Expert Reviews

Ab interno trabeculotomy: Trabectome™ surgical treatment for open-angle glaucoma

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Glaucoma is a group of diseases that lead to the loss of retinal ganglion cells and damage to the optic nerve with associated visual function loss. The primary risk factor is elevated intraocular pressure and therapy is directed toward lowering the pressure through medical and surgical interventions. The Trabectome™ is a novel device used to remove a portion of the trabecular meshwork and inner layer of Schlemm's canal within the anterior chamber to allow for increased aqueous outflow. It is similar to trabeculotomy, with the primary difference being the permanent ablation and removal of trabecular meshwork tissue rather than a simple incision through this tissue. It offers a safer and more efficient procedure than the current gold standard, filtering surgery, while still providing reduction of intraocular pressure without reports of vision-threatening complications. Therefore, it can be offered earlier in patient management, as well as in conjunction with cataract extraction. Trabeculotomy was previously only reserved for treatment of congenital glaucoma, but the Trabectome has demonstrated its effectiveness in adults with open-angle glaucoma.

Keywords: ab interno trabeculectomy • glaucoma • goniotomy • open-angle glaucoma • surgical glaucoma • Trabectome™ • trabeculotomy

Glaucoma remains the second leading cause of blindness worldwide and increases in prevalence with age [1]. With the continued growth of the world's population, the potential burden of blindness secondary to this eye disease continues to be a significant problem. Glaucoma is defined as a group of eye diseases involving the loss of retinal ganglion cells, leading to irreversible optic neuropathy. Among the different types of glaucoma, open-angle glaucoma is the most common in the USA and causes visual loss, leading to difficulty with mobility, driving and many aspects involving a patient's quality of life [2].

Intraocular pressure (IOP) remains one of the major risk factors for optic nerve damage and a main treatment goal for glaucoma patients is IOP control. Reducing IOP can be accomplished by decreasing the amount of aqueous humor produced by the ciliary body or by increasing its outflow [2]. Available treatment for glaucoma includes medical management with topical eye drops or surgical procedures, such as laser trabeculoplasty or filtering surgery. Current surgical therapy for open-angle glaucoma can be further divided into procedures directed at decreasing aqueous inflow or increasing outflow [3].

Overview of the current options

Outflow surgeries are based on the hypothesis that the majority of outflow obstruction in primary open-angle glaucoma lies in the juxtacanalicular trabecular meshwork (TM) or inner wall of Schlemm's canal (SC) [4,5]. In order to overcome this obstruction, surgical procedures can be performed to bypass the normal outflow channels via a direct opening into the episcleral space across the sclera, such as the current gold standard for surgical treatment, trabeculectomy with adjunctive 5-fluoruracil or mitomycin-C [6,7]. Also, due in part to the results of the Tube versus Trabeculectomy study, aqueous shunt surgeries are being considered and performed earlier in the treatment regimen, and not necessarily reserved for eyes where trabeculectomy has failed or is at high risk for failure [8]. Although long-term success can be achieved with low IOPs, both of these procedures have potential complications. Trabeculectomy with antifibrotic agents presents

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the risks of hypotony, hypotony maculopathy, bleb leaks, late blebitis, choroidal effusion and hemorrhage, bleb-related endophthalmitis, peripheral anterior synechiae formation, posterior synechiae, and cataract formation [9–14]. Glaucoma drainage devices may also develop early hypotony, choroidal effusion, suprachoroidal hemorrhage, shallow anterior chamber, diplopia, tube obstruction, conjunctival erosion, tube migration, corneal decompensation, plate encapsulation and late failure [15–17].

As resistance to outflow is secondary to the trabecular meshwork, another surgical option with fewer risk complications includes removing this area and creating a direct pathway to SC and the aqueous collector channels, which will increase outflow. Goniotomy and trabeculotomy were the first surgical procedures directed at the TM and have had success rates between 58 and 100% in congenital glaucoma cases [18–21]. Both procedures were attempted in the adult glaucoma population with moderate success [22]. It is believed that adult angle tissue has thicker trabecular beams with less elastic tissue morphology, perhaps explaining why the severed ends of the TM after goniotomy in adults are more likely to scar back together [20,23,24]. Since their development, many other ab interno alternatives, such as goniocurretage, trabeculopuncture or goniopuncture have also been developed but have had similar limited long-term success in adults [19,25–33].

Introduction to the Trabectome™

This review describes the development of a novel ab interno trabeculotomy procedure utilizing the Trabectome™ device (NeoMedix, Inc., CA, USA), which was approved in April 2004 by the US FDA. Based on the principle of removing a portion of the TM and inner wall of SC, this procedure utilizes electrocautery to selectively ablate TM tissue and create an opening from the anterior chamber into SC and the collector channels. It also has several other clinical advantages, such as a temporal clear cornea approach, which leaves the conjunctiva available for subsequent conventional filtration surgery as necessary [3,15], an infection complication rate comparable with modern phacoemulsification and the potential for combined cataract extraction using the same temporal cornea incision [14,34]. Now in its fourth year of clinical use, the ab interno trabeculotomy with the Trabectome has had clinically significant success in returning IOP to normal physiologic levels based on several prospective trials covered in this review.

Indications for ab interno trabeculotomy

Ab interno trabeculotomy with the Trabectome is appropriate in patients with variations of open-angle glaucoma including primary open-angle glaucoma, pseudoexfoliation, pigment dispersion, uveitic glaucoma and possible steroid-induced glaucoma [14,35]. It has also been performed in chronic angle-closure glaucoma with lysis of goniosynechiae and lens extraction. Based on previous prospective clinical trials, the Trabectome procedure does not result in as low an IOP as with trabeculectomy with antimetabolites. Therefore, it is not suitable for patients with end-stage optic nerve damage who are in need of extremely low IOPs [14]. Candidates who have early to moderately advanced glaucoma and have an IOP that is likely to lead to progressive nerve injury recieving maximal available or tolerated medications, disc or visual field findings, or both, are good candidates for Trabectome treatment [14]. According to Francis *et al.* in 2008, lens status is not a determining factor of whether a patient can have the surgery. Since the temporal corneal incision site is the same site used during phacoemulsification, a combined procedure can be performed if the patient has a visually significant cataract [34].

Specific contraindications related to this procedure

The Trabectome trabeculotomy requires a clear gonioscopic view of the angle throughout the procedure. If the view is blocked by corneal edema, opacities or other external problems such as advanced pterygia, then this procedure is not possible, secondary to the limited view and increased risk of damage to surrounding structures. Another contraindication is an anterior chamber that is too shallow, therefore increasing the risk of damage to the corneal endothelium and/or iris and also limiting the surgeon's visibility. This surgery can only be applied to eyes with open angles nasally (Shaffer grade 1 or above) and an absence of pathologic peripheral anterior synechiae in the area of treatment [35,36]. An exception is the previously mentioned combined procedure for chronic angle-closure glaucoma. Generally, it is not performed on eyes that have failed prior filtering surgery such as trabeculectomy or aqueous shunt because this protocol has not been adequately studied at this time. The surgeon should also be wary of anatomically confusing angles without clear definition of the scleral spur or meshwork and neovascularization of the iris or angle, which would increase the risk for bleeding and complications [36].

Goals in the development of the trabectome

The original design of the device was to create an instrument to achieve several goals: first and foremost, the instrument should be able to permanently ablate a strip of TM and SC's inner wall so that the remaining tissue remnants will not reapproximate during secondary fibrosis. Also, the device should be specific in its area of ablation so as not to damage surrounding structures. The device should be able to reliably gain access to the TM and SC complex. Lastly, the ab interno trabeculotomy procedure should take place under controlled conditions while maintaining the anterior chamber and allowing the surgeon detailed viewing of the TM and angle throughout operation [3].

The Trabectome device

The system consists of three major components: a mobile stand with a gravity-fed bottle of basic-salt solution, a handpiece console with automated irrigation, aspiration and microbipolar electrocautery, and a foot pedal to control these functions. The intraocular disposable handpiece (Figure 1) tip contains a 19.5-gauge infusion sleeve and a 25-gauge irrigation and aspiration port with a coupling for the ablation unit at the tip. The instrument incorporates a specially designed insulated triangular footplate that is bent at 90° at the end and is pointed in order to allow proper insertion through the TM into SC [35]. The footplate's curve is key in lifting the TM and putting it on a slight stretch, positioning the tissue for maximal discharge effect from above while protecting the underlying and surrounding tissue [3]. The insulation

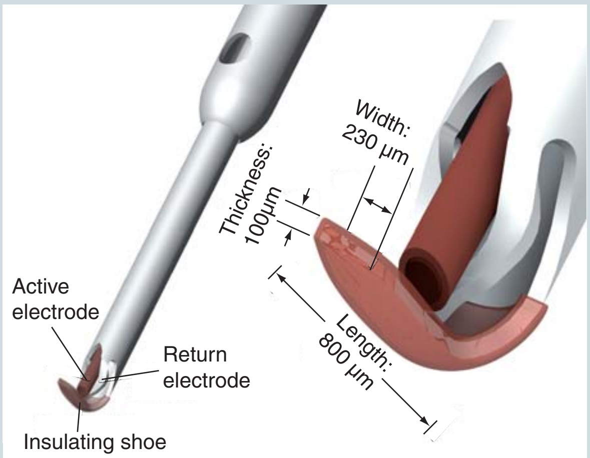

Figure 1. Trabectome™ handpiece. The handpiece incorporates irrigation and aspiration ports, active and return electrocautery electrodes and a guiding footplate for anatomical placement of the tip in Schlemm's canal and protection of surrounding structures from thermal damage.

coat on the footplate is made of a multilayered polymer coating that allows the instrument to glide along within the canal and protects the outer wall of SC from thermal and electrical injury. This polymer film has exceptional thermal stability (>500°C), mechanical strength, biocompatibility and chemical resistance [3].

The handpiece also includes an irrigation and aspiration unit and high-frequency electrocautery generator. The aspiration port is approximately 0.3 mm away from the electrode and removes debris generated during ablation. The irrigation is recessed 3 mm from the surgical site and serves the dual purpose of maintaining anterior chamber pressure and dissipating heat energy produced by the electrocautery [3]. The irrigation and aspiration port has a pinch valve for on and off control of irrigation flow from a hanging bottle of balanced salt solution. This height is adjusted manually with a standard height being 80 cm. The aspiration pump is peristaltic and allows for adjustable flow rates up to 10 ml/min. The standard flow rate is 3 ml/min. The electrocautery generator is a modified 800 EU unit from Aaron/Bovie (St Petersburg, FL, USA) and operates at a frequency of 550 kHz with adjustable power settings from 0.1 W increments up to 10 W. The standard power setting is 0.7 W and it is recommended by the manufacturer not to exceed 1.5 W during the procedure [3]. The surgeon has control of the irrigation, aspiration and electrocautery power with each being in position 1, 2 and 3 on the foot pedal, respectively [34]. This stepwise pattern is similar to that seen in the phacoemulsification pedal [3].

Mechanism of action

The tip of the footplate is positioned so as to receive and ablate the TM tissue and is moved along an arc parallel, and just anterior to, the scleral spur under direct gonioscopic control. The target TM is disrupted by applying heat energy in bursts that are bunched into small increments with comparably long time intervals in between energy bursts. This pattern of electrocautery, known as high peak power and low duty cycle, allows for disruption and disintegration of tissue rather than a 'cooking' effect, as seen in cautery of blood vessels [3].

Evidence of histology separation

Histopathological analysis was performed by Francis *et al.* in 2006 to confirm the ability of the Trabectome device to remove the target tissue and compare it to simulated goniotomy [3]. Treated areas were examined by confocal microscopy for 20 donor human corneoscleral rims that underwent trabeculotomy with a Trabectome device and two specimens that received simulated goniotomy.

The two specimens treated with simulated goniotomy showed evidence of full-thickness disruption of the TM and SC; however, one of the specimens displayed anterior and posterior segments of the TM that were overlapped, leaving no separation in the TM. The other goniotomy sample showed an incision extending 110.71 µm into the sclera, reaching SC.

In total, 20 specimens were treated by the Trabectome at various power levels (0.3–5.0 W) to determine the width of the TM gap created and to monitor for surrounding tissue damage. At 0.3 W, the average gap was 79.55 µm, which included one sample where SC was not cannulated by the footplate. At 0.5 W, the TM gap averaged 106.8 µm, with one sample that only demonstrated damage to the superficial TM. At 0.7 W, the average TM gap was 126.8 µm; one sample showed full-thickness TM damage but had reapproximated ends.

All samples that underwent trabeculotomy at power levels greater than 0.7 W (except one sample at 1.0 W) showed disruption of the TM with separation of the severed ends. There was no evidence of thermal damage in any of the tissue samples seen deep in the TM or in the surrounding tissues. Coagulation was visible in 10 out of 20 samples treated by Trabectome, which commonly affected the anterior TM more than the posterior TM. These areas were isolated from the TM and affected areas showed homogenous eosinophilic staining with thickening and increased folding.

Preoperative considerations

Patients should be medically evaluated as possible surgical candidates prior to their operation. Preoperatively, pilocarpine 1% and installation of a topical antibiotic can be given prophylactically. The routine use of pilocarpine preoperatively is to decrease the risk of lens injury during surgery [35]. Recently, users have advocated the preoperative use of apraclondine 0.5% or brimonidine 0.1–0.2% in order to possibly limit anterior chamber blood reflux.

Anesthesia

Trabectome surgery has been accomplished under various anesthetic methods including general anesthesia: retrobulbar and sub-Tenon's irrigation with a 0.5–0.75% bupivicaine/2% lidocaine mixture (epinephrine/hyaluronidase-free); and use of topical lidocaine gel only with intracameral preservative-free lidocaine 1%.

Operative technique of the ab interno trabeculotomy with Trabectome

Patients are placed on the operating table supine and are routinely prepared with povidone-iodine and draping. The surgeon's position is at the patient's side next to the operative eye to facilitate a temporal approach to the targeted nasal meshwork (Figures 2 & 3) [35].

Multiple surgical goniolenses can be used including the Thorpe, Swan-Jacobs, Hoskins-Barkan or Khaw four-mirror with the operating microscope tilt variably adjusted to optimize the angle of viewing appropriately for the goniolens chosen [36]. A special Trabectome surgical goniolens has been developed by Ocular Instruments that is designed for either right- or left-hand use. It is a direct-view lens used with a 20–30° microscope tilt combined with a 30–40° head tilt. The surgeon should verify that the view of the target meshwork is adequate with the goniolens prior to beginning the procedure, and then temporarily place the lens aside [35].

A near limbal 1.6- or 1.7-mm temporal clear corneal incision is made parallel to the iris with a keratome [34–36]. This is the appropriate size for optimizing instrument mobility and maintaining anterior chamber depth during surgery [35]. Preservative-free lidocaine 1% is injected into the anterior chamber in case this area did not receive a retrobulbar or peribulbar block [34]. Viscoelastic material may be injected to inflate, deepen and stabilize the anterior chamber, although the procedure has been performed with the irrigation of basic-salt solution, only [34]. The surgical gonioscopy lens is then replaced and used to visualize the target TM nasally, while advancing the Trabectome nasally across the anterior chamber with the infusion on. The instrument footplate is then inserted through the TM into SC [3].

Once the tip is located in the correct position, the footswitch activates the electrosurgical element that ablates and removes the strip of TM and the inner wall of SC. The initial power setting should be approximately 0.7–0.8 W and can be titrated up or down depending on the desire to ablate a wider strip of TM or to prevent charring of the surrounding tissue [34]. Utilizing the corneal incision site as a fulcrum, the surgeon slowly advances the instrument along the meshwork in either a clockwise or counterclockwise direction up to the limit of good visualization [34,35]. This usually creates an arc of approximately 40–60° in one direction with a total arc of approximately 90–110° ablated [3,35]. Compared with earlier clinical studies, Minckler *et al.* reported in 2006 that a total of approximately 60–90° (2–3 clock-hours) of meshwork can be ablated with a significant reduction in IOPs [36].

The instrument is then disengaged from the angle and removed from the eye. The viscoelastic material and any blood or cellular debris is aspirated, typically with an automated irrigation/aspiration device or Simco handpiece connected to the Trabectome tubing. There is also a variable response of reflux bleeding after the instrument is withdrawn from the corneal wound. This intraoperative reflux of blood through the TM is common and actually confirms appropriate 'unroofing' of SC [14]. Immediate irrigation of the anterior chamber with basic-salt solution and infusion of air tamponade can be used to decrease the bleeding. Corneal wound suture placement with 10–0 nylon or vicryl can be completed to prevent wound leaks and maintain an approximate IOP of 15 mmHg [34].

Operative technique of the combined cataract extraction with Trabectome

In July 2008, Francis *et al.* reported the success of the combined technique of cataract extraction and ab interno trabeculectomy with the Trabectome in patients with visually significant cataracts and open-angle glaucoma [34]. In the initial experience with combined surgery, cataract extraction was performed first, followed by Trabectome. It was thought that this would open up the angle more to facilitate access to the TM and, also, to avoid reflux of blood from SC during the cataract removal. However, it was discovered that the view of the angle after cataract extraction was suboptimal due to the lack of a good seal at the incision site and remained suboptimal even when the cataract incision was sutured. This caused loss of the anterior chamber depth and also corneal striae. It was also noted that the anterior chamber deepens quite well once the infusion is started with the Trabectome handpiece, even in a phakic eye. In addition, any blood reflux after the Trabectome procedure is quickly evacuated once the irrigation and aspiration is activated on the phacoemulsification handpiece.

Preoperatively, the patient is given standard dilating drops for cataract extraction, including phenylephrine hydrochloride (Neo-Synephrine® 1%) and tropicamide (Mydriacyl® 0.5%) in the operative eye. Antibiotic and nonsteroidal antiflammatory drops can be applied as per institution protocol. Unlike the Trabectome stand-alone procedure, pilocarpine is not given before the combined procedure [34].

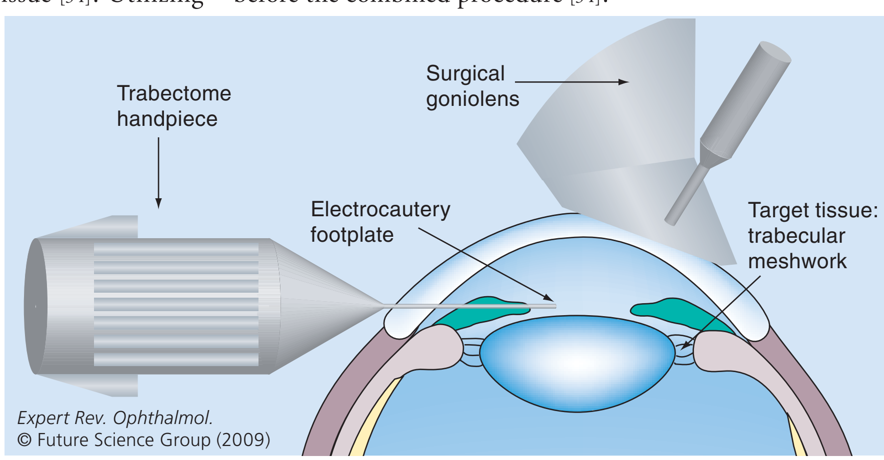

Figure 2. The Trabectome™ procedure. The surgical goniolens is placed on the cornea and the handpiece is inserted into the anterior chamber through a temporal clear corneal incision. Under direct visualization through the goniolens, the tip is advanced across the anterior chamber and then inserted through the trabecular meshwork into Schlemm's canal.

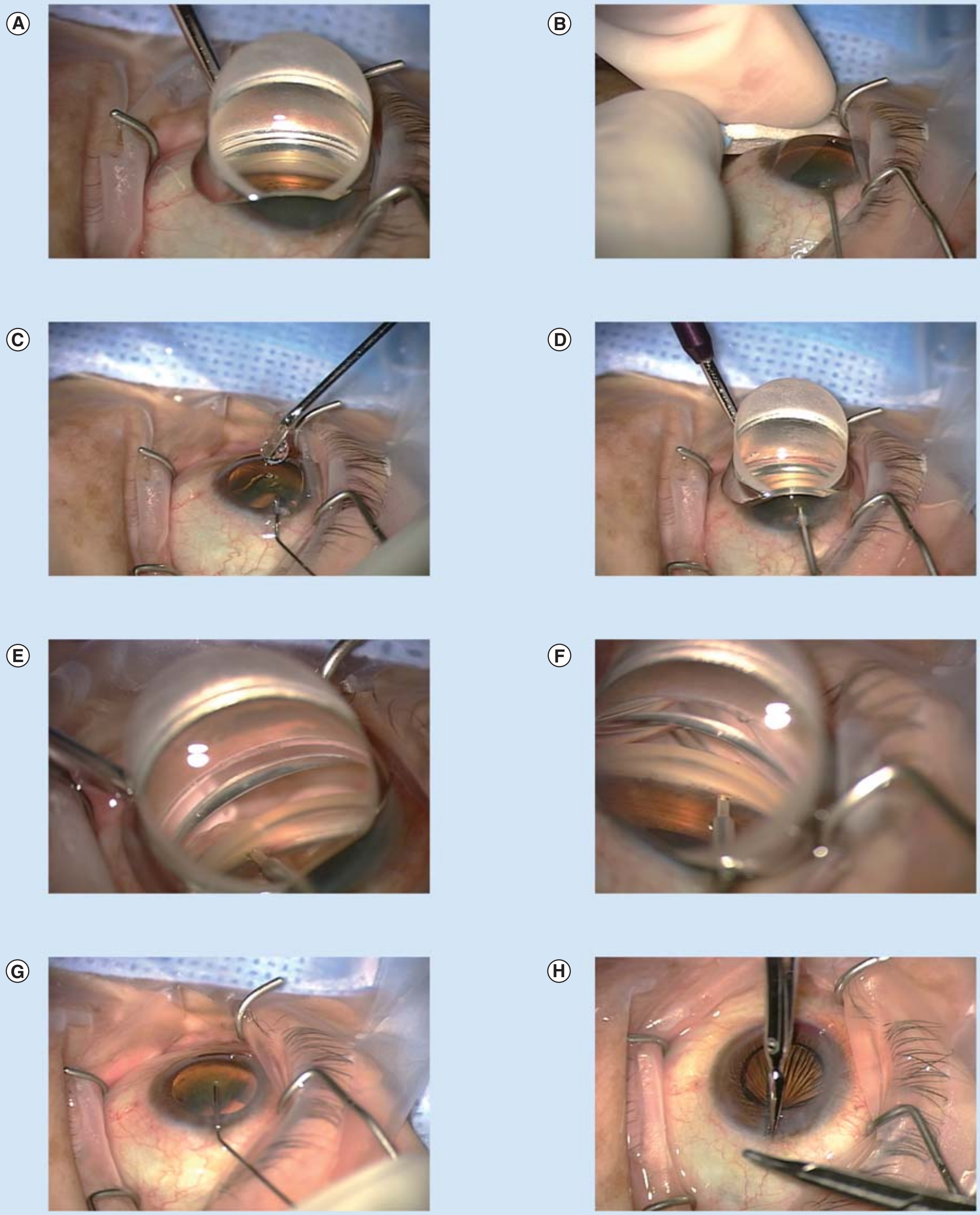

Figure 3. Trabectome procedure. (A) The surgical goniolens is placed on the cornea to verify the angle view. **(B)** The temporal clear corneal incision is made with the keratome blade. **(C)** Lidocaine 1%, preservative-free, is flushed into the anterior chamber followed by viscoelastic (Ocucoat®). **(D)** The handpiece tip is inserted into the anterior chamber and the goniolens is placed back onto the cornea. **(E)** The tip is inserted through trabecular meshwork into Schlemm's canal. The electrocautery is activated and the tip is rotated counterclockwise. Note the cleft formation to the right of the tip and the reflux of blood from Schlemm's canal. **(F)** The handpiece is rotated 180° and the ablation is continued in a clockwise direction. **(G)** The viscoelastic is removed by irrigation of basic-salt solution or by automated irrigation/aspiration. **(H)** The corneal incision is sutured and air bubble placed if necessary.

After the area is prepped and draped, the procedure is performed as previously described in the stand-alone protocol. Once the handpiece footplate is removed from the TM, the angle is viewed for evidence of blood reflux from SC, then the Trabectome is removed from the anterior chamber. The anterior chamber is filled with a viscoelastic device in preparation for the cataract extraction. The head and microscope need to be returned to the straight up-and-down position. A paracentesis is made and the corneal wound is enlarged with a keratome. Cataract extraction and intraocular lens implantation is performed based on the surgeon's preferred technique. Prior to completion of the combined procedure, acetylcholine chloride (Miochol®) or carbachol intraocular solution (Miostat) can be instilled depending on the pupil size. If there is continued bleeding from SC, an air-bubble tamponade can be injected to provide for better hemostasis. Wound closure and pressure titration is performed similarly to how it has been described in the stand-alone protocol [34].

Postoperative management

Postoperative management varies by surgeon, but an example from our clinical practice is as follows. Patients are discharged home the same day of the operation with a light dressing or shield applied to the operative eye. They are instructed to use topical antibiotic drops four-times daily for 7 days, steroid drops four-times daily tapered over 8 weeks, and pilocarpine 1 or 2% in the operative eye four-times daily tapered over 2–8 weeks [34]. Pilocarpine, used postoperatively is intended to minimize peripheral anterior synechiae formation and help with short-term IOP reduction [35]. All preoperative glaucoma medications can be restarted immediately and tapered starting the first postoperative day depending on IOPs [34].

Specific possible complications to the Trabectome

As first reported in the large clinical study by Minckler *et al.* in 2006, the Trabectome procedure has a specific complication of back bleeding from SC that occurs during ablation or removal of the instrument from the anterior chamber [36]. Irrigation with balanced salt solution or additional aspiration with irrigation/aspiration tip can decrease the amount of remaining hyphema and an air bubble may be installed for internal tamponade. The hyphema transiently affects vision postoperatively, but clears in approximately 1 week [35].

As with all ab interno procedures, there are possible complications such as corneal endothelium or Descemet's injury, iris injury, and possible damage to the anterior lens capsule from the handpiece tip [34]. Later in this review, the complications from each clinical prospective study will be discussed.

An IOP spike of 10 mmHg or greater has been reported in both Trabectome trabeculotomy alone and in the combined procedure with cataract extraction [34,36]. This pressure spike is commonly transient and diminishes postoperatively after 1 week [14]. The patient's glaucoma eyedrops can be continued postoperatively until the spike diminishes or the pre-existing temporal corneal incision can be used to decompress the anterior chamber under local anesthesia using a 25-gauge needle at the slit lamp. These steps in postoperative management can help control the elevated pressure and allow the surgeon time to evaluate if the Trabectome procedure was successful or not. Anecdotally, IOP spikes occurring 1 week and later after surgery have been attributable to steroid response, and have resolved, after switching from prednisolone acetate 1% to loteprednol 0.5% or discontinuing steroids.

Overview of clinical studies

Clinical outcomes of Trabectome

The first clinical study of trabeculotomy was performed by Minckler *et al.* in 2005 [35]. This prospective, interventional case series was a pilot study that evaluated 37 patients with uncontrolled open-angle glaucoma with or without prior ocular surgery or laser treatment. Patients were recruited from the Codet Eye Institute in Tijuana, Mexico. Outcomes were measured using IOPs and visual acuities before and after surgery, and they were observed for intraoperative and postoperative complications for a period of up to 13 months. All patients underwent trabeculotomy by Trabectome with or without viscoelastic, corneal suturing or air instillation. These surgical techniques were adapted throughout the course of the study.

Patient follow-up ranged from 3 (n = 37) to 13 months (n = 11). Overall, patients were found to have a 40% decrease in IOP after trabeculotomy surgery, ranging from 28.2 ± 4.4 mmHg preoperatively to 16.3 ± 2.0 mmHg at 12 months postoperatively. There was also a decrease in the number of glaucoma medications, ranging from 1.2 ± 0.6 mmHg preoperatively to 0.4 ±0.6 at 6 months postoperatively. Every patient experienced an intraoperative event with reflux of blood from SC. As a consequence, the most common postoperative complication was anterior chamber blood, which was found in 59% of patients on postoperative day 1; on average, it took 6.4 days for the blood to clear. Visual acuity generally decreased in this period as well, but recovered to within two lines of preoperative visual acuity by 3 weeks. Only one patient, who was not sutured at the time of surgery, had hyphema at 3 weeks postoperatively after accidental blunt trauma.

Other postoperative complications included peripheral anterior synechiae (24.3%), corneal injury (16.2%), goniosynechiae (13.5%) and pressure spike (5.4%). There were no observations of postoperative complications typically associated with the filtration surgery by trabeculectomy, such as flat or shallow anterior chamber, iris injury, hypotony, infection, cataract progression, wound leaks, problematic pain, choroidal effusion or choroidal hemorrhage.

Minckler *et al.* later expanded the pilot study and included a total of 101 patients from both Mexico and the USA with extended follow-up of up to 30 months [36]. This prospective interventional case series utilized the same outcome measures as the initial pilot study of IOP and visual acuity. A similar 40% decrease in IOP was observed at 30 months, with an overall success rate of 84% (n = 85/101, defined as IOP less than or equal to 21 mmHg with or without medications and no subsequent surgery). IOP decreased on average from 27.6 ± 7.2 mmHg preoperatively to 16.3 ± 3.3 mmHg at 30-month follow-up. Both of these studies had variable follow-up, with a small minority of patients reaching the maximum follow-up time of 30 months.

Of the 16 patients whose IOPs failed to respond to trabeculotomy, nine patients underwent trabeculectomy and another seven had IOP levels above 21 mmHg, with or without medication. A majority of those with high postoperative IOPs were within the 1-month postoperative period with abstained glaucoma medications. Postoperative complications included rates of 14% partial goniosynechiae (n = 14) and 3% epithelial defects (n = 3). There was one case of postoperative hypotony with an IOP level of 2 mmHg on postoperative day 1.

Combined Trabectome & cataract extraction

This prospective, interventional case series by Francis *et al.*, performed in 2008, studied combined trabeculotomy with cataract extraction [34]. The study included 304 consecutive eyes with open-angle glaucoma and clinically significant cataracts. Outcomes were measured by IOP, number of glaucoma medications, and intraoperative and postoperative complications. Patients generally underwent trabeculotomy first, before cataract extraction by phacoemulsification. The primary outcome of the study defined success as a decrease in IOP of 20% from baseline (without an increase in medications) or a decrease in glaucoma medications with maintenance of target IOP. After combined trabeculotomy and phacoemulsification, the success rate was 78% at 6 months and 64% at 12 months. IOP dropped from 20.0 ± 6.3 mmHg preoperatively to 16.7 ± 3.5 mmHg at 21 months postoperatively, with a per person mean decrease of 25%. Glaucoma medications similarly dropped from 2.65 ± 1.13 preoperatively to 1.43 ± 1.28 at 21 months postoperatively, with a per person mean decrease of 32% .

For secondary analysis, patients were subdivided into two categories by preoperative IOP and each group had its own definition of postoperative success. Group 1 had a preoperative IOP of over 21 mmHg and success was defined as a decrease in IOP of 20% or more. Group 2 had a preoperative IOP of 21 mmHg and below and success was defined as a decrease in number of glaucoma medications. Group 1 seemed to have a better success rate than Group 2; however, the groups could not be directly compared due to the varying success definitions. The authors explained these findings in that Group 2 tended to have medically controlled glaucoma but developed visually significant cataracts; the trabeculotomy was performed as an elective procedure to reduce the number of glaucoma medications. This resulted in an overall smaller decrease in IOP for this group but a significant reduction in the number of glaucoma medications.

Intraoperative complications included blood reflux, which is an expected event from the procedure. Postoperative complications included iris injury in four patients and lens capsule damage in two patients that did not affect ability to perform phacoemulsification. Visual acuities all returned to within two lines of preoperative acuities. An IOP spike was noted in 8.6% of patients on postoperative day 1 and in 2.0% at 1 week. There were none of the postoperative complications that are usually associated with trabeculectomy with mitomycin-C. For patients whose IOP was not controlled with trabeculotomy, seven patients went on to undergo trabeculectomy, one received an aqueous shunt placement and one patient received selective laser trabeculoplasty (SLT).

Latest Trabectome results

As of this writing, 1688 eyes had undergone the Trabectome procedure either alone or with combined phacoemulsification cataract extraction. This included 1093 with Trabectome only, 576 combined with phacoemulsification, seven combined with tube shunt (in order to lower IOP in the interim prior to ligature release), five combined with lysis of goniosynechiae, three with bleb revision, and two each with endoscopic cyclophotocoagulation and penetrating keratoplasty. The mean age is 70 years ± 15, with 923 females (54.7%). The racial backgrounds for those reported was 1096 patients were Caucasian, 123 were African American, 111 were Hispanic, 71 were Japanese, 58 were from other Asian descent and 229 were of other enthicities. The recorded diagnoses were: primary open-angle glaucoma: 1208 patients; exfoliation glaucoma: 186; pigmentary glaucoma: 55; uveitic glaucoma: 44; steroid-induced glaucoma: 19; and other or not recorded: 176. Visual field damage recorded was described by the treating surgeon as: minimal: 57 patients; moderate: 408; and advanced: 477. Cup-to-disc ratio, if reported, was 0.7: 353 patients; 0.7–0.8: 492; and greater than 0.8: 579. Prior surgeries included: SLT: 424 patients; argon laser trabeculoplasty: 275; trabeculectomy: 133; aqueous tube shunt: 28; Trabectome: eight; and endocyclophotocoagulation: seven.

The baseline IOP was 23.5 mmHg ± 7.7. The mean postoperative IOP was 15.9 ± 4.2 at 3 months, 15.8 ± 3.7 at 6 months, 15.8 ± 3.3 at 12 months, 16.4 ± 3.8 at 2 years, 16.1 ± 2.6 at 3 years, 16.1 ± 2.6 at 4 years and 16.4 ± 2.3 at 5 years. The baseline number of glaucoma medications was 2.83 ± 1.2. The mean number of postoperative glaucoma medications was 2.13 ± 1.4 at 3 months, 1.89 ± 1.4 at 6 months, 1.71 ± 1.3 at 12 months, 1.39 ± 1.1 at 2 years, 1.16 ± 1.0 at 3 years, 0.96 ± 0.96 at 4 years and 1.0 ± 0.94 at 5 years. The total number of secondary glaucoma procedures following failed Trabectome was 162 (9.6%), and included trabeculectomy (96; 5.7%), aqueous tube shunt (41; 2.4%), repeat Trabectome (14; 0.8%), SLT (5; 0.3%), diode cyclophotocoagulation (4; 0.2%) and endoscopic cyclophotocoagulation (2; 0.1%).

Complications included 96 patients (5.7%) with IOP elevation of greater than 10 mmHg from baseline, 24 (1.4%) with hypotony (IOP < 5 mmHg) on postoperative day 1, iris injury in five (0.3%), corneal Descemet's membrane tear (limited) in four (0.2%), aqueous misdirection (intraoperative, resolved) in one (0.06%) and choroidal hemorrhage in one (0.06%).

Comparison of outcomes with other techniques

Goniotomy and trabeculotomy were the first surgical procedures aimed at disrupting layers of the TM that had success rates of 58% and higher in congenital glaucoma [18]. However, both of these techniques had limited success in the adult population [20,22].

Goniocurretage is a technique to mechanically remove the TM using a spoon-like instrument. However, it lacks a footplate to guide the instrument along SC, and it does not provide the consistent depth of TM and SC interruption that can be achieved with the Trabectome [3,25].

An alternative procedure performed in congenital glaucoma is 360° suture trabeculotomy, which utilizes one or two sutures to mechanically open SC. However, this has had limited success secondary to postoperative hypotony and has not been attempted in the adult population [31,32].

Other alternatives include laser trabecular ablation and laser goniopuncture and are unproven methods for the treatment of open-angle glaucoma [26,33].

For combined trabeculotomy and cataract extraction, other techniques include cataract extraction combined with trabeculectomy, endoscopic cyclophotocoagulation, deep sclerectomy, viscocanalostomy and manual stripping of the TM similar to that achieved by the Trabectome [34,37–40]. Although these other techniques have been demonstrated to reduce IOP and number of glaucoma medications, none have been directly compared with the Trabectome, and thus, no conclusions can be made about their relative efficacy rates. Other, more recent procedures that have focused on surgical treatment of the angle are canaloplasty, trabecular stent and excimer laser trabeculotomy [41–43]. The IOP lowering of these procedures is similar to that of ab interno trabeculotomy, but none of the techniques have been compared in clinical trials.

Future challenges

Control of IOP with the Trabectome is limited to physiologic levels (15–16 mmHg) with current surgical techniques [36]. The safety profile of the Trabectome has significantly lower complications than that of trabeculectomy; however, these rates can be further lowered with critical evaluation of surgical techniques and pre- and postoperative medication management. Further study may also reveal what patient characteristics are most predictive of success or failure.

Conclusion

Ab interno trabeculotomy with the Trabectome provides a surgical technique to remove the TM and inner layer of SC to increase aqueous outflow for the management of open-angle glaucoma. It provides a decrease in IOP and glaucoma medications with less postoperative complications than the current gold standard, trabeculectomy with antifibrotics. The reduction of IOP is to the physiologic range, approximately 15–16 mmHg and is therefore, not appropriate for patients with a target IOP below this range. The device design allows for accurate anatomical positioning and ease of skill transfer to new surgeons. There have been no documented complications of those usually associated with bleb formation, such as leaks, infection, severe hypotony or choroidal detachment or hemorrhage. The safety profile allows for concurrent surgery with cataract extraction despite only mild-to-moderate uncontrolled glaucoma.

Expert commentary

Currently, the role of trabeculotomy is not completely defined with regards to its timing in the treatment algorithm of glaucoma (i.e., as primary surgery, or only after medication or laser trabeculoplasty failure). Future reports should endeavor to include longer follow-up and better retention of subjects. The main shortcoming of the published reports is that data are reported voluntarily by centers and there is a significant drop off in follow-up after the 6-month time period. Randomized, controlled studies need to be performed comparing Trabectome to trabeculectomy with various medical managements. Randomized surgical trials are the next step in evaluation and may involve a comparison with trabeculectomy, laser trabeculoplasty or other newer glaucoma surgical procedures (e.g., canaloplasty and trabecular stent), as well as a comparison of combined cataract extraction and Trabectome versus cataract alone.

Studies also need to address the amount of TM to remove by studying IOP control based upon degrees of meshwork removed. More than 110° could be removed by making a larger initial corneal incision or by introducing a second incision; however, it is not certain whether this would result in a higher success rate.

The proper protocol for surgery still needs to be identified, such as the ideal power settings, histological studies did not have enough power to correlate TM opening with power setting. In addition, the effect of the use of viscoelastic, corneal suturing and air instillation for control of postoperative hyphema and pressure spikes also lacks sufficient data.

Five-year view

The use of the Trabectome device will grow substantially with its excellent risk-to-benefit profile compared with current standard filtration surgery. As more trabeculotomies are performed using the Trabectome device, surgeons will develop improved techniques and develop interventions to decrease the already low rate of complications associated with the procedure.

Financial & competing interests disclosure

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Key issues

- Trabectome™ achieves consistent removal of the trabecular meshwork and inner layer of Schlemm's canal to increase aqueous outflow for the treatment of open-angle glaucoma without scarring.
- Trabectome provides a procedure with lower rates of complications than that of the gold-standard glaucoma filtration surgery (trabeculectomy).
- Potential combination with cataract extraction.
- Preserves the conjunctiva for future conventional filtration surgery as necessary.

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