



REACHING NEW DEPTHS with iTrack

MIGS has triggered a shift in the glaucoma paradigm, enabling surgical intervention that bridges the gap between medical management and invasive surgery. While much of the focus has been on stent-based procedures, Dr Nathan Kerr says surgeons should be excited by an entirely different approach by Australia's Nova Eye Medical.

It's easy to overlook the masterful design and impact of minimally invasive glaucoma surgery (MIGS) procedures available in the modern-day surgeon's armamentarium.

Available in Australia since 2014, the introduction of such technology has provided an entirely new field of interventional glaucoma therapies, promising better patient outcomes and an enhanced safety profile much earlier in the disease process.

MIGS of the trabecular micro-bypass stent variety account for most procedures performed locally today due to their longevity, safety, effectiveness, and greater accessibility through Medicare. But other procedures are beginning to cement their place.

The R&D underpinning these microscopic devices that work to improve aqueous outflow is quite remarkable when you consider they are among the smallest human medical implants known. The Glaukos iStent inject W measures 360 microns in depth and width, while the larger Ivantis Hydrus Microstent is just the size of an eyelash; each angle, outlet, material and coating of these scaffold-like structures serving a special purpose, along with sophisticated injector systems.

Another MIGS procedure featuring high levels of precision engineering – but with an entirely different approach – is the iTrack ab-interno canaloplasty microcatheter by Australian company Nova Eye Medical.

At merely 250 microns, the first-of-its-kind system is equivalent to several strands of hair, yet within that it contains an infusion pathway for the delivery of ophthalmic viscosurgical device (OVD) and an illuminated fibre optic tip to keep the surgeon informed of its position.

In a delicate balancing act, the system's internal guide wire is designed to provide just enough rigidity to push past occlusions in the Schlemm's canal, but also sufficient flexibility to avoid forging a new pathway into the collector channels or suprachoroidal space. And the system is capable of providing tactile feedback on the patency of the canal which, when combined with the ability to adjust the volume of OVD delivered, enables the surgeon to customise OVD delivery on an individual patient basis and thus optimise clinical outcomes.

Every element has been meticulously designed so that it impacts on all points of resistance in the trabecular meshwork, Schlemm's canal and the collector channels via a two-step process of catheterisation, followed by pressurised viscodilation.

Leading glaucoma surgeon Dr Nathan Kerr is among a handful of ophthalmologists performing iTrack in Australia. He believes the system's ability to address all potential points of blockage in the conventional outflow pathway makes it one of the most comprehensive MIGS procedure available. He hopes it will be more widely available to Australian surgeons soon.

"While safe and effective, stent procedures treat a focal area of the drainage system, and tend to only address upstream, more proximal areas of blockage, and don't always address the downstream collector channels," he explains.

"But the iTrack goes further by treating the entire drainage system, including all three areas of resistance to aqueous outflow. Not only addressing the trabecular meshwork, iTrack treats the entire 360 degrees of Schlemm's canal, helping to dilate it and break herniations. It also features pressurised viscodilation, which helps dilate Schlemm's canal, as well as the distal downstream collector channels which we think are important in glaucoma."

ITRACK IN AUSTRALIA

iTrack's mechanism of action has been built on the pioneering work of Professor Robert Stegmann (South Africa) and Dr Murray Johnstone (US) more than two decades ago. It was eventually cleared by the US Food and Drug Administration in 2008, and originally performed via an ab-externo approach. Later, through a process of physician-led refinement, it became the ab-interno procedure it remains today.

iTrack came to be Australian-owned after Adelaide company Ellex Medical Lasers acquired it from US-based iScience Interventional in 2014. The

company trades today as glaucoma-focussed Nova Eye Medical, following divestiture of the Ellex laser and ultrasound business last year.

Despite being an Australia-owned platform, iTrack has had limited uptake among local surgeons compared to counterparts in the US, Europe and Asia where it is routinely deployed.

Although it has the relevant regulatory approvals, the company believes this is partly due to a lack of reimbursement available for its system in Australia. But there is now a concerted effort to change this.

Its current focus is a Medicare Services Advisory Committee (MSAC) application regarding item number 42504. This current item for standalone MIGS only mentions trabecular micro-bypass stent surgery in its descriptor, excluding Nova Eye's microcatheter technology. Its application to alter the wording has reached the third and final stage of the MSAC process, and has the support of the Australian and New Zealand Glaucoma Society (ANZGS), Glaucoma Australia and The Australian Society of Ophthalmologists (ASO).

According to Nova Eye, the iTrack canaloplasty microcatheter meets the requirements of the combined-cataract surgery item 42705 – although this item number is also currently under MSAC review, with a view to harmonising its nomenclature in relation to item number 42504.

Kerr remains hopeful of public funding for iTrack so Australians can access what he describes as a world-leading therapy by a homegrown company.

"To me, there are no clinical limitations. It's an effective procedure, it can be done with or without cataract surgery, and can be performed across all stages of the disease spectrum from mild, moderate to severe glaucoma," he says.

"For surgeons who are comfortable with the skill of intraoperative gonioscopy and implanting a stent, inserting a catheter is a very similar skill with a manageable learning curve. It's also great you have 100% certainty that you're treating the target tissue because of the illuminated tip, whereas it can be challenging at times to ensure stents are correctly placed in Schlemm's canal."

After completing MIGS training under the world-renown ophthalmic surgeon Mr Keith Barton at Moorfields Eye Hospital in 2016, Kerr himself has performed thousands of cataract and stent-based procedures. He began implanting iTrack this year and, along with Sydney glaucoma specialist Dr Jason Cheng is gathering data on the degree of intraocular pressure (IOP) reduction, speed of recovery and subsequent medication dependence.

He says while stent procedures are safe and effective, he's found iTrack features other capabilities that are appealing to glaucoma surgeons.

Chief among those is safety. As an implant-free, complete tissue-sparing procedure, he says iTrack has demonstrated minimal endothelial cell loss (ECL). It's an important issue that cataract and glaucoma surgeons are acutely aware of after



Dr Nathan Kerr, glaucoma surgeon, Eye Surgery Associates and Centre for Eye Research Australia.

Alcon voluntarily withdrew its CyPass MicroStent – the first supraciliary stent – in 2018 due to ECL rates after five years.

"As cataract surgeons we are particularly careful of corneal safety and minimising endothelial cell damage. While the stent procedures are safe, I think the iTrack gives you the highest level of endothelial cell safety because there is no stent left behind," he says.

"A theory for ECL focuses on aqueous preferentially draining to one focal point, and that is one of the reasons we think traditional procedures like trabeculectomy and tube surgery can have high rates of endothelial cell loss. Potentially that could hold true for stents. Because the iTrack increases outflow over 360°, there is no preferential outflow. Preliminary interim 12-month data show iTrack has some of the lowest rates of ECL – under 5% - which is similar to cataract surgery alone. This is important, particularly as we treat younger patients and those who do not have cataracts."

While MIGS procedures, in general, defer the need for more invasive procedures like trabeculectomy and tube shunts, Kerr says the restorative, non-destructive nature of iTrack also helps preserve the angle and conjunctiva for future treatments if required.

"It allows all potential trabecular meshwork treatment options, including selective laser trabeculoplasty, a trabecular bypass stent, or a repeat procedure with iTrack. It also keeps open the opportunity for filtration procedures like XEN, PreserFlo, or trabeculectomy, so it's really nice that you aren't removing or damaging any of the trabecular meshwork or conjunctiva," he says.

IOP REDUCTION

Alongside the safety profile, IOP reduction and medication dependence are the other key

1999

Professor Robert Stegmann (Chairman of Ophthalmology, Medical University of South Africa) publishes seminal investigations for viscanalostomy, demonstrating dilation of Schlemm's canal and clearance of the collector channels.

2002

Dr Murray Johnstone publishes first systematic in vitro examination of the histologic effects of viscodilation of Schlemm's canal, relative to untreated controls.

2004

Canaloplasty is cleared by the US FDA for glaucoma.

2004

Development of prototype iTrack canaloplasty microcatheter. Data presented at the 2004 Annual Glaucoma Society meeting demonstrates increased diameter of Schlemm's canal from 150 to 300 microns.

2008

The first generation iTrack is launched by iScience Interventional.

2011

Dr Richard Lewis et al publish prospective, three-year, multi-centre ab-externo canaloplasty data with iTrack.

2014

Nova Eye Medical (formerly Ellex Medical Lasers) acquires iTrack technology portfolio from iScience Interventional.

2015

In a world first, canaloplasty is performed via an ab-interno approach with iTrack (Dr Mahmoud Khaimi, Dean McGee Eye Institute, University of Oklahoma).

2021

Nova Eye Medical commences "MAGIC" prospective, multi-centre ab-interno canaloplasty trial with the iTrack canaloplasty microcatheter.

performance indicators glaucoma surgeons look for in MIGS procedures.

Although it's never been tested in a head-to-head study, Kerr says iTrack offers substantial IOP reduction rates comparable to stent procedures.

In recent 24-month peer-reviewed data, published in *Clinical Ophthalmology* by US surgeon Dr Mark Gallardo, of El Paso Eye Surgeons, iTrack demonstrated a significant and stable reduction in IOP of more than 30% from baseline in both the iTrack-alone and iTrack+phaco (combined cataract) groups at 24 months.

In iTrack-alone, IOP reduced by 34% from 21.6±5.7 mmHg to 13.8±3.1mmHg. Patients in the iTrack+phaco group achieved a similar IOP reduction, with the mean 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). There were similar reductions in mean IOP at the 24-month mark for cases of mild-to-moderate and severe glaucoma at 33% and 34%, respectively.

The reduction in medication use was also 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).

Professor Maya Müller and colleagues in Germany recently published 24-month data showing not only did iTrack achieve a reduction in mean IOP from 20.24 ± 5.92 mmHg (n = 25) at baseline to 13.67 ± 2.15 mmHg (n = 21, p < 0.001), it also reduced glaucoma medication usage from 1.92 ± 1.04 medications at baseline to 0.05 ± 0.23 medications at 24 months – with 80% medication-free at the 24-month follow-up.

"Patients really do enjoy being medication-free," Kerr says. "Some are no longer having to put in multiple drops, multiple times during the day, their eyes feel more comfortable and they can see better if they've had MIGS with their cataract surgery."



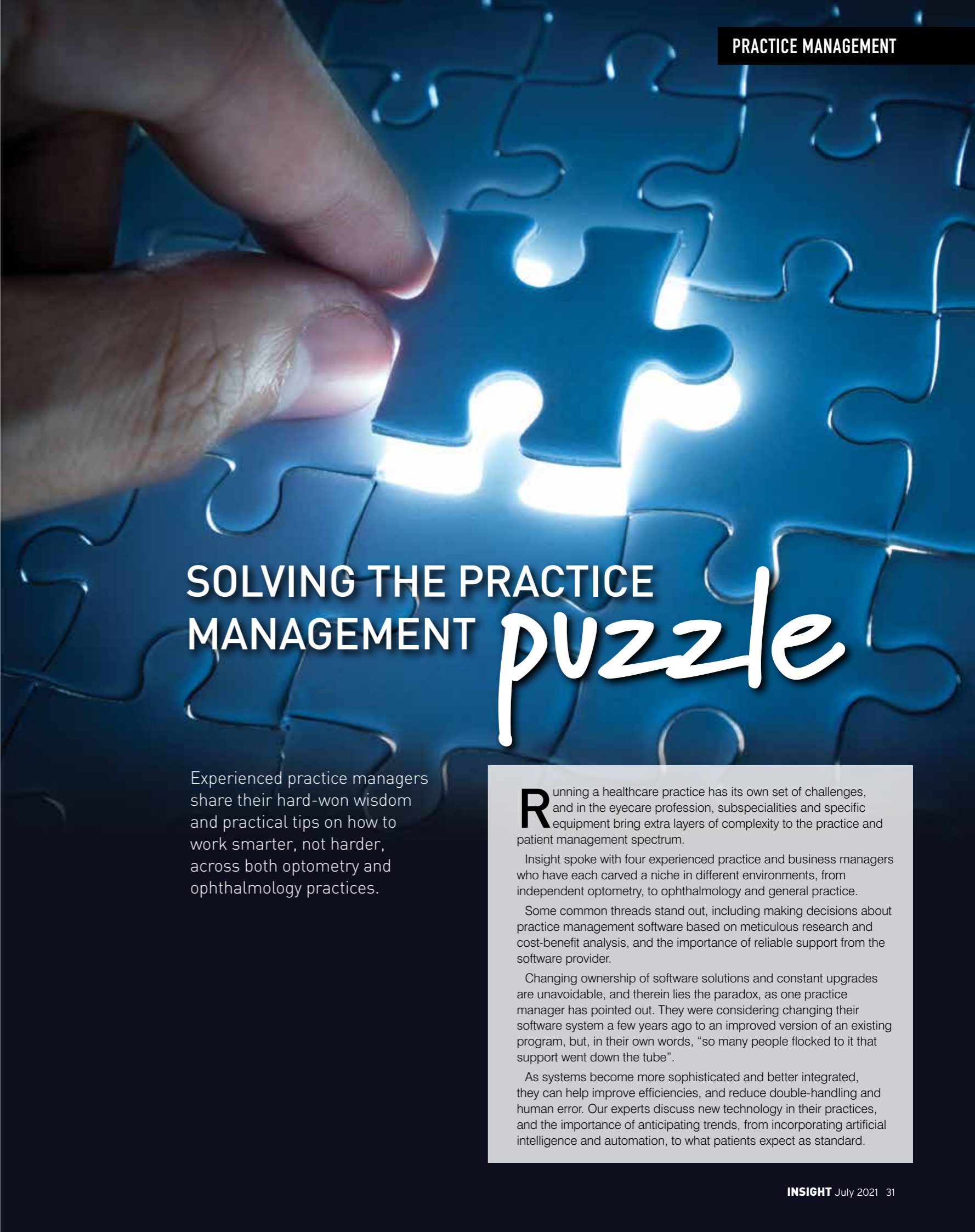
Dr Nathan Kerr performing the iTrack procedure. The red illuminated fibre optic tip can be seen at eight o'clock in the Schlemm's canal.

WHAT'S ON THE HORIZON?

Looking ahead, Kerr believes MIGS technology will continue to evolve, with real-time IOP sensor monitoring and drug release capabilities as potential next steps. He also expects the return of interventions that target the supraciliary route.

For Nova Eye, it recently revealed its R&D team is developing a next generation iTrack system, aimed at improving ease of use for surgeons.

Although further details of this program are firmly under wraps, it stated the iTrack design provides significant scope to broaden its clinical applications. What capabilities future iTrack models will harbour, only time will tell. ■



SOLVING THE PRACTICE MANAGEMENT puzzle

Experienced practice managers share their hard-won wisdom and practical tips on how to work smarter, not harder, across both optometry and ophthalmology practices.

Running a healthcare practice has its own set of challenges, and in the eyecare profession, subspecialties and specific equipment bring extra layers of complexity to the practice and patient management spectrum.

Insight spoke with four experienced practice and business managers who have each carved a niche in different environments, from independent optometry, to ophthalmology and general practice.

Some common threads stand out, including making decisions about practice management software based on meticulous research and cost-benefit analysis, and the importance of reliable support from the software provider.

Changing ownership of software solutions and constant upgrades are unavoidable, and therein lies the paradox, as one practice manager has pointed out. They were considering changing their software system a few years ago to an improved version of an existing program, but, in their own words, "so many people flocked to it that support went down the tube".

As systems become more sophisticated and better integrated, they can help improve efficiencies, and reduce double-handling and human error. Our experts discuss new technology in their practices, and the importance of anticipating trends, from incorporating artificial intelligence and automation, to what patients expect as standard.

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