AB-INTERNO CANALOPLASTY
CANALOPLASTY: SNAPSHOT

• Approved by FDA in 2007
• More than 60,000 procedures performed to date
• More than 60-peer review publications (incl. long-term data in the USA and Europe) demonstrating a significant and sustained reduction in IOP and the number of glaucoma medications.
• Medicare Category 1 Reimbursement Code
• Ellex acquired Canaloplasty portfolio from US-based Ellex iScience, Inc. in late 2013
• Preliminary case series performed in 2015 to evaluate clinical efficacy of ab-interno Canaloplasty (known as “ABiC”) – a new MIGS procedure
HISTORY OF CANALOPLASTY

First Canaloplasty procedure performed in USA (Kearney)

3-year multi-center trial results published in JCRS


First Canaloplasty procedure performed by Robert Stegmann, MD (USA)

Multi-center (three-year) international trial initiated

iScience commercializes iTRACK microcatheter

Medicare Category I CPT Code

Ellex acquires iScience Canaloplasty business

Introduction of ABiC (ab-interno Canaloplasty)
WHAT IS CANALOPLASTY?

Canaloplasty is a restorative procedure designed to re-establish the eye’s natural outflow drainage system.

• Canaloplasty includes use of the patented iTrack™ microcatheter with inner lumen to inject high viscosity sodium hyaluronate for safe and effective 360-degree dilation effect of Schlemm's canal, the trabecular meshwork, and the outflow collector channels – ALL areas of outflow resistance.
WHAT IS CANALOPLASTY? (CONT.)

“ANGIOPLASTY” for the eye

- Canaloplasty uses a “ballooning effect” to open Schlemm’s Canal, the Collector Channels and the trabecular meshwork

Canaloplasty compared to trabeculectomy

- Trabeculectomy reduces IOP in an unnatural way. It is “By-Pass surgery” i.e. trabeculectomy by-passes the eye’s natural outflow mechanisms. In contrast, Canaloplasty reduces IOP by restoring the eye’s natural way of maintaining pressure.
- Canaloplasty offers an improved safety profile over trabeculectomy.
• iTrack comprises an ophthalmic microcatheter and an ophthalmic viscoelastic-injector.

• Microcatheter features a round bulbous tip, which is designed for atraumatic cannulation of Schlemm’s canal, and for infusion of viscoelastic into Schlemm’s canal. It also prevents misdirection into the collector channels.
  • Lubricious coating on distal tip of microcatheter reduces trauma during catheterization inside Schlemm’s canal.
  • Illuminated fiber-optic tip ensures microcatheter can be continuously monitored during 360-degree navigation through Schlemm’s canal (Note: important patient safety element.)
  • Microcatheter support wire, which ensures greater control during catheterization.

• Viscoelastic-injector is manually-operated for precise delivery of viscoelastic, such as Healon GV.
  • Infusion and Aspiration Lumen
INDICATIONS FOR USE:

- iTrack™ canaloplasty microcatheter is indicated for fluid infusion and aspiration during surgery.

- 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
500253 MKT14 Rev A
Precisely Injects viscoelastic to dilate and Restore all areas of outflow resistance Restoring the Natural fluid outflow pathway throughout the distal collector system.

Ab-externo: passes tensioning suture through canal

- Adequate suture tension was thought to be the key to achieving optimal Canaloplasty results – but a review of three-year data by Lewis et al found that 360° visco-dilation alone, i.e., traditional Canaloplasty without a suture, successfully lowers IOP.

- Discussions with practising Canaloplasty surgeons over the years have also highlighted that patients who do not receive a suture still achieve satisfactory reductions in IOP.
BENEFITS OF CANALOPLASTY

Sustained control of IOP
  • 34% reduction: stand-alone procedure
  • 42% reduction: combined with cataract surgery

Addresses all stages of glaucoma

Reduced dependence on medications

Minimally invasive; no bleb needed

Better recovery
  • Less eventful post-operative care (compared to trabeculectomy)
  • Rapid VA recovery
  • Minimal complications
RESTORE THE OUTFLOW SYSTEM

All other procedures address only one aspect of the outflow system; Canaloplasty addresses ALL aspects of the outflow system.

One of the challenges of glaucoma treatment is that the location of increased aqueous outflow resistance is generally unclear. If a physician were to remove the site(s) where increased outflow resistance resides, IOP would be reduced. However, if it is not possible to identify the site(s) of increased outflow resistance, it is difficult to determine which parts of the outflow system are most relevant in terms of lowering IOP. Consequently, it is important to address ALL aspects of the ocular outflow system.
THE IMPORTANCE OF THE COLLECTOR CHANNELS

- Compared to normal controls, POAG eyes showed a decrease in the height of Schlemm canal and the width of the collector channel ostia, as well as an increased number of herniations that partially or completely obstructed the CC ostia.

- These morphological findings suggest diminished outflow in the herniated collector channel ostia regions, which likely contribute to the increased outflow resistance and consequent elevated IOP in POAG eyes.

The images with CC ostia were examined and graded as open (Fig. B), partially obstructed (Fig. C), or completely obstructed (Fig. D) by herniated tissue.

THE IMPORTANCE OF THE COLLECTOR CHANNELS

- There were significantly more herniations into collector channel (CC) ostia in POAG eyes than in normal eyes.

- In normal eyes, most of the herniations were partial herniations, whereas in POAG eyes approx. half of the herniations were partial and half were complete.


KEY FINDING: INCREASED HERNIATION INTO CC OSTIA IN POAG EYES
CANALOPLASTY: 3-YEAR RESULTS

- At 36 months: mean decrease in IOP from baseline = 34%
- At 36 months: mean reduction in medication = 53%

<table>
<thead>
<tr>
<th>Reference</th>
<th>N</th>
<th>Baseline</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peckar et al</td>
<td>97</td>
<td>27 mm Hg 2.6 meds</td>
<td>12.8 mm Hg 0.2 meds</td>
<td>14.0 mm Hg 0.2 meds</td>
<td></td>
</tr>
<tr>
<td>Grieshaber, Fraenkl, et al</td>
<td>32</td>
<td>27.3 mm Hg 2.7 meds</td>
<td>12.8 mm Hg 0.2 meds</td>
<td>18 Months 13.1 mmHg 0.1 meds</td>
<td></td>
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<tr>
<td>Barnebey</td>
<td>20</td>
<td>23.4 mm Hg 2.2 meds</td>
<td>13.4 mm Hg 0 meds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bull et al</td>
<td>82</td>
<td>23.0 mm Hg 1.9 meds</td>
<td>15.5 mm Hg 0.6 meds</td>
<td>15.4 mm Hg 0.7 meds</td>
<td></td>
</tr>
<tr>
<td>Cardoso</td>
<td>20</td>
<td>23.7 mm Hg 3.4 meds</td>
<td>13.7 mm Hg 0.2 meds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grieshaber, Pienaar, et al</td>
<td>60</td>
<td>45.0 mm Hg 0 meds</td>
<td>15.4 mm Hg 0 meds</td>
<td>16.3 mm Hg 0 meds</td>
<td></td>
</tr>
<tr>
<td>Matthaei et al</td>
<td>46</td>
<td>18.2 mm Hg 2.3 meds</td>
<td>12.6 mm Hg 1.0 meds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Klink</td>
<td>19</td>
<td>19.0 mmHg 3.0 meds</td>
<td>11.2 mm Hg 0.0 Meds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Koerber</td>
<td>15</td>
<td>26.5 mm Hg 2.1 meds</td>
<td>18 Months 14.5 mm Hg 0.3 meds</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PHACO-CANALOPLASTY: 3-YEAR RESULTS

- At 36 months: mean decrease in IOP from baseline = 42%
- At 36 months: mean Reduction in medication = 80%
- Note: 78% of ALL patients are treatment-free at three years!

# 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>N</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>Total number of patients with serious complications</td>
<td>1 (0.6%)</td>
<td>28 (27%)</td>
<td>24 (22%)</td>
</tr>
</tbody>
</table>

2. Gedde, SJ et al. Review of the results from the Tube vs. Trabeculectomy Study Current Opinion in Ophthalmology 2010, 21:123-128
**COMPARISON: POST-OP CARE**

<table>
<thead>
<tr>
<th>CANALOPLASTY</th>
<th>TRABECULECTOMY</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Lotemax qid x 1wk and taper over next 3-4wks</td>
<td>• Pred Forte q2° x 2wks, then PF taper over 8-10wks</td>
</tr>
<tr>
<td>• Topical antibiotics qid 1wk</td>
<td>• Topical antibiotics qid 2-3wks</td>
</tr>
<tr>
<td>• Restrictions 2wks</td>
<td>• Topical steroid ointment qhs x 2-3wks</td>
</tr>
<tr>
<td></td>
<td>• Restrictions for 4-6wks</td>
</tr>
<tr>
<td></td>
<td>• Lifetime restrictions</td>
</tr>
</tbody>
</table>
## COMPARISON: QUALITY OF LIFE

<table>
<thead>
<tr>
<th></th>
<th>CANALOPLASTY</th>
<th>TRABECULETOMY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>176</td>
<td>152</td>
</tr>
<tr>
<td>Highly Satisfied</td>
<td>57%</td>
<td>41%</td>
</tr>
<tr>
<td>Positive Mood</td>
<td>54%</td>
<td>37%</td>
</tr>
<tr>
<td>Less Stressed About Surgery</td>
<td>84%</td>
<td>51%</td>
</tr>
<tr>
<td>Postop Care Stress</td>
<td>14%</td>
<td>46%</td>
</tr>
<tr>
<td>Revision Surgeries Needed</td>
<td>8%</td>
<td>35%</td>
</tr>
</tbody>
</table>

Josefina P. Salgado, Johannes Sauer, Norbert J. Korber, Franz J. Grehn, Thomas Klink
University Eye Hospital Wurzburg, Augencentrum Köln Porz. EGS 2012.
## 360 VISCO-DILATION ALONE LOWERS IOP

<table>
<thead>
<tr>
<th>Exam</th>
<th>CANALOPLASTY WITH SUTURE</th>
<th>CANALOPLASTY WITHOUT SUTURE</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>12 Months</td>
<td>91</td>
<td>16.1 ± 3.9</td>
</tr>
<tr>
<td>18 Months</td>
<td>87</td>
<td>16.2 ± 4.1</td>
</tr>
<tr>
<td>24 Months</td>
<td>89</td>
<td>16.1 ± 4.0</td>
</tr>
<tr>
<td>30 Months</td>
<td>82</td>
<td>16.3 ± 4.5</td>
</tr>
<tr>
<td>36 Months</td>
<td>89</td>
<td>15.5 ± 3.5</td>
</tr>
</tbody>
</table>

**AB-INTERNO CANALOPLASTY, ABIC**

- Ab-interno Canaloplasty is a new Minimally Invasive Glaucoma (MIGS) procedure, which achieves similar IOP-lowering effects to traditional (ab-externo) Canaloplasty in patients with mild-to-moderate POAG without ever touching the sclera.

- Ab-interno Canaloplasty conserves the clinically proven benefits of 360° visco-dilation of Schlemm canal provided by traditional Canaloplasty via a clear corneal incision – and with the speed and ease of implementation of current MIGS procedures.

- ABiC can be considered a “new, comprehensive MIGS”
  - Whereas MIGS techniques to date have addressed only one aspect of outflow, ABiC™ restores the natural outflow pathways and addresses all potential sites of outflow resistance.
ABIC is a highly effective, simple and quick procedure that offers the same clinically proven benefits of traditional Canaloplasty, but with the speed and ease of implementation of a MIGS procedure. Whereas other MIGS procedures treat only one aspect of aqueous outflow, ABiC accesses, catheterizes, and viscodilates the trabecular meshwork, Schlemm’s canal, and also the distal outflow system, beginning with the collector channels. Performed as a stand-alone procedure or as an adjunct to cataract surgery, ABiC easily and comprehensively restores the natural outflow pathways for your glaucoma patients.
WHY ABIC?

• Follows strong science behind traditional Canaloplasty
• Follows safety-first premise of MIGS
• Preserves conjunctiva
• Can be performed before, in conjunction with, or after, cataract extraction
• Restores natural outflow pathways with minimal tissue trauma
• No permanent implant or stent
• Patient selection criteria are similar to current MIGS procedures
• Comprehensive: addresses trabecular meshwork, Schlemm canal and Collector Channels
CONJUNCTIVAL BLANCHING WITH ABIC

IMMEDIATE PRE-OP

IMMEDIATE POST-OP
POST-OPERATIVE COMPARISON: DAY ONE
ABiC CASE SERIES

- 228 patient case series study; 6-month follow up as of Sep 2015
- Dr. Mark J. Gallardo (El Paso, TX) and Dr. Mahmoud Khaimi (Dean McGee, Oklahoma City, OK).
- Total reduction in mean IOP of 28% (at 6 months)
- 50% reduction in number of medications (at 6 months)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>1 Month</th>
<th>3 Months</th>
<th>6 Months</th>
<th>% Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>228</td>
<td>215</td>
<td>123</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td>Mean IOP</td>
<td>19.0</td>
<td>15.7</td>
<td>14.3</td>
<td>13.7</td>
<td>28%</td>
</tr>
<tr>
<td>Mean Medications</td>
<td>2.0</td>
<td>0.3</td>
<td>1.0</td>
<td>1.0</td>
<td>50%</td>
</tr>
</tbody>
</table>
ABiC CASE SERIES (CONT.)

ABiC performed as a stand-alone procedure:
- Total reduction in mean IOP of 41% (at 6 months)
- 50% reduction in number of medications (at 6 months)

ABiC performed in conjunction with cataract surgery:
- Total reduction in mean IOP of 24% (at 6 months)
- 100% reduction in number of medications (at 6 months)

ABiC performed on PseudoPhakic patients:
- Total reduction in mean IOP of 33% (at 6 months)
- 67% reduction in number of medications (at 6 months)
After Cataract surgery perform goniotomy – open the trabecular meshwork.
Prime the catheter with viscoelastic and feed it through Schlemm canal 360 degrees.
ABiC: THREE SIMPLE STEPS

3 STEP THREE

Withdraw the catheter and viscodilate the trabecular meshwork, Schlemm canal and collector channels every 2 clock hours.
Cataract surgery patient on one or two medications
Mild-to-moderate glaucoma – IOP ranging from 12-20 on 1-2 medications.
Overall patient selection consideration: earlier intervention in disease process recommended.
A Comprehensive Approach to MIGS

Canaloplasty achieves similar IOP-lowering effects to traditional (ab-externo) Canaloplasty in patients with mild-to-moderate POAG and offers the speed and ease of implementation of current MIGS procedures.

Learn more

Canaloplasty: Restorative Glaucoma Surgery

One of the key advantages of Canaloplasty is that it works in the absence of a filtering bleb. Not only does this lead to more predictable outcomes and easier post-operative management, but it can reduce or eliminate many of the intra-operative and post-operative complications associated with trabeculectomy. Watch a video interview with glaucoma specialist Howard E. Barabey, MD (USA), to learn about some of the key advantages of Canaloplasty, including its high safety profile. Having performed nearly 1000 procedures, Dr. Barabey describes Canaloplasty as his “go to” procedure for glaucoma.