

# Targeting the Conventional Outflow Pathway

A glaucoma specialist discusses expanding his scope with implant-free surgical procedures.



*Cataract & Refractive Surgery Today* asked glaucoma specialist and surgeon Nathan M. Radcliffe, MD, to discuss the current landscape in microinvasive glaucoma surgery (MIGS) and his thoughts on the importance of addressing all three points of resistance in the conventional outflow pathway. We also asked Dr. Radcliffe about the latest advancement by Sight Sciences: the OMNI Surgical System, a dually indicated device intelligently designed to make procedures, such as transluminal viscoelastic delivery and trabeculotomy, which were formerly very challenging procedures, accessible for not just glaucoma specialists but cataract surgeons, too.

## How has the emergence of MIGS implants and procedures changed your practice?

I do not perform cataract surgery on patients who have glaucoma without offering something additional for their glaucoma. That was not necessarily the case 5 years ago. The cataract opportunity becomes part of a patient's glaucoma management plan basically from the moment of diagnosis. Fortunately, we now have options for all patients, even those who do not have cataracts.

## What can you tell us about targeting the conventional outflow pathway? Do you prefer to start there and, if so, why?

From a conceptual standpoint, the conventional outflow system is attractive, because we want to restore the eye to its normal physiologic state, if possible. This target is also appealing from a practical standpoint because it is readily accessible using gonioscopic visualization in ab interno glaucoma surgery.

Glaucoma tends to worsen and become more difficult to control over time, which seems to imply a feedback mechanism whereby the pressure shuts down the outflow system. Imagine someone who has had glaucoma for 40 years. The canal probably is not functioning well because little, if any, fluid has been flowing through it for years. The episcleral veins may have atrophied. The meshwork may not allow fluid through, and the distal collector channel system may not be functioning. Targeting the conventional outflow system early may increase the potential of improving all these functions, which may help keep the tissue healthy and functioning longer.

## What does the new OMNI Surgical System enable you to do?

OMNI allows you to target the conventional outflow pathway including the three points of resistance: the trabecular meshwork (TM), Schlemm canal, and the collector channels through two procedures, transluminal viscoelastic delivery and a titratable trabeculotomy. Specifically, by first performing transluminal

viscoelastic delivery, I am looking to break any septae, relieve areas where the TM has herniated into the collector channels and relieve any areas of microstenosis. However, you still may have resistance at the level of the TM. Utilizing OMNI to perform a titratable trabeculotomy following transluminal viscoelastic delivery can provide the canal access to more aqueous humor.

## What are the unique benefits of transluminal viscoelastic delivery and then performing a titratable trabeculotomy?

My first point—which is particularly important for ab interno glaucoma surgery—has to do with safety. As much as we want to lower the pressure, we are very much into the “do no harm” mindset, and while canal procedures like transluminal viscoelastic delivery are not without risk, they are generally safe.

Transluminal viscoelastic delivery and trabeculotomy are compatible with standard cataract surgery, and in my experience the postoperative care is no different than for standard cataract surgery. My patients do not require additional steroids postoperatively. I have noticed the amount of pressure lowering can be significant, and in my practice, I have not observed very low pressures or complications related to sudden changes in pressure.

Now the OMNI Surgical System offers an efficient way to perform transluminal viscoelastic delivery and a titratable trabeculotomy. It allows a controlled delivery of viscoelastic fluid and enables the surgeon to perform a titratable trabeculotomy customized to meet the surgical plan, which enables the surgeon to access all three potential points of resistance. The surgery may be efficiently combined with cataract extraction or can be done as a standalone procedure.

## Prior to the availability of the OMNI Surgical System, how did you perform these two procedures, and how would you characterize the learning curve for them?

I have performed more than 100 procedures utilizing VISCO360 (Sight Sciences) to conduct transluminal viscoelastic delivery. This is a procedure that takes advantage of a surgeon's current ab interno glaucoma surgery skills, but it also requires the surgeon to expand them a bit.

Transluminal viscoelastic delivery is similar to placing a trabecular bypass stent, as the principles are the same. You need a good gonioscopic view of the angle in order to identify and target the TM. The procedure takes a little more time than placing a stent but is still efficient. The way I conduct this procedure is by performing a goniotomy first. This can be done with the tip of the cannula from the device or with a separate blade. Then, I access the canal of Schlemm. While holding the device just outside the canal, I advance the catheter tip into the canal for 180° (Figure 1).

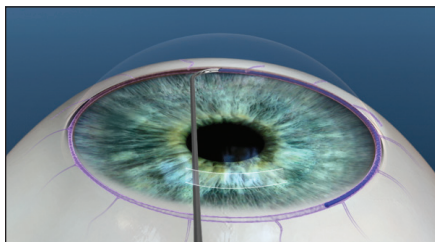


Figure 1. While holding the device just outside the canal, the catheter tip is advanced into the canal for 180°.

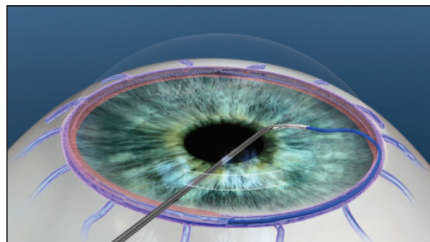


Figure 2. The catheter is reintroduced into the canal, and the TM is gently unroofed using the microcatheter.

As the catheter is withdrawn, a device inside of the hand piece delivers a metered, controlled amount of viscoelastic.

Before the OMNI device was available, I used both VISCO360 and TRAB360, depending on the patient scenario. With OMNI, the two procedures can be performed sequentially with a single instrument. The device was engineered to allow for this. Because the viscoelastic delivery mechanism in the handpiece is activated first, I first perform the transluminal viscoelastic delivery part of the procedure. After transluminal viscoelastic delivery is complete, the catheter is reintroduced into the canal to perform a trabeculotomy which can be titrated based on the surgeon's surgical plan (Figure 2). The instrument's engineering is designed to help you perform these procedures combined and in a titratable fashion.

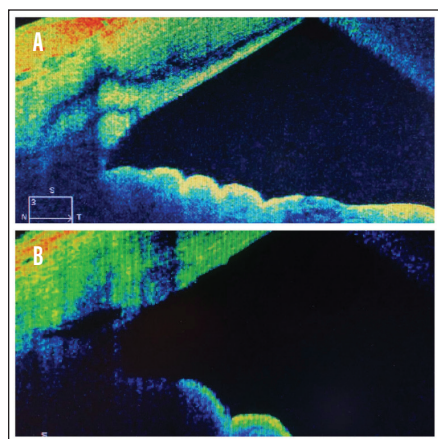


Figure 3. A baseline OCT (A) and an OCT showing visibly enlarged canals of Schlemm at 2 years (B).

### How long do you expect the effects of the procedure to last?

I am looking at consistently getting “base hits” with these procedures, and I have an interesting example of one patient where an anterior segment OCT shows visibly enlarged canals of Schlemm at 2 years (Figure 3).

### What interests you most about the OMNI Surgical System?

What appeals to me most about the OMNI Surgical System is the opportunity to use it as a standalone procedure and also in combination with other surgeries. For example, if a patient needs an IOL exchange, is using antiglaucoma drops, and has borderline pressure, I may take the opportunity to do what I can for the conventional outflow system while inside the eye. Also, OMNI is also a good standalone option for patients who

have excellent VA and have not yet had cataract surgery or had it before the era of MIGS.

### What additional value does the OMNI Surgical System offer you as a surgeon?

The category 1 codes for both transluminal canal dilation and ab interno trabeculotomy means it has nearly universal coverage, and it is not coupled with cataract surgery. We can perform it as a standalone procedure, even in patients who had their cataracts removed years ago. This is important, because even for surgeons who are absolutely in love with the idea of implanting stents in the eye, this procedure may be suitable for many patients in their practices, including those covered by Medicaid and many commercial health maintenance organizations. We must have options available to serve all of our patients.

### What would you share with your peers about the OMNI Surgical System?

The OMNI Surgical System is an amazing option for us to have available to expand our scope to target the entire conventional outflow system with a robust and established reimbursement pathway making it accessible to a significant number of 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™ Surgical 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.

#### Disclaimer

The views of Dr. Radcliffe are his own and represent his view in the practice of medicine. 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 and ab interno trabeculotomy, for which it is FDA-cleared, is referred to as a MIGS procedure in the literature and 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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