



6-Year Data Published in Journal of Glaucoma Demonstrates Effective, Sustained Reduction in Intraocular Pressure with iTrack™ Canaloplasty

California, USA, 1st November 2023 – Nova Eye Medical Limited, a medical technology company committed to advanced ophthalmic treatment technologies and devices, is pleased to announce the peer review publication of 6-year data in *Journal of Glaucoma* that demonstrates the long-term effectiveness and safety profile of canaloplasty using the Company's proprietary iTrack™ canaloplasty microcatheter.

Conducted at the Augencentrum Köln-Porz, Köln, Germany, by Prof. Norbert Koerber and Dr. Simon Ondrejka, the retrospective, single-center study recruited 27 eyes to undergo canaloplasty performed via an ab interno surgical technique. Canaloplasty was performed as a standalone procedure, or in combination with cataract surgery, across cases of primary open angle glaucoma (POAG) and pseudoexfoliative (PEX) glaucoma.

Importantly, this is the longest follow-up for ab interno canaloplasty available in the published literature.

At the 6-year follow up, mean IOP was reduced significantly from 19.9 ± 5.2 mmHg at baseline to 14.6 ± 3.3 mmHg ($p < 0.001$). There was no statistically significant difference between standalone canaloplasty procedures and those combined with cataract surgery. Additionally, the mean number of medications were reduced by more than 50% from 1.9 ± 1 to 0.9 ± 0.9 ($p = 0.005$) at six years.

An internationally renowned glaucoma surgeon and one of the pioneers of the canaloplasty procedure, Prof. Koerber has been using the iTrack™ canaloplasty microcatheter in clinical practice for nearly two decades.

“I was an early adopter of canaloplasty. I have always been a big believer in its stent-free, tissue sparing approach. Unlike other MIGS procedures which stent or remove diseased tissue in the conventional outflow pathway, canaloplasty allows me to work with patient physiology to re-establish the natural flow of aqueous throughout the entire conventional outflow pathway, including the collector channels.”



“Based on the results I have observed with ab interno canaloplasty, I believe that its comprehensive approach, which targets and treats the trabecular meshwork, Schlemm’s canal and collector channels, contributes to its sustained duration of effect, as demonstrated by our recently published 6-year data.”

According to Nova Eye Medical Chief Commercial Officer, Kate Hunt, this study will help to continue to drive increased surgeon uptake of canaloplasty.

“The results from doctors Koerber and Ondrejka point to a sustained reduction in IOP following canaloplasty in cases of mild-moderate glaucoma. Not only will this data help to build advocacy for canaloplasty in the glaucoma treatment paradigm, but it will also support the commercial roll-out of our next generation iTrack™ technology, iTrack™ Advance,” commented Ms. Hunt.

“This data, while being limited by its small population, does provide compelling real-world evidence in support of working with patient physiology, rather than removing it or stenting it, to deliver effective, long-term reduction in IOP,” added Ms. Hunt.

Paper reference:

“6-Year Efficacy and Safety of iTrack Ab-interno Canaloplasty as a Standalone Procedure and Combined with Cataract Surgery in Primary Open-Angle and Pseudoexfoliative Glaucoma”

Koerber, Norbert MD, PhD, FEBO; Ondrejka, Simon MD

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https://journals.lww.com/glaucomajournal/abstract/9900/6_year_efficacy_and_safety_of_itrack_ab_interno.285.aspx

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 the iTrack™ portfolio of canaloplasty devices for the treatment of glaucoma. The Company also manufactures and sells the proprietary Molteno3® glaucoma drainage device for the treatment of severe or complex glaucoma. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by sales offices in Adelaide, Australia and Berlin, Germany, and a global network of more than 50 distribution partners. Manufacturing facilities are located in Fremont, California and Dunedin, New Zealand.

ABOUT CANALOPLASTY

First introduced in 2008, canaloplasty is a surgical treatment for glaucoma that targets the main sites of outflow resistance in the conventional outflow pathway: the trabecular meshwork, Schlemm's canal, and the distal collector channels. Based on the same principles as angioplasty, a flexible microcatheter is cannulated 360 degrees around Schlemm's canal during the procedure to manually break and remove blockages. Next, viscoelastic fluid is injected into Schlemm's canal as the microcatheter is withdrawn to dilate the distal outflow system and to improve the function of the trabecular meshwork.

The iTrack™ Advance canaloplasty device has a US Food and Drug Administration (FDA) 510(k) and CE Mark (Conformité Européenne) for the treatment of open-angle glaucoma.

The iTrack™ Advance canaloplasty device 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.

For additional information about the iTrack™ Advance, including safety information, please visit: <https://itrack-advance.com>

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