Glaucoma: Address the Entire Conventional Outflow Pathway Without Damaging or Removing Tissue

Ab-interno canaloplasty with the iTrack microcatheter lowers IOP, reduces medication burden, and preserves tissue

BY MAHMOUD A. KHAIMI, MD

Minimally invasive glaucoma surgery (MIGS) has been a game-changer, filling the gap between topical therapy and invasive procedures that carry formidable risks. With MIGS, we can treat patients at an earlier stage of their disease, potentially reducing topical medication dependence and delaying the need for more aggressive surgeries. While early MIGS procedures focused on bypassing or removing diseased portions of the trabecular meshwork, we're now realizing the importance of addressing the entire conventional outflow pathway—the trabecular meshwork, Schlemm's canal, and the distal collector channels.

I was an early adopter of canaloplasty, which has seen a rapid evolution as it takes its place in the MIGS space. Today, it is my first go-to MIGS procedure.

Canaloplasty

iTrack ab-interno canaloplasty has been shown to increase aqueous outflow to deliver sustained reductions in IOP and medication burden.[1-3] It is approved as a standalone procedure or in combination with cataract surgery. Based on the same principles as angioplasty, iTrack combines 360° catheterization and pressurized viscodilation of Schlemm's canal to remove resistance in both the proximal and distal outflow system.

iTrack: A New Pathway

With iTrack, I'm introducing the world's smallest, almost transparent, catheter—with a 250-micron diameter lumen—into Schlemm's canal through a 1 mm or less clear corneal incision.

iTrack is designed with an infusion pathway to deliver OVD, an internal wire to guide the catheter through Schlemm's canal, and a fiber optic that illuminates the distal tip, enabling the surgeon to see, second-by-second, exactly where the catheter is coursing, thus safeguarding against misdirection of the catheter into the suprachoroidal space or the collector channels.

iTrack delivers, on average, more than 100 microliters of OVD over 360° of Schlemm's canal via a pressurized mechanism, which has been shown to improve flow through the entire conventional outflow pathway. I routinely observe this in clinical practice via blanching of the episcleral veins immediately following the procedure.

My Results with iTrack

A nonrandomized, retrospective review documented long-term surgical outcomes of patients who had undergone ab-interno canaloplasty with the iTrack microcatheter.[4] The majority of patients had mild to moderate disease; 594 underwent ab-interno canaloplasty combined with cataract surgery (iTrack+phaco), and 275 underwent standalone procedure (iTrack-Alone).

In both groups, IOPs were reduced approximately 20%; patients in the iTrack-Alone group had higher overall IOPs but showed a larger percentage reduction of mean IOP at all follow-up points. More than 50% of iTrack-Alone patients and 40% of iTrack+phaco patients achieved IOP reductions of ≥20% from baseline, with medications, over 36 months. Patients in both treatment groups reduced their medication dependence.

Adverse events are typically limited to intraoperative bleeding at the goniotomy site, and postoperative IOP spikes and microhyphema development, all of which self-resolve without sequelae. Only two iTrack+phaco patients and zero iTrack-Alone patients required additional surgery to address IOP spikes. Approximately 6% of iTrack+phaco patients and 14% of iTrack-Alone patients required additional surgery to control their disease during follow-up.

Tissue-Sparing and Implant-Free

In my opinion, iTrack ab-interno canaloplasty is the least invasive and most natural way to reinstate and rejuvenate the biological functions that govern aqueous dynamics while preserving both the conjunctiva and angle for future procedures, if needed. It has been nothing short of revolutionary for me and my patients.

Patients who have glaucoma carry the burden of knowing they have a disease that is, by definition, progressive and may lead to vision loss. They now have newfound hope—iTrack ab-interno canaloplasty—to control their glaucoma and potentially reduce their medication burden. That has been huge for patients, but also gratifying for me. I've been fortunate to lead the development of this procedure, and my goal is to encourage the rest of the world to adopt it, because it truly is the wave of the future.

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CANALOPLASTY: Treat the Proximal and Distal Outflow Pathway

Pioneering research by Stegmann, Johnstone, and others laid the groundwork for the development of ab-interno canaloplasty with the iTrack microcatheter.[1-3]

Exploring the physiology of the conventional outflow pathway and its relationship with IOP, researchers amassed evidence to support targeting all parts of the outflow pathway—trabecular meshwork, Schlemm's canal, and the collector channels—for the treatment of primary open-angle glaucoma (POAG). For example:

TRABECULAR MESHWORK

- **70% to 90% of aqueous humor flows through the conventional outflow pathway.[4]**
- **Extracellular matrix proteins and banded fibrillar elements that accumulate in the trabecular meshwork of POAG eyes compromise function and lead to pathologic changes that increase resistance to outflow.[5,6]**

SCHLEMM'S CANAL

- **Elevated IOP causes Schlemm's canal to narrow or collapse, obstructing the flow of aqueous from the anterior chamber into the bloodstream via the anterior ciliary veins. This correlates with a decrease in outflow facility by as much as 50% in POAG eyes.[3,7]**

COLLECTOR CHANNELS

- **Elevated IOP causes the trabecular meshwork to herniate into the ostia of the collector channels, obstructing the flow of aqueous.[8] Up to 90% of collector channels may be blocked by herniated trabecular meshwork in POAG eyes.[8]**

The Evolution of Canaloplasty

Stegmann conceptualized canaloplasty while developing hyaluronic acid (HA)-based OVDs. He postulated that POAG could be treated by OVD expansion of Schlemm's canal and the distal outflow system.[2] The positive early findings were corroborated by Johnstone and colleagues,[9] and intensive research ensued, focusing on mechanical, hydrostatic, and biophysical mechanisms of action.

The evolution of canaloplasty continued with the design and development of a microcatheter capable of traversing the entire 360 degrees of Schlemm's canal and delivering pressurized OVD into the canal to safely reduce IOP in POAG eyes. Yamamoto and colleagues took up the cause, conducting a series of laboratory assessments to validate the overall effect on outflow facility with a prototype iTrack canaloplasty microcatheter. They designed the iTrack to be sufficiently small and flexible to travel the circumference of Schlemm's canal, yet large enough to hold an infusion line for the delivery of OVD. A specialized injector delivers precise microquantities of HA-based OVD via a pressurized mechanism. A series of tests followed to validate the safety of the device, and in 2004, Yamamoto and colleagues reported on the performance of the prototype on human cadaver eyes.[10] Further physician-led refinements resulted in FDA approval in 2008.

Ab-Interno Canaloplasty with iTrack

Today, ab-interno canaloplasty with the iTrack microcatheter is a highly effective and safe MIGS procedure that can decrease IOP and medication burden, while preserving the angle for future interventions, thus making it a highly viable option in cases of mild-moderate glaucoma.

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Dr. Khaimi is a clinical professor, the James P. Luton, MD, Endowed Chair in Ophthalmology, and the Glaucoma Fellowship Director at the University of Oklahoma Dean McGee Eye Institute in Oklahoma City, OK. He is chief medical consultant for Nova Eye