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CHANGING PERSPECTIVES IN GLAUCOMA MANAGEMENT

in combination with cataract surgery, iStent establishes the physiological foundation to sustain target pressures while reducing or eliminating medication use.
Recent advancements in glaucoma management have resulted in significant proposed changes to the traditional treatment algorithm for primary open-angle glaucoma (POAG). Based on new clinical findings combined with medical innovations, glaucoma specialists have proposed earlier intervention with minimally invasive and surgical procedures versus drug therapy alone.

The iStent Trabecular Micro-Bypass Stent Model GTS100R/L is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in subjects with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication.

**THE CHANGING PERSPECTIVE**

Recent advancements in glaucoma management have resulted in significant proposed changes to the traditional treatment algorithm for primary open-angle glaucoma (POAG). Based on new clinical findings combined with medical innovations, glaucoma specialists have proposed earlier intervention with minimally invasive and surgical procedures versus drug therapy alone.

**THE ISTENT IS THE SMALLEST MEDICAL DEVICE KNOWN TO BE IMPLANTED IN THE HUMAN BODY**

- Length: 1 mm
- Height: 0.33 mm
- Snorkel: 0.25 mm × 120 µm (bore diameter)
- Weight: 60 µg
- Surgical-grade nonferromagnetic titanium
- Heparin coated to promote self-priming and facilitate outflow

**THE ONLY COMMERCIALLY AVAILABLE DEVICE FOR THE TREATMENT OF MILD-TO-MODERATE GLAUCOMA**

- First available ab interno micro-bypass stent for the treatment of glaucoma
- Reduces or eliminates dependence on glaucoma medications
- Spares conjunctival tissue
- Preserves potential for future treatment options

**ISTENT DIMENSIONS ARE CUSTOMIZED FOR A NATURAL FIT WITHIN SCHLEMM’S CANAL**

- Three retention arches ensure secure placement
- Rail design protects and accesses the underlying collector channels

**DESIGNED FOR INSTINCTIVE CONTROL**

- Preloaded, single-use, sterile inserter with a secure, rotatable grip
- Inserter has reacquisition capability to facilitate manipulation and placement into Schlemm’s canal
- Two orientations of the iStent are available, one for the right eye (OD) and one for the left eye (OS)

**ISTENT SURGICAL PROCEDURE**

The iStent is inserted ab interno through the phaco incision, and can be performed under topical anesthesia.

**expand options with iStent®**

**customized for optimal performance**
The primary cause of elevated eye pressure in patients with POAG is abnormality of the trabecular meshwork. With up to 75% of resistance to outflow located in the juxtacanalicular tissue, the patent bypass, created by the iStent, reestablishes physiological outflow through Schlemm’s canal.

The use of the iStent Trabecular Micro-Bypass Stent has not been studied as an alternative to the primary treatment of glaucomatous symptoms with medications. The effectiveness of this device has been demonstrated only in patients with mild-to-moderate open-angle glaucoma who are currently treated with ocular hypotensive medication and who are undergoing concurrent cataract surgery.

In an in vivo study of enucleated anterior segments from 21 eyes that were placed in perfusion culture, trabecular bypass stents were inserted through the trabecular meshwork, with the lumen of the stent opening into Schlemm’s canal. The reduction in IOP presented herein was seen in in vivo data and may not translate to clinical outcomes.

reduce or eliminate medication use with iStent

**PERCENTAGE OF PATIENTS WHO SUSTAINED IOP ≤21 mm Hg WITHOUT MEDICATION USE**

<table>
<thead>
<tr>
<th></th>
<th>Cataract surgery (n=123)</th>
<th>iStent (n=117)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>50%</td>
<td>73%</td>
</tr>
<tr>
<td>20%</td>
<td>40%</td>
<td>40%</td>
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<tr>
<td>40%</td>
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<td>60%</td>
<td>0%</td>
<td>0%</td>
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<tr>
<td>100%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

12-month results from a prospective, randomized, multicenter study across 27 US sites of 240 patients with cataract and mild-to-moderate glaucoma treated with ocular antihypertensive medications. All patients were assigned to a medication washout period before undergoing cataract surgery or iStent implantation plus cataract surgery.

**OF PATIENTS WHO RECEIVED iSTENT REMAINED MEDICATION FREE WHILE SUSTAINING TARGET IOPs OF ≤21 mm Hg VERSUS ONLY 50% OF THOSE WHO UNDERWENT CATARACT SURGERY ALONE** (P<.001) LOCFS ANALYSIS AT 12 MONTHS

**SUSTAIN IOP CONTROL AND REDUCE MEDICATION USE WITHOUT SIGNIFICANT ADDITIONAL RISK COMPARED WITH CATARACT SURGERY ALONE**

<table>
<thead>
<tr>
<th></th>
<th>Cataract surgery alone (n=122)</th>
<th>iStent plus cataract surgery (n=111)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCVA LOSS ≥1 LINE AT ≥3 MONTHS</td>
<td>5/5</td>
<td>5/5</td>
</tr>
<tr>
<td>STENT OBSTRUCTION</td>
<td>N/A</td>
<td>4/5</td>
</tr>
<tr>
<td>POSTERIOR CAPSULAR OPACIFICATION</td>
<td>7/5</td>
<td>3/5</td>
</tr>
<tr>
<td>BLURRY VISION OR VISUAL DISTURBANCE</td>
<td>5/5</td>
<td>1/5</td>
</tr>
<tr>
<td>IRITIS</td>
<td>5/5</td>
<td>1/5</td>
</tr>
</tbody>
</table>

Excerpts from complete listing of study-safety population
Glaucoma will affect more than 60.5 million people by 2010 and nearly 80 million people by 2020. With over 20% of cataract cases having concomitant glaucoma/OHT, a combined procedure that does not increase risk, restores physiologic function, and reduces or eliminates the need for ocular hypotensive medications is a clinically logical and cost-effective option.

The iStent is contraindicated in patients with angle-closure glaucoma and other secondary glaucomas such as neovascular glaucoma and uveitic glaucoma. The iStent is also contraindicated in patients with retrobulbar tumor, chronic inflammatory disease, thyroid eye disease, Sturge-Weber syndrome, or any other type of condition where the trabecular meshwork, Schlemm’s canal, or collector channels at the implant site are compromised.

**THE CHANGING PERSPECTIVE**

- **Glaucoma** will affect more than 60.5 million people by 2010 and nearly 80 million people by 2020. With over 20% of cataract cases having concomitant glaucoma/OHT, a combined procedure that does not increase risk, restores physiologic function, and reduces or eliminates the need for ocular hypotensive medications is a clinically logical and cost-effective option.

**Figure 1:**

- **Percentage of patients who sustained a ≥20% reduction in IOP without medication use.**
- **Percentage of patients on ocular hypotensive medications.**

**Table 1:**

- Of patients who received iStent, 67% remained medication free while sustaining a mean IOP reduction of ≥20% versus only 48% who underwent cataract surgery alone. (P<.002)
- Patients who had cataract surgery alone were more than twice as likely to require medication than the iStent group.

The iStent is contraindicated in patients with angle-closure glaucoma and other secondary glaucomas such as neovascular glaucoma and uveitic glaucoma. The iStent is also contraindicated in patients with retrobulbar tumor, chronic inflammatory disease, thyroid eye disease, Sturge-Weber syndrome, or any other type of condition where the trabecular meshwork, Schlemm’s canal, or collector channels at the implant site are compromised.
patients are more likely to remain medication free with iStent®

patients had a significantly greater likelihood of remaining medication free with iStent versus cataract surgery alone

patients who received iStent achieved a mean 33% reduction in IOP with 50% less medication than patients who underwent cataract surgery alone

achieve additional IOP reduction beyond cataract surgery alone

67% of patients who received iStent remained medication free at 15 months versus only 24% of patients who underwent cataract surgery alone (P=.027)

at 15 months

patients who received iStent sustained target pressures at 15 months with one less medication than patients who underwent cataract surgery alone (P=.007)

after washout

at 16 months, patients who received iStent had a significantly lower mean IOP versus patients who underwent cataract surgery alone (P=.042)

Results from a prospective, randomized, double-masked study of iStent plus cataract surgery versus cataract surgery alone in patients with primary open-angle glaucoma treated with ocular antihypertensive medications. Medications were discontinued after surgery and reintroduced only as required. Medications were discontinued at Month 15 and patients returned for Month 16 visit.10
The safety and effectiveness of iStent remain to be determined in patients experiencing significant complications during cataract surgery. Efficacy of iStent has not been affirmed in patients with pseudophakic, secondary, uveitic, or neovascular glaucoma or discernible congenital anomalies of the anterior chamber angle. Surgeons are advised to maintain proper intraocular pressure post-operation with medical regimens as necessary.

Prescription therapy is the most common treatment for glaucoma. However, for many patients, glaucoma medication is unable to effectively control IOP because of poor compliance. Studies have shown that up to 90% of patients are unable to take their glaucoma medications exactly as prescribed. Noncompliance to medications can increase the risk for diurnal fluctuations and vision loss.

Most patients with glaucoma are being treated with one or more ocular antihypertensive medications. More than 90% of patients are nonadherent to their ocular medication dosing regimens and nearly 50% discontinue taking their medications before 6 months. 41% of patients who are nonadherent indicated that they experience challenges in paying for their medications. Nonadherence can result in large fluctuations in IOP, which are associated with a risk for vision loss that is higher than the risk associated with nonintervention. Long-term, compounded exposure to the preservatives found in many eye drop medications can cause corneal surface damage.

The iStent provides a sustainable foundation in reestablishing physiological outflow, achieving target pressures, and reducing or eliminating the need for ocular antihypertensive medications. A single iStent implanted in conjunction with cataract surgery:

- Reestablishes continuous, physiologic outflow
- Sustains target pressures while reducing or eliminating medication use
- Spares the conjunctiva
- Is not associated with the serious complications of end-stage filtration and shunt procedures
- Safely preserves patient candidacy for future treatment options

The burden of ocular hypotensive medications

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- 41% of patients who are nonadherent indicated that they experience challenges in paying for their medications.
- Nonadherence can result in large fluctuations in IOP, which are associated with a risk for vision loss that is higher than the risk associated with nonintervention.
- Long-term, compounded exposure to the preservatives found in many eye drop medications can cause corneal surface damage.

Sustain target pressure with less medication use

- 67% of patients who received iStent remained medication free at 15 months versus only 24% of patients who underwent cataract surgery alone (P=.027)
- 67% of patients who received iStent remained medication free at 12 months while sustaining a mean IOP reduction of ≥20% versus only 48% of patients who underwent cataract surgery alone (P=.002)
- A consistently greater percentage of patients who received iStent remained medication free at 12 months while sustaining target IOPs of ≤15, ≤18, and ≤21 mm Hg versus cataract surgery alone.

alleviate the burden with iStent

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Contact your Glaukos® Representative to learn more about the iStent Trabecular Micro-Bypass.
REFERENCES:


