Ab Interno Trabeculectomy: Development of a novel device (Trabectome®) and surgery for open angle glaucoma

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Purpose
To design an instrument to selectively remove trabecular meshwork and Schlemm’s canal inner wall (SCIW), and demonstrate its effectiveness by histologic analysis of treated cadaveric human tissue.

Methods
The design parameters of the instrument were the ability to permanently remove a segment of TM and SCIW without causing damage to surrounding tissue, and to allow use with standard anterior segment surgical techniques and equipment via an ab interno approach.

Treatment was applied to 2 segments of human corneoscleral rims. The treated areas were examined using a confocal microscope and compared to matching areas in untreated controls and simulated goniotomy.

Results
• The resultant instrument system surgically removes the TM and SCIW from an anterior chamber approach. It consists of a disposable surgical handpiece with irrigation, aspiration and electrocautery to focally ablate the target tissues. The attached console includes a high-frequency (550 Khz) electrosurgical generator and irrigation/aspiration controlled by a foot pedal.

• The Trabectome™ system consists of a disposable handpiece, console with irrigation and aspiration and an electrocautery generator.

• Handpiece: 19.5 gauge, fits through a 1.6 mm corneal incision with a specially designed insulated footplate (figure 1) pointed for insertion through TM into SC.

• The footprint of the TM and puts it on a slight stretch, positioning the tissue for maximal discharge while protecting underlying tissues.

• Footplate insulation: multi-layered polymer coating protects the outer wall of SC from thermal injury with a temperature increase of 1.2°C. Thin coats of the material are applied in multiple layers to the footplate and then thermally cured into a smooth, rigid, intractable polymeric film.

• Aspiration port 0.3 mm from cautery electrode removes debris, and irrigation 3 mm from the surgical site keeps the eye pressurized and further dissipates heat energy.

• The console (figure 2) includes an I/A unit and high frequency electrocautery generator, a modified 800 EU unit from Aaron/Bovie (St. Petersburg, FL), with a frequency of 550-kHz and power in 0.1 watt increments up to 10 watts (recommended range 0.5 – 1.5W).

• Ablation: tissue is disrupted and disintegrated by applying heat energy in bursts with a high peak power and low duty cycle. High energy bursts are bunched into small intervals with longer time intervals in between, causing a disruptive and disintegrating, rather than a "cooking" effect.

• Irrigation/Aspiration: pinch valve for irrigation flow from BSS; height is adjusted manually with a standard height of 80 cm. The aspiration pump is peristaltic with adjustable flow rates up to 10 ml/min (standard = 3 ml/min).

• Foot-pedal control: activates irrigation, aspiration and electrocautery power in a stepwise fashion similar to that used in phacoemulsification.

Conclusion
• Minimally invasive, safe removal of Trabecular Meshwork and inner wall of Schlemm’s canal.

• Creates direct access for aqueous to outflow channels

• User-friendly, simple skill transfer.

• Anterior segment surgery requiring only small clear-anterior chamber corneal incision.

• Can be easily combined with phaco cataract extraction

• Controlled anterior segment surgery with continual irrigation/aspiration.

• Low patient risk – no conjunctival or scleral manipulations.

• Excellent safety profile with minimal post-operative complications

• Does not preclude subsequent standard filtering procedures.

Trabectome® Features
• Minimally invasive, safe removal of Trabecular Meshwork
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Reference

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