Treatment Outcomes in the Ahmed Baerveldt Comparison Study after 1 Year of Follow-up

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Purpose: To determine the relative efficacy and complications of the Ahmed glaucoma valve (AGV) model FP7 (New World Medical, Ranchos Cucamonga, CA) and the Baerveldt glaucoma implant (BGI) model 101-350 (Abbott Medical Optics, Abbott Park, IL) in refractory glaucoma.

Design: Multicenter, randomized, controlled clinical trial.

Participants: Two hundred seventy-six patients, including 143 in the AGV group and 133 in the BGI group.

Methods: Patients 18 to 85 years of age with refractory glaucoma having intraocular pressure (IOP) of 18 mmHg or more in whom an aqueous shunt was planned were randomized to undergo implantation of either an AGV or a BGI.

Main Outcome Measures: The primary outcome was failure, defined as IOP >21 mmHg or not reduced by 20% from baseline, IOP ≤5 mmHg, reoperation for glaucoma or removal of implant, or loss of light perception vision. Secondary outcomes included mean IOP, visual acuity, use of supplemental medical therapy, and complications.

Results: Preoperative IOP (mean±standard deviation [SD]) was 31.2±11.2 mmHg in the AGV group and 31.8±12.5 mmHg in the BGI group ($P = 0.71$). At 1 year, mean±SD IOP was 15.4±5.5 mmHg in the AGV group and 13.2±6.8 mmHg in the BGI group ($P = 0.007$). The mean±SD number of glaucoma medications was 1.8±1.3 in the AGV group and 1.5±1.4 in the BGI group ($P = 0.071$). The cumulative probability of failure was 16.4% (standard error [SE], 3.1%) in the AGV group and 14.0% (SE, 3.1%) in the BGI group at 1 year ($P = 0.52$). More patients experienced early postoperative complications in the BGI group (n = 77; 58%) compared with the AGV group (n = 61; 43%; $P = 0.016$). Serious postoperative complications associated with reoperation, vision loss of ≥2 Snellen lines, or both occurred in 29 patients (20%) in the AGV group and in 45 patients (34%) in the BGI group ($P = 0.014$).

Conclusions: Although the average IOP after 1 year was slightly higher in patients who received an AGV, there were fewer early and serious postoperative complications associated with the use of the AGV than the BGI.

Financial Disclosure(s): Proprietary or commercial disclosure may be found after the references.
Ophthalmology 2011;118:443–452 © 2011 by the American Academy of Ophthalmology.

**Group members listed online in Appendix 1 (available at http://aaojournal.org).*

Aqueous shunts have been used increasingly in the management of glaucoma considered refractory to trabeculectomy. These include eyes with previous incisional eye surgery causing scarring of the conjunctiva (e.g., cataract extraction and trabeculectomy) and secondary glaucomas that are known to have poor success rates with trabeculectomy (e.g., neovascular glaucoma and uveitic glaucoma). Data from the United States Medicare database for glaucoma procedures performed between 1995 and 2004 demonstrate a 184% increase in the number of aqueous shunt procedures.[1] The number of trabeculectomies performed in eyes with previous surgery or trauma, most closely resembling the types of patients in which aqueous shunts traditionally have been performed, increased only 9% in this same period.[1] In addition, 2 surveys of the surgical practice patterns of the membership of the American Glaucoma Society, one performed in 1996 and a follow-up survey performed in 2002, demonstrated a marked and statistically significant increase in the use of aqueous shunts in patients who had undergone prior surgery or who had neovascular or uveitic glaucoma compared with trabeculectomy with mitomycin C.[2,3] In addition, the ongoing Tube versus Trabeculectomy (TVT) Study, which showed a higher success rate using a Baerveldt glaucoma implant (BGI; Abbott Medical Optics, Abbott Park, IL) than trabeculectomy with mitomycin C in patients with prior failed filtration surgery, cataract surgery, or both, has stimulated interest in aqueous shunt implantation in similar patient groups.[4–6]

Commonly used aqueous shunts include the Ahmed glaucoma valve (AGV; New World Medical, Ranchos Cucamonga, CA), the BGI, the Eagle Vision glaucoma drainage device (Eagle Vision, Memphis, TN), and the Molteno implant (Molteno Ophthalmic Limited, Dunedin, New Zealand). These implants share a common design consisting of a tube that shunts aqueous humor from the anterior chamber to an end plate located at the equatorial region of the globe.

ISSN 0161-6420/11/$–see front matter
doi:10.1016/j.ophtha.2010.07.016

Aqueous shunts differ in terms of materials and design features, including the presence or absence of a valve that limits aqueous flow through the device if the intraocular pressure (IOP) becomes too low. Surgeons choose specific aqueous shunts for various reasons, including perceived efficacy in controlling IOP, perceived risks of complications, and ease of implantation.

In the United States, the AGV and BGI implants currently are the 2 most widely used aqueous shunts. A 2008 unpublished survey of the American Glaucoma Society membership demonstrated that approximately half of the respondents favor the AGV and half prefer the BGI when operating on patients with previous incisional eye surgery or refractory glaucoma (Desai M, personal communication, August 2, 2009). Several retrospective studies comparing the AGV and BGI have been inconclusive as to the relative success rates and complications of these 2 types of implants in refractory glaucomas[7–11] and suffer from selection bias. The purported advantage of the AGV is in its early postoperative IOP control and reduced risk of hypotony resulting from a restrictive valve-like mechanism. The suggested advantage of the BGI is its larger surface area, 350 mm^2 versus 184 mm^2 for the AGV, which could result in lower long-term IOP if one accepts the premise that the level of IOP is dependent on the surface area of the drainage plate.[12] Success rates reported for the AGV range from 68% to 100% and those for the BGI range from 43% to 100%; these are highly dependent on the length of follow-up, type of glaucoma, and success criteria.[13] A recent Ophthalmic Technology Assessment report by the American Academy of Ophthalmology states, "Too few high-quality direct comparisons of various available shunts have been published to assess the relative efficacy or complication rates of specific devices . . . ,"[14] highlighting the need for randomized clinical trials in this area.

The Ahmed Baerveldt Comparison (ABC) Study was designed to prospectively compare the safety and efficacy of these 2 commonly implanted glaucoma drainage devices. Patients with uncontrolled glaucoma who had prior incisional surgery or other glaucoma diagnoses known to be poor candidates for trabeculectomy were enrolled in this multicenter clinical trial and were randomized to placement of an AGV model FP7 or a BGI model 101-350.

Patients and Methods

The institutional review board at each clinical center approved the study protocol before recruitment was started, and each patient gave informed consent. The study is registered at www.clinicaltrials.gov. The design and methods of the ABC Study are described in detail in a companion article[15] and are summarized as follows.

Randomization and Treatment

The ABC Study was conducted at 16 clinical centers. Eligibility, as described in the accompanying baseline article,[15] was confirmed independently at the Statistical Coordinating Center at the Bascom Palmer Eye Institute. Individuals enrolled in the study were randomized to placement of an AGV model FP7 or a 350-mm^2 BGI. Randomization was performed after informed consent was obtained for participation in the study at the Statistical Coordinating Center using a permuted block design stratified by clinical center and glaucoma diagnosis. Because this was a surgical study and proper surgical informed consent was necessary, neither the subject nor the investigator could be masked to the randomization assignment. Details of the surgical procedures for AGV and BGI implantation used in this study are described in detail in an accompanying article.[15]

Patient Visits

Follow-up visits were scheduled 1 day, 1 week, 1 month, 3 months, 6 months, 1 year, 18 months, 2 years, 3 years, 4 years, and 5 years after surgery. Additional information about data obtained at baseline and follow-up visits is contained in the accompanying baseline article.[15]

Primary and Secondary Outcome Measures

The primary outcome measure was failure, which was defined prospectively as IOP >21mmHg or less than a 20% reduction from baseline on 2 consecutive study visits after 3 months, IOP ≤5 mmHg on 2 consecutive study visits after 3 months, reoperation for glaucoma, loss of light perception vision, or removal of the implant for any reason. Eyes with successfully controlled IOPs (≤21 mmHg and >5 mmHg and reduced by at least 20% from baseline) were considered complete successes if medications were not used at either the 6- or 12-month visits and were considered qualified successes otherwise. Reoperation for glaucoma was defined as additional glaucoma surgery requiring a return to the operating room, such as for placement of an additional aqueous shunt. Cyclodestruction also was counted as a reoperation for glaucoma. Interventions performed at the slit lamp, such as needling procedures, removal of occluding stents, or laser suture lysis, were not considered glaucoma reoperations.

Intraocular pressure and the rate of surgical complications were secondary outcome measures in the ABC Study. Early complications were those that were recorded by the 3-month follow-up visit, whereas late complications were those that were experienced after the 3-month follow-up visit. A serious complication was defined as any complication, early or late, that was associated with a 2-line Snellen acuity decrease, a major surgery (reoperation in the operating room) to manage the complication, or both. If a patient lost 2 lines or more of Snellen visual acuity (VA) compared with baseline, the investigator was asked to determine the cause of the visual loss. A revision to manage an occluded tube was considered a reoperation for a complication. The Snellen visual acuity decrease was assessed at the 1-year visit or, if that visit was missed, at the 6-month visit. If the patient did not have either a 6- or 12-month visit, then their complications (n = 8) could not be categorized as serious by vision loss, but could be categorized by virtue of reoperation.

Sample Size Calculations

A recent retrospective comparison from Singapore reported an 83% success rate for the BGI and 67% for the AGV. This study was powered to detect a true difference in success rates of this size. Setting the power at 80% and α at 5%, 125 patients in each group were required to detect this difference. The overall study size of 275 was determined to allow for a 10% dropout rate.

Statistical Analysis

Snellen VA measurements were converted to logarithm of minimum angle of resolution equivalents for the purpose of data

analysis, as reported previously.[16] The time to failure was defined as the time from surgical treatment to reoperation for glaucoma, loss of acuity to no light perception in the study eye, or the time from surgical treatment to the first of 2 consecutive follow-up visits after 3 months in which the patient had persistent hypotony (IOP ≤5 mmHg) or inadequately controlled IOP (IOP >21 mmHg or not reduced by 20% from baseline). Data on IOP and number of glaucoma medications were censored after a subject underwent a reoperation for glaucoma, explantation of the implant for a complication, or loss of light perception vision, but not after failure resulting from high IOP, hypotony, or reoperation for complication. There was no censoring of VA results. Univariate comparisons between treatment groups were performed using the 2-sided Student *t* test for continuous variables and the chi-square test or Fisher exact test for categorical variables. Risk factors for treatment failure were assessed for statistical significance with the Kaplan-Meier survival analysis log-rank test. Multivariate analysis was performed using Cox proportional hazard regression analysis with forward stepwise elimination. Patient data were analyzed in the group to which they were assigned during randomization (intent-to-treat analysis). A *P* value of .05 or less was considered statistically significant.

Results

Recruitment and Retention

A total of 276 patients were enrolled in the ABC Study between October 2006 and April 2008. Randomization assigned 143 patients (52%) to placement of an AGV and 133 patients (48%) to a 350-mm^2 BGI. Protocol violations are described in the accompanying baseline article.[15] All patients were analyzed in the group to which they were originally assigned according to the intent-to-treat protocol.

The progress of patients in the study is shown in Figure 1. In the overall study group, 260 (94.2%) patients had at least 1 year of follow-up. There were 132 (92%) patients in the AGV group and 117 (88%) in the BGI group who had 1-year follow-up data available. Eleven patients who missed the 1-year follow-up visit

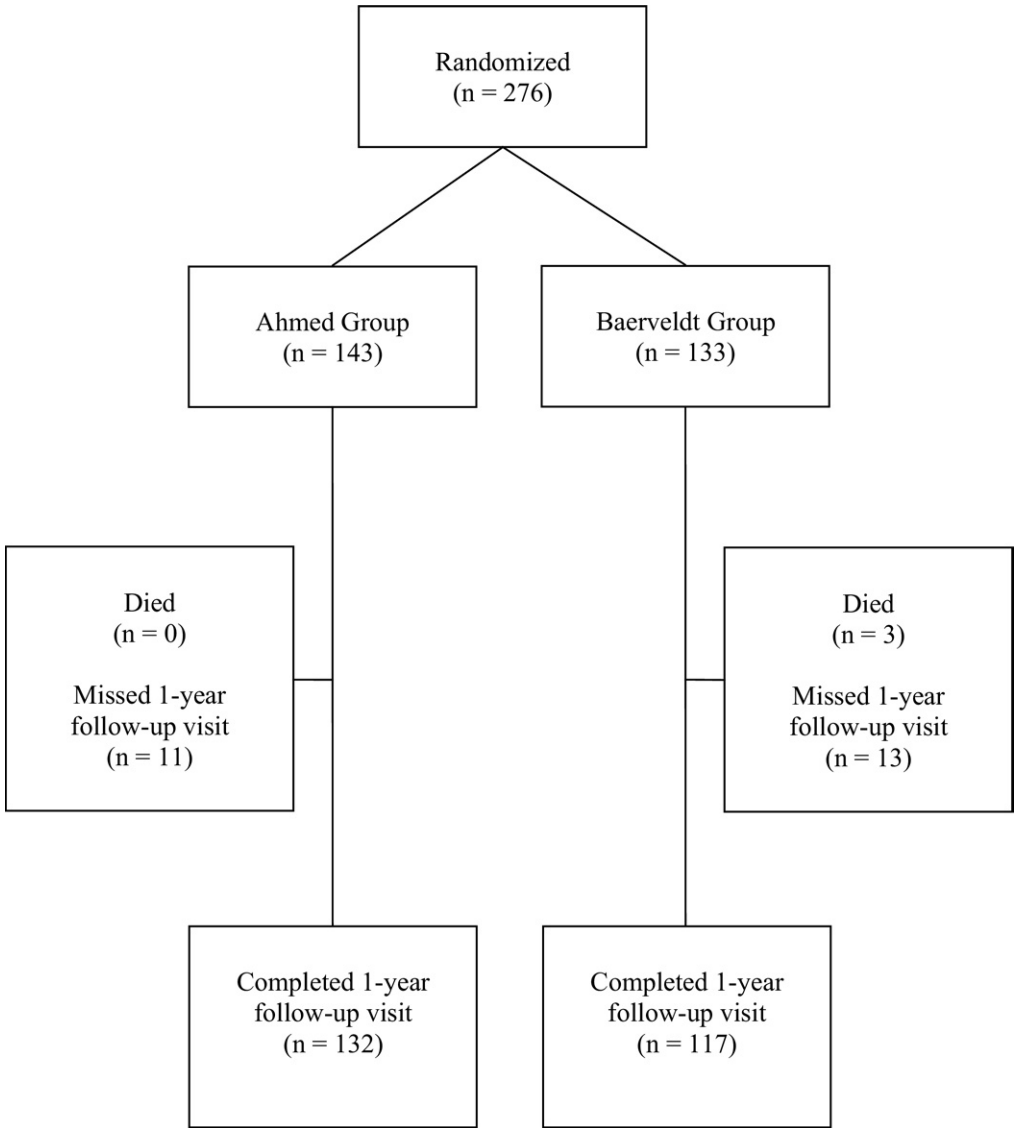

Figure 1. Flowchart showing subject progress in the Ahmed Baerveldt Comparison Study.

window did have a study visit subsequent to the 1-year visit, accounting for the discrepancy in the number of patients with at least 1-year follow-up (260) and the number of patients with follow-up at 1 year (249). Eighty-eight percent of patients in the AGV group completed both the 6-month and 12-month visits, compared with 86% in the BGI group. This is important because these were the proportion of patients who would have been at risk for failure by the IOP criterion at the 1-year visit. The number of patients completing each follow-up visit is shown in Table 1.

Baseline Characteristics

The baseline characteristics of the study population are provided in an accompanying publication.[15] There were no differences in baseline demographic or clinical characteristics between the 2 groups.

Intraocular Pressure Reduction

The baseline and follow-up IOPs for the 2 groups are reported in Table 1 and Figure 2. Patients who underwent additional glaucoma surgery were censored from analysis after the time of reoperation. Both surgical procedures produced a significant reduction in IOP. In the AGV group, mean±standard deviation (SD) IOP decreased from 31.2±11.2 mmHg at baseline to 15.4±5.5 mmHg at the 1-year follow-up visit ($P<0.001$, paired t test). In the BGI group, mean±SD IOP was reduced from 31.8±12.5 mmHg at baseline to 13.2±6.8 mmHg at the 1-year follow-up visit ($P<0.001$, paired t test). The AGV group had a significantly lower mean IOP than the BGI group at the 1-day and 1-week follow-up visits. However, the mean IOP in the BGI group was approximately 2 mmHg lower than that of the AGV group at the 1-month, 3-month, and 1-year visits.

Table 1. Intraocular Pressure and Medical Therapy at Baseline and Follow-up in the Ahmed Baerveldt Comparison Study*

	Ahmed Glaucoma Valve Group	Baerveldt Glaucoma Implant Group	P Value†
Baseline			
IOP (mmHg)	31.2±11.2	31.8±12.5	0.71
Glaucoma medications	3.4±1.1	3.5±1.1	0.34
No.	143	133	
1 day			
IOP (mmHg)	10.0±7.9	18.6±13.7	<0.001
No. followed up (% of baseline)	142 (99%)	130 (98%)	
1 wk			
IOP (mmHg)	10.6±5.6	17.2±12.0	<0.001
Glaucoma medications	0.2±0.7	0.9±1.4	<0.001
No. followed up (% of baseline)	140 (98%)	118 (89%)	
1 mo			
IOP (mmHg)	20.7±9.7	18.0±10.0	0.024
Glaucoma medications	0.5±1.0	1.3±1.5	<0.001
No. followed up (% of baseline)	139 (97%)	130 (98%)	
3 mos			
IOP (mmHg)	18.8±8.3	16.7±8.2	0.043
Glaucoma medications	1.4±1.3	1.2±1.3	0.32
No. followed up (% of baseline)	133 (93%)	125 (94%)	
6 mos			
IOP (mmHg)	15.7±5.3	14.8±6.8	0.26
Glaucoma medications	1.7±1.4	1.3±1.3	0.012
No. followed up (% of baseline)	131 (92%)	125 (94%)	
1 yr			
IOP (mmHg)	15.4±5.5	13.2±6.8	0.007
Glaucoma medications	1.8±1.3	1.5±1.4	0.071
No. followed up (% of baseline)	132 (92%)	117 (88%)	

IOP = intraocular pressure.
Data are presented as mean±standard deviation.
*Intraocular pressure censored after treatment failure by no light perception vision, reoperation for glaucoma, explantation for complication.
†Student t test.

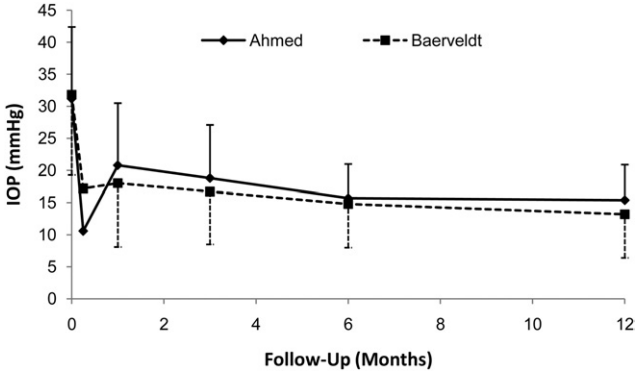

Figure 2. Graph showing mean intraocular pressures (IOP; with standard error bars) from baseline until the 12-month follow-up visit in the Ahmed Baerveldt Comparison Study.

Medical Therapy

Table 1 also shows the number of glaucoma medications in both groups at baseline and follow-up. Patients who underwent additional glaucoma surgery were censored from analysis after the time of reoperation. There was a significant reduction in the need for medical therapy in both treatment groups. The mean±SD number of glaucoma medications in the AGV group decreased from 3.4±1.1 at baseline to 1.8±1.3 at the 1-year follow-up visit ($P<0.001$, paired t test). The mean±SD number of glaucoma medications in the BGI group was reduced from 3.5±1.1 at baseline to 1.5±1.4 at the 1-year follow-up visit ($P<0.001$, paired t test). There was a tendency toward greater use of glaucoma medical therapy at 1 year in the AGV group compared with the BGI group, but this difference did not reach the level of statistical significance ($P = 0.071$).

Primary Treatment Outcomes

Table 2 (available at http://aaojournal.org) compares the outcomes and reasons for failure of randomized patients, unadjusted for follow-up time. All patients who were seen at the 1-year follow-up visit, who failed during the first year of the study, or both were included in this analysis. There was no significant difference in failure rates at 1 year between the 2 treatment groups. At 1 year, treatment failure had occurred in 23 (16%) patients in the AGV group and in 18 (14%) patients in the BGI group ($P = 0.61$, chi-square test). An additional analysis was performed using the same primary failure criteria (with IOP of more than 21 mmHg as the cutoff), but defining complete success as eyes that had not failed and were not receiving supplemental medical therapy and qualified success as eyes that had not failed but required supplemental medical therapy. In the AGV group, 27 (23%) successful

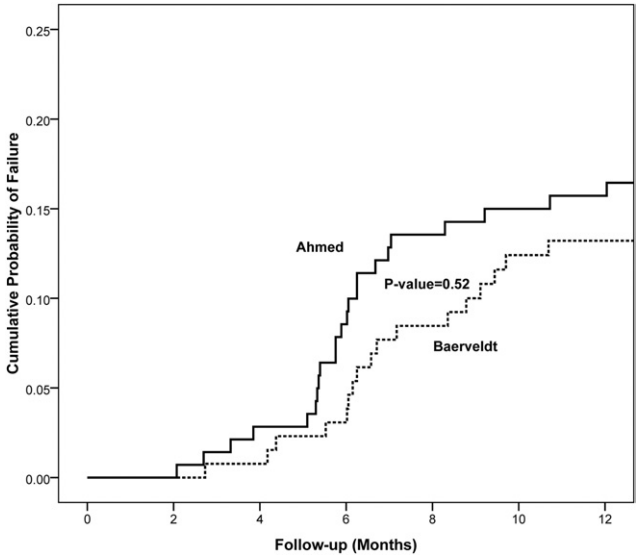

Figure 3. Kaplan-Meier curves showing the cumulative probability of failure from any cause in the Ahmed Baerveldt Comparison Study.

patients were classified as complete successes and 92 (77%) patients were classified as qualified successes. In the BGI group, 41 (36%) successful patients were complete successes and 73 (64%) patients were qualified successes. Although there was no difference in overall success rates after 1 year of follow-up, the BGI group had more complete successes ($P = 0.031$, Fisher exact test).

Kaplan-Meier survival analysis also was used to compare failure rates between the 2 treatment groups (Fig 3). The cumulative probability of failure was 16.4% (standard error, 3.1%) in the AGV group and 14% (standard error, 3.1 %) in the BGI group at 1 year. The reasons for treatment failure are listed in Table 2 (available at http://aaojournal.org). There were 20 patients in the AGV group who had inadequately controlled IOP, including 11 patients who required a reoperation for glaucoma. Failure because of inadequate IOP control occurred in 7 patients in the BGI group, including 1 patient who had additional glaucoma surgery. Persistent hypotony was the cause for treatment failure in 0 patients in the AGV group and in 2 patients in the BGI group ($P = 0.23$, Fisher exact test). There were 2 (1%) eyes in the AGV group and 6 (5%) eyes in the BGI group that lost light perception during the first year of follow-up ($P = 0.16$, Fisher exact test). All of the eyes that lost light perception vision were in the neovascular glaucoma stratum, and vision loss was related to underlying disease rather than to glaucoma in all of these cases. Kaplan-Meier analysis of time to failure did not reveal a significant difference in failure for any reason between the 2 groups (Fig 3; $P = 0.56$, stratified log-rank test).

Figure 4 presents the failure rates for the 2 treatment groups using alternative outcome criteria. Patients with persistent hypotony or reoperation for glaucoma were still classified as treatment failures; however, the upper IOP limit defining success and failure was changed. When inadequate IOP control was defined as IOP of more than 17 mmHg or IOP not reduced by 20% from baseline on 2 consecutive follow-up visits after 3 months, the cumulative probability of failure at 1 year was 22.2% in the AGV group and 16.3% in the BGI group ($P = 0.24$, stratified log-rank test). When inadequate IOP control was defined as IOP of more than 14 mmHg or not reduced by 20% from baseline on 2 consecutive follow-up visits after 3 months, the cumulative probability of failure was 38.6% in the AGV group and 24.0% in the BGI group at 1 year ($P = 0.008$, stratified log-rank test).

Baseline demographic and clinical features were evaluated as possible predictors for treatment failure and are shown in Table 3 (available at http://aaojournal.org). Univariate and multivariate analyses are presented. In the univariate analysis, type of glaucoma (stratum), higher baseline IOP, a prior laser procedure, and fewer than 20 prior surgeries with a particular implant type by the operating surgeon were associated with higher failure rates for any reason. Complicated type of glaucoma (neovascular), a prior laser procedure, and less surgical experience remained significant risk factors for failure in the multivariate analysis.

Reoperation for Glaucoma

Patients in the AGV group required more reoperations for glaucoma than did those the BGI group (Table 2, available at http://aaojournal.org). Eleven (8%) patients in the AGV group had reoperations for glaucoma, whereas 1 (1%) patient in the BGI group underwent reoperation for glaucoma ($P = 0.016$, Fisher exact test).

Because the surgeon was not masked to the treatment assignment, a potential bias existed in the decision to reoperate for IOP control. To evaluate for reoperation bias, the IOP levels were compared between treatment groups among patients who failed because of inadequate IOP control. For the cases failing by high IOP at 2 consecutive study visits (i.e., 6 and 12 months) without reoperation, there were no significant differences ($P = 0.36$ and $P = 0.65$ for 6 and 12 months, respectively). The 6- and 12-month AGV mean (SD) IOPs were 20.3 mmHg (4.4

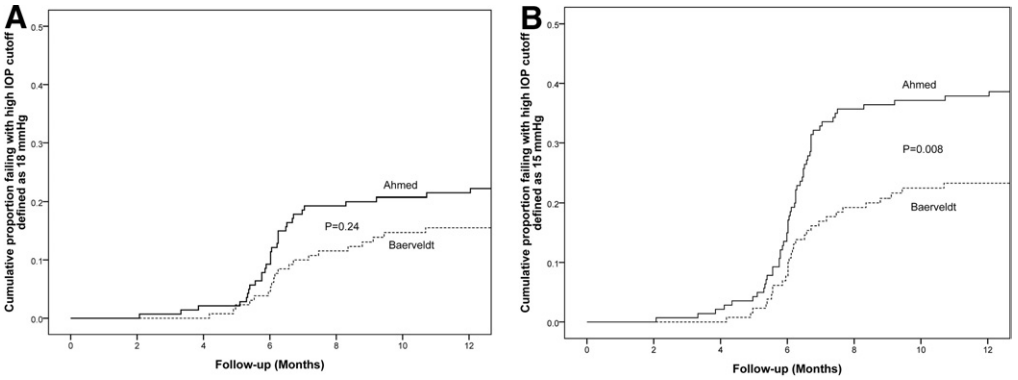

Figure 4. Kaplan-Meier curves showing the cumulative probability of failure from any cause in the Ahmed Baerveldt Comparison Study defining inadequate intraocular pressure (IOP) control as (**A**) IOP of more than 17 mmHg or (**B**) IOP of more than 14 mmHg.

mmHg) and 22.9 mmHg (8.2 mmHg), respectively, whereas the 6- and 12-month BGI mean (SD) IOPs were 23.7 mmHg (9.3 mmHg) and 25.8 mmHg (16.0 mmHg). Among AGV cases reoperated for glaucoma (N = 11), the mean (SD) preoperative IOP immediately before surgery was 34.8 mmHg (9.5 mmHg). The IOP before reoperation for the patient in the BGI group was unavailable (N = 1).

Visual Acuity

Visual acuity results are shown in Table 4. There was a significant decrease in Snellen VA in both treatment groups during the first year of follow-up. In the AGV group, mean±SD logarithm of minimum angle of resolution Snellen VA decreased from 1.07±1.01 at baseline to 1.18±1.07 at the 1-year follow-up visit ($P = 0.017$, paired t test). In the BGI group, mean±SD logarithm of minimum angle of resolution Snellen VA decreased from 1.04±1.00 at baseline to 1.20±1.19 at the 1-year follow-up visit ($P = 0.001$, paired t test). There was no significant difference in Snellen VA ($P = 0.74$, Student t test) between the 2 groups at 1 year.

Snellen VA was decreased by 2 lines or more from baseline in 40 (30%) patients in the AGV group and 40 (34%) patients in the BGI group at 1 year, and this difference in rate of vision loss between treatment groups was not statistically significant ($P = 0.57$, chi-square test). The most frequent causes of vision loss during the first year of the study were glaucoma, macular disease, and cataract. The reason for decreased vision was unknown in 11 (28%) patients in the AGV group and in 6 (15%) patients in the BGI group. Other miscellaneous causes for reduced vision in 12 patients in the AGV group included vitreous hemorrhage, corneal epithelial defect, retinal detachment, diabetic retinopathy, band keratopathy, and neovascular membrane. Other causes of vision loss in 15 patients in the BGI group included corneal edema, retinal detachment, diabetic retinopathy, endophthalmitis, and posterior capsular opacification. There were no significant differences in the reasons for visual acuity loss between the 2 groups. All 8 patients who lost light perception had neovascular glaucoma.

A multivariate linear regression analysis with loss of 2 Snellen lines or more of visual acuity at 1 year as the dependent variable and diagnostic stratum, baseline acuity, treatment assignment, and any incidence of complication as independent variables was performed to investigate the reason(s) for decreased visual acuity. The single most important predictor of acuity loss was diagnostic stratum ($P<0.001$), and the only other variable to enter the model was baseline acuity ($P = 0.006$; patients with better preoperative VA were more likely to lose 2 lines or more of vision by 1 year). Cases from the neovascular and high-risk strata were, respectively, 5.7 times (95% confidence interval, 2.5–13.3) and 2.2 times (95% confidence interval, 0.9–5.0) more likely to experience VA loss than cases in the primary or prior surgery stratum. Neither postoperative complication ($P = 0.10$) or treatment assignment ($P = 0.63$) was statistically significant.

Table 4. Visual Acuity Results in the Ahmed Baerveldt Comparison Study

	Ahmed Glaucoma Valve Group	Baerveldt Glaucoma Implant Group	*P* Value
Snellen VA, logMAR, mean±SD			
Baseline	1.07±1.01	1.04±1.00	0.80*
1 yr	1.18±1.07	1.23±1.19	0.74*
Loss of ≥2 Snellen lines, n (%)†	40 (30)	40 (34)	0.57‡
Glaucoma	5 (13%)	7 (18%)	
Macular disease	5 (13%)	6 (15%)	
Cataract	7 (18%)	6 (15%)	
Other	12 (30%)	15 (38%)	
Unknown	11 (28%)	6 (15%)	

logMAR = logarithm of the minimum angle of resolution; SD = standard deviation; VA = visual acuity.
*Two-sided Student t test.
†Patients may have more than one reason for decreased vision.
‡Chi-square test.

Postoperative Interventions

The number and frequency of patients who required postoperative interventions during the first 12 months of follow-up before glaucoma reoperation are listed in Table 5 (available at http://aaojournal.org). The most frequently performed postoperative intervention was reformation of the anterior chamber, which occurred in 9 patients (6%) in the AGV group compared with 15 patients (11%) in the BGI group. The total number of interventions was higher in the BGI group, but this was not statistically significant ($P = 0.077$).

Postoperative Complications

Table 6 lists the early postoperative complications, and Table 7 (available at http://aaojournal.org) shows late postoperative complications. Tube occlusion occurred more commonly in the BGI group than the AGV group in both the early ($P = 0.015$) and late ($P = 0.059$) postoperative periods. Corneal edema ($P = 0.035$) also was observed more frequently in the BGI group compared with the AGV group in the early postoperative period. The percent of patients with early complications was significantly higher in the BGI group (n = 77; 58%) than in the AGV group (n = 61; 43%; $P = 0.016$). There was no significant difference between the percent of patients with late postoperative complications in the AGV group (n = 41; 29%) and in the BGI group (n = 49; 37%; $P = 0.16$).

The number of patients experiencing serious complications, defined a priori as complications that required a return to the operating room to manage the complication, that were associated with loss of 2 lines or more of Snellen vision, or both was significantly higher in the BGI group (n = 45; 34%) than in the AGV group (n = 29; 20%; $P = 0.014$). Table 8 provides complete data for serious complications.

Reoperation for Complications

Reoperations for complications were performed in 7 (5%) patients in the AGV group and in 17 (13%) patients in the BGI group ($P = 0.031$, Fisher exact test). The reasons for reoperations in the AGV group included extension of a retracted tube (n = 2), clearing of an occluded tube (n = 1), repair of a conjunctival wound leak (n = 1), replacement of patch graft (n = 1), implant removal secondary to diplopia (n = 1), and surgical iridectomy for suspected pupillary block resulting in a flat anterior chamber (n = 1). The reasons for reoperations in the BGI group included clearing of an occluded tube (n = 7), conjunctival repair for leak or tube erosion (n = 3), replacement of patch graft (n = 1), pars plana vitrectomy to clear postoperative hemorrhage (n = 1), ligation of tube for overfiltration (n = 1), tube removal secondary to tube–corneal touch (n = 1), implant removal secondary to an exposed plate (n = 1), implant removal secondary to suspected *Propionibacterium acnes* endophthalmitis (n = 1), and drainage of suprachoroidal hemorrhage (n = 1).

Table 6. Number (%) of Early (≤3 Months) Postoperative Complications in the Ahmed Baerveldt Comparison Study

Complication	Ahmed Glaucoma Valve Group	Baerveldt Glaucoma Implant Group	*P* Value	Total
Tube occlusion	3 (2%)	12 (9%)	0.015	15 (5%)
Choroidal effusion	21 (15%)	13 (10%)	0.37	34 (123%)
Suprachoroidal hemorrhage	0	2 (2%)	0.23	2 (1%)
Endophthalmitis	0	1 (1%)	0.48	1 (0.4%)
Cystoid macular edema	8 (6%)	2 (2%)	0.11	10 (4%)
Shallow anterior chamber	27 (19%)	26 (20%)	1.00	53 (19%)
Hypotony maculopathy	5 (3%)	3 (2%)	0.72	8 (3%)
Diplopia	9 (6%)	7 (5%)	0.80	16 (6%)
Corneal edema	17 (12%)	29(22%)	0.035	46 (17%)
Tube–corneal touch	7 (5%)	8 (6%)	0.79	15 (5%)
Tube erosion	1 (1%)	1 (1%)	1.00	2 (1%)
Hyphema	13 (9%)	22 (17%)	0.072	35 (13%)
Vitreous hemorrhage	2 (1%)	3 (2%)	0.675	5 (2%)
Total no. of patients with early complications	61 (43%)	77 (58%)	0.016	138 (50%)

Data are presented as number (percentage).

Cataract Surgery during Follow-up

There were 92 phakic patients in the study, 47 in the AGV group and 45 in the BGI group. Of these patients, 6 (13%) in the AGV group had cataract surgery before any reoperation for glaucoma, and 9 (20%) in the BGI group had cataract surgery before glaucoma reoperation ($P = 0.41$, Fisher exact test).

Effect of Surgeon Experience on Treatment Outcome and Complications

As reported in the baseline article,[15] there were differences in surgeon experience in implanting the 2 types of devices. Two surgeons (8%) had performed fewer than 5 AGV implantations, although both were experienced BGI surgeons. Five surgeons (20%) had performed fewer than 5 BGI procedures, but all 5 were experienced AGV surgeons. A preplanned separate analysis was performed using cases from surgeons who had performed at least 20 of each type of implant before the beginning of the study. Table 3 (available at http://aaojournal.org) shows the effect of experience with implantation of a particular device on risk of failure. There was a small effect in the univariate and multivariate analyses demonstrating that failure was perhaps 20% less likely (95% confidence interval, 0.6–1.0) in the AGV group if the surgeon had placed 20 or more AGVs before the study and 30% less likely in the BGI group (95% confidence interval, 0.6–0.9) if the surgeon had placed 20 or more BGIs before the study.

Table 9 (available at http://aaojournal.org) presents the effect of surgeon experience with a particular type of implant on postoperative complications. Tube–corneal touch occurred more often in cases performed by surgeons with fewer than 20 prior cases using the BGI. When both treatment groups were combined, surgical experience with a particular type of implant was related significantly to the occurrence of tube–corneal touch ($P = 0.032$).

Table 8. Serious Complications Associated with Reoperation or Vision Loss in the Ahmed Baerveldt Comparison Study

	Ahmed Glaucoma Valve Group (n = 143)	Baerveldt Glaucoma Implant Group (n = 133)	*P* Value*
Reoperation for complications	7 (5)	17 (13)	0.031
Vision loss ≥2 Snellen lines†	26 (18)	36 (27)	0.085
Total no. of patients with serious complications‡	29 (20)	45 (34)	0.014

Data are presented as number (percentage).
*Fisher exact test.
†Some patients did not have Snellen visual acuity at 1 year because they missed the 1-year visit.
‡Patients could have reoperation for both a complication and a vision loss.

Discussion

The ABC Study was designed to compare the outcomes and complications for 2 aqueous shunts commonly used for refractory glaucoma, the AGV and the BGI. Both procedures lowered IOP and medication use significantly from baseline. In addition, the failure rates by predetermined criteria were similar for both implants. However, the AGV group had a higher rate of reoperation for glaucoma than the BGI group. This is consistent with a greater efficacy of the BGI, as indicated by slightly greater pressure reduction and a tendency for greater glaucoma medication use by the AGV group. The average IOP after 1 year of follow-up was 2.2 mmHg lower in the BGI group, a statistically significant difference. During the first postoperative month, IOP was lower in the AGV than the BGI group, as may be expected as a result of the valve mechanism in the AGV. Surgeons had the option of using tube fenestrations in the BGI group for early IOP pressure control, but this surgical maneuver has variable success.[17] The patients in the BGI group required twice as many postoperative interventions and experienced one third more serious postoperative complications, which also were statistically significant. Although the BGI

provided slightly better IOP lowering at 1 year and less need for reoperation for elevated IOP, this improved success came at the price of more serious complications.

There have been numerous retrospective case series reporting the results of the use of a single-model implant such as the AGV and BGI in refractory glaucoma. Schwartz et al[13] recently published a review of the literature comparing results with different types of aqueous shunts. They point out that it is difficult to compare results from single-model implant case series because each of these studies involves different groups of patients, surgeons, definitions of success, and follow-up times.[13] Four studies have directly compared the results of the AGV and the BGI in retrospective, comparative case series.[7–11] Tsai et al[7,10] published early- and intermediate-term results in a group of patients who underwent either implantation of the older, AGV model S2 or the 350-mm^2 or 250-mm^2 BGI by a single surgeon. The 2 groups differed significantly in age, preoperative IOP, and diagnosis. Similar to the current study, IOP was lower in the AGV group at the 1-day and 1-week postoperative visits, and no significant difference in overall survival rates between the implants was found. Intraocular pressure was the same in the 2 groups at 1 year, but after 1 year, the IOP in the AGV group steadily became higher and stayed higher to 4 years of follow-up. Wang et al[9] published a retrospective, comparative case series of 41 Asian patients who received either an AGV model S2 or a 350-mm^2 BGI by a single surgeon. The patients were followed up for an average of 23 months in both groups. The average age in the AGV group was 12 years older than that of the BGI group. They found no statistically significant differences in survival rates or IOP at last follow-up in their small group of patients, although the survival rate was higher in the BGI group (88%) compared with the AGV group (77%), and the final IOP was 2.5 mmHg lower in the AGV group. To attempt to compensate for the selection bias inherent in retrospective studies, Syed et al[8] performed a comparison of patients who received the AGV model S2 (n = 32) and the 350-mm^2 BGI (n = 32) matching for age, glaucoma diagnosis, and preoperative IOP. A non–time-adjusted survival comparison failed to find any difference in success, and the average IOPs were similar in the 2 groups throughout the approximate 1-year of the study. Survival analysis, which takes into account length of follow-up and drop outs, was not performed. Goulet et al[11] performed a retrospective, comparative case series in their institution of 59 patients who received an AGV model S2 implant and 133 patients who received a 250-mm^2 BGI. Their study showed a higher success rate and lower IOP for patients who received the BGI after an average follow-up of 20 to 23 months. Thus, the current retrospective evidence is inconclusive as to which implant lowers IOP better, has higher a success rate, and has fewer complications. These studies all suffer from their retrospective design and selection bias of which patients received which implant, although one study[8] matched on several potentially confounding variables. In addition, all of the aforementioned studies used the AGV model S2, which has a polypropylene plate, rather than the AGV model FP7, which has a silicone plate (as does the 350-mm^2 BGI). There is evidence that the silicone material in the AGV model FP7 provides better IOP reduction than the AGV model S2.[18,19] The strength of the randomized, prospective trial design used in the current study is that selection bias is eliminated and confounding variables tend to be balanced in the 2 groups, making conclusions stronger. The comparability of the 2 treatment groups created by randomization was examined in the baseline article, and no significant differences were found. In addition, the multicenter study design with 25 different surgeons operating on patients on 4 continents improves the generalizability of the results.

Visual acuity decreased by 2 lines or more of Snellen visual acuity in approximately 32% of patients overall and was not different between the groups. Among patients with complications, 18% of patients in the AGV group and 27% of patients in the BGI group lost 2 or more lines of vision by 1 year of follow-up. Snellen VA was similar between treatment groups at 1 year, and no significant differences in the rates and reasons for vision loss were present in the 2 groups. These rates of visual acuity loss are high but consistent with those found in the TVT Study groups at 1 year.[5] Most of the causes of loss of 2 lines or more of Snellen VA were related to cataract, age-related macular degeneration, and glaucoma, which also was found in the TVT Study.[5,6] It is unclear whether the vision loss was associated more with surgical complications or with the underlying severity of disease in the group of patients studied. Of note, all 8 patients who lost light perception vision were in the neovascular glaucoma stratum, and there was a higher prevalence of surgical complications in this group as well.

Many surgical complications were reported in the ABC Study, but most were transient and did not require intervention. A similarly high rate of complications was reported in the TVT Study at 1 year.[5] More patients in the BGI group experienced early postoperative complications than in the AGV group in the ABC Study, and the complication rate between groups was similar for late complications. However, all surgical complications are not equal in severity, and the rate of serious complications associated with reoperation, vision loss, or both was higher in the BGI group.

The specific design features of the AGV and BGI may explain some differences in clinical outcomes. The AGV has a restrictive valve device designed to prevent hypotony. This is particularly important in the immediate postoperative period before a capsule forms around the end plate, which restricts flow later. The BGI does not have a flow restrictor, and hypotony with its resultant complications is much more common[20] if flow is not restricted by the surgeon using a suture ligature,[13,21] which either dissolves or is removed after the end plate encapsulates to limit flow. It therefore is not surprising that in the current study, IOP was higher in the BGI group in the period before flow was established 4 to 6 weeks after surgery. Although there were only 2 cases of failure resulting from persistent hypotony by 1 year, both cases occurred in the BGI group. The second important design difference between the 2 implants is the size of the drainage plate: 184 mm^2 for the AGV and 350 mm^2 for the BGI. Several studies have shown that lower mean IOP can be achieved with larger implant plate sizes of the same general design. Heuer et al[12] performed a prospec-

tive, randomized trial of the single-plate (134 mm^2) versus double-plate (268 mm^2) Molteno implant and found both higher success rates and lower IOPs with the larger implant. There were also more postoperative complications associated with the double-plate Molteno implant. This same group performed a study randomizing 73 patients to the 350-mm^2 and the 500-mm^2 BGI and found no difference in success or IOP lowering[22] at 18 months. A subsequent longer-term analysis of the same patients found the 350-mm^2 implant to have a slightly higher success rate than the 500-mm^2 implant.[23] In the current study, the BGI, with a larger surface area, provided slightly lower IOPs at 1 year and fewer failures resulting from inadequate IOP control. Subsequent reports with longer follow-up of the current patients will provide additional information on the relative efficacy of these 2 implants on long-term IOP control.

One of the potential limitations in the current study is surgical experience with the 2 treatment arms of the study. Although one would hope that randomization would distribute patients receiving a particular implant to surgeons of differing experiences equally, there was concern about this as a source of bias. Investigators were required to submit an estimate of the number of surgical procedures that they had performed using each type of implant. If a surgeon had performed fewer than 5 surgeries using a particular implant, they were required to submit a videotape of themselves performing the procedure to make sure proper surgical techniques were followed. In addition, an analysis of success and complications dividing surgeons into those who had performed fewer than 20 procedures versus 20 procedures or more of a particular device implantation was performed. This analysis showed that experience ($\geq$20 prior cases) with a particular implant reduced the risk of failure in the multivariate analysis, but not in the univariate analysis. There was no relationship between the total number of complications and surgical experience with a particular implant. It does not seem that relative inexperience with implantation of either the AGV or BGI affected success rates or complications.

In summary, the ABC Study found greater IOP reduction with the BGI after 1 year of follow-up, but fewer early and serious complications were observed with the AGV. The efficacy of glaucoma procedures in reducing IOP must be evaluated in light of the adverse events associated with their use. Therefore, this study does not demonstrate clear superiority of one implant over the other. Also, with a significance level set at 0.05, there is always a 1 in 20 chance that any statistically significant results found in this study occurred by chance alone. Additional follow-up is needed to evaluate fully the risk-to-benefit ratio of both devices in the surgical management of refractory glaucomas. The ABC Study is designed to continue follow-up of participants to 5 years.

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Footnotes and Financial Disclosures

Originally received: February 5, 2010.
Final revision: July 2, 2010.
Accepted: July 22, 2010.
Available online: October 8, 2010. Manuscript no. 2010-199.

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Financial Disclosure(s):
The author(s) have made the following disclosure(s):
Keith Barton - Lecturer - New World Medical, Inc., Rancho Cucamonga, California; Abbott Medical Optics, Inc.

Supported by the National Institutes of Health, Bethesda, Maryland (grant no.: P30 EY014801); and unrestricted grants from New World Medical, Rancho Cucamonga, California; and from Research to Prevent Blindness, Inc., New York, New York.

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