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SEIZING A Golden Opportunity

The iStent *inject* is a two-stent, revolutionary microinvasive glaucoma system for patients undergoing cataract surgery.

BY SAHAR BEDROOD, MD, PHD

When planning cataract surgery for a patient who has glaucoma, I'm initially focused on the patient's refractive goal, especially if the patient has mild-to-moderate glaucoma and good visual potential. Once that's established, however, I evaluate the status of the glaucoma. A patient who has mild-to-moderate disease and is using one to three IOP-lowering drops is an excellent candidate for the iStent *inject* (Glaukos).

The iStent *inject* offers a golden opportunity to not only take care of patients' cataracts and lower IOP, but also potentially reduce the burden of using multiple IOP-lowering eyedrops to manage their glaucoma, and, in the long term, preserve the ocular surface.

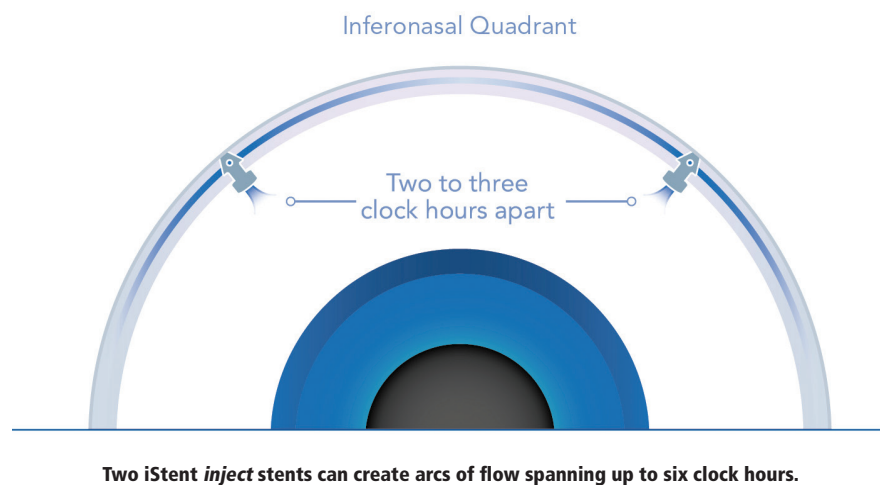
Putting a New Device to the Test

When evaluating any new device, surgeons are most interested in safety and efficacy. The device has to work, and the side effects must be minimal. This is particularly important when a microinvasive device is intended for patients who have mild-to-moderate glaucoma. Typically, these patients are doing well with their current medication regimen, and we don't want to expose them to unnecessary risks or complications.

Examining data from FDA clinical trials is a valuable first step in my assessment of a new device, but the most important measure of its worth is the results in my hands. I have used devices that other surgeons have loved, and sometimes I've found they didn't work as well as I had hoped they would. In my hands, the iStent *inject* is even more effective than what was shown in the preliminary studies.

I know this because whenever I start using a new device, I track my results to see how patients are doing. After a couple of months, I usually have a clear idea of how a device is working and if I should continue using it.

Thus far, I have data from approximately 40 patients in whom I've used the iStent *inject* during cataract surgery. Their starting IOPs were 19 mm Hg, and at the 3-month data point the average IOP was 14 mm Hg. That is a meaningful decrease in a patient with glaucoma. What's more, a number of patients were able to stop using IOP-lowering drops, and a large percentage were able to reduce the number of drops they were using. These data are preliminary and ongoing and will be presented in their entirety once my study is complete, but they serve as an early assessment for the efficacy of the device in my hands.



iStent *inject* Optimizes Outflow

The iStent *inject* is comprised of two micro-bypass stents preloaded in a single-use injector inserted through the trabecular meshwork into Schlemm's canal. Not only does each stent have four multidirectional outlets, but the benefit of two patent bypasses provides a significant outflow and efficacy advantage. Placed 2 to 3 clock hours apart, these stents have demonstrated the ability to provide arcs of flow that span up to 6 clock hours of the canal. By contrast, the first-generation iStent and other devices have only one inlet for aqueous to flow unilaterally. iStent *inject* is designed to improve the odds that we will access multiple collector channels and optimize physiologic outflow while minimizing unnecessary disruption to the system.

In addition, the iStent *inject* doesn't significantly affect cataract surgery. Some other microinvasive techniques can have a more profound impact on the cataract surgery outcome. For instance, a patient's vision after surgery may be blurrier or there may be more inflammation. With the iStent *inject*, I've seen minimal post-operative sequelae and little to no effect on lens positioning or refractive outcomes.

A Memorable Case

My most memorable iStent *inject* case to date was a patient in her mid-50s who had been in my care for several years as a glaucoma suspect. Eventually, the disease advanced to primary open-angle glaucoma with mild thinning and nasal steps on the visual field, so I prescribed latanoprost and dorzolamide/timolol. During the 3 years I had been monitoring this patient, her IOPs were always in the 16 mm Hg to 18 mm Hg range.

Recently, the patient developed cataracts, and we discussed cataract surgery. I explained that I had the option of placing iStent *inject* implants during her cataract surgery to help lower her pres-



Truly micro in size, note two iStent *inject* stents relative to the size of this penny.

ures. After hearing about the potential benefits and the risks, she was all for it.

The surgery went well. She was a moderate myope, who is now happy with her refractive outcome. At her last visit, her IOPs were 11 mm Hg, and she's been able to stop all drops. This outcome is revolutionary for this patient because it has changed her life from both a refractive and a glaucoma standpoint, and she's really happy.

What's memorable about this case is not that it was particularly extraordinary, but rather, it was an ordinary case that serves as an example of how far we've come in glaucoma surgery. We can now perform a procedure in a few minutes and potentially save this patient 15 to 20 years of eyedrop use while slowing her rate of glaucoma progression.

Patients' Reactions

My patients have been very open to learning about the iStent *inject*. I explain that it's a low-risk procedure that I perform in conjunction with cataract surgery to lower their eye pressures, and they could potentially reduce or eliminate their need for IOP-lowering drops. Most patients are enthusiastic about moving forward.

In fact, I've counseled a few patients who came to my office just to discuss the iStent *inject* after hearing about it from friends or family. Patients really don't like using drops. Even reducing the number of drops they need by one drop helps reduce their burden.

Conclusion

In my practice, if a patient with mild to moderate glaucoma who is using drops is about to undergo cataract surgery, I offer the iStent *inject* as a means to reduce IOP and reduce the burden of the drops. For me, the iStent *inject* has proven to be a safe and effective way to achieve both. •

INDICATION FOR USE. The iStent *inject*[®] Trabecular Micro-Bypass System Model G2-M-IS is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma. **CONTRAINDICATIONS.** The iStent *inject* is contraindicated in eyes with angle-closure glaucoma, traumatic, malignant, uveitic, or neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retrolbulbar tumor, thyroid eye disease, or Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. **WARNINGS.** Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. **MRI INFORMATION.** The iStent *inject* is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details. **PRECAUTIONS.** The surgeon should monitor the patient postoperatively for proper maintenance of IOP. The safety and effectiveness of the iStent *inject* have not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, abnormal anterior segment, chronic inflammation, prior glaucoma surgery (except SLT performed > 90 days preoperative), glaucoma associated with vascular disorders, pseudoexfoliative, pigmentary or other secondary open-angle glaucomas, pseudophakic eyes, phakic eyes without concomitant cataract surgery or with complicated cataract surgery, eyes with medicated IOP > 24 mmHg or unmedicated IOP < 21 mmHg or > 36 mmHg, or for implantation of more or less than two stents. **ADVERSE EVENTS.** Common postoperative adverse events reported in the randomized pivotal trial included stent obstruction (6.2%), intraocular inflammation (5.7% for iStent *inject* vs. 4.2% for cataract surgery only), secondary surgical intervention (5.4% vs. 5.0%) and BCVA loss ≥ 2 lines ≥ 3 months (2.6% vs. 4.2%). **CAUTION:** Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.

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