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A LONG-TERM LOOK AT THE HORIZON 5-YEAR MIGS PIVOTAL STUDY

The Hydrus Microstent: clinically proven long-term safety and efficacy for patients.

BY CATHLEEN MCCABE, MD, ABMS, MOC

The Hydrus Microstent (Ivantis) was the first MIGS device I used in a surgical setting. I was fortunate to have been introduced to the Hydrus Microstent in 2014 as an investigator in the HORIZON Trial, so my experience pre-dates most other surgeons. I was immediately impressed with the ability to confirm proper placement by visualizing the Hydrus Microstent in Schlemm's canal through the trabecular meshwork (TM). As I started trying other MIGS devices, I gained a greater appreciation for the Hydrus Microstent design and how it stands out.

HORIZON STUDY TRIAL DATA

MIGS with cataract surgery for glaucoma patients has experienced a rapid surge of adoption over a relatively short period, and the HORIZON Study's 5-year results mark a significant milestone. With 556 patients, HORIZON is the largest prospective, randomized, controlled trial in MIGS. The trial achieved a remarkable 80% patient follow-up at the 5-year mark, which provides a complete picture of long-term safety and effectiveness for the Hydrus Microstent. Furthermore, at the end of last year, the Academy published the 2020 update to the Preferred Practice Pattern for Primary Open-Angle Glaucoma, and the Hydrus Microstent received a strong treatment recommendation based on the body of published clinical data. The Academy only makes treatment recommendations based on credible published evidence, usually from randomized clinical trials. The AAO's grades for the Hydrus Microstent's level of evidence and evidentiary quality in this year's PPP were higher than any other MIGS device.

So, what do these data demonstrate? From my perspective, two main takeaways make it compelling for me to confidently and reliably offer this surgical intervention to my patients. As a refractive cataract surgeon, I see many patients who also struggle with mild-to-moderate glaucoma. These patients typically take one or two glaucoma medications, experience varying intraocular pressure (IOP) levels, and are at risk of more invasive surgical interventions later in life. Of vital importance for physicians is identifying measures to achieve both quality of vision and quality of life. Many of today's glaucoma medications add toxicity to the ocular surface.[1] To make a meaningful impact on the surgical outcomes for these patients, physicians must address the negative impact on quality of the ocular surface and quality of life that topical medications cause in patients with mild-to-moderate glaucoma, as well as how to improve the ability for these patients to remain drop-free.

The 5-year data demonstrate a medication-free rate of 73% for cataract patients who were taking 1 drop at the time of cataract surgery (Figure 1), which is the most common patient we typically see. For the entire patient cohort, data show that 66% of the Hydrus Microstent patients remained medication-free. This indicates a 20 to 30% benefit over cataract surgery alone through five years. Additionally, medication-free patients who received the Hydrus Microstent were approximately 2 IOP points lower compared to baseline versus medication-free patients who had cataract surgery only.

These data are important because, as a surgeon, I'm trying to think of the quality-of-life impact over the patient's lifetime. This is the more significant focus. Our job is to protect patients, predict what might happen to them in the future, and assess what we can do today to reduce any risk to their quality of vision and quality of life.

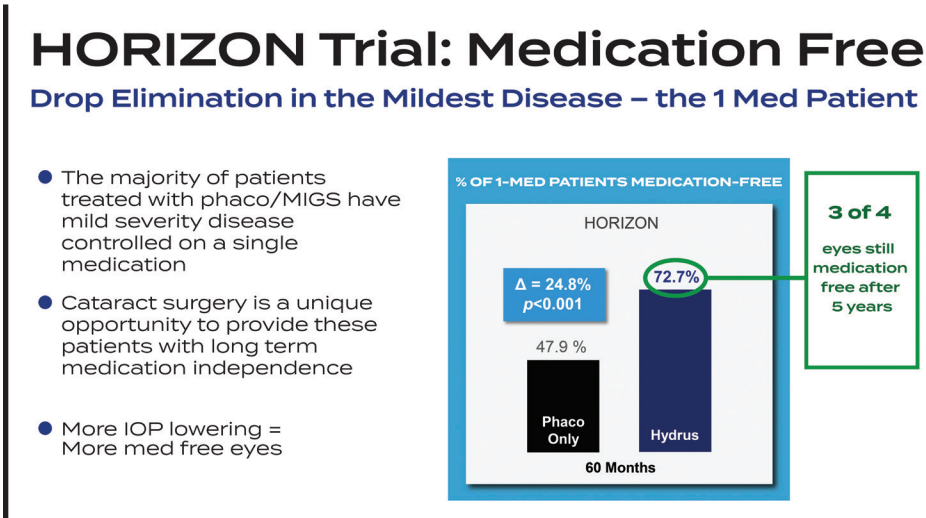

Figure 1. Data from the HORIZON 5-Year Pivotal Trial.

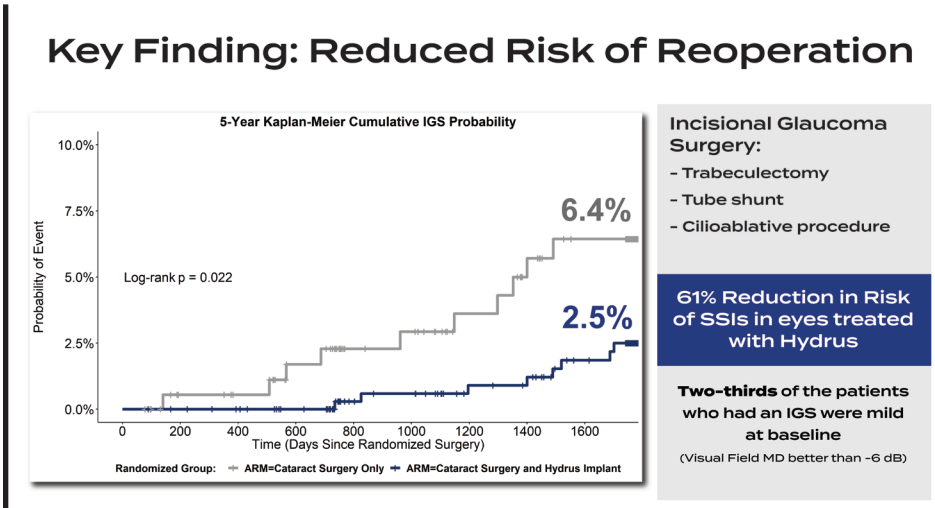

Figure 2. Data from the HORIZON 5-Year Pivotal Trial.

REDUCING THE NEED FOR FUTURE INVASIVE SURGICAL PROCEDURES

The second exciting takeaway from the HORIZON Study is the reduction in the need for further surgery. Invasive glaucoma procedures, such as trabeculectomy and tube shunt surgeries, are essential for late-stage patients who need more profound IOP-lowering intervention. We want to do everything possible to prevent the need for these procedures, as they may induce immediate and long-term complications.[2] Most of the patients treated in the HORIZON study had mild glaucoma when they were enrolled. Yet over 5 years of follow-up, a surprising number progressed to a point where incisional glaucoma surgery was required. The HORIZON Study shows that eyes treated with the Hydrus Microstent are less likely to require invasive incisional glaucoma surgery compared to control by more than 2:1 (Figure 2). This highlights a tangible benefit for early-stage patients. Early intervention with a clinically proven device like the Hydrus Microstent can have lasting effects.

The HORIZON Study data demonstrate that physicians can intervene at the time of a patient's cataract surgery to address their glaucoma with very little associated risk and a very high likelihood of keeping the patient medication-free for at least 5 years, while significantly decreasing their chance of secondary incisional surgery. To me, this is incredibly compelling to share with patients. It provides me with the confidence to inform patients that performing the Hydrus Microstent procedure at the time of cataract surgery is an important strategy for their long-term outcomes. This is the first MIGS device to show these benefits versus cataract surgery alone.[3] Furthermore, the rate of persistent inflammation was lower in Hydrus Microstent patients, and there was no clinically meaningful difference in mean endothelial cell loss through 5 years.

HYDRUS MICROSTENT: AN IMPORTANT EARLY INTERVENTION STRATEGY

Glaucoma is indeed a progressive disease, and early intervention is the best course of action when possible.[4] As a cataract surgeon, I am evaluating my patients at one point in time and do not know how their glaucoma will progress. Glaucoma progression is not always linear and can be difficult to predict. For patients presenting with mild open-angle glaucoma, how do you balance safety and efficacy in your decision to treat these patients?

Patients who have mild glaucoma today may not stay that way going forward. The HORIZON Study data demonstrated this in the number of patients in the control arm who required invasive glaucoma procedures as early as 3 years postoperative compared to the Hydrus Microstent treatment group. It's for this reason that early intervention with MIGS is beneficial. Having a solution that shows long-term safety and efficacy should give physicians the confidence to treat patients early.

When considering early glaucoma intervention at the time of cataract surgery, our priorities should be to minimize complications, avoid side effects, and to not complicate the postoperative course. This is extremely important from the patient perspective, as they want to feel as comfortable with the glaucoma intervention as they are with the cataract surgery.

CONCLUSION

As a physician, we want to minimize risks for patients, and we always seek treatment strategies that have a reasonable expectation of a positive benefit. This is why the HORIZON Study's 5-year data are extremely important. The data showed that employing the Hydrus Microstent during cataract surgery for mild-to-moderate glaucoma patients resulted in a high percentage of medication-free outcomes and very low progression to more invasive surgeries, as well as beneficial safety findings to overall vision and quality of life. This strongly emphasizes the important impacts we make today in the lifelong management of glaucoma. ■

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CATHLEEN MCCABE, MD, ABMS, MOC
- Chief Medical Officer, Eye Health America, Roswell, Georgia
- Medical Director, The Eye Associates, Bradenton, Florida
- Editorial advisor, *CRST*
- cmccabe13@hotmail.com
- Financial disclosure: Ivantis