ABiC™ is a new ab-interno MIGS procedure that can comprehensively restore the natural outflow pathways for your glaucoma patients.
Minimally Invasive & Maximally Effective.

ABiC™ may finally be the answer we have been waiting for – a MIGS procedure that flushes out the natural outflow channels, without damaging tissue, and without leaving behind a stent or shunt. A truly comprehensive MIGS, ABiC™ accesses, catheterizes, and viscodilates the trabecular meshwork, Schlemm’s canal, and the distal outflow system, beginning with the collector channels.
RESTORING THE NATURAL OUTFLOW PATHWAYS

Canaloplasty works by restoring the natural outflow pathways for aqueous humor in glaucoma patients, using a technique similar to angioplasty. Performed with our proprietary iTrack™ microcatheter, Canaloplasty comprehensively addresses all aspects of potential outflow resistance, including Schlemm’s canal, the trabecular meshwork and, importantly, the distal outflow system, beginning with the collector channels.

With more than 60,000 procedures performed to date, clinical studies have shown that Canaloplasty, performed alone or in conjunction with phacoemulsification, can significantly and durably reduce IOP in many patients.\(^1,2\) It can also reduce or eliminate the medication burden.\(^1,2\)

Importantly, Canaloplasty addresses the full spectrum of the glaucoma disease process: it can be performed via both ab externo and ab interno approaches in order to meet all glaucoma criteria.

During the procedure, 360-degree viscodilation of Schlemm’s canal opens up the ostia of the collector channels, re-establishing outflow. Specifically, the precisely controlled delivery of Healon/Healon GV during withdrawal of the iTrack™ microcatheter separates the compressed tissue planes of the trabecular meshwork, and also triggers the withdrawal of any herniated inner wall tissue from the collector channels. To provide further reduction in IOP, the ab externo Canaloplasty procedure also entails performing a deep sclerectomy, creating a Descemet’s window and deploying a tensioning suture in Schlemm’s canal.

Canaloplasty has been clinically proven to provide long-term reduction in IOP and reduced dependance on medications.\(^1,2\)

Unlike other glaucoma treatments, which only address one or two aspects of ocular outflow, Canaloplasty works by comprehensively opening up all components of the eye’s natural outflow system.

Canaloplasty does not result in a bleb or bleb-related complications, offering an unprecedented level of safety and quality of life for glaucoma patients.\(^3\)

Canaloplasty can be used in conjunction with existing drug based glaucoma treatments, after laser or after other types of incisional surgery and does not preclude or affect the outcome of future surgery.

With the recent addition of ab interno Canaloplasty, dubbed ABiC™, Canaloplasty can address the full spectrum of the glaucoma disease process.

THE IMPORTANCE OF THE COLLECTOR CHANNELS

Canaloplasty is the only currently available glaucoma procedure to address blockages in the collector channels. Studies undertaken in human POAG eyes by Haiyan Gong, MD, PhD (University of Boston) have shown that many of the collector channels may be partially or totally blocked with herniated trabecular meshwork tissue.\(^4\) Cannulating the whole of Schlemm’s canal with Canaloplasty, via a process of 360-degree viscodilation, may “pop” open these herniations and enable full access to collector channel ostia for the egressing aqueous. In the case of other glaucoma treatments, where only a segment of Schlemm’s canal is addressed, or where the trabecular meshwork is targeted in isolation, any herniated tissue would most likely prevent improved outflow.
Highly effective as a stand-alone procedure or as an adjunct to cataract surgery, ABiC™ is a new, comprehensive MIGS procedure that flushes out the natural outflow channels, without touching the sclera, and without leaving behind a stent or shunt.

Performed via a self-sealing, clear corneal incision, ABiC™ offers the clinically proven benefits of 360° viscodilation of Schlemm’s canal provided by traditional Canaloplasty but via a simplified and much faster ab interno approach. On average, the procedure can be performed within 5 minutes.

The most defining aspect of ABiC™ is its comprehensive approach. Whereas other MIGS procedures treat only one aspect of aqueous outflow, ABiC™ comprehensively accesses, catheterizes, and viscodilates the trabecular meshwork, Schlemm’s canal, and the collector channels. Another hallmark of ABiC™ is that it preserves tissue. And because it does not require permanent placement of an implant or stent, it does not preclude or compromise future surgery if it should become necessary.

Based on a 12-month case series review of 228 eyes by Mark J. Gallardo (El Paso Eye Surgeons, PA) and Mahmoud A. Khaimi, MD (Dean McGee Eye Institute, University of Oklahoma, OK), the preliminary results for ABiC™ are very encouraging – at this point similar to traditional Canaloplasty. (See Table 1.)

Of the 130 patients who underwent ABiC™ in combination with cataract surgery, mean preoperative IOP was reduced from 17.1 mm Hg to 13.1 mm Hg at 12 months. The mean number of medications was also reduced by 50% from 2.0 to 1.0. Importantly, ABiC™ was shown to be highly effective outside of cataract surgery. Of the 98 patients who underwent ABiC™ as a stand-alone procedure mean IOP was reduced by 36.74% to 13.6 mm Hg at 12 months. The mean number of medications was also reduced by 66.66% to 1.0.

**TABLE 1: ABiC CASE SERIES - 12 MONTH RESULTS**

<table>
<thead>
<tr>
<th>Exam</th>
<th>ABiC with Phacoemulsification</th>
<th>ABiC without Phacoemulsification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean IOP (mm Hg) ± SD</td>
</tr>
<tr>
<td>Baseline</td>
<td>130</td>
<td>17.1 ± 5.0</td>
</tr>
<tr>
<td>3 Months</td>
<td>92</td>
<td>13.5 ± 3.1</td>
</tr>
<tr>
<td>6 Months</td>
<td>83</td>
<td>14.0 ± 3.6</td>
</tr>
<tr>
<td>12 Months</td>
<td>34</td>
<td>13.1 ± 2.1</td>
</tr>
</tbody>
</table>

**BENEFITS AT A GLANCE**

1. Comprehensive: treats trabecular meshwork, Schlemm’s canal and collector channels.
2. No permanent implant or stent.
3. Effective outside of cataract surgery.
4. Patient selection criteria similar to current MIGS procedures.

**MINIMALLY INVASIVE**

Gonioscopic view of nasal angle one month postoperative. Note the normal appearance of the drainage angle despite previous surgical manipulation.

*Image courtesy of Mark J. Gallardo, MD*
Traditional Canaloplasty, performed via an ab-externo approach to Schlemm’s canal, is ideally suited for patients with advanced glaucoma. By addressing all of the possible sites of resistance, including potentially occluded collector channels, and with the addition of the scleral lake, Descemet’s window and tensioning suture, Canaloplasty enables surgeons to obtain post-operative pressures in the range of 12-14 mm Hg, similar to that achieved with trabeculectomy - but with a reduced risk of complications. In a three-year multi-center trial by Lewis et al, Canaloplasty was found to significantly lower IOP and dependence on medications. (See Table 3.) Specifically, in patients that underwent Canaloplasty outside of cataract surgery, mean IOP was reduced by 35% from 23.5 mm Hg to 15.5 mm Hg at 36 months. When performed in conjunction with cataract surgery, Canaloplasty resulted in a 42% reduction in mean IOP from 23.5 mm Hg to 13.6 mm Hg, combined with an 80% reduction in medications.

### TABLE 2: COMPARISON - COMPLICATION RATES

<table>
<thead>
<tr>
<th></th>
<th>CANALOPLASTY (Multi-Center Trial)</th>
<th>TRABECULECTOMY (TvT)</th>
<th>TUBE SHUNTS (TvT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>157</td>
<td>107</td>
<td>105</td>
</tr>
<tr>
<td>Reoperation for Complications</td>
<td>5 (3.2%)</td>
<td>9 (9%)</td>
<td>15 (14%)</td>
</tr>
<tr>
<td>Vision Loss of ≥2 Snellen Lines</td>
<td>0 (0%)</td>
<td>23 (22%)</td>
<td>17 (16%)</td>
</tr>
<tr>
<td>Serious Complications</td>
<td>1 (0.6%)</td>
<td>28 (27%)</td>
<td>24 (22%)</td>
</tr>
</tbody>
</table>

### TABLE 3: CANALOPLASTY MULTI-CENTER TRIAL - THREE YEAR RESULTS

<table>
<thead>
<tr>
<th>Exam</th>
<th>Canaloplasty</th>
<th>Phaco-Canaloplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean IOP (mm Hg) ± SD</td>
</tr>
<tr>
<td>Baseline</td>
<td>103</td>
<td>23.5 ± 4.5</td>
</tr>
<tr>
<td>6 Months</td>
<td>86</td>
<td>16.1 ± 3.4</td>
</tr>
<tr>
<td>12 Months</td>
<td>91</td>
<td>16.1 ± 3.9</td>
</tr>
<tr>
<td>24 Months</td>
<td>89</td>
<td>16.1 ± 4.0</td>
</tr>
<tr>
<td>36 Months</td>
<td>89</td>
<td>15.5 ± 3.5</td>
</tr>
</tbody>
</table>
canaloplasty microcatheter

Designed specifically for 360° viscodilation of Schlemm’s canal in open-angle glaucoma patients, the iTrack™ enables surgeons to:

1. Open a collapsed Schlemm’s canal;
2. Stretch the trabecular plates to allow aqueous into Schlemm’s canal; and,
3. Break adhesions and separate herniations to open the atrophied outflow collector channels.

The iTrack™ system comprises the iTrack™ microcatheter, the ViscoInjector™ viscoelastic injector and the iLumin™ illumination source:

iTrack™
- Illuminated, micron-scale microcatheter.
- Illuminated tip for transscleral visualization during 360˚ cannulation, allowing surgeon to monitor location of catheter tip at all times.
- Choice of intermittent “blinking” or “constant” illumination for patient safety.
- Small-gauge support wire for greater control during advancement through Schlemm’s canal.
- Infusion lumen for the controlled delivery of viscoelastic.
- Round, bolus atraumatic tip and lubricious coating to minimize trauma to Schlemm’s canal during catheterization.

ViscoInjector™
(Note: included with iTrack™ microcatheter.)
- Viscoelastic injector which attaches to iTrack™ microcatheter.
- Manually operated for precise delivery of a specific volume of viscoelastic.
- Tactile and audible knob: clicks every 1/8 turn (as per Canaloplasty protocol); alignment marks to guide priming/use.

iLumin™
- Portable laser diode illumination source.
- Proprietary connector for use with iTrack™ microcatheter.

INDICATIONS FOR USE: The iTrack Canaloplasty microcatheter is indicated for fluid infusion and aspiration during surgery. The iTrack Canaloplasty microcatheter is indicated for catheterization and viscodilation of Schlemm’s canal to reduce intraocular pressure in adult patients with open-angle glaucoma. FDA Cleared. 510(k) # K080067.

REFERENCES: