Peer Review Publication of 36- and 48-month Canaloplasty Data Demonstrates Sustained Reduction in Intraocular Pressure with iTrack™

Fremont, California, May 5th, 2022 – Nova Eye Medical Limited, a medical technology company committed to advanced ophthalmic treatment technologies and devices, is pleased to report the recent publication of three investigator-led, retrospective case series which evaluated the long-term **effectiveness of canaloplasty in patients with open-angle glaucoma (OAG) over 36- and 48-month periods, and in post-keratoplasty patients**.

Performed by leading MIGS surgeon Mark J. Gallardo, MD, El Paso Eye Surgeons, Texas, USA and published in the March 2022 issue of *Ophthalmology Glaucoma*, a journal collaboration between the American Academy of Ophthalmology and the American Glaucoma Society, the 36-month case series demonstrated a significant reduction in mean IOP as compared to baseline, along with a significant decrease in the mean number of glaucoma medications, following canaloplasty performed with the Company's proprietary iTrack™ device.

Performed by Prof. Norbert Koerber and Dr. Simon Ondrejka, glaucoma surgeons at the Augencentrum Köln-Porz, Germany and published in the April 2022 issue of *Klinische Monatsblätter für Augenheilkunde,* the 48-month case series demonstrated a significant reduction in mean IOP as compared to baseline, along with a significant decrease in the mean number of glaucoma medications, following canaloplasty performed with the Company's proprietary iTrack™ device. An internationally renowned glaucoma surgeon and one of the pioneers of the canaloplasty procedure, Prof. Koerber has been using the iTrack™ device in clinical practice for nearly two decades.

Together, these publications raise awareness of canaloplasty, a procedure that acts on all aspects of the conventional outflow system (trabecular meshwork, Schlemm's canal and collector channels) and its role in the glaucoma treatment paradigm.

Forty-four (44) eyes of 44 patients were included in the Gallardo study. Twenty-three (23) eyes underwent iTrack™ as a standalone procedure (iTrack-alone group) and 21 eyes iTrack™ in combination with cataract surgery (iTrack+phaco group). There was a statistically significant reduction in IOP and number of medications between baseline and all post-operative visits ($p<0.0001$) either when canaloplasty was performed as a standalone procedure or in combination with cataract surgery. Refer to Table 1 for summary of results.

The study by Prof. Koerber corroborated the findings of Dr. Gallardo, demonstrating that the comparable reduction in IOP and medications is **sustained 48 months postoperatively**. Indeed, performed as a standalone procedure (n=4) or in conjunction with cataract surgery (n=23), canaloplasty demonstrated a sustained reduction in IOP and in medication burden 4 years after surgery. Refer to Table 2 for summary of results.

In Prof. Koerber's cohort, approximately half of the eyes in the case series (n=13) were defined as controlled with medications at baseline, with an IOP equal to or less than 18 mmHg. In these eyes, canaloplasty was performed to reduce patient reliance on medications due to intolerance or non-compliance, while maintaining IOP within target range. The mean number of medications for this group was 1.77 ±0.93 at baseline and reduced by more than 50% to 0.83 ±0.98 at 48 months. In addition, 50% of these eyes were on zero medications at the 48-month follow-up.

Mean ± SD (n) of IOP and number of medications (Gallardo, 2022)			
	All Eyes	*iTrack+Phaco*	*iTrack-Alone*
IOP (mmHg)			
baseline	20.5 ± 5.1 (44)	20.0 ± 3.9	20.9 ± 6.1
12 mos	13.3 ± 2.1 (43)	13.0 ± 1.8	13.7 ± 2.3
24 mos	13.1 ± 2.4 (36)	12.4 ± 1.5	13.8 ± 2.9
36 mos	13.3 ± 2.1 (44)	13.5 ± 2.2	13.2 ± 2.1
Medications			
baseline	2.8 ± 0.9 (44)	2.5 ± 1.1	3.0 ± 0.5
12 mos	1.1 ± 1.1 (43)	0.8 ± 1.0	1.5 ± 1.2
24 mos	1.0 ± 1.1 (39)	0.8 ± 1.0	1.3 ± 1.1
36 mos	1.3 ± 1.3 (44)	1.0 ± 1.2	1.6 ± 1.4

Table 1. *36-month results of eyes treated with iTrack alone, iTrack combined with phacoemulsification, and all eyes considered together (Gallardo, 2022).*

Mean ± SD (n) of IOP and number of medications (Koerber & Ondrejka, 2022)	
	All Eyes
IOP (mmHg)	
baseline	19.85 ± 5.2 (27)
12 mos	14.98 ± 2.6 (26)
24 mos	15.58 ± 3.3 (25)
36 mos	14.71 ± 3.8 (21)
48 mos	14.56 ±3.0 (18)
Medications	
baseline	1.93 ± 1.0 (27)
12 mos	0.30 ± 0.54 (27)
24 mos	0.40 ± 0.64 (25)
36 mos	0.80 ± 0.83 (20)
48 mos	0.89 ± 0.83 (18)

Table 2. *48-month results of all eyes considered together (Koerber & Ondrejka, 2022).*

Led by Dr. Kamran Riaz, a corneal specialist from the Dean McGee Eye Institute, University of Oklahoma, USA, and Dr. Mahmoud A. Khaimi, a novel study on canaloplasty performed in 17 eyes post-keratoplasty has shed new light on the safety profile of the procedure in patients with fragile corneas. Published in the March 2022 issue of *Cornea*, this case series demonstrated that canaloplasty performed via an

ab-interno surgical technique effectively reduced IOP and maintained graft survivability in post-keratoplasty eyes for at least 12 months. The reduction in IOP observed in post-keratoplasty eyes is consistent with the results in non-keratoplasty eyes, as per the published literature. While a variety of MIGS procedures may be considered in post-keratoplasty patients, the study demonstrated that canaloplasty is associated with a low risk of complications in this unique and challenging patient population.

The frequency of surgical and post-surgical complications reported was low in all studies, with no serious adverse events recorded.

According to Dr. Gallardo, canaloplasty is typically one of his first treatment choices because it rejuvenates the natural outflow system while preserving the eye tissue for subsequent treatments. “When it comes to treating mild-moderate glaucoma patients, my preference is to first manipulate the patient’s natural system to its maximum potential. Canaloplasty allows me to do this. Rather than bypass diseased parts of the outflow system, or remove disease tissue, canaloplasty combines a mechanical process of microcatheterization, followed by the delivery of high-molecular weight viscoelastic via a process described as viscodilation, to improve the overall patency and structure of the system, improving outflow facility. It also removes physical blockages within the outflow pathway. In short, it aims to get the patient’s natural system working again and, in most of my patients, it has proven to be a highly effective option over the long-term.”

According to Prof. Koerber, canaloplasty via an ab-interno surgical technique offers utility in the earlier stages of the glaucoma disease process in reducing patient reliance on medications. “Glaucoma medications are associated with compliance issues. Canaloplasty is an ideal procedure as it mediates medication reduction with minimal risk and does not preclude future surgical approaches. It is a procedure that is safe and easily combined with other interventions, which is why there is growing interest in the

procedure among cataract surgeons and other ophthalmologists, in addition to glaucoma surgeons," commented Prof. Koerber.

According to Dr. Riaz, performing surgery for glaucoma in a patient with a compromised cornea requires a delicate balance: there is a need to safely and effectively reduce the IOP without impacting the health of the cornea. "The optimal glaucoma procedure for patients with corneal disease or previous corneal surgery is one that effectively lowers IOP without causing unwanted inflammation, corneal damage, and corneal decompensation. With canaloplasty we can effectively improve physiologic outflow rather than opening up one or more isolated points of drainage that might create a potentially damaging preferential outflow pathway. Additionally, no device is left behind in the eye, so there is nothing to touch and mechanically damage the cornea during or after the procedure. Based on my experience, canaloplasty with iTrack can be safely performed in patients with corneal disease and even previous PK."

(Images, pictured from left: Dr. Gallardo; Prof. Koerber; Dr. Riaz)

References:
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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 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.

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

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.

Canaloplasty is typically performed using either of the following two surgical techniques:

- Performed via an ab-interno surgical technique, canaloplasty is a highly effective treatment option for cases of mild-moderate glaucoma. It typically reduces intraocular pressure (IOP) to the low teens. It has also been observed to reduce patient dependence on medications. The ab-interno surgical technique is an implant-free, tissue-sparing procedure that preserves future treatment options.
- Performed via an ab-externo surgical technique, canaloplasty is a highly effective treatment option for patients with severe glaucoma that overcomes the risks and discomfort associated with traditional glaucoma surgery. With over 100,000 procedures performed to date, clinical studies show that canaloplasty has an excellent safety profile, with minimal post-operative follow-up, fast recovery time, and infrequent intra-operative and postoperative complications.

ABOUT THE iTRACK™ PORTFOLIO

Nova Eye Medical (formerly iScience Interventional) pioneered the canaloplasty market with the launch of the world's first canaloplasty device, *iTrack*™, in 2008. Since then, more than 100,000 canaloplasty procedures have been performed with the *iTrack*™ device, cementing its role in the treatment of glaucoma both as a standalone procedure and in combination with cataract surgery. Launched in 2022, the *iTrack*™ *Advance* leverages the proprietary features of the original *iTrack*™ device but incorporates a new handheld injector and custom-designed cannula.

iTrack™ *Advance has a CE Mark (Conformité Européenne) for the treatment of open-angle glaucoma and is currently available in selected markets in Europe and the Asia Pacific. iTrack*™ *Advance is not available for use or sale in the USA. The iTrack*™ *Advance is indicated for 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.*

iTrack™ *has a CE Mark (Conformité Européenne) and US Food and Drug Administration (FDA) 510(k) # K080067 for the treatment of open-angle glaucoma. 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. The iTrack*™ *canaloplasty microcatheter is currently not 510(k) cleared for use with the ab-interno technique in the United States.*

For additional information about the iTrack™ portfolio, including safety information, please visit: https://nova-eye.com