

IS THE ANGLE THE NEW CONJUNCTIVA?



Like the conjunctiva, the angle's preservation permits broader surgical options in the future.

BY MARK J. GALLARDO, MD

Much focus is placed on how MIGS can lower intraocular pressure (IOP) while preserving conjunctival tissue, thereby keeping options open for future surgical procedures. To further expand future treatment options, I suggest an additional focus for preservation: the angle. If a patient's glaucoma progresses or IOP elevates above target, we might want to add a medication that targets the trabecular meshwork (TM) cytoskeleton, comprehensively perform selective laser trabeculoplasty, implant a trabecular micro-bypass stent, or try a new procedure that's not yet available—all of which are possible if the first MIGS procedure we perform preserves both the conjunctiva and the angle.

The iTrack canaloplasty microcatheter (Nova Eye Medical) has emerged as an excellent MIGS option that preserves both the angle and conjunctiva. In a retrospective 36-month analysis of patients that have undergone circumferential catheterization and viscodilation of Schlemm canal using the iTrack microcatheter as a stand-alone procedure or in combination with cataract surgery, we have found that the procedure has durable results (Figure).¹

ANGLE PRESERVATION AND MIGS SELECTION

When I select a MIGS procedure, part of the process is evaluating the angle—specifically, the pattern of pigmentation on the TM, which may elucidate the health and patency of the outflow system. The endothelial cells lining the trabecular columns are phagocytic in nature. As aqueous traverses the trabeculum into Schlemm canal, endothelial cells in the area of the posterior or pigmented TM engulf pigment. As a result, more outflow through a region leads to a higher degree of pigmentation.

If the posterior TM (or pigmented TM) has a variegated pigmentation pattern, it may suggest that the patency of the outflow system, which we know to be segmented in nature, is fractionated. A more homogenous TM pigmentation indicates that aqueous outflow may be more uniform and associated with a system that is more diffusely patent.

If the drainage angle looks healthy (homogenous pigmentation), I choose iTrack or iStent (Glaukos). If the angle has a variegated pattern of pigmentation, however, I choose a MIGS procedure that treats more of the proximal system, such as the Kahook Dual Blade (New World Medical) or the Hydrus Microstent (Ivantis). iTrack and the Kahook Dual Blade have the option of being

performed as stand-alone procedures independently of cataract surgery, and studies are currently being conducted to evaluate the safety and efficacy of stand-alone implantation of both the iStent infinite and Hydrus Microstent.

When iTrack is one of the options, it is usually my first choice because it rejuvenates the natural outflow system while sparing both the angle and the tissue from permanent adulation. There is little damage to ocular tissue and no implant, so it is one of the most minimally invasive of all MIGS procedures and rarely causes postoperative complications.^{2,3} Interim data noted 4.8% (SD ± 6.5%) endothelial cell loss 12 months after iTrack (D.M. Lubeck, MD, and R.J. Noecker, MD, unpublished data, 2020; accepted for presentation at ASCRS 2021). Studies have shown that endothelial cell loss 12 months after iStent ranges from 9 to 14.6%.^{4,5}

When MIGS procedures targeting the conventional outflow pathway fail, I am comfortable knowing that the patient's natural system has been manipulated to its maximum potential. This tempers my discussion with patients when larger, more invasive procedures, including MIGS that target the suprachoroidal space, are required: We've tried to utilize their natural system, but it was just too diseased to provide the control that we sought. This is especially true in those rare occasions when the outflow system was "rejuvenated" following circumferential microcatheterization and viscodilation using the iTrack microcatheter.

In addition, given its benign nature, the iTrack microcatheter can be used earlier in the disease process to reduce IOP and alleviate the twin burdens of medication and compliance. It can also be used in patients who have already undergone non-ablative MIGS procedures like trabecular micro-bypass, should they suffer from an elevated IOP or an unwanted dosage of topical glaucoma medications.

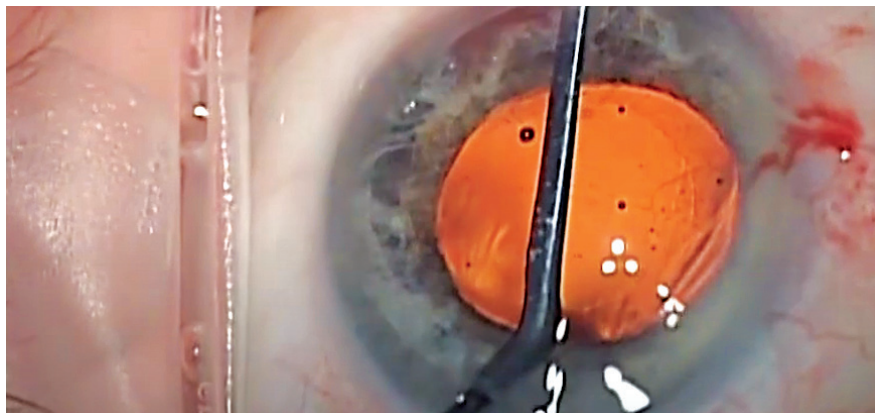


Figure. Dr. Gallardo performs *ab interno* canaloplasty with the iTrack canaloplasty microcatheter system.

36-MONTH ITRACK DATA

I recently presented the 36-month outcomes of *ab interno* 360° catheterization and viscodilation using the iTrack canaloplasty microcatheter in patients with mild-to-severe glaucoma at the American Glaucoma Society (AGS) 2021 Virtual Meeting.¹ The 80 patients included in the retrospective study underwent *ab-interno* canaloplasty as a stand-alone procedure or in combination with cataract surgery. In the mild-to-moderate group (n = 44), mean IOP decreased from 20.4 to 13.1 mm Hg (87% ≤ 15 mm Hg), and mean medications decreased from 2.7 to 1.2 (67% taking one or no medications).¹ Results were similar for patients with severe glaucoma (n = 36). Mean IOP dropped from 20.1 to 13.7 mm Hg (81% ≤ 15 mm Hg), and mean medications went from 3.0 to 1.6 (62% taking one or no medications).¹

Three years after the iTrack procedure, treatment was still highly effective in meeting the primary goal of

reducing IOP. It was also still effective in reducing the medication burden by half, which is important for minimizing both burdensome costs and the impacts on the ocular surface. Reducing medications can curb ocular surface disease (OSD) and endothelial cell damage (ECD): Nearly half of patients using topical glaucoma medications have an ocular surface disease index (OSDI) score of 13 or higher, and more than 1 in 4 has moderate or severe OSD,⁶ and is shown to reduce ECD.⁷ And as we know, fewer medications also mean markedly better compliance and, therefore, better disease management.^{8,9} An additional rarely discussed factor is that benzalkonium chloride, a common preservative in glaucoma medications, can induce apoptosis in the endothelial cells lining the trabecular columns,¹⁰ compromising the health of the outflow pathway.

As demonstrated in the 36-month data, iTrack's efficacy in lowering IOP allows us to reduce or eliminate

medications for our patients, which in turn provides more reliable management and less medication-associated endothelial cell loss. In addition, the procedure does not ablate tissue or require device implantation, so it minimizes overt change to the drainage angle. Instead, iTrack *ab interno* canaloplasty optimizes the natural outflow system for patients with all stages of open-angle glaucoma while preserving both the conjunctiva and the angle for the future. ■

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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.

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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