

# WHY I CAME BACK TO iTRACK



An exploration of two competing technologies for *ab interno* canaloplasty.

BY DAN B. TRAN, MD

Performed concurrently with cataract surgery or as a standalone procedure, *ab interno* canaloplasty has been proven to lower IOP and reduce the medication burden for patients with primary open-angle glaucoma.<sup>1,2</sup> For physicians who take a step-wise approach to treatment as I do, it is important that glaucoma procedures which aim to intervene earlier in the disease process, such as *ab interno* canaloplasty, achieve their purpose without altering or damaging the structure of the eye, and thus do not preclude us from performing other glaucoma procedures in the future.

In my use of two different devices to perform *ab interno* canaloplasty—the iTrack canaloplasty microcatheter (Nova Eye Medical, Figure) and the OMNI Surgical System (Sight Sciences)—some clear differences have emerged in their IOP-lowering effect, leading iTrack to become my personal preferred choice.\*

## FROM iTRACK TO OMNI

When I began using iTrack for *ab interno* canaloplasty a few years ago, I was immediately pleased with both the procedure and its results. I used it to lower the pressures in the eye concurrent with cataract surgery, particularly in cases of moderate glaucoma where a stent

implant alone would not be adequate. I quickly felt comfortable performing this straightforward procedure. As an added benefit, the iTrack features an optical fiber equipped with an LED light that allows surgeons to see where we're going, so we have the comfort of knowing we're in the right place as we track that microcatheter 360° around the canal.

The results were excellent. The iTrack reduced pressure when paired with cataract surgery or paired with both cataract surgery and a stent device such as the iStent Trabecular Micro-Bypass Stent (Glaukos) or the Hydrus Microstent (Ivantis). Because this canal dilation procedure leaves the trabecular meshwork (TM) intact, other surgeries were possible in the future, if needed, which was particularly beneficial for patients having iTrack as a standalone procedure years before cataract surgery, which might 1 day include a stent placement.

When the OMNI system was introduced, I tried the procedure and

decided to switch because it takes about 5 to 10 minutes less than iTrack. The OMNI procedure is similar to stent implantation: use a gonioscope to view the anatomy, position the cannula at the TM, and advance the microcatheter. iTrack requires a few extra steps: create a goniotomy to open the TM, introduce the device, set up the iTrack, microcatheter, fiber optic cable, and guide wire in the right place, and sometimes make an additional incision.

Although the OMNI was a little faster to use, after performing a number of cases with it, I realized that my patients' pressures did not drop quite as much or quite as consistently as they did with iTrack. When I use a stent in cataract surgery, my patients usually have a 2 to 4 mm Hg reduction in pressure. With a stent and OMNI, the effect was about 50% greater. With a stent and iTrack, my patients doubled their pressure reduction.

## SWITCHING BACK TO iTRACK

I switched back to the iTrack canaloplasty microcatheter because I saw a trend where iTrack delivered a more consistent drop in pressure with or without a stent compared to the OMNI. My results are consistent with published data on the two procedures.\*\* Although different study designs make it difficult to compare this data head-to-head, the numbers seem to reflect a difference similar to my experience. For iTrack performed in conjunction with cataract surgery, Gallardo et al reported a mean IOP reduction of 33%, from baseline IOP of 19.4 (±3.7) mm Hg to 13.0 (±1.8) mm Hg at 12 months.<sup>1</sup> For OMNI performed in conjunction with cataract

**“I SWITCHED BACK TO THE iTRACK CANALOPLASTY MICROCATHETER BECAUSE I SAW A TREND WHERE iTRACK DELIVERED A MORE CONSISTENT DROP IN PRESSURE WITH OR WITHOUT A STENT COMPARED TO THE OMNI.”**

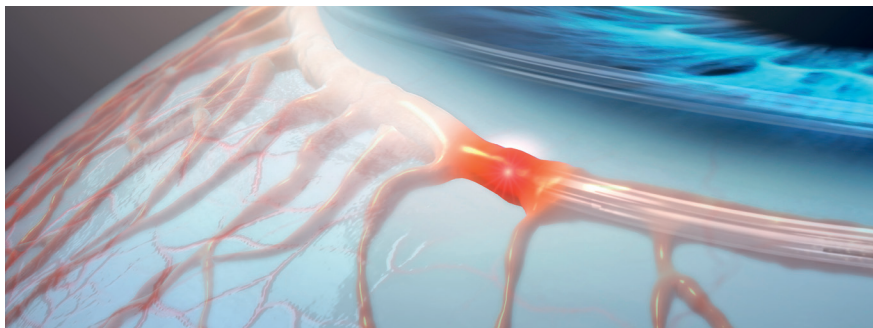


Figure. The iTrack canaloplasty microcatheter is designed to intubate and viscodilate the full 360° of the canal.

surgery, patients with baseline IOP  $\geq$  18 mm Hg saw a 22% reduction, while those with baseline IOP  $<$  18 mm Hg experienced no change.<sup>3</sup>

The reason for the disparity between the two devices may lie in the unique methods of viscoelastic dispensing for each device. The OMNI delivery system dispenses viscoelastic into the canal automatically as the catheter is retracted. With iTrack, the viscoelastic is pressurized. A technician delivers the viscoelastic by clicking the iTrack delivery device and counting, while the surgeon controls how much is injected to dilate the canal by speeding or slowing retraction of the iTrack microcatheter. The theoretical concept is that the iTrack delivers sufficient volume and pressure of OVD to dilate Schlemm's canal and the collector channels and improve outflow through the episcleral venous system. OVD delivered in lower volume or at lower pressure may pass through the patent collector channels without impacting on the areas of outflow resistance. I am currently taking part in the prospective, randomized, multi-center "MAGIC" study (NCT0469453) involving eight sur-

gery centers in the United States to assess the device-related impacts on the clinical outcomes of *ab interno* canaloplasty, directly comparing the iTrack canaloplasty microcatheter to the OMNI device. In addition to IOP reduction, medication reduction, and complications/side effects, the study will also assess whether the type of viscoelastic used and the ability to adjust the amount of viscoelastic delivered during the procedure impacts clinical outcomes.

### ITRACK IN MY PRACTICE

I've performed the procedure on patients with a range of pathologies and stages of open-angle glaucoma, but the patients for whom iTrack makes the biggest difference are those with mild glaucoma that is uncontrolled with medication or those with moderate glaucoma, with or without a need for cataract surgery. In cataract patients, iTrack helps decrease the need for drops after surgery, which is particularly important for patients with moderate glaucoma taking more than one drop. I have used iTrack for some patients with severe glaucoma, some of whom were saved from under-

going trabeculectomy by a combination of cataract, stent, and iTrack. Off-label, I have used iTrack for some cataract patients with angle-closure glaucoma who still have the TM open at certain areas to help lower their IOP. I usually deliver between 30 to 36 clicks of viscoelastic with the iTrack microcatheter. However, for cases of moderate or advanced glaucoma, I withdraw the iTrack a little more slowly to deliver a bit more viscoelastic into the canal.

### IN THE PIPELINE

Since I began using the iTrack device it has become easier to use. At the same time, pipeline changes to iTrack promise to reduce some steps of the procedure. I'm looking forward to continuing my use of the iTrack's pressurized viscoelastic delivery and its predictable IOP-lowering effects, possibly with a few minutes shaved off the procedure time in the not-so-distant future. ■

1. Gallardo MJ, Supnet RA, Ahmed IK. Viscodilation of Schlemm's canal for the reduction of IOP via an *ab-interno* approach. *Clinical Ophthalmology*. 2018;2018:2149-2155.
2. Gallardo MJ, Supnet RA, Ahmed IK. Circumferential viscodilation of schlemm's canal for open-angle glaucoma: *ab-interno* vs *ab-externo* canaloplasty with tensioning suture. *Clinical Ophthalmology*. 2018;12:2493-2498.
3. Tracer N, Dickerson JE, Radcliffe NM. Circumferential viscodilation *ab interno* combined with phacoemulsification for treatment of open-angle glaucoma: 12-month outcomes. *Clin Ophthalmol*. 2020;20;14:1357-1364.

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\*The views/opinions expressed in this article are personal to Dan B. Tran, MD.  
\*\* The data referenced is for the OMNI Surgical System predicate device (VISCO360, Sight Sciences).

### IMPORTANT SAFETY INFORMATION

iTrack™ has a CE Mark (Conformité Européenne) and US Food and Drug Administration (FDA) 510(k) # K080067 for the treatment of open-angle glaucoma.

**INDICATIONS:** The iTrack™ canaloplasty microcatheter has been cleared for the indication of fluid infusion and aspiration during surgery, and for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open-angle glaucoma.

**CONTRAINDICATIONS:** The iTrack™ canaloplasty microcatheter is not intended to be used for catheterization

and viscodilation of Schlemm's canal to reduce intraocular pressure in eyes of patients with the following conditions: neovascular glaucoma; angle closure glaucoma; and, previous surgery with resultant scarring of Schlemm's canal.

**ADVERSE EVENTS:** Possible adverse events with the use of the iTrack™ canaloplasty microcatheter include, but are not limited to: hyphema, elevated IOP, Descemet's membrane detachment, shallow or at anterior chamber, hypotony, trabecular meshwork rupture, choroidal effusion, Peripheral Anterior Synechiae (PAS) and iris prolapse.

**WARNINGS:** The iTrack™ canaloplasty microcatheter is intended for one time use only. DO NOT re-sterilize and/

or reuse, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

**PRECAUTIONS:** This iTrack™ canaloplasty microcatheter should be used only by physicians trained in ophthalmic surgery. Knowledge of surgical techniques, proper use of the surgical instruments, and post-operative patient management are considerations essential to a successful outcome.

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