

The Changing MIGS Landscape

The OMNI Surgical System offers an innovative new approach.

BY IQBAL IKE K. AHMED, MD, FRCSC



We asked Iqbal Ike K. Ahmed, MD, FRCSC,** who coined the term minimally invasive glaucoma surgery (MIGS), to discuss how the OMNI Surgical System (Sight Sciences, Inc.) fits into the current landscape (Figure 1).



Figure 1. The OMNI Surgical System.

Cataract & Refractive Surgery Today (CRST): How has the emergence of MIGS implants and procedures changed glaucoma practice?

They have completely changed the way we approach glaucoma. We have gone from a reactive, passive approach for treating glaucoma to a proactive, dynamic approach, taking every opportunity to address compliance and medication side effects with these safe interventions.

CRST: Most MIGS target the conventional outflow pathway. What are the benefits? Do you prefer to start there and, if so, why?

I do not have a dogmatic answer as far as always targeting the conventional outflow pathway first. Certainly, it is high on my list. While all MIGS procedures have an element of safety, the conventional outflow system is the safest place to facilitate outflow. Using an *ab interno* approach avoids a bleb, which is an advantage for patients over the long term. Entering the canal, there is virtually no risk of hypotony and minimal risk of anatomical shallowing of the eye. Significant bleeding is not common.

The less severe the disease, the less willing I am to take risks. Therefore, to treat eyes in the earlier stages of glaucoma and those that do not need a very low pressure, the conventional outflow system is my first choice and would be a good starting point for managing patients with mild to moderate glaucoma.

CRST: Why do you choose to perform *ab interno* transluminal viscoelastic delivery and a trabeculotomy?

The idea is basically to flush and expand the conventional outflow system. Essentially, I believe we are rejuvenating the outflow system using viscoelastic to gently stretch the inner wall, so to speak, and enhance filtration through unroofing the trabecular meshwork to try to relieve any obstruction that may be present. I like to perform these two procedures to work at multiple levels in the conventional pathway, targeting all three potential points of resistance (trabecular meshwork, Schlemm's Canal, and distal collector channels). I routinely use the OMNI Surgical System to perform these two procedures. One of the features I like best is the ability to titrate toward a predetermined surgical plan. For example, depending on the severity of the disease, I may perform a full 360° of transluminal viscoelastic delivery and a 180° trabeculotomy. While canal procedures, like transluminal viscoelastic delivery and trabeculotomy, are not without risk, they are generally safe. Transient postoperative hyphema can occur but typically dissipates with observation.

CRST: What is your experience with performing these procedures? How would you characterize the learning curve for these procedures?

As experienced MIGS surgeons, our group found adopting transluminal

viscoelastic delivery and a trabeculotomy quite simple to do. For any surgeon who has performed MIGS, the transition is straightforward.

The learning curve is not so much for the device as it is for the surgical approach, which involves setting up the patient, making the incision, and learning how to hold the gonioprism for a good view of the angle. For surgeons who are not experienced with MIGS, that is where the biggest learning curve is, and that is independent of the device itself. For someone who has never performed angle procedures, it may take 10, 15, or 20 cases to become comfortable with the view.

Once you master visualization, then performing transluminal viscoelastic delivery and/or a trabeculotomy with the OMNI Surgical System is a short learning curve. The mechanism of this device is unique, as it enables single-handed delivery of a flexible microfilament, which can be used to inject viscoelastic or to incise the inner wall (Figure 2). There are nuances involved with holding the device, learning what incision is best for placing it, learning how to actuate it, and how to roll the filament forward; however, this should take only a few cases.

CRST: In your hands, what outcomes are you typically seeing when performing transluminal viscoelastic delivery and a trabeculotomy with the OMNI Surgical System?

On the first postoperative day, my patient's pressures are usually lower. VA

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returns quickly, and bleeding is minimal. Typically, I instruct the patient to stop antiglaucoma medications immediately after surgery.

From week 1 to week 4, I expect a smooth recovery. Some patients may start showing a steroid response and, therefore, I think patients should be using less steroids compared to conventional glaucoma surgery. I taper the steroids within the first 4 weeks. After the second month, I reassess the pressures and decide whether I need to add back any antiglaucoma medications. This decision varies, depending on a patient's preoperative pressures and medication use.

CRST: What results are you seeing in your patients?

I have only about 1 year's worth of follow-up, but during that time, I have seen generally good persistence. As with any glaucoma procedures, there will always be patients who will need to use antiglaucoma medications at some point and over the long term to help stop disease progression. In my experience, I find the majority of patients stay reasonably controlled after these procedures, thus delaying the progression of the disease.

CRST: Are you currently performing these procedures in combination with cataract surgery or as a standalone procedure? Why?

I have performed these procedures in both cases. When cataract is a patient's primary indication for surgery, being able to do something for the coexisting glaucoma at the same time via the conventional outflow system is an advantage.

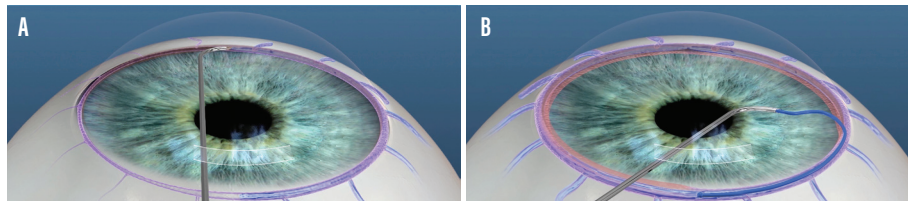


Figure 2. The OMNI Surgical System enables the single-handed delivery of a microfilament, which can be used to inject viscoelastic and to perform a titratable trabeculotomy.

I am already working in the eye, and the additional risk of performing transluminal viscoelastic delivery and a trabeculotomy versus the cataract procedure alone is minimal. In my opinion, the two meld together well. Most MIGS available today are only approved to be used in conjunction with cataract surgery. Having a device that allows me to perform these procedures in standalone cases too gives me an option for these patients, especially with an increasing number of pseudophakic patients on one or more IOP-lowering drops.

The expectation from a standalone procedure is that pressure lowering will be sufficient to warrant going into surgery. Therefore, I find that patients who have mild to moderate disease and are using a few antiglaucoma medications may be good candidates for the standalone procedure with transluminal viscoelastic delivery and a trabeculotomy, particularly if they already have had cataract surgery. Performing these procedures with the OMNI Surgical System is a great opportunity to help these patients.

Conclusion

Many different MIGS options are available, even for the conventional outflow system, and they all have their own unique features, whether it is their risk profile, their pressure-lowering

ability, their technical ease of use, or whether they employ an implantable or a non-implantable device.

The OMNI Surgical System is a sophisticated delivery system. I appreciate the fact that the two implant-free procedures it performs—transluminal viscoelastic delivery and a titratable trabeculotomy—can target all three potential points of resistance in the conventional outflow pathway, especially since we do not know the cause of the resistance.

I am looking forward to seeing longer-term data and more comparative data, but preliminarily, I have had good experiences with the OMNI Surgical System, and my results are very promising. The device allows me to perform these procedures well. I have found the risk to be low, my patients have done well, and it provides me an option for my pseudophakic patients. ■

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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 microcatheter placement: corneal edema, corneal haze, corneal opacity, or any other conditions that may inhibit surgeon view.

For additional Important Safety Information, please visit omnisurgical.com

**Disclaimer

The views of Dr. Iqbal Ike K. Ahmed 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, ab 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.

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