Revisiting Angle Surgery in Adults and Children for Management of Open-angle Glaucoma

a report by

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Several new *ab interno* and *ab externo* approaches to angle surgery in adults and children with open-angle glaucoma show promise for improving the control of intraocular pressure (IOP) less invasively and with fewer complications than current *ab externo* filtering procedures. These include the Trabectome®, iScience canaloplasty, Glaukos®, laser goniopuncture, and Solx—a new translimbal shunt into the suprachoroidal space. Updates on all these procedures have recently been presented in the US at major meetings of the American Academy of Ophthalmology (AAO), the American Glaucoma Society (AGS), the Association for Research in Vision and Ophthalmology (ARVO), and the American Association of Cataract and Refractive Surgeons (ASCRS).

Trabectome

The Trabectome (see *Figure 1*), approved by the US Food and Drug Administration (FDA), permits *ab interno* trabeculotomy—including ablation of a strip of trabecular meshwork and the inner wall of Schlemm's canal—with simultaneous aspiration and irrigation to remove tissue debris while maintaining a stable anterior chamber.^{1,2} The device includes a ceramic-coated insulated footplate that acts as a glide within Schlemm's, and also protects adjacent tissues from heat or mechanical injury.³

This procedure is performed through a clear 1.6mm near-limbal temporal corneal incision under direct gonioscopic control via a modified Swan-Jacob goniolens (see *Figure 2*). The goal is to unroof a 90–120° arc of Schlemm's by removing the meshwork, juxtacanalicular connective tissue, and inner wall of the canal, allowing direct aqueous access to collector channels in the posterior canal wall. A foot-pedal control maintains aspiration and ablation

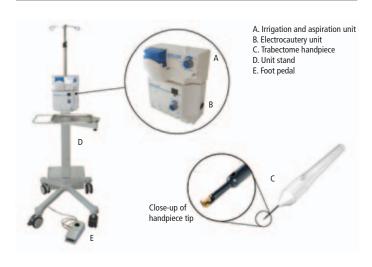


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1999 and 2006, President of the Glaucoma Research Society of the International Congress of Ophthalmology (ICO) from 1998 to 2003, and Chair of the American Academy of Ophthalmology (AAO) Skills Transfer Committee from 1986 to 1991. As well as acting as Editor in Chief for Ophthalmology between 1995 and 2005, Dr Minckler has authored 163 peer-reviewed publications. He received his medical training at the University of Oregon Medical School, Portland, Oregon, served an internship at the US Naval Hospital, San Diego, California, from July 1964 to June 1965, and served in the US Navy Medical Corps (USNMC) as a flight surgeon between 1963 and 1967.

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Figure 1: The Trabectome System



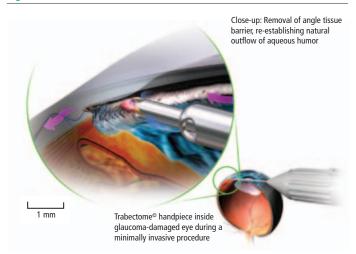
at constant levels. An infusion sleeve allows continuous or intermittent inflow of fluid. Ablation power and aspiration rates are adjustable.

The most useful anatomical landmarks for identifying Schlemm's intra-operatively include the scleral spur and pigmented meshwork, if present. Alternatively, blood in Schlemm's canal after installation of viscoelastic into the anterior chamber often clearly marks the location of Schlemm's. The inferior nasal quadrant is specifically targeted as collector channels are thought to be most numerous there. As ablation proceeds, the back wall of Schlemm's appears as a white band in the trail of the instrument's footplate.

Back bleeding from exposed collector channels or Schlemm's typically occurs during the latter part of canal opening or when IOP drops as the instrument is removed. Back bleeding typically stops spontaneously over several minutes, or when an internal tamponade is installed via fluid or an air bubble. Only rarely among the more than 400 procedures performed and reported so far has the resulting hyphema been more than 10–20%, persisted for more than a few days, or been associated with a post-operative IOP spike. Intra-operative back bleeding may be decreased by pre-operative use of apraclonidine. Ocucoat® has proved to be a satisfactory viscoelastic when required, and seems to be relatively easily cleared from the anterior chamber. A single 10-0 nylon or polyglactin suture has been routinely placed across the corneal wound.

Post-operatively, most eyes have been treated with 1% pilocarpine twice daily for two weeks, and pre-operative medications resumed temporarily

Figure 2a: The Trabectome Procedure



pending IOP results over ensuing weeks. Overall, topical medications have been reduced from a pre-operative mean of 2.7 to a post-operative mean of 0.8 (see *Figure 3*). Reduction of IOP in an ongoing prospective case series has averaged 40% (mean pre-operative IOP of 24mmHg) to mid-teen levels (mean post-operative IOP of 16mmHg) persisting for at least 40 months in 15 patients (see *Figure 4*).

To date, disadvantages of the Trabectome include the handpiece being only single-use and IOP outcomes generally in the mid-teens, limiting its use to patients with mid-teen IOP goal ranges. Advantages include short

Figure 2b: The Trabectome Procedure



surgical times, simplified post-operative follow-up, no bleb formation or late infection risk, and no damage to conjunctiva that would preclude any necessary standard surgery thereafter. Thus far, progression of cataract in phakic eyes has been minimal, which also contrasts sharply with standard filtering procedures. Other than the expected back bleeding, in general complications have been minimal and non-vision-threatening.

In theory, this procedure should improve outcomes in children compared with *ab externo* trabeculotomy or goniotomy, but the clinical experience



...restoring natural pathways

Nature works in wondrous cycles of renewal and refreshment. Tiny mists of dew on a leaf—multiplied many times—can eventually replenish rivers, streams, and even oceans.

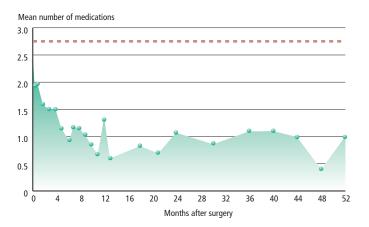
Taking a cue from nature, Trabectome is an FDA-cleared device for minimally invasive surgical treatment of open angle glaucoma. Designed to improve aqueous outflow, this breakthrough procedure is fast becoming a viable alternative to traditional therapies. Using a focused electrosurgical pulse, Trabectome safely ablates and removes a 90°-120° strip of trabecular meshwork and inner wall of Schlemm's canal, thereby re-establishing access to the eye's natural drainage pathways.



Ab interno trabeculotomy Removal of diseased tissue using electrosurgical pulse. Continuous irrigation and aspiration removes debris and regulates temperature.

For latest patient data and published scientific papers, please log on to www.Trabectome.com

Figure 3: Graph Illustrating Intraocular Pressure Outcomes up to 52 Months Post-Trabectome Surgery

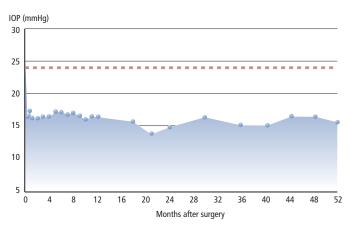


[434 eyes] (ARVO 2007).

to date has been too minimal for comparative assessment. The Trabectome procedure has been combined with cataract extraction (phacoemulsification and intraocular lens (IOL) placement) in approximately 100 cases with reasonable IOP improvement.

Skill transfer has been easy among the approximately 25 surgeons involved so far. This procedure probably ranks between laser trabeculoplasty and standard filtering procedures in relation

Figure 4: Graph Illustrating the Decrease in Adjunctive Medications Following Trabectome



[434 eyes] (ARVO 2007).

to the efficacy of other current management schemes for open-angle glaucoma. No prospective trials comparing Trabectome with standard filtering surgery or with medicine and laser have yet been reported.

Disclosure

Dr Minckler is a paid consultant for NeoMedix, manufacturer of the Trabectome $^{\text{TM}}$.

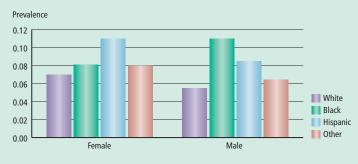
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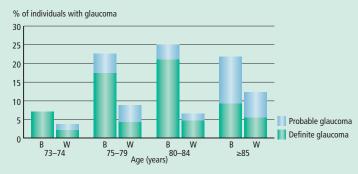
Glaucoma—The Facts

- Glaucoma is the second leading cause of blindness in the world.
- There will be 60.5 million people with open-angle glaucoma and angleclosure glaucoma by 2010, increasing to 79.6 million by 2020.
- Women will comprise 55% of open-angle glaucoma cases, 70% of angle-closure glaucoma cases, and 59% of all glaucoma cases by 2010.
- End-stage glaucoma costs patients approximately \$2,511 per annum.
 The cost of medication was responsible for one-third to half of the total direct patient cost.

US Prevalence Rates for Definite Primary Open-angle Glaucoma (Age 80+)



US Prevalence of Open-angle Glaucoma Among Black Persons (B) and White Persons (W) (Age 73+)



- African-Americans aged 45–65 are 14–17 times more likely to go blind from glaucoma than Caucasians with glaucoma in the same age group.
- Studies suggest that there is a correlation between glaucoma and systemic hypertension.

Sources: Quigley and Broman, International Glaucoma Association, Duke University Eye Center.

8