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A NEW LEVEL OF Efficacy and Safety IN MIGS

The iStent *inject* delivers sustained IOP and medication reduction in patients with mild-to-moderate glaucoma undergoing cataract surgery

BY DEBORAH RISTVEDT, DO

Microinvasive glaucoma surgery (MIGS) has changed the trajectory of glaucoma therapy for many patients in my practice. After MIGS, patients often can manage their glaucoma well with fewer (or no) IOP-lowering medications and avoid more invasive surgeries. A microinvasive approach is particularly important in glaucoma cases, as it minimizes tissue destruction and avoids unnecessary disruption to the outflow system, resulting in less risk and shorter recovery times.

The latest advancement in MIGS, the iStent *inject* (Glaukos), takes microinvasive eye surgery to a new level of efficacy and safety. It is the smallest medical device known to be implanted in the human body, yet its impact is remarkable.

iStent *inject* at a Glance

The iStent *inject* system is comprised of two micro-bypass stents preloaded on a single-use injector. Inserted through the trabecular meshwork into Schlemm's canal, each stent is designed with multidirectional flow characteristics that optimize outflow while minimizing unnecessary disruption to the system. Placed two to three clock hours apart, the stents access multiple collector channels and have been shown to create arcs of flow that span five to six clock hours. In addition, studies have demonstrated iStent *inject* can potentially re-establish flow in previously dormant outflow channels.

iStent *inject* is manufactured from an implant grade titanium alloy that is in compliance with standard ASTM F136, which is made without nickel. The procedure is complementary to cataract surgery, as the stents are implanted ab interno through the phaco incision — no additional incisions are required unlike other procedures. The technique is precise, tissue-sparing, and astigmatically neutral. Postoperative care is similar to that for cataract surgery alone.

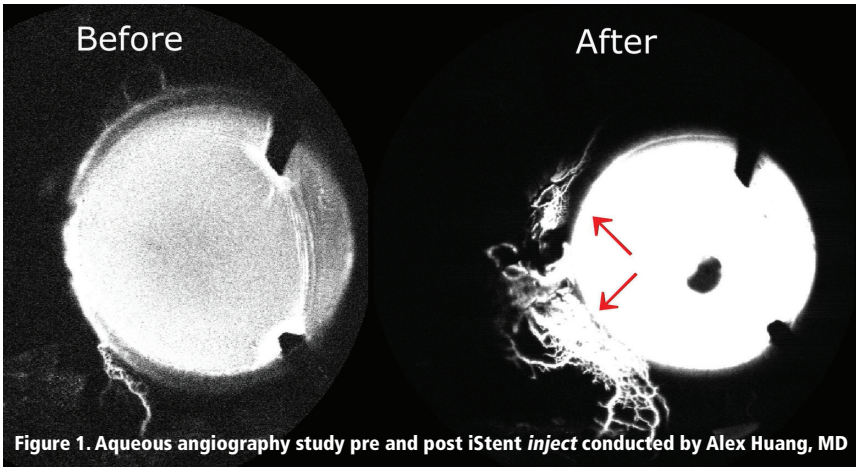

Figure 1. Aqueous angiography study pre and post iStent *inject* conducted by Alex Huang, MD

Proven Efficacy

When evaluating a new device, my primary concern is how it will help my patients. I examine the safety profile and weigh the risks and benefits associated with adopting the new technology.

In the U.S. pivotal trial, the iStent *inject* demonstrated strong clinical performance in relevant measures such as mean IOP and the number of patients who were medication-free at the end of the study.[1] In vivo studies by Huang and colleagues demonstrated that iStent *inject* can significantly increase aqueous outflow in glaucomatous eyes (Figure 1).[2]

Published clinical papers have consistently demonstrated sustained IOP and medication reduction after iStent *inject* implantation. As an example, Hengerer and colleagues reported an IOP reduction of 37% from baseline, mean medication reduction of 68%, and a mean IOP of 14.3 mmHg at 3 years post-op.[3] 100% of eyes had IOPs ≤18 mm Hg, and 71% had readings of ≤15 mm Hg. Additionally, 54% of eyes were medication-free compared to only 1% preoperatively; 93% of eyes required fewer medications postoperatively; and only 2% of eyes required ≥3 medications compared to 56% prior to surgery. There were no intraoperative complications, and a favorable post-operative course was noted.[3]

My Clinical Experience

Having successfully used the first-generation iStent, I was anxious to see

what the iStent *inject* could do. I began using it as soon as it became available in Minnesota.

Overall, my patients are experiencing increased pressure reductions, and I am finding more opportunities to reduce or eliminate IOP-lowering drops with the iStent *inject* compared to the first-generation iStent. In addition, if a patient's glaucoma progresses or becomes more severe in the future, the iStent *inject* leaves us more real estate to perform a more invasive glaucoma surgery.

Among many iStent *inject* success stories in my practice is that of a 70-year-old woman referred by her optometrist for a glaucoma evaluation. She was intolerant of many IOP-lowering medications, and had stopped drops altogether because of burning and redness, as well as systemic side effects, such as fatigue and flu-like symptoms. She also had coexisting emphysema, which limited her treatment options. The patient's presenting IOPs were 24 mmHg OD and 26 mmHg OS. OCT revealed retinal nerve fiber layer loss inferiorly in each eye, and her visual fields were full in each eye.

I performed selective laser trabeculoplasty to enhance the natural outflow pathway, which helped initially. Over time, however, the patient's IOPs started to climb back into the 20s. When she was ready for cataract surgery, it was a natural segue to discuss the iStent *inject*. I was confident the procedure would reduce the patient's IOPs and her need for topical drops, and that her visual recovery would be faster than with some more invasive procedures.

Since undergoing cataract-iStent *inject* surgery, the patient has not needed IOP-lowering drops. At her 6-month examination, her IOPs continue to hold steady at 15 mmHg OD and 16 mmHg OS. She is happy to avoid the side effects and toxicity issues of topical drops to manage her glaucoma.

It's not unusual for us to see patients who are just tolerating the side effects of their anti-glaucoma medications, and many patients are burdened with the addition of a second or third eye drop. Not only can a new drop regimen be confusing and inconvenient for patients, but costs can also be problematic. All of these issues can affect compliance.

My patients are excited and often relieved to learn about the potential benefits of the iStent *inject*. It's an easy conversation about a minimally invasive procedure that is just as safe as cataract surgery and can provide good pressure reduction and stabilization with fewer topical medications.

Minimal Learning Curve

The learning curve for the first-generation iStent was relatively easy, mainly involving visualization of the trabecular meshwork and learning to work comfortably in that space. Surgeons who have experience with the iStent should easily transition to the iStent *inject*.

The design of the iStent *inject* insertion device is somewhat different from that of the original iStent to facilitate the slight difference in surgical approach. With the iStent *inject*, the surgeon enters the trabecular meshwork directly instead of at an angle. The key is to stay perpendicular to the trabecular meshwork, not exert torque on the bevel, and become familiar with the rotation needed to span enough clock hours in the trabecular meshwork to implant the second stent.

Beyond Cataract Surgery Alone

This is an exciting time in glaucoma management, and as a cataract surgeon, I feel good that I can offer my patients with mild-to-moderate open-angle glaucoma a treatment benefit beyond cataract surgery alone.

I believe in the iStent *inject* technology and its benefits. It enables me to treat patients in an earlier phase of glaucoma to lower their pressures and avoid progression and vision loss. At the same time, I'm helping them become less dependent on IOP-lowering drops and perhaps alleviating the cost burdens.

With its favorable risk-to-benefit profile, iStent *inject* is my preferred treatment for patients who have mild-to-moderate open-angle glaucoma and need cataract surgery.

REFERENCES

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3. Hengerer FH, Auffarth GU, Riffel C, Conrad-Hengerer I. Prospective non-randomized, 36-month study of second-generation trabecular micro-bypass stents with phacoemulsification in eyes with various types of glaucoma. *Ophthalmol Ther.* 2018;7:405-415.

iStent *inject*