

Premium Cataract + CyPass Micro-Stent

High-volume surgeons discuss how innovation in surgical glaucoma care produces very happy patients.

*A roundtable of exceptional ophthalmologists led by Nathan M. Radcliffe, MD, discussed the **CyPass** Micro-Stent (Alcon), a microinvasive glaucoma surgery (MIGS) device. The group was quick to agree that the prevalence of cataract patients with glaucoma and the safety and efficacy of MIGS devices makes simultaneous treatment a cannot-miss opportunity.*



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Cataract and Glaucoma

Nathan M. Radcliffe, MD: About 20% of the 3.6 million patients having cataract surgery each year also have glaucoma.¹ That is a high number. How do you address that intersection between cataract and glaucoma in your practice?

William F. Wiley, MD: I have a primarily cataract and refractive practice, and it is very common for patients who come to our practice to also have glaucoma—in my practice, about 15% of cataract patients. Premium refractive cataract surgery and glaucoma treatment dovetail very logically. Premium cataract surgery is a lifestyle choice for people who want less dependence on glasses, and MIGS offers the

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opportunity to have less dependence on IOP-lowering medications. That is a natural fit for a refractive cataract practice.

Dr. Radcliffe: That is a good point. As a glaucoma specialist, almost every one of my cataract patients has glaucoma—far above the 20% average. It is just a question of whether my patient will have a MIGS procedure or another option. Blake, what do you see in your neck of the woods?

Blake K. Williamson, MD: We do mostly high-volume refractive cataract and LASIK and less general ophthalmology. When I joined the practice—before the MIGS revolution—we referred out most glaucoma patients. Today, we do a high volume of MIGS procedures for a refractive cataract practice, a bit higher than 30%. It has been rewarding to see the effects of treating two problems at one time.

Dr. Radcliffe: Dr. Okeke, let us hear about your practice.

Constance O. Okeke, MD: I work at a high-volume, referral-based multispecialty group practice. I was an early adopter of MIGS in 2009, and today the majority of my surgeries are MIGS procedures combined with cataract surgery. As the glaucoma population continues to increase, MIGS will bring all anterior segment surgeons into glaucoma surgery to handle the load.

By performing more MIGS procedures and far fewer traditional glaucoma surgeries, I rarely deal with the complications of bleb surgery, with all the chair time, angst, and sleepless nights that come with them. With MIGS, I teach my optometric colleagues how to handle postoperative care, which allows me to do more surgery and treat more patients. It enhances my satisfaction with being a surgeon.

Efficacy in the Supraciliary Space

Dr. Radcliffe: We use prostaglandin analogs to allow

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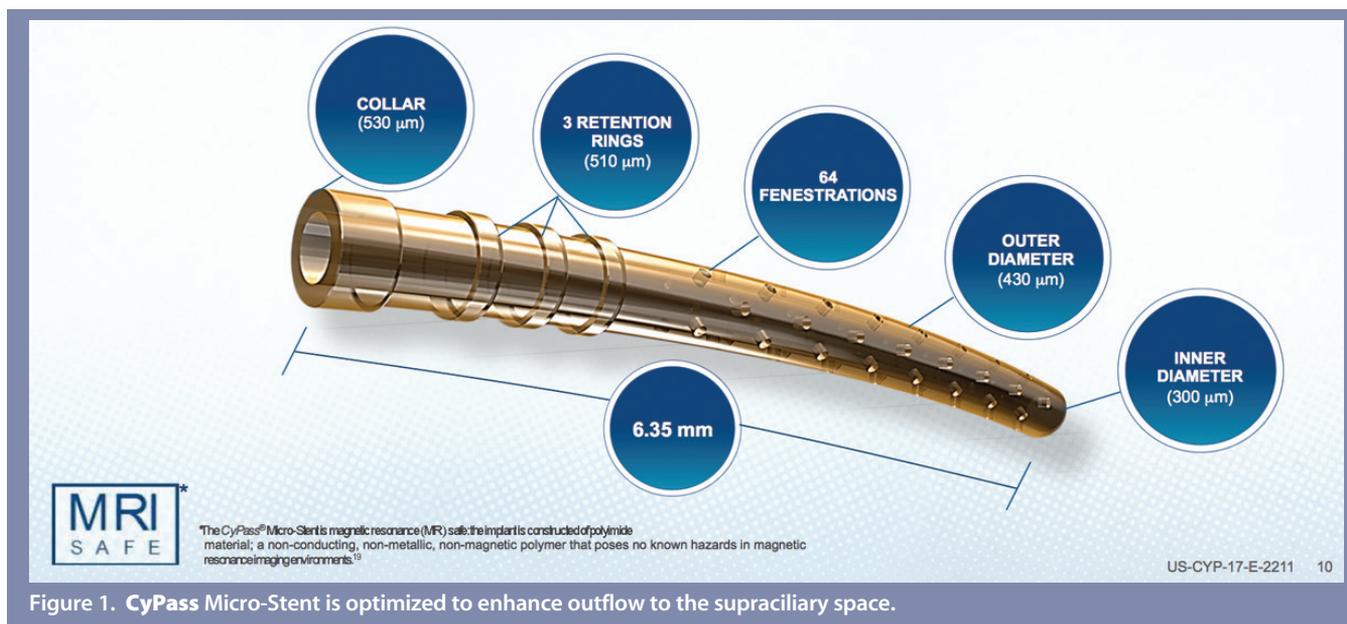


Figure 1. **CyPass Micro-Stent** is optimized to enhance outflow to the supraciliary space.

uveoscleral outflow, in effect treating the supraciliary space. **CyPass Micro-Stent** addresses the same area of resistance. We could use another device or procedure to bypass the trabecular meshwork, but if there is downstream resistance in the collector channels or episcleral system, the pressure stays a little high, leaving us wondering if we targeted the collector channels adequately.

The outcomes speak for themselves. In the COMPASS trial, unmedicated pressures of more than 500 patients were compared pre- and post-**CyPass Micro-Stent**.¹ After 2 years, 72% of 374 patients had more than 20% lower pressures, compared to 58% of 131 patients with cataract surgery alone. Patients with baseline pressures between 16 and 18 mm Hg did especially well, with pressures basically in the mid-teens or lower after 2 years. And 93% of responders were medication-free at 2 years. Those are happy patients. That is also the type of information that you can relay to patients to get them pretty excited about undergoing this procedure.

Dr. Okeke: When you start using **CyPass Micro-Stent**, it does not take long to start seeing these results in your own experience. That is one reason I am so excited about it. I had a patient whose pressure was 27 mm Hg without medications and was taking three drops to bring it down. I did a combined toric IOL and **CyPass Micro-Stent** procedure. Her pressure was 12 mm Hg the next day. Two months later, her pressure is maintained without use of any medications. It is great to be able to offer this to my patients.

Dr. Radcliffe: The safety data are obviously of critical importance to us and to our patients. The COMPASS trial included both standard and premium cataract procedures, combined

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with **CyPass Micro-Stent**.¹ There was intraoperative bleeding in 2% of cases, compared to none with cataract surgery alone. About 2.9% of people had a pressure below 6 mm Hg after surgery. That is something we want to keep an eye on, but I think hypotony has a different definition with MIGS. With trabeculectomy, a low pressure usually came with choroidal effusion, a shallow chamber, and other worrying problems. With MIGS, hypotony is low pressure achieved with a device that consistently limits outflow without big peaks and valleys, and when it occurs, the eye often has a perfect, deep chamber. Dr. Williamson, do cases with low pressures concern you?

Dr. Williamson: As you inferred, there is a difference between numerical and clinical hypotony. If you have a deep chamber, good visual acuity, no choroidals, and the patient's doing well, then transient numerical hypotony really does not concern me, especially with this device. Frankly, I think it is amazing that we are using the word "hypotony" in the same sentence as "MIGS." It is a testament to how far the space has come and how confident I am in the results **CyPass Micro-Stent** delivers.

Surgical Pearls for Success

Dr. Radcliffe: Like other MIGS procedures, **CyPass Micro-Stent** implantation is straightforward and intuitive. It is about 6 mm long, with an inner diameter of 300 μm, 64 fenestrations, and 3 retention rings to provide guidance and keep it in place. The procedure is routine cataract surgery right up until you put in the device. Dr. Okeke, you are doing combination surgery with **CyPass Micro-Stent** perhaps more than any of us. What surgical pearls for success would you share?

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Dr. Okeke: First, it is critical to choose patients with good anatomy, especially for your first cases. You want to see a good separation between the trabecular meshwork and the scleral spur. It is nice to have a deep angle, but not essential. I think it is very important to implant **CyPass** Micro-Stent after cataract surgery to make sure that the device is stable, without the need for additional manipulation for the cataract procedure.

After successful cataract surgery, fill the chamber with viscoelastic to make it very taut. This makes it easier to push forward and insert the **CyPass** Micro-Stent. Advance the tip, aiming to just slightly depress it on the scleral spur, and then move the tip just below it for the entry point. As you insert and move forward, you should have a clean glide. You should advance fairly far until the device is almost completely in. You might feel a little resistance. If that happens, release it and gently push, and it will go in smoothly.

One of the great features of **CyPass** Micro-Stent is its set of landmarks—retention rings and a proximal collar (Figure 1). Make sure the collar is right at the tip of the trabecular meshwork and Schwalbe's line, which will keep you from going too far. Gently tap it until you get to the right spot. Advancing the stent this way eliminates any concern about corneal edema. Once you are done, remove all of the viscoelastic to avoid any pressure spikes the next day. I use the gonio lens as I remove the viscoelastic to make sure that the I&A tip does not come too close to the stent and cause any horizontal shift that may result in a cleft.

Dr. Radcliffe: Those are great tips. You mentioned what happens postoperatively day 1, which is a significant differentiator of **CyPass** Micro-Stent, in my experience. With trabecular stents, I use acetazolamide, and I use carbachol at the end of a case to prevent high IOPs on day 1. With **CyPass** Micro-Stent, I am not concerned about pressure spikes on day 1, when usually the pressure hovers around 10 mm Hg, and patients can be safely taken off drops. Day 1 looks very different between **CyPass** Micro-Stent and trabecular microbypass.

MIGS and the Cataract Surgeon

Dr. Radcliffe: Adding a separate glaucoma procedure to cataract surgery is relatively new but, as we said, it seems to be a natural fit for premium cases. Blake, can you share a case that illustrates that relationship?

Dr. Williamson: When we consider the problems we can fix in advanced refractive cataract surgery, glaucoma is yet another box we can check. I routinely tell my refractive colleagues that “glaucoma is the new astigmatism”—and we should all choose to treat it with MIGS. In one cataract/glaucoma case, my patient's BCVA was around 20/30, but he experienced glare and had an IOP of about 25 mm Hg on two medications. He had very irritated eyes, and the slit lamp and topography showed significant ocular surface disease.

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We were able to kill four birds with one stone: glaucoma, astigmatism, cataract, and ocular surface problems. I prescribed tears, gel drops, and low-dose steroids to clear up the topography and achieve some refractive stability in terms of magnitude and meridian of cylinder. A month later, we elected to perform femtosecond surgery with a toric IOL combined with **CyPass** Micro-Stent to reduce the IOP quickly. Postoperatively, the patient was 20/25 with a pressure of 7 mm Hg. I stopped both of his medications. Postoperative week 1, he was 20/20 with an IOP around 13 mm Hg on no drops.

Dr. Wiley: MIGS can really help to improve patients' lives, but ophthalmologists are only beginning to address the population of MIGS candidates. A lot of candidates are not getting glaucoma treatment during cataract surgery. We have a huge opportunity to increase penetration the same way we have premium treatment of astigmatism—there is no reason not to treat glaucoma during cataract surgery.

Dr. Okeke: We let every cataract patient know that we can correct vision and astigmatism. We all need to start treating glaucoma the same way, regardless of the level of control achieved with medications. We have to give them a MIGS choice, or the option of reducing or eliminating glaucoma drops. Once people become more aware of these options, more surgeons will be obligated to learn and offer MIGS procedures, just like they did with premium cataract surgery.

Dr. Wiley: Another nice feature, in the context of premium surgery, is that MIGS procedures are almost always reimbursed by insurance. This is not a financial hurdle. In fact, patients may be able to save money by reducing medications.

Broad Indication of **CyPass** Micro-Stent

Dr. Radcliffe: If a candidate for refractive cataract surgery comes to you with IOP in the 20s and you decide to combine cataract and MIGS, how do you choose between **CyPass** Micro-Stent and iStent* Trabecular Micro-Bypass Stent (Glaukos)?

Dr. Williamson: The choice can depend on the doctor's notions of certain MIGS devices. For example, for early, mild glaucoma, a lot of physicians think they should only target the aqueous conventional outflow pathway. That makes sense, but I think that because the gold-standard medical treatment of prostaglandins target uveoscleral outflow, **CyPass** Micro-Stent could make sense as well. I tend to prefer the nonconventional outflow pathway device (**CyPass** Micro-Stent) when I am targeting lower pressures in patients who already have perimetric field loss at the time of phaco.

Dr. Okeke: I agree with you, and **CyPass** Micro-Stent is indicated for mild to moderate disease. The iStent* is a good option for

very early cases, but I would be much more cautious with moderate disease and not consider it for anyone with severe disease as a single device. Also, if a patient has not responded well to selective laser trabeculoplasty (SLT), I would rather use **CyPass Micro-Stent** than trabecular meshwork removal or bypass.

Dr. Radcliffe: Dr. Wiley, does this decision process sound like what you go through in your practice? What does a typical cataract-MIGS patient look like for you?

Dr. Wiley: I will give you an example of a MIGS patient who came in with cataracts in both eyes, myopia with astigmatism, and moderate glaucoma with IOP of 23 mm Hg on latanoprost. The patient wanted refractive cataract surgery, and I recommended adding MIGS to control her glaucoma. At the time, I was very comfortable with the iStent, so I combined refractive cataract, endoscopic cyclophotocoagulation, and iStent procedures. Surgery went well and day 1 vision was good, but the pressure spiked to 51 mm Hg. I burped the incision and added brimonidine tartrate/timolol maleate. When the patient returned at day 3, the pressure was 19 mm Hg.

For the second eye, I chose **CyPass Micro-Stent**. At day 1, the pressure was 9 mm Hg without glaucoma medication; the iStent* eye was still 24 mm Hg on brimonidine tartrate/timolol maleate. **CyPass Micro-Stent** was the right procedure for this patient.

Dr. Radcliffe: iStent* was a reasonable choice in the first eye, but the high pressure guided you to **CyPass Micro-Stent** in the second eye. That points to the struggle we can go through to determine the best approach. We all have preferences based on our experiences. I particularly like **CyPass Micro-Stent** for challenging high myopes, where SLT does not work particularly well, and safety is critical. Emmetropes are also excellent candidates.

Dr. Wiley: Dr. Radcliffe, what about premium cataract patients paying out of pocket for that “perfect” outcome? Does ciliary bypass and the risk of hypotony scare them away?

Dr. Radcliffe: No. I think high expectations put the pressure on us to deliver. When patients are on several drops and still cannot get their pressure down, they are frustrated and worried. This gives us a chance to fill that need while we deliver the vision they are seeking. It is a homerun. When you see the study results—93% of patients off drops—those are a lot of happy patients.¹ They knew they had a problem, they had to manage it daily, and now the problem is essentially solved. The cost, inconvenience, and ocular surface problems associated with drops are gone. When we are under pressure to deliver exceptional outcomes, I think that is the way to do it. ■

1. Vold S, Ahmed IK, Craven ER, et al; for the CyPass Study Group. Two-year COMPASS trial results: supraciliary microstenting with phacoemulsification in patients with open-angle glaucoma and cataracts. *Ophthalmology*. 2016;123(10):2103-2112.

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CyPass® Micro-Stent **Important Product Information**

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.

MRI Information: The **CyPass® Micro-Stent** is magnetic resonance (MR) Safe: the implant is constructed of polyimide material, a non-conducting, non-metallic, non-magnetic polymer that poses no known hazards in all magnetic resonance imaging environments.

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 \leq 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 **CyPass® Micro-Stent** to cataract surgery alone, the most common post-operative adverse events included: BCVA loss of 10 or more letters at 3 months after surgery (8.8% for **CyPass®** 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 Product Instructions for a complete list of contraindications, warnings, precautions, and adverse events.