



Prospective Case Series Data for iTrack™ to be Presented at the European Glaucoma Society (EGS) 2020 Meeting

Fremont, California, 12 December 2020 – Nova Eye Medical Limited, a medical technology company committed to advanced ophthalmic treatment technologies and devices, is pleased to report the presentation of prospective clinical data in support of the Company's proprietary iTrack™ canaloplasty microcatheter technology at the European Glaucoma Society (EGS) meeting, December 12-13, 2020.

Professor Marek Rekas from the Military Institute of Medicine, Ophthalmology Department, Warsaw, Poland, will present the 12-month results of a prospective comparative case series assessing the outcomes of three modifications of canaloplasty performed with the iTrack™ canaloplasty microcatheter, including: ab-externo canaloplasty (14 eyes), ab-interno canaloplasty (12 eyes) and mini-canaloplasty (14 eyes). All canaloplasty procedures were performed in combination with cataract surgery in cases of mild-moderate primary open-angle glaucoma (POAG).

An internationally renowned glaucoma surgeon, Professor Rekas has been performing canaloplasty with the iTrack™ canaloplasty microcatheter for more than 10 years and has developed a modification of the ab-externo canaloplasty procedure, known as mini-canaloplasty, which offers an improved risk-benefit ratio. Specifically, mini-canaloplasty utilizes smaller scleral flaps and eliminates the scleral lake (intrascleral reservoir), as compared to the ab-externo canaloplasty procedure.

Performed with the iTrack™ microcatheter, canaloplasty offers a highly versatile treatment option for adult patients with primary open-angle glaucoma (POAG) and is indicated in a wide variety of POAG types, including pigmentary glaucoma, pseudoexfoliation glaucoma and ocular hypertension. First introduced in 2005 via an ab-externo approach as an alternative to trabeculectomy, physician refinement of canaloplasty in recent years has seen the procedure performed via an ab-interno approach to preserve the conjunctiva and sclera, thus enabling it to be deployed earlier in the disease process.

According to the results at 12 months, there was no statistically significant difference in IOP between the three groups, with success rates of 93%, 92% and 86% in the ab-



externo canaloplasty, ab-interno canaloplasty and mini-canaloplasty groups respectively. Complete success defined as IOP \leq 18mmHg.

Mean pre-washout IOP was 16.4 ± 0.8 mmHg, 18.2 ± 0.5 mmHg and 17.8 ± 0.6 mmHg in the ab-externo canaloplasty, ab-interno canaloplasty and mini-canaloplasty groups respectively. At 12 months, mean IOP reduced to 13.5 ± 0.8 mmHg, 14.7 ± 0.8 mmHg and 14.6 ± 0.9 mmHg in the ab-externo canaloplasty, ab-interno canaloplasty and mini-canaloplasty groups respectively ($p = 0.254$, $p = 0.177$, $p = 0.039$ respectively).

The mean number of medications at baseline was 2.0 ± 0.3 , 2.0 ± 0.2 and 2.0 ± 0.4 in the ab-externo canaloplasty, ab-interno canaloplasty and mini-canaloplasty groups. At 12 months all medications were withdrawn, except for two patients (Patient 1: 4 medications after mini-canaloplasty; Patient 2: 3 medications after ab-interno canaloplasty). The most frequent complication was microhyphema and hyphema.

Based on the results, the study authors concluded that all three variants of canaloplasty were effective in patients with mild to moderate POAG, achieving an effective reduction in IOP with minimal complications.

Table 1: Efficacy Outcomes at 12 Months – Ab-Externo Canaloplasty, Ab-Interno Canaloplasty and Mini-Canaloplasty

	Group 1: Ab-Externo Canaloplasty (with cataract surgery)	Group 2: Ab-Interno Canaloplasty (with cataract surgery)	Group 3: Mini-Canaloplasty (with cataract surgery)
Baseline Mean IOP (mmHg)	16.4 ± 0.8	18.2 ± 0.5	17.8 ± 0.6
Postop Mean IOP (12 months) (mmHg)	13.5 ± 0.8	14.7 ± 0.8	14.6 ± 0.9
Success Rate (IOP \leq 18mmHg)	93%	92%	86%



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 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

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