Supplement to

Cataract & Refractive Surgery TODAY

CME ACTIVITY

January 2013

CHANGING THE GLAUCOMA TREATMENT PARADIGM

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A CME activity jointly sponsored by the Dulaney Foundation and *Cataract & Refractive Surgery Today*

Changing the Glaucoma Treatment Paradigm

Release date: January 2013. Expiration date: January 2014.

Jointly sponsored by the Dulaney Foundation and *Cataract & Refractive Surgery Today.*

Supported by an educational grant from Glaukos Corporation.

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 suffering 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 comprehensive cataract surgeons.

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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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 Corporation; and Transcend Medical, Inc.

Dr. Chang: Abbott Medical Optics Inc.; Allergan, Inc.;

Glaukos Corporation; Transcend Medical, Inc.

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

Dr. Katz: Alcon Laboratories, Inc; Allergan, Inc.; Pfizer Inc.; Glaukos Corporation; Lumenis Inc.

Dr. Lindstrom: Abbott Medical Optics Inc.; Alcon Laboratories, Inc.; Bausch & Lomb; AqueSys, Inc.; Glaukos Corporation; Transcend Medical, Inc.

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

Dr. Solomon: Alcon Laboratories, Inc.; AqueSys, Inc.; Glaukos Corporation

All others involved in the planning, editing, and peer review of this educational activity have indicated they have no financial relationships to disclose.

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Changing the Glaucoma Treatment Paradigm

THE ROLE OF THE COMPREHENSIVE CATARACT SURGEON

Dr. Lindstrom: Cataract surgery is a dynamic field that has regularly welcomed new technology. The surgery itself has been used as a platform to treat astigmatism and presbyopia, and now, with the evolution of IOL and femtosecond laser technologies, cataract surgery is inextricably linked with refractive surgery. Cataract surgery is also an ideal procedure for treating glaucoma, but many physicians do not want to mar the experience of cataract surgery with the complications of traditional glaucoma surgeries. Cataract surgery boasts a 90% satisfaction rate in quality-of-life issues and a complication rate of less than 5%, with very few potential sight-threatening risks.[1] This track record is in stark contrast to traditional glaucoma treatments such as trabeculectomy and tube shunts, which have complication rates of 39% and 60%, respectively.[2]

However, the world of glaucoma treatment is changing with the development of micro invasive glaucoma surgery (MIGS). These procedures, designed around ab interno microincisions, are aimed at patients with mild-to-moderate glaucoma and have high safety profiles, which makes them appealing to all ophthalmologists. Because an estimated 20% of cataract patients also have comorbid hypertension or glaucoma,[3] it is practical to address both conditions at the same time. Combined glaucoma treatment is the next logical step in comprehensive cataract surgery, and it could be a significant driver of growth for practices.

In the following roundtable, cataract and glaucoma surgeons discuss their clinical needs and the new technologies they are using to meet them.

ADDRESSING AN UNMET NEED

Dr. Lindstrom: You are all busy surgeons. Can you discuss the unmet need for earlier and safer glaucoma treatments and the potential market size?

Dr. Chang: I agree that a significant number of our cataract patients has mild-to-moderate glaucoma. Their disease is not so advanced that they require IOPs in the low teens or single digits, and therefore they do not need a penetrating filtering procedure, which carries the risk of hypotony. However, these are patients who are typically taking one or more topical medications and would benefit from the opportunity of having a very low-risk glaucoma procedure combined with their cataract surgery.

> "Combined glaucoma treatment is the next logical step in comprehensive cataract surgery, and it could be a significant driver of growth for practices."
>
> —Richard L. Lindstrom, MD

Dr. Solomon: Approximately 20% of my cataract patients have mild-to-moderate open-angle glaucoma and are on one or more drops. With the rapid aging of the population and the total number of persons who have cataract estimated to rise to more than 30 million by 2020,[4] we are dealing with a large amount of patients. Previously, I would just treat the cataract and see how much the IOP lowered as a result of the phacoemulsification. In my experience, phacoemulsification alone has not been enough to reduce the use of IOP-lowering medications for most patients. If a patient's glaucoma progressed, I would refer him or her to a glaucoma specialist.

Dr. Chang: The risks of combined phaco-trabeculectomy and the nuances of managing the postoperative complications have caused many cataract surgeons, like myself, to avoid this procedure. One very important development has been the increasing number of cataract surgeons who are performing clear corneal incisions. Because this approach spares the conjunctiva, there is no pressing need to perform a definitive penetrating glaucoma filtration procedure at the same time as cataract surgery. We can assess whether phacoemulsification alone lowers the IOP enough, and if not, the patient can have a trabeculectomy later. However, many of these mild-to-moderate glaucoma patients would benefit from a further reduction in IOP or in their number of glaucoma

TABLE 1. EARLY AND LATE POSTOPERATIVE COMPLICATIONS IN THE TUBE VERSUS TRABECULECTOMY STUDY.[5]		
	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 (onset > 1 month)		
Persistent corneal edema	17 (16)	9 (9)
Dysesthesia	1 (1)	8 (8)
Persistent diplopia	6 (6)	2 (2)
Encapsulated bleb	2 (2)	6 (6)
Bleb leak	0	6 (6)
Choroidal effusion	2 (2)	4 (4)
Cystoid macular edema	5 (5)	2 (2)
Hypotony maculopathy	1 (1)	5 (5)
Tube erosion	5 (5)	--
Endophthalmitis/blebitis	1 (1)	5 (5)
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

medications, and combining MIGS with cataract surgery is a very appealing option.

Dr. Lindstrom: Like Dr. Chang, I stopped performing combined procedures almost a decade ago, just because of the technical complexity and the postoperative care and risks involved. Dr. Katz, will you also address the risks associated with trabeculectomies?

Dr. Katz: Trabeculectomy and tube shunts have been the mainstays for glaucoma surgeons for a couple of decades in terms of effective incisional surgery when large drops in pressure are needed. As a glaucoma specialist, my practice is prepared to handle all of the postoperative care. It is a common quip that the surgery is the easy part compared to the postoperative management. Some of the more serious complications include endophthalmitis, which can happen even years after the surgery; suprachoroidal hemorrhage, which can occur both intraoperatively and postoperatively; as well as the risk of the surgery's being too effective and resulting in hypotony maculopathy.

There are a lot of issues with trabeculectomy. It has been suggested that tube shunts be used in lieu of trabeculectomy,[5] although tube shunts introduce problems such as corneal edema and diplopia (Table 1), which are very

disconcerting for patients. So, these glaucoma surgeries are wonderful when they work well, but dealing with all of the care involved—cutting sutures, adjusting medications, etc.—sometimes results in poor outcomes, and it always requires significant time on the part of the physician.

REDUCING THE MEDICATION BURDEN

Dr. Lindstrom: When we perform glaucoma surgery, we certainly want to lower the IOP. However, it is also important to try and reduce the medication burden. If there were a procedure that produced a similar pressure reduction but that significantly reduced the medication burden, would you feel it was a success?

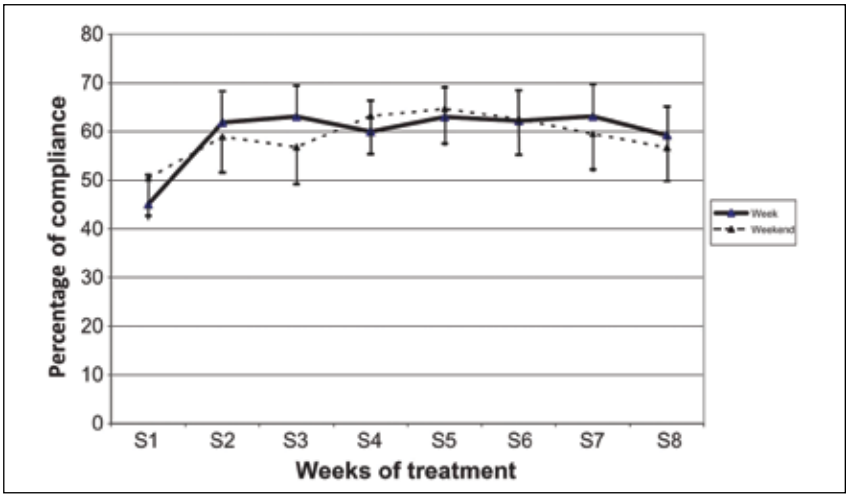

Figure 1. Average compliance with glaucoma drops (n=113).[8] (Reprinted from Nordmann JP, Baudouin C, Renard JP, et al. Measurement of treatment compliance using a medical device for glaucoma patients associated with intraocular pressure control: a survey. *Clin Ophthalmol.* 2010;4:731–739.)

Dr. Samuelson: Our patients would certainly consider such a procedure successful. When they are presented with an opportunity to safely reduce or get off their medicines, they typically jump at the chance. Of course, when you offer them the chance to stop taking medications with combined phaco-trabeculectomy, they often prefer medication over the risks of surgery. Surgical opportunities coincident with cataract surgery that do not particularly change their postoperative management really do appeal to patients, however. If you present an option that does not pose additional risk, will not change their refractive outcome, and will not burden them with a lot of extra visits, I think patients will always find that desirable.

Dr. Chang: Before latanoprost was available and when many patients were on pilocarpine to manage their glaucoma, it was fairly common for me to perform combined procedures, because the morbidity from the miosis or the compliance problems with q.i.d. dosing was significant. Then along came the prostaglandin analogs, which dramatically improved the medical management of glaucoma with very few side effects and easier dosing. However, some reports show that compliance is still an issue (Figure 1),[6] and we are now learning that there is a common and significant side effect with these drugs: prostaglandin-associated periorbitopathy.[7]

In addition, the advent of premium IOLs has changed our thinking about the consideration of the patient's quality of life, and not just improving their visual acuity, when we undertake cataract surgery. We now have a similar opportunity with glaucoma patients presenting for cataract surgery, if we are able to reduce the number of topical medications required. Not only is frequent dosing very inconvenient, but those using multiple medications are more prone to chronic ocular surface irritation from the active drug or the preservatives. I think many of our patients would embrace the potential of reducing their medication load with a combined MIGS procedure.

Dr. Solomon: Comprehensive cataract surgery strives to improve the quality of life for an ever-broadening range of patients. Providing a means of controlling IOP in conjunction with cataract surgery, without significantly changing the surgery's safety profile, is a huge benefit for the patient, the practice, and the healthcare system. Apart from issues with compliance and side effects, chronic medications represent a large cost for both the patient and insurance companies as well as significant time in managing them from the physician.

INTRODUCING THE MIGS CATEGORY

Dr. Lindstrom: We surgeons have been waiting for something to couple with cataract surgery that makes sense—that is synergistic in terms of mechanism and that does not add to the complexity or risk of surgery. I think that is what MIGS stands to provide. Let's start with an overview of the category.

Dr. Ahmed: As specified in the peer-review paper I coauthored with Hady Saheb,[9] MIGS share five specific characteristics: (1) an ab interno microincision; (2) minimal

trauma; (3) efficacy; (4) a high safety profile; and (5) rapid recovery (Figure 2). The ab interno approach allows for 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 can be performed in three different spaces: Schlemm canal, the suprachoroidal space, and the subconjunctival space.

MIGS combine easily with cataract surgery, and thus 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 with more invasive glaucoma treatments is balanced by an ultra-low risk profile.

There are currently eight devices either approved or currently undergoing review by the FDA that I believe fall into the MIGS category *(see Table 2 for their current status).*

1. The AqueSys implant (AqueSys, Inc.) procedure involves the ab interno placement of a microfistula to the subconjunctival space.
2. The Cypass suprachoroidal microstent (Transcend Medical, Inc.) is made of polyamide 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 90°, 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 suprachoroidal micro-bypass implant made of polyethersulfone (PES) and 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.

FIGURE 2. CHARACTERISTICS OF MICROINVASIVE GLAUCOMA SURGERY

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

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 far fewer 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.

Dr. Lindstrom: This is clearly a category with a lot of potential. Let's discuss the two devices that are currently approved, the Trabectome and the iStent Trabecular Micro-Bypass.

TABLE 2. 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 supra	Recruiting for US pivotal trial
iStent Trabecular Micro-Bypass	FDA approved
Trabectome	FDA approved

Dr. Samuelson: Trabeculotomy performed ab interno with the Trabectome is the removal of a 60° to 120° strip of the trabecular meshwork and the inner wall of Schlemm with electrocautery. Studies report that it results in a mean decrease in IOP of 40%.[10] Even so, my own personal experience suggests a much more modest reduction in pressure. Although typically the Trabectome procedure is performed before phacoemulsification, in someone with a shallow anterior chamber, you would probably do it after removing the cataract.

Dr. Chang: The iStent Trabecular Micro-Bypass is a 1-mm long stent that is inserted into Schlemm canal and facilitates aqueous outflow through the trabecular meshwork. Some of the notable features include: (1) the fact that it can be implanted at the conclusion of cataract surgery, and (2) that the technique requires intraoperative gonioscopy, which is well within the skill set of anterior segment surgeons. In addition, the iStent does not add a lot of time to the cataract procedure, and it will not alter the refractive outcome, the recovery of vision, or the postoperative care of the patient. Most importantly for cataract surgeons, there is no risk of hypotony or wound leak and no bleb—all intimidating potential problems with trabeculectomy.

From a logistics standpoint, cataract patients consent to an additional glaucoma procedure. There is a separate reimbursement code that allows the facility to be reimbursed for the cost of the device and for the surgeon to be reimbursed for the procedure. This procedure will fit seamlessly into a typical cataract practice.

EFFICACY OF THE TRABECULAR MICRO-BYPASS IMPLANT

Dr. Lindstrom: Dr. Samuelson, can you share the study data and the most appropriate indication for the trabecular micro-bypass device?

Dr. Samuelson: The results from the US pivotal study 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.[11] Of the 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 an IOP reduction of greater than or equal to 20% without medications, compared to 48% of the control group. From these results, we can see that the placement of a single micro-bypass device makes a significant contribution toward reducing IOP and the burden of medications in patients.

> "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."
>
> —Ike K. Ahmed, MD

A lot of the data on the effectiveness of cataract surgery by itself lowering IOP were published almost simultaneously to the conception of this study, influencing the design. For safety reasons, the study included two very important parameters. The first was that if IOP was higher than 21 mm Hg, medications were added back. Second, if the physician felt that the patient was progressing toward changes to the optic nerve or optic disc or showed changes in visual field, they were allowed to add medications back, even if the IOP was not greater than 21 mm Hg. Thus, it is not very effective to look at IOP outcomes as a definitive measure of the study. The easiest way to understand the study's significance is that twice as many patients in the cataract surgery-alone group went back on medications at 1 year as compared to those patients who received cataract surgery plus the trabecular micro-bypass implant.

Also impactful was the study's safety analysis. Obviously, any intervention includes some increased risk, but there was no measurable increased risk in adding the micro-bypass to cataract surgery alone.

Dr. Lindstrom: Actually, when I looked at the data, the complication rate was lower in the trabecular micro-bypass group.

Dr. Samuelson: You are right, but saying it that way sounds too good to be true. There really was no measureable difference between the two groups in regards to paracentesis rate, IOP spikes, or the degree of vision loss/preservation. The way I present this procedure to my patients is, "I have a procedure that I can combine with your cataract surgery, and it will not have a measurable difference in terms of safety, but in the US clinical trial, twice as many patients receiving this intervention remained off medications at 1 year as compared to those who didn't receive it." I think it is very impactful to add a glaucoma procedure to what is, in my opinion, the best operation in all of medicine— cataract surgery—and not change the safety profile. Most patients are very encouraged by this.

Dr. Ahmed: The reduction in medications is an important benefit for any mild-to-moderate glaucoma patient. In a very similar study to Dr. Samuelson's, Fea performed a terminal washout at month 15 to analyze how many medications a patient needed. He found that the group that received the trabecular micro-bypass device achieved a greater reduction in IOP by approximately 3 mm Hg, which translated to a mean IOP of 16.6 mm Hg.[12] 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 while the iStent and Trabectome are the only ones currently approved by the FDA, they all have the ability to reduce the burden of medication.

> "The [trabecular micro-bypass] procedure essentially doubles a patient's chance of getting off [IOP-lowering] medication without adding morbidity or complications."
> —David F. Chang, MD

Dr. Katz: Reducing medication is a huge plus for patients in terms of compliance and also quality of life. I have had to use drops briefly for various things, and it is not pleasant. In regards to the trabecular micro-bypass implant, you are talking about a procedure that does not add much time to cataract surgery, it seems to be pretty safe, and it lowers pressure. It spares the conjunctiva, so you still have the ability to perform a more aggressive filtering procedure down the road if necessary.

Dr. Lindstrom: As I read the literature, the Ocular Hypertension Treatment Study[13] suggests that a reduction in pressure of 3 mm Hg reduces the risk of progressive damage by about 30%, or arguably a 10% risk reduction per mm Hg of pressure reduction. We can tell patients that most of the time, the trabecular micro-bypass will give them an additional 3 mm Hg of reduction in pressure or 30% reduction in risk of progressive damage. What percentage of patients will have a reduced burden?

Dr. Chang: In the pivotal FDA study, 72% of patients were free of medication after cataract surgery and implantation of the trabecular micro-bypass, as compared to 50% of patients who had cataract surgery alone, without additional measurable risks.

Dr. Ahmed: Although effective, the performance of a single microstent is somewhat limited by the capacity of the area through which the aqueous flows.[14] 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, we saw a significant reduction in IOP across all patients, to 13.8 mm Hg and 14.8 mm Hg, respectively.[15] Those who received two devices had an average 64% reduction in medications, while those who received three implants had an average 85% reduction in medications.

Dr. Donnenfeld: We found similar results in the iStent Dose-Response Study.[16] My coinvestigators and I examined the effects of implanting one versus two versus three microstents plus one 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 or equal to 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 all eyes that received two or three of the implants reached an IOP of less than or equal to 15 mm Hg on one medication, and 82% had reductions of greater than or equal to 40% from pretreatment baseline IOPs.

Dr. Chang: I was not personally involved in the US IDE clinical trial. When the data first came out, it was natural to question if the IOP-lowering benefit was from the trabecular micro-bypass stent or from the cataract surgery. Once I understood the design of the study, I saw that the stent procedure essentially doubles a patient's chance of getting off medication without adding morbidity or complications. That is excellent news.

Dr. Solomon: As I stated previously, cataract surgery alone is not enough to reduce glaucoma medications, in my experience. The trabecular micro-bypass stent represents the opportunity for me to treat glaucoma at the same time as cataract. Since it received FDA approval, I have offered this procedure to many of my patients, and all have accepted. They ask about its history and safety profile, and what they hear makes them very excited to get rid of their drops. In my experience, the only downside to the ab interno micro-bypass procedure is that sometimes patients need to continue with drops because they do not receive enough pressure-lowering

effect. However, I have yet to hear a patient turn down the trabecular micro-bypass procedure, because in their minds, as well as mine, if the only downside is that it may not reduce IOP to the desired target, and the upside is that they may be able to get off drops that are an expensive hassle, why not? In addition, with drops, there are slight fluctuations. The trabecular micro-bypass stent provides 24/7 control, which I feel makes it better than drops over the long term.

LEARNING A NEW PROCEDURE

Dr. Lindstrom: Many US cataract surgeons have been intimidated by tube shunts and even mitomycin trabeculectomy due to intraoperative and postoperative experiences. What have your experiences been with the trabecular micro-bypass stent, and is the procedure feasible for the cataract surgeon?

Dr. Donnenfeld: I had not performed a glaucoma procedure since I was asked to go to Armenia to participate in a trial for the ab interno micro-bypass device. I asked representatives of Glaukos Corporation why they would want a cataract and refractive surgeon to perform this procedure. They responded that they believe this is the future of ophthalmology, and that cataract surgeons will embrace this technology because it has all the benefits of a refractive cataract procedure. It improves quality of life.

To my surprise, we implanted well over 100 micro-bypass devices in just under a week, and I found the surgery to be very enjoyable. It is a very accessible procedure for the average cataract surgeon. The downside risks of the procedure are so small and the benefit to the patient so great, that I agree that this procedure will be embraced by cataract surgeons.

IMPLANTATION AND LEARNING CURVE

Dr. Lindstrom: Dr. Samuelson, what are your feelings about the learning curve of the micro-bypass device? Is it necessary to practice in a lab?

Dr. Samuelson: I do not want to underplay the delicacy of the surgery—it is quite delicate. It starts with getting a good intraoperative view, so I advise beginning to perform intraocular gonioscopy on some routine cataract patients. You have to turn the patient's head, position the microscope, and find a comfortable position for yourself. By practicing gonioscopy, you will determine how to get a good view, you will understand the landmarks, and you can simulate what you would be doing with the device in a real eye with a viscoelastic cannula.

The next step is to become familiar with the tactile nature of the inserter trocar, entering the eye and touching the trabecular meshwork and getting a feel for the three-dimensionality of it. If you are already familiar with intraoperative gonioscopy, it is just a matter of getting used to inserting both the right-handed and left-handed stents. I would say that within a half-dozen cases, maybe less, you start to feel pretty comfortable.

Dr. Donnenfeld: Visualization—specifically, the ability to see the angle structures, is the key to success. It took me maybe five or six cases before I felt comfortable with this procedure.

With every surgery, you have to evaluate the potential rewards and downsides. The potential downside of implanting the micro-bypass device is simply that it will not go in. There is no hypotony, risk of endophthalmitis, or corneal decompensation. This is a "first do no harm" procedure, true to the Hippocratic Oath. A procedure with a potential benefit and essentially minimal risk should be embraced by most ophthalmologists.

Dr. Chang: I also participated in the Armenian trial, and I think that the learning curve for implanting the ab interno micro-bypass device is about 6 to 10 cases. As expected, the surgeon must learn how to place the stent—what the approach angle should be, how much pressure to apply, how much resistance is felt, and how a properly placed stent should look. What surgeons may not anticipate is that it really takes some practice to position and manipulate the goniolens in order to optimize the view. Visualization is really important, and the dexterity needed to position the goniolens makes this truly a bimanual procedure. Fortunately, one can first practice positioning the patient's head and holding the goniolens on routine cataract patients. This is a helpful exercise, because the more adept you are at manipulating the goniolens, the more you can just concentrate on placing the stent.

Dr. Solomon: The procedure itself is really very straightforward. I have used all three generations of the ab interno micro-bypass device. Initially, I worried that the trabecular micro-bypass may be the most cumbersome, but it absolutely is not. I have successfully and efficiently achieved implantation in every case. In Armenia, most of the implantations were in aphakic eyes. Now, I am finding that after cataract surgery, the angle is really deep, making it easier to find the ocular landmarks. Schlemm canal fills with blood and shows just where the micro-bypass implant should go. In my opinion, the biggest part of the learning curve is not the insertion, but getting used to tilting the patient's head in one direction while

you use the gonioscope with the other hand. However, I have had several colleagues begin using this procedure recently, and all of them have picked up this technique very easily. They have been so impressed that they are now using the micro-bypass implant regularly.

The first implantations of the micro-bypass device that I performed in my practice I scheduled at the end of the day, to allow for more time during surgery. Now that I am familiar with the procedure, however, I have found such scheduling to be unnecessary. Once you get the procedure down, the micro-bypass implant enters the eye readily, and the procedure is elegant and fun to perform.

Dr. Samuelson: Regarding safety, I think is important to emphasize that while the procedure itself does not put the patient at risk for any of the traditional complications, patient selection is still an important component. A very small minority of patients react to cataract surgery with unmanageable IOP spikes. Therefore, it is important to parse out those patients who have particularly bad disease states that might need a more definitive treatment.

Dr. Lindstrom: Is there a difference in early postoperative control, referring to the concern for pressure spikes?

Dr. Samuelson: That is a great question that emphasizes the degree of surveillance we want to exert on all our patients. Probably the best way to compare early IOP spikes is to look at the paracentesis rate between the two groups in the pivotal study. There was not a significant difference. My colleagues and I checked IOP 4 to 7 hours after surgery and then again on postoperative day 1. A little over one quarter of the patients in each group required a paracentesis tap to acutely lower IOP. The study was well designed to incorporate that additional IOP measurement for these patients.

PATIENT SELECTION

Dr. Lindstrom: If my professional recommendation to a patient that they would do well with cataract surgery and a trabecular micro-bypass was incorrect, and for some reason they had a poor outcome, has the success of their cataract surgery or their candidacy for trabeculectomy been hurt in any way by implanting this device?

Dr. Samuelson: No. One of the beauties of this procedure is that subsequent surgical management is not affected. One caveat is that it may be hard to perform canaloplasty on an eye implanted with the micro-bypass device, but if someone fails with this therapy, most likely they will go to a transscleral procedure.

Dr. Lindstrom: There are two categories of cataract patients: those whose primary issue is cataract and happen to have associated glaucoma, and those who are going blind from glaucoma and happen to have a cataract. In the extremes, it is easy to identify the better candidate for a MIGS. With routine patients, however, how do we define the ideal candidate for these treatments?

> "One of the beauties of this procedure is that subsequent surgical management is not affected."
> —Thomas W. Samuelson, MD

Dr. Katz: My preferred candidate for a MIGS is someone who is having cataract surgery and is on one or more medications. This would include patients who are well controlled on medications, because we cannot predict who will be compliant. Patients who express an interest in reducing or eliminating their medication burden are also ideal candidates for MIGS.

Dr. Solomon: 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 using two of these devices reduces IOP to a greater degree than one, ultimately lowering mean IOP to less than or equal to 15 mm Hg. So, depending on the desired target pressure, I could place one or two devices. If I decide to place one micro-bypass implant, 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 become available in the United States, I can implant one or two micro-bypass devices and enhance IOP reduction with a suprachoroidal device later if the specific case dictates. Having such options is the true revolution that these MIGS devices provide.

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 fewer per day. As a general rule, for a target pressure of 18 mm Hg or so, I use one ab interno micro-bypass device, and for a target pressure of 15 mm Hg or less, I use two devices.

Other surgical alternatives to MIGS include canaloplasty (iScience International), the Gold Shunt (SOLX), and the ExPress Glaucoma Filtration Device (Alcon Laboratories, Inc.). Canaloplasty appears to have a lower risk profile

than traditional bleb forming surgery.[16] In comparison, the ExPress device is quite efficacious, but carries significant additional risk.[17,18] The SOLX Gold Shunt, although blebless, is inserted into the supraciliary space via an ab externo procedure. From a lifestyle perspective, I believe nonmedical intervention is superior for both the patient and the physician.

ENHANCING COMPREHENSIVE CATARACT SURGERY

Dr. Lindstrom: My final questions pertain to the growing interest among patients and surgeons alike in enhancing refractive outcomes with lifestyle-enhancing technologies such as premium IOLs, femtosecond lasers, etc. Are MIGS compatible with this growing trend? Can a patient want to see better and reduce his or her dependence on glasses and also want to lower their IOP and get rid of their drops? Are these potentially synergistic lifestyle-enhancing goals: to see better without glasses and be on less medications?

Dr. Donnenfeld: I would have to give a resounding yes to that question. The new MIGS category is the next step in the evolution of refractive cataract surgery, and it improves patients' quality of life. It is not visual acuity that we look for in cataract surgery necessarily; the goal is to improve the patient's life. This is an opportunity to improve quality of life in many respects. MIGS devices lower the medication burden, reduce dependence on eye drops, improve compliance, and reduce the cost burden for many glaucoma patients. In addition, long-term medications have a great impact on the ocular surface, creating a negative impact on quality of vision. If we can eliminate these chronic medications and the intrinsic toxicity associated with them, we can improve the patient's experience with cataract surgery.

Dr. Chang: The great thing about refractive cataract surgery is that patients who are visually impaired receive an unexpected opportunity to enhance their lifestyle by reducing their spectacle dependence. Now, glaucoma patients needing cataract surgery may have an unexpected lifestyle-enhancing proposition—potentially reducing their number of medications.

Dr. Donnenfeld: It is an added value. When patients come in for cataract surgery, they have certain expectations. If I can exceed that expectation, I can make the patients extraordinarily happy. Reducing or eliminating the need for glaucoma medications would count as exceeding most patients' expectations, and that is our goal as cataract surgeons.

Dr. Samuelson: The litmus test for me has always been: would I have the procedure performed on myself? I wouldn't hesitate to have a MIGS procedure done. I have performed a lot of trabeculectomy and tube shunts, and if I really needed one of those, I would have it done, but I would still be quite concerned about the potential complications. With the trabecular micro-bypass device, the risk is so small and micro-invasive that I would not hesitate to have one of these implanted if I needed it.

Dr. Chang: I think that MIGS devices also have great potential for treating glaucoma in the developing world. Glaucoma management is very challenging in this setting because of the ongoing need for testing, medication, and follow up. Having a safer surgical alternative to medication might prove to be a better treatment where proper medical management is impractical or unavailable.

Dr. Lindstrom: This category is certainly going to change glaucoma surgery. We perform 3.2 to 3.3 million cataract operations per year, and 20% of them have ocular hypertension or glaucoma. Multiplied out, that makes 600,000 to 700,000 potential candidates every year. It is our responsibility to decide, along with the patient, the most appropriate procedure. I think that MIGS and its flagship device, the micro-bypass implant, is one that will be commonly selected. ■

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CME QUESTIONS

1. When performing MIGs surgery with the micro-bypass stent
- a. There is no difference in IOP reduction between inserting one microstent or two
- b. There is a greater reduction in IOP when two microstents are inserted
- c. There is a greater reduction in IOP when one microstent is inserted rather than two

2. The chronic 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. 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

5. 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

6. An important tool to master in order to be proficient at the trabecular micro-bypass procedure is:
- a. a microcatheter
- b. a gonioprism
- c. a crescent blade
- d. a probe

7. I feel that this activity has met the stated learning objective.
- True
- False

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