Sponsored by IVANTIS®

THE GLAUCOMA OPPORTUNITY

Performing MIGS during cataract surgery offers patients a chance for more efficient disease management

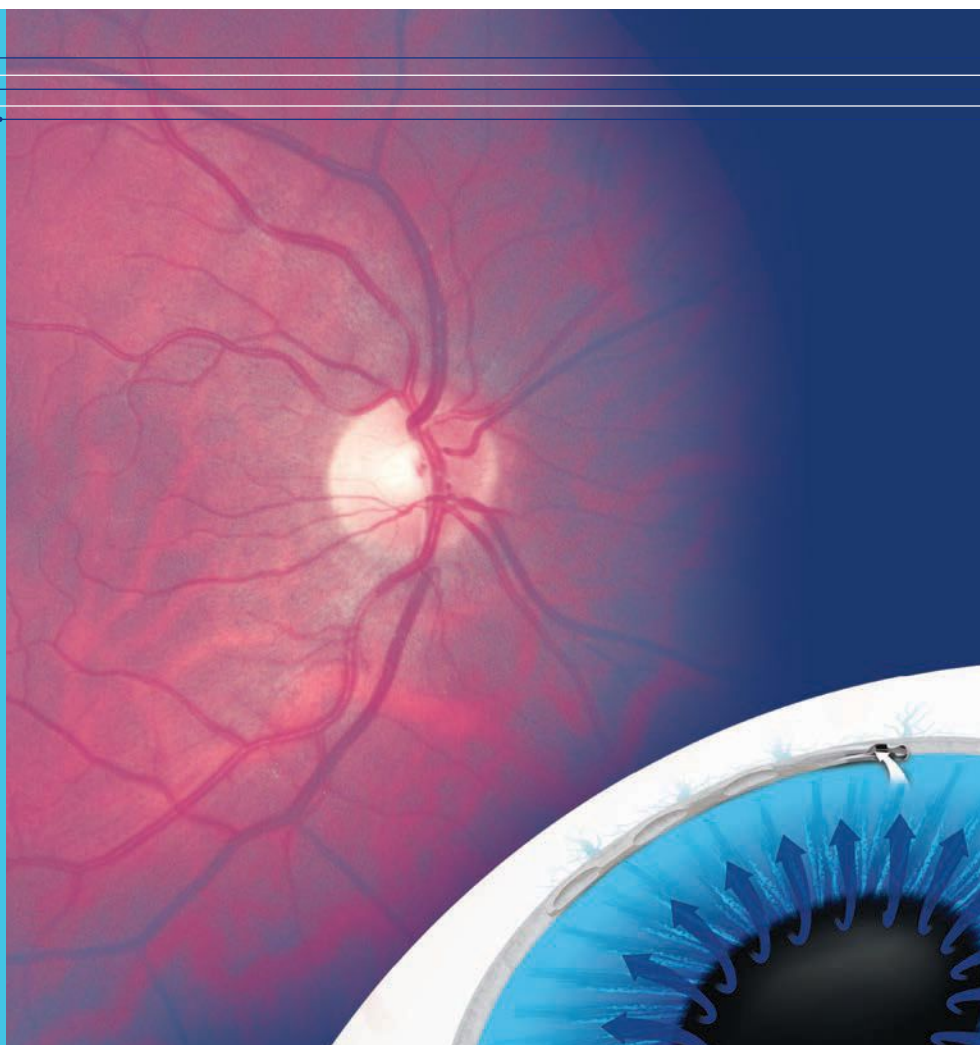
Paul M. Karpecki, OD, FAAO,
Moderator
Kentucky Eye Institute

Ian Ben Gaddie, OD, FAAO
Gaddie Eye Centers

G. Richard Bennett, MS, OD
The Eye Institute of Salus University

Cecelia C. Koetting, OD, FAAO
Virginia Eye Consultants

Thomas M. Chester, OD, FAAO
Cleveland Eye Clinic



THE GLAUCOMA OPPORTUNITY

Performing MIGS during cataract surgery offers patients a chance for more efficient disease management

Though no cure exists for glaucoma, early detection and the right management strategy can help slow progression of the sight-threatening disease. Diligent management of the patient's disease along with therapeutic strategies such as medication and various procedures for intraocular pressure (IOP) lowering all play an important role toward that goal.

Today's therapies include options to increase aqueous humor outflow, or decrease aqueous humor production, including: topical or systemic drugs; selective laser trabeculoplasty (SLT); minimally invasive glaucoma surgery (MIGS); and more conventional incisional surgeries offering the potential for effective IOP lowering, but at the risk of serious complications.[1]

Historically, because of its low risk profile, medication therapy has been the long-term management strategy for many glaucoma patients. However, this strategy is associated with a number of obstacles for both doctors and patients. Perhaps, the most difficult obstacle may be overcoming patients' non-adherence to their therapies.[2,3]

For the patient, use of topical therapies increases the chance of initiating or exacerbating

EXPERTS:

MODERATOR
Paul M. Karpecki, OD, FAAO,
Kentucky Eye Institute

Cecelia C. Koetting, OD, FAAO
Virginia Eye Consultants

Ian Ben Gaddie, OD, FAAO
Gaddie Eye Centers

Thomas M. Chester, OD, FAAO
Cleveland Eye Clinic

G. Richard Bennett, MS, OD
The Eye Institute of Salus University

ocular surface disease.[4] Furthermore, the need to remember to take prescribed drops and instill them correctly with concomitant topical medical therapy poses a time and financial burden. In addition, the patient must refill one or more prescriptions regularly and navigate changes with their health insurance plans. All of these factors can serve to decrease overall quality of life for the patient.

When it comes to SLT, the LiGHT trial showed this low-risk procedure to be as effective as eye drops as a first-line medical treatment in treatment-naïve patients with ocular hypertension or open-angle glaucoma (OAG) in producing a >20% decrease in IOP from baseline at three years.[5] However, SLT may need to be repeated to maintain target IOP.[6]

The advent of MIGS almost a decade ago offered glaucoma patients undergoing cataract surgery the chance to have a minimally invasive procedure designed to reduce eye pressure and reliance on eye drops. In 2018, the Hydrus® Microstent MIGS device was approved by the FDA to be performed during cataract surgery to treat patients with mild to moderate primary OAG. It was shown during the HORIZON pivotal trial to lower eye pressure and in many cases reduce the number of glaucoma medicines patients were prescribed.[7] In the trial, 77% of Hydrus Microstent patients saw a 20% or greater reduction in eye pressure compared to baseline, and 78% were drop-free at 2 years[7] with 66% still medication-free at 5 years.[8] The improvements compared to cataract surgery alone were the highest reported for any MIGS device in a clinical trial. The HORIZON trial is the only MIGS pivotal trial to continuously follow patients through 5 years.

Glaucoma patients with mild to moderate POAG considering cataract surgery now have a once-in-a-lifetime opportunity to have an innovative MIGS device at the same time. While the cataract surgery can improve their vision, MIGS may help to decrease the patient's eye pressure and reduce or eliminate their need for glaucoma medications.

The number of patients who may be eligible for combined cataract and MIGS procedures is projected to increase.

- More than three million Americans over age 40 are living with glaucoma,[9] and this number is projected to grow to 6.3 million by 2050.[10]
- Among those with glaucoma, 75% are estimated to be in the mild to moderate range.[11]
- Furthermore, there are over 4 million cataract surgeries performed in the US each year and this number is estimated to increase at a rate of 3.1% each year.[12]
- Studies have shown that 20% of patients undergoing cataract surgery have a concurrent diagnosis of glaucoma.[13]

As eye care professionals on the front line of clinical care, we owe it to our patients to cultivate relationships with nearby cataract and glaucoma surgeons who can perform MIGS procedures such as the Hydrus Microstent and identify individuals who might be good candidates to undergo it. At the same time, we can continue to pre- and postoperatively care for those patients who choose to have the procedure—helping them best manage their disease to ensure the most positive outcomes over the short- and long-term.

MIGS & THE EYE CARE PRACTICE

Dr. Karpecki: Today we have gathered several optometric thought leaders to help share their experience with treating glaucoma and MIGS. Thank you all for joining. We've all seen the use of MIGS increase significantly over the last several years with many optometrists playing an active role in that growth. Tell me a little bit about your experience with MIGS usage in your practice.

Dr. Koetting: At my practice, three of our current surgeons are doing MIGS. One is a glaucoma surgeon who's also performing cataract surgery with MIGS, and two of our cataract surgeons are performing MIGS along with their cataract surgeries.

Dr. Gaddie: For the most part, we don't have a lot of glaucoma specialists in Louisville. We have one surgeon who is cornea and glaucoma-fellowship trained. We have a collaborative approach on deciding which procedures we're going to perform for each patient.

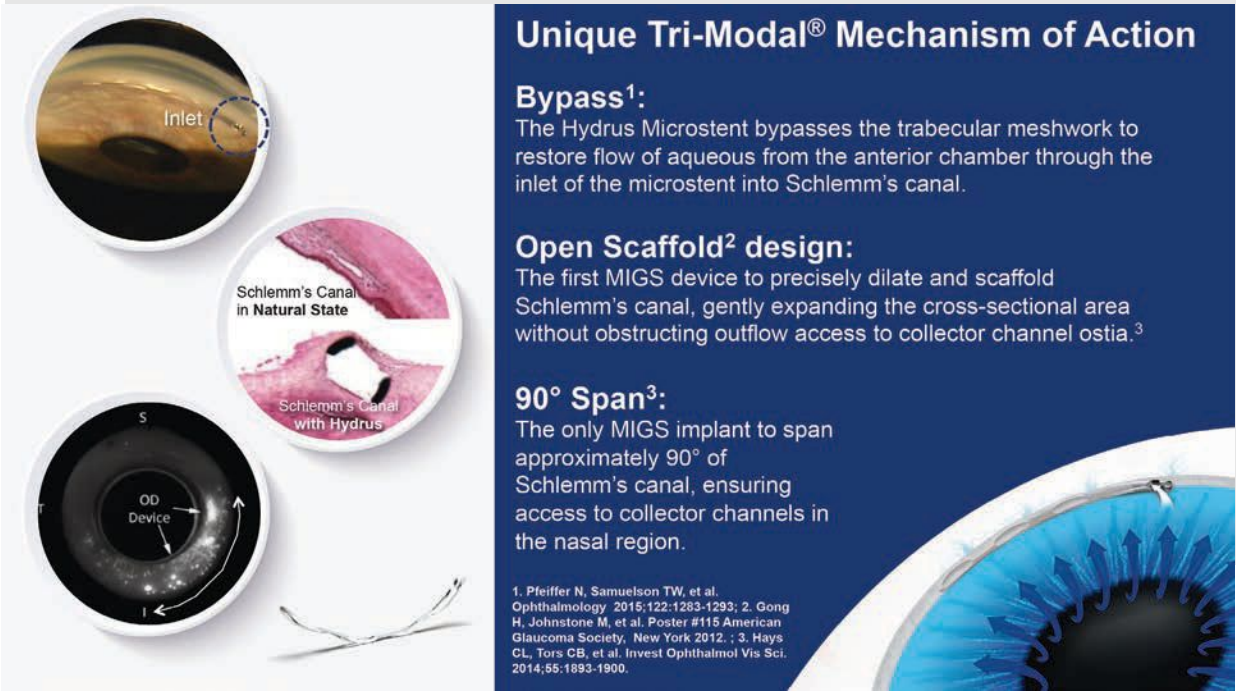
Dr. Chester: We have four dedicated cataract surgeons as well as a glaucoma specialist doing MIGS along with their cataract procedures. We also have a rather robust ophthalmology fellowship program in which the fellows have the opportunity to implant MIGS during the one-year program with us.

Dr. Bennett: We have a cataract surgeon who

THE HYDRUS MICROSTENT DEVICE

- Is a flexible, biocompatible 8mm-long microstent contoured to match the curvature of Schlemm's canal
- Open scaffold design faces the anterior chamber
- Is made of nitinol—a safe and highly biocompatible material commonly used in implants throughout the body[1]
- Bypasses the trabecular meshwork (TM) through the inlet of the device to allow optimum aqueous ouflow to pass from the anterior chamber into Schlemm's canal
- Dilates and scaffolds Schlemm's canal to augment flow along the canal
- Spans ~90° of the canal for unobstructed access to multiple collector channels without the need for the stent targeting

1. FDA In Brief: FDA outlines considerations on medical devices containing the metal alloy nitinol as part of ongoing efforts to evaluate materials in devices to address potential safety questions. Available at: https://www.fda.gov/news-events/fda-brief/fda-brief-fda-outlines-considerations-medical-devices-containing-metal-alloy-nitinol-part-ongoing



performs certain MIGS and two glaucoma surgeons we use in private practice usually for trabeculectomies and other incisional surgeries, as well as MIGS. We also work closely with several surgeons at Wills Eye.

THE GLAUCOMA PATIENT

Dr. Karpecki: What are some keys to early glaucoma diagnosis? Do you need to have an OCT to catch early disease?

Dr. Koetting: Make sure you're performing diagnostic testing, like OCT and visual fields, that we know are tried and true for these patients. We've introduced corneal hysteresis in the last two years in conjunction with our glaucoma specialist. And for me, it's been kind of interesting to watch those patients who were at higher risk because of a poor hysteresis who have started to develop glaucoma.

Dr. Chester: For the traditional optometric practice, you don't need a lot of equipment to recognize family history or demographics that put a patient in a high-risk category. Obviously, visual fields and OCT imaging are important but having an awareness of the patient's systemic medical history will also help the provider identify and recognize patients who are predisposed to glaucoma.

Dr. Bennett: The majority of ODs in the country probably don't have the kind of equipment that we use in the academic setting. But they likely have a slit lamp, a 90-diopter lens, a tonometer and a gonioprism. And most people have some sort of visual field device. So maybe they can't reach a definitive diagnosis, but if there's a suspicion, sending the patient to a surgeon that has the tools to handle particularly the early patients is the next step. Too many ODs think the Goldmann tonometer is the glaucoma machine. It's important for optometrists to be able to detect a glaucomatous nerve early on with an elevated pressure and then feel comfortable enough to refer the patient, in order to properly manage these early glaucoma cases. It really comes down to education and getting a comfort level with our surgical colleagues in the field.

Dr. Karpecki: What percentage of your patients do you think might have glaucoma?

Dr. Koetting: Ten to 15 percent of patients referred into our clinic are either early glaucoma cases or suspects that we may have detected with the utilization of our in-house diagnostic equipment.

Dr. Chester: I would concur with that. A lot of patients are in that mild category where they're just starting to develop glaucoma, maybe it's even subclinical, but it's at that early stage where doctors can begin to recognize it.

Dr. Bennett: I think our job is to educate optometrists in the field that you can better service your patients—whether they're "train wrecks" like this group sees, coming through private practice, ocular hypertensives, or diagnosed glaucoma patients who are being treated—and intervene much earlier in the disease process.

"For patients new to the practice, I tend to think of them as fast progressors until proven otherwise."

— Thomas M. Chester, OD

Dr. Karpecki: What is your current thinking on fast glaucoma progressors?

Dr. Gaddie: I've been concentrating on this—it comes from Donald Hood, PhD, the James F. Bender Professor of Psychology and Professor of Ophthalmic Science at Columbia University—looking at the OCT images in what he calls the macular vulnerability zone, the temporal side of the macula. When I see macular damage in conjunction with other RNFL damage, that's really predictive of a central visual field defect, which

is what we're trying to avoid in glaucoma. So if I can look at that one measure in a patient and say, "Wow, you're at risk for losing central vision," to me that's a way to potentially identify a fast progressor.

Dr. Chester: The only thing that I would add is, for patients new to the practice, I tend to think of them as fast progressors until proven otherwise.

Dr. Karpecki: What are some of the main drawbacks of medication therapy for patients?

Dr. Chester: Aside from the obvious potential issues with the cornea and ocular surface disease, the doctor may prescribe a medication that works great, and there aren't any issues with prior authorizations. Six months later, the insurance formulary changes or the patient changes insurance companies and now they're on a different formulary, and the office has to deal with prior authorizations if the drug is even covered. This leads to a snowball effect of more chair time, more staff time, more expense, and more frustration for the patient.

Dr. Koetting: I've noticed in the last four or five years of treating patients, there is a lot less tolerance of the drops, and more corneal toxicity and irritation. I've had many more patients coming in with early OSD so that I'm feeling the need to take them off these drugs and get away from them. I'm having a lot of conversations that sound like, "You've got early cataracts. We're not quite there, but when we get there, we can do these things." And I'm starting those conversations early with patients, just as I do about cataract surgery, to prep them to know that there is something else.

Dr. Bennett: What's patient compliance with MIGS? One hundred percent if they showed up for surgery.

REDUCING PHYSICIAN AND PATIENT BURDEN

The variables listed below help explain why it may be beneficial to both healthcare providers as well as patients to reduce the burden of medical management.

Drawbacks to Topical Medications

Physician Burden

- Administrative Time
- Educational Reinforcement
- Non-adherence

Patient Burden

- Financial Burden
- Systemic Adverse Events
- Decrease In Health-related Quality Of Life
- Ocular Surface Disease

>30%
decrease in compliance as complexity increases.[1]

10%
of glaucoma patients continuously refilled their prescription within 12 months.[2]

5.5x
greater risk of developing OSD with a history of at least 3 years of glaucoma therapy.[3]

3.3x
greater risk of glaucoma progression in patients reporting ocular side effects.[3]

1. Reardon G1, Kotak S, Schwartz GF. Objective assessment of compliance and persistence among patients treated for glaucoma and ocular hypertension: a systematic review. Patient Prefer Adherence. 2011;5:441-63. doi:0.2147/PPA.S23780. Epub 2011 Sep 23.
2. Friedman DS, Quigley HA, Gelb L. Using pharmacy claims data to study adherence to glaucoma medications: methodology and findings of the Glaucoma Adherence and Persistency Group (GAPS). Invest Ophthalmol. Vis Sci. 2007;48:5052–5057.
3. Rossi GC1, Pasinetti GM, Scudeller L. Risk factors to develop ocular surface disease in treated glaucoma or ocular hypertension patients. Eur J Ophthalmol. 2013 May-Jun;23(3):296-302.

WHEN TO CONSIDER SURGERY

Dr. Karpecki: At what point should eye care practitioners consider surgical treatment options?

Dr. Gaddie: Referencing the LiGHT study, think about the tolerability, the progression rate, the complication rate, the progression to interventional surgery between the SLT versus eye drop groups; they weren't hugely different. But the fact that 74% of patients no longer required drops at 36 months[5] to maintain target IOP was significant. When you really change your mindset and go from only recommending drops to recommending other procedures, it is an evolution. I've gone from maximum medical therapy to talking about maximum tolerable therapy. What can the patient tolerate? For some patients, that's zero medicines, and for others, it's one plus a combo. Maybe you think you're helping by adding that third bottle of drops. I'm not sure, but my mind is changed now to where I'm thinking about how I can keep medicines off the eye. And that's where options like MIGS and the Hydrus Microstent are a huge benefit.

"What's patient compliance with MIGS? One hundred percent if they showed up for surgery."

— G. Richard Bennett, OD

Dr. Chester: The paradigm shift in the past couple of years has created a sense of hope for patients that they might not need to take drops for the rest of their lives because there are better options. And when you can combine them with cataract surgery, that's something to look forward to now, as opposed to anticipating surgery in the future.

Dr. Bennett: It depends on the severity of the glaucoma, but I think in the field in general, what Ben is talking about is the wave of the future. Certainly, doing Hydrus at the time of cataract surgery makes total sense even for a patient who's on one drug and doing well.

Dr. Koetting: You also need to think about your future patient—not the patient who's in your chair now, but the same patient 20 years from now who may have arthritis, who may have financial issues. So even if they may not be what you would consider an ideal candidate because they're currently controlled, are they going to have issues 5, 10 years from now? Are they going to benefit from not having the burden of taking those drops? And no matter what, patients are human: they're fallible, they're going to forget to take medication. And if we've got something that will work continuously and keep the pressures down on a more consistent basis, we're going to help that patient long-term with preventing progression of the glaucoma.

MIGS CANDIDATES

Dr. Karpecki: Can you describe the ideal MIGS patient?

Dr. Chester: For patients who have ocular surface issues, especially those who are on multiple drops and who are exposed to a lot of BAK preservative, that is a big concern. The financial burden is also an issue as patients with ocular surface issues, who are already paying for medication are then having to pay for glaucoma drops. And it's the constant need to work with the formularies to make sure that a drop is covered on a given plan. Those are the three main factors that lean us in the direction of MIGS—cost, compliance, and cornea: the "three Cs."

Dr. Gaddie: Anyone with glaucoma and a cataract is an ideal candidate; I can't think of a lot of exceptions to that. In addition, the site of the disease is in the angle itself, in Schlemm's canal. What we see in patients who have chronic glaucoma for the 5, 10, 15 years before they have cataract surgery is that their whole aqueous outflow system is really atrophied. So when

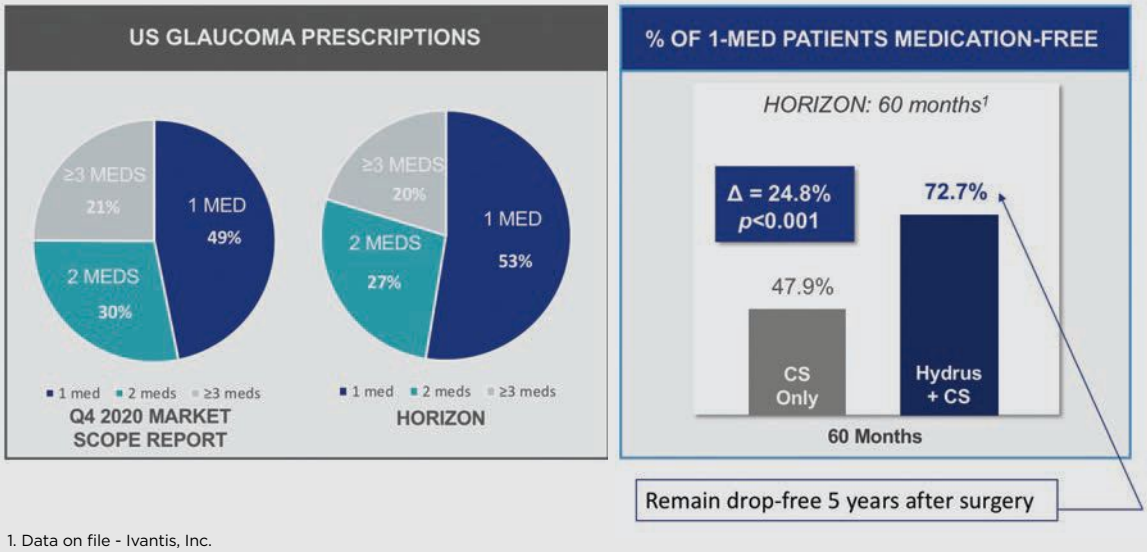
EFFICACY OF HYDRUS MICROSTENT, AS SHOWN IN THE HORIZON PIVOTAL TRIAL[1]

The HORIZON study is the largest, prospective, randomized, controlled MIGS pivotal trial to date with 556 patients at 38 centers in 9 countries. Researchers compared cataract surgery with implantation of the Hydrus Microstent vs. cataract surgery alone for reduction of IOP and medication use after 24 months. Subjects with concomitant POAG, visually significant cataract, and washed-out modified diurnal IOP between 22 and 34 mmHg were randomized 2:1 to receive a single Hydrus Microstent in Schlemm's canal or no stent after uncomplicated phacoemulsification. A total of 369 eyes were randomized after phacoemulsification to the Hydrus Microstent (HMS) and 187 to no microstent (NMS). The HORIZON trial is unique as it's the only MIGS study with 5-year continuous follow up with over 80 percent of the patients followed. Some of the findings from the 5-year follow up are summarized in the following:

- 73% of mild Hydrus Microstent patients (those on one glaucoma medication at baseline) remained medication-free at five years, compared with 48% in the cataract-surgery-alone arm. This represents the highest margin total of medication eliminations compared to a control group reported for any MIGS pivotal trial. There was a 20% to 30% improvement in the medication-free rate in the Hydrus group versus controls at all time points.
- There was a 61% reduction in the likelihood for requiring subsequent invasive glaucoma surgery for patients treated with the Hydrus Microstent as compared to cataract surgery alone (2.5% for Hydrus vs. 6.4% for cataract surgery alone).
- The overall safety profile was similar in both groups. This includes continued stability of endothelial cell counts as well as rates of persistent inflammation (0.5% Hydrus vs. 2.1% cataract surgery alone).

HORIZON TRIAL: MEDICATION FREE

Drop Elimination in the Mildest Disease — the 1-Med Patient



1. Data on file - Ivantis, Inc.

thinking about whether to refer a patient, I prefer to refer a patient who's been chronic for a period of time, and then recommend a procedure that targets restoration of that structure in the angle. Now I feel like we have some options there.

Dr. Bennett: The majority of patients who benefit from a MIGS have little or no field loss, moderate structural loss, if any; elevated pressures, or other risk factors. The same patients for whom it's logical and ethical to initiate a prostaglandin at night could benefit from a MIGS and improve quality of life.

"Think about your future patient—not the patient who's in your chair now, but the same patient 20 years from now...are they going to benefit from not having the burden of taking those drops?"

— Cecelia C. Koetting, OD

Dr. Karpecki: When you've noticed enough of a cataract present in your glaucoma patients, how do you offer the Hydrus Microstent as an option?

Dr. Gaddie: I say, 'We're going to do cataract surgery. While we're in there, we're going to do something to help the glaucoma.' Of course, I explain to patients the benefits and any potential risks of the surgery, and then ask them if there are any questions. It's worked every time for me so far. I have never had a patient say, 'No, I'm not doing that.'

Dr. Karpecki: You make a good point, Ben. If they have any questions after that, they'll ask. They'll say, 'Well, what is that? Why are we doing it?' And that's when you can explain the chance to potentially get the IOP down on one med and possibly not have meds five years later, along with the decreased risk of needing invasive surgical procedures.

Dr. Chester: I say to patients that we hope to reduce your medications, and frankly there's probably a good chance of that, but because you are human and not made out of plastic, the way you heal is just as unpredictable—trying to set appropriate expectations.

Dr. Bennett: I usually present it to the patient by saying, 'You need to have cataract surgery because we want to make you see better. And we can play a little trick on the glaucoma at the same time. And maybe we take you off or reduce the drops for a period of time or forever. One possible outcome is that we make you see better but the pressure is the same and you have to go back on the drops; but the more likely outcome is we make you see better, drop the pressure, and get you off drops possibly forever.'

DESIGN BENEFITS OF THE HYDRUS MICROSTENT

Dr. Karpecki: Can you share how the Hydrus Microstent differs from some of the other glaucoma options available to patients?

Dr. Chester: I like what the Hydrus Microstent does to the angle in terms of the structure, how it adds extra drainage through the angle, and the fact that it covers ~90 degrees.

Its ability to target the initial areas of conventional outflow resistance are what give it a kind of "triple play," and the patients who get the device are very well off because of it.

Dr. Gaddie: Being able to bypass a structure is one thing, and that can work, especially when well placed. But to be able to bypass it and then restore the structure itself, I think is very valuable. When you look at the data from the clinical trials, you can see that it has endurance. So I definitely think the design provides a benefit and is what make the Hydrus Microstent different.

Dr. Koetting: The Hydrus Microstent has been a great addition. Our two cataract surgeons have found it easy to implant and confirm proper placement. And it offers immediate benefits right after surgery, with a limited amount of inflammation.

POSTOPERATIVE CARE OF THE MIGS PATIENT

Dr. Karpecki: Can you talk about your postoperative experience regarding patients who undergo the Hydrus Microstent procedure?

Dr. Bennett: There's going to be a varied amount of postoperative inflammation, depending on the patient. But in my experience, dealing with postop Hydrus is not much different than dealing with a straightforward cataract surgery. There's no reason a well-trained optometrist in the field can't do postops on our Hydrus patients.

"Being able to bypass a structure is one thing, and that can work, especially when well placed. But to be able to bypass it and then restore the structure itself, I think is very valuable."

— Ian Ben Gaddie, OD

Dr. Gaddie: I think our comanaging surgeons need to communicate with referring optometrists that, for example, with the procedure, you might see a little microhyphema; it's not going to be a huge, layered presentation. Or you might see some minor corneal bloodstaining.

Dr. Bennett: You expect microhyphema, but you're checking to make sure there's not too much blood and that the device is in proper position.

Dr. Koetting: At one week I'll do a gonioscopy, but I haven't had a problem identifying that the device is in place, even on day one.

Dr. Karpecki: Post-surgery, how do you manage the patient's glaucoma drops?

Dr. Koetting: We'll pull them off for the first week if they're on one medication. If they're on multiple drops, we'll at least get rid of the prostaglandin and then look at how they're doing within one week. Then, depending on how the pressure's doing, we may see the patient sooner than three to four weeks.

Dr. Chester: I have a tendency to be more aggressive in taking patients off their drops, knowing that I'm going to see them one day and one week later. I agree that the prostaglandin is the first one to come off. If I need any extra coverage, I may leave one of the combo meds in.

THE LATEST FINDINGS ON THE HYDRUS MICROSTENT

Dr. Karpecki: As highlighted earlier, the latest clinical findings reveal that patients implanted with the Hydrus Microstent showed excellent safety and efficacy through 5 years. This includes keeping the majority of patients off of medications and significantly reducing the likelihood for invasive secondary glaucoma surgeries.[14] Does this long-term data and/or the results that you're seeing add value for you and your patients?

Dr. Koetting: Absolutely, because we're able to attest to our patients that we have five years worth of data to support the benefits of this device. SLT is great, but unfortunately we sometimes have to redo it, and then we get the diminishing returns every time we do it. This offers a little more stability.

Dr. Chester: At this point, it's as close to a permanent fix as we can have although we caution our patient that no surgery offers a 100% guarantee. To have a procedure that's still working at the same efficacy five years later, I

think that's fantastic.

Dr. Karpecki: When you have those kind of numbers, it does help us set the right expectations.

Dr. Bennett: I can't tell you the number of Hydrus patients who have achieved what I would have been pleased with the mitomycin C trab or a phaco-trab done at the time of cataract surgery.

Dr. Koetting: With the Hydrus Microstent, I really enjoy how quickly I see the pressures come down. Our glaucoma specialist has found that some patients who were on the border of moving forward with more aggressive Ahmed valve or Baerveldt implants have been able to avoid immediately going that route.

Dr. Karpecki: Yes, many of us are finding that the Hydrus Microstent is helping our glaucoma patients effectively manage their disease while at the same time helping to avoid or put off more invasive surgeries that carry higher risks of serious complications. This has been a great discussion. Thank you all for sharing your insights and perspectives on MIGS, and your experience with the Hydrus Microstent. ■

The Hydrus® Microstent Receives the Highest Designation for a MIGS Device in the American Academy of Ophthalmology's 2020 Preferred Practice Pattern (PPP) for Glaucoma

Dr. Karpecki: The PPP guidelines are established by the AAO to provide evidence-based guidance for best practices in quality eye care. Given the increased adoption of MIGS by surgeons it was great to see for the first time three MIGS devices (iStent *inject*® [Glaukos], XEN® Gel Stent [Allergan], Hydrus Microstent [Ivantis]) qualified to receive a rating by the AAO based on the quality of clinical data supporting each platform. Of these, the Hydrus Microstent received the highest grade of any MIGS device. This represents a meaningful step in regard to validation for the MIGS category, and reflects well on the quality of data supporting the Hydrus Microstent and as a treatment option for patients.

1. Bar-David L, Blumenthal EZ. Evolution of Glaucoma Surgery in the Last 25 Years. Rambam Maimonides Med J. 2018 Jul 30;9(3):e0024.
2. Reardon G, Kotak S, Schwartz GF. Objective assessment of compliance and persistence among patients treated for glaucoma and ocular hypertension: a systematic review. Patient Prefer Adherence. 2011;5:441-63.
3. Friedman DS, Quigley HA, Gelb L. Using pharmacy claims data to study adherence to glaucoma medications: methodology and findings of the Glaucoma Adherence and Persistency Group (GAPS). Invest Ophthalmol. Vis Sci. 2007;48:5052–7.
4. Rossi GC, Pasinetti GM, Scudeller L. Risk factors to develop ocular surface disease in treated glaucoma or ocular hypertension patients. Eur J Ophthalmol. 2013 May-Jun;23(3):296-302.
5. Gazzard G, Konstantakopoulou E, Garway-Heath D, et al; LiGHT Trial Study Group. Selective laser trabeculoplasty versus eye drops for first-line treatment of ocular hypertension and glaucoma (LiGHT): a multicentre randomised controlled trial. Lancet. 2019; Apr 13;393(10180):1505-16.
6. Garg A, Vickerstaff V, Nathwani N, et al; Laser in Glaucoma and Ocular Hypertension Trial Study Group. Efficacy of Repeat Selective Laser Trabeculoplasty in Medication-Naive Open-Angle Glaucoma and Ocular Hypertension during the LiGHT Trial. Ophthalmology. 2020 Apr;127(4):467-76.
7. Samuelson TW, Chang DF, Marquis R, et al; HORIZON Investigators. A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: The HORIZON Study. Ophthalmology. 2019;126:29-37.
8. Ahmed IK (2021, March 4-7). Long-term Safety and Effectiveness of Combined Phacoemulsification and Minimally Invasive Glaucoma Surgery: Five-Year Follow-up from the Randomized Multicenter HORIZON Trial. Paper presented at the annual meeting of the American Glaucoma Society, Virtual.
9. Vision Health Initiative. Centers for Disease Control and Prevention. https://www.cdc.gov/visionhealth/resources/features/glaucoma-awareness.html#:~:text=About%203%20million%20Americans%20have,results%20in%20increased%20eye%20pressure.
10. National Eye Institute. https://www.nei.nih.gov/learn-about-eye-health/resources-for-health-educators/eye-health-data-and-statistics/glaucoma-data-and-statistics
11. Market Scope. 2017 Glaucoma Surgical Device Report.
12. MarketScope Report: 2017 Cataract Surgical Equipment Report. A Global Market Analysis For 2016 To 2022.
13. Tseng VL, Yu F, Lum F, et al. Risk of fractures following cataract surgery in Medicare beneficiaries. JAMA. 2012 Aug 1;308(5):493-501.
14. Rhee D. (2020, February 27) Reduction in incisional glaucoma surgery after 4 years with a Schlemm's canal microstent combined with cataract surgery for treatment of primary open angle glaucoma. Poster presented at the annual meeting of the American Glaucoma Society; Washington, DC.

Hydrus® Microstent Important Safety Information
For Distribution in the US

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE:
The Hydrus Microstent 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:
The Hydrus Microstent is contraindicated under 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 (AC) angle.

WARNINGS:
Clear media for adequate visualization is required. Conditions such as corneal haze, corneal opacity or other conditions may inhibit gonioscopic view of the intended implant location. Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, peripheral anterior synechiae (PAS), angle closure, rubeosis and any other angle abnormalities 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 Hydrus Microstent has not been established as an alternative to the primary treatment of glaucoma with medications, in patients 21 years or younger, eyes with significant prior trauma, eyes with abnormal anterior segment, eyes with chronic inflammation, eyes with glaucoma associated with vascular disorders, eyes with preexisting pseudophakia, eyes with uveitic glaucoma, eyes with pseudoexfoliative or pigmentary glaucoma, eyes with other secondary open angle glaucoma, eyes that have undergone prior incisional glaucoma surgery or cilioablative procedures, eyes that have undergone argon laser trabeculoplasty (ALT), eyes with unmedicated IOP < 22 mm Hg or > 34 mm Hg, eyes with medicated IOP > 31 mm Hg, eyes requiring > 4 ocular hypotensive medications prior to surgery, 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. The safety and effectiveness of use of more than a single Hydrus Microstent has not been established.

ADVERSE EVENTS:
Common post-operative adverse events reported in the randomized pivotal trial included partial or complete device obstruction (7.3%); worsening in visual field MD by > 2.5 dB compared with preoperative (4.3% vs 5.3% for cataract surgery alone); device malposition (1.4%); and BCVA loss of ≥ 2 ETDRS lines ≥ 3 months (1.4% vs 1.6% for cataract surgery alone). For additional adverse event information, please refer to the Instructions for Use.

MRI INFORMATION:
The Hydrus Microstent is MR-Conditional meaning that the device is safe for use in a specified MR environment under specified conditions.

Please see the Instructions for Use for complete product information.

IVANTIS®