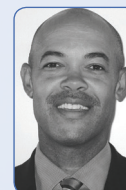


MIGS *RESOURCE CENTER*



In this episode of the MIGS Resource Center, we talk with Brian Flowers, MD, of Fort Worth, Texas. Dr. Flowers is a renowned glaucoma specialist and has a great deal of experience within the microinvasive glaucoma surgery (MIGS) arena, including participation in several clinical trials of the new surgical devices. Dr. Flowers has also been an integral part of American Society of Cataract and Refractive Surgery's panels on the topic. Here, we talk about integrating MIGS into a cataract surgery practice. Dr. Flowers shares his knowledge and experience in this rapidly changing world of surgical glaucoma. His expertise will help surgeons select the best surgical procedure for individual patients and hopefully shorten the MIGS learning curve.

—Thomas W. Samuelson, MD



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MIGS, CATARACT SURGERY, AND PATIENT MANAGEMENT

Two respected surgeons talk about MIGS practice integration for cataract surgeons.

Learning Curve

Thomas W. Samuelson, MD: Starting with some basics, how do you explain to cataract surgeons who have not treated glaucoma surgically in the past that dealing with glaucoma—and microinvasive glaucoma surgery (MIGS) in particular—is different? What advice would you give?

Brian Flowers, MD: Cataract surgeons will benefit from setting a target IOP ahead of time. For this they will need to have a sense of the stage of glaucoma. They will also need to pay closer attention to the postoperative course and even the ocular surface. Glaucoma patients may have additional surface irregularities depending on the number of years they have been on glaucoma medications. They may also have a steroid response in the postoperative period. Overall, there is an increased need for more surveillance with these patients throughout their postoperative management because they also have a potentially vision-threatening disease.

Cataract surgeons can now look at their role in helping their glaucoma patients in a new way. They now have an opportunity to impact both of their patients' conditions. To me, cataract surgery combined with MIGS is an opportunity to make a meaningful impact on vision and pressure for a patient without introducing longer recovery times or significant safety issues.

We know from multiple studies on glaucoma that every point matters, every millimeter of mercury counts. Cataract surgery alone can have a meaningful impact on IOP, and now with MIGS, surgeons can optimize the benefit they are giving their patients. Once you observed your patients out to about 8 weeks after a combined procedure, you will have a valid sense of what the response to therapy has been.

Dr. Samuelson: In your experience, about how many cases will it take for cataract surgeons to be comfortable with implantation? Does it vary by procedure and/or device?

Dr. Flowers: For cataract surgeons embarking on angle surgery (especially those who are naïve to angle surgery), several points

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are important: (1) first and foremost, the surgeon has to be comfortable with visualization; (2) he or she has to be comfortable with the anatomy, with gonioscopy, and with maneuvering instruments in that space. Each of those points needs to be addressed differently.

Understanding the anatomy could be done simply by having the surgeon do gonioscopy in the office on more patients. For achieving a good view in the operating room there is no substitute for practice. Paying attention to important details like the most appropriate amount to rotate the head and microscope. It is also very important to have a light touch with the goniolens. These can be practiced on patients who are only having cataract surgery.

Each surgeon may find one procedure or another easier or more difficult for them. Right now, there are only a few implantable devices approved by the FDA (Alcon's CyPass Micro-Stent, Allergan's Xen45, and Glaukos' iStent Trabecular Micro-Bypass Stent), but more are on the immediate horizon. I think for most surgeons it will take around five patients to be comfortable with the iStent or the CyPass. The CyPass is a little easier to place than the iStent. The CyPass does not require quite the specificity of the iStent in terms of location.

Dr. Samuelson: Do we expect similar IOP reduction from the various MIGS surgeries? How do you select which MIGS class to offer individual patients, and what skills sets do surgeons typically need to hone to be successful with MIGS? What pearls can you offer for those just getting started with canal-based, supraciliary, and subconjunctival procedures?

Dr. Flowers: As you know, we do not have any head-to-head studies that can help address that question from a trial perspective, but, in my experience, slightly lower pressures can be achieved with supraciliary procedures.

Generally speaking, though, some patients will respond better to supraciliary devices, while others will respond better to canal-based procedures. I do suggest surgeons consider starting with a supraciliary procedure, because it might be a little easier if they are not as comfortable with the anatomy or visualization.

If a patient presents with very mild glaucoma, and you want them to be on fewer medications, you could consider a canal-based procedure.

For most surgeons, they will find it is a little easier to implant the left-directed iStent since most of us are right-handed and that is a more natural motion for a right-handed surgeon. That is not as much of an issue with the CyPass.

The iStent needs to be near collector channels, which is not the case with the CyPass. But surgeons should avoid the 3 o'clock and 9 o'clock positions, if possible. There are more blood vessels in that area, and some have found it occasionally more difficult to implant the device at those meridians. We recommend the 4 o'clock or 5 o'clock positions.

Some may consider performing the MIGS procedure before cataract surgery as it can make visualization easier. I would stay away from that approach with a CyPass, as we are not sure how the fluidics of the phacoemulsification process will affect the size of the dialysis. Once surgeons newer to the procedure get a little more comfortable with the anatomy, they tend to move the MIGS to after cataract removal. Other devices that are also using the supraciliary space are likely to be similar in terms of ease of implantation.

IOL Considerations for MIGS Patients

Dr. Samuelson: Do you alter your IOL calculations when you know you have a MIGS patient? What should cataract surgeons do differently for their MIGS patients?

Dr. Flowers: We have about 45 patients who underwent the CyPass procedure and, for most, we have long-term outcomes up to several years. We looked at their refractive outcomes compared to what was predicted, and we compared that to an age-matched control population with glaucoma undergoing cataract surgery alone. The results were statistically identical. There were a couple of refractive surprises with the CyPass, and all but one resolved completely by 6 months.

Generally speaking, I think if you go supraciliary you may have a slightly longer visual refractive recovery. But I will offer the same spectrum of IOLs to patients with mild to moderate glaucoma. If you start getting patients with meaningful visual field loss, I stay away from diffractive optics.

Monitoring Glaucoma as a New Step

Dr. Samuelson: Are there any typical pitfalls to be aware of? Which is more daunting to the nonglaucoma surgeon: tracking and adequately monitoring the disease, or the actual surgical procedure itself when utilizing MIGS?

Dr. Flowers: Surgeons who are not used to monitoring glaucoma will need to refresh those skills as well. I think experienced surgeons will probably be able to pick up the surgical component pretty readily, but if they are not used to monitoring glaucoma that may require modifying the postoperative surveillance. Performing the surgery is just the first step of treating glaucoma patients.

Dr. Samuelson: So many of our cases in the current medical milieu are comanaged, and it is within that domain that we need to be particularly careful, making certain that nothing falls through the cracks. There can be no breakdown in communication, and we must ensure timely visual fields and adequate follow-up. I agree with Dr. Flowers that there are a variety of effective arrangements for managing these patients. The point we both feel very strongly about and would like to emphasize is that follow-up care is every bit as important as the cataract-MIGS surgery itself. Being successful in just one of those areas is not enough, you need both.

The other point Dr. Flowers touched upon is that newer MIGS surgeons need to get used to performing delicate tasks with just one hand. There are numerous other intraocular procedures where we use the second hand to steady the dominant hand, but with MIGS the nondominant hand is holding the gonioscope and that may take some getting used to.

The point we both feel very strongly about and would like to emphasize is that follow-up care is every bit as important as the cataract-MIGS surgery itself. Being successful in just one of those areas is not enough, you need both.

—Thomas W. Samuelson, MD

Patient Selection and Flow

Dr. Samuelson: What is the relative importance of IOP, visual fields, and optical coherence tomography? We want to ensure patients are safe candidates for the procedures, but are all patients on medical therapy for glaucoma candidates for MIGS?

Dr. Flowers: If you are a general ophthalmologist, those tests would be prerequisites for patients considering MIGS surgery.

Dr. Samuelson: When you have a patient with cataract in both eyes, what is your standard time between first and second surgery, and does that change if you are also implanting a MIGS device?

Dr. Flowers: I typically wait 2 weeks before doing the second eye. That does not change if I am also performing a MIGS procedure, regardless of if it is canal-based or supraciliary-based. Ultimately, this is determined by the patient. We will not move on to the second eye unless the patient is satisfied with his or her recovery from the first.

Surgical Time Implications

Dr. Samuelson: If your typical cataract surgery time is “X,” how much time should new MIGS surgeons allow for their first cases (including time for patient positioning, scope positioning, etc)? Should it be twice the duration of a cataract procedure? More time? Less time?

Let us start with a surgeon who is planning to do a cataract procedure plus a canal-based procedure. Do you have any generalizations you can offer? For instance, I would recommend surgeons new to MIGS procedures double their OR time for the first five cases. They may not need that full amount of time, but that is a good starting point.

Dr. Flowers: I would say newer surgeons should add about 10 minutes, if I am being optimistic. So if they normally block X minutes, I would recommend 2X. You want to avoid the trap of having other patients behind the MIGS case backing up and waiting.

Talking to Patients About MIGS

Dr. Samuelson: What are some key points to cover when educating patients? Does it vary by procedure?

Dr. Flowers: We need to ensure patients understand this is not just standard cataract surgery. They should be prepared for the possibility that their visual recovery may not be exactly the same as their spouse or friend who did not have glaucoma.

Dr. Samuelson: How is the conversation with the patient different when MIGS is combined with cataract surgery versus MIGS as a standalone, or compared to cataract surgery as a standalone procedure?

I can say with confidence that there is a significant difference in IOP in glaucoma patients who have a MIGS procedure and those who have not.

—Brian Flowers, MD

Dr. Flowers: We really need to address that glaucoma is a chronic disease. Patients, in general, are used to having a surgery to treat a disease, but even with MIGS, that is not the whole story. We are not “curing” glaucoma, and it is our job to ensure patients know that.

We track all of our data and have for a long time. I can say with confidence that there is a significant difference in IOP in glaucoma patients who have a MIGS procedure and those who have not. You do have to be aware of a potential steroid response, however, that can impact a patient in the short term.

But what we do not want is to have this opportunity to make an impact and reduce topical glaucoma medication use in a cataract patient and let the opportunity pass you by. In the future, I believe standard of care for these patients will be combined procedures.

Dr. Samuelson: How do you set realistic expectations for patients? Does it vary by procedure or by disease severity? For example, if a patient with severe glaucoma has had a stable visual field for 10 years, would you consider that patient for a MIGS procedure? Personally, I do not strictly adhere to the labeling for these devices and do consider the overall patient, likelihood of progression, compliance and adherence to medication regimens, etc. Patient selection is very nuanced and not easily confined to two to three labels based on disease severity alone.

Dr. Flowers: MIGS provides us with an opportunity to reduce a patient’s reliance on medications, and to lower his or her pressure in a safe manner. There is always a risk-benefit analysis we need to do before presenting options to our patients. One of the things I like about MIGS is that it does not prohibit further interventions. So if the patient continues to progress to a point where visual field loss is problematic, we still have options to treat them.

My bias here, of course, is to do the safest procedure that can provide the desired result first.

I take all my patients on a case-by-case basis and may recommend MIGS in a patient who has more advanced disease if we are highly focused on safety and rapid visual recovery.

TIPS AND PEARLS FOR NEW SURGEONS

Dr. Samuelson: What are some of your best trouble-shooting tips? What are one or two of the more common pitfalls newer surgeons need to know about?

Dr. Flowers: These are some of my tips for surgeons just starting out with MIGS.

- I would encourage people to hold the inserter and rehearse the insertion of the CyPass prior to putting the inserter into the eye. One does not want to be adjusting their hand position while the inserter is in the supraciliary space.
- Intraoperatively, you want to avoid creating a cyclodialysis that is larger than intended. Having a steady hand is important.
- Avoid an initial overimplantation. Get about 70% of the implant in, release the guidewire, then tap the rest in to the desired depth. Ideally, you want the implant to be barely anterior to the pigmented trabecular meshwork. Postoperatively, you would prefer to be slightly deep versus anywhere near the cornea. We have seen focal corneal decompensation in tubes that are very close to the cornea.
- Lastly, we all need to be wary of a potential steroid response during the postoperative management phase with MIGS procedures as in glaucoma patients who have had cataract surgery alone.

Dr. Samuelson: Those are all very important points. I would add being cautious of too rapidly withdrawing patients from medications, at least while they are on steroids. So, like you, I caution surgeons to be aware of the potential steroid response.

Dr. Samuelson: I agree—we should eliminate the restriction for use based on severity and add these to our overall list of options. Limiting which patients should be considered for these procedures (especially with concurrent cataract surgery) is really unfair. The surgeon should be able to select the surgery they feel most comfortable with and which they think will benefit the patients most. Likelihood of progression is probably the most important element in my mind. For example, a patient with mild glaucoma but a very high preoperative IOP may be very likely to progress, and while they are officially a MIGS candidate based on labeling, they may not be a good candidate based on their high probability of progressing. Conversely, a patient with advanced disease, but well-controlled IOP and long-term visual field stability may be a perfectly acceptable MIGS candidate. We should not be limited by the label. The advanced but stable patient

should be able to opt for a safe surgery if they choose to; especially with our improved pharmacologic options.

Dr. Flowers: I recently had a patient who is in her late 50s and had an IOP around 35 mm Hg on three medications. She was working and did not want the delayed visual recovery associated with trabeculectomy. I gave her a CyPass because that gave us the opportunity to improve her IOP and meet her vocational needs. Gonioscopy-assisted transluminal trabeculotomy also may have been an option.

Dr. Samuelson: What is the most asked question from patients about MIGS?

Dr. Flowers: Patients want to know how much lower their pressures will be if they get these devices. Most of my patients do not ask about recovery time, but I will always discuss the effect these will have on recovery. With the true canal-based procedures, I have not noticed any measurable increase in recovery time. There may occasionally be a slight delay in recovery compared to patients who have phacoemulsification only, but it is rarely significant. I have found recovery times to be very similar to phaco, and patients report recovery times are about the same as their friends or family members have undergone. Supraciliary procedures can occasionally have a slightly longer recovery time.

Dr. Samuelson: Since glaucoma is a long-term disease, will earlier intervention with MIGS interrupt or keep the disease from becoming worse over time? How do you feel about earlier disease intervention with MIGS? How do you make this decision and what factors move you in that direction?

Dr. Flowers: I make those decisions on a case-by-case basis. And we have to bring the patient into the conversation. If they only have one eye, they may not want to risk more aggressive surgery. Or maybe they are scared of blebs after hearing about them, and want to stay on medication. It is our job to recommend what we think is the best treatment, and I rarely get pushback from my patients.

Postoperative Visits

Dr. Samuelson: What should surgeons expect to see during postoperative visits? Does it vary by procedure?

Dr. Flowers: These MIGS procedures were designed to reduce or eliminate the need for topical medications; the IOP on postoperative day 1 is, in my opinion, a telltale sign. With the iStent, there is a more modest drop in pressure in the immediate postoperative period. I recommend surgeons tailor the medication withdrawal to the IOP response. Typically, on postoperative day 1, we try to reduce or eliminate at least one medication from the patient's regimen. We do not necessarily stop all medications on that first day.

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References: 1. CyPass[®] Micro-Stent Instructions for Use. 2. Vold S, Ahmed IIK, Craven ER, et al. Two-year COMPASS trial results: supraciliary microstenting with phacoemulsification in patients with open-angle glaucoma and cataracts. *Ophthalmology*. 2016;123(10):2103-2112.



CyPass® Micro-Stent

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CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

INDICATION: The CyPass® Micro-Stent is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG).

CONTRAINDICATIONS: Use of the CyPass Micro-Stent is contraindicated in the following circumstances or conditions: (1) in eyes with angle-closure glaucoma; and (2) in eyes with traumatic, malignant, uveitic, or neovascular glaucoma or discernible congenital anomalies of the anterior chamber angle.

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WARNINGS: Gonioscopy should be performed prior to surgery to exclude peripheral anterior synechiae (PAS), rubeosis, and other angle abnormalities or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard.

PRECAUTIONS: The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The safety and effectiveness of the CyPass Micro-Stent has not been established as an alternative to the primary treatment of glaucoma with medications, in patients 21 years or younger, in eyes with significant prior trauma, chronic inflammation, eyes with an abnormal anterior segment, eyes with chronic inflammation, eyes with glaucoma associated with vascular disorders, pseudophakic eyes with glaucoma, eyes with uveitic glaucoma, eyes with pseudoexfoliative or pigmentary glaucoma, eyes with other secondary open-angle glaucomas, eyes that have undergone prior incisional glaucoma surgery or cilioablativ procedures, eyes with laser trabeculoplasty performed ≤ 3 months prior to the surgical screening visit, eyes with unmedicated IOP less than 21 mmHg or greater than 33 mmHg, eyes with medicated IOP greater than 25 mmHg, in the setting of complicated cataract surgery with iatrogenic injury to the anterior or posterior segment, and when implantation is without concomitant cataract surgery with IOL implantation for visually significant cataract. The safety and effectiveness of use of more than a single CyPass Micro-Stent has not been established.

ADVERSE EVENTS: In a randomized, multicenter clinical trial comparing cataract surgery with the CyPass Micro-Stent to cataract surgery alone, the most common postoperative adverse events included: BCVA loss of 10 or more letters at 3 months after surgery (8.8% for the CyPass Micro-Stent vs. 15.3% for cataract surgery only); anterior chamber cell and flare requiring steroid treatment 30 or more days after surgery (8.6% vs. 3.8%); worsening of visual field mean deviation by 2.5 or more decibels (6.7% vs. 9.9%); IOP increase of 10 or more mmHg 30 or more days after surgery (4.3% vs. 2.3%); and corneal edema 30 or more days after surgery, or severe in nature (3.5% vs. 1.5%).

ATTENTION: PLEASE REFER TO THE INSTRUCTIONS FOR A COMPLETE LIST OF CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE EVENTS.

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MIGS provides us with an opportunity to reduce a patient's reliance on medications, and to lower his or her pressure in a safe manner.

—Brian Flowers, MD

insertion system, and 18 of those patients were between 9 mm Hg and 11 mm Hg on postoperative day 1; importantly, none of the patients were lower than that. I am very comfortable reducing or eliminating all medications on the first postoperative day in those circumstances. The only exception is with patients who had a severely compromised optic nerve who I may leave on a single agent. I will typically taper steroids (3, 2, 1), but it will depend on how quiet they are on week 1.

Dr. Samuelson: Finally, knowing that all glaucoma surgeries can sometimes fail, how long do you wait to determine when a MIGS procedure has failed? What are the telltale signs?

Dr. Flowers: If on postoperative day 90 there has been no meaningful effect on pressure.

Dr. Samuelson: These were some great insights, and I agree with you. On behalf of the MIGS Resource Center, I would like to thank you, Dr. Flowers, for sharing your knowledge and experience in this rapidly changing world of surgical glaucoma. Your comments will help surgeons select the best surgical procedure for individual patients and hopefully help shorten the MIGS learning curve. I would also like to remind our readers to check out previous interviews with Reay Brown, MD, and Steven D. Vold, MD. ■

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