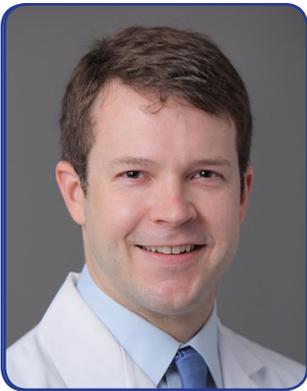


Unlocking the potential of the supraciliary space

by Nathan Radcliffe, MD



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Over the past 4 years or so, many cataract surgeons have become familiar with the ab interno approach to minimally invasive glaucoma surgery (MIGS). For many of us, this has been achieved by implanting trabecular microbypass stents. In the more recent years, we have had alternative approaches to addressing glaucoma through the angle, such as ab interno goniotomy and ab interno viscocanalostomy. As a result, we are becoming familiar and comfortable with the algorithm of treating glaucoma in the angle at the time of cataract surgery.

The ciliary body represents a large, easily visualized, and easily treatable target that can be comfortably

approached using intraoperative gonioscopy at the time of cataract surgery. Unlike the trabecular meshwork, which varies in pigmentation, appearance, and microanatomy, the ciliary body can be reliably found at the iris root. The CyPass Micro-Stent is placed into the supraciliary space under gonioscopic visualization after cataract extraction and intraocular lens implantation.

My experience has been that the ciliary body is the easiest landmark to identify gonioscopically, and the tissue has also been the most intuitive target to hit with the supraciliary stent. When we target the trabecular meshwork, we know there is a floor in terms of how low we can get the intraocular pressure because we will have additional resistance to the remainder of Schlemm's canal, the collector channels, and the episcleral venous system. Episcleral venous pressures can typically be around 12 mm Hg, so with the added resistance, trabecular bypass can often result in pressures higher than that.

The ciliary space presents a unique opportunity to achieve significant pressure reduction in a safe and minimally invasive manner. The design of the CyPass Micro-Stent provides a level of resistance to aqueous outflow, and the supraciliary space provides access to the uveoscleral outflow

pathway, whereby the intraocular pressure will not be limited by episcleral venous pressure. Significant pressure reduction can occur, and, because the tip of the CyPass Micro-Stent remains in the angle and free of obstruction, iris adhesions and other forms of scar formation are less likely to influence pressure reduction. Because we are accessing a space with so much pressure-lowering potential and using a microstent that is designed to protect against clinically significant hypotony, we are maximizing the potential of the supraciliary space without compromising on safety as compared to cataract surgery alone. Therefore, it makes so much sense to approach the supraciliary space using a MIGS implant—so that we can control the flow.

Glaucoma is a progressive and blinding disease, and medications themselves carry risk of ocular surface disease and are often difficult for patients to comply with. We cannot call topical therapy risk-free. Cataract surgery provides us the opportunity to lower the pressure. Often, the pressure reduction from cataract surgery alone is insufficient to meet our patients' needs.

The 2-year COMPASS trial showed significant additive intraocular pressure lowering as well as significant reduction in the requirements for topical medications with a safety signature that was

similar to cataract extraction by itself.¹ These data, which carry out to 2 years without a degradation in the procedure's value, show us that the risk-to-benefit ratio of performing supraciliary micro-stenting in combination with cataract surgery in patients with mild to moderate open-angle glaucoma is indeed favorable.

It is always important for patients to understand the procedure they are having and the risks and benefits. My patients have been excited at the prospect of getting better glaucoma control and reducing their eyedrop burden along with the burden of the side effects from drops. In my discussion with patients, I have found that they are open to the idea of internally draining the fluid and using a micro-stent to do so. Typically, patients will have concerns with drains that are external to the eye because they know that they can be seen and felt. I have been impressed with patient acceptance and excitement about this approach. ■

Reference

1. Vold S, Ahmed II, Craven ER, et al; 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 is a successful treatment for cataract patients with mild to moderate glaucoma

by Quang H. Nguyen, MD



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C CyPass Micro-Stent is a novel approach for treating patients with mild to moderate glaucoma in conjunction with phacoemulsification. The supraciliary Micro-Stent provides an opportunity for ophthalmologists to perform a surgical treatment earlier in the disease. Surgeons have another option to control

pressure better. CyPass Micro-Stent is a novel approach for treating patients with mild to moderate glaucoma in conjunction with cataract surgery, and may possibly reduce the burden of topical glaucoma medication.

CyPass Micro-Stent creates a controlled cyclodialysis and maintains a permanent cleft due to the “tenting” effect of the implant. It improves uveoscleral outflow similar to a mechanism of action of prostaglandin analog, which contributes greatly to pressure reduction. An attribute of CyPass Micro-Stent is the intuitive nature and the fact that it bypasses Schlemm’s canal and collector channels that may be atrophic in glaucoma patients.

The COMPASS trial, a pivotal clinical trial of 2 years’ duration, demonstrated the effectiveness of CyPass Micro-Stent for lowering IOP with an excellent safety profile.* The COMPASS trial recruited 505 patients with randomization of 3:1 (3 patients with phacoemulsification + CyPass Micro-Stent (374 patients) to every 1

• **32% increase in reduction of IOP with the CyPass Micro-Stent**

• **93% of CyPass Micro-Stent responders were medication-free at the end of 2 years**

Case highlight

In my practice, a 68-year-old Caucasian woman underwent CyPass Micro-Stent in conjunction with uncomplicated phacoemulsification and posterior chamber IOL implantation. The right eye was operated on first, and the left eye underwent surgery a few weeks later.

Preoperatively, best-corrected visual acuity was 20/100 in the left eye and 20/80 in the right eye. The patient had moderate glaucoma that was treated with a prostaglandin analog and fixed-dose combination therapy. Intraocular pressure was 18 mm Hg in the right eye and 17 mm Hg in the left eye.

Postoperatively, best-corrected visual acuity was 20/20 in both eyes. Intraocular pressure in the immediate postoperative period was stable with no IOP spikes or hypotony. Intraocular pressure remained at 10 mm Hg in the right eye and 11 mm Hg in the left eye. The patient discontinued the fixed-dose combination within a week of surgery. IOP was still stable in the low teens, and the plan is to discontinue the prostaglandin analog in the coming weeks.

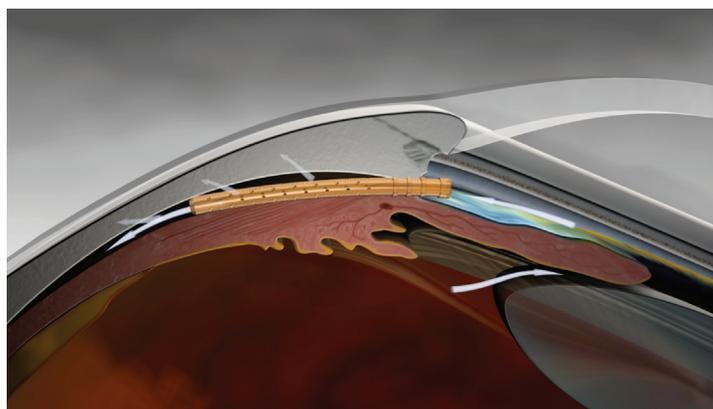
patient who underwent phacoemulsification alone (131 patients). This is the largest MIGS trial to date. Moreover, the COMPASS trial has washout IOP measurements at 1 and 2 years to truly demonstrate the effectiveness of CyPass Micro-Stent compared to phacoemulsification alone. Patients in both groups had similar baseline mean IOPs: 24.5±3.0 mmHg in the control group and 24.4±2.8 mmHg in the CyPass Micro-Stent group. The study found early and sustained pressure reduction, with 72.5% of CyPass Micro-Stent patients compared with 58% of controls achieving 20% or more unmedicated IOP lowering compared with baseline at 24 months (Fig. 1). Mean IOP reduction was 7.0 mmHg in the CyPass Micro-Stent group

compared with 5.3 mmHg in the control group, a 32% increase in reduction of IOP with the CyPass Micro-Stent ($p<0.0001$). Patients’ mean 24-month medication use was 20.6% lower in the CyPass Micro-Stent patients, and 72.4% of patients in the control group and 93.0% of CyPass Micro-Stent patients were medication-free at the end of two years (Fig. 2). No sight-threatening adverse events occurred in the CyPass Micro-Stent group. Visual acuity was high in both groups through 24 months, with more than 98% of patients achieving 20/40 or better best-corrected visual acuity.¹

The 1-year results of an ongoing open-label, interventional, multicenter study provide additional information on the use

*Primary outcome measure was unmedicated diurnal IOP reduction at 24 months versus cataract surgery alone at baseline. Secondary outcomes measures included mean change in 24 month DIOP from baseline and 24 month unmedicated mean IOP (between 6 mmHg to 18 mmHg) versus cataract surgery alone. Medication use at 24 months was also analyzed. The primary and secondary effectiveness analyses were performed using intent to treat (ITT) population.

of the CyPass Micro-Stent for the surgical treatment of open-angle glaucoma when implanted in conjunction with cataract surgery. The study included 167 eyes of 142 patients with open-angle glaucoma who underwent combined phacoemulsification with intraocular lens insertion and Micro-Stent implantation into the supraciliary space. Patients were divided into two groups: those with a baseline IOP of 21 mmHg or higher (65 patients) and those with a medicated baseline IOP of less than 21 mmHg (102 patients). Glaucoma medications were discontinued or tapered at surgery. Patients' mean follow-up was 294±121 days, and no major intra-operative or postoperative complications occurred. Patients' mean preoperative baseline IOP was 20.2±6.0 mmHg, and their mean



CyPass Micro-Stent in the supraciliary space

number of IOP-lowering medications was 2.0±1.1. Patients with a medicated baseline IOP of 21 mmHg or higher demonstrated a 35% decrease in mean IOP and a 49% reduction in mean glaucoma medication usage. Those with a medicated baseline IOP of less than 21 mmHg had a 75% reduction in mean medication usage while maintaining a mean

IOP of less than 21 mmHg. Mean IOP at 12 months was 15.9±3.1 mmHg in all eyes, which was a reduction from baseline of 14%.²

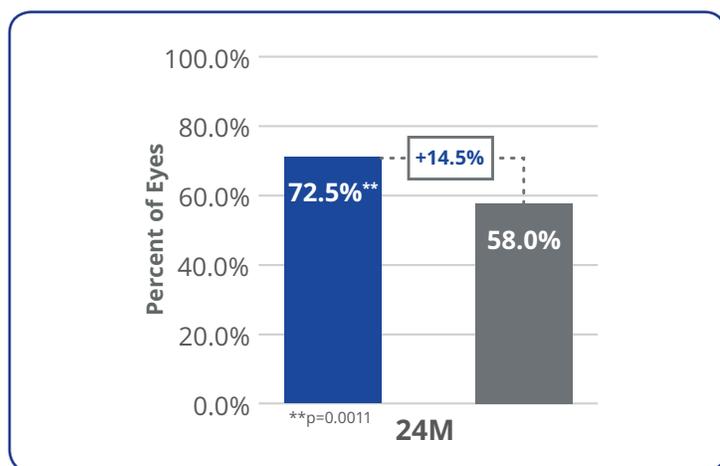
In summary, the CyPass Micro-Stent, in conjunction with phacoemulsification, effectively demonstrated sustained unmedicated IOP lowering along with an excellent safety profile as

demonstrated in the COM-PASS trial. This is truly a special time for ophthalmologists to treat glaucoma in patients undergoing cataract surgery. Surgeons now have another MIGS option for their patients to control IOP at the time of cataract surgery with the high potential of reducing the glaucoma medication burden. ■

References

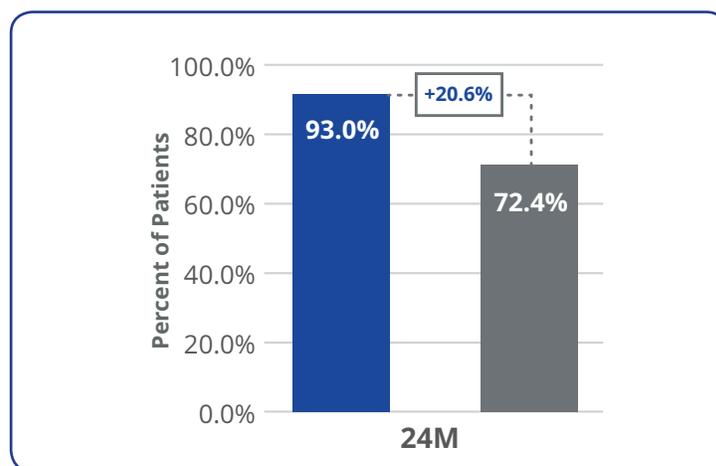
1. Vold S, Ahmed II, Craven ER, et al; CyPass Study Group. Two-year COMPASS trial results: Supraciliary microstenting with phacoemulsification in patients with open-angle glaucoma and cataracts. *Ophthalmology*. 2016;123(10):2103-2112.
2. Hoeh H, Vold SD, Ahmed IK, et al. Initial clinical experience with the CyPass Micro-Stent: Safety and surgical outcomes of a novel supraciliary microstent. *J Glaucoma*. 2016;25(1):106-112.

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■ CyPass® Micro-Stent + Cataract surgery (n=374) ■ Cataract surgery (n=131)

Fig. 1: Percentage of eyes achieving ≥20% reduction in unmedicated IOP at 24 months



■ CyPass® Micro-Stent + Cataract surgery (n=374) ■ Cataract surgery (n=131)

Fig. 2: Percentage of responders[†] that were medication-free at 24 months

[†]Those patients who attained an unmedicated mean diurnal IOP reduction of 20% or more as compared with baseline in the absence of IOP-affecting surgery during the study

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.