

ISTENT INJECT® W: A GAME CHANGER FOR CLINICAL PRACTICE



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Preserving patients' visual function and acuity.

MIGS devices have come to the forefront of the glaucoma landscape, challenging the paradigm of patient care. Notably, the **iStent inject® W (Glaukos) has emerged as a valuable tool for interventional glaucoma**, transforming the way we approach patients with mild to moderate disease. It is tempting to think about the ideal patient for the iStent *inject*® W, focusing primarily on aspects of the disease and treatment targets and goals. My experience with the iStent® technologies in clinical practice has been transformative to the way I care for patients. **Rather than thinking about the treatment first, I now think about treating the patient first.** This, in my opinion, includes **considering the iStent *inject*® W for all glaucoma patients undergoing cataract surgery** who have no contraindications for the procedure. **We must think about patients' best long-term interests and involve them in the treatment decision.**

BENEFITS OF COMBINED PROCEDURES

Combining the iStent *inject*® W with cataract surgery in patients with mild to moderate glaucoma can help **reduce their medication burden, improve their quality of life, and reduce the progression of their functional disease**¹. Performing a trabecular microbypass procedure earlier in the disease state helps curb the progression of functional disease over time.

The iStent technologies have traditionally been reserved for patients with mild to moderate glaucoma, especially those taking medications for other conditions such as ocular surface disease and those patients who have difficulty instilling their eye drops such as those with arthritis.

Combining procedures also shifts patients from a moderate to low-risk category for disease progression.

	STAND ALONE (N=44)	COMBINED WITH CATARACT (N=81)
VF MD	-7.0 vs -7.1 (P = 0.502)	-6.6 vs -6.7 (P = 0.462)
RNFL	82.1 vs 80.9 (P = 0.194)	81.4 vs 80.2 (P = 0.497)
C:D RATIO	0.78 vs 0.79 (P = 0.386)	0.74 vs 0.76 (P = 0.324)

TABLE 1. Disease Stability: Standalone Versus Combined iStent inject Procedures

Regardless of the target glaucoma patient population, including a trabecular microbypass strategy such as the iStent *inject*® W technologies as a routine procedure is important in the current management landscape.

LONG-TERM SAFETY AND STABILITY

iStent *inject*® W has an overall high safety profile similar to standalone cataract surgery².

Long-term studies also demonstrate that the iStent technologies effectively lower IOP and ultimately preserve visual function and acuity. In a 5-year prospective, longitudinal case series of standalone and combined iStent *inject*® procedures in 125 patients with a high preoperative treatment burden, the visual field, retinal nerve fiber layer thickness, and cup:disc ratio were positive (Table 1)³. **Patients who underwent combined cataract and iStent procedures exhibited stable visual fields and reduced reliance on glaucoma medications over 5 years.** In another study of 41 patients in low- and high-risk subgroups, only five patients required further surgery during a 7-year follow-up period. Four of the five were in the high-risk group (Table 2)⁴.

PERSONAL EXPERIENCE

I have been implanting iStents for over 10 years. I recently performed an observational, retrospective, longitudinal cohort study of 91 well-matched patients with open-angle glaucoma or ocular hypertension who underwent either cataract surgery plus the first-generation iStent (n = 47) or cataract surgery alone (n = 44).

The results showed that **patients who received the iStent had statistically significantly less visual field progression and were better controlled on fewer**

	LOW RISK SUBGROUP (N=27)	HIGH RISK SUBGROUP (N=14)
VF MD	-7.58 vs -8.16 (P = 0.44)	-10.31 vs -10.79 (P = 0.67)
IOP (mmHg)	19.5 vs 17.9 (P = 0.05)	24.7 vs 17.9 (P = 0.0006)
C:D RATIO	0.63 vs 0.67 (P = 0.01)	0.75 vs 0.79 (P = 0.04)

TABLE 2. Disease Stability: Low-Risk Versus High-Risk Groups



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medications. Further, 26% were medication-free at 5 years. At that time, the mean IOP reduction was 6.8 mmHg in the combination group but only 4 mmHg in the standalone group.

Patients in the combination group also had a mean reduction in medications at 5 years postoperative (2.36 to 1.39) whereas the standalone group experienced an increase in medication use (1.65 medications). Visual field changes are found in the Figure.

CONCLUSION

In my practice, the **iStent inject® W** is an important treatment modality for the management of glaucoma. It can be seamlessly integrated into our cataract surgery workflow, helping patients reduce the medication burden and maintain stable visual function at both mild to moderate stages of disease. ■

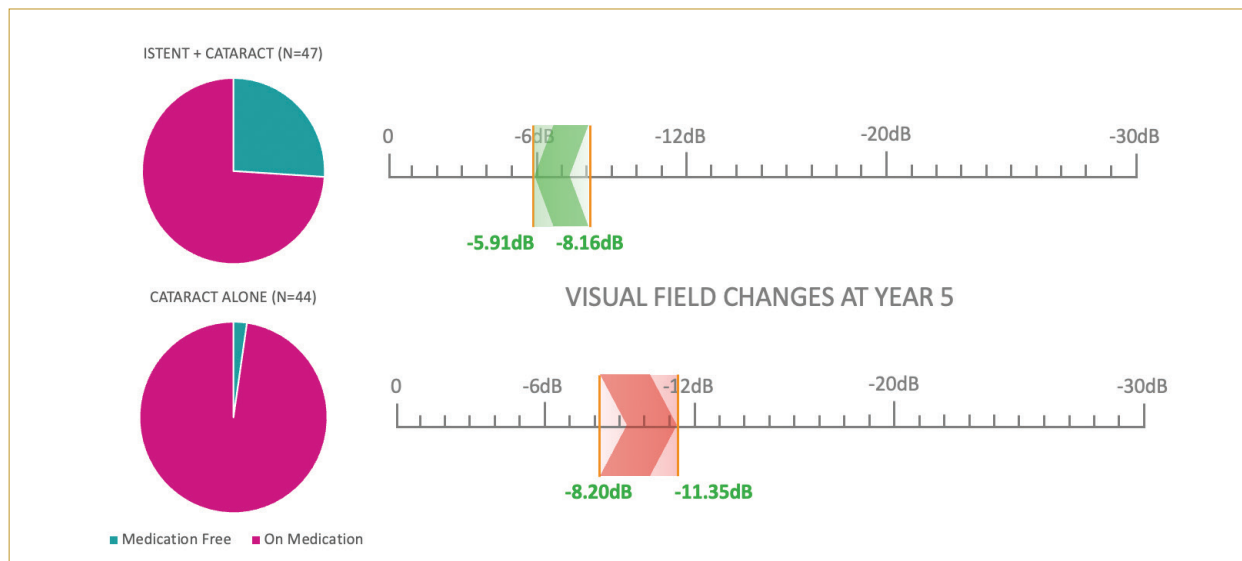


Figure. Data from Dr. Ahmed's practice showing the visual field changes and medication burden 5 years after iStent implantation.

References:

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iStent inject® IMPORTANT SAFETY INFORMATION

INDICATION FOR USE: The iStent inject, 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, 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 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 is MR-Conditional; see MRI Information below. • Physician training is required prior to use of the iStent inject 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 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.

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