

The Literature

BY NATHAN M. RADCLIFFE, MD

THE AHMED VERSUS BAERVELDT STUDY ONE-YEAR TREATMENT OUTCOMES

Christakis PG, Kalenak JW, Zurakowski D, et al*
Ophthalmology, September 2011

This or That

Among other reasons, the field of glaucoma is particularly fascinating because many debates within the specialty remain unsettled. Is glaucomatous optic neuropathy caused by mechanical or ischemic stress? Should glaucoma initially be treated with laser therapy, medications, or surgery? Is tube implantation better than trabeculectomy? Which tube is better, the Ahmed Glaucoma Valve (New World Medical, Inc., Rancho Cucamonga, CA) or Baerveldt glaucoma implant (Abbott Medical Optics Inc., Santa Ana, CA). Prospective randomized multicenter clinical trials have been helpful in addressing these classic debates.

We glaucoma specialists learned that initial treatment with laser trabeculoplasty is at least as efficacious as treatment with topical medications,¹ and medication seems to preserve the visual field as well as trabeculectomy, even if this surgery achieves a lower IOP.² Even the tube versus trabeculectomy debate has been addressed, with 3-year data from the Tube Versus Trabeculectomy (TVT) Study's demonstrating a higher failure rate in trabeculectomy with mitomycin C (31%) compared to a 350 mm² Baerveldt glaucoma implant (15%). This outcome was also evident when both treatments were associated with rather high complication rates (60% and 39%, respectively).³

The publication of the 1-year treatment outcomes from the Ahmed Versus Baerveldt (AVB) Study will help surgeons decide which tube shunt to implant.⁴ In an international, randomized trial performed by 10 surgeons at seven international sites, 238 patients with inadequately controlled glaucoma refractory to conventional medicinal, laser, and surgical therapy were randomized to receive an Ahmed FP7 (n = 124) or Baerveldt-350 (n = 114). Failure was defined as an IOP reduction of less than 20% from baseline or an IOP of more than 18 mm Hg or less than 5 mm Hg at two consecutive visits occurring past the 3-month postoperative mark. Patients enrolled in the study had a baseline IOP of 31.4 mm Hg and were, on average, taking three glaucoma medications, with 37% having undergone a previous trabeculectomy. Roughly

half of the patients had open-angle glaucoma, 21% had neovascular glaucoma, and 10% had uveitic glaucoma. As could be expected, the early postoperative IOPs were lower in the first month with the Ahmed versus the Baerveldt implant, but this difference disappeared by 1 month. After 1 year, the mean IOP was 16.5 mm Hg (47% reduction from baseline) in the Ahmed group and 13.8 mm Hg (57% reduction from baseline) in the Baerveldt group ($P = .001$), with slightly fewer glaucoma medications required in the Baerveldt group compared to the Ahmed group (1.2 vs 1.6, $P = .03$). Kaplan-Meier survival plots demonstrated that a higher proportion of patients in the Baerveldt group survived at 1 year compared to the Ahmed group when using the primary criteria (IOP of 5-18 mm Hg) but not using less stringent criteria (IOP 5-21 mm Hg). Most failures occurred due to high IOP, and only one patient (Baerveldt, of course) developed persistent hypotony. Visual acuity was similar between the two groups at 1 year. As with most prospective studies where the investigators are actually looking for and documenting all adverse events, complication rates were high in the two groups (45% for Ahmed, 54% for Baerveldt; $P = .19$), and more patients in the Baerveldt group required intervention for these complications (26% Ahmed vs 42% Baerveldt; $P = .009$). In general, the interventions themselves were modest and mostly included anterior chamber reformation, anterior chamber paracentesis, and bleb needling. A few more substantial interventions were required, including cataract extraction, vitrectomy, and tube revision.

Will the results of the AVB study change clinical practice? For the answer to this question, we can consider other randomized clinical trials such as the Advanced Glaucoma Intervention Study (AGIS), the Collaborative Initial Glaucoma Treatment Study (CIGTS), and the Glaucoma Laser Trial (GLT) and how they have not influenced practice. Before attributing the rise in the popularity of tube shunt surgery to the TVT study, we should remember that this trend occurred prior to the publication of the study's results. In some cases, we may be hesitant to make clinical changes based on the results of a study, because we feel the inclusion criteria, study protocol, patient population, surgical technique, or duration of follow-up are not what we would desire in order to make an informed decision for our patients. For many of us who use both glaucoma drainage devices, the clinical sce-

nario (eg, degree of preoperative IOP elevation or disease stage) may determine which device we implant, and the AVB study cannot provide specific guidance in this arena. Finally, as Joseph Caprioli, MD, said in a thoughtful editorial on the results of the TVT study, “The sheer inertia of long-established clinical practice is often difficult to change.”⁵

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INCIDENCE OF, RISK FACTORS FOR, AND COMBINED MECHANISM OF LATE-ONSET OPEN-ANGLE GLAUCOMA AFTER VITRECTOMY.

Koreen L, Yoshida N, Escario P, et al*
Retina, July 2011

Is Pars Plana Vitrectomy Associated With Primary Open-Angle Glaucoma?

In his 2006 LXII Edward Jackson lecture titled “Open-Angle Glaucoma After Vitrectomy,” Stanley Chang, MD, proposed that there is an increased risk of open-angle glaucoma after vitrectomy.⁶ In an article recently published in *Retina*, Dr. Chang and colleagues revisited this issue using a retrospective cohort and matched case-controlled study design for 285 vitrectomized eyes.⁷ They found that 11.6% ($n = 33$) developed glaucoma within 6 months of vitrectomy. The only variable significantly associated with the development of glaucoma was cataract extraction, whether it had been performed prior to or during the vitrectomy (odds ratio = 16.4; 95% confidence interval, 2.1-127.4; $P = .007$). For phakic eyes, the incidence of glaucoma was low at 1.4%, and the incidence in nonphakic eyes was 15%. The authors concluded that patients with lens extraction prior to or during vitrectomy surgery should be carefully monitored for the development of open-angle glaucoma. This work suggests that a discussion of the risks of glaucomatous development should be a part of the informed consent process for some patients requiring vitrectomy.

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LOWER CORNEAL HYSTERESIS IS ASSOCIATED WITH MORE RAPID GLAUCOMATOUS VISUAL FIELD PROGRESSION

De Moraes CG, Hill V, Tello C, et al*
Journal of Glaucoma, June 2011

Corneal Thickness or Hysteresis?

Despite some continued controversy on the subject, a lower central corneal thickness (CCT) has been indepen-

dently associated with the onset and progression of glaucoma.⁸⁻¹⁰ In 2006, Nathan Congdon, MD, MPH, and colleagues reported that a measure of corneal stiffness (corneal hysteresis) was associated with visual field progression and that CCT was not, although CCT was associated with the structural state of glaucomatous damage (cup-to-disc ratio).¹¹ De Moraes and colleagues recently revisited the issue by evaluating factors associated with visual field progression in 153 patients who had taken more than five visual field tests (mean, 8.5) over an average of 5 years of follow-up.¹² The investigators found that 16% of progressing eyes had lower corneal thickness ($525.0 \pm 34.2 \mu\text{m}$ vs $542.3 \pm 38.5 \mu\text{m}$, $P = .04$) and lower hysteresis ($7.5 \pm 1.4 \text{ mm Hg}$ vs $9.0 \pm 1.8 \text{ mm Hg}$, $P < .01$) compared to nonprogressing eyes. In a multivariable analysis, peak IOP, age, and corneal hysteresis (but not thickness) were significantly associated with progression. This study provides a strong rationale for the investigation of corneal hysteresis in prospective studies of glaucomatous progression. Furthermore, it suggests that, in the future, we may depend on corneal biomechanical properties to help guide our therapeutic decisions.

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CANALOPLASTY: THREE-YEAR RESULTS OF CIRCUMFERENTIAL VISCODILATION AND TENSIONING OF SCHLEMM CANAL USING A MICROCATETER TO TREAT OPEN-ANGLE GLAUCOMA.

Lewis RA, von Wolf K, Tetz M, et al*
Journal of Cataract and Refractive Surgery, April 2011

Three-Year Data for Canaloplasty

Lewis and colleagues reported 3-year safety and efficacy data for 157 patients who underwent either canaloplasty or combined cataract extraction and canaloplasty.¹³ In the canaloplasty procedure, after the creation of a scleral flap, the surgeon used a flexible microcatheter through an ab externo (transconjunctival, transscleral) approach to viscodilate the full circumference of Schlemm canal and placed a 10-0 Prolene trabecular-tensioning suture (Ethicon Inc., Somerville, NJ). At 3 years, the overall mean IOP fell to $15.2 \pm 3.5 \text{ mm Hg}$ from a mean preoperative IOP of 23.8 mm Hg , and the mean use of glaucoma medication fell to 0.8 ± 0.9 compared with 1.8 ± 0.9 medications preoperatively. These figures correspond to an 8.6-mm Hg or 36% reduction from baseline. The mean IOP of eyes that underwent both cataract and canaloplasty surgery fell to $13.6 \pm 3.6 \text{ mm Hg}$, and the number of medications needed postoperatively

decreased to 0.3 ± 0.5 . In this group, the mean baseline IOP was 23.5 ± 5.2 mm Hg on 1.5 ± 1.0 medications (42% IOP reduction). The only significant complications reported were cataract formation in 12.7% of eyes and a transient elevation in IOP in 6.4% of eyes.

The results are encouraging. Although it may not be valid to compare one surgical population's outcome to that of another study, the percentage of IOP reduction and safety profile obtained compare well with those of other surgical trials.¹⁴ This noncomparative series certainly provides a rationale for a head-to-head comparison of canaloplasty and more traditional penetrating glaucoma surgeries. □

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1. The Glaucoma Laser Trial (GLT) and glaucoma laser trial follow-up study: 7. Results. Glaucoma Laser Trial Research Group. *Am J Ophthalmol*. 1995;120(6):718-731.
2. Lichter PR, Musch DC, Gillespie BW, et al. Interim clinical outcomes in the Collaborative Initial Glaucoma Treatment Study comparing initial treatment randomized to medications or surgery. *Ophthalmology*. 2001;108(11):1943-1953.
3. Gedde SJ, Schiffman JC, Feuer WJ, et al. Three-year follow-up of the Tube Versus Trabeculectomy Study. *Am J Ophthalmol*. 2009;148(5):670-684.
4. Christakis PG, Kalenak JW, Zurakowski D, et al. The Ahmed Versus Baerveldt Study one-year treatment outcomes [published online ahead of print September 1, 2011]. *Ophthalmology*. doi:10.1016/j.ophtha.2011.05.004.
5. Caprioli J. The Tube Versus Trabeculectomy Study: why its findings may not change clinical practice? *Am J Ophthalmol*. 2011;151(5):742-744.
6. Chang S. LXII Edward Jackson lecture: open angle glaucoma after vitrectomy. *Am J Ophthalmol*. 2006;141:1033-1043.
7. Koren L, Yoshida N, Escariso P, et al. Incidence of, risk factors for, and combined mechanism of late-onset open-angle glaucoma after vitrectomy [published online ahead of print July 14, 2011]. *Retina*. doi: 10.1097/IAE.0b013e318217fffb.
8. Leske MC, Wu SY, Hennis A, et al. Risk factors for incident open-angle glaucoma: the Barbados Eye Studies. *Ophthalmology*. 2008;115:85-93.
9. Leske MC, Heijl A, Hyman L, et al. Predictors of long-term progression in the early manifest glaucoma trial. *Ophthalmology*. 2007;114(11):1965-1972.
10. Gordon MO, Beiser JA, Brandt JD, et al. The Ocular Hypertension Treatment Study: baseline factors that predict the onset of primary open-angle glaucoma. *Arch Ophthalmol*. 2002;120:714-720.
11. Congdon NG, Broman AT, Bandeen-Roche K, et al. Central corneal thickness and corneal hysteresis associated with glaucoma damage. *Am J Ophthalmol*. 2006;141(5):868-875.
12. De Moraes CG, Hill V, Tello C, et al. Lower corneal hysteresis is associated with more rapid glaucomatous visual field progression [published online ahead of print June 21, 2011]. *J Glaucoma*. doi:10.1097/IJG.0b013e3182071b92.
13. Lewis RA, von Wolff K, Tetz M, et al. Canaloplasty: three-year results of circumferential viscodilatation and tensioning of Schlemm canal using a microcatheter to treat open-angle glaucoma. *J Cataract Refract Surg*. 2011;37(4):682-690.
14. Merkow RP, Ko CY. Evidence-based medicine in surgery: the importance of both experimental and observational study designs. *JAMA*. 2011;306(4):436-437.