

# Standalone MIGS: What Are You Waiting For?



The OMNI® Surgical System enables surgeons to perform a comprehensive, implant-free procedure that can be used to treat mild to moderate glaucoma.

**CHRISTINE FUNKE, MD; DOUGLAS MCGRAW, DO; AND JAI G. PAREKH, MD, MBA**

In a recent presentation, three glaucoma experts discussed why they implemented the OMNI® Surgical System (Sight Sciences) as a standalone procedure in their practices.

**Jai G. Parekh, MD, MBA:** Since the OMNI Surgical System came on the market in 2018, it has had a huge impact on the interventional treatment of glaucoma in our practices. This technology comprehensively addresses all three points of resistance in the conventional outflow pathway, which is what we aim for when treating glaucoma. The canaloplasty expands and dilates Schlemm's canal and the collector channels, and the trabeculotomy unroofs Schlemm's canal (Figure 1). I appreciate having the capability to do a comprehensive procedure with one technology. What do my colleagues think?

**Christine Funke, MD:** I completely agree. When we look at the anatomical structures of the eye that are implicated in glaucoma, the trabecular meshwork (TM) is one of the main points of resistance. As glaucoma progresses, the Schlemm's

canal herniates and becomes smaller in diameter. The OMNI technology allows us to open those structures back up.

**Douglas McGraw, DO:** Absolutely. Unfortunately, when we see a glaucoma patient, we don't know the point of failure in the drainage system. This technology gives us a way to target all three components of that system.

**Dr. Parekh:** The OMNI Surgical System gives us flexibility. Not all our patients who have glaucoma also have cataracts, and not all our patients who have cataracts have glaucoma. We can tailor our intervention to the patient's needs. The technology can be used in a standalone procedure, or in combination with cataract surgery. What do you think about its flexibility?

**Dr. Funke:** As we are becoming more interventionalists with glaucoma, we are trying to treat this disease earlier in its process. Minimally Invasive Glaucoma Surgery (MIGS) is an exciting option that we glaucoma specialists didn't have before. It is a way to treat our patients early in the disease progression.

**Dr. McGraw:** OMNI gives us a treatment option for the full spectrum of disease severity. We can treat patients who either had earlier intervention at the time of cataract surgery, who are pseudophakic, or maybe those who are hoping to delay incisional surgery. Intervening early in the disease process allows us to preserve the tissue and function.

**Dr. Parekh:** Great points. The OMNI Surgical System is the only MIGS technology that

is indicated for canaloplasty followed by trabeculotomy and can be used in mild to moderate glaucoma cases. It gives us 360° access to the diseased conventional outflow pathway, and the procedure can be calibrated to the individual eye. Standalone glaucoma patients are a large and underserved population. These individuals can be 15 or 20 years away from developing a cataract, or they can be 10 to 20 years past cataract surgery. A standalone procedure with the OMNI technology is going to lower the IOP for our patients regardless of the condition of the lens in the eye.

**Dr. Funke:** A standalone procedure with the OMNI technology is a great option, for example, in patients who underwent cataract surgery and maybe a minimally invasive procedure, but whose IOP is still not under control.

**Dr. McGraw:** I agree. A standalone procedure is also a great solution for patients who do not tolerate their medications well. Maybe they have ocular surface disease. A procedure with the OMNI technology might allow us to bypass some of those drops or lower the medication burden.

**Dr. Funke:** We know that compliance with topical drops can be an issue for patients. We are starting to see more and more data on patients who have received surgical intervention compared to ongoing medication, and we're finding that those who undergo MIGS fare better. I think that we need to start changing the paradigm in how we care for our patients and consider a surgical solution so that we don't have to rely only on the medications.



Figure 1. The OMNI technology effectively opens Schlemm's canal and collector channels by advancing the cannula (in blue), which allows for great visibility.

**Dr. Parekh:** Like any paradigm shift, it has to be underwritten by good science.

**Dr. Funke:** The ROMEO study investigated the outcomes of pseudophakic eyes 12 months after a standalone procedure with the OMNI Surgical System. Patients' IOP was reduced from 21.8 mmHg at medicated baseline to 15.6 mmHg 12 months later, which is a 28% reduction. In addition, 38% of these patients continued to be medication-free.<sup>1</sup>

**Dr. Parekh:** Yes. Polypharmacy mitigation is something we all strive for within the interventional mindset.

**Dr. McGraw:** In the real world, if patients don't take their prescribed drops, the medications are not going to work. The data suggest that nearly 50% of glaucoma patients stop taking their medication after 6 months.<sup>2</sup> Lack of medication adherence is significantly associated with visual field loss,<sup>3</sup> which means that these medications work well as long as patients take them consistently. However, if patients miss their medications, they experience a substantial increase in visual field loss.<sup>3</sup>

### CASE REPORT 1

**Dr. Funke:** An 83-year-old female patient presented with a history of mild primary open-angle glaucoma in both eyes. She had an intolerance to glaucoma medications like Lumigan (bimatoprost; AbbVie), Rocklatan (netarsudil and latanoprost; Alcon), Dorzolamide, or Brimonidine, and a history of bradycardia. Her Tmax was 38 OD and 24 OS — a significant amount of pressure, even with fields and OCT that were not overly advanced. This patient was already pseudophakic, which limited the treatment options. I could have done a tube or trabeculectomy, which would have been fairly invasive for an otherwise healthy

eye. So, we decided to do a standalone procedure with the OMNI technology. One year after surgery, the patient is medication-free and her IOP is stable at 14 mmHg OD and 13 mmHg OS.

### CASE REPORT 2

**Dr. McGraw:** A 73-year-old white female presented with uncontrolled IOP. She had an allergy to Rhopressa® (Netarsudil Mesylate, Alcon) and multiple medication intolerances. Her IOP in both eyes was in the 20s with a Tmax of 28. The patient was pseudophakic, and the OCT imaging indicated moderate disease progression. After performing a standalone procedure with the OMNI Surgical System, her IOP was reduced to 9-11 mmHg. In addition, the patient reported less discomfort OS and is medication-free.

### CASE REPORT 3

**Dr. Parekh:** A 49-year-old female of Asian descent presented with a 19-year history of primary open-angle glaucoma. She had a strong family history of hypertension, diabetes, hypothyroid, peripheral neuropathy, and tingling fingers, the latter of which presented a challenge to her drop application. Her IOP ranged between 17 and 21 mmHg with a Tmax of 28. Her OCT showed some changes to the nerve fiber layer. A standalone procedure with OMNI achieved an IOP in the lower teens and curtailed some of the polypharmacy. Postoperatively, this patient remained 20/20, and she referred three family members to our practice for eye care.

### STANDALONE OMNI CANDIDATES

**Dr. Parekh:** The OMNI Surgical System can be used as a standalone procedure in pseudophakic patients or in combination with cataract surgery in phakic eyes. Patients with ocular surface disease who are on a polypharmacy regimen and have low compliance are great candidates as well. These individuals can benefit from this low-cost, minimally invasive

procedure to lower IOP and delay incisional glaucoma surgery.

**Dr. Funke:** I have noticed as I've started to do more and more of these cases, especially standalone procedures, that word gets out to the community, not only through patients' word-of-mouth, but also through referrals. This helps reach a broader patient population (e.g., standalone cases), which also makes a huge difference in the lives of these patients.

**Dr. McGraw:** I agree, and as someone who is performing comprehensive surgery, MIGS with the OMNI technology has been a huge practice builder. My staff and I are seeing more and more time scheduled for this type of procedure as word-of-mouth travels through the community. ■

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2. Nordstrom BL, Friedman DS, Mozaffari E, et al. Persistence and adherence with topical glaucoma therapy. *Am J Ophthalmol*. 2005;140(4):598 e1-598 e11.
3. Newman-Casey PA, Niziol LM, Gillespie BW, et al. The association between medication adherence and visual field progression in the collaborative initial glaucoma treatment study (CIGTS). *Ophthalmology*. 2020;127(4):477.

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#### IMPORTANT PRODUCT INFORMATION

**Indications for Use:** The OMNI Surgical System is indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculectomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma. Contraindications: Do not use the OMNI in any situations where the iridocorneal angle is compromised or

has been damaged (e.g., from trauma or surgery), since it may not be possible to visualize the angle or to properly pass the microcatheter. Do not use the OMNI in patients with angle recession; neovascular glaucoma; chronic angle closure; narrow-angle glaucoma; traumatic or malignant glaucoma; or narrow inlet canals with plateau iris. Do not use the OMNI Surgical System in quadrants with previous MIGS implants.

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