

The Right Patients, The Right Device: A MIGS Case Study

Transluminal viscoelastic delivery with titratable trabeculotomy for a wider patient pool.

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Microinvasive glaucoma surgery (MIGS) has revolutionized the way we treat glaucoma patients, becoming the preferred

approach to glaucoma management for patients with mild-to-moderate glaucoma, especially those undergoing concurrent cataract surgery.

Prior to MIGS, we conducted very few glaucoma surgeries—a handful every year—which were mostly trabeculectomy, tube shunts, or we used the EX-PRESS Glaucoma Filtration Device (Alcon).

MIGS opened a new pathway to properly treat thousands of patients that we previously could not help. Current MIGS implants are one approach. However, in the absence of diagnostics, targeting all three points of resistance in the conventional outflow pathway is an approach that has become very appealing to me.

Many believe that targeting the normal outflow track including the trabecular meshwork (TM), Schlemm's canal, and the distal collector channels can provide the benefit of directing fluid to where it is supposed to naturally flow.

THE RIGHT PROCEDURES, NEW OPPORTUNITIES

Transluminal viscoelastic delivery and a trabeculotomy are two procedures that allow me to target all three points of resistance in the conventional outflow pathway and treat a broad range of patients, offering, what I believe, are several benefits compared with the use of implants. I can perform these procedures on patients at the time of their cataract surgery as well with the growing pool of pseudophakic patients whose pressures are difficult to control but who do not meet the immediate need of an

advanced glaucoma procedure. Another demonstrated advantage for me is not leaving any hardware behind, and therefore never having to worry about the possibility of an implant-related complication down the road. Lastly, conducting transluminal viscoelastic delivery and performing a partial trabeculotomy preserves the ability for me to conduct other procedures later and leaves me in a stronger position to treat patients in the future if further surgery is necessary.

DISCOVERING NEW CAPABILITIES

What initially interested me in the OMNI Surgical System (Sight Sciences) was the ability to conduct transluminal viscoelastic delivery and trabeculotomy with one device (Figure 1).**A transluminal catheter is utilized to go into the TM to access Schlemm's canal. Because Schlemm's canal is essentially a fixed space, I advance the catheter 180° through the canal, and as I am retracting the catheter, a precise amount of viscoelastic is deposited.

I am also able to perform a trabeculotomy to give direct access to Schlemm's canal by unroofing the TM. In doing both procedures, I am targeting all three potential points of resistance in the conventional outflow pathway. The ability to perform these two procedures with one device is an exciting new function, and I am currently discovering its full capabilities in a practice setting.

LEARNING CURVE

The OMNI Surgical System allows me to perform microinvasive surgery efficiently. With noted experience in gonioscopy and angle-based MIGS,

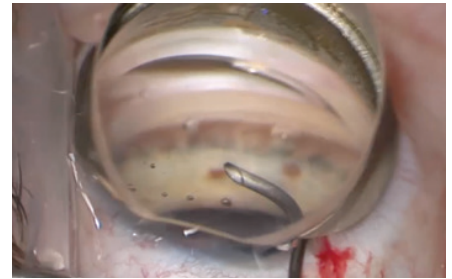


Figure 1. The OMNI surgical system inside the anterior chamber.

I found transitioning to the OMNI Surgical System a very natural process. My advice for successful use of the OMNI Surgical System is to go slow and steady. After I practiced the surgical positions and became comfortable with the device in my hands, use of the device was fairly seamless.

GRATIFYING OUTCOMES

I have used the OMNI device to perform transluminal viscoelastic delivery and trabeculotomy in more than 20 patients to date with the longest patient out 10 months postoperative. I have used it since the inception of the device.

It is important to keep in mind that every case is different, and patient selection depends largely on several qualifying factors. In my experience, patients with highly pigmented TM who are very compliant and not in need of aggressive amounts of IV sedation have been a great starting point. In the beginning, I selected patients in the mild to moderate range because I found it can be challenging to complete a full goniotomy or transluminal viscoelastic delivery until I was completely comfortable with the placement of the device and movement of my hands.

I have not experienced any significant adverse effects from a postoperative

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management perspective. I have experienced minimal blood reflux, which is common with all MIGS devices, and I consider it a side effect, not a complication. Postoperative blood reflux is normal into the anterior chamber, and we have experienced slight inflammation resulting from the goniotomy, which may require a few more inflammatory eye drops issued for postoperative care. Longer term follow-up will be necessary as glaucoma is a chronic disease.

A CASE STUDY

The following patient is an example of a typical case in my practice.

An 86-year-old man presented with moderate glaucoma, VA of 20/70 in each eye, and an IOP measuring 17 mm Hg and 16 mm Hg. This patient tried multiple drops but stopped all of them with complaints of burning and stinging. The patient tried Lumigan (Allergan) at night but continued to struggle. Furthermore, mild cataracts were observed in each eye, and his optic nerves measured 0.65 to 0.7 mm. When the patient stopped Lumigan his pressures increased to 19 mm Hg in each eye.

Fearing his pressures were worse, we conducted visual field tests and found scattered defects and a superior nasal step in his right eye and inferior arcuate defects in his left eye. Additionally, his

optic nerve OCT showed thinning of the retinal nerve fiber layer in each eye and a severely damaged temporal retinal nerve fiber in the left eye (Figure 2).

Because of his intolerance to eye drops and a projected BCVA outcome of 20/70, the decision was made to conduct cataract surgery, along with transluminal viscoelastic delivery and trabeculotomy with the OMNI Surgical System in the left eye. Our ultimate goal was to lower his IOP without the need for drops.

The patient's day 1 postoperative exam showed an IOP of 8 mm Hg; we placed him on a steroid to reduce some corneal edema and small blood reflux in the anterior chamber. By week 3, the patient was off all eye drops with pressures of 15 and 14 mm Hg. His 4-month postoperative examination showed pressures of 14 mm Hg in each eye and VA of 20/40 uncorrected in the left eye. By 9 months, the patient had stabilized pressures of 15 mm Hg and was off all drops.

CONCLUSION

In summary, the OMNI Surgical System has provided me with new opportunities—discovering the capability to target all three points of resistance in the conventional outflow pathway, achieving satisfying outcomes in a broad range of patients, and

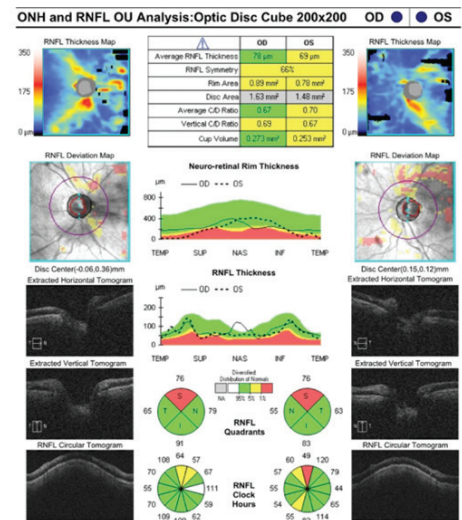


Figure 2. Patient case study OCT analysis.

addressing reimbursement challenges with established CPT codes. The OMNI Surgical System offers a new approach to MIGS and represents the beginning of a very exciting technology. ■

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Indications for use

The OMNI™ Surgical System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example Healon® or HealonGV® from Abbott Medical Optics (AMO), Amvisc® from Bausch & Lomb, or PROVISC® from Alcon, during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures.

Warning

The OMNI™ System should not be used in cases where there is insufficient visualization of the anterior chamber. The following conditions may prohibit sufficient visualization required for safe and successful cannula and microcather placement: corneal edema, corneal haze, corneal opacity, or any other conditions that may inhibit surgeon view.

**Disclaimer

The views of Dr. Michael Patterson are his own and represent his view in the practice of medicine. This case study may not be

representative of the results other surgeons may observe with other patients when using the OMNI™ Surgical System. The OMNI™ Surgical System is cleared (indicated) by FDA for the uses set forth above. While the OMNI system is not specifically cleared for transluminal canal dilation, there is support for its use (and the use of one of its parent devices, the VISCO360) in transluminal canal dilation in the literature and medical textbooks. In addition, an interno trabeculotomy, for which it is FDA-cleared, is referred to as a MIGS procedure in the literature, medical textbooks, and dictionaries. Please visit omnisurgical.com to access published literature about these uses.

For additional Important Safety Information, please visit omnisurgical.com

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