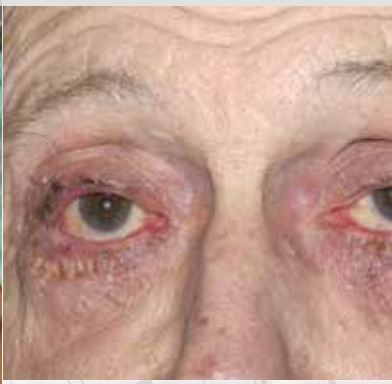
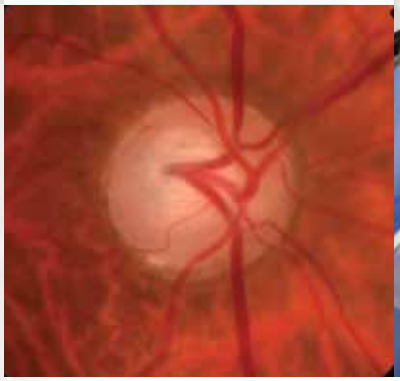
CME MONOGRAPH

Individualizing New Minimally Invasive

Surgical Approaches for Glaucoma





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FACULTY

Iqbal Ike K. Ahmed, MD *(Chair)*
Richard K. Parrish II, MD
Thomas W. Samuelson, MD
Tarek M. Shaarawy, MD, MSc

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CONTENT SOURCE

This continuing medical education (CME) activity captures content from a roundtable discussion held on May 7, 2017.

ACTIVITY DESCRIPTION

Minimally invasive glaucoma surgeries (MIGSs) are noninvasive, permitting use in nonrefractory glaucoma and much earlier in the glaucoma treatment algorithm. New and emerging MIGS procedures offer improved safety, with the efficacy of bleb-based procedures. This activity will use expert insight and evidence from the literature to provide an update on the various MIGS procedures and which procedure would be best suited for which patient.

TARGET AUDIENCE

This educational activity is intended for glaucoma specialists and other ophthalmologists in Europe, Canada, and the United States caring for patients with glaucoma.

LEARNING OBJECTIVES

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

- Differentiate the characteristics of MIGS procedures
- Review the relevant patient characteristics that guide optimal selection of MIGS procedures
- Appraise the rationale and optimal techniques for MIGS bleb-based procedures

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Last Review Date: September 5, 2017

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FACULTY

Iqbal Ike K. Ahmed, MD *(Chair)*
Assistant Professor
Fellowship Director, Glaucoma and
Anterior Segment Surgery Fellowship
Research Director, Kensington Eye Institute
University of Toronto
Division Head, Ophthalmology
Trillium Health Partners
Medical Director, Prism Eye Institute
Co-Medical Director, TLC Mississauga
Mississauga, Canada

Richard K. Parrish II, MD
Edward W. D. Norton Chair in Ophthalmology
Professor
Director, Glaucoma Service
Bascom Palmer Eye Institute
University of Miami Miller School of Medicine
Miami, Florida

Thomas W. Samuelson, MD
Attending Surgeon
Minnesota Eye Consultants
Adjunct Professor
University of Minnesota
Minneapolis, Minnesota

Tarek M. Shaarawy, MD, MSc
Senior Lecturer
Geneva University
Head, Glaucoma Sector
Geneva University Hospitals
Geneva, Switzerland

CME REVIEWER FOR
NEW YORK EYE AND EAR INFIRMARY OF MOUNT SINAI

Joseph F. Panarelli, MD
Assistant Professor of Ophthalmology
Icahn School of Medicine at Mount Sinai
Associate Residency Program Director
New York Eye and Ear Infirmary of Mount Sinai
New York, New York

Individualizing New Minimally Invasive

Surgical Approaches for Glaucoma

INTRODUCTION

Since the advent of the modern guarded trabeculectomy in 1968,[1] glaucoma surgery has evolved tremendously. The array of glaucoma surgical procedures today is diverse: antimetabolite-augmented trabeculectomy, tube-shunt procedures, minimally invasive trabecular and scleral bypass implants, devices that shunt aqueous humor into the suprachoroidal space, and now minimally invasive approaches to bleb-based filtering procedures. Selection of a given procedure for an individual patient is typically based on careful assessment of both the efficacy and the safety of each procedure. Regrettably, these 2 traits are not always optimized in any single procedure; the most effective procedures tend to be the least safe, whereas the safest tend to be the least effective. A glaucoma surgical procedure that combines the efficacy of trabeculectomy with the safety and technical ease of minimally invasive glaucoma surgery (MIGS) remains a significant unmet need. In this educational activity, participants will learn to identify and assess the relevant attributes of a glaucomatous eye in order to select the best-suited procedure for intraocular pressure (IOP) reduction.
–Iqbal Ike K. Ahmed, MD, Chair

GOAL OF GLAUCOMA THERAPY: A SHIFTING PARADIGM

Dr Ahmed: During the past 2 decades, we have seen prodigious innovation in glaucoma pharmacotherapy, laser development, and surgical technique. We have more options for treating glaucoma than ever before. Our primary objective in treating glaucoma is to preserve our patients' visual function. Has our approach to this goal evolved in recent years?

Dr Shaarawy: In the past, we have focused on the mechanics of glaucoma therapy: reduction of IOP, prevention of optic nerve damage, and preservation of the visual field. Over the past 10 years, we have become more focused on conserving quality of life for our patients, as spelled out by both the European Glaucoma Society and the American Academy of Ophthalmology guidelines.[2,3] This is a paradigm shift that has significant implications for both the patient and the glaucoma specialist.

Quality of Life

Dr Samuelson: The expansion of our treatment options has given us the opportunity to select treatments that control glaucoma while simultaneously meetings patients' individual needs regarding quality of life. Two important aspects of quality of life that I consider frequently when treating my patients with glaucoma are visual quality, the primary goal, and cosmesis, among several secondary goals. Some of our treatments tend to have side effects, such as hyperemia, that affect cosmesis. Others can aggravate ocular surface disease and compromise visual acuity. When our therapeutic choices were more limited, we had to simply accept some of these side effects. Now we have more options and can tailor our treatment regimens to better meet our patients' expectations, both for glaucoma control and quality of life.

Dr Parrish: Advances in laser and surgical therapies have allowed us to offer these interventions earlier in the treatment plan. This liberates us from reliance on medications that may have undesirable side effects. For our elderly patients with several comorbidities and extensive systemic medication regimens, the newer laser and surgical treatments may offer glaucoma management options that avoid the addition of medications with side effects and potential drug interactions.

Lower Target Intraocular Pressure

Dr Ahmed: Quality of life is important to consider when developing a treatment regimen. Adequate reduction of IOP is also important. We have learned from long-term studies, such as the Early Manifest Glaucoma Trial, that even our treated patients have high rates of progression over time. In that study, 45% of patients with early disease treated with beta blockers and laser trabeculoplasty manifested visual field progression over a 6-year period, despite mean IOP reductions of approximately 25%.[4] Eventually, we may need to consider striving for lower target IOP, especially in patients at high risk for vision loss in their lifetime, such as younger patients and those with more than mild disease. Achieving lower IOP while still preserving quality of life and minimizing treatment-related side effects is a difficult challenge.

> ***"Eventually, we may need to consider striving for lower target IOP, especially in patients at high risk for vision loss in their lifetime, such as younger patients and those with more than mild disease."*** *– Iqbal Ike K. Ahmed, MD*

Dr Shaarawy: We are diagnosing glaucoma at a younger age, thanks in part to improved diagnostics. Also, we are living longer. This means our patients are living longer with glaucoma, which increases their lifetime risk of blindness. These shifting demographics also warrant more aggressive treatment to achieve a lower target IOP.

Dr Parrish: Another at-risk subgroup of concern is the rising number of people who have had keratorefractive surgery. Refractive surgery, specifically LASIK (laser-assisted in situ keratomileusis) for correction of myopia, affects measurement of IOP. Corneas that are thinner, flatter, and more compliant cause us to underestimate IOP. The earliest cohorts of people who underwent refractive surgery in their 20s and 30s are now reaching the age when the risk of glaucoma increases. We cannot rely on IOP as a meaningful risk factor in these patients. We must search for evidence of glaucomatous damage to the optic disc. When we diagnose and treat these patients, we should be mindful that their true IOP is probably higher than what it really is. We should consider lowering the target IOP in these eyes.

THERAPEUTIC OPTIONS FOR INTRAOCULAR PRESSURE REDUCTION

First-Line Treatment Options

Dr Ahmed: In recent years, we have gained new medications, new laser techniques, and new surgical procedures. Is medical therapy still the preferred first-line treatment for glaucoma?

Dr Samuelson: My practice is largely referral in nature, and most of the patients I see are already on medical therapy. On the basis of the patients who are referred in to me, it is my sense that most clinicians still prescribe medications first. When I do have the opportunity to initiate therapy, I discuss both medications and laser procedures with my patients. Several studies have demonstrated that selective laser trabeculoplasty (SLT) lowers IOP comparably to a prostaglandin analogue,[5,6] so while medication-first is the most common strategy, laser-first is a viable option as well.

Dr Ahmed: Assuming first-line therapy with a prostaglandin analogue fails to achieve a target IOP, what is the optimal next step?

Dr Shaarawy: I typically add a beta blocker in fixed combination with a prostaglandin analogue, but each patient is different, and for some patients, SLT would be the next step to avoid adding additional medications. I tend to favor SLT in younger patients in whom the more insidious side effects of beta blockers, such as exercise intolerance and depressed mood, can be a problem.[7]

Novel Treatment Options

Dr Ahmed: Several new molecules with novel mechanisms of action are in late-stage development and may achieve regulatory approval in the very near future. What is known about these drugs, and where might they fit into the treatment regimen?

Dr Samuelson: Latanoprostene bunod, which is a nitric oxide–donating form of latanoprost, has been submitted to the US Food and Drug Administration (FDA). This drug dissociates into latanoprost acid, which lowers IOP by enhancing uveoscleral outflow of aqueous humor,[8] and nitric oxide, which lowers IOP by relaxing the trabecular meshwork and Schlemm canal, thus enhancing trabecular outflow of aqueous humor.[9] In clinical trials, this new drug lowers IOP significantly more than does latanoprost or timolol.[10,11] Another drug in review with the FDA is the Rho-kinase inhibitor netarsudil. This drug has 3 potential mechanisms of action.[12,13] The first is increasing trabecular outflow of aqueous humor; the second is reducing episcleral venous pressure, which might also enhance trabecular outflow; and the third is a possible effect on reducing the production of aqueous humor. A fixed combination of netarsudil and latanoprost is also in clinical development.[14] Where these drugs will fit into our practice patterns is unclear at this time, although both are certain to be welcome additions.

Multidrug Treatment Regimens

Dr Ahmed: Is there a role for adding a third or even a fourth medication to the treatment regimen in patients with uncontrolled IOP?

Dr Shaarawy: In the era of single-agent formulations, conventional wisdom was that the third or fourth medication was unlikely to provide significant additive efficacy to an already multidrug regimen and that therefore it was generally not worth the hassle for patients to manage 4 different bottles of medication and 6 to 8 drops per day. Now, in the era of fixed combinations, we can deliver a 4-drug regimen using only 2 bottles and 3 drops per day. Such a regimen is helpful as an option prior to considering surgery because if this much medication is ultimately necessary, we have exhausted all efforts before considering surgery. Also, there are limited data supporting the efficacy of adding a fourth medicine; we sometimes get meaningful IOP reductions.[15]

Surgical Intervention

Dr Ahmed: This raises an important issue. Given the breadth of pharmacologic options available, when do we decide to move beyond medications and consider surgical interventions?

Dr Shaarawy: My 25 years of experience as a clinician has taught me that the earlier you operate, the better for your patients. There is no benefit to delaying surgery in patients who are inadequately controlled by less invasive means. Our patients are living longer, and we can no longer safely assume that a 90-year-old patient does not warrant aggressive treatment to preserve his vision for an additional 10 to 15 years. For our younger patients, the importance of surgical intervention is even greater.

> ***"My 25 years of experience as a clinician has taught me that the earlier you operate, the better for your patients. There is no benefit to delaying surgery in patients who are inadequately controlled by less invasive means."*** *– Tarek M. Shaarawy, MD, MSc*

Dr Samuelson: We once considered surgery an intervention of last resort for our patients with glaucoma. In recent years, however, our surgical options have expanded greatly, and we now have the opportunity to intervene sooner than we might once have. Surgery is now a viable option to help avoid the side effects of topical medical therapy for our patients, in whom these side effects might compromise their quality of life. This is particularly true in our patients with visually significant cataract, for whom

we now have effective and safe surgical options for controlling IOP as add-on procedures at the time of their cataract surgery.

DIFFERENT PROCEDURES, DIFFERENT APPROACHES

First-Line Surgical Procedures

Dr Ahmed: In a patient with progressive glaucoma and inadequate IOP control on medical therapy, what is your initial surgical procedure of choice?

Dr Parrish: The Tube Versus Trabeculectomy Study supports the long-term success of tubes over trabeculectomy.[16] My first-line incisional surgical preference in someone who has an open angle and uncontrolled IOP is a large surface area drainage implant, usually a Baerveldt implant. Trabeculectomy would also be a reasonable option.

Dr Shaarawy: I generally start with deep sclerectomy, a nonpenetrating glaucoma surgery, as my first incisional surgery when not combined with cataract surgery. It provides good IOP lowering, is less likely to promote cataract formation, and has an overall safety profile that is superior to full-thickness procedures.[17]

Dr Samuelson: For patients who need significant IOP reduction—because of very high preoperative IOP, very low target IOP, or more rapid ongoing progression—I rely on a transscleral procedure, either a trabeculectomy or a drainage implant. There are a number of newer transscleral procedures, such as XEN Gel Stent and the MicroShunt device, that incorporate the MIGS strategy of microincision technology and reducing tissue disruption. These procedures reduce surgical time and tissue trauma compared with trabeculectomy or drainage implants and also reduce complications, such as hypotony and flattening of the anterior chamber.[18] The long-term outcomes with these MIGS procedures, however, are less well characterized. A prospective randomized comparison of MicroShunt and trabeculectomy is currently being conducted.

> ***"For patients who need significant IOP reduction—because of very high preoperative IOP, very low target IOP, or more rapid ongoing progression—I rely on a transscleral procedure, either a trabeculectomy or a drainage implant."***
> *– Thomas W. Samuelson, MD*

Minimally Invasive Glaucoma Surgery

Dr Ahmed: We are learning about the optimal use of the newer MIGS procedures. Currently, what proportion of your glaucoma surgeries are MIGS procedures?

Dr Shaarawy: For standalone procedures, I generally start with nonpenetrating surgery. When performing a combined cataract and glaucoma case, I use a MIGS procedure. Working in a tertiary referral center, I typically perform more standalone cases than combined procedures, given that most cataracts would have been extracted before the patient is referred to me.

Dr Samuelson: A fairly high percentage of my glaucoma interventions are MIGS procedures when done in conjunction with cataract surgery. I welcome the day when we can do more of these procedures as standalone procedures. Currently, for a standalone canal procedure, I favor gonioscopy-assisted transluminal trabeculotomy (GATT).

Dr Ahmed: Our current array of MIGS procedures can be classified in several ways **(see Sidebar: Minimally Invasive Glaucoma Surgery Choices Around the World)**. We can classify them according to the structures they bypass, according to where they drain, or whether they are performed via an ab interno or ab externo approach. I tend to think of the MIGS procedures in 2 broad classes: those that drain aqueous internally (iMIGS) vs those that drain aqueous externally (eMIGS).

What are the risks and benefits of the various approaches and the use of different ocular spaces for drainage?

Dr Shaarawy: This is a challenging question because we lack medium- and long-term efficacy and safety data for many of these devices and procedures. Bleb-based MIGS procedures—or, as you called them, eMIGS—produce a bleb with which we are familiar and provide an opportunity for postoperative manipulation that we do not get with many of the 1-shot implants. I predict that over the next few years, it will be the cataract surgeons and not the glaucoma surgeons who define the surgical MIGS paradigm. They want an effective, safe, and easy-to-perform procedure that requires minimal postoperative care.

Dr Parrish: The need for intraoperative gonioscopy is 1 factor that could affect the adoption of these procedures by cataract surgeons. The average phacoemulsification surgeon rarely performs intraoperative gonioscopy. Certainly, they can learn this skill, but it is likely they would be far more comfortable going from the outside in than from the inside out to increase aqueous humor outflow.

Dr Samuelson: For most of my patients with glaucoma who are undergoing cataract surgery, I add a MIGS procedure. Unless the patient has significantly uncontrolled or aggressive glaucoma and requires a very low target IOP, I tend to avoid transscleral procedures because of safety issues, although the newer transscleral options could alter that strategy over time. My preference for most combined cases is to use a device that drains into either Schlemm canal or supraciliary space. One point I want to make is that the demographics of patients undergoing cataract surgery are changing. When I started my practice, the average age of patients undergoing cataract surgery was mid- to late 70s. Now I am operating on people in their 50s every day, and the average patient is in his or her mid- to late 60s. We are taking cataracts out earlier, and we are going to have a lot of people diagnosed with glaucoma after they become pseudophakic. We need to sort out which of these procedures work as standalone procedures because patients will be living as pseudophakes for 20 to 30 years or longer. The demand will be significant in this population.

ISSUE OF WOUND HEALING

Dr Ahmed: We know that drainage into the canal space has the best overall safety profile, but efficacy will be limited by distal outflow disease in collector channels and the episcleral venous system, which is likely the site of outflow obstruction in some of our patients. The suprachoroidal, or supraciliary, space lacks an episcleral venous floor, which is potentially an advantage in terms of reduced distal outflow resistance, but this space also seems to have more issues regarding healing. We can achieve very low IOP by shunting aqueous into the suprachoroidal space, but we have to be prepared for a healing response that may reduce or even eliminate the IOP reduction in some eyes. The subconjunctival space is also unencumbered by distal outflow obstruction, so shunting aqueous to this space can deliver very low IOP, but is even more susceptible to reduced function on the basis of wound healing of the bleb **(see Sidebar: New Bleb-Based Minimally Invasive Glaucoma Surgery Procedures)**.

Dr Parrish: Wound healing of the bleb will continue to be a problem. It causes failure of our traditional surgeries—trabeculectomies and tubes—and it can also lead to failure of the newer bleb-based MIGS procedures.

"Wound healing of the bleb will continue to be a problem. It causes failure of our traditional surgeries—trabeculectomies and tubes—and it can also lead to failure of the newer bleb-based MIGS procedures." – Richard K. Parrish II, MD

Dr Ahmed: The common problem with all these procedures—canal, supraciliary, and subconjunctival—is that wound healing is the 1 aspect that we cannot completely control and that can limit the efficacy of the procedures. How does the risk of bleb failure affect your choice of an iMIGS vs an eMIGS procedure?

Dr Samuelson: I have experience with both of the eMIGS devices (XEN Gel Stent and MicroShunt). The technique is straightforward and will be familiar to anyone with glaucoma surgery experience. Although both of these devices are made of inert, biocompatible materials that do not incite inflammation, it is important to realize that the presence of a filtering bleb itself stimulates subconjunctival fibrosis, and in the medium and long term, this fibrosis can reduce the efficacy of the procedure or even lead to failure.

Dr Shaarawy: I agree. The presence of filtration stimulates inflammation. For this reason, I am not convinced that the difference in approach between the 2 eMIGS procedures—ab interno for the XEN Gel Stent and ab externo for the MicroShunt device—is as important as some make it seem. Yes, we have to make a conjunctival incision, manipulate the conjunctiva, and suture the conjunctiva to implant the MicroShunt, but it is a very small incision. The subsequent subconjunctival fibrosis that occurs is likely more attributable to having a foreign body and aqueous in the subconjunctival space, where it is not supposed to be. Although there is a theoretical advantage in not needing a conjunctival incision when using the XEN Gel Stent, it is less clear whether this is a real issue or not. One other key issue with the XEN Gel Stent is its position within the external space. With the MicroShunt, the distal tip is beneath both the conjunctiva and Tenon capsule. With the XEN Gel Stent, we still are not sure if optimal filtration arises from subconjunctival or sub-Tenon placement.

Dr Samuelson: One factor that may be important is surgical time. The ab interno approach is technically faster and reduces time in the operating room. Also, with the ab interno approach, wound leaks should be far less common because the only wounds are the needle track through which the mitomycin C (MMC) was injected and any holes that were created inadvertently during device insertion, which should be uncommon. Conversely, an important advantage of the ab externo approach is that you save money by not needing to use any viscoelastic.

Dr Shaarawy: One advantage of both of these bleb-based MIGS procedures over traditional transscleral surgery is that they may be more amenable to surgical revision. I have revised approximately a dozen surgeries for each of these 2 devices. Once you open the conjunctiva and remove the scar tissue, you reestablish flow. Overall, I think that both devices have advantages and disadvantages, and the only way we can determine if one is better than the other is a head-to-head randomized trial, which we do not have at present.

Dr Ahmed: What are our options for modulating wound healing? What is the role of MMC in bleb-based MIGS?

Dr Shaarawy: Whenever we need long-term subconjunctival filtration, there is a role for antimetabolites. I use an antimetabolite in virtually all my eMIGS cases. Steroids and nonsteroidal agents in the preoperative and postoperative periods may also suppress inflammation and reduce wound healing, but the most effective way to modulate wound healing is with MMC. I suspect MMC would also augment the survival of canal- and supraciliary-based procedures if we could ascertain how to get it to the relevant tissue beds.

Dr Parrish: It is hard to fool Mother Nature. No matter how inert a material is, the body's response to a foreign body is to try to wall it off. We see this with glaucoma drainage devices, such as Molteno, Ahmed, and Baerveldt, and we see it with the XEN Gel Stent and MicroShunt implants. I agree with Dr Shaarawy that scarring likely happens around all our devices in all the various filtration spaces. The eMIGS procedures are unique in that they provide the opportunity to apply antimetabolites to modulate wound healing. Doing so is not currently possible with canal- or supraciliary-based procedures, which may ultimately be limited in the long term by subsequent wound healing and not by surgical technique or by the device itself.

Dr Samuelson: The MicroShunt is CE marked and thus approved in European countries, but is still in clinical development in the United States. The protocol for the ongoing clinical trial requires a large enough peritomy to insert several MMC-soaked pledgets into the subconjunctival space during the procedure.[19] Ideally, I would deliver MMC via a subconjunctival injection and let it diffuse broadly through the surgical space, thus allowing me to make a much smaller peritomy. When implanting the XEN Gel Stent, I use a subconjunctival MMC injection because there is no peritomy and we have no access point to the subconjunctival space.

SELECTING THE RIGHT PROCEDURE FOR EACH PATIENT

Dr Ahmed: Your patient with glaucoma now has a visually significant cataract. What are the key factors that you consider when deciding if you should add a glaucoma procedure, and which procedure would be the most appropriate?

Dr Shaarawy: The 2 indications for adding a glaucoma procedure are to reduce IOP or to reduce the medication burden. We should not miss the opportunity to relieve our patients of the burdens of daily medical therapy by performing a safe and effective procedure that takes only a few minutes while already in the operating room. As for selecting procedures, the first consideration is the status of the conjunctiva. If there is extensive conjunctival scarring, a bleb-based MIGS procedure would be a poor choice.

Dr Samuelson: There has been much discussion about the importance of disease stage when selecting a procedure, specifically given that MIGS is best suited for those with early to moderate disease, but not necessarily appropriate for patients with advanced glaucoma. I respectfully disagree. The important issue is not how much damage is present, but rather the likelihood of progression and the rate of progression—these are the issues that matter most. Age and target IOP are important. I like the fact that procedure selection is complex because the process is nuanced. You really need to give a lot of thought to your decision; it is not just a cookbook approach. I use each of the different MIGS procedures all the time. On every clinic day, I schedule patients for canal surgery, supraciliary surgery, and transscleral surgery. I would feel compromised if I had to give up any of the procedures.

Dr Parrish: I agree that target IOP is important. If the baseline IOP is in the upper 20s or low 30s and your goal is a reduction to the mid-teens, then a transscleral or translimbal filtering procedure into the subconjunctival space will likely be needed. The other approaches are unlikely to achieve that goal. Alternatively, if your goal is to reduce a 3-drug regimen to 1 medication in a well-controlled patient, a canal-based procedure offers a great likelihood for success, with fewer potential risks than a transscleral procedure.

Dr Ahmed: My approach is to consider several factors in sequence. First is the status of the eye. As Dr Shaarawy pointed out, factors such as conjunctival scarring preclude the likelihood of success with eMIGS.

Next is efficacy. I define my IOP goal and eliminate the procedures that are unlikely to achieve that target IOP goal. From the choices left, I select the procedure that offers the best balance of safety and recovery rate.

Dr Samuelson: I use the same approach, and I include the patient in the discussion and decision making. As experienced surgeons, we are often comfortable with risk because we have the expertise to address complications if they occur. Invariably, however, my patients will opt for safer procedures, even if it means that they will still need to use medications postoperatively. One additional consideration that often leads me to initial iMIGS is the reality that none of our surgeries lasts forever. A conjunctival-sparing procedure does not initially burn any bridges; we still have all the options on the table if another surgery is needed months or years down the road. This approach has the additional advantage of delaying or entirely avoiding the known long-term risks of bleb-based procedures, such as blebitis and endophthalmitis.

Minimally Invasive Glaucoma Surgery Choices Around the World

A wide array of minimally invasive glaucoma surgery (MIGS) procedures are available throughout the world, with regional variations based on local regulatory requirements and processes. These procedures can be divided into 2 broad categories according to the site of drainage: internal MIGS procedures drain into either Schlemm canal or supraciliary space, whereas external MIGS procedures drain into the subconjunctival space and depend on the formation of a filtering bleb. Other key differences include the surgical approach (ab interno vs ab externo) and whether the procedure is approved as a standalone technique or must be combined with cataract surgery. The **Table** summarizes the features of the various MIGS procedures.

Table. MIGS Procedures Available in Global Markets

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

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

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New Bleb-Based Minimally Invasive Glaucoma Surgery Procedures

Two new minimally invasive glaucoma surgery procedures rely on the formation of a bleb for subconjunctival filtration. These are the XEN Gel Stent (approved for use in the United States) and the MicroShunt (has CE mark in Europe; investigational in the United States).

The XEN Gel Stent is a gelatin stent designed for ab interno insertion through the trabecular meshwork and sclera so that one end rests in the anterior chamber and the other end rests in the subconjunctival space. In a prospective, nonrandomized cohort study of 49 eyes undergoing implantation, mean intraocular pressure (IOP) was reduced 36% 12 months postoperatively ($P < .001$), with nearly 90% achieving both IOP ≤ 18 mm Hg and a ≥ 20% reduction in IOP from baseline (with 40% requiring no medications to achieve these goals).[1] No serious complications (endophthalmitis, wound leak, device exposure or migration, macular edema, choroidal effusion or hemorrhage, iritis, or retinal detachment) were seen. Only 4 eyes (9%) required anterior chamber reformation, all within the first postoperative week, all of which subsequently resolved. In a separate cohort study of 13 eyes undergoing XEN Gel Stent implantation, mean IOP was reduced by 25% 12 months postoperatively ($P = .01$), with a reduction in IOP-lowering medications from a mean of 1.9 preoperatively to 0.3 postoperatively ($P = .003$).[2]

The MicroShunt is also a tube device designed for ab externo implantation through sclera and trabecular meshwork into the anterior chamber, thus shunting fluid from the anterior chamber into the subconjunctival space. In a cohort study of 23 eyes failing maximal medical therapy and undergoing MicroShunt implantation either alone or in combination with elective cataract surgery, mean IOP reductions at 3 years postoperatively were 55% (from a mean of 23.8 mm Hg to 10.7 mm Hg), with a reduction in IOP-lowering medications from a mean of 2.4 preoperatively to 0.7 at 3 years.[3] Overall, 95% of patients achieved a target IOP of 14 mm Hg or less and a minimum 20% IOP reduction from baseline at 3 years. Transient hypotony occurred in 3 eyes (13%) and transient choroidal effusions occurred in 2 eyes (8.7%), with no serious long-term adverse events and no migrations/erosions noted.

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Case 1. Managing Well-Controlled Glaucoma at the Time of Cataract Surgery

From the Files of Tarek M. Shaarawy, MD, MSc

A 75-year-old woman has been under care for primary open-angle glaucoma (POAG) for nearly 2 decades. She has been well controlled on prostaglandin monotherapy, with IOP of 12 mm Hg and 16 mm Hg in the right and left eye, respectively. **Figure 1** shows her visual fields. She has now developed visually significant cataracts, and surgery is planned. Should she undergo a combined procedure, and, if so, which one?

Dr Samuelson: Early in my career, when combined surgery meant phacoemulsification plus trabeculectomy, I would not have advocated

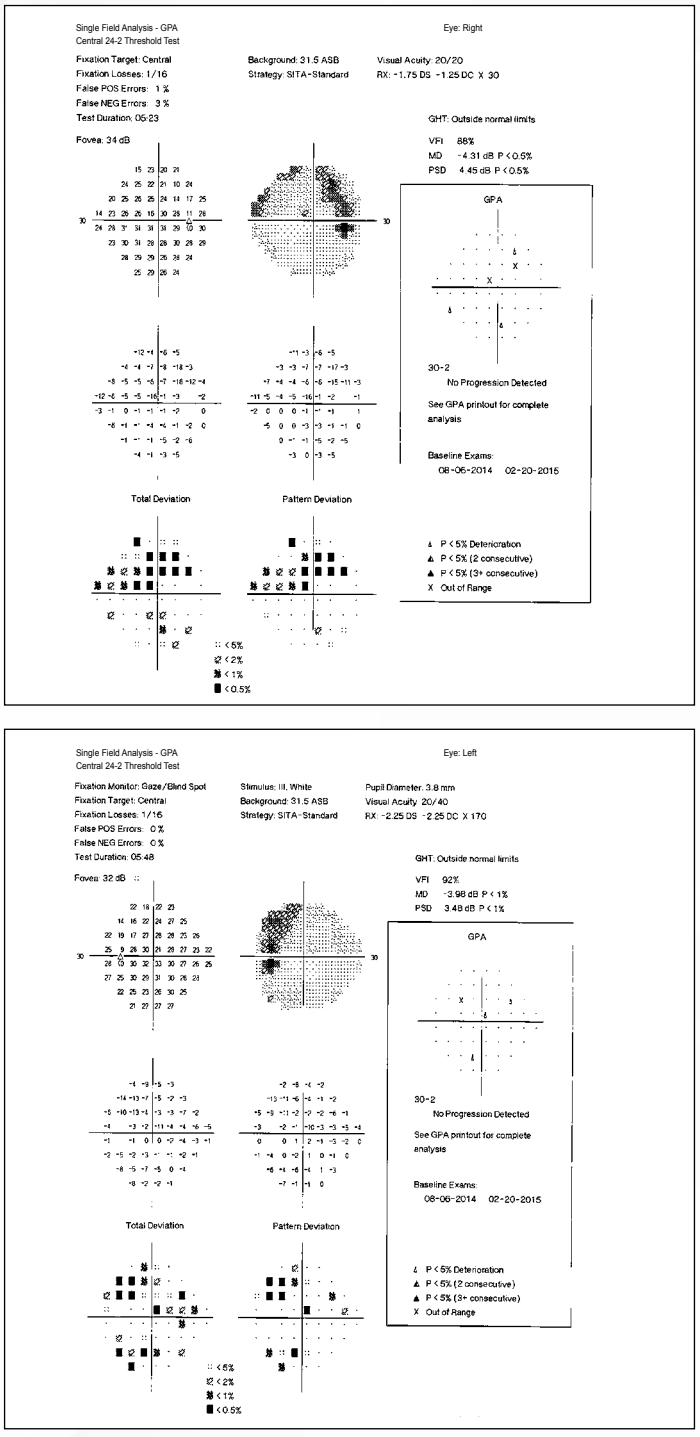
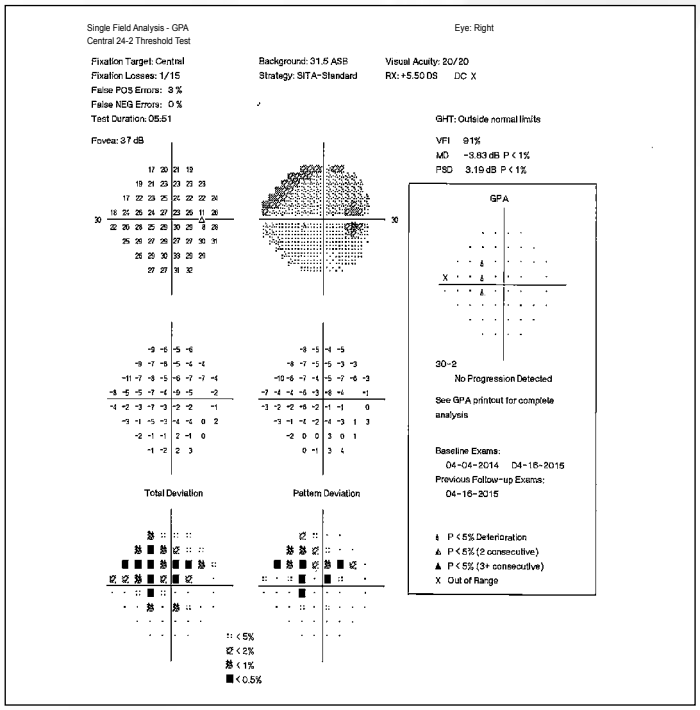


Figure 1. Visual fields for the patient presented in Case 1

for combined surgery in this patient. The benefit—a potential reduction in medication burden—was unlikely worth the potential long-term risks of a bleb. Today, however, with the array of safe procedures that do not require bleb formation, this is an ideal case for a combined procedure. I would offer an iMIGS procedure, and my preference would be a canal-based procedure, but a supraciliary procedure would also be reasonable.

Dr Ahmed: Cataract surgery alone is known to reduce both IOP and the need for IOP-lowering medications in eyes with glaucoma.[20] With a safe and easy-to-perform iMIGS add-on, we can significantly increase this patient's probability of getting off her medication postoperatively.



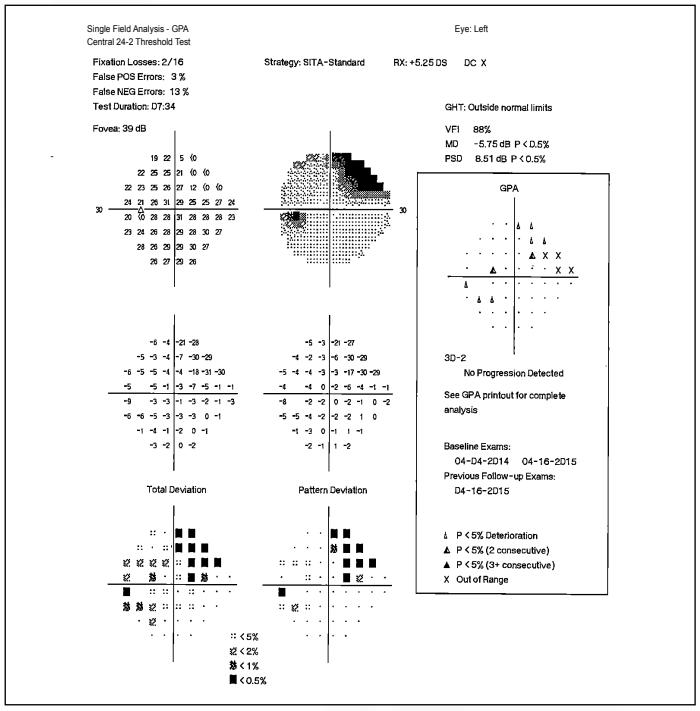


Figure 2. Visual fields for the patient presented in Case 2

Case 2. Achieving Lower Target Intraocular Pressure at the Time of Cataract Surgery

From the Files of Tarek M. Shaarawy, MD, MSc

A 60-year-old woman has moderate POAG, and her IOP is 18 mm Hg in both eyes while using a 3-drug regimen. **Figure 2** shows her visual fields. She has now developed cataracts and is scheduled for surgery. Is she a candidate for a combined procedure, and, if so, which procedure would you recommend?

Dr Samuelson: The key factor to consider in this case is the patient's age. She is young; she is going to live with glaucoma for a long time. There are 2 paths we can take with young patients. We can be either very aggressive up front with a higher-risk bleb-based procedure to achieve low IOP and protect these patients from future damage, or we can be conservative and select an iMIGS procedure to achieve moderate IOP reduction at a lower risk, knowing that if we need to, we can always opt for a more aggressive procedure in the future. So long as the patient is not progressing rapidly, I typically opt for the second strategy.

Dr Shaarawy: I generally take the opposite approach. My goal is to go to the operating room the lowest number of times, so I select the procedure most likely to provide long-term stability—an eMIGS procedure.

Dr Parrish: My approach is more like Dr Samuelson's. In the absence of rapid progression, I would add an iMIGS procedure, knowing that I still have options if we need further IOP reduction down the road.

Dr Samuelson: Many of our 60-year-old patients are still in the workforce and may benefit from a rapid recovery—another argument for an iMIGS procedure.

Dr Ahmed: This patient has a significant visual field defect and likely has significant cupping to go with it. Given her age and the length of time for which I have to preserve her visual function, I want her target IOP down in the low teens. It is possible to achieve this with iMIGS procedures, but not very likely. I would opt for an eMIGS procedure. As for the rate of visual recovery, most of my XEN Gel Stent and MicroShunt patients achieve a visual acuity of 20/40 or better quite quickly, which is usually adequate for them to return to work while they complete their visual recovery.

Case 3. Primary Standalone Surgery for Intraocular Pressure Reduction

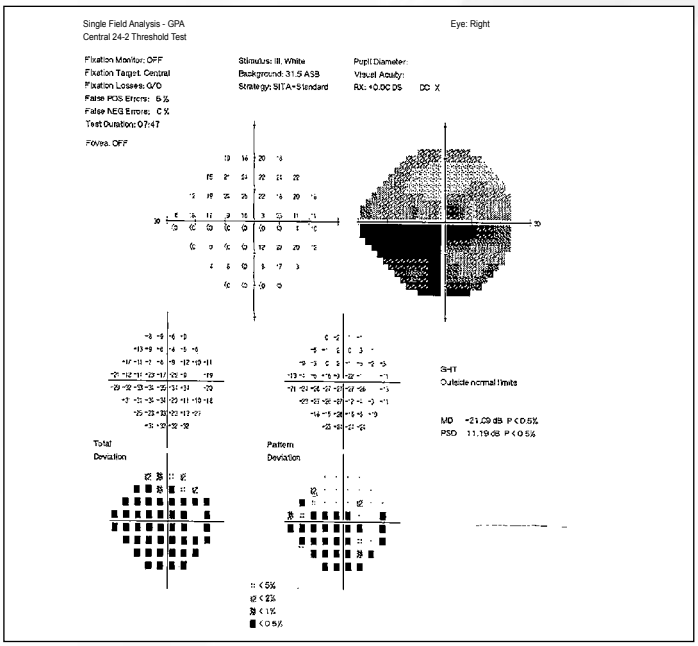
From the Files of Tarek M. Shaarawy, MD, MSc

A 67-year-old pseudophakic woman with high myopia (axial length of 28 mm) has POAG with early visual field loss. She has lost vision in 1 eye to an old retinal detachment. Her IOP is in the mid-20s in both eyes despite maximally tolerated medical therapy. She is not functionally impaired; she still drives, but reports that she can no longer play tennis. **Figure 3** shows her visual fields. Given that she has uncontrolled IOP on maximal medical therapy, is functionally monocular, and has virgin conjunctiva, what would be your standalone glaucoma procedure of choice?

Dr Parrish: I am not sure I would advocate for incisional surgery in this very – high-risk patient. My inclination is to offer transscleral cyclophotocoagulation limited to 270 degrees, which could potentially be repeated several times as needed over time. In my hands, that would be the safest of all available interventions. If the idea of killing off healthy ciliary body tissue is not acceptable to her, my alternate approach would be to perform GATT.

Dr Samuelson: I like the idea of GATT. If she were not such a high myope, I would probably go straight to an eMIGS procedure. But in light of her axial length issues contributing to a retinal detachment in the other eye, rendering her monocular, a safer first-line approach is reasonable. If needed, we could still go with a XEN Gel Stent or MicroShunt procedure later on.

Dr Ahmed: In this case, I would go straight to an eMIGS procedure. She is a young patient whose optimal target IOP is below 15 mm Hg. iMIGS procedures are unlikely to get her there. Given the surgical risk with her high myopia and monocular status, I am motivated to address her glaucoma with a single operation rather than incurring the risk over several operations. One concern I have with bleb procedures is the use of MMC. As we know, high myopes have thin and elastic scleras and there is a higher risk for chronic hypotony and hypotony maculopathy. It is likely a very low risk with these modern eMIGS procedures, but it is something I have to consider.



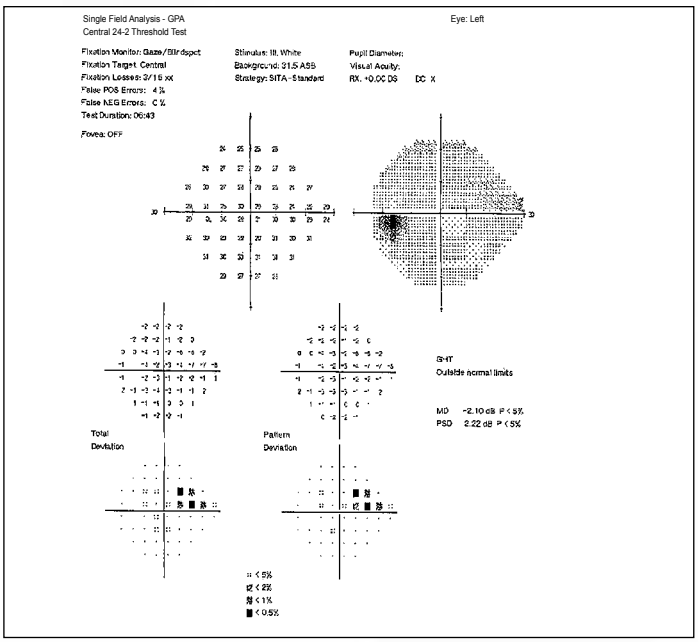


Figure 3. Visual fields for the patient presented in Case 3

SUMMARY AND TAKE-HOME POINTS

The rapid expansion of therapeutic options for IOP reduction in eyes with glaucoma provides both great opportunities to personalize care and also the potential for great confusion when selecting optimal therapy. New medications with new mechanisms of action are emerging. The role of laser therapy for open-angle glaucoma continues to grow. The surgical glaucoma space has seen unprecedented expansion in recent years. New devices and procedures allow us to divert aqueous to the canal, supraciliary space, and subconjunctival space with greater ease and safety than ever before. When selecting the best intervention for glaucoma patients requiring IOP reduction, several factors should be considered, including the goal of treatment (to lower IOP or reduce medication burden), target IOP, age of the patient, status of the eye, and potential consequences of adverse events. Carefully assessing these factors, in collaboration with the patient, will clarify the optimal approach that maximizes efficacy while minimizing risk, ensuring the best possible outcomes for our patients with glaucoma.

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CME POST TEST QUESTIONS

To obtain *AMA PRA Category 1 Credit*™ for this activity, complete the CME Post Test by writing the best answer to each question in the Answer Box located on the Activity Evaluation/Credit Request form on the following page. Alternatively, you can complete the CME Post Test online at https://tinyurl.com/IndividualizingMIGS.

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

1. In the new glaucoma treatment paradigm, what is the most important goal of glaucoma therapy?
   a. Maintaining the visual field
   b. Preserving quality of life
   c. Lowering IOP
   d. Preventing optic nerve damage

2. Selective laser trabeculoplasty has been demonstrated to provide IOP reduction that is comparable to the _____ class of glaucoma medications.
   a. Beta blocker
   b. Prostaglandin analogue
   c. Carbonic anhydrase inhibitor
   d. Adrenergic agonist

3. Of the following procedures, which is considered a canal-based procedure?
   a. GATT
   b. CyPass
   c. EX-PRESS
   d. MicroShunt

4. Of the various MIGS procedures, which 2 require the formation of a bleb?
   a. iStent and MicroShunt
   b. CyPass and XEN Gel Stent
   c. MicroShunt and XEN Gel Stent
   d. XEN Gel Stent and Trabectome

5. What is the standard clinical approach to controlling wound healing after glaucoma surgery?
   a. Postoperative use of topical steroids
   b. Preoperative course of nonsteroidal anti-inflammatory drugs
   c. Intraoperative application of MMC
   d. Sub-Tenon injection of steroids at the end of the procedure

6. Achieving the lowest target IOP requires filtering aqueous humor into the _____ space.
   a. Canal
   b. Supraciliary
   c. Subretinal
   d. Subconjunctival

7. Implantation of a XEN Gel Stent requires an _____ approach, and implantation of a MicroShunt requires an _____ approach.
   a. Ab interno and ab interno, respectively
   b. Ab externo and ab interno, respectively
   c. Ab interno and ab externo, respectively
   d. Ab externo and ab externo, respectively

8. A patient with extensive conjunctival scarring has both cataract and glaucoma and is scheduled for surgery. Of the following glaucoma procedures, which is the MOST dependent on the status on the conjunctiva?
   a. XEN Gel Stent
   b. iStent
   c. CyPass
   d. Kahook Dual Blade

9. What is the standard clinical approach for a patient with glaucoma that is progressing with a high IOP?
   a. Canal-based MIGS
   b. Supraciliary-based MIGS
   c. Bleb-based MIGS
   d. Trabeculectomy or tube-shunt surgery

ACTIVITY EVALUATION/CREDIT REQUEST

INDIVIDUALIZING NEW MINIMALLY INVASIVE SURGICAL APPROACHES FOR GLAUCOMA

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

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

Signature Required _____**Date Completed** _____

OUTCOMES MEASUREMENT

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

_____

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

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

• Differentiate the characteristics of MIGS procedures	5	4	3	2	1
• Review the relevant patient characteristics that guide optimal selection of MIGS procedures	5	4	3	2	1
• Appraise the rationale and optimal techniques for MIGS bleb-based procedures	5	4	3	2	1

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

_____

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

4 3 2 1

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

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

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

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

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

ADDITIONAL COMMENTS _____

POST TEST ANSWER BOX

1	2	3	4	5	6	7	8	9