

CANALOPLASTY AND TRABECULOTOMY RESULTS IN GLAUCOMA PATIENTS



Studies assessed data registry outcomes using two different devices.

BY SARAH ATTA, MD; BARAA NAWASH, MD; SAMANTHA GOLDBURG, MD; AND MARY QIU, MD

A PROSPECTIVE, REAL-WORLD, MULTICENTER STUDY TO SUPPORT THE ROLE OF AB-INTERNO CANALOPLASTY IN GLAUCOMA MANAGEMENT

Kerr N, Lubeck D, Barton K, et al¹

Industry support for this study: Several study authors disclosed consulting relationships with Nova Eye Medical

ABSTRACT SUMMARY

This prospective, real-world, multicenter study drew on the iTrack Global Data Registry to evaluate ab interno canaloplasty (ABiC) outcomes in 254 patients (344 eyes) with ocular hypertension or open-angle glaucoma (primary or secondary, all severities) over a mean follow-up period of 20.5 months. The study assessed ABiC combined with phacoemulsification and ABiC alone.

For combined cases ($n = 313$ eyes), at the last follow-up visit, the mean IOP had decreased from 17.2 to 14.1 mm Hg, and the mean number of medications had decreased from 2.1 to 1.3 ($P < .001$). Success was defined using 2024 AAO criteria² as either a reduction in medication usage of at least one agent without an increase in IOP or at least a 20% decrease in IOP to a level of 21 mm Hg or less without an increase in the number of medications, additional procedures, a loss of light perception, or hypotony. Overall, 61.9% of eyes in

STUDY IN BRIEF

- ▶ A prospective, real-world, multicenter study found that, whether performed alone or in combination with phacoemulsification, ab interno canaloplasty using the iTrack (Nova Eye Medical) had a favorable safety profile and significantly reduced patients' IOP and medication burden.

WHY IT MATTERS

This study provided large-scale evidence supporting ab interno canaloplasty using the iTrack as a safe and effective procedure for lowering IOP across diverse glaucoma subtypes and levels of severity, thereby positioning the procedure as a versatile MIGS option.

the combined group achieved success, and 43% became medication-free (vs 7% preoperatively).

For standalone ABiC ($n = 24$ eyes), mean IOP decreased from 20.2 to 15.3 mm Hg, and the mean number of medications was reduced from 2.3 to 1.5 ($P < .01$). Success was achieved in 35% of eyes, and 46% became medication-free.

IOP and medication reductions were significant across all disease subtypes and severities. The rate of additional procedures was 4.9%, with no sight-threatening complications reported. A loss of 2 or more lines of BCVA occurred in 7.3% of eyes, mostly due to advanced disease or unrelated comorbidities.

The study authors concluded that ABiC using the iTrack

(Nova Eye Medical) significantly reduced patients' IOP and medication burden and had a favorable safety profile, regardless of whether the procedure was performed alone or in conjunction with phacoemulsification.

DISCUSSION

How did standalone ABiC compare with combined ABiC and phacoemulsification in this study?

Standalone ABiC demonstrated a greater absolute IOP reduction but lower success rates (as defined earlier) compared to the combined procedure. Eyes that underwent ABiC alone achieved a mean IOP reduction of 4.9 mm Hg ($P < .01$) compared to 3.1 mm Hg ($P < .001$) in eyes that underwent both ABiC and

phacoemulsification. The success rates, however, were 35% and 61.9% for the standalone and combined groups, respectively. Although the number of medications at baseline was slightly higher in the standalone versus the combined group (2.3 vs 1.5 classes), the reduction in medication use was comparable between groups (average reduction of 0.8).

The higher baseline IOP in the standalone group (20.2 vs 17.2 mm Hg) might reflect patient selection. The decision to undergo ABiC combined with phacoemulsification might have been driven by the concurrent cataract, whereas the decision to undergo ABiC alone would have been driven solely by the need to decrease the IOP and/or reduce the medication burden.

How can the results of this study be applied to surgical decision-making in real-world practice?

Combining ABiC with phacoemulsification appeared to be effective for patients with coexisting cataract and moderate glaucoma, particularly when their baseline IOP was greater than 18 mm Hg. For these patients, the success rate reached 83%. The additive IOP-lowering effect of cataract extraction might have contributed to these favorable outcomes.

Standalone ABiC was a viable option for pseudophakic and phakic patients requiring a reduction in their IOP (particularly those with higher baseline pressures) or number of medications. Although the success rate was lower at 35%, the procedure still achieved a clinically meaningful

IOP reduction (-4.9 mm Hg) and enabled nearly half of the patients to discontinue medications entirely. Limitations of the success criteria might not apply to real-world practice, because some patients who do not meet these criteria might still achieve meaningful results.

Canaloplasty's favorable safety profile across both approaches supported the procedure as a reasonable first-line surgical option before more invasive filtration surgery is considered. The low rate (4.9%) of subsequent glaucoma procedures and an absence of sight-threatening complications suggest that ABiC could be a particularly attractive option for patients with mild to moderate glaucoma who wish to avoid the risks associated with trabeculectomy or tube shunt implantation.

STANDALONE CANALOPLASTY AND TRABECULOTOMY USING THE OMNI SURGICAL SYSTEM IN EYES WITH PRIMARY OPEN-ANGLE GLAUCOMA: A 36-MONTH ANALYSIS FROM THE AMERICAN ACADEMY OF OPHTHALMOLOGY IRIS REGISTRY (INTELLIGENT RESEARCH IN SIGHT)

Radcliffe NM, Harris J, Garcia K, Zwick E, Chang RT, Mbagwu M³

Industry support for this study: Sight Sciences

ABSTRACT SUMMARY

This retrospective cohort study from the AAO IRIS (Intelligent Research in Sight) Registry analyzed 230 eyes of 196 patients with primary open-angle glaucoma (POAG) or ocular hypertension who underwent standalone ABiC and trabeculotomy using the Omni Surgical System (Sight Sciences), with follow-up extending to 36 months. The cohort consisted predominantly of moderate (40.0%) and severe (41.3%) POAG, and two-thirds of the eyes were pseudophakic. Less than half of the

procedures (44.4%) were performed by glaucoma specialists. Eyes with a history of filtration surgery, recent trabeculoplasty, or concomitant cataract surgery were excluded.

The mean baseline IOP was 22.1 mm Hg, and it decreased to 15.1 mm Hg by 36 months ($P < .0001$). The mean number of glaucoma medications at baseline was 2.1, and it decreased to 1.1 by

36 months ($P = .081$), with statistically significant reductions through 18 months ($P \leq .001$). A subgroup analysis found that eyes with a baseline IOP of 18 mm Hg or less demonstrated sustained medication reductions through 36 months, whereas eyes that had a baseline IOP that was greater than 18 mm Hg showed sustained IOP reductions through 36 months.

STUDY IN BRIEF

- A retrospective cohort study from the AAO Intelligent Research in Sight Registry found that standalone canaloplasty and trabeculotomy performed using the Omni Surgical System (Sight Sciences) provided clinically and statistically significant IOP reductions that were sustained through 36 months in patients with primary open-angle glaucoma. Two-thirds of the eyes were pseudophakic.

WHY IT MATTERS

This study provided long-term evidence that standalone canaloplasty and trabeculotomy performed using the Omni Surgical System were effective in achieving lasting reductions in IOP and medication burden. Additionally, the findings were generalizable across practice settings, with many of the reported cases performed by non-glaucoma specialists.

The study authors concluded that standalone ABiC and trabeculotomy performed using the Omni Surgical System provided clinically and statistically significant IOP reductions that were sustained through 36 months. They deemed this MIGS option reasonable for patients with POAG seeking to reduce their IOP, medication burden, or both.

DISCUSSION

How did baseline IOP affect the efficacy of canaloplasty and trabeculotomy?

The outcome patterns of eyes stratified by baseline IOP diverged. Eyes with a baseline IOP that was 18 mm Hg or less achieved sustained medication reductions through 36 months, but IOP reductions in this subgroup were either less pronounced or not statistically significant by that time point. Conversely, eyes with a baseline IOP that was greater than 18 mm Hg demonstrated statistically significant IOP reductions that were sustained through 36 months, but medication reductions were less durable in this group.

The different responses suggest that the procedure's mechanism (ie, improving aqueous outflow through Schlemm canal) was most effective at lowering IOP when the baseline pressure was elevated but that ABiC combined with trabeculotomy still provided a meaningful benefit in eyes that had lower IOPs by reducing the medication burden. The overall cohort achieved mean IOP reductions of up to 7.1 mm Hg from a baseline of 22.1 mm Hg ($P < .0001$ at all time points); the final IOP ranged from 15.1 to 16.7 mm Hg over 36 months. Of note, there was a floor effect to the IOP reduction from angle-based surgery due to episcleral venous pressure.

Regarding patient selection, information concerning the preoperative goal (medication reduction, IOP reduction, etc) was unavailable with registry data. It is

possible that the procedure was performed on patients with a lower baseline IOP for a preoperative goal of reducing the number of medications, whereas patients with a higher baseline IOP had a goal of IOP reduction.

How can the results of this study be applied to surgical decision-making in real-world practice?

Standalone canaloplasty and trabeculotomy with the Omni Surgical System appeared to be particularly well-suited to pseudophakic patients with moderate to severe POAG who required better IOP control because two-thirds of the cohort was pseudophakic and achieved meaningful outcomes. This study addressed a common clinical scenario in which cataract surgery has already been performed but glaucoma continues to progress. Surgical intervention using the Omni might be a good option for patients with a low baseline IOP (≤ 18 mm Hg) who aim to reduce their medication burden. Of note, the degrees of treatment performed to achieve these outcomes were not described in the registry data presented.

The finding that less than half of the procedures were performed by glaucoma specialists demonstrated the procedure's accessibility to comprehensive ophthalmologists, potentially expanding access to MIGS for patients who may not reach subspecialty care. The consistent outcomes across this diverse provider base suggest that the technique is reproducible across practice settings.

The sustained 36-month efficacy found in this study supports the Omni procedure as a reasonable intermediate step between medical therapy and more invasive filtration surgery. Angle-based procedures such as this offer a reasonable next step for patients whose glaucoma is inadequately controlled with

medication if they have an open angle, have no contraindications to angle-based surgery, and are reliable with follow-up. ■

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