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# The Primary Tube Versus Trabeculectomy Study

## Methodology of a Multicenter Randomized Clinical Trial Comparing Tube Shunt Surgery and Trabeculectomy with Mitomycin C

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**Purpose:** To describe the methodology of the Primary Tube Versus Trabeculectomy (PTVT) Study.

**Design:** Multicenter randomized clinical trial.

**Participants:** Patients with medically uncontrolled glaucoma and no prior incisional ocular surgery.

**Methods:** Patients are being enrolled at 16 clinical centers and randomly assigned to treatment with a tube shunt (350-mm<sup>2</sup> Baerveldt glaucoma implant) or trabeculectomy with mitomycin C (0.4 mg/ml for 2 minutes).

**Main Outcome Measures:** The primary outcome measure is the rate of surgical failure, defined as intraocular pressure (IOP) more than 21 mmHg or reduced by less than 20% from baseline, IOP of 5 mmHg or less, reoperation for glaucoma, or loss of light perception vision. Secondary outcome measures include IOP, glaucoma medical therapy, visual acuity, visual fields, and surgical complications.

**Conclusions:** Practice patterns vary in the surgical management of glaucoma, and opinions differ among surgeons regarding the preferred primary operation for glaucoma. The PTVT Study will provide valuable information comparing the 2 most commonly performed glaucoma surgical procedures. *Ophthalmology* 2017;■:1–8 © 2017 by the American Academy of Ophthalmology



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Glaucoma surgery generally is indicated when additional intraocular pressure (IOP) reduction is needed despite the use of maximum tolerated medical therapy and appropriate laser treatment. Trabeculectomy and tube shunt implantation are the most commonly performed incisional glaucoma procedures worldwide. Trabeculectomy historically has been the initial glaucoma operation of choice, and tube shunts have been reserved for refractory glaucomas at high risk of filtration failure. However, a growing concern about bleb-related complications associated with trabeculectomy and a greater appreciation for the efficacy of tube shunts has prompted an expanded use of shunts as an alternative to trabeculectomy.

Medicare claims data show a 72% decrease in the number of trabeculectomy procedures and a concurrent 410% increase in tube shunt implantation between 1994 and 2012.<sup>1</sup> Anonymous surveys of the American Glaucoma Society membership also have demonstrated a shift in glaucoma surgical practice patterns.<sup>2–5</sup> The use of trabeculectomy to manage medically uncontrolled glaucoma in several clinical settings has declined, whereas selection of

tube shunts has risen. These surveys also indicate differing opinions regarding the preferred primary operation for glaucoma.<sup>4,5</sup>

The Primary Tube Versus Trabeculectomy (PTVT) Study is a multicenter randomized clinical trial comparing the safety and efficacy of tube shunt implantation and trabeculectomy with mitomycin C (MMC) in eyes without prior ocular surgery. The goal of this investigator-initiated trial is to provide information that will assist in surgical decision making in similar patient groups. This article describes the methodology of the PTVT Study.

### Methods

Patients with medically uncontrolled glaucoma who have not previously undergone incisional ocular surgery are randomized in a 1:1 ratio to placement of a 350-mm<sup>2</sup> Baerveldt glaucoma implant (Abbott Medical Optics, Santa Ana, CA) or trabeculectomy with MMC. A synopsis of the PTVT Study is provided in Table 1. The institutional review board at each clinical center approved the study protocol before recruitment began. An effort is being made to

Table 1. The Primary Tube Versus Trabeculectomy Study Synopsis

Purpose	To compare the safety and efficacy of tube shunt surgery and trabeculectomy with MMC
Treatment groups	350-mm <sup>2</sup> Baerveldt glaucoma implant Trabeculectomy with MMC (0.4 mg/ml for 2 minutes)
Patient eligibility	
Inclusion criteria	Age 18–85 yrs Glaucoma inadequately controlled with tolerated medical therapy with IOP $\geq 18$ mmHg and $\leq 40$ mmHg No previous incisional ocular surgery
Exclusion criteria	No light perception vision Pregnancy or breastfeeding Narrow anterior chamber angle Iris neovascularization or active proliferative retinopathy Iridocorneal endothelial syndrome Epithelial or fibrous downgrowth Chronic or recurrent uveitis Steroid-induced glaucoma Severe posterior blepharitis Unwillingness to discontinue contact lens use after surgery Previous cyclodestructive procedure Conjunctival scarring from prior ocular trauma or cicatrizing disease precluding a trabeculectomy superiorly Functionally significant cataract Need for glaucoma surgery combined with other ocular procedures (i.e., cataract surgery, penetrating keratoplasty, or retinal surgery) or anticipated need for additional ocular surgery Unwillingness or inability to give consent, unwillingness to accept randomization, or inability to return for scheduled protocol visits
Treatment assignment	Random Stratified by clinical center, age, ethnicity, and previous failed filtering surgery in nonstudy eye
Follow-up examinations	1 day, 1 wk, 1 mo, 3 mos, 6 mos, 12 mos, 18 mos, 1 yr, 2 yrs, 3 yrs, 4 yrs, 5 yrs
Outcome measures	Failure (IOP $>21$ mmHg or reduced $<20\%$ from baseline, IOP $\leq 5$ mmHg, reoperation for glaucoma, or loss of light perception vision) IOP Glaucoma medical therapy VA Visual fields Surgical complications
Enrollment	242 patients
Study centers and committees	16 clinical centers Safety and data monitoring committee Statistical coordinating center Steering committee

IOP = intraocular pressure; MMC = mitomycin C; VA = visual acuity.

enroll every eligible patient in the study. Written informed consent is obtained from all participants. The study adheres to the Declaration of Helsinki and the Health Insurance Portability and Accountability Act. This study is registered at [clinicaltrials.gov](http://clinicaltrials.gov) (identifier, NCT00666237).

## Study Organization

Participating centers and committees in the PTVT Study are listed in the [Appendix](#) (available at [www.aaojournal.org](http://www.aaojournal.org)). Investigators at 16 clinical centers are responsible for screening potential study patients, enrolling eligible patients, and following the patients according to the study protocol set forth in detail in the PTVT Study *Manual of Procedures*. An independent safety and data monitoring committee (SDMC) monitors all aspects of the study, including evidence of adverse and beneficial treatment effects. The statistical coordinating center (SCC) generates the random allocation sequence and assigns patients to the 2 surgical treatments. The SCC receives, edits, processes, analyzes, and stores all study data. The SCC coordinates activities at the clinical centers and monitors adherence to the study protocol. The steering committee comprises the principal investigators from each clinical center and the study chairpersons. The steering committee provides leadership for the study, and this

committee has overall responsibility for directing activities and formulating policy for the study.

## Eligibility Criteria

Patients 18 to 85 years of age who have had no previous incisional ocular surgery and inadequately controlled glaucoma with IOP of 18 mmHg or more and 40 mmHg or less while taking tolerated medical therapy are eligible for the PTVT Study. Exclusion criteria include no light perception vision, pregnancy or breastfeeding, narrow anterior chamber angle, iris neovascularization or proliferative retinopathy, iridocorneal endothelial syndrome, epithelial or fibrous downgrowth, chronic or recurrent uveitis, steroid-induced glaucoma, severe posterior blepharitis, unwillingness to discontinue contact lens use after surgery, previous cyclodestructive procedure, conjunctival scarring from prior ocular trauma or cicatrizing disease precluding a superior trabeculectomy, functionally significant cataract, need for glaucoma surgery combined with other ocular procedures or anticipated need for additional ocular surgery, unwillingness or inability to give consent, unwillingness to accept randomization, or inability to return for scheduled protocol visits. Among patients in whom both eyes are eligible, only the first eye undergoing surgical treatment is enrolled in the study.

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