

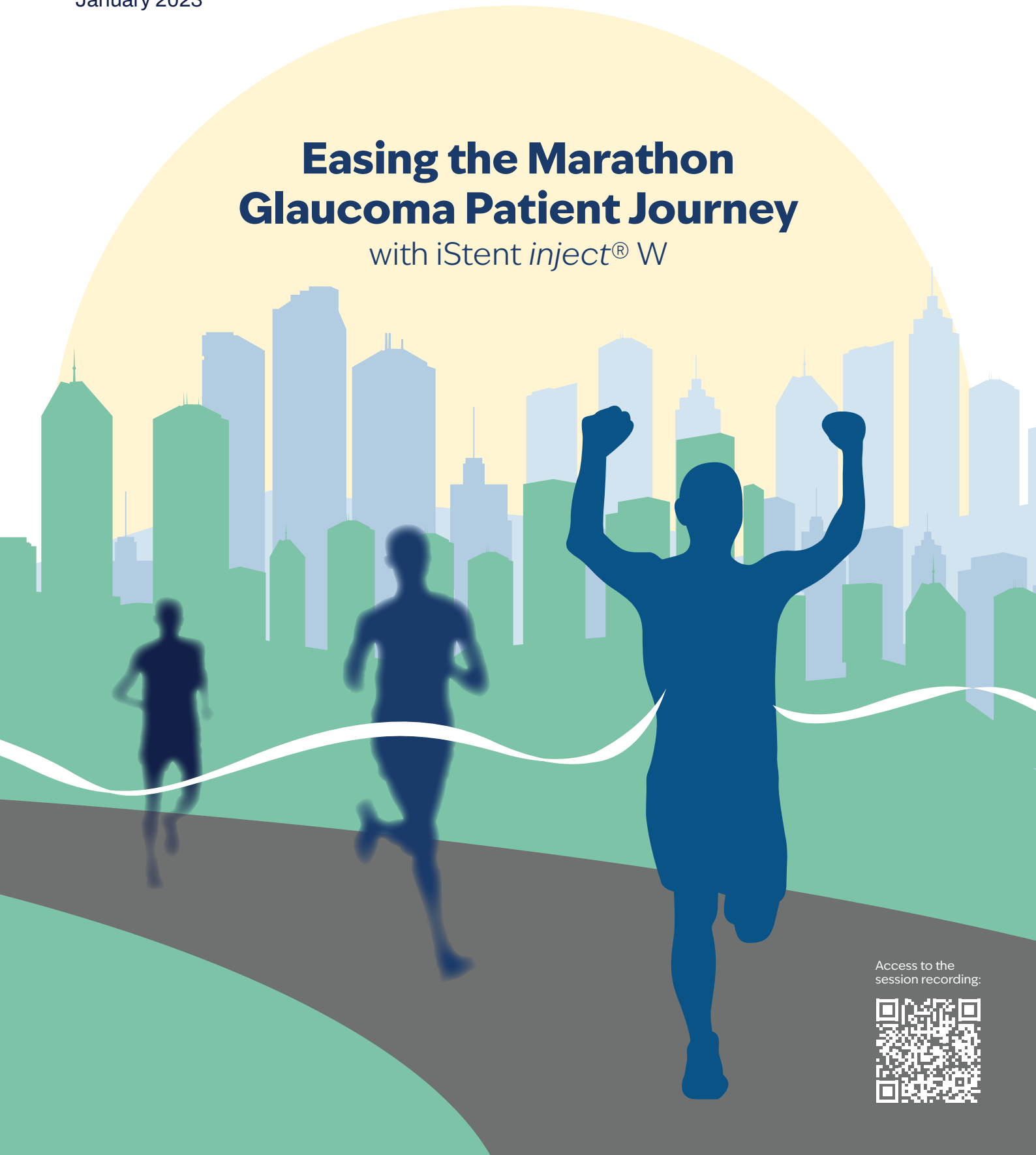


GLAUKOS[®]

Supplement
January 2023

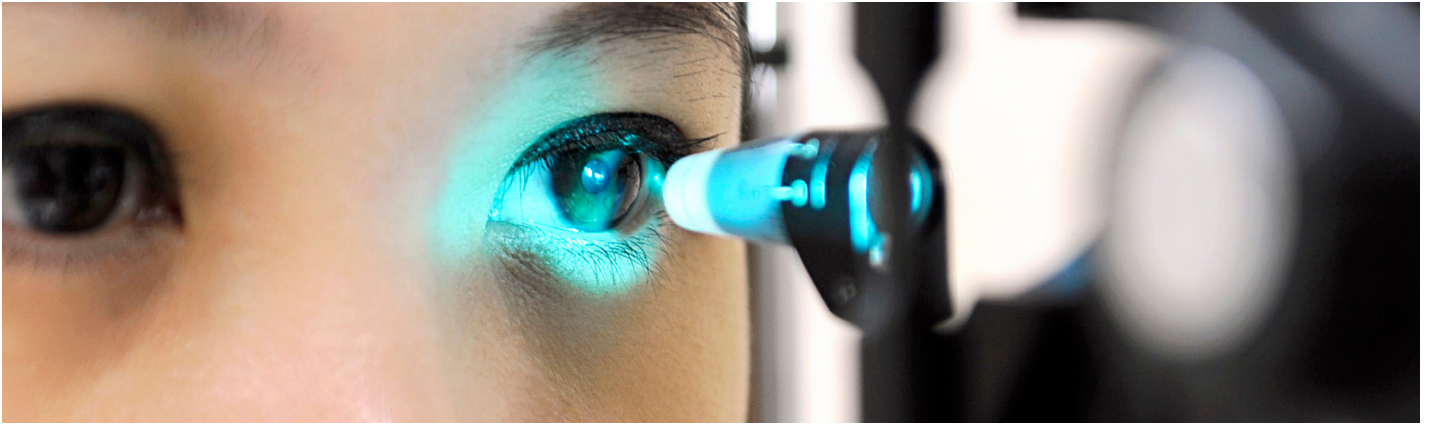
Easing the Marathon Glaucoma Patient Journey

with iStent *inject*[®] W



Access to the
session recording:





INTRODUCTION

Glaucoma is a group of chronic disorders of the optic nerve characterized by progressive visual field loss (1) affecting an estimated 76 million people in 2020 (2). **Glaucoma is the leading cause of irreversible vision loss and the second leading cause of blindness worldwide (3).** Open-angle glaucoma (OAG) is the most common form, accounting for about 74% of diagnosed cases (4, 5), with recent worldwide estimates ranging from 44 million (6) to 68 million (7). It is often seen with cataract, with approximately one-in-five cataract patients also needing glaucoma medication (8).

The glaucoma patient journey is long and arduous. Average age of diagnosis for primary open-angle glaucoma (POAG) is about 55 years with most cases developing after age 40 (9). However, POAG prevalence varies greatly by population, with an estimated 0.4% at age 40 years rising to 5.3% at age 80 years among whites, compared with 2.1% at age 40 years rising to 12.2% at age 80 years among Blacks (10).

As a result, **many patients spend decades trying to slow or prevent progression** – placing a premium on treatments with long-lasting efficacy, safety, and comfort for what is often a decades-long marathon.

Reducing intraocular pressure (IOP) is the only proven way to slow glaucoma progression. Studies show that each 1.0mmHg IOP reduction slows visual field progression by about 10% (11), and IOP reduction in patients with ocular hypertension (OHT) can cut the odds of progressing to POAG by half (12).

Most current treatments, including pharmacological, laser and surgical interventions, focus on lowering IOP (13).

Ocular **hypotensive medications** are reasonably safe and effective, but they **can lead to ocular surface disease and conjunctival hyperemia**, and **medication non-compliance is notoriously problematic** (14-18).

Laser trabeculoplasty reliably reduces IOP but **can lose effectiveness after three to five years** and in some cases may induce inflammation in the intermediate term (19).

And while **incisional surgeries** such as trabeculectomy and tube shunt implantation can reduce IOP dramatically, they **expose patients to safety risks, including endophthalmitis and hypotony**, that can persist for the lifespan of treatment (20-22). Prior use of topical medications may also increase the risk of failure of filtration surgery (23). Additionally, managing unwanted side effects of medications poses a burden to doctors and patients alike.

These shortcomings sparked development of micro-invasive glaucoma surgery, including the original iStent®, the second generation iStent *inject*®, and the current iStent *inject*® W. Measuring 360 microns deep and wide, iStent *inject* W is one of the smallest medical implants now available. In bypassing the trabecular meshwork, which is often the major obstruction to fluid drainage in open-angle glaucoma (13), the stent is designed to restore physiological aqueous outflow directly to Schlemm's canal (24). The W model has a wider base than the previous model, which increases the visibility of the device in the angle and provides surgeons with increased confidence during implantation.

Studies with up to five to nine years of follow-up have shown that in select patients with OHT or mild to moderate POAG, **iStent devices reliably reduce IOP up to 40% while lessening the need for medications (25-36), and spare conjunctival tissue in the event filtration surgery is later needed.** What's more, the **safety profile is similar to cataract surgery alone (24, 32, 33), secondary procedures are rarely needed (5, 34, 35), and, when implanted with phacoemulsification, endothelial cell loss is also similar to cataract surgery alone (37).**

iStent also has been shown to **slow glaucoma progression** when implanted with cataract surgery. In an eight-year study, visual field mean deviation remained stable for five years before beginning to progress, according to the natural history of the disease; while best correct visual acuity, cup-to-disc ratio, retinal nerve fibre layer thickness, and ganglion cell-inner plexiform layer remained stable for the entire eight years (38). Similarly, a decibel mean change of less than 0.01 was detected in visual field mean deviation 24 months after iStent implantation in the iStent *inject* pivotal trial (39).

As a result, iStent technologies are gaining popularity as an IOP-lowering option. **More than 1 million have been implanted to date, making it the leading MIGS device worldwide.**

Based on a Glaukos-sponsored symposium at the 40th Congress of the European Society of Cataract and Refractive Surgeons in Milan, Italy, this supplement discusses **how iStent *inject*® W can help to slow glaucoma progression, reduce medication burden, preserve tissue for possible future interventions, and maintain an excellent safety profile** – easing patients' glaucoma marathon by making it more and manageable.

TAKING THE FIRST STEP WITH ISTENT INJECT® W - SMALL THINGS CAN MAKE A BIG DIFFERENCE

Prof Prokosch shares tips on customising IOP targets and proper technique

Balancing individual risk and benefit

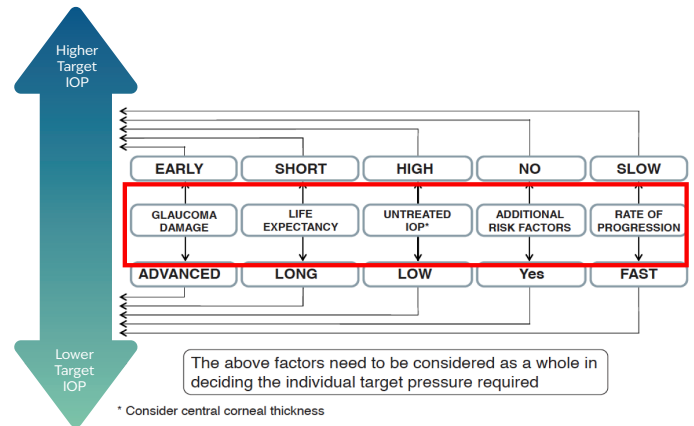
IOP lowering is the main treatment for glaucoma, said Prof Verena Prokosch MD of Uniklinik Köln of the University of Cologne, Germany. "We all know that with ocular hypertension it reduces the risk ... even a small difference, like 1mm of mercury, may be small but makes a big difference because it reduces the risk of progression by more than 10%." (40, 41)

Trabeculectomy, traditionally seen as the "gold standard" for IOP reduction, has been in use for more than half a century, with some updates such as the use of antimetabolites, Prof Prokosch noted. But while very effective in achieving low IOP long term, it is an **involved procedure requiring a lot of follow up, and intra-operative and postoperative complication rates are high**. Therefore, it meets only the first two of the three criteria of the "10-10-10 rule" for glaucoma procedures – 10mmHg for 10 years from a 10-minute procedure (42).

But not all patients need a pressure of 10mmHg for 10 years, Prof Prokosch said. Individualised treatment calls for balancing the risks of treatment against the benefits in each case when setting a target IOP.

Factors to consider include the patient's initial pressures, existing glaucoma damage, rate of progression, life expectancy, and any additional risk factors. Higher untreated IOP, severe glaucomatous damage, fast progression, presence of additional risk factors such as lack of compliance, and longer life expectancy suggest a lower target IOP, while the reverse suggest a higher target may be appropriate. "The benefits for the patient should be maximum and the risks very low," Prof Prokosch said.

Target Pressure



The 10/10/10 Rule

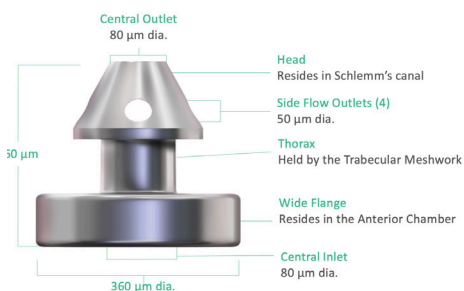
A pressure of 10 mmHg or lower for 10 years in advanced cases

©European Glaucoma Society 2020

Terminology and Guidelines for Glaucoma, 5th Edition, European Glaucoma Society, www.eugs.org
Lee, R., Material differences - do they matter " 15th EGS Congress Athens 4-8 June 2022; Talk

"The benefits for the patient should be maximum and the risks very low."

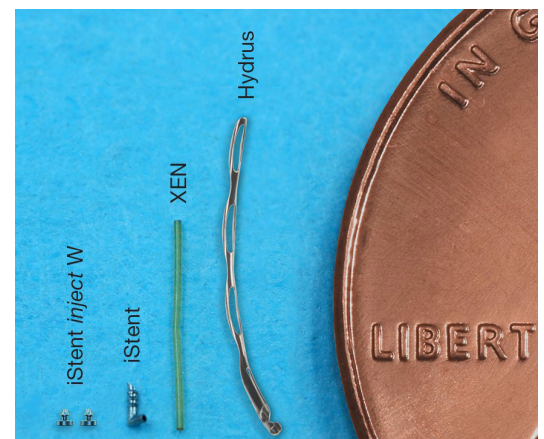
iStent technology is one of the smallest stents in the world



iStent inject® W is designed to:

- Enhance visibility
- Facilitate seamless placement
- Provide observable positioning confirmation
- Deliver procedural consistency and predictability

Featuring a wide flange at its base, the new precision-engineered iStent inject W is designed to optimize stent visualization while maintaining a truly micro-scale footprint, streamline implantation, and deliver procedural predictability.



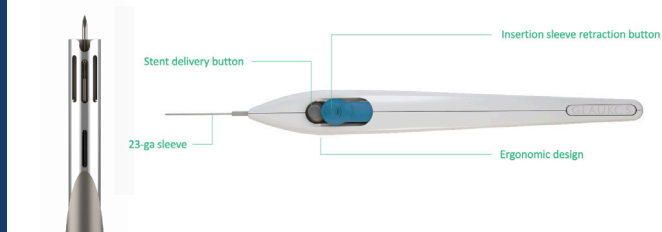
TECHNICAL TIPS FOR IMPROVING THE BENEFIT TO RISK RATIO OF THE ISTENT *INJECT*® W

Successful surgery depends on good tools and proper technique. Prof Prokosch shared insights about the latest design of the iStent *inject*® W injector and how great surgical technique can improve surgical performance.

Among the improvements in the latest iStent *inject*® W injector are **three windows cut into the sleeve** in which the tri-beveled trocar and the two iStent *inject*® W stents sit before and during injection. These windows allow the surgeon to better see if the trocar is lined up straight at the point of insertion, which is essential to proper placement of the device in the trabecular meshwork. "This is done to deliver with maximum precision," Prof Prokosch said.

Viewing windows enable maximal precision

The 23 Gauge injector with its tri-beveled trocar tip and multiple viewing windows ensures maximum visibility, so that the stents are delivered with maximum precision and minimal trauma to surrounding tissues.



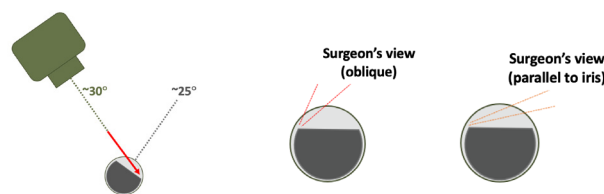
Proper positioning of the surgeon's body during insertion also aids precision delivery as well, Prof Prokosch said. She recommended positioning yourself at 15° off axis away from your dominant hand for greater ease of hand movement during insertion.

To better visualise the angle and procedure, Dr Prokosch recommended tilting the head about 25° and the microscope about 30°.

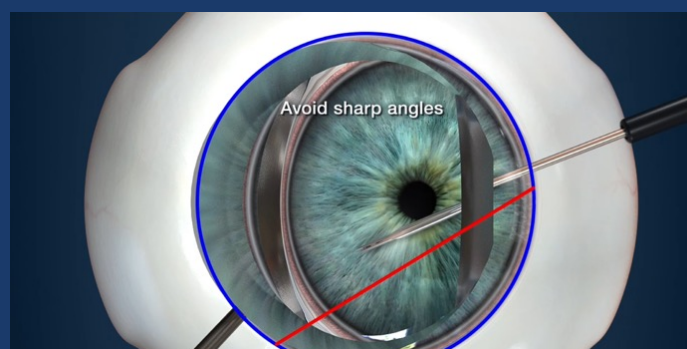
Taking a patient's specific benefit-to-risk profile into consideration, one may decide that an aqueous drainage tube is the best choice to reach a lower target IOP in more advanced cases, while a MIGS trabecular bypass stent may be suitable for a more moderate target IOP. And in addition to being effective, "we all know that the iStent *inject*® W is, no doubt, one of the smallest stents in the world," Prof Prokosch said.

Indeed, the risk of trabeculectomy is what launched the movement toward minimally invasive glaucoma surgery (MIGS), Prof Prokosch noted. First described in 2000, MIGS procedures offer the benefit of IOP lowering while minimising tissue destruction, reducing surgical time, streamlining instrumentation use and procedural steps, and shortening postoperative recovery (39).

Proper surgeon's view makes implantation more comfortable



The micro insertion tube should be aligned perpendicularly to the trabecular meshwork at 8 or 10 o'clock, Prof Prokosch said. "Avoid sharp angles, and then move forward toward the meshwork." Centre the trocar on the trabecular meshwork and apply gentle pressure, then insert, and move on to the second one.



Prof Prokosch also recommended not using too little viscoelastic, warning that it could result in a cloudy cornea.

Proper technique and positioning are key to achieve the best results for patients and surgeons, she concluded.

Benefit without added risk with iStent technologies

iStent technologies fulfil the promise of MIGS by providing the benefit of IOP reduction with very little intraoperative or postoperative risk vs cataract surgery alone, Prof Prokosch said. She cited **randomised trials that have demonstrated the superiority of adding iStent technologies to phacoemulsification for reducing IOP whilst maintaining an excellent safety profile that is similar to cataract surgery alone.**

Thomas W Samuelson reported in 2011 that 66% of patients receiving a combined iStent-phaco procedure achieved a 20% or greater reduction in IOP without medication compared with 48% of phaco-only eyes with similar safety (24). A year later in 2012, the 24-month report by E Randy Craven MD and col-

leagues of the same iStent *inject* pivotal trial found a significantly higher proportion of patients with mild-to-moderate glaucoma and cataract who underwent a combined phaco-iStent had IOPs of 21.0mmHg or below without topical medications than did those who had phaco only. The combined group also saw lower IOPs than the phaco-only group, and had stable IOP from month 12 to 24, while the phaco-only group saw a slight rise. “Patients with combined single trabecular micro-bypass stent and cataract surgery had significantly better IOP control on no medications than patients having cataract surgery alone. Both groups had a similar favourable long-term safety profile.” (32)

Similarly, a study by Antonio M Fea MD found lower IOP after washout in a combined iStent-phaco group than a phaco-only group with similar safety outcomes (33). More recently,

Dr Samuelson reported similar results in the pivotal trial of the iStent *inject* in 2019, with 87% of combined eyes and 67% of control eyes off topical IOP medications 23 months after surgery, again with similar safety profiles (39).

“They all come to the same conclusion: **effective lowering of IOP and fewer medications than cataract surgery alone, with similar safety,**” Prof Prokosch said. “**Small things can make a big difference.**”

Combining phaco with surgical glaucoma treatment also improves patient quality of life by improving vision, which was found to be more important for improving quality of life than visual field progression or type of treatment, according to a 2005 study by the Early Manifest Glaucoma Trial, Prof Prokosch added (43).

SAFE AND PREDICTABLE - ISTENT INJECT® W ON THE CATARACT JOURNEY

Dr Gundersen shares his 4-year experience with iStent inject in a high-volume cataract practice

Specialising in cataract and glaucoma surgery, Kjell Gunnar Gundersen MD, PhD and his staff do about 2,000 intraocular surgeries and 10,000 consultations annually at his clinic; iFocus Øyeklinikk in Haugesund, Norway. Of these about 20%, or 2,000, are on some form of glaucoma treatment. He began implanting the iStent *inject* in suitable patients four years ago.

Trained as a cataract and refractive surgeon after researching glaucoma as a PhD, he found working the iStent into his cataract workflow to be straightforward. Sharing a video of his third implant procedure, he was successful despite what he described as less-than-perfect gonioscopy handling and shaking hands. **“I was able to put in two stents, and the patient now, four years later, is still without any [glaucoma] medication,”** Dr Gundersen said.

His advice for successful procedures: practice gonioscopy technique to ensure good angle visualisation; avoid bleeding in the main incision (though blood reflux through the stent after insertion is a sign of success); recognize anatomic landmarks to guide proper placement, and “be patient, find a relaxed position and enjoy the ride.”

Finding suitable patients

Dr Gundersen considers any cataract patient on any kind of glaucoma treatment a potential candidate for iStent technologies, and this includes approximately 20% of his patients. **“If the anterior chamber angle and the trabecular meshwork are visible by gonioscopy, they are good candidates from a medical point of view,”** he added.

Dr Gundersen’s indications for iStent technology surgery include:

- Unstable glaucoma, including visual field deterioration, IOP asymmetry between the eyes, or IOP increase
- Unacceptable medical side effects of medications including redness and stinging, serious dry eye, or periorbital skin discolouration.
- Any compliance issues
- Patient requests for iStent surgery

Safe after 4 years

Summarising more than 4 years of clinical experience, Dr Gundersen reported no serious sight-threatening complications, and few cases of postoperative IOP spikes or anterior chamber hyphema.

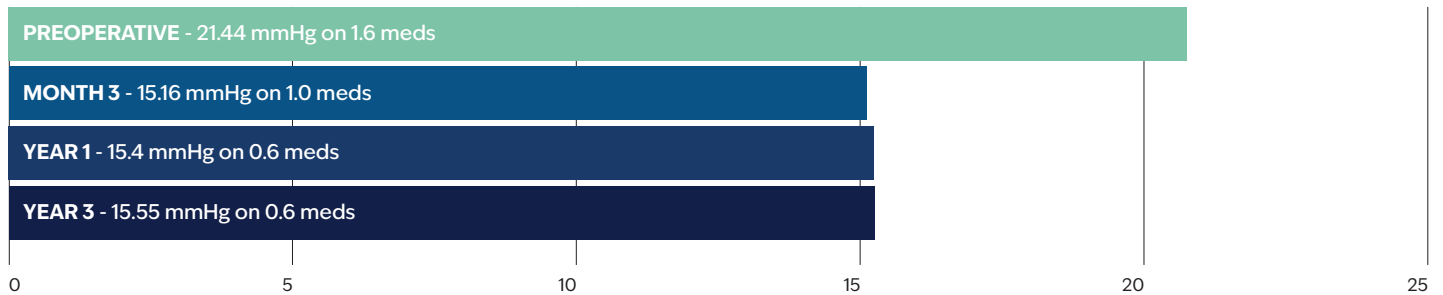
Effective IOP and medication reduction out to 3 years

In Dr Gundersen’s own experience with 86 patients implanted with iStent 3 years ago or more, mean IOP fell from 21.44mmHg on 1.6 meds before surgery to 15.55 mmHg – a reduction of 27% -- on 0.6 meds three years later.

Dr Gundersen’s results are consistent with many published studies showing IOP reduction of up to 40% in patients implanted with iStent with cataract surgery (24-39), and real-world studies showing up to 71% medication reduction at five years after implant (44).

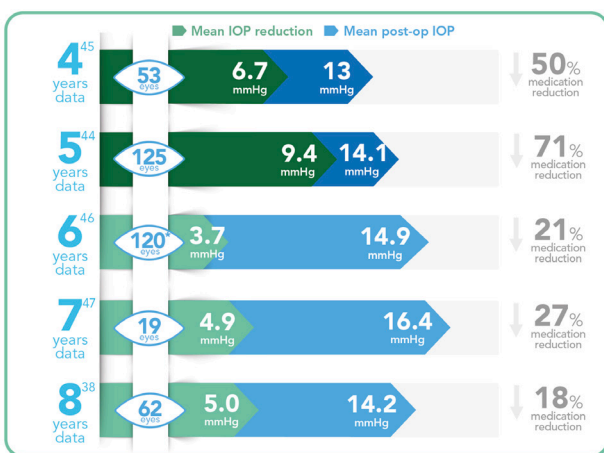
Predictability of results IOP & medical burden (my own results)

IOP



Multiple independent real-world studies demonstrate the long-term outcomes of iStent technologies. 4-year data (45), 5-year data (44), 6-year data (46), 7-year data (47), 8-year data (38)

Indeed, a meta-analysis of 13 studies of standalone iStent implantation showed an overall mean IOP reduction of more than 30% from baseline at time points from 6 months to 60 months after surgery (48).



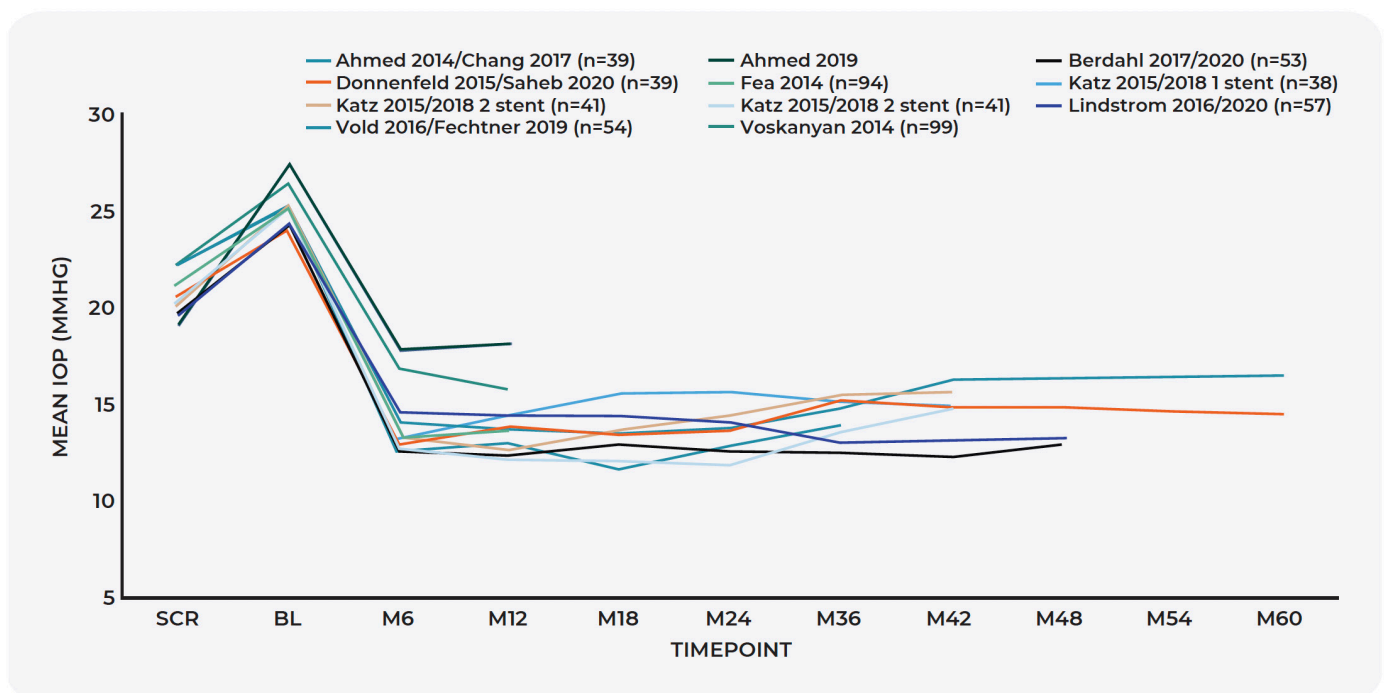
Low secondary procedure rate

In addition, only 7%, or five eyes, had to undergo further procedures during three years of follow up in Dr Gundersen's practice. This finding is consistent with published studies, which show an overall secondary procedure rate of 4% and a filtration surgery rate of 0% after five years in a real-world study of 125 patients (44), 1% requiring an incisional procedure after three years in a randomised controlled trial of 186 eyes (35), and 2.6% requiring a secondary incisional procedure in a meta-analysis of standalone iStent implants (48).

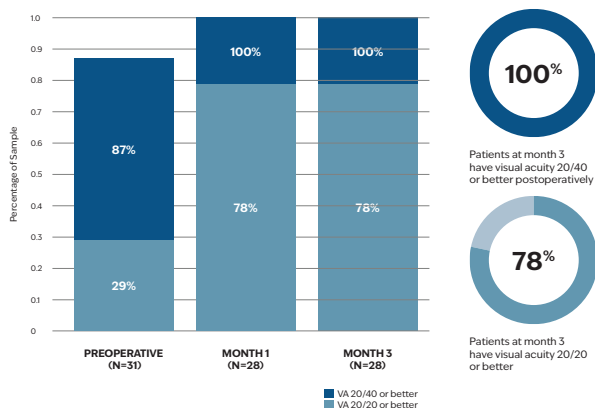
Refractive neutrality

For Dr Gundersen, iStent refractive outcomes are excellent. "It doesn't affect your refractive outcome at all," he said.

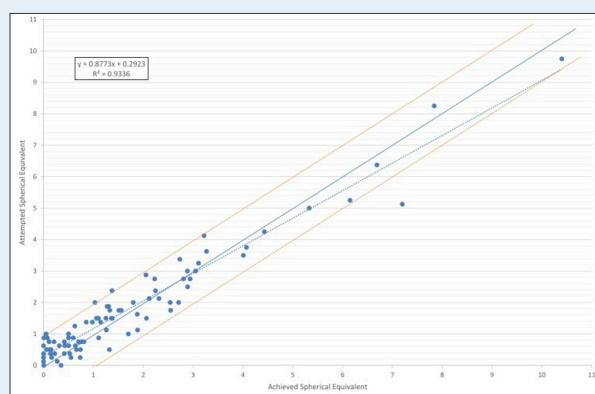
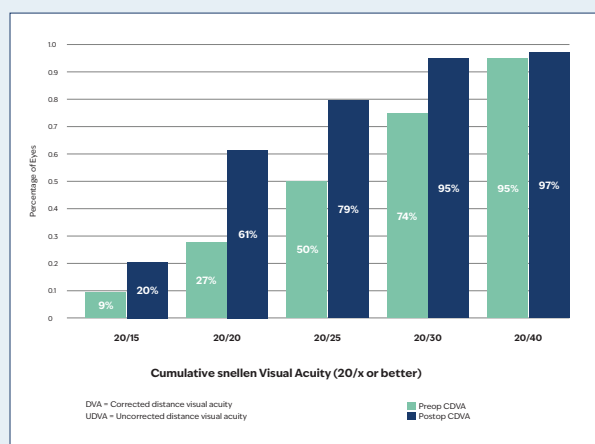
Meta-Analysis Shows Consistent IOP Reduction for Standalone iStent Devices



Predictability of Results Refractive outcome and stability over time (my own results)



Predictability of Results Refractive outcome and stability over time (Ioannidis et al 2020)



Ioannidis, Alexandros S, et al. "Refractive outcomes after trabecular micro-bypass stents (iStent inject) with cataract extraction in open-angle glaucoma." *Clinical Ophthalmology* (Auckland, NZ) 14 (2020): 517

"iStent refractive outcomes are excellent, it doesn't affect your refractive outcome at all"

In a study he conducted among his own patients, nearly 80% of patients achieved best corrected visual acuity of 20/20 or better, and 100% 20/40 or better one and three months after surgery, which is similar to his overall cataract surgery results.

These results, too, are in line with published literature (49).

Postoperative management

iStent fits well into the workflow of a high-volume cataract practice, Dr Gundersen said.

Postoperatively, Dr Gundersen conducts follow up on day one or two after surgery, week one, and week six. "At week six we consider reducing medication, then we follow them to find if their IOP is where we want it to be, then we return to regular glaucoma visits every six to 12 months."

In conclusion, Dr Gundersen noted not only that iStent inject W implantation integrates well into a high-volume cataract workflow without much alteration, the surgery itself is uncomplicated and every skilled cataract surgeon can learn to do it with a steep but short learning curve. Success rate in terms of lowering IOP and/or glaucoma medication use is about 80%, with no reduction in safety or refractive outcomes compared with cataract surgery alone. He recommended a review article from the *Journal of Cataract and Refractive Surgery* as a good resource for surgeons wanting to learn more about iStent (50).

Dr Gundersen's case study in IOP reduction

Dr Gundersen presented a case that illustrates the potential impact he sees from implanting iStent devices with cataract surgery

Male, born 1946

- The patient presented with cataract and an initial IOP of more than 40mmHg in both eyes, and optic disc cupping.
- By December 2017, this was reduced to 31 and 35mmHg on three glaucoma drops.
- In January, 2018, he had bilateral cataract and iStent inject implantation surgery.
- By three weeks postoperative, IOP bilaterally was 16mmHg on three meds.
- At month three, IOP bilaterally fell to 14mmHg on one med.
- At month 6, IOP bilaterally fell to 13mmHg on no meds.
- At year 4, IOP remains at 13mmHg on no meds. Visual fields and OCT topography are stable.

IMPROVING QUALITY OF LIFE ON THE GLAUCOMA JOURNEY WITH ISTENT INJECT® W

Mr Ratnarajan shared patient-reported quality-of-life outcomes after iStent inject implantation

Quality of life (QoL) matters in medicine, and evidence suggests that **adding iStent inject to cataract surgery may improve QoL outcomes for the patient**, said Gokulan Ratnarajan MBBS, FR-COphth, consultant ophthalmic surgeon and head of glaucoma at Queen Victoria Hospital, East Grinstead, UK.

A study of patient-reported outcomes from 505 patients in the iStent inject pivotal trial in 2021 found that iStent inject combined with cataract surgery may improve ocular surface symptoms and vision-related activities compared with cataract surgery alone. These improvements may be due to patients' greater eye comfort from being medication free, Mr Ratnarajan said (51).

"The hypothesis was that by combining phaco with iStent inject, the patients' ocular surface would improve, and their quality of life and ocular comfort would improve," Mr Ratnarajan said.

The study found that 58% of combined surgery patients compared with 45.8% of cataract-only patients were responders on the composite score of the Visual Function Questionnaire (VFQ-25) ($P < 0.05$) while 56.7% v 48.9% ($P < 0.05$), respectively, were responders on the Ocular Surface Disease Index (OSDI)

composite score after two years. Driving, ocular pain, general health, and general vision were the subscales responsible for the VFQ-25 differences, and medication reduction was proposed as one of the key contributors to the differences on the subscales. Not surprisingly, at month 24, 76.5% of VFQ-25 responders and 62.5% of non-responders were medication-free regardless of treatment group ($P < 0.05$).

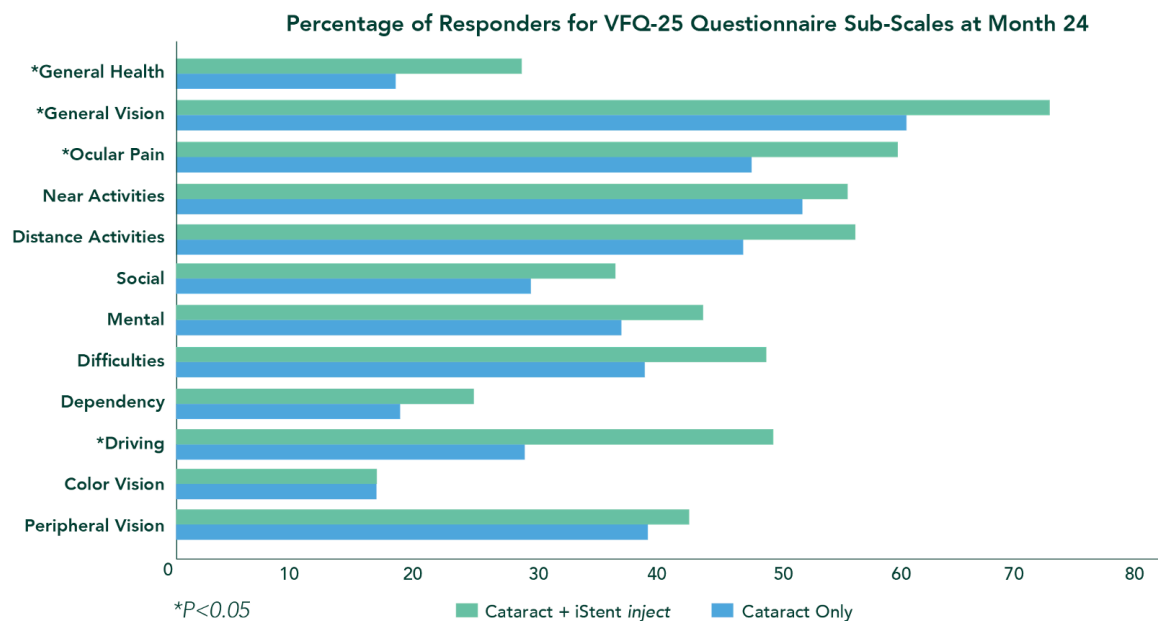
This makes iStent inject the first and only MIGS device to show significant, durable vision-related quality-of-life improvements from a pivotal trial, Mr Ratnarajan added.

With this in mind, Mr Ratnarajan and colleagues conducted their own study at Queen Victoria Hospital. "The reason we did that was for the first time in a long time we were actually having happy patients in our [glaucoma] post-op clinics as opposed to our previous patients, who, whatever you do, even if they have 20/20 before and 20/20 afterwards, they could never quite see the same."

Mr Ratnarajan also noticed an increase in patients who commented that their quality of life had improved and their confidence improved after receiving combined iStent phaco surgery. "You

iStent inject PIVOTAL TRIAL Significant Differences in Visual Function¹

Differences in VFQ-25 response rates most pronounced in General Vision, Ocular Pain, and Driving subscales ($p < 0.05$)



1. Samuelson TW. Long-term corneal endothelial safety and patient-reported outcomes of iStent inject trabecular micro-bypass. ASCRS 2020 Presentation.

“This is not just phaco alone, this is the iStent adding extra value.”

could see it in their demeanour.” They were less anxious about glaucoma because their pressures were down and they would often volunteer that their eyes felt more comfortable, he said.

In a study of 60 patients before and after receiving the iStent *inject* W with cataract surgery, Mr Ratnarajan found significant improvements after surgery in quality of life as measured by the European Quality of Life in 5 Dimensions (EQ-5D), which measures overall quality of life (not just vision related quality); the Glaucoma Quality of Life-15 (GQL-15); and the Ocular Surface Disease Index (OSDI) four and 12 months after surgery. The improvements were both statistically and

clinically significant, he said. “It’s encouraging to note this is maintained at 12 months.”

Significant improvements were also seen in ocular surface disease as measured by tear film breakup time (TFBUT); and the Oxford Grading Scale (OGS) for corneal staining. Significant reductions were also seen in IOP and glaucoma medication use.

In summary, **all patient-reported outcomes were significantly improved, and OSDI surface signs were markedly improved in medication-free patients**, Mr Ratnarajan said. This improvement was also noted when compared with phaco alone in the pivotal trial, he added. **“This is not just phaco alone, this is the iStent adding extra value.”**

Refractive outcomes, IOP, and medication need after surgery should always be part of the conversation about the risks and benefits before glaucoma surgery. **Quality of life and ocular comfort are important considerations for patients and should be added to that list**, he concluded.

Quality of Life

	Baseline	4-month follow-up	12-month follow-up	p-value
EQ5D Index	0.848 [0.768 – 1.0]	1.0 [0.837 – 1.0]	1.0 [0.837 – 1.0]	0.02*
GQL-15	18 [16 – 20]	16 [15 – 18]	16 [15 – 17]	<0.001*
GSS	85 [75 -95]	92.5 [85 – 97.5]	95 [88.8 – 100]	<0.001*
Symptom subscale	85.4 [70.8 – 91.7]	91.7 [83.3 – 100]	91.7 [87.5 – 100]	<0.001*
Function subscale	87.5 [81.3 – 100]	100 [87.5 – 100]	100 [90.6 – 100]	<0.001*
OSDI	4.2 [0 – 9.1]	2.1 [0 – 6.8]	2.1 [0 – 4.5]	0.001*

Median [IQR] scores pre and post MIGS on ocular surface parameters and significance as determined by Wilcoxon sign rank test

TFBUT, OGS, IPO and Medication

	Baseline	4-month follow-up	p-value
TBUT	4 [3.75 – 5] seconds	6 [5 – 7] seconds	<0.001*
Oxford Scale	1 [1 – 2]	1 [0 – 1]	<0.001*
IOP	18.0 (4.2) mmHg	14.0 (4.6) mmHg	<0.001*
Meds	1.8 ± 0.8	1.1 ± 0.9	p = <0.001

Median [IQR] scores pre and post MIGS on ocular surface parameters and significance as determined by Wilcoxon sign rank test

ISTENT INJECT® W OVER THE LONG HAUL: RELIABLE IOP CONTROL, LOW COMPLICATIONS, REDUCED CORNEAL ENDOTHELIAL CELL LOSS

Dr Williamson discusses long-term safety and efficacy outcomes and the benefits for his practice

Glaucoma is a life-long disease. So as a third-generation community cataract and refractive surgeon performing over 2,000 surgeries per year, Blake Williamson MD, MPH, MS of Williamson Eye Center, Baton Rouge, Louisiana, USA, knows he'll likely be seeing his glaucoma patients for decades to come.

That's a big reason why Dr Williamson focuses on the long-term effects of any glaucoma treatment he delivers. In addition to efficacy, he prioritises micro-invasive, tissue-sparing approaches to keep future treatment options open, and to potentially improve patient quality of life.

"When I think about glaucoma, I think, how does this improve the patient's life, how does it improve flow, how does it bring about more happiness in my patients so I can continue to build relationships and grow my own private practice? Every week I am shocked by patients who are just as happy to get off their glaucoma meds as they are to get out of glasses. I wouldn't have thought that, but I see it more and more."

Treatment durability is just as important. "I live in a small town, so I am going to be seeing these patients for the next 25 years, so it's important that these things last," Dr Williamson added.

Reduced IOP and Medications

For Dr Williamson, iStent *inject* checks all the boxes – 7mmHg IOP reduction and 76% medication reduction at 24 months in a US pivotal trial with cataract surgery, giving **iStent *inject* the lowest IOP reported at 24 months of any MIGS device in a pivotal trial (39).**

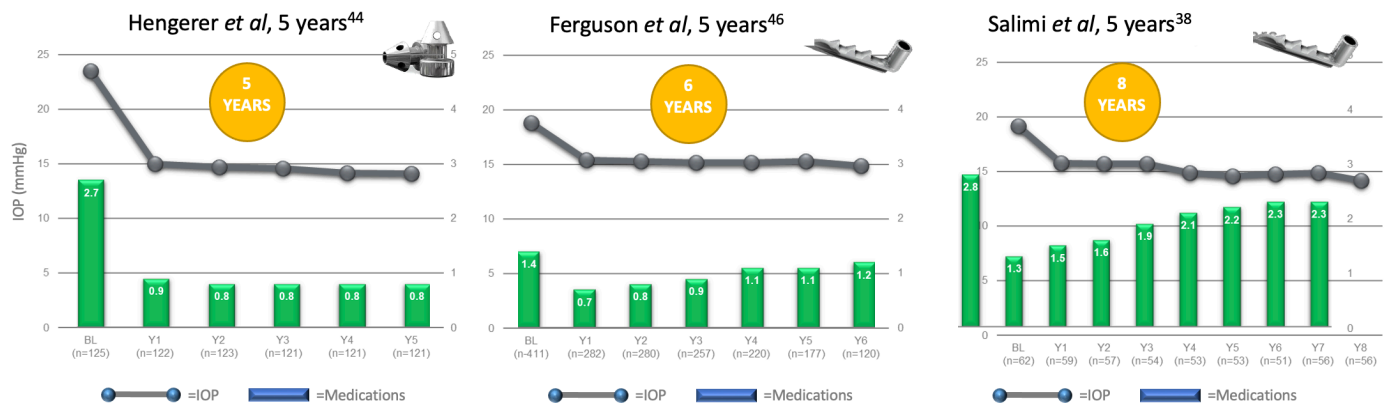
"What I really love is the long-term efficacy," Dr Williamson said. This includes a German study that found approximately 9mmHg IOP reduction and 70% medication reduction at five years with or without cataract surgery with iStent *inject* (34).

With more than 250 peer-reviewed publications, iStent technologies have the largest accumulation of clinical data of any MIGS procedure, including 16 published studies with 4 to 8 years follow up, which also gives iStent technologies the longest follow-up data of any modern MIGS device.

And, with **more than 1 million devices implanted worldwide, iStent technologies are the most frequently used MIGS procedure.**

Longest-Term Data of Any MIGS Procedure

- Prospective consecutive case series
- Germany
- High preoperative burden (drops, surgery)
- Combined (n=81) or standalone (n=44)
- Retrospective case series
- USA
- Mild (57%), Mod (23%) or Sev (20%) POAG
- No exclusions
- Combined with cataract surgery
- Longitudinal case series
- Canada
- Combined with cataract surgery
- Average VF MD -5.9 ± 6.6 dB
- No exclusions based on diagnosis or severity

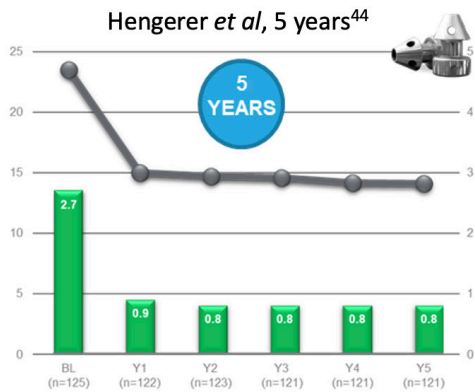


44. Hengerer, Fritz H., Gerd U. Auffarth, and Ina Conrad-Hengerer. "iStent *inject* Trabecular Micro-Bypass with or Without Cataract Surgery Yields Sustained 5-Year Glaucoma Control." *Advances in Therapy* 39.3 (2022): 1417-1431.
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Slowing visual field loss

iStent also shows substantial efficacy in preventing visual field loss out to at least five years. Although some visual field loss was seen at eight years, this is not surprising considering the progressive nature of the disease, Dr Williamson noted.

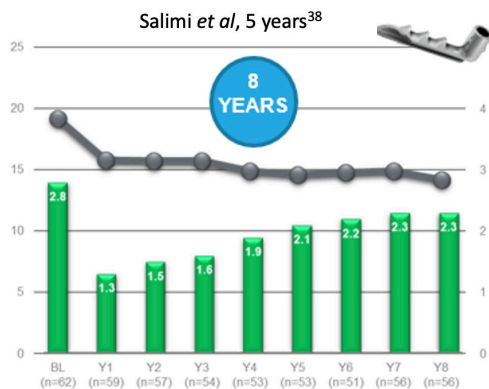
Longest-Term Data of Any MIGS Procedure



	Stand alone group		Cataract combo group	
	BL	Y5	BL	Y5
VF MD	-7.0 dB (p=0.502)	-7.1 dB	-6.6 dB (p=0.462)	-6.7 dB
RNFL	82.1 µm (p=0.194)	80.9 µm	81.4 µm (p=0.497)	80.2 µm
C:D Ratio	0.78 (p=0.386)	0.79	0.74 (p=0.324)	0.76

44. Hengerer, Fritz H, Gerd U. Auffarth, and Ina Conrad-Hengerer. "iStent inject Trabecular Micro-Bypass with or Without Cataract Surgery Yields Sustained 5-Year Glaucoma Control." *Advances in Therapy* 39.3 (2022): 1417-1431

Longest-Term Data of Any MIGS Procedure



	BL	Y5	Y8
VF MD	-5.9 dB (p=0.634)	-5.5 dB (p=<0.001)	-8.0 dB
RNFL	70.5 µm (p=0.222)	74.7 µm (p=0.228)	74.3 µm
C:D Ratio	0.71 (p=0.187)	0.70 (p=0.176)	0.70

38. Sallmi, Ali, Harrison Watt, and Paul Harasymowycz. "Long-term outcomes of two first generation trabecular micro-bypass stents (iStent) with phacoemulsification in primary open-angle glaucoma: eight-year results."

Sparing tissue

Dr Williamson added that when choosing an initial surgical approach, the long-term risks and benefits need to be considered. He noted that his definition of MIGS has shifted over the years from "anything that is not a trab" to "what is the most tissue-sparing approach to keep future options open."

By that definition, iStent is one of the most "MIGS-y" procedure there is, Dr Williamson said. "You always have time to do some incisional surgery if you need to; you are not taking that away."

"By that definition, iStent is one of the most "MIGS-y" procedure there is"

iStent vs. the Competition

Over the long term, iStent does at least as well as the competition in efficacy, Dr Williamson said.

He pointed to the first large published study comparing the second-generation iStent *inject* with the Hydrus microstent. iStent *inject* and Hydrus both reduced IOP and medication use, with a trend toward greater medication reduction with iStent *inject*.

"Twenty-four-month outcomes showed sustained IOP reduction with a good safety profile for both groups. There was no significant difference in IOP outcomes between the groups. There may be a small additional reduction in glaucoma medication usage following cataract surgery with iStent *inject* compared to Hydrus," the study authors concluded (53).

Comparing safety data in a pivotal trial extension for iStent *inject* vs. published pivotal trial data for Hydrus, iStent *inject* showed lower rates of loss of two lines of vision at three months, lower rates of loss of 2.5 decibels or more in visual field mean deviation, and lower rates of peripheral anterior synechiae at five years after surgery (54, 55).

Cumulative Adverse Events Reported through 5 Years	% of Subjects with Event (n)			
	iStent <i>inject</i> pivotal study extension		Hydrus pivotal study 5-year data	
	iStent <i>inject</i> * 54	Cataract Sx 54	Hydrus* 55	Cataract Sx 55
BSCVA loss 2 lines ≥ 3 months postoperative	0.3%	0.8%	1.9%	2.1%
Worsening in VF MD ≥ 2.5 dB	1.3%	1.7%	8.4%	9.6%
Peripheral anterior synechiae	1.8%	0%	14.6%	3.7%

54. iStent *inject* pivotal trial extension data on file

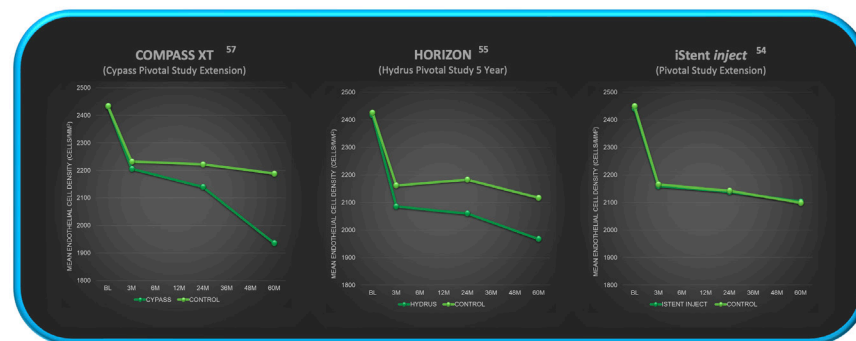
55. Ahmed, Iqbal Ike K, et al. "Long-term Outcomes from the HORIZON Randomized Trial for a Schlemm's Canal Microstent in Combination Cataract and Glaucoma Surgery." *Ophthalmology* (2022).

No Increased Corneal Endothelial Cell Loss

Preserving the corneal endothelium is an important concern for any intraocular surgery, and the iStent *inject* does so, Dr Williamson said.

In a pivotal study extension, endothelial cell density in iStent *inject* plus cataract surgery eyes was similar to cataract-surgery-only eyes, as were the percentages of eyes that lost 30% or more of endothelial cells five years after surgery. "It's critical to note that between phaco alone and phaco with iStent there was no statistical difference at all," Dr Williamson said (54, 56).

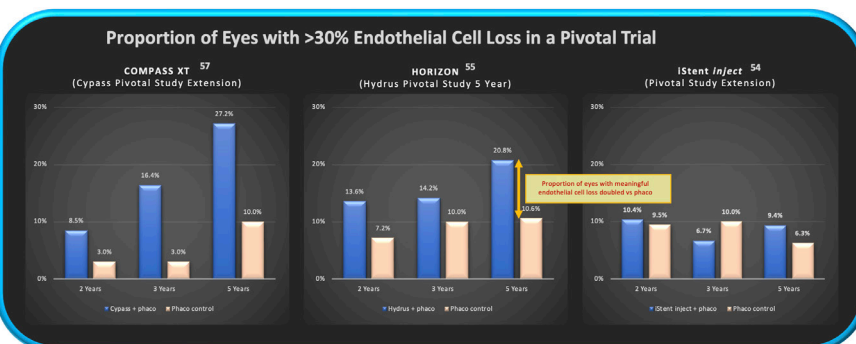
By comparison, both the CyPass and Hydrus microstents with cataract surgery showed greater mean endothelial cell loss and higher percentages of patients with greater than 30% endothelial cell loss five years after surgery than cataract surgery alone in the respective pivotal trial and pivotal trial extension (51, 53). "This loss was primarily around the time of surgery for Hydrus; however, it was progressive beyond 3 years for CyPass," according to one analysis (56). iStent *inject* demonstrated the most favourable safety profile, with no statistical difference in the proportion of eyes with clinically significant [endothelial cell loss] (>30%) compared to [cataract surgery] alone," the analysis concluded.



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54. iStent *inject* pivotal trial extension data on file



57. Lass, Jonathan H, et al. "Corneal endothelial cell loss and morphometric changes 5 years after phacoemulsification with or without CyPass Micro-Stent." *American Journal of Ophthalmology* 208 (2019): 211-218.

55. Ahmed, Iqbal Ike K, et al. "Long-term Outcomes from the HORIZON Randomized Trial for a Schlemm's Canal Microstent in Combination Cataract and Glaucoma Surgery." *Ophthalmology* (2022).

54. iStent *inject* pivotal trial extension data on file

For me it's just more data proving [iStent's] safety over time, its long-term predictability, and how powerful it is... what I like about it is it's an elegant device. Even though I am not a glaucoma surgeon, I am a refractive surgeon, the reason I can do it is it brings so many happy patients into the practice and adds some variation to my day, it saves my patients a lot of heartache about the ocular surface, and I just think it is the right thing to do," Dr Williamson said.

iStent *inject* W also provides a highly efficacious procedure whilst maintaining a high degree of safety, Dr Williamson said. "It really doesn't change a lot of my pre- and post-cataract surgery procedure, which I love, being the type of practice that we are."

CONCLUSION

A growing body of long-term research, including up to nine-year outcomes data from completed and ongoing studies of iStent and iStent *inject*, show that the technology reliably reduces IOP and IOP-lowering medication need, with an excellent safety profile, including minimal corneal endothelial cell loss. For qualified OAG glaucoma patients, iStent *inject* W may provide substantial clinical and lifestyle advantages, giving glaucoma and cataract surgeons a new tool to help prevent long-term vision loss while improving patient quality of life. Indeed, iStent *inject*® W is #1 because it eases the marathon glaucoma journey

PROVEN COST UTILITY WITH ISTENT *INJECT*®

As health services consume an ever-growing slice of national income, cutting treatment costs is critical. Several recent studies show that iStent *inject*'s favourable efficacy and safety profile contributes to reduced need for post-operative medication and follow-up. This saves money and time for patients, their families, physicians and society at large – making iStent *inject* a cost-effective treatment option for many patients with mild to moderate open-angle glaucoma.

A comparison of the costs of cataract surgery alone with combined cataract and iStent *inject* in France found the combined procedure improved patient quality of life as measured by Quality Adjusted Life Years (QALY) by 0.065 at a cost of €75 per patient over their lifetimes. That works out to €1,154 per QALY gained, making it a bargain at less than four percent of the ~€30,000 the UK's National Health Service considers a reasonable cost per QALY gained. (58)

"iStent *inject* implantation in conjunction with cataract surgery offers a mechanism for IOP reduction that is more effective than cataract surgery alone while reducing the need for medication use and its associated side-effects. ... [And] it can be considered cost-effective in patients with mild-to-moderate OAG by improving the patient's quality-of-life at very low incremental costs," the French study concluded. (58)

A similar comparison in Spain found that combined iStent *inject* cataract surgery cost the Spanish National Health System €1,002 more than cataract surgery alone, for a cost per QALY gained of €13,077. When the cost of informal caregiver time was included, the combined procedure actually reduced overall societal costs. "iStent *inject* ... provides good value for money in patients with mild-to-moderate OAG," The Spanish study concluded. (59)

iStent *inject* may also be more cost-effective than subconjunctival procedures in eligible mild to moderate OAG patients. One study found that substituting iStent *inject* combined with cataract surgery for 41 per cent of Xen gel stent (Allergan) + cataract combined surgeries would save the Spanish National Health System more than €3 million annually by reducing complications and follow up costs. (60)

Likewise, substituting iStent *inject* with or without cataract surgery for trabeculectomy would save the German statutory health insurance system about €300 per patient for inpatient iStent procedures and more than €1,800 for outpatient iStent procedures over a three-year period. Overall, substituting iStent *inject* for 10 per cent of trabeculectomies would save German insurers about €17 million. (61) Together these studies suggest a compelling economic case can be made for using iStent *inject* in suitable patients.

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iStent *inject*® W IMPORTANT SAFETY INFORMATION

INDICATION FOR USE: The iStent *inject*® W, 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*® W, 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*® W 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 retrolental 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*® W is MR-Conditional; see MRI Information below. • Physician training is required prior to use of the iStent *inject*® W 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*® W 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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