CLINICAL RESULTS WITH THE TRABECTOME, A NOVEL SURGICAL DEVICE FOR TREATMENT OF OPEN-ANGLE GLAUCOMA

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ABSTRACT

Purpose: To describe treatment outcomes after Trabectome surgery in an initial series of 101 patients with open-angle glaucoma.

Methods: A 19-gauge micro-electrosurgical device enabled ab interno removal of a strip of trabecular meshwork and inner wall of Schlemm's canal under gonioscopic control with continual infusion and foot-pedal control of aspiration and electrosurgery. A smooth, pointed ceramic-coated insulating footplate was inserted into Schlemm's canal to act as a guide within the canal and to protect adjacent structures from mechanical or heat injury during ablation of a 30- to 90-degree arc of angle tissue.

Results: Mean preoperative intraocular pressure (IOP) in the initial 101 patients was 27.6 ± 7.2 mm Hg. Thirty months postoperatively, mean IOP was 16.3 ± 3.3 mm Hg (n = 11). The mean percentage drop over the whole course of follow-up was 40%. At all times postoperatively, the absolute and percent decrease in IOP from preoperative levels were statistically significant (paired *t* test, $P < .0001$). Overall success (IOP ≤ 21 mm Hg with or without medications and no subsequent surgery) was 84%. Nine eyes subsequently underwent trabeculectomy, two others had IOP greater than 21 mm Hg in spite of resuming topical medications, and the rest of the patients either refused to resume medications or were still in the 1-month postoperative period without medications (total failure rate including trabeculectomies, 16/101 = 16%). Intraoperative reflux bleeding occurred in 100% of cases. Complications have been minimal and not vision-threatening.

Conclusions: The Trabectome facilitates minimally invasive and effective glaucoma surgery, which spares the conjunctiva and does not preclude subsequent standard filtering procedures.

Trans Am Ophthalmol Soc 2006;104:40-50

INTRODUCTION

Goniotomy, the first surgical procedure directed at the trabecular meshwork, was introduced in 1936 and has had success rates between 68% and 100% in infants and young children with congenital glaucoma but relatively poor outcomes in adults[1] (Table 1).

TABLE 1. OUTCOMES AFTER TRABECULOTOMY IN ADULTS: OLDER LITERATURE SURVEY

INVESTIGATOR	EYES, FOLLOW-UP (MO)	IOP (MM HG)
Harms[6] (1969)	227 eyes (no data)	22% adults "failed"
Gillies[9] (1977)	12 eyes, 24.3 ± 11.9	13.3 ± 2.96
Luntz[10] (1977)	19 eyes (no data)	30% "failed"

IOP, intraocular pressure.

Opening Schlemm's canal to direct aqueous outflow by incision (goniotomy or goniotrabeculotomy as originally described by Barkan) or by mechanical rupture (trabeculotomy) can be accomplished in adults from either an ab externo or an ab interno approach with favorable intraocular pressure (IOP) outcomes, according to some reports,[1-6] including two recent randomized clinical trials.[7,8] A newly described instrument, the Trabectome, offers theoretical and potentially clinically important advantages over previous trabeculotomy methods.[9,10] This report extends clinical follow-up of a previously published case series of 37 adults who underwent Trabectome surgery and adds short-term data on an additional 64 cases, for a total of 101 patients (Table 2).

From the University of Southern California Keck School of Medicine, Los Angeles, California (Dr Minckler, Ms Dustin, Dr Francis); University of California Irvine, Irvine, California (Dr Baervedlt, Dr Mosaed, Dr Zack); Codet Eye Institute, Tijuana, Mexico (Dr Ramirez); Wills Eye Hospital, Philadelphia, Pennsylvania (Dr Wilson); and Hospital of University of Geneva, Geneva, Switzerland (Dr Shaarawy). Dr Minckler, Dr Francis, and Dr Ramirez are paid consultants for NeoMedix. Dr Baerveldt is one of the inventors and has a financial interest in the technology.

*Presenter.
Bold type indicates AOS member.

TABLE 2. DEMOGRAPHIC INFORMATION FOR 101 PATIENTS WHO UNDERWENT TRABECTOME SURGERY

VARIABLE	NO. OF PATIENTS
Age (years)	
Mean	65
SD	17
Minimum	2
Maximum	90
Sex	
Male	48
Female	53
Race (self-defined)	
African American	3
Asian	2
Caucasian	39
Hispanic	57
Eye operated on	
Right	51
Left	50
Diagnosis	
Primary open-angle glaucoma	82
Pseudoexfoliation	12
Juvenile rheumatoid arthritis	2
Myopic degeneration	2
Pigment dispersion	2
Steroid-induced	1
Visual field status (if known)	
Minimal	19
Moderate	46
Advanced	36
Cup-disk ratio (if known)	
>0.4 -0.6	22
0.7-0.8	25
>0.8	31
Lens status (if known)	
Pseudophakic	14
Phakic	86
Aphakic	1
Gonioscopy-Schaffer grade (if known)	
I	3
II	8
III	41
IV	49
Pterygium	6
Combined cataract extraction and Trabectome	11

METHODS

The Trabectome has been cleared for clinical use by the US Food and Drug Administration (FDA). The initial series, performed in Mexico, was approved by the Mexican equivalent of the FDA and the local institutional review board. US cases after January 2006 were done with the approval of the hospital surgical committee. In all cases, the patient was administered a comprehensive informed consent in the appropriate language.

The Trabectome has been described in detail previously.[11,12] The novel aspects of the instrument include a triangular ceramic-coated footplate, the point and body of which are sized to fit into and act as a guide within Schlemm's canal (Figure 1). A power-adjustable microbipolar cautery is positioned so as to receive and ablate angle tissues fed into the spark as the tip is moved along an arc parallel and just anterior to the scleral spur under direct gonioscopic control (Figure 2). Continual infusion during ablation helps avoid heat-related damage to adjacent tissues, and aspiration out through the instrument's shaft removes tissue debris. Histologic study of human angle tissues after Trabectome application revealed minimal injury to the back wall of Schlemm's and relatively clean removal of a strip of meshwork and inner wall of the canal.[12]

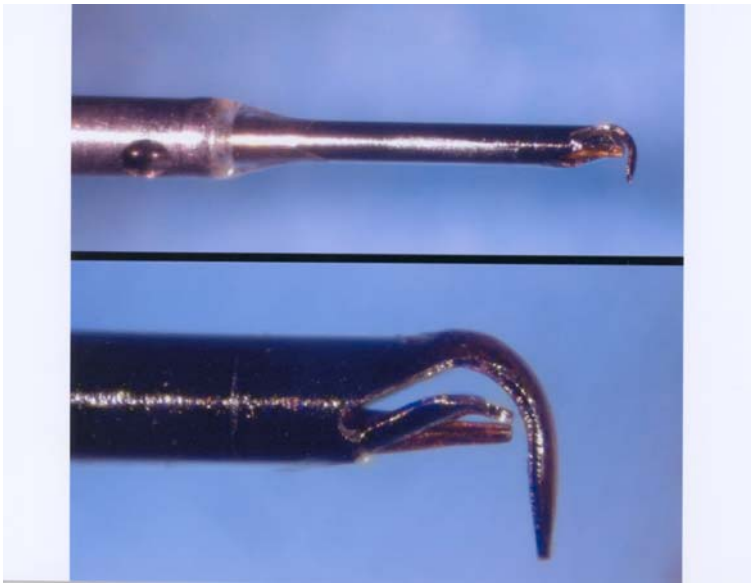

FIGURE 1

Trabectome surgical tip showing infusion port of microelectrocautery unit (footplate, active straight electrode, return curving electrode).

Inclusion criteria consisted of the following: elevated IOP judged likely to lead to progressive nerve injury on maximal available or tolerated medications; disc or visual field findings, or both, consistent with primary open-angle glaucoma or its variations; ability to maintain follow-up through the study period; open angles (Shaffer grade 1 or above); and a valid informed consent. A history of filtering or laser surgery was acceptable. Both phakic and pseudophakic eyes were considered appropriate.

Exclusion criteria were as follows: vision less than hand motion; corneal edema or other opacities preventing a good gonioscopic view; inability to maintain follow-up; a too shallow anterior chamber; anatomically confusing angles without clear definition of the scleral spur or meshwork; and neovascularization of the iris or angle. For this series, no patients were included if they had serious cardiovascular problems, uncontrolled diabetes or bleeding and clotting disorders, or chronic obstructive pulmonary disease. All patients were relatively healthy, ambulatory, and easily manageable in an outpatient setting.

Trabectome surgery has been accomplished after presurgical instillation of pilocarpine 1% by various anesthetic methods, including pharyngeal mask general anesthesia; retrobulbar needle and retrobulbar sub-Tenon's irrigation with 0.5 to 0.75 of a bupivacaine/2% lidocaine mixture (epinephrine/hyaluronidase-free); use of topical lidocaine gel only; and use of intracameral 1% preservative-free lidocaine. The surgeon has routinely been seated on the patient's operative side. The patient's head has been tilted about 15 degrees away from the surgeon and the microscope eyepieces axially aligned.

The initial 37 cases were done with a variety of surgical gonioscopic lenses, including the Thorpe, Hoskins-Barkan, Swan-Jacobs, and Khaw four-mirror. More recent cases have been done with a modified Swan-Jacobs lens (Ocular Instruments, Bellingham, Washington), that provided an excellent view during surgery (Figure 2).

After a good view was ensured, the goniolens was temporarily put aside and a 1.6-mm keratome incision made in near-limbal clear cornea, recently enlarged internally to facilitate rotation of the shaft. In the initial series, viscoelastic was routinely installed in the anterior chamber, but many recent cases have been done without viscoelastics. The Trabectome tip was inserted into the anterior chamber just beyond the infusion port, and the goniolens was then replaced and the tip advanced to engage the meshwork, anterior to the scleral spur nasally, under direct visual control with continual infusion (Figure 2). Once inserted through the meshwork into Schlemm's canal, arcs of tissue were ablated in both clockwise and counterclockwise directions totaling approximately 60^{o} to 90^{o} of arc (2+ clock-hours) or to the limit of an adequate view.

In every case, minor back bleeding from Schlemm's occurred during ablation or removal of the instrument from the anterior chamber. Irrigation with balanced salt solution or additional aspiration, sometimes with either the infusion-aspiration tip from a phacoemulsification machine or a disposable Simcoe irrigator, was then done via the corneal wound. In most cases, a single 10-0 nylon suture was placed across the corneal wound and an air bubble installed as an aid to internal tamponade. Routine postoperative

medications included 1% pilocarpine twice daily for 2 weeks and topical antibiotics and corticosteroids.

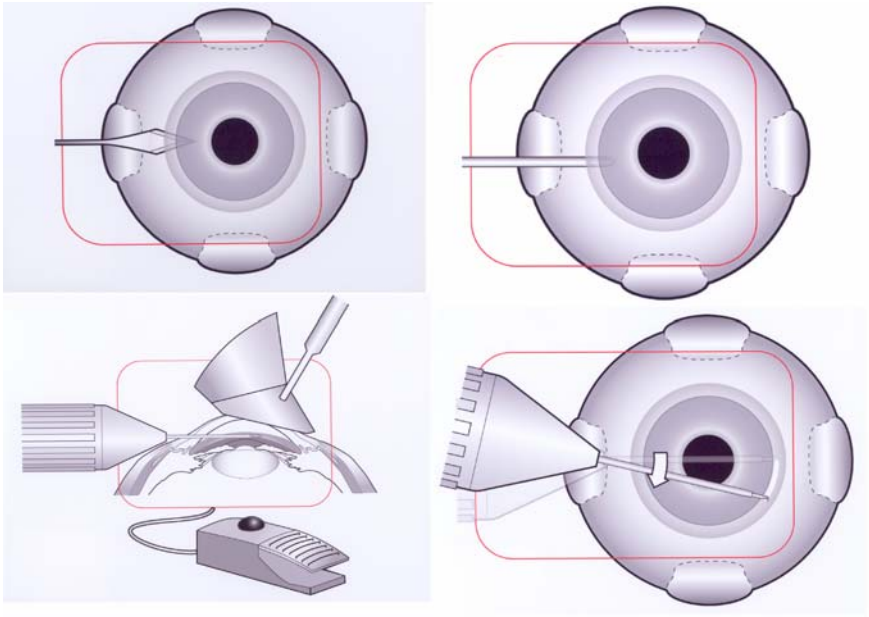

FIGURE 2

The four major steps in Trabectome surgery for open-angle glaucoma. Top left, A clear corneal near-limbal 1.6-mm keratome incision is made. Top right, Viscoelastic may or may not be necessary to allow safe insertion of the instrument tip to allow infusion flow and anterior chamber stability. Bottom left, Surgical tip is advanced under gonioscopic control to engage nasal meshwork before activating aspiration and ablation by progressively depressing the foot pedal and rotating the tip parallel to the iris just anterior to the scleral spur. Bottom right, Ablation with continual infusion and aspiration is performed along an arc of 30^{o} to 60^{o} to ensure complete viscoelastic removal thereafter**.**

RESULTS

The mean decrease in IOP for all cases over the whole course of follow-up, including 11 cases at 30 months, was 40%. At all times postoperatively, the absolute and percent decreases in IOP from preoperative levels were statistically significant (paired *t* test, $P < .0001$). Overall success (IOP ≤ 21 mm Hg with or without medications and no subsequent surgery) was 84%. Nine eyes subsequently underwent trabeculectomy, two others had IOP greater than 21 mm Hg in spite of resuming topical medications, and the rest of the patients either refused to resume medications or were still in the 1-month postoperative period without medications; the failure rate including subsequent trabeculectomies (16/101) was16%. IOP outcomes are tabulated in Table 3 and displayed graphically in Figure 3.

TABLE 3. IOP OUTCOMES AFTER TRABECTOME SURGERY*

TIME AFTER SURGERY	IOP		% DROP IN IOP	NO. OF PATIENTS
	MEAN	SD		
Preoperative	27.6	7.2	0%	101
1 day	18.8	11.2	–33%	89
1 week	17.5	5.0	–38%	86
2 weeks	18.8	6.3	–35%	85
1 month	18.2	5.8	–36%	81
2 months	17.6	4.0	–38%	61

TABLE 3. (CONTINUED) IOP OUTCOMES AFTER TRABECTOME SURGERY*

TIME AFTER SURGERY	IOP		% DROP IN IOP	NO. OF PATIENTS
	MEAN	SD		
3 months	17.6	3.4	–40%	51
4 months	17.3	3.3	–40%	47
5 months	16.7	2.7	–42%	45
6 months	18.4	4.5	–36%	46
7 months	17.1	3.0	–41%	45
8 months	16.8	2.8	–42%	36
9 months	16.5	2.5	–43%	35
10 months	16.1	2.7	–44%	36
11 months	16.8	3.1	–42%	37
12 months	16.4	2.2	–44%	37
13 months	16.0	2.3	–44%	36
18 months	15.9	2.0	–41%	30
21 months	14.5	2.1	–47%	21
24 months	15.2	2.4	–44%	18
30 months	16.3	3.3	–33%	11
TOTAL MEAN	**16.9**	**3.7**	**–40%**	

IOP, intraocular pressure.
*Data for 101 patients, including initial 37 patients previously reported.[11]

DISCUSSION

Trabeculotomy as most commonly performed in children and adults requires inserting a smooth-surfaced Harms or Nagata trabeculotomy probe into the canal of Schlemm with the aid of an operating microscope through an external scleral incision and rotating it inward paralleling the iris to rupture the probe through angle structures (inner wall of Schlemm's and meshwork) into the anterior chamber. The cleft created allows aqueous direct access to the canal and collector channels. If the probe is passed in both directions, 60 ^{o} to 90^{o} of angle can be opened. More recently, suture-goniotomy has been performed by rupturing a suture passed circumferentially into Schlemm's canal, providing a 360^{o} opening.[13,14] This procedure has not been reported in adults and has been associated with significant hypotony in some children.[15]

Ab interno trabeculotomy is accomplished under direct visualization through an operating microscope and appropriate goniolenses by passing a knife or other instrument through the temporal near-limbal cornea or sclera across the anterior chamber to incise, plow, or remove angle tissues 180^{o} opposite, usually including an arc between 45 ^{o} and 90 ^{o}. Variations of ab interno trabeculotomy (opening or unroofing Schlemm's) have included laser goniopuncture and goniocurettage.[16,17]

Goniotomy, generally reserved for application to congenital glaucoma with clear corneas, is an ab interno procedure in which a needle or knife is passed through the cornea and across the chamber under gonioscopic view, with the intent, according to most current advocates, of incising only the inner layers of the trabecular meshwork over an arc of approximately 90^{o}. This procedure was originally described by Barkan,[1-5] who had theorized that congenital glaucoma was due to an imperforate inner layer of "pretrabecular" tissue (Barkan's membrane), never confirmed to actually exist as a separate structure. Confusion no doubt persists as to how deep the ideal goniotomy incision should be and whether or not Schlemm's should be unroofed as Barkan described; most likely the explanation for back-bleeding is commonly observed. The combination of trabeculotomy with small-incision cataract surgery has been recently advocated, especially in Japan.[18-25]

In summary, compared with previous methods of ab interno or ab externo trabeculotomy, the Trabectome has been demonstrated to have equivalent or better short-term IOP outcomes in adults through 30 months of follow-up (Tables 3 and 4, Figure 3). The Trabectome has a superior safety profile with substantially fewer serious or vision-threatening complications than trabeculectomy with mitomycin-C and is equivalent to those reported with other methods of trabeculotomy[7,8,26-29] (Table 5). The only common complication reported with any method of trabeculotomy is intraoperative reflux bleeding, which clears rapidly without residual vision damage. As

is often the case, previously described techniques that utilized similar approaches to opening Schlemm's to direct aqueous access should be acknowledged and appreciated.[30-33] Our strong initial impression is that viscoelastics such as Ocucoat or relatively cohesive viscoelastics (Viscoat, Healon GV) that either solubilize or are easily removed are preferable if needed intraoperatively. In several recent cases, the Trabectome has been used without any viscoelastic when simple infusion adequately stabilizes the anterior chamber.

TABLE 4. SUMMARY OF SUCCESS AND FAILURE WITH THE TRABECTOME

SUCCESS	
Mean % IOP decrease all 101	40%
IOP ≤1 mm Hg with or without medication	85/101 (84%)
FAILURE	**16/101 (15.8%)**
Trabeculectomy*	9/101 (8.9%)
IOP > 21 mm Hg with or without medication	7/101 (7.9%)

IOP, intraocular pressure.
*One of the trabeculectomies was due to unrelated trauma postoperatively.

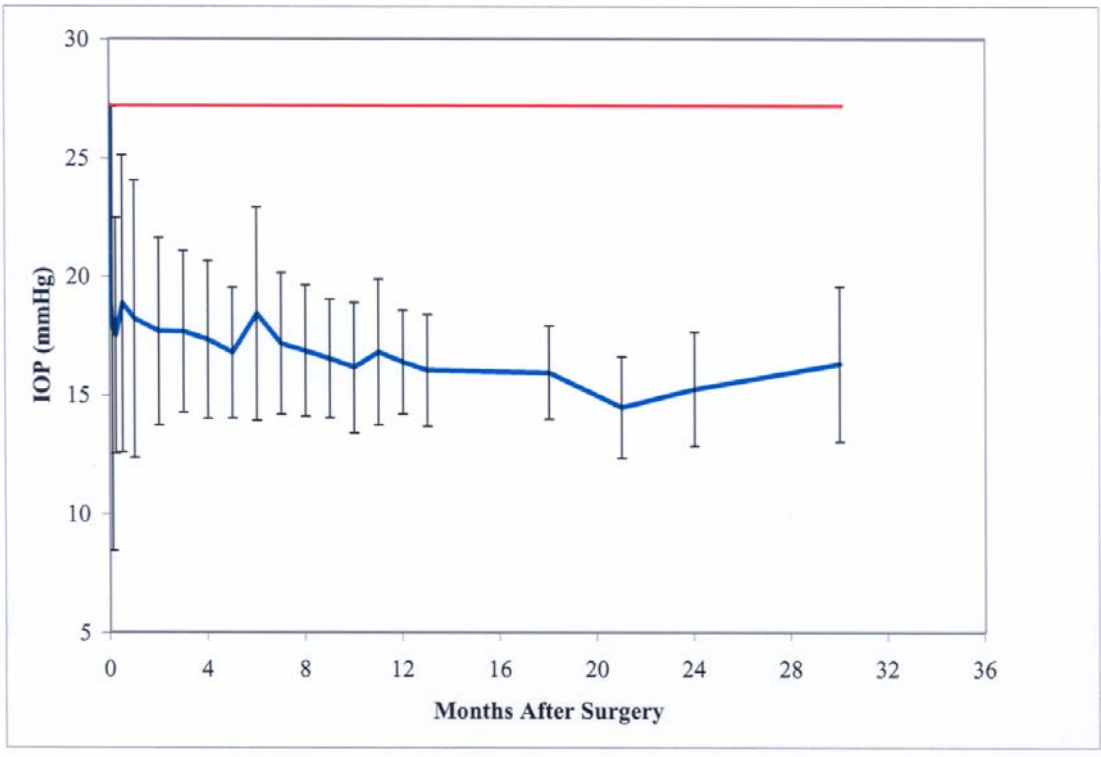

FIGURE 3

Intraocular pressure (IOP) outcomes after Trabectome surgery. Standard deviation bars and mean preoperative IOP (27.6 mm Hg at baseline) are shown. One patient from the initial series in Tijuana, Mexico, is deceased. Only 11 IOP measurements were available at 30 months postoperatively.

It seems highly probable that the safety profile and efficacy of the Trabectome procedure for surgically controlling IOP will improve with additional experience. The instrument's most unique and important design features include the insulated footplate, which acts as a glide within Schlemm's canal, greatly enhancing anatomic precision, and the associated electrosurgical removal of trabecular meshwork with continual infusion and aspiration. Trabectome's minimally invasive surgical procedure should not impact subsequent standard filtering surgery because it spares the conjunctiva. Randomized trials comparing the Trabectome with other therapies for glaucoma (medical, laser, trabeculectomy) are obviously desirable. Trials will be organized in the near future pending clarification of the appropriate comparisons and questions.

TABLE 5. COMPLICATIONS WITH THE TRABECTOME PROCEDURE*

COMPLICATION	TOTAL
Blood reflux	100% (20% hyphema largest)
Epithelial defects	3/101 (3%)
Descemet's hemorrhage	1/101 (1%)
Descemet's scroll/detachment	1/101 (1%)
Persisting Descemet's injury	1/101 (1%)
Partial goniosynechiae at follow-up	14/101 (14%)
Day 1 postoperative IOP spikes (40 to 60 mm Hg)	4 of 5 cases in which Amvisc was used intraoperatively at USC
Hypotony (IOP 2 mm Hg) on day 1	1/101 (1%)
Vision loss during follow-up ≥2 lines below preoperative	1 (20/25 to 20/40? from lens change)

IOP, intraocular pressure; USC, University of Southern California.
*With the exception of early postoperative IOP spikes among the first few cases at USC, complications other than failure to control IOP, necessitating additional surgery, were few and not vision-threatening.

ACKNOWLEDGMENT

Michael Van Buskirk, MD, of Portland, Oregon, kindly provided historical perspectives and references 30 through 33.

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PEER DISCUSSION

DR GEORGE A. CIOFFI. Dr. Minckler and colleagues provide extended outcome data on the efficacy of the trabectome, a surgical device for the treatment of open-angle glaucoma. The reality of our present surgical interventions for glaucoma (which have primarily been variations of filtration surgery), is that some fraction of these eyes go on to develop scar tissue that limit their pressure lowering abilities, some are prone to infections, some develop leaks and subsequent hypotony, and some will even develop fulminant endophthalmitis with loss of useful vision. However, to date, trabeculectomy remains the best way to significantly lower intraocular pressure, with many patients no longer requiring medications. The continuous search for new surgical procedures for the treatment of glaucoma is based on a single goal: to chronically lower the intraocular pressure in the safest manner possible. This manuscript reports a novel surgical intervention, with several unique qualities that should be highlighted. As well, I would like to provide suggestions for future data analysis. Finally, I will provide one thought as to the potential mechanism of action of this procedure

The trabectome is a method of removing a small segment of the trabecular meshwork and the inner wall of Schlemm's canal. The authors, in previous publications and presentations, have shown that the use of this micro-electro cautery device can minimize the surgical trauma, allowing this ablation to be completed. This presumably enhances outflow via increased access to Schlemm's canal, allowing aqueous to escape the anterior chamber without the impedance of the trabecular meshwork and the inner wall of Schlemm's canal. The authors present data from 100 eyes on the average intraocular pressure (IOP) over several months after surgical intervention.

It should be noted that only 47 of the 100 eyes reached the four months time point, 37 reached the twelve month time point, 18 reached the 24 month time point, and 10 reached the 30 month time point. Therefore, I believe the data would be easier to interpret using some form of survival analysis, such as Kaplan-Meier plots. This would better represent the data with the variable length of follow-up and patients reaching endpoints at differing times. It must be acknowledged that the group of patients returning for care and reaching any of the time point milestones, may represent a biased selection of the overall population. This may jade our view of the success or failure of the procedure.

In future analysis, the authors should also indicate how failures were handled. Were failures censored after their IOPs became elevated, and they had to go on to subsequent surgery? Were they still included in the intraocular pressure averages shown in the graph? The authors report an 84% success rate of achieving less than or equal to 21mmHg. However, they do not state at what time point this success rate was found or how many patients this success rate represents. In addition, they do not make comment regarding the 11 patients of the original 101 that had combined procedures. In future analysis, these eyes should be excluded because the simple removal of the patient's crystalline lens often has a pressure-lowering effect of its own, comparable to the effects of trabectome.

Review of this manuscript also highlights a need to look historically at other procedures that have attempted to enhance outflow via penetration, perforation, or antagonism of the trabecular meshwork. In the early 1970s, multiple attempts were made with laser and with microsurgical devices by authors such as Krasnov, Worthen, Wickham, Ticho, Moses, Hager and Maselli, among others. Conservatively, it is estimated that 50 to 75% of the outflow resistance resides in the trabecular meshwork and the inner wall of Schlemm's canal. Therefore, one would expect a more immediate and profound drop in the IOP if the tissues are mechanically by-passed by this procedure. The data suggests that another potential mechanism of action could be considered for the trabectome. In 1979, Wise and Witter established parameters for a sustained pressure-lowering procedure, known as Argon Laser Trabeculoplasty. They realized that with non-penetrating laser applications to the trabecular meshwork, outflow could be enhanced. Initial hypotheses

suggested that collagen shrinkage, with its alterations of the architecture of the meshwork, resulted in greater opening of the outflow pathways. Acott and Van Buskirk proposed a trabecular cell repopulation theory. Most investigators now believe that localized trauma initiates a biological cascade of events that enhances outflow.

I was struck when looking at the pressure plots from the present manuscript, that they look much like the pressure plots provided by the Glaucoma Laser Trial (GLT), an NIH trial in the late '80s and early '90s. The pressure lowering profiles in the GLT study took pressures from the mid-to-high 20s, down to the high teens, as is seen in the present study. As well, the success rates reported by the GLT at two years in a 1990 publication in the journal Ophthalmology, showed success rates very comparable to the present report. The study reported 89% success with the addition of two or three medicines in their population. Similarly, the present investigation presents 84% success when topical medicines are allowed.

In summary, I would like to consider both the "pros and cons" as I see them of this new surgical intervention. This is an exciting technique that surgically ablates the trabecular meshwork and opens Schlemm's canal, with substantial pressure lowering abilities. This is accomplished by minimal surgical trauma, and there is no filtration bleb. The absence of a bleb is not a minor point, in that filtration blebs carry with them a wide range of difficulties and possible complications. However, there are several items that warrant further investigation prior to adopting the wide-spread use of this procedure. Presently the authors have not directly compared this to any other technique in a randomized clinical trial. As well, the IOP lowering effects reported for this procedure are probably insufficient for many glaucoma patients, especially those intolerant or unresponsive to medications. Long-term data is limited and survival analysis should be considered. Finally, there is the possibility that the mechanism of action is not as simple as a mechanical opening of Schlemm's canal and may actually be a non-specific initiation of a biological cascade that enhances outflow, similar to other forms of trabecular injury.

DR GERHARD W. CIBIS: When Harms and Dannheim originally developed the trabeculotomy, they thought that it would be the cure for adult open-angle glaucoma; they did a very large adult study but did not find long-term success. However, it did seem to be effective in pediatric glaucoma. Could you please comment?

DR M. BRUCE SHIELDS: We are all searching for a better operation, one that's more physiological, and this procedure may represent that opportunity. We are, of course, trying to get the aqueous humor to the scleral outlet channels, but are we getting the aqueous only into that portion of the canal and associated outlet channels that is directly exposed by removing the meshwork or is the aqueous getting into the rest of the canal? I think we are finding from the surgeons who are designing shunts that go into Schlemm's canal that there is a problem with lack of circumferential flow. So, my question is how much meshwork do we have to remove to expose enough outlet channels to significantly reduce the intraocular pressure?

DR EDWARD L. RAAB: You describe discontinuous goniosynechiae as a complication of the procedure. It is not uncommon to see that in pediatric cases, even when their glaucoma is well controlled. Do you call it a complication because it compromised the result or is it more accurate to call it an occurrence?

DR DONALD S. MINCKLER: According to older literature, trabeculotomy and goniotomy in adults were not very successful. However recent case series, especially from Japan, have touted the efficacy of ab-externo trabeculotomy for adult glaucoma, including its being combined with cataract surgery.[1-4] A randomized trial from Europe has also reported good outcomes in adult open-angle glaucoma with mechanical ab-interno trabeculotomy in adults. [5]

Many of the important questions brought up by Dr. Cioffi in his discussion would be most appropriately addressed by a prospective randomized trial (RCT) comparing the Trabectome to trabeculectomy, laser trabeculoplasty, or medical therapy. We hope to initiate such studies in the near future. Our initial strategy has been to complete a large prospective case series in the process of which several surgeons would be familiarized with the procedure, technique issues standardized, at least short-term clinical outcomes determined, and complications assessed. As all clinical investigators well-appreciate, there are daunting problems including financial burdens for the sponsors and investigators involved in organizing and conducting an RCT utilizing a new surgical device. Importantly without a favorable initial experience in pilot studies, there would be no reason to proceed to a comparative clinical trial. Dr. Cioffi's comment about the advantages of survival curve analysis, including details of drop outs and failures are well-taken in addition to the exclusion of combined cataract and Trabectome patients from data analysis. All these important issues would be part of analyzing comparative trials. Subsequent to this presentation, the Editor of TAOS has kindly allowed us to append a survival curve based on 116 patients, including 26 combined cataract and Trabectome™ procedures (see Table and survival graph below). P-values [paired t-test] were highly statistically significant ($p < .004$) at all time-points for both absolute drop in IOP and % drop in IOP from baseline.

Aqueous flow in Schlemm's canal, from prior comments made by David Epstein, is thought to be compartmentalized in adults whereas in children it is probably circumferential. We do not know how much of the angle needs to be opened using the Trabectome but have assumed the more the better and it is technically possible to open between 90 and 120 degrees via a single incision. Two separate incisions could be used to allow even more of Schlemm's to be un-roofed. Johnson and collaborators have reported perfusion experiments in an autopsy eye anterior segment organ culture model indicating that trans-trabecular tubes (Glaukos®) inserted into Schlemm's canal increase outflow in proportion to the number inserted.[6] The conclusions were consistent with previous studies indicating that the initial opening into Schlemm's makes the largest difference in outflow but that additional openings add effect.[7]

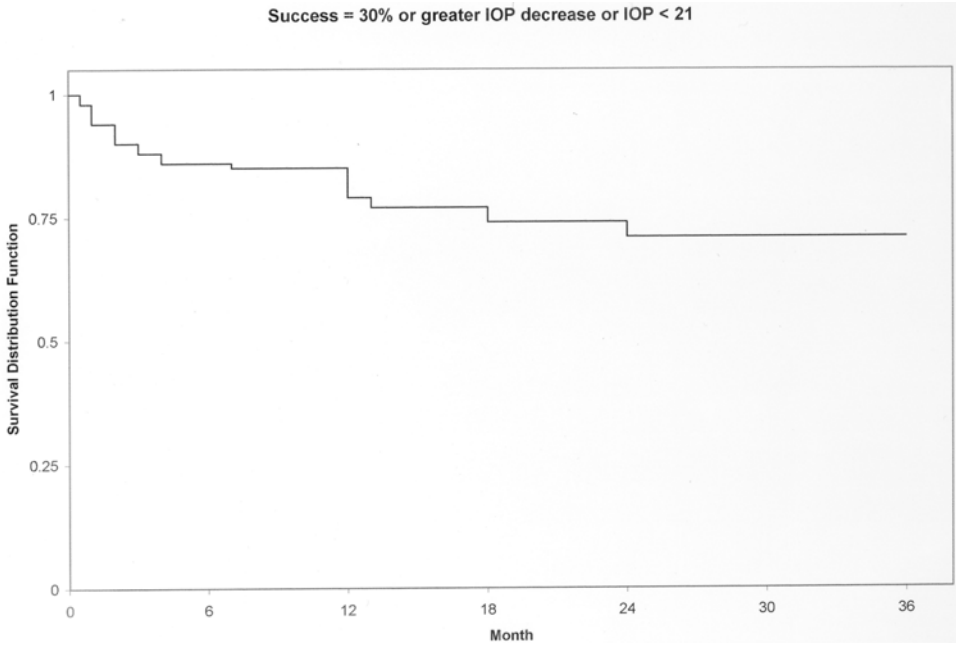
Goniosynechiae and frank PAS, in my experience, are common after goniotomy or trabeculotomy in children noted during subsequent EUAs when the segments of angle previously treated may be found to appear completely closed, even though IOP is improved. Those adult patients in our present series with post operative gonioscopy out at least several months have demonstrated only minimal goniosynechiae or PAS formation. In the majority the surgical opening into Schlemm's remains unchanged from the

intra-operative appearance. I favor categorizing post operative goniosynechiae or PAS as untoward events, rather than “occurrences”, simply based on hope that the ideal procedure would not lead to these changes. Clearly, at this juncture, we have no means of knowing whether or not focal segments of post operative angle closure negatively affect surgical results.

TABLE. UPDATED TRABECTOME CASES AS OF 8/25/06 WITH 2 WEEKS OR MORE FOLLOW-UP.

MONTH	CUMULATIVE SURVIVAL	NUMBER OF FAILURES / NUMBER AT RISK
½	98%	2/116
1	94%	5/112
2	90%	4/99
3	88%	2/78
4	86%	1/64
5	86%	0/54
6	86%	0/54
7	85%	1/50
8	85%	0/45
9	85%	0/43
10	85%	0/43
11	85%	0/43
12	79%	3/43
13	77%	1/37
18	74%	1/30
21	74%	0/23
24	71%	1/22
30	71%	0/13
36	71%	0/5

Success = IOP reduction 30% or greater, or IOP < 21 and no repeat surgeries



FIGURE

Survival graph plotting "success" over time in months after Trabectome surgery. Success was defined for this illustration as a 30% or greater drop in IOP from baseline and or IOP < 21 mmHg.

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