

# Demystifying iStent *inject*<sup>®</sup> W for glaucoma surgery



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## INTRODUCTION

Glaucoma is the largest cause of irreversible blindness globally.<sup>1</sup> To prevent vision impairment, timely diagnosis and effective treatment are required. Prior to the advent of MIGS, glaucoma treatment relied upon decreasing intraocular pressure (IOP) through filtering surgery (that accounts for 48% mean IOP decrease),<sup>2,3</sup> medication (18-35% mean decrease),<sup>4,5</sup> or laser (25.6% mean decrease).<sup>6</sup> **More important than IOP, however, we should focus on surgical success,<sup>7</sup> quality of life,<sup>8</sup> and complications.** Classical glaucoma surgery has a steep learning curve<sup>9</sup> and presents a risk of potentially blinding complications,<sup>10-12</sup> which triggered the development of microinvasive glaucoma surgeries (MIGS).<sup>13</sup> **iStent<sup>®</sup> technologies (Glaukos) are the most well-studied of the MIGS procedures.** Nevertheless, many myths exist regarding this surgery; we intend to demystify them using scientific evidence.

## Myth 1: My patient doesn't need an iStent *inject*<sup>®</sup> W—he's fine with eyedrops

Though medical treatment may suffice for many patients, we must be vigilant regarding quality of life, adverse effects, compliance, and glaucoma progression.

Quality of life (QoL) is low in advanced and mild glaucoma.<sup>14-16</sup> Unfortunately, **medical treatment also significantly decreases QoL,<sup>17,18</sup>** namely when the treatment is not tolerated<sup>8</sup> or complex, when there are adverse effects, when patients have difficulty applying their eyedrops,<sup>19</sup> when they cause ocular surface changes (OSC),<sup>20</sup> and even sometimes when the eyedrops are tolerated.<sup>17,21</sup> There is ample

evidence of the multiple adverse effects of glaucoma medical treatment.<sup>8,22-25</sup> Even when the eyedrops are tolerated, they can cause OSC, decreasing QoL,<sup>17,21</sup> and eventually impairing surgical results.<sup>26</sup> **Filtering surgery failure risk increases with hyperemia and chronic preservative use.<sup>27-29</sup>** To further aggravate the problem, glaucomatous patients are frequently non-compliant with their treatment<sup>30</sup> (nonadherence varying between 5% and 80%),<sup>30,31</sup> particularly if not tolerated, provoking glaucoma progression and further QoL impairment.

In conclusion, the quality of life of glaucomatous patients is low,<sup>14-16</sup> and it can be further decreased due to medical treatment; consequently, we should consider alternatives such as laser or surgery. Selective laser trabeculoplasty (SLT) may increase QoL; some studies affirmed finding higher QoL after laser but didn't measure QoL in a validated scale,<sup>30,31</sup> while others didn't identify significant improvement (as the EQ15 score in the LIGHT trial).<sup>34,35</sup> SLT's IOP-lowering effect usually declines through the years.<sup>8,36</sup> Classical filtering surgery decreases QoL in the early postoperative period and sometimes later with bleb-associated complaints.<sup>37,38</sup> Isolated phacoemulsification surgery in glaucomatous patients may increase QoL,<sup>31</sup> but may also cause IOP spikes,<sup>39</sup> previous trabeculectomy failure,<sup>40,41</sup> and does not address the real problem of glaucoma progression. Phacoemulsification may decrease IOP, but temporarily,<sup>42-44</sup> unlike phacoemulsification with iStent<sup>®</sup>.<sup>45</sup> As for combined phacoemulsification and glaucoma surgery, many studies failed to identify differences in QoL,<sup>46,47</sup> except for Samuelson et al.<sup>48</sup>

Samuelson et al.<sup>48</sup> performed a posthoc analysis of the **iStent *inject*<sup>®</sup> pivotal trial** (comparing phacoemulsification with phacoemulsification + iStent *inject*<sup>®</sup>) **focusing on QoL.** While both groups increased QoL, interestingly, **the phacoemulsification + iStent *inject*<sup>®</sup> group showed a higher increase.** More specifically, there was higher QoL in the categories of **driving** (49.0% vs. 28.8%;  $P < 0.05$ ), **ocular pain** (59.3% vs. 47.2%;  $P < 0.05$ ), and **general vision** (71.8% vs. 60.0%;  $P < 0.05$ ),<sup>46</sup> perhaps due to decreasing medication need.

**These arguments favor the use of iStent *inject*<sup>®</sup> W with phacoemulsification for glaucoma patients.**

## Myth 2: MIGS are minimally effective

**iStent<sup>®</sup> technologies are very effective for glaucoma surgery,<sup>49-51</sup> even with high baseline IOP,** as found by Singh et al.<sup>50</sup> In patients with preoperative IOP of  $\geq 30$  mm Hg, 74.4% remained medication-free 24 months after phacoemulsification + iStent *inject*<sup>®</sup>, as opposed to 33.3% in the phacoemulsification group ( $P < 0.05$ ). Multiple iStents decrease the IOP more than a single stent;<sup>52,53</sup> a meta-analysis identified a mean IOP decrease of 9% with phacoemulsification and one iStent<sup>®</sup>, and 27% with phacoemulsification and two iStents.<sup>54</sup> Studies show continued effectiveness up to 8 years postoperatively.<sup>45,55</sup>

## Myth 3: iStent<sup>®</sup> technologies are not safe or well known

The iStent technologies are currently the smallest devices in the human body,

approximately 360 µm in length. Unlike trabeculectomies, the iStent *inject*<sup>®</sup> procedure's learning curve is short. This device has a **low rate of complications, comparable to cataract surgery.**<sup>52,53</sup> It is the most well-studied MIGS device<sup>56</sup> with **over 250 articles published and 1 million devices implanted.** As mentioned before, it has had no severe adverse effects.

## Myth 4: For a patient with advanced glaucoma, just operate on the cataract

Isolated cataract surgery in glaucoma patients may cause postoperative IOP spikes,<sup>39,57</sup> which can cause fixation loss<sup>58</sup> in advanced glaucoma patients. **Combined phacoemulsification with iStent *inject*<sup>®</sup> W is a safe approach, allowing better IOP control due to its micro-trabecular design (postoperative surveillance is needed in all patients, and an IOP spike can happen even in combined surgery, namely with steroid response).** Fortunately, there are **no reports of fixation loss with iStent and no reports of serious adverse events,**<sup>49,50</sup> even in advanced glaucoma.<sup>51</sup> And, since they are small and usually implanted nasally or inferiorly, iStents do not preclude a future trabeculectomy.

**In conclusion, iStent *inject*<sup>®</sup> W is safe, effective long-term, easy to learn, and improves QoL. We should carefully choose the most appropriate treatment for each patient in a multifactorial decision, considering not only glaucoma staging, progression, and IOP but also the patient's age, daily tasks, ability to drive, eye comfort, vision stability, and QoL. ■**

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### iStent *inject*<sup>®</sup> W IMPORTANT SAFETY INFORMATION

**INDICATION FOR USE:** The iStent *inject*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup> 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<sup>®</sup> 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*<sup>®</sup> W is MR-Conditional; see MRI Information below. • Physician training is required prior to use of the iStent *inject*<sup>®</sup> 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*<sup>®</sup> 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. Glaukos<sup>®</sup>, iStent<sup>®</sup>, iStent *inject*<sup>®</sup>, iStent *inject*<sup>®</sup> W and iDose<sup>®</sup> are registered trademarks of Glaukos Corporation. All rights reserved. ©2023 PM-EU-0267