

Preclinical Investigation of Ab Interno Trabeculectomy Using a Novel Dual-Blade Device

LEONARD K. SEIBOLD, JEFFREY R. SOOHOO, DAVID A. AMMAR, AND MALIK Y. KAHOOK

- **PURPOSE:** To evaluate the effects of a novel ab interno trabeculectomy device on human trabecular meshwork (TM).
- **DESIGN:** Laboratory evaluation.
- **METHODS:** The TM from human cadaveric corneal rim tissue was incised using 3 instruments: (1) novel dual-blade device; (2) microvitreoretinal (MVR) blade; and (3) Trabectome. Tissue samples underwent histologic processing and comparative analyses. Subsequently, human eye perfusion studies were performed to evaluate intraocular pressure (IOP)-lowering effects of each device. Main outcome measures were degree of TM removal by histology and IOP in a perfusion model.
- **RESULTS:** The MVR blade exhibited minimal removal of TM and obvious injury to the adjacent sclera. The Trabectome removed a large portion of the central TM, but leaflets of residual tissue remained and thermal injury was noted in all samples. The dual-blade device achieved a more complete removal of TM without injury to surrounding tissues. All devices resulted in statistically significant lowering of IOP during perfusion model studies. MVR blade treatment across 170.0 ± 14.1 degrees of TM resulted in a decrease of IOP from 18.5 ± 1.9 mm Hg to 12.8 ± 2.2 mm Hg ($P < .01$). Trabectome treatment across 117.5 ± 12.6 degrees resulted in a decrease of IOP from 18.8 ± 1.7 mm Hg to 11.3 ± 1.0 mm Hg ($P < .01$). Dual-blade device treatment across 157.5 ± 26.3 degrees resulted in a decrease of IOP from 18.3 ± 3.0 mm Hg to 11.0 ± 2.2 mm Hg ($P < .01$).
- **CONCLUSIONS:** The novel dual-blade device demonstrated a more complete removal of TM without residual TM leaflets or damage to surrounding tissues and significantly reduced IOP in a human eye perfusion model. (Am J Ophthalmol 2013; ■:■-■. © 2013 by Elsevier Inc. All rights reserved.)

GLAUCOMA IS A LEADING CAUSE OF BLINDNESS worldwide.¹ The only known modifiable disease risk factor is intraocular pressure (IOP).

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Treatment centers on lowering IOP pharmacologically with hypotensive medications or surgically through the use of lasers or incisional procedures. The main area of obstruction to aqueous outflow, with subsequent dysregulation of IOP, is thought to be located at the juxtacanalicular trabecular meshwork (TM) and distal outflow structures.²⁻⁴ Performing a goniotomy or trabeculotomy in adults with glaucoma has not been associated with great success in lowering IOP.^{5,6} In contrast, these procedures are more successful in congenital glaucoma, where a membrane covering the TM is thought to be a major factor in impedance of aqueous outflow.⁷ More recently, there have been attempts to use novel ab interno trabeculectomy procedures to remove TM in adult patients and results have been mixed.⁸⁻¹⁰

One reason for poor long-term outcomes with this approach in adults might be related to incomplete removal of TM and membrane formation across the remaining TM leaflets with subsequent elevation in IOP.¹¹ It is unclear how a more complete removal of TM tissue might compare to procedures that simply incise TM, such as goniotomy, or procedures that cauterize TM with tissue removal, such as Trabectome (Neomedix, Tustin, California, USA). This study investigates the preclinical use of a novel dual-blade device to more completely remove TM tissue. The dual-blade device is specifically designed to conform to the drainage angle anatomy of the human eye. The device is meant to perform an ab interno trabeculectomy by engaging TM and cutting the target tissue while minimizing leaflets left in place and damage to adjacent tissues. The device was designed and manufactured at the University of Colorado Eye Center (patent filing # 61637611). Tissue effects from the novel device are compared to those from a goniotomy using a microvitreoretinal (MVR) blade (BD, Franklin Lakes, New Jersey, USA) and cautery of TM with the Trabectome device. Human eye perfusion studies were also completed to assess the IOP-lowering efficacy of each approach.

METHODS

APPROVAL FOR THIS PRECLINICAL STUDY WAS OBTAINED from the Colorado Multiple Institutional Review Board for the use of human material prior to initiation of this study and the tenets of the Declaration of Helsinki were followed. Informed consent was obtained from donors or

relatives for use in research by the eye bank from which human globes were obtained.

For histologic analyses, 6 corneal rim specimens were obtained from the Rocky Mountain Lions Eye Bank (Aurora, Colorado, USA) and the San Diego Eye Bank (San Diego, California, USA). Tissue samples were removed from the storage medium and mounted on a platform with the TM side facing up and secured in place using tissue pins. A total of 2 samples were used for each of the 3 treatment methods studied. An MVR blade was used to incise the central TM under microscopic visualization along the length of 2 corneal rims. For the Trabectome device, the foot plate of the device tip was inserted into the Schlemm's canal under microscopic visualization. Once in place, the foot pedal was used to apply continuous ablation while advancing the tip slowly across the extent of the TM sample. A standard power setting of 0.8 W was used during treatment. The dual-blade device was used to incise the TM of 2 samples. The blade tip was used to incise TM in a manner similar to that used for goniotomy and the blade was then advanced in a clockwise fashion along the extent of the TM. At the distal end, the blade tip was tilted upwards to incise a complete ribbon of TM and the process was repeated in a counterclockwise fashion to incise the remaining TM tissue.

All tissue samples were then immediately preserved in 4% paraformaldehyde/phosphate-buffered saline overnight at 4 C and then radially cut into quadrants. Rim sections were processed for histology and embedded into paraffin so that the cut edge of the tissue was facing the front of the block. Tissue sections (6 μ m thick) were cut and stained with Mayer's hematoxylin-eosin Y (Richard-Allan Scientific, Kalamazoo, Michigan, USA). Bright-field imaging was performed using a Nikon Eclipse 80i microscope (Nikon, Melville, New York, USA) equipped with a Nikon D5-Fi1 color camera and a Nikon CFI 10 \times /Plan Fluor objective lens.

• **HUMAN EYE PERFUSION STUDIES:** A total of 12 human globes from pseudophakic donors with no history of glaucoma were obtained from various eye banks around the country for perfusion studies on each device. The perfusion system used a standard programmable syringe pump (Pump 11 Plus; Harvard Apparatus, Holliston, Massachusetts, USA). Pressure was monitored via an in-line real-time pressure transducer (Research Grade Pressure Transducer; Harvard Apparatus) connected to a single-channel chart recorder (Pharmacia REC-481; Pharmacia/Pfizer New York, New York, USA). Polyethylene tubing with a 1.14 mm inner diameter (PE-160; Warner Instruments, Hamden, Connecticut, USA) was used for all connections.

In each case, the human globe was first prepared by injecting Dulbecco's modified Eagle medium (DMEM; Invitrogen/Life Technologies, Carlsbad, California, USA) through the optic nerve with a 26-gauge needle until the globe had returned to a spherical shape. The perfusion

line (terminating in another 26-gauge needle) was inserted diagonally through the anterior chamber of the eye, passing through the cornea and pupil and ending with the tip beneath the iris. The globe was surrounded by damp gauze and the perfusion pump (filled with DMEM) was set to an initial inflow rate of 7 μ L/min. IOP was allowed to increase until it reached 30 mm Hg. The infusion rate was then reduced to 2-5 μ L/min to maintain a steady-state IOP for at least 60 minutes prior to TM incision. A preoperative IOP was measured immediately prior to incision in each case. A 1.7 mm stainless steel keratome blade (BD) was used to create a tri-beveled clear corneal incision near the limbus, and the anterior chamber was filled with enough viscoelastic (HealonGV; Abbott Medical Optics, Abbott Park, Illinois, USA) to maintain the anterior chamber and provide adequate visualization during the procedure in each case. Each technique was performed under gonioscopic view using a standard direct gonioscope with microscope assistance. The surgical procedure used for each device is described above. In each case, approximately 100-180 degrees of TM was treated. For each device, treatment was started 180 degrees away from the corneal wound and extended along the angle in a clockwise direction. The device was then extended in a counterclockwise direction from the same starting point. Every effort was made to treat the maximum amount of degrees possible with each device. In the case of the dual-blade device and Trabectome, the instrument was rotated 180 degrees after the initial pass to direct the device tip in the direction of treatment. IOP was allowed to reach a steady state before measuring the postprocedure IOP. Each of the 3 studied surgical techniques was performed on a total of 4 eyes.

• **DATA ANALYSIS:** The mean and standard deviation of preprocedure and postprocedure IOP was calculated for each device as well as percent change in IOP. Student paired *t* tests were used to compare preprocedure and postprocedure IOP for each device. A calculated *P* value < .05 was considered to be statistically significant.

RESULTS

TWO CORNEAL RIM SECTIONS WERE ANALYZED FOR EACH device. Six-micron-thick histologic sections were taken from various clock hours treated with each device and stained with Mayer's hematoxylin-eosin Y (Richard-Allan Scientific). Findings were consistent across all sections from each device tested. Cuts with the MVR blade exhibited complete incision through the entire thickness of TM tissue. However, there was minimal removal of TM with large leaflets of tissue remaining over the Schlemm's canal. The incision extended deeply through the Schlemm's canal with obvious injury to the adjacent deep sclera in the majority of sections (Figure 1). The

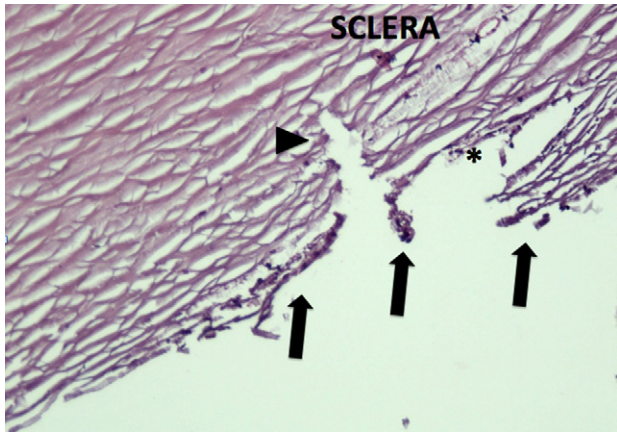


FIGURE 1. Histologic specimen of human anterior chamber angle structures following incision with a microvitrectomy (MVR) blade. The incision extends through full-thickness trabecular meshwork and the Schlemm's canal and into adjacent sclera (black arrow head). A large portion of trabecular meshwork remains on either side of the incision (black arrows). An asterisk labels the Schlemm's canal. Light micrograph, hematoxylin-eosin, magnification $\times 100$.

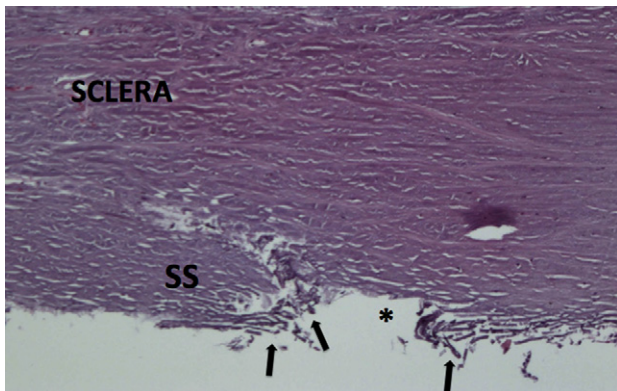


FIGURE 2. Histologic specimen of human anterior chamber angle structures following incision with Trabectome. The incision extends through full-thickness trabecular meshwork without damage to adjacent sclera. A portion of trabecular meshwork has been removed centrally with a moderate amount of residual tissue on either side of the incision (black arrows). Charring of the incision edges is noted. An asterisk labels the Schlemm's canal. SS = scleral spur. Light micrograph, hematoxylin eosin, magnification $\times 100$.

Trabectome also achieved an opening through the entirety of TM tissue into the Schlemm's canal. Although the device also removed a large portion of the central TM, significant leaflets of residual tissue still remained. The residual TM demonstrated extensive charring from thermal injury. Tissue debris was also noted to be occluding distal collector channels (Figure 2). Tissue incised with the

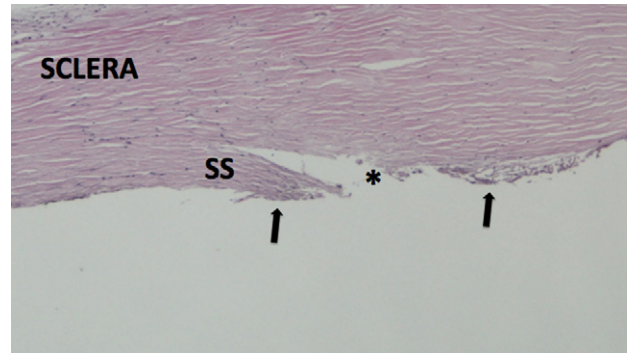


FIGURE 3. Histologic specimen of human anterior chamber angle structures following incision with the dual blade device. The incision extends through full-thickness trabecular meshwork without injury to adjacent sclera. A near-complete removal of trabecular meshwork tissue has been accomplished (black arrows). An asterisk labels the Schlemm's canal. SS = scleral spur. Light micrograph, hematoxylin-eosin, magnification $\times 100$.

dual-blade device demonstrated a more complete removal of TM without collateral damage (Figure 3).

Data from human eye perfusion studies are included in the Table. The extent of TM treatment varied between devices and between eyes from 100 to 180 degrees. All 3 treatment modalities achieved a significant reduction in measured IOP 30 minutes after treatment. Treatment with the dual-blade device and Trabectome resulted in a mean IOP reduction of 40% each, whereas the MVR blade achieved a 31% reduction. Although the percentage of IOP decrease was greater for Trabectome and the dual-blade device, there was no statistically significant difference in the IOP lowering between devices (dual-blade/MVR $P = .13$; dual-blade/Trabectome $P = .96$; Trabectome/MVR $P = .12$). There was no correlation between the number of degrees of TM treated and the percentage IOP change for any device ($r^2 = 0.077-0.271$).

DISCUSSION

IN THIS STUDY, WE PRESENT THE INITIAL PRECLINICAL evaluation of a novel dual-blade device for the treatment of glaucoma. Histologic analysis of human cadaver eye tissue treated with the dual-blade device achieved more complete removal of TM tissue while avoiding any discernible damage to surrounding tissue. Treatment with other methods of TM removal such as MVR blade goniotomy and ab interno trabeculectomy with the Trabectome device failed to attain equivalent histologic results to the novel dual-blade device. While histology data were obtained from ex vivo-treated corneal rims, similar findings were noted when treatment was performed using the ab interno approach on perfused eyes. The near-absence

TABLE. Human Eye Perfusion Studies After Treatment of Trabecular Meshwork by Various Devices

	Eye	Degrees of Angle Treated	Preprocedure IOP	Postprocedure IOP	Absolute IOP Change	Percent IOP Change	P Value
Dual-blade device	1	140	17	10	-7	-41	
	2	180	19	11	-8	-42	
	3	130	15	9	-6	-40	
	4	180	22	14	-8	-36	
	Mean	157.5 ± 26.3	18.3 ± 3.0	11.0 ± 2.2	-7.3	-40	.00063
MVR blade	1	180	20	14	-6	-30	
	2	180	20	15	-5	-25	
	3	150	18	12	-6	-33	
	4	170	16	10	-6	-38	
	Mean	170.0 ± 14.1	18.5 ± 1.9	12.8 ± 2.2	-5.8	-31	.00018
Trabectome	1	120	18	12	-6	-33	
	2	130	21	12	-9	-43	
	3	100	17	11	-6	-35	
	4	120	19	10	-9	-47	
	Mean	117.5 ± 12.6	18.8 ± 1.7	11.3 ± 1.0	-7.5	-40	.00324

IOP = intraocular pressure; MVR = microvitrectomy.

of TM leaflets with the dual-blade device may be beneficial in reducing the chances of future physical obstruction, and the lack of tissue damage may also reduce the inflammatory response or subsequent fibrosis at the surgical site.

In addition to potentially favorable histologic outcomes, the dual-blade device resulted in significant IOP lowering in a human eye perfusion model. Although all 3 devices yielded similar immediate reduction in IOP after use in a perfusion model, it is unclear how a more complete removal of TM tissue and decreased collateral damage with the novel dual-blade device will translate into long-term surgical outcomes when used to treat glaucoma. Interestingly, we found no correlation between degrees of TM treated and IOP reduction. It is plausible that IOP reduction may depend more on the number of downstream collector channels exposed rather than the absolute amount of TM removal alone. More clinical studies are needed to understand this relationship.

Recently, there has been a growing trend toward innovations in minimally invasive glaucoma surgery (MIGS). The risks and imperfections of guarded filtration surgery and tube shunt procedures have driven this paradigm shift despite the proven long-term efficacy of these incisional procedures. Drawbacks of traditional incisional procedures include unpredictable IOP-lowering results, prolonged visual recovery, long-term risk of infection and vision loss, frequency of follow-up visits, and long-term failure rate.¹² Procedures such as endoscopic cyclophotocoagulation, ab interno trabeculectomy with Trabectome, and canaloplasty with the iScience illuminated catheter (iScience, Menlo Park, California, USA) were all introduced to address limitations of full-thickness surgery, most notably to eliminate the presence of a filtering bleb. However, a major drawback of all of these procedures is

the additional equipment cost required and, in some cases, a steep learning curve. The added equipment cost in particular presents a significant hurdle to providers, hospitals, and surgery centers that may require several procedures to recoup the initial investment. Providers and patients may also face opposition from insurance companies regarding coverage of a novel procedure lacking long-term efficacy data. The requirement for additional equipment also limits patient access to these procedures in underserved areas of the world.

In an effort to provide a low-cost MIGS device that can be widely used by ophthalmic surgeons, we designed a novel medical-grade stainless steel dual-blade device that can successfully remove TM with no discernible collateral damage. The unique dual-edge blade design uses precise geometries to allow for more complete removal of TM tissue (Figure 4). The procedure is performed from an ab interno approach and requires viscoelastic to maintain the anterior chamber. The size and tip of the blade allows for smooth entry into the Schlemm's canal, similar to techniques used for traditional goniotomy procedures. Once in place, the tip is advanced through the Schlemm's canal and the TM is elevated along a designed ramp that guides tissue toward a set of blades positioned specifically to incise and remove TM. In contrast to the Trabectome footplate, which is juxtaposed between the outer wall of the Schlemm's canal and the inner wall of the Schlemm's canal to provide protection during cautery, the dual-blade device transects TM and has a primary purpose of elevating TM off of the outer wall of the Schlemm's canal. Elevating the TM along the ramp of the device as it moves forward leads to maximal tissue removal when incised by the superiorly placed and strategically angled dual blades. The angle between the distal cutting edge and the handle is engineered to allow



FIGURE 4. The dual blade device for treatment of glaucoma. The device is illustrated to reveal the dual cutting blades (black arrows) as well as the distal point (asterisk) that is designed to pierce the trabecular meshwork (TM) and enter into the Schlemm's canal. Once in the canal, the device is advanced so that the TM moves up the ramp from the distal point toward the dual cutting blades, which then cleanly incise the presented TM. The distance between the dual blades is designed to closely match that of the width of the TM. The inset is a photo of the first prototype device that was made of medical-grade stainless steel.

maximal angle treatment through 1 incision while avoiding trauma to the cornea above or the scleral spur below. The excised TM may then be removed from the eye with forceps or aspirated during the irrigation/aspiration phase if combined with cataract extraction. In addition, the device can easily pass through clear corneal incisions as small as 1.2 mm, thus obviating the need for additional incisions when coupled with phacoemulsification.

Another device that has been used for ab interno trabeculectomy is known as the "gonioscraper," as described by Jacobi and associates.¹³ This device consisted of a handle and curette tip and was used to remove TM by scraping the curette within the Schlemm's canal. The curette tip is in line with the handle and does not conform to the geometry of the drainage angle and adjacent structures. After promising preclinical experiments, a nonrandomized clinical trial of 25 eyes was completed.¹⁴ Preoperative IOP was 34.7 ± 7.1 mm Hg on 2.2 ± 0.56 medications and mean follow-up time was 32 months. Based on the success criteria of postoperative IOP of 19 mm Hg or less with 1 pressure-reducing agent, 15 eyes (60%) were successful. Complications included localized Descemet membrane detachments and anterior chamber bleeding. Histologic analysis of banked human eyes treated with the curettage showed successful removal of TM tissue, but with damage to the septa and endothelium of the external and posterior wall of the Schlemm's canal.¹³ In our experiments, this damage to adjacent sclera was also observed with the

MVR blade, but was absent with use of the dual-blade device. In addition, the novel blade device geometry is designed to minimize any impact to adjacent tissues such as Descemet membrane by leveraging specific angles between the handle and the distal blade as well as use of specific angles between the cutting blade and the adjacent cutting tip. Whether these improvements will result in superior surgical outcomes compared to the gonioscraper remains to be seen.

There have been reports of both success and failure with the Trabectome device over the past few years.^{8-11,15} In a recent retrospective study of Trabectome versus ab externo trabeculectomy, Jea and associates found poor success rates in eyes treated with Trabectome at 2 years.⁸ Of the 115 eyes treated with Trabectome, only 22.4% achieved success with failure defined as IOP >21 mm Hg or $<20\%$ reduction in IOP. It is conceivable that, after initial opening of the canal with TM removal, the residual leaflets occlude the Schlemm's canal and/or the more distal collector channels, leading to failure of the intervention. This mechanism of failure after Trabectome treatment would be overcome by the dual-blade device, as a more complete removal of TM tissue is produced without residual leaflets.

There are several practical advantages of this device for use in ab interno trabeculectomy, in addition to the findings presented here. First, the device may be reusable and can be added to a standard cataract surgical tray. Second, the lack of moving parts or the need for coupled irrigation or a separate power source allows for inexpensive manufacturing and rapid acquisition of surgical expertise. This would permit easy, economical access to a new technique, especially in underserved locations around the world. For comparison, the Trabectome requires a substantial initial investment for the irrigation/aspiration unit and generator in addition to the cost of one-time-use items such as the hand piece and tubing. The simple design and material requirements for the dual-blade device would be more economical. Finally, in contrast to other techniques for TM removal, this device's design conforms to the Schlemm's canal anatomy, minimizes damage to adjacent tissues, and provides excellent control over excised tissue. It should be noted that the favorable histologic results for the dual-blade device were performed under experimental settings in this study, and it is therefore unclear if similar findings would be achieved from an ab interno approach clinically. While the device has the potential to damage the outer wall of the Schlemm's canal in a clinical setting, all of the compared devices carry the same potential risk.

In conclusion, the presented novel dual-blade MIGS device represents a novel technique to perform ab interno trabeculectomy with or without concomitant cataract extraction. The device is capable of more complete removal of TM tissue from the anterior chamber angle in a simple and inexpensive manner. Perfusion eye studies support the potential for significant IOP reduction with

this technique. Although preclinical use is encouraging, future clinical studies are needed to elucidate the safety and efficacy of the device compared to other reference devices.

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Biosketch

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Biosketch

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