

iStent: A Powerful, Predictable, and Proven Technology

Five-year data and more than 200 published studies show that iStent technology decreases IOP, reduces patients' medication burden, and provides predictable and consistent refractive outcomes.

A summary of five previously published studies.

INTRODUCTION

Since the introduction of the MIGS category, the iStent, iStent *inject*, and iStent *inject* W devices have been a standard of care for the surgical treatment of mild-to-moderate glaucoma worldwide. Whether combined with cataract surgery or implanted as a standalone procedure, studies show the iStent devices significantly reduce IOP¹⁻³ and the mean number of topical medications needed to control IOP. In many cases, trabecular micro-bypass stenting eliminates the need for glaucoma medication entirely.^{1,4,5} By intervening at the time of cataract surgery, iStent technology may delay the need for more invasive or bleb-forming surgeries,¹ reduce the number of follow-up appointments,⁴ and potentially reduce medication and health costs⁶ making it easier for physicians

to meet the current and future needs of their patients.

Five-year data on the iStent *inject* is now available. The overarching results from the five studies outlined herein demonstrate that the device can reliably decrease IOP in combination with cataract surgery or as a standalone procedure while reducing patients' medication burdens and providing predictable and consistent refractive outcomes.¹⁻⁹ The iStent devices are a **powerful, predictable, and proven** technology (see the accompanying sidebar).

POWERFUL TECHNOLOGY FOR SUSTAINED IOP AND MEDICATION REDUCTION

Hengerer and colleagues evaluated the effectiveness and safety of the iStent *inject* for the treatment of OAG in two settings—combined with cataract surgery and as a standalone intervention.¹

A total of 125 patients were enrolled in the prospective longitudinal study, and a subgroup analysis was performed to determine results for combination and standalone treatment groups. The 5-year follow-up was completed by 121 eyes (97%), and results are shown in Figure 1.

Overall cohort. The mean IOP decreased from 23.5 mm Hg \pm 6.2 mm Hg preoperatively to 14.1 \pm 1.8 mm Hg at 5 years postoperatively, representing a 40% reduction from baseline ($P < .001$). Mean medications also decreased, from 2.68 \pm 1.02 preoperatively to 0.77 \pm 0.82 at 5 years postoperatively, indicating a 71% reduction ($P < .001$) after patients received the iStent *inject*. Additionally, before surgery, 99% of eyes were on medication, and by 5 years postoperative 46% were medication-free ($P < .001$).

At the final follow-up visit, most eyes (83%) had achieved a reduction of IOP of 20% or greater, and all eyes had either maintained or reduced their medication burden compared to baseline. No eye required filtration surgery through the 5 years of follow-up. Lastly, visual fields, retinal nerve fiber layer thickness, and cup-to-disc ratio, which are all long-term indicators of disease stability, were unchanged throughout the duration of the study.

Combined group. A total of 81 eyes underwent iStent *inject* implantation combined with cataract surgery. The mean IOP decreased from 22.6 mm Hg to 13.8 mm Hg, representing a 39% decrease ($P < .001$). Medication usage also decreased, from 2.52 preoperatively to 0.78 at 5 years

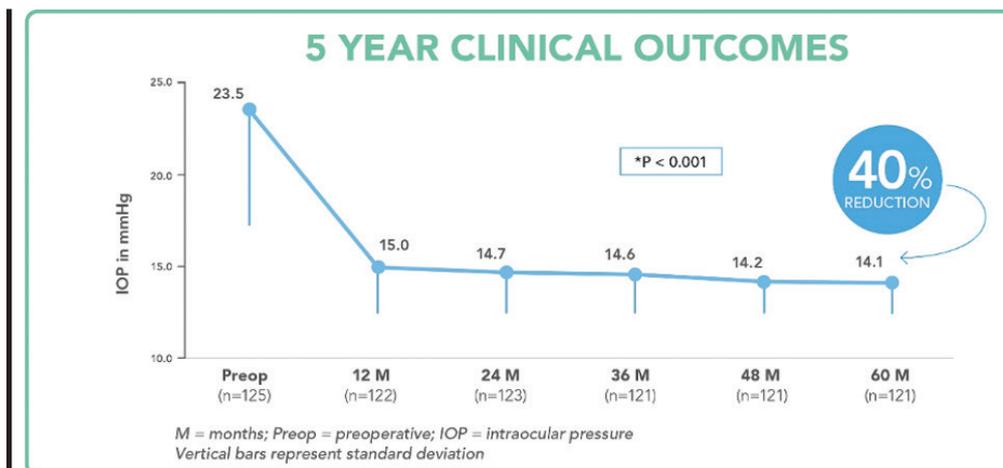


Figure 1. Data from 121 patients at 5 years postoperative showed a 40% reduction in IOP with the iStent *inject*.

"The overarching results from the five studies outlined herein demonstrate that the device can reliably decrease IOP in combination with cataract surgery or as a standalone procedure while reducing patients' medication burdens and providing predictable and consistent refractive outcomes."¹⁻⁹

postoperatively ($P < .001$). This represented a 69% decrease in medication use in this group.

Standalone group. In these 44 patients, the mean IOP improved from 25.3 mm Hg before surgery to 14.6 mm Hg at 5 years postoperatively ($P < .001$), representing a 42% decrease. Additionally, medication use decreased from 2.98 preoperatively to 0.74 at 5 years postoperatively ($P < .001$). This was a 75% decrease.

Conclusion. IOP reduction was both significant and durable 5 years after iStent *inject* implantation. There was

nearly a 2-medication reduction at the study's conclusion.

In their prospective, randomized, controlled study, Samuelson and colleagues showed that the safety of the iStent *inject* procedure combined with cataract surgery is similar to cataract surgery alone.² All patients had mild to moderate primary open-angle glaucoma and a washed out diurnal IOP between 21 and 36 mm Hg. A total of 387 eyes that received the iStent *inject* at the time of cataract surgery, and 118 that received cataract surgery alone, were followed for 2 years.

Results. At the 2-year follow-up, most patients in the iStent *inject* group (75.8%) achieved a 20% reduction in unmedicated diurnal IOP, compared to 61.9% of eyes in the control group ($P < .005$). Additionally, the mean reduction in unmedicated diurnal IOP from preoperative to 2 years postoperative was greater in the eyes that received the iStent *inject* (7.0 ± 4.0 mm Hg vs 5.4 ± 3.7 mm Hg; $P < 0.001$), and 84% and 67% of iStent *inject* and control eyes, respectively, were not on ocular hypotensive medication at 23 months. At 2 years, more eyes in the iStent *inject* group had a medication-free diurnal IOP of 18 mm Hg or less, versus control (63.2% vs 50.0%, respectively). At the 2-year follow-up, the overall safety profile was similar in both groups.

Conclusion. The researchers concluded that, combined with cataract surgery, the iStent *inject* produced clinically and statistically greater reductions in IOP without medication compared to cataract surgery alone.

In a study conducted by Schweitzer and colleagues, implantation of either the iStent or iStent *inject* combined with cataract surgery resulted in significant improvements in ocular surface health, IOP, and topical medication usage.³

OVERVIEW OF 5-YEAR RESULTS WITH THE ISTENT AND ISTENT INJECT

POWERFUL

- ▶ In a recent study, 81% of patients who received the iStent *inject* with or without cataract surgery had an IOP below 15 mm Hg at 5 years versus only 2% at baseline.¹
- ▶ In that same study, there was a 40% reduction in IOP and a 71% reduction in medication burden. Only 2% of the cohort was on three or more medications at 5 years versus more than 60% at baseline.¹
- ▶ Another study showed significant improvements in both objective and subjective measures of ocular surface health were achieved after the iStent or iStent *inject* procedure.³ In particular, the mean ocular surface disease index score improved from 40.1 (severe ocular surface disease) to 17.5 (mild ocular surface disease) by 3 months postoperative. The authors noted that the primary factor contributing to the improvement was the significant reduction in medications.

PREDICTABLE

- ▶ A study from 2020 demonstrated that 99% of patients were within ± 1.00 D of the refractive target and 74% were within ± 0.50 D.⁸
- ▶ Another study confirmed that the safety of the iStent and iStent *inject* procedure is similar to cataract surgery alone.²
- ▶ In a survey sent to UK ophthalmologists, respondents reported that patients who received the iStent had fewer follow-up visits compared to those who had undergone traditional glaucoma procedures and other MIGS procedures.⁹

PROVEN

- ▶ More than 200 peer-reviewed studies have been published on the iStent technology.
- ▶ More than 20 years of data, including preclinical data, are available for the iStent technology.
- ▶ Study results to date include more than 20,000 eyes.
- ▶ The iStent technologies are used in more than 20 countries worldwide.
- ▶ More than 900,000 iStent devices have been implanted worldwide to date.

"A UK national survey conducted by Rodriguez-Una and colleagues and sent to 75 glaucoma specialists showed that patients who received the iStent required fewer follow-up visits compared to those who had undergone traditional glaucoma procedures (trabeculectomy, tube surgery) and other MIGS procedures."⁹

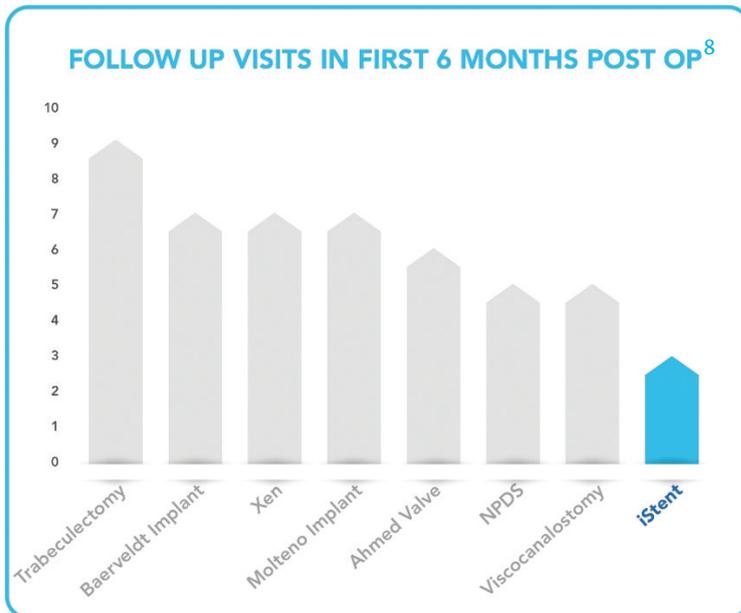


Figure 2. Patients required fewer follow-up visits in the first 6 months after surgery with the iStent compared to other glaucoma procedures.⁸

A total of 47 eyes with mild to moderate OAG were enrolled. All were on at least one but no more than 4 glaucoma medications.

Results. Preoperatively, 73% of eyes had moderate or severe ocular surface disease index (OSDI) scores; the mean score was 40.1 ± 21.6 . At 3 months postoperatively, only 29% of eyes had a moderate or severe OSDI score, and the mean score improved to 17.5 ± 15.3 ($P < .0001$). The mean tear breakup time improved from 4.3 ± 2.4 seconds (preoperatively) to 6.4 ± 2.5 seconds at 3 months ($P < .0001$). The mean IOP decreased

from 17.4 ± 4.2 mm Hg preoperatively to 14.5 ± 3.4 mm Hg at 3 months postoperatively ($P < .0001$), and the number of glaucoma medications decreased from 1.5 preoperatively to 0.9. This represented a 60% reduction in medication burden. Furthermore, 55% of eyes were medication-free at 3 months postoperative compared to 0% at baseline.

PREDICTABLE PROCEDURE REDUCING FOLLOW-UP VISITS

A UK national survey conducted by Rodriguez-Una and colleagues and sent

to 75 glaucoma specialists showed that patients who received the iStent required fewer follow-up visits compared to those who had undergone traditional glaucoma procedures (trabeculectomy, tube surgery) and other MIGS procedures (Figure 2).⁸

Number of follow-up visits. On average, iStent patients required three follow-up visits in 6 months. Trabeculectomy required more follow-up than any other intervention, followed by tube surgery (nine and seven follow-up visits in 6 months, respectively). Nonpenetrating



Figure 3. The refractive outcomes from OAG patients who received the iStent *inject* with cataract extraction.

deep sclerectomy on average required five follow-ups in 6 months.

Conclusion. iStent surgery required the fewest follow-up appointments.

PROVEN REFRACTIVELY NEUTRAL

Ioannidis and colleagues combined laser cataract surgery with the implantation of two iStent *inject* devices in 106 eyes of 89 patients to determine the refractive outcomes and the potential implications of combined surgery in patients with open-angle glaucoma.⁸

Results. The mean absolute difference in the target refraction from baseline

to the 4-week postoperative visit was 0.36 ± 0.25 D. Most eyes (73.9%) were within ± 0.50 D of intended refraction, and 98.9% were within ± 1.00 D. Of the eyes with preoperative astigmatism, the residual astigmatism was 0.50 D or less in 73.8% (Figure 3).

Conclusion. Refractive outcomes were predictable and consistent after combining laser cataract surgery with the implantation of two iStent *inject* devices. ■

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cataract: two-year results. *Ophthalmology*. 2019;126(6):811-821.

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8. Rodriguez-Una I, Azuara-Blanco A, King AJ. Survey of glaucoma surgical preferences and postoperative care in the United Kingdom. *Clin Exp Ophthalmol*. 2017;45:232-240.

9. Ioannidis AS, Töteberg-Harms M, Hamann T, Hodge C. Refractive outcomes after trabecular micro-bypass stents (iStent inject) with cataract extraction in open-angle glaucoma. *Clin Ophthalmol*. 2020;14:517-524.

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 retrolbulbar 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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