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CHANGING THE GLAUCOMA TREATMENT PARADIGM

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Changing the Glaucoma Treatment Paradigm

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STATEMENT OF NEED

Given the amount of data, emerging research, and the sheer volume of peer-reviewed publications on the topic of glaucoma, the burden on ophthalmologists to identify and learn about new diagnosis and treatment strategies remains high. Due to the projected increases in glaucoma patient care services,[1] it is especially critical that clinicians are aware of the most recent developments and are treating glaucoma in the most effective manner possible.

Undiagnosed and suboptimally treated glaucoma results in irreversible vision loss. Specifically, patients may lose more than 40% of their optic nerve fibers before noticing a loss of peripheral vision.[2]

Glaucoma and cataracts are often comorbid diseases, which brings glaucoma management within the purview of comprehensive ophthalmologists. Busy glaucoma specialists and anterior segment surgeons need to be aware of emerging information and patient management strategies to optimize their treatment planning.

Glaucoma is the second most common cause of legal blindness in the United States[3] and the leading cause of irreversible blindness in the world.[4,5] As many as half of the nearly 3 million people in the United States who suffer from glaucoma may be unaware they even have the disease.[4]

The objective of glaucoma management is to halt the disease's progression by providing a clinically significant, sustained drop in intraocular pressure (IOP) in a way that ensures patient compliance and has a favorable risk profile.

Topical ophthalmic medications have long been considered the first line of therapy for glaucoma patients. Their side effects are considered to be benign, especially compared to options such as trabeculetomy and tube shunts. However, it is well documented that among those glaucoma patients who have been diagnosed and are prescribed drug therapy, compliance is far from optimal—which is common in chronic conditions that are largely asymptomatic (ie, hyperlipidemia, hypertension, etc).[6-8]

If medical therapy fails to lower IOP to acceptable levels, treatment generally moves on to laser trabeculoplasty and then to penetrating or nonpenetrating surgical interventions with or without shunt placement. Surgical glaucoma procedures that remove tissue or use an ab externo device to filter fluid via an artificially created pathway have been shown to effectively lower IOP, and in many cases eliminate the need for medications. However, these procedures are associated with numerous complications, including infection, inflammation, vision loss, bleb leak, bleb encapsulation, hypotony, cataract, and the need for subsequent surgery.[9-11]

There has been a gap in glaucoma treatment options until recently. Newly FDA-approved therapies are now available that reduce the drug burden on patients without introducing the risks associated with trabeculectomy and tube shunts.

TARGET AUDIENCE

This certified CME activity is intended for glaucoma specialists and general eye care professionals.

LEARNING OBJECTIVES

Upon completion of this activity, the participant should be able to:

- Effectively manage patients given issues of compliance with glaucoma medications
- Cite the role of cataract surgery in lowering IOP
- Develop appropriate treatment strategies for glaucoma that include newly approved treatment options

METHOD OF INSTRUCTION

Participants should read the continuing medical education (CME) activity in its entirety. After reviewing the material, please complete the self-assessment test, which consists of a series of multiple-choice questions. To answer these questions online and receive real-time results, please visit http://www.dulaneyfoundation.org and click "Online Courses."

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ACCREDITATION AND DESIGNATION

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the Dulaney Foundation and *Glaucoma Today*. The Dulaney Foundation is accredited by the ACCME to provide continuing education for physicians. The Dulaney Foundation designates this enduring material for a maximum of 1 *AMA PRA Category 1 Credit*.™ Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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FACULTY/STAFF DISCLOSURE DECLARATIONS

The faculty of this educational activity acknowledge they have received funding for speaking, consulting, and/or research from multiple companies, including the following that are relevant to the content herein.

Dr. Ahmed: Alcon Laboratories, Inc.; AqueSys, Inc.; Glaukos Corporation; Ivantis, Inc.; NeoMedix, Inc.; and Transcend Medical, Inc.

Dr. Donnenfeld: Alcon Laboratories, Inc.; Allergan, Inc.; AqueSys, Inc.; Glaukos Corporation; and Pfizer Inc.

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Dr. Samuelson: Alcon Laboratories, Inc.; AqueSys, Inc.; Glaukos Corporation; and Ivantis, Inc.

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1. Schmier JK. Medicare expenditures decrease for glaucoma surgery as number of procedures increases. *Arch Ophthal.* 2009;127:900–905.
2. NEI. National Eye Institute Report of the Ocular Epidemiology Strategic Planning Panel, September 2007. www.nei.nih.gov/strategicplanning/finalreport.asp.
3. Distelhorst JS, Hughes GM. Open-angle glaucoma. *Am Fam Phys.* 2003;67:1937–1944, 1950.
4. NEI. National Eye Institute Report of the Ocular Epidemiology Strategic Planning Panel, September 2007. www.nei.nih.gov/strategicplanning/finalreport.asp. Accessed July 20, 2009.
5. Vision 2020. What is avoidable blindness? Glaucoma. London: International Agency for the Prevention of Blindness; World Health Organization; n.d.; http://www.vision2020.org/main.cfm?type=WIBGLAUCOMA. Accessed September 21, 2012.
6. Gurwitz JH, Glynn RJ, Monane M, et al. Treatment for glaucoma: adherence by the elderly. *Am J Public Health.* 1993;83(5):711-716.
7. Nordstrom BL, Friedman DS, Mozaffari E, et al. Persistence and adherence with topical glaucoma therapy. *Am J Ophthalmol.* 2005;140(4):598-606.
8. Friedman DS, Quigley HA, Gelb L, et al. Using pharmacy claims data to study adherence to glaucoma medications: methodology and findings of the Glaucoma Adherence and Persistency Study (GAPS). *Invest Ophthalmol Vis Sci.* 2007;48(11):5052-5057.
9. Lichter PR, Musch DC, Gillespie BW, et al. Interim clinical outcomes in the Collaborative Initial Glaucoma Treatment Study comparing initial treatment randomized to medications or surgery. *Ophthalmology.* 2001;108:1943-1953.
10. The AGIS Investigators. The Advanced Glaucoma Intervention Study (AGIS): 7. The relationship between control of intraocular pressure and visual field deterioration. *Am J Ophthalmol.* 2000;130:429-440.
11. DeBry PW, Perkins TW, Heatley G, et al. Incidence of late-onset bleb-related complications following trabeculectomy with mitomycin. *Arch Ophthalmol.* 2002;120:297-300.

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Changing the Glaucoma Treatment Paradigm

THE FUTURE OF GLAUCOMA SURGICAL THERAPIES

Dr. Samuelson: The past few years have seen a plethora of new glaucoma treatment options become available. I have been practicing for 20 years, and I feel that this is clearly the most exciting time in the evolution toward expanded treatment options for the management of glaucoma. Great technological advances are enabling us to enjoy measurable improvements in the surgical management of glaucoma, especially in terms of safety.

The greatest research interest has been in finding treatments that are less invasive and have lower risk profiles compared to traditional glaucoma surgeries such as trabeculectomy and the implantation of glaucoma drainage devices. A new group of devices and procedures known for their low risk profile and minimally invasive nature are changing the glaucoma treatment algorithm. No longer should patients be placed on maximum medical therapy until uncontrolled IOP and vision deterioration justify invasive and complicated surgery. New treatment options not only can reduce medications, but they may also open up the field for comprehensive ophthalmologists, who see the majority of mild-to-moderate glaucoma cases.

Dr. Ahmed: To define a specific subset of the many advances in glaucoma treatment in the past few years, I have coined the term *micro invasive glaucoma surgery* (MIGS). As specified in the peer-review article I coauthored with Hady Saheb,[1] MIGS procedures share five specific characteristics: (1) an ab interno microincision, (2) minimal trauma, (3) efficacy, (4) a high safety profile, and (5) rapid recovery (Figure 1). The ab interno approach allows the direct visualization of anatomic landmarks while also sparing the conjunctiva, minimizing the refractive impact, and avoiding the serious complications seen with other glaucoma surgeries. MIGS procedures can occur in three different spaces: Schlemm canal, the suprachoroidal space, and the subconjunctival space.

Because MIGS procedures combine easily with cataract surgery, both glaucoma specialists and comprehensive ophthalmologists should be able to perform them with a relatively short learning curve. The modest efficacy of most MIGS procedures compared to more invasive glaucoma treatments is balanced by an ultra-low risk profile.

FIGURE 1. CHARACTERISTICS OF MICROINVASIVE GLAUCOMA SURGERY

- Ab interno microincision
- Minimal trauma
- Efficacious
- High safety profile
- Rapid recovery

There are currently eight devices either approved or currently undergoing review by the FDA that I believe fall into the MIGS category (*see Table 1 for their current status*).

1. The AqueSys implant (Aquesys, Inc.) procedure involves the ab interno placement of a microfistula to the subconjuntival space.
2. The Cypass suprachoroidal microstent (Transcend Medical, Inc.) is made of polymide material and is inserted ab interno into the suprachoroidal space through a manual inserter.
3. Excimer laser trabeculostomy (ELT), invented by Michael Berlin, MD, creates small holes in the trabecular meshwork and inner wall of Schlemm canal by using energy from a quartz fiberoptic probe connected to a xenon chloride pulsed excimer laser. Eight to 10 laser punctures are spaced over 90º, with visible whitening of the trabecular meshwork and bubble formation.
4. The Hydrus Microstent (Ivantis, Inc.) is a nitinol intracanalicular (in the canal) scaffold that has an inlet into the anterior chamber and contains three windows along its 8-mm length.
5. The iStent Inject device (Glaukos Corporation) is a second-generation trabecular micro-bypass implant that allows for the implantation of two stents without having to leave the eye.
6. The iStent Supra (Glaukos Corporation) is a micro-bypass implant made of Polyethersulfone (PES) that is inserted ab interno into the suprachoroidal space.
7. The FDA-approved iStent Trabecular Micro-Bypass implant from Glaukos Corporation is a heparin-coated titanium device that is implanted into Schlemm canal following cataract surgery.
8. The ab interno Trabectome (NeoMedix, Inc.) procedure removes a strip of trabecular meshwork and inner wall of Schlemm canal using high-frequency electrocautery.

Because these new surgical options avoid conjunctival incisions, they preserve the possibility of subsequent conjunctival surgery should it be necessary. Most importantly, these MIGS procedures have few side effects, yet still control pressure. For most patients, an IOP in the mid-teens is sufficient to halt visual damage and eliminate the need for medication.

As procedures, devices, and diagnostic technologies continue to be developed within this surgical space, it is important to address the gaps in our current glaucoma treatment algorithm and identify ways to better serve our patients.

CHALLENGES WITH MEDICAL THERAPY FOR GLAUCOMA

In the following roundtable, glaucoma specialists discuss the impact of recent studies on clinical practice.

Dr. Samuelson: Let's discuss the adequacy or inadequacy of medications as a management for glaucoma.

Dr. Kahook: Once the decision to treat glaucoma or ocular hypertension (OHT) is made, primary therapy typically consists of a topical drop designed to lower IOP. Most commonly, we use the prostaglandin analog class of medication, which is prescribed once per day. However, many patients require a second or third medication, which can increase the dose load per day from one to eight or more drops per day.

One of the common problems with medical therapy for glaucoma is poor patient adherence. Investigators in the Glaucoma Adherence and Persistency Study (GAPS)[2] conducted a retrospective analysis of a pharmacy claims database and found that 1 year after the initial prescription, only 10% of subjects were 100% persistent in filling their prescriptions for ocular hypotensive medication. Another study[3] that allowed the definition for adherence to include patients who intermittently refilled their prescriptions found that only 37% of patients had refilled their initially prescribed medication within 60 to 120 days at 3 years after their initial dispensing. So, we know that large percentages of patients do not take their medications as prescribed (Table 2[4]). The reasons for the lack of adherence range from physical limitation in the elderly population all the way through to issues with side effects. Thus, although topical therapy is the overall mainstay of glaucoma therapy, medications fail in many cases, and we have to advance to laser trabeculoplasty or invasive surgery.

Dr. Katz: The biggest limitation with medical therapy, in my mind, is the compliance issue. We would like to think that all patients are taking their medications as prescribed, but many indications point otherwise. A large percentage of our patients are so noncompliant that their condition is probably going to worsen as a result, as evidenced by studies showing that poor compliance is associated with higher IOPs and greater visual field loss.[5]

I think the biggest challenge for us in terms of medical therapy for a chronic condition like glaucoma is to convince our patients to continue to use their medications. We know it costs them money, it is hard for them to remember to take it, and there may be side effects associated with the use of medication.

Although newer and better medications may be in the pipeline, we are certainly not going to develop a drug that patients only have to take once per week or once per month to achieve IOP control. Any other drop will still have all of the same issues with compliance that we currently have (Table 3[6]). There may be interesting ways of delivering drugs on the horizon, but we have been talking about those options for the past 2 decades, and we are still waiting for something other than eye drops. In addition,

TABLE 1. CURRENT STATUS OF MIGS DEVICES

MIGS Device	Approval Status
AqueSys	Conducting phase 3 trials
Cypass Suprachoroidal Microstent	Recruiting for US pivotal trial
Excimer laser trabeculostomy	Not yet approved in the US
Hydrus Microstent	Initiated US pivotal trial in March 2012
iStent inject	Recruiting for US pivotal trial
iStent upra	Recruiting for US pivotal trial
iStent Trabecular Micro-Bypass	FDA approved
Trabectome	FDA approved

TABLE 2. SUMMARY OF PILOCARPINE COMPLIANCE BY PATIENT REPORT AND BY EYE DROP MONITOR[4]

	Patient Report (n=184)		Eye drop monitor	
Percent of prescribed doses taken	Number	%	Number	%
0 – 24.9%	0	0	11	6.0
25 – 49.9%	0	0	17	9.2
50 – 74.9%	2	1.1	35	19.0
75 – 100%	182	98.9	121	65.8

TABLE 3. PROBLEMS ENCOUNTERED DURING SELF-ADMINISTRATION OF EYE DROPS[6]

Problem	% Patients
Directing the bottle Miss frequently Miss occasionally	 36 13
Shaky hand	8
Difficulty squeezing the bottle	20
Blinking	12
Poor visibility of dropper tip	13
Inadvertently inserting dropper tip into eye	9
Reading labels and identifying medication	14

physicians are terrible at gauging who is adherent and who is not. Patients typically do take their medication 1 or 2 days before seeing the doctor, so we think they are controlled when really they are not.

Dr. Donnenfeld: We must also consider the quality of the ocular surface and quality-of-life issues associated with glaucoma drops that are sometimes ignored. Long-term use of glaucoma medications affects the ocular surface negatively, reduces quality of vision, and leaves the patient with erythema and foreign body sensation.[7] Ocular discomfort also reduces compliance. Furthermore, some medications have systemic side effects that we physicians tend to ignore, but that are real and can have an impact on morbidity in these patients.

Finally, in the economic environment we live in today, it is worth noting the cost of glaucoma medications and patients' ability to pay for them. Many people cannot afford their medications, even with copays; they cannot afford to use two or three medications every day for years on end. A treatment that would allow them to reduce or eliminate the need for daily medications would relieve a significant financial burden. As responsible physicians, we have to understand that issue.

Dr. Katz: Further to Dr. Donnenfeld's comments, studies have found that even with patients who fill their prescriptions and report they are using them correctly, the vast majority are not, in fact, able to instill a single drop into their eye without touching the corneal surface.[8] Thus, among those individuals who are covered by insurance and can pay for their medications, many run out before they are due for their next refill, and they simply do not take any medication during that time.

PROS AND CONS OF CURRENT SURGICAL INTERVENTIONS

Dr. Samuelson: Let's discuss now the surgical options for the treatment of glaucoma. Dr. Katz, you have conducted some work on the efficacy of laser trabeculoplasty as compared to medical therapy. It seems to me that we do not use this strategy as much as we could or arguably should as an initial treatment for managing glaucoma. Why is that?

Dr. Katz: I agree that we do not use laser trabeculoplasty enough, and I do not think there is one reason why. Part of the explanation is that laser trabeculoplasty works best when used as an initial treatment as opposed to adding it onto a medication, and historically, we have tended to use laser trabeculoplasty after failing medical therapy. An example would be placing a patient on timolol maleate 0.5% ophthalmic solution and then adding a prostaglandin. The prostaglandin, which is currently the number-one option for most patients, would not as effectively lower IOP as an adjunctive therapy as it would as an initial monotherapy.

Over the years, we surgeons have been taught to use medications, lasers, and surgery in that order, and it is hard to break that habit. Another drawback to using lasers is that many patients have a negative misconception of them; they equate all lasers with high-risk treatments such as panretinal photocoagulation in cases of diabetic retinopathy. We must educate patients that this is a totally different laser.

Dr. Kahook: When I diagnose patients with glaucoma, I review the three kinds of treatments typically used: medication, laser trabeculoplasty, and surgery. When patients hear the word *laser* uttered, oftentimes they think about applications such as those discussed

by Dr. Katz, but I think a lot of their impression has to do with how the option is presented. I find that a large percentage of my patients do accept trabeculoplasty as the first-line therapy. We do not have the issues of compliance and adherence with laser therapy that we do with medical therapy, and that is a great benefit. However, laser trabeculoplasty does not necessarily work on everybody, so we often have to resort to medical therapy, which brings us back to the problems with adherence previously discussed.

Dr. Lewis: Because we know that patients are often noncompliant with medications, we start investigating surgical management. I agree that the initial approach is with laser trabeculoplasty. Although a laser is effective at lowering IOP, the effects often do not last long term, and there is some question about the efficacy of repeating treatments.

Dr. Samuelson: What role does endoscopic cyclophotocoagulation or transscleral cyclophotocoagulation play in your practices?

Dr. Donnenfeld: As a cataract and corneal surgeon, I see a tremendous amount of glaucoma in my practice, and I often initiate medical therapy. I will transfer these patients' care to my partners who are glaucoma specialists once these individuals develop a significant glaucomatous problem. However, endoscopic cyclophotocoagulation (ECP) is the one procedure that I perform. When I see a patient scheduled for penetrating keratoplasty and who has significant glaucoma, it is very simple to perform ECP at the same time as the corneal procedure with good results. ECP is an inflammatory process, and these patients will generally have very hot eyes for a period afterward, but I think we are moving toward combining glaucoma procedures with a primary procedure such as a corneal transplant or cataract surgery. I feel much more comfortable, however, letting glaucoma specialists manage isolated glaucoma procedures.

Dr. Katz: ECP really is not a mainstream procedure for glaucoma surgeons, for a number of reasons. As Dr. Donnenfeld mentioned, it is fairly inflammatory; it destroys the ciliary body and tissue inside the eye that secretes aqueous fluid to regulate IOP. Glaucoma is an outflow disease, not a hypersecretion disease, so it really does not make sense to perform ECP in eyes with generally good vision. Having said that, there are great examples where ECP is very helpful. In our institution, my colleagues and I tend to use it in patients who really are at the end of the road. For example, it is wonderful in cases in which we do not want to implant a third tube shunt. Thus, we reserve ECP for select cases; it certainly is not a mainstream glaucoma procedure for us.

Dr. Kahook: I typically reserve ECP for patients who are undergoing cataract extraction and have already had a glaucoma drainage device implanted, or those who have had one or more failed trabeculectomies. I do not find that ECP works well for most patients undergoing cataract extraction in the setting of mild-to-moderate glaucoma.

Dr. Samuelson: For patients who need something more, our traditional treatment options have been trabeculectomy and aqueous drainage devices. Let's discuss the relative strengths and weaknesses of those surgical categories.

TRABECULECTOMY VERSUS AQUEOUS DRAINAGE DEVICES

Dr. Katz: We have a long historical track record with trabeculectomy, as both a standalone procedure and combined with cataract surgery. It can be performed with phacoemulsification as a single-site or double-site approach, with and without antimetabolites. Of course, we also know the potential dangers of a filtering procedure.

There is some experience with inserting tube shunts as well, even combined with phacoemulsification. For some surgeons, that is another effective way of controlling IOP in many patients. Trabeculectomy and tube shunts have been our two most common procedures in the glaucoma community, with ECP used more by the comprehensive ophthalmologist in combination with phacoemulsification to gain additional control of IOP.

Dr. Kahook: In my practice, with most patients whose glaucoma is progressing despite maximum medical therapy, and regardless of whether their disease is considered moderate or severe, the surgery of choice is often a trabeculectomy, insertion of an Ex-Press Glaucoma Filtration Device (Alcon Laboratories, Inc.), or use of a glaucoma drainage device. All of these approaches are invasive and carry with them the possibility of significant morbidity. In my opinion, there is a great need for an effective, minimally invasive treatment option for patients with early-to-moderate-stage glaucoma. Such options would allow us to tailor therapy for our patients.

Dr. Donnenfeld: I do not perform trabeculectomy or use tube shunts due to the demands of managing the patient postoperatively and the high complication rate.

If I had a procedure that would offer lower IOP with less morbidity, I would certainly gravitate toward it.

Dr. Samuelson: My colleagues and I often delay filtration surgery until the eye's target pressure is closer to 10 or 12 mm Hg so that we can justify the risks. I often wonder what would happen if we had something safer that could be used earlier in the process of the disease, when the target IOP is less aggressive. For example, a safe procedure, used earlier, might yield a pressure of 14 to 18 mm Hg and still meet the target for that particular patient. If such a device were available, we would not delay surgery until the disease is so advanced that an IOP of 10 to 12 mm Hg is required.

Dr. Lewis: The most definitive way of controlling glaucoma currently is to perform a trabeculectomy. That procedure still plays a big role in advanced disease, where the risks are offset by the benefits for patients who have more profound visual loss. We are looking for a surgical treatment for early glaucoma that is safe and controls the disease in the long term. Medications work when patients take them, but patients often fail to do so. This is where these new MIGS procedures are going to play a big role. They allow us the opportunity to surgically treat glaucoma earlier in the disease course, safely and effectively.

Dr. Donnenfeld: In the United States, people who undergo cataract surgery now have significant expectations for their postoperative quality of vision and quality of life. They expect to see well. If a patient with glaucoma and cataracts could be offered a safe and effective procedure that allowed the rapid return of visual quality and a reduction or elimination of their glaucoma medications, this would be a technology that would change my approach to combining cataract and glaucoma surgery.

Dr. Kahook: Usually, the discussion about which glaucoma procedure is most preferable and how to move through the decision-making process occurs between glaucoma specialists. We think in terms of at what point a trabeculectomy or glaucoma drainage device is needed. But the truth is, most glaucoma cases are seen by general ophthalmologists and busy cataract surgeons who do not use these modalities. I have heard that approximately 20% of the cataract surgeries performed in the United States are on patients who also have coexistent glaucoma. By the time I see them in my practice, those individuals have already undergone phacoemulsification and have been followed to the point where the risk-to-reward ratio, as it relates to invasive surgery, has tilted toward sending them to a glaucoma specialist.

EARLY-TO-MODERATE GLAUCOMA

Dr. Samuelson: We all agree that for people with very aggressive and advanced glaucoma—the worst form of the disease that we see—trabeculectomy is the gold standard. I do not see that standard changing anytime soon. However, I want to discuss patients with early-to-moderate glaucoma in particular. How has your management of phakic glaucoma changed in the last decade with the advent of new medicines and since clear corneal cataract surgery has become the gold standard?

Dr. Kahook: Numerous articles have reported on the IOP-lowering efficacy of phacoemulsification.[9] As a fellow with Joel Shuman, MD, I was exposed to his teachings on the pathophysiology of the changes noted in the trabecular meshwork after phacoemulsification that lead to a decrease in IOP.[10] With patients who have a visually significant cataract and are on a single IOP-lowering medication, oftentimes phacoemulsification alone can decrease IOP in a significant and sustained fashion. In many cases, the decrease in IOP can last 3 to 5 years.

Dr. Donnenfeld: I think that all of the data out there confirm that yes, phacoemulsification can lower IOP. However, that does not mean that every patient who undergoes phacoemulsification experiences a decrease in IOP. As a group they do, but there are some patients who do not, and some patients who actually have a sustained increase in pressure. I have performed successful cataract surgery in patients who were on one medication prior to surgery, and 2 months out, they are on three medications, and their IOP is 35 mm Hg. Their glaucoma is uncontrolled, and I send them to a glaucoma specialist for further management. So yes, in general, phacoemulsification in the right eyes can lower IOP to target levels, but not in every patient.

Dr. Samuelson: This discussion underscores that glaucoma is such a heterogenous disease. We have to continue to be mindful that some patients have much more aggressive courses than others. When considering all patients, early and advanced, that have both cataract and glaucoma, has your use of combined phaco-trabeculectomy procedures increased or decreased in recent years?

Dr. Kahook: I would say that my use of combined phaco-trabeculectomy, or even more rarely, phaco-tube,

has decreased over the years. I do not combine these procedures unless a patient has very advanced glaucoma with advanced visual field defects along with a visually significant cataract, and there is a compelling need to limit visits to the OR.

In patients with advanced glaucoma, I usually perform the glaucoma surgery first and then give the eye some time to recover, followed by phacoemulsification if needed. In cases of early-to-moderate glaucoma, I perform the phacoemulsification first and then see how the IOP responds, to gauge if the glaucoma procedure is still needed.

Dr. Lewis: Combined phaco-trabeculectomy is the most widely reported procedure for combined surgery.[9] MIGS procedures provide the opportunity to surgically manage glaucoma without the risks of trabeculectomy and all its inherent complications (Table 4[11]). Now, we will be able to give the patient who is on one to three medications at the time of cataract surgery greater control of their pressure over time, and hopefully get them off the medications as well.

Dr. Ahmed: Other surgical alternatives to MIGS include Canaloplasty (iScience International), the SOLX

TABLE 4. POSTOPERATIVE COMPLICATIONS IN THE TUBE VERSUS TRABECULECTOMY STUDY[11]

	Tube group n (%) (n=107)	Trab. group n (%) (n=105)
Early postoperative complications		
Choroidal effusion	15 (14)	14 (13)
Shallow or flat anterior chamber	11 (10)	10 (10)
Wound leak	1 (1)	12 (11)
Hyphema	2 (2)	8 (8)
Aqueous misdirection	3 (3)	1 (1)
Suprachoroidal hemorrhage	2 (2)	3 (3)
Vitreous hemorrhage	1 (1)	1 (1)
Decompression retinopathy	0	1 (1)
Cystoid macular edema	0	1 (1)
Late postoperative complications		
Persistent corneal edema	10 (9)	8 (8)
Dysesthesia	1 (1)	8 (8)
Encapsulated bleb	2 (2)	6 (6)
Choroidal effusion	2 (2)	4 (4)
Cystoid macular edema	5 (5)	1 (1)
Hypotony maculopathy	1 (1)	4 (4)
Persistent diplopia	5 (5)	0
Bleb leak	0	5 (5)
Tube erosion	5 (5)	-
Endophthalmitis/blebitis	1 (1)	3 (3)
Chronic or recurrent iritis	2 (2)	1 (1)
Tube obstruction	3 (3)	-
Retinal detachment	1 (1)	1 (1)
Corneal ulcer	0	1 (1)
Shallow or flat anterior chamber	1 (1)	0
Total no. of patients with postoperative complications	42 (39)	63 (60)

Gold Shunt (SOLX), and the ExPress Glaucoma Filtration Device. Canaloplasty may be more efficacious than MIGS and appears to have a lower risk than traditional bleb-forming surgery. In comparison, the ExPress device is quite efficacious but carries significant additional risk. The SOLX Gold Shunt, while blebless, is inserted into the supraciliary space via an ab externo procedure.

EFFICACY AND PATIENT PROFILE OF THE AB INTERNO MICRO-BYPASS IMPLANT

Dr. Samuelson: We all long for a safe glaucoma procedure that we can combine with cataract surgery. As the medical monitor for the iStent FDA Trial,[12] what is your analysis of the ab interno micro-bypass device in terms of safety and efficacy, Dr. Katz?

Dr. Katz: As far as safety, the micro-bypass implant combined with phacoemulsification was compared to cataract surgery alone, and there was very little difference between the two groups. The FDA trial did not manifest anything unforeseen in terms of intra- or postoperative problems, and there was no apparent effect on the cornea. So from a safety angle, this looks like a pretty safe procedure to perform in eyes that are undergoing concurrent cataract surgery, as was concluded in the article.

Dr. Lewis: The results from the US pivotal study[12] showed that IOP reduction with fewer medications was clinically and statistically significantly better after implantation of the micro-bypass device plus cataract surgery versus cataract surgery alone. Of eyes that received the micro-bypass device, 72% achieved unmedicated IOP of less than 21 mm Hg at 1 year, compared to 50% of eyes that had cataract surgery alone. In addition, 66% of the eyes that received the micro-bypass device achieved greater than 20% in IOP reduction without medications, compared to 48% of the control group. From these results, we can see that placement of a single micro-bypass device makes a significant contribution toward reducing IOP and the burden of medications in patients.

Dr. Ahmed: There is a great synergy between cataract surgery and the use of the ab interno micro-bypass device, and the combination allows for a more consistent reduction of IOP as well as reduced medication burden for the patient. In a terminal washout study[13] that compared cataract surgery alone to cataract surgery with an iStent Trabecular Micro-Bypass device, the latter group achieved a greater reduction in IOP by approximately 3 mm Hg, which translated to a mean IOP of 16.6 mm Hg. Whereas cataract surgery alone tends to lower IOP, when it is combined with a micro-bypass implant, a greater percentage of patients are able to be free of medication after surgery. I have participated in the investigational trials for AqueSys, Cypass, Hydrus, iStent and Trabectome, and although the iStent and Trabectome are the only ones currently approved by the FDA, they all have the ability to reduce the burden of medication.

Dr. Samuelson: Dr. Donnenfeld, recently you have shown some enthusiasm for getting involved in glaucoma, and I know you traveled to Armenia to gain some experience with the ab interno micro bypass-device. Can you tell us your analysis of this new technology?

Dr. Donnenfeld: I decided to not get involved with surgical glaucoma because in my opinion, the complication rate was too high for me and my patients as a cataract and corneal specialist. I felt surgical management should be left to a specialist dedicated to glaucoma surgery. For the past 25 years, I have been looking for a glaucoma treatment that would offer similar efficacy to what we achieve with phacoemulsification—a procedure with a very high rate of patient acceptance that is performed and tolerated with a very low complication rate. The first surgical glaucoma procedure that I have seen that meets my criteria is the ab interno micro-bypass implant. It offers comprehensive cataract surgeons glaucoma management opportunities that have not been available in the past. The device provides the ability to control IOP and improve patients' quality of life in a way that is comfortable for me.

My experience in Armenia was implanting the micro-bypass device in a mostly phakic population that could not afford glaucoma medications. My colleagues and I were giving the individuals the opportunity to receive a surgical treatment for a disease that, if left untreated, would cause blindness in many of them. I was working with a population that spoke a different language from me, using an inferior microscope to what I normally have available, and working on phakic patients who have narrow anterior chambers and narrow angles, and the results were spectacular. In my experience, this procedure is as safe as any I have ever performed in my career in ophthalmology. I saw no vision-threatening side effects. Sometimes it took me longer to implant the device in certain patients, but every patient successfully received a micro-bypass device and achieved surgical success.

We are now seeing 1-year postoperative results that show that these patients have done extremely well—again, without cataract surgery. Thus, we see that the IOP-lowering effect had nothing to do with phaco-

emulsification, that it came purely from the micro-bypass implant. I am very excited that we now have something available to the comprehensive ophthalmologist that was so desperately needed. I think this will be a huge asset for surgeons and more importantly, for our patients.

Dr. Kahook: I concur with everything Dr. Donnenfeld said regarding the more difficult circumstances of working in Armenia. In this patient population that did not undergo phacoemulsification, we are still seeing a significant reduction in IOP that can only be attributed to the device implanted.

The long-term data now coming out of this study show that the IOP-lowering curve is stable throughout the follow-up. This is great evidence that this technique is efficacious and sustainable.

Dr. Donnenfeld: The exciting thing about the Armenian study was that we looked at three generations of the micro-bypass implant: the original device, the suprachoroidal version, and the second-generation injectable version. We now have data on all three devices without the compounding variable of phacoemulsification. The data show that each device provides a pure IOP-lowering effect, which should give surgeons confidence that this procedure offers medical advantages without doing harm.

Dr. Ahmed: Although effective, the performance of a single microstent is limited by the capacity of the area through which the aqueous flows. For this reason, I have been involved in trials using multiple microstents. In the first prospective case series of 53 patients who received two or three micro-bypass implants at the time of cataract surgery,[14] we saw a significant reduction in IOP across all patients. Those who received two devices had an average 64% reduction in medications, while those who received three implants had an average 84% reduction in medications.

Dr. Donnenfeld: We found similar results in the iStent Dose-Response Study.[15] My coinvestigators and I examined the effects of implanting one versus two versus three microstents plus 1 medication on patients who had uncontrolled glaucoma on two medications. One year after surgery, 94% of the eyes (n=50) that received one microstent had an IOP of less than 18 mm Hg on one medication, and 100% of eyes that received two or three microstents had an IOP of less than 18 mm Hg on one medication. Additionally, 88% of eyes that received two or three of the implants reached an IOP of less than 15 mm Hg on one medication.

LEARNING CURVE

Dr. Kahook: With any new procedure, there is always a learning period. I found the learning curve with the micro-bypass device to be very short, even though the technique was unfamiliar to me. In the first three to five procedures, I learned how exactly to move my hand toward the angle and how the device fits into Schlemm canal. I find the placement of the device to be quite reproducible. Moreover, the microstent has an excellent safety profile, and the data from Armenia show that it does not depend on phacoemulsification for its efficacy. I think this is a great testament to using this approach in mild-to-moderate glaucoma patients. During the study conducted in Armenia, I saw no major complications from the micro-bypass implant.

Dr. Lewis: I was an early investigator for the microstent, and the ease of the procedure is very apparent. It does not require extensive training to learn how to perform the procedure. The key to implanting the device is to have a comfort level with gonioscopy. The learning phase will be focused on positioning the patient correctly at the microscope during surgery and then becoming comfortable with a gonioprism while passing an ab interno device. Although this technique will not be difficult for most ophthalmologists, it's important to practice. I suggest that surgeons perform gonioscopy in their offices and become familiar with the angles. Prior to surgery, they should practice using the gonioprism and angling the head to maximize the view of the angle. The positioning is very important with this procedure.

Dr. Ahmed: For those surgeons who are experienced working in the angle, this procedure will not be a problem. I encourage those who do not have this experience to place the gonioscope on the angle, move it around without touching the sides, and get used to the angle of the head and of the hand when working in this space.

MINING TRADITIONAL OUTFLOW PATHWAYS

Dr. Katz: We are now back to the fundamental problem in glaucoma, which is improving outflow without creating an artificial subconjunctival filtration access that is obviously not physiologic. We have been taught for years that the outflow problem exists in the trabecular meshwork and the inner wall of Schlemm canal. Here, we have a device that addresses exactly that in a nondestructive manner. This tiny, 1-mm device bypasses the primary source of resistance.

Dr. Lewis: Historically, most glaucoma treatments have created artificial channels; blebs, tubes, and other

similar devices all bypass the conventional outflow systems. With MIGS procedures such as the iStent Trabecular Micro-Bypass and Trabectome currently, and the Hydrus Microstent, ELT, iStent inject and iStent supra when they receive FDA approval, we will be able to enhance existing outflow for a more physiologic control of pressure, which is a real advantage for avoiding complications long term.

Dr. Kahook: The beauty of the MIGS procedures is that they do not preclude trabeculectomy if we still need it in the future. These procedures spare the conjunctiva and do not paint us into a corner for future procedures, if needed.

Dr. Samuelson: Currently, several companies are investigating the use of suprachoroidal filtration to manage glaucoma. Dr. Kahook, would you attempt a canal procedure before trying the suprachoroidal space, or do you feel you can go directly to the latter?

Dr. Kahook: Regarding the use of Schlemm canal versus the suprachoroidal space, I prefer treating the disease process itself by targeting the tissue mainly responsible for obstructing the outflow of aqueous humor. I would start with a Schlemm canal device first, and then if need be, I would place a suprachoroidal device to add synergy with the existing Schlemm canal device. I think this strategy provides the best of both worlds.

The optimal therapy would be tailored to the individual eye. The ability to use a microinvasive modality followed by a second or third microinvasive surgery allows utility for the glaucoma surgeon that once only existed for the cataract surgeon. For example, we could start with phacoemulsification plus an ab interno microstent, and still reserve the option down the road for an additional procedure if necessary. As mentioned previously, preclinical studies performed in ex-vivo perfused human eyes found that two micro-bypass implants are better than one, and that adding a microstent in the suprachoroidal region produced additional IOP lowering compared to having two microstents in place.[16]

PATIENT PROFILE

Dr. Samuelson: Describe your ideal candidate for a MIGS procedure.

Dr. Katz: My candidate for a MIGS procedure is someone for whom I feel that cataract surgery alone will not provide sufficient IOP control. This would not include the truly advanced glaucoma patients. I would also suggest a MIGS device to patients who are well controlled on medications but with whom I am worried about compliance, particularly if the patient is expressing interest in discontinuing their medications.

Dr. Samuelson: How will we approach titratable therapy?

Dr. Kahook: The beauty of this type of approach is the option to use one or more devices. From the clinical studies with the micro-bypass implant, we know that two microstents reduce IOP to a greater degree than one. So, depending on the target pressure, I could place one or two devices. If I decide to place one microstent, I can always go back in and implant a second device if needed with a lower risk than more invasive surgeries. Alternatively, when suprachoroidal devices are available in the US, I can implant one or two microstents and follow with a later suprachoroidal device if the specific case dictates. Having such options is the true revolution that these MIGS devices provide.

Dr. Donnenfeld: I would like to see some simple guidelines developed by glaucoma specialists, but I think any patient with ocular hypertension or a visual field loss that is real but not significant benefits from these devices. The number of medications the patient is on will dictate how many devices he or she should receive. We are seeing now that the IOP-lowering effect of added devices is commensurate with the number of medications the patient is taking. If someone is taking two medications, I would probably implant two microstents, versus one microstent in someone on one glaucoma medication.

Dr. Ahmed: I see MIGS procedures entering the continuum of glaucoma care for patients who are on one medication, before starting multiple medications. My top priority after lowering IOP is to get patients on one medication or less per day. As a general rule, for a target pressure of 18 mm Hg or so, I use one microstent, and for a target pressure of 15 mm Hg or less, I use two microstents. From a lifestyle perspective, I believe nonmedical intervention is superior for both the patient and the physician.

REIMBURSEMENT

Dr. Samuelson: How do we justify the increased expense of MIGS procedures as compared to trabeculectomy?

Dr. Katz: We start with the patient. Patients demand certain results from cataract and refractive surgery, and they are becoming more savvy in reading about glaucoma

surgery and the problems associated with trabeculectomy. If we offer these patients a very low-risk procedure that may cost more versus a procedure that is less expensive but has higher risks, I know which one I would choose as a patient. I personally would go with the low-risk procedure, even if I had to pay additional money for it. Like our earlier discussion of laser trabeculoplasty: When you sit down and explain to the patient the relative risks and benefits of these procedures, I think many of them are going to opt for a MIGS device.

Dr. Kahook: Schlemm canal devices like the iStent from Glaukos and the Hydrus from Ivantis, as well as suprachoroidal devices like the iStent Supra from Glaukos or the Cypass from Transcend, all have the potential to lessen the burden of medical therapy while addressing concerns involving poor adherence to prescribed treatments. Oftentimes, we discuss the cost of a device or the expense involved in the procedure. In this case, it is important to keep in mind the quality-of-life benefit. If we can measure quality of life monetarily and compare it to the cost of medications, time, or hardware, I think we would find that these newer procedures offer a great benefit.

Dr. Donnenfeld: As a comprehensive cataract surgeon, I am looking at this as a procedure that is going to benefit my patients, improve their quality of life, eliminate compliance issues, and maintain good IOP control. In my opinion, a microstent offers all of that.

Dr. Katz: If you are healthcare conscious, you need to look at the whole process of surgery and not just the cost of the device. The number of postoperative visits and the possible returns to the OR for a choroidal effusion drainage or vitrectomy for endophthalmitis all have to be included in a comparative analysis.

According to Medicare data, the number of trabeculectomies performed in the United States has been going down steadily over the past few years, even as the number of glaucoma patients has increased. There is a huge patient population out there that can really benefit from better pressure management, less medication, and less disease severity down the road. Healthcare economists can undoubtedly find many ways we may actually save money with a MIGS procedure, rather than it being an added expense.

Dr. Donnenfeld: This is the only time that I have been excited about glaucoma surgery in the last 25 years, and that is because I feel comfortable that I can provide improved care to my patients without increasing risk to their surgical management for the first time.

Dr. Samuelson: This is a very exciting time in glaucoma treatment. Until recently, we have not seen the technological advances in glaucoma surgery that we have witnessed in refractive, cataract, and retinal surgery. In the past decade, numerous startup companies have invested considerable research and development toward finding a safer, less minimally invasive approach to glaucoma surgery. It is time that we bring these surgical improvements in glaucoma management to our patients. ■

1. Saheb, H. Ahmed, IK. Micro-invasive glaucoma surgery: current perspectives and future direction. *Curr Opin Ophthalmol.* 2012;23:96-104.
2. Friedman DS, Quigley HA, Gelb L, et al. Using pharmacy claims data to study adherence to glaucoma medications: methodology and findings of the Glaucoma Adherence and Persistency Study (GAPS). *Invest Ophthalmol Vis Sci.* 2007;48(11):5052-5057.
3. Nordstrom BL, Freidman DS, Mozaffari E, et al. Persistence and adherence with topical glaucoma therapy. *Am Journal of Ophthalmol.* 2005;140(4): 598.e1-11.
4. Kass MA, Meltzer DW, Gordon M, et al. Compliance with topical pilocarpine. *Am J Ophthalmol*. 1986;101:515-523.
5. Stewart WC, Chorak RP, Hunt HH, Sethuraman G. Factors associated with visual loss in patients with advanced glaucomatous changes in the optic nerve head. *Am J Ophthalmol*. 1993;116:176–181.
6. Winfield AJ, Jessiman D, Williams A, Esakowitz L. A study of the causes on noncompliance by patients prescribed eyedrops. *Br J Ophthalmol.* 1990;74:477-480.
7. Xalatan, Lumigan and Timpotic package inserts.
8. Stone JL, Robin AL, Novack GD, et al. An objective evaluation of eyedrop instillation in patients with glaucoma. *Arch Ophthalmol*. 2009;127(6):732-736.
9. Friedman DS, Jampel HD, Lubomski LH, et al. Surgical strategies for coexisting glaucoma and cataract. An evidence-based update. *Ophthalmology*. 2002;109:1902-1915.
10. Wang N, Chintala SK, Fini ME, Schuman JS. Ultrasound activates the TM ELAM-1/IL-1/NF-kappaB response: a potential mechanism for intraocular pressure reduction after phacoemulsification. *Invest Ophthalmol Vis Sci*. 2003;44(5):1977-1981.
11. Gedde SJ, Schiffman JC, Feuer WJ, et al. Three-year follow-up of the tube versus trabeculectomy study. *Am J Ophthalmol.* 2009;148:670–684.
12. Samuelson TW, Katz LJ, Wells JM, et al; US iStent Study Group. Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. *Ophthalmology*. 2011;118(3):459-467.
13. Fea AM. Phacoemulsification versus phacoemulsification with micro-bypass stent implantation in primary open-angle glaucoma. *J Cataract Refract Surg*. 2010;36:407-412.
14. Belovay GW, Naqi A, Chan BJ, et al. Using multiple trabecular micro-bypass stents in cataract patients to treat open-angle glaucoma. *J Cataract Refract Surg*. 2012 Sep 13 [Epub ahead of print].
15. Solomon KD. Randomized trial of 1,2 or 3 trabecular micro-bypass stents and travoprost in open-angle glaucoma uncontrolled on 2 medications. Paper presented at: The American Society of Cataract and Refractive Surgery Annual Meeting; April 23, 2012; Chicago, IL.
16. Heitzmann H, Hunter K, Rech B, et al. Intraocular pressure and flow characterization of micro-invasive trabecular bypass stents by in vitro perfusion and computational flow modeling. Poster presented at: The American Glaucoma Society; New York, NY; March 1-4, 2012.

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CME QUESTIONS

1. When performing MIGS surgery with the iStent,
a. There is no difference in IOP reduction between inserting one stent or two
b. There is a greater reduction in IOP when two stents are inserted
c. There is a greater reduction in IOP when one stent is inserted rather than two

2. The long-term use of topical glaucoma medications is not associated with:
a. Dry eye disease
b. Noncompliance
c. Cataract formation
d. High cost

3. Microinvasive glaucoma devices can:
a. Bypass the trabecular meshwork
b. Drain into the suprachoroidal space
c. Drain into the subconjunctival space
d. a and b
e. All of the above

4. Which MIGS devices mine traditional outflow channels?
a. Trabectome, iStent Trabecular Micro-Bypass, and Hydrus
b. iStent Trabecular Micro-Bypass, AqueSys, and Hydrus
c. AqueSys, Hydrus, and Cypass
d. Hydrus, Cypass, and Trabectome
e. Cypass, Trabectome, and iStent Trabecular Micro-Bypass

5. MIGS procedures enter the continuum of care:
a. Before a patient begins glaucoma medication
b. After a patient is on one medication, before starting multiple medications
c. After a patient has failed multiple medications

6. Which MIGS devices are currently FDA approved?
a. AqueSys and iStent Trabecular Micro-Bypass
b. Hydrus and AqueSys
c. AqueSys and Trabectome
d. iStent Trabecular Micro-Bypass and Trabectome
e. Hydrus and iStent inject

7. The Glaucoma Adherence and Persistency Study found that:
a. Glaucoma medications were less effective over time
b. Only 10% of subjects were 100% persistent in filling their glaucoma medication
c. The majority of glaucoma patients are unable to instill a drop correctly
d. Glaucoma medications were shown to damage the ocular surface over time

8. Trabeculoplasty works best when used:
a. As an initial treatment
b. After one medication
c. After failing medical therapy
d. After failure of a MIGS procedure

9. An important skill set to be proficient at the iStent Trabecular Micro-Bypass procedure is:
a. Cataract extraction
b. Surgical gonioscopy
c. Astigmatic keratotomy
d. Trabeculoplasty

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