Ab-Interno Canaloplasty

Microinvasive Technique for Circumferential Viscodilation of Schlemm Canal Using a Microcatheter



6-Month Data Review

Mark J. Gallardo, MD El Paso Eye Surgeons, P.A.



Ellex: Speaker and Consultant Glaukos: Speaker and consultant

The author has no financial or proprietary interest in any material or method mentioned.

BACKGROUND

Canaloplasty, a blebless glaucoma procedure used to treat OAG, is thought to be a comprehensive and restorative procedure of the conventional aqueous outflow system. The procedure involves circumnavigation of Schlemm canal with a flexible microcatheter, 360° viscodilation, and placement of a tension suture to maintain canal patency. Obstructions within the canal can prohibit circumferential intubation of the canal which prevents stent suture placement. Anecdotal and published¹ data has revealed that patients not receiving the tension suture exhibited similar intraocular pressure (IOP) control to those that did receive the tension suture. Given this data, we have adopted a procedure which provides the benefits of 360° of canal viscodilation, but in a a minimally invasive nature.

^{1.} Lewis RA, von Wolff K, Tetz M, et al. Canaloplasty: three-year results of circumferential viscodilation and tensioning of Schlemm's canal using a microcatheter to treat open angle glaucoma. J Cataract Refract Surg. 2011;(37):682-690.

To evaluate the efficacy of ab-interno canaloplasty (ABiC) – a novel minimally invasive glaucoma surgery (MIGS) for reducing IOP and glaucoma medication dependence – in adult OAG patients over a 6-month period.

PURPOSE

METHODS

- This was a non-randomized, single center, consecutive case series of 122 patients. ABiC was performed (as described on next slide) as a stand-alone procedure in pseudophakic patients, while those with a crystalline lens had either a stand alone ABiC or a combined ABiC/cataract extraction with intraocular lens implantation depending on lens grade. The two groups were then further stratified based on their level of pre-operative pressure/glaucoma control:
 - Controlled glaucoma (IOP \leq 16 mmHg)
 - Uncontrolled glaucoma (IOP ≥ 17 mmHg)
- Patients were evaluated at 1, 3, and 6 months and IOP, medication burden, and any adverse event or intervention was recorded. Analyses was performed to evaluate and compare the level of IOP and medication burden reduction from baseline in the various sub-groups.

Methods (Surgical Steps of ABiC)

Following the creation of a temporal clear corneal incision, the iTrack 250 microcatheter (Ellex) (Figure 1) is inserted into the anterior chamber through a parecentesis 90° away from the nasal drainage angle. Under direct visualization, a small otomy is created in the trabecular meshwork (TM) through which the microcatheter is introduced into the canal of Schlemm. The catheter is circumnavigated 360° allowing for complete catheterization of the canal. Aliquots of the ocular viscoelastic device Healon GV are injected into the canal and distal drainage system at each clock hour upon catheter removal.



Figure 1: iTrack[™] microcatheter (with ViscoInjector[™])



- Case series review consisted of 122 eyes with a baseline IOP of 18.6 ± 6.4 mmHg
- Mean IOP was reduced by 28.49% at 6 months (n=32)
- Mean number of medications was reduced by 50% at 6 months
- At six months over half of the study population (n=17) were medication free with a mean IOP of 12.1 ± 2.1 mmHg.

ABiC All Eyes					
Exam	n	Mean IOP (mm Hg) ± SD	Mean Medications (n) ± SD		
Baseline	122	18.6 ± 6.4	2.0 ± 1.0		
1 Month	115	15.1 ± 4.7	0.4 ± 0.8		
3 Months	75	13.7 ± 3.2	1.0 ± 1.0		
6 Months	32	13.3 ± 3.2	1.0 ± 1.0		

RESULTS

(WITH/WITHOUT CATARACT SURGERY)

- In patients who underwent ABiC in conjunction with cataract surgery (n=59) there was a mean IOP reduction of 17.19% and a 50% reduction in the number of medications at 6 months.
- In phakic patients who underwent ABiC as a stand-alone procedure (n=15), there was a mean IOP reduction of 38% and a 50% reduction in the number of medications at 6 months.

ABiC with Cataract Surgery (Patients with controlled and uncontrolled OAG)			Standalone Procedure (Phakic Patients with uncontrolled OAG)			
Exam	n	Mean IOP (mm Hg) ± SD	Mean Medications (n) ± SD	n	Mean IOP (mm Hg) ± SD	Mean Medications $(n) \pm SD$
Baseline	59	15.7 ± 3.4	2.0 ± 1.0	15	21.1 ± 7.1	2.0 ± 1.0
1 Month	56	13.6 ± 3.6	0.3 ± 0.6	13	15.3 ± 4.8	0.6 ± 1.0
3 Months	46	13.1 ± 2.7	0.0 ± 1.0	6	14.3 ± 2.3	1.0 ± 1.0
6 Months	21	13.0 ± 3.2	1.0 ± 1.0	3	13.0 ± 3.6	1.0 ± 1.0

RESULTS (CONTROLLED GLAUCOMA)

- This subgroup of patients had controlled OAG on topical therapy. Given the overall low preoperative IOP, the purpose of the procedure was to reduce medication burden while maintaining IOP control. This group included patients who had a stand-alone or combined ABiC.
- All patients at 6 months in this group were medication free at 6 months.

Controlled Glaucoma (IOP <u><</u> 16 mm Hg)						
Exam	n	Mean IOP (mm Hg) ± SD	Mean Medications (n) ± SD			
Baseline	46	13.2 ± 1.9	2.0 ± 1.0			
1 Month	44	13.6 ± 3.5	0.1 ± 0.4			
3 Months	33	13.1 ± 2.3	0.0 ± 1.0			
6 Months	14	13.8 ± 3.2	0.0 ± 1.0			

RESULTS (UNCONTROLLED GLAUCOMA)

- In patients with uncontrolled OAG there was a 40.63% decrease in IOP and a 66.66% reduction in medications at 6 months.
- In those patients with uncontrolled OAG that were on maximum therapy there was a 37.55% decrease in IOP and a 66.66% reduction in medications at 6 months.

Uncontrolled Glaucoma (IOP <u>></u> 17 mm Hg)			Uncontrolled Glaucoma (IOP ≥ 17 mm Hg) on MAX Therapy (+ 3 gtts)			
Exam	n	Mean IOP (mm Hg) ± SD	Mean Medications (n) ± SD	n	Mean IOP (mm Hg) ± SD	Mean Medications (n) ± SD
Baseline	76	21.9 ± 6.0	3.0 ± 1.0	44	22.1 ± 6.7	3.0 ± 0.0
1 Month	71	16.0 ± 5.1	0.6 ± 0.9	40	17.0 ± 5.6	0.8 ± 1.0
3 Months	42	14.2± 3.8	1.0 ± 1.0	24	14.9 ± 4.0	1.0 ± 1.0
6 Months	18	13.0 ± 3.3	1.0 ± 1.0	11	13.8 ± 3.3	1.0 ± 1.0

RESULTS (INTRA AND POST-OPERARTIVE COMPLICATIONS)

- No intra-operative adverse events were recorded. Patients often developed a little bleeding at the otomy site which was easily evacuated during viscoelastic aspiration from the anterior chamber. No Descematic detachments were seen.
- Micro-hyphemas were common but resolved within one week without sequelae.



Figure 2: Slit lamp photograph of a post-operative day one visit. Note limited blood in inferior angle.

CONCLUSIONS

According to preliminary 6-month results, ABiC provides a safe and effective stand-alone means of managing mild-to-moderate open angle glaucoma compared to traditional glaucoma surgery and other MIGS alternatives. ABiC is also effective when combined with cataract surgery.

Not only can ABiC be used to provide IOP reduction in uncontrolled glaucoma patients, but it can also be used to effectively reduce the medication burden in controlled glaucoma patients.

- Comparable effectiveness to other MIGS procedures
- Only MIGS that does not require a permanent implant or extensive tissue destruction/ablation
- Can be performed as a stand-alone procedure or as an adjunct to cataract extraction
- Can be performed in phakic and pseudophakic patients