

Prioritizing Quality of Life for Glaucoma Patients with Ab-Interno Canaloplasty

The glaucoma treatment paradigm is shifting from long-term use of topical medications to restoring natural outflow.

By **Mahmoud A. Khaimi, MD**



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The past decade has been very exciting for glaucoma surgeons. The advent of minimally invasive glaucoma surgery (MIGS) has filled the frustrating treatment gap between topical medications and invasive filtration surgery for patients who have uncontrolled intraocular pressure (IOP) despite topical therapy. It is a long-awaited change, and one that supports growing awareness of the need to preserve patient quality of life. While filtration surgery such as trabeculectomy and aqueous shunts is undeniably effective, it is very invasive and often associated with infections and bleb-related problems that negatively impact patient quality of life.¹ In contrast, topical medication use may seem innocuous in the short term but, because glaucoma is a chronic disease, it is important to consider the consequences of long-term exposure that can lead to a higher risk of ocular surface disease.² For example, the damaging effect of benzalkonium chloride (BAK), the most commonly used preservative in topical glaucoma medications, on trabecular meshwork cells may be underappreciated. Exposure to BAK is toxic to trabecular meshwork cells and was found responsible for inducing apoptosis in the endothelial cells and along the trabecular columns.³ The deterioration of the trabecular cells might cause major changes, including fusion of the trabecular meshwork,⁴ with collapse of Schlemm's canal and obstruction of the collector channels, com-

promising the natural outflow and the viability of other treatments.⁵ Ultimately, glaucoma patients often fail to adhere to topical treatment as advised, leading to optic nerve damage and disease progression.

Bearing in mind that patients with mild to moderate glaucoma, who are controlled with multiple antiglaucoma therapies, may benefit from a reduction in the number of topical medications required to maintain their intraocular pressure (IOP), finding a safer but equally effective way to lower IOP has long been the goal in glaucoma treatment, especially because just a 1-mmHg reduction in IOP is associated with an 11% decrease in disease progression.⁶

This is why I was an early adopter of canaloplasty via an ab-externo approach as an alternative to trabeculectomy. Indeed, its improved safety and efficacy profile as compared to trabeculectomy⁷ is the reason why I still continue to use it in advanced glaucoma patients.

More recently, inspired by MIGS, a less invasive yet equally effective approach⁸ to canaloplasty was introduced for mild to moderate glaucoma patients: ab-interno canaloplasty.

Ab-interno canaloplasty ticks all the boxes of MIGS, but it then excels. It uses an ab-interno approach, has a high safety profile, does not damage eye tissue, is effective at lowering IOP and has a rapid recovery time. Importantly, it addresses and treats both the proximal and distal portion of the conventional outflow pathway.

Most types of MIGS are focal in their approach and aim to improve outflow facility by using an implant to bypass the trabecular meshwork or to increase drainage via the subconjunctival or suprachoroidal space, but this can lead to complications.⁹ More importantly, however, they fail to address that glaucoma is associated with a pathophysiology of the entire outflow system, both proximal and distal. In contrast, ab-interno canaloplasty employs a comprehensive approach designed to restore the natural outflow of the eye by targeting all sites of resistance in both the proximal and distal outflow pathway, such as Schlemm's canal, the trabecular meshwork, and occluded collector channels. And it does it atraumatically, sparing the conjunctiva from manipulation and allowing future procedures to be performed if necessary.¹⁰

The Surgical Procedure

In my practice we have been using the iTrack canaloplasty microcatheter (Nova Eye Medical) for more than a decade with excellent results and no significant complications. During the ab-interno procedure, the iTrack canaloplasty microcatheter is inserted via a clear corneal incision into Schlemm's canal. It has an LED light at its tip, which allows the surgeon to know exactly where it is going and feel confident that it is in the right position while passing through the full length of Schlemm's canal, breaking adhesions and separating herniations of the inner wall of the trabecular meshwork (**Figure 1**). Once the device has circumnavigated all 360° of Schlemm's canal, the surgeon withdraws it while injecting high-molecular-weight, hyaluronic-acid-based OVD through the microcatheter. The OVD delivery is not automatic, but performed by clicking the viscoinjector device and counting, allowing the surgeon to precisely control the amount of OVD used to dilate the canal. The speed of withdrawal of the iTrack microcatheter can also be adjusted to impact the volume of OVD delivered.

Pressurized OVD delivery with the iTrack canaloplasty microcatheter has been shown to dilate the full circumference of Schlemm's canal, leading to enhanced outflow facility.¹¹ In my experience, 40 clicks, on average (using

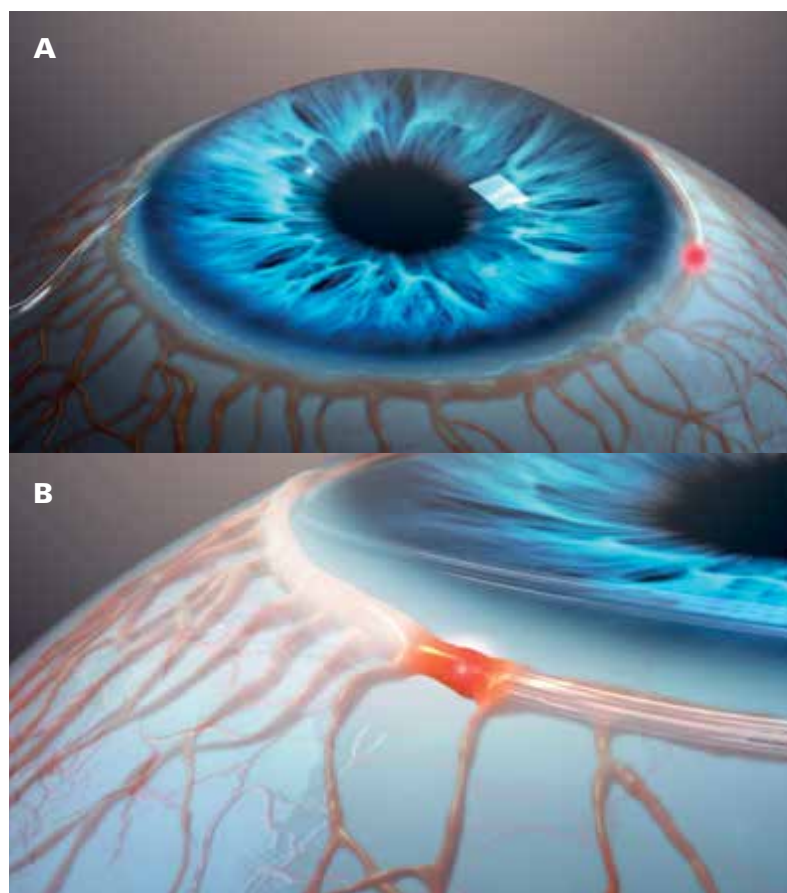


Figure 1. Representation of iTrack (Nova Eye Medical) surgical procedure.

Healon Pro, Johnson & Johnson Vision), successfully viscodilates the canal over 360°, but this is dependent on the patency of the canal. If I consider the canal to be particularly stenotic or occluded, I will deliver 50 or more clicks. This is one of the benefits of the iTrack canaloplasty microcatheter, that the surgeon can adjust the amount of OVD delivered on an individual patient basis.

It is a procedure designed to leave no implant or tensioning suture in place, therefore allowing the eye to reestablish its natural functions. The noninvasive approach also avoids damage to delicate ocular tissue, which is one of the reasons why the intraoperative and postsurgical complications rate in my practice and in the published literature is so low.^{10,12,13} To date, no serious adverse events have been recorded. Intraoperative bleeding at the goniotomy site, postoperative IOP elevation, and postoperative microhyphema development are the only notable side effects associated with ab-interno canaloplasty,

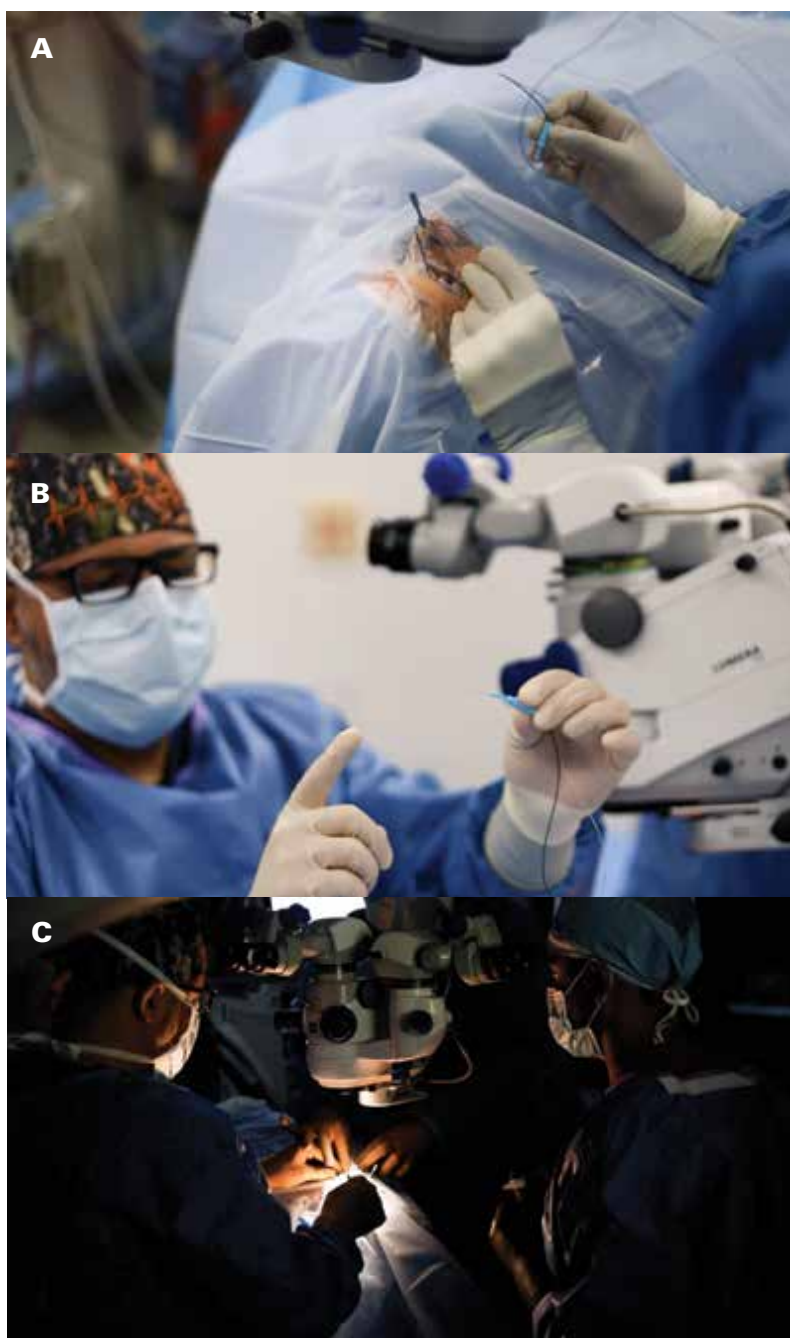


Figure 2. The iTrack surgical procedure (A), device (B), and microscope (C).

but these usually resolve within 1 week postoperatively and without sequelae.

Reducing Patient Reliance on Glaucoma Medications

As noted earlier, reducing the burden of glaucoma medications can contribute significantly to improved quality of life for glaucoma patients. In a consecutive case series at our eye

center (Dean McGee Eye Institute, University of Oklahoma), we assessed the ability of ab-interno canaloplasty to reduce the mean number of medications required to maintain IOP below 18 mmHg in a cohort of 45 eyes of 35 patients (mean age of 73 years) with controlled glaucoma. The baseline mean number of medications was 1.89 ± 0.93 . At 36 months postoperatively, the mean number of medications fell to 0.60 ± 0.82 — a 61% reduction from baseline. Even more encouraging was that 56% of eyes were medication free at 36 months. In this cohort, 11 eyes underwent ab-interno canaloplasty outside of cataract surgery (iTrack-alone) while 34 eyes underwent ab-interno canaloplasty in combination with cataract surgery (iTrack+phaco). At 12 and 36 months there was no significant difference in the percentage reduction in medication use between both groups. Mean IOP was within the target at baseline (14.42 ± 2.2 mmHg) and remained under control at 12, 24 and 36 months (14.19 ± 2.91 mmHg).

Reducing IOP and Medications

These 36-month results, which demonstrate the ability of ab-interno canaloplasty to effectively reduce the number of glaucoma medications required to control IOP, are not the only encouraging data my team and I have collected with ab-interno canaloplasty. Results presented at the 2020 annual meeting of the American Society of Cataract and Refractive Surgery (ASCRS) arise from 859 eyes treated with ab-interno canaloplasty at our eye center (594 eyes in the iTrack+phaco and 275 eyes in the iTrack-alone group) and they show a meaningful reduction in IOP and medications in both groups. At the 24-month follow-up, the percentage reduction in IOP among the iTrack+phaco group remained in line with that of the iTrack-alone group, particularly in patients with a high baseline IOP. Specifically, at 24 months, patients with a baseline IOP of 22 mmHg or higher experienced a fall in IOP of 34% and 39% in the iTrack+phaco and iTrack-alone groups, respectively. And among patients with a baseline IOP of 25 mmHg or higher, IOP fell by 38% and 39% in the iTrack+phaco and iTrack-alone groups, respectively.

By 24 months, the number of medications used had fallen from 1.7 and 2.1 in the iTrack+phaco and iTrack-alone groups to 0.7 and 1.2, respectively, reflecting a reduction of approximately 59% and 43%. When stratifying the data to account for baseline IOP, there was a reduction of 47% and 38% at 24 months in the iTrack+phaco and iTrack-alone groups, respectively, in patients with a baseline IOP of 22 mmHg or higher. In patients with a baseline IOP of 25 mmHg or higher, the number of medications fell by 44% and 41% in the iTrack+phaco and iTrack-alone groups at 24 months.

There were a low number of adverse events reported across both treatment groups: mostly a postoperative IOP elevation (≥ 30 mmHg, predominantly at 1 week), which resolved spontaneously, in 8% and 10% of eyes in the iTrack+phaco and iTrack-alone group, respectively. Only 2 eyes (0.3%) in the iTrack+phaco group required additional surgery to address IOP spikes. In total, 6% of iTrack+phaco eyes and 14% of iTrack-alone eyes underwent additional surgery to keep IOP under control during follow-up. Other minor complications included intraoperative bleeding at the goniotomy site and microhyphema development, but these resolved spontaneously.

iTrack and the Evolving Glaucoma Treatment Algorithm

Ab-interno canaloplasty represents a highly effective, minimally invasive glaucoma treatment that enables glaucoma specialists to both reduce medication dependence and IOP – and so to enhance patient quality of life. Importantly, it also provides surgeons with an opportunity to rethink their use of medications in the management of glaucoma patients. There is a broad consensus that long-term use of topical glaucoma medications can be linked with ocular surface diseases in both the cornea and conjunctiva³ and, based on the excellent clinical results I have achieved with ab-interno canaloplasty, I am of the opinion that, in the treatment of mild-moderate glaucoma, topical medications should be avoided or used occasionally as an adjunct between different procedures like selective laser trabeculoplasty (SLT) or ab-interno canaloplasty.

Based on the results achieved to date, the safety profile of ab-interno canaloplasty with the iTrack microcatheter and its long-term efficacy make it an excellent option for mild to moderate glaucoma patients undergoing cataract surgery as well as for those who need a standalone procedure. Although our 24-month and 36-month results are promising, I am very much looking forward to confirming this data with the prospective, randomized, multi-center “MAGIC” study (NCT0469453) currently involving 8 surgery centers in the United States. In the meantime, current evidence suggests that ab-interno canaloplasty provides a tissue-preserving, implant-free glaucoma procedure that will greatly benefit patients and surgeons alike. **GP**

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