Minimally Invasive & Maximally Effective.

Canaloplasty revitalizes all of the natural aqueous outflow channels, ensures excellent IOP reduction, and does not produce a bleb or result in bleb-related complications – providing an unprecedented level of efficacy and safety in the surgical treatment of glaucoma.

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.
- Small-gauge support wire for greater control during advancement through Schlemm’s canal.
- Round, bolus atraumatic tip and lubricious coating to minimize trauma to Schlemm’s canal during catheterization.

**ViscoInjector™**
- Viscoelastic injector which attaches to iTrack™ microcatheter.
- Manually operated for precision delivery of viscoelastic.
- Tactile and audible knob: clicks every 1/8 turn (as per Canaloplasty protocol); alignment marks to guide priming and 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:**

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AB-EXTERNO CANALOPLASTY

Canaloplasty works by restoring the natural outflow pathways for aqueous humor in glaucoma patients, using a technique similar to angioplasty. Performing with our proprietary i(track)™ microcatheter technology, 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.

Patients who have undergone ab externo Canaloplasty, performed alone or in conjunction with phacoemulsification, can significantly and durably reduce IOP and patients’ dependence on medications.1

In a three-year multi-center trial by Lewis PA) and Mahmoud Khaimi, MD (Dean McGee Eye Institute, OK), evaluated the efficacy of the precorneal delivery of Healon/GV during withdrawal of the ostia of the collector channels, re-establishing outflow. Specifically, the reshaping process is facilitated by 360-degree viscodilation, which expands the 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.

AB-INTERNO CANALOPLASTY

Highly effective as a stand-alone procedure or in conjunction with cataract surgery, ABiC™ can restore and improve the major components of the normal outflow system. Traditional Canaloplasty, performed via an ab externo approach to Schlemm’s canal, provides significant and sustained outflow improvement and results in a marked reduction in medication usage.2

Although the backwall of ABiC™ is preserved tissue, and because it does not require permanent placement of an implant or stent, it does not provide or compromise future surgery if it should become necessary.

ABiC™ is a new, comprehensive MIGS procedure that flushes out the natural outflow pathways for aqueous outflow,5 ABiC™ comprehensively addresses and corrects outflow resistance, including potentially occluded collector channels, and with the normal appearance of the drainage angle despite previous surgical manipulation. When performed in conjunction with cataract surgery, ABiC™ resulted in a 42% reduction in mean IOP from 25.5 mm Hg to 15.5 mm Hg, combined with an 80% reduction in medications.2

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.

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MINIMALLY INVASIVE

Gonioscopic view of nasal angle one month postop. Note the normal appearance of the drainage angle despite previous surgical manipulation. Courtesy of Alcor, Ltd., Galway, Ireland.

RESTORING THE NATURAL OUTFLOW PATHWAYS

Canaloplasty has been clinically proven to provide long-term reduction in IOP and reduced dependence on medications.1,2

Unlike other glaucoma treatments, which only address one or two aspects of outflow resistance, Canaloplasty comprehensively opens up all aspects of the eye’s natural outflow system.

Canaloplasty does not result in a bleb or bleb-related complications, offering an unparalleled level of safety and quality of life for glaucoma patients.

Canaloplasty can be used in conjunction with existing drug-based glaucoma treatments, after, or after other forms 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.

AB-CASE SERIES - 6 MONTH RESULTS6

<table>
<thead>
<tr>
<th>Exam</th>
<th>Mean IOP (mm Hg) ± SD</th>
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BENEFITS AT A GLANCE

- Ab-commerce does trabecular meshwork, Schlemm’s canal, and collector channels
- No permanent implant or stent
- Effective outside of cataract surgery
- Any glaucoma criteria similar to current MIGS procedures

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AB-INTERNO CANALOPLASTY

Traditional Canaloplasty, performed as an ancillary procedure in a cul-de-sac, is ideally suited for patients with advanced glaucoma. By addressing all of the possible factors that contribute to resistance, Canaloplasty can unblock obstructed collector channels, and with the normal appearance of the drainage angle despite previous surgical manipulation. When performed in conjunction with cataract surgery, Canaloplasty resulted in a 42% reduction in mean IOP from 25.5 mm Hg to 15.5 mm Hg, combined with an 80% reduction in medications.2

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Canaloplasty revitalizes all of the natural aqueous outflow channels, ensures excellent IOP reduction, and does not produce a bleb or result in bleb-related complications – providing an unprecedented level of efficacy and safety in the surgical treatment of glaucoma.
Canaloplasty is the only currently available glaucoma procedure to address blockages in the collector channels. Studies undertaken in human POAG eyes by Huygin, Los, MD (University of Brussels) and Huygin, MD (University of Navarra) have shown that many of the collector channels may be partially or totally occluded due to the natural outflow resistance, including Schlemm’s canal, the trabecular meshwork and, importantly, the distal outflow system, beginning with the collector channels.

In the case of other glaucoma treatments, where only a segment of Schlemm’s canal is addressed, or where the trabecular meshwork is 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.

AB-EXTERNAL CANALOPLASTY

Traditionally performed on an open eye in an external approach to Schlemm’s canal, is ideally suited for patients with advanced glaucoma. By addressing all of the possible areas of resistance, including Schlemm’s canal, the trabecular meshwork and the normal appearance of the drainage angle despite previous drainage procedures, Canaloplasty is ideally suited for patients with advanced glaucoma. By addressing all of the possible areas of resistance, including Schlemm’s canal, the trabecular meshwork and the normal appearance of the drainage angle despite previous drainage procedures, Canaloplasty is ideally suited for patients with advanced glaucoma.

AB-INTERNAL CANALOPLASTY

Highly effective as a stand-alone procedure or as an ad incept to cataract surgery, ABiC™ is a new, comprehensive MIGS procedure that focuses on the natural outflow characteristics of the eye and lowering intraocular pressure without leaving behind a stent or shunt. Performed as a self-sealing, clear corneal incision, ABiC™ offers the clinically proven benefits of 360-degree viscodilation of Schlemm’s canal provided by Traditional Canaloplasty but in a one-shot and rapid bilateral surgical approach. As a result, the pressure can be reduced within minutes and is well tolerated by patients.

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

Canaloplasty has been clinically proven to provide long-term reduction in IOP and reduced dependence on medications.1,2

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During the procedure, 360-degree viscodilation of Schlemm’s canal opens up the outlet of the collector channels, re-establishing outflow. Specifically, the precisely controlled delivery of Hyalosoft™ OCT dilates and opens the trabecular meshwork, allowing aqueous to egress into the normal appearance of the drainage angle. At the end of the procedure, the OCT is retracted into the anterior chamber, creating a clear unobstructed vision for the patient.

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

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In Traditional Canaloplasty, performed on an open eye in an external approach to Schlemm’s canal, is ideally suited for patients with advanced glaucoma. By addressing all of the possible areas of resistance, including Schlemm’s canal, the trabecular meshwork and the normal appearance of the drainage angle despite previous drainage procedures, Canaloplasty is ideally suited for patients with advanced glaucoma. By addressing all of the possible areas of resistance, including Schlemm’s canal, the trabecular meshwork and the normal appearance of the drainage angle despite previous drainage procedures, Canaloplasty is ideally suited for patients with advanced glaucoma.

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**AB-INTERNO CANALOPLASTY**

Highly effective as a stand-alone procedure or as an adjunct to cataract surgery, ABiC™ is a technology that focuses on the normal outflow channels of the eye, and thereby is not limited by or dependent on medications.1,2 Performing it as a self-scaling, clear corneal incision, ABiC™ offers the clinically proven benefits of 360° viscodilation of Schlemm’s canal provided by Traditional Canaloplasty but has two major and resultant benefits.1,2 One of these is that the incision of ABiC™ is self-sealing and can be performed via a simplified and much faster surgical approach. The other is that the incision of ABiC™ is well tolerated by patients.

The most defining aspect of ABiC™ is its comprehensive approach. Whereas other MIGS procedures treat only one segment of aqueous outflow,1,2 ABiC™ comprehensively accesses, restructures, and communicates the trabecular meshwork, Schlemm’s canal, and importantly, the collector channels. Another hallmark of ABiC™ is that it preserves tissue. And because it does not require permanent placement of an implant or shunt, it does not preclude or compromise future surgery if it should become necessary.

ABiC™ can be used in conjunction with existing-drug brand 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, called ABiC™, Canaloplasty can address the full spectrum of the glaucoma disease process.

**AB-EXTERNO CANALOPLASTY**

Traditional Canaloplasty, performed as an incisional approach for a surgeon’s canal, is usually suited for patients with advanced glaucoma. By addressing all of the possible causes of increased IOP, including a blocked trabecular meshwork, obstacles at the drainage angle, and with the normal appearance of the trabecular meshwork, Schlemm’s canal, and importantly, the collector channels, ABiC™ is ideally suited for patients with advanced glaucoma, and for those with advanced glaucoma.

In a three-year multi-center trial by Lewis et al,6 ADioC™ successfully moved to significantly lower mean IOP and reduced dependence on medications. Specifically, in patients that underwent Traditional Canaloplasty, mean IOP was reduced by 20% from 23.5 mm Hg to 18.2 mm Hg at 12 months. When compared to modifican’s 360° incision by Mark J. Gallardo, MD (Pan-Eye Surgeons, P.C. and Martinez Kalan, MD (San McHugh Eye Institute, OK), evaluated the efficacy of ABiC™ as a stand-alone procedure, and ABiC™ comprehensively opened up all components of the eye’s natural outflow system.

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