



24-Month iTrack™ Data Demonstrate Real-World Efficacy of Canaloplasty as Both a Standalone and Combined MIGS Procedure

Fremont, California, 20 April 2021 – Nova Eye Medical Limited, a medical technology company committed to advanced ophthalmic treatment technologies and devices, is pleased to report the peer-reviewed publication of 24-month data for its proprietary iTrack™ minimally invasive glaucoma surgery (MIGS) technology.

Published in *Clinical Ophthalmology*, the retrospective case series by Mark J. Gallardo, MD, El Paso Eye Surgeons, USA, assessed the efficacy and safety outcomes of the iTrack™ ab-interno canaloplasty procedure in a cohort of 60 POAG eyes (53 patients) over a 24-month period.¹ The case series compared the efficacy outcomes of iTrack™ performed as a standalone procedure (iTrack-alone) versus in combination with cataract surgery (iTrack+phaco). It also assessed the ability of iTrack™ to reduce both IOP and medication burden in cases of mild-to-moderate and severe glaucoma.

Dr. Gallardo is a highly regarded glaucoma and MIGS expert and was one of the original pioneers of the ab-interno canaloplasty procedure. He is widely published in the peer-reviewed medical literature and is the principal investigator for multiple ongoing clinical trials in the fields of cataract and glaucoma surgery, including the MAGIC multi-center randomized clinical trial (NCT04769453), which will assess a number of factors that impact clinical outcomes of the ab-interno canaloplasty procedure. The MAGIC Trial will include a comparison of the Company's proprietary iTrack™ canaloplasty microcatheter with the OMNI® Surgical System (Sight Sciences).

“Dr. Gallardo is arguably one of the industry's most experienced MIGS surgeons. He has an intimate understanding of the pathology of the outflow system and how the various MIGS procedures interact with this system in order to reduce outflow resistance. Dr. Gallardo has been an advocate for the tissue-sparing, implant-free mechanism of iTrack™ since the very beginning and we commend him on the publication of this 24-month data,” commented Joe Bankovich, President of Nova Eye Medical.

“In the case series, iTrack™ achieved an average reduction in mean IOP of 30%, irrespective of whether ab-interno canaloplasty was performed as a standalone procedure or in combination with cataract surgery. Further, this result was noted across all grades of glaucoma severity, speaking to the significant utility of iTrack™ in clinical practice,” added Mr. Bankovich.



iTrack™ Effective as A Standalone Procedure

iTrack™ demonstrated a significant and stable reduction in IOP of more than 30% from baseline in both the iTrack-alone and iTrack+phaco groups at 24 months. In the iTrack-alone group, IOP reduced by 34% from 21.6±5.7 mmHg to 13.8±3.1mmHg. Patients in the iTrack+phaco group achieved a similar reduction in IOP, with mean IOP falling by 31% from 19.8±3.9 mmHg at baseline to 13.2±2.1 mmHg at the 24-month visit (P=0.512). Refer to Table 1.

The reduction in medication use was statistically significant in both groups at 24 months, decreasing from 3.0±0.7 to 2.1±1.3 in the iTrack-alone group, and from 2.5±1.1 to 1.3±1.2 in the iTrack+phaco group (P<0.001). Refer to Table 1. It is worth noting that patients in the iTrack-alone group had a significantly higher baseline medication burden.

According to Dr. Gallardo, iTrack™ ab-interno canaloplasty is a key player in this MIGS treatment armamentarium.

“When iTrack™ is an available treatment option, it is usually one of my first choices because it rejuvenates the natural outflow system while sparing both the angle and the tissue from permanent adulteration. 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,” said Dr. Gallardo.

Table 1: iTrack™ Efficacy Outcomes at 24 Months – Standalone Versus Combined with Cataract Surgery

	iTrack, All Eyes	iTrack-alone	iTrack+phaco
Baseline Mean IOP (mmHg)	20.0 ± 4.9	21.6 ± 5.7	19.8 ± 3.9
Postop Mean IOP at 24 Months (mmHg)	13.5 ± 2.6	13.8 ± 3.1	13.2 ± 2.1
Baseline Mean Number of Medications (n)	2.8 ± 0.9	3.0 ± 0.7	2.5 ± 1.1
Postop Mean Number of Medications at 24 Months (n)	1.7 ± 1.3	2.1 ± 1.3	1.3 ± 1.2



iTrack™ Effective Across All Grades of Glaucoma Severity

The 24-month case series also assessed the efficacy outcomes of iTrack™ in mild-to-moderate glaucoma as compared to severe glaucoma. Of the 60 eyes included, glaucoma severity was categorized as mild (38%), moderate (17%) and severe (38%). iTrack™ achieved similar reductions in mean IOP at the 24-month mark for cases of mild-to-moderate and severe glaucoma at 33% and 34%, respectively. Refer to Table 2.

While MIGS procedures were first introduced to fill the treatment gap in the surgical management of mild-to-moderate glaucoma, according to Dr. Gallardo the ability to also deploy iTrack™ ab-interno canaloplasty in cases of severe glaucoma offer significant utility in offering the potential to defer or eliminate the need for invasive surgical options.

“Given its benign nature, the iTrack™ canaloplasty microcatheter can be used earlier in the disease process to reduce IOP and alleviate the burden of compliance and side effects associated with medications. It can also be used in patients with more advanced disease who have previously undergone non-ablative MIGS procedures like trabecular micro-bypass, should they suffer from an elevated IOP or an unwanted dosage of topical glaucoma medications.”

Table 2: iTrack™ Efficacy Outcomes at 24 Months – Mild-to-Moderate Glaucoma Versus Severe Glaucoma

	Mild-Moderate	Severe
Baseline Mean IOP (mmHg)	20.8 ± 5.3	20.7 ± 4.4
Postop Mean IOP at 24 Months (mmHg)	13.5 ± 2.5	13.2 ± 2.8
Baseline Mean Medications (n)	2.6 ± 1.1	2.9 ± 0.7
Postop Mean Medications at 24 Months (n)	1.4 ± 1.3	2.1 ± 1.2

The paper, “24-Month Efficacy of Viscodilation of Schlemm’s Canal and the Distal Outflow System with iTrack Ab-Interno Canaloplasty for the Treatment of Primary Open-Angle Glaucoma”, can be accessed via the Dove Press website [here](#)

1. Gallardo, MJ. 24-Month Efficacy of Viscodilation of Schlemm’s Canal and the Distal Outflow System with iTrack Ab-Interno Canaloplasty for the Treatment of Primary Open-Angle Glaucoma. *Clinical Ophthalmology* 2021;15: 1591–1599.

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ABOUT NOVA EYE MEDICAL

Nova Eye Medical Limited is a medical technology company that develops, manufactures and sells a portfolio of proprietary ophthalmic treatment technologies and devices. Used by eye surgeons in more than 100 countries globally, these technologies include iTrack™ minimally invasive glaucoma surgery (MIGS), a consumable surgical device that restores the eye's natural outflow pathway to lower pressure inside the eye and to eliminate patient reliance on anti-glaucoma medications for mild-moderate glaucoma. The Molteno3® glaucoma drainage device platform is designed to enhance surgical utility and optimize clinical outcomes for long-term IOP control in cases of severe or complex glaucoma. It also offers the benefit of a simplified and faster surgical profile. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by a global network of more than 50 distribution partners. Manufacturing facilities are located in Fremont, California and Dunedin, New Zealand.

For additional information about Nova Eye Medical and its technologies, please visit: www.nova-eye.com

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