iStent *inject*® Pivotal Trial: Greater Efficacy and Better Patient-Reported Quality of Life

Study findings confirm clinicians' postoperative observations.

BY INDER PAUL SINGH, MD

I have been performing micro-invasive glaucoma surgery (MIGS) for nearly a decade, particularly with the iStent® Trabecular Micro-Bypass (Glaukos).[1] This revolutionary technology is implanted ab interno during cataract surgery, creating a bypass through the trabecular meshwork to facilitate aqueous outflow to reduce intraocular pressure (IOP) (Figures 1-3).

Performing MIGS with the iStent *inject* has been a paradigm shift in my practice. By intervening earlier and performing safer, less invasive surgeries in patients with mild to moderate primary open-angle glaucoma (POAG), we are now more than ever able to reduce IOP as well as potentially decrease the need for medication, which can result in improvement in their quality of life. Topical glaucoma medications may be associated with ocular surface disease and other side effects, and their efficacy may be limited by patient nonadherence.[2]

Additionally, the iStent *inject* can prevent tissue damage associated with more invasive procedures. Furthermore, because the iStent *inject* is tissue sparing in nature, it also enables the use of other glaucoma surgical procedures, if necessary, in the future.

GREATER EFFICACY ACROSS DISEASE LEVELS

We now have datasets supporting our observations in clinical practice. We participated in recent studies examining data from the phase 3 pivotal trials of the second-generation iStent *inject* (Glaukos), which is FDA-approved for patients with mild to moderate POAG.[1,3,4] These studies demonstrated that cataract surgery combined with the iStent *inject* decreased IOP greater than cataract surgery alone, and patients had an improved quality of life after surgery. The iStent *inject* has two stents compared to the single stent of the first-generation design.

The trial included 505 subjects with cataracts and mild to moderate POAG.[1] Follow-up continued for 24 months.

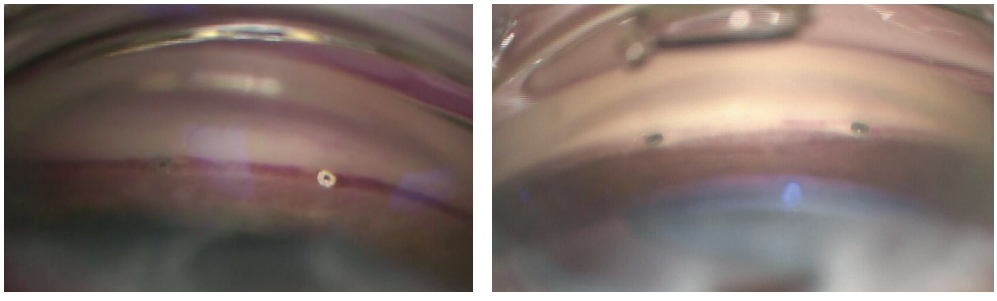
We stratified patients according to whether they had cataract surgery alone or cataract surgery with the iStent *inject*.[3] In addition, patients were grouped based on their unmedicated baseline washed out mean diurnal IOPs, classified as low (IOP less than 25 mm Hg), mid (25 to <30 mm Hg), and high (>30 mm Hg).[3] They also were categorized by their preoperative glaucoma medications (low, one medication; mid, two medications; high, three or more medications).

After two years of follow-up, unmedicated IOP decreased by at least 20% in 75.8% of iStent *inject*-treated eyes compared to 61.9% of those treated with cataract surgery alone.

Although cataract surgery alone decreases IOP, there is a ceiling effect. We can only achieve approximately a 5.5-mm Hg reduction regardless of baseline. Cataract surgery alone decreased IOP 5.2 mm Hg (low group), 5.8 mm Hg (mid group), and 5.4 mm Hg (high group).

Eyes receiving the iStent *inject* that had an unmedicated IOP of 25 mm Hg or less had a pressure reduction of approximately 6.2 mm Hg; however, those with an IOP of 30 mm Hg or greater experienced nearly a 10-mm Hg reduction. Therefore, as the unmedicated baseline IOP increased, the IOP decreased further in patients receiving the iStent *inject* versus cataract surgery alone. This demonstrates that we are improving the outflow facility of patients receiving the iStent *inject* compared with the group that had cataract surgery alone, which had an effect but was limited.

Mean medication use decreased by 75% in iStent *inject*-treated eyes compared with 47% of those treated with cataract surgery alone. Eighty-four percent of responders that received iStent *inject* were medication-free at



Figures 1 and 2. Post iStent *inject* W implantations seen seeded in the nasal canal.

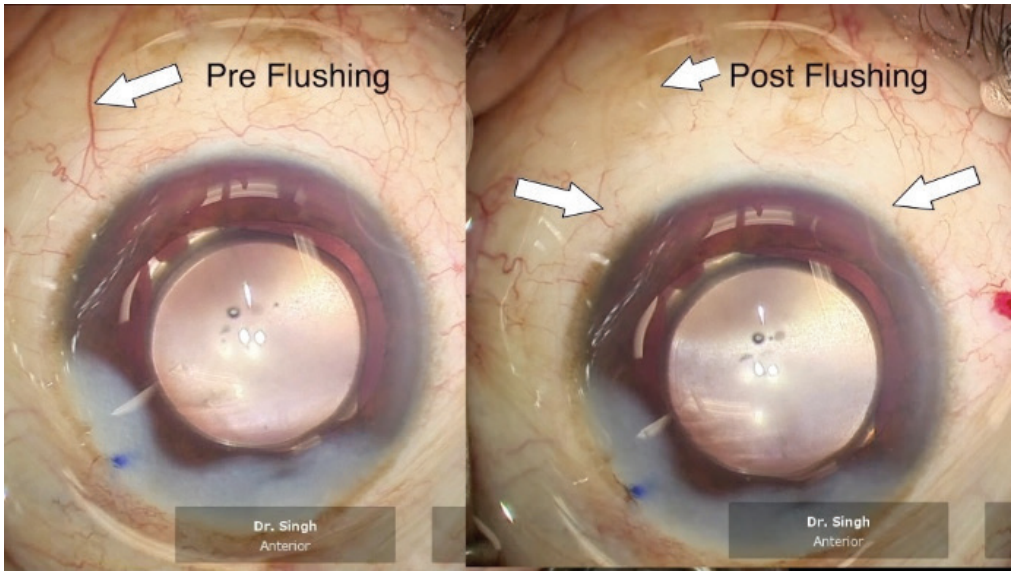


Figure 3. The left image was taken before irrigating the eye with BSS. The arrow is pointing at a larger episcleral vessel. On the right image, you can see signifiant blanching of that large vessel and surrounding vessels post irrigation with BSS on a cannula. This demonstrates the improvement in outflow of the conventional pathway all the way to the distal channels.

23 months, as compared to 67% of responders treated only with cataract surgery.

The iStent *inject* had favorable safety outcomes compared with cataract surgery alone, as reported by Samuelson et al.[1]

IMPROVED QUALITY OF LIFE

In my experience, patients are much happier after surgery, especially when we can reduce or eliminate the need for medication after implanting the iStent.

Using data from the phase 3 trials, we also assessed quality of life and patient-reported outcomes.[4] We used the Vision Function Questionnaire (VFQ-25) and the Ocular Surface Disease Index (OSDI) at baseline and months 1, 6, 12, and 24.

In the iStent *inject*-treated group, a greater proportion of patients had a significant improvement in patient-reported outcomes in terms of quality of life with the VFQ-25 and OSDI scores compared with those who had cataract surgery alone. In fact, if we look at the VFQ-25 specifically, we found more iStent *inject*-treated patients had improvement in driving, overall vision, and overall health compared with those who had cataract surgery alone.

Furthermore, patients who were able to discontinue medications reported greater improvement in their outcomes in terms of their quality of life compared with those still using medications.

EVIDENCE-BASED SUPPORT

Our dataset from this study supports what we have presumed for the last 10 years: that patients who have iStent technologies have a better quality of life when medication is discontinued. When I am talking with patients, now I can confidently tell them I have data supporting that I have a better chance of improving their quality of life with cataract surgery and with an iStent *inject* implantation compared with cataract surgery alone.

Not only do we have data demonstrating a greater reduction in IOP with the combined procedure compared with cataract surgery alone, but if the patient's IOP is elevated, cataract surgery alone will not reach the target IOP as effectively as it will with the combination of the iStent *inject* and cataract surgery.

CONCLUSION

This is an exciting time. We are learning much more about MIGS and specifically iStent technologies with cataract surgery. I encourage everyone to intervene earlier to try to eliminate glaucoma medications for these patients. We want to maximize their quality of life. It's the new paradigm we're seeing in surgical management of glaucoma. ■

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