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MIGS
WHEN MAXIMUM MEDICAL THERAPY IS NOT ENOUGH

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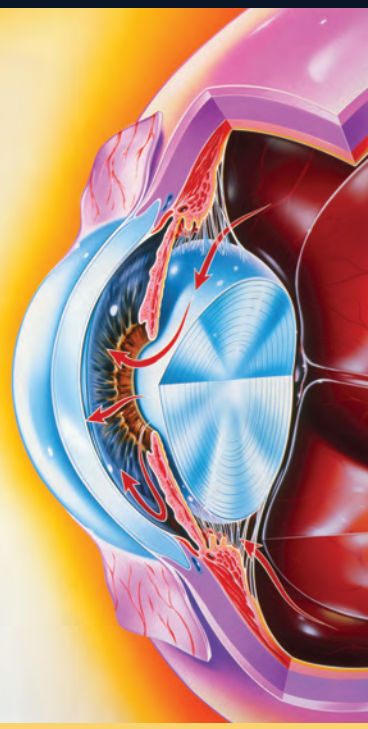

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New York Eye and Ear Infirmary of Mount Sinai

MedEdicus

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ACTIVITY DESCRIPTION

New surgical techniques have expanded treatment options for patients with moderate-to-advanced glaucoma. Minimally invasive glaucoma surgery (MIGS) procedures offer novel shunting techniques to increase aqueous outflow. However, with few head-to-head studies of these new procedures, their relative strengths and weaknesses remain to be determined. This monograph reviews the various MIGS procedures and their optimal use in individual patients with glaucoma.

TARGET AUDIENCE

This educational activity is intended for US ophthalmologists, including glaucoma specialists.

LEARNING OBJECTIVES

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

- Compare the characteristics and efficacy and safety data of current and emerging MIGS procedures
- Apply evidence on MIGS procedures for individual patients with primary open-angle glaucoma
- Appraise the role of antimetabolites for bleb-based MIGS

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INTRODUCTION

Innovation in glaucoma therapy is changing the therapeutic landscape. New drugs with novel mechanisms of action offer new treatment choices early in the glaucoma disease spectrum, and new surgical techniques provide expanded options for patients with moderate or advanced glaucoma. The minimally invasive glaucoma surgeries—collectively known as MIGS—seek to optimize the balance of efficacy and safety that has characterized more traditional glaucoma surgical procedures, such as trabeculectomy and tube-shunt implants. These new devices use a variety of novel shunting techniques to increase aqueous outflow through the trabecular and uveoscleral outflow pathways. There are many benefits to surgeons and patients alike as the options expand, but there are challenges as well. With few head-to-head studies of the new MIGS procedures, the relative strengths and weaknesses of these techniques have not been fully characterized, thereby limiting optimal patient selection for each procedure. In this educational activity, a panel of experts will share their experiences with and insights regarding novel glaucoma surgical techniques. The goal of this activity is to clarify the optimal use of MIGS procedures for individual patients with primary open-angle glaucoma.

This monograph is derived from a roundtable discussion. You can listen to select discussion points at https://tinyurl.com/MIGSdiscussion

1. Dr Weinreb and Dr Myers discuss maximal medical therapy
2. Dr Weinreb and Dr Sheybani discuss adding a glaucoma procedure to a planned cataract surgery
3. Dr Weinreb summarizes his approach to glaucoma surgery in eyes undergoing elective cataract surgery
4. Dr Feldman, Dr Weinreb, Dr Sheybani, and Dr Myers discuss MMC use in trabeculectomy surgery
5. Dr Weinreb, Dr Sheybani, Dr Feldman, and Dr Myers discuss MMC use in drainage device surgery
6. Dr Myers describes his gel stent needling technique

MAXIMUM MEDICAL THERAPY

Dr Weinreb: Medical therapy for the reduction of intraocular pressure (IOP) in glaucoma is highly effective, particularly in the modern era of glaucoma pharmacology. There is, however, a subset of patients whose IOP cannot be adequately controlled using medications alone. For a given patient, when do we make the transition from medicines to surgery? Historically, we have defined the limit of medical therapy in terms of tolerability. With 5 classes of medications from which to draw, the point at which the patient can tolerate no further medical therapy is termed "maximal tolerated medical therapy." Granted, this term was coined in the era of pilocarpine and oral acetazolamide, and modern drugs are far more tolerable than these agents.

As drugs become safer and better tolerated, we are able to add more of them before reaching the limit of tolerability. What is the limit of medical therapy today?

Dr Feldman: My threshold for medical therapy is typically 3 drugs in 2 bottles **(Table 1)**. After this, the law of diminishing returns comes into play. The medicine that we reach for after the third drug is our fourth choice for a reason—it lacks either efficacy or tolerability compared with our more preferred drugs. The likelihood of such a drug providing adequate efficacy and tolerability to achieve IOP control is low. In some cases, patients do not even tolerate the third medication, in which case I usually move beyond medical therapy rather than tinker with the regimen to find an alternative third-line drug.

Dr Weinreb: Do you add each drug 1 at a time, or are you using fixed combinations as first adjuncts?

Dr Feldman: If we are within 2 to 4 mm Hg of target IOP with prostaglandin monotherapy, I usually add a single agent as my first adjunct because studies have indicated that this is the additive effect we should expect.[1-3] If we are 5 to 6 mm Hg from target, I typically add a fixed combination as first adjunct because the single agents do not typically provide this level of additional IOP reduction when added to a prostaglandin.[1-3] The fewer bottles and drops per day we prescribe, the easier the regimen becomes for the patient to adhere to.

Dr Myers: It can be hard enough to administer 2 or 3 eye drops every day faithfully, but it becomes an even more difficult task when there are 5, 10, or 15 other medications that the patient is self-dosing multiple times a day. I try not to advance beyond 2 bottles because I am concerned about the burden that a regimen of more than 2 bottles poses in terms of cost, side effects, inconvenience, and adherence **(Table 1).**

Table 1. Thresholds for Maximum Medical Therapy

Dr Weinreb	No more than 3 drugs, depending on the patient
Dr Feldman	3 drugs in 2 bottles
Dr Myers	2 bottles; the number of drugs depends on the patient
Dr Sheybani	3 bottles

Dr Weinreb: Do 2 bottles mean 2 drugs, 3, or more?

Dr Myers: The number of drugs varies depending on the patient. For some patients, at least 1 bottle might be a fixed combination. For other patients, because of cost or side effects, only 2 drugs might be involved. If more advanced treatment is necessary, I think we have better options now that allow us to move into a nonmedical realm, with a lower risk than before.

Dr Sheybani: The adherence issue is important. I often think of maximal tolerated medical therapy as maximum tolerated *and taken* medical therapy to remind me that multidrug regimens are susceptible to poor adherence patterns.

Dr Weinreb: For a patient whose IOP is inadequately controlled on 2 or 3 medications in 2 bottles, what is your next step?

Dr Myers: I often consider selective laser trabeculoplasty (SLT) in that setting.

Dr Sheybani: SLT is a fantastic choice in this setting. I do not often get to diagnose glaucoma and initiate treatment in my referral practice, but when I do, I consistently offer SLT as a primary therapy in lieu of medications. For those who are not adequately controlled on a single agent, I typically offer SLT as my first adjunct. Now that we have safer surgical options, we might consider them sooner, depending on a patient's IOP and lifestyle goals as well as on the presence or absence of a visually significant cataract.

Dr Weinreb: How much additional IOP reduction do we expect with a third or fourth medication?

Dr Feldman: One study found that adding a third or fourth medication lowered IOP by 20% or more for at least a year in approximately 50% of patients.[4] However, that study was conducted under obsolete treatment patterns; the most commonly added third or fourth medication was a prostaglandin. In a prostaglandin-first setting, it would likely be unusual to get a further 20% IOP reduction when adding a third or fourth medication to a regimen of a prostaglandin and your favorite second-line drug. The third or fourth drug also brings with it incrementally more excipient ingredients, such as preservatives. The risk of developing ocular surface disease and the severity of ocular surface disease symptoms increase with the number of glaucoma drops used per day.[5-7]

Dr Weinreb: The diversity of our opinions on this topic reflects the need to individualize our approach to each patient. In patients who have very early disease, we have the luxury of trying different medical therapies in hopes of finding a safe regimen that works. In patients with moderate-to-advanced disease, we do not always have the luxury of time to try different drug combinations and observe for progression over time, so we consider advancing these patients to some other form of treatment, such as SLT or another surgical intervention.

BEYOND MEDICATIONS: WHEN TO TAKE THE NEXT STEP

Dr Weinreb: What are the clinical events or scenarios that prompt us to move from nonsurgical interventions to surgical interventions for glaucoma?

Dr Feldman: A number of reasons cause us to advance from medicines to surgical intervention **(Table 2)**. Generally, they all come down to a risk-benefit analysis. The easiest scenario is the patient who is progressing at his or her current target IOP level; he or she has the highest risk for further progression. In this setting, the benefits of surgical IOP reduction typically outweigh the risks of surgical complications. Another straightforward scenario is the patient who is above his or her target IOP. The target IOP is our best estimate of the IOP below which we do not expect progression. The corollary is that we do expect progression when IOP is above the target IOP. Our tolerance of IOP above the target depends on both the magnitude of the IOP and the stage of glaucoma. If we are only 1 to 2 mm Hg above target, most of us would accept this and observe the patient for possible progression rather than assume the risks of surgery for minimal gains. The stage of glaucoma, however, matters as well. If the patient has only a small central island of vision left, we might not tolerate even a few points, whereas we might tolerate more than a few points if the patient has very early glaucoma and little, if any, visual field loss.

Dr Weinreb: For the 2 patients you described whose IOPs were inadequately controlled, the consequences of progression are very

different. One could lose central visual function, whereas the other could remain asymptomatic. Glaucoma and surgery for glaucoma pose risks of vision loss. If patients are progressing within the earliest stages of disease and are still asymptomatic, should we incur the risks of surgery? If patients are above target but not progressing, should we incur the risks of surgery? How do we decide when the risks are high enough to justify surgical intervention?

Dr Sheybani: We do not have a validated tool to provide an estimate of risk for individual patients with glaucoma, nor standards for what constitute the risk thresholds to intervene vs staying the course. To a large extent, we find ourselves within the realm of the art of medicine more than the science of medicine. We are fortunate, however, that the new MIGS procedures offer us safer ways to lower IOP surgically. When considering whether or not to operate, the safety of modern MIGS procedures can tip the scale in favor of operating.

Dr Weinreb: In some cases, medical therapy fails because of intolerance to topical therapy. In other cases, nonadherence contributes to the failure of medical therapy. These scenarios represent additional indications for glaucoma surgery. As the MIGS family of procedures continues to expand, the opportunity to add glaucoma surgery to cataract surgery represents an additional indication.

Table 2. Rationale for Advancing to Surgery

- Patient progressing at target intraocular pressure
- Patient above target intraocular pressure
- Maximum medical therapy
- Maximum tolerated medical therapy
- Nonadherence to medical therapy

THE ARRAY OF MIGS PROCEDURES

Dr Weinreb: The glaucoma surgical space has expanded significantly in recent years. The quest for a safer and easier procedure has given rise to a group of MIGS procedures **(Table 3)**,[8-18] which offer efficacy and safety profiles that are quite distinct from our traditional glaucoma surgeries, that is, trabeculectomy and tube-shunt implantation.

The MIGS procedures typically fall into 3 categories according to where the aqueous humor drains. There are procedures that bypass the trabecular meshwork and inner wall of Schlemm canal, sending aqueous into Schlemm canal and the distal outflow system. There are procedures that shunt aqueous into the supraciliary space, which lies beneath the ciliary body and is continuous with the suprachoroidal space. Once in the suprachoroidal space, aqueous humor exits the eye through the uveoscleral outflow system. Finally, there are procedures that shunt aqueous humor into the subconjunctival space, much like traditional trabeculectomy and tube-shunt procedures. Some MIGS procedures are performed through an ab interno approach, whereas others are performed via an ab externo approach. To date, not all have been approved by the US Food and Drug Administration, and some have been approved only for use in conjunction with cataract surgery.

INDIVIDUALIZING MIGS FOR PATIENTS

Glaucoma Surgery at the Time of Cataract Surgery

Dr Weinreb: What are the considerations for glaucoma surgery as an add-on to planned cataract surgery?

Dr Sheybani: Certainly, a planned cataract surgery provides an opportunity to surgically address coexisting glaucoma. For the

Table 3. Summary of MIGS Procedures

Site of Bypass (Type of Procedure)	Device	Maker	Approved in the United States	Stand-alone	Approach	Filtration
Trabecular meshwork/ Schlemm canal	Trabectome trabecular ablation[8]	NeoMedix Corporation	Yes	Yes	Internal	Internal
	iStent trabecular microbypass[8,9]	Glaukos Corporation	Yes	Yes (Europe) No (United States)	Internal	Internal
	Hydrus trabecular bypass microstent[8]	Ivantis Inc	No*	Yes	Internal	Internal
	Kahook Dual Blade goniotomy[10]	New World Medical, Inc	Yes	Yes	Internal	Internal
	iTrack microcatheter[11] (for GATT[8] and ABiC[12])	Ellex	Yes	Yes	Internal	Internal
	Trab360/VISCO360/ Omni viscosurgical systems[13]	Sight Sciences	Yes	Yes	Internal	Internal
Suprachoroidal space	CyPass supraciliary microstent[8]	Alcon	Yes	No	Internal	Internal
	iStent Supra microdevice[14,15]	Glaukos Corporation	No*	Yes	Internal	Internal
	Gold shunt[12]	SOLX, Inc	No*	Yes	External	Internal
Subconjunctival space	EX-PRESS miniature glaucoma shunt[16]	Alcon	Yes	Yes	External	External
	XEN Gel Stent[17]	Allergan	Yes	Yes	Internal	External
	MicroShunt glaucoma drainage implant[18]	Santen Pharmaceutical Co, Ltd	No*	Yes	External	External

Note: All these MIGS procedures can be combined with cataract surgery, and some are also approved for stand-alone use.
Abbreviations: ABiC, ab interno canaloplasty; GATT, gonioscopy-assisted transluminal trabeculotomy; MIGS, minimally invasive glaucoma surgery.
* Available outside of the United States

patient whose IOP is above target or whose visual field or optic nerve examination is equivocal for progression, adding a glaucoma procedure makes sense to reduce progression risk. Likewise, for the patient with medication intolerance or adherence issues, a glaucoma add-on procedure can address these issues. More recently, glaucoma surgery had been paired with cataract surgery as a means to reduce the glaucoma medication burden. In this setting, safety is of utmost importance, and we typically use the MIGS procedures here rather than trabeculectomy or tube-shunt surgery.[8] Clinical studies have shown that the MIGS procedures do not typically eliminate the need for medications, but they can reduce the number of medications needed to maintain IOP control.[18-22] Doing so can have a meaningful effect on quality of life for patients with glaucoma, and preservation of quality of life is the ultimate goal of glaucoma therapy.[23,24]

Dr Weinreb: Is there agreement that a desire to reduce medication burden at the time of cataract surgery is an indication for adding a glaucoma procedure?

Dr Myers: The opportunity should be considered, but this is not always necessary. Some patients are well managed on a single drop per day and tolerate treatment well. I am not convinced that an operation is warranted in this case. Also, we should not overlook the IOP-lowering efficacy of cataract surgery alone. This has been shown in numerous studies, and a recent meta-analysis of the best of these studies demonstrated mean IOP was reduced by 12%, 14%, 15%, and 9% at 6, 12, 24, and 36 months, respectively, after phacoemulsification, and the mean number of IOP-lowering medications was reduced by 0.57, 0.47, 0.38, and 0.16 medications, respectively, per patient at the same time points.[25]

Dr Feldman: One additional indication for glaucoma surgery at the time of cataract surgery is for the patient with advanced glaucoma in whom a postoperative IOP spike could snuff out his or her remaining central vision.

Dr Weinreb: There are many approaches to the patient with glaucoma who is undergoing cataract surgery. Once again, it comes down to individualizing patient care. I take the long view that glaucoma is a chronic disease, and I like to keep options in reserve should I need them later. To this end, I often do cataract surgery alone for my patients with glaucoma who are stable on 1 or 2 medications. For higher-risk patients or for those with medication tolerance or adherence issues, a combined approach makes sense as well. I also want to point out that most of the data we rely on for management planning are very short term, a year or less, whereas many of our patients live with glaucoma for 20 years or more. Long-term data showing the optimal order of interventions in a lifelong care process would be of great value.

Selecting a Procedure to Combine With Cataract Surgery

Dr Sheybani: When considering a glaucoma add-on procedure at the time of cataract surgery, I base my choice of procedures, in part, on the stage of glaucoma. In patients with early disease—with visual field defects in the mild-to-moderate range—I tend to use trabecular meshwork–based procedures. These can be either stripping procedures, such as trabecular ablation or goniotomy, or stenting procedures, as with the implantable trabecular bypass device. These are safe procedures with moderate efficacy that typically meet the modest IOP-lowering needs of patients with early or moderate disease.[8-12] For instance, the trabecular microbypass stent produced a ≥ 20% IOP reduction in 72% of eyes when paired with cataract surgery, whereas only 50% of eyes undergoing cataract surgery alone achieved this IOP reduction.[19] In addition, 85% of eyes receiving the combined surgery were medication free at 12 months, whereas 65% of eyes receiving cataract surgery alone were medication free at 12 months. The safety profile of the combined procedure was comparable to that of cataract surgery alone, although stent-specific complications, including malpositioning and obstruction, did rarely occur.

A supraciliary procedure can also be effective. The supraciliary microstent lowered IOP by a mean of 7.4 mm Hg at 24 months when combined with cataract surgery, and 85% of eyes were medication free at the 24-month mark; both IOP reduction and medication reduction were greater in eyes receiving the combined surgery than in eyes receiving cataract surgery alone.[20] Common complications include transient blurred vision and iritis. These studies are controlled, and some of them had washout periods. Therefore, when applying the results to clinical practice, one must be aware that patients might not have met study criteria, and results can vary. Following your own results is paramount.

For patients with more advanced glaucoma, there might be atrophic changes in the distal outflow channels that would compromise the efficacy of a trabecular meshwork–based procedure. For these patients, I tend to use a subconjunctival filtration option, such as the gel stent. The formation of a bleb comes with a less favorable safety profile but also delivers lower IOP levels, balancing the risk-benefit equation.[8,17]

Dr Feldman: I am very cautious when approaching cataract surgery. Patients have high expectations for visual outcomes after surgery, in part because everyone knows someone who had a great cataract surgery experience and also because I tell my patients that they should expect better vision after surgery. Anything we do in addition to cataract surgery has the potential to diminish visual outcomes, and in some cases, the combined problems cataract surgery can create are difficult to fix. For example, shunting aqueous humor into the supraciliary space could create ciliary effusions, which could lead to significant refractive changes. I have one such patient in my practice who is 6 months postoperative from a combined cataract and supraciliary microstent procedure who still has 3 diopters of myopic shift that I cannot easily remedy. These are considerations that must be balanced against the benefits of reducing the glaucoma medication burden. I discuss these issues with my patients and together we decide what makes the most sense for them on the basis of their goals and expectations.

Dr Myers: Unlike with medications, these MIGS devices have labels that constrain our use to specific stages of glaucoma if their use is to be reimbursed; there might not be coverage for every procedure. As we consider the various subclasses of MIGS based on the filtration location, we should also consider that there are significant differences even within these subclasses. For instance, patients on blood thinners might not be optimal candidates for trabecular meshwork–stripping procedures, in which blood reflux is common[21,26] and can be significant if clotting is impaired. In contrast, the trabecular bypass device has a low rate of early and late postoperative hyphema and might be quite safe in such a patient.[17] The rate of visual recovery likely differs between these procedures. When approaching a monocular patient, for example, the likelihood of clear vision on the first postoperative day is different with a trabecular bypass than with a more extensive procedure, such as a gonioscopy-assisted

transluminal trabeculotomy procedure. These procedures give us more options. In general, some of the MIGS procedures might not provide the success rates we expect from trabeculectomy and tube-shunt procedures,[8] but in many cases, I am willing to tolerate a greater risk of failure if there is a lower risk to the patient.

Dr Feldman: In my mind, adding glaucoma surgery to cataract surgery is done for 2 distinct reasons: (1) to lower IOP in someone who is progressing or is at high risk for progression; and (2) to reduce the medication burden in a stable, medically treated patient. These goals, however, have different risk thresholds. For the patient who is progressing and needs lower IOP, I will tolerate higher risk to get the disease under control because the cost of failure is disease progression. In these eyes, I can do a traditional procedure or I can do a MIGS procedure.

Of the MIGS devices, I am most likely to use the gel stent because the subconjunctival filtration approach is most likely, in my experience, to achieve the low target IOP that progressing patients need. For the stable patient, my tolerance for risk is much lower. I would trade efficacy for safety in this case because the indication is one of convenience rather than necessity. I would rather have the procedure fail and end up putting the patient on the same medications than have a complication that compromises visual rehabilitation.

MIGS AS A STAND-ALONE PROCEDURE

Dr Weinreb: All the MIGS devices can be paired with cataract extraction. What is the role of MIGS in a stand-alone setting?

Dr Feldman: There are only a few procedures that are approved in the United States for stand-alone use (see **Table 3**): some of the trabecular bypass procedures and gel stent implantation. From a purely reimbursement perspective, the options are limited and we would have to select 1 of these.

Dr Sheybani: Of the approved choices for stand-alone use, my choice would generally be the bleb-based gel stent. The gel stent is the only bleb-based MIGS procedure currently approved in the United States, and it is approved for stand-alone use **(Figure 1).** It delivers a mean IOP reduction of 9.1 mm Hg at 12 months and reduces the medication burden by approximately half.[22] In a stand-alone case, the decision to operate is being made primarily on the glaucoma status, which is refractory to current treatment as determined by the physician. In this case, we want to prioritize efficacy over safety while striving to optimize both. Although we lack head-to-head trials to inform us on the relative efficacy and safety of these procedures, my experience with glaucoma surgery tells me that a bleb-based procedure is more likely to achieve lower target IOP than a trabecular bypass procedure. Common complications of the gel stent included transient hypotony and the need for needling.

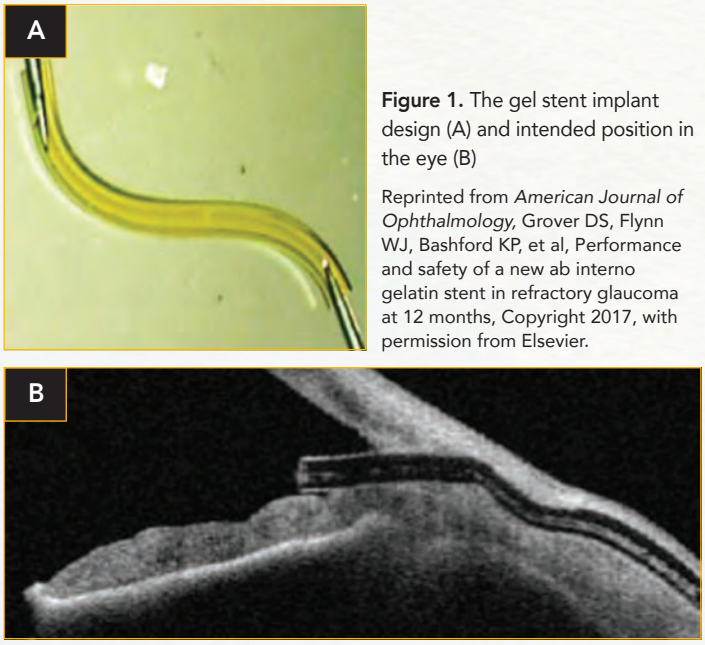

Figure 1. The gel stent implant design (A) and intended position in the eye (B)

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Dr Myers: Some clinicians have found the goniotomy-type procedures especially effective in some secondary open-angle glaucomas. For patients not needing maximal IOP reduction, in whom we wish to avoid or defer external drainage procedures, a goniotomy-type surgery, such as the dual blade device, the viscosurgical system, or GATT (gonioscopy-assisted transluminal trabeculotomy), can be adequate. For those requiring lower IOPs or fewer medications, I find external filtration to be more dependable.

Dr Weinreb: How might the MIGS marketplace change in the near future, and how might that affect our treatment decisions?

Dr Myers: Another bleb-based MIGS device—the glaucoma drainage implant performed using the external approach—is in late-stage clinical development **(Figure 2).** This device requires a conjunctival peritomy similar to a trabeculectomy.[18] This might or might not be the implantation method used once the device is approved, but either way, the surgery will require the formation of a filtering bleb. Mean IOP reductions of 55% and medication reductions of 71% have been reported at 3 years.[18] Complications were similar to those of trabeculectomy, including transient hypotony and choroidal effusions. Also in development is a trabecular bypass 2-pack that is intended to recruit a greater proportion of the outflow system to achieve better IOP reduction,[27] a trabecular bypass for pseudophakic eyes,[28] and a novel supraciliary shunt.[15]

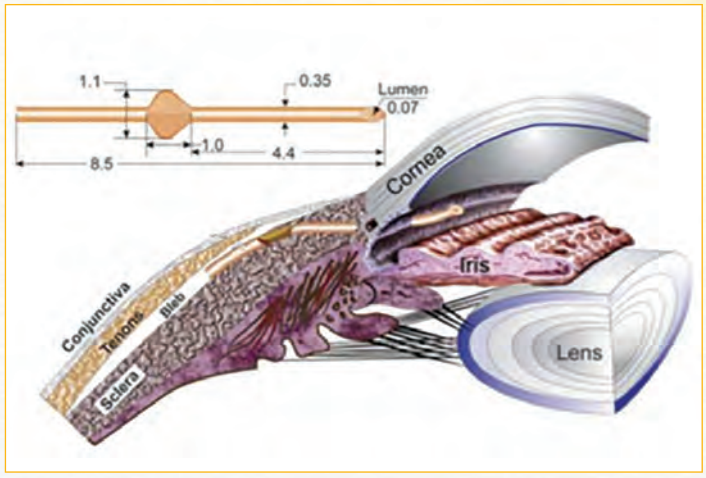

Figure 2. Glaucoma drainage implant design and its intended position in the eye[18]

Reprinted with permission from Wolters Kluwer: 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. https://journals.lww.com/glaucomajournal/pages/default.aspx

ANTIMETABOLITES AND MIGS

Dr Weinreb: Our long history with trabeculectomy has taught us that blebs are more successful in the long term when antimetabolites are used. As bleb-based MIGS procedures emerge, intraoperative antimetabolite augmentation most likely will be necessary to optimize surgical success. How has our use of antimetabolites in trabeculectomy changed over the years?

Dr Feldman: Over the past 10 to 15 years, we have learned better techniques for applying mitomycin C (MMC). Broad-based application of MMC has produced more diffuse, low blebs with lower risks for leaks and related complications, such as hypotony, blebitis, and endophthalmitis.[29]

Dr Weinreb: For patients in whom trabeculectomy was performed with MMC, bleb revision is sometimes needed. There is a paucity of well-designed studies evaluating MMC's optimal concentration, duration of exposure, route of exposure—be it sponges or subconjunctival injection—or timing of application—preoperative, intraoperative, or postoperative. Despite using this toxic substance so frequently, there are still little evidence-based data to guide our practice.

How are you using MMC for trabeculectomy now?

Dr Feldman: I switched to subconjunctival injection of MMC several years ago, but like you, I felt that my bleb leak rate increased, so I went back to application by sponge. I typically use 0.2 or 0.4 mg/mL for 2 to 4 minutes, depending on risk factors for failure.

Dr Myers: I switched to injecting MMC 3 to 5 years ago. It is very convenient for trabeculectomy under topical anesthesia. Less dissection is necessary, and I have not detected an increase in bleb-related complications. I inject 1% nonpreserved lidocaine mixed with an equal volume of MMC 0.4 mg/mL, and typically inject a total of 0.1 to 0.3 mL, which I spread diffusely between 10 o'clock and 2 o'clock. A randomized study demonstrated comparable efficacy between MMC applied by sponge and by subconjunctival injection in trabeculectomy, but the follow-up precludes analysis of long-term bleb-related safety issues.[30]

Dr Weinreb: What is the role of MMC with glaucoma drainage devices?

Dr Myers: In a randomized trial evaluating MMC vs no MMC in eyes undergoing Molteno implantation, there was no significant difference in outcomes.[31] I use MMC only in rare cases of tube implantation, in which the risk of failure is very high, such as a previous tube shunt failure with aggressive scarring.

Dr Weinreb: Now that we have bleb-based MIGS procedures, what is the role of MMC with the gel stent?

Dr Sheybani: Mitomycin C is essential with the gel stent. In early trials without MMC, gel stent failure rates were high,[17,32] but they improved when we started using MMC.[18,22] I use MMC in gel stent surgery exactly as I do in trabeculectomy. I inject 20 mg subconjunctivally in low-risk patients and 40 to 60 mg in high-risk patients, such as those who are younger, are of African descent, or who have failed a prior subconjunctival filtration procedure. I inject postoperatively after I have placed the gel stent, so I can place the MMC right where I want the filtration to occur.

Dr Feldman: With the gel stent, I inject MMC, and I use the same amount as Dr Sheybani. However, I inject preoperatively. Once the MMC is injected, I spread it around the subconjunctival space with a cellulose sponge because if the conjunctiva is ballooned up, it is difficult to visualize the tip of the stent during implantation to be sure you are in the subconjunctival space.

POSTOPERATIVE NEEDLING

Dr Weinreb: In studies of several models of the gel stent, including the commercialized model, the needling rate is in the range of 43% to 47%.[17,33] Is this a problem?

Dr Sheybani: Not if we look at it from the right perspective. In the Tube Versus Trabeculectomy Study, the rate of postoperative interventions for trabeculectomy at 1 year was high: 49% required laser suture lysis, 22% required an antimetabolite injection, and 8% required bleb needling.[34] Overall, 57% of eyes needed 1 or more postoperative interventions. With the gel stent technique, we have eliminated the need for the single most common postoperative trabeculectomy intervention: suture lysis. With a MIGS procedure, we have gained a measure of safety over trabeculectomy.[8] I think that offsets the higher bleb needling rate.

Dr Feldman: Placement of the device is crucial. The tip should be in the subconjunctival space. I have found that the risk of distal obstruction with fibrous tissue is higher if the tip ends up in the sub-Tenon space.

Dr Weinreb: What is your needling technique with the gel stent?

Dr Myers: I perform needling either at the slit lamp or in the minor procedure room and usually use betadine and lidocaine jelly. I will sometimes use 5-fluorouracil or MMC. I use a 30-gauge needle, and I sweep from the limbus to the fornix, just on top of and just below the implant, trying to free Tenon tissue from the tip of the tube.

Dr Weinreb: Do you have a sense of your success rate?

Dr Sheybani: We have looked at our own data, and we can reestablish flow approximately 50% to 60% of the time.

Dr Weinreb: How do you decide when it is time to needle the bleb?

Dr Sheybani: I do it when the IOP rises. Typically, I will needle once we get to 18 to 20 mm Hg. I rely less on bleb morphology, although I will needle a bleb that flattens early. Another factor is the orientation of the implant. If the tube tip is sticking straight up toward the conjunctiva, I often manipulate the implant through the conjunctiva at the slit lamp or otherwise needle the bleb to flatten the tip and reduce the possible risk of erosion over time.

CASE 1

From the Files of Jonathan Myers, MD

I present a case of a primary care physician in his early 60s who has moderate primary open-angle glaucoma ***(Figure 3).*** *His maximum IOP was 24 mm Hg. He is currently borderline controlled, with IOP in the high teens on bimatoprost and the fixed combination of timolol and dorzolamide. He is intolerant to brimonidine. He states that he tolerates the other medications, but on examination, his eyes are chronically hyperemic. He has visually significant cataracts, with best-corrected visual acuity in the 20/40 range, and is beginning to complain of glare when driving at night. He is motivated to improve his vision with cataract surgery. This affords the opportunity to reduce both his IOP and his medication burden and potentially improve his red eyes. Target IOP is in the mid-teens. An additional goal is to eliminate at least 1 medication. To do this, a full-thickness glaucoma procedure—either trabeculectomy, tube-shunt surgery, or gel stent implantation—is recommended. Because he has moderate disease and only borderline IOP control, the likelihood of achieving his surgical goals with a trabecular or suprachoroidal MIGS approach is low.*

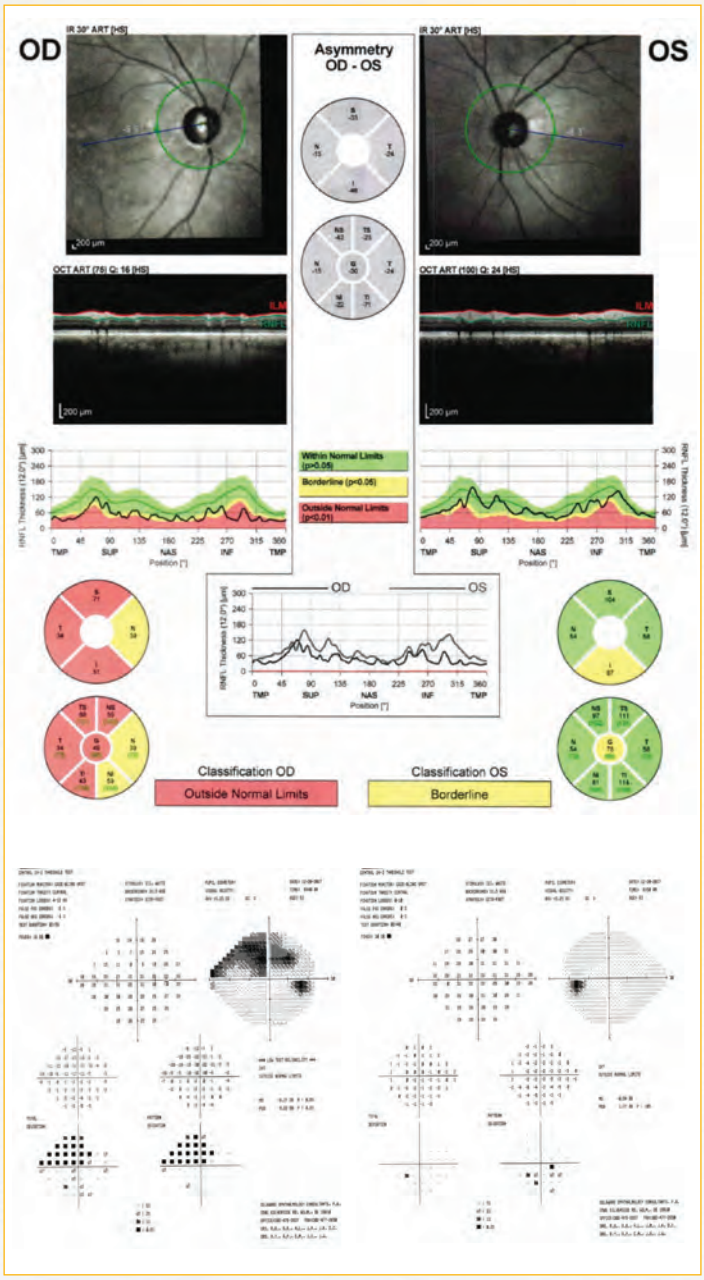

Figure 3. Optical coherence tomography images and visual fields of the patient presented in Case 1

Dr Feldman: He has significant disease, his IOP is not optimally controlled, and therefore you have no further medical options. I would be aggressive with him. Before MIGS was available, this is a patient in whom I would have performed a phaco-trabeculectomy.

Dr Sheybani: He is young, still working, and needs a fast postoperative recovery time. He is more likely to achieve the latter with a gel stent procedure than with a trabeculectomy or tube-shunt surgery.

Dr Weinreb: Those are the salient issues. I would offer 2 options: (1) a procedure with higher success potential but longer rehabilitation (trabeculectomy) or (2) a procedure with lower success potential but shorter rehabilitation (gel stent implantation). I will tell him that if we opt for the lower-success procedure and it fails, we can still undertake the higher-success procedure later, if needed. If cost is not an issue, I typically do gel stent procedures in this setting; but if cost is an issue, I do trabeculectomy.

Dr Myers: Cost was an issue. The patient's insurance company did not cover the gel stent procedure at the time, so he is deferring surgery for now, hoping that the procedure will be covered by his insurance company soon. We are watching him closely, and if he progresses, our hand will be forced, but if not, we are comfortable waiting for a short time. He is a physician and is aware of the trade-offs and accepts the risk.

CASE 2

From the Files of Arsham Sheybani, MD

I present a case of a 74-year-old retired medical professional with primary open-angle glaucoma who presented with an IOP of 23 mm Hg. He has had recent visual field progression on 5 medications, including pilocarpine 4 times a day. He already had primary tube-shunt surgery, which has failed. He is pseudophakic, with a vision of 20/25. A trabecular bypass or suprachoroidal shunt will most likely not achieve the low IOP this patient needs. Trabeculectomy might not be a good option, given that his conjunctiva had been manipulated during the tube-shunt procedure, but is fairly mobile. The surgical options that are being considered are a second tube-shunt surgery, a gel stent procedure, or a cyclodestructive procedure.

Dr Myers: This is the type of patient with whom I spend a long time talking. There are issues to consider, and he has the medical background to understand them. One issue is that he has already failed 1 filtration procedure and he has conjunctival scarring, so his risk for subsequent failure is high no matter what we do. Another issue is that whatever we do will likely not be his last procedure. Our surgeries do not last 20 years. We need to talk about a staged procedure: what we need to do now, and what we will need to do next.

Dr Feldman: Given that he is pseudophakic, I am leaning toward a cyclodestructive procedure for him, perhaps endocyclophotocoagulation.

Dr Sheybani: The patient does understand the issues. He has read the literature and already decided he wants a gel stent procedure. He was on pilocarpine specifically to buy time until it was approved by the US Food and Drug Administration. We had a conversation about the unpredictability of the procedure in the setting of conjunctival scarring; he wanted to proceed. Intraoperatively, the tip of the device curled a bit as it was deployed in the subconjunctival space, which indicated to me that it was stuck within the Tenon layer. I did a primary needling, using a 27-gauge needle, to attempt to free the tip from the Tenon tissue. The implant flattened out, and when I was happy with the placement, I injected MMC. Nine months later, the stent is still in a good position, the bleb is low and diffuse, and he is well controlled, with an IOP of 13 mm Hg on no therapy.

Dr Weinreb: There are 2 lessons here. The first is that the bleb morphology with the gel stent does not always correlate with its function. The second is that primary needling can be effective. I might have incised the conjunctiva and performed a partial tenonectomy in the area of the stent in this case. Your more limited approach worked very well.

CASE 3

From the Files of Robert M. Feldman, MD

I present a case of a 63-year-old Hispanic man with a history of early primary open-angle glaucoma and a remote history of nerve changes over time, but essentially no field loss. He has been adequately treated with prostaglandin monotherapy ***(Figure 4).*** *His IOP is 18 mm Hg. He is now having blurry vision and difficulty driving at night, and specifically reports seeing glare with headlights. He works as a security guard, and his job requires driving. He has moderate cataract changes, and his best-corrected visual acuity is 20/40, which drops to 20/80 with glare testing. He has 2 diopters of astigmatism. Cataract surgery with a toric IOL was scheduled, and a discussion was held about what—if anything—to do about his glaucoma. The options presented to him included cataract surgery alone, a trabecular bypass procedure, or a suprachoroidal procedure. These offered the optimal balance of efficacy and safety because his glaucoma needs are modest and he does not need a full-thickness subconjunctival filtering procedure.*

Dr Myers: A less-invasive surgery for a patient who has early disease and is medically well controlled seems the correct balance of risk and benefit. Cataract surgery alone might allow him to discontinue his medication, at least for a reasonable period of time. How motivated is he to get off his drops? That would be the deciding factor for me. If he is motivated, I would add 1 of the procedures listed. If not, I would do cataract surgery alone.

Dr Sheybani: You really want good vision on postoperative day 1 to make this patient happy. For this reason, I would avoid trabecular stripping procedures, such as ablation or goniotomy/trabeculotomy, and instead lean toward a trabecular bypass. For the reasons we discussed before with the potential for refractive changes, I would avoid a suprachoroidal procedure, especially because you plan to use a premium toric implant.

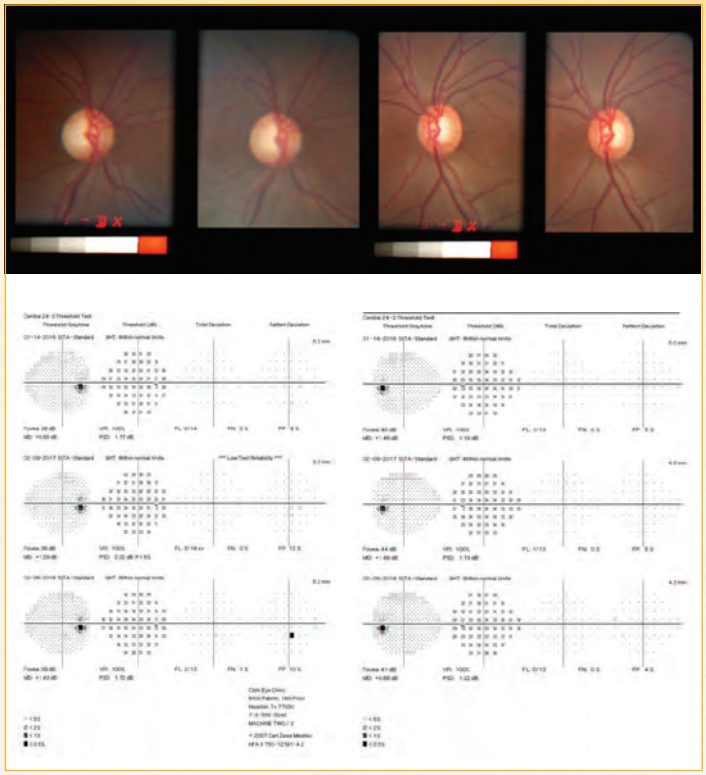

Figure 4. Disc photographs and visual fields of the patient presented in Case 3

Dr Feldman: We discussed his options and elected to perform cataract surgery without a glaucoma add-on procedure. He has been well controlled without medications and without progression for more than a year now.

TAKE-HOME POINTS

- Reasons for transitioning from medical therapy to surgical interventions in glaucoma include progression, an IOP above target, maximum medical therapy that has been reached for efficacy or tolerability, nonadherence to medical therapy, and a desire to reduce the medication burden
- MIGS procedures offer an efficacy/safety profile that complements traditional glaucoma procedures, such as trabeculectomy and tube-shunt surgery; MIGS procedures are generally safer but less effective than traditional procedures
- Because of their distinct efficacy and safety profiles, MIGS procedures have expanded the indications for glaucoma surgery to include lifestyle issues, such as cosmesis and reduction of medication burden, which often do not justify the risks of traditional procedures
- In general, trabecular and suprachoroidal MIGS procedures are appropriate for patients who require modest incremental IOP reduction, whereas bleb-based MIGS procedures are appropriate for patients who require greater IOP reductions
- Bleb-based MIGS procedures necessitate the use of MMC to prevent failure due to fibrosis at the device tip, and needling is commonly needed to disrupt fibrosis in this location

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1. Adding a single agent to a prostaglandin typically produces an additional _____ mm Hg reduction in IOP.
   a. 1 to 2
   b. 2 to 4
   c. 5 to 6
   d. 7 to 8

2. A common clinical scenario for advancing from medical therapy to surgical therapy for glaucoma is _____.
   a. A patient with stable glaucoma whose IOP is at target
   b. A patient who is tolerating his or her medications well
   c. A patient who is progressing on maximal medical therapy
   d. A patient with stable, early-stage glaucoma

3. Cataract surgery alone can lower IOP by an average of _____ 12 months postoperatively in eyes with glaucoma.
   a. 5%
   b. 9%
   c. 14%
   d. 18%

4. Into which of the following spaces do MIGS procedures generally divert aqueous humor?
   a. Subconjunctival space, Schlemm canal, and suprachoroidal space
   b. Schlemm canal, subretinal space, and subconjunctival space
   c. Suprachoroidal space, intravitreal space, and Schlemm canal
   d. Subconjunctival space, suprachoroidal space, and subretinal space

5. Which MIGS procedure is performed via an external approach?
   a. Trabecular bypass
   b. Trabecular ablation
   c. Miniature glaucoma shunt implantation
   d. Gel stent

6. In the United States, which procedure would be considered off-label use in a pseudophakic eye?
   a. Dual blade goniotomy
   b. Trabecular bypass
   c. Gel stent implantation
   d. Miniature glaucoma shunt implantation

7. When contemplating using MIGS, which patient characteristic should be considered in the selection of a specific MIGS procedure?
   a. Central corneal thickness
   b. Need for rapid visual rehabilitation
   c. Refractive status
   d. History of excellent adherence to medical therapy

8. Which scenario represents a high-risk patient who might warrant a higher-risk glaucoma procedure with a greater chance of surgical success?
   a. Well controlled on 1 medication and undergoing elective cataract surgery
   b. Borderline IOP control on 2 medications in an eye with very early glaucoma and no visual field loss
   c. Well controlled on 2 medications and experiencing mild medication-related eye irritation that does not affect adherence
   d. Uncontrolled IOP on 3 medications and recent visual field progression

9. Which MIGS procedure should be performed with MMC augmentation?
   a. Dual blade goniotomy
   b. Trabecular bypass
   c. Gel stent implantation
   d. Supraciliary microstent implantation

10. The postoperative needling rate associated with the gel stent procedure is approximately:
    a. 5% to 10%
    b. 20% to 30%
    c. 40% to 50%
    d. 75% to 80%