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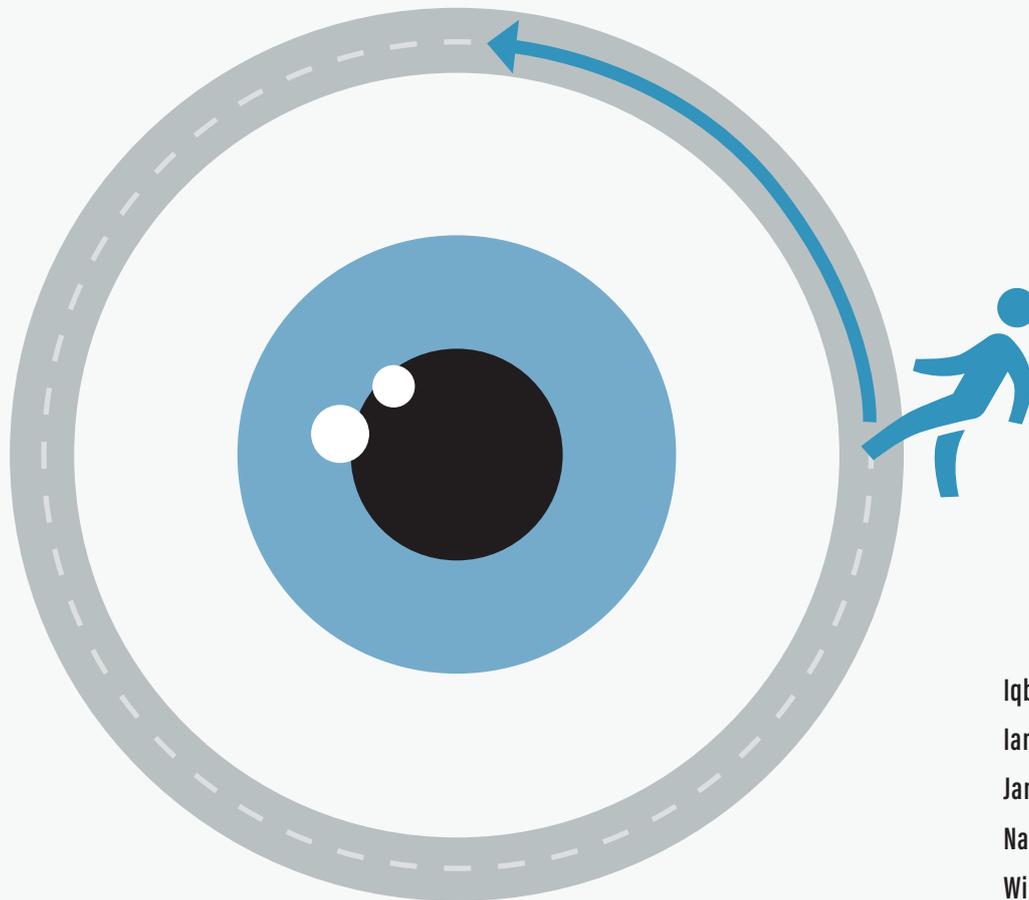
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Cataract & Refractive Surgery Today



Changing the Course of Glaucoma With the

HYDRUS MICROSTENT



Iqbal Ike K. Ahmed, MD, FRCSC

Ian Conner, MD, PhD

James S. Lewis, MD

Nathan M. Radcliffe, MD

William F. Wiley, MD



PARTICIPANTS

MODERATOR



IQBAL IKE K. AHMED, MD, FRCS

- Assistant Professor and Director of the Glaucoma and Advanced Anterior Surgical Fellowship, University of Toronto, Canada
- Chief Medical Editor, *Glaucoma Today*
- ike.ahmed@utoronto.ca
- Financial disclosure: Consultant (Ivantis)



NATHAN M. RADCLIFFE, MD

- New York Eye Surgery Center, New York
- Associate Clinical Professor of Ophthalmology, New York Eye and Ear Infirmary, New York
- drradcliffe@gmail.com
- Financial disclosure: Consultant (Ivantis)

PANEL



IAN CONNER, MD, PHD

- Chief of Ophthalmology, University of Pittsburgh Medical Center Shadyside
- Assistant Professor of Ophthalmology, University of Pittsburgh
- connerip@gmail.com
- Financial disclosure: Consultant (Ivantis, Iridex, Allergan), Owner (Ocugenix)



WILLIAM F. WILEY, MD

- Private practice, Cleveland Eye Clinic, Ohio
- Executive Advisor, *Cataract & Refractive Surgery Today*
- drwiley@clevelandeyeclinic.com
- Financial disclosure: Consultant (Ivantis)



JAMES S. LEWIS, MD

- Private practice, Elkins Park, Pennsylvania
- Director of Cataract, LASIK, and Corneal Surgery, Pennsylvania College of Optometry
- jslewis@jameslewismd.com
- Financial disclosure: Consultant (Ivantis)

Changing the Course of Glaucoma With the Hydrus Microstent

Five surgeons discuss eye-opening data on the safety and performance of this canal-based MIGS procedure.

At the American Academy of Ophthalmology's annual meeting in October, Ivantis brought together a mix of glaucoma, cataract, and refractive surgeons to talk about the latest advances and data in the growing MIGS category and to share their thoughts and experiences with the Hydrus Microstent (Ivantis). Moderated

by Iqbal Ike K. Ahmed, MD, FRCS, the group covered a range of topics, including safety, efficacy, and tips for implanting the Hydrus Microstent.

Dr. Ahmed: We've all seen MIGS grow tremendously over the last 5 years, with close to 40% growth year-over-year.¹ Still,

data indicates that more than half of patients who are eligible for MIGS procedures don't receive them.¹ Although growth is strong, there is still a lot of untapped potential to treat patients with MIGS.

The premise of MIGS is to address some of the treatment gaps that exist with medications and traditional surgery. MIGS can lower intraocular pressure (IOP) with less risk than traditional surgery, while still allowing for future surgery. MIGS also resolves some of the issues we have with medication side effects, adherence, and quality of life. We now have data on the ability of MIGS to change the course of the disease and reduce the need for more invasive surgery, providing added benefit for MIGS.

How do you view the role of MIGS in your practice? How do these procedures help you meet therapeutic goals for patients with glaucoma?

Ian Conner, MD, PhD: I'm a glaucoma subspecialist, and I do a lot of glaucoma-cataract combination surgery. This is my eighth year in practice, so I trained right at the dawn of the MIGS era. I have many patients with both cataracts and glaucoma, and I have patients covering the full disease spectrum of glaucoma. Many patients in our tertiary care academic institution really need and deserve filtering surgery such as trabeculectomy or tube shunt, but many other patients benefit from MIGS procedures.

We have multiple goals with MIGS surgeries. One goal, obviously, is to better control glaucoma. Another very important goal is to minimize medication utilization. And now we have a lot of good options to help us achieve those goals.

James S. Lewis, MD: If patients are comfortable with their cataract surgeon and that same surgeon can simultaneously address related ocular issues, I have found patients quite accepting. During cataract surgery we routinely reduce astigmatism and enhance spectacle independence—why not also ameliorate the patient's glaucoma medication burden? We are trying to enrich lifestyle by resolving multiple health issues during a single surgical encounter.

William F. Wiley, MD: I am using MIGS for my cataract patients with glaucoma. In the past, patients with glaucoma were some of our most anxiety-provoking cataract surgery patients. They would come back day 1 with pressure spikes, sometimes in the 40s or 50s. We do a fair amount of comanagement, so we had a protocol for glaucoma patients that explained the risk of a high spike within the first 24 hours and laid out what to do. We'd see them 4 hours after cataract surgery, and then they might return to their home an hour away, so we needed a protocol to limit the morbidity of cataract surgery with glaucoma.

Adding MIGS to cataract surgery basically took those high-risk patients and leveled the risk to align with other cataract patients. MIGS do not completely eliminate the chance of pressure spikes,

but the likelihood is dramatically reduced. It's been a blessing for our practice and our referring network. It's now unheard of for us not to offer MIGS to a patient with cataracts and glaucoma.

In addition to changing the risk profile of cataract surgery, MIGS are improving patients' lifestyles and quality of life long term. More and more, our patients are looking for lifestyle improvements. With refractive surgery, we can decrease their need for glasses. They have better vision and quality of life after cataract surgery. In the same way, MIGS can eliminate the lifestyle hindrance of glaucoma drops. MIGS can also improve patients' lifestyles financially by moving them away from the high deductibles or copays of medication. I typically advise patients with cataracts and glaucoma that this is a one-time chance to treat both conditions simultaneously and make a big lifestyle change to decrease or eliminate the need for drops.

"I typically advise patients with cataracts and glaucoma that this is a one-time chance to treat both conditions simultaneously and make a big lifestyle change to decrease or eliminate the need for drops."

- William F. Wiley, MD

Nathan M. Radcliffe, MD: I have a glaucoma practice in a challenging environment in New York City, where I don't always get to do as much MIGS as I'd like because I'm referred many more severe, advanced cases. These patients need a lot of incisional glaucoma surgery. Many of them are also pseudophakic, so they've missed the chance for MIGS combination surgery.

I'm a big advocate of offering MIGS to every potential candidate, because we can't predict who will end up needing glaucoma surgery. This is true even among early glaucoma patients. As an example, in the LiGHT study we saw patients with ocular hypertension and early glaucoma heading to glaucoma surgery 3 years later at a rate of about 3% treated with drops.² Cataract surgery gives us an opportunity to make the first intervention, and we don't want to miss it because every day I see how high the risk of traditional incisional glaucoma surgery can be.

CHOOSING THE RIGHT MIGS PROCEDURE

Dr. Ahmed: We have a lot of choices for MIGS procedures, including various stenting options, cutting approaches, and methods of canal dilation. There's probably not one choice that's right for every single patient, and I'm sure you've had experience with different technologies. What are the most important things you look for when selecting the right MIGS approach for your patient? How do you balance risk, effectiveness, and effort of performing the procedure?



Dr. Wiley: I think we're always weighing the balance of safety and efficacy when we approach a MIGS device. Ease of use in your hands is a factor as well because a procedure that's very safe and effective but difficult for you to perform might not be the MIGS for you.

Right now, the stenting procedures appear to have a similar level of safety across the board, but there are some differences in efficacy. I think if safety is neutral, then we should consider the stent with the most efficacy.

I know there has been some discussion as well surrounding whether, if the glaucoma is milder, you might not need the stent that is more effective. I'm not sure whether I believe in that logic. To me, you should choose the stent that's most effective regardless of whether glaucoma is mild or moderate, because none of us have a crystal ball, and we don't know what's down the road for the patient. Because the patient is having cataract surgery, we only have one chance to get it right. Thus, assuming safety is equal, I think the best choice of stent is the most effective one.

Dr. Conner: Sometimes we have to make decisions in a very practical way. When patients have cataract surgery, we have choices. If they're pseudophakic, they don't have a visually significant cataract, or they're young and we don't want to do a clear lens exchange, the options are different.

Outside of cataract surgery, I do a fair amount of ab interno canaloplasty. It's a challenge to make the best decision for long-term management of the disease. The concern is that if I do a goniotomy procedure in a phakic patient, I might not have the option to use a trabecular stent later after the patient develops cataracts. I do look forward to seeing a trabecular stent become approved down the road for use as a standalone procedure.

Dr. Lewis: Even in patients that may eventually require a more aggressive glaucoma procedure, I perform canal stenting because I am sparing the trabecular meshwork (TM), the canal, the sclera, and the conjunctiva. This strategy preserves all pathways for future intervention.

Dr. Ahmed: Patients with a cataract and glaucoma are not a homogeneous group. They might be taking one, two, or more classes of topical medication. They may have ocular hypertension, as well as mild, moderate, or severe glaucoma. IOP might be controlled at target with no evidence of progression, or it could be uncontrolled. Do you have an algorithm for choosing MIGS based on these variables?

Dr. Wiley: My nomogram is pretty simple. For patients with glaucoma who are undergoing cataract surgery, my go-to is a stenting procedure, whether they're on one drop or four. In addition to stenting, I may add endoscopic cyclophotocoagulation depending on the severity of disease. If I feel like a patient is more on the extreme end of moderate

glaucoma, and they are on their way to a likely trabeculectomy, I get the opinion of a glaucoma specialist and say, "Hey, do you want to do a combined trab, or would you like me to do a cataract surgery with MIGS first and see how they do? If the patient handles it, great. If not, they can always do a trab later."

Dr. Conner: The way I think about the management of glaucoma is that this is a chronic disease. It's going to last for your entire life. We're going to have to continue the management. I think of it like a ladder. You're climbing a ladder of glaucoma management. Many times these procedures can take a patient down a few rungs on the ladder. They're still on the ladder, right?

We can always add a drop back, a year from now, 2 years from now, 5 years from now. But the top of the ladder is that filtering procedure. We take them a few rungs away from the filter. That, I think, is all of our goals, right? Nobody really wants a hole in the eye when we get down to it. Some of us have to have it, but nobody really wants it. If we can take them down the ladder it's a good thing.

In early to moderate stage disease, controlled or uncontrolled, with any number of medications, I think a trabecular bypass MIGS procedure in conjunction with cataract surgery is a good bet. I also use it for patients with moderate disease who are controlled on medications, as I think a procedure like this combined with cataract surgery is a good option because we're not going to make their disease uncontrolled with the procedure. It's very safe, and IOP spikes, as you alluded to, Bill, are very, very uncommon with a procedure like the Hydrus (Figure 1).

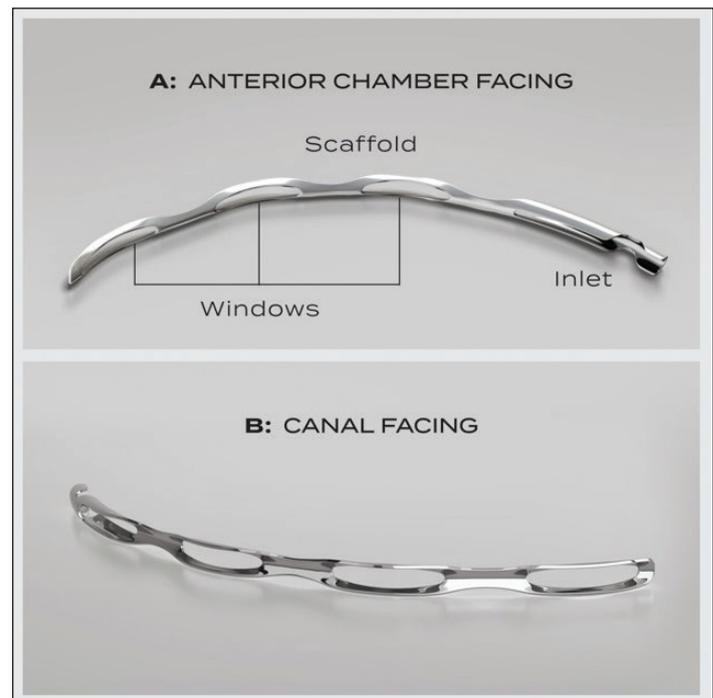


Figure 1. The Hydrus Microstent is a flexible, biocompatible, 8-mm long microstent. The canal facing surface is completely open for unobstructed collector channel access.

Dr. Ahmed: What about patients who have early disease and are taking only one medication? Why do you choose to combine MIGS with their cataract surgery?

Dr. Lewis: I consistently recommend MIGS as an appropriate intervention because glaucoma is a progressive disease. While the drugs may be affordable now and compliance might be a non-issue today, those facts will change as the patient ages and the disease advances.

I tell my patients MIGS is much like wearing a seatbelt. You don't necessarily need it, but you can't predict the future. Comorbidities and financial turbulence will develop; consequently, it is proactive to perform this technically simple, low-risk, effective, and affordable procedure with cataract surgery. In my mind a competent surgeon must justify why they are not recommending MIGS.

Dr. Radcliffe: I like the concept of the seatbelt. To me, there is an aspect of MIGS that is similar to insurance policies, against noncompliance, against life's vicissitudes. To that point, it always reminds me to make sure I taper the patient off drops, because if you've done this surgery, everything looks great, and their pressure's well at target, you might not even notice that you left them on two eyedrops. But you don't really know what you got out of the surgery until you try to taper the drops. It

may be the case that a pressure that is controlled with a device like Hydrus is a higher quality pressure because drugs don't always last for 24 hours.

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-James S. Lewis, MD

They may look great in our office, but they may not be working as well at night depending on what agent we're using. We know that side effects are cumulative over time, and people will develop dry eyes after 6 years on a drop. If you can get a device like the Hydrus stent at year three, you can potentially change whether or not patients pick up a new diagnosis by getting them off that offending agent.

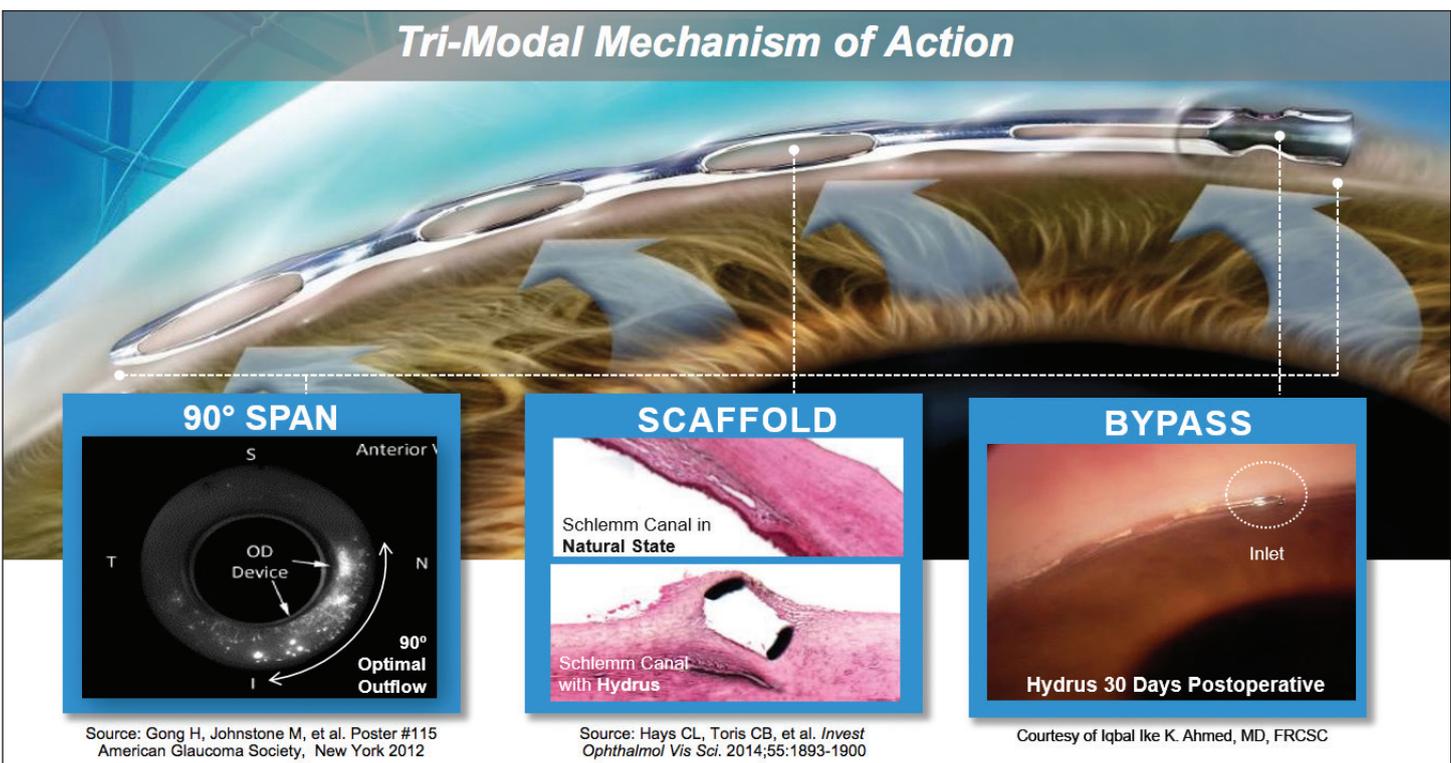


Figure 2. The Hydrus Microstent has a Tri-Modal mechanism of action: (1) It creates a bypass through the TM, allowing outflow of aqueous humor; (2) it dilates and scaffolds Schlemm canal to augment outflow; and (3) its length spans 90° of the canal to provide consistent access to the fluid collection channels of the eye.



HYDRUS MICROSTENT STUDIES

Dr. Ahmed: We've talked about having a lot of MIGS options. One option, the Hydrus Microstent, has a unique Tri-Modal mechanism of action, which makes it a beneficial option for many patients. Can you explain that mechanism of action and some of its study results?

Dr. Radcliffe: Sure, I can. Hydrus comprehensively addresses several aspects of outflow resistance with a Tri-Modal approach to stenting (Figure 2). It's an 8-mm microstent made out of nitinol, a flexible, biocompatible, safe material used in many medical devices. The stent bypasses the TM, dilating and scaffolding Schlemm canal to augment flow. It opens up Schlemm canal and breaks any interruptions in the tissue, permitting access to collector channel ostia. The length of the device, along with canal scaffolding, is what provides the access to many collector channels and limits the need for stent targeting.

One of the things we've learned in the MIGS era about Schlemm canal is that it's not always contiguous, and you may not always have access. This means you could bypass one area and, if there is an interruption in the canal just a few millimeters away, you won't have access to those collector channels. But with Hydrus, you'll open up the canal. You'll break any of those interruptions in the tissue, allowing you access to many collector channel ostia.

In bench studies, Drs. Carol Toris and Doug Rhee did some work showing Hydrus had superior improvement in outflow versus baseline compared to two first-generation iStent trabecular microbypass devices (Glaukos) in cadaver eye models.³ This provided support to the idea of stenting three clock hours compared to more of a focal bypass approach.

Dr. Ahmed: How do you evaluate the prospective and comparative data for Hydrus in terms of its value for your patients?

Dr. Conner: The HORIZON pivotal study data is pretty clear. At 2 years, nearly 80% of patients were still medication-free.⁴ That's best in class. It's a big deal for patients and for us. It's a relief to me to potentially not have to prescribe glaucoma medications to a large percentage of my patients, which we know have side effects and are not the physiologic way to deal with the disease. Getting the best chance to take patients off of medications or reduce medications is a big value proposition to my patients.

"When we're doing cataract surgery in a glaucoma patient, we have one shot to get this right and to put a stent in. Assuming the safety is the same, why not choose the stent that has the best efficacy?"

- William F. Wiley, MD

Dr. Radcliffe: HORIZON showed Hydrus is safe and effective, reducing IOP and medication use without any significant differences in safety compared to cataract surgery alone.⁴ It's particularly reassuring to me that data collection is ongoing without interruption beyond that 2-year study. Three-year data has been presented (Figure 3), and 4-year data will be presented soon.⁵ Data collection will continue for 5 years, in addition to a massive Spectrum patient registry collecting even more data from Hydrus performed internationally.

Dr. Wiley: When we're doing cataract surgery in a glaucoma patient, we have one shot to get this right and to put a stent in. Assuming the safety is the same, why not choose the stent that has the best efficacy? Under current reimbursement, we do not have a way to do a stent later on, so you can't go back after surgery and try something later.

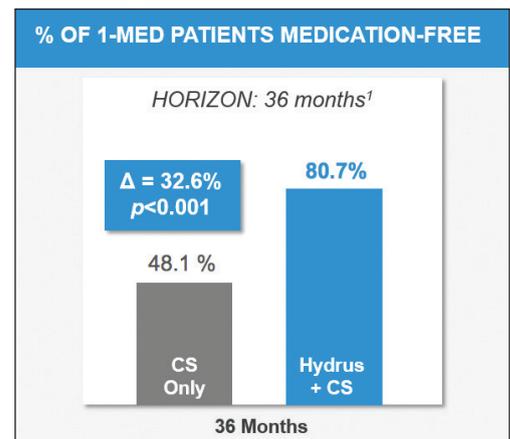
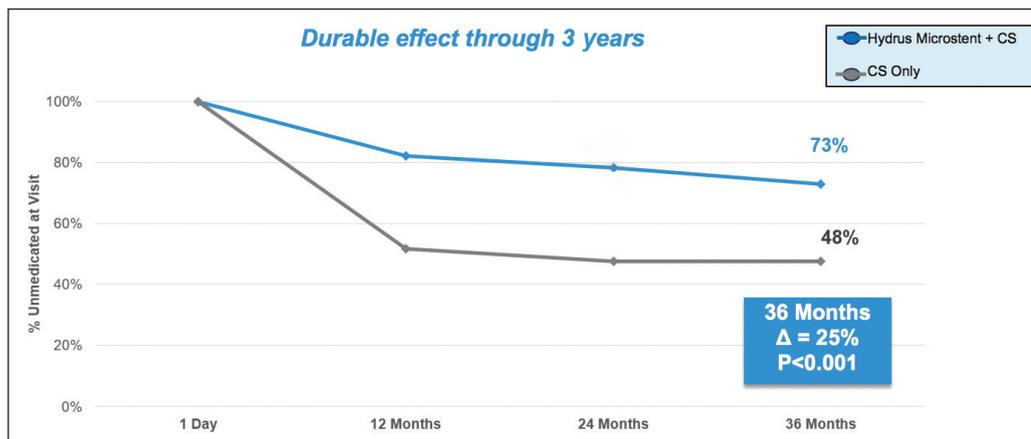


Figure 3. Data from the HORIZON study showed 73% of Hydrus Microstent patients remained medication-free at 3 years versus 48% in the control group. Of the patients who were originally on one medication, more than 80% were medication-free at 3 years.

Dr. Lewis: I choose Hydrus for all of those reasons. It's the most effective trabecular bypass and canal stenting technology available. In addition, by stopping or reducing glaucoma drops, I reduce dry eye complaints. Patients love the cost savings and increased convenience. I love not dealing with red, irritated, itchy, and burning eyes.

Dr. Ahmed: In the latest data on reduction of secondary surgical intervention, meaning trabeculectomy and tube shunts, 3.9% of patients with phaco alone needed surgery at 3 years, compared to 0.6% of patients who had phaco with Hydrus.⁵ What do you take away from that data point?

Dr. Radcliffe: For me, a very important finding was that disease severity did not affect the likelihood of secondary surgery. In other words, at the time of cataract surgery, for mild to moderate patients who were on one or two drops, it is impossible to know which one of those will end up needing a trabeculectomy or tube shunt within only a few years. This is why we need to treat patients with mild to moderate disease at the time of cataract surgery. We simply cannot predict which patients will end up needing trabeculectomy, even just 3 years later.

Cataract surgery is one of the greatest changes that an eye will undergo. If it goes well, that can set the glaucoma more at ease. If it doesn't go well, as glaucoma specialists can tell you, that can often push people towards surgery. I think it really is upon us to make sure we're doing those procedures that have been proven to reduce the impact or the likelihood of secondary surgical interventions.

In the Primary Tube Versus Trabeculectomy Study, 10% of patients who had a tube shunt went on to persistent corneal edema.⁶ There was a 30 to 40% complication and reoperation rate, and a failure rate somewhere between 20 to 30%

at 5 years. Tubes and trabs don't have any particularly wonderful data to boast, and so it's better to get this disease under control when you can in a low-risk environment.

The 2- and 3-year Horizon data showed a rather significant and, to me, a very meaningful difference in secondary surgical intervention (Figure 4). It is a big driver of my Hydrus use, because I feel like I have solid data to support my decision. My two main goals for a glaucoma patient are to avoid blindness and to avoid incisional glaucoma surgery. Now we may have a treatment at the time of cataract surgery that may let us better address both of those concerns.

"For me, a very important finding was that disease severity did not affect the likelihood of secondary surgery. In other words, at the time of cataract surgery, for mild to moderate patients who were on one or two drops, it is impossible to know which one of those will end up needing a trabeculectomy or tube shunt within only a few years."

-Nathan M. Radcliffe, MD

Dr. Ahmed: Avoiding the potential for lifelong changes and issues associated with tube and trabeculectomy is a huge step, and we're talking about an 85% reduction in 3 years that may expand over 5 years.⁵ How does that change the value proposition for a cataract surgeon?

Dr. Wiley: It certainly provides peace of mind. I think, like Dr. Lewis said, it's that seatbelt analogy. It allows us to sleep better at night. Trabs are definitely something that cataract surgeons in general like to avoid, and more and more, it seems we are sending fewer patients out for trabs. The morbidity on trabs is so high—anytime we can avoid it, it is a huge step forward.

Dr. Lewis: It's sobering to learn that a disease called "mild or moderate"

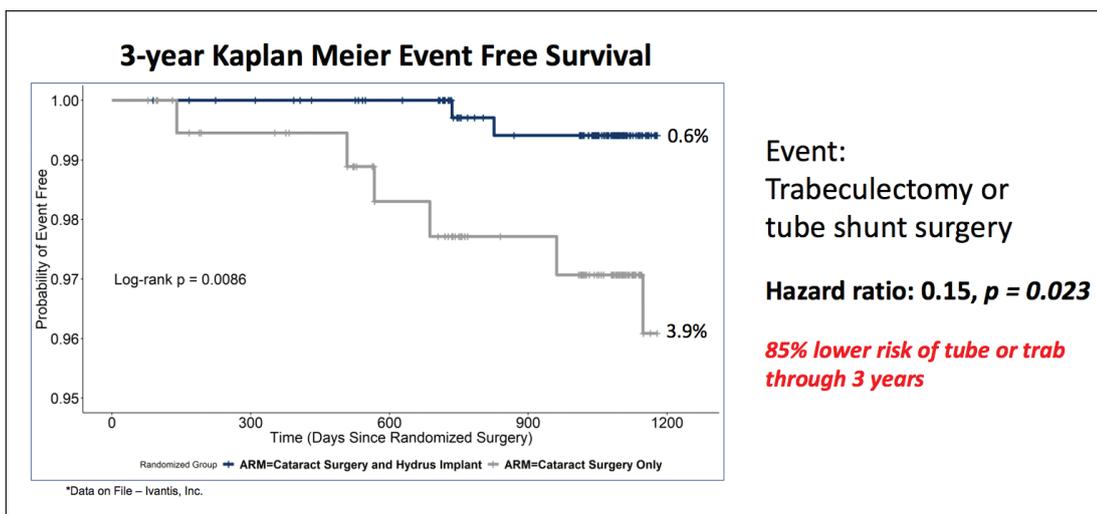


Figure 4. HORIZON Study: Hydrus Microstent is the first MIGS device to report a statistically significant reduction in risk of incisional glaucoma surgery at 3 years.



is not mild or moderate in the conventional sense. In this cohort, close to 4% will require trabeculectomy or a valve.

Dr. Ahmed: That’s meaningful for patients to know as well. Sometimes patients are wondering, “Why do something additional to cataract?” or “Why don’t you do either one procedure or the other?” I think it’s something that’s worth discussing with patients. I love the way Jim said it. We don’t know what the future predicts, right? We don’t know what is going to happen next, but we do know what can happen, and I think doing things at low risk, even though the value may not be evident now, is a great example of that.

A LOOK AT THE HYDRUS SAFETY PROFILE

Dr. Ahmed: MIGS has always been very much about safety, particularly offering lower risks compared to traditional glaucoma surgeries and adding minimal risk to cataract surgery. The HORIZON data show the Hydrus Microstent has an excellent safety profile,⁴ but we get questions about potential complications. One is nickel allergy, because Hydrus is made of a nickel-titanium alloy called nitinol. Are you concerned about nickel allergy?

Dr. Radcliffe: This issue has been raised mainly as a theoretical concern, but it doesn’t seem to apply with respect to the eye. The medical community has relied on nitinol for 30 years. Nitinol has been used in countless medical devices across many fields in medicine (e.g., stents, heart valves, vena cava filters) and has allowed the development of unique innovations, according to the FDA. One-third of implants approved for the human body by the FDA in 2018 contained nitinol.⁷

We know nitinol to be a safe material for medical implants, and while nitinol contains nickel, it is actually a titanium-containing alloy that has unique properties from nickel. To understand why, we need to understand that “nickel allergy” is a type IV hypersensitivity reaction of the skin that usually results from exposure to things like cheap nickel jewelry. In someone with a nickel allergy, the reaction may not be the same with a nitinol implant. In fact, many of our cataract patients already have a nitinol stent for coronary artery disease.

Given that nickel skin sensitivity is not uncommon, there is no doubt some Hydrus recipients have had it. It is statistically impossible that

they did not, yet there were no allergic reactions reported in the HORIZON study⁴ or in the Spectrum registry. That may be attributed to the nature of nickel sensitivity or to the electro polishing that encapsulates the nickel contained in nitinol in a layer of titanium oxide. The layer that is in contact with the canal and the TM has the same titanium oxide coating as other stents such as the iStent, which is made of titanium. We can feel comfortable implanting the Hydrus in our patients.

Dr. Ahmed: Thanks, I think that is a good summary. The rest of medicine has spoken loud and clear on the approach with nitinol and nickel allergy, and we’re all on the same page. Do you have other safety concerns? What about peripheral anterior synechiae (PAS)? Studies have shown that the MIGS procedures can cause PAS, including Hydrus. How much impact does it have?

Dr. Conner: Every MIGS procedure I’ve ever performed has some incidence of PAS formation. The only way you don’t have PAS with any of your angle-based surgeries is if you never look again after you place the device or remove the TM. It happens, and I have some Hydrus patients who have focal PAS adjacent to the goniotomy, which is where it forms, but I’ve not seen an issue with that. I have one I implanted a little bit too deeply that had a membrane, like a descemetization across the window that I had opened without any complication at all. It may recur, so be sure not to implant them too deep into the canal. That’s the lesson I learned there.

Dr. Ahmed: The PAS is interesting. Like Ian has said, I think we see PAS with every MIGS procedure that could occur. We

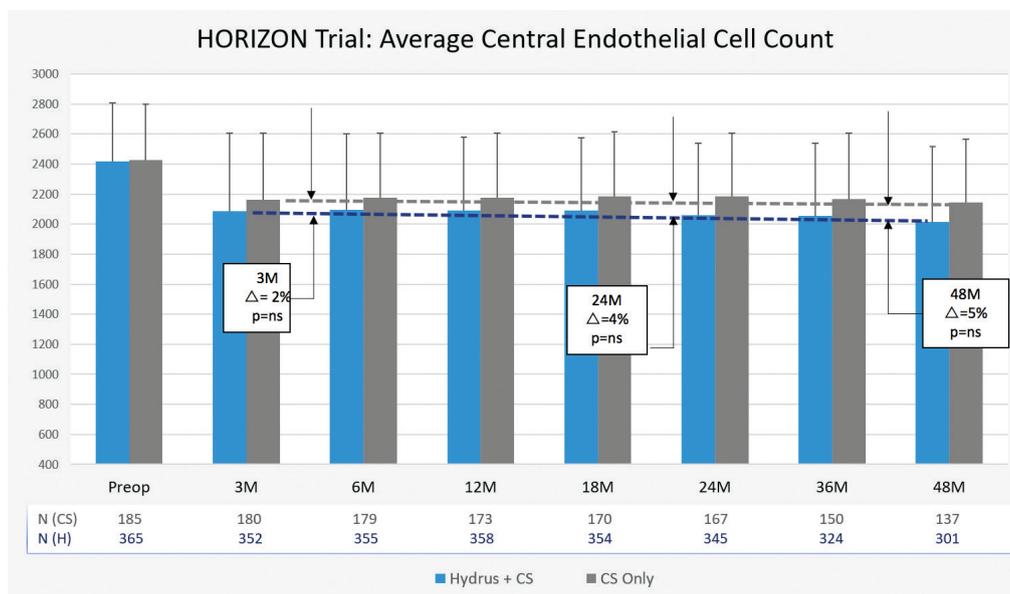


Figure 5. The Hydrus Microstent shows stability in endothelial cell count compared to control through 4-year follow-up.

see PAS that occurs with Hydrus. I don't look at it specifically as a complication. It's an anatomical healing aspect of how the eye heals and reacts. We see many eyes that have some PAS that are still functioning and IOP is controlled, and I think that's the nature of the way this device works.

Dr. Ahmed: What about endothelial cell loss? We're all very sensitive to that possibility, and people ask if it's a problem with the Hydrus. Perhaps I should begin because we've seen 4-year data on endothelial cell density. Early on, there was 2% more compared to phaco alone, and that grew to about 5% at 4 years.⁸ That's a pretty small range, especially compared to CyPass Microstent (Alcon), which showed about 11% difference at 4 and 5 years.⁹ In 10 years of my own experience, I've measured cell density in a few hundred Hydrus eyes and observed no significant decompensation. Cell densities have been very robust.

Dr. Wiley: Yes, I agree. Looking at the data, I feel very comfortable that the Hydrus is safe as far as endothelial cell count is concerned (Figure 5). Theoretically when you look at the Hydrus and when you look at CyPass, it is different. CyPass really only posed an issue if it wasn't implanted correctly, if it was implanted shallow, and/or if it was protruding into the anterior chamber and pointing up toward the endothelium. The way Hydrus is implanted, it's parallel to the iris and not perpendicular, and therefore I just don't see how it would typically pose an issue. The data supports that as well.

Dr. Ahmed: I agree, I think theoretically and anatomically the CyPass is in a different position. The fact is any device that is placed in the wrong position can potentially cause an issue, even a cutting procedure that cuts Descemet's off, but for Hydrus there is nothing inherently concerning based on its design.

"I have found that it is currently our easiest MIGS to train. For a number of reasons, it seems intuitive. Working in the angle, I think its size actually helps with visualization. You can see where it is and confirm that it's implanted correctly."

-William F. Wiley, MD

PEARLS FOR IMPLANTING THE HYDRUS

Dr. Ahmed: Given that it is still relatively early in the commercial release of Hydrus, there are a number of surgeons who are just starting to learn to implant. Cataract surgeons in particular ask me if it's difficult to do. It's a long implant.

It has to be threaded into the canal. The canal is a mysterious space if you don't spend a lot of time in glaucoma surgery. There are some natural concerns, like "How long will it take?" and "What will I do if I can't implant it?" Cataract surgeons, what was your initial experience implanting the Hydrus? Do you have any surgical pearls for your peers?

Dr. Wiley: I've taught fellows how to do MIGS, and I've been very pleasantly surprised with how easy the learning curve is for the Hydrus. I have found that it is currently our easiest MIGS to train. For a number of reasons, it seems intuitive. Working in the angle, I think its size actually helps with visualization. You can see where it is and confirm that it's implanted correctly (Figure 6).

I think with some of the other stent devices, often the reason you may need two devices is you increase your chance of at least getting one correct, which is not always a great way to feel about it. I think with Hydrus you are sure that this is in the proper place. You know it's implanted correctly, and I found that our

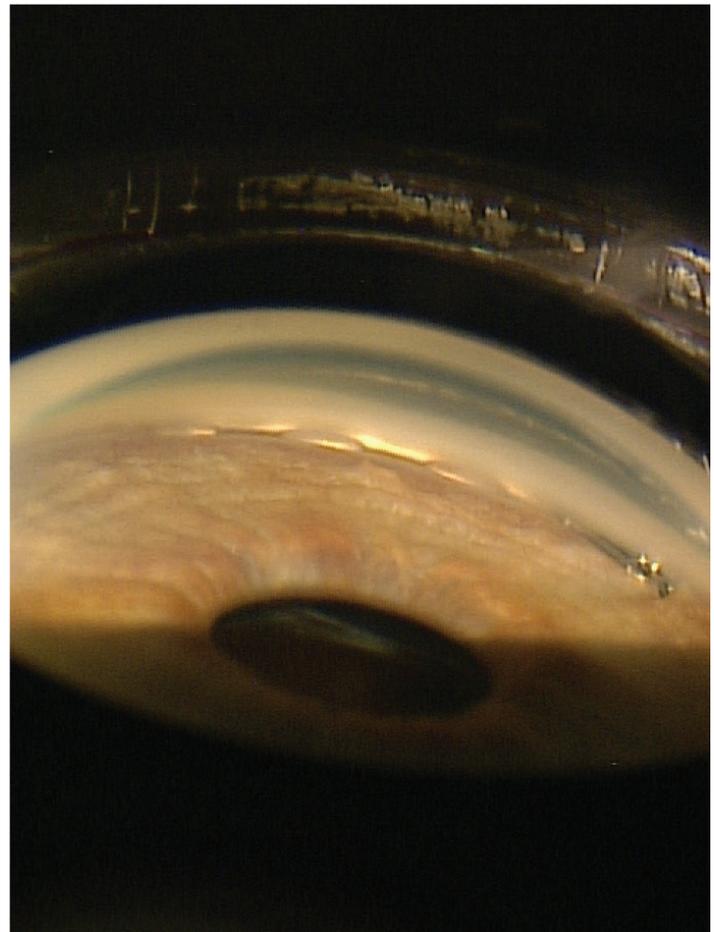


Figure 6. Final placement with the Hydrus Microstent showing proper position of the inlet extending through the TM and into the anterior chamber. Photo courtesy of Dr. Jason Jones.



learning curve with our fellows has been surprisingly easy. I think any MIGS is better than no MIGS, so if a cataract surgeon is more comfortable with a specific option over other alternatives, they should use it. Assuming ease of use and safety are equivalent, the surgeon should then look to efficacy as a deciding factor on which MIGS to use.

Dr. Radcliffe: A recent OCT study showed that 54.3% of iStent inject did not have the implant positioned in Schlemm canal as intended.¹⁰ While I like to believe that most have better success than that, I see it as an advantage to get tactile feedback as we implant Hydrus, and due to its size, it cannot easily be implanted and left in the wrong space. It's easy to see and confirm that it's implanted ideally.

Dr. Ahmed: You're describing a short learning curve, but Hydrus can have some implantation nuances like any other device. What surgical pearls would you offer for accurate placement of the Hydrus?

Dr. Lewis: Check your work by looking at the scaffold windows after insertion (Figure 7). When I began Hydrus, I didn't think inspection was necessary. After more experience, I recognize its value. Make sure the stent is inserted in the canal and advanced to bisect the transition window.

Unlike any other MIGS, the Hydrus procedure is reversible. One can easily remove the device with minimal bleeding and negligible tissue damage. The inserter serves as an excellent extractor. Surgeons can go into surgery knowing they can reposition or remove the device at any time.

Dr. Ahmed: I would add that incisional placement is important because of the curved cannula. If we use our main incision, the cannula will enter very steep into the TM, and with that steep approach, as the implant's being delivered, there's more force being placed on the device, into the canal, and more

resistance can be met. The key is to make sure that we enter at less of an angle of attack. If you use the main incision, you could be entering at 45° into the TM. You want to be entering at 10 to 20° angulation to get in and then flatten, so you can follow the TM. I do think that's important.

I think the initiation of the incision should be to the right of your field to ensure you have a nice, flat landing. When you're looking at the TM, it provides a good wide view to look at it, so I say start on the right side of your field. When you're approaching the TM, dig into it. Do a little wiggle so you can get the device in. Once you see the TM tissue overlying (with high magnification ideally) the tip, start delivering, but then relax the hand. I think you have to relax the hand. If you're pushing against the outer wall, again, you're transferring all that force to the stent as it goes in, and you're risking more resistance. Relax the hand, slide a little bit slowly and purposely, and within a period of time it's delivered. The interior side interlock releases the device.

I think there's a perception that because this is a bigger device, it might be difficult to get it in the eye properly. Instead, all the effort that went into designing the cannula to enter properly and the delivery system to work smoothly is evident in the experience of using the Hydrus Microstent. So for me, incision placement, correct angulation for entering the TM, and relaxing the hand are all important pearls for Hydrus.

Dr. Ahmed: We've talked about many of the benefits MIGS is now providing to patients but there remain a number of folks that are not doing it as of yet. Why is that? What pearls would you add to surgeons who are not doing MIGS or have stayed on the sidelines thus far?

Dr. Wiley: I think there are probably two main reasons that surgeons were sitting on the sidelines initially. They were looking at, number one, the learning curve. I think that was real for a lot of surgeons. Now, new-generation MIGS devices like Hydrus reduce that learning curve, even for surgeons new to working in the angle. But number two, the initial MIGS efficacy was questionable. Some people thought, were we really making a difference and was it worth it to add that MIGS to the cataract surgery? I think now that the value proposition, when you look at the newest data with Hydrus, is truly effective. I think if they've been sitting on the sidelines because of efficacy that reason is no longer really valid.

Dr. Conner: I understand the desire to wait until new procedures have years of data behind them and become easier to perform. The safety of DSEKS and DMEKS and the

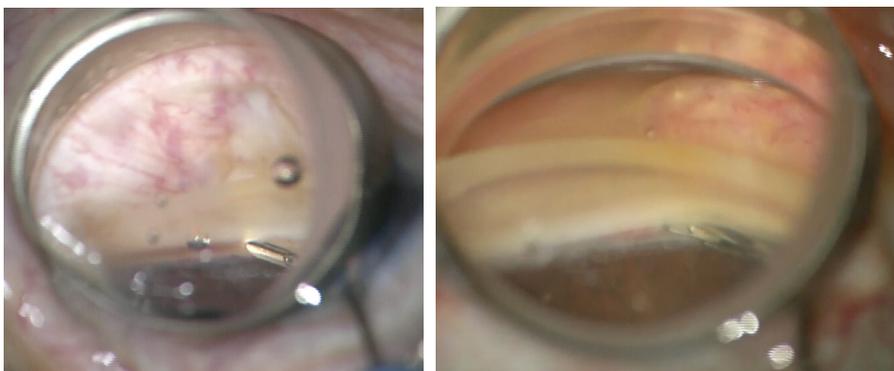


Figure 7. The first photo shows the cannula tip of the delivery system angled at approximately 15°. The second photo shows the first window of the Hydrus being delivered into Schlemm canal as the operator rolls the wheel forward. Photos courtesy of Dr. Claudio Orlich, Clinca 2020.

range of patients that they should be treating is much broader now than the cornea surgeon might have thought 20 years ago. That's where we are now with MIGS surgeries. But with the accumulated data, we now know that MIGS really should be offered to patients who are undergoing cataract surgery to better control any stage of glaucoma and alter the disease's trajectory. There's no longer a justification for not either performing MIGS or having a plan to refer those patients.

"I think the day's coming where patients are expecting that their glaucoma should be addressed if they are going to have cataract surgery. Then it becomes a matter of picking the right device that matches what they need from a disease perspective, prevention perspective, safety, and efficacy."

-Iqbal Ike K. Ahmed, MD, FRCSC

Dr. Lewis: Excellent cataract surgeons are committed to a lifetime of technique refinement and skill enhancement. Proficiency with Hydrus is achieved at the conclusion of a modest and reasonably gentle learning curve.

Dr. Conner: I would say to the interested, comprehensive ophthalmologist, or the interested cataract surgeon, it is really important to learn to do good gonioscopy, right? If you're interested in getting started in MIGS procedures, then start performing gonioscopy frequently in your patients in clinic. It really helps. It helps to be able to identify the anatomy, to be

able to go into the operating room with confidence and get started with these procedures. It's something that we know is not performed often enough in comprehensive clinics.

Dr. Ahmed: I think that's well said. I think that every year it's growing, and gonioscopy is absolutely essential. It would almost be similar to not suggesting or considering a toric lens for someone who's got a couple of diopters of astigmatism, or even less nowadays. I think the day's coming where patients are expecting that their glaucoma should be addressed if they are going to have cataract surgery. Then it becomes a matter of picking the right device that matches what they need from a disease perspective, prevention perspective, safety, and efficacy. That's where we have choices develop, and surgeons need to make those decisions based on all those choices to find what works for them. There are a lot of options out there, and I think it's great to have all these options. We need to learn the data, learn what works best in our hands, and have confidence in what we do. ■

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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 cilioablativ 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 \geq 2 ETDRS lines \geq 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.