

The Literature

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FIVE-YEAR TREATMENT OUTCOMES IN THE AHMED BAERVELDT COMPARISON STUDY

Budenz DL, Barton K, Gedde SJ, et al¹

ABSTRACT SUMMARY

The Ahmed Baerveldt Comparison (ABC) study was a multicenter, randomized, controlled clinical trial comparing surgical outcomes with the FP7 Ahmed Glaucoma Valve (AGV; New World Medical) versus the 101-350 Baerveldt glaucoma implant (BGI; Abbott Medical Optics). The study included 276 patients, aged 18 to 85 years, with refractory glaucoma or a history of intraocular surgery and an IOP of at least 18 mm Hg in whom glaucoma drainage devices (GDDs) were indicated. The AGV and BGI groups consisted of 143 (52%) and 133 (48%) patients, respectively.

At the 5-year follow-up visit, mean IOP was significantly lower in the BGI group compared to the AGV group (12.7 ± 4.5 vs 14.7 ± 4.4 mm Hg; $P = .015$) without a significant difference in glaucoma medication use between the groups (BGI 1.8 ± 1.5 vs AGV 2.2 ± 1.4 ; $P = .28$). Visual acuity had decreased significantly in both groups (AGV 0.42 ± 0.99 vs BGI 0.43 ± 0.84 ; $P = .97$) at 5 years. As the primary outcome measure, the cumulative probability of failure at 5 years was 44.7% in the AGV group and 39.4% in the BGI group ($P = .65$). The AGV group had significantly more failures (80% of AGV failures) secondary to inadequate IOP control (defined as an IOP > 21 mm Hg) or reoperation for glaucoma than the BGI group (53% of BGI failures; $P = .003$). The BGI was associated with twice as many complications such as persistent hypotony, implant explantation, or loss of light perception than the AGV group (47% of BGI failures vs 20% of AGV failures).

DISCUSSION

Are the AGV and BGI equally safe and effective?

The purpose of the ABC study was to compare the safety and efficacy of the two most commonly used GDDs, with the primary outcome measure's being cumulative failure at the 5-year follow-up visit. There were no differences between the baseline characteristics of the AGV and BGI groups.² Failure was defined as

- an IOP greater than 21 mm Hg, a reduction less than 20% below baseline, or an IOP that was 5 mm Hg or

lower on two consecutive study visits after 3 months

- reoperation for glaucoma
- loss of light perception vision
- removal of the implant for any reason

The study suggested that both GDDs were effective at lowering IOP. The AGV and BGI groups achieved a significant reduction ($> 50\%$) in IOP, with baseline averages of 31 to 32 mm Hg in both groups that had decreased to 14.7 ± 4.4 mm Hg in the AGV group and 12.7 ± 4.5 mm Hg in the BGI group at the 5-year follow-up visit. IOP decreased more significantly in the AGV than BGI group only in the early postoperative period (the 1-day and 1-week postoperative visits), after which time the BGI group retained a lower IOP at all time points. In addition, both groups had attained a significant reduction in glaucoma medications at the 5-year follow-up visit.

The study found differences in safety endpoints between the implants. Although both groups failed at a similar rate of around 40%, the AGV group failed more due to high IOP or reoperation for glaucoma, whereas the BGI group failed more due to complications such as hypotony.

How do the results compare to the 3-year ABC study outcomes?

The 3-year ABC study results suggested that the failure rates of both implants were around 10% per year (30% cumulative failure at year 3).³ The 5-year results, however, found that the failure rate was only 5% per year for years 4 and 5, which perhaps indicates that the failure rate slows after the first 3 years. IOP and number of glaucoma medications needed remained similar 5 years postoperatively compared with the 3-year results.

Does one GDD produce conclusively better results?

The results for the 5-year ABC study did not demonstrate the clear superiority of either implant. During the 5 years of follow-up, the BGI provided better long-term IOP control than the AGV, with a difference of about 2 mm Hg, which was statistically significant. Patients in the BGI group also required fewer glaucoma medications and fewer glaucoma reoperations than those in the AGV group. Other studies have demonstrated that tubes with

large end plates such as the BGI may offer better IOP control than those with small end plates.^{4,5} The investigators also hypothesized that, because the BGI tube was occluded for the first 4 to 6 weeks, the bleb might have been exposed to less inflammatory material.

The researchers concluded that the benefit of approximately 2 mm Hg more IOP lowering with the BGI must be weighed against the increased risks of hypotony, explantation of the GDD, or loss of light perception vision, which were twice as high as in the AGV group.

The Ahmed Versus Baerveldt (AVB) clinical trial had comparable findings at the 3-year follow-up.⁶ It will be interesting to compare the 5-year outcomes of these two studies once the AVB is complete.

LONG-TERM EFFICACY OF THE BAERVELDT 250 MM² COMPARED WITH THE BAERVELDT 350 MM² IMPLANT

Allan EJ, Khaimi MA, Jones JM, et al⁷

ABSTRACT SUMMARY

This retrospective study evaluated the long-term efficacy and safety of two BGI models. Researchers reviewed the data from 89 consecutive eyes in 86 patients at one study center. Fifty-two eyes (58.43%) received the 350-mm² implant, with a mean follow-up time of 31 months. Thirty-seven eyes (41.57%) received the 250-mm² implant, with a mean follow-up time of 40 months. There was no significant difference found in surgical success (ie, any outcome not qualifying for failure), visual acuity, IOP, number of glaucoma medications, complication rates, or failure rates between the two groups.

DISCUSSION

Are the two implants equally safe and effective?

This study suggests that the 250-mm² and 350-mm² implants are equally safe and effective. This investigation was conducted because prior studies had indicated that a plate with a larger surface area might provide better filtration and IOP control. In one study comparing the 250-mm², 350-mm², and 500-mm² implants with a shorter follow-up period of 14 months, IOP was statistically significantly better with the 350-mm² BGI than the 250-mm² BGI, with the 500-mm² implant's trending toward better IOP control.⁸ Similar success and safety between the devices were demonstrated in another study comparing the 350-mm² and 500-mm² models.⁹ In this study, the tube procedures were performed by two surgeons with identical surgical technique, the plate size was chosen by the surgeon, and more difficult cases (such as those involving neovascular or uveitic glaucoma)

were included. Although the patients who received the 350-mm² implant were older and had better visual acuity, these factors were adjusted for.

Does one BGI model produce conclusively better results?

This study suggests no clear, conclusive benefit to implanting a BGI with a larger surface area. The findings are consistent with the conclusion of another retrospective study in Asian eyes with complicated glaucoma.¹⁰ On the other hand, the investigators of the current study mentioned that their findings were limited by its retrospective nature and might be underpowered. For more conclusive results, future prospective controlled clinical trials are needed.¹¹ ■

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1. Budenz DL, Barton K, Gedde SJ, et al. Five-year treatment outcomes in the Ahmed Baerveldt Comparison Study. *Ophthalmology*. 2015;122:308-316.
2. Barton K, Gedde SJ, Budenz DL, et al; Ahmed Baerveldt Comparison Study Group. The Ahmed Baerveldt Comparison Study: methodology, baseline patient characteristics, and intra-operative complications. *Ophthalmology*. 2011;118:435-442.
3. Barton K, Feuer WJ, Budenz DL, et al; Ahmed Baerveldt Comparison Study Group. Three-year treatment outcomes in the Ahmed Baerveldt Comparison Study. *Ophthalmology*. 2014;121:1547-1557.
4. Gedde SJ, Panarelli JF, Banitt MR, Lee RK. Evidence-based comparison of aqueous shunts. *Curr Opin Ophthalmol*. 2013;24:87-95.
5. Heuer DK, Lloyd MA, Abrams DA, et al. Which is better? One or two? A randomized clinical trial of single-plate versus double-plate Molteno implantation for glaucomas in aphakia and pseudophakia. *Ophthalmology*. 1992;99:1512-1519.
6. Christakis PG, Tsai JC, Kalenak JW, et al. The Ahmed Versus Baerveldt study: three-year treatment outcomes. *Ophthalmology*. 2013;120:2232-2240.
7. Allan EJ, Khaimi MA, Jones JM, et al. Long-term efficacy of the Baerveldt 250 mm² compared with the Baerveldt 350 mm² implant. *Ophthalmology*. 2015;122:486-493.
8. Siegner SW, Netland PA, Urban RC Jr, et al. Clinical experience with the Baerveldt glaucoma drainage implant. *Ophthalmology*. 1995;102:1298-1307.
9. Britt MT, LaBree LD, Lloyd MA, et al. Randomized clinical trial of the 350-mm² versus the 500-mm² Baerveldt implant: longer term results: is bigger better? *Ophthalmology*. 1999;106:2312-2318.
10. Seah SK, Gazzard G, Aung T. Intermediate-term outcome of Baerveldt glaucoma implants in Asian eyes. *Ophthalmology*. 2003;110:888-894.
11. Baerveldt Plate Area Comparison (BPAC). ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT01159314?term=NCT01159314&rank=1>. Verified March 2015. Accessed July 9, 2015.