

BE ILLUMINATED



Nova Eye recently partnered with The Ophthalmologist to host an illuminating panel discussion featuring some of the world's leading glaucoma surgeons. The panel shared their clinical experience with canaloplasty. An implant-free, tissue sparing, minimally invasive glaucoma surgery (MIGS) which allows surgeons to work with patient physiology, rather than against it, canaloplasty offers significant utility in the treatment of mild-moderate glaucoma. The panel also spotlighted their early surgical experience with the iTrackTM Advance, a breakthrough canaloplasty device that combines an illuminated microcatheter with an easy-to-use handheld injector.

the
Ophthalmologist

Featuring

Mahmoud Khaimi, Head of the Glaucoma Fellowship Program, Dean McGee Eye Institute, University of Oklahoma, and chief medical consultant for Nova Eye



Norbert Koerber, Professor of Ophthalmology and cataract and glaucoma surgeon at Clinica Oculistica in Cologne, Germany



Ike K. Ahmed, Assistant Professor, Director, Glaucoma & Advanced Anterior Segment Surgery (GAAS) Fellowship, Research Director, Kensington Eye Institute, University of Toronto; Clinical Professor, University of Utah; Director, Division Head, Ophthalmology, Trillium Health Partners, Mississauga; Medical Director, Prism Eye Institute, Mississauga; Co-Medical Director, TLC Mississauga, Ontario, Canada



David M. Lubeck, Director of Advanced Anterior Segment Surgery, Arbor Centers for Eye Care, Orland Park, Illinois, USA



Shamil Patel, Eye Physicians and Surgeons of Arizona, Glendale, Arizona, USA



For an Easier Route to Improved Outcomes – Follow the iTrack

Nova Eye Medical is committed to making canaloplasty more easily adopted by surgeons – thereby enabling more patients across the globe to benefit from its comprehensive, stent-free and tissue-sparing approach. How does the iTrack™ Advance meet this altruistic ambition? Here to explain is Mahmoud Khaimi, Head of the Glaucoma Fellowship Program, Dean McGee Eye Institute, University of Oklahoma, and chief medical consultant for Nova Eye.

By Mahmoud Khaimi, Head of the Glaucoma Fellowship Program, Dean McGee Eye Institute, University of Oklahoma, and chief medical consultant for Nova Eye

I've been performing canaloplasty for nearly two decades. I started off with the ab externo surgical technique, but always wished for a minimally invasive way of rejuvenating the natural outflow pathway.

And that's why I teamed up with Nova Eye Medical to develop the ab interno surgical technique back in 2014. Since then, I've performed tens of thousands of ab interno canaloplasty procedures, and now teach the procedure to residents, fellows, and colleagues at the Dean McGee Eye Institute at the University of Oklahoma. The ab interno canaloplasty method is now my go-to MIGS – and the new iTrack™ Advance is a major development in this field.

The iTrack™ Advance offers the same technical and clinical advantages as the original iTrack microcatheter, including the illuminated tip and the unique viscoelastic injector. The former gives visual verification of the microcatheter tip location at all times – critical to confirm the device has remained within Schlemm's canal rather than entering the suprachoroidal space or a collector channel. The viscoelastic injector permits administration of precise volumes of viscoelastic, up to 100 microliters, depending on surgeon preference; this ability to titrate the delivery of viscoelastic enables us to take a truly nuanced treatment approach for each and every patient. Crucially, the comprehensive approach of canaloplasty addresses the entire outflow system, including the collector channels. This is an important distinction of canaloplasty, when you consider that other MIGS procedures address only a couple of clock hours of the conventional outflow pathway; remember that we still have no diagnostic that defines the site of canal constriction, so localized treatment is not an option.





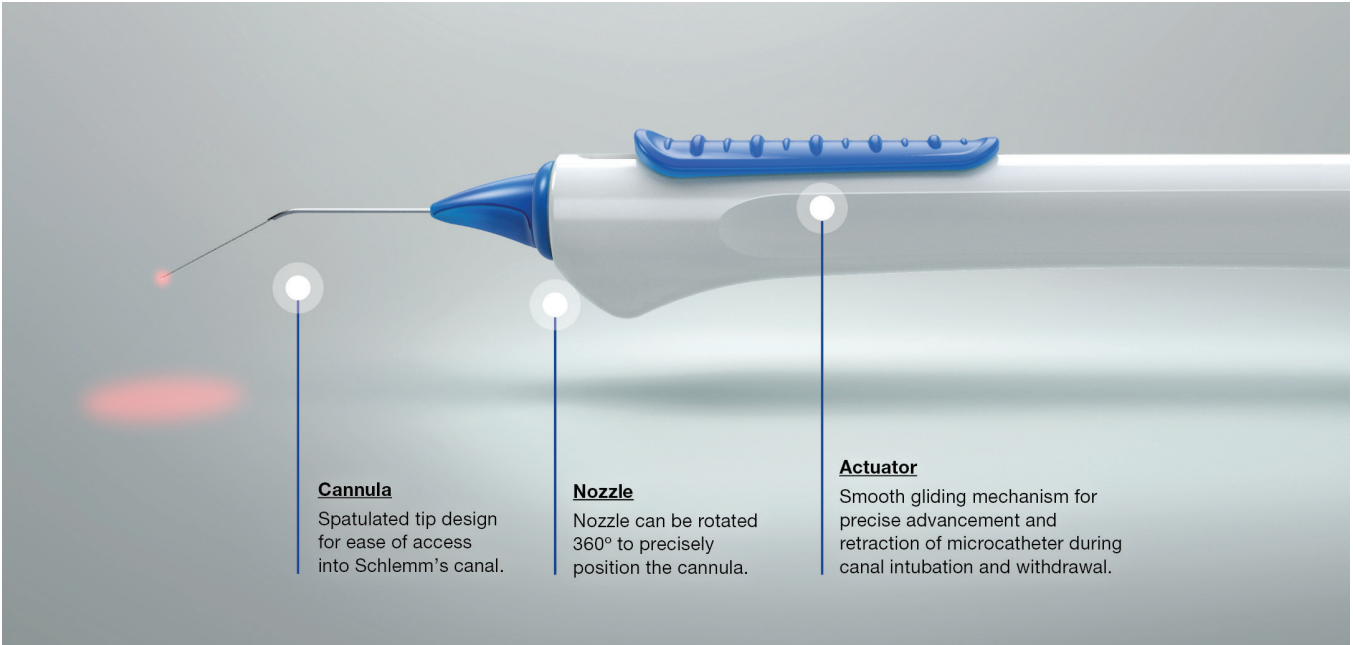
“iTrack™ Advance has equivalent safety and effectiveness to the original iTrack; indeed, the main differences relate to how easily it can be adopted into a surgeon’s treatment paradigm.”

Easier for new users
iTrack™ Advance has equivalent safety and effectiveness to the original iTrack; indeed, the main differences relate to how easily it can be adopted into a surgeon’s treatment paradigm. The original procedure required needle-based goniotomy, needle removal, forceps use, and catheter insertion. Next, the surgeon was required to feed the microcatheter through the main incision, often traversing the pupil to reach all the way across to the angle. Some residents and fellows found this approach challenging, and the elimination of these steps with **iTrack™ Advance** is very welcome. Dispensing with the need for needle and forceps makes the technique much easier for new users. Notably, for standalone procedures, the new **iTrack™ Advance** only requires a 1.0 incision, which is sufficient for anterior chamber access, microcatheter insertion, progression through 360 degrees, and egress.
A more subtle usability feature comes in the form of iTrack™ Advance’s rotatable nozzle, which allows both left- and right-handers to conveniently and precisely position the cannula, as required.

Finally, the new actuator mechanism on the handpiece uses a 2:1 gear ratio to prevent unwanted movement – critical when undertaking surgery next to the cornea.
Those new to **iTrack™ Advance** can see some of its advantages for – one of many benefits showcased in the video is the phenomenal efficiency of the procedure.
Together, these advantages make the procedure uniquely efficient: once you engage the actuator, the microcatheter just shoots out – it’s the Ferrari of MIGS! – but in a safe and precisely controlled manner.
Trusted, with a serious makeover
The original iTrack is backed up by over 120,000 procedures performed over 10 years of global use. And the same three-year data – from over a thousand eyes, treated by multiple surgeons – that supports the original iTrack also apply to the iTrack™ Advance. The new device retains the same proprietary features, including the illuminated tip that lends iTrack a clear safety advantage. In short, **iTrack™ Advance** is evidently just as safe and effective as the original – both when used as a standalone procedure and when combined with cataract surgery – but we’ve given it a serious makeover. It’s now more ergonomic, more efficient, and easier to use.
iTrack™ Advance represents a new route into the advantages of canaloplasty; namely, the comprehensiveness nature of approach, which acts on distal collector channels, the TM, and Schlemm’s canal.

The iTrack™ Advance Combines Proven Benefits of iTrack with New Features and a Simpler Technique

- Original iTrack:*
- 200-micron illuminated canaloplasty microcatheter: continuous visual confirmation of tip location
 - viscoelastic injector
- The new iTrack™ Advance:*
- spatulated cannula tip: facilitates insertion into TM, access to Schlemm’s canal
 - adjustable nozzle: rotatable to suit left- or right-handed use
 - actuator mechanism: advance/withdraw the microcatheter without the need for forceps
 - simpler technique



My Canaloplasty Journey

Norbert Koerber, Professor of Ophthalmology and cataract and glaucoma surgeon at Clinica Oculistica in Cologne, Germany, has travelled far with canaloplasty – and found that ab interno canaloplasty with the new iTrack™ Advance is a safe and highly effective early intervention in mild-to-moderate glaucoma patients

By Norbert Koerber, Professor of Ophthalmology and cataract and glaucoma surgeon at Clinica Oculistica in Cologne, Germany

I began performing ab externo canaloplasty as an alternative to trabeculectomy over 15 years ago. I ceased trabeculectomy altogether when it became clear that it was no better than canaloplasty in terms of IOP reduction. The next step was the development of ab interno canaloplasty. This procedure, which I introduced to Germany in 2014, is useful in many patients (see box), particularly those early-stage cases in whom medication is ineffective. Furthermore, ab interno canaloplasty is more efficient than the ab externo approach because of its relatively simple two-step approach: i) clear corneal incision and microcatheterisation to remove blockages in Schlemm’s canal and ii) viscodilation (24–36 clicks) to expand canal and collector channels and create microperforations in the trabecular meshwork. By contrast, the ab externo procedure involves multiple steps: creation of an outer flap, creation of an inner flap/Descemet window, intubation and stenting of Schlemm’s canal, viscodilation (~6 clicks), suture tying and tensioning, and incision closure.

Notably, the ab interno technique – unlike other MIGS procedures – does not destroy tissue or alter aqueous currents;

rather, it aims to preserve trabecular meshwork physiology and therefore preserves future treatment options, too. Also, the ab interno approach is uniquely comprehensive in that it targets all resistance sites, including collector channel ostia. Finally, the new iTrack™ Advance is more easily adopted than previous techniques, making it more accessible to surgeons and thus available to more patients.

We have now published a retrospective, single-center, consecutive case series (1) summarizing our experience with ab interno canaloplasty (iTrack) in cases of mild-to-moderate POAG with insufficiently reduced IOP and poor medication tolerance. Patients (28 eyes) underwent ab interno canaloplasty, either alone or combined with cataract surgery. Cases were grouped according to the number of medications (0–4). Four-year data are summarized in Table 1. We also now know that, at five years, all groups had statistically significant IOP reductions.

We are now participating in CATALYST, a prospective, multicenter, randomized clinical study that commenced in 2022. Conducted across five sites in Germany, the study compares iTrack™ Advance and cataract surgery with cataract surgery alone (2). Briefly, CATALYST will recruit up to 80 patients with mild-to-moderate, uncontrolled, primary open-angle glaucoma and randomize them between test and control groups in a 2:1 ratio. Patients will be followed for 12 months. Primary endpoints will be reduction in mean IOP and mean number of medications. Secondary endpoints include adverse events, visual acuity, endothelial cell count, and quality of life outcomes. The study is expected to reinforce the known clinical utility of ab interno canaloplasty in the treatment of mild-to-moderate glaucoma.

In summary, the key feature of ab interno canaloplasty is that it can be combined with cataract surgery for early intervention

All eyes	Baseline	12M	24M	36M	48M
Mean ± SD	19.85 ± 5.2	14.98 ± 2.6	15.58 ± 3.3	14.71 ± 3.8	14.56 ± 3.0
N (eyes)	27	26	25	21	18
Standalone	Baseline	12M	24M	36M	48M
	23.5 ± 9.26	17.67 ± 2.3	17.25 ± 7.37	16.33 ± 4.73	17.67 ± 4.16
Combined with phaco	Baseline	12M	24M	36M	48M
	19.22 ± 4.20	14.63 ± 2.51	15.27 ± 2.01	14.44 ± 3.37	13.93 ± 2.43

Table 1. Impact of ab interno canaloplasty on IOP in eyes with open-angle glaucoma four-year data.



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Norbert Koerber: How I Perform Ab Interno Canaloplasty

- I make the clear corneal incision close to the limbus.
- After inserting the microcatheter, I viscodilate on the way in and out, one click per clock hour.
- Many surgeons inject viscoelastic during withdrawal of the microcatheter only, but I am of the opinion that injecting viscoelastic while advancing the microcatheter dilates the canal in front of the tip, loosening adhesences and pushing herniated endothelium away from collector channels. This makes for a gentler procedure.
- Also, the viscoelastic reduces microcatheter-mediated mechanical stress on the endothelium, making endothelial damage less likely.

to avoid trabeculectomy or tube shunt procedures. Having performed close to 50 procedures with **iTrack™ Advance**, I can state that it has major advantages over competing systems – notably, that the simplified nature of the technique makes it a truly single-handed surgical procedure. Briefly, the surgeon uses the uniquely designed cannula to create an opening in the meshwork and then guides the microcatheter into the canal using the handpiece injector – all with only one hand. Further, the device has been designed to catheterise the full 360 degrees of the canal in just one intubation. With other devices, you can only catheterise 180 degrees of the canal at a time.

I believe **iTrack™ Advance** should be adopted by any practice that manages early-stage glaucoma cases, especially for patients intolerant of or noncompliant with medication.

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in mild-to-moderate patients, in whom it controls IOP and reduces medication burden. By contrast, the ab externo approach is indicated for severe or late-stage disease, typically

Early Canaloplasty Makes Sense

By Ike K. Ahmed, Assistant Professor, Director, Glaucoma & Advanced Anterior Segment Surgery (GAAS) Fellowship, Research Director, Kensington Eye Institute, University of Toronto; Clinical Professor, University of Utah; Director, Division Head, Ophthalmology, Trillium Health Partners, Mississauga; Medical Director, Prism Eye Institute, Mississauga; Co-Medical Director, TLC Mississauga, Ontario, Canada

We have many MIGS options for treating glaucoma – but where does canaloplasty sit in this array of interventions? The answer becomes clear when we consider the canaloplasty technique and its associated benefits: in brief, this approach catheterizes and viscodilates Schlemm’s canal, thereby restoring natural aqueous flow while preserving trabecular meshwork and other aspects of ocular anatomy. Being stent-free, canaloplasty has no safety issues regarding long-term consequences of implant placement. The technique therefore closely approaches the MIGS ideal: namely, a safe approach to restoration of natural physiology with minimal tissue damage.

That said, different patients have different needs, and surgeons must match the intervention to the individual accordingly. Relevant factors include disease severity, medication load, target pressure, comorbidities, history, and need for cataract surgery. In general, however, canaloplasty is ideally suited for i) reduction of IOP and medication burden in mild-to-moderate uncontrolled patients (both phakic and pseudophakic), and ii)

MIGS procedures, categorized by anatomical site

- Schlemm’s canal:
 - dilate Schlemm’s to restore natural outflow pathway
 - stent through meshwork
 - ablate or excise meshwork
- Supraciliary space:
 - stent to bypass obstructed outflow pathway
- Subconjunctival space:
 - stent to bypass obstructed outflow pathway
 - form a bleb

reduction of medication burden in non-compliant individuals, and cases of symptomatic OSD. The suitability of canaloplasty for early-stage patients is a consequence of the mechanism behind elevated IOP in glaucomatous eyes. Briefly, diseased trabecular meshwork accumulates extracellular matrix proteins, which trigger chronic inflammation and fibrosis. In late-stage disease, meshwork sclerosis becomes irreversible; at this point, dilation of the canal is ineffective, and bypass procedures may be the only option. In early-stage disease, before fibrosis has become unmanageable, dilation of the canal can improve outflow. Canaloplasty is a far better option for these patients than decades of eyedrops which – even if effective and well-tolerated – cannot interrupt meshwork fibrosis. In summary, fibrotic progression will ultimately result in non-responsiveness to IOP medications and at the same time make the eye refractory to canaloplasty – so early canaloplasty makes sense.





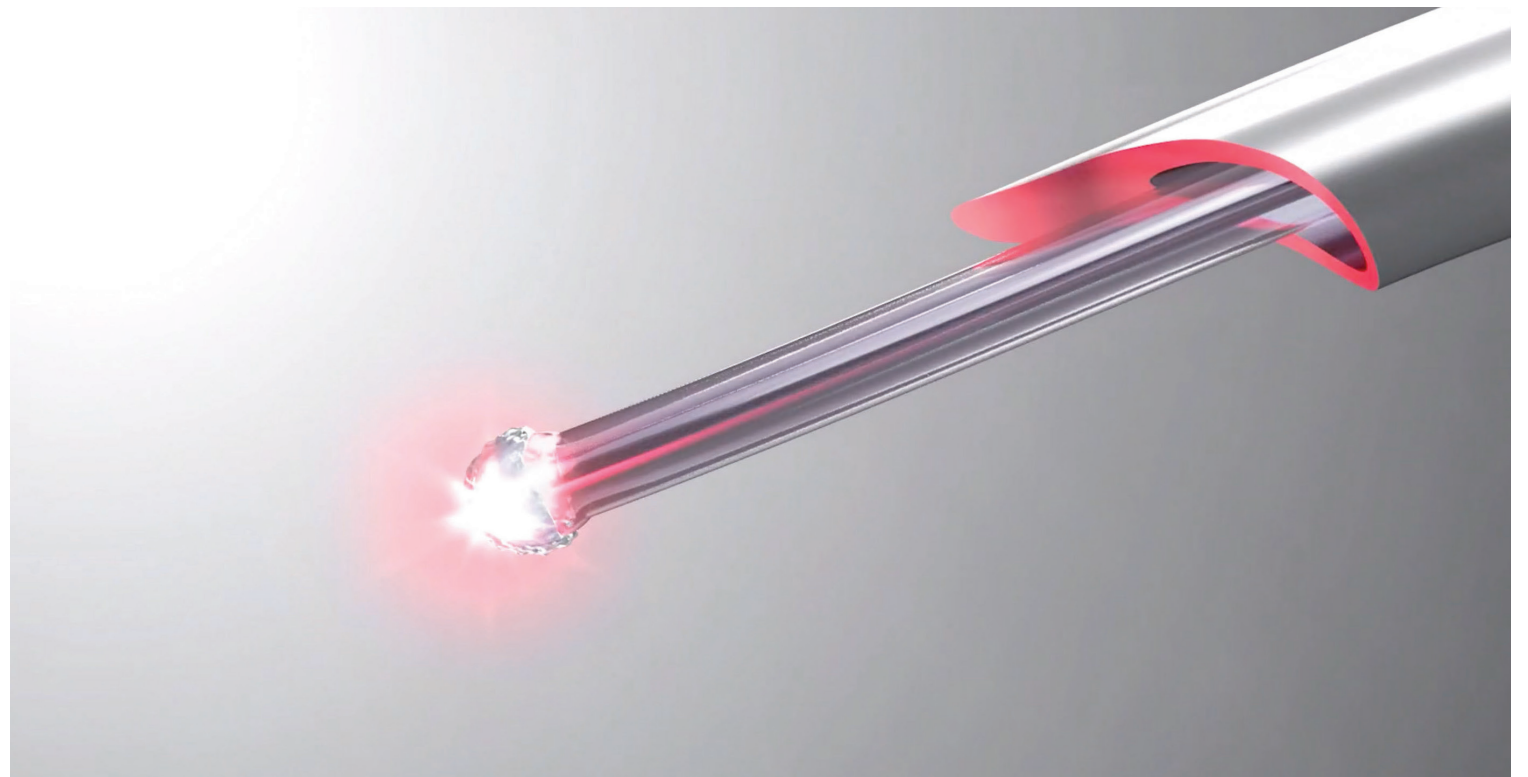
“In early-stage disease, before fibrosis has become unmanageable, dilation of the canal can improve outflow. Canaloplasty is a far better option for these patients than decades of eyedrops which – even if effective and well-tolerated – cannot interrupt meshwork fibrosis.”

“The iTrack Advance really is an advance – it’s not just a name.” The new iTrack canaloplasty device, known as **iTrack™ Advance**, has a number of advantageous features, including a spatulated cannula (which assists intubation of the microcatheter into the canal and can also be used to incise the trabecular meshwork tissue), and a slider that helps control

microcatheter movement. Moreover, the method has been significantly improved; previously, surgeons needed to make an incision, use forceps, apply a blade to open the meshwork, and then insert the microcatheter. With the **iTrack™ Advance**, these steps have been eliminated or simplified. After making the incision, the surgeon simply pushes the microcatheter through 360 degrees of the canal and back out again. Importantly, the illuminated tip of the microcatheter visually confirms its location as it traverses the canal – and this is a key point because, if we can continually track the passage of the device, we can ensure it doesn’t end up in the wrong place. As it is withdrawn from the canal, the **iTrack™ Advance** employs pressurized injection of hyaluronic acid (HA)-based OVD to stretch the inner canal wall, thereby clearing collapsed regions of the canal and opening collector channels. This also has the mechanism of stretching the trabecular meshwork, to create a more porous structure. Note, too, that **iTrack™ Advance** is designed to be equally suitable for both left- and right-handed surgeons.

In conclusion, canaloplasty is a safe and effective intervention suitable for a broad range of glaucoma patients, particularly early-stage cases. These patients can expect reductions in IOP and medication burden via canaloplasty-mediated restoration of natural outflow, without undue ocular trauma. The **iTrack™ Advance** is an excellent device for achieving these aims. From a surgeon’s perspective, it is a very easy and convenient technique. Finally, it’s a very efficient procedure – **iTrack™ Advance** is the MIGS equivalent of a hot rod!

Watch a panel of experts discuss the iTrack Advance and canaloplasty: <https://bit.ly/3BQRQme>



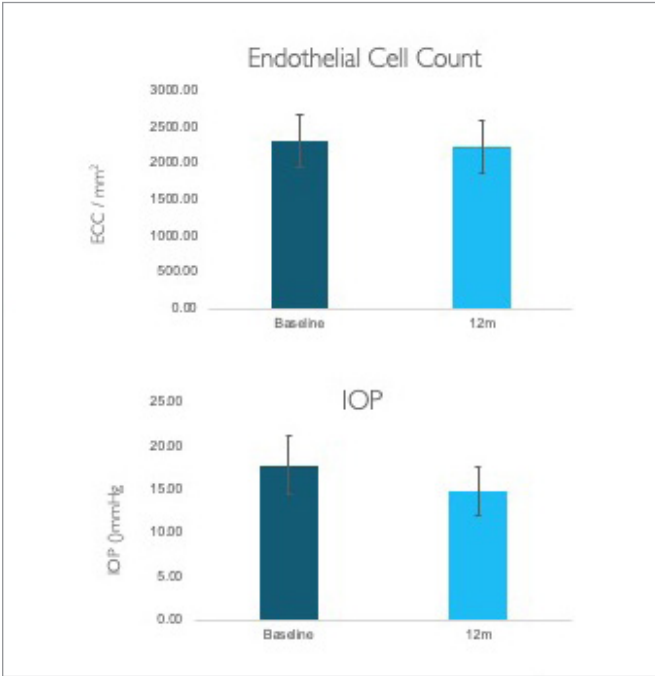
Canaloplasty: Maximal Impact, Minimal Trauma

How can you look after the corneal health of your glaucoma patients?

By David M. Lubeck, Director of Advanced Anterior Segment Surgery, Arbor Centers for Eye Care, Orland Park, Illinois, USA

Since the Cypass supraciliary stent was withdrawn from the market in 2018, we've become more aware that the corneal endothelium can be damaged by even minimally invasive procedures. Nevertheless, we need to remember that anti-proliferative medications, preservative-containing eye drops, and glaucoma surgical procedures also have deleterious effects on the corneal endothelium, which is already compromised by the direct effects of elevated IOP. How can we mitigate endothelial cell loss (ECL) while effectively managing glaucoma? One factor under our control is choice of intervention. Ideal approaches minimize corneal trauma by i) avoiding stents and the associated potential mechanical damage to the endothelium; (ii) restoring natural outflow, thus avoiding endothelial trauma associated with artificial flow at isolated points; and iii) preserving meshwork, thus eliminating post-operative

inflammation and consequent endothelial trauma. Canaloplasty meet these criteria; for example, canaloplasty works with patient physiology, not against it, to restore aqueous outflow. Not only does it preserve the trabecular meshwork, but it aims to reestablish the function of the trabecular meshwork and, in doing so, help to reset the physiological mechanism of the trabecular meshwork in counteracting IOP fluctuations and elevations. Furthermore, it is an implant-free procedure. But does canaloplasty really result in improved effectiveness and safety outcomes? To answer this question, we instigated a study assessing ECL as a measure of canaloplasty safety using the iTrack canaloplasty device (Nova Eye Medical) the results of which will be presented at ASCRS 2023. The results were extremely striking; mean ECL was only 100 cells per milliliter at 12 months, while mean IOP was reduced by around 20 percent. We found no significant difference in ECL between mild-to-moderate and severe cases (around 3.5 percent loss in each). Similarly, mean IOP dropped from ~17.9 to ~15 mmHg in mild-to-moderate patients, and from ~17.5 to 14.4 mmHg in severe cases (12-month readings); IOP reduction was more significant in uncontrolled than controlled cases. Thus, our study shows that canaloplasty does not cause significant ECL. By contrast, trabeculectomy ECL rates are 9.5–28 percent at 1–2 years (1, 2, 3, 4, 5), and tube shunt ECL rates are 8–24.6 percent at 2–4 years (6, 7, 8, 9). Further, when we compare our study results against other MIGS devices and



Eyes (Patients)	77 (46)
Age	74.5 ± 6.6
Baseline ECC	2303.9 ± 360 /mm²
12 month ECC	2230.4 ± 356 /mm²
Baseline IOP	17.8 ± 3.3 mmHg
12 month IOP	14.8 ± 2.9 mmHg

procedures, canaloplasty presents as one of the safety MIGS available. Indeed, canaloplasty is probably the safest MIGS procedure available in terms of corneal preservation. In conclusion, canaloplasty is a gentler, safer alternative to stent-based or ablative glaucoma surgery, being expressly designed to restore the conventional outflow pathway without inserting implants or otherwise damaging tissue. This comprehensive approach targets all outflow resistance sites, including collector channel ostia, and it is suitable for both phakic and pseudophakic mild-to-moderate cases. The iTrack has been in use in the USA since 2008. More recently, the **iTrack™ Advance** has been introduced as the next generation canaloplasty device, combining the tried and trusted iTrack microcatheter with an easy-to-use handpiece. The **iTrack™ Advance** is easily adopted by anyone interested in angle surgery. Furthermore, it is a very efficient procedure – advancing through 360 degrees of Schlemm's canal is easily achieved. I recommend that surgeons consider **iTrack™ Advance** when planning management of glaucoma patients.

Canaloplasty and endothelial cell preservation: study overview

- Prospective multicenter registry study in USA, commenced 2019
- Inclusion criteria: patients undergoing ab interno canaloplasty combined with cataract surgery
- Outcome measures: endothelial cell density and loss, IOP, medications, BVCA, visual field, optic nerve measured with OCT
- Methods: specular microscopy at 0, 6, 12, and 24 months
- Recruitment: 46 patients, 77 eyes (mean age 74.5)
- Controls: age-matched patients undergoing cataract surgery only

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Beyond the Meshwork

Using canaloplasty to restore outflow at every level

By Shamil Patel, Eye Physicians and Surgeons of Arizona, Glendale, Arizona, USA

Given that outflow resistance occurs throughout the outflow system – namely, trabecular meshwork (TM), Schlemm’s canal, and collector channels – optimal interventions should address all three levels of this continuum. Does canaloplasty measure up to this challenge? Let’s examine each region in turn.

In POAG eyes, up to 75 percent of outflow resistance may be associated with the meshwork, especially the juxtacanalicular portion – a consequence of accumulated extracellular matrix proteins, which fibrose the meshwork and compromise its function (1, 2, 3, 4, 5, 6). Because this fibrosis is irreversible, we must intervene early if we are to preserve meshwork function. At the same time, we should minimize damage to the ocular anatomy to retain options for future interventions. The **iTrack™ Advance** employs pressurized viscodilation to remove debris from the meshwork while stretching trabecular

“Wherever possible, the first step should be to restore and rejuvenate tissue – and that means canaloplasty.”

beams and creating micro perforations that connect to the anterior chamber. Furthermore, **iTrack™ Advance** allows delivery of hyaluronic acid (HA) to the meshwork during viscodilation, which may support meshwork physiology (see below); combining surgery and pharmacology in this way testifies to the sophisticated approach of Nova Eye Medical. In short, canaloplasty is an ideal meshwork treatment because it restores physiological outflow without trauma.

Schlemm’s canal may account for up to 50 percent of

“I now consider early intervention with canaloplasty for almost any glaucoma patient– it is the obvious choice for outflow restoration. And that’s why it is generating so much excitement in the field of glaucoma.”

outflow resistance. Age-related weakening of the ciliary muscle decreases tension in the meshwork, which drives IOP-driven meshwork herniation into canal and collector channels. Consequences include smaller canal lumens, canal collapse, and reduced outflow (7, 8). Timely application of canaloplasty, however, can dilate the canal two- to three-fold, restoring outflow (9). Similarly, up to 90 percent of collector channels in POAG eyes are obstructed by meshwork herniations (10), but canaloplasty can efficiently dilate collector channels and remove herniations, thereby reducing outflow resistance.

In summary, approaches that disrupt TM, for example by ablation, also disturb meshwork-mediated IOP regulation. Furthermore, these invasive approaches often preclude future interventions. Similarly, devices intended to alter outflow patterns may be associated with endothelial problems. The new **iTrack™ Advance** canaloplasty device not only avoids the above issues, but is also very easy to adopt. The incision is quite similar to the Hydrus approach; when you get it right, the device advances very quickly, with no significant resistance. Maintaining contact between the tip of the cannula and the meshwork is easy, perhaps because the narrow incision restricts device movement, and the bulbous tip of the microcatheter permits comprehensive herniation clearance without causing damage.

I now consider early intervention with canaloplasty for almost any glaucoma patient– it is the obvious choice for outflow restoration. And that’s why it is generating so much excitement in the field of glaucoma.

Trabecular meshwork physiology

- Normal TM:
 - Endothelium regulates HA levels
 - HA activates matrix metalloproteinases
 - Metalloproteinases clear extracellular matrix proteins
- Glaucomatous TM:
 - Low HA results in conversion of HA receptor CD44 to a form toxic to endothelial cells
 - ECL further compromises HA regulation
 - Poor HA regulation results in accumulation of extracellular matrix proteins and meshwork fibrosis
 - Meshwork fibrosis leads to inadequate IOP control

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Disclaimer: iTrack™ Advance has been cleared for the indication of fluid infusion and aspiration during surgery, and for catheterization and viscodilation of Schlemm's canal for the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma. iTrack™ Advance has a CE Mark (Conformité Européenne) for the treatment of open-angle glaucoma. iTrack™ Advance is not available for use or sale in the USA.