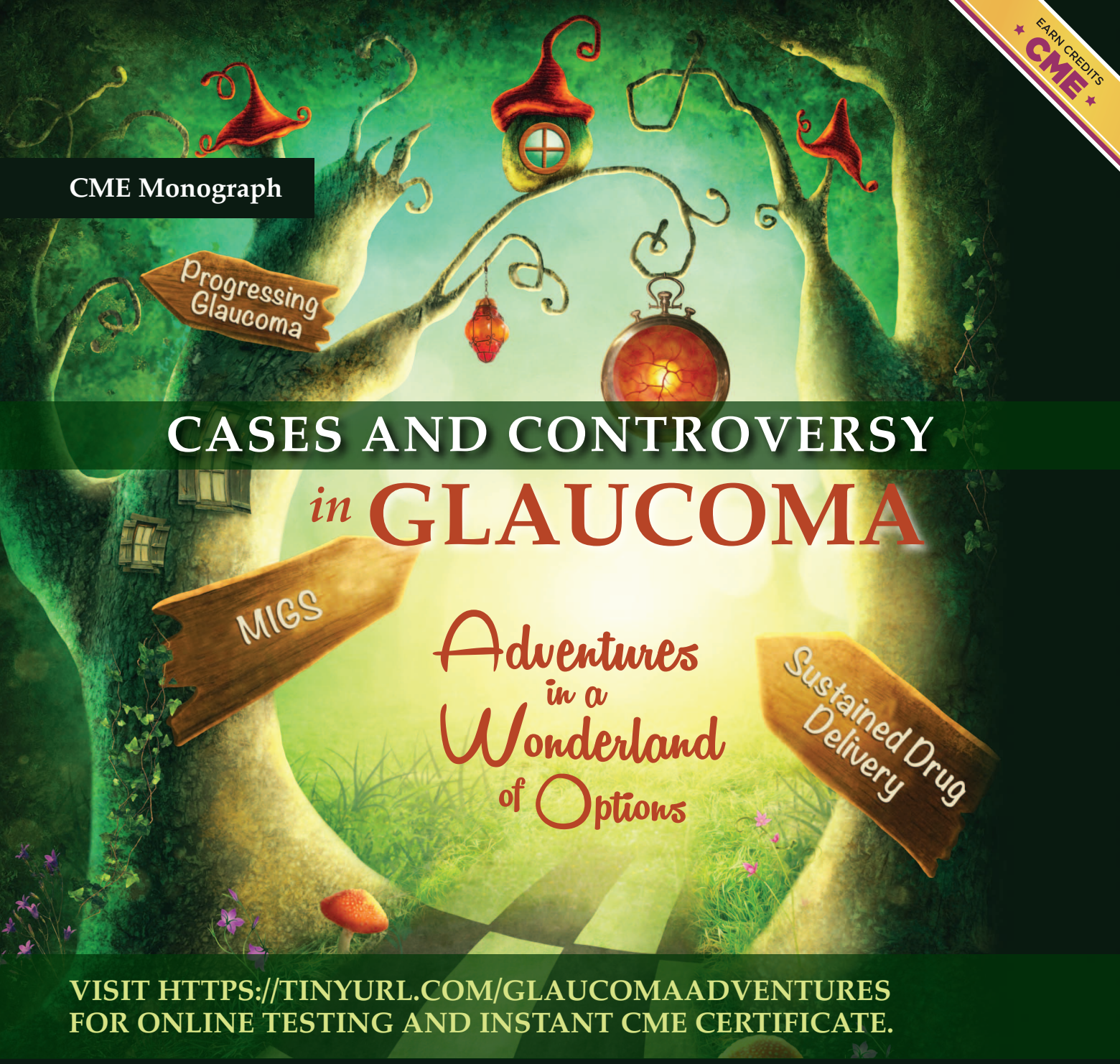

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ORIGINAL RELEASE: MAY 1, 2021
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This continuing medical education activity is provided by **New York Eye and Ear Infirmary of Mount Sinai**. This educational activity was developed and implemented in collaboration with **MedEdicus LLC**.

New York Eye and Ear Infirmary of Mount Sinai

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This educational activity consists of a supplement and ten (10) study questions. The participant should, in order, read the learning objectives contained at the beginning of this supplement, read the supplement, answer all questions in the post test, and complete the Activity Evaluation/Credit Request form. To receive credit for this activity, please follow the instructions provided on the post test and Activity Evaluation/Credit Request form. This educational activity should take a maximum of 1.5 hours to complete.

ACTIVITY DESCRIPTION

Topical treatments for glaucoma have important limitations related to efficacy over time, adverse effects, and the burden of frequent instillation. When patients and their clinicians decide that it is time to move to a different treatment modality, the vast array of options can be daunting. In this educational activity, based on a live virtual symposium held during the 2020 Annual Meeting of the American Academy of Ophthalmology, experts discuss recent advances in both implantable sustained drug delivery and minimally invasive glaucoma surgery. Several cases will be used to illustrate patient-centered decision-making to achieve the best possible visual and quality of life outcomes. The desired results of this educational activity are for learners to employ patient-centered care to select treatment options for glaucoma that achieve the best possible outcomes.

TARGET AUDIENCE

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

LEARNING OBJECTIVES

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

- Discuss safety and efficacy data for approved and emerging sustained drug delivery devices for glaucoma
- Identify patients with glaucoma most likely to benefit from sustained drug delivery
- Select appropriate MIGS procedures according to individual patient needs and characteristics

ACCREDITATION STATEMENT

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Adventures in a Wonderland of Options

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INTRODUCTION

The glaucoma treatment paradigm is shifting. The role of topical medical therapy—long the mainstay of first-line treatment—is being challenged by novel drug delivery systems, laser therapy, and minimally invasive glaucoma surgery (MIGS). In this educational activity, a panel of expert clinicians will review the shortcomings of topical medical therapy, provide insights on data supporting novel first-line approaches to glaucoma care, and present a series of clinical cases demonstrating the roles of novel therapies and the process of individualizing patient care using these new therapeutic options.

QUALITY OF LIFE, GLAUCOMA, AND TOPICAL THERAPY

Glaucoma has a significant negative impact on patient quality of life (QOL). Various studies have demonstrated reduced QOL in patients with glaucoma compared with age-matched patients without glaucoma and greater reductions in QOL with more advanced glaucoma and visual field loss.[1,2] The adverse effects of glaucoma on QOL are evident from the time of diagnosis.[3-5] In the Collaborative Initial Glaucoma Treatment Study, approximately 50% of 607 newly diagnosed patients expressed at least a moderate fear of blindness upon being told they had glaucoma, a proportion that decreased to approximately 25% over the 5-year study.[6]

Glaucoma therapy also affects QOL. Multiple aspects of daily self-dosing of topical medications are determinants of patient satisfaction with glaucoma therapy, including adverse effects and difficulty administering eye drops.[7,8] In one study, patients were willing to pay more for topical medications that did not cause blurred vision, drowsiness, stinging, or tearing and that could be dosed once daily vs 3 times daily.[9,10] In another study, patient satisfaction with therapy was adversely affected by ocular irritation, conjunctival hyperemia, and lack of ease and convenience of dosing.[11] The ocular surface disease (OSD) aggravated by glaucoma therapy also adversely affects QOL. Symptoms of OSD, which are comorbid in 30% to 70% of patients with glaucoma,[12-18] also adversely affect glaucoma-related QOL.[18,19]

ADVANCING THROUGH THE GLAUCOMA TREATMENT PARADIGM

The standard clinical approach to glaucoma management starts with topical eye drop medications, followed, if needed, by laser therapy, with surgical interventions reserved for those whose glaucoma proves recalcitrant to less-invasive options. Medical therapy, however, has multiple important limitations, and there are numerous reasons in 2021 to revisit this traditional approach to intraocular pressure (IOP) reduction.

The most important limitation of topical medical therapy for glaucoma is poor adherence. Low adherence rates to chronic glaucoma medical therapy have been well documented and extensively reviewed.[20] Poor adherence to therapy has important clinical consequences; patients who are < 80% adherent are significantly more likely to have more severe visual field defects than those who are more adherent.[21] In addition, many patients require > 1 topical medication to achieve their IOP goals.[22] Multidrug regimens increase the risk of both adverse effects and nonadherence, and the addition of a third or fourth topical medication has a low probability of long-term success.[23]

Laser and surgical interventions are feasible alternatives to medical therapy as first-line interventions.[24-27] In recent years, MIGS procedures—many with more favorable safety profiles than traditional trabeculectomy or tube-shunt surgery—have positioned surgery earlier in the treatment cascade.[28,29] Most recently, the emergence of sustained drug delivery platforms offers the potential for long-term glaucoma therapy without adherence issues.[30,31]

SUSTAINED DRUG DELIVERY PLATFORMS FOR GLAUCOMA

Unlike topical therapy, which delivers pulsed therapy with each dose, sustained drug delivery devices have in common the goal of delivering a constant supply of medication over the device's lifespan. This has the effect of maintaining steady-state pharmacokinetics and pharmacodynamics, eliminating the peak and trough IOP effects seen as each dose wears off before the next is administered.

The bimatoprost sustained-release (SR) intracameral implant (Durysta) has already received approval from the US Food and Drug Administration (FDA), and the travoprost implant (iDose) is currently in phase 3 evaluation. Several other innovative sustained drug delivery platforms for glaucoma medications are in clinical development **(Figure 1)**.

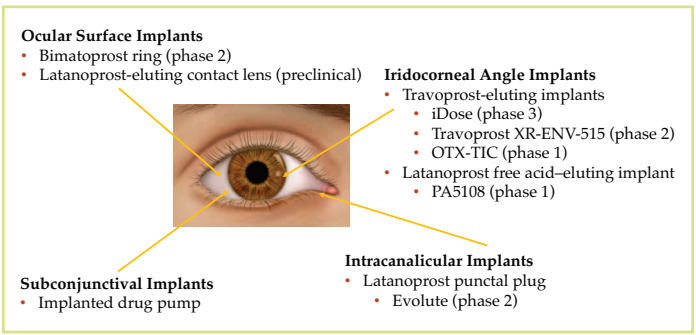

Figure 1. Overview of sustained drug delivery platforms in development for glaucoma

Bimatoprost Sustained-Release Implant

The bimatoprost SR implant is a biodegradable polymer-based delivery system that gradually releases bimatoprost into the aqueous humor over 4 to 6 months **(Figure 2)**.[32] The implant is administered to the anterior chamber via a peripheral corneal injection using an integrated, preloaded delivery handpiece. It is approved for single administration for the reduction of IOP in patients with open-angle glaucoma (OAG) or ocular hypertension.[33]

Following favorable results in a phase 2 trial (APOLLO),[32] bimatoprost SR was evaluated in a pair of phase 3 studies (ARTEMIS 1 and 2).[34,35] Together, the ARTEMIS studies enrolled 1122 patients with OAG (approximately three-fourths) or ocular hypertension (approximately one-fourth) who received bimatoprost SR 10 μg or 15 μg dosed at day 1, week 16, and week 32, or topical timolol, 0.5%, twice daily with a sham injection for masking purposes.[35,36] In a pooled analysis, both implant strengths were noninferior to timolol through week 12 (the studies' primary end point), with mean IOP reductions of approximately 6 to 8 mm Hg at weeks 2, 6, and 12 that were

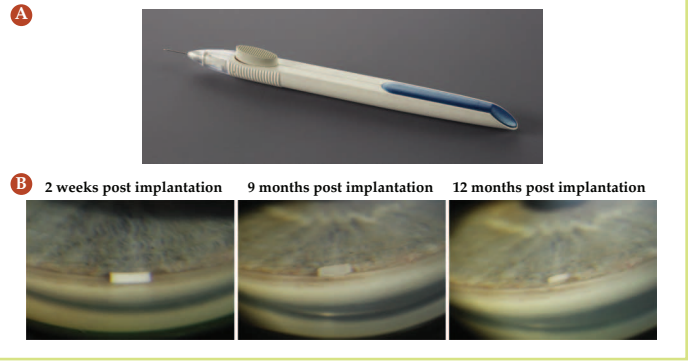

Figure 2. Bimatoprost sustained-release intracameral implant on its preloaded inserter (A) and in the anterior chamber at various timepoints after implantation (B)[32]

Reprinted from *American Journal of Ophthalmology*, 175, Lewis RA, Christie WC, Day DG, et al, Bimatoprost sustained-release implants for glaucoma therapy: 6-month results from a phase I/II clinical trial, 137-147, Copyright 2017, with permission from Elsevier.

numerically greater than those seen in the timolol group. At 12 months, approximately 80% of eyes remained adequately controlled without the need for further interventions after the last implant at week 12.

Significant differences in the rate of visual field loss were seen between the bimatoprost SR and timolol groups in ARTEMIS.[36] Among 293 patients in the bimatoprost SR 10 μg and timolol groups who had visual field data at baseline and 12 months, the visual field mean deviation worsened by 0.8 dB/year in the timolol group, but remained unchanged in the bimatoprost SR group ($P = .049$).

Common safety issues with bimatoprost SR 10 μg (n = 372) vs timolol (n = 370) in the ARTEMIS trials included conjunctival hyperemia (27.2% vs 16.8%, respectively), foreign body sensation (10.2% vs 3.5%, respectively), eye pain (9.7% vs 4.3%, respectively), photophobia (8.6% vs 1.1%, respectively), and conjunctival hemorrhage (7.5% vs 5.9%, respectively).[36] To distinguish between injection- and drug-related adverse events, a separate analysis of adverse events occurring > 2 days after implant/sham was conducted and revealed substantially lower rates of these adverse events that were similar between groups, suggesting they are primarily attributable to the injection procedure. Differences in endothelial cell density changes between groups in ARTEMIS were minimal (5.4% over 20 months with bimatoprost SR 10 μg vs 3.0% with timolol; difference was not significant), and no changes in central corneal thickness were observed over 20 months. The extent of endothelial cell loss increased with repeated dosing, with 10.2% of eyes receiving bimatoprost SR 10 μg and 21.8% of eyes receiving bimatoprost SR 15 μg manifesting endothelial cell loss ≥ 20% following 3 implantations at every-16-week intervals.

Travoprost Implant

The travoprost implant is a titanium implant measuring 1.8 × 0.5 mm, featuring a scleral anchor on one end and a drug repository of high-potency travoprost on the other end.[37] The device is preloaded onto an inserter and is intended for ab interno implantation through the trabecular meshwork, with the anchor engaging sclera to ensure stability of the device **(Figure 3)**.[38] Drug elution is membrane controlled with zero-order kinetics.

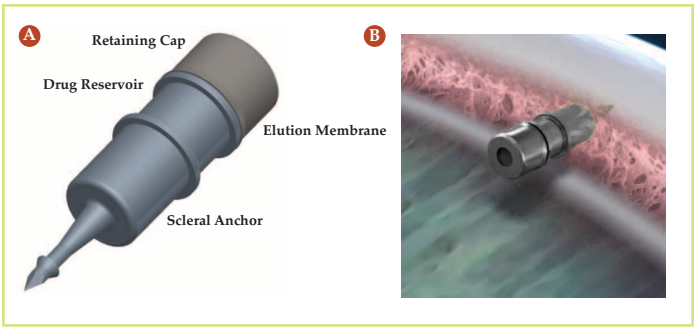

Figure 3. Travoprost sustained-release trabecular implant: (A) elements of the insert; (B) placement in the anterior chamber[38]

Reprinted with permission from Shouchane-Blum K, et al. *Clin Exp Vis Eye Res J.* 2019;2:22-29. Copyright 2019 by Shouchane-Blum K, Geffen N, Zahavi A.

In a phase 2 trial in the United States, fast- and slow-eluting versions of the travoprost implant were compared with topical timolol, 0.5%, twice daily.[39] Through 1 year of follow-up, mean IOP reductions in the pooled implant groups ranged from 7.9 to 8.5 mm Hg, whereas timolol consistently delivered mean IOP reductions of 7.6 mm Hg. By month 12, the timolol group required 31% more supplemental medications than did the implant groups (average of 0.55 medications/eye in the implant groups and 0.72 medications/eye in the timolol group). Interestingly, no cases of hyperemia were reported in either of the implant groups. A phase 3 trial is under way.[40]

CASE 1: GLAUCOMA CARE IN THE COVID-19 ERA

From the Files of E. Randy Craven, MD

A 68-year-old woman with early primary open-angle glaucoma (POAG) OD was reluctant to attend office visits for glaucoma monitoring because of COVID-19. She lived alone and only infrequently left her home. Her peak IOP at the time of diagnosis was 26 mm Hg OD. ***Figure 4*** *shows her retinal nerve fiber layer optical coherence tomography images and visual fields. She had little IOP response to timolol, developed allergic conjunctivitis while using dorzolamide/ timolol, and was now well controlled on latanoprost once daily OD, with an IOP of 17 mm Hg. The appearance of her right eye, which was hyperemic and had an asymmetrical lash appearance, was bothersome to her. She requested an alternate therapy. After discussion with the patient, the decision was made to proceed with the bimatoprost SR implant OD, with the goal of controlling her IOP while minimizing the ocular surface adverse effects associated with prostaglandin therapy.*

Dr Craven: Intraocular delivery of prostaglandins should theoretically reduce the ocular surface adverse effects of these medications by reducing ocular surface exposure. In the bimatoprost SR phase 2 study, the incidence of conjunctival hyperemia with onset > 2 days after implantation was lower in the 75 patients receiving bimatoprost SR than in the 75 patients receiving topical bimatoprost (17.3% vs 28%).[41] Also, in the phase 2 travoprost implant study, no conjunctival hyperemia was seen in implanted eyes.[42] This observation is consistent with a study in dogs demonstrating undetectable levels of bimatoprost on the ocular surface following bimatoprost SR intracameral implantation.[43]

Owing to COVID-19, I have not yet had the chance to reevaluate the patient in Case 1 to assess her ocular surface status after implantation. What is your experience with the bimatoprost implant?

Dr Bedrood: In my practice, I look for people who have a documented good IOP response to topical prostaglandin therapy and who would benefit from discontinuing topical therapy. This may be related to adverse effects such as redness or lash changes, as seen in the patient in Case 1. Other patients may have trouble with self-dosing because of tremor or cognitive limitations. Also, some people simply prefer to avoid the daily responsibility of medical therapy. These are all indications for considering the bimatoprost implant in my practice. I tell patients that it is a one-time treatment, and we hope that they will be among the subset that enjoys long-term IOP reduction after implantation.

Dr Ristvedt: I consider the bimatoprost implant as well as selective laser trabeculoplasty in many of my patients with glaucoma and comorbid OSD. I discuss both options with my patients in order to reduce medication reliance and select the one that is best for each patient. I agree with Dr Bedrood that I want to see a good IOP response to topical therapy before I inject the implant into the eye so that I can avoid risk in patients who will derive little or no benefit.

Dr Craven: There are potential advantages for this option for patients with glaucoma at every age. Although it is not approved for use in pediatric glaucoma, in younger patients—perhaps those with juvenile OAG—sustained-release therapies offer the potential to avoid years of exposing the ocular surface to the toxic effects of eye drops.[44] In older patients, as Dr Bedrood pointed out, this approach can reduce the challenges of self-dosing for those who struggle to get the drops in their eyes.

Dr Ahmed: I also use the bimatoprost implant in patients who admit to significant nonadherence with their current topical

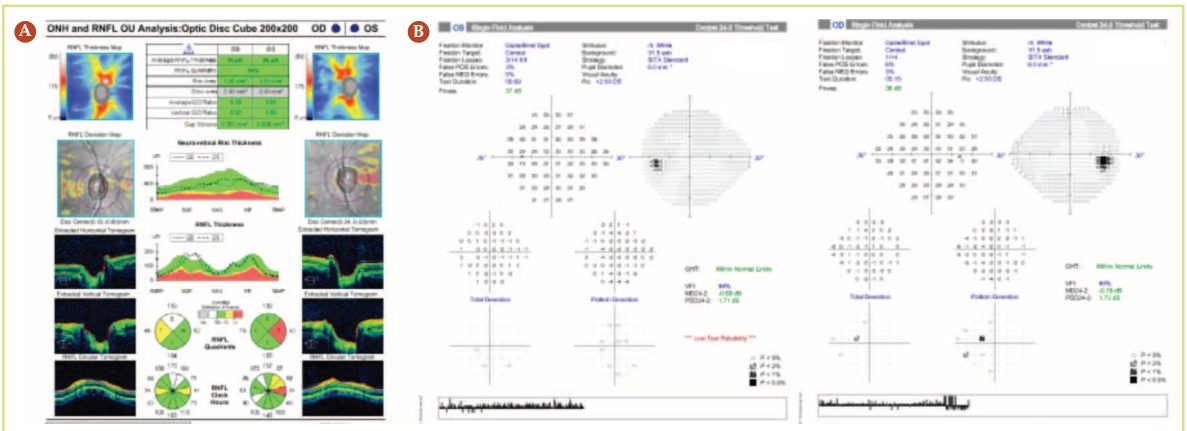

Figure 4. Retinal nerve fiber layer optical coherence tomography images (A) and visual fields (B) of the patient presented in Case 1

therapy. Can we share some pearls both for talking to patients about this option and for the implantation process?

Dr Craven: I have done the implantation both at the slitlamp in the office and under the microscope in the surgery center. This is a very patient-centered choice, based on both how comfortable the patient feels about an office procedure and on how comfortable I feel that he or she can stay still during the procedure. I prep with topical anesthetic and 5% povidone iodine in either setting.

Dr Bedrood: There is value in doing the first few implantations in the more controlled setting of a surgery center and transitioning to the slitlamp. I use a lid speculum and lidocaine gel. I enter the eye temporally on a downward angle and inject once I see 2 bevel lengths of injector in the anterior chamber. I use the same technique for phakic and pseudophakic eyes. I do not use postoperative antibiotics.

Dr Ahmed: I am often asked if I perform specular microscopy before and after implantation to monitor for corneal endothelial cell loss, and the answer is No. I am also asked if implant movement is a potential cause of endothelial cell loss, and I do not think it is. These implants tend to settle in the inferior angle and stay in place once implanted. Questions on the use of multiple implants in the eye at one time, stacking, and the impact on the peripheral cornea in certain patients still need further study. I look forward to answers to these questions.

MINIMALLY INVASIVE GLAUCOMA SURGERY

The MIGS family of procedures has expanded in recent years **(Table 1)**.[28,29] In the United Sates, numerous procedures have been cleared by the FDA to enhance aqueous humor drainage through Schlemm canal without bleb formation or into the

Table 1. Overview of the Minimally Invasive Glaucoma Surgery Family of Procedures

Procedure	Device	Approved in the United States	Bleb Forming
Schlemm canal	Trabectome	Yes	No
	iStent/iStent Inject	Yes*	No
	Hydrus	Yes*	No
	Kahook Dual Blade	Yes	No
	iTrack (for GATT and ABiC)	Yes	No
	OMNI/ VISCO360	Yes	No
Suprachoroidal	iStent Supra	No	No
	Gold Shunt	No	No
Subconjunctival	EX-PRESS	Yes	**Yes**
	XEN	Yes	**Yes**
	PreserFlo MicroShunt	No†	**Yes**

Abbreviations: ABiC, ab interno canaloplasty; GATT, gonioscopy-assisted transluminal trabeculotomy.

* Approved in the United States ***only in combination with cataract surgery***

† Currently in phase 3 clinical trials

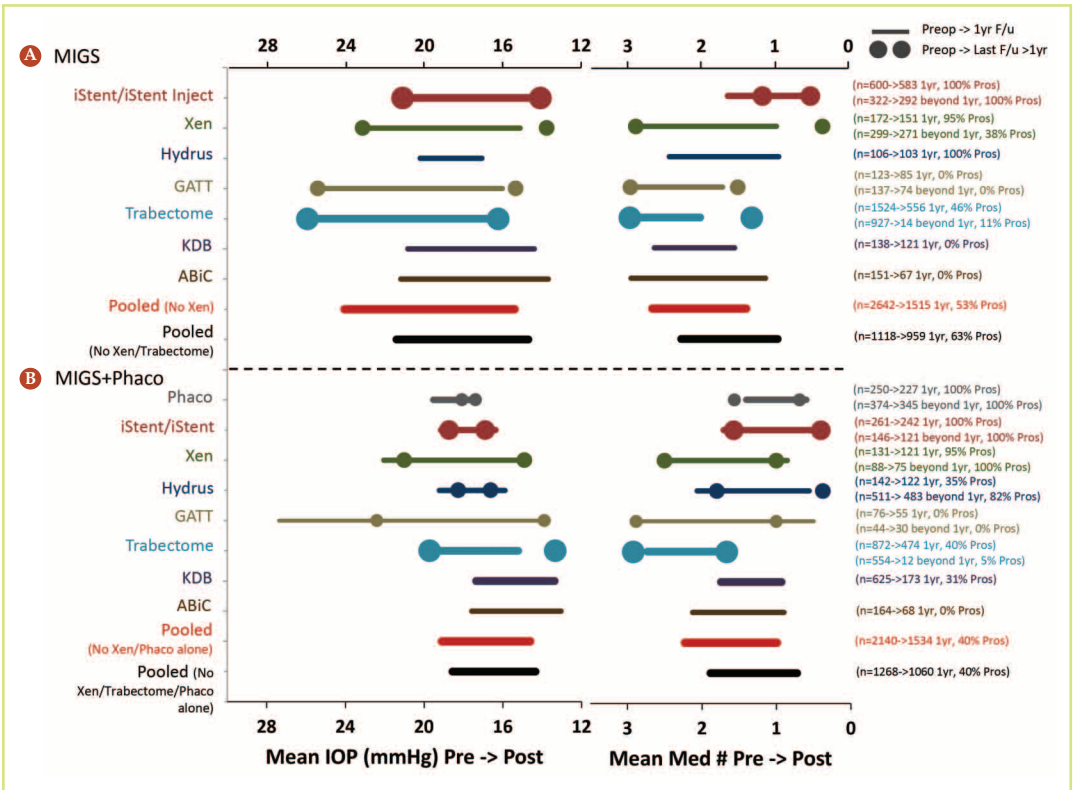

Figure 5. Summary of intraocular and medication reductions in trials evaluating minimally invasive glaucoma surgery standalone procedures (A) and in combination with phacoemulsification (B)

Note: These were not head-to-head studies, and cross-procedural comparisons cannot be made. N are total participants across trials. % Pros is the proportion of trials that were prospective. Line length indicates mean change across studies. Thickness is proportional to the number of studies included. Dots indicate the results of studies with > 1 year of follow-up. Distance between dots is the mean change in those studies.

Abbreviations: ABiC, ab interno canaloplasty; F/u, follow-up; GATT, gonioscopy-assisted transluminal trabeculotomy; KDB, Kahook Dual Blade; MIGS, minimally invasive glaucoma surgery; Phaco, phacoemulsification.

subconjunctival space with bleb formation. Some require pairing with cataract surgery, whereas others can be performed as standalone procedures. Additional techniques deliver aqueous to the suprachoroidal space, although none are currently available in the US marketplace.

The quality of evidence supporting the absolute and relative efficacy and safety of many MIGS procedures is limited by the reality that many were cleared by the FDA through the 510(k) pathway, so that high-quality data from prospective multicenter registry studies are unavailable. As a result, many studies of MIGS procedures are single-center reports, collected retrospectively, and typically without control groups.

A recent comprehensive review of the MIGS literature summarized the findings of 275 studies reporting the efficacy and safety of 7 common surgeries performed either as standalone procedures or in combination with phacoemulsification (G. Durr, MD, S. Samet, MD, and I. K. Ahmed, MD, unpublished data, 2020). **Figure 5** summarizes key efficacy outcomes—reductions in both IOP and in the need for IOP-lowering medications. In general, mean IOP reductions were approximately 6 to 8 mm Hg, and mean medication reductions were approximately 1.5 to 2 medications for most procedures.

From a safety perspective, intraoperative complications were uncommon aside from the expected blood reflux into the anterior chamber associated with incisional and excisional meshwork procedures. **Table 2** summarizes postoperative complications occurring in > 2% of eyes (G. Durr, MD, S. Samet, MD, and I. K. Ahmed, MD, unpublished data, 2020).

WHICH MIGS TO CHOOSE? INDIVIDUALIZING CARE

Several factors inform the selection of a specific MIGS procedure for each patient **(Figure 6)**.[28,29] A key issue is the severity of the disease, which is related to both the magnitude of IOP reduction sought from surgery and the threshold for surgical risk balanced against the potential of additional surgery in the future. Eyes with mild to moderate glaucoma typically do not have fixation-threatening visual field loss and most often require modest IOP reductions, in which case only modest surgical risk is justifiable. Conversely, eyes with advanced disease typically require larger IOP reductions to achieve low target IOP and prevent progression to symptomatic or more symptomatic vision loss; in these eyes, the risk of surgery is warranted, considering the risk of disease progression if IOP reduction is not achieved. If the goal of surgery is to reduce the glaucoma medication burden, risk tolerance is typically quite low and favors the use of the safest procedures available.

Another key issue is the eye's phakic status. A sufficiently large cataract can contribute a phacomorphic component to glaucoma and may warrant removal on that basis alone. Also, a visually significant cataract may afford the opportunity for a combined glaucoma surgical procedure that would not have been indicated as a standalone procedure; an example is the desire to reduce the medication burden in an eye with well-controlled glaucoma. Additionally, from a pragmatic perspective, some MIGS procedures are only indicated in combination with cataract surgery.

Table 2. Common (> 2%) Postoperative Complications* Reported in Minimally Invasive Glaucoma Surgery Studies

Procedure	N	Common Complications (> 2%)
iStent	1223	• Device malposition (3.6%) or obstruction (6.4%) • IOP spike (2.1%-3.1%) • Ocular surface disease (16.1%) • Endothelial cell loss (13.2%) • Cataract progression (7.1% in standalone cases)
XEN	504	• Shallow anterior chamber (5.6%) • Hypotony (3.6%) • Needling (38.8%) • Secondary surgery (4.3%)
Hydrus	542	• Obstruction (2.8%) • Uveitis (5.6%) • Conjunctivitis (5.7%) • Cystoid macular edema (2.2%) • Focal PAS (13.3%) • Visual field progression (2.9%)
GATT	317	• IOP spike (6%) • Secondary surgery (18.6%) • Cystoid macular edema (3.1%) • Visual acuity loss (5.6%)
Trabectome	2419	• IOP spike (7.3%) • Secondary surgery (15.9%) • Recurrent uveitis (20%)
KDB	763	• IOP spike (6.7%)
ABiC	315	• Secondary surgery (1.0%)

Abbreviations: Abbreviations: ABiC, ab interno canaloplasty; GATT, gonioscopy-assisted transluminal trabeculotomy; IOP, intraocular pressure; KDB, Kahook Dual Blade; PAS, peripheral anterior synechiae.

* Excluding blood reflux/hyphema

The mechanism of IOP elevation is another key consideration. In eyes with elevated episcleral venous pressure, for example, angle-based procedures are unlikely to succeed because the impediment to aqueous outflow is distal to the trabecular meshwork and Schlemm canal.[28] Although relatively uncommon, elevated episcleral venous pressure can occur in eyes with thyroid eye disease, scleral buckling procedures, and Sturge-Weber syndrome, among others.

Other issues can occur in some patients. Treatment-naïve patients may benefit from primary MIGS procedures to avoid the safety and QOL issue associated with medical therapy.[45] A prior positive response to selective laser trabeculoplasty suggests that the distal outflow system is intact and may favor the use of angle-based procedures.[46] Bleb-based MIGS procedures typically deliver the greatest IOP reductions and lowest target IOP,[28,29] but these may be less effective in eyes with conjunctival scarring, such as after retinal detachment repair or prior failed glaucoma filtering surgery. Blebs may also be undesirable in patients who wish to use contact lenses for refractive correction postoperatively.

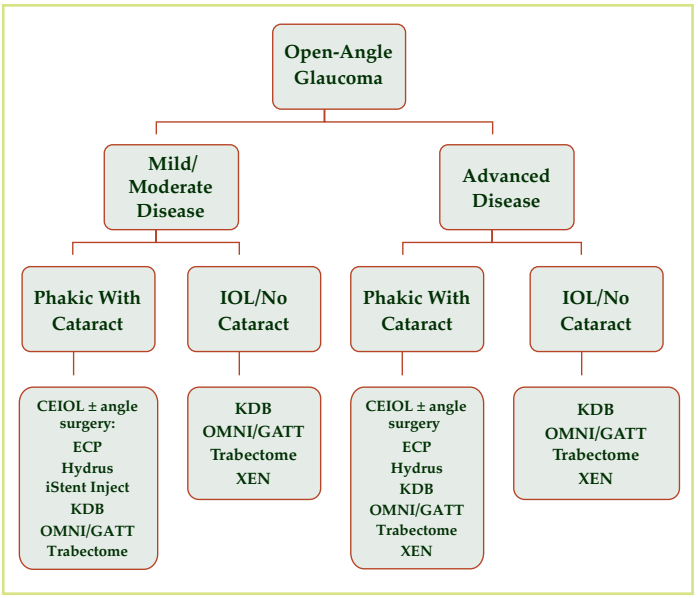

Figure 6. Algorithm with which to assess patient factors in selecting appropriate minimally invasive glaucoma surgical procedures

Note: Algorithm based on literature review and expert opinion (Sahar Bedrood, MD, PhD)

Abbreviations: ABiC, ab interno canaloplasty; CEIOL, cataract extraction with intraocular lens placement; ECP, endoscopic cyclophotocoagulation; GATT, gonioscopy-assisted transluminal trabeculotomy; IOL, intraocular lens; KDB, Kahook Dual Blade.

CASE 2: EARLY PIGMENTARY GLAUCOMA AND CATARACT

From the Files of Sahar Bedrood, MD, PhD

A 71-year-old woman with bilateral pigment dispersion syndrome had pigmentary glaucoma OS and was a glaucoma suspect OD. Her best-corrected visual acuity (BCVA) was 20/25 OD and 20/30 OS. Her IOP was 15 mm Hg OD without treatment and 19 mm Hg OS using bimatoprost, with a peak IOP of 18 and 30 mm Hg, respectively. Her pachymetry was an average of 540 µm OU. Her iridocorneal angles were open with moderate pigment. The right eye was pseudophakic, and the left eye had 2+ nuclear sclerosis; the patient was bothered by glare. ***Figure 7*** *shows her retinal nerve fiber layer optical coherence tomography images and visual fields. After discussion with the patient, the decision was made to proceed with combined phacoemulsification and trabecular microbypass shunt (iStent Inject) in the left eye.*

Dr Ahmed: Dr Bedrood's algorithm for selecting procedures according to patient characteristics **(Figure 6)** presents several options for combined procedures in phakic eyes with mild to moderate disease. Once we get to the bottom boxes of the algorithm, how do we select from among the various procedures?

Dr Ristvedt: In patients with early disease who have responded well to prostaglandin monotherapy, I tend to combine cataract surgery with an angle procedure, such as a trabecular stent or combined trabeculotomy and viscodilation (OMNI), with the goal of achieving medication independence.

Dr Craven: The patient's expectations are also an important consideration. I strive to help my patients understand that the goal of most angle procedures is the reduction of medications, but not necessarily the elimination of medications. Also, if rapid visual recovery is critical, this can also inform my selection of procedures to pair with cataract surgery. In such cases, I might select a stenting procedure over a cutting procedure in order to minimize bleeding.

Dr Ahmed: That is a key point. I also tend toward selecting stenting procedures over incisional or excisional procedures if rapid visual recovery is desirable. If this patient was pseudophakic, I would consider a procedure that improves aqueous egress over a larger extent of the meshwork/canal/collector channel system to optimize the efficacy of a standalone procedure.

Dr Bedrood: This patient's disease was early stage, with minimal visual field loss, and her IOP goal was in the mid-high teens, which she was essentially meeting preoperatively. Her surgical goal was primarily medication reduction, so I wanted a low-risk procedure. The nature of her disease—pigmentary glaucoma—is a primary meshwork condition, so bypassing the meshwork was logical. Her desire for rapid visual recovery was another reason that led me to select stenting rather than a cutting procedure. Both the iStent and the iStent Inject are indicated for the reduction of IOP in patients with medically treated mild to moderate OAG undergoing cataract surgery. In a randomized trial comparing combined phacoemulsification and iStent implantation with phacoemulsification alone, 72% of the 117 patients in the combination group and 50% of the 123 patients in the phacoemulsification-alone group had IOP ≤ 21 mm Hg at

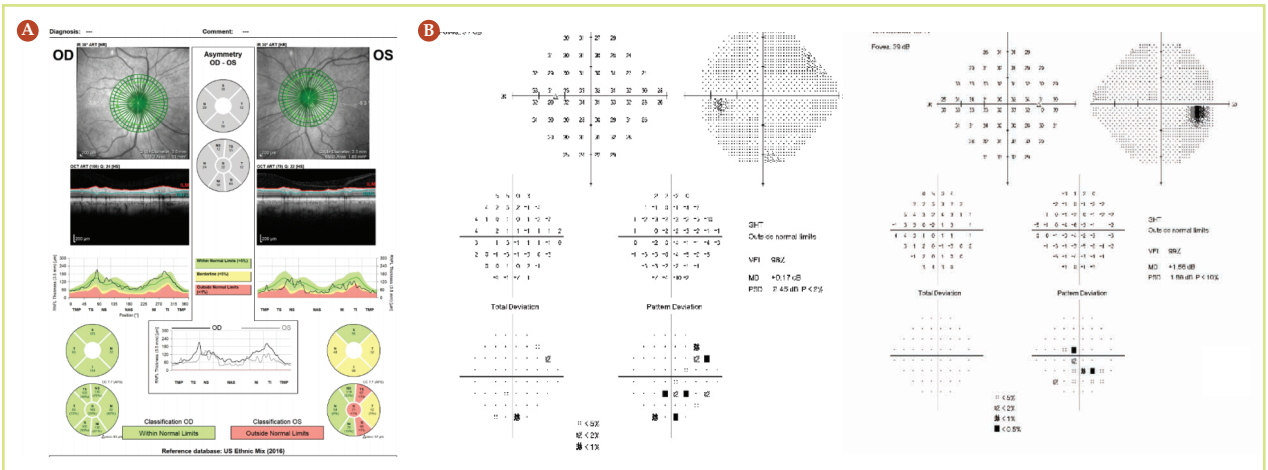

Figure 7. Retinal nerve fiber layer optical coherence tomography images (A) and visual fields (B) of the patient presented in Case 2

12 months ($P < .001$); the proportions of eyes with IOP reductions ≥ 20% were 66% and 48%, respectively ($P = .003$).[47] Stent-related complications in the 111 patients in the combination group included obstruction (4%), malposition (3%), and repositioning (3%). In a similar randomized trial comparing combined phacoemulsification and iStent Inject implantation with phacoemulsification alone, 76% of the 380 patients in the combination group and 62% of the 118 patients in the phacoemulsification-alone group had unmedicated diurnal IOP reductions ≥ 20% at 24 months ($P = .005$).[48] Common complications in 386 stented eyes included obstruction (6.2%), inflammation (5.7%), and secondary surgery (5.4%).

Dr Ahmed: How does the use of blood thinners affect your choice of procedures?

Dr Bedrood: It really does not because the bleeding is so minimal in most of the procedures. I do not generally have patients hold their blood thinners.

Dr Ahmed: For cutting procedures involving more than 30° to 40° of the angle, I am somewhat concerned for bleeding. If we cannot safely stop blood thinners, I will opt for a stenting procedure instead.

Dr Ristvedt: I stop blood thinners for cutting procedures.

Dr Craven: In my experience, the iStent Inject has a lower likelihood of bleeding than that seen with any of the other devices, and certainly less than that with cutting procedures. Endocyclophotocoagulation is another option if I am concerned about bleeding.

CASE 3: SEVERE PRIMARY OPEN-ANGLE GLAUCOMA WITH CATARACT

From the Files of Deborah Ristvedt, DO

An 82-year-old woman with advanced glaucoma has IOP of 15 mm Hg OD and 16 mm Hg OS on 3 medications. She was noted to have visual field progression approximately 3 years ago that had since stabilized at her current level of IOP control. Her BCVA was 20/30 OD and 20/25 OS, and she had thin corneas (514 µm OD and 517 µm OS). She also had 2+ nuclear sclerotic cataracts with posterior subcapsular cataract changes in both eyes. Her visual fields are shown in ***Figure 8*** *and reveal more advanced disease OD than OS. She would like to see better and was open to combined glaucoma surgery to better control her disease. After discussion with the patient, the decision was made to perform phacoemulsification with a gel stent (XEN) OD and phacoemulsification with combined trabeculotomy and viscodilation OS.*

Dr Craven: This is a patient with moderate to advanced POAG with IOP in the mid-teens on 3 medications who also has a visually significant cataract. I agree with the plan to address the glaucoma at the time of cataract surgery. A reduction in the medication burden from 3 medications would be helpful, and given her recent progression, she may benefit from a lower IOP as well. Also, given that she has paracentral visual field loss threatening fixation in both eyes, the addition of a glaucoma procedure reduces the risk of a snuff-out event from a postoperative IOP spike. Starting with the left eye, how did you select the specific procedure you performed?

Dr Ristvedt: We chose a gel stent in the right eye because of the more advanced disease. In the XEN registry trial, mean IOP reductions at 12 months were on the order of 9 mm Hg, medications were reduced by a mean of 51% in patients with refractory glaucoma, and 75.4% of 65 patients achieved IOP reductions ≥ 20% on the same or fewer medications.[49] Common adverse events included hypotony (24.6%) and IOP spikes (21.5%), and 32.3% of eyes required bleb needling. In a multicenter retrospective comparison of XEN to trabeculectomy in eyes with uncontrolled glaucoma, the 30-month success rates of both procedures were comparable, with similar proportions of patients achieving IOP between 6 and 17 mm Hg inclusive with or without medications.[50] Bleb leaks/dehiscences occurred in 12 eyes receiving trabeculectomy and in 3 eyes receiving the device, and needling was required in 52 and 80 eyes, respectively.

Dr Ahmed: Has the COVID-19 pandemic affected your decision-making in any way?

Dr Ristvedt: Yes. This case occurred in spring 2020 when we anticipated that elective surgery might soon be suspended as a result of COVID-19. The patient was reluctant to return repeatedly to the office because of the pandemic. This also informed our decision to perform XEN implantation vs trabeculectomy. In the multicenter retrospective study, compared with patients receiving trabeculectomy, those receiving the device required fewer in-clinic interventions ($P = .0004$), had fewer postoperative visits ($P < .001$), and lost less BCVA postoperatively ($P = .0383$).[51]

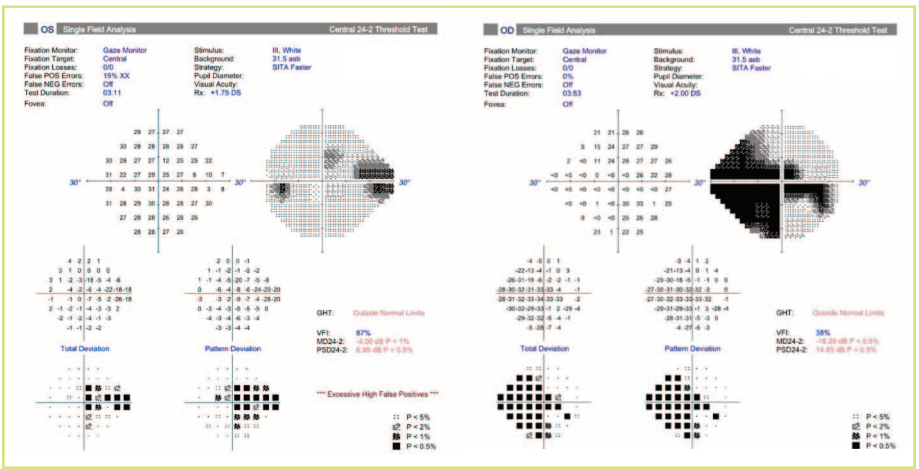

Figure 8. Visual fields of the patient presented in Case 3

Dr Ahmed: I agree with your decision to optimize safety by selecting a subconjunctival MIGS procedure over trabeculectomy. The microshunt (PreserFlo MicroShunt) is also an option in patients such as this, although it is not yet available in the United States. A recent randomized trial compared the microshunt with trabeculectomy in eyes with POAG on maximal medical therapy.[52] After the first 12 months of this planned 24-month trial, mean IOP reductions were 33% in the 395 patients receiving the device and 47% in the 132 patients receiving trabeculectomy, with medication reductions of 72% and 85%, respectively. Common complications included elevated IOP requiring treatment (53% and 56%, respectively) and hypotony (31% and 51%, respectively). Additional studies have reported similar outcomes.[53-55]

Dr Ristvedt: As with trabeculectomy, it appears that the use of mitomycin C (MMC) is essential to the success of these subconjunctival MIGS procedures.

Dr Ahmed: Absolutely. In a 2-year European study of PreserFlo MicroShunt surgery with MMC 0.2 mg/mL vs 0.4 mg/mL, IOP and medication burden were slightly better in the higher-dose group (n = 58) than in the lower-dose group (n = 66); mean IOP reductions were 41.3% and 34.8%, respectively, and mean medication reductions were 90.5% and 66.7%, respectively.[53] There is some reluctance on the part of many surgeons to use such high concentrations of MMC, but these procedures have a lower rate of hypotony than does trabeculectomy, so we can use higher MMC concentrations safely. Also, because flow through these MIGS implants is directly posterior, we achieve more posterior blebs and are less likely to get the elevated, cystic, avascular blebs that can arise with trabeculectomy. This bleb morphology is less prone to MMC-related bleb complications such as leaks and blebitis.

Dr Craven: Turning now to the left eye, how did you select the specific procedure you performed?

Dr Ristvedt: The left eye had less extensive visual field loss, so we elected to avoid the risks of bleb-based MIGS. Given that the patient's visual field defects were paracentral and threatened fixation, I felt that a cutting procedure was preferable to a stenting procedure because the former opens a larger channel between the anterior chamber and Schlemm canal and can thus potentially lower IOP better. We selected combined viscodilation and trabeculotomy using OMNI. This procedure uses a common cannula that injects viscoelastic material into Schlemm canal to dilate it and the distal collector channel openings and also allows passage of a microcatheter with which trabeculotomy is performed. Thus, IOP reduction can be achieved by addressing 3 points of resistance to aqueous outflow through the conventional outflow pathway: (1) trabecular meshwork; (2) Schlemm canal; and (3) collector channels.[56–59] In an ongoing prospective, multicenter study (GEMINI) (N = 150), mean IOP reduction at 6 months was 37% and mean medication reduction was 80%.[60] Complications were uncommon and included layered hyphema (4.6%), IOP spikes (2%), and blepharitis (1.3%). Other cutting options include excisional goniotomy with the ab interno goniotomy dual blade (Kahook Dual Blade), incisional goniotomy with an electrosurgical device (Trabectome or TrabEx), and gonioscopy-assisted transluminal trabeculotomy (GATT) performed with a microcatheter (iTrack) or with a 5-0 prolene suture. Excisional goniotomy has been shown in a randomized trial to deliver IOP and medication reductions (17% and 79%, respectively) that were comparable to iStent implantation.[61] Mean IOP reductions following incisional goniotomy range from 23% to 39%,[62-67] and mean medication reductions range from 7% to 45% in studies of various designs and follow-up periods.[63-71] In retrospective studies of various durations, mean IOP reductions of 6% to 67% and mean medication reductions of 37.5% to 93% have been reported following GATT.[72-79]

Dr Craven: Do you have any follow-up data from the patient's postoperative course?

Dr Ristvedt: She did well. Three months postoperatively, she was off all medications, with IOP of 12 mm Hg OD and 11 mm Hg OS.

Dr Ahmed: I would like to ask the same question I asked in Case 2. If we follow the procedure selection algorithm **(Figure 6)** for advanced glaucoma with cataract, the boxes at the bottom have multiple procedural options. How do we select an angle- vs bleb-based procedure for our patients who fall into this category?

Dr Bedrood: I reserve the bleb-based procedures for eyes with moderate or severe glaucoma, those with IOP that is inadequately controlled on multiple medications, or those in which I want a low target IOP—say, in the low teens.

Dr Ahmed: One key feature of MIGS procedures is that they are generally easier to perform than are traditional filtering procedures. As such, they may fall into the armamentarium of non–glaucoma-trained anterior segment surgeons. Dr Ristvedt, as a comprehensive ophthalmologist, can you provide any insight into that perspective?

Dr Ristvedt: I have many patients with glaucoma in my practice, and I believe that there is value in minimizing long-term exposure to chronic topical medical therapy, both in terms of its effects on ocular tissues[44] and on our patients' QOL.[9,11,80] The MIGS family of procedures offers me a chance to address my patients' glaucoma surgically without, as you said, the need for specialty training in traditional glaucoma surgeries. For me, the adoption of bleb-based MIGS was a natural evolution from angle-based MIGS. The XEN is implanted via the same ab interno approach as are the angle stents, so the procedure is familiar. Because its safety profile is more favorable than that of trabeculectomy, with a less intense postoperative course,[51] I feel confident managing these patients postoperatively. I have had to become comfortable with both MMC use and bleb needling for those patients who need them, but these become straightforward with practice.

Dr Ahmed: Dr Craven, please share your thoughts on ab interno vs ab externo XEN implantation.

Dr Craven: When I first started using the XEN, I used the same ab interno approach that was described in the seminal study.[49] I rapidly discovered that this imposed significant limitations in terms of both quadrant location and tissue plane location. With an open-conjunctiva approach, we have much greater freedom to select the best quadrant for implantation, and we have better control over Tenon layer, so we can decide whether to place the distal tip above or below Tenon. We recently evaluated outcomes of ab interno vs ab externo XEN surgery in our practice. In a paper that will be published soon, we found that greater control of Tenon led to lower needling rates.[81]

TAKE-HOME POINTS

Sustained delivery platforms that deliver glaucoma medications over extended periods provide safe and effective reduction of IOP while eliminating nonadherence to topical therapy and reducing ocular surface adverse effects.

Patients with intolerance to topical formulations, with physical or cognitive limitations precluding self-dosing, and with known or suspected nonadherence to topical therapy are excellent candidates for sustained drug delivery options.

Appropriate selection of MIGS procedures for individual patients should be based on factors such as disease severity, phakic status, and therapeutic goals.

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1. In the phase 3 ARTEMIS trials, a series of 3 bimatoprost SR implants delivered at 16-week intervals provided treatment-free IOP control through month 12 in approximately ___ of patients.
   a. 14%
   b. 36%
   c. 54%
   d. 80%

2. In a phase 2 trial, the travoprost-eluting SR device resulted in IOP reductions of approximately _____ mm Hg at 12 months of study.
   a. 5.0 to 5.5
   b. 6.0 to 6.5
   c. 8.0 to 8.5
   d. 10.0 to 10.5

3. According to results of the bimatoprost SR phase 2 study, intraocular delivery of prostaglandins _____ the incidence of conjunctival hyperemia compared with topical dosing.
   a. Increases
   b. Does not affect
   c. Decreases

4. Which of the following patients would be the best candidate for a bimatoprost SR implant?
   a. A patient with a history of nonresponse to topical prostaglandins
   b. A patient with a narrow angle who has difficulty adhering to his/her topical medication
   c. A patient with ocular hypertension and mild OSD
   d. A patient with progressing pseudoexfoliation glaucoma and endothelial cell loss

5. When considering the use of bimatoprost SR, which of the following characteristics does NOT support its use over topical bimatoprost?
   a. Poor adherence with topical bimatoprost
   b. Ocular surface adverse effects of topical bimatoprost
   c. Poor IOP reduction with topical bimatoprost
   d. Arthritis of the hand, making self-administration of drops difficult

6. Why is lens status an important consideration when selecting a MIGS procedure?
   a. The presence of an intraocular lens implant makes MIGS harder to perform
   b. Phakic eyes have a higher risk of a postoperative IOP spike than do pseudophakic eyes
   c. Some procedures require concurrent cataract surgery according to the device's FDA label
   d. MIGS stenting procedures often cause bleeding that can prolong visual recovery and decrease patient satisfaction with concurrent cataract surgery

7. In randomized trials comparing combined phacoemulsification and implantation of an iStent or iStent Inject with phacoemulsification alone, patients receiving the combination were approximately _____ more likely to achieve a ≥ 20% IOP reduction 12 months postoperatively than those receiving phacoemulsification alone.
   a. 5% to 10%
   b. 15% to 20%
   c. 25% to 30%
   d. 40% to 45%

8. A 72-year-old man with a bleeding disorder that requires anticoagulation therapy has visually significant cataracts and early pseudoexfoliation glaucoma that is well controlled with a single medication. He dislikes the hassles of daily self-dosing. Which MIGS device would be most appropriate to offer him in combination with his upcoming cataract surgery?
   a. Excisional goniotomy with the Kahook Dual Blade
   b. iStent
   c. XEN
   d. Trabeculectomy

9. A 78-year-old pseudophakic female with moderate POAG and conjunctival scarring due to severe dry eye disease is considering a MIGS procedure. Which device is the most appropriate for this patient?
   a. Hydrus
   b. iStent
   c. XEN
   d. Excisional goniotomy with the Kahook Dual Blade

10. A 74-year-old pseudophakic woman with advanced POAG has uncontrolled IOP on 3 medications. Which MIGS device is most likely to result in adequate control of her glaucoma?
    a. Excisional goniotomy with the Kahook Dual Blade
    b. iStent
    c. Trabectome
    d. XEN