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Long-term Efficacy of the Baerveldt 250 mm^2 Compared with the Baerveldt 350 mm^2 Implant

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Purpose: To investigate the long-term surgical outcomes of the Baerveldt 250 mm^2 versus Baerveldt 350 mm^2 glaucoma drainage implants (GDIs) (Abbott Laboratories Inc., Abbott Park, IL) in the treatment of refractory glaucoma.

Design: Comparative case study.

Participants: A total of 89 consecutive eyes in 86 patients treated at Dean McGee Eye Institute between January 2006 and December 2008.

Methods: We retrospectively reviewed patient data from the following postoperative visits: 1 week, 1 month, 2 months, 3 months, 6 months, and every 3 months thereafter. Postoperative complications were also recorded. The mean follow-up time was 40 months (range, 2–78 months) for the Baerveldt 250 mm^2 group and 31 months (range, 3–75 months) for the Baerveldt 350 mm^2 group.

Main Outcome Measures: The primary outcome measure was surgical success. Secondary outcome measures included visual acuity (VA), intraocular pressure (IOP), and number of medications.

Results: There was no difference in surgical success ($P = 0.98$). No significant differences were observed in VA measured using the logarithm of the minimum angle of resolution (logMAR) scale, IOP, and number of medications at the last visit ($P = 0.09$, 0.23, and 0.82, respectively). Complication and failure rates were comparable ($P = 0.82$ and 0.64, respectively).

Conclusions: With a mean follow-up of 40 and 31 months, no differences in surgical success, VA, IOP, number of medications at the last visit, and complication/failure rates were noted between the Baerveldt 250 mm^2 and 350 mm^2 GDIs, respectively. The size of the GDI may not be associated with surgical outcomes. *Ophthalmology 2015;122:486-493 © 2015 by the American Academy of Ophthalmology.*

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Multiple diverse attempts have been made to decrease intraocular pressure (IOP) with aqueous diversion, including long silicone tubes attached to a plate. Aqueous flows through the tube to an encapsulated space around an implanted plate and diffuses through the fibrous bleb walls. A large number of publications have described the efficacy of different implants, including the Molteno (Molteno Ophthalmic, Dunedin, New Zealand),[1–19] Baerveldt (Abbott Laboratories Inc., Abbott Park, IL),[20–31] and Ahmed implants (New World Medical, Rancho Cucamonga, CA).[21,24,25,32–36]

The Baerveldt implant currently is available with a surface area of 250 or 350 mm^2. The idea that a larger surface area leads to more substantial filtering and better IOP control has led to multiple studies analyzing glaucoma implants of different surface areas.[1,20,23,37] A systematic review indicated that this surface area differential may not be as significant among the implant designs.[38] Specifically, by comparing the smallest surface area implant, the single-plate Molteno (130 mm^2), with the largest surface area implant in the study, the Baerveldt 350 mm^2 implant, this review showed no statistically significant difference in final IOP, change from baseline IOP, or number of medications required postoperatively.[38] A trial comparing the single-plate Molteno with the double-plate Molteno showed that the double-plate Molteno had better IOP control and surgical success with 24-month follow-up.[1] A prospective study comparing the 350 and the 500 mm^2 Baerveldt implants with a follow-up of approximately 18 months found no statistical difference in surgical success or IOP control between the implants.[22] A longer-term study with a 37-month follow-up comparison between these groups indicated that the smaller surface area had better overall IOP control.[20] A smaller study comparing the 350 mm^2 Baerveldt with the double-plate 270 mm^2 Molteno implant showed similar results for mean IOP at 11 months between the 2 implants.[26]

These studies seem to indicate that there could be some contribution of larger surface area plates to lower IOP but that there may be an upward limit of effectiveness when increasing the implant surface area. Two studies before our first retrospective study had combined data for the Baerveldt

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250 mm^2 and Baerveldt 350 mm^2 implants. One study looked at overall long-term results of the Baerveldt implant in general, in which 26 patients received the 250 mm^2 implant and 25 patients received the 350 mm^2 implant. In subgroup analysis, there was no statistical difference in surgical success, mean IOP, or number of postoperative medications required between the 2 groups.[39] The other study comparing the Ahmed shunt with the Baerveldt shunt for refractory glaucoma included 70 patients receiving Baerveldt implants (20 with the 250 mm^2 implant and 50 with the 350 mm^2 implant), which showed no clinical or statistical differences between the groups in subgroup analysis.[24] Our study aims to report the long-term assessment of surgical outcomes of 89 eyes that received the 250 or 350 mm^2 Baerveldt GDI.

Methods

This was a 48-month extension of a previously reported retrospective chart review of 89 consecutive eyes that had undergone aqueous shunt surgery with the Baerveldt 250 mm^2 or Baerveldt 350 mm^2 tube shunt between January 2006 and December 2008. Protocol and data accumulations were approved by the institutional review board of the University of Oklahoma Health Sciences Center before initiation of the study.

Eighty-nine glaucoma shunt implant procedures performed in 86 patients at Dean McGee Eye Institute were reviewed. Two surgeons (G.L.S. and M.A.K.) completed all of the surgeries and all preoperative and postoperative visits. Surgical technique between the 2 surgeons was compared and found to be identical, and this did not change throughout the catchment period. Patients with high-risk disease, such as neovascular glaucoma, were included in the review. Patients were excluded only if they had previously undergone glaucoma shunt implant procedures. The plate size was chosen by the surgeon.

Chart review consisted of examining documented visits from the preoperative visit to the last recorded postoperative visit. Recorded at each visit were visual acuity (VA), IOP, and number of glaucoma medications measured preoperatively, at 1 week, 1 month, 2 months, 3 months, and every 3 months thereafter up to 78 months. Patients' VA measurements were analyzed using the logarithm of the minimum angle of resolution (logMAR) scale. For VA measurements recorded as count fingers and hand motions, we used estimated VA given by Schulze-Bonsel et al.[40] For VA measurements recorded as light perception, we used estimated VA given by Grover et al.[41] The quadrant of implant placement in the eye was recorded for each surgery. All postoperative complications over the follow-up period were recorded. Specific attention was paid to diplopia caused by the implant placement and whether this resolved during the follow-up period. Demographic information was collected at the preoperative visit.

The primary outcome for the long-term chart review was surgical success, which was defined as any outcome not qualifying for failure. Surgical failure was defined as consecutive IOPs >21 or <6 mmHg at the last 2 postoperative visits regardless of use of ocular hypotensives; no light perception vision; additional glaucoma procedures (including cyclodestructive procedures); removal of the shunt implant; or serious complications (suprachoroidal hemorrhage, malignant glaucoma, endophthalmitis, retinal detachment, chronic hypotony, or serous choroidal effusions necessitating surgical drainage or that had a kissing appearance).

Mean and standard deviation were used to summarize continuous data, and number (percentage) was used to summarize categoric data. The paired t test was used to compare preoperative and last postoperative visit outcomes. Two-sample t tests and chi-square tests were used to compare the 2 treatment groups for unadjusted analyses, and regression models were used to perform adjusted comparisons. Time to surgical failure was summarized using the Kaplan–Meier survival curve compared using the log-rank test. The Cox proportional hazards model was used to investigate the association between failure time and covariates, including age, sex, race, diagnosis, quadrant, prior trabeculectomy, preoperative VA, IOP, and number of medications. Effect estimates and 95% confidence intervals were reported. Statistical significance was determined using a 2-sided P value <0.05. SAS software version 9.3 (SAS Inc, Cary, NC) was used for data analyses. Post hoc power analysis was performed using PASS 11 software (NCSS, LLC, Kaysville, UT).

Results

A total of 89 eyes in 86 patients underwent glaucoma drainage implant (GDI) procedures. Of these, 52 eyes (58.43%) received the 350 mm^2 and 37 eyes (41.57%) received the 250 mm^2 Baerveldt GDI. Patient demographic characteristics are portrayed in Table 1. Baseline diagnosis and prior trabeculectomy are summarized in Table 2. Of note, those receiving a 350 mm^2 GDI were older (71.6 vs. 63.3 years; $P = 0.02$) and had better preoperative VA (0.47 vs. 0.8 logMAR; $P = 0.004$) than those receiving a 250 mm^2 GDI. There was no significant difference between the 2 groups in terms of preoperative IOP or number of medications. Mean follow-up time was 40 months (2–78 months) for the 250 mm^2 GDI and 31 months (3–75 months) for the 350 mm^2 GDI. Median follow-up time was 45 months for the 250 mm^2 GDI and 27 months for the 350 mm^2 GDI.

Figure 1 shows the Kaplan–Meier survival curve for the 250 mm^2 and 350 mm^2 groups, where the outcome is the time to surgical failure. Failure occurred at approximately equal rates between the 2 groups, and there was no significant difference in the probability of success ($P = 0.98$). The group difference remained nonsignificant using a multivariate Cox proportional hazards model ($P = 0.78$).

Postoperative complications leading to surgical failure are demonstrated in Table 3. Eleven of 37 (29.73%) of the 250 mm^2 GDIs and 13 of 52 (25%) of the 350 mm^2 GDIs resulted in surgical failure, and the failure rates were not significantly different ($P = 0.64$). The most common cause of surgical failure in both groups was the need for additional glaucoma surgery (8/37 [21.6%] and

Table 1. Patient Demographics

	250 mm^2 GDI	350 mm^2 GDI	P Value
No. of patients	36	50	
Age (yrs), mean (SD)	63.3 (18.1)	71.6 (15.0)	**0.02**
Sex, no. (%)			
Female	18 (50)	30 (60)	0.39
Male	18 (50)	20 (40)	
Race, no. (%)			
White	28 (77.78)	36 (72)	0.73
Black	2 (5.56)	7 (14)	
Asian	2 (5.56)	2 (4)	
Hispanic	1 (2.78)	0 (0)	
Native American	1 (2.78)	1 (2)	
Unknown	2 (5.56)	4 (8)	

SD = standard deviation.