Treatment Outcomes in the Tube Versus Trabeculectomy (TVT) Study After Five Years of Follow-up

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• PURPOSE: To report 5-year treatment outcomes in the Tube Versus Trabeculectomy (TVT) Study.
• DESIGN: Multicenter randomized clinical trial.
• METHODS: SETTINGS: Seventeen clinical centers. STUDY POPULATION: Patients 18 to 85 years of age who had previous trabeculectomy and/or cataract extraction with intraocular lens implantation and uncontrolled glaucoma with intraocular pressure (IOP) ≥18 mm Hg and ≤40 mm Hg on maximum tolerated medical therapy. INTERVENTIONS: Tube shunt (350-mm^2 Baerveldt glaucoma implant) or trabeculectomy with mitomycin C ([MMC]; 0.4 mg/mL for 4 minutes). MAIN OUTCOME MEASURES: IOP, visual acuity, use of supplemental medical therapy, and failure (IOP >21 mm Hg or not reduced by 20%, IOP ≤5 mm Hg, reoperation for glaucoma, or loss of light perception vision).
• RESULTS: A total of 212 eyes of 212 patients were enrolled, including 107 in the tube group and 105 in the trabeculectomy group. At 5 years, IOP (mean ± SD) was 14.4 ± 6.9 mm Hg in the tube group and 12.6 ± 5.9 mm Hg in the trabeculectomy group (P = .12). The number of glaucoma medications (mean ± SD) was 1.4 ± 1.3 in the tube group and 1.2 ± 1.5 in the trabeculectomy group (P = .23). The cumulative probability of failure during 5 years of follow-up was 29.8% in the tube group and 46.9% in the trabeculectomy group (P = .002; hazard ratio = 2.15; 95% confidence interval = 1.30 to 3.56). The rate of reoperation for glaucoma was 9% in the tube group and 29% in the trabeculectomy group (P = .025).
• CONCLUSIONS: Tube shunt surgery had a higher success rate compared to trabeculectomy with MMC during 5 years of follow-up in the TVT Study. Both procedures were associated with similar IOP reduction and use of supplemental medical therapy at 5 years. Additional glaucoma surgery was needed more frequently after trabeculectomy with MMC than tube shunt placement. (Am J Ophthalmol 2012;153:789–803. © 2012 by Elsevier Inc. All rights reserved.)

DESPITE THE INTRODUCTION OF SEVERAL NEW glaucoma operations in recent years,[1–4] trabeculectomy (or guarded filtration procedure) and tube shunt (or aqueous shunt) surgery remain the most commonly performed incisional procedures for the management of glaucoma. Trabeculectomy has historically been preferred over tube shunt implantation, except in refractory glaucomas at high risk for filtration failure. However, concern about bleb-related complications has contributed to an expanded use of tube shunts as an alternative to trabeculectomy. Medicare claims data show a 43% decrease in the number of trabeculectomy procedures and a concurrent 184% increase in tube shunt surgery between 1995 and 2004.[5] Recent surveys of the American Glaucoma Society membership have demonstrated a rise in the proportion of surgeons using tube shunts and a decline in the popularity of trabeculectomy.[6–8] These surveys have also indicated a lack of consensus regarding the best surgical approach for managing glaucoma in patients who have undergone prior ocular surgery. In particular, some surgeons favor placement of a tube shunt while others prefer a trabeculectomy with an adjunctive antifibrotic agent in eyes with previous cataract or glaucoma surgery.

The Tube Versus Trabeculectomy (TVT) Study was designed to prospectively compare the safety and efficacy of tube shunt surgery and trabeculectomy with mitomycin C (MMC) in eyes with prior ocular surgery. Patients with uncontrolled glaucoma who had previously undergone cataract extraction with intraocular lens implantation and/or failed filtering surgery were enrolled in this multicenter clinical trial and randomized to receive either a 350-mm^2 Baerveldt glaucoma implant (Abbott Medical Optics, Santa Ana, California, USA) or a trabeculectomy with MMC. The goal of this investigator-initiated study is to provide information that will assist in surgical decision making in similar patient groups. This article reports the

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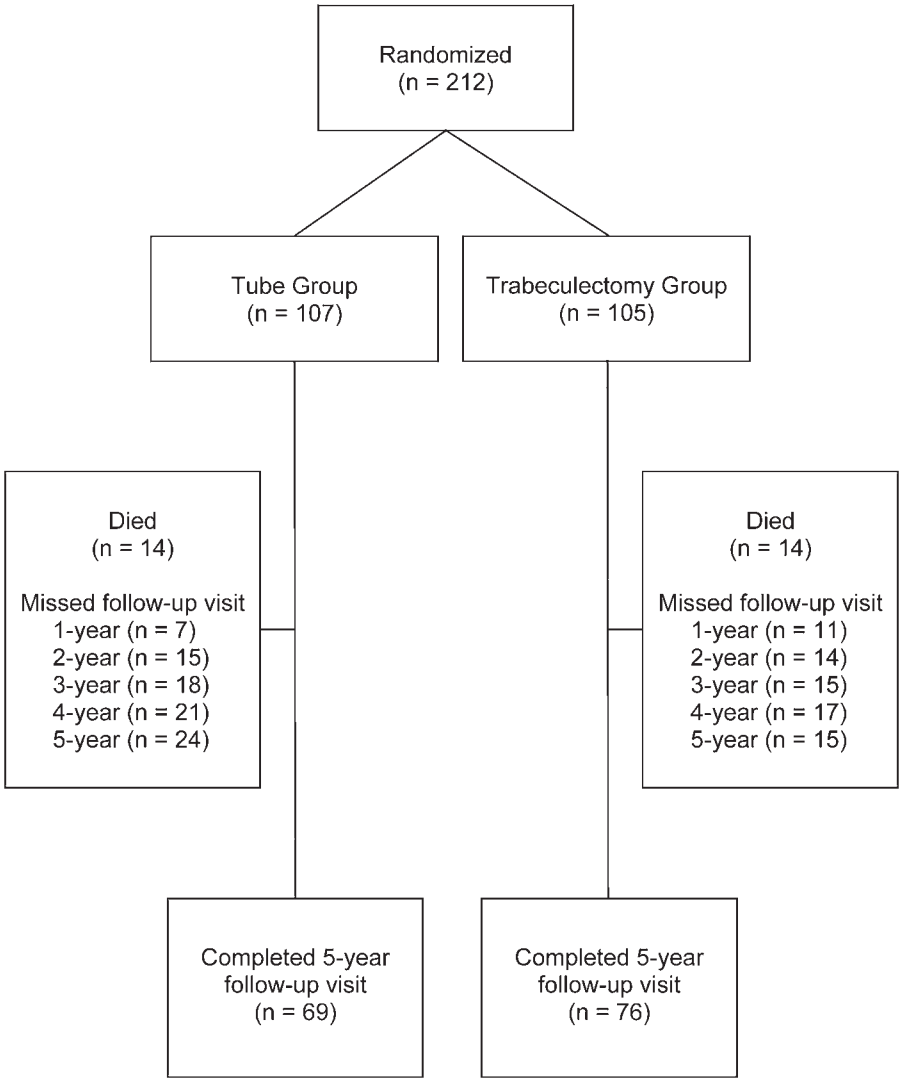

FIGURE 1. Flow chart of patient progress in the Tube Versus Trabeculectomy Study.

outcomes of treatment during 5 years of follow-up in the TVT Study.

METHODS

THE DESIGN AND METHODS OF THE TVT STUDY WERE previously described in detail,[9] and are summarized herein.

• **ELIGIBILITY CRITERIA:** Inclusion criteria included age 18 to 85 years, previous trabeculectomy and/or cataract extraction with intraocular lens implantation, and intraocular pressure (IOP) ≥18 mm Hg and ≤40 mm Hg on maximum tolerated medical therapy. Exclusion criteria included no light perception vision, pregnant or nursing women, active iris neovascularization or proliferative retinopathy, iridocorneal endothelial syndrome, epithelial or fibrous downgrowth, aphakia, vitreous in the anterior chamber for which a vitrectomy was anticipated, chronic or recurrent uveitis, severe posterior blepharitis, unwillingness to discontinue contact lens use after surgery, previous cyclodestructive procedure, prior scleral buckling procedure, presence of silicone oil, conjunctival scarring precluding a superior trabeculectomy, and need for glaucoma surgery combined with other ocular procedures or anticipated need for additional ocular surgery. Only 1 eye of eligible patients was included in the study.

• **RANDOMIZATION AND TREATMENT:** The TVT Study was conducted at 17 clinical centers. Eligibility was independently confirmed at the Statistical Coordinating Center. Patients enrolled in the study were randomized to placement of a 350-mm^2 Baerveldt glaucoma implant or trabeculectomy with MMC. Randomization was performed using a permuted block design stratified by clinical center and type of previous intraocular surgery. Neither the patient nor the clinician was masked to the randomization assignment during follow-up.

TABLE 1. Baseline Characteristics of Tube Versus Trabeculectomy Study Patients

	Tube Group (n = 107)	Trabeculectomy Group (n = 105)	*P* Value
Age (years), mean ± SD	70.9 ± 11.0	71.1 ± 9.9	.89[a]
Sex, n (%)			.055[b]
Male	43 (40)	57 (54)	
Female	64 (60)	48 (46)	
Race, n (%)			.53[c]
White	52 (49)	43 (41)	
Black	40 (37)	42 (40)	
Hispanic	12 (11)	18 (17)	
Other	3 (3)	2 (2)	
Diabetes mellitus, n (%)	31 (29)	36 (34)	.49[b]
Hypertension, n (%)	61 (57)	63 (60)	.76[b]
IOP (mm Hg), mean ± SD	25.1 ± 5.3	25.6 ± 5.3	.56[a]
Glaucoma medications, mean ± SD	3.2 ± 1.1	3.0 ± 1.2	.17[a]
Diagnosis, n (%)			.057[c]
POAG	88 (82)	84 (80)	
CACG	7 (7)	11 (10)	
PXFG	7 (7)	1 (1)	
PG	1 (1)	0 (0)	
Other	4 (4)	9 (9)	
Lens status, n (%)			.85[c]
Phakic	24 (22)	21 (20)	
PCIOL	80 (75)	80 (76)	
ACIOL	3 (3)	4 (4)	
Previous intraocular surgery			.35[a]
Mean ± SD	1.3 ± 0.5	1.2 ± 0.5	
Range	1–3	1–4	
Interval (months), mean ± SD[e]	54 ± 50	60 ± 55	.42[a]
ETDRS VA, mean ± SD	62.7 ± 24.1	64.4 ± 19.6	.56[a]
Snellen VA			
Median	20/30	20/40	.76[d]
Range	20/17–HM	20/20–2/200	
LogMAR mean ± SD	.42 ± .54	.37 ± .38	.40[a]
Humphrey visual fields			
MD, mean ± SD	−16.0 ± 10.2	−15.8 ± 9.6	0.87[a]
PSD, mean ± SD	7.1 ± 3.5	6.9 ± 3.5	0.73[a]

ACIOL = anterior chamber intraocular lens; CACG = chronic angle-closure glaucoma; ETDRS = Early Treatment Diabetic Retinopathy Study; HM = hand motion; IOP = intraocular pressure; MD = mean deviation; PCIOL = posterior chamber intraocular lens; PG = pigmentary glaucoma; POAG = primary open-angle glaucoma; PSD = pattern standard deviation; PXFG = pseudoexfoliation glaucoma; SD = standard deviation; VA = visual acuity.

[a]Student *t* test.

[b]χ^2 test.

[c]Exact permutation χ^2 test.

[d]Mann-Whitney *U* test.

[e]Interval between last intraocular surgery and surgical treatment in study.

A 350-mm^2 Baerveldt glaucoma implant was placed in the superotemporal quadrant in all patients randomized to the tube group. A limbus-based or fornix-based conjunctival flap was dissected, and the implant was sutured to sclera 10 mm posterior to the limbus. The Baerveldt tube was completely occluded to temporarily restrict flow through the device until encapsulation of the plate occurred. The surgeon was given the option of fenestrating the tube for early IOP reduction. The Baerveldt tube was inserted into the anterior chamber through a 23-gauge needle track. A patch graft was used to cover the limbal portion of the tube, and the conjunctiva was closed.

All patients randomized to the trabeculectomy group underwent a trabeculectomy with MMC superiorly. A limbus-based or

TABLE 2. Intraocular Pressure and Medical Therapy at Baseline and Follow-up in the Tube Versus Trabeculectomy Study

	Tube Group[a,b]	Trabeculectomy Group[a,b]	*P* Value[c]
Baseline			
IOP (mm Hg)	25.1 ± 5.3	25.6 ± 5.3	.56
Glaucoma medications	3.2 ± 1.1	3.0 ± 1.2	.17
n	107	105	
1 year			
IOP (mm Hg)	12.5 ± 3.9	12.7 ± 5.8	.75
Glaucoma medications	1.3 ± 1.3	0.5 ± 0.9	<.001
n	97	87	
2 years			
IOP (mm Hg)	13.4 ± 4.8	12.1 ± 5.0	.097
Glaucoma medications	1.3 ± 1.3	0.8 ± 1.2	.019
n	83	72	
3 years			
IOP (mm Hg)	13.3 ± 5.0	13.5 ± 6.9	.83
Glaucoma medications	1.3 ± 1.3	1.0 ± 1.5	.31
n	78	68	
4 years			
IOP (mm Hg)	13.5 ± 5.4	12.9 ± 6.1	.58
Glaucoma medications	1.4 ± 1.4	1.2 ± 1.5	.33
n	68	65	
5 years			
IOP (mm Hg)	14.4 ± 6.9	12.6 ± 5.9	.12
Glaucoma medications	1.4 ± 1.3	1.2 ± 1.5	.23
n	61	63	

IOP = intraocular pressure.
[a]Data presented as mean ± standard deviation.
[b]Data censored after a reoperation for glaucoma.
[c]Student *t* test.

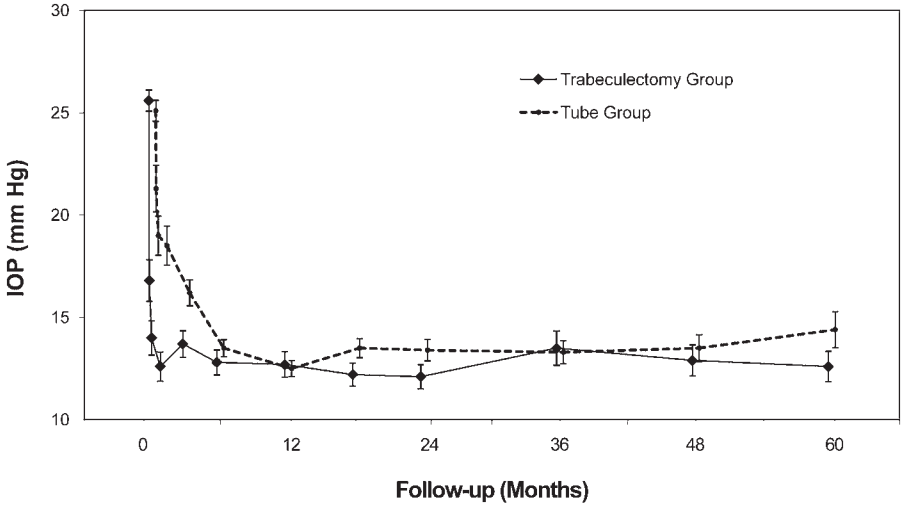

FIGURE 2. Intraocular pressure (IOP) at baseline and follow-up in the Tube Versus Trabeculectomy Study. Data are presented as mean ± standard error of the mean and are censored after a reoperation for glaucoma.

fornix-based flap was created, and a fluid-retaining sponge soaked in MMC (0.4 mg/mL) was applied to the superior sclera for 4 minutes. A partial-thickness scleral flap was dissected, and a paracentesis was made. A block of limbal tissue was excised underneath the trabeculectomy flap. The scleral flap was reapproximated to the scleral bed with interrupted or releasable

10–0 nylon sutures. The conjunctiva was closed, and Seidel testing was performed at the conclusion of the case.

• **PATIENT VISITS:** Baseline demographic and clinical information were collected for enrolled patients. Follow-up visits were scheduled at 1 day, 1 week, 1 month, 3 months, 6 months, 1 year, 18 months, 2 years, 3 years, 4 years, and 5 years postoperatively. Each examination included measurement of Snellen visual acuity (VA), IOP, slit-lamp biomicroscopy, Seidel testing, and ophthalmoscopy. Humphrey perimetry, Early Treatment Diabetic Retinopathy Study (ETDRS) VA, and quality of life using the National Eye Institute Visual Function Questionnaire (NEI VFQ-25) were assessed at baseline and at the annual follow-up visits. A formal motility evaluation was performed in all patients at baseline and at the 1-year and 5-year follow-up visits, and at any visit after 3 months at which the patient reported diplopia. Investigators provided an explanation for loss of 2 or more lines of Snellen VA at follow-up visits after 3 months. Postoperative interventions and surgical complications were documented at each follow-up visit. Additional information was collected for patients undergoing a reoperation, including the date of surgery, type of procedure, and IOP level and number of glaucoma medications immediately prior to reoperation.

• **OUTCOME MEASURES:** Outcome measures assessed in the TVT Study include IOP, VA, use of supplemental medical therapy, surgical complications, visual fields, quality of life, and failure. Failure was prospectively defined as IOP >21 mm Hg or less than 20% reduction below baseline on 2 consecutive follow-up visits after 3 months, IOP ≤5 mm Hg on 2 consecutive follow-up visits after 3 months, reoperation for glaucoma, or loss of light perception vision. Reoperation for glaucoma was defined as additional glaucoma surgery requiring a return to the operating room, such as placement of a tube shunt. Cyclodestruction was also counted as a reoperation for glaucoma. Interventions performed at the slit lamp, such as needling procedures and laser suture lysis, were not considered glaucoma reoperations. Eyes that had not failed by the above criteria and were not on supplemental medical therapy were considered complete successes. Eyes that had not failed but required supplemental medical therapy were defined as qualified successes. An independent Safety and Data Monitoring Committee (SDMC) met twice a year to monitor the conduct of the study.

• **STATISTICAL ANALYSIS:** Univariate comparisons between treatment groups were performed using the 2-sided Student *t* test for continuous variables and the χ^2 test, Fisher exact test, or exact permutation χ^2 test for categorical variables. Snellen VA measurements were converted to logMAR equivalents for the purpose of data analysis, as reported previously.[10] The time to failure was defined as the time from surgical treatment to reoperation for glaucoma, loss of light perception vision, or the first of 2 consecutive study visits after 3 months in which the patient had persistent hypotony (IOP ≤5 mm Hg) or inadequately reduced IOP (IOP >21 mm Hg or not reduced by 20% below baseline). Treatment comparisons of time to failure and time to reoperation for glaucoma were assessed with the stratified Kaplan-Meier survival analysis log-rank test. Risk factors for failure were evaluated with the Kaplan-Meier survival log-rank test. Multivariate analysis was performed using Cox proportional hazard regression analysis with forward

TABLE 3. Treatment Outcomes After 5 Years of Follow-up in the Tube Versus Trabeculectomy Study

	Tube Group[a] (n = 73)	Trabeculectomy Group[a] (n = 84)
Stratum 1—previous cataract extraction		
Failure	8 (26)	23 (59)
Qualified success	15 (48)	10 (26)
Complete success	8 (26)	6 (15)
Stratum 2—previous trabeculectomy or combined procedure without an antifibrotic agent		
Failure	8 (47)	8 (47)
Qualified success	6 (35)	1 (6)
Complete success	3 (18)	8 (47)
Stratum 3—previous trabeculectomy with 5-FU or combined procedure with 5-FU or MMC		
Failure	1 (8)	5 (36)
Qualified success	4 (33)	3 (21)
Complete success	7 (58)	6 (43)
Stratum 4—previous trabeculectomy with MMC		
Failure	7 (54)	6 (43)
Qualified success	6 (46)	4 (29)
Complete success	0	4 (29)
Overall group		
Failure[b]	24 (33)	42 (50)
Qualified success	31 (42)	18 (21)
Complete success[c]	18 (25)	24 (29)

5-FU = 5-fluorouracil; MMC = mitomycin C.

[a]Data presented as number of patients (percentage).

[b]$P = .034$ for the difference in failure rates between treatment groups (χ^2 test adjusted for stratum).

[c]$P = .58$ for the difference in complete success rates between treatment groups (χ^2 test adjusted for stratum).

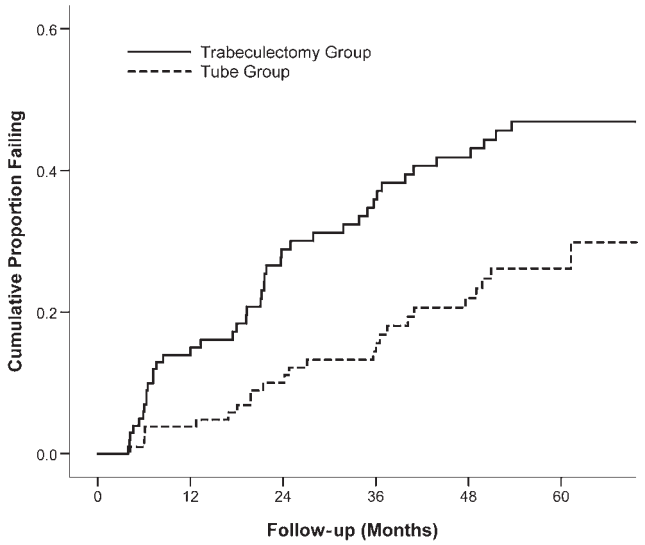

FIGURE 3. Kaplan-Meier plots of the probability of failure in the Tube Versus Trabeculectomy Study.

stepwise elimination. A *P* value of .05 or less was considered statistically significant in our analyses.

RESULTS

• **RECRUITMENT AND RETENTION:** The TVT Study enrolled 212 eyes of 212 patients between October 1999 and April 2004. Randomization assigned 107 patients to placement of a 350-mm^2 Baerveldt glaucoma implant and 105 patients to a trabeculectomy with MMC. All patients received their assigned treatment.

Figure 1 shows the progress of patients in the study. In the overall study group of 212 patients, 28 patients (13%) died within 5 years of enrollment. An additional 39 patients (18%) missed their 5-year study visit. During the first 5 years, 13.0% of follow-up visits were missed because of deaths and losses to follow-up. The visit completion rate did not significantly differ by treatment group ($P = .22$, χ^2 test).

• **BASELINE CHARACTERISTICS:** Table 1 presents the baseline characteristics of study patients. No significant differences in any of the demographic or clinical features were observed between treatment groups at enrollment. Additional information on randomized patients was provided in a previous publication.[9] Similar mean IOPs and glaucoma medications were seen among patients who were and were not lost to follow-up in both treatment groups (Supplemental Table, available at AJO.com).

• **INTRAOCULAR PRESSURE REDUCTION:** Table 2 and Figure 2 provide baseline and follow-up IOP measurements for the tube and trabeculectomy groups. Patients who underwent additional glaucoma surgery were censored from analysis after reoperation. Both surgical procedures produced a significant and sustained reduction in IOP. At 5 years, IOP (mean ± SD) was 14.4 ± 6.9 mm Hg in the tube group and 12.6 ± 5.9 mm Hg in the trabeculectomy group ($P = .12$, Student *t* test; 95% confidence interval −0.5 mm Hg to 4.1 mm Hg). Among patients who completed 5-year follow-up visits, IOP reduction from baseline (mean ± SD) was 10.2 ± 7.4 mm Hg (41.4%) in the tube group ($P < .001$, paired *t* test) and 12.4 ± 7.2 mm Hg (49.5%) in the trabeculectomy group ($P < .001$, paired *t* test). The degree of IOP reduction was similar between the 2 treatment groups at 5 years ($P = .097$, Student *t* test). No significant difference in mean IOP was seen between treatment groups after 3 months. The proportion of patients with IOP ≤14 mm Hg was also similar between the tube and trabeculectomy groups. At 5 years, 39 patients (63.9%) in the tube group and 40 patients (63.5%) in the trabeculectomy group had an IOP of 14 mm Hg or less ($P > .99$, χ^2 test).

An additional intent-to-treat analysis was performed, which included patients who required further surgery for glaucoma. No significant difference in mean IOP was present between treatment groups taking into account all medical and surgical management during 5 years of follow-up. At 5 years, IOP (mean ± SD) was 14.3 ± 6.8 mm Hg in the tube group and 13.6 ± 6.2 mm Hg in the trabeculectomy group ($P = .54$, Student *t* test; 95% confidence interval −1.4 mm Hg to 2.8 mm Hg).

• **MEDICAL THERAPY:** Table 2 shows the number of glaucoma medications in the tube and trabeculectomy groups at baseline and follow-up. Patients who underwent additional glaucoma surgery were censored from analysis after reoperation. A significant reduction in the use of medical therapy was seen in both treatment groups. The number of glaucoma medications (mean ± SD) decreased from baseline by 1.8 ± 1.8 in the tube group ($P < .001$, paired *t* test) and 1.7 ± 2.0 in the trabeculectomy group ($P < .001$, paired *t* test) in patients who completed 5-year follow-up visits. A significantly greater use of supplemental medical therapy was observed in the tube group compared with the trabeculectomy group at all follow-up visits during the first 2 postoperative years. However, the mean number of glaucoma medications was similar between treatment groups at 3 years and at all subsequent study visits.

No significant difference in the mean number of medications was seen between treatment groups after 5 years of follow-up when patients who underwent additional glaucoma surgery were included in the analysis. The mean number of medications was 1.4 ± 1.3 in the tube group and 1.2 ± 1.4 in the trabeculectomy group at 5 years in an intent-to-treat analysis ($P = .25$, Student *t* test).

• **TREATMENT OUTCOMES:** Table 3 presents the outcomes of randomized patients, unadjusted for follow-up

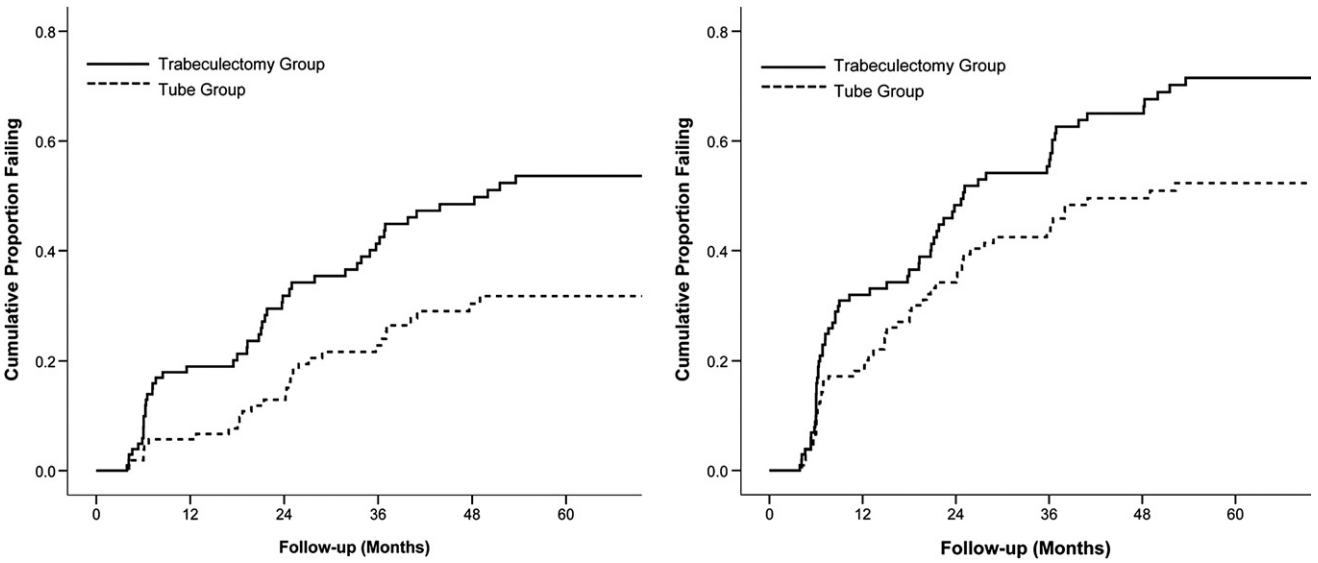

FIGURE 4. Kaplan-Meier plots of the cumulative probability of failure in the Tube Versus Trabeculectomy Study defining inadequate intraocular (IOP) reduction as IOP >17 mm Hg or not reduced by 20% below baseline (Left) or IOP >14 mm Hg (Right). Inadequate IOP reduction criteria must have been present on 2 consecutive visits after 3 months to qualify as failure. Patients with persistent hypotony, reoperation for glaucoma, and loss of light perception vision are classified as failures.

TABLE 4. Reasons for Treatment Failure in the Tube Versus Trabeculectomy Study

	Tube Group[a] (n = 24)	Trabeculectomy Group[a] (n = 42)
Inadequate IOP reduction[b,c]	13 (54)	17 (40)
Reoperation for glaucoma	7 (29)	11 (26)
Persistent hypotony[d]	3 (13)	13 (31)
Loss of light perception	1 (4)	1 (2)

IOP = intraocular pressure.

P = .43 for the difference in distribution of reasons for failure between treatment groups (exact permutation χ^2 test).

[a]Data are presented as number (percentage).

[b]IOP >21 mm Hg or not reduced by 20% below baseline on 2 consecutive follow-up visits after 3 months.

[c]Some patients underwent reoperation for glaucoma subsequent to failure because of inadequate IOP reduction.

[d]IOP ≤5 mm Hg on 2 consecutive follow-up visits after 3 months.

time. All patients who completed 5-year follow-up visits and/or had a prior failure were included in this analysis. A significantly higher failure rate was seen in the trabeculectomy group than in the tube group after 5 years. Treatment failure had occurred in 24 patients (33%) in the tube group and 42 patients (50%) in the trabeculectomy group at 5 years (*P* = .034, χ^2 test adjusted for stratum). In the tube group, 18 patients (25%) were classified as complete successes and 31 patients (42%) were qualified successes. In the trabeculectomy group, 24 patients (29%) were complete successes and 18 patients (21%) were qualified successes. While the tube group had a higher overall success rate after 5 years, the rate of complete success was similar between treatment groups (*P* = .58, χ^2 test adjusted for stratum).

Kaplan-Meier survival analysis was also used to compare failure rates between the 2 treatment groups, and the results are presented in Figure 3. The cumulative probability of failure was 29.8% in the tube group and 46.9% in the trabeculectomy group at 5 years (*P* = .002, log-rank test adjusted for stratum; hazard ratio = 2.15; 95% confidence interval = 1.30 to 3.56). No significant differences in treatment efficacy were found between strata (*P* = .143, test of treatment-stratum interaction).

Figure 4 presents the failure rates for the 2 treatment groups using alternative outcome criteria. Patients with persistent hypotony, reoperation for glaucoma, or loss of light perception vision were still classified as treatment failures. However, the upper IOP limit distinguishing success from failure was changed. When inadequate IOP reduction was defined as IOP greater than 17 mm Hg or not reduced by 20% from baseline on 2 consecutive follow-up visits after 3 months, the cumulative probability of failure at 5 years was 31.8% in the tube group and 53.6% in the trabeculectomy group (*P* = .002, log-rank test adjusted for stratum; hazard ratio = 2.04; 95% confidence interval = 1.29 to 3.24). When inadequate IOP reduction was defined as IOP greater than 14 mm Hg on 2 consecutive visits after 3 months, the cumulative probability of failure was 52.3% in the tube group and 71.5% in the trabeculectomy group at 5 years (*P* = .017, log-rank test adjusted for stratum; hazard ratio = 1.57; 95% confidence interval = 1.09 to 2.26). Significantly higher failure rates were observed in the trabeculectomy group compared with

TABLE 5. Risk Factor Analysis for Failure in the Tube Versus Trabeculectomy Study

Risk Factor	Number (%)	Cumulative Probability of Failure at 5 Years (%)[b]	*P* Value	
			Univariate	Multivariate
Stratum[a]			.18[c]	.18[d]
1	94 (44)	39.0		
2	49 (23)	40.4		
3	35 (17)	25.1		
4	34 (16)	44.1		
Age (years)			.39[c]	.39[d]
<60 years	31 (15)	42.9		
60–69	59 (28)	44.6		
70–79	79 (37)	38.3		
≥80	43 (20)	28.6		
Sex			.47[c]	.78[d]
Male	100 (47)	42.1		
Female	112 (53)	34.6		
Race			.64[c]	.67[d]
White	95 (45)	35.7		
Black	82 (39)	40.4		
Hispanic	30 (14)	41.3		
Other	5 (2)	50.0		
Diabetes mellitus			.88[c]	.76[d]
Yes	67 (32)	35.2		
No	145 (68)	39.5		
Hypertension			.095[c]	.073[d]
Yes	124 (59)	31.6		
No	88 (42)	46.7		
Lens status			.19[c]	.23[d]
Phakic	45 (21)	47.7		
PCIOL	160 (76)	34.2		
ACIOL	7 (3)	65.7		
Previous intraocular surgery			.52[c]	.43[d]
1	163 (77)	38.2		
2	41 (19)	36.0		
3 or 4	8 (4)	56.3		
Time since last intraocular surgery (months)			.22[c]	.35[d]
<6 months	15 (7)	47.5		
≥6 months	190 (93)	38.1		
Glaucoma type			.99[c]	.76[d]
Primary	190 (90)	37.1		
Secondary	22 (10)	47.5		
Preoperative number of glaucoma medications			.97[c]	.97[d]
0–1	21 (10)	35.7		
2–3	108 (51)	40.9		
4–6	83 (39)	35.2		
Preoperative IOP (mm Hg)			.60[c]	.59[d]
<23	77 (36)	36.1		
23–26	66 (31)	42.8		
>26	69 (33)	39.3		
Preoperative Snellen VA			.21[c]	.17[d]
≥20/30	106 (50)	31.6		
20/40–20/150	74 (35)	39.8		
≤20/200	32 (15)	64.4		

TABLE 5. Risk Factor Analysis for Failure in the Tube Versus Trabeculectomy Study (*Continued*)

Risk Factor	Number (%)	Cumulative Probability of Failure at 5 Years (%)[b]	*P* Value	
			Univariate	Multivariate
Clinical centers			.81[c]	.95[d]
Enrolled ≥50% patients	133 (63)	41.4		
Enrolled <50% patients	79 (37)	32.6		
Treatment			.002[c]	–
Tube	107 (50)	29.8		
Trabeculectomy	105 (50)	46.9		

ACIOL = anterior chamber intraocular lens; IOP = intraocular pressure; PCIOL = posterior chamber intraocular lens; VA = visual acuity.

[a]Stratum 1 = previous cataract extraction; stratum 2 = previous trabeculectomy or combined procedure without an antifibrotic agent; stratum 3 = previous trabeculectomy with 5-fluorouracil or combined procedure with 5-fluorouracil or mitomycin C; stratum 4 = previous trabeculectomy with mitomycin C.

[b]Kaplan-Meier survival analysis.

[c]Log-rank test.

[d]Cox proportional hazard regression analysis, *P* value adjusted for treatment.

TABLE 6. Reoperations for Glaucoma in the Tube Versus Trabeculectomy Study

	Tube Group[a] (n = 107)	Trabeculectomy Group[a] (n = 105)
Tube shunt	4	15
Transscleral cyclophotocoagulation	4	1
Endocyclophotocoagulation and cataract extraction	1	0
Bleb revision and tube shunt	0	2
Trabeculectomy with 5-FU	0	1
Total number of patients (cumulative percentage) with reoperation for glaucoma[b]	8[c] (9)	18[c] (29)

5-FU = 5-fluorouracil.

[a]Data are presented as number of patients.

[b]*P* = .025 for the difference in 5-year cumulative reoperation rates for glaucoma between treatment groups from Kaplan-Meier analysis (log-rank test adjusted for stratum).

[c]One patient had 2 different types of reoperations for glaucoma.

the tube group when more stringent IOP criteria were used to define success and failure.

Table 4 lists the reasons for classification as a treatment failure. The most common cause for failure during 5 years of follow-up in both treatment groups was inadequate IOP reduction (IOP >21 mm Hg or not reduced by 20% below baseline on 2 consecutive follow-up visits after 3 months). There were 6 patients in the trabeculectomy group and 1 patient in the tube group who failed because of inadequate IOP reduction and subsequently underwent reoperation for glaucoma. One patient in the trabeculectomy group who failed because of persistent hypotony subsequently underwent a bleb revision for a bleb leak, and a reoperation for glaucoma was later performed when the bleb failed. Seven patients in the tube group and 11 patients in the trabeculectomy group had a reoperation for glaucoma before meeting the failure criteria for inadequate IOP reduction. Among the patients who failed because of inadequate IOP reduction or glaucoma reoperation, the number of medications (mean ± SD) at the time of failure was 2.2 ± 1.4 in the tube group and 2.4 ± 1.1 in the trabeculectomy group ($P = .54$, Student *t* test). Persistent hypotony was the cause of treatment failure in 3 patients in the tube group and 13 patients in the trabeculectomy group. Loss of VA from baseline was seen in 13 patients in the overall group of 16 hypotony failures (81%). Despite failing because of hypotony, 2 patients in the trabeculectomy group and 1 patient in the tube group retained their preoperative level of vision throughout the 5 years of follow-up. When the 3 patients with hypotony and stable vision were reclassified as successes instead of failures, the cumulative probability of failure using survival analysis was 28.6% in the tube group and 44.4% in the trabeculectomy group at 5 years ($P = .003$, log-rank test adjusted for stratum). Loss of light perception vision occurred in 1 patient in each treatment group. No significant difference in the distribution of reasons for failure was present between treatment groups ($P = .43$, exact permutation χ^2 test).

Baseline demographic and clinical features were evaluated as possible predictors for treatment failure and are shown in Table 5. Treatment failures were pooled from both treatment groups for this risk factor analysis. Only assigned treatment was significantly associated with treatment outcome in univariate analysis ($P = .002$, log-rank test). Stratum, age, sex, race, diabetes mellitus, hypertension, lens status, number of previous intraocular surgeries, time since last intraocular surgery, glaucoma type, preoperative number of medications,

TABLE 7. Visual Acuity Results in the Tube Versus Trabeculectomy Study

	Tube Group (n = 107)	Trabeculectomy Group (n = 105)	*P* Value
ETDRS VA, mean ± SD (n)			
Baseline	63 ± 24 (107)	64 ± 20 (105)	.56[d]
5 years	40 ± 34 (37)	53 ± 27 (41)	.068[d]
Change	15 ± 26 (37)	14 ± 25 (41)	.83[d]
Snellen VA, logMAR mean ± SD (n)			
Baseline	.42 ± .54 (107)	.37 ± .38 (105)	.40[d]
5 years	.85 ± .97 (67)	.65 ± .73 (76)	.15[d]
Change	.38 ± .72 (67)	.34 ± .60 (76)	.73[d]
Loss of ≥2 Snellen lines, n (%)[ab]	31[c] (46)	33 (43)	.93[e]
Glaucoma	12	14	
Macular disease	5	5	
Cataract	2	3	
Other	10	16	
Unknown	5	2	

ETDRS = Early Treatment Diabetic Retinopathy Study; SD = standard deviation; VA = visual acuity.

[a]Five-year rate of visual acuity.

[b]Some patients had more than 1 reason for decreased vision.

[c]One patient who did not have Snellen VA measured at 5 years was determined to have lost >2 Snellen lines based on change in ETDRS VA.

[d]Student *t* test.

[e]χ^2 test.

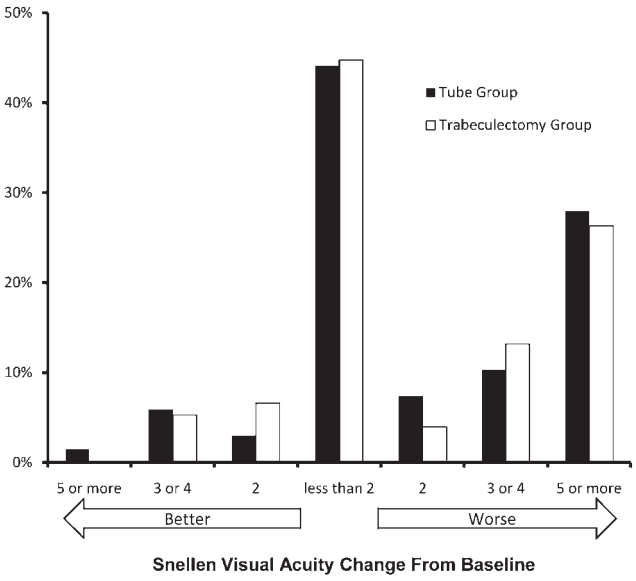

FIGURE 5. Distribution of change in visual acuity from baseline to the 5-year follow-up visit in the Tube Versus Trabeculectomy Study.

preoperative IOP, preoperative Snellen VA, and clinical centers were not associated with treatment failure either univariately or in a multivariate model adjusted for treatment. Separate risk factor analyses were also performed for each treatment group, and none of the baseline factors predicted failure for tube shunt surgery or trabeculectomy with MMC.

• **REOPERATION FOR GLAUCOMA:** Table 6 presents the reoperations that were performed for glaucoma. A higher rate of reoperation for glaucoma was observed in the trabeculectomy group compared with the tube group. The 5-year cumulative reoperation rate for glaucoma using Kaplan-Meier survival analysis was 9% in the tube group and 29% in the trabeculectomy group ($P = .025$, log-rank test adjusted for stratum). A total of 18 patients in the trabeculectomy group underwent additional glaucoma surgery, which involved placement of a tube shunt in 15 patients, a bleb revision with tube shunt placement in 2 patients, and a trabeculectomy with 5-fluorouracil in 1 patient. One of the patients who received a tube shunt subsequently underwent a transscleral cyclophotocoagulation in the study eye as a second reoperation for glaucoma. In the tube group, 8 patients had glaucoma reoperations, including placement of a second tube shunt in 4 patients, transscleral cyclophotocoagulation in 3 patients, and endocyclophotocoagulation performed in conjunction with cataract surgery in 1 patient. Repeat transscleral cyclophotocoagulation was performed in the patient who had endocyclophotocoagulation.

Because the surgeon was not masked to the treatment assignment, a potential bias existed in the decision to reoperate for glaucoma. To evaluate for selection bias, the IOP levels were compared between treatment groups in patients who underwent glaucoma reoperation, as well as those who failed because of inadequate IOP reduction but did not have additional glaucoma surgery. The IOP (mean ± SD) was 21.1 ± 5.7 mm Hg for the 8 patients in the tube group and 27.0 ± 9.0 mm Hg for the 18 patients in the trabeculectomy group at the time of reoperation for glaucoma ($P = .11$, Student t test). The IOP levels were also compared between the 12 patients in the tube group and 11 patients in the trabeculectomy group who failed because of inadequate IOP reduction but did not undergo additional glaucoma surgery during 5 years of follow-up. In this patient subgroup, the IOP (mean ± SD) was 23.0 ± 5.1 mm Hg in the tube group and 20.1 ± 2.6 in the trabeculectomy group ($P = .11$, Student t test). The mean IOP prior to reoperation for glaucoma was similar in the tube and trabeculectomy groups, and no significant difference was seen between treatment groups in mean IOP among patients who failed because of inadequate IOP reduction but did not undergo additional glaucoma surgery.

• **VISUAL ACUITY:** Table 7 and Figure 5 show VA results. Significant decreases in Snellen VA and ETDRS VA were observed in both treatment groups during 5 years of follow-up. Among patients who completed 5-year follow-up visits, logMAR Snellen VA (mean ± SD) decreased 0.38 ± 0.72 units from baseline ($P < .001$, paired t test) and ETDRS VA (mean ± SD) was reduced by 15 ± 26 letters from baseline ($P = .001$, paired t test) in the tube group. In the trabeculectomy group, logMAR Snellen VA (mean ± SD) decreased 0.34 ± 0.60 units ($P < .001$, paired t test) and ETDRS VA (mean ± SD) declined 14 ± 25 letters ($P = .001$, paired t test) from baseline to the 5-year follow-up visit. No significant differences in Snellen VA ($P = .15$, Student t test) or ETDRS VA ($P = .068$, Student t test) were seen between the tube and trabeculectomy groups at 5 years. The changes in Snellen VA ($P = .73$, Student t test) and ETDRS VA ($P = .83$, Student t test) from baseline were also similar between treatment groups in patients who completed 5 years of follow-up. ETDRS VA was not measured at the 5-year follow-up visit in 32 patients in the tube group and 35 patients in the trabeculectomy group. Snellen VA was not assessed at the 5-year visit in 2 patients in the tube group, but 1 of these patients was determined to have lost more than 2 Snellen lines of vision based on change in ETDRS VA.

The rate of loss of 2 or more lines of Snellen VA was similar in the tube and trabeculectomy groups. At 5 years, 31 patients (46%) in the tube group and 33 patients (43%) in the trabeculectomy group had lost 2 or more Snellen lines from baseline ($P = .93$, χ^2 test). The distribution of change in Snellen VA from baseline to 5 years in each treatment group is shown in Figure 5. The examining clinician was asked to provide an explanation for reduction of 2 or more lines of Snellen VA from baseline. The most frequent causes of vision loss after 5 years of follow-up were glaucoma in 12 patients in the tube group and 14 patients in the trabeculectomy group, macular disease in 5 patients in the tube group and 5 patients in the trabeculectomy group, and cataract in 2 patients in the tube group and 3 patients in the trabeculectomy group. Other miscellaneous causes for reduced vision in 10 patients in the tube group included corneal edema, diabetic retinopathy, and retinal detachment. Other causes of vision loss in 16 patients in the trabeculectomy group included corneal edema, suprachoroidal hemorrhage, diabetic retinopathy, dislocated intraocular lens, posterior capsular opacification, and endophthalmitis. The reason for decreased vision was unknown in 5 patients in the tube group and 2 patients in the trabeculectomy group.

DISCUSSION

THE TVT STUDY IS A MULTICENTER CLINICAL TRIAL THAT prospectively enrolled patients with medically uncontrolled glaucoma who had previous cataract extraction with intraocular lens implantation and/or failed filtering surgery and randomized them to surgical treatment with a 350-mm^2 Baerveldt glaucoma implant or a trabeculectomy with MMC. Patients who underwent tube shunt surgery had a higher success rate compared to trabeculectomy during 5 years of follow-up in the study. At 5 years, the cumulative probability of failure was 29.8% in the tube group and 46.9% in the trabeculectomy group. Previously reported data identified a higher failure rate for trabeculectomy with MMC at 1 year and 3 years.[11,12] The TVT Study shows a persistent treatment benefit of tube shunt surgery over trabeculectomy through 5 years of follow-up in this patient group.

The trabeculectomy failure rate in the TVT Study was comparable to other studies,[10,13–23] but the failure rate of tube shunt surgery was lower than in prior reports.[24–33] Based upon a systematic review of the published ophthalmic literature, a panel of glaucoma specialists recently concluded that the rates of failure of trabeculectomy and tube shunts are similar and average approximately 10% per year.[33] The failure rates of trabeculectomy with MMC in the TVT Study (13.5% at 1 year,[11] 30.7% at 3 years,[12] and 46.9% at 5 years) and trabeculectomy with 5-fluorouracil in the Fluorouracil Filtering Surgery Study (FFSS) (16% at 1 year,[13] 29% at 3 years,[14] and 51% at 5 years[10]) were consistent with this estimate, and both are multicenter randomized clinical trials that recruited patients with previous cataract or glaucoma surgery and employed similar success/failure criteria. In contrast, the failure rate of tube shunt surgery averaged about 5% per year in the TVT Study (3.9% at 1 year,[11] 15.1% at 3 years,[12] and 29.8% at

5 years). This more favorable result relative to previous reports may relate to differences in study populations, refinements in surgical technique, and/or variations in the definition of failure/success. The TVT Study enrolled eyes at lower risk of surgical failure than have historically undergone tube shunt surgery (eg, eyes with only prior clear cornea cataract surgery), and it excluded several secondary glaucomas with poorer surgical prognoses (eg, neovascular glaucoma) that were included in other case series of tube shunts.

Both tube shunt surgery and trabeculectomy with MMC were effective in lowering IOP. Placement of a Baerveldt glaucoma implant produced a 41.4% reduction in IOP, and trabeculectomy with MMC achieved a 49.5% decrease in IOP in patients who completed 5 years of follow-up. These results are comparable with previous studies of similar patient groups that reported IOP reduction ranging from 46.4% to 58.3% for tube shunt surgery[25,31] and 38.6% to 61.4% for trabeculectomy with an adjunctive antifibrotic agent.[14,17–19,21–23] Glaucoma specialists have suggested that low IOP levels cannot generally be achieved with tube shunts, and the IOP typically settles in the high teens postoperatively.[33] However, the TVT Study found a mean IOP of 14.4 mm Hg in the tube group at 5 years, and 63.9% had IOP of 14 mm Hg or less.

Treatment success was subdivided into complete and qualified successes, based on the use of supplemental medical therapy. Although the overall success rate was higher for the tube group after 5 years, the rates of complete success were not significantly different between treatment groups. This is consistent with the observed similar use of supplemental glaucoma medications by both the tube and trabeculectomy groups at 5 years. The trabeculectomy group had a progressive increase in adjunctive medical therapy during 5 years of follow-up, while the use of glaucoma medications remained relatively constant in the tube group.

The ideal measure of success for any glaucoma therapy is the prevention of further glaucomatous optic nerve damage with preservation of visual function. We recognize that treatment success for individual patients cannot be defined by an arbitrary IOP level, because individuals vary in their susceptibility to the damaging effect of IOP. Nevertheless, IOP lowering remains the primary goal of all current glaucoma therapy and no other surrogate measure better reflects therapeutic success for this disease at the present time. The outcome criteria for the TVT Study were developed *a priori*, and our definitions of success and failure are similar to previous studies involving the surgical treatment of glaucoma, which facilitates comparison with other published results.[15–32,34–38]

The results of several recent multicenter randomized clinical trials have suggested that IOP of 21 mm Hg or less may not be adequate to prevent glaucomatous progression in many patients.[39–41] In order to determine if the TVT Study results changed if more stringent IOP criteria were applied to define success, several post hoc analyses were performed using alternative outcome criteria. Higher failure rates in the trabeculectomy group compared with the tube group were still seen when the upper IOP level defining success was reduced from 21 mm Hg to 17 mm Hg and 14 mm Hg. Because the differences in treatment outcomes were present using a broad range of IOP success criteria, the study results seem applicable to patients with early or advanced glaucomatous damage.

While the overall failure rate was higher in the trabeculectomy group compared with the tube group, the reasons for failure were distributed similarly between treatment groups. Inadequate IOP reduction was the most common reason for failure in both treatment groups. Failure because of persistent hypotony occurred more frequently in the trabeculectomy group than in the tube group. It has been argued that hypotony may be an acceptable outcome of glaucoma surgery if it is not associated with vision loss.[42] It is noteworthy that the vast majority of patients who failed because of persistent hypotony in the TVT Study also had associated vision loss, and the study results did not significantly change when the 3 patients with hypotony and stable vision were reclassified as successes instead of failures. Several baseline factors were examined as possible risk factors for treatment failure, and only treatment assignment predicted treatment outcome.

The rate of reoperation for glaucoma was higher in the trabeculectomy group relative to the tube group. Patients who fail trabeculectomy and need additional glaucoma surgery will generally undergo repeat trabeculectomy or placement of a tube shunt. However, additional glaucoma surgery in eyes that have failed tube shunt surgery is more complex and usually involves placement of a second tube shunt or cyclodestruction.[34,35] Because investigators in the TVT Study were not masked to the treatment assignment and the decision to reoperate was left to the surgeon's discretion, a potential for bias existed in the decision to reoperate for glaucoma. We explored for the possibility that surgeons may have had a higher threshold to perform additional glaucoma surgery in the tube group than in the trabeculectomy group. No significant difference in mean IOP at the time of failure was seen between treatment groups in patients who had a reoperation for glaucoma, or in patients who failed because of inadequate IOP reduction but did not have additional glaucoma surgery. These observations suggest that no selection bias was present for glaucoma reoperation.

Reduction of VA occurred in both treatment groups during 5 years of follow-up. Snellen and ETDRS VA were similar in the tube and trabeculectomy groups at 5 years, and no significant differences in the rates and reasons for vision loss were present between treatment groups. Vision loss of 2 or more Snellen lines was most frequently attributed to glaucoma by the examining clinicians. The high rate of vision loss from glaucoma in the TVT Study may relate to the advanced stage of disease of many patients, with an average mean

deviation on Humphrey visual field testing of −15.9 decibels in the overall study group at baseline. Some of the causes of vision loss, such as diabetic retinopathy and posterior capsular opacification, were not directly attributable to the surgical procedures under study.

Wilson and associates compared the Ahmed glaucoma valve implant (New World Medical, Inc, Rancho Cucamonga, California, USA) to trabeculectomy with or without an antifibrotic agent in a randomized clinical trial involving 117 patients.[37] Lower mean IOP was observed in the trabeculectomy group, and the Ahmed group had a greater adjunctive medication requirement with a mean follow-up of 9.7 months. The cumulative probabilities of success (IOP <21 mm Hg and at least 15% reduction in IOP from preoperative level) were similar between the 2 treatment groups. This study was performed in Saudi Arabia and Sri Lanka and included patients with all glaucoma types and some eyes that had undergone previous ocular surgery. A follow-up study continued enrollment in Sri Lanka to a total of 123 patients with primary open-angle glaucoma and angle-closure glaucoma without previous ocular surgery.[38] With a mean follow-up of 31 months, mean IOPs and success rates were comparable between the trabeculectomy and Ahmed groups. The difference in study results between the TVT Study and the studies by Wilson and associates may relate to differences in study populations, success and failure criteria, and retention during follow-up. The TVT Study also used the Baerveldt implant for patients randomized to the tube group, and the end plate of this implant has a larger surface area than the Ahmed implant. There is evidence suggesting that implants with larger plates produce greater pressure reduction.[27,33,43]

There are several limitations to the TVT Study. The study population was restricted to patients who had undergone previous cataract extraction with intraocular lens implantation and/or trabeculectomy, and several patient types were ineligible for enrollment. Results of the TVT Study cannot be directly applied to dissimilar patient groups. All patients randomized to the tube group received a 350-mm^2 Baerveldt glaucoma implant, and the study results should not be generalized to different implant types. A trend toward use of a lower dosage of MMC has developed since the TVT Study was initiated,[44] and it is unclear whether the higher MMC dosage in this study may have been associated with a higher rate of hypotony and/or a lower rate of trabeculectomy failure attributable to bleb fibrosis. While aspects of both surgical procedures were standardized (eg, quadrant of tube shunt placement, dosage of MMC), some variation in surgical technique occurred because surgeons were allowed some latitude to perform the operations in a manner with which he or she was comfortable. A subgroup of patients enrolled in the TVT Study (ie, those with a history of prior trabeculectomy with MMC) had already failed 1 treatment arm of the study, and potentially could have introduced bias in favor of the tube group. We felt that the study question of how one surgical procedure compares to the other was clinically relevant in eyes that had failed a MMC trabeculectomy, and a separate stratum (stratum 4) was created for these eyes to facilitate data analysis and address concerns about possible bias. No significant differences in treatment efficacy were observed between strata.

The 5-year results of the TVT Study provide further evidence that the role of tube shunts has appropriately been expanding beyond the surgical management of refractory glaucomas. This study enrolled patients at lower risk of surgical failure than have traditionally had tube shunt surgery. In eyes with previous cataract and/or glaucoma surgery, the TVT Study found that tube shunt surgery had a higher success rate compared to trabeculectomy with MMC during 5 years of follow-up. The 2 surgical procedures were associated with similar IOP reduction and use of supplemental medical therapy at 5 years. The rate of reoperation for glaucoma was higher after trabeculectomy with MMC than tube shunt placement. Vision loss occurred at a similar rate after both procedures.

The TVT Study does not demonstrate clear superiority of one glaucoma operation over the other, but indicates that both tube shunt surgery and trabeculectomy with MMC are viable surgical options for treating medically uncontrolled glaucoma in patients with previous cataract extraction or failed filtering surgery. The study results have supported a shift in practice patterns among glaucoma surgeons toward greater use of tube shunts in similar patient groups. When Chen and associates conducted an anonymous survey of members of the American Glaucoma Society and Japanese Glaucoma Society to evaluate use of antifibrotic agents and tube shunts in 1996, the vast majority of surgeons favored trabeculectomy with MMC for clinical situations requiring glaucoma surgical intervention.[6] Desai and associates readministered the same survey to the American Glaucoma Society membership in 2008 and found a marked increase in the use of tube shunts, with the greatest practice pattern shift occurring in the management of patients with prior cataract and glaucoma surgery.[8] In particular, selection of tube shunts as the preferred surgical approach increased from 7% to 46% in eyes with previous trabeculectomy, and increased from 8% to 45% in eyes with prior extracapsular and intracapsular cataract extraction.

Even though randomized clinical trials like the TVT Study offer the highest level of evidence-based medicine, other factors must be considered when selecting a glaucoma surgical procedure. The surgeon's skill and experience with both operations, the patient's willingness to undergo repeat glaucoma surgery, and the surgeon's planned surgical approach should failure occur are other important factors in surgical decision making. The benefit of tube shunt surgery and trabeculectomy with MMC in reducing IOP must be interpreted in the context of their adverse events. Our companion paper describes the postoperative complications encountered in the TVT Study during 5 years of follow-up and the management of these complications.

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Biosketch

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SUPPLEMENTAL TABLE. Intraocular Pressure and Medical Therapy Among Patients Who Were and Were Not Lost to Follow-up in the Tube Versus Trabeculectomy Study

	Tube Group[a,b]			Trabeculectomy Group[a,b]		
Last Follow-up Visit	Lost to Follow-up	Not Lost to Follow-up	*P* Value	Lost to Follow-up	Not Lost to Follow-up	*P* Value
Baseline[c]						
IOP (mm Hg)	26.2 ± 5.4	24.5 ± 5.1	.12	26.6 ± 4.9	25.1 ± 5.4	.2
Glaucoma medications	3.1 ± 1.2	3.3 ± 1.1	.5	3.1 ± 1.1	2.9 ± 1.3	.4
n	38	69		29	76	
1 year						
IOP (mm Hg)	13.2 ± 6.5	12.4 ± 3.8	.7	10.4 ± 3.3	13.1 ± 6.2	.2
Glaucoma medications	.7 ± 1.2	1.3 ± 1.3	.4	.4 ± 1.1	.5 ± .9	.8
n	3	95		8	84	
2 years						
IOP (mm Hg)	16.3 ± 6.6	13.3 ± 4.6	.2	18.0	12.5 ± 5.4	.3
Glaucoma medications	.3 ± .5	1.4 ± 1.3	.009	2.0	.8 ± 1.2	.3
n	4	83		1	80	
3 years						
IOP (mm Hg)	13.2 ± 4.9	13.3 ± 4.9	1.00	15.0 ± 10.0	13.2 ± 6.5	.6
Glaucoma medications	1.1 ± .9	1.3 ± 1.3	.5	1.0 ± 1.4	1.1 ± 1.5	.9
n	11	73		4	75	
4 years						
IOP (mm Hg)	14.2 ± 3.8	13.1 ± 5.6	.6	12.5 ± 2.9	13.4 ± 6.2	.8
Glaucoma medications	2.0 ± 1.8	1.3 ± 1.3	.3	.6 ± .9	1.2 ± 1.4	.4
n	10	66		5	70	

IOP = intraocular pressure.

[a]Data presented as mean ± standard deviation.

[b]Data not censored after a reoperation for glaucoma.

[c]Baseline IOP and glaucoma medications among patients who did and did not complete 5-year follow-up visits.