ORIGINAL RESEARCH

# The Impact of Interventional Glaucoma with and without Cataract Surgery in Early Open-angle Glaucoma: 24-month Results with a New Canaloplasty Device

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## Abstract

**Purpose:** To investigate outcomes of interventional glaucoma therapy with canaloplasty in early glaucoma.

**Methods:** This retrospective single-center study included patients with mild-to-moderate open-angle glaucoma (OAG) who underwent Ab-interno canaloplasty (ABiC) with iTrack Advance (Nova Eye Medical) with or without combined phacoemulsification. Primary outcomes were intraocular pressure (IOP) and glaucoma medications at 12-, 24-month, and last follow-up (LFU) visits. Secondary outcomes included the proportion of eyes reaching target IOPs, requiring no medications, and achieving success as per American Academy of Ophthalmology (AAO) criteria.

**Results:** Ninety-eight eyes (60 patients, mean age: 71.4 ± 7.0 years) were included, with a mean follow-up of 19.0 ± 5.7 months. Mean IOP (mm Hg) reduced from 18.3 ± 4.3 at baseline ($n = 98$) to 14.2 ± 3.1 at 12 months ($n = 93$), 14.1 ± 3.3 at 24 months ($n = 67$), and 14.6 ± 3.2 at LFU ($p < 0.001$). Mean medications decreased from 1.9 ± 0.8 at baseline to 0.1 ± 0.5 at both 12 and 24 months, and 0.1 ± 0.4 at LFU, respectively ($p < 0.001$). At LFU, 89% of eyes achieved IOP ≤ 18 mm Hg, while 95% were medication-free compared to none at baseline. Success rates following combined canaloplasty and phacoemulsification ($n = 90$) and stand-alone canaloplasty ($n = 8$) were 81% and 50%, respectively. The average visual field mean deviation at baseline was −1.90 ± 2.8 dB, which remained stable at LFU ($p = 0.439$). The postoperative complication was a transient IOP spike (≥30 mm Hg) in two eyes. No sight-threatening complications were observed, and no additional glaucoma procedures were required.

**Conclusion:** Interventional treatment with iTrack Advance canaloplasty in early OAG showed high safety and achieved IOP control, with near-elimination of medication dependence sustained over 24 months postoperatively.

**Clinical significance:** iTrack Advance canaloplasty provides sustained IOP control and strong medication reduction in the medium term.


**Keywords:** Ab-interno canaloplasty, Glaucoma, iTrack Advance, Minimally invasive glaucoma surgery.

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## Introduction

Glaucoma is a neurodegenerative disorder involving gradual retinal ganglion cell loss, which, if untreated, culminates in irreversible blindness. The traditional treatment strategy involves a 'medications first' approach, starting with topical ocular hypotensives and gradually escalating to invasive surgery based on disease progression.[1] While effective, this algorithm involves long-term treatment with daily eyedrops, often multiple, leading to complications including ocular surface toxicity,[2] ongoing costs,[3] impaired quality of life (QOL),[4] and poor treatment adherence, increasing the risk of vision loss.[5,6] Due to these significant drawbacks, there have been growing calls to replace the traditional treatment approach with a paradigm of earlier procedural intervention via minimally invasive therapies, called "interventional glaucoma" (IG).

In this new treatment paradigm, minimally invasive glaucoma surgery (MIGS) plays a vital role. MIGS was originally designed to bridge the gap between medications and filtration surgery due to their ability to achieve intraocular pressure (IOP) control with minimal tissue destruction and a high safety profile,[7] providing a safer alternative to invasive surgery, especially in mild-to-moderate glaucoma. Accordingly, IG therapy is based on the proven benefits of MIGS, making an argument for minimally invasive surgical intervention earlier in the disease course across all glaucoma stages, even before attempting maximal tolerated medical therapy. This would proactively prevent disease progression, while eliminating the limitations of medication use and avoiding or delaying invasive surgery.[8]

Cataract extraction offers a natural juncture to address glaucoma proactively, and leveraging the timing of cataract surgery to introduce minimally invasive glaucoma procedures aligns with the goals of IG therapy without necessitating additional surgical interventions.

Canaloplasty via an ab-interno technique with the iTrack exemplifies the benefits of MIGS in IG therapy due to its effective yet minimally invasive action. Adhesions and trabecular meshwork (TM) herniations in Schlemm's canal (SC) are mechanically cleared by 360° circumnavigation of a flexible microcatheter, while pressurized viscodilation flushes open the canal and collector channels, and

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creates microperforations in the TM into the anterior chamber.[9,10] Thus, the physiological aqueous outflow pathway is restored while preserving healthy ocular tissue, making it an optimal early surgical intervention in the IG treatment paradigm. Studies have demonstrated the significant safety and efficacy of IOP and medication reduction with canaloplasty in a range of glaucoma severities,[11–13] in patients with preoperative low and high IOP,[14–16] in primary and secondary open-angle glaucoma (OAG) as well as angle closure glaucoma,[17,18] and performed with or without concomitant phacoemulsification.[12,19] The iTrack Advance (Nova Eye Medical, Fremont, USA) represents the next generation of the iTrack canaloplasty device, which combines the clinically validated iTrack microcatheter with an ergonomic all-in-one handpiece.[20] The design enhancements of the iTrack Advance enable single-handed microcatheter manipulation with greater control compared to canaloplasty with the iTrack, which requires microforceps to maneuver the microcatheter through SC. The iTrack Advance has been CE marked and cleared by the Food and Drug Administration (FDA) for use in OAG with or without concomitant cataract surgery. This study reports the outcomes of IG therapy with iTrack Advance canaloplasty in patients with mild-to-moderate OAG over 24 months of follow-up.

# Methods

## Study Design

This was a retrospective, single-center, consecutive case series of patients who underwent canaloplasty with the iTrack Advance from March 2022 to March 2024 at the Augencentrum Köln-Porz, Germany. The study abided by the tenets of the Declaration of Helsinki, and patients provided written informed consent. Since the study involved a retrospective review of medical records, institutional ethical approval was not sought for the study.

Inclusion criteria were age ≥ 18 years, a diagnosis of primary open-angle glaucoma (POAG) or pseudoexfoliative glaucoma (PEX), mild-to-moderate disease (visual field mean deviation ≥ −12 dB),[21] canaloplasty surgery as a stand-alone procedure or combined with cataract surgery, and a minimum follow-up of 12 months. Exclusion criteria were anterior chamber angle abnormalities (peripheral anterior synechiae, narrow angles, angle closure), neovascular, uveitic, or traumatic glaucoma, visual acuity (VA) worse than 0.8 logMAR, ocular comorbidities, previous glaucoma surgery (including ab-externo canaloplasty and argon laser trabeculoplasty (ALT)), and mixed MIGS procedures. Patients with prior selective laser trabeculoplasty (SLT) were not excluded.

In eyes with coexisting cataract, canaloplasty was combined with phacoemulsification and intraocular (IOL) lens implantation.

Preoperatively, patients underwent a full ophthalmological examination, including VA, visual field (VF), IOP (Goldmann applanation tonometry), endothelial cell count (ECC), retinal nerve fiber layer (RNFL) thickness measured with optical coherence tomography (OCT), gonioscopy, slit lamp, and fundus examinations. IOP (measured by multiple observers) and glaucoma medications were documented at 1 day, and at 1, 3, 6, 9, 12, 18, 24, and 30 months postoperatively. VA, VF, ECC, and RNFL thickness were recorded at the last available follow-up (LFU).

## Device

The iTrack Advance combines the original iTrack microcatheter with an ergonomic all-in-one handpiece.[20] The 220-µm microcatheter has an illuminated fiber optic tip for continuous location feedback, while the handpiece consists of a spatulated cannula to create an opening in the TM, a rotatable nozzle to precisely angle the cannula, and an actuator to advance or retract the microcatheter via a sliding motion. The microcatheter is connected to the ViscoInjector™ system, which delivers 2.5 µL of ophthalmic viscosurgical device (OVD) per turn of the leadscrew-driven plunger (or per "click"), allowing OVD to be precisely titrated during viscodilation.

## Surgical Procedure

All surgeries were performed by an experienced surgeon under local anesthesia (peribulbar injection of carbocaine and lidocaine). If combined with cataract surgery, phacoemulsification was performed prior to canaloplasty.

The cannula of the iTrack Advance was passed into the anterior chamber through a clear corneal incision. Under gonioscopic visualization, TM was incised using the spatulated cannula tip, and the microcatheter was inserted into SC by sliding the actuator forward. The movement of the microcatheter through the canal was monitored by tracking its illuminated tip. After 360° catheterization, the microcatheter was slowly withdrawn by sliding the actuator backwards. For all patients, pressurized viscodilation was performed both during microcatheter advancement (intubation) and retraction (withdrawal) ("double viscodilation"). Healon Pro (Johnson and Johnson) was injected into the SC at an average rate of 24 clicks per eye, delivering an average volume of 60 µL over the entire canal.

At the end of surgery, intracameral cefuroxime was administered. Postoperatively, patients applied topical dexamethasone eight times daily for 1 week, followed by QID application with weekly tapering for 4 weeks.

## Data Collection

Primary efficacy outcomes were IOP and the number of glaucoma medications at 12-, 24-month, and LFU timepoints. Visits occurring between 18 and 30 months after surgery were aggregated under the 24-month timepoint. Secondary outcomes were the proportion of eyes at LFU with IOP ≤ 18 and ≤15 mm Hg, IOP ≤ 18 and ≤15 mm Hg on no medications, ≥20% IOP reduction from baseline, proportion of medication-free eyes, and proportion of eyes achieving surgical success. Surgical success was defined according to the American Academy of Ophthalmology (AAO) criteria:[22]

- For stand-alone canaloplasty: IOP ≤ 21 mm Hg and ≥20% IOP reduction without medication increase and without additional laser or glaucoma surgery, no loss of light perception, and no hypotony.
- For canaloplasty combined with cataract surgery: Reduction of ≥1 medication without IOP increase, or IOP ≤ 21 mm Hg and ≥20% IOP reduction without medication increase and without additional laser or glaucoma surgery, no loss of light perception, and no hypotony.

Safety outcomes were intraoperative and postoperative complications, and change in VA, VF mean deviation (VF MD), ECC, and RNFL thickness at LFU compared to baseline.

## Statistical Analysis

Descriptive statistics were used for continuous variables. Categorical variables were summarized as counts and percentages. Comparisons between timepoints were made using a mixed effects model accounting for inter-eye correlations.[23] Subgroups were compared using Mann–Whitney U test. A $p$-value of $< 0.05$ was

considered statistically significant. Graphs and tables followed the guidelines on design and reporting glaucoma trials.[24]

## Results

This study included 98 eyes of 60 patients (31 female and 29 male; mean age: 71.4 ± 7.0 years). Mean follow-up duration was 19.0 ± 5.7 months.

### Efficacy Outcomes

Intraocular pressure and medications were significantly reduced from baseline at all timepoints ($p < 0.001$) (Table 1 and Figs 1 and 2). Mean IOP was 18.3 ± 4.3 mm Hg at baseline, reducing to 14.2 ± 3.1 mm Hg at 12 months ($n = 93$), 14.1 ± 3.3 mm Hg at 24 months ($n = 67$), and 14.6 ± 3.2 mm Hg at LFU ($n = 98$). Mean baseline medication burden was 1.9 ± 0.8, which reduced to 0.1 ± 0.5 at 12 months and remained stable at 24 months and at LFU ($p < 0.001$).

Table 2 shows outcomes in different patient subgroups.

Intraocular pressure and medications were significantly reduced following canaloplasty performed with phacoemulsification ($p < 0.001$; $n = 90$) or as a stand-alone procedure ($p = 0.035$ and $p < 0.001$, respectively; $n = 8$). While medications were higher at baseline and LFU in the stand-alone surgery group ($p = 0.002$ and $p = 0.008$), IOP values were comparable (baseline: $p = 0.124$; LFU: $p = 0.601$).

In both PEX ($n = 15$) and POAG ($n = 83$) eyes, IOP and medications were significantly reduced from baseline ($p < 0.001$), with comparable values at baseline ($p = 0.097$ and $p = 0.763$) and LFU ($p = 0.385$ and $p = 0.816$).

In eyes with a lower preoperative IOP (≤18 mm Hg; $n = 51$), the mean baseline IOP (mm Hg) of 15.1 ± 2.4 was decreased further to 13.4 ± 3.1 at LFU ($p < 0.001$), with a concomitant decrease in medications from 1.9 ± 0.9 to 0.0 ± 0.3 ($p < 0.001$). Forty-nine eyes (96%) maintained IOP ≤ 18 mm Hg with a mean medication use of almost zero medications. In eyes with a higher preoperative IOP (>18 mm Hg; $n = 47$), mean baseline IOP was 21.7 ± 3.1, which reduced to 15.9 ± 2.7 at LFU ($p < 0.001$) along with a reduction in medications from 1.8 ± 0.8 to 0.2 ± 0.5 ($p < 0.001$). In those eyes, 38 eyes (81%) achieved IOP≤ 18 mm Hg with substantially reduced medication usage.

Table 3 shows the results of the proportional analyses at LFU.

IOP was reduced by ≥20% in 53 eyes (54%) (as indicated by the points below the dashed line in Fig. 1A). IOP ≤ 18 mm Hg was achieved in 87 eyes (89%) (points on or below the horizontal line in Fig. 1A), of which 83 eyes (85%) required no medications. Ninety-three eyes (95%) were medication-free compared to none at baseline (Fig. 2A). Success by the AAO criteria for MIGS was achieved in 50% of the eyes in the stand-alone group and in 81% of eyes in the combined group.

### Consistent 24-month Follow-up Cohort

Forty-one eyes had consistent follow-up at the 24- and 30-month timepoints. IOP and medications were significantly reduced from 18.4 ± 4.6 and 1.8 ± 0.9 at baseline to 14.2 ± 3.0 and 0.2 ± 0.6 at LFU ($p < 0.001$; mean: 25 months).

### Safety Outcomes

Intraoperatively, phacoemulsification-related complication of posterior capsule rupture was observed in two eyes; following sulcus IOL implantation with optic capture, canaloplasty was completed successfully in both eyes. Canaloplasty-related complications comprised incomplete catheterization in two eyes. In one eye, SC stenosis limited catheterization to 120°, while in the other, catheter deviation into a collector channel restricted advancement—in the latter case, the deviation was identified intraoperatively by the illuminated microcatheter tip, prompting cessation of advancement.

Postoperatively, both eyes showed immediate postoperative IOP spikes with IOP ≥ 30 mm Hg, likely due to residual OVD in the anterior chamber. Both resolved spontaneously on the next visit (resolved with no glaucoma medications in one eye and with the existing topical medication in the other).

Corrected distance VA (logMAR) improved from 0.19 ± 0.14 preoperatively ($n = 97$) to 0.03 ± 0.08 at last follow-up ($n = 94$, $p < 0.001$). No eyes lost any lines of CDVA.

Visual field mean deviation was unchanged from baseline to LFU: –1.90 ± 2.8 dB ($n = 83$) to –1.60 ± 2.2 dB ($n = 72$) ($p = 0.439$). VF preoperative and postoperative data were available for 61 eyes: 3 eyes showed an improvement greater than 4 dB, 58 eyes remained within ±4 dB of baseline, and no eyes deteriorated VF more than 4 dB.

Endothelial cell count was obtained in a subset of 37 eyes postoperatively. ECC was slightly decreased from baseline to LFU: 2357.3 ± 389.5 cells/mm$^2$ to 2249.8 ± 403.1 cells/mm$^2$ (–4.6%; $p = 0.003$).

Retinal nerve fiber layer thickness was obtained in 48 eyes postoperatively, in which the parameter remained stable from baseline to LFU: 76.8 ± 12.6 to 76.6 ± 13.2 µm ($p = 0.921$).

There were no instances of Descemetolysis, hyphema, or any severe sight-threatening complications intraoperatively or postoperatively. No additional glaucoma procedures were required in any eye.

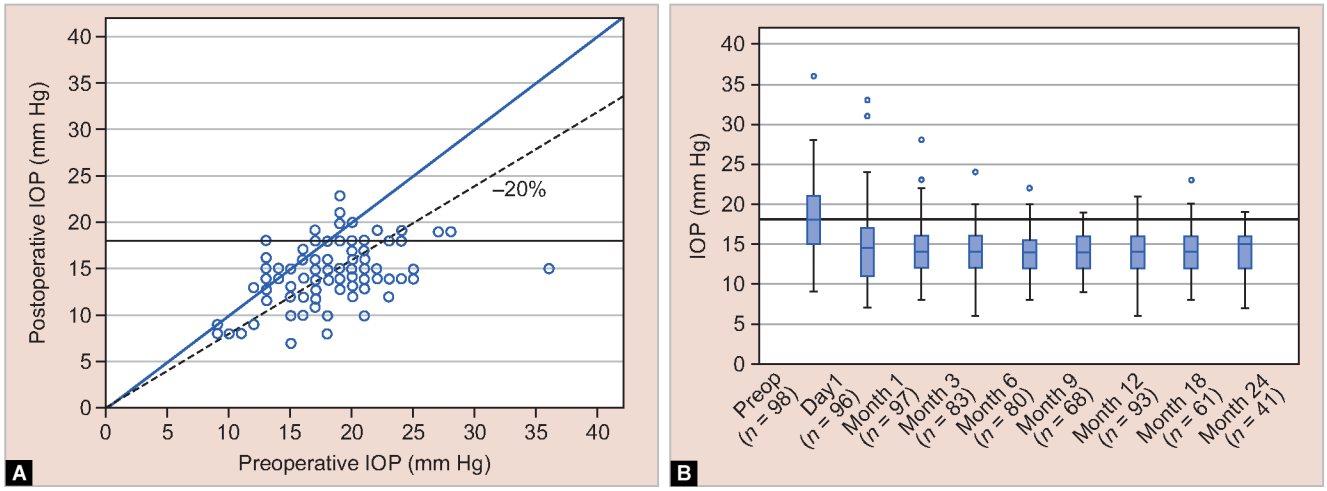
## Discussion

With growing recognition that a medications-first approach is not without the consequences of prolonged pharmacotherapy—ranging from ocular surface disease and adherence challenges to reduced QOL—there is increasing support for a shift toward IG

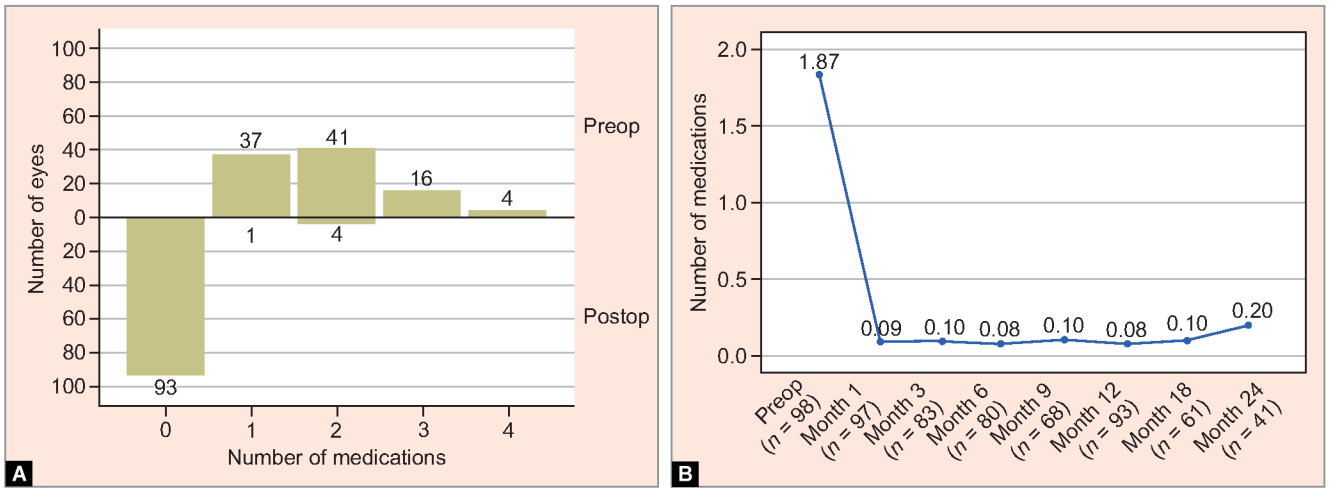
**Table 1:** Intraocular pressure (IOP) (in mm Hg) and number of glaucoma medications for all eyes at all timepoints. Data presented as mean ± SD. Last follow-up mean: 19.0 ± 5.7 months. *p*-values calculated using mixed effects model

| | *Baseline (n = 98)* | *Month 12 (n = 93)* | *Month 24† (n = 67)* | *Last follow-up (n = 98)* |
|---|---|---|---|---|
| IOP (mm Hg) | 18.3 ± 4.3 | 14.2 ± 3.1 | 14.1 ± 3.3 | 14.6 ± 3.2 |
| Range | 9–36 | 6–21 | 7–23 | 7–23 |
| *p*-value vs baseline | – | < 0.001* | < 0.001* | < 0.001* |
| Medications (no.) | 1.87 ± 0.83 | 0.08 ± 0.47 | 0.12 ± 0.48 | 0.09 ± 0.41 |
| Range | 1–4 | 0–4 | 0–2 | 0–2 |
| *p*-value vs baseline | – | < 0.001* | < 0.001* | < 0.001* |

*Statistically significant; †Includes 18M and 30M data




**Figs 1A and B:** (A) IOP scatterplot of data at baseline and last follow-up (LFU mean: 19.0 ± 5.7 months). Points on or below the dashed line indicate eyes with ≥20% reduction in IOP from baseline; (B) Box plot of IOP outcomes at all timepoints. Horizontal line represents 18 mm Hg




**Figs 2A and B:** (A) Bar diagram of medications outcomes at baseline and last follow-up (LFU); (B) Line graph of medication outcomes at all timepoints

treatment. Within this framework, continued refinement of MIGS technologies is essential to improve patient outcomes through safer, tissue-preserving procedural interventions earlier in the disease course. To the author's knowledge, this is the first study reporting outcomes with the iTrack Advance at 24 months. IOP and medications were significantly reduced with a high safety profile in patients with early OAG, with sustained efficacy over 24 months postoperatively. Reductions were significant in eyes that underwent stand-alone canaloplasty and canaloplasty combined with phacoemulsification, in both POAG and PEX eyes, and in eyes with baseline IOP ≤ 18 mm Hg and >18 mm Hg.

Baseline IOP (mm Hg) of 18.3 ± 4.3 was reduced to 14.2 ± 3.1 at 12 months (−4.1 mm Hg), 14.1 ± 3.3 at 24 months (−4.2 mm Hg), and 14.6 ± 3.2 at LFU (−3.7 mm Hg) ($p < 0.001$). Studies on the previous-generation iTrack have reported IOP reductions of 6.5–9.4 mm Hg at 12–24 months in OAG; it must be noted that baseline IOP was higher in these studies (from 20.0 ± 4.9 to 23.6 ± 7.4 mm Hg).[13,25,26] In a literature review, iTrack canaloplasty was found to reduce IOP by 6.2 mm Hg and 6.0 mm Hg at 12 and 24 months, respectively, from a weighted mean baseline of 20.0 ± 2.5 mm Hg.[27] Compared to the current study, the mean baseline IOP of the pooled studies was higher, which could explain the higher IOP reduction observed. It is worth noting that 52% of eyes in the current study already had IOP controlled (≤18 mm Hg) on topical medications preoperatively. Despite this, iTrack Advance canaloplasty successfully achieved IOP control to well below the safe level of 18 mm Hg to prevent disease progression, as found in the Advanced Glaucoma Intervention Study,[28] and maintained this control throughout the follow-up period. Notably, the final mean IOP of approximately 14 mm Hg in the current study is comparable to that observed with bleb-forming MIGS, such as the PreserFlo MicroShunt[29] and nonpenetrating surgery such as ab-externo canaloplasty[30] at similar timepoints.

More importantly, significant and sustained IOP control was achieved with near elimination of medications. Mean medication usage reduced from 1.9 ± 0.8 at baseline to near zero at all follow-ups, decreasing by 1.8 medications to 0.1 ± 0.5 at 12 months, then remaining stable at that level at 24 months and LFU ($p < 0.001$). Therefore, canaloplasty fulfilled the main aim of IG therapy in the study cohort, which was to achieve or maintain IOP control while reducing or eliminating medication dependence, thereby avoiding the adherence and QOL issues associated with glaucoma medications. These results are consistent with previous iTrack studies at similar follow-up durations reporting mean reductions of 1.1–2.3 medications.[13,25,26] Review of pooled iTrack outcomes

**Table 2:** Intraocular pressure (IOP) (in mm Hg) and number of glaucoma medications for all eyes by group at baseline and at last follow-up (LFU mean: 19.0 ± 5.7 months). Data presented as mean ± SD. *p*-values calculated between timepoints using mixed effects model; *p*-values between groups calculated using Mann–Whitney *U* test

| | *IOP (mm Hg)* | | | *Medications (No.)* | | |
|---|---|---|---|---|---|---|
| | *Baseline* | *Postoperative* | *p-value* | *Baseline* | *Postoperative* | *p-value* |
| By procedure | | | | | | |
| Combined (*n* = 90) | 18.0 ± 3.9 | 14.6 ± 3.3 | < 0.001* | 1.78 ± 0.76 | 0.06 ± 0.31 | < 0.001* |
| Stand-alone (*n* = 8) | 21.5 ± 6.9 | 15.1 ± 1.6 | 0.035* | 2.88 ± 0.99 | 0.50 ± 0.93 | < 0.001* |
| *p*-value between groups | 0.124 | 0.601 | | 0.002* | 0.008* | |
| By glaucoma type | | | | | | |
| PEX (*n* = 15) | 19.8 ± 4.7 | 15.1 ± 3.3 | < 0.001* | 1.80 ± 0.77 | 0.07 ± 0.26 | < 0.001* |
| POAG (*n* = 83) | 18.0 ± 4.2 | 14.5 ± 3.2 | < 0.001* | 1.88 ± 0.85 | 0.10 ± 0.43 | < 0.001* |
| *p*-value between groups | 0.097 | 0.385 | | 0.763 | 0.816 | |
| By preoperative IOP | | | | | | |
| Low IOP ≤ 18 mm Hg (*n* = 51) | 15.1 ± 2.4 | 13.4 ± 3.1 | < 0.001* | 1.88 ± 0.89 | 0.04 ± 0.28 | < 0.001* |
| High IOP >18 mm Hg (*n* = 47) | 21.7 ± 3.1 | 15.9 ± 2.7 | < 0.001* | 1.85 ± 0.78 | 0.15 ± 0.51 | < 0.001* |
| *p*-value between groups | < 0.001* | < 0.001* | | 0.985 | 0.148 | |

*Statistically significant; IOP, intraocular pressure; PEX, pseudoexfoliative glaucoma; POAG, primary open-angle glaucoma

**Table 3:** Success of all eyes (*n* = 98) at baseline and last follow-up (LFU mean: 19.0 ± 5.7 months). Data presented as *N* (%)

| *Parameter* | *Baseline* | *Postoperative* |
|---|---|---|
| Eyes with IOP ≤ 15 mm Hg | 26 (27%) | 63 (64%) |
| Eyes with IOP ≤ 18 mm Hg | 51 (52%) | 87 (89%) |
| Eyes with IOP ≤ 15 mm Hg on no medications | 0 (0%) | 61 (62%) |
| Eyes with IOP ≤ 18 mm Hg on no medications | 0 (0%) | 83 (85%) |
| Eyes with at least 20% IOP reduction | – | 53 (54%) |
| Eyes that are medication-free | 0 (0%) | 93 (95%) |
| Success by AAO criteria (combined with cataract) | – | 73 (81%) |
| Success by AAO criteria (stand-alone) | – | 4 (50%) |

IOP, intraocular pressure; AAO, American Academy of Ophthalmology

showed comparable mean reductions of 1.7 and 1.6 medications at 12 and 24 months, respectively.[27]

Notably, the results showed not only a mean reduction in medications, but also a consistent elimination of medication usage, with almost all eyes (95%) becoming medication-free at LFU compared to none at baseline. The majority of eyes (89%) achieved IOP ≤ 18 mm Hg, while 85% achieved IOP ≤ 18 mm Hg with no medications. Previously, consistent outcomes following iTrack canaloplasty have been reported by Khaimi et al., when efficacy was evaluated on an eye-by-eye basis, 89% of eyes achieved IOP reduction and 86% of eyes achieved IOP ≤18 mm Hg at 12 months.[14]

The current study also observed consistency in success outcomes. Success definitions in this study followed the AAO guidelines, which specify IOP reduction criteria for success in stand-alone MIGS and alternate medication or IOP reduction criteria for success in MIGS combined with cataract surgery,[22] reflecting the importance of reducing medications as a treatment goal for MIGS procedures. The minimal clinically important difference (MCID) for surgical success at 2 years recommended by the AAO is 50% for stand-alone MIGS and 65% for MIGS combined with cataract surgery. In this study, success was observed in 81% of eyes following canaloplasty with phacoemulsification.

iTrack Advance canaloplasty reduced IOP and medications irrespective of whether IOP was controlled at baseline. In eyes with higher preop IOP (>18 mm Hg), IOP was controlled to 15.9 ± 2.7 with an accompanying reduction in medications to a mean of 0.2 ± 0.5 ($p < 0.001$). In eyes with lower preoperative IOP (≤18 mm Hg), IOP control was improved further from 15.1 ± 2.4 at baseline to 13.4 ± 3.1 at LFU, with a concomitant reduction of mean medication burden to near zero (0.0 ± 0.3; $p < 0.001$). This is consistent with previous studies on iTrack canaloplasty in uncontrolled OAG[14] and controlled OAG.[15] Efficacy outcomes in the current study showed no statistically significant differences between PEX and POAG eyes, consistent with previous studies by the author.[18] IOP and medications were significantly reduced following canaloplasty combined with phacoemulsification ($p < 0.001$) as well as stand-alone canaloplasty ($p = 0.035$ and $p < 0.001$). While cataract surgery itself can also reduce IOP,[31] IOP at baseline and LFU were found to show no statistically significant differences between stand-alone and combined surgery groups ($p = 0.124$ and $p = 0.601$), suggesting canaloplasty efficacy independent of the influence of cataract surgery. Previous studies on the iTrack have observed comparable efficacy between stand-alone canaloplasty and canaloplasty with concomitant phacoemulsification.[11,12,19]

The iTrack Advance showed a high safety profile. The only canaloplasty-related intraoperative complication was incomplete catheterization in two eyes. In general, obstructions in SC can be addressed by injecting OVD to clear the distal lumen or by reversing the direction of catheterization. Importantly, in one eye, misdirection of the microcatheter into a collector channel was promptly identified by the illuminated tip of the microcatheter, underscoring the safety advantage of continuous visual feedback during the procedure.

Persistent obstructions could indicate scarring or anatomical anomalies of SC.[32] Studies on ab-externo canaloplasty have observed incomplete catheterization in 3–20% cases,[33,34] while studies on ab-interno canaloplasty (ABiC) have not reported this complication. It would be interesting to investigate any associations

between the extent of catheterization and canaloplasty outcomes, correlated with outflow pathway imaging, in future studies.

The most common postoperative complication was transient IOP spike in two eyes. This is consistent with the most frequently reported complications associated with the iTrack device, which include IOP spikes treatable with medications.[27] Hyphema or microhyphema is another known complication of canaloplasty; however, no cases were reported in this cohort, perhaps courtesy of an active hyphema prevention strategy where the anterior chamber was kept pressurized until hydration of paracentesis at the end of the procedure. Serious sight-threatening complications such as endophthalmitis, hypotony maculopathy, or suprachoroidal hemorrhage were not observed in this study, confirming the minimally invasive profile of canaloplasty compared to filtration surgeries. VF MD and RNFL thickness remained stable from baseline to LFU, showing that there was no disease progression. Mean ECC decreased by 4.6% from baseline to LFU; this can be attributed to combined canaloplasty and phacoemulsification performed in the majority of eyes (92%), since mean ECC loss of 4–27% can be observed following phacoemulsification, depending on surgical technique.[35,36] No additional glaucoma procedures were required, consistent with the low reoperation rates observed with the iTrack in the literature.[12,14,18]

The limitations of this study include its retrospective design, lack of randomization, and possible selection bias due to the inclusion of subjects from a single center. The standalone canaloplasty cohort was small compared to the combined surgery group, and it is possible that statistically significant differences in IOP reduction could be observed between both groups with larger sample sizes. Further prospective studies with larger comparison groups and longer follow-up durations will be required to establish the long-term efficacy of the iTrack Advance.

## Conclusion

In patients with early OAG, interventional treatment with canaloplasty performed via an ab-interno technique with the iTrack Advance showed a high safety profile and achieved IOP control alongside near-elimination of medication dependence up to 24 months postoperatively. Elimination of medication use was noted consistently across the cohort, with 95% of eyes becoming medication-free at the latest visit. Eyes undergoing combined canaloplasty and cataract surgery demonstrated a particularly high rate of surgical success, supporting the integration of MIGS at the time of phacoemulsification to maximize the benefit of early glaucoma intervention and minimize the number of surgical interventions. Eyes with higher preop IOP achieved IOP control on reduced medications, while eyes with lower preop IOP maintained and improved IOP control while also reducing medication use substantially.

### Clinical Significance

This is the first study to provide data on a new canaloplasty device (iTrack Advance). We performed ab-interno canaloplasty in early open-angle glaucoma, showing durable intraocular pressure reduction and near-elimination of medication dependence. The procedure demonstrated a strong safety profile with stable visual function. Notably, canaloplasty performed with phacoemulsification achieved high success rates. These findings support the integration of MIGS at the time of cataract surgery in appropriate patients.

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## Disclosures

The authors are consultants to Nova Eye Medical.

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