to disclose.

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