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 IOP[1-3] 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 costs[6] 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]

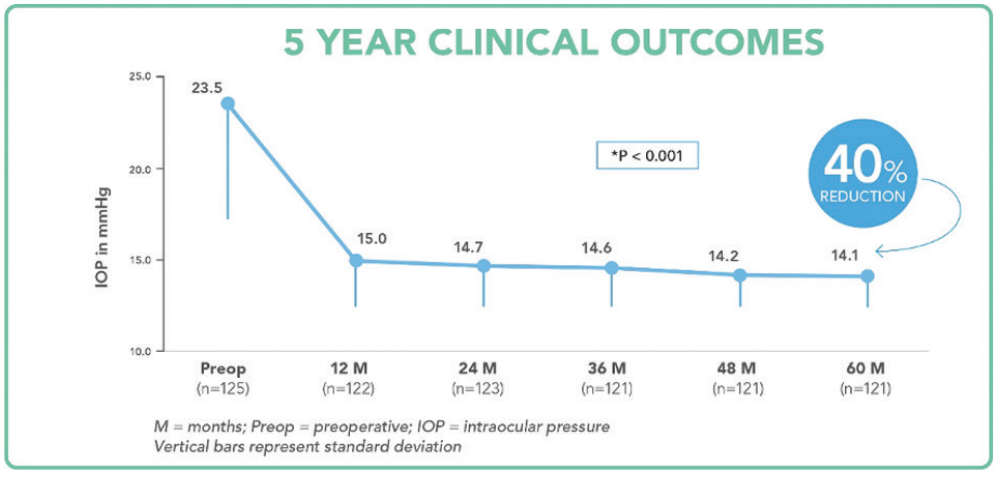

Figure 1. Data from 121 patients at 5 years postoperative showed a 40% reduction in IOP with the iStent *inject*.

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 ±6.2 mm Hg preoperatively to 14.1 ±1.8 mm Hg at 5 years postoperatively, representing a 40% reduction from baseline (P <.001). Mean medications also decreased, from 2.68 ±1.02 preoperatively to 0.77 ±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

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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]

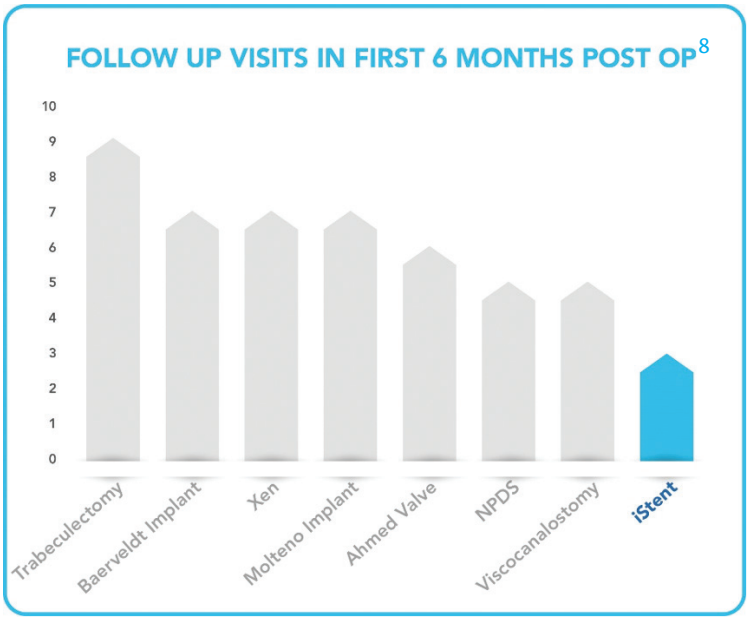

Figure 2. Patients required fewer follow-up visits in the first 6 months after surgery with the iStent compared to other glaucoma procedures.[8]

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 ±34.2 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

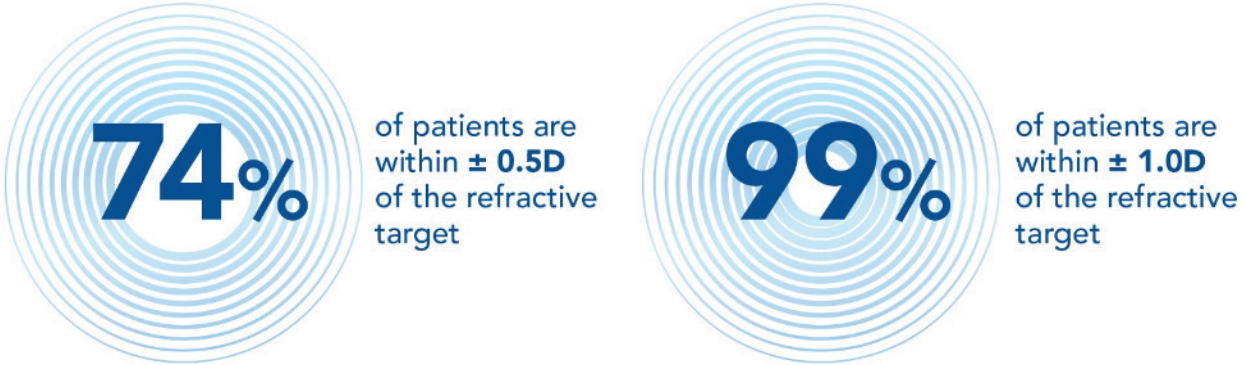

Figure 3. The refractive outcomes from OAG patients who received the iStent *inject* with cataract extraction.

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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