Primary open-angle glaucoma (POAG) is a sight-threatening condition caused by suboptimal ocular outflow leading to elevated intraocular pressure (IOP). While conventional surgical interventions such as aqueous shunts and trabeculectomy are effective in lowering IOP and are still widely used, they can be associated with numerous intraoperative and postoperative complications and safety issues and so are usually reserved for late-stage glaucoma or patients who need to achieve very low pressure levels. Consequently, surgeons are increasingly turning towards non-penetrating, bleb-free, minimally-invasive glaucoma surgery (MIGS) procedures, including the Trabectome® or iStent®, for their early or mid-stage patients. However, while MIGS procedures appear to be safer than conventional surgical interventions, they are not as clinically effective.

Canaloplasty, a restorative surgical procedure that reestablishes the function of the natural ocular outflow system without the need for a filtering bleb, has been shown to be both safe and effective in more than 50 peer-reviewed clinical studies. It has also been shown to be equally effective as trabeculectomy.

Canaloplasty performed ab-interno is a new MIGS procedure, which, like traditional (ab-externo) Canaloplasty, is designed to access, catheterize and visco-dilate all potential sites of outflow resistance, i.e., the trabecular meshwork, Schlemm’s canal and the distal outflow system beginning with the collector channels.

The Mechanism of Ab-Interno Canaloplasty

Ab-interno Canaloplasty is based on time-tested experience with traditional Canaloplasty, where visco-dilation of Schlemm’s canal acts as a form of angioplasty and opens up the ostia of the collector channels, re-establishing outflow. Ab-interno Canaloplasty is most frequently performed in conjunction with phacoemulsification; however, it is not limited to the combination procedure and may be performed alone.

Like traditional Canaloplasty, Ab-interno Canaloplasty addresses the trabecular meshwork, Schlemm’s canal and collector channels – structures that control ocular outflow. It also follows the same dilation principles of traditional Canaloplasty, where precisely controlled delivery of Healon/Healon GV during withdrawal of the catheter allows the compressed tissue planes of the trabecular meshwork to separate, and any herniated inner wall tissue to withdraw from the collector channels.

Indeed, studies undertaken in human and bovine POAG eyes by Haiyan Gong, MD, PhD, from the University of Boston, have shown that when inner wall tissue of Schlemm’s canal herniates into the collector channels, it blocks aqueous outflow. Specifically, in POAG eyes fixed at 0 mmHg (N=5), 73 collector channel ostia regions were examined, with 51 showing herniations (70%). In POAG
eyes fixed at 10 mmHg (N=2), 22 collector channel ostia regions were examined, with 21 showing herniations (95%). In contrast, in normal eyes (fixed at 0 mmHg), 53 collector channel ostia regions were examined, and 8 herniations were found (15%). A significant difference was found between normal and POAG eyes fixed at 0mmHg (p=0.0008).8,9 Canaloplasty, performed ab-interno and ab-externo, is the only currently available procedure that addresses blockages in the collector channels.

Although traditional Canaloplasty employs placement of a 9-0 or 10-0 Prolene tensioning suture to ensure added longevity, a review of three-year data by Lewis et al indicated that 360° visco-dilation alone, i.e., Canaloplasty without a suture successfully lowered IOP (refer to Figure 1).6 Mapping the results of visco-dilation to suture tension also showed that visco-dilation was driving the IOP reduction more than how tight the suture was tied.7 Additionally, discussions with practicing Canaloplasty surgeons indicates that patients who do not receive a suture still experience satisfactory reductions in IOP.

### The Ab-Interno Canaloplasty Difference

To-date, Ab-interno Canaloplasty is the only MIGS procedure that successfully and comprehensively addresses all aspects of potential outflow resistance. Moreover, based on the preliminary results of a 70-eye case series by Mark J. Gallardo, MD (El Paso Eye Surgeons, PA), it may also offer better clinical outcomes than any other currently available MIGS procedure.

MIGS procedures lower IOP by addressing different aspects of (rather than all aspects of) the ocular outflow system. For example, the Trabectome®, uses an electrosurgical pulse to ablate the trabecular meshwork and inner wall of Schlemm’s canal, while the iStent® works as a trabecular micro-bypass by allowing aqueous humor to flow directly from the anterior chamber into Schlemm’s canal, thus circumventing the trabecular meshwork.10 Meanwhile, the Hydrus™, an 8mm long device that is inserted into Schlemm’s canal to improve ocular outflow from the anterior chamber to Schlemm’s canal acts as an intracanalicular scaffold.3 The CyPass Suprachoroidal Microstent, an investigational MIGS device, facilitates outflow from the

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**FIGURE 1: Three-Year Treatment Outcomes - Canaloplasty Without Suture**

<table>
<thead>
<tr>
<th>Exam</th>
<th>n</th>
<th>Mean IOP (mm Hg) ± SD</th>
<th>Mean Medications (n) ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>18</td>
<td>25.2 ± 6.4</td>
<td>2.1 ± 1.0</td>
</tr>
<tr>
<td>12 Months</td>
<td>16</td>
<td>16.8 ± 4.9</td>
<td>0.5 ± 0.6</td>
</tr>
<tr>
<td>18 Months</td>
<td>16</td>
<td>15.5 ± 4.2</td>
<td>0.8 ± 0.8</td>
</tr>
<tr>
<td>24 Months</td>
<td>14</td>
<td>18.1 ± 5.4</td>
<td>1.0 ± 1.0</td>
</tr>
<tr>
<td>30 Months</td>
<td>11</td>
<td>15.5 ± 3.5</td>
<td>0.8 ± 0.9</td>
</tr>
<tr>
<td>36 Months</td>
<td>13</td>
<td>16.2 ± 3.3</td>
<td>1.1 ± 0.8</td>
</tr>
</tbody>
</table>

Anterior chamber to the suprachoroidal space, while the AquSys Subconjunctival Implant (also an investigational MIGS device) is placed into the subconjunctival space to create a filtering bleb.³

In addition to addressing all aspects of ocular outflow, Ab-interno Canaloplasty is also fast and easy to perform. The combined procedure (phacoemulsification and Ab-interno Canaloplasty) is routinely performed in 10-15 minutes, with the Ab-interno Canaloplasty aspect taking approximately five minutes to perform.

**Clinical Evidence**

Surgeons in the USA and in Europe have commenced use of the iTrack™ microcatheter to perform Canaloplasty ab-interno and the early results are very encouraging – at this point similar to traditional Canaloplasty.

In a case series study of 70 eyes, mean preoperative IOP was 20.3 ± 5.8 mm Hg and the mean number of medications was 2.4 ± 0.9. At one, three and six months post-treatment, mean IOP was 14.3 ± 3.7 mm Hg, 13.0 ± 3.6 mm Hg and 12.3 ± 3.8 mm Hg, respectively, while the mean number of medications was 0.5 ± 0.9 at one and three months, and 0.5 ± 1.0 at six months post-treatment (refer to Figure 2).

Subgroup analyses were also performed including patients with (n=10) or without (n=48) previous surgery. The effect of Ab-interno Canaloplasty on IOP and medication-use was also evaluated in pseudophakic patients (n=12).

In patients who had not undergone surgery prior to treatment, mean IOP improved from 18.8 ± 4.7 mm Hg at baseline to 13.9 ± 3.6 mm Hg at one month and 12.2 ± 1.9 mm Hg at three months post-treatment. Six-month data for three patients showed that mean IOP was 11.3 ± 4.0 mm Hg at this follow-up visit.

The mean number of anti-glaucoma medications also reduced, from 2.2 ± 0.9 at baseline to 0.4 ± 0.7 and 0.2 ± 0.6 at three and six months post-treatment, respectively. Improvements in IOP and medication-use were also observed in patients who had undergone prior glaucoma surgeries. Mean IOP and mean medication-use improved from 25.8 ± 8.0 mm Hg and 3.0 ± 0.8 medications pre-treatment, to 15.3 ± 4.1 mm Hg and 1.0 ± 1.5 medications at one month post-treatment and 18.3 ± 7.5 mm Hg and 2.3 ± 0.6 medications at three months post-treatment. Furthermore, over 70% of patients were off medication entirely at one month and three months post-treatment (Refer to Figure 3).

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**FIGURE 2: Ab-Interno Canaloplasty Case Series (All Eyes)**

<table>
<thead>
<tr>
<th>Exam</th>
<th>n</th>
<th>Mean IOP (mm Hg) ± SD</th>
<th>Mean Medications (n) ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>70</td>
<td>20.3 ± 5.8</td>
<td>2.4 ± 0.9</td>
</tr>
<tr>
<td>1 Month</td>
<td>47</td>
<td>14.3 ± 3.7</td>
<td>0.5 ± 0.9</td>
</tr>
<tr>
<td>3 Months</td>
<td>23</td>
<td>13.0 ± 3.6</td>
<td>0.5 ± 0.9</td>
</tr>
<tr>
<td>6 Months</td>
<td>4</td>
<td>12.3 ± 3.8</td>
<td>0.5 ± 1.0</td>
</tr>
</tbody>
</table>

Source: Mark J. Gallardo, MD (El Paso Eye Surgeons, PA)
Ab-Interno Canaloplasty

In pseudophakic patients, mean IOP improved from 21.8 ± 5.2 mm Hg at baseline to 15.1 ± 4.1 mm Hg at one month post-operative. Medication-use was also reduced, from 2.8 ± 0.7 mm Hg at baseline to 0.8 ± 1.0 mm Hg at one month post-treatment. Case observation of Ab-interno Canaloplasty also revealed that the safety profile of the procedure was similar to that of traditional Canaloplasty and the newer MIGS procedures.

**Clinical Considerations**

Similar to the treatment plan for MIGS, Ab-interno Canaloplasty is recommended early in the disease process, thus the primary indication is patients with mild-to-moderate glaucoma. However, it may also be considered as a first-line option or in patients who have undergone laser trabeculoplasty and for patients non-compliant to medications. Patients with exfoliative glaucoma and those in whom glaucoma surgery in the fellow eye has failed, may also be considered for Ab-interno Canaloplasty. However, it should not be performed in patients with neovascular glaucoma, chronic angle closure, angle recession/peripheral anterior synechiae or narrow angle glaucoma.

It is also important to note that Ab-interno Canaloplasty does not require a permanent bypass stent or implant in the eye, and thus future surgery is never compromised.

**Summary**

Clinical evidence indicates that Ab-interno Canaloplasty, a new MIGS procedure, is safe and effective in mild-to-moderate POAG with similar IOP-lowering effects to tried and true traditional Canaloplasty. Unlike other MIGS procedures, Ab-interno Canaloplasty ensures that all potential “blockages” in the ocular outflow pathway are addressed, including distal structures such as the collector channels, which have been shown to play a key role in blocking aqueous outflow in POAG eyes. Ab-interno Canaloplasty is also fast to perform and, unlike other currently available MIGS procedures, preserves tissue and does not require permanent placement of an implant in the eye. Furthermore, based on preliminary data it may, potentially, offer better clinical outcomes than any other currently available MIGS procedure.

**FIGURE 3: Ab-Interno Canaloplasty Case Series (With No Medication)**

<table>
<thead>
<tr>
<th>Exam</th>
<th>n</th>
<th>Mean IOP (mm Hg) ± SD</th>
<th>Mean Medications (n) ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>54</td>
<td>20.2 ± 6.3</td>
<td>2.3 ± 0.9</td>
</tr>
<tr>
<td>1 Month</td>
<td>33</td>
<td>13.3 ± 3.1</td>
<td>0.0</td>
</tr>
<tr>
<td>3 Months</td>
<td>17</td>
<td>12.5 ± 2.1</td>
<td>0.0</td>
</tr>
<tr>
<td>6 Months</td>
<td>3</td>
<td>11.0 ± 3.5</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Source: Mark J. Gallardo, MD (El Paso Eye Surgeons, PA)
Ab-Interno Canaloplasty

AB-INTERNO CANALOPLASTY: BENEFITS AT A GLANCE

1. Comprehensive: treats trabecular meshwork, Schlemm’s canal and collector channels

2. Opens outflow system behind the trabecular meshwork, thus ensuring better aqueous outflow

3. No permanent implant or stent

4. On label – patient does not have to pay additionally out of pocket

5. Reimbursement is higher than current MIGS procedures

6. Patient selection criteria are similar to current MIGS procedures

7. Easy to explain to the patient, for example: “I am going to perform circumferential angioplasty in your eye to reduce pressure” or, “We want to avoid cutting tissue or inserting devices; so let’s try Ab-interno Canaloplasty first”.

References:


