

Glaucoma in a new era

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Recent advances in minimally-invasive glaucoma surgery

The rise of MIGS and the promise of drop-free IOP-lowering treatment with less risk

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A string of recent innovations have seen a rise in the development of glaucoma drainage devices, namely MIGS.

Variously referred to as 'minimally' or 'micro' invasive glaucoma surgery, MIGS devices are now in the spotlight as a viable and less-invasive option than penetrating glaucoma surgery, to assist in lowering intra-ocular pressure in glaucoma patients.

Optometry is at the forefront of primary patient care, and optometrists are increasingly managing a growing number of glaucoma patients. With the advent of MIGS devices, it's important for optometrists to understand the landscape of MIGS surgery, including available devices, indications for their use, identifying suitable patients and recognising potential complications.

The topic of MIGS devices is very broad, and a comprehensive analysis is not possible within the scope of this article. Ultimately, the goal of these devices is to lower intraocular pressure (IOP) in patients with open angle glaucoma, when medical therapies alone are inadequate, or, in suitable patients, where an alternative option can be undertaken at the time of cataract surgery.

CASE REPORT

The following case example illustrates the pivotal role of the optometrist in helping guide and manage MIGS options for patients.

Mrs NA is a 72-year-old female with right eye primary open angle glaucoma (POAG), uncontrolled on dual drop therapy including prostaglandin analogue and a carbonic anhydrase inhibitor. She has restricted mobility due to spinal problems, and suffers from asthma and heart disease, which precludes her from beta-blocker eye drops. She had tried alpha-antagonists, but was highly intolerant of them. Mrs NA lives in a small town, and my practice (an hour away) was the nearest ophthalmic service available to her. She'd previously undergone laser trabeculoplasty which was only modestly effective.

She was referred by her optometrist to help manage her glaucoma and cataracts. Mrs NA was noted as having increasing difficulty with drop toxicity despite preservative-free options, and her husband—who was helping instil

the drops—has been increasingly unable to assist due to his declining health. Her referring optometrist, who had some experience in co-managing glaucoma patients, had discussed treatment options with her, including MIGS devices and penetrating glaucoma surgery combined with cataract surgery.

On presentation at my practice, her best corrected visual acuity (BCVA) was 6/12 in each eye due to moderate nuclear and cortical cataracts. Goldmann IOPs were 18-20 mmHg in her right eye, and 14 mmHg in her left eye. Her corneas were of normal thickness, and her angles were open on gonioscopy, with clear media and good visualisation of the angle structures. Her optic discs showed moderate cupping with an inferior notch in her right eye, and cup-to-disc ratio (CDR) measuring 0.8 compared to a normal left optic disc with CDR 0.3. Maculae were healthy. On Humphrey 24-2 perimetry, her right eye was affected by a reproducible superior arcuate scotoma and an inferior advancing nasal step, while her left visual field (VF) was normal. The findings were supported by OCT, with retinal

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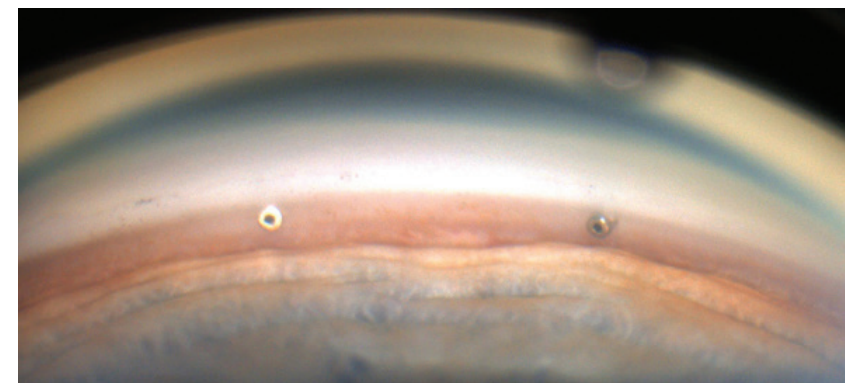


Figure 1. Two iStent injects are deployed into the trabecular meshwork

MIGS

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nerve fibre layer (RNFL) thinning and ganglion cell loss noted in the glaucomatous right eye.

Thanks to the informative discussion with her optometrist, Mrs NA had already thought about her treatment options. As she had limited mobility and comorbidities, she did not wish to undergo any invasive procedures that carry higher risks of complications, or any procedures that may require further management such as needling, effectively ruling out penetrating surgery and Xen Gel stent.

The options of trans-trabecular and supraciliary devices were discussed with her in detail. For ease of insertion, minimal risk of complications and likely least aftercare requirements, she opted for iStent injects combined with cataract surgery, aware that this would not be as efficacious as the more invasive options, but reassured by the fact that her post-operative care would likely be the least onerous.

She underwent her procedures successfully with cataract surgery combined with two iStent injects deployed into the nasal trabecular meshwork via gonio-prism visualisation (Figure 1). The expected amount of mild blood reflux was noted from Schlemms canal, which indicated good placement of the devices.

On day two post-operatively, her right eye vision was 6/9, and Goldmann IOP was 14 in the absence of pressure-lowering drops. There was mild microhyphaema, otherwise symptoms were minimal.

She was instructed to continue with her post-operative anti-inflammatory and antibiotic drops, without modifying usual post-cataract

treatment. Due to travel logistics, I discussed her management with her local referring optometrist, who was happy to see her at one and two weeks after surgery. Fortunately, her IOP remained under 15, with distance vision improving to 6/6 and no complications otherwise. I assessed her again at four-six weeks when she had completed her post-surgical eye drops and was able to remain drop-free.

Mrs NA's IOP remained in the 14-15 range without drops in her right eye. She was grateful for her optometrist's initiative and his understanding of MIGS devices as an option for her management, leading up to her referral to see me.

The collaborative team management of Mrs NA ensured that she was able to make the most informed decision for her combined cataract and glaucoma surgery, with an optimised outcome for her in the context of the available options.

Discussion

The development of MIGS devices spans over a decade, and was originally born out of a desire to provide gentler alternatives to penetrating glaucoma surgery, without the inherent risks and ongoing management issues.

Treatment options before MIGS

Options which have been available to us, with variable efficacy, include:

Eye drops. Prostaglandin analogues, beta blockers, alpha-agonists, and Carbonic anhydrase inhibitors (while miotics are very infrequently used now).

Laser therapies. Laser trabeculoplasty (Argon/ALT mostly superseded now by Selective/SLT).

Ciliary body ablative procedures. Cyclodiode, endoscopic cyclo-ablation.



Figure 2. Trans-trabecular devices: Stent and iStent inject (Glaukos)

Penetrating surgeries. Trabeculectomy and drainage tubes.

MIGS devices

In developing these less invasive devices, the 'ideal' therapy would be considered as being safe, predictable, efficacious, titratable and complication-free. They would also be free of requiring patient compliance, and quietly work away in the background. Realistically however, this doesn't exist. Nevertheless, setting these goals have been important in the development MIGS devices.

The following is an overview of some of the more commonly available devices, with a summary of their key features.

Trans-Trabecular devices: Stent and iStent inject (Glaukos)

Effectiveness depends on the targeted placement into areas of optimal aqueous outflow. The device, which consists of an inert titanium material coated with an anticoagulant, is inserted directly into the trabecular meshwork, secured by a collar (Figure 2). It is safe in current MRI and x-ray devices.

Intra-canalicular devices: Hydrus (Ivantis)

Less reliant on targeted placement, as the broader placement of the device along the trabecular meshwork improves its chances of corresponding to collector channels and aqueous veins (Figure 3).

Supraciliary devices: Cypass (Alcon)

Initially, these devices showed promise as a novel and effective means of lowering IOP by introduction along the supraciliary space between the

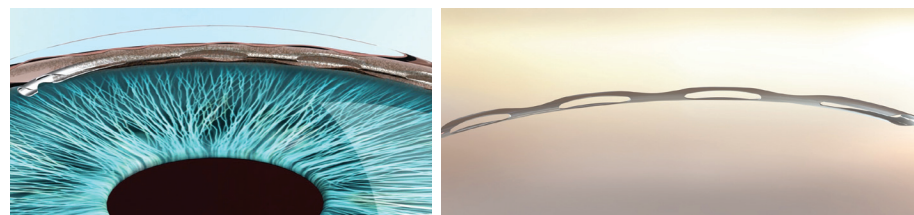


Figure 3. Intra-canalicular devices: Hydrus (Ivantis).

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ciliary body and sclera internally, which was demonstrated favourably in the COMPASS trial.¹ While they were shown to be effective in lowering the IOP, the recently available five-year data on the extension study revealed that the device was associated with increased endothelial cell loss when combined with cataract surgery, compared to cataract surgery alone (20.5 per cent vs 10.1 per cent at five years).¹ As a result, this device was voluntarily and responsibly withdrawn from the market on 29 August 2018, and is no longer available (Figure 4).

Subconjunctival devices: Xen Gel Stent (Allergan)

As MIGS devices become more creative and potentially more invasive, we start to see blurring of the lines defining 'minimally' invasive surgery. This could make room for another class of devices dubbed 'moderately' invasive glaucoma surgery ('MOGS' perhaps?).

The main currently-available device in Australia is the Xen Gel stent device. The Xen implant is ideally suited to patients with uncomplicated open angle, pseudoexfoliative, or pigmentary glaucoma, who have healthy conjunctiva and can manage the post-operative care which includes bleb management. It is indicated in patients with moderate-to-advanced uncontrolled glaucoma unresponsive to maximum tolerated

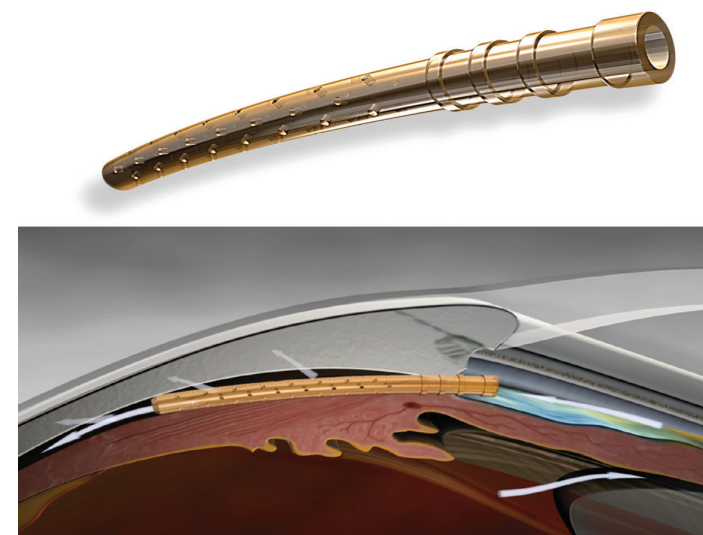


Figure 4. Supraciliary devices: Cypass (Alcon).

medical therapy (Figure 5).

Ultimately, each drainage device comes with its own learning curve, and paramount to all drainage devices is the requirement for optimal visualisation of the anterior chamber angle.

In relation to MIGS devices, as a general rule, the more invasive the procedure, the more effective it will be. For example: trans-trabecular devices such as iStent inject have a

very good safety profile and low risk of complications, albeit with a relatively modest pressure-lowering effect when compared to trabeculectomy. In comparison, subconjunctival procedures such as Xen Gel stent can have a more dramatic pressure lowering effect, but they come with a higher risk of potential morbidity, including risks of infections, greater risk of hypotony and the patient engagement required in bleb management and subconjunctival anti-scarring injections.

1. Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts Vold, Steven et al. *Ophthalmology* 2016; 127: 2103-2112.

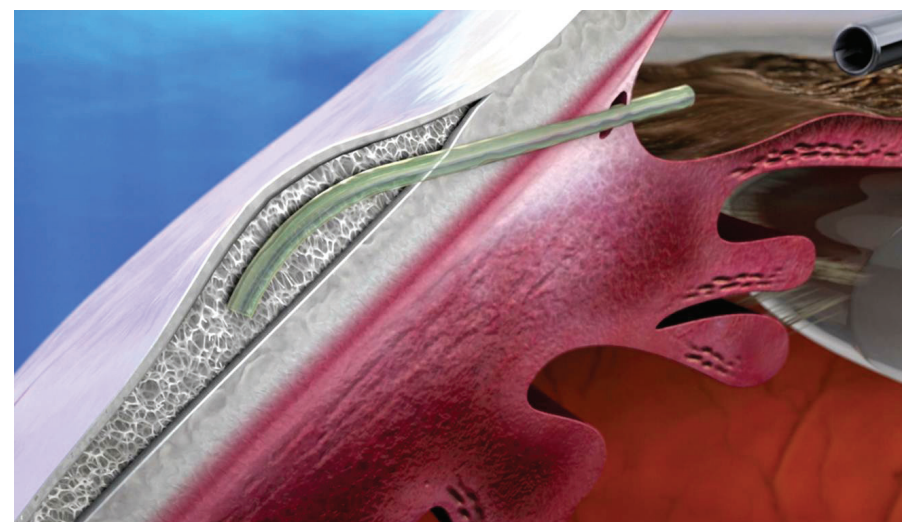


Figure 5. Subconjunctival devices: Xen Gel Stent (Allergan)