

ABiC 12-MONTH CASE SERIES REVIEW

With ABiC, IOP reduction is just as important as safety.

Ab interno canaloplasty (ABiC) is a new microinvasive glaucoma surgery (MIGS) procedure that can comprehensively restore the natural outflow pathways in glaucoma patients. Performed via a self-sealing, clear corneal incision, ABiC (Ellex) conserves the clinically proven benefits of 360° viscodilation of Schlemm canal provided by traditional canaloplasty, but with the speed and ease of implementation of a MIGS procedure. It has also been shown to be effective as both a standalone procedure and when combined with cataract surgery.

Mark J. Gallardo, MD, and Mahmoud A. Khaimi, MD, present the findings from a 12-month case series review of 228 eyes treated with ABiC. These early results are very encouraging; at this point, they are similar to results from previously published canaloplasty studies, notably the landmark multicenter prospective trial carried out at 15 clinical sites in 2005.¹



Mark J. Gallardo, MD



Mahmoud A. Khaimi, MD

EFFECTIVENESS IN REDUCING IOP AND THE MEDICATION BURDEN

In combining Drs. Khaimi and Gallardo's cohorts (n = 228 eyes), the mean preoperative IOP was 19.0 ±6.5 mm Hg, and the mean number of medications was 2.0 ±1.0. At 3, 6, and 12 months posttreatment, the mean IOP was 14.7 ±3.9 mm Hg, 14.5 ±3.8 mm Hg, and 13.3 ±2.0 mm Hg, respectively, whereas the mean number of medications was 0.0 ±1.0 at 3 months, and 1.0 ±1.0 at 6 and 12 months posttreatment (Table 1). At 12 months (n = 48), the average IOP reduction was 30%, combined with a 50% reduction in the number of medications.

TABLE 1. REDUCTIONS IN IOP AND MEDICATION USE FOR ALL ENROLLED PATIENTS

Examination	n	Mean IOP (mm Hg) ±SD	Mean Medications (n) ±SD
Baseline	228	19.0 ±6.5	2.0 ±1.0
3 Months	157	14.7 ±3.9	0.0 ±1.0
6 Months	134	14.5 ±3.8	1.0 ±1.0
12 Months	48	13.3 ±2.0	1.0 ±1.0

EFFECTIVENESS OF ABIC WITH AND WITHOUT CATARACT SURGERY

Of the 130 patients who underwent ABiC in combination with phacoemulsification, the mean preoperative IOP was 17.1 ±5.0 mm Hg. At 12 months (n = 34), the mean IOP was reduced to 13.1 ±2.1 mm Hg, for an overall reduction in mean IOP of 23.39%. The number of medications was reduced by 50% from 2.0 ±1.0 to 1.0 ±1.0 by 12 months postoperatively (Table 2).

Of the 98 patients who underwent ABiC as a standalone procedure, the mean preoperative IOP was 21.5 ±7.4 mm Hg, and the mean number of medications was 3.0 ±1.0. At

TABLE 2. REDUCTIONS IN IOP AND MEDICATION USE FOR PATIENTS WHO UNDERWENT ABIC PLUS CATARACT SURGERY

Examination	n	Mean IOP (mm Hg) ±SD	Mean Medications (n) ±SD
Baseline	130	17.1 ±5.0	2.0 ±1.0
3 Months	92	13.5 ±3.1	0.0 ±1.0
6 Months	83	14.0 ±3.6	0.0 ±1.0
12 Months	34	13.1 ±2.1	1.0 ±1.0

TABLE 3. REDUCTIONS IN IOP AND MEDICATION USE FOR PATIENTS WHO UNDERWENT STANDALONE ABiC

Examination	n	Mean IOP (mm Hg) ±SD	Mean Medications (n) ±SD
Baseline	98	21.5 ±7.4	3.0 ±1.0
3 Months	65	16.4 ±4.3	1.0 ±1.0
6 Months	51	15.5 ±3.9	1.0 ±1.0
12 Months	14	13.6 ±1.9	1.0 ±1.0

12 months (n = 14), the mean IOP was reduced by 36.74% to 13.6 ±1.9 mm Hg, while the mean number of medications was reduced by 66.66% to 1.0 ±1.0 (Table 3).

IOP CONTROL IN PATIENTS WITH UNCONTROLLED GLAUCOMA

Of the 228 patients in the combined cohorts, 161 individuals were classified as having uncontrolled glaucoma (defined as IOP ≥ 16 mm Hg), with a mean preoperative IOP of 21.6 ±6.1 mm Hg, and an average of 2.0 ±1.0 medications. At 12 months postoperatively (n = 31), the mean IOP was reduced by 38.88% to 13.2 ±2.0 mm Hg, combined with a 50% reduction in the number of mean medications to 1.0 ±1.0.

“ ABiC preserves tissue and does not require the permanent placement of an implant in the eye.

In patients with uncontrolled glaucoma on maximum medical therapy (+3 gtts), ABiC also achieved a significant reduction in mean IOP, of 40.46% from 21.5 ±6.2 mm Hg to 12.8 ±1.9 mm Hg at 12 months (n = 17). The mean number of medications was also reduced from 3.0 ±0.0 to 1.0 ±1.0 (66.66%).

REDUCING THE MEDICATION BURDEN IN PATIENTS WITH CONTROLLED GLAUCOMA

Additionally, ABiC was shown to effectively lower the medication burden in patients with controlled glaucoma. At 12 months, medication usage was reduced by 50%, from 2.0 ±1.0 at baseline to 1.0 ±1.0, with IOP remaining stable in the low teens (Table 4).

TABLE 4. REDUCTIONS IN IOP AND MEDICATION USE FOR PATIENTS WITH CONTROLLED GLAUCOMA

Examination	n	Mean IOP (mm Hg) ±SD	Mean Medications (n) ±SD
Baseline	67	12.9 ±1.7	2.0 ±1.0
3 Months	48	13.2 ±3.0	0.0 ±1.0
6 Months	44	13.4 ±2.9	0.0 ±1.0
12 Months	17	13.4 ±2.1	1.0 ±1.0

SAFETY PROFILE

Case observation of ABiC revealed that the safety profile of the procedure was similar to that of traditional canaloplasty and the newer MIGS procedures. In the 12-month studies by Drs. Gallardo and Khaimi, overall, the frequency of surgical and postsurgical complications was low, with no serious adverse events recorded.

SUMMARY

Clinical evidence indicates that ABiC, a new MIGS procedure, is safe and effective in mild to moderate primary open-angle glaucoma with IOP-lowering effects similar to traditional canaloplasty. Based on the same dilation principles of traditional canaloplasty, ABiC ensures that all potential “blockages” in the ocular outflow pathway are addressed, including in distal structures such as the collector channels, which have been shown to play a key role in the aqueous outflow in primary open-angle glaucoma eyes. Unlike other currently available MIGS procedures, ABiC preserves tissue and does not require the permanent placement of an implant in the eye. It has also been shown to be effective as both a standalone procedure and when combined with cataract surgery. Furthermore, based on the preliminary 12-month data, it may potentially offer better clinical outcomes than any other currently available MIGS procedure. ■

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.
 2. Ellex iScience, Inc. Data on File.

Mark J. Gallardo, MD

- in private practice at El Paso Eye Surgeons in El Paso, Texas
- gallardomark@hotmail.com
- consultant to Ellex; clinical investigator for the ABiC procedure

Mahmoud A. Khaimi, MD

- clinical associate professor at the Dean McGee Eye Institute, University of Oklahoma, Oklahoma City
- mahmoud-khaimi@dmei.org
- consultant to Ellex; clinical investigator for the ABiC procedure