# Glaucoma Disease Progression

Safety data for iStent *inject*® is comparable to cataract surgery, giving surgeons the confidence to intervene early in the disease state.

AN INTERVIEW WITH ROBERT PETRARCA, MD, FRCOPHTH, MBBS, MCOPTOM, BSC (HONS)

**How has the focus on glaucoma disease progression changed over the past few years?**

**Robert Petrarca, MD, FRCOphth, MBBS, MCOptom, BSc (Hons):** Reducing disease progression to prevent functional blindness in the patient's lifetime has always been the aim of glaucoma treatment. What is different, however, is the available treatment options. Newer surgical interventions such as MIGS procedures provide a different balance of safety and efficacy compared with traditional filtering surgery.[1]

**Regarding disease progression, we tend to think about the more severe end of the glaucoma spectrum. Are MIGS procedures suitable in patients with advanced glaucoma?**

**Dr. Petrarca:** Over the past few years, the MIGS category has grown vastly. Even within this category, there is a lot of variation in the efficacy and safety of the devices. I don't believe that MIGS is a replacement for filtering surgery, but some procedures within the MIGS category such as trabecular micro-bypass, for example **iStent *inject*® W (Glaukos), have an excellent balance between safety and efficacy.**[2] As a result, they **can be used much earlier in the disease process,** such as in patients with mild to moderate glaucoma, when we might not be comfortable performing a trabeculectomy.

**What are the benefits of early intervention with iStent *inject*® W?**

**Dr. Petrarca:** This question has two parts.

**No. 1: What is the benefit of early intervention?** Due to improvements in technology, we can diagnose glaucoma faster than ever before. Additionally, the population is aging; around 27% of people in western Europe are aged over 60 years, and it is estimated to grow significantly over the next 5 years.[3] The costs of treating glaucoma increase as visual impairment and blindness increase. As more patients are diagnosed with glaucoma, **we need to intervene as early as we can to delay disease progression and prevent visual impairment and blindness.**

**No. 2: What is the benefit of early intervention with iStent *inject*® W?** I favor iStent *inject*® W for early intervention because it has an **extremely high safety profile, similar to cataract surgery.**[2] I feel comfortable using the device even in the mildest disease, when the patient is having their cataract removed anyway. Apart from patients presenting with glaucoma late, one of the biggest challenges we have in terms of disease progression is patient adherence to medication.[4] **iStent *inject*® W improves natural flow of aqueous and works continuously,**[5] providing surgeons with reassurance that the **IOP can be controlled throughout the day.**

**Is medication reduction the main goal with procedures such as iStent *inject*® W?**

**Dr. Petrarca:** No, the goal of any glaucoma treatment is to reduce IOP. This is still the only modifiable risk factor. Reducing medication burden and improving quality of life at the same time are additional benefits, but the primary goal has to be to reduce IOP.

**What is body of evidence for iStent *inject*® W in terms of IOP reduction and disease progression?**

**Dr. Petrarca:** iStent technologies have been available for more than a decade, and **more than 1 million devices have been implanted worldwide.** Between the various iStent devices, there has been more than 250 peer-reviewed publications. There is a high degree of consistency between data from randomized controlled trials (RCTs), real world studies, and even meta-analyses.[6] Not only does the data show **powerful IOP reduction and a very low degree of visual field progression** over the long term (between 5 and 8 years),[7-11] but they demonstrate that iStent *inject*® W may also **delay the need for secondary surgical interventions.**[12]

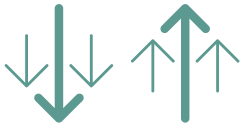
**"THE SAFETY DATA BEHIND ISTENT *INJECT*® SHOWS A LOW RATE OF POSTOPERATIVE COMPLICATIONS SUCH AS PERIPHERAL ANTERIOR SYNECHIAE (PAS) DEVELOPMENT[2] AND ENDOTHELIAL CELL LOSS[13] THAT IS COMPARABLE TO CATARACT SURGERY IN THE IMMEDIATE POSTOPERATIVE PERIOD AND OVER THE LONGER TERM. THIS GIVES SURGEONS THE CONFIDENCE TO INTERVENE EARLY."**

**What is the future of MIGS?**

**Dr. Petrarca:** There are many exciting developments in the pipeline, both in terms of glaucoma devices such as iStent

# 250+ PEER-REVIEWED PUBLICATIONS

iStent *inject*® W is the gold standard in trabecular micro-bypass surgery, continuing the legacy of excellence throughout 20 years of iStent® devices. It is backed by the most robust, diverse, and longest-term body of clinical evidence for any MIGS procedure, driven through clinical rigor and integrity.



## QUALITY OF LIFE

The first and only MIGS device with significant and durable quality of life improvements in a pivotal trial.[1]

## CLINICALLY PROVEN

Consistent demonstrated IOP and medication reductions in independent real world studies[2-6]

## PROCEDURAL ELEGANCE

Predictability and precision meet the needs of your practice

## PROVEN SAFETY

Safety profile similar to cataract surgery alone[1]

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2. Lindstrom R, et al. Four-year outcomes of two second-generation trabecular micro-bypass stents in patients with open-angle glaucoma on one medication. *Clin Ophthalmol*. 2020;14:71.
3. Berdahl J, et al. iStent *inject* trabecular micro-bypass stents with topical prostaglandin as standalone treatment for open-angle glaucoma: 4-year outcomes. *Clin Exp Ophthalmol*. 2020;48(6):767-774.
4. Hengerer FH, Auffarth GU, Conrad-Hengerer I. iStent *inject* trabecular micro-bypass with or without cataract surgery yields sustained 5-year glaucoma control. *Adv Ther*. 2022:1-15.
5. Healey PR, et al. Standalone iStent trabecular micro-bypass glaucoma surgery: a systematic review and meta-analysis. *J Glaucoma*. 2021;30(7):606-620.
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infinite® and drug delivery devices such iDose® (Glaukos). In the immediate future, I think we will see iStent *inject*® W taking its place as a bona fide treatment for mild to moderate glaucoma—not just a way to reduce drops or ocular surface disease but to actually **slow disease progression.**

The **safety data behind iStent *inject*® shows a low rate of postoperative complications such as peripheral anterior synechiae (PAS) development[2] and endothelial cell loss[13]** that is comparable to cataract surgery in the immediate postoperative period and over the longer term. This gives surgeons the confidence to intervene early. ■

1. Saheb H, Ahmed IIK. Micro-invasive glaucoma surgery: current perspectives and future directions. *Curr Opinion Ophthalmol*. 2012;23(2):96-104.
2. Samuelson TW, Sarkisian SR Jr, Lubeck DM, et al. Prospective, randomized, controlled pivotal trial of an ab interno implanted trabecular micro-bypass in primary open-angle glaucoma and cataract: two-year results. *Ophthalmology*. 2019;126(6):811-821.
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5. Data on File (Glaukos).
6. Healey PR, Clement CI, Kerr NM, Tilden D, Aghajanian L. Standalone iStent trabecular micro-bypass glaucoma surgery: a systematic review and meta-analysis. *J Glaucoma*. 2021;30(7):606-620.
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- Financial disclosure: Consultant (Glaukos)

**iStent *inject*® W IMPORTANT SAFETY INFORMATION**

**INDICATION FOR USE:** The iStent *inject*® W, is intended to reduce intraocular pressure safely and effectively in patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma. The iStent *inject*® W, can deliver two (2) stents on a single pass, through a single incision. The implant is designed to stent open a passage through the trabecular meshwork to allow for an increase in the facility of outflow and a subsequent reduction in intraocular pressure. The device is safe and effective when implanted in combination with cataract surgery in those subjects who require intraocular pressure reduction and/or would benefit from glaucoma medication reduction. The device may also be implanted in patients who continue to have elevated intraocular pressure despite prior treatment with glaucoma medications and conventional glaucoma surgery. **CONTRAINDICATIONS:** The iStent *inject*® W System is contraindicated under the following circumstances or conditions: • In eyes with primary angle closure glaucoma, or secondary angle-closure glaucoma, including neovascular glaucoma, because the device would not be expected to work in such situations. • In patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. **WARNINGS/ PRECAUTIONS:** • For prescription use only. • This device has not been studied in patients with uveitic glaucoma. • Do not use the device if the Tyvek® lid has been opened or the packaging appears damaged. In such cases, the sterility of the device may be compromised. • Due to the sharpness of certain injector components (i.e. the insertion sleeve and trocar), care should be exercised to grasp the injector body. Dispose of device in a sharps container. • iStent *inject*® W is MR-Conditional; see MRI Information below. • Physician training is required prior to use of the iStent *inject*® W System. • Do not re-use the stent(s) or injector, as this may result in infection and/or intraocular inflammation, as well as occurrence of potential postoperative adverse events as shown below under "Potential Complications." • There are no known compatibility issues with the iStent *inject*® W and other intraoperative devices. (e.g., viscoelastics) or glaucoma medications. • Unused product & packaging may be disposed of in accordance with facility procedures. Implanted medical devices and contaminated products must be disposed of as medical waste. • The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. If intraocular pressure is not adequately maintained after surgery, the surgeon should consider an appropriate treatment regimen to reduce intraocular pressure. • Patients should be informed that placement of the stents, without concomitant cataract surgery in phakic patients, can enhance the formation or progression of cataract. **ADVERSE EVENTS:** Please refer to Directions For Use for additional adverse event information. CAUTION: Please reference the Directions For Use labelling for a complete list of contraindications, warnings and adverse events.