AMERICAN ACADEMY OF OPHTHALMOLOGY®

In partnership with the AMERICAN GLAUCOMA SOCIETY

36-Month Effectiveness of Ab-Interno Canaloplasty Standalone versus Combined with Cataract Surgery for the Treatment of Open-Angle Glaucoma

Mark J. Gallardo, MD

Purpose: To report the 36-month effectiveness of ab-interno canaloplasty performed with the iTrack microcatheter (Nova Eye Medical) as a standalone procedure or combined with cataract surgery.

Design: A single-center, retrospective case series.

Participants: Eyes diagnosed with primary open-angle glaucoma (POAG).

Methods: Eyes with POAG were treated with either ab-interno canaloplasty as a standalone procedure (iTrack alone) or in conjunction with phacoemulsification (iTrack+phaco).

Main Outcome Measures: The main outcomes were mean reductions in intraocular pressure (IOP) and numbers of glaucoma medications at 12, 24, and 36 months postoperatively. The secondary endpoints consisted of visual acuity and the rate of complications.

Results: Forty-four eyes of 44 patients with open-angle glaucoma were included: 23 eyes in the iTrack-alone group and 21 eyes in the iTrack+phaco group. When both groups were analyzed together, both the IOPs and numbers of medications were significantly reduced at 12 months ($P < 0.0001$) and remained stable at 24 and 36 months. IOPs decreased from 20.5 ± 5.1 mmHg preoperatively to 13.3 ± 2.1, 13.1 ± 2.4, and 13.3 ± 2.1 mmHg at 12, 24, and 36 months, respectively; the numbers of medications were reduced from 2.8 ± 0.9 preoperatively to 1.1 ± 1.1, 1.0 ± 1.1, and 1.3 ± 1.3 at 12, 24, and 36 months postoperatively, respectively. Comparable IOP results were observed in the iTrack-alone and iTrack+phaco groups, from baseline values 20.9 ± 6.1 and 20.0 ± 3.9 mmHg, respectively, to 13.2 ± 2.1 and 13.5 ± 2.2 mmHg at 36 months, respectively. At 36 months, 95.5% of eyes had an IOP of ≤ 17 mmHg and 68.2% of eyes were on ≤ 1 medication. No serious intraoperative or postoperative complications were reported.

Conclusions: Ab-interno canaloplasty performed with the iTrack microcatheter was found to be effective in reducing IOP and medication dependence. Comparable results were observed when employed as a standalone procedure or when combined with cataract surgery. *Ophthalmology Glaucoma 2022;■:1–7 © 2022 by the American Academy of Ophthalmology*

An increasing number of minimally invasive glaucoma surgery (MIGS) options are nowadays routinely deployed in cases of mild-to-moderate glaucoma to overcome the challenges associated with chronic use of medications and to defer the need for traditional surgical interventions, such as trabeculectomy and filtering tubes, which carry a high risk of complications.[1]

MIGS is a growing field of glaucoma surgery that aims to manage intraocular pressure (IOP) via a less invasive surgical profile to avoid significant disruption to the ocular structures, thus allowing the possibility of surgery and drainage procedures in the future. There are several MIGS options that differ in their locations and mechanisms of action and can be classified by their intended targeted area of outflow as trabecular or conventional, suprachoroidal, and subconjunctival.[2] Generally speaking, stent-based MIGS options of the conventional outflow system are focal in their approach and aim to bypass the site of diseased tissue to permit improved aqueous outflow directly from the anterior chamber to Schlemm's canal.

Conversely, ab-interno canaloplasty (ABiC) is a MIGS that is designed to treat both the proximal and distal portions of the conventional outflow pathway. Specifically, it aims to disrupt the compressed tissue planes of the trabecular meshwork and to dilate the entire circumference of Schlemm's canal, collector channels, and the distal system without removing tissue and without placing a stent or permanent implant. ABiC[3,4] has been shown to lower IOPs and medication burdens across the glaucoma disease spectrum and is particularly well suited for those with mild-to-moderate disease,[5] owing to its tissue-sparing approach.

In this study, ABiC was performed using the iTrack microcatheter (Nova Eye Medical).[6] The procedure can be

https://doi.org/10.1016/j.ogla.2022.02.007
ISSN 2589-4196/22

performed alone or in conjunction with phacoemulsification. To account for the confounding effect of cataract surgery in contributing to a reduction in IOP,[7,8] this study sought to investigate the 36-month outcomes of ABiC when performed as a standalone procedure, as compared to ABiC performed in combination with phacoemulsification.

Methods

Study Design

This study was a single-center, single-surgeon (M.J.G.), retrospective review of a consecutive case series of eyes treated with ABiC either as a standalone procedure (iTrack-alone) or in combination with phacoemulsification (iTrack+phaco) between September 24, 2014, and June 29, 2016. The study was conducted according to the tenets of the Declaration of Helsinki, followed the Health Insurance Portability and Accountability Act regulations for patients, and written consent for surgery was obtained from patients. In accordance with the committee of Surgical Center of El Paso, Texas, institutional review board or ethics approval was not required for this study because of its retrospective nature and because the medical device used has already been approved by the Federal Drug Administrative.

Patient Selection

All patients aged $\geq$ 18 years with a diagnosis of primary open-angle glaucoma and uncontrolled IOP or intolerance to medications, having either mild-to-moderate or severe glaucoma based on the Hodapp-Parish-Anderson classification method, were eligible for inclusion. Patients were required to exhibit optic disc changes characteristic of glaucomatous optic neuropathy and a thinning of the retinal nerve fiber layer on OCT. Patients were excluded if any angle disease was noted on gonioscopy: that is, evidence of peripheral anterior synechiae, angle recession, or heterogeneous angle pigmentation. In the author's experience, patients with dysgenic appearing angles do not respond well to viscodilation alone and instead benefit from procedures that bypass the trabecular meshwork, such as goniotomy or trabecular microbypass stent surgery.

All patients who had undergone laser trabeculoplasty or another MIGS procedure within 6 months of the surgical date were excluded. Additionally, patients who had any comorbid diseases, such as uveitis or secondary glaucoma, were excluded. Patients were allocated to undergo ABiC in combination with phacoemulsification if they presented with a cataract.

Twenty-two of 23 eyes in the standalone group and 16 of 21 eyes in the combined group had a preoperative IOP above 17 mmHg and required ABiC to decrease both their IOP and number of medications. The remaining eyes underwent the procedure, as they were on the maximum topical therapy or were intolerant to medications. The medications were stopped on day 1 postoperatively and were reinitiated in a titrated fashion if the patients' IOP elevated above the target, which was dependent on many factors, most notably the stage of glaucoma.

To account for the correlation of both eyes of the same patients, the left eye of patients who had both eyes treated was excluded from the analysis, and only the data of the right eye were included in the study.[9]

Surgical Technique

All surgeries were performed by a single surgeon (M.J.G.), as previously described.[10,11] In those eyes that underwent ABiC in combination with cataract surgery, phacoemulsification and lens implantation was performed first. A paracentesis using a 27-gauge needle was then created either superiorly or inferiorly, depending on patient access, and directed toward the nasal angle. High molecular weight ophthalmic viscosurgical device (OVD) (Healon GV, Johnson & Johnson) was used to prime the iTrack microcatheter. The microcatheter was then inserted into the anterior chamber via the paracentesis and directed toward the nasal drainage angle. A gonioprism was used to observe the nasal angle, and a microgoniotomy was created using a 25-gauge needle or a straightened Cystotome (Cook Medical) through the temporal clear corneal incision used for phacoemulsification. Microforceps were used to retrieve the distal end of the microcatheter within the anterior chamber to intubate Schlemm's canal via the goniotomy site. The microcatheter was then advanced using the microforceps. The advancement of the microcatheter through the full circumference of Schlemm's canal was monitored transsclerally via its illuminated fiber-optic tip. A Lester hook (BVI Medical) was used via the clear corneal incision to stabilize the iTrack microcatheter at the site of goniotomy and to prevent the extension of the goniotomy during the subsequent surgical steps. After 360° circumferential advancement of the microcatheter, it was withdrawn at a rate of 1 clock hour per 1.5 seconds, while simultaneously injecting 2 "clicks" of Healon GV per clock hour. Approximately 2.8 µl of OVD were delivered per microbolus or click, resulting in an average of 100 µl delivered over the entirety of Schlemm's canal. Any residual cohesive viscoelastic was then removed from the anterior chamber using an Alcon Centurion I/A handpiece (Alcon Laboratories) before hydrating the corneal wounds and refilling the anterior chamber to approximately 20 mmHg using a balanced-salt solution as measured intraoperatively using a Barraquer tonometer.

In eyes that underwent ABiC as a standalone procedure, a paracentesis and clear corneal tunnel were created at the beginning of the procedure, followed by filling of the anterior chamber with a cohesive viscoelastic. The pressurization of the anterior chamber with a cohesive viscoelastic, both in cases of standalone and combined ABiC, creates a tamponade effect, which facilitates the delivery of 100 µl of OVD during the procedure. The procedure was otherwise completed as described above.

Postoperatively, patients were administered prednisolone acetate 1% for 4 times a day for the first week and twice per day for the following 3 weeks; a nonsteroidal anti-inflammatory drug and topical antibiotic were administered during the first week after the procedure.

Preoperative and Postoperative Visits and Medications

The preoperative assessments included corrected distance visual acuity, IOP measured using Goldman tonometry, gonioscopy, slit lamp examination, and examination of the fundus and optic disc, as well as a visual field test.

Postoperatively, data were collected at 12, 24, and 36 months. IOP, medications, visual field, and corrected distance visual acuity data were collected at all postoperative visits.

All glaucoma medications were removed 1 day postoperatively, which is customary for the surgeon (M.J.G.), and titrated back 1 medication at a time as the surgeon deemed necessary (i.e., IOP not at target).

Primary and Secondary Outcomes and Adverse Events

The primary outcome measures were the IOP and number of required glaucoma medications. The secondary outcome was measured by the best-corrected visual acuity (corrected distance visual acuity). Any adverse events were recorded.

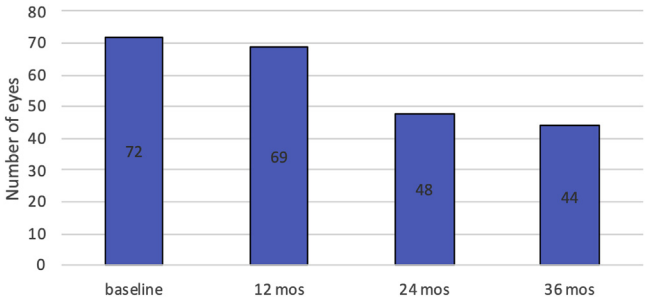

Figure 1. Numbers of eyes available at baseline and at 12, 24, and 36 months postoperatively.

Statistical Analysis

The overall and intragroup comparisons between changes in IOPs and numbers of medications between 2 time points were analyzed using a paired *t* test. The overall comparisons between changes in IOPs and numbers of medications between 2 time points were analyzed with a *t* test for independent samples. The intergroup comparisons between the frequency of categorical changes in IOPs and numbers of medications between 2 time points were analyzed with a Pearson chi-square test. A P value of < 0.05 was considered statistically significant.

Results

Demographics

In this study, 72 eyes underwent ABiC, but only 44 eyes were able to complete the follow-up period. Forty-four eyes of 44 patients, with a mean age of 74.1 ± 9.0 years, ranging from 52 to 88 years, were included in the analysis. There were 25 female (56.8%) and 19 male (43.2%) patients. Hispanic ethnicity represented 77.3% of the eyes and White ethnicity represented 22.7%.

The left eye of patients who had both eyes treated was excluded from the analysis, and only the data of the right eye were included. Also, only eyes that have completed the 36-month follow-up period were included. Of the 44 eyes, 23 were treated with iTrack alone and 21 eyes were treated with iTrack+phaco.

Follow-Up

From the original cohort of 72 eyes of 72 patients, 28 eyes of 28 patients were not included in the analysis. The reasons are as follows: 2 eyes were treated with filtration surgery with the Express shunt (Alcon Laboratories); 2 eyes developed neovascular glaucoma (NVG) as a consequence of diabetic retinopathy; 2 eyes developed a visually significant cataract requiring cataract extraction, 1 of which underwent trabecular microbypass stent surgery (iStent, Glaukos); 1 eye was excluded due to complicated phacoemulsification; 1 eye developed age-related macular degeneration with choroidal neovascularization (CNV) requiring Avastin anti-vascular endothelial growth factor (anti-VEGF) injection; 2 patients were deceased; and 1 eye required additional treatment with the Xen45 gel stent (Allergan Inc). The other eyes were not included because they did not complete the 36-month follow-up. Figure 1 shows the cumulative numbers of eyes available at baseline and at 12, 24, and 36 months postoperatively.

In this study, data were analyzed only for those 44 eyes that reached the 36-month follow-up.

Table 1. Preoperative Characteristics*

Characteristics	iTrack+Phaco (n = 21)	iTrack-Alone (n = 23)
IOP, mmHg	20.0 ± 3.9 (17–33)	20.9 ± 6.1 (16–47)
Medications	2.5 ± 1.1 (0–4)	3.0 ± 0.5 (2–4)
CDVA, logMAR	0.66 ± 0.61 (0 to LP)	0.40 ± 0.58 (0 to CF)

*Data are shown as the mean ± SD (range). CDVA = corrected distance visual acuity; CF = counting fingers; IOP = intraocular pressure; logMAR = logarithm of the minimum angle of resolution; LP = light perception; phaco = phacoemulsification.

Table 2. Preoperative Glaucoma Severity Frequency

Severity	% (n)
Mild	36% (16)
Moderate	14% (6)
Severe	48% (21)
Unavailable	2% (1)

Baseline

The mean preoperative IOPs were 20.5 ± 5.1 mmHg when both groups were analyzed together, 20.0 ± 3.9 mmHg in the iTrack+-phaco group, and 20.9 ± 6.1 mmHg in the iTrack-alone group, ranging from 16 to 47 mmHg, with an average of 2.8 ± 0.9 glaucoma medications: 2.5 ± 1.1 in the iTrack+phaco group and 3.0 ± 0.5 in the iTrack-alone group, ranging from 0 to 4 medications. Preoperative characteristics are presented in Tables 1 and 2.

IOP

There was a statistically significant decrease in the average IOP values between baseline (20.5 ± 5.1 mmHg) and all postoperative visits ($P < 0.0001$) when both groups were considered together. Twelve months after the procedure, the IOP was 13.3 ± 2.1 mmHg and was stable between all postoperative visits at 24 and 36 months, with values of 13.1 ± 2.4 mmHg and 13.3 ± 2.1 mmHg, respectively.

Table 3. Mean IOPs (mmHg) and Mean Numbers of Medications at All Visits for Eyes in Both Groups, for Eyes Treated with iTrack Alone, and for Eyes Treated with iTrack Combined with Phacoemulsification*

	Both Groups	iTrack+Phaco	iTrack-Alone
IOP, mmHg			
Baseline	20.5 ± 5.1 (44)	20.0 ± 3.9 (21)	20.9 ± 6.1 (23)
12 mos	13.3 ± 2.1 (43)	13.0 ± 1.8 (20)	13.7 ± 2.3 (23)
24 mos	13.1 ± 2.4 (36)	12.4 ± 1.5 (18)	13.8 ± 2.9 (18)
36 mos	13.3 ± 2.1 (44)	13.5 ± 2.2 (21)	13.2 ± 2.1 (23)
Medications			
Baseline	2.8 ± 0.9 (44)	2.5 ± 1.1 (21)	3.0 ± 0.5 (23)
12 mos	1.1 ± 1.1 (43)	0.8 ± 1.0 (20)	1.5 ± 1.2 (23)
24 mos	1.0 ± 1.1 (39)	0.8 ± 1.0 (21)	1.3 ± 1.1 (18)
36 mos	1.3 ± 1.3 (44)	1.0 ± 1.2 (21)	1.6 ± 1.4 (23)

*Data are shown as the mean ± SD (n). IOP = intraocular pressure; phaco = phacoemulsification.

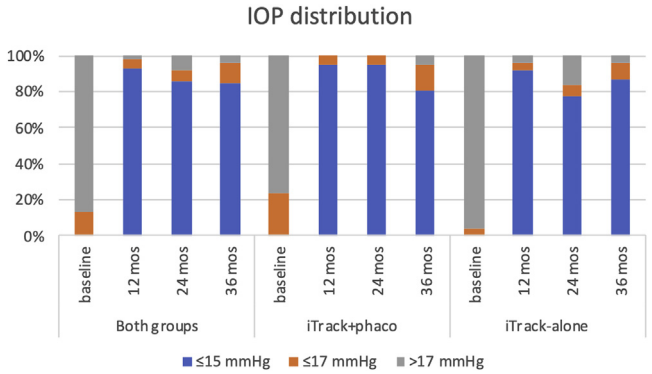

Figure 2. Percentages of intraocular pressure (IOPs) for eyes in both groups, for eyes treated with iTrack standalone, and for eyes treated with iTrack combined with phacoemulsification. phaco = phacoemulsification.

At 36 months postoperatively, the average IOPs were 13.5 ± 2.2 mmHg in the iTrack+phaco group and 13.2 ± 2.1 mmHg in the iTrack-alone group. The mean IOPs at all visits are presented in Table 3.

The mean percentage reductions in IOPs for both groups together were 33.9% at 12 months, 33.3% at 24 months, and 32.5% at 36 months. The iTrack+phaco and iTrack-alone groups showed comparable results, of 35.8%, 37.0%, and 31.3% and 32.1%, 29.7%, and 33.6% at 12, 24, and 36 months, respectively.

When the iTrack+phaco and iTrack-alone groups were considered together, the IOP was reduced to ≤ 17 mmHg in 97.7% of eyes at 12 months, 91.7% of eyes at 24 months, and 95.5% of eyes at 36 months, compared with 13.6% preoperatively. The IOP was ≤ 15 mmHg in 93.0% of eyes at 12 months, 86.1% of eyes at 24 months, and 84.1% of eyes at 36 months, compared with 0% preoperatively. Similar results were observed regardless of whether eyes were treated with ABiC as a standalone procedure or in combination with cataract surgery, as shown in Figure 2 and Table 4.

Glaucoma Medication Use

There was a statistically significant decrease in the number of medications between baseline (2.8 ± 0.9) and all postoperative visits when both groups were considered together: 1.1 ± 1.1 at 12 months, 1.0 ± 1.1 at 24 months, and 1.3 ± 1.3 at 36 months ($P < 0.0001$).

Table 4. Eyes with IOPs within Target at Baseline and at 36 Months Postoperatively, and Percentages of Eyes with an IOP Reduction Equal To or Higher Than 20% or 30%

	Percentages of Eyes					
	Both Groups		*iTrack+Phaco*		*iTrack-Alone*	
	Baseline	*36 Mos*	*Baseline*	*36 Mos*	*Baseline*	*36 Mos*
IOP						
≤17 mmHg	13.6%	95.5%	23.8%	95.2%	4.3%	95.7%
≤15 mmHg	0%	84.1%	0%	81.0%	0%	87.0%
Reduced in IOP						
≥20%		86.4%		85.7%		87.0%
≥30%		68.2%		61.9%		73.9%

IOP = intraocular pressure; phaco = phacoemulsification.

At 36 months postoperatively, the numbers of medications were 1.0 ± 1.2 in the iTrack+phaco group and 1.6 ± 1.4 in the iTrack-alone group. The mean numbers of medications at all visits are presented in Table 3.

When the iTrack+phaco and iTrack-alone groups were considered together, there were reductions in the numbers of medications in the majority of eyes postoperatively for 83.7% of eyes at 12 months, 92.3% of eyes at 24 months, and 68.2% of eyes at 36 months. The percentages of eyes requiring no medication were 2.3% at baseline, 39.5% at 12 months, 43.6% at 24 months, and 34.1% at 36 months (Fig 3). Similar results were observed for eyes treated with ABiC as a standalone procedure or in combination with cataract surgery, except for the percentage of patients requiring zero medications, which was higher in the iTrack+phaco group (at 36 months, 42.9% in the iTrack+phaco group versus only 26.1% in the iTrack-alone group).

Visual Acuity Outcomes

Preoperatively, visual acuity (logarithm of the minimum angle of resolution) was 0.66 ± 0.61 (n = 21) in the iTrack+phaco group and 0.40 ± 0.58 (n = 23) in the iTrack-alone group. At the 36-month visit, it was 0.40 ± 0.58 (n = 21; $P < 0.0001$) and 0.44 ± 0.53 (n = 23; $P = 0.5$), respectively.

Of the baseline 72 eyes, 1 eye in the iTrack+phaco group and 3 eyes in the iTrack-alone group lost 2 or more lines (Snellen) of vision acuity. However, those losses were attributed to ocular surface disease and not progression of the visual field defect.

Complications and Adverse Events

There were no serious adverse events recorded. We included in the complications section all 81 eyes that underwent ABiC, regardless of the correlation of both eyes of the same patient. Ten eyes (7 in the iTrack+phaco group and 3 in the iTrack-alone group) had a microhyphema (circulating red blood cells). Two eyes in the iTrack+phaco group had a layered hyphema (1 with a 1-mm hyphema and 1 with a 0.5-mm hyphema), and 1 eye in the standalone group had a layered hyphema of 0.5 mm. Two eyes in the iTrack+phaco group had an IOP spike of ≥ 10 mmHg, 1 on 1 day and the other at 1 week postoperatively. One patient suffered from an IOP spike of ≥ 10 mmHg on 1 day postoperatively in the standalone group. There were 3 eyes that required additional treatment to further control IOP, as detailed in the above section titled "Follow-Up."

Discussion

Traditional ab-externo canaloplasty is a nonpenetrating surgery designed to re-establish the natural ocular outflow system. During the procedure, the iTrack canaloplasty microcatheter is inserted into Schlemm's canal, and viscodilation is performed by injecting OVD while withdrawing the microcatheter. Finally, a suture may be placed in the canal and tightened to maintain tension and permanent expansion of the canal. Previous studies have demonstrated canaloplasty to be an effective procedure for reducing IOPs in patients affected by severe glaucoma,[12–14] with a low rate of complications, particularly compared with trabeculectomy.[15,16]

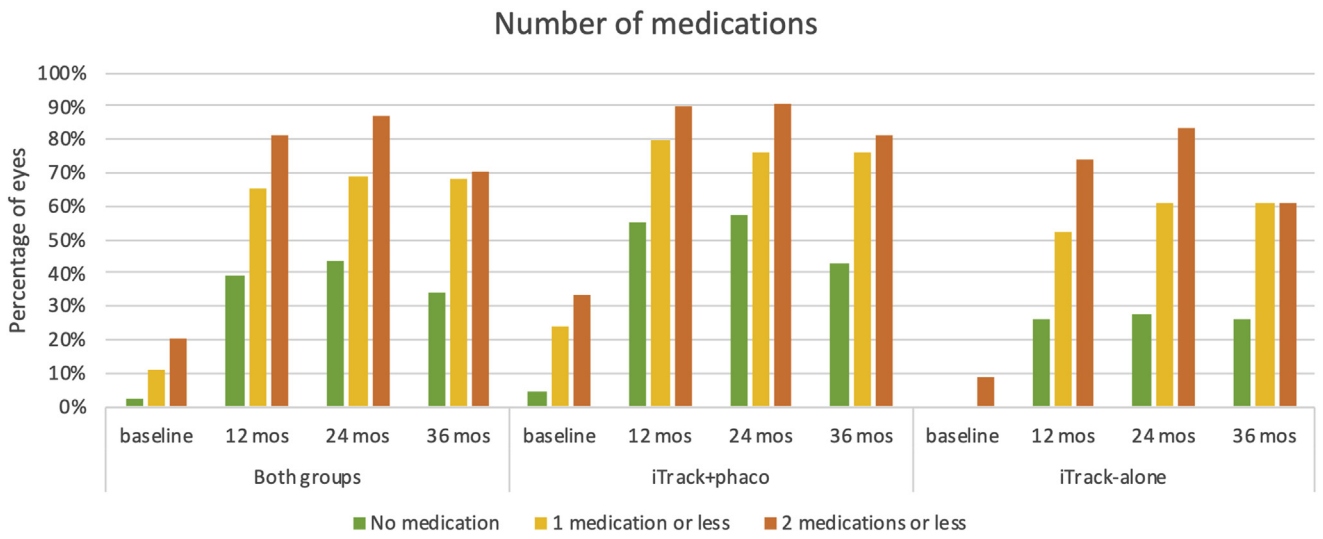

Figure 3. Percentages of medications for eyes in both groups, for eyes treated with iTrack standalone, and for eyes treated with iTrack combined with phacoemulsification. phaco = phacoemulsification.

The introduction of canaloplasty preceded the birth of MIGS, a term first created by Ahmed in 2009 to describe a growing field of glaucoma surgeries.[16] Specifically, MIGS typically employs an ab-interno procedure[17] with minimal disruption of normal anatomy, has a high safety profile, is effective at lowering IOP, and has a short recovery time.

It was the advent of MIGS that led to the belief that canaloplasty could be modified with a MIGS perspective, resulting in the creation of an innovative approach to glaucoma surgery known as ABiC. Although traditional ab-externo canaloplasty has continued to be a standard treatment for late-stage glaucoma, ABiC has started to be used in the treatment of mild-to-moderate glaucoma cases.[3,10]

ABiC follows the same principles of traditional ab-externo canaloplasty, with the exceptions that it is performed via an ab-interno surgical technique and requires no conjunctival or scleral dissection and no tensioning suture.[10,18] ABiC adheres to all criteria to be considered a MIGS procedure but addresses the outflow resistance in the conventional outflow pathway via a tissue-sparing, implant-free approach, unlike other MIGS procedures targeting the conventional outflow system. [5]

A paired-eye study of 12 eyes, conducted by this article's author, observed that ABiC is effective in lowering IOPs and reducing the numbers of glaucoma medications needed by patients and is comparable to traditional ab-externo canaloplasty in primary open-angle glaucoma out to 12 months,[19] although the study was not sufficiently powered to compare results incontrovertibly.

MIGS is often combined with cataract surgery to provide a number of advantages for the patient, such as reducing the number of surgeries, the associated infection risk, and the cost of having to undergo multiple procedures. Although the physiological mechanism of action remains speculative, cataract surgery alone has been shown to lower the IOP.[8] Thus, the aim of this consecutive case series was to assess whether the confounding effect of cataract surgery would determine the outcomes of ABiC in terms of IOPs and reductions in the number of medications.

In this study, ABiC seemed equally effective as a standalone procedure or combined with cataract surgery. IOP lowering and reductions in the mean number of medications were statistically similar in both the stand-alone and the combined groups from the 12-month visit up to the last follow-up at 36 months, although a higher proportion of patients in the iTrack+phaco group were able to eliminate their reliance on medications at each time point. Importantly, the reduction in IOP observed in both groups is higher than the reduction of phaco-emulsification alone reported in the literature; in a dedicated study with comparable glaucoma eyes, Shingleton et al[8] reported an IOP decrease of 1.8 mmHg after 5 years.

The significant reductions in IOP observed at 12 months in both the iTrack-alone and the iTrack+phaco groups are comparable with the results of other 12-month studies, such as the author's own 24-month study [20] and a study by Davids et al[21] (device not specified), which compared ABiC combined with phacoemulsification (from a preoperative value of 19.7 ± 4.1 mmHg to 14.3 ± 2.5 mmHg at 12 months postoperatively) and as a standalone procedure (from a preoperative value of 20.2 ± 4 mmHg to 13.6 ± 3.6 mmHg at 12 months postoperatively). The results demonstrate that the reduction observed remains stable for up to 36 months, with no significant change from the 12-month visit.

Looking at other MIGS options, trabecular microbypass stents are among the most commonly used and are supported by a plethora of robust prospective data. Although it is challenging to compare ABiC with trabecular microbypass stents, given that multiple stents can be implanted with different outcomes,[22,23] this study's results with ABiC are comparable with the IOP reductions achieved with those devices reported in the literature[22,24] and with previous

studies conducted by the author's group with trabecular microbypass stents MIGS and goniotomy (Kahook Dual Blade) in a similar patient population.[25,26]

Considering this case series and the scientific literature, the frequency of surgical complications associated with ABiC is low, with no serious adverse events reported. The only adverse events noted include intraoperative bleeding and limited descemetolysis near the limbus, as well as postoperative IOP elevation and hyphema. Most of these resolved spontaneously with no late sequelae.[20,21,25]

A major limitation of this study is that the regression to the mean effect can partially account for the results or overestimate the effectiveness of the procedure. This is due to the heterogeneous nature of the retrospective design. Several patients in this study, particularly those in the cataract group, were referred to us for surgery, and therefore the preoperative data points were limited to a single value. Others may have had medication changes in the visits leading up to surgery, both in terms of addition and subtraction of medications, and that may have caused an IOP elevation. In addition, IOP tends to fluctuate over time,[27] and the times between the preoperative, ultimate, and penultimate visits varied between subjects. Having a longer preoperative follow-up and a concise pattern for consecutive IOP measurements over time with a stable medication regimen, as we would in a prospective study, then analyzing several presurgery measurements and using the mean of those measurements as a baseline would have given a more precise understanding of the preoperative IOPs and of the effects of the procedure. Other weaknesses associated with the single-center, retrospective study design are acknowledged, such as selection bias and losses to follow-up. Moreover, collecting additional data and addressing the effectiveness of ABiC in relation to the severity of glaucoma will enhance patient selection and outcomes.

Footnotes and Disclosures

Originally received: August 13, 2021.
Final revision: February 10, 2022.
Accepted: February 11, 2022.
Available online: ■■■. Manuscript no. D-21-00241R7.

El Paso Eye Surgeons, PA, El Paso, Texas.

Disclosure:

The author has completed and submitted the ICMJE disclosure form.

The author has made the following disclosure: M.J.G.: Clinical investigator and speaker − Nova Eye Medical.

HUMAN SUBJECTS: The study was conducted according to the tenets of the Declaration of Helsinki, followed the Health Insurance Portability and Accountability Act regulations for patients, and written consent for surgery was obtained from patients. In accordance with the committee of Surgical Center of El Paso, TX, institutional review board/ethics approval was not required for this study due to its retrospective nature and because the medical device used is already approved by the Federal Drug Administrative.

No animal subjects were used in this study.

Author Contributions:

Conception and design: Gallardo

Data collection: Gallardo

Analysis and interpretation: Gallardo

Obtained funding: N/A; Study was performed as part of regular employment duties at Surgical Center of El Paso, Texas. No additional funding was provided.

Overall responsibility: Gallardo

Abbreviations and Acronyms:
ABiC = ab-interno canaloplasty; **IOP** = intraocular pressure; **MIGS** = minimally invasive glaucoma surgery.

Keywords:
Canaloplasty, Glaucoma, MIGS, Minimally invasive glaucoma surgery, iTrack, ABiC.

Correspondence:
Mark J. Gallardo, MD, El Paso Eye Surgeons, PA, 1201 N Mesa St, Ste G, El Paso, TX 79902. E-mail: submissiondrgallardo@gmail.com.

References

1. Borisuth NS, Phillips B, Krupin T. The risk profile of glaucoma filtration surgery. *Curr Opin Ophthalmol*. 1999;10:112−116.
2. Pillunat LE, Erb C, Jünemann AG, Kimmich F. Micro-invasive glaucoma surgery (MIGS): a review of surgical procedures using stents. *Clin Ophthalmol*. 2017;11:1583−1600.
3. Khaimi MA. Canaloplasty: a minimally invasive and maximally effective glaucoma treatment. *J Ophthalmol*. 2015;2015:485065.
4. Stegmann R, Pienaar A, Grieshaber MC. Schlemm's canal surgery: restoring physiological aqueous outflow. In: Grieshaber MC, Orgul S, Flammer J, eds. *Glaucoma Therapy—State of the Art*. Basel, Switzerland: Association for Continuing Education in Ophthalmology; 2009:113−120.
5. Zhang J, Wang NL. Progression on canaloplasty for primary open angle glaucoma. *Int J Ophthalmol*. 2019;12:1629−1633.
6. Smit BA, Johnstone MA. Effects of viscoelastic injection into Schlemm's canal in primate and human eyes: potential relevance to viscocanalostomy. *Ophthalmology*. 2002;109:786−792.
7. Gallardo MJ, Supnet RA, Ahmed IIK. Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach. *Clin Ophthalmol*. 2018;12:2149−2155.
8. Shingleton BJ, Pasternack JJ, Hung JW, O'Donoghue MW. Three and five year changes in intraocular pressures after clear corneal phacoemulsification in open angle glaucoma patients, glaucoma suspects, and normal patients. *J Glaucoma*. 2006;15:494−498.
9. Murdoch IE, Morris SS, Cousens SN. People and eyes: statistical approaches in ophthalmology. *Br J Ophthalmol*. 1998;82:971−973.
10. Gallardo MJ, Supnet RA, Ahmed IIK. Circumferential viscodilation of Schlemm's canal for open-angle glaucoma: ab-interno vs ab-externo canaloplasty with tensioning suture. *Clin Ophthalmol*. 2018;12:2493−2498.
11. Lewis RA, von Wolff K, Tetz M, et al. Canaloplasty: three-year results of circumferential viscodilation and tensioning of Schlemm canal using a microcatheter to treat open-angle glaucoma. *J Cataract Refract Surg*. 2011;37:682−690.

12. Riva I, Brusini P, Oddone F, et al. Canaloplasty in the treatment of open-angle glaucoma: a review of patient selection and outcomes. *Adv Ther*. 2019;36:31−43.
13. Bull H, von Wolff K, Körber N, Tetz M. Three-year canaloplasty outcomes for the treatment of open-angle glaucoma: European study results. *Graefes Arch Clin Exp Ophthalmol*. 2011;249:1537−1545.
14. Brüggemann A, Despouy JT, Wegent A, Müller M. Intraindividual comparison of canaloplasty versus trabeculectomy with mitomycin C in a single-surgeon series. *J Glaucoma*. 2013;22:577−583.
15. Klink T, Sauer J, Körber NJ, et al. Quality of life following glaucoma surgery: canaloplasty versus trabeculectomy. *Clin Ophthalmol*. 2015;9:7−16.
16. Ahmed I. A brief history of MIGS: the long and controversial journey to microinvasive glaucoma surgery (MIGS), and the quest to retire trabeculectomy. https://theophthalmologist.com/business-profession/a-brief-history-of-migs. Accessed February 22, 2021.
17. Cha EDK, Xu J, Gong L, Gong H. Variations in active outflow along the trabecular outflow pathway. *Exp Eye Res*. 2016;146:354−360.
18. Ammar DA, Kahook MY. Effects of benzalkonium chloride- or polyquad-preserved fixed combination glaucoma medications on human trabecular meshwork cells. *Mol Vis*. 2011;17:1806−1813.
19. Beckers HJMM, Schouten JS, Webers CABB, et al. Side effects of commonly used glaucoma medications: comparison of tolerability, chance of discontinuation, and patient satisfaction. *Graefes Arch Clin Exp Ophthalmol*. 2008;246:1485−1490.
20. Gallardo MJ. 24-month efficacy of viscodilation of Schlemm's canal and the distal outflow system with iTrack ab-interno canaloplasty for the treatment of primary open-angle glaucoma. *Clin Ophthalmol*. 2021;15:1591−1599.
21. Davids AM, Pahlitzsch M, Boeker A, et al. Ab interno canaloplasty (ABiC)-12-month results of a new minimally invasive glaucoma surgery (MIGS). *Graefes Arch Clin Exp Ophthalmol*. 2019;257:1947−1953.
22. Yook E, Vinod K, Panarelli JF. Complications of microinvasive glaucoma surgery. *Curr Opin Ophthalmol*. 2018;29:147−154.
23. Hengerer FH, Auffarth GU, Riffel C, Conrad-Hengerer I. Prospective, non-randomized, 36-month study of second-generation trabecular micro-bypass stents with phacoemulsification in eyes with various types of glaucoma. *Ophthalmol Ther*. 2018;7:405−415.
24. Porter M, Garza A, Gallardo M. Excisional goniotomy in Latino patients with open-angle glaucoma: outcomes through 24 months. *Clin Ophthalmol*. 2020;14:3619−3625.
25. Gallardo MJ, Supnet RA. Three-year outcomes of combined trabecular micro-bypass and phacoemulsification in a predominantly Hispanic population with primary open-angle glaucoma. *Clin Ophthalmol*. 2019;13:869−879.
26. Arnljots TS, Economou MA. Kahook dual blade goniotomy vs istent inject: long-term results in patients with open-angle glaucoma. *Clin Ophthalmol*. 2021;15:541−550.
27. Bhorade AM, Gordon MO, Wilson B, et al. Variability of intraocular pressure measurements in observation participants in the ocular hypertension treatment study. *Ophthalmology*. 2009;116:717−724.