CME Monograph

EARN CREDITS CME

ACHIEVING SURGICAL SUCCESS AND PATIENT SATISFACTION WITH MIGS

International Perspectives

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This continuing medical education activity is provided by **New York Eye and Ear Infirmary of Mount Sinai**.
This educational activity was developed and implemented in collaboration with **MedEdicus LLC**.

New York Eye and Ear Infirmary of Mount Sinai

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ACTIVITY DESCRIPTION

More than 40% of patients with glaucoma require maximal medical treatment (MMT) to reach their target intraocular pressure (IOP). MMT can fail to achieve IOP targets, however, because of overt treatment failure or the presence of ocular surface disease, which can lead to a lack of adherence to medication schedules. For these patients, another strategy is needed to reach target IOP. Bleb-based minimally invasive glaucoma surgery (MIGS) procedures balance efficacy and safety and provide a viable option for patients with moderate to severe glaucoma who cannot achieve their IOP goal on MMT. As compared with tube-shunt surgery, subconjunctival bleb-based MIGS also provides favorable postsurgical quality of life outcomes. Optimization of bleb health is an important component of this strategy, and new data provide insight into best practices for antimetabolite treatment and follow-up examination. The desired results of this educational activity are for ophthalmologists to gain the knowledge and competence they need to ensure the best possible outcomes for their patients with glaucoma, now and as new therapies are approved.

TARGET AUDIENCE

This educational activity is intended for glaucoma specialists and other ophthalmologists caring for patients with glaucoma.

LEARNING OBJECTIVES

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

- Discuss the safety and efficacy of MIGS devices for patients with moderate to severe glaucoma
- Describe clinically relevant quality of life outcomes associated with various MIGS procedures
- Choose appropriate MIGS procedures according to individual patient factors
- Integrate evidence-based best practices for prevention of bleb failure into practice

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ACHIEVING SURGICAL SUCCESS AND PATIENT SATISFACTION WITH MIGS

International Perspectives

GLAUCOMA SURGERY AND QUALITY OF LIFE

The advent of minimally invasive glaucoma surgery (MIGS) has broadened the indications for glaucoma surgery. Specifically, with safer operations for patients who may not require the intraocular pressure (IOP) reductions provided by trabeculectomy or tube shunts, surgery can be considered earlier in the treatment process than in the past, particularly among patients undergoing elective cataract surgery.[1,2] MIGS procedures have been shown to effectively lower IOP and, equally importantly, to reduce the medication burden.[1,2] Reducing the medication burden can improve or eliminate the need for daily adherence, minimize or eliminate topical therapy-related adverse effects, and reduce exposure to active and excipient ingredients in glaucoma medications. These attributes would be expected to improve patients' quality of life (QOL), although there are very little data to support this belief.[3]

In broad terms, QOL is defined as individuals' perception of their position in life in the context of the culture and value systems in which they live.[3] This is a wide-ranging concept affected in a complex way by many different factors, including physical health, personal circumstances—such as living conditions—relationships, functional activities, and socioeconomic status.

Very little is known about the relationship between glaucoma surgery and QOL. A recent systematic review on the topic identified only a single study—CIGTS (Collaborative Initial Glaucoma Treatment Study)—to formally evaluate the effect of glaucoma surgery on QOL.[3] In CIGTS, newly diagnosed patients with open-angle glaucoma (OAG) were randomly assigned to receive initial medical therapy or initial surgery (trabeculectomy).[4,5] QOL was assessed using several validated instruments at baseline, at 3 and 6 months after initiating therapy, and every 6 months thereafter for at least 4 years.[4] Investigators found that the effect of glaucoma surgery on eye symptoms was initially significant, but the magnitude of this effect decreased over time. Additionally, the fear of blindness was approximately 80% at baseline—the time of diagnosis of glaucoma—and decreased to approximately 50% over time.[6] Glaucoma is also associated with significant rates of anxiety (13%) and depression (11%), attributable in part to the asymptomatic nature of this potentially blinding disease and patients' inability to assess or perceive their glaucoma status.[7]

In the absence of clear data defining the relationship and determinants of QOL after glaucoma surgery, it can be useful to consider the features of an ideal glaucoma procedure likely to minimally affect QOL. Ideally, the procedure would have minimal effect on visual acuity (VA) in the immediate postoperative period, with rapid visual rehabilitation to baseline. The need for secondary procedures—such as suture lysis or bleb needling—should be minimal, with consistent IOP control throughout the postoperative period. The need for eye drops—both for inflammation/infection control in the perioperative period and for IOP reduction postoperatively—should be minimized. The procedure should be minimally traumatic and cause minimal pain or discomfort.

Many of the new MIGS procedures offer these attributes, and for patients who require glaucoma surgery or who opt for combined surgery at the time of cataract extraction, MIGS is a viable option. The MIGS family is diverse and growing, with procedures that

Table 1. Family of Minimally Invasive Glaucoma Surgical Procedures

Site of Bypass (Type of Procedure)	Device	Maker	Approved in the United States	Approved in Canada	Approved in Europe	Standalone	Approach
Schlemm canal (internal MIGS)	Trabectome	NeoMedix Corporation	Yes	Yes	Yes	Yes	Interno
	iStent	Glaukos Corporation	Yes	Yes	Yes	Yes (Europe and Canada) No (United States)	Interno
	Hydrus	Ivantis Inc	Yes	Yes	Yes	No	Interno
	Kahook Dual Blade	New World Medical, Inc	Yes	Yes	Yes	Yes	Interno
	GATT	Ellex	Yes	Yes	Some countries	Yes	Interno
	Ab interno canaloplasty	Ellex	Yes	Yes	Some countries	Yes	Interno
	VISCO360	Sight Sciences	Yes	Yes	Yes	Yes	Interno
	iStent Supra	Glaukos Corporation	No	No	Yes	Yes	Interno
Subconjunctival space (external MIGS)	XEN Gel Stent	Allergan	Yes	Yes	Yes	Yes	Interno/ Externo
	PreserFlo MicroShunt	Santen Inc	No (in phase 3 trials)	No	Yes	Yes	Externo

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

shunt aqueous humor from the anterior chamber into Schlemm canal and the subconjunctival space **(Table 1)**. These latter procedures rely on the formation of a filtering bleb, and thus offer the potential for greater IOP reductions in eyes with advanced glaucoma and/or those needing low target IOPs.

For patients with newly diagnosed glaucoma who may not yet be surgical candidates, selective laser trabeculoplasty (SLT) is a minimally invasive option that can be appropriately deployed earlier in the treatment process. A recent study has demonstrated the value of primary SLT for long-term IOP control. In the LiGHT (Laser in Glaucoma and Ocular Hypertension) study, 718 patients newly diagnosed with OAG or high-risk ocular hypertension received either primary SLT or medical therapy and were followed for 3 years.[8] SLT could be repeated and medications could be added to attain disease- and severity-specific target IOP. Outcomes, including QOL, VA, IOP, and progression rates, were similar between the 2 groups. At 3 years, 78% of 419 SLT-treated eyes remained medication free and at target IOP; of these, 76% required just a single SLT treatment. SLT is a viable first-line alternative to medical therapy. For patients who wish to avoid drops and their attendant drawbacks from the time of diagnosis onward, SLT and MIGS together represent treatment options for every stage of glaucoma.

CASE 1: MODERATE GLAUCOMA

From the Files of Anna T. Do, MD

*A 52-year-old woman with a 6-year history of OAG was referred to consider surgical options because of increasing intolerance of topical medical therapy. She was a busy attorney, and bothered by chronic hyperemia and symptoms of ocular surface disease (OSD). Her peak pretreatment IOP was 28 mm Hg OU. Over the past several visits, her IOP ranged from 16 to 20 mm Hg. Her central corneal thickness (CCT) was normal (540 μm OD and 545 μm OS). She was using a prostaglandin analogue and a beta blocker/alpha agonist fixed combination OU and reported good adherence. She had previously undergone bilateral SLT several times, with minimal response to the most recent treatment. A review of her visual fields and optical coherence tomography (OCT) images of the retinal nerve fiber layer (RNFL) demonstrated modest progression OD over the past 4 years and possibly mild progression OS **(Figure 1)**. A week of home tonometry (iCare Home, iCare) revealed IOP ranging from 14 to 18 mm Hg OU, and an in-office water-drinking test demonstrated peak IOP of 28 mm Hg OD and 25 mm Hg OS at 15 minutes.*

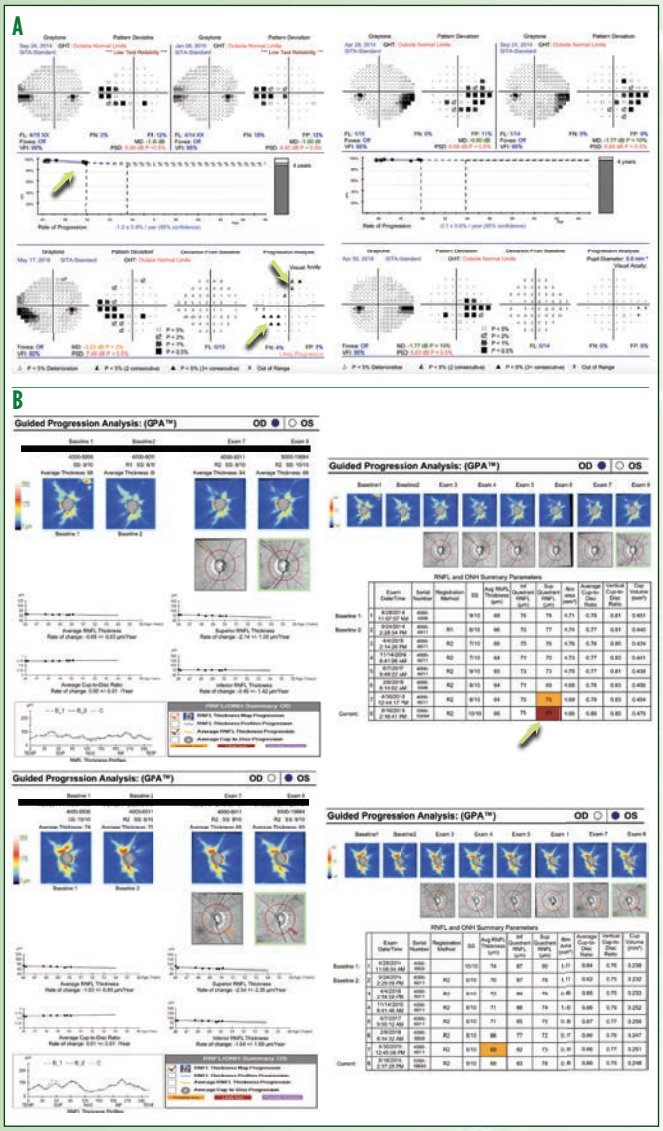

Figure 1. Visual fields (A) and retinal nerve fiber layer optical coherence tomography images (B) of the patient presented in Case 1. Note modest progression in the right eye (green arrows) and possible progression in the left eye.

Dr Barton: Her rate of progression is quite slow, manifesting over 4 years on the visual fields. The patient is rather young. She is bothered by adverse effects of her topical therapy. She had maximized the benefits of SLT. She is now a candidate for surgery; she would be an ideal patient for a MIGS procedure. In general, I tend to perform an external subconjunctival MIGS standalone procedure when the goal is IOP reduction, as it is for this patient.

Dr Panarelli: Her IOP variability—particularly with the water-drinking test—demonstrates that she has impaired ability to regulate her IOP. This suggests significant impairment of her outflow system, whether it is the trabecular meshwork (TM), Schlemm canal, collector channels, episcleral veins, or all the aforementioned.[9] An internal MIGS procedure can address the TM obstruction, but will not address any post-TM outflow impairment in the canal or collector channels.[10] Therefore, I agree that an external MIGS procedure is best for this patient.

Dr Do: We also want to reduce her medication burden to improve her OSD symptoms. OSD affects 30% to 70% of patients on glaucoma therapy,[11-17] and chronic topical medication use can aggravate it even further.[18]

Dr Feijoo: The nonresponsiveness to repeat SLT may indicate that the distal outflow system is impaired, which also supports the use of an external MIGS procedure.

Dr Panarelli: It would not be unreasonable to consider a trabeculectomy or tube-shunt procedure, but I do not think this patient needs the low target IOP these procedures can deliver. A reasonable IOP goal for her is the midteens, with fewer medications to improve her symptoms, so I would lean toward an external MIGS procedure to balance the modest IOP requirement with the better safety profile of MIGS over traditional filtering surgery.[1]

Dr Ahmed: Conversely, if she were a bit older and had less visual field damage, I would consider an internal MIGS procedure as a first step because the chief goal in that case would be medication reduction.

Dr Moster: Planning ahead, a superonasal subconjunctival MIGS procedure will leave you plenty of room, with untouched conjunctiva, for a future filtering surgery if needed. Given the patient's young age, this is a real possibility.

Dr Do: We performed a gel stent implantation in the right eye, augmented with mitomycin C (MMC) 0.4 mg/mL subconjunctivally, with the goal of reducing both IOP variability and medication burden so the patient would be less bothered by OSD symptoms. The gel stent is 6 mm in length, has a 45-µm lumen, and is made out of porcine gelatin.[19] In the gel stent's pivotal trial, 65 patients with refractory glaucoma (IOP uncontrolled on maximally tolerated medical therapy [MTMT] or after failed glaucoma surgery) underwent gel stent implantation via an ab interno approach with subconjunctival MMC 0.2 mg/mL augmentation.[19] At 12 months, 75.4% of patients achieved a ≥ 20% IOP reduction from baseline on the same or fewer medications, with mean IOP reductions of 9.1 mm Hg (35.6%) and mean medication reductions of 51.4%. Common adverse events included IOP elevations ≥ 10 mm Hg from baseline in 21.5% of patients and hypotony in 24.6% of patients. Needling of the bleb was required in 32.3% of patients.

In another study, 149 eyes with uncontrolled glaucoma on MTMT underwent gel stent implantation via the ab interno approach following subconjunctival injection of 0.1 mL of MMC 0.2 mg/mL, either standalone or combined with cataract surgery.[20] By 24 months, mean IOP reduction was 29.3%. Complete success (IOP ≤ 12 mm Hg and ≥ 20% IOP reduction) was achieved in 18.2% of eyes; using a less stringent IOP threshold (≤ 15 mm Hg), the success rate was 44.4% at 24 months. Needling was required in 58 eyes (45%).

A third study retrospectively compared the outcomes of standalone gel stent implantation vs those of trabeculectomy in 354 eyes that included in-office interventions, bleb needling, number of postoperative visits, vision loss (> 2 lines), complete visual recovery (return to preoperative best-corrected VA [BCVA]), and incidence of surgically induced astigmatism.[21] The median follow-up was approximately 19 to 20 months. Postoperative interventions were performed in 51.4% of 185 gel stent eyes and in 62.1% of 169 trabeculectomy eyes (56.7% and 63.9%, respectively, based on survival estimates [log-rank $P = .0004$]).

Table 2. Outcomes Related to the Postoperative Course of Gel Stent Implantation vs Trabeculectomy[21]

QOL Metric	Gel Stent (n = 185)	Trabeculectomy (n = 169)	*P* Value
In-clinic interventions	51.4% (56.7% based on survival estimates)	62.1% (63.9% based on survival estimates)	.0004 (log rank)
Needle revision with antifibrotic	42.2%	32.5%	.02
Visits within 1 month postoperation (average)	3.94	4.62	< .001 (adjusted for baseline differences)
Visits within 3 months postoperation (average)	5.94	6.70	< .001 (adjusted for baseline differences)
Postoperative vision loss ≥ 2 lines	12.4%	21.9%	.0383
Visual recovery at last follow-up	83.2%	74.0%	.025 (log rank)
> 0.5 D surgically induced astigmatism	22.3%	46.7%	Not significant

Abbreviation: QOL, quality of life.

Bleb needling was performed in 42.2% of gel stent eyes and in 32.5% of trabeculectomy eyes (*P* = .02). Gel stent eyes required fewer postoperative visits (*P* < .001), lost less VA (*P* = .0383), recovered BCVA more often (*P* = .025), and had less surgically induced astigmatism, but this difference did not reach statistical significance **(Table 2)**.[21] In this study, white ethnicity was associated with a lower bleb failure rate and diabetes with a higher failure rate.

Dr Moster: These outcomes are likely to impact our patients' QOL. Patients' satisfaction with surgery would be expected to be substantially better if they require fewer follow-up procedures and fewer office visits, and experience quicker visual recovery and less vision loss.

Dr Panarelli: One issue I always consider when reading studies is generalizability. How closely do the patients in the study match the patient in my chair? The patients in these studies were inadequately controlled on MTMT,[19-21] which is very much like the case patient we are discussing here. So, I would expect the results of these studies to be predictive of the outcomes for this patient. If we were to perform this surgery on patients with less severe or less refractory glaucoma, we might get different results. One key point with the pivotal study is that Grover et al[19] took down the conjunctiva specifically to apply MMC, even though device implantation can be performed via an ab interno approach. Sub-Tenon injection of MMC has been shown to be comparable to application by sponges,[22] which makes the ab interno implantation of this device possible without having to take down the conjunctiva.

Dr Moster: This procedure can significantly reduce the medication burden as well. In the pivotal trial, medication use was reduced by half at 12 months.[19] This can improve symptoms of OSD, which in turn likely improves QOL.

Dr Ahmed: Success with this surgery begins with proper surgical technique. It is critically important to place the gel stent properly. With ab interno insertion, we have to make sure the distal tip is not caught up in Tenon capsule, but rests in the subconjunctival space.[23,24] I test this intraoperatively by gently moving the proximal tip of the implant back and forth a bit. If the distal tip is free, the stent tends to stay where I move it, but if it is caught in Tenon capsule, it will spring back into its starting position. If I suspect engagement with Tenon capsule, I will intraoperatively sweep the subconjunctival space above and below the distal tip with a 30G needle to ensure it is free. I have also made 2 adjustments to MMC use: (1) I inject at the end of the procedure so I can assess the tip placement before hydrating the conjunctiva and Tenon capsule (as would happen if I injected MMC preoperatively); and (2) I have increased the concentration of MMC that I use, from 0.2 to 0.4 mg/mL. These adjustments during the learning curve have reduced our needling rate compared with the rate in the pivotal trial.[19]

Dr Panarelli: I place my gel stents under Tenon capsule entirely via an external approach (open conjunctiva). This technique allows me to be certain that the distal end of the gel stent is not obstructed, and I can make microadjustments to ensure the gel stent is ideally positioned. Another benefit to sub-Tenon gel stent placement is that there is a lower incidence of exposure/extrusion of the device (1.5%).[19]

Dr Ahmed: From a safety perspective, it makes sense to put the tip under Tenon capsule to minimize the risk of erosion, but with ab interno implantation, this is difficult to do consistently.

Dr Do: Despite our best efforts, bleb failure does still occur in some eyes after gel stent implantation. Risk factors for bleb failure include young age, aphakia, conjunctival inflammation, uveitis, chronic medication use, previously failed glaucoma surgery, and, most importantly and as has been pointed out, if the distal tip is caught in Tenon capsule.[23]

Dr Ahmed: I believe one reason young age is a risk factor for failure is that as we get older, we have less Tenon tissue to potentially occlude the distal tip.

Dr Panarelli: Mitomycin C at the time of implantation is crucial to long-term success. Early studies without MMC had very high failure rates,[24,25] which were reduced once we started using MMC.[19,26]

Dr Ahmed: Also, needling procedures for bleb fibrosis tend to reestablish the IOP control achieved before bleb failure in eyes with gel stents.[27]

Dr Do: We have heard Dr Ahmed's MMC routine. How do others use MMC when implanting gel stents?

Dr Panarelli: I inject approximately 0.15 to 0.2 mL of MMC 0.4 mg/mL, which is on the order of 60 to 80 µg total, and inject approximately 10 mm posterior to the limbus.

Dr Moster: I use MMC 0.4 mg/mL as well, and inject a mixture of 0.1 mL of MMC and 0.1 mL of unpreserved lidocaine as far posteriorly as I can.

Dr Do: The patient did well after gel stent implantation of the right eye. Her IOP was 11 mm Hg off all medications 12 months later.

CASE 2: MODERATE GLAUCOMA

From the Files of Julian Garcia Feijoo, MD, PhD

A 49-year-old woman was referred for possible newly diagnosed glaucoma. She had a history of systemic hypotension, with diastolic blood pressure in the range of 35 to 52 mm Hg at night. Her BCVA was 20/20 OU, with a myopic correction (-5 D OD and -4 D OS). Her untreated IOP was 22 to 26 mm Hg OD and 18 to 22 mm Hg OS, with CCT of 504 µm OD and 500 µm OS. ***Figure 2*** *shows her optic nerve photographs, RNFL OCT images, and visual fields. She had large optic nerves OU, and the photograph of the right eye revealed a notch in the inferior rim of the optic nerve, with an RNFL bundle defect at 7:00. The OCT images revealed superior and inferior RNFL loss in both eyes, and the visual fields demonstrated superonasal loss consistent with the RNFL defect.*

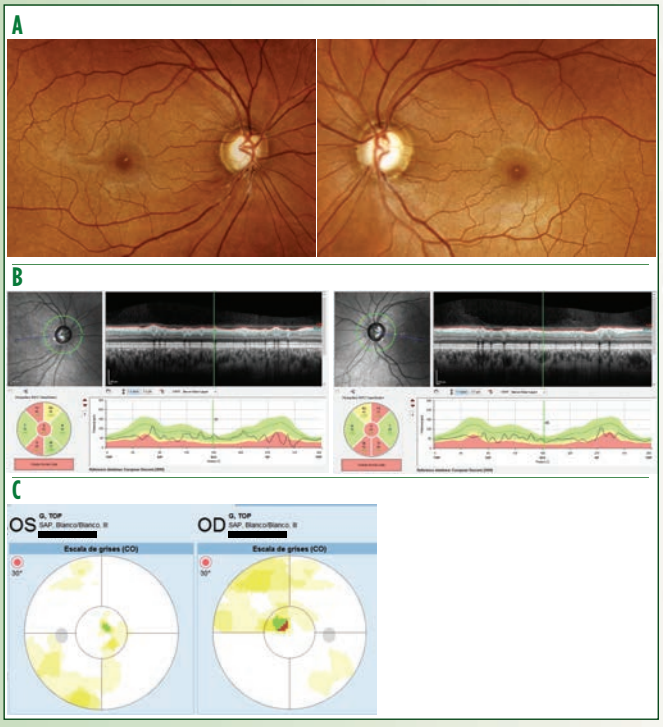

Figure 2. Posterior pole photographs (A), retinal nerve fiber layer optical coherence tomography images (B), and visual fields (C) of the patient presented in Case 2

The patient was diagnosed with primary OAG (POAG) and begun on daily prostaglandin analogue therapy in both eyes, resulting in an initial IOP of 15 to 17 mm Hg OD and 12 to 14 mm Hg OS. Over the next year, however, IOP OD crept up to 20 mm Hg and remained at 20 mm Hg despite the addition of a twice-daily brimonidine/brinzolamide fixed combination; the IOP OS remained stable at 14 mm Hg on prostaglandin analogue monotherapy.

Dr Panarelli: This is a young patient with a fixation-threatening field defect in the right eye. Her thin CCT also suggests that her true IOP may be higher than 20 mm Hg. The RNFL defect on the OCT images is also visible on the fundus photograph, and it is not a small or subtle defect. This is a patient at high risk of glaucoma-related vision loss, and someone in whom I would consider surgery earlier rather than later.

Dr Ahmed: So far there is no evidence of progression. Although her IOP is significantly higher in the right eye than in the left eye, there is a case to be made for accepting this IOP and maintaining the treatment course. In EMGT (Early Manifest Glaucoma Trial), patients with newly diagnosed OAG were assigned to treatment (a 25% IOP reduction by whatever means necessary) or observation.[28] Over 5 years, nearly 40% of untreated eyes did not progress. In CNTGS (Collaborative Normal-Tension Glaucoma Study), 65% of 79 eyes with normal-tension glaucoma assigned to observation without treatment remained stable without progression over 5 to 7 years.[29] My point is that glaucoma—be it high- or low-IOP OAG—often does not progress, or does so very slowly; so in many of these eyes, it is not unreasonable to observe them without treatment and reserve therapy for those who demonstrate true progression on our watch. In our present case, however, the patient is young and has fixation-threatening field loss. Because of the risk that even modest further progression could affect her central VA, I would treat this patient to a lower target—say, the low teens—rather than leaving her IOP at 20 mm Hg.

Dr Feijoo: Not only do many patients remain stable over time, but the prevalence of fast progressors—those with visual field mean deviation reductions > 1 and < 2 dB per year—is typically 8%, and the prevalence of catastrophic progressors—those losing > 2 dB per year—is approximately 3% or less.[30,31]

Dr Barton: Significant numbers of patients do remain stable without treatment for 5 or even 7 years. But, in my experience, if observed for 10 or 20 years, most of them will eventually progress. As young as this patient is, she will live with the disease for a long time, and she will likely progress at some point. I agree with Dr Panarelli; I would pursue a lower target IOP now, before she progresses.

Dr Moster: This is a common scenario: a patient who is stable at an IOP that makes us uncomfortable. Our job is to figure out which patients will progress and lower their IOP, and which will not need any further intervention. We distinguish between these 2 groups according to both risk assessment and a careful appraisal of the consequences if we are wrong. Risk assessment includes examination elements, such as IOP level and CCT, and other issues, such as comorbid conditions or lifestyle issues. This patient has systemic hypotension, so she is at risk of poor ocular perfusion at night. Does she have evidence of vasculopathy, eg, Raynaud phenomenon, disc hemorrhages, cold hands or feet? Does she practice yoga with frequent headstands, lift weights, or play a brass or woodwind instrument? These can all raise IOP during the activity.[32-34] Any of these might push me to lower her target IOP. We also have to consider the cost of being wrong. If we have a patient with ocular hypertension and full visual fields, the cost of a little progression—enough to convince us we need a lower IOP—is minimal. As will be shown in Case 3, the cost of a little progression could be split fixation, so we might err on the side of being too aggressive rather than not aggressive enough.

Dr Ahmed: A family history of glaucoma would also raise the patient's risk profile significantly. Was there glaucoma in her family?

Dr Feijoo: No. The discussion about waiting or not waiting for progression is at the heart of this case. MIGS has changed how I approach these patients.

Fifty years ago, if the only option was a trabeculectomy, I would have waited for progression before recommending surgery. But now with MIGS, we can offer a safer procedure, so we have a lower threshold for operating. Together, the patient and I decided that a lower IOP was prudent now, before she got worse. We opted for an external subconjunctival MIGS procedure. In Europe, we have the microshunt, which is implanted via an ab externo approach.[35] It is 8.5 mm long, with a 70-µm lumen, and has 2 small fins to anchor it into sclera. It is inserted through a scleral tunnel fashioned by a 25G or 27G needle, with the fins resting in a shallow scleral pocket formed by a specialty blade provided with the implant. In a preliminary study, 23 eyes with uncontrolled IOP despite MTMT underwent either standalone surgery or surgery in combination with cataract extraction.[35] MMC 0.4 mg/mL was applied for 3 minutes intraoperatively. Mean IOP reductions at 1, 2, and 3 years postoperatively were 55%, 50%, and 55%, respectively, demonstrating endurance of the procedure's effect over time. Mean IOPs in the low teens (10 to 11 mm Hg) were achieved at 3 years postoperatively, and 82% of 22 eyes had IOP ≤ 14 mm Hg. Medication reduction at 3 years was 70%, and 64% of eyes were medication free. Common adverse events included transient hypotony (13%), shallow or flat anterior chambers (13%), and hyphema (9%). Through 3 years of follow-up, only 1 eye developed subconjunctival fibrosis requiring needling.

In a prospective, multicenter study in Europe, 101 patients with mild to severe POAG underwent microshunt implantation with MMC 0.2 mg/mL for 2 minutes.[36] At 12 months, mean IOP reduction was 28% (mean IOP was 14.6 mm Hg) **(Figure 3)**, and 74% of patients receiving microshunt were medication free. IOP elevation requiring additional medications or SLT occurred in 21% of patients, and keratitis was noted in 9% of patients.

In an additional study, 124 eyes with mild to severe POAG and baseline IOP ≥ 18 mm Hg underwent microshunt implantation with MMC 0.2 mg/mL or 0.4 mg/mL.[37] Mean IOP reduction at 2 years was 34.8% in the group receiving MMC 0.2 mg/mL and 41.2% in the group receiving MMC 0.4 mg/mL. Medication reductions in the 2 groups were 67% and 90%, respectively. Common adverse events included need for IOP medications or SLT in 33% of the 58 eyes receiving MMC 0.2 mg/mL and in 18% of the 66 eyes receiving MMC 0.4 mg/mL, and hypotony in 12% and 14% of eyes, respectively.

A phase 3 multicenter study comparing the microshunt with trabeculectomy has been conducted but not yet published.[38] Both groups received MMC 0.2 mg/mL for 2 minutes. At 12 months, mean diurnal IOP was reduced from 21.1 to 14.2 mm Hg in the microshunt group and from 21.1 to 11.2 mm Hg in the trabeculectomy group. Medications were reduced by 80% in the microshunt group and by 90% in the trabeculectomy group, and 71.6% and 84.8% of patients, respectively, were medication free at 12 months. Hypotony occurred in 30.6% of microshunt patients and in 51.1% of trabeculectomy patients; suture lysis was required in 52.3% of trabeculectomy patients (and not in any microshunt patients).

This patient underwent surgery with the microshunt with MMC 0.2 mg/mL for 3 minutes. There were no complications and no hypotony. IOP through the first 6 months was 10 to 13 mm Hg on no medications.

Dr Barton: This procedure has replaced trabeculectomy for all but my most severe patients, in whom we must succeed with surgery the first time around. You get a more posterior bleb with the microshunt than with the ab interno gel stent because opening the conjunctiva affords the opportunity to use more MMC than most of us are comfortable with via subconjunctival injection. If you implant the gel stent externally, as Dr Panarelli does, this is not an issue because a wider area of MMC application is also possible. Also, in my experience, there is less peritubular flow with the microshunt than with the gel stent, so I see less hypotony and less need for anterior chamber reformation. I leave a little cohesive viscoelastic in the anterior chamber with the gel stent because it will exit the eye via peritubular flow, but I do not leave any viscoelastic in the eye with the microshunt because there is no peritubular flow, it cannot exit through the shunt, and IOP will therefore spike dramatically.

CASE 3: MODERATE TO ADVANCED GLAUCOMA

From the Files of Marlene R. Moster, MD

A 48-year-old woman was referred for evaluation. She is a physician with a busy internal medicine practice. Seven months previously, she had developed blurred VA in both eyes and was found to have bilateral anterior uveitis. The uveitis workup result was negative. She was managed with topical and oral steroids; the oral steroids were eventually replaced with subcutaneous adalimumab. At the time of referral, she was using prednisolone acetate, 1%, 1 to 2 times daily for several months. Her BCVA was 20/20 OD and 20/40 OS with -8 D contact lenses. Her IOP was 55 mm Hg OD and 51 mm Hg OS despite bimatoprost, brimonidine, dorzolamide/timolol fixed combination, and oral acetazolamide 500 mg twice

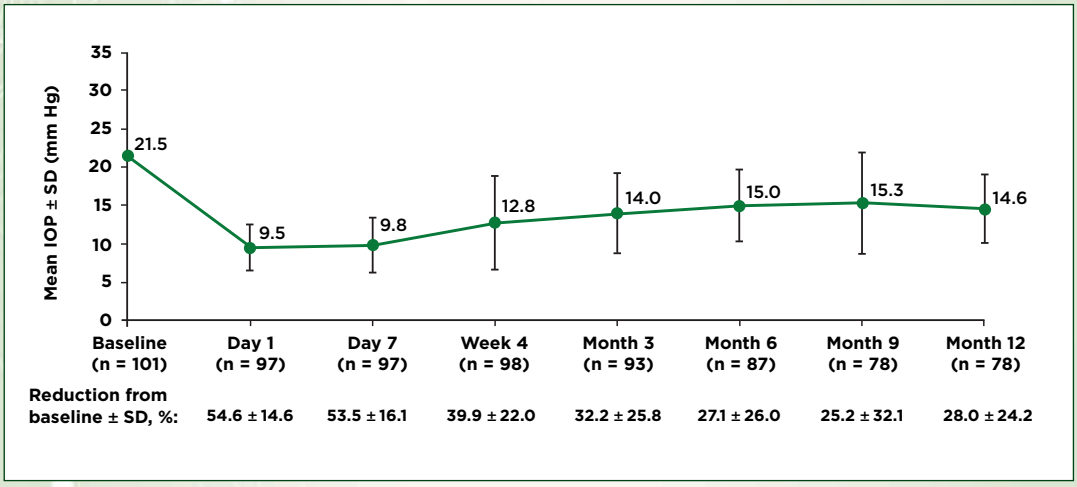

Figure 3. Mean intraocular pressure through 12 months of follow-up after microshunt implantation[36]

Abbreviations: IOP, intraocular pressure; SD, standard deviation.

daily. Her corneas were clear. There was rare cell and 1+ flare in both eyes. Her angles were open. Her optic nerve examination result, RNFL OCT images, and visual fields were all completely normal in both eyes. She had mild macular edema OS, accounting for her reduced VA.

Dr Do: This patient has severe ocular hypertension secondary to steroid use or uveitis, fortunately with no glaucomatous damage to date. She needs significant IOP reduction, most likely with surgery, before she begins to acquire damage. How important is it to her that she continue using contact lenses?

Dr Moster: She has never worn glasses and does not want to do anything that would prevent her from wearing contacts. The least invasive intervention would be SLT. Is it likely to help in this case?

Dr Barton: SLT is often used in steroid-related ocular hypertension, albeit with some, but not hard, evidence for efficacy.[39-41] It is unlikely to lower her IOP to a safe level from 55 mm Hg while also reducing her medication burden.

Dr Moster: At the other end of the spectrum is trabeculectomy. She is young and has uveitis, 2 risk factors for failure of trabeculectomy.[42] Also, contact lenses are a risk factor for bleb-related complications,[43] but trabeculectomy is a very effective procedure. A tube-shunt procedure is another option, but the likelihood of attaining a low IOP on no medications with no complications is only 8% to 14% with tube shunts.[44] I did not favor a subconjunctival MIGS procedure for this patient because of the contact lens issue. What about a TM or Schlemm canal stent?

Dr Panarelli: In the United States, these devices are approved for use only in combination with cataract surgery,[45,46] and there is no indication for removing the patient's lenses. Second, I try to avoid the implantation of permanent devices in eyes with uveitis whenever possible.

Dr Feijoo: In steroid-induced ocular hypertension or glaucoma, I would consider a trabecular MIGS procedure.

Dr Moster: My preference in these eyes is a TM procedure. I considered the various trabeculotomy and goniotomy procedures. Of these, we chose to perform gonioscopy-assisted transluminal trabeculotomy (GATT). It offers 360° trabecular splitting while sparing the conjunctiva for future surgery if needed. GATT can be performed using a suture or an illuminated microcatheter. I prefer the microcatheter because it is easier to visualize the tip throughout the 360° pass. As a standalone procedure, GATT can lower IOP by 30% to 44% and number of medications by 28% to 70% in eyes with POAG.[47-52] In secondary glaucomas, even greater efficacy can be achieved.[47,50] Drawbacks that we discussed include an 8% to 25% incidence of IOP spikes and a 9% to 40% 12-month reoperation rate.[47–50] Also, intraoperative bleeding is universal, but typically clears in 1 to 3 weeks. We operated on both eyes 3 weeks apart. Now, 3 years later, her IOP is in the low teens OU using dorzolamide/timolol once daily, and her VA is 20/20 OD and 20/30 OS with her contact lenses.

CASE 4: ADVANCED GLAUCOMA

From the Files of Keith Barton, MD, FRCP, FRCS

A 57-year-old man with a history of LASIK (laser-assisted in situ keratomileusis) in 2006 was diagnosed with POAG in 2009. He was referred in 2014 for glaucoma care. At the time of referral, VA was 20/20 OU without correction (the magnitude of his myopia before LASIK was unknown), IOP was 16 mm Hg OD and 13 mm Hg OS using a preservative-free dorzolamide/timolol fixed combination, and CCT was 464 µm OD and 454 µm OS. Over the next 4 years, despite treatment escalation to 4 medications in each eye, the patient had demonstrable visual field progression ***(Figure 4)****, with IOP of 15 mm Hg OD and 13 mm Hg OS.*

Dr Panarelli: The right eye was approaching split fixation in 2014, and has now progressed to a near-altitudinal defect. The left eye has a paracentral scotoma inferiorly that does not yet encroach on fixation, but it is close. Assuming this has occurred with IOP of 15 mm Hg or less over the past 4 years, a very low target IOP is needed.

Dr Feijoo: SLT is an option, and has been shown to be effective in eyes with low baseline IOP.[53,54] Given the stage of disease and the current use of 4 medications, however, surgery would be more appropriate.

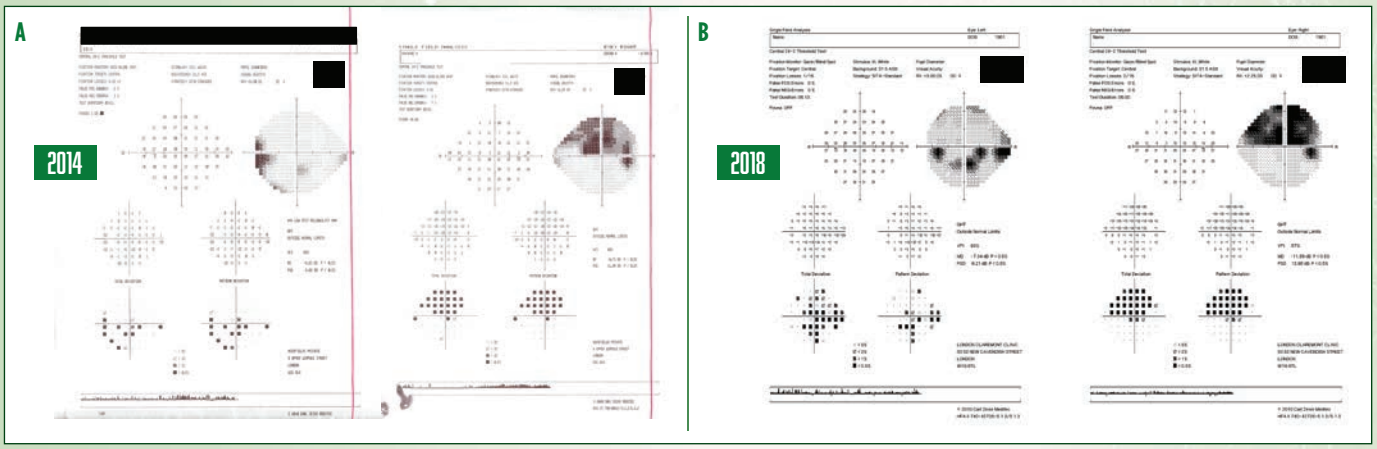

Figure 4. Visual fields in 2014 (A) and 2018 (B) of the patient presented in Case 4

Dr Do: In patients progressing at low IOP, achieving very low—single digit—IOP with surgery effectively halts progression in most cases.[55] This patient may not really have such low IOP. The history of LASIK and the thin corneas suggest that his true IOP is likely higher than in the low-mid teens.

Dr Panarelli: Regardless of what the "true" IOP is, we would all agree that a significant reduction is needed. The history of myopia is a concern in this case because it is associated with an increased risk of hypotony with trabeculectomy or tube-shunt surgery.[56] Balancing efficacy and safety is a challenge in cases such as this one.

Dr Barton: We discussed the pros and cons of trabeculectomy vs a subconjunctival MIGS procedure, and the patient opted for the latter on the basis of safety and more rapid visual rehabilitation. We performed an ab externo microshunt implantation using MMC 0.4 mg/mL for 2 minutes in the left eye, and followed that shortly thereafter with a similar procedure in the right eye, but with MMC exposure extended to 3 minutes. One month later, IOP was 10 mm Hg OU on no medications. Over the next 6 months, we added 2 medications back to the right eye to maintain an IOP that was consistently 10 mm Hg or less; the left eye maintained an IOP of less than 10 mm Hg without additional medications.

TAKE-HOME POINTS

- MIGS procedures have expanded the role of surgery in glaucoma management. Advantages over medications include fewer chronic medication-related adverse effects and reduced medication burden. Advantages over filtering surgery include faster recovery time and fewer postoperative procedures. These benefits are determinants of QOL.
- Trabecular meshwork and Schlemm canal MIGS procedures provide modest reductions of IOP and medications, whereas subconjunctival MIGS procedures offer IOP and medication reductions consistent with those associated with trabeculectomy.
- Selection of the right MIGS procedure for a given patient is made on the basis of surgical goals (IOP vs medication reduction, target IOP), glaucoma type and severity, age of the patient, need for rapid visual recovery, and patient-specific needs, such as desire to wear contact lenses.
- Subconjunctival MIGS procedures require augmentation with MMC to prevent fibrosis and the need for needling.

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1. In the gel stent pivotal trial, medication use was reduced by _____ at 12 months.
    a. 25%
    b. 50%
    c. 75%
    d. 100%

2. In the prospective multicenter study conducted in Europe, which of the following best summarizes the outcomes at 12 months in eyes receiving the microshunt?
    a. IOP was reduced from 21.5 to 14.6 mm Hg, and 70% of patients were medication free
    b. IOP was reduced from 20.0 to 10.0 mm Hg, and 80% of patients were medication free
    c. IOP was reduced from 21.5 to 9.0 mm Hg, and 25% of patients were medication free
    d. IOP was reduced from 19.5 to 16.5 mm Hg, and 50% of patients were medication free

3. According to clinical studies, an IOP reduction of _____ would be reasonable after GATT.
    a. 10% to 15%
    b. 30% to 45%
    c. 50% to 65%
    d. 75% to 85%

4. QOL is a complex descriptor of individuals' perception of their position in life and is determined in part by:
    a. Physical health
    b. Interpersonal relationships
    c. Living conditions
    d. All the above

5. According to CIGTS, which of the following describes the fear of blindness due to glaucoma?
    a. It affects 50% of people at diagnosis and increases with time
    b. It affects 25% of people at diagnosis and increases with time
    c. It affects 50% of people at diagnosis and decreases with time
    d. It affects 25% of people at diagnosis and decreases with time

6. Which outcome was reported in the LiGHT study comparing SLT with medical therapy in newly diagnosed patients with OAG or high-risk ocular hypertension?
    a. QOL was better in SLT-treated patients because they did not have to use eye drops
    b. Medications lowered IOP better than did SLT
    c. 78% of SLT-treated patients were medication free and at target IOP at 3 years
    d. More medication-treated eyes than SLT-treated eyes progressed over time

7. A 66-year-old female with a history of uveitic glaucoma in the left eye presents with an IOP of 43 mm Hg on maximally tolerated medical therapy. Visual acuity is 20/20 in the affected eye, the optic disc is healthy on OCT, and the VF is within normal limits. The angle appears open on gonioscopy. What is the best treatment option for this patient?
    a. SLT
    b. Phacoemulsification/iStent
    c. Phacoemulsification/Hydrus
    d. GATT
    e. Subconjunctival MIGS
    f. Trabeculectomy

8. A 71-year-old female with pseudoexfoliative glaucoma presents with an IOP of 29 mm Hg in her right eye on 3 topical agents. She is a high myope (-7D OU), but refracts to 20/20. The optic disc has extensive cupping with a dense superior arcuate scotoma on VF. The left eye appears healthy. What is the best treatment option for this patient?
    a. SLT
    b. Phacoemulsification/iStent
    c. Phacoemulsification/Hydrus
    d. Ab interno canaloplasty
    e. Subconjunctival MIGS

9. Which of the following is true regarding bleb failure after subconjunctival MIGS procedures?
    a. MMC does not reduce the risk of bleb failure
    b. The needling rate in the gel stent pivotal study was higher than that in the microshunt pivotal study
    c. Needling failed blebs is ineffective at reestablishing IOP control
    d. Patients with diabetes are less likely to experience bleb failure than those without diabetes