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Motility Disturbances in the Tube Versus Trabeculectomy Study During the First Year of Follow-up

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Abstract

PURPOSE—To describe the preoperative and postoperative motility disturbances encountered in the Tube Versus Trabeculectomy (TVT) Study during the first year of follow-up.

DESIGN—Multicenter randomized clinical trial.

METHODS—SETTINGS: Seventeen clinical centers. POPULATION: Patients 18 to 85 years old who had previous trabeculectomy and/or cataract surgery and uncontrolled glaucoma with intraocular pressure ≥18 mm Hg and ≤40 mm Hg on maximum tolerated medical therapy. INTERVENTIONS: 350-mm^2 Baerveldt glaucoma implant or trabeculectomy with mitomycin C (MMC). MAIN OUTCOME MEASURES: Preoperative and postoperative evaluation of ocular motility and diplopia.

RESULTS—Motility disturbances were detected in 55 patients (28%) at baseline. New-onset persistent diplopia was reported in 5 patients (5%) in the tube group and no patients in the trabeculectomy group at 1 year (P = .06). A new postoperative motility disturbance developed or worsened in 7 patients (9.9%) in the tube group and no patients in the trabeculectomy group during the first year of follow-up (P = .005). Postoperative motility disturbances were also associated with increasing age (P < .001) and right eye surgery (P = .044).

CONCLUSIONS—Preoperative motility disturbances were common among patients in the TVT Study. New postoperative motility disturbances were more frequent following tube shunt surgery than trabeculectomy with MMC after 1 year of follow-up.

THE TUBE VERSUS TRABECULECTOMY (TVT) STUDY IS a multicenter randomized clinical trial designed to compare the safety and efficacy of nonvalved tube shunt surgery using the Baerveldt glaucoma implant to trabeculectomy with mitomycin C (MMC) in eyes with previous ocular surgery. Diplopia is an important complication that may occur following tube shunt surgery. The incidence of persistent postoperative strabismus associated with the Baerveldt implant has ranged from 2.1% to 77% in case series. [1–7] The

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TVT Study is the first prospective randomized clinical trial to rigorously evaluate the incidence of preoperative and postoperative motility disturbances in patients undergoing trabeculectomy or placement of a tube shunt.

METHODS

STUDY DESIGN

The study protocol is described in detail in a previous publication.[8] In brief, patients 18 to 85 years of age who had previous cataract extraction with intraocular lens implantation and/or trabeculectomy with intraocular pressure (IOP) ≥18 mm Hg and ≤40 mm Hg on maximum tolerated medical therapy were enrolled in the study. Baseline demographic and clinical information were collected for each patient. One eye of each eligible patient was randomized to placement of a 350-mm^2 Baerveldt glaucoma implant (Advanced Medical Optics, Irvine, California, USA) or trabeculectomy with MMC (0.4 mg/ml for 4 minutes). Follow-up visits were scheduled 1 day, 1 week, 1 month, 3 months, 6 months, 1 year, 18 months, 2 years, 3 years, 4 years, and 5 years postoperatively. Each examination included measurement of Snellen visual acuity (VA), IOP, slit-lamp biomicroscopy, Seidel testing, and ophthalmoscopy. Humphrey visual field (VF) testing and Early Treatment Diabetic Retinopathy Study (ETDRS) VA were evaluated at the annual follow-up visits. Patients were asked about subjective diplopia at every follow-up visit. Persistent diplopia was defined as the new onset of diplopia postoperatively with continued presence at the 6-month follow-up visit or after. This study was monitored by an independent Safety and Data Monitoring Committee.

A formal motility evaluation was performed in all patients at baseline and at the 1-year follow-up visit. Additional motility evaluations were done in those patients with diplopia at the 6-month follow-up visit or after. The cover-uncover and alternate cover tests were performed with the patient looking in primary gaze, upgaze, downgaze, left gaze, and right gaze. Motility evaluations were done with the patient fixating at distance and near targets. Any heterophoria or heterotropia was identified, and deviations were quantified with hand-held prism. In patients who were unable to fixate for cover testing, the deviation was measured by centering the corneal light reflexes with a prism using the modified Krimsky method. Motility data at baseline and 1 year were compared for each position of gaze at both distance and near. A significant postoperative motility disturbance was defined as a worsening of ocular alignment by 4 prism diopters (PD) or more for any measurement. This definition was chosen to reflect the typical variation in measurements observed when repeated motility examinations are performed. Patients were classified as binocular if the best-corrected Snellen VA was better than 20/200 in both eyes and monocular if the best-corrected Snellen VA was 20/200 or worse in one or both eyes.

SURGICAL PROCEDURES

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. The Baerveldt plate was positioned under or over the superior rectus and lateral rectus muscles according to the surgeon’s usual practice, 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.[9,10] The Baerveldt tube was trimmed to extend 1 to 2 mm into the anterior chamber, and the tube was inserted 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 at the superior limbus. A limbus-based or fornix-based conjunctival flap was created, and a fluid-retaining sponge soaked with 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.

STATISTICAL ANALYSIS

Univariate comparisons between treatment groups at baseline were made using the two-sided Student *t* test, χ^2 test, or Fisher exact test. These statistical tests were also used to test for risk factors for preoperative motility disturbance and separately for postoperative development or worsening of motility disturbance. Multivariate analyses were performed using forward stepwise logistic regression analysis. Since no patients in the trabeculectomy group developed a postoperative motility disturbance, only the patients in the tube group were included in this analysis. A *P* value of .05 or less was considered statistically significant.

RESULTS

A BASELINE MOTILITY EXAMINATION WAS PERFORMED IN 200 patients (94.3%) enrolled in the TVT Study, including 101 in the tube group and 99 in the trabeculectomy group. The 12 patients who did not receive a preoperative motility evaluation were excluded from the analyses concerning development or worsening of motility disturbances. Baseline characteristics of these study patients are shown in Table 1. No significant difference in any of the baseline characteristics between treatment groups was observed.

The numbers and types of preoperative motility disturbances are shown in Table 2. A baseline motility disturbance was detected in 55 patients (28%), including 29 in the trabeculectomy group and 26 in the tube group (*P* = .69). The distribution of exodeviations, esodeviations, and vertical deviations was similar in both treatment groups. Diplopia was reported preoperatively in 2 patients in the tube group and 5 patients in the trabeculectomy group (*P* = .28).

Postoperatively, no patients in the trabeculectomy group developed persistent diplopia. Transient diplopia was reported by 1 patient (1%) in the trabeculectomy group during the early postoperative period, which resolved by 3 months. In the tube group, persistent diplopia developed postoperatively in 5 patients (5%). There were 3 additional patients (3%) in the tube group who experienced transient diplopia that resolved within 3 months

postoperatively. The incidence of persistent diplopia was higher in the tube group (5/99) than in the trabeculectomy group (0/92), but this difference did not quite reach statistical significance ($P = .06$).

Postoperative motility examinations were completed at the 1-year follow-up visit in 71 patients (70.3%) in the tube group and 76 patients (76.8%) in the trabeculectomy group. No patients in the trabeculectomy group developed a postoperative motility disturbance. There were 7 patients (9.9%) in the tube group who developed motility disturbances postoperatively, including 5 who experienced a new disturbance and 2 who had worsening of an existing disturbance. Postoperative motility disturbances were more common in the tube group than in the trabeculectomy group ($P = .005$).

Among the 7 patients with postoperative motility disturbances in the tube group, 4 appeared to follow a similar strabismus pattern (Table 3) consisting of an exotropia and hypertropia in the operated eye that worsened with down-gaze. Among the other 3 patients with new postoperative motility disturbances, 1 had an esotropia that was present when the operated eye was moved into lateral gaze consistent with lateral rectus dysfunction and 2 patients had comitant exotropias.

Risk factor analysis was performed to evaluate possible baseline predictors of preoperative and postoperative motility disturbances, and the results are shown in Table 4. Age, gender, ethnicity, study eye, treatment, binocularity, and VF mean deviation and VF pattern standard deviation (PSD) were not associated with baseline motility disturbances. However, tropias were more common among monocular patients occurring in 11 of 46 (24%) with monocular status compared to 16 of 153 (11%) with binocular status ($P = .037$). Increasing age ($P < .001$), right operative eye ($P = .044$), and treatment with a tube shunt ($P = .005$) were significant predictors for development of a new or worsening postoperative motility disturbance. The presence of a baseline motility disturbance was not associated with subsequent worsening of the disturbance after surgery. Monocularity, gender, ethnicity, VF mean deviation, VF PSD, and postoperative IOP were also not significant predictors of postoperative motility disturbances. Multivariate logistic regression confirmed these results.

Baseline risk factors for development of postoperative diplopia were similar to those for development of postoperative motility disturbances. Older age ($P < .001$) and right eye surgery ($P = .022$) were statistically significant, and treatment was borderline significant ($P = .06$).

The association between surgical technique and postoperative motility disturbances was investigated. The Baerveldt plate was placed under the adjacent rectus muscles in only 1 patient (1%) and over the muscles in 70 patients (99%). The 1 patient who had positioning of the plate over the muscles did not develop a postoperative motility disturbance. Tube shunt implantation was performed using a fornix-based conjunctival flap in 49 patients (69%), and 4 (8%) developed a new or worsening motility disturbance after surgery. A limbus-based flap was used in 22 patients (31%), and 3 (14%) were found to have a postoperative motility disturbance. There was no significant association between the type of

conjunctival flap and the development of a new or worsening motility disturbance postoperatively (P = .7, Fisher exact test).

Comparisons were made between the 147 patients who had a postoperative motility evaluation and the 53 patients who did not. Most baseline variables, such as gender, race, age, and number of glaucoma medications, were similar between these 2 groups. Patients without an examination tended to have a higher baseline IOP (27 mm Hg) vs those with an examination (25 mm Hg) (P = .016); a worse mean deviation on Humphrey VF test (− 19.6 vs −15.1) (P = .006); and a worse median baseline VA (20/40 vs 20/30) (P = .043). However, no difference was observed between treatment groups, ie, 30 of 101 (30%) of the Baerveldt group and 23 of 99 (23%) of the trabeculectomy group did not have a postoperative motility examination (P = .38).

DISCUSSION

OCULAR MOTILITY DISTURBANCES ARE KNOWN TO OCCUR after tube shunt surgery. However, the reported prevalence of this complication has been quite variable in previous studies (Table 5). The TVT Study provided a unique opportunity to investigate motility disturbances following tube shunt placement in the setting of a large prospective randomized clinical trial. Motility examinations were performed preoperatively and post-operatively on enrolled patients. The trabeculectomy group served as a control group to identify the incidence of motility disturbances attributable to tube shunt implantation.

Asymptomatic motility disturbances were a common finding at baseline. Previous studies suggest that motility disturbances are more common with age[11,12] and cataract formation.[13] However, the prevalence of motility disturbances in a moderately advanced glaucoma population has not previously been reported to our knowledge. It has been proposed that partial sensory deprivation, including VF or acuity deficits, may cause or exacerbate sensory heterophorias and heterotropias.[13] We found that VA, in particular acuity less than 20/200 in one or both eyes, was associated with preoperative tropias. It is not surprising that monocular status is significantly associated with tropias at baseline, as binocular fusion can maintain ocular alignment in the presence of a phoria but the deviation manifests as a tropia when binocular fusional control is not present. However, no significant association between preoperative motility disturbances and VF mean deviation and PSD was found in the present study.

The incidence of postoperative motility disturbances after tube shunt surgery that has been reported in retrospective studies may be confounded by several variables. The high incidence of motility disturbances at baseline in the TVT Study suggests that previous case series, which typically have not measured preoperative motility, may have overestimated the number of motility disturbances attributable to the surgery. Conversely, motility risk may have been underestimated in retrospective studies because motility disturbances were identified only by records review rather than prospectively planned motility examinations. The high incidence of heterophorias and heterotropias at baseline in the TVT Study raises the question of whether patients with a preoperative motility disturbance are more likely to experience worsening of their disturbance postoperatively. In our study, we did not find a

higher incidence of worsening disturbance postoperatively in patients with preoperative deviations; however, there were too few patients to rule this out as a risk factor.

Increasing age and right eye surgery were significant risk factors for the development of postoperative motility disturbances. Previous studies have found that fusional vergences[11] and ocular movements[12] decrease with aging, and this may explain the association between postoperative motility disturbances and increasing age in the present study. We are unable to identify a reason why right eye surgery would increase the risk of motility disturbances postoperatively. However, the large number of significance tests that were performed in this study increases the probability of finding statistically significant results by chance alone.

In the only previous study that prospectively evaluated ocular motility before and after tube shunt surgery, Dobler-Dixon and associates reported 24 consecutive patients who underwent double-plate Molteno implantation.[14] With follow-up ranging from 6 to 12 months, 5 patients (21%) had transient motility disturbances within the first 6 months, and 6 patients (25%) had persistent disturbances at 1 year, including 4 (17%) with diplopia and 1 (4%) requiring extraocular muscle surgery. These prospective data from double-plate Molteno implantation significantly exceeded the rates of motility disturbance encountered in the TVT Study with the Baerveldt glaucoma implant.

Smith and associates[7] reported a retrospective case series of 30 patients who underwent placement of a Baerveldt glaucoma implant. Significant restriction of eye movement in the direction of the implant was observed in 23 patients (77%), and 11 patients (37%) reported diplopia in primary gaze. Explantation of the device was required in 5 patients to manage the strabismus. Superotemporally placed implants resulted in hypertropia (average, 8 PD) and exotropia (average, 9 PD) in 8 of 15 patients (53%), with all but one experiencing persistent diplopia. Superonasal implants produced a consistent hypotropia (average, 9 PD) and exotropia (average, 9 PD) in 5 of 11 patients (45%), with poor elevation in adduction (ie, Brown syndrome). Interestingly, the same authors found the incidence of strabismus to be 6% among 100 patients with double-plate Molteno implants.[7] Although the frequency of motility disturbances reported by Smith and associates was much higher than in other reported studies, the manufacturer of the Baerveldt glaucoma implant subsequently added fenestrations to the plate. The purpose of these fenestrations was to allow fibrous ingrowth through the plate, thereby reducing bleb height and the risk of restrictive strabismus.

In a randomized trial comparing the 350- and 500-mm^2 Baerveldt plates in 73 patients, postoperative strabismus developed in 16% and 19% of patients, respectively. Although follow-up motility examinations to determine which disturbances were persistent proved difficult to obtain, 6 patients (8%) required extraocular muscle surgery after 6 months.[5] Longer-term follow-up of 103 patients from the same trial reported that 16 patients (15.5%) had persistent strabismus at 1 year, including 17% for the 350-mm^2 and 14% for the 500-mm^2 Baerveldt implant.[6] Interestingly, a similar proportion of fenestrated and nonfenestrated implants were used in each group (18 of 53 vs 19 of 50). Fewer cases of strabismus were observed in eyes with fenestrated implants, though the numbers were too few to determine significance.[6]

The incidence of motility disturbances in the TVT Study of 9.9% is comparable to that reported in other studies (Table 5), which ranged from 2% to 77%.[1–7,15,16] The incidence of diplopia was 5% in our study, and ranged from 1.4% to 37% in other reports.[1,2,4–7,14–16] Previously published data and the TVT Study show that many patients with persistent disturbances do not report subjective diplopia. This likely reflects a high prevalence of advanced VF loss and/or monocularity among glaucoma populations that receive drainage implants.

A prior systematic review of the glaucoma implant literature by Hong and associates[17] suggested that the incidence of diplopia was significantly higher with the Baerveldt implant compared with other implants. In one large retrospective series of 159 patients undergoing Ahmed glaucoma valve implantation, Huang and associates[16] found diplopia in 4 patients (2.5%), 3 requiring extraocular muscle surgery and 1 who had removal of the device. To date, the 7 patients who developed motility disturbances in the TVT Study have not needed surgery to correct strabismus. Treatment was not required in 5 patients, and the other 2 patients have been treated with prism-containing spectacles.

The mechanism of motility disturbance associated with Baerveldt implants was described in a case series by Muñoz and Parrish.[18] They reported 4 patients with strabismus following placement of a 350-mm^2 Baerveldt implant, each case presenting as a persistent exotropia (range, 8 to 25 PD) and hypertropia (range, 3 to 16 PD) in the surgically treated eye. All implants were positioned superotemporally, and in each case the strabismus appeared restrictive in nature with positive forced duction testing, and appeared coincident with bleb formation. This characteristic finding, occurring in Patients 1 through 4 in the present study (Table 3), likely represents a persistent lengthwise stretching of the extraocular muscles by an underlying bleb. Patient 5 demonstrated evidence of persistent dysfunction of the lateral rectus muscle, from either bleb formation, surgical trauma to the muscle, or scarring between the muscle and the implant device. Lastly, Patients 6 and 7 showed a persistent exotropia, possibly related to a ballooning or dragging effect from temporal bleb formation. Reported factors that may lower the risk of motility disturbances after tube shunt surgery include reduced surgical trauma,[19] reduced fibrosis,[20,21] avoidance of superonasal placement,[22] and reduced implant size.[6,19] All implants used in the TVT Study were uniformly 350 mm^2 in size and placed in the superotemporal quadrant, and antifibrotic agents were not permitted.

In the TVT Study, complete resolution of the postoperative diplopia occurred within 3 months in 3 patients (3%). The remaining 5 (5%) had persistent diplopia. The 3 transient cases likely had extraocular muscle or peribulbar swelling attributable to surgical trauma. Ayyala and associates[15] reported an incidence of transient diplopia of 4.7% (4 of 85) patients who had Ahmed implantation; 50% of these occurred within 3 months of surgery. Dobler-Dixon and associates[14] reported a 46% incidence of temporary motility disturbance after Molteno implantation, with about half (5 of 11) resolving after 6 months. In contrast, Smith and associates reported a 77% incidence of early postoperative motility disturbance with the unfenestrated Baerveldt implant, and none resolved over time.[7]

There are several weaknesses in our study. Preoperative motility examinations were not performed in 12 of 212 patients (5.7%) enrolled in the TVT Study, and postoperative motility evaluations at the 1-year visit were lacking in 65 of 200 patients (32.5%) in the present study. This may have introduced some bias into the reported incidence of motility disturbance. Patients who complained of diplopia or manifested obvious motility disturbances were probably more likely to have undergone a formal motility evaluation, and this could have resulted in an overestimation of the incidence of diplopia and motility disturbances in this study. Furthermore, many glaucoma patients in this study (23%) had poor vision in at least 1 eye and were unable to fixate for cover testing. These patients, therefore, had to be assessed by Krimsky (prism light reflex) examination, a method known to provide less resolution in quantifying motility defects compared with cover testing.[23] The power of our study to detect risk factors for postoperative motility disturbances was limited by the low occurrence rate of acquired disturbances. Although patients were classified as monocular if their best-corrected VA was 20/200 or worse in 1 or both eyes, it is still possible to experience diplopia with vision worse than 20/200. Additionally, forced duction testing was not performed to differentiate restrictive from paretic motility disturbances.

In summary, preoperative motility disturbances were common in patients enrolled in the TVT Study. Persistent postoperative motility disturbances developed or worsened more frequently following tube shunt surgery than trabeculectomy with MMC during the first year of follow-up. The development of motility disturbances postoperatively was associated with advancing age and right eye surgery. Patients who are being considered for tube shunt surgery should be made aware of the risk of motility disturbances postoperatively.

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Appendix

THE TUBE VERSUS TRABECULECTOMY STUDY GROUP

Participating Centers and Committees in the Tube Versus Trabeculectomy Study Clinical Centers:

- **Bascom Palmer Eye Institute, Miller School of Medicine, University of Miami**: *Miami, Florida*. Steven Gedde (Principal Investigator); Co-investigators: Douglas Anderson, Donald Budenz, Madeline Del Calvo, Francisco Fantes, David Greenfield, Elizabeth Hodapp, Richard Lee, Alexia Marcellino, Paul Palmberg, and Richard Parrish II.

- **Duke University**: *Durham, North Carolina*. Leon Herndon (Principal Investigator); Co-investigators: Pratap Challa and Cecile Santiago-Turla.
- **Indiana University**: *Indianapolis, Indiana*. Darrell WuDunn (Principal Investigator).
- **Loyola University**: *Maywood, Illinois*. Geoffrey Emerick (Principal Investigator).
- **Medical College of Wisconsin**: *Milwaukee, Wisconsin*. Dale Heuer (Principal Investigator).
- **Medical University of South Carolina**: *Charleston, South Carolina*. Alexander Kent (Principal Investigator); Co-investigators: Carol Bradham and Lisa Langdale.
- **Moorfields Eye Hospital**: *London, England*. Keith Barton (Principal Investigator); Co-investigators: Francesca Amalfitano and Poornima Rai.
- **New York Eye and Ear Infirmary**: *New York, New York*. Paul Sidoti (Principal Investigator); Co-investigators: Amy Gedal, James Luayon, Roma Ovase, and Katy Tai.
- **Scripps Clinic**: *La Jolla, California*. Quang Nguyen (Principal Investigator); Co-investigator: Neva Millar.
- **St Louis University**: *St Louis, Missouri*. Steven Shields (Principal Investigator); Co-investigators: Kevin Anderson and Frank Moya.
- **University of California Davis**: *Sacramento, California*. James Brandt (Principal Investigator); Co-investigators: Michele Lim and Marilyn Sponzo.
- **University of Florida**: *Gainesville, Florida*. Mark Sherwood (Principal Investigator); Co-investigator: Revonda Burke.
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- **University of Southern California**: *Los Angeles, California*. Rohit Varma (Principal Investigator); Co-investigators: Brian Francis and Frances Walonker.
- **University of Texas Houston**: *Houston, Texas*. Robert Feldman (Principal Investigator); Co-investigators: Laura Baker, Nicholas Bell, JoLene Carranza, and Athena Espinoza.
- **University of Virginia**: *Charlottesville, Virginia*. Bruce Prum (Principal Investigator); Co-investigator: Janis Beall.
- **University of Wisconsin**: *Madison, Wisconsin*. Todd Perkins (Principal Investigator); Co-investigators: Paul Kaufman, Tracy Perkins, and Barbara Soderling.
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Safety and Data Monitoring Committee: Philip Chen, William Feuer, Joyce Schiffman, Kuldev Singh, George Spaeth, and Martha Wright.

Steering Committee: Keith Barton, James Brandt, Geoffrey Emerick, Robert Feldman, Steven Gedde, Leon Herndon, Dale Heuer, Alexander Kent, Quang Nguyen, Richard Parrish II, Todd Perkins, Bruce Prum, Mark Sherwood, Steven Shields, Paul Sidoti, Gregory Skuta, Rohit Varma, and Darrell WuDunn.

Study Chairmen: Steven Gedde, Dale Heuer, and Richard Parrish II.

REFERENCES

1. Harbick KH, Sidoti PA, Budenz DL, et al. Outcomes of inferonasal Baerveldt glaucoma drainage implant surgery. J Glaucoma. 2006; 15:7–12. [PubMed: 16378010]
2. Tsai JC, Johnson CC, Dietrich MS. The Ahmed shunt versus the Baerveldt shunt for refractory glaucoma: a single-surgeon comparison of outcome. Ophthalmology. 2003; 110:1814–1821. [PubMed: 13129882]
3. Krishna R, Godfrey DG, Budenz DL, et al. Intermediate-term outcomes of 350-mm^2 Baerveldt glaucoma implants. Ophthalmology. 2001; 108:621–626. [PubMed: 11237919]
4. Roy S, Ravinet E, Mermoud A. Baerveldt implant in refractory glaucoma: long-term results and factors influencing outcome. Int Ophthalmol. 2001; 24:93–100. [PubMed: 12201350]
5. Lloyd MA, Baerveldt G, Heuer DK, Minckler DS, Martone JF. Initial clinical experience with the Baerveldt implant in complicated glaucomas. Ophthalmology. 1994; 101:640–650. [PubMed: 8152758]
6. Britt MT, LaBree LD, Lloyd MA, et al. Randomized clinical trial of the 350-mm^2 versus the 500-mm^2 Baerveldt implant: longer term results: is bigger better? Ophthalmology. 1999; 106:2312–2318. [PubMed: 10599663]
7. Smith SL, Starita RJ, Fellman RL, Lynn JR. Early clinical experience with the Baerveldt 350-mm^2 glaucoma implant and associated extraocular muscle imbalance. Ophthalmology. 1993; 100:914–918. [PubMed: 8510906]
8. Gedde SJ, Schiffman JC, Feuer WJ, Parrish RK II, Heuer DK, Brandt JD. Tube Versus Trabeculectomy Study Group. The tube versus trabeculectomy study: design and baseline characteristics of study patients. Am J Ophthalmol. 2005; 140:275–287. [PubMed: 16086949]
9. Trible JR, Brown DB. Occlusive ligature and standardized fenestration of a Baerveldt tube with and without antime-tabolites for early postoperative intraocular pressure control. Ophthalmology. 1998; 105:2243–2250. [PubMed: 9855154]
10. Emerick GT, Gedde SJ, Budenz DL. Tube fenestrations in Baerveldt glaucoma implant surgery: 1-year results compared with standard implant surgery. J Glaucoma. 2002; 11:340–346. [PubMed: 12169972]
11. Alvarez CP, Puell MC, Sanchez-Ramos C, Villena C. Normal values of distance heterophoria and fusional vergence ranges and effects with age. Graefes Arch Clin Exp Ophthalmol. 2006; 244:821–824. [PubMed: 16331485]
12. Clark RA, Isenberg SJ. The range of ocular movements decreases with aging. J AAPOS. 2001; 5:26–30. [PubMed: 11182669]
13. Spierer A, Priel A, Sachs D. Strabismus in senile cataract patients. J AAPOS. 2005; 9:422–425. [PubMed: 16213390]
14. Dobler-Dixon AA, Cantor LB, Sondhi N, Ku WS, Hoop J. Prospective evaluation of extraocular motility following double-plate Molteno implantation. Arch Ophthalmol. 1999; 117:1155–1160. [PubMed: 10496387]
15. Ayyala RS, Zurakowski D, Smith JA, et al. A clinical study of the Ahmed glaucoma valve implant in advanced glaucoma. Ophthalmology. 1998; 105:1968–1976. [PubMed: 9787371]
16. Huang MC, Netland PA, Coleman AL, et al. Intermediate-term clinical experience with the Ahmed glaucoma valve implant. Am J Ophthalmol. 1999; 127:27–33. [PubMed: 9932995]

17. Hong CH, Arosemena A, Zurakowski D, Ayyala RS. Glaucoma drainage devices: a systematic literature review and current controversies. Surv Ophthalmol. 2005; 50:48–60. [PubMed: 15621077]

18. Muñoz M, Parrish RK II. Strabismus following implantation of Baerveldt drainage devices. Arch Ophthalmol. 1993; 111:1096–1099. [PubMed: 8352692]

19. Christmann LM, Wilson ME. Motility disturbances after Molteno implants. J Pediatr Ophthalmol Strabismus. 1992; 29:44–48. [PubMed: 1583580]

20. Prata JA Jr. Minckler DS, Green RL. Pseudo-Brown's syndrome as a complication of glaucoma drainage implant surgery. Ophthalmic Surg. 1993; 24:608–611. [PubMed: 8233335]

21. Coats DK, Paysse EA, Orenga-Nania S. Acquired Pseudo-Brown's syndrome immediately following Ahmed valve glaucoma implant. Ophthalmic Surg Lasers. 1999; 30:396–397. [PubMed: 10334029]

22. Ball SF, Ellis GS Jr. Herrington RG, Liang K. Brown's superior oblique tendon syndrome after Baerveldt glaucoma implant. Arch Ophthalmol. 1992; 110:1368. [PubMed: 1417532]

23. Choi RY, Kushner BJ. The accuracy of experienced strabismologists using the Hirschberg and Krimsky test. Ophthalmology. 1998; 105:1301–1306. [PubMed: 9663237]

TABLE 1

Baseline Characteristics of Tube Versus Trabeculectomy Motility Study Patients

	Tube Group (n = 101)	Trabeculectomy Group (n = 99)	*P* value
Age (yrs), mean ± SD	71.1 ±11.0	71.3 ± 9.6	.89[a]
Gender, n (%)			
Male	41 (41)	54 (55)	.067[b]
Female	60 (59)	45 (45)	
Race, n (%)			
White	50 (50)	41 (41)	.53[c]
Black	36 (36)	38 (38)	
Hispanic	12 (12)	18 (18)	
Other	3 (3)	2 (2)	
IOP (mm Hg), mean ± SD	25.4 ± 5.2	25.7 ± 5.4	.68[a]
Glaucoma medications, mean ± SD	3.2 ±1.1	3.0 ± 1.3	.24[a]
Diagnosis, n (%)			
POAG	82 (81)	79 (80)	.069[c]
CACG	7 (7)	10 (10)	
PXFG	7 (7)	1 (1)	
PG	1 (1)	0	
Other	4 (4)	9 (9)	
Lens status, n (%)			
Phakic	21 (21)	19 (19)	.92[c]
PCIOL	77 (76)	76 (77)	
ACIOL	3 (3)	4 (4)	
Previous intraocular surgery, mean ± SD	1.3 ± 0.5	1.2 ± 0.6	.40[a]
ETDRS VA, mean ± SD	62.5 ± 24.4	64.6 ± 18.8	.50[a]
Snellen VA			
Median	20/30	20/40	.81[d]
Range	20/17 to HM	20/20 to 20/500	
Binocularity			
Monocular	29 (29)	18 (18)	.11[b]
Binocular	72 (71)	81 (82)	
Humphrey visual fields			
MD, mean ± SD	−16.0 ± 10.4	−15.9 ± 9.6	.94[a]
PSD, mean ± SD	7.0 ± 3.6	7.1 ± 3.6	.89[a]

ACIOL = anterior chamber intraocular lens; CACG = chronic angle-closure glaucoma; ETDRS = Early Treatment Diabetic Retinopathy Study; 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; yrs = years.

[a] Student *t* test.

[b] χ^2 test.

[c] Exact permutation χ^2 test.

[d] Mann-Whitney *U* test.

TABLE 2

Preoperative Ocular Alignment of Tube Versus Trabeculectomy Study Patients

	Tube Group (n = 101)	Trabeculectomy Group (n = 99)	*P* value
Orthophoric			
Distance	87	78	.24
Near	76	70	.57
Both	75	70	.69
Esodeviation			
Distance	0	2	.24
Near	0	2	.24
Exodeviation			
Distance	14	19	.41
Near	25	27	.81
Vertical deviation			
Distance	2	3	.68
Near	2	3	.68
Diplopia	2	5	.28
Total number of patients with motility disturbances[a]	26	29	.69

[a]Some patients had both horizontal and vertical deviations.

TABLE 3

Persistent Postoperative Motility Disturbances in Tube Versus Trabeculectomy Study

Patient No./ Gender/Age (yrs)	Treatment Group	Study Eye	Postoperative VA		Preoperative Motility	Postoperative Motility	Diplopia		Management
			RE	LE			Preoperative	Postoperative	
1/F/79	Tube	RE	20/25	20/25	Orthophoric (D/N)	12 RHT, worse in downgaze (D/N) 10 XT (N)	No	Yes	Prism
2/F/79	Tube	RE	20/25	20/50	Orthophoric (D/N)	8 RHT, worse in downgaze (D/N) 8 XT (D/N)	No	Yes	Prism
3/F/77	Tube	RE	LP	20/400	Orthophoric (D) 10 XT (N)	20 RHT (D/N) 20 XT (D/N)	No	No	None
4/M/79	Tube	LE	20/25	20/60	14 XT (D) 16 XT (N)	3 LHT in downgaze (N/D) 35 XT (D) 40 XT (N)	No	No	None
5/M/83	Tube	RE	20/50	20/20	Orthophoric (D/N)	10 ET in right gaze (N/D)	No	Yes	None
6/M/84	Tube	RE	20/25	20/30	Orthophoric (D/N)	Orthophoric (D) 10 X(T) (N)	No	Yes (near only)	None
7/M/78	Tube	RE	20/40	20/30	Orthophoric (D/N)	2 X(T) (D) 4 X(T) (N)	No	Yes	None

D = distance; ET = esotropia; LE = left eye; LHT = left hypertropia; N = near; RE = right eye; RHT = right hypertropia; XT = exotropia; X(T) = intermittent exotropia; VA = visual acuity; yrs = years.

TABLE 4

Risk Factor Analysis for Preoperative and New Postoperative Motility Disturbances

	Preoperative			Postoperative		
Risk Factor	**Motility Disturbance (n = 55)**	**No Motility Disturbance (n = 145)**	***P* value**	**New Motility Disturbance (n = 7)**	**No New Motility Disturbance (n = 140)**	***P* value**
Age (yrs), n (%)						
<60 years	6 (11)	23 (16)		0	21 (15)	
60–69	20 (36)	35 (24)		0	42 (30)	
70–79	23 (42)	52 (36)		5 (71)	51 (36)	
≥80	6 (11)	35 (24)		2 (29)	26 (19)	
Mean ± SD	70.3 ± 9.7	71.5 ± 10.6	.44[a]	80.4 ± 2.6	70.8 ± 10.3	<.001[a]
Gender, n (%)						
Male	25 (45)	70 (48)	.84[b]	4 (57)	67 (48)	.71[c]
Female	30 (55)	75 (52)		3 (43)	73 (52)	
Ethnicity, n (%)						
White	19 (35)	72 (50)		4 (57)	69 (49)	
Black	24 (44)	50 (34)		3 (43)	50 (36)	
Hispanic	10 (18)	20 (14)		0	19 (14)	
Other	2 (4)	3 (2)	.28[c]	0	2 (1)	.78[c]
Study eye, n (%)						
Right	26 (47)	69 (48)	1.00[b]	6 (86)	59 (42)	.044[c]
Left	29 (53)	76 (52)		1 (14)	81 (58)	
Treatment, n (%)						
Tube	26 (47)	75 (52)	.69[b]	7 (100)	64 (46)	.005[c]
Trabeculectomy	29 (53)	70 (48)		0	76 (54)	
Binocularity at baseline, n (%)						
Monocular	13 (24)	34 (23)	1.00[b]	0	30 (21)	.35[c]
Binocular	42 (76)	111 (77)		7 (100)	110 (79)	
Humphrey VF MD (decibels) at baseline, n (%)						
>−6	6 (12)	31 (24)		1 (14)	30 (23)	

Risk Factor	Preoperative			Postoperative		
	Motility Disturbance (n = 55)	No Motility Disturbance (n = 145)	*P* value	New Motility Disturbance (n = 7)	No New Motility Disturbance (n = 140)	*P* value
−6 to −12	10 (20)	22 (17)		1 (14)	27 (21)	
<−12	33 (67)	79 (60)		5 (71)	72 (56)	
Mean ± SD	−16.9 ± 8.6	−15.9 ± 9.8	.52[a]	−15.0 ± 8.1	−15.1 ± 9.6	.97[a]
Humphrey VF PSD (decibels) at baseline, n (%)						
<5	14 (29)	43 (33)		2 (29)	46 (36)	
5–10	25 (51)	54 (41)		5 (71)	51 (40)	
>10	10 (20)	35 (27)		0	32 (25)	
Mean ± SD	6.9 ± 3.4	7.1 ± 3.7	.79[a]	7.3 ± 3.2	6.9 ± 3.7	.79[a]
Preoperative motility disturbance, n (%)	—	—	—			
Present				5 (71)	98 (70)	1.00[c]
Absent				2 (29)	42 (30)	
Postoperative IOP (mm Hg), n (%)	—	—	—			
<12				3 (43)	61 (47)	
12–18				3 (43)	59 (45)	
>18				1 (14)	11 (8)	
Mean ± SD				11.9 ± 5.0	12.7 ± 5.2	.69[a]

MD = mean deviation; PSD = pattern standard deviation; SD = standard deviation; VA = visual acuity; VF = visual field; yrs = years.

[a] Student *t* test.

[b] χ^2 test.

[c] Exact permutation χ^2 test.

TABLE 5

Comparison of Reported Incidences of Persistent Motility Disturbance and Diplopia Following Tube Shunt Surgery in Published Studies

Authors	Implant Type	Study Design	Implant Location	N	Incidence of Diplopia[a]	Incidence of Strabismus[a]
Present study	Baerveldt	Randomized clinical trial	Superotemporal	101	5%	9.9%
Harbick and associates[1]	Baerveldt	Retrospective case series	Inferonasal	182	2%	N/R
Tsai and associates[2]	Baerveldt	Retrospective case series	Superotemporal	70	1.4%	N/R
Krishna and associates[3]	Baerveldt	Retrospective case series	Variable	65	N/R	3%
Roy and associates[4]	Baerveldt	Retrospective case series	N/R	51	2.1%	2.1%
Lloyd and associates[5]	Baerveldt	Randomized clinical trial	Variable	73	8%	18%
Britt and associates[6]	Baerveldt	Randomized clinical trial	Variable	103	1.9%	15.5%
Smith and associates[7]	Baerveldt	Retrospective case series	Variable	30	37%	77%
Dobler-Dixon and associates[14]	Molteno	Prospective clinical series	Variable	24	17%	25%
Smith and associates[7]	Molteno	Retrospective case series	Variable	100	N/R	6%
Ayyala and associates[15]	Ahmed	Retrospective case series	N/R	85	2.4%	N/R
Huang and associates[16]	Ahmed	Retrospective case series	N/R	159	2.5%	N/R

N = number of subjects studied; N/R = not reported.

[a]Only persistent cases were tabulated.