

CANALOPLASTY IN A PSEUDOPHAKIC MONOCULAR PATIENT



The safety profile in a monocular patient coupled with the potential to reduce or eliminate drop burden and improve physiologic aqueous outflow leads Dr. Murphy to consider an iTrack procedure.

BY JAMES T. MURPHY, MD

A 73-year-old man was referred to my office for uncontrolled IOP following cataract surgery 5 weeks prior. Five years earlier, he had cataract surgery in the fellow eye, but unfortunately, he experienced an IOP spike that caused vision loss to the level of no light perception due to an ischemic central retinal vein occlusion (CRVO). During our initial consultation, the patient relayed that he was fearful of history repeating itself.

Imaging and visual field testing demonstrated overall stable glaucoma (Figures 1 and 2). Results of the initial examination were as follows:

- IOP OS: 40 mm Hg
- BCVA: 20/25 (pseudophakic; posterior chamber IOL)
- Anterior chamber = deep and quiet
- Current medications: latanoprost, brimonidine, and dorzolamide-timolol drops; one 500 mg acetazolamide (Diamox Sequel,

Wyeth Pharmaceuticals) capsule three times daily

- Patient reported bothersome side effects related to Diamox, including paresthesia involving his fingers and toes and malaise

Based on the patient's monocular status with sight-threatening pressure elevation, I emphasized three main points during the consultation: noninvasive measures (ie, drops and laser treatment) would be unlikely to achieve target IOP, there was a small but finite risk of a vision-threatening vascular event if the IOP was to remain at its current level, and that the recommended next step would be a surgical procedure. After a thorough discussion of the comparative risk and benefits of traditional surgery versus MIGS, the patient preferred a minimally invasive approach; he was willing to accept the possibility of an additional future surgery to benefit from the lower surgical risk associated

with a less invasive surgical approach. Given the relatively acute time course of the patient's IOP spike, I elected to proceed with canaloplasty utilizing the iTrack (Nova Eye Medical).

The iTrack procedure was uneventful, and there were no complications. Per usual protocol, I discontinued all glaucoma drops and Diamox following the operation. On postoperative day 1, the IOP was 12 mm Hg. Over the next 6 weeks, the IOP rose to 18 mm Hg and then plateaued in the high teens. Due to the patient's monocular status and out of an overabundance of caution, I started a regimen of one drop of latanoprostene bunod ophthalmic solution 0.024% (Vyzulta; Bausch + Lomb) before bed, which reduced the IOP to the mid-teens. The patient's IOP has been stable in the mid-teens with non-progressing fields and a stable retinal nerve fiber layer since 2018 using monotherapy that is well-tolerated with no reported side effects (Table).

CONSIDERING THE RISK-BENEFIT PROFILE

While safety is an ever-present concern, a monocular patient presents additional impetus to think about the risk-benefit profile of the various options for treating glaucoma. Because this patient was pseudophakic at the time of the initial visit, from an insurance standpoint, stenting procedures were not a cost-effective option. Additionally, a stenting procedure would likely not achieve sufficient IOP lowering.

TABLE. Summary of pertinent case variables.

	Baseline	Year 1	Year 3
IOP	40 mm Hg	13	17
Medications	4; plus 1 oral	1	1

In this case, canaloplasty and gonioscopy-assisted transluminal trabeculotomy (GATT), in addition to more invasive bleb-forming procedures, were viable options. Associated risks of the canaloplasty and GATT procedures include the spectrum of circulating red blood cells, hyphema, Descemet detachment, and cyclodialysis cleft, among others. In comparison to a bleb-forming procedure, one of the risks that is rarely encountered is hypotony. The risk of bleeding is lower in canaloplasty compared to GATT as there is minimal unroofing of Schlemm canal (SC); as the trabecular meshwork (TM) is left intact, any amount of intact TM would be expected to confer some degree of resistance to aqueous outflow. As a counterpoint, removing TM interferes with a physiologic mechanism for responding to IOP changes. The TM plays a vital role in regulating hyaluronic acid levels,¹ which in turn activates pathways involved in clearing deposits that contribute to resistance.² Particularly in a monocular patient, it is important to preserve and improve natural outflow dynamics with a procedure associated with a low risk profile.

In this case, a trabeculectomy or glaucoma drainage device implantation, with the attendant risk for hypotony among other considerations, presented a risk profile that was unacceptable to the patient. We also discussed the finite nature of these procedures in terms

of conjunctival scarring and the conjunctival “real estate” dilemma. In contrast, one of the advantages of iTrack and the enhancement

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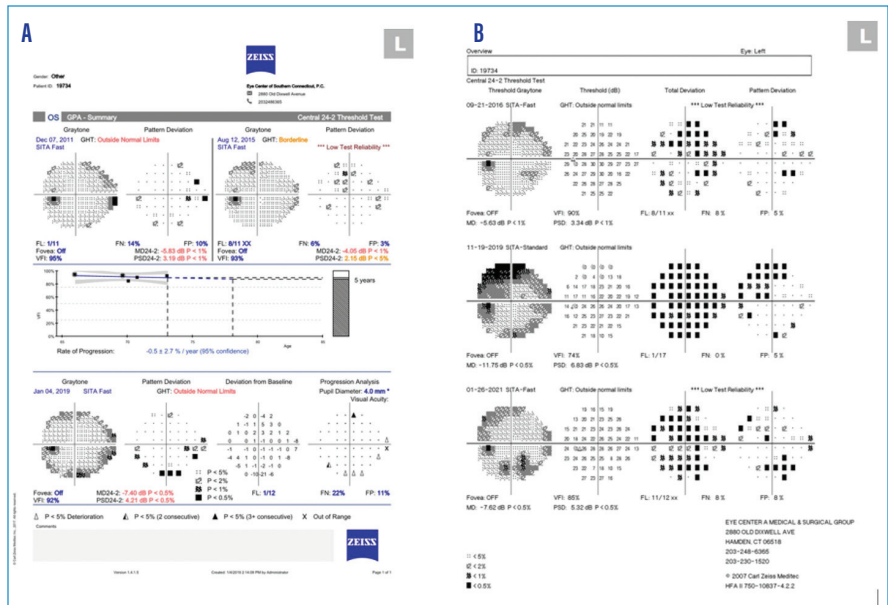


Figure 1. Guided progression analysis starting in 2011 (A) and an overview of the patient’s visual field testing over time (B).

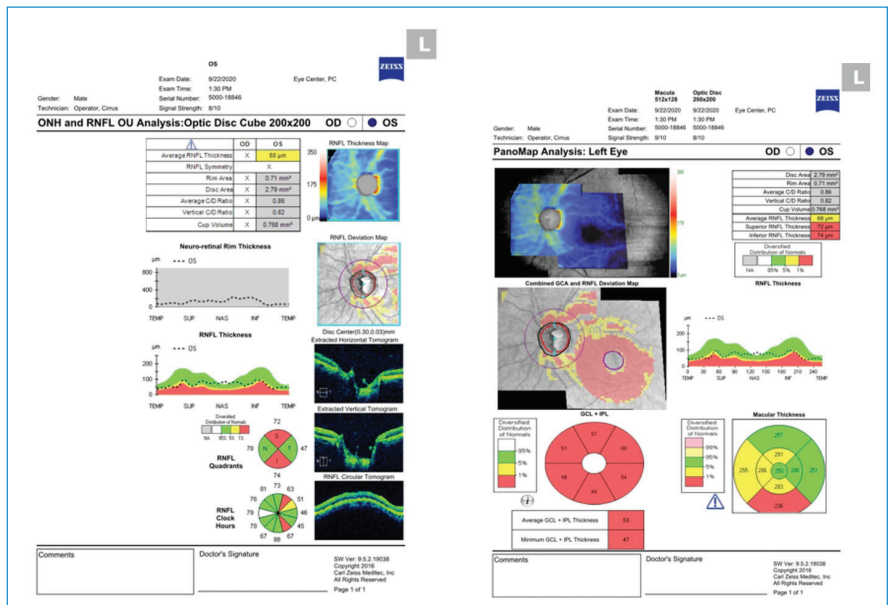


Figure 2. OCT analysis captured during the initial visit.

of physiologic outflow is that results are more predictable with the potential to have a significant impact on IOP—often to the same level as more invasive procedures. There is no indwelling implant remaining in the eye, and therefore no risk of migration, exposure, or extrusion of an

implant, nor any other risks associated with use of ocular implants. In most cases, it is reasonable to expect at least a reduction in the need for topical aqueous suppressants as well, including their associated side effects, and associated improvement in quality of life.

“One of the advantages of iTrack and the enhancement of physiological outflow is that results are more predictable with the potential to have a significant impact on IOP—often to the same level as more invasive procedures.”

DISCUSSION

Because the patient’s trabecular outflow was functional and relatively normal only weeks prior, there was potential to re-establish this outflow. Because iTrack is performed through the complete 360° of the SC (Figure 3), it has a high likelihood of reducing or eliminating potential points of outflow resistance and addressing any areas of collapsed SC

and distal outflow pathways with mechanical viscodilation.³ This also increases the chance of reducing or even eliminating the patient’s dependence on topical and oral aqueous suppressants.^{4,5}

In talking with colleagues about their current practice patterns with minimally invasive procedures, a sentiment I hear often is that iTrack is only useful in early stage or mild glau-

coma. I would argue, however, that iTrack can be considered for a wider range of glaucoma severity based on specific patient scenarios and what the patient considers an acceptable risk for their unique situation. This case demonstrates a particularly positive outcome in a monocular patient; while the safety profile relative to other glaucoma procedures was an easy selling point, we were also able to achieve an excellent IOP reduction that has proven to persist for several years. The patient’s natural aqueous outflow pathways proved to be viable and able to be restored to adequate function. Meanwhile, the TM was left intact to continue its physiological function and is available in the future should it be required or targeted for further surgical modification by either an existing device or one yet to be conceived.

Largely among the glaucoma community, the treatment paradigm has evolved to laser first, then topical therapies, then on to an ever-expanding array of minimally invasive procedures, skipping drops entirely, or at least introducing them later in treatment. Although there is still a place for topical aqueous suppressants and invasive glaucoma procedures within the treatment paradigm, our surgical armamentarium has expanded, and so too has our ability to individualize our approach to every patient.

The wide array of minimally invasive surgical options in many ways broadens the definition of a successful outcome because we can start to consider quality-adjusted life year gains in a meaningful way. The ability to offer a less invasive surgical option that could delay or obviate the need for a more invasive procedure is beneficial for patients and surgeons. Additionally, any intervention that reduces or eliminates the patient’s eye drop burden can have a significant

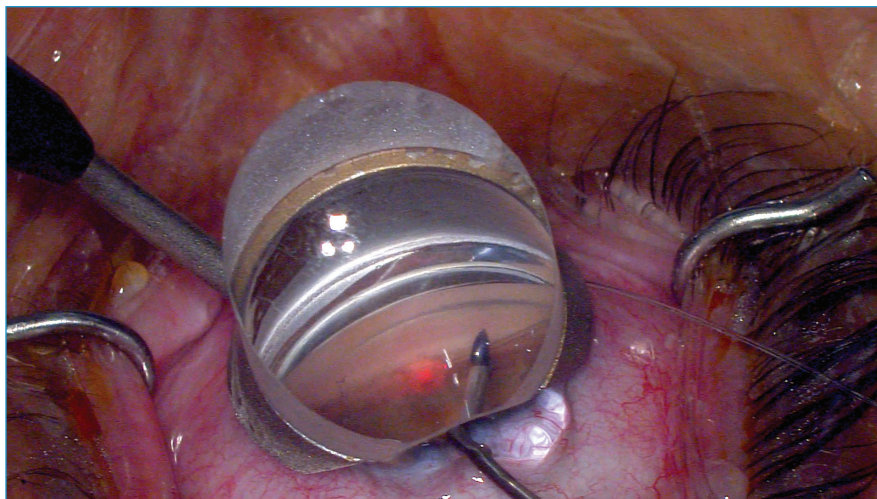


Figure 3. The iTrack is advanced under gonioscopy for 360° through the SC, with the LED tip aiding visualization. The device mechanically clears adhesions in the device's pathway, and later introduction of viscodilation is additive in facilitating outflow.

impact on their quality of life. Because iTrack functions to restore physiologic outflow, there is excellent potential to reduce medications postoperatively, as we were able to do successfully in this case. The patient was having disturbing but temporarily tolerable side effects from an oral carbonic anhydrase inhibitor, and it was only a matter of time before those side effects became intolerable. He went from dangerously high IOP, despite using four topical agents in addition to an oral agent, to stable, controlled IOP

using one drop a day and sleeping through the night without having to get up to use the bathroom. His eyes see better, feel better from an ocular surface standpoint, and look better without constant hyperemia from exposure to benzalkonium chloride, vehicle solutions, and topical medication. Not only is this beneficial from an immediate benefit sense, but down the road, if he does require a more invasive procedure that uses up some of his conjunctival real estate, it will be healthier and less likely to fail as a result of postoperative scarring.

Not every patient has a perfect outcome as any glaucoma specialist knows all too well, but this patient's case demonstrates the power that a canaloplasty can have on lowering IOP beyond what is expected classically. At the time of his iTrack procedure, preserving the option for future surgical interventions was an important part of the preoperative decision-making process, but thankfully, to date, he has been stable, and the iTrack procedure has thus far bought him years without more of the knife. ■

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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.

Based on current FDA 510(k) intended use labelling, the canaloplasty ab-interno surgical technique is not an on-label indication for the iTrack™ canaloplasty microcatheter in the USA.

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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