Intermediate-term Results of a Randomized Clinical Trial of the 350- versus the 500-mm^2 Baerveldt Implant

Mary Ann Lloyd, MD, George Baerveldt, MD, Paul S. Fellenbaum, MD, Paul A. Sidoti, MD, Don S. Minckler, MD, James F. Martone, MD, MPH, Laurie LaBree, MS, Dale K. Heuer, MD

Background: The Baerveldt glaucoma implant is a large equatorial aqueous shunting device that is installed through a single-quadrant conjunctival incision. The intermediate-term results of a randomized study comparing the 350- and 500-mm^2 Baerveldt implants are reported.

Methods: Seventy-three patients with medically uncontrollable, nonneovascular glaucomas associated with aphakia, pseudophakia, or failed filters were enrolled in a randomized, prospective study comparing 350- and 500-mm^2 Baerveldt implants. Surgical success was defined as 6 mmHg $\leq$ final intraocular pressure $\leq$ 21 mmHg without glaucoma reoperation or devastating complication.

Results: Of patients with 350- and 500-mm^2 implants, 93% and 88%, respectively, achieved surgical success (18-month life-table analysis, $P = 0.93$). The 500-mm^2 implants afforded intraocular pressure control with significantly fewer medications (0.7 versus 1.3; $P = 0.006$). The postoperative visual acuities remained within one line of the preoperative visual acuities or improved in 62% and 66% of patients in the 350- and 500-mm^2 groups, respectively ($P = 0.93$). Complication rates were statistically similar. The most frequent ones in the 350- and 500-mm^2 groups, respectively, were serous choroidal effusion (16% and 32%), strabismus (16% and 19%), anterior uveitis (14% and 11%), and corneal or corneal graft edema (11% each).

Conclusion: The intermediate-term results of the 350- and 500-mm^2 Baerveldt implants were statistically comparable with respect to surgical and visual outcomes, as well as complications, although the larger implant was associated with a higher rate of some complications. However, the 500-mm^2 Baerveldt implant afforded intraocular pressure control with fewer medications than the 350-mm^2 implant. *Ophthalmology 1994;101:1456–1464*

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From the Department of Ophthalmology, University of Southern California School of Medicine and the Doheny Eye Institute, Los Angeles, California.

Dr. Lloyd currently is with the Palo Alto Medical Foundation, Palo Alto, and affiliated with the Department of Ophthalmology, Stanford University School of Medicine, Stanford, California.

Dr. Fellenbaum currently is in private practice in North Carolina.

Dr. Martone currently is affiliated with Project Orbis, New York, New York.

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Reprint requests to Mary Ann Lloyd, MD, Department of Ophthalmology, Palo Alto Medical Foundation, 300 Homer Ave, Palo Alto, CA 94301.

The Baerveldt glaucoma implant (Iovision, Inc, Irvine, CA) consists of a nonvalved silicone tube (0.64-mm external diameter and 0.30-mm bore) inserted into a 1-mm high ridge on the anterior edge of a 1-mm–thick barium-impregnated silicone plate. The plates originally were made with surface areas of 200 mm² (20 × 13 mm), 350 mm² (32 × 14 mm), and 500 mm² (36 × 17.5 mm). Aqueous flows through the tube to an encapsulated space around the equatorial plate and diffuses through the fibrous bleb walls. The Baerveldt implant is easier to install than other large implants, and it uses only one quadrant of the eye.[1]

Studies of the Molteno implant in a primate glaucoma model demonstrated that Molteno tube perfusion rates were proportional to the surface areas of the plates.[2] A prospective clinical trial of 132 patients with glaucomas associated with aphakia and pseudophakia who were randomized to undergo single- or double-plate Molteno implantation confirmed that the larger implants provide significantly better intraocular pressure (IOP) control (46% versus 71% 2-year life-table success rates for single- and double-plate Molteno implants, respectively, with success defined as IOP ≤ 21 mmHg without additional glaucoma surgery or devastating complication). Serious complications were, however, more frequently associated with the double-plate implants.[3]

Although these studies suggest that devices with larger surface areas provide better IOP regulation, the ideal surface area of glaucoma implants remains unknown. We report the preliminary results of a randomized, prospective clinical trial comparing the safety and effectiveness of the 350- and the 500-mm² Baerveldt implants (Fig 1) in patients with glaucomas associated with aphakia, pseudophakia, or failed filters.

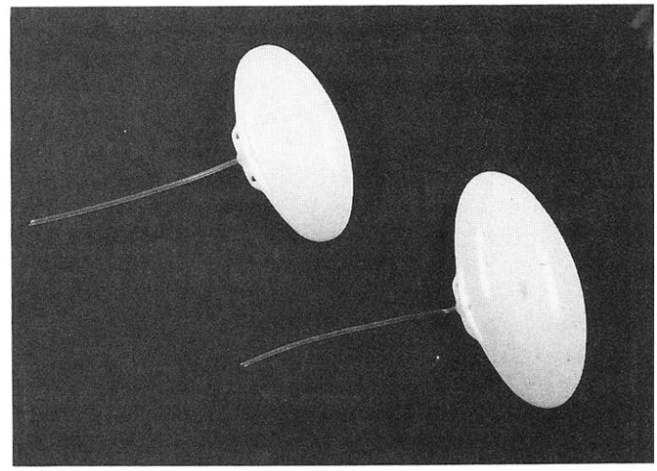

Figure 1. Nonfenestrated 350- and 500-mm² Baerveldt implants.

Subjects and Methods

From March 21, 1991, to April 29, 1993, patients with medically uncontrollable glaucomas associated with aphakia, pseudophakia, or failed filters were chosen randomly to undergo either 350- or 500-mm² Baerveldt implantation at the Doheny Eye Institute. All patients gave informed consent; the study protocol and consent form regarding Baerveldt implantation was approved by the Los Angeles County/University of Southern California Medical Center Institutional Review Board (research protocol number 906-020). Patients were excluded if they were younger than 12 years of age, had neovascular glaucomas or uveitis, had technical limitations to placing the implants (such as patients who had undergone previous muscle surgery or who had extensive scarring), had existing scleral buckles or other glaucoma implants, or had undergone previous cyclodestruction. Seventy-three patients (37 patients in the 350-mm² implant group and 36 patients in the 500-mm² implant group) had the potential for at least 6-months of follow-up, and they are the subjects of this report.

The randomization list was generated from a random numbers table. The surgeons made the initial conjunctival incision and confirmed that installation of either plate was technically feasible; randomization assignments then were requested. Operating room personnel read the assignment from the randomization list, to which the surgeons were masked. Aphakic and pseudophakic patients who had undergone previous conventional filtering procedures were placed in the aphakic/pseudophakic diagnostic group; phakic patients who had failed filters were categorized in the failed filter group.

All patients underwent one-stage Baerveldt implantation as previously described.[1] The plates were installed through limbus- or fornix-based conjunctival incisions after conjunctival and Tenon's capsule adhesions had been cleared by blunt dissection. The superior temporal quadrant often was preferred over other quadrants because it afforded the maximum area for plate placement and bleb formation, as well as minimized interference with the oblique muscles. The lateral plate edges were placed under the two adjacent rectus muscles after muscle hooks had been used to free any adhesions under the muscles. Plates were placed over the oblique muscle tendons if placed in temporal quadrants. The anterior edges of the plates were secured to the sclera at least 10 mm from the limbus with two 8–0 nylon sutures, the knots of which were rotated through each anterior fixation hole. The tubes were ligated, most often with 8–0 polyglactin suture; releasable suture techniques or collagen plugs were used to occlude the tubes in a few patients. Tubes were backflushed to confirm total occlusion. Paracentesis tracts then were made at the limbus temporally. In some eyes, air or sodium hyaluronate (Healon) was injected into the anterior chamber to deepen or maintain it and later removed. The tubes were trimmed in a beveled fashion and inserted into the eye at the limbus through 22- or 23-gauge needle tracts 0.5 to 1.0 mm posterior to the blue limbus, or through the pars plana via 21- or 22-gauge needle tracts 2 to 3 mm from the limbus in eyes in which total pars plana vitrectomy had been performed. Glycerin-preserved donor scleral grafts then were attached to the host sclera over the proximal ends of the tubes with interrupted 7–0 or 8–0 polyglactin sutures. Tenon's capsule and conjunctiva were closed with

8–0 polyglactin suture in separate running layers in patients with limbus-based incisions. Relaxing incisions made in patients with fornix-based incisions were closed in single running layers with 7–0 or 8–0 polyglactin sutures, with mattress sutures at the limbus. Atropine sulfate drops (1%) were instilled topically at the conclusion of the procedures, and separate subconjunctival injections of 12 mg dexamethasone phosphate (24 mg/ml) and 20 mg gentamicin sulfate (40 mg/ml) were administered in most eyes. The eyes then were patched overnight.

The postoperative regimen included topical antibiotics (usually 0.3% tobramycin) for 2 weeks postoperatively, and 1% atropine sulfate and 1% prednisolone acetate or phosphate for 4 to 6 weeks postoperatively. No adjunctive systemic antifibrosis agents were administered.

The IOPs were measured with a Goldmann applanation tonometer or a Tonopen (Mentor O & O, Inc, Norwell, MA) on the day of surgery or on the first postoperative day, and on each subsequent visit. Topical antiglaucoma medications (usually starting with a beta-blocker) and/or a carbonic anhydrase inhibitor were used if the IOPs became uncontrolled in the early postoperative period, and often were administered immediately after surgery in anticipation of elevated IOP levels. Surgical ligature release (by conventional means or transconjunctival krypton laser) was performed if the IOPs remained unacceptably elevated. Standardized echography was used to determine the presence of a bleb if results of slit-lamp examination were inconclusive.[4]

Surgical success parameters were adopted before reviewing the data (Table 1). Surgical success was defined as 6 mmHg ≤ final IOP ≤ 21 mmHg without additional glaucoma surgery (excluding surgical or laser ligature release), and without devastating complication. The preoperative IOPs and visual acuities were those obtained on the most recent examinations before surgery. The final IOPs and visual acuities recorded for patients categorized as successes or qualified failures were those of the most recent examinations at either Doheny Eye Institute or at the referring ophthalmologists' offices. In those patients categorized as complete failures, the IOPs and visual acuities were those recorded on the dates when further intervention was recommended or a devastating complication occurred.

Table 1. Categories of Surgical Outcome

Success	
Complete	IOP ≤ 21 (and ≥6) mmHg without medication
Qualified	IOP ≤ 21 (and ≥6) mmHg with medication(s)
Failure	
Qualified	IOP > 21 mmHg with medication(s)
Complete	Further glaucoma surgery (or recommendation thereof), hypotony (IOP < 6 mmHg), devastating complication, or loss of light perception

IOP = intraocular pressure.

Results

Patient demographics and preoperative data are summarized in Table 2. The 350- and 500-mm^2 implant groups were statistically comparable with respect to age and race of patients, types of glaucomas, and preoperative IOPs. The mean age of patients in the 350- and 500-mm^2 groups was 66.4 ± 20.0 years (range, 12–87 years) and 66.5 ± 18.6 years (range, 16–90 years), respectively. The majority of patients in both groups had glaucomas associated with aphakia and pseudophakia (89% and 86% of patients in the 350- and 500-mm^2 groups, respectively). Preoperative IOPs averaged 31.1 ± 10.8 mmHg (range, 15–58 mmHg) and 31.4 ± 14.2 mmHg (range, 12–78 mmHg) among patients in the 350- and 500-mm^2 groups, respectively. (The one patient in the 500-mm^2 group with a preoperative IOP of 12 mmHg had variable IOPs up to 37 mmHg while receiving maximally tolerated medical therapy.)

Postoperative data are summarized in Table 3. The overall conventional surgical success rates were 84% and 83% in the 350- and 500-mm^2 groups, respectively. Eighteen-month life-table success rates were 93% and 88% (P = 0.93, log-rank test) for the 350- and 500-mm^2 groups, respectively (Fig 2). Follow-up averaged 15.5 ± 4.8 months (range, 7–23 months) and 14.1 ± 5.4 months (range, 6–24 months) in the 350- and 500-mm^2 groups, respectively. The percent IOP reduction was similar in the 350- and 500-mm^2 groups—52.3% ± 25.6% (range, −22%–82%) versus 51.9% ± 22.5% (range, 10%–86%), respectively (P = 0.94, Student's t test). Of the nine patients in the 350-mm^2 group and ten in the 500-mm^2 group who had preoperative IOPs of 21 mmHg or less, three and five patients, respectively, achieved final IOPs at least 25% lower than the preoperative levels (but greater than 5 mmHg). The average number of medications used to achieve IOP control (excluding patients with less than 6 months of follow-up and those categorized as complete failures) was 1.3 ± 0.9 (range, 0–4) in the 350-mm^2 group versus 0.7 ± 0.8 (range, 0–3) in the 500-mm^2 group (P = 0.006, Wilcoxon rank-sum test).

Because patients often cannot tolerate medications or require an IOP lower than 21 mmHg to prevent progression of glaucomatous optic neuropathy, alternate success criteria were determined before data analysis. Defining success as 6 mmHg ≤ final IOP ≤ 21 mmHg without medications, success was achieved in 15% and 38% of patients in the 350- and 500-mm^2 groups, respectively (P = 0.05, chi-square test). Defining success as 6 mmHg ≤ final IOP ≤ 15 mmHg (with or without medications), 74% of patients in the 350-mm^2 group versus 65% in the 500-mm^2 group achieved success (P = 0.60, chi-square test).

The postoperative visual acuities remained within one line of the preoperative visual acuities or improved in 62% and 66% of patients in the 350- and 500-mm^2 groups, respectively (P = 0.93, chi-square test). Of the 11 patients in the 350-mm^2 group and 10 in the 500-mm^2 group

Table 2. Randomization, Demographic and Preoperative Data

	350 mm² (n = 37)	500 mm² (n = 36)
Randomization	37 (51%)	36 (49%)
Age (yrs; mean ± SD)*	12–87 (66.4 ± 20.0)	16–90 (66.5 ± 18.6)
Ethnicity†		
Asian-Pacific Islander	2 (5%)	2 (5%)
Black	3 (8%)	5 (14%)
White	32 (87%)	29 (81%)
Hispanic	5 (14%)	8 (22%)
Non-Hispanic	27 (73%)	21 (58%)
Glaucoma diagnosis‡		
Glaucomas associated with aphakia/pseudophakia	33 (89%)	31 (86%)
Aphakic	5 (14%)	14 (39%)
Anterior chamber intraocular lens	8 (22%)	4 (11%)
Posterior chamber intraocular lens	20 (54%)	13 (36%)
Glaucomas after failed filters	4 (11%)	5 (14%)
Preoperative IOP§ (mmHg; mean ± SD)	15–58 (31.1 ± 10.8)	12–78 (31.4 ± 14.2)

SD = standard deviation; IOP = intraocular pressure.

* $P = 0.98$, Student's t test.

† $P = 0.73$, chi-square.

‡ $P = 0.69$, chi-square.

§ $P = 0.92$, Student's t test.

whose postoperative visual acuity level worsened from the preoperative level, seven and four patients, respectively, potentially lost vision from elevated IOP at some time during their postoperative courses, although the exact mechanism for visual decline was undetermined in some patients. Some patients lost vision from other complications, as listed in Table 4.

No statistically significant differences among complication rates existed between the two implant groups (Table 4). The most frequent complications in the 350- and 500-mm² groups, respectively, included serous choroidal effusion (16% and 32%), strabismus (16% and 19%), anterior uveitis (14% and 11%), and corneal or corneal graft edema (11% each). Other complications were relatively infrequent in both groups.

Discussion

The Molteno implant has been the standard device among glaucoma drainage implants.[3,5–9] The Baerveldt implant is a newer glaucoma shunting device that is easier to implant than other large implants, such as the double-plate Molteno implant (270 mm²) or Schocket implant (300 or 450 mm²), which are installed into two or more quadrants. Eighteen-month life-table success rates were 93% and 88%, respectively, in the 350- and 500-mm² Baerveldt implant groups, which compare favorably with our 18-month life-table success rate of 82% achieved with double-plate Molteno implants in patients with glaucomas associated with aphakia and pseudophakia.[3] In this study, there were no statistically significant differences in the 18-month life-table success rates, final IOPs, mean percent IOP reduction, numbers of patients who achieved IOPs less than 16 mmHg (but greater than 5 mmHg), and visual outcomes between the 350- and 500-mm² implant groups.

However, the difference in number of medications was statistically significant; patients with the smaller implant required nearly twice the number of medications (1.3) as patients with the larger implant (0.7) to maintain IOP control. Thirty-eight percent of patients in the 500-mm² implant group achieved IOPs below 22 mmHg without medications versus 15% of patients in the 350-mm² group. These results suggest that, although IOP reduction may not be directly proportional to the sizes of larger implants, surface area remains an important element in determining the amount of aqueous diffusion and level of IOP control, as demonstrated in earlier studies.[2,3]

Overall, most complications were comparable between the two Baerveldt implant groups. Serous choroidal detachment occurred more often in patients with 500-mm² implants than 350-mm² implants (32% versus 16%, respectively), although this difference was not statistically significant. Serous choroidal detachment occurred after initial installation or after ligature release, and persisted in only one patient (who was in the 500-mm² group and underwent temporary religature and blood injection into the bleb). In a retrospective study of 37 eyes of 36 patients with complicated glaucomas who underwent 350-mm² Baerveldt implantation,

Table 3. Postoperative Data

	350 mm² (n = 37)	500 mm² (n = 36)
Life-table (survival) analysis (Fig 2)*		
6-mo success rate	97%	100%
12-mo success rate	93%	93%
18-mo success rate	93%	88%
Conventional outcome analysis by final IOPs		
Success	31 (84%)	30 (83%)
Complete success	5 (14%)	13 (36%)
Qualified success	26 (70%)	17 (47%)
Failure	3 (8%)	4 (11%)
Qualified failure	1 (3%)	1 (3%)
Complete failure on IOP basis	0 (0%)	1 (3%)
Complete failure on complication basis	2 (5%)	2 (6%)
Insufficient follow-up (<6 mo)	3 (8%)	2 (6%)
Follow-up (mos; mean ± SD)†‡	7–23 (15.5 ± 4.8)	6–24 (14.1 ± 5.4)
Final IOP (mmHg; mean ± SD)†§	6–22 (13.0 ± 3.6)	6–23 (13.2 ± 4.7)
Percentage postoperative IOP reduction (mean ± SD)†‖	−22–82 (52.3 ± 25.6)	10–86 (51.9 ± 22.5)
Postoperative antiglaucoma medications (mean ± SD)†¶	0–4 (1.3 ± 0.9)	0–3 (0.7 ± 0.8)
Alternate success criteria		
6 mmHg ≤ IOP ≤ 21 mmHg (without medications)#	5 (15%)	13 (38%)
6 mmHg ≤ IOP ≤ 15 mmHg (with or without medications)**	25 (74%)	22 (65%)
Visual acuity outcome††		
Better‡‡	13 (35%)	12 (33%)
Same§§	10 (27%)	12 (33%)
Worse‖‖	11 (30%)	10 (28%)
Insufficient follow-up (<6 mos)	3 (8%)	2 (6%)

IOP = intraocular pressure; SD = standard deviation.

* $P = 0.93$, log-rank test.

† Excludes two patients in the 350 mm² group and one patient in the 500 mm² group who had less than 6 months follow-up and patients who were complete failures.

‡ $P = 0.30$, Student's t test.

§ $P = 0.90$, Student's t test.

‖ $P = 0.94$, Student's t test.

¶ $P = 0.006$, Wilcoxon rank sum test.

$P = 0.05$, chi-square.

** $P = 0.60$, chi-square.

†† $P = 0.93$, chi-square.

‡‡ Postoperative visual acuity at least two lines better than preoperative visual acuity.

§§ Postoperative visual acuity within one line of preoperative visual acuity.

‖‖ Postoperative visual acuity at least two lines worse than preoperative visual acuity.

Smith and colleagues[10] reported a 25% incidence of choroidal effusion, although they did not completely occlude the tube during the initial postoperative period. It is possible that a larger sample size in our study may have shown a statistically significant difference in the rates of choroidal effusion between the two groups. In any case, serous choroidal effusion was clinically significant in only a few patients in this study.

Hemorrhagic choroidal detachment occurred in one patient (3%) in the 350-mm² group (a partially hemorrhagic choroidal detachment after ligature release). Hemorrhagic choroidal detachment occurred in two patients (5%) in the 500-mm² group (1 who had a large hemorrhage after ligature release, which spontaneously resolved, and 1 who had a large hemorrhage at the time of pars plana fistula creation and had a history of intraoperative choroidal hemorrhage at the time of penetrating keratoplasty, in whom phthisis bulbi eventually developed). Choroidal drainage was performed on the one patient in the 350-mm² group who had persistent effusion and flat anterior chamber.

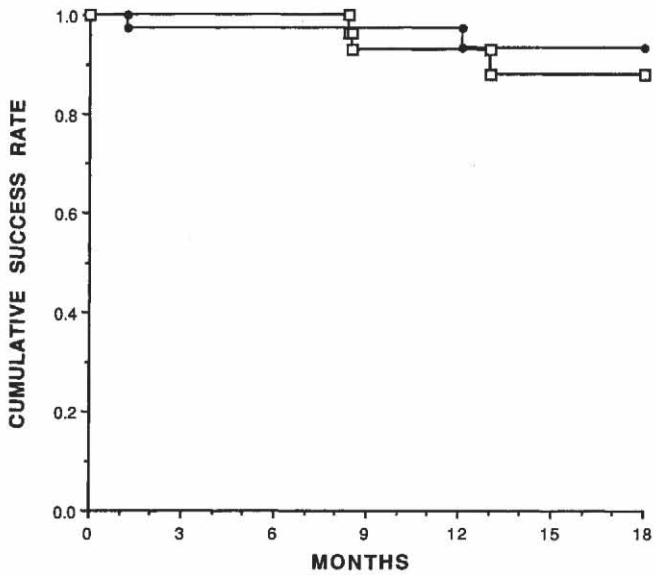

Figure 2. Life-table cumulative success rate versus postoperative follow-up months. Solid circles = patients with 350-mm² Baerveldt implants; open squares = patients with 500-mm² Baerveldt implants.

No cases of retinal detachment occurred in the 350-mm² group. Traction retinal detachment occurred in three patients (8%) in the 500-mm² group (2 were associated with large hemorrhagic choroidal detachment [1 in combination with a rhegmatogenous retinal detachment], and 1 was associated with large serous choroidal detachment). Retinal reattachment surgery was performed only on the patient who also had a rhegmatogenous retinal detachment; spontaneous resolution occurred in the other patients. Although the 500-mm² group had a higher rate of retinal detachment than the 350 mm² group, the difference was not statistically significant. Larger numbers of patients are needed to determine if the overall incidence of retinal detachment is higher with the larger implant.

Plate extrusion occurred in one patient in each group; endophthalmitis also developed in the patient in the 350-mm² group.

Four patients in the 350-mm² group and eight patients in the 500-mm² group had undergone penetrating keratoplasty before Baerveldt implantation. Corneal graft decompensation did not occur in any patients in the 350-mm² group; it did occur in three patients in the 500-mm² group (1 patient had only transient corneal graft rejection, and the other 2 had mild to moderate graft edema before Baerveldt implantation). Corneal edema occurred in one patient who had no preoperative edema and progressed in three patients who had existing mild to moderate preoperative aphakic or pseudophakic corneal edema in the 350-mm² group; it occurred in one patient in the 500-mm² group who had localized peripheral corneal edema postoperatively. No eyes with corneal or corneal graft edema were associated with cornea–tube touch. These corneal complication rates are similar to those reported with other glaucoma shunts.[11,12]

Clinically apparent strabismus occurred with similar frequency in the 350- and 500-mm² implant groups (16% and 19%, respectively). It occurred with both nasally and temporally placed implants and usually presented with limitation of gaze into the quadrant of the implant, most often after flow through the tube had been established. Although strabismus did resolve in some eyes, motility follow-up on all patients was difficult to obtain. Six patients in this series underwent muscle surgery to correct motility dysfunction or diplopia. Our experience differs from Smith and associates,[10] who reported a 77% incidence (23 of 30 eyes of patients on whom postoperative motility measurements were available) of heterotropia in primary gaze and extraocular motility restriction.

Strabismus associated with Baerveldt implants is likely due to a mass effect in the orbit due to the large blebs. The blebs also extend under the muscles, as has been demonstrated echographically,[4] and may potentially cause functional impairment. Motility disorders also may be due to a posterior fixation or Faden effect, as proposed by Christmann and Wilson[13] for strabismus associated with Molteno implantation. Baerveldt implants now have two fenestrations in the plates that allow ingrowth of fibrous tissue, connecting the upper and lower walls of the blebs, thereby limiting their heights (Figs 3–7). Additional plate fenestrations can

Table 4. Complications

	350 mm² (n = 37)	500 mm² (n = 37)	P*
Serous choroidal effusion	6 (16%)	12 (32%)	0.18
Strabismus	6 (16%)	7 (19%)	1.00
Anterior uveitis	5 (14%)	4 (11%)	1.00
Corneal or corneal graft edema	4 (11%)	4 (11%)	1.00
Tube block	2 (5%)	2 (5%)	1.00
Reactivation herpetic keratitis	2 (5%)	0 (0%)	0.49
Hemorrhagic choroidal detachment	1 (3%)	2 (5%)	1.00
Hyphema	1 (3%)	2 (5%)	1.00
Endophthalmitis	1 (3%)	0 (0%)	1.00
Plate extrusion	1 (3%)	1 (3%)	1.00
Flat anterior chamber	1 (3%)	1 (3%)	1.00
Retinal detachment	0 (0%)	3 (8%)	0.24
Phthisis bulbi	0 (0%)	1 (3%)	1.00
Conjunctival wound leak	0 (0%)	3 (8%)	0.24
Vitritis with hypopyon	0 (0%)	1 (3%)	1.00
Malignant glaucoma†	0 (0%)	1 (3%)	1.00
Cataract‡	1/4 (25%)	1/5 (20%)	1.00

* Fisher's exact test (two-tailed).

† One patient in the 500 mm² group in whom malignant glaucoma developed and refused further treatment was excluded from the study but is included in the complication analysis.

‡ Four patients in the 350 mm² group and five patients in the 500 mm² group were phakic.

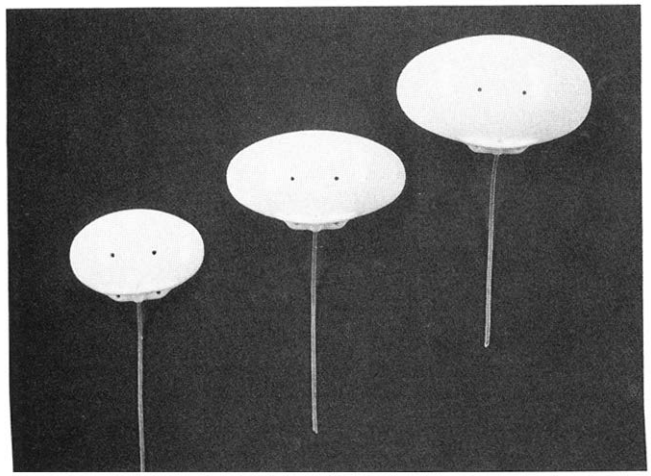

Figure 3. Fenestrated 200-, 350-, and 500-mm^2 Baerveldt implants.

be made intraoperatively with a trephine. Eight patients in the 350-mm^2 group and six in the 500-mm^2 group received implants with two or four fenestrations; one patient in the 350-mm^2 group and two in the 500-mm^2 group had transient or persistent diplopia. The numbers of patients are as yet too small to demonstrate whether plate fenestrations reduce the rates of strabismus in patients with Baerveldt implants.

The ideal glaucoma implant size that will provide the best IOP control with the fewest medications and complications is yet unknown. Glaucoma implants with large surface areas afford better IOP control than smaller implants, although IOP reduction is not directly proportional to explant size. The Baerveldt implant design allows installation of a plate with very large surface area into a single quadrant, requiring minimal conjunctival manipulation. This study showed that no significant differences exist in the overall 18-month surgical success rates or visual outcomes between the 350- and 500-mm^2 Baerveldt implant groups. However, patients with the larger implant used significantly fewer medications to achieve IOP control than did patients with the smaller implant. Although some adverse occurrences, such as serous choroidal effusion, were more common with the 500-mm^2 implant, complication rates were statistically comparable in both groups. Additional follow-up of this study and others is

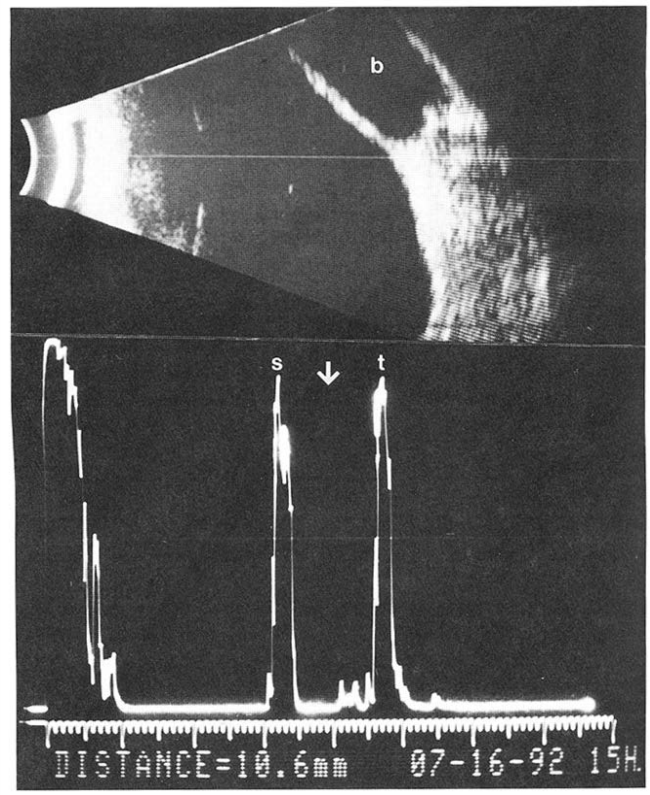

Figure 5. Echographic appearance of nonfenestrated Baerveldt plate (not shown) associated with underlying and overlying bleb (b), longitudinal B-scan **(top)** and A-scan **(bottom)**. s = scleral spike; t = Tenon's capsule spike; arrow = bleb space. Bleb height is 10.6 mm.

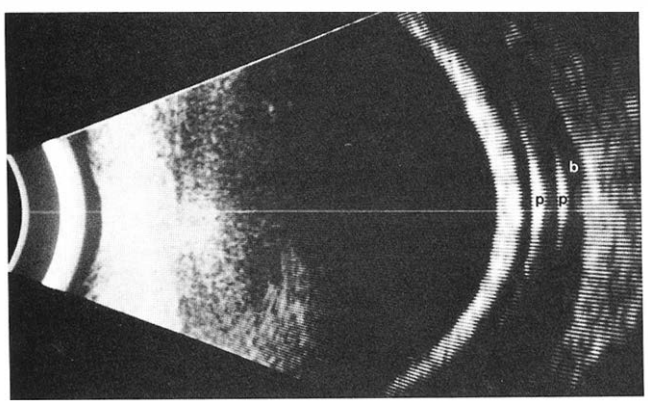

Figure 4. Echographic appearance of nonfenestrated Baerveldt plate (p) associated with underlying and overlying bleb (b), transverse B-scan. Plate appears as two echodense lines.

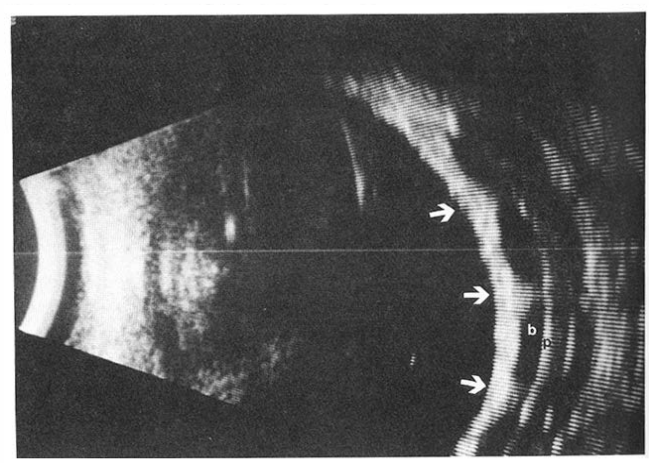

Figure 6. Echographic appearance of fenestrated Baerveldt plate (p) with underlying and overlying bleb (b), transverse B-scan. Arrow = fibrous tissue bridging bleb through fenestrations.

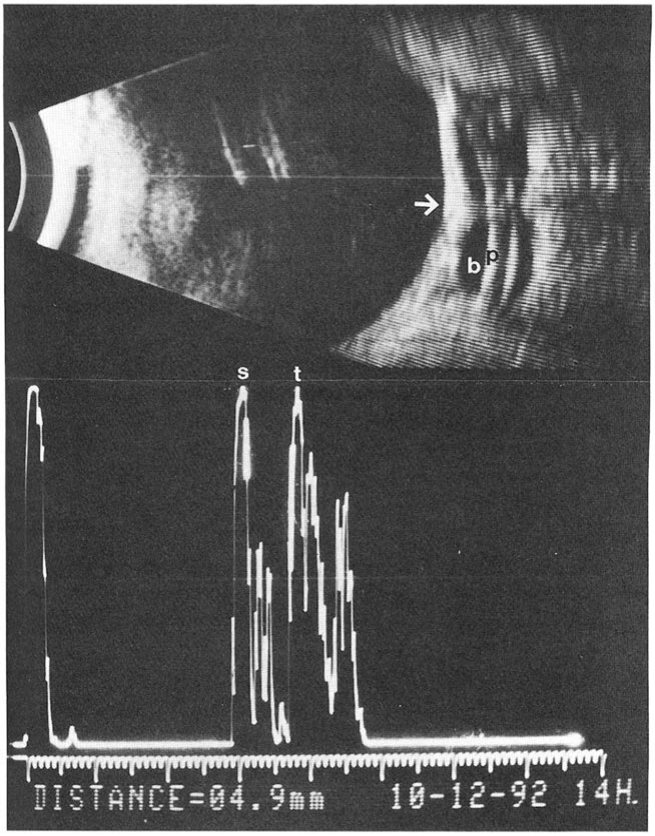

Figure 7. Echographic appearance of fenestrated Baerveldt plate (p) associated with underlying and overlying bleb (b), longitudinal B-scan **(top)** and A-scan **(bottom)**. Arrow = fibrous tissue bridging bleb through fenestrations. s = scleral spike; t = Tenon's capsule spike. Bleb height is 4.9 mm.

necessary to determine long-term outcomes of patients with the Baerveldt implant.

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Discussion
by
Theodore Krupin, MD

Molteno[1] in 1969 described the use of an episcleral explant to promote formation of a filtration bleb. Before this report, foreign materials had been used during filtration surgery, primarily to maintain patency of the sclerostomy. The original limbal location of Molteno's 8-mm circular disc resulted in a large anterior bleb causing dellen and irritation. The procedure was modified to attach the disc posteriorly at the equator of the globe. This permitted Molteno to enlarge the disc diameter to 13 mm, introducing the concept of posterior tube filtration surgery. Aqueous humor is shunted through an anterior chamber tube to an encapsuled episcleral plate which functions as the filtration bleb.[2]

Several styles of posterior tube shunt implants have been described, including the Baerveldt implant presented in the article by Lloyd et al. Implant designs are based on studies indicating that the final intraocular pressure (IOP) achieved after any tube shunt procedure is determined by the size and resistance of the fibrous pseudocapsule surrounding the episcleral explant.[3,4] Modifications such as explant size, shape, type of material, and configuration are incorporated in modern devices to maximize surface area and possibly enhance permeability of the capsule wall.

It is reasonable to assume that the size of the episcleral explant determines, at least in part, the size of the encapsulated bleb. The study by Heuer et al[5] reported a higher success rate and

From the Department of Ophthalmology, Northwestern University Medical School, Chicago.

lower IOP after implantation of the double-plate compared with the single-plate Molteno device. However, the double-plate success and final IOP reduction are not twice as great as the results with the single-plate implant. Moreover, studies by Wilson et al[6] and Smith et al[7] reported lower or similar IOPs using the double-plate Molteno implant compared with the Schocket encircling device, an implant with a larger calculated surface area than the Molteno device.

Factors other than explant surface area clearly affect the level of IOP reduction. In eyes with an episcleral plate placed in one quadrant between two rectus muscles and attached by sutures at the anterior edge, ultrasonography demonstrates that the fluid reservoir surrounding the plate is significantly larger than the plate itself. The plate appears to "float in a lake of aqueous." Presumably, diffusion of aqueous humor occurs across the entire enveloping pseudocapsule. As the size of the explant increases to approach adjacent rectus muscles, encapsulation involves the muscles. Adhesions to the rectus muscles are facilitated when the explant is placed beneath the muscle. This is the situation with the current design of the Baerveldt implant. When encapsulation involves the muscle, its surrounding fibrous tissue may not be as permeable to aqueous humor. These adhesions also may interfere with ocular motility, a frequently reported complication with the Baerveldt implant.[8]

As described by Molteno[9] in 1981, the circumferential distance between rectus muscles delimits the size and shape of an episcleral plate. A plate larger than an ocular quadrant that extends to involve rectus muscles may not increase functioning encapsulation. In addition, the posterior dimension of an episcleral plate is limited by the posterior ciliary arteries. Encapsulation in the orbit, because of its distance from the conjunctiva, probably has reduced exchange of aqueous humor.

Lloyd et al report very similar IOP-lowering results comparing the 350- and 500-mm^2 Baerveldt implant. Although they report a statistically significant reduction in the number of postoperative antiglaucoma medications in eyes with a 500-mm^2 implant, the difference is of marginal clinical significance. Also, they do not present their protocol for either initiating or increasing the postoperative administration of medical therapy. However, I do agree with their conclusion that the calculated surface area of the plastic explant[10] is not directly proportional with the final IOP reduction.

In conclusion, the authors have compared two different sizes of Baerveldt implants that are inserted beneath adjacent rectus muscles. Their high success rate with either explant size may relate to the exclusion of high-risk eyes, especially neovascular glaucoma and eyes with scarred conjunctiva, which frequently occurs in eyes undergoing posterior tube implant surgery. Also, approximately 25% of the eyes had a preoperative IOP of 21 mmHg or less, and approximately only 12% of eyes had prior failed filtration surgery. One may wonder if an antimetabolite filtration procedure would have achieved a similar rate of success with fewer complications. Regarding complications, the authors have not addressed their high incidence of motility problems with either Baerveldt implant. Despite my concerns, the similar results with either explant confirms that the position and attachment to the globe of the episcleral plate may be as important as the actual size of the explant. It appears that there is a maximum useful explant surface area beyond which there is minimal improvement in IOP control. The 350-mm^2 Baerveldt implant reaches, and may surpass, this limit. Additional pressure lowering with a maximum-sized explant will depend on the resistance of the encapsulation.

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