CME MONOGRAPH Original Release: December 1, 2017 | Expiration: December 31, 2018

MINIMALLY INVASIVE GLAUCOMA SURGERY

Clinical Experience From Europe, Canada, and the United States

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CONTENT SOURCE

This continuing medical education (CME) activity captures content from a roundtable discussion held on August 29, 2017.

ACTIVITY DESCRIPTION

Glaucoma surgical procedures are shifting from traditional filtration procedures to minimally invasive glaucoma surgery (MIGS) procedures that take advantage of both traditional and nontraditional drainage pathways to offer significant intraocular pressure reductions and favorable safety profiles. The various MIGS procedures and glaucoma devices available, however, necessitate consideration of certain factors, including surgical skill requirements, efficacy and safety profiles, and optimal patient selection. This monograph reviews the MIGS procedures, including their different approaches to aqueous humor drainage, and provides guidance for selecting the appropriate device for each patient with glaucoma.

TARGET AUDIENCE

This educational activity is intended for ophthalmologists who specialize in glaucoma.

LEARNING OBJECTIVES

Upon completion of this activity, participants will be better able to:

- Differentiate the characteristics of current and emerging MIGS procedures
- Compare the safety and efficacy data of MIGS devices
- Describe patient characteristics for selection of the appropriate MIGS procedure based on evidence
- Review the rationale and optimal techniques for MIGS bleb-based procedures

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MINIMALLY INVASIVE GLAUCOMA SURGERY

Clinical Experience From Europe, Canada, and the United States

Introduction

Glaucoma surgery is undergoing significant evolution. Although the traditional filtration procedures, trabeculectomy and tube-shunt implantation, remain the gold standard in eyes with inadequately controlled intraocular pressure (IOP), new procedures are emerging that take advantage of both traditional and nontraditional drainage pathways. These minimally invasive glaucoma surgery (MIGS) procedures divert aqueous humor into Schlemm canal (SC), the suprachoroidal space, or the subconjunctival space. As the busy surgeon attempts to incorporate MIGS into clinical practice, factors to consider include surgical skill requirements, efficacy and safety profiles, and the process of optimal patient selection. In this monograph, the attributes of each glaucoma device will be discussed, the patients for whom each device is suitable will be identified, and surgical pearls will be shared.

Are We Operating Earlier in Glaucoma?

Dr Palmberg: Largely on the basis of safety, we tend to start glaucoma therapy with medications, or, in some cases, with laser as first-line therapy, and save surgery for later. The new MIGS procedures **(Table 1)**,[1-11] however, offer significant IOP reductions, with safety profiles that are generally more favorable than those of traditional glaucoma surgeries, trabeculectomies, and tube shunts. Has the development of these new MIGS procedures caused us to change our practice patterns? Specifically, are we offering surgery earlier in the course of glaucoma therapy?

Dr Samuelson: Yes, we are. The ability to achieve substantial IOP reduction safely with MIGS procedures definitely favors their use earlier in the treatment regimen. In my opinion, there are many advantages to this change in practice patterns: we are less reliant on patient adherence to glaucoma medications; the patients are less burdened by often complex multidrug regimens; and we avoid some of the ocular surface toxicity associated with chronic use of topical IOP-lowering medications.[12-14] One significant factor slowing this transition to earlier surgery is that not all the MIGS procedures are approved for standalone use in the US marketplace. Trabecular ablation with Trabectome, goniotomy with the Kahook Dual Blade, and implantation of the XEN Gel Stent can be performed as solo procedures, but trabecular bypass with iStent[1] and supraciliary filtration with CyPass[15] are only approved in conjunction with cataract surgery, limiting their broader use, at least for now.

Dr Palmberg: Dr Barton, is the role of surgery changing in the United Kingdom and Europe as well?

Table 1. The MIGS Family of Glaucoma Devices/Procedures and Current Approval Status

Site of Bypass (Type of Procedure)	Device	Maker	Approved in the United States	Approved in Canada	Approved in Europe	Standalone	Approach	Filtration
Trabecular meshwork/Schlemm canal	Trabectome[1]	NeoMedix Corporation	Yes	Yes	Yes	Yes	Interno	Interno
	iStent[1,2]	Glaukos Corporation	Yes	Yes	Yes	Yes (Europe) No (United States)	Interno	Interno
	Hydrus[1]	Ivantis Inc	No	No	Yes	Yes (Europe)	Interno	Interno
	Kahook Dual Blade[3]	New World Medical, Inc	Yes	Yes	Yes	Yes	Interno	Interno
	iTrack[4] (GATT,[1] ABiC[5])	Ellex	Yes	Yes	Yes	Yes	Interno	Interno
	VISCO360[6]	Sight Sciences	Yes	Yes	Yes	Yes	Interno	Interno
Suprachoroidal space	CyPass[1]	Alcon	Yes	Yes	Yes	No	Interno	Interno
	iStent Supra[7,8]	Glaukos Corporation	No	No	Yes	Yes (Europe)	Interno	Interno
	Gold[5]	SOLX, Inc	No	Yes	Yes	Yes (Europe)	Externo	Interno
Subconjunctival space	EX-PRESS[9]	Alcon	Yes	Yes	Yes	Yes	Externo	Externo
	XEN Gel Stent[10]	Allergan	Yes	Yes	Yes	Yes	Interno	Externo
	MicroShunt[11]	Santen Pharmaceutical Co, Ltd	No	No	Yes	Yes	Externo	Externo

Abbreviations: ABiC, ab interno canaloplasty; GATT, gonioscopy-assisted transluminal trabeculotomy; MIGS, minimally invasive glaucoma surgery.

Dr Barton: For our patients undergoing cataract surgery, there is a very low threshold for adding a MIGS procedure. The MIGS procedures are generally safe and effective, and, as Dr Samuelson said, there are many potential advantages for early MIGS in eyes that are already facing surgery for cataracts. The harder question is, what do we do with patients who are not facing cataract surgery? Do we move to early surgery and perform MIGS as a standalone procedure? The answer to this question is less clear. Certainly, we have learned from procedures such as selective laser trabeculoplasty that we may be doing our patients a favor in the long run by intervening early rather than saving the procedure for the time when maximal medical therapy has become ineffective. When used in treatment-naïve eyes, selective laser trabeculoplasty lowers IOP to a greater extent than when used in eyes previously treated with medications.[16] Likewise, some studies,[17,18] but not all,[19] have suggested that early trabeculectomy surgery preserves the visual field better than medications or laser treatment. It is likely that the same will hold for the MIGS procedures as well, but we are still in the early days of the MIGS era and are not yet seeing a major paradigm shift. One factor working against us in promoting early surgery is the asymptomatic nature of glaucoma. Medications and laser are reasonably accepted by patients to prevent further loss, but surgery is a more intense intervention. Patients may be reluctant to undergo incisional surgery in the absence of symptoms without trying a less invasive treatment first.

Dr Palmberg: The patient perspective is important to consider. Cataract surgery has become more readily accepted because it has become safer, with consistently favorable outcomes. As patients learn more about MIGS procedures from their doctors and the media, they may come to appreciate that recovery occurs more quickly with these procedures than with traditional surgeries, and also wish to have freedom from daily topical medication(s).

Dr Barton: I agree, but it will come down to efficacy. Some of the bleb-based MIGS devices, such as the XEN Gel Stent[10,20-22] and MicroShunt,[11] can provide significant IOP reductions, with favorable safety profiles. These make sense as standalone alternatives to trabeculectomy in eyes that require IOP reduction. It is less clear if some of the blebless procedures can consistently deliver adequate IOP reduction in eyes that need lower IOP, so their role in standalone surgery remains to be seen.[23]

Dr Samuelson: One important factor to remember is that eyes undergoing MIGS combined with cataract surgery are undergoing 2 IOP-lowering procedures. Cataract surgery alone lowers IOP effectively and can reduce reliance on IOP-lowering medications for up to 3 years postoperatively.[24] When combining cataract surgery and MIGS, the MIGS procedure is also reducing both IOP and the need for medications. In standalone MIGS cases, we do not obtain the IOP-lowering benefit of cataract surgery, so many of these eyes should be expected to need adjunctive medical therapy.

Dr Palmberg: In the context of earlier surgery for glaucoma, a recent post hoc analysis of the Collaborative Initial Glaucoma Treatment Study (CIGTS) data set demonstrated that some patients with glaucomatous visual field loss experience significant improvement in the visual field after consistent IOP reduction **(Table 2)**, and the lower the peak IOP, the more likely this improvement was to occur.[25] That analysis sought to separate genuine changes from apparent changes ("statistical noise") that would occur randomly approximately 5% of the time just from performing visual field testing repeatedly. In the case of subjects whose peak IOP was 13 mm Hg during the first 5 years of the study, the field test result was better than the baseline value by 3 dB of mean deviation on 18.7% of tests and worse only 6.3% of the time. Therefore, the difference, 12.4% of the tests, has to be genuine. Furthermore, the percentage appearing to be worsening was just approximately at the level of noise (ie, unmeasurably low) and much lower than in the study as a whole. These data support the previous observation by Spaeth that visual field loss may be partially reversible in glaucoma.[26] Additional support comes from an observation

Table 2. Visual Field Improvement in CIGTS Correlated to IOP[25]

Maximum IOP in First 5 Years	Mean Percentage of Visit With 3-dB Gain	Mean Percentage of Visits With 3-dB Loss	Mean Difference	Mean Deviation Change at 5 Years, dB
≤ 13 mm Hg (n = 24)	18.7	6.3	12.4	0.39
14-17 mm Hg (n = 80)	13.4	6.3	7.1	0.65
18-21 mm Hg (n = 151)	10.6	11.7	-1.2	0.01
≥ 22 mm Hg (n = 221)	8.0	10.6	-2.5	-0.46

Abbreviations: CIGTS, Collaborative Initial Glaucoma Treatment Study; IOP, intraocular pressure.

by Caprioli that retinal sensitivity in glaucomatous scotomas improved with significant IOP reduction.[27] Keeping in mind that CIGTS enrolled patients with generally early-stage glaucoma (average visual field mean deviation of -5.4 dB),[25] would the existence of a safer glaucoma operation motivate you to operate sooner to achieve a target IOP level in the low teens for your patients with early glaucoma?

Dr Samuelson: If we could do so safely in a consistent manner, I would like to achieve an IOP level in the low teens in all my patients, even if the only benefit is visual field stability. With the prospect of reversal of visual field loss, motivation is even greater. The easiest patient with glaucoma in the clinic is one with an IOP of 10 mm Hg after filtration surgery. This patient is easy to care for because the IOP has been optimized and there is not much more to do for him or her. Although there are exceptions, this is the patient we feel confident is unlikely to progress over time. Therefore, if I can achieve an IOP level in the low teens safely and consistently, that would be my goal.

Dr Ahmed: I agree. I have come to believe that most of our patients benefit in the long run from consistently lower IOP. In my experience, surgery is usually required to accomplish these lower IOP levels. The deterrent to surgery in all patients is safety. Quigley once estimated that trabeculectomy, if applied to all patients with glaucoma, would cause blindness due to complications for roughly the same number of patients as those who would go blind from glaucoma without surgery.[28] So this is currently not the preferred standard of care. With a safer procedure, however, the math could change to surgery's favor.

Dr Barton: My practice is skewed toward more severe glaucoma, with the need for a lower target IOP, so many of my patients undergo surgery. I can certainly see the logic of early surgery in early disease if a low target IOP can be achieved safely. Many patients with glaucoma, regardless of severity, will do better in the long run with lower IOP.

MIGS Without a Bleb

Trabecular Disruption

Dr Palmberg: Let us discuss specific MIGS procedures. We will begin with procedures that disrupt the trabecular meshwork (TM) and/or SC. This is generally considered to be an important point of resistance to aqueous humor outflow. The strategy of disrupting the TM/SC complex dates to the 1940s when Barkan used goniotomy (which he had pioneered for use in infants with primary congenital glaucoma)[29] in adults with open-angle glaucoma, which lowered IOP briefly before failing in many eyes. Today, the trabecular disruption procedures include trabecular ablation with Trabectome **(Figure 1)**[30] and goniotomy using the Kahook Dual Blade **(Figure 2)**.[31] What is your experience with these procedures?

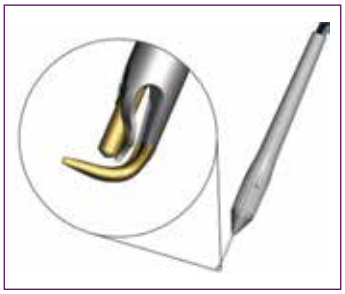

Figure 1. The Trabectome handpiece. The tip is inserted through the trabecular meshwork into Schlemm canal and, as advanced, electrocauterizes the trabecular meshwork/Schlemm canal complex.[30]

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Figure 2. The Kahook Dual Blade. The tip is inserted through the trabecular meshwork into Schlemm canal and, as advanced, excises a strip of the trabecular meshwork/Schlemm canal complex.[31]

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Dr Samuelson: I tend not to use the tissue-disruptive procedures widely, given that we now have more elegant procedures that can bypass the TM/SC complex without extensive tissue disruption. However, I have found that gonioscopy-assisted transluminal trabeculotomy can be very effective in younger patients and in those with high myopia, pigmentary glaucoma, or juvenile open-angle glaucoma.

Suprachoroidal Drainage

Dr Palmberg: Let us move on to suprachoroidal drainage devices. The CyPass device is now available in the United States[15] and also in select countries in Europe[1] **(Figure 3)**.[32] Dr Barton, what is the European perspective on this approach?

Dr Barton: The suprachoroidal space has tremendous potential for aqueous drainage, and this procedure provides an internal filtration procedure that could help us avoid all the long-term complications known to plague bleb-based surgeries.[33] In a multicenter randomized clinical trial, the CyPass device combined with cataract surgery lowered IOP significantly more than did cataract surgery alone (7.4 mm Hg vs 5.4 mm Hg; $P < .001$).[32] The most common adverse event was best-corrected visual acuity loss of > 10 letters, which occurred in 8.8% of eyes receiving the CyPass device and in 15.3% of eyes receiving only cataract surgery ($P = .0466$). Other complications were uncommon and evenly distributed between groups. The challenge with the suprachoroidal space is that scarring limits the outcome over time.

A modification of the CyPass procedure has been described, in which viscoelastic is first injected in the suprachoroidal space before the device is implanted; this technique has

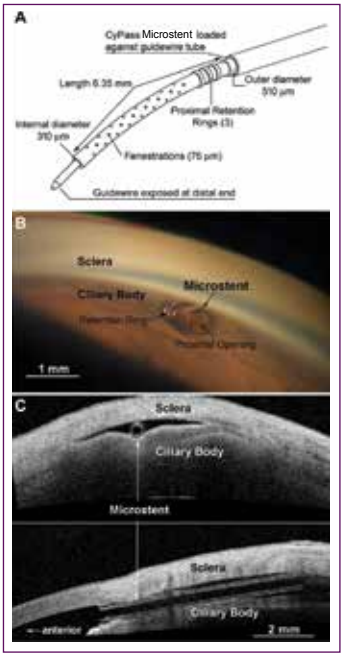

Figure 3. The CyPass device design (A), its proximal end correctly positioned within the anterior chamber (B), and transverse (C) and longitudinal (D) optical coherence tomography views of the device correctly placed in situ[32]

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undergone a recent clinical trial, but the results have not yet been made public.[34] I have performed 2 to 3 dozen of these procedures, which are very straightforward. I tend to use CyPass in patients who have failed an external filtering procedure, such as a trabeculectomy or tube shunt. It is an elegant choice because it accesses a completely distinct filtration pathway.

Dr Palmberg: Have you seen hypotony with the CyPass, and how do you handle it?

Dr Barton: I have had 2 cases of hypotony with the CyPass. In 1 case, I cut a 5-mm segment of 4-0 Ethicon suture material and inserted it into the anterior chamber end of the device. It partially blocked the outflow and restored IOP above the hypotony level.

Dr Palmberg: Dr Ahmed, what is the role of CyPass in your practice in Canada?

Dr Ahmed: I appreciate that with CyPass and other devices, we have a novel filtration pathway, adding the suprachoroidal space to the existing trabecular bypass and subconjunctival filtering routes. I tend to use CyPass in patients with mild-to-moderate glaucoma undergoing cataract surgery. In my experience, IOP reductions are modest, which is generally appropriate for these patients. As with all new procedures, its place in the treatment algorithm will become clearer with time.

Trabecular Bypass

Dr Palmberg: Because you raised the issue of trabecular bypass, how do you use the iStent device?

Dr Ahmed: The most important attribute of the canal-based surgical procedures for me is safety. In my experience, these procedures have the most favorable safety profile of all the glaucoma procedures.[35] As for efficacy, the IOP reductions also tend to be modest and are limited by factors such as distal outflow resistance in collector channels and the episcleral venous system.[35] In a phase 3 study comparing combined iStent and cataract surgery vs cataract surgery alone, the mean IOP reductions were identical (8.4 mm Hg vs 8.5 mm Hg, respectively), although the proportion of eyes achieving IOP ≤ 21 mm Hg without ocular hypotensive medications was significantly greater in the iStent group (66% vs 48%; $P < .001$).[36] Aside from device-specific events, such as obstruction or malposition, adverse events were comparable between the 2 groups. For this reason, I use iStent in the same types of patients for whom I use CyPass, that is, those with early-to-moderate glaucoma undergoing cataract surgery. In these patients, my primary goal is often medication reduction, and any additional IOP reduction is also welcome. If my goal is IOP reduction, I will consider placing 2 devices during surgery, which can deliver moderately greater IOP reductions, comparable with prostaglandin therapy.[37] I have also used iStent as a standalone procedure and would consider it in eyes with a high target IOP or in those with medication intolerance issues.

Dr Samuelson: Dr Ahmed makes an important point. The safety profile of the iStent is remarkable.[1] Unlike virtually all our other glaucoma surgeries, there are no unexpected complications if the surgery is done correctly. With trabeculectomy and tube shunts, we have all had the experience of performing a perfect surgery only to have unanticipated complications, such as bleeding or hypotony. To a much lesser extent, the same is true with CyPass; even a perfect placement can lead to complications, such as hyphema, transient choroidal effusion with myopic shift, or at least transient hypotony.[1] In contrast, if I place iStent perfectly, I have never had a complication attributable to the device. If done properly, the risk is exceedingly small. The device may or may not successfully lower IOP and, in some cases, the efficacy may be modest, but I am confident that it will not cause safety issues.

Dr Palmberg: If a cataract surgeon was interested in adding angle-based surgery to his or her repertoire as either an add-on or standalone option, which of the procedures would you recommend he or she use first?

Dr Samuelson: This is a frequently asked question. Technically, the easiest to perform is the trabecular disruptive procedure, such as for Trabectome or Kahook Dual Blade goniotomy. In either case, you can incise a few clock hours of TM, adjust your position, incise a few more clock hours, and, in this manner, perform the procedure incrementally. This is in contrast with the implantable device procedure, in which the technique is a single deft movement to implant the device—and proper placement is essential. The trade-off for safety with the trabecular disruptive procedure, as we discussed previously, is a reduction in efficacy compared with other procedures such as trabeculectomy. But the trabecular disruptive procedure is a good place to begin. The key for any new angle-based surgeon is to acquire excellent intraoperative gonioscopy skills to provide the visualization needed to perform the procedure.

Dr Barton: In the case of combined cataract and glaucoma surgery, I think it is worth mastering the technique of iStent placement because, in my opinion and as Dr Samuelson

pointed out, it is the safest procedure of them all. However, as a starting point, implanting a CyPass device is probably the technically most intuitive of the procedures to master.

Dr Ahmed: Different surgeons will have different skills sets and comfort levels that will guide the procedure selection process. Some will be more comfortable working in the canal, whereas others may feel more comfortable working in the suprachoroidal space.

Dr Palmberg: I believe we have consensus that the canal-based and suprachoroidal procedures are best suited for patients with mild-to-moderate glaucoma and a target IOP in the mid-to-upper teens, given the modest IOP reductions we expect from these procedures.

MIGS With a Bleb

Dr Palmberg: Let us now discuss novel treatment options for patients who require more robust IOP reduction, that is, bleb-based procedures that include the XEN Gel Stent **(Figure 4)**[22] and MicroShunt **(Figure 5)**[11] implants.

Figure 4. The XEN Gel Stent (A) and its intended position within the eye (B)[22]

Reprinted from *Am J Ophthalmol,* 183, Grover DS, Flynn WJ, Bashford KP, et al, Performance and safety of a new ab interno gelatin stent in refractory glaucoma at 12 months, 25-36, Copyright 2017, with permission from Elsevier.

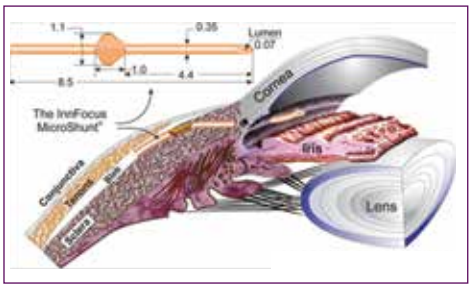

Figure 5. The MicroShunt device and its intended position within the eye[11]

Reprinted from Batlle JF, Fantes F, Riss I, et al, Three-year follow-up of a novel aqueous humor MicroShunt, *J Glaucoma,* 25, 2, e58-e65, https://insights.ovid.com/pubmed?pmid=26766400

Dr Ahmed: Dr Palmberg, you have advocated for lower target IOP for years, and I am convinced that you are right. Most patients do better in the long run with a target IOP level in the low teens. Low-target IOP and long-term glaucoma stability can be achieved with medications,[19] but low IOP can be difficult to accomplish consistently with medications, in part because of the aqueous dynamics of the eye and the known issues of nonadherence with medical therapy. Given the risk profile of traditional procedures, such as trabeculectomy and tube shunts, they have not been widely advocated to achieve low target IOP for most patients. The microtube devices that you mentioned fill an unmet need in our glaucoma treatment armamentarium. The procedures for implanting these devices are effective, safe, and relatively easier to perform and manage compared with traditional filtration procedures. They offer a great opportunity to safely achieve low target IOP, whether combined with cataract surgery or as standalone procedures.

XEN Gel Stent

Dr Palmberg: The XEN Gel Stent is a porcine collagen tube 6 mm in length, with an internal diameter of 45 µm, that is cross-linked with glutaraldehyde to extend its persistence in situ after implantation.[22] Devices with larger internal diameters—63 and 140 µm—were evaluated but not commercialized because the 45-µm device provided the optimal balance of efficacy and safety. At 45 µm, the pressure gradient from end to end was calculated to be approximately 8.5 mm Hg at 2.5 µL/mL (normal aqueous flow). The stent is supplied preloaded in an inserter that incorporates a 27-gauge needle. The inserter is passed across the anterior chamber under viscoelastic, through the TM and into the sub-Tenon or subconjunctival space at least 3 mm posterior to the limbus to prevent eyelid friction with blinks and thus minimize erosion risk. When the plunger is engaged on the inserter, the microtube is released and immediately hydrates, which causes it to swell and anchor in place passively. Once in place, the microtube shunts aqueous humor from the anterior chamber into the subconjunctival space, forming a bleb. As with all bleb-based procedures, mitomycin C (MMC) is needed to modulate wound healing.

In a pivotal multicenter case series, MMC was applied by sponge after performing a conjunctival peritomy in refractory glaucoma cases.[22] This was necessary because the only US Food and Drug Administration (FDA)-approved means of applying MMC in registration trials is the use of the FDA-approved MMC kit with sponge application.[38] Doing so effectively negated the key benefit of this procedure, namely, the ability to create a bleb without a conjunctival incision. In the case series, 12-month IOP reduction averaged 36.7%, with a success rate of 76% (≥ 20% IOP reduction from baseline).[22] Complications were those expected from glaucoma surgery and included early hypotony (24.6%), wound leaks (9.2%), and the need for postoperative needling procedures (32.3%), among others; stent-related complications (eg, erosion and migration) were uncommon (1.5% each).

Dr Ahmed, you have conducted a trial in primary glaucoma surgery with the XEN Gel Stent, in which you injected MMC directly into the subconjunctival space without making a conjunctival incision.[39] Please describe that study.

Dr Ahmed: In trabeculectomy, if the conjunctiva is not closed in a watertight fashion, acute bleb leaks and hypotony can contribute to delayed visual recovery postoperatively. As you said, we felt that a key strength of the XEN Gel Stent procedure is the no-touch approach to the conjunctiva, which is lost if we need to open the conjunctiva to apply MMC. We recently reported a retrospective comparison of the XEN Gel Stent with injected MMC vs trabeculectomy with either injected or sponge-delivered MMC.[39] In our study of 354 eyes, we found comparable safety, IOP reductions, and overall success rates for both procedures up to 30 months of follow-up, with a median IOP in the range of 13.0 mm Hg at the last follow-up. I have been injecting MMC directly into the subconjunctival space approximately 20 minutes preoperatively for my filtration procedures for 4 to 5 years now and can attest to the safety of this approach.

Dr Palmberg: What is your experience with the XEN Gel Stent?

Dr Barton: I have been using the XEN Gel Stent for the last 5 years. My early experience was with the XEN63, which, as you said, was ultimately not the commercialized device. More recently, I have used the XEN45, which proved rather more predictable in terms of performance. I have been reasonably happy with the results.

Dr Samuelson: The ab interno approach is used to implant the XEN Gel Stent, and the device design limits postoperative hypotony. I, too, avoid opening the conjunctiva by injecting MMC subconjunctivally preoperatively. I like the fact that I can avoid external cautery, which can both promote inflammation and induce astigmatism. What I do not like is the high rate of external fibrosis. Many of these eyes require needling postoperatively,[22,39] and a few patients had to return to the operating room for surgical revision.

Dr Barton: The needling process for a XEN Gel Stent procedure can be difficult. The fibrosis is focally located at the tube tip, and there is a risk of damaging the tube with the needle. I have found it easier in many cases to open the conjunctiva, remove the fibrosis under direct visualization, and apply more MMC at the same time.

Dr Palmberg: The XEN Gel Stent procedure has a key advantage over trabeculectomy in that it is technically easier to perform. In trabeculectomy, we rely on a well-constructed scleral flap, sutured with the appropriate tension to adjust the IOP at equilibrium flow to the target IOP and above the hypotony threshold. This takes considerable skill, experience, and judgment. In contrast, the XEN Gel Stent produces a pressure gradient to achieve this target IOP range by virtue of its own design, simplifying the procedure greatly and theoretically reducing the rate of hypotony. As Dr Samuelson mentioned, however, the needling rate with the XEN Gel Stent can be quite high.[22,39] Dr Ahmed, please tell us about your experience with the XEN Gel Stent with regard to postoperative needling.

Dr Ahmed: In our series, the needling rate was 43% in the XEN Gel Stent group and 31% in the trabeculectomy group.[39] In a separate study using XEN140—with a larger internal diameter and thus more flow—the distal tube tip was placed in the subconjunctival space without MMC, and the rate of needling was 47%,[10] which is consistent with our study using XEN45.[39] I agree with you that a lower rate of bleb needling would be beneficial. As our technique has evolved, including the placement of the XEN Gel Stent more "supra-Tenon" to reduce distal interstitial resistance beyond the implant, we have found our needling rates have decreased significantly. Surgical technique will be important for success of the XEN Gel Stent. As for hypotony, in my experience, the rate of postoperative hypotony with XEN45 is negligible.[39] There were 2 cases of hypotony maculopathy in the 185 XEN Gel Stent eyes in our study.[39] In the XEN140 study, the rate of hypotony requiring anterior chamber reformation with viscoelastic was 9%,[10] which partly explains why XEN140 was not commercialized.

MicroShunt

Dr Palmberg: Now let us turn to the second bleb-based MIGS device—the MicroShunt. This device is an 8.5-mm-long tube made of poly(styrene-block-isobutylene-block-styrene), with an internal diameter of 70 µm.[11] Given these dimensions and its hydrophobic properties, the end-to-end pressure gradient is approximately 6 mm Hg. Also, because the MicroShunt is hydrophobic, it must be primed at the time of implantation. Unlike the XEN Gel Stent, the MicroShunt is implanted via an ab externo approach, so the conjunctiva must be opened, permitting application of MMC by subconjunctival injection or intraoperative sponge delivery.

The device is in late-stage clinical development in the United States and is therefore not approved or available here, nor is it available yet in Canada. It is, however, approved in Europe. In a small study, mean IOP reductions of 38% to 55% and IOP-lowering medication reductions of 72% to 88% were observed, depending on how much MMC was used and where it was placed, with the best outcomes arising from MMC placement closer to the limbus rather than deep in the sulcus.[40] We conducted a pilot study in the Dominican Republic and published 3-year data from that study.[11] We included 23 eyes undergoing MicroShunt implantation with sponge-delivered MMC, with or without cataract surgery. The 3-year success rate was 95%, with success defined as an IOP level of 21 mm Hg or lower that was reduced from baseline by a minimum of 20%, with or without medications **(Figure 6)**.[11] The mean IOP reduction at 3 years was 13.1 mm Hg, from 23.8 mm Hg to 10.7 mm Hg, and medication use was reduced from a mean of 2.4 medications to 0.7 medications per patient at 3 years. At 3 years, 82% of subjects had an IOP level of ≤ 14 mm Hg. Transient hypotony occurred in 3 eyes (13%). Only 1 eye (4.3%) required needling.

How will this efficacy and safety profile, coupled with the surgical approach, affect the MicroShunt's uptake in clinical practice?

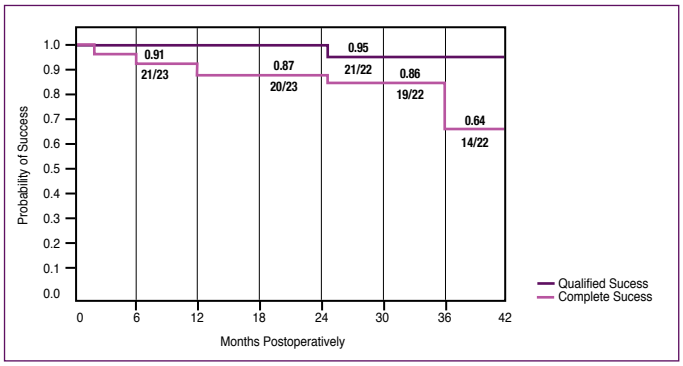

Figure 6. Success rates following MicroShunt implantation through 3 years of follow-up.[11] Success was defined as an IOP level of 21 mm Hg or lower that was reduced from baseline by a minimum 20% with (qualified) or without (complete) medications.

Reprinted from Batlle JF, Fantes F, Riss I, et al, Three-year follow-up of a novel aqueous humor MicroShunt, *J Glaucoma,* 25, 2, e58-e65, https://insights.ovid.com/pubmed?pmid=26766400.

Dr Barton: My initial reaction to this device was that it seemed less refined than the XEN Gel Stent. The ab externo approach seemed like a step backward, more like trabeculectomy than a MIGS procedure. As I gained experience with the device, my perception changed completely. I find the device easier to implant than the XEN Gel Stent. Less skill is needed for optimal placement because visibility is direct and the approach is familiar because of our tube-shunt experience.

Dr Samuelson: My experience with the MicroShunt is as an investigator in the clinical trial. I agree with Dr Barton that the implantation technique is familiar to surgeons who insert a lot of tube shunts.

Dr Ahmed: This device is a microtube without a plate. What I have learned from performing the implantation procedure is that the plates limit bleb size. Our MMC protocol for this device has evolved over time to address long-term fibrosis. I use 0.5 mg/mL MMC, injecting it preoperatively and applying it by sponge intraoperatively for 2 minutes. This is a megadose, and it produces large, diffuse blebs, with no appreciable safety issues due to the posterior diversion of aqueous and controlled flow from the implant. Another key factor is tube position. I prefer for the external tip to be adequately posterior to produce a more posterior bleb, and I carefully place it under Tenon layer to avoid entrapment within this tissue. This creates beautiful diffuse blebs with very low IOP while avoiding hypotony.

Dr Palmberg: I agree that we can use higher doses of MMC to augment operations that should be, because of the calculated pressure gradient created by the tube, inherently safer than trabeculectomy with regard to hypotony. With experience, we will better understand what, if any, are the consequences of these megadoses. The optimal MMC regimen will become clearer with time. For those glaucoma surgeons who are comfortable with their trabeculectomy technique and perhaps hesitant to move toward these bleb-based MIGS procedures, are there data that will guide their clinical decisions?

Dr Samuelson: As Dr Ahmed mentioned, there was a retrospective comparison of the XEN Gel Stent vs trabeculectomy that showed comparable efficacy and safety profiles.[39] The ongoing MicroShunt US phase 2/3 trial is a randomized comparison with an MMC trabeculectomy that should also provide surgeons with data to guide their choice of procedures.[41]

Dr Palmberg: Another potential advantage of this device is its minimal effect on refraction. In trabeculectomy, making the scleral flap and suturing it can induce astigmatism. Has it been your experience that visual recovery is faster with these microstents?

Dr Ahmed: Absolutely. It is gratifying to see a high proportion of patients return to baseline vision within a few days after surgery with either of these microtube devices. The effect of these procedures is so minimal that I feel comfortable combining them with toric intraocular lenses in patients with cataracts.

The Future of Glaucoma Surgery

Dr Palmberg: What are the important unmet needs in glaucoma therapy that still need to be addressed?

Dr Samuelson: Within the context of our 3 approaches to glaucoma surgery—those focused on the canal, the suprachoroidal space, or the subconjunctival space—it would be beneficial to better understand the nature of aqueous outflow resistance in individual eyes as a guide for proper procedure selection. For instance, if we could measure distal outflow resistance, we might be able to identify patients who are unlikely to benefit from canal-based surgery. If we better understood why suprachoroidal filtration procedures fail, we could modify these procedures. We still lose a number of trabeculectomies to wound-healing complications, so alternatives to MMC for modulation of wound healing would be useful.

Dr Ahmed: As encouraging as the data for these new bleb-based MIGS procedures are, the longest follow-up so far has been only 3 years. Glaucoma is a long-term disease, so I think we will need longer-term data—similar to the 5-year data from the Tube Versus Trabeculectomy study[33,42]—to better guide our surgical decisions on an individual patient basis. I would also find it helpful to better characterize patient satisfaction and quality of life with these various surgeries and to attempt to quantify the benefits of reducing reliance on medications. Again, I point to the Tube Versus Trabeculectomy study, which incorporated and reported patient-perspective outcomes.[43]

Dr Barton: Along those lines, I would like to see long-term data on the durability of these new microtubes. Does their IOP-lowering efficacy endure over time? Long-term efficacy will be critical to determine their role in the treatment portfolio.

Dr Palmberg: As we enter the era of the electronic health record, I hope we are not too far from a day when this technology takes into account the outcome data from clinical trials such as CIGTS,[19] the Advanced Glaucoma Intervention Study,[44] the Early Manifest Glaucoma Trial,[45] and the Ocular Hypertension Treatment Study,[46] thereby enhancing our clinical decision making. I imagine a day when the electronic health record integrates with the visual field data to provide a comprehensive risk calculation for each patient at the time of initial evaluation. On the basis of individual risk factors (eg, age, central corneal thickness, and initial IOP), the calculator would estimate the probability of progression/stability/improvement over 5 years, assuming achievement of various target IOP levels. We could review the expected outcomes at each target IOP level and make better informed decisions about the risks and benefits of potential interventions to achieve specific IOP reductions.

Summary and Take-Home Points

The various MIGS procedures take advantage of different aqueous outflow pathways. The IOP-lowering characteristics and safety profiles of these procedures are determined in large part according to these outflow pathways. Modest IOP reductions can be derived from the canal-based and suprachoroidal shunt procedures: these options are best used in combination with cataract surgery in eyes with early-to-moderate glaucoma and a target IOP level in the high teens. Patients undergoing such procedures are also likely to require adjunctive medical IOP-lowering therapy over time. The bleb-based MIGS procedures rely on subconjunctival outflow and necessitate wound-healing modulation with MMC. These procedures provide greater IOP reduction than other MIGS options while apparently preserving the excellent

safety profiles of the MIGS family overall, and are of benefit both in combination with cataract surgery and as standalone procedures. Nonetheless, for all the MIGS procedures, longer-term follow-up will be needed to compare their outcomes with those of trabeculectomy and tube shunts. The randomized FDA registration trial comparing the MicroShunt with MMC to a trabeculectomy with MMC is currently under way and should provide important comparative data on safety and efficacy.[41]

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1. Cataract surgery alone has been shown to lower IOP and glaucoma medication reliance for up to _____ years.
   a. 1
   b. 2
   c. 3
   d. 5

2. What percentage of visual field tests in CIGTS appeared to show a visual field improvement of ≥ 3 dB at a peak IOP of 13 mm Hg? (Statistical noise was expected to be approximately 5%.)
   a. 6%
   b. 19%
   c. 30%
   d. 50%

3. MIGS procedures facilitate aqueous humor drainage into the Schlemm canal, the subconjunctival space, or the _____ space.
   a. Intraretinal
   b. Retrobulbar
   c. Suprachoroidal
   d. Interpalpebral

4. Which MIGS device is considered a trabecular disruptive procedure?
   a. iStent
   b. Kahook Dual Blade
   c. CyPass
   d. XEN Gel Stent

5. A key long-term limitation of the CyPass procedure is:
   a. Hypotony
   b. Astigmatism
   c. Scarring
   d. Cataract formation

6. Which of the following is widely considered to be the safest glaucoma procedure?
   a. Trabeculectomy
   b. MicroShunt
   c. CyPass
   d. iStent

7. Which of the following skills is essential for the new angle-based glaucoma surgeon?
   a. Phacoemulsification
   b. Ultrasound
   c. Intraoperative gonioscopy
   d. Tonometry

8. Which of the following is likely the safest procedure to combine with cataract surgery in a patient with early glaucoma and a target IOP level in the high teens?
   a. iStent
   b. XEN Gel Stent
   c. MicroShunt
   d. Trabeculectomy

9. Which of the following is the most likely standalone procedure to achieve an IOP level in the low teens for a patient with moderate-to-advanced glaucoma whose IOP is inadequately controlled on 2 medications?
   a. Trabectome
   b. CyPass
   c. XEN Gel Stent
   d. Kahook Dual Blade goniotomy

10. Which of the following 2 procedures necessitate the formation of a bleb and the use of MMC to prevent fibrosis, scarring, and surgical failure?
    a. iStent and trabeculectomy
    b. Trabectome and XEN Gel Stent
    c. MicroShunt and XEN Gel Stent
    d. CyPass and MicroShunt

ORIGINAL RELEASE: December 1, 2017
EXPIRATION: December 31, 2018

Activity Evaluation/Credit Request

MINIMALLY INVASIVE GLAUCOMA SURGERY: CLINICAL EXPERIENCE FROM EUROPE, CANADA, AND THE UNITED STATES

To receive *AMA PRA Category 1 Credit*™, you must complete this **Evaluation** form and the **Post Test.** Record your answers to the **Post Test** in the Answer Box located below. Scan this completed page and return via e-mail to cme-nyee@nyee.edu or fax it to 212-870-8128. Your comments help us to determine the extent to which this educational activity has met its stated objectives, assess future educational needs, and create timely and pertinent future activities. Please provide all the requested information below. This ensures that your certificate is filled out correctly and is e-mailed to the proper address. It also enables us to contact you about future CME activities. Please print clearly or type. Illegible submissions cannot be processed.

PARTICIPANT INFORMATION *(Please Print)* ☐ Home ☐ Office

Last Name _____ First Name _____

Specialty _____Degree ☐ MD ☐ DO ☐ OD ☐ PharmD ☐ RPh ☐ NP ☐ RN ☐ PA ☐ Other

Institution _____

Street Address _____

City _____State _____ ZIP Code _____Country_____

E-mail _____ Phone_____Fax_____

Please note: We do not sell or share e-mail addresses. They are used strictly for conducting post-activity follow-up surveys to assess the impact of this educational activity on your practice.

Learner Disclosure: To ensure compliance with the US Centers for Medicare and Medicaid Services regarding gifts to physicians, **New York Eye and Ear Infirmary of Mount Sinai** CME requires that you disclose whether or not you have any financial, referral, and/or other relationship with our institution. **CME certificates cannot be awarded unless you answer this question.** For additional information, please e-mail NYEE CME at cme-nyee@nyee.edu. Thank you.

☐ Yes ☐ No I and/or my family member have a financial relationship with **New York Eye and Ear Infirmary of Mount Sinai** and/or refer Medicare/Medicaid patients to it.

☐ **I certify that I have participated in the entire activity and claim 1.5 *AMA PRA Category 1 Credits*™.**

Signature Required _____**Date Completed** _____

OUTCOMES MEASUREMENT

☐ Yes ☐ No **Did you perceive any commercial bias in any part of this activity? IMPORTANT! If you answered "Yes," we urge you to be specific about where the bias occurred so we can address the perceived bias with the contributor and/or in the subject matter in future activities.**

_____

Circle the number that best reflects your opinion on the degree to which the following learning objectives were met:
5 = Strongly Agree 4 = Agree 3 = Neutral 2 = Disagree 1 = Strongly Disagree

Upon completion of this activity, I am better able to:

• Differentiate the characteristics of current and emerging MIGS procedures	5	4	3	2	1
• Compare the safety and efficacy data of MIGS devices	5	4	3	2	1
• Describe patient characteristics for selection of the appropriate MIGS procedure based on evidence	5	4	3	2	1
• Review the rationale and optimal techniques for MIGS bleb-based procedures	5	4	3	2	1

1. Please list one or more things, if any, you learned from participating in this educational activity that you did not already know.

_____

2. As a result of the knowledge gained in this educational activity, how likely are you to implement changes in your practice?
4 = definitely will implement changes 3 = likely will implement changes 2 = likely will not implement any changes
1 = definitely will not make any changes 4 3 2 1

Please describe the change(s) you plan to make: _____

_____

3. Related to what you learned in this activity, what barriers to implementing these changes or achieving better patient outcomes do you face?_____

4. Number of patients with glaucoma I see per week
☐ 0 ☐ 1-5 ☐ 6-10 ☐ 11-25 ☐ More than 25

5. Please check the Core Competencies (as defined by the Accreditation Council for Graduate Medical Education) that were enhanced for you through participation in this activity.
☐ Patient Care ☐ Practice-Based Learning and Improvement ☐ Professionalism
☐ Medical Knowledge ☐ Interpersonal and Communication Skills ☐ Systems-Based Practice

6. What other topics would you like to see covered in future CME programs? _____

ADDITIONAL COMMENTS _____

POST TEST ANSWER BOX

1	2	3	4	5	6	7	8	9	10