

CME Monograph



# Evolving Role of Subconjunctival MIGS

## A CASE-BASED DISCUSSION

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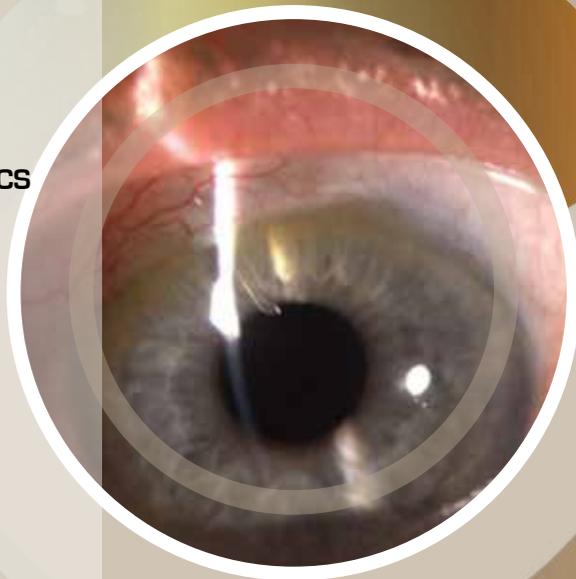
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## ACTIVITY DESCRIPTION

Minimally invasive glaucoma surgery (MIGS) has expanded options for glaucoma surgeons and patients, with treatments that are generally safer than trabeculectomy and tube-shunt procedures. The subconjunctival MIGS procedures divert aqueous humor to the subconjunctival space and require a filtering bleb, which, in clinical trials, have resulted in low target intraocular pressure. With the use of an antimetabolite, bleb management can be successfully achieved in a variety of patients with glaucoma. This activity will update glaucoma specialists and ophthalmologists on practical approaches to subconjunctival MIGS, enabling clinicians to improve visual outcomes for patients with glaucoma.

## TARGET AUDIENCE

This educational activity is intended for glaucoma specialists and ophthalmologists.

## LEARNING OBJECTIVES

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

- Describe the characteristics of current and emerging MIGS procedures
- Identify clinically relevant data on bleb-based MIGS procedures
- Select appropriate subconjunctival MIGS procedures for a variety of patients
- Summarize appropriate antimetabolite techniques for bleb-based MIGS

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# Evolving Role of Subconjunctival MIGS

## A CASE-BASED DISCUSSION

### Introduction

The development of minimally invasive glaucoma surgery (MIGS) has significantly altered the surgical approach to primary open-angle glaucoma (POAG). MIGS procedures expand the options for glaucoma surgeons and patients, providing a series of treatments that are generally safer—although perhaps less efficacious—than trabeculectomy and tube-shunt procedures.<sup>1</sup> Some MIGS procedures shunt aqueous humor into Schlemm canal or the supraciliary space, whereas others divert aqueous humor to the subconjunctival space, forming a filtering bleb.<sup>1</sup> This review focuses on subconjunctival MIGS procedures in particular, discusses optimal patient selection, and describes surgical pearls, including the appropriate use of antimetabolites to enhance surgical success.

### Goals of Glaucoma Therapy

**Dr Ahmed:** As new treatments for glaucoma emerge, we are able to offer different and more approaches to glaucoma care. How has the expansion of new treatment options changed our goals of glaucoma therapy?

**Dr Panarelli:** When I treat patients with glaucoma, my goal is to ensure that they do not lose functional vision in their lifetime. The new surgical procedures provide us with options for effective ways to lower intraocular pressure (IOP) and prevent vision loss.

**Dr Sng:** The expansion of glaucoma therapies over the past 2 decades offers me a variety of tools to improve the quality of life of my patients with glaucoma. My happiest patients are those who can discontinue daily topical medical therapy after glaucoma surgery. Now that this is a realistic goal for many patients who have required 1 or 2 medications for IOP control, I find that rendering patients medication free has become a goal of therapy.

**Dr Barton:** My practice is skewed toward more advanced disease and might not be representative of other practices. Although a target IOP in the mid-teens can be adequate for many patients with glaucoma, several of my patients with advanced glaucoma are progressing with IOP in this range. These patients require very low IOP—perhaps in the 8- to 12-mm Hg range. In such cases, the achievement of low IOP takes priority over improvements in quality of life. Low target IOP has been shown to stabilize glaucoma in eyes progressing at an IOP of 15 mm Hg or less.<sup>2</sup>

**Dr Ahmed:** Consistent IOP control is critical.<sup>3</sup> As we have developed new tools for IOP assessment, including the Triggerfish contact lens sensor and the Icare HOME tonometer, I have come to realize that many of my patients with advanced glaucoma are not as well controlled as I thought they were. These patients have significant IOP variability outside of office hours. I am now operating on patients with advanced glaucoma more often because they need more robust IOP control than they are getting from medical therapy. This is particularly important given that our patients are living longer and are at greater lifelong risk of vision loss from glaucoma.

## Role of MIGS in Glaucoma Management

**Dr Ahmed:** The surgical glaucoma space has expanded greatly in the past several years. The term MIGS has been coined to collectively describe a number of very different procedures that share some attributes. What exactly do we mean when we say that a procedure is a MIGS procedure?

**Dr Panarelli:** Dr Ahmed, you coauthored a review of MIGS that outlines the 5 features that characterize a MIGS procedure (**Table 1**): (1) it is performed by a microincisional approach; (2) it is minimally traumatic to the targeted tissue; (3) it is efficacious to a satisfactory degree; (4) it permits rapid recovery of patients' vision; and (5) it has a favorable safety profile. These characteristics should be considered guidelines rather than hard-and-fast rules.<sup>4</sup> Certainly, not every procedure that we consider a MIGS procedure will meet every one of these criteria to the same degree.

**Table 1.** Characteristics of a MIGS Procedure

1. Performed by a microincisional approach
2. Minimally traumatic to the targeted tissue
3. Satisfactory efficacy
4. Rapid visual recovery
5. Favorable safety profile

**Dr Ahmed:** Does a procedure that requires a conjunctival peritomy, the use of mitomycin C (MMC), and the creation of a subconjunctival filtering bleb as we have in subconjunctival MIGS still qualify as minimally invasive?

**Dr Panarelli:** To me, MIGS represents a broad spectrum of procedures. Although the subconjunctival MIGS procedures are *more* invasive than Schlemm canal–based procedures, they do offer improved efficacy with a favorable safety profile and can be performed with minimal trauma to the surrounding tissue. They are still considerably less invasive than traditional glaucoma surgeries.

**Dr Sng:** Safety is a deciding factor for me. Procedures with a more favorable safety profile than that of trabeculectomy are preferred. A safer procedure is one that I would be more confident offering earlier to my patients.

**Dr Ahmed:** When we first coined the term MIGS, the goal was to differentiate these procedures from trabeculectomy, in terms of not only anatomy and technique but also surgery's position within the treatment strategy. The MIGS procedures do not replace trabeculectomy; they offer surgical options for patients in whom trabeculectomy might not have been the best fit but at the time it was all we had.

**Dr Panarelli:** To expand on that point, I think the subconjunctival MIGS procedures specifically can be used to span the entire spectrum of disease. In early disease, they offer a safe option to reduce medication burden while still providing significant IOP reductions for patients with advanced disease. For glaucoma surgeons dealing with more advanced disease, these procedures are a natural extension of our filtration surgery techniques. For cataract surgeons dealing with, perhaps, less advanced disease, I believe that these procedures are far easier to perform than trabeculectomy and can improve patients' quality of life by reducing both IOP and medication burden in eyes with glaucoma undergoing cataract surgery.

**Dr Barton:** In my experience, another benefit for cataract surgeons is the significantly reduced intensity of the postoperative course when implanting MIGS as opposed to trabeculectomy. The visual recovery rate is important, and so is the fact that there is much less active intervention required in the early postoperative period with MIGS than with trabeculectomy.<sup>5,6</sup>

## The Family of MIGS Procedures

**Dr Ahmed:** The MIGS procedures fall into 3 general categories according to the space into which aqueous humor is diverted from the anterior chamber (**Table 2**).<sup>1,7-13</sup> One group of procedures bypasses the trabecular meshwork and delivers aqueous humor to Schlemm canal. A second group shunts aqueous humor into the supraciliary space. A third group provides a conduit from the anterior chamber to the subconjunctival space, where aqueous humor forms a filtering bleb. Let us take these one at a time. What are the pros and cons of trabecular bypass and Schlemm canal procedures?

**Dr Sng:** Of the trabecular bypass procedures, I use the iStent in my practice. The biggest advantage of the iStent is its highly favorable safety profile, which, in a pivotal trial, was comparable to that of cataract surgery alone.<sup>5</sup> The significant disadvantage of the iStent is its modest efficacy. In my practice, I tend to attain IOPs in the mid- to high-teen range, which is consistent with the IOP levels attained in the pivotal trial (17 mm Hg).<sup>5</sup> I find the iStent most appropriate for patients with early or moderate glaucoma, but I would not use it in patients with advanced glaucoma who require low target IOP.

**Dr Panarelli:** My experience with the iStent is similar. I have recently begun to perform gonioscopy-assisted transluminal trabeculotomy procedures and have found them to be safe and effective, especially in patients with various forms of secondary open-angle glaucoma. In a recent retrospective analysis of gonioscopy-assisted transluminal trabeculotomy outcomes, the mean IOP reduction with stand-alone surgery at 2 years was 40.0% (10.4 mm Hg, achieving a mean IOP of 15.6 mm Hg at 24 months) in eyes with POAG and 55.3% (17.1 mm Hg, achieving a mean IOP of 13.8 mm Hg at 24 months) in eyes with secondary open-angle glaucoma.<sup>14</sup> Safety issues included transient hyphema in 28% to 38% of eyes and 3 cases of transient iridodialysis.

The Hydrus implant, which was recently approved for use in the United States, is another new option. This 8-mm device stents open a large portion of Schlemm canal.<sup>1</sup> In a pivotal trial, mean IOP at 24 months was reduced by 7.6 mm Hg to 17.4 mm Hg in eyes undergoing Hydrus implantation plus cataract extraction compared with a reduction of only 5.3 mm Hg to 19.2 mm Hg in eyes receiving only cataract surgery ( $P \leq .001$ ).<sup>15</sup> Aside from the development of focal peripheral anterior synechiae (14.9% with Hydrus implantation vs 2.1% without Hydrus implantation), there were no differences in adverse event rates between the groups. I do not have any experience with this device yet because it was only recently approved for use in the United States.

**Dr Ahmed:** Let us now talk about the supraciliary MIGS approach. What are the pros and cons of supraciliary outflow MIGS?

**Dr Panarelli:** The supraciliary space is a potential space. Shunting aqueous into this space takes advantage of the uveoscleral outflow pathway, without forming a bleb or creating bleb-related risks.

**Table 2.** The MIGS Family of Procedures<sup>1,7-13</sup>

Site of Bypass (Type of Procedure)	Device	Maker	Approved in the United States and Canada	Approved in Europe	Stand-alone	Approach	Filtration
Schlemm canal (internal MIGS)	Trabectome <sup>1</sup>	NeoMedix Corporation	Yes	Yes	Yes	Interno	Interno
	iStent <sup>1</sup>	Glaukos Corporation	Yes	Yes	Yes (Europe) No (United States)	Interno	Interno
	Hydrus <sup>1</sup>	Ivantis Inc	Yes	Yes	Yes (Europe) No (United States)	Interno	Interno
	Kahook Dual Blade <sup>7</sup>	New World Medical, Inc	Yes	Yes	Yes	Interno	Interno
	iTrack for GATT <sup>1</sup>	Ellex	Yes	Some countries	Yes	Interno	Interno
	iTrack for ab interno canaloplasty <sup>8</sup>	Ellex	Yes	Some countries	Yes	Interno	Interno
	VISCO360 <sup>9</sup>	Sight Sciences	Yes	Yes	Yes	Interno	Interno
Suprachoroidal space (internal MIGS)	CyPass* <sup>1</sup>	Alcon	Yes	Yes	No	Interno	Interno
	iStent Supra <sup>10</sup>	Glaukos Corporation	No	Yes	Yes (Europe)	Interno	Interno
	Gold shunt <sup>8</sup>	SOLX, Inc	Yes (United States) No (Canada)	Yes	Yes	Externo	Interno
Subconjunctival space (external MIGS)	EX-PRESS <sup>11</sup>	Alcon	Yes	Yes	Yes	Externo	Externo
	XEN Gel Stent <sup>12</sup>	Allergan	Yes	Yes	Yes	Interno	Externo
	MicroShunt <sup>13</sup>	Santen Inc	No	Yes	Yes	Externo	Externo

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

\* Off market August 29, 2018

**Dr Barton:** The downside of shunting aqueous into the supraciliary space is the wound-healing response that contributes to variability in outcomes. Also, as the 5-year follow-up data from the COMPASS XT trial have demonstrated, the CyPass was associated with significant long-term endothelial cell loss<sup>16</sup>—enough loss, in fact, that the device has been withdrawn from the marketplace worldwide.<sup>17</sup>

**Dr Ahmed:** Now that endothelial cell loss is on the radar for MIGS procedures, do you believe this is limited to the CyPass, or will we see it with other MIGS procedures as well?

**Dr Barton:** My opinion of the CyPass is that it was a reasonable prototype device for the supraciliary space, but it was insufficiently developed and it was too big. Modifications might result in a supraciliary device with a more favorable safety profile.

**Dr Ahmed:** Now let us discuss MIGS subconjunctival filtration. There are 2 MIGS procedures that deliver aqueous humor to the subconjunctival space: the ab interno gel stent (XEN Gel Stent) and the ab externo implant (MicroShunt device). XEN gel stent is 6 mm long and has an internal diameter of 45 μm, whereas MicroShunt is 8.5 mm long and has an internal diameter of 70 μm.<sup>18</sup> The **Sidebar: Clinical Studies of Subconjunctival MIGS** summarizes data from

pivotal trials evaluating these devices. What are the pros and cons of these bleb-based MIGS procedures?

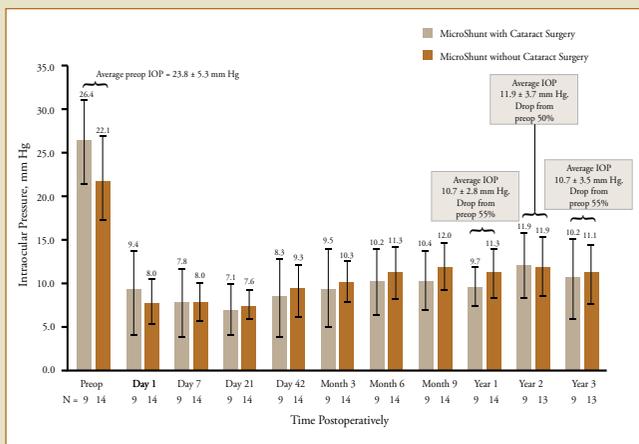
**Dr Sng:** Subconjunctival filtration makes trabeculectomy-like efficacy attainable. These procedures might potentially offer a safer, easier alternative to trabeculectomy in eyes with advanced glaucoma that require low target IOP, although more data are needed to confirm this. We are all eagerly awaiting the results of the randomized controlled trial comparing MicroShunt with trabeculectomy.<sup>19</sup> Besides the efficacy of subconjunctival MIGS devices in POAG, we have also reported that XEN gel stent can be effective for the treatment of patients with medically uncontrolled uveitic glaucoma.<sup>20</sup> This efficacy advantage comes at the expense of safety; these procedures bring with them the well-known constellation of bleb-related complications, including leaks, hypotony, and infections.<sup>20,21</sup>

**Dr Panarelli:** In patients with more advanced glaucoma, there might be advantages to subconjunctival filtration. First, we can attain a low target IOP. Second, we are avoiding the diseased trabecular outflow tract, which might be less amenable to enhancement with MIGS compared with that in eyes with earlier-stage glaucoma. Future studies—particularly head-to-head studies with trabeculectomy—will be needed to establish if bleb-based MIGS procedures offer safety advantages over trabeculectomy.

## Clinical Studies of Subconjunctival MIGS

### MicroShunt Device

The efficacy and safety of the MicroShunt device were evaluated in a pivotal trial of 23 open-angle glaucoma eyes with intraocular pressure (IOP) refractory to maximal medical therapy that received the implant in either a stand-alone procedure or in combination with cataract surgery.<sup>1</sup> The device was implanted into the sub-Tenon space via an ab externo technique that included a conjunctival peritomy and application of mitomycin C 0.4 mg/mL by sponge for 3 minutes. Mean baseline IOP was 23.8 mm Hg, and at 1, 2, and 3 years, was reduced to 10.7 mm Hg (55% reduction), 11.9 mm Hg (50% reduction), and 10.7 mm Hg (55% reduction), respectively (**Figure 1**). The mean number of IOP medications at baseline was 2.4, and was reduced to 0.3 (87.5% reduction), 0.4 (83.3% reduction), and 0.7 (70.8% reduction) medications at 1, 2, and 3 years, respectively. Adverse events included 3 cases each of tube-iris contact, transient hypotony, and transient shallow or flat anterior chamber that resolved spontaneously, as well as 2 cases each of hyphema, exposed Tenon capsule, and choroidal effusion/detachment. Only 1 eye required postoperative needling, and 1 eye failed and required secondary glaucoma surgery.



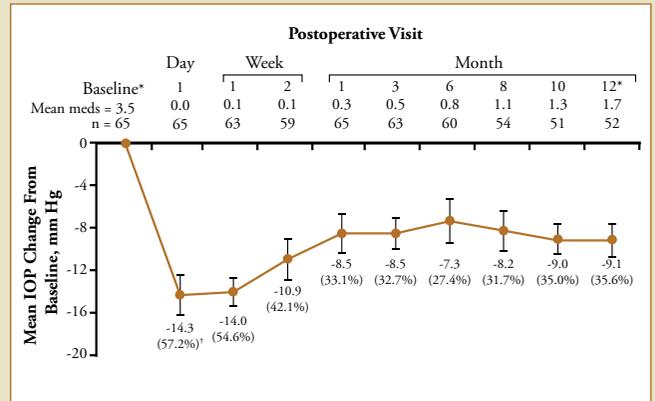
**Figure 1.** Change in intraocular pressure over time for MicroShunt implanted with and without phacoemulsification with intraocular lens implantation

Abbreviation: IOP, intraocular pressure.

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### XEN Gel Stent

The efficacy and safety of XEN gel stent were evaluated in a pivotal trial of 65 eyes with refractory glaucoma (failed surgery and maximal medical therapy) that received the implant as a stand-alone procedure.<sup>2</sup> The device was implanted into the subconjunctival space via an ab interno technique that included a conjunctival peritomy and application of mitomycin C 0.2 mg/mL by sponge for 2 minutes. Mean baseline IOP was 25.1 mm Hg. By month 12, IOP was reduced to 15.9 mm Hg (36.7%) (**Figure 2**). The mean number of IOP medications decreased from 3.5 at baseline to 1.7 at month 12 (51.4%). Common adverse events included hypotony (24.6%) and IOP elevations of 10 mm Hg or more (21.5%). Postoperatively, 32.3% of eyes required needling, and 12.2% of eyes failed and required secondary glaucoma procedures.



**Figure 2.** Mean observed intraocular pressure change from baseline over time with the XEN Gel Stent procedure

\* Mean diurnal intraocular pressure

† Shown in parentheses are the mean percentage changes from baseline

Abbreviation: IOP, intraocular pressure.

Reprinted from *American Journal of 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.

### References

1. Batlle JF, Fantes F, Riss I, et al. Three-year follow-up of a novel aqueous humor MicroShunt. *J Glaucoma*. 2016;25(2):e58-e65.
2. Grover DS, Flynn WJ, Bashford KP, et al. Performance and safety of a new ab interno gelatin stent in refractory glaucoma at 12 months. *Am J Ophthalmol*. 2017;183:25-36.

### Subconjunctival MIGS Procedures: Patient Selection

**Dr Ahmed:** The development of MIGS procedures that rely on subconjunctival aqueous filtration is a significant development in glaucoma surgery. In my opinion and in the absence of head-to-head studies comparing these procedures, we can now attain low target IOP, albeit with a slightly higher risk of complications than that of other MIGS procedures. Who are the ideal patients to consider for these procedures?

**Dr Panarelli:** I participated in the pivotal trial comparing MicroShunt with trabeculectomy, the results of which are not yet available.<sup>18</sup> In my experience with this device, I feel it has broad application across the spectrum of glaucoma disease severity. I see value using it in patients with early disease on multiple medications to help lower IOP and relieve the medication burden and also in patients with advanced disease who are uncontrolled on medical therapy and require low target IOP. I also have experience with XEN gel stent. In considering these 2 subconjunctival procedures, I am inclined to use XEN gel stent more often in patients with earlier disease on multiple medicines, in which my goal is primarily medication reduction; I tend to use MicroShunt in patients with more advanced disease, in which my goal is to achieve lower target IOP. I base this determination on the longer tube length and larger diameter of MicroShunt compared with XEN gel stent, which could theoretically deliver lower IOP, although we have no clinical head-to-head data yet.

**Dr Sng:** In my practice, I tend to use the trabecular bypass devices for milder glaucoma cases and reserve the subconjunctival devices for those with more advanced glaucoma. With more data on the safety profiles of the subconjunctival procedures, I might use them earlier in the disease course.

**Dr Ahmed:** In the various clinical trials, and with their availability in Canada, I have performed at least 500 of each of the subconjunctival filtering MIGS procedures. I am still refining my techniques, both for implantation and for MMC application required for bleb formation. Certainly, XEN gel stent is easier to implant because it does not require a conjunctival peritomy. For that extra effort, we are going to require better efficacy and/or safety. As Dr Panarelli noted, there are as yet no head-to-head data comparing MicroShunt with XEN gel stent. Also, we still do not have data comparing the subconjunctival MIGS procedures with trabeculectomy in head-to-head trials. Such data would help clarify the optimal use of these procedures for me.

**Dr Barton:** I think case selection is absolutely critical to success with XEN gel stent. When I first started using XEN 45 Gel Stent in 2015, by coincidence, it was in younger patients in their late 30s and 40s who had very high IOPs requiring urgent surgery at a time when I had no available operating theater space. XEN gel stent is capable of producing dramatic pressure lowering, so it offered a potential short-term solution that necessitated very little operating time. Surprisingly, in these younger patients, the long-term results seemed significantly better than those in the elderly who had lower IOPs but conjunctiva that had been exposed to long-term medication application.

### Subconjunctival MIGS Procedures: Surgical Techniques

**Dr Ahmed:** We should share our pearls for surgical techniques for these procedures. I implant XEN gel stents via the recommended ab interno technique, and I leave the conjunctiva untouched, other than to inject MMC subconjunctivally. I strive to get the distal tube tip into the subconjunctival space. With MicroShunt, the tube is placed into the anterior chamber via a needle track. It is important that the entry into the anterior chamber be posterior to—and angled away from—the cornea. I carefully open both the conjunctiva and Tenon capsule, place the device under Tenon, and close each layer separately. Because I have to open the conjunctiva, I apply MMC by sponge to optimize the exposure. I typically use 0.4 mg/mL and titrate the time on the basis of risk factors.

**Dr Panarelli:** I have modified the XEN gel stent technique considerably from the methods used in the pivotal trial. Preoperatively, I inject 40 to 80  $\mu$ g of MMC 0.4 mg/mL subconjunctivally. Intraoperatively, I insert the device ab interno, but place the distal tube tip into the sub-Tenon space, and I open the conjunctiva to be certain the tip is sub-Tenon. For MicroShunt, the key for me is to properly fashion the needle track through which the tube will be inserted into the eye. The tube is 8.5 mm in length, so the needle track will be quite long. You must start your tunnel more posteriorly and keep the blade flat to ensure that the length of tube in the anterior chamber is not too long and is not directed anteriorly.

**Dr Sng:** I agree that opening the conjunctiva for XEN gel stent can create a more predictable posterior bleb. I do not do this for everyone—usually not in my patients with early glaucoma. If I need a low target IOP, however, as is often the case with advanced glaucoma, I will consider a peritomy to ensure proper placement of the distal tube tip. In some of my Asian patients, the Tenon capsule is very thick, and it might be easier to implant XEN gel stent with conjunctival peritomy. In my experience, the distal lumen of XEN gel stent is less likely to be obstructed with Tenon tissue if conjunctival peritomy is performed; hence, the rate of postoperative needling is reduced.

**Dr Barton:** Although the ideal position for XEN gel stent would arguably be in the sub-Tenon potential space, this is almost impossible to achieve reliably with an ab interno implantation. The only logical alternative, in order to avoid obstruction, is to have XEN gel stent as superficial as possible. I therefore agree with Dr Ahmed's tip about subconjunctival placement. I am concerned about XEN gel stent bleb morphology. For this reason, I limit the amount of MMC to 0.1 mL of 0.2 mg/mL. It is essential to inject as far from the limbus as possible.

### Subconjunctival MIGS Procedures: Postoperative Management

**Dr Ahmed:** A common adverse event with both of the subconjunctival MIGS procedures is failure, which is typically related to distal tube obstruction with Tenon tissue. This can often be corrected by needling the bleb. When do you consider needling after these procedures?

**Dr Sng:** It is very important to monitor the bleb morphology. I do anterior segment optical coherence tomography (OCT) on all postoperative blebs. If I see a reduction in bleb height in association with an increase in IOP, I consider needling at that point. The IOP does not have to be above target—just higher than before.

**Dr Panarelli:** I agree that when IOP begins to rise postoperatively, that is the time to consider needling. I like to be able to see the tip of the shunt before I decide how to needle the bleb. If the distal tip is visible, I will needle aggressively in the operating room. If the tip is not visible, I will often perform an open revision to remove as much fibrotic tissue surrounding the implant as possible. Antifibrotic agents are usually needed when using either technique.

**Dr Sng:** In my practice, the use of antimetabolite depends on the vascularity of the bleb. If I see a very injected bleb, I am more likely to use MMC. Avascular blebs have occurred after some XEN gel stent procedures, but the tube tip is curled up in Tenon. In these cases, I typically needle without MMC. I also tend to needle only if I see the distal tube tip, which is one reason I place it in the subconjunctival space, because Asians have thick Tenon layers.

**Dr Ahmed:** What is your needling technique?

**Dr Panarelli:** I inject MMC, often at a lower dose (20  $\mu$ g) than that used during the primary surgery, 10 mm posterior to the limbus. Using a bent microvitrectomy blade, I enter the subconjunctival space far from the bleb and advance the tip until it is close to the distal end of the device. I sweep above and below the device tip until I see that flow is reestablished. These MIGS blebs often behave differently from trabeculectomy blebs: they do not always expand suddenly upon the reestablishment of flow; rather, they will appear low lying and might not be very impressive on the table. I perform most of my needling procedures in the operating room, where I have more control.

**Dr Sng:** Patient costs also dictate in which setting we needle. In Asia, patients pay out of pocket when they return to the operating room. I perform my needling mostly in the clinic because then the patients do not have to pay for it, and they are much happier.

**Dr Ahmed:** What are your needling rates for these procedures?

**Dr Sng:** For XEN gel stent, approximately 30%; for MicroShunt, I estimate 10% to 20%.

**Dr Panarelli:** By placing XEN gel stent under Tenon and using higher concentrations of MMC (up to 80  $\mu\text{g}$ ), I have not had to needle with many of these devices at all. For MicroShunt, I have found needling is necessary approximately 30% of the time using the protocol in the phase 3 trials. Patient selection is also key. My rate of needling has gone down because I have been more selective in whom I place these devices.

**Dr Ahmed:** Our MicroShunt needling rate is approximately 10% to 15%, and it tends to be higher in combined cataract cases than in stand-alone cases. Our XEN gel stent needling rates have dropped from approximately 40% to less than 20% as we have gained experience and modified our implantation technique.

**Dr Barton:** I do not tend to needle with XEN gel stent or MicroShunt, except when there is clearly an encapsulated bleb. I find needling too imprecise and that it offers very little diagnostic information in terms of the reason for failure to control the pressure. I prefer to open the conjunctiva at the limbus, mobilize the conjunctiva, apply MMC on sponges, irrigate, and then explore XEN gel stent or MicroShunt with direct visualization. This approach offers several advantages. First, I can ensure that XEN gel stent/MicroShunt is completely free. Second, I can directly visualize flow (or lack thereof). Third, if a clearly patent XEN gel stent or MicroShunt is not draining, I can flush it to reestablish flow and even replace it, if necessary. This approach offers a more definitive solution than needling.

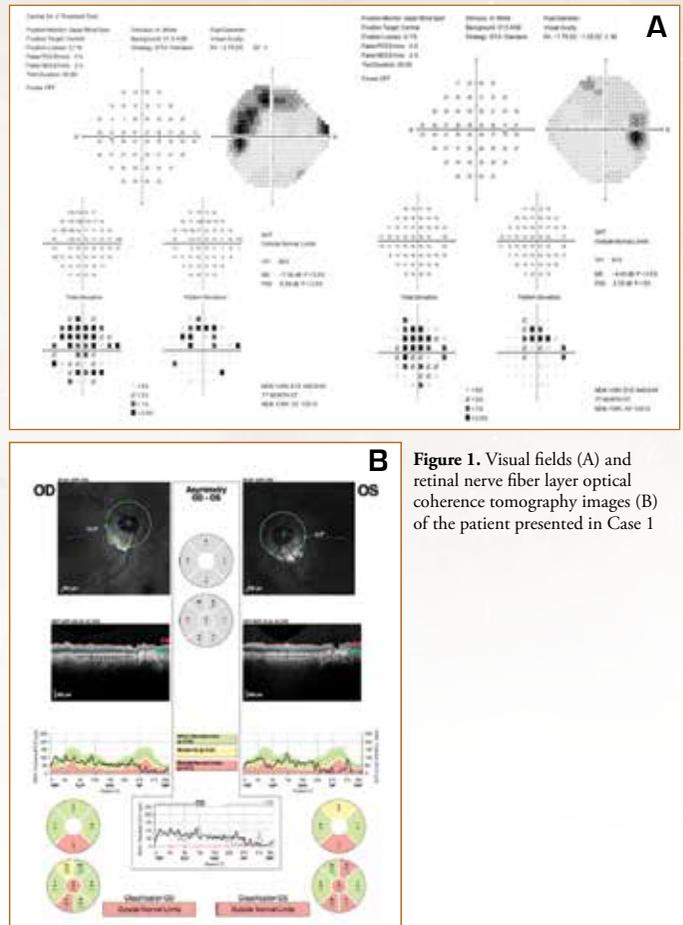
### Case 1. Cataract and Medically Uncontrolled Glaucoma From the Files of Joseph F. Panarelli, MD

**Dr Panarelli:** A 71-year-old blue-eyed female with visually significant cataract and medically uncontrolled open-angle glaucoma was referred to me for surgical evaluation. She was using 5 medications to control her IOP in the left eye (a prostaglandin, beta blocker, a fixed combination of carbonic anhydrase inhibitor and alpha-adrenergic agonist, and a miotic) and 4 (all but the miotic) in the right eye, had previously undergone selective laser trabeculoplasty in both eyes, and was adamantly opposed to trabeculectomy or tube-shunt surgery because of risks she had read about on various Web sites. On examination, her best-corrected visual acuity (BCVA) was 20/40 OU, with a high myopic correction (-6D OD and -7D OS), and IOP was 23 mm Hg OD and 26 mm Hg OS. She had 2 to 3+ nuclear sclerotic cataracts, with exfoliation material evident on both lenses. Her angles were wide open. Her cup-to-disc ratio was 0.8, with inferior thinning in both eyes. **Figure 1** shows her visual fields and retinal nerve fiber layer OCT images.

**Dr Ahmed:** At a minimum, this patient needs cataract surgery. Does she also need a glaucoma procedure? If so, which one?

**Dr Sng:** Given that she has inadequately controlled IOP on 5 medications, this patient requires a highly effective procedure. Trabecular bypass and supraciliary procedures are unlikely to be adequately effective in this case. Subconjunctival filtration will be best for her. If she has staunchly ruled out trabeculectomy or tube-shunt surgery because of perceived risks, we are left with a subconjunctival MIGS procedure. In fact, given that she is a high myope and has light-colored irises, she might be at increased risk for hypotony after a combined phacoemulsification/trabeculectomy procedure, so her instincts are good.

**Dr Ahmed:** I assume her eyes were quiet and noninflamed. Often, in eyes receiving 4 or 5 medications, there is chronic ocular surface disease, which can compromise the efficacy of subconjunctival procedures.<sup>21,22</sup>



**Figure 1.** Visual fields (A) and retinal nerve fiber layer optical coherence tomography images (B) of the patient presented in Case 1

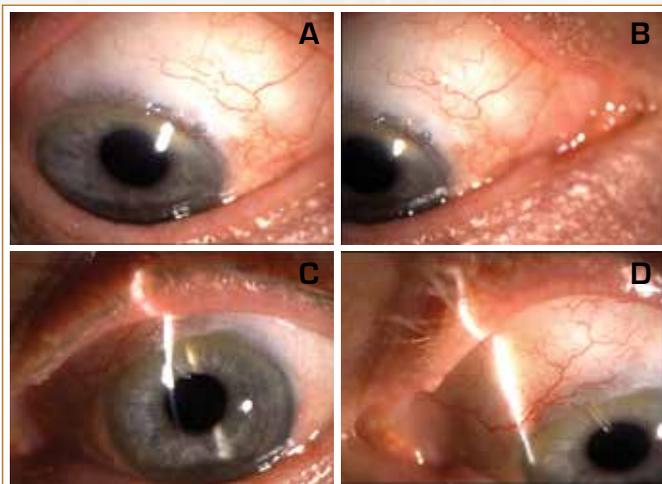
**Dr Panarelli:** In her case, there was minimal ocular surface disease, but your point is well made. I have occasionally switched patients to preservative-free medications or even temporized with oral carbonic anhydrase inhibitors and discontinued topical therapy to quiet the inflammation before surgery. This patient is highly motivated to reduce her medication burden and also wants rapid visual recovery.

**Dr Ahmed:** As a class, the MIGS procedures tend to offer rapid visual recovery, which is important when pairing them with cataract surgery. In some cases, however, in which rapid visual recovery is the most important consideration—say, in a monocular patient—there is an argument to be made for staging the procedures—cataract surgery first, followed by glaucoma surgery. This has the advantage of assessing the IOP-lowering effect we know we can get from cataract surgery alone,<sup>23</sup> which can further inform our selection of glaucoma surgeries. Also, the outcome of the glaucoma procedure might be better if it is not complicated by the added inflammation associated with simultaneous cataract surgery.

**Dr Barton:** I tend to separate cataract and glaucoma surgery. I will add, however, that the safety and efficacy profiles of the MIGS procedures have somewhat lowered my threshold for performing combined surgery. I tend to perform the glaucoma procedure first, followed approximately 6 months later by cataract surgery. I would do that in this case because the glaucoma is driving the need for surgery more than is her loss of vision.

**Dr Panarelli:** Together, the patient and I elected to perform a combined phacoemulsification and subconjunctival MIGS procedure in the left eye

as the first procedure. Because the left eye had the higher IOP and was on 5 medications, I felt she would benefit more from MicroShunt than from XEN gel stent. Because MicroShunt is not available in the United States, I referred her to Dr Ahmed, in Canada, for the procedure. Two months later, I performed a combined phacoemulsification and XEN gel stent procedure in her right eye, which had lower IOP and was on slightly fewer medications. Eight to ten months postoperatively, her uncorrected distance visual acuity was 20/20 OU, and IOP was 8 mm Hg OD and 9 mm Hg OS on no topical IOP-lowering medications. **Figure 2** shows her blebs.

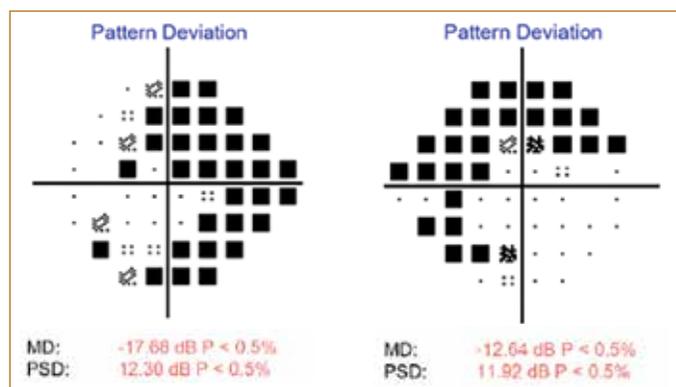


**Figure 2.** Right (A and B) and left (C and D) eyes of the patient presented in Case 1, showing the blebs at low (A and C) and high (B and D) magnification 8 to 10 months postoperatively. The right eye received XEN gel stent; the left eye received MicroShunt.

**Dr Ahmed:** This patient achieved perfect visual outcomes, is now free of glasses, and has perfectly controlled IOP on no medications. She should be very happy.

### Case 2. Advanced Glaucoma in a Young Patient From the Files of Chelvin C. A. Sng, MD

**Dr Sng:** A 47-year-old Chinese male with bilateral open-angle glaucoma presented with uncontrolled IOP in 1 eye. His BCVA was 20/20 OU, with a myopic (-6D) correction OU. He was phakic, with clear lenses. Intraocular pressure was 14 mm Hg OD and 23 mm Hg OS on the once-daily latanoprost/timolol fixed combination OU. His ocular surface was quiet, without inflammation. His glaucoma was quite advanced. **Figure 3** shows his visual fields.



**Figure 3.** Visual fields of the patient presented in Case 2. Abbreviations: MD, mean defect; PSD, pattern standard deviation.

**Dr Ahmed:** This is a young, highly myopic man with advanced glaucoma who is inadequately controlled on 2 medications in 1 bottle dosed once daily. Treatment options in this case include adding yet another medication, performing selective laser trabeculoplasty, or perhaps performing a MIGS procedure. What do you think about these options?

**Dr Barton:** Being a high myope, this patient might be at increased risk of hypotony after traditional glaucoma surgery. Also, being phakic, he might be at risk of developing cataracts postoperatively as well.

**Dr Sng:** I weighed his risks and benefits. He is young, with advanced disease and high IOP. We could add medications, but then run the risk of producing ocular surface toxicity that might reduce the success of subsequent surgery. Selective laser trabeculoplasty is reasonable, but unlikely to lower his IOP from the mid-20s to the low teens and its benefit does not last forever. He has a high risk of eventual vision loss and blindness in his lifetime. For this reason, I chose a surgical approach. Because I wanted a very low target IOP—in the low teens—I selected a subconjunctival MIGS procedure—MicroShunt.

**Dr Ahmed:** Did you use MMC? If so, how much?

**Dr Sng:** I routinely use 0.4 mg/mL—applied by sponge—and did so in this case. I tend to place sponges very close to the limbus and also very far posteriorly to maximize bleb distribution. Specifically, for MicroShunt, posterior placement has been shown to increase efficacy in terms of both IOP reduction and IOP medication reduction.<sup>24</sup>

**Dr Panarelli:** When I perform these procedures, I try to get at least 1 sponge placed in the area where the tube tip will lie.

**Dr Ahmed:** What is your typical postoperative anti-inflammatory regimen?

**Dr Sng:** In Asian patients—who tend to scar more aggressively—I tend to use at least 6 months of steroids. I begin prednisolone every 3 hours on the first week and then 4 times a day through the first few months before I begin tapering to finish by month 6. I also evaluate the bleb by anterior segment OCT throughout this period (see **Figure 4**). I tend to get diffuse, posterior blebs. In this patient's case, the postoperative IOP was between 4 and 10 mm Hg throughout the first 6 months.



**Figure 4.** Postoperative intraocular pressure (IOP) (A), anterior segment optical coherence tomography images (B), and bleb morphology (C) of the patient presented in Case 2

**Dr Ahmed:** An IOP of 4 mm Hg on the first postoperative day can be of concern following trabeculectomy. Those are the types of eyes I see every day, and I often start cycloplegics on day 1. How does your postoperative approach to early low IOP differ when it occurs after subconjunctival MIGS?

**Dr Sng:** I tend not to intervene because early low IOP resolves on its own. In addition, this patient did not develop any complications

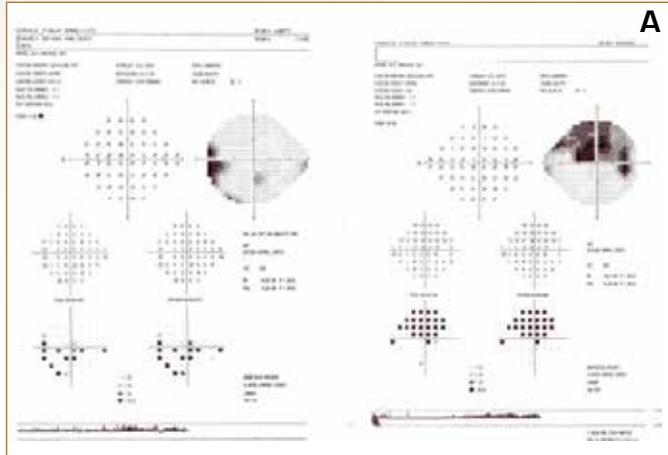
from the hypotony and had a deep anterior chamber with good vision. Hence, this was just numerical hypotony and not symptomatic hypotony. So far, I have not had to go back to the operating room to address a case of persistent hypotony after either XEN gel stent or MicroShunt surgery.

**Dr Panarelli:** That has also been my experience. Short-term low IOP resolves without any interventions. Even when the IOP remains low, the eyes seem to tolerate it quite well.

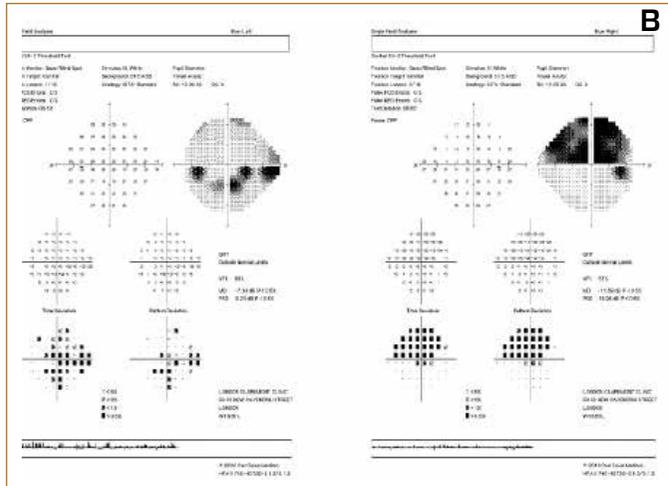
**Case 3. Glaucoma Progression at Low Intraocular Pressure**  
*From the Files of Keith Barton, MD, FRCS, FRCS*

**Dr Barton:** A 57-year-old white male presented with a 5-year history of POAG in both eyes. His past ocular history is also notable for myopic LASIK (laser assisted in situ keratomileusis) in both eyes 8 years previously. His BCVA was 20/20 OU, and IOP was 16 mm Hg OD and 13 mm Hg OS using a twice-daily preservative-free dorzolamide/timolol fixed combination OU. His central corneal thickness (post-LASIK) was 464  $\mu$ m OD and 454  $\mu$ m OS. I felt that his IOP was reasonably well controlled in both eyes and continued his current regimen. Over the next 4 years, his visual fields (see **Figure 5**) progressed in both eyes, whereas IOP remained consistently in the mid-teens, albeit after now receiving 4 medications.

2014



2018



**Figure 5.** Visual fields from 5 years ago (A) and 2018 (B) for the patient presented in Case 3

**Dr Ahmed:** This patient is clearly progressing on 4 medications and so requires surgery. Although it appears that he is progressing at a fairly low IOP, the fact that he had LASIK and has very thin corneas suggests that his true IOP is likely higher than what is being measured with applanation tonometry. This also means that his target IOP will have to be comparably adjusted. What was your approach?

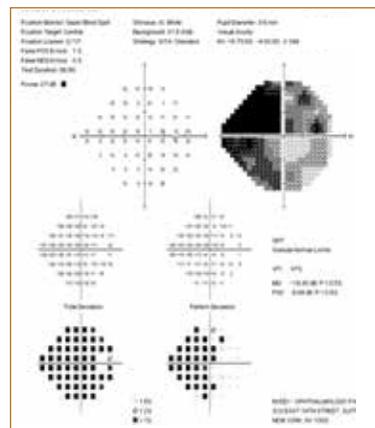
**Dr Barton:** I suggested that he would benefit best from trabeculectomy, but I also offered subconjunctival MIGS as an alternative. After careful consideration, and on the basis of the relative safety profiles, he opted for MicroShunt, with the full understanding that he might not achieve optimal IOP with this choice.

**Dr Ahmed:** Was the procedure successful?

**Dr Barton:** Fortunately, for him, it was. I implanted MicroShunt in each eye, augmented with MMC 0.4 mg/mL applied by LASIK shield sponge for 2 minutes OD and 3 minutes OS. I recently saw him for the 1-month postoperative visit after operating on both eyes. His IOP was 10 mm Hg OD and 11 mm Hg OS on no medications. Ultimately, he appeared to have made the right choice. One could argue, in view of the thin corneas, that these levels might not be low enough, but he still has the option to add a medication.

**Case 4. Uncontrolled Glaucoma in a Monocular Patient With a Prior Suprachoroidal Hemorrhage**  
*From the Files of Joseph F. Panarelli, MD*

**Dr Panarelli:** A 78-year-old white female was referred for surgical evaluation in her right eye, which previously underwent cataract extraction with endocyclophotocoagulation 5 years ago. She has advanced and poorly controlled glaucoma (IOP in the range of 28-34 mm Hg) in the right eye despite receiving 5 medications (a prostaglandin, the timolol/brimonidine fixed combination, a miotic, and oral acetazolamide). Her left eye was lost to an expulsive suprachoroidal hemorrhage during a tube-shunt implantation 8 years ago (which followed a failed trabeculectomy 5 years prior). On examination, her BCVA was 20/40 OD, central corneal thickness was 548  $\mu$ m, the angle was open, the posterior chamber intraocular lens was well positioned, and her IOP was 30 mm Hg. **Figure 6** shows her visual field.



**Figure 6.** Visual field of the right eye of the patient presented in Case 4

**Dr Ahmed:** This is a monocular woman with advanced and uncontrolled glaucoma who is understandably reluctant to have any further surgery. She needs a procedure that is both effective and safe, but safety might be the more important issue in this case. What are your thoughts?

**Dr Barton:** A subconjunctival MIGS procedure offers the best balance of efficacy and safety in this case. I might even leave a little viscoelastic in the anterior chamber at the end of the procedure. I would much rather deal with a transient postoperative IOP spike than risk hypotony and a repeat of the disaster that affected the fellow eye.

**Dr Sng:** Also, given that she is monocular, rapid visual recovery will be important.

**Dr Panarelli:** Those were my thoughts exactly. I performed XEN gel stent implantation using my preferred open-conjunctiva technique, with 40 µg of MMC injected subconjunctivally preoperatively, and I closed Tenon and the conjunctiva in separate layers. On the first postoperative day, her visual acuity was 20/80, her IOP was 6 mm Hg, and her anterior chamber was well formed. On day 3, however, she began to develop choroidal effusions and her visual acuity dropped to counting fingers, but her IOP remained 6 mm Hg. This is not uncommon when we drop the IOP so acutely, but, as mentioned earlier, the eye remained stable at this low IOP. I elected to inject a cohesive viscoelastic to bring up her IOP slightly. After several days, the effusions began to resolve. Her visual acuity improved to 20/50, and her IOP was 9 mm Hg by 3 weeks postoperatively.

### Summary and Take-Home Points

**Dr Barton:** In my experience, subconjunctival MIGS procedures offer superior efficacy to many of the MIGS procedures that target the trabecular meshwork, Schlemm canal, or supraciliary space.

**Dr Sng:** With the increased safety and predictability of the subconjunctival MIGS procedures, we are more confident in offering these procedures to patients with severe glaucoma and to those with earlier stages of the disease if attaining low target IOP is necessary.

**Dr Ahmed:** These procedures alter our current assessment of the risk-benefit ratio in the context of glaucoma surgery. Given that many of our patients will require multiple glaucoma procedures over their lifetime, a less invasive procedure, with a safer profile and with fewer anatomical and structural and refractive changes compared with trabeculectomy, is a reasonable first procedure.

**Dr Sng:** In terms of surgical technique, it is crucial to ensure that the distal tube tip is not obstructed by Tenon tissue at the completion of the case.

**Dr Panarelli:** We are still learning the optimal techniques for implanting MIGS devices and managing their postoperative course. The blebs we produce now are excellent and can likely be improved with further modifications of surgical technique and antimetabolite use.

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## CME POST TEST QUESTIONS

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See detailed instructions under **To Obtain AMA PRA Category 1 Credit™** on page 2.

- Which of the following is NOT a typical characteristic of MIGS procedures?
  - Performed via a microincisional approach
  - Rapid visual recovery
  - Favorable safety profile compared with that of trabeculectomy
  - Consistently greater efficacy compared with that of trabeculectomy
- Which of the following is true regarding the efficacy of MIGS procedures?
  - Trabecular bypass procedures generally deliver efficacy comparable to that of trabeculectomy
  - Data from head-to-head studies comparing subconjunctival MIGS with trabeculectomy show comparable efficacy
  - There are no head-to-head trials comparing the relative efficacy of XEN gel stent and MicroShunt subconjunctival MIGS procedures
  - MIGS procedures typically reduce the IOP-lowering medication burden, but do not generally lower IOP
- A 65-year-old female has advanced glaucoma and IOP of 28 mm Hg despite using 4 medications. Her target IOP is 14 mm Hg. Which of the following procedures is LEAST likely to attain her target IOP?
  - Trabecular bypass MIGS
  - Subconjunctival XEN gel stent MIGS
  - Subconjunctival MicroShunt MIGS
  - Trabeculectomy
- A 77-year-old male lost his right eye to trauma as a child and now has moderate open-angle glaucoma in the left eye. His IOP is 24 mm Hg on 3 medications, and his target IOP is 16 mm Hg. He lives alone. Which of the following details of this case favor the use of a MIGS procedure over trabeculectomy?
  - His need for rapid visual recovery for self-care
  - His need for a safe procedure given his monocular status
  - His modest target IOP in the mid-teens
  - All the above
- For which glaucoma procedures is MMC augmentation routinely necessary?
  - Trabecular bypass MIGS and supraciliary MIGS
  - Supraciliary MIGS and trabeculectomy
  - Subconjunctival MIGS and trabeculectomy
  - Trabecular bypass MIGS and trabeculectomy
- Needling is sometimes necessary after subconjunctival MIGS because of:
  - Obstruction of the proximal tube tip in the anterior chamber
  - Subconjunctival hemorrhage blocking the distal tube tip
  - Tenon tissue blocking the distal tube tip
  - Positioning of the proximal tube tip too close to the corneal endothelial surface
- Which of the following is true regarding MIGS procedures as a group?
  - All are performed via an ab interno approach
  - All facilitate flow across the trabecular meshwork into Schlemm canal
  - Mitomycin C use is essential for all MIGS procedures
  - All offer a surgical alternative to trabeculectomy in patients with early glaucoma
- Following subconjunctival MIGS, needling of the bleb should be considered if:
  - The anterior chamber becomes shallow
  - The bleb becomes cystic and avascular
  - IOP begins to rise
  - Blebitis develops
- For a risk-averse patient with inadequately controlled IOP on 4 or 5 medications who has moderate cataract-related vision loss, which procedure is most likely to achieve IOP control?
  - Cataract surgery alone
  - Trabecular bypass MIGS
  - Supraciliary MIGS
  - Subconjunctival MIGS
- Which is the most relevant consideration when selecting a treatment approach for a patient with progressive glaucoma despite low IOP?
  - History of corneal refractive surgery, such as LASIK
  - Refractive status
  - Presence of cataract
  - Presence of ocular surface disease