

# Trabecular Micro-Bypass for the Treatment of Glaucoma



The iStent *inject* W plays a major role in early intervention.

BY VINCENT QIN, MD



WATCH IT NOW

The population is aging, and the prevalence of glaucoma is on the rise. In Western Europe alone, diagnosed and undiagnosed primary open-angle glaucoma (POAG) are projected to increase by 8.6% and 13.7%, respectively, from 2020 to 2026.<sup>1</sup> The challenge with glaucoma management lies not only with the growing number of diagnosed cases overall but also with late-stage diagnoses. Patients with advanced disease often have irreversible visual field loss.

Traditionally, the first-line treatment for glaucoma is medication, followed by laser and then more invasive surgery. Unfortunately, this treatment paradigm comes at a steep cost. Less than 50% of patients adhere to their prescribed medication regimen after 12 months,<sup>2</sup>

and intervention for advanced disease is more costly.<sup>3</sup> The economic costs of glaucoma management outside the health and social care system constitute about 85% of total expenses.<sup>4</sup> **Shifting to an early interventional mindset therefore is key to reduce health care costs, prevent disease progression, and improve the overall quality of life for glaucoma patients.**

MIGS procedures, including devices like the iStent *inject*® W (Glaukos), **address the challenges associated with late-stage glaucoma diagnosis and noncompliance with topical medications.** These procedures can be performed in patients with mild to moderate glaucoma, offering a more efficient approach to disease management.

## THE LATEST-GENERATION ISENT

The evolution of iStent® spans 2 decades. The first-generation device was relatively complicated to implant in the trabecular meshwork, but the latest generation, iStent *inject* W, is more straightforward. In my hands, I can perform the procedure elegantly due to the device's enhanced visibility. The iStent *inject* W also **includes observable positioning confirmation to ensure the device is implanted safely, efficiently, and seamlessly.**

The iStent *inject* W is implanted into the trabecular meshwork. There are four outflow pathways on the sides and one at the tip of the implant. The flange, visible during injection, stabilizes the implant in the trabecular meshwork. The injection system is very straightforward to use; two stents are included in each injector. The injector has two buttons; the first and second buttons are depressed to retract the sleeve of the trocar when the anterior segment is entered and deliver the stents perpendicularly into the trabecular meshwork, respectively. Once the first stent is delivered, the injector is moved 2 clock hours away on the nasal side of the trabecular meshwork, and the second one is implanted, again perpendicular to the trabecular meshwork. Only a small tenting of the sclera is required for implantation.

The anterior segment OCT scans in Figure 1 show the location of the iStent

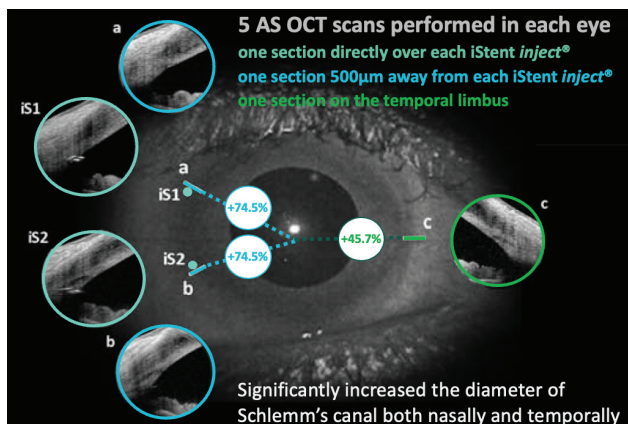
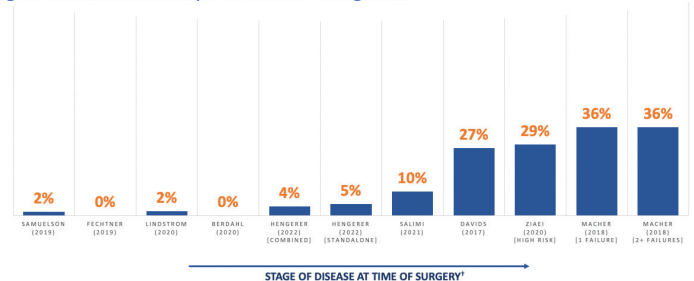


Figure 1. The location of the iStent *inject* in the trabecular meshwork as seen on anterior segment OCT.

Intervening with iStent *inject*® W earlier in the disease pathway results in fewer secondary surgical interventions compared to intervening later.



\* Advancing disease defined by (1) visual fields (Hodapp-Anderson-Parrish) (2) previous glaucoma surgery (3) baseline IOP and (4) number of medications

Figure 2. Intervening with iStent *inject* W earlier in the disease pathway results in fewer secondary surgical interventions compared to intervening later.

## ENDOTHELIAL CELL LOSS

Proportion of Eyes >30% or ≥30% significant ECL at post-op 5 years vs. their respective control group

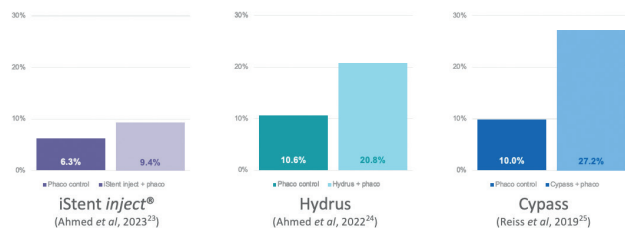


Figure 3. Endothelial cell loss at 5 years.

*inject* W in the trabecular meshwork. Note the improvement in the diameter of the Schlemm canal both nasally as well as temporally, signifying an increased pathway for aqueous outflow.<sup>5</sup> Additionally, an angiography study found improved drainage of aqueous fluid in the episcleral veins immediately after surgery when the stents are placed 2 to 3 clock hours apart.<sup>6</sup>

The iStent technologies can achieve a significant decrease in IOP across various stages of glaucoma disease as a standalone procedure and in combination with cataract surgery.<sup>7,10</sup> Long-term studies on the iStent technologies show the stability of visual fields over 7 years regardless of glaucoma stage, optic nerve cupping, and retinal nerve fiber layer thickness.<sup>11,12</sup>

Intervening with iStent *inject*® W earlier in the disease pathway results in fewer secondary surgical interventions compared to intervening later (Figure 2). In a retrospective study of 333 patients undergoing trabecular bypass surgery, the rate of postoperative hyphema was four times greater with the Hydrus Microstent (Alcon) than the iStent *inject* in the setting of antithrombotic therapy.<sup>13</sup>

Additionally, the rate of postoperative peripheral anterior synechiae in the Hydrus pivotal trial<sup>14</sup> was almost 10 times greater than in the iStent *inject* pivotal trial.<sup>15</sup> Evidence from pivotal trials also showed the proportion of patients experiencing more than 30% endothelial cell loss at 5 years was lower in the iStent versus other micro-bypass stent procedures (Figure 3).<sup>8,16,17</sup>

## CONCLUSION

The iStent technologies have evolved from an unproven technology in 2012 to an efficient solution for glaucoma. Long-term data have showed predictable reduction in IOP,<sup>10</sup> visual outcomes,<sup>18</sup> and safety.<sup>8,14</sup> The device is proven to stabilize visual fields over the long term<sup>11,12</sup> with a low rate of secondary surgical interventions when used early in the disease state.<sup>11,14,19</sup> This device is playing a crucial role to improve patients' quality of life as we continue to move toward early glaucoma intervention and navigate an aging population. ■

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**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 retrolbulbar 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.