



Trabectome®—Forging a New Frontier in Primary Open Angle Glaucoma Management An Advanced Medical Device which Greatly Reduces Glaucoma Surgery Time and Improves Outcome

a report by
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Glaucoma surgical intervention has now advanced a step further - from trabeculectomy to Trabectome. Trabectome is a Food and Drug Administration (FDA) cleared device for minimally invasive surgical treatment of primary open angle glaucoma. It safely ablates and removes a 90-120° strip of trabecular meshwork and re-establishes access to the eye's natural drainage pathway. On average, patients can go home within two hours of this minimally invasive procedure.

Features and Ease of Use

Trabectome has three major components:

- * a mobile console stand equipped with a high frequency generator and an irrigation and aspiration unit;
- * a disposable handpiece with an automated irrigation/aspiration port and electro-surgical ablation tip; and
- * a three-stage foot-pedal to control.

The disposable Trabectome handpiece incorporates a variable power bipolar micro-surgical pulse with simultaneous irrigation and aspiration. The micro-surgical pulse allows for safe ablation and removal of the trabecular meshwork, unroofing Schlemm's canal and exposing the natural drainage pathway of the eye (collector channels) to aqueous humor.

The intraocular portion of the instrument consists of a handle including a 19-gauge infusion sleeve, a 25-gauge aspiration port, and a coupling for the ablation unit at the tip. The surgical end of the instrument is bent 90° to the shaft to create a triangular footplate. The footplate has a moderately sharp point to facilitate penetration of the meshwork into Schlemm's canal and is coated with a smooth ceramic insulating material to help act as a guide within Schlemm's canal. It glides along the inside of the canal, protecting the canal's outer wall and adjacent tissues from thermal or mechanical injury. The hook design serves to feed trabecular and adjacent tissues into the ablative device as the instrument tip is advanced through angle tissues. The elliptical footplate is sized to fit into Schlemm's canal, and protect the posterior wall and adjacent tissues from thermal injury.

Safety Profiles

Trabectome has excellent operative and post-operative safety profiles. This device has not resulted in any of the following post operative complications:

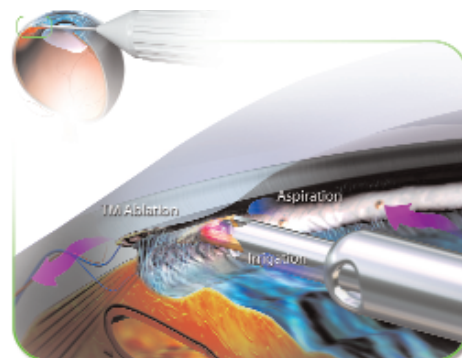
- flat or shallow anterior chamber;
- persisting corneal edema;
- iris injury;
- hypotony or hypotony maculopathy;
- infection;

- wound leak;
- bleb formation and infection;
- choroidal effusion;
- choroidal hemorrhage; and
- visual acuity decrease (>2 lines)

Trabectome System



Ab Interno Trabeculectomy



- ▶ **Ab interno trabeculectomy** Removal of diseased tissue using electro-surgical pulse. Continuous irrigation and aspiration removes debris and regulates temperature.

Removal of diseased tissue using electro-surgical pulse. continuous irrigation and aspiration removes debris and regulates temperature.



Don Minckler, MD, Professor of Ophthalmology, University of California, Irvine says, "Reduction of intraocular pressure (IOP) in an ongoing prospective case series eyes has averaged 40% - mean pre-operative IOP of 24 mmHg to mid-teen levels (mean post-operative IOP of 16 mmHg - persisting for at least 40 months in 15 patients.

Advantages include short surgical times, simplified post-operative followup, no bleb formation or late infection risk, and no damage to conjunctiva, precluding standard filtering surgery thereafter, if necessary. Thus far, progression of cataract in phakic eyes has been minimal, also in sharp contrast to standard filtering procedures. Complications in general, other than expected back-bleeding, have been minimal and non-vision threatening.

Trabectome Training for Physicians

Currently, trainees fly into one of the qualified US based Trabectome Centers from all over the world to participate. NeoMedix offers a two-day monthly training program for glaucoma physicians interested in the Trabectome procedure. Day one consists of a didactic presentation and a hands-on wet lab training session using Trabectome on donor corneal rims with inventor of Trabectome, George Baerveldt, MD, Irving H. Leopold Professor and Chair of Ophthalmology, University of California, Irvine. Day two of the training gives physicians first-hand observations of Trabectome procedure both as stand alone and as combined cases. Physicians are subsequently mentored by a Trabectome trainer. Please visit www.trabectome.com or send email to info@NeoMedix.NET. ■

1. Minckler DS, Baerveldt G, Ramirez-Alfaro M, et al, Clinical Results with the Trabectome for treatment of Open Angle Glaucoma. *Ophthalmology* 2005; 112(6):962-967.
2. Francis BA, See RF, Rao NA, et al, Ab-interno Trabeculectomy: Development of a novel device (Trabectome(r)) and surgery for open angle glaucoma." *Journal of Glaucoma* 2006; 15:68-73.

3. Baerveldt G, Chuck R, Minimally invasive Glaucoma Surgical Instrument and Method. *US Patent Number: US 6,979,328 B2 Issued: Dec. 27, 2005.*
4. Trabectome is produced under issued US Patent. Foreign patent applications are pending.