



New Surgical Technologies to Expand Your Treatment Algorithm



Innovative devices shift treatment strategies.

BY **INDER PAUL SINGH, MD; MARK J. GALLARDO, MD; JACOB BRUBAKER, MD; AND SAHAR BEDROOD, MD, PHD**

Micro-invasive glaucoma surgery (MIGS), starting with the introduction of the iStent (Glaukos) and subsequently with the iStent *inject* and iStent *inject W*, created a paradigm shift, directing treatment to *ab interno*, tissue-sparing surgery. iStent technologies are efficacious, with a high safety profile and rapid recovery.^{1,2} We can offer iStent procedures much earlier in the disease state to reduce intraocular pressure (IOP) and medication burden.

VAST QUANTITY OF DATA

More than 200 peer-reviewed publications have reported on iStent pivotal trials and investigator-driven research, demonstrating its efficacy in reducing patients' medications and IOP safely.³ Real-world, long-term data have shown that iStent technologies provide statistically significant IOP and medication reduction, better control of glaucoma disease progression, and a reduction in the progression to a secondary surgical intervention as compared to cataract surgery alone.⁴

The first independent, non-company-sponsored data set comparing iStent *inject* and Hydrus Microstent (Ivantis) in 344 eyes at 24 months was recently published.⁵ Glaucoma tended to be slightly more advanced in patients receiving the Hydrus.⁵ Mean IOP was 18.1 mm Hg in patients receiving the Hydrus versus 16.3 mm Hg in those receiving the iStent *inject*. Visual field mean deviation was -8.8 for the Hydrus versus -4.1 for the iStent *inject*. This indicates that iStent *inject* may be used more commonly in patients with lower baseline

metrics, hence why it is critical to evaluate not just reduction from baselines, but a holistic view of broader metrics.

However, after propensity score matching (a widely-accepted rigorous statistical methodology to normalize baseline metrics between groups), iStent *inject* demonstrated trends toward greater efficacy in IOP and medication reductions compared to Hydrus. Patients' average medication burden reduced by 1.0 medications (50%) after iStent *inject* versus reducing by 0.5 medication (22.7%) after Hydrus. While safety was similar between groups, iStent *inject* demonstrated a lower rate of secondary surgical interventions (5.4%) as compared to the Hydrus group (7.5%). In summary for this first-of-kind, independent data set at 24 months, iStent *inject* demonstrated a greater reduction in IOP from baseline, lower post-operative mean IOP (14.4 mm Hg vs 15.9 mm Hg), greater medication reduction, and lower post-operative interventions.

Multiple studies have demonstrated the long-term benefits that iStent technologies provide.⁶⁻⁸ A prospective 5-year consecutive case series studied eyes with a variety of glaucoma disease states.^{2,8} Nearly a third had previous glaucoma surgery, and more than half were treated with three to four pre-operative medications.

In the combination cataract-iStent *inject* subgroup, mean IOP decreased from 22.6 mm Hg pre-operatively to 13.8 mm Hg 60 months after surgery for a 39% reduction from baseline. This subgroup showed a 69% reduction in medication use, and no traditional filtering procedures were performed during the 5-year follow-up.

Lastly, in stratified results from the pivotal trial comparing iStent *inject* with cataract surgery versus cataract surgery alone, iStent *inject* reduced IOP at all levels regardless of baseline IOP (< 25 mm Hg, ≥ 25 to < 30 mm Hg, ≥ 30 mm Hg).⁹ Larger reductions occurred in patients with a higher baseline IOP, similar to data reported in previous literature. Of note, IOP decreased by 6.2 mm Hg in the < 25 mm Hg group, 7.8 mm Hg in the > 25 to < 30 mm Hg group, and 9.8 mm Hg in the > 30 mm Hg group. Although IOP decreased in the cataract surgery-alone group, it maxed out at 5.4 mm Hg and did not demonstrate greater reductions with higher baseline IOPs. These data suggest iStent *inject* can provide significant and sustained reductions of IOP above what cataract surgery alone can provide.

ADVANCING TECHNOLOGY

Nearly 1 million iStents have been implanted throughout the world, and new devices are under development. Glaukos' portfolio of tissue-sparing, micro-invasive technologies are designed to minimize disruption of the trabecular meshwork (TM) to preserve the blood-aqueous barrier and the eye's natural mechanical pump. For every 1-mm Hg reduction in IOP that we achieve, we reduce the risk of progression by approximately 10%.¹⁰ Research has shown that having multiple outflow channels through the TM increases efficacy,

WATCH NOW



" Nearly 1 million iStents have been implanted throughout the world, and new devices are under development. Glaukos' portfolio of tissue-sparing, micro-invasive technologies are designed to minimize disruption of the TM to preserve the blood-aqueous barrier and the eye's natural mechanical pump."

which led to development of the iStent *inject*, iStent *inject W*, and iStent infinite.¹¹ iStent infinite is a three-stent system designed to be performed as a standalone or combo-cataract procedure. All three stents are preloaded in an elegant injector system that provides surgeons an unlimited number of delivery attempts to place the stents in the TM in order to provide access to place the stents within up to 240° of Schlemm's canal.

Additionally, Glaukos has built a robust portfolio of technologies designed to help surgeons optimize patient outcomes. Some of these other unique innovations include the:

- iAccess Trabecular Trephine
- iPRIME Viscodelivery System
- iDose TR Sustained Drug-Delivery System (this is an investigational product; not approved by the FDA).

NEW TREATMENT PHILOSOPHY

Advanced technologies enable us to intervene earlier to reduce patients' medications, which carry issues of compliance, cost, side effects, and more.

If a patient has glaucoma and a cataract, we can treat them with MIGS during their cataract surgery. Moreover, these procedures anticipate the next stage of glaucoma, sparing tissue if another procedure is needed in the future.

This approach supports patients' quality of life as well. With data from the phase 3 trials and OSDI scores and VFQ-25 questionnaires,

Samuelson et al, found that there was an increase in patient-reported outcome responders regarding quality of life in those who had cataract surgery with the iStent *inject* compared with those having cataract surgery alone.¹² Patients in the cataract surgery-iStent group had a greater improvement in patient-reported outcomes in categories such as general vision, ocular pain, and activities such as driving compared with the cataract surgery-alone group. Patients who were no longer taking glaucoma medications had the greatest chance of improving their quality of life or their patient-reported outcomes compared with cataract patients who were still using drops.

Early intervention for glaucoma is essential to achieve the best outcomes. By reducing medication burden, MIGS devices and other technologies will help address adherence issues and risks associated with invasive surgeries for later-stage disease.

For more content from Glaukos, scan the QR code on the first page. ■

1. Saheb H, Ahmed II. Micro-invasive glaucoma surgery: current perspectives and future directions. *Curr Opin Ophthalmol*. 2012;23(2):96-104.
2. Samuelson TW, Sarkisian SR Jr, Lubeck DM, et al. iStent inject study group. prospective, randomized, controlled pivotal trial of an ab interno implanted trabecular micro-bypass in primary open-angle glaucoma and cataract: two-year results. *Ophthalmology*. 2019;126(6):811-821.
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(2):405-415.
4. Samuelson TW, on behalf of the iStent inject Pivotal Trial Study Team. Three-year effectiveness and safety of 2nd-generation trabecular micro-bypass (iStent inject). Presented at: American Academy of Ophthalmology Annual Meeting; November 13-15, 2020; virtual.
5. Holmes DP, Clement CI, Nguyen V, et al. A comparative study of 2-year outcomes for Hydrus or iStent inject microinvasive glaucoma surgery implants with cataract surgery. Presented at: World Glaucoma e-Congress; June 30-July 3, 2021; virtual.

6. Ferguson TJ, Mechals KB, Dockter Z, et al. iStent trabecular microbypass stent implantation with phacoemulsification in patients with open-angle glaucoma: 6-year outcomes. *Clin Ophthalmol*. 2020;14:1859-1866.
7. Salimi A, Watt H, Harasymowicz P. Long-term outcomes of two first-generation trabecular micro-bypass stents (iStent) with phacoemulsification in primary open-angle glaucoma: eight-year results. *Eye Vis (Lond)*. 2021 Nov 16;8(1):43.
8. Hengerer FH, Auffarth GU, Conrad-Hengerer I. iStent inject trabecular micro-bypass with or without cataract surgery yields sustained 5-year glaucoma control. *Adv Ther*. 2022;39(3):1417-1431.
9. Singh IP, Sarkisian S, Hornbeak D, Katz LJ, Samuelson T; iStent inject study group. Treatment success across different levels of preoperative disease burden: stratified two-year outcomes from the pivotal trial of iStent inject* trabecular micro-bypass in primary open-angle glaucoma and cataract. *Clin Ophthalmol*. 2021;15:3231-3240.
10. Heijl A, Leske MC, Bengtsson B, et al. Early manifest glaucoma trial group. Reduction of intraocular pressure and glaucoma progression: results from the early manifest glaucoma trial. *Arch Ophthalmol*. 2002;120:1268-1279.
11. Katz LJ, Erb C, Guillet AC, et al. Long-term titrated IOP control with one, two, or three trabecular micro-bypass stents in open-angle glaucoma subjects on topical hypotensive medication: 42-month outcomes. *Clin Ophthalmol*. 2018;12:255-262.
12. Samuelson TW, Singh IP, Williamson BK, et al. Quality of life in primary open-angle glaucoma and cataract: an analysis of VFQ-25 and OSDI from the iStent inject* pivotal trial. *Am J Ophthalmol*. 2021;229:220-229.

INDER PAUL SINGH, MD

- The Eye Centers of Racine & Kenosha
- Racine & Kenosha, Wisconsin
- ipsingh@amazingeye.com
- Financial disclosures: AbbVie/Allergan, Glaukos, Ivantis, New World Medical, Nova Eye Medical, NICOX, iStar Medical, Sight Sciences

MARK J. GALLARDO, MD

- El Paso Eye Surgeons
- El Paso, Texas
- gallardomark@hotmail.com
- Financial disclosures: AbbVie/Allergan, Aerie Pharmaceuticals, Alcon, Bausch + Lomb, Glaukos, Ivantis, Sight Sciences, Nova Eye Medical

JACOB BRUBAKER, MD

- Sacramento Eye Consultants
- Sacramento, California
- jbrubaker@saceye.com
- Financial disclosures: AbbVie/Allergan, Aerie Pharmaceuticals, Alcon, Equinox, Glaukos, Iridex, Ivantis, New World Medical, NICOX, Santen, Twenty/Twenty Therapeutics

SAHAR BEDROOD, MD, PHD

- Advanced Vision Care
- Los Angeles
- saharbedrood@gmail.com
- Financial disclosures: AbbVie/Allergan, Alcon, Glaukos, Visus Therapeutics

For full product information, please visit <https://www.glaukos.com/important-safety-information>.