9 Other Procedures for Pediatric Glaucoma Surgery: New Devices and Techniques

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Introduction

In recent years, there have been multiple new devices developed in glaucoma surgery that target the angle and can be grouped in the category of minimally invasive glaucoma surgeries (MIGS). These procedures were mainly developed for adult glaucoma surgery, but by the very fact that they are variations on angle surgery, many may have application in pediatric glaucoma patients. With that being said, it should be noted that information regarding outcomes is limited for many of these devices in adults and even more so in children. Given the paucity of data regarding risk and/or benefit of these procedures in children, one should make the clinical decision for use of these newer techniques on an individual basis.

When considering new and novel techniques, it is always best to look back at the principal foundations that led to these innovations. The origin of pediatric glaucoma surgery dates back to 1938 with Barkan describing his goniotomy technique [1]. While classical angle surgery still continues to be a first-line treatment in primary congenital glaucoma (PCG) [2, 3], in recent years modifications in this technique and new devices have been developed. If the first angle surgery is not successful and the angle has not been treated 360°, many surgeons will further treat the angle before performing a filtering procedure (trabeculectomy) or glaucoma drainage device (GDD) [4]. Several instruments and techniques have been developed to extend the area of angle treated and/or to remove the trabecular meshwork (TM) from the eye or dilate Schlemm's canal.

This chapter presents these new surgical techniques and devices that target the angle via an ab interno approach. The following will be discussed: trabeculotomy with TRAB™360, viscodilation with VISCO™360, combined trabeculotomy and viscodilation with the OMNI™, gonioscopic-assisted transluminal trabeculotomy (GATT) with fiber optic or suture, and TM destruction and removal with Trabectome/Goniotome and the Kahook dual blade®. These devices share indications, complications, advantages, and limitations. We also introduce an ophthalmic surgery model eye (Bioniko, Miami, FL, USA) that can be used to teach angle surgery in a safe environment.

In PCG, the inhibited posterior sliding of the ciliary body (CB) from the Schwalbe line to scleral spur has been theorized to result in an

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anterior position of the CB and peripheral iris overlapping with the TM [5]. This arrest in maturation of the angle leads to a wide variation in appearance of the angle on gonioscopy and is felt to be the etiology of the obstruction to outflow. This anatomic anomaly in PCG and obstruction to outflow make the TM and the inner wall of Schlemm's canal the site of greatest resistance to aqueous outflow [6, 7]. Once opened, this allows aqueous humor flow from the anterior chamber (AC) to the collector channels in the external wall of Schlemm's canal [8–10].

Augmentation of the conventional (trabecular) outflow pathway can facilitate physiologic outflow and subsequently lower intraocular pressure (IOP). Recent techniques to enhance the conventional outflow pathway via an internal approach to the TM and Schlemm's canal fall into three novel surgical approaches:

1. Disruption of the TM and inner wall of Schlemm's canal via an internal approach (ab interno trabeculotomy) with the use of an illuminated microcatheter to perform gonioscopic-assisted transluminal trabeculotomy (GATT): iTrack™ catheter (Ellex iScience, Fremont, CA, USA) or with TRAB™360 (Sight Sciences, Menlo Park, CA, USA)
2. Dilation of Schlemm's canal with viscoelastic via an internal approach (ab interno canaloplasty): AbiC™ (iTrack™ catheter, Ellex iScience) VISCO™360 or with OMNI™ (Sight Sciences)
3. Removal of the TM and inner wall of Schlemm's canal by an internal approach (ab interno trabeculotomy) with the Trabectome®/Goniotome (NeoMedix, Tustin, CA, USA) and the Kahook dual blade® (New World Medical, Rancho Cucamonga, CA, USA)

In contrast to external filtration surgeries (trabeculectomy and GDD) and ab externo angle surgeries, the procedures above are performed from an internal approach via gonioscopic visualization of the angle and are aimed to remove obstruction to a natural outflow pathway. There are published reports of some of these techniques via an external approach, e.g., GATT for the treatment of selective types of glaucoma [10].

Indications and Contraindications (Table 9.1)

Given that these procedures are done from an ab interno approach on the same area of the outflow system, the indications and contraindications are similar to those of angle surgery. The common thread to all surgical procedures performed ab interno is the requirement to visualize the angle to safely complete the surgery. While areas of high insertion and iris adhesions can be overlooked, for the most part the angle must be identified [11].

Risks Factors for Failure

The risk factors for failure include the inability to clearly visualize the angle, a shallow AC, and the inability to fully cannulate Schlemm's canal.

Advantages and Disadvantages

Multiple studies describe the advantages of treatment of the TM in its entirety [12–15]. The unique advantage to the ab interno approach is similar to goniotomy, requiring only small corneal incisions leading to a significant reduction in surgical time and, in addition, the ability to treat the complete angle in one surgical event. While

Table 9.1 Indications and contraindications for ab interno procedures

Indications
Primary congenital glaucoma (PCG)
Juvenile open-angle glaucoma (JOAG)
Glaucoma following cataract surgery
Glaucoma associated with non-acquired ocular anomalies
Glaucoma associated with non-acquired systemic disease or syndrome
Some glaucoma associated with acquired conditions:
Uveitic glaucoma
Steroid-induced glaucoma
Contraindications
Corneal opacity of a degree that obscures the view of the angle
Complete secondary angle closure
Traumatic glaucoma
Neovascular glaucoma
Secondary glaucoma due to ciliary body or iris tumor

less clearly determined, there may also be an advantage to the simultaneous dilation and irrigation of the distal collecting system [16].

Similar to goniotomy, the disadvantage is manipulation in the AC with the attendant risk of damage to adjacent structures (lens, iris, and cornea).

Ab Interno Angle Surgery: Preoperative Surgeon Preparation

Ab interno angle surgery is becoming a more common procedure in the armamentarium of adult cataract and glaucoma surgeons. Glaucoma surgery for infants and children is not the same as glaucoma surgery for adults. The anterior segment of the child is a much different environment, and the task should not be taken lightly. Observation and training with skilled pediatric glaucoma surgeons is recommended. Wet labs and model eyes, while not perfect, do provide some level of competence for the surgeon who plans to do angle surgery in children. Bioniko (Miami, FL, USA) has developed an artificial eye with a canal that provides realistic access to the angle and practice for goniotomy, TRAB™ 360, VISCO™ 360, and GATT procedures (Fig. 9.1). The eye model is placed in a tilting holder that allows visualization with the goniolens at the same time as performing intraocular manipulation. Video 9.1 shows the SCHLEMM™ Model from Bioniko being used for TRAB™ 360 and GATT practice.

Fig. 9.1 Bioniko eye model for angle surgery simulation is a 3D printing model with Schlemm's canal that is held in a tilting holder and allows to visualize the angle and practice angle surgical procedures

Ab Interno Angle Surgery: Preoperative Patient Considerations and Preparation

In addition to surgeon preparation, careful patient selection and procedure selection are also key. Above all for ab interno surgery, one must be able to visualize the angle during the examination under anesthesia (EUA) preceding surgery. The examination in the office is often indicative of the ability to visualize the angle; a clear cornea or minimal corneal haze will often predict an adequate view of the angle. In some cases, the ability to see the angle at the time of surgery is improved if the cornea has cleared with interim topical treatment and/or the IOP is reduced with general anesthesia. At the time of the EUA, gonioscopy should be performed and the microscope and the child's head positioned appropriately to assist in the examination and incision of the angle. Once the decision to proceed with ab interno angle surgery is made, pilocarpine 1% or 2% may be instilled or a direct acting cholinergic (either acetylcholine chloride [Miochol™, Bausch & Lomb, Bridgewater, NJ, USA] or carbachol [Miostat®, Alcon Laboratories, Fort Worth, TX, USA]) at the time of surgery into the AC for miosis, before instillation of the viscoelastic. The surgeon sits temporally and the head of the patient is tilted 30° away from the surgeon. The microscope is tilted 40° towards the surgeon (Fig. 9.2). Table 9.2 shows the instruments and supplies needed for ab interno procedures.

Ab Interno Angle Surgery: Surgical Procedures

Intraoperative Preparation

- Position microscope: tilted approximately 40°
- Position child: head turn away from surgeon approximately 30°

Fig. 9.2 Positioning for ab interno angle procedures. The surgeon sits temporally and the head of the patient is tilted 30° away from the surgeon. The microscope is tilted 40° towards the surgeon

Table 9.2 Surgical list of instruments and supplies for ab interno procedures

Instruments
Gonioscopic lens
Tying forceps
Microforceps (for GATT procedure)
Supplies
Balanced salt solution
75 blade or MVR blade or 2.2 mm keratome
Intraoperative miochol/miostat or preoperative pilocarpine 1%
Healon®
10-0 Vicryl® suture or 10-0 nylon

GATT gonioscopic-assisted transluminal trabeculotomy

- Position surgeon: temporal
- Review equipment (in particular intraoperative gonioprisms and device)

Ab Interno Angle Surgical Techniques

TRAB™360/VISCO™360/OMNI™ TRAB™360/VISCO™360/OMNI™ (Sight Sciences) are designed to treat the angle by disrupting 180°–360° of the internal wall of Schlemm's canal and TM by an ab interno approach. The VISCO™360 differs from the TRAB™360 in that there is the ability to use a microcatheter to inject and dilate the canal with viscoelastic (Healon®) simultaneous to the trabeculotomy. The OMNI™ also has the ability to perform both viscoelastic dilation and trabeculotomy.

Each of these devices is a handheld, single-use device that has a bent sharp needle tip to pierce the TM and inner Schlemm's canal wall and a nylon catheter that can be threaded 180° in Schlemm's canal (Fig. 9.3). After threading Schlemm's canal with the blue nylon catheter, the canal can then be unroofed. The same procedure can then be performed in the opposite direction, threading and unroofing Schlemm's canal 180° in the opposite direction. The VISCO™360 can be used just for irrigation and dilation of the canal with viscoelastic; however, there is no evidence in children that this procedure alone is efficacious (Fig. 9.4).

TRAB™360 Technique A 1 mm clear corneal incision is made with a paracentesis blade near the limbus and parallel to the iris. Acetylcholine chloride (Miochol™) is injected in the AC to achieve pupillary constriction and protect the lens. Ophthalmic viscoelastic (e.g., Healon®, Johnson & Johnson Vision, Santa Ana, CA, USA) is injected in the AC. The TRAB™360 instrument is unlocked by removing the safety pin at the base. After confirming the function and spinning the wheel minimally to advance and withdraw the blue filament, the instrument is introduced into the AC and advanced across the AC under direct visualization towards the nasal angle. Viscoelastic is placed on the corneal surface and a Swan-Jacob gonioprism lens is held by the nondominant hand of the surgeon and used to visualize the nasal angle. The TRAB™360 tip is used to pierce the TM and enter Schlemm's canal. The wheel in the handpiece is turned to allow the nylon inner filament to thread along Schlemm's canal until it comes to a stop. At this point, approximately 180° of the canal has been cannulated with the microfilament and the surgeon per-

Fig. 9.3 The TRAB™360 is a single-use instrument with a bent sharp needle tip with a nylon filament to thread Schlemm's canal. It is advanced and withdrawn with a wheel mechanism. (Courtesy of Sight Sciences, Menlo Park, CA, USA)

Fig. 9.4 The VISCO™360 is an instrument similar to TRAB™360 but also allows viscodilation of Schlemm's canal. (Courtesy of Sight Sciences, Menlo Park, CA, USA)

forms a maneuver to unroof Schlemm's canal by slowly withdrawing the handpiece through the corneal incision. If desired, the device is turned over and redirected to treat the opposite 180° of the angle after refilling the AC with viscoelastic (Video 9.2). At the time of writing, the filament can be advanced and withdrawn only two times before it locks and the instrument becomes nonfunctional.

VISCO™360 Technique Viscodilation with VISCO™360 is a surgical technique that intends to surgically restore the aqueous drainage system by catheterization and viscodilation of Schlemm's canal to decrease the resistance to aqueous outflow in the collector channels (see Fig. 9.4).

Surgical technique mirrors that for TRAB™360. Of note, the device is prepped with an ophthalmic viscoelastic and a small amount used to flush the instrument. As with the TRAB™360, the instrument is introduced into the eye and advanced across the AC until near the nasal angle. Using the gonioprism the angle is identified and the instrument is used to pierce the TM. Using the wheel on the handpiece, the microcatheter then advances in Schlemm's canal 180°. The wheel is turned in the opposite direction, and this allows the viscoelastic (usually Healon®) to be delivered in Schlemm's canal as the microcatheter is retracted and Schlemm's canal is incised. Then the instrument is removed from the AC, rotated,

and inserted again in the eye to treat the remaining 180° of Schlemm's canal.

Both of these procedures result in some bleeding reflux into the AC.

Potential Modifications of TRAB™360, VISCO™360, and OMNI™: Combination Viscodilation-Trabeculotomy

The VISCO™360 device can be used to viscodilate 180° of Schlemm's canal and then reintroduced into the same region of the canal to disrupt the TM, creating a trabeculotomy. While this effectively treats only 180° of the angle, it combines the canal dilation and episcleral venous fluid wave irrigation with circumferential trabeculotomy [16]. Use of the OMNI™ actually allows 360° of both viscodilation and circumferential trabeculotomy.

GATT: Gonioscopic Ab Interno Assisted Trabeculotomy

Similar to the other techniques in this section, GATT is an ab interno approach to the angle. The technique offers the unique advantage of a small corneal incision to perform 360° disruption of the internal wall of Schlemm's canal with simultaneous infusion of viscoelastic [14, 17, 18]. Unlike TRAB™360, with GATT the treatment cannot be titrated into 180°. Similar to TRAB™360, GATT depends on successful ab interno access and cannulation of Schlemm's canal 360°.

GATT Surgical Technique

Following the standard surgeon and patient positioning discussed previously and confirmation of visualization of the angle, two clear cornea incisions are made at the temporal limbus: the first at the 3 or 9 o'clock position, depending on the surgical eye, and the second incision 2–3 clock hours to the right or left of this principal incision. The initial incision can be created with a 2.2 keratome angled incision, much like an entry for adult cataract extraction, and the second incision more like a paracentesis entry site. Miotic is instilled in the eye followed by a viscoelastic. An MVR blade or 30 g needle is used to cross the AC towards the nasal angle under direct visualization. The gonioprism is placed on the eye and the angle brought into focus. The blade/needle is used to unroof 1–2 clock hours of Schlemm's canal and then removed. The Iscience catheter with Healon® attached at the infusion site

Fig. 9.5 Positioning and securing of the iTrack™ catheter and Healon® for gonioscopic-assisted transluminal trabeculotomy (GATT). (Courtesy of Davinder Grover MD, MPH, Glaucoma Associates of Dallas, Dallas, TX, USA)

(Fig. 9.5) is passed through the paracentesis incision into the AC. The gonioprism is placed on the cornea and the angle visualized. Using a micro-retinal forceps passed into the AC at the keratome incision site, the iScience catheter is grasped and directed to the opening in Schlemm's canal. The catheter is then fed into the canal with a grasp-regrasp technique to advance the iScience fiber optic around the canal. Once the end reappears, the micro forceps grasp the end and hold it in the AC while the external portion is grasped and pulled with a steady force until the catheter has incised the entire canal (Video 9.3).

Potential Modifications of GATT: Thermal Suture Modification with Dye-Stained Tip and Partial Angle Treatment

Grover and Fellman described a technique to perform the GATT procedure with a 4-0 or 5-0 nylon suture that is pretreated with a hand held cautery to blunt the tip before threading. In order to assist in the visualization of the suture as it advances, they also recommend staining the tip with a blue marker [19].

Another modification of the GATT procedure is partial angle treatment. There are occasions when the catheter or suture will not pass completely around the canal 360°. In these instances and depending on the location, one can attempt to go the other direction to see if the area that does not appear continuous can be passed or dilated with Healon®. If, however, the block persists, a small "cutdown" over the tip site, using the paracentesis blade, can be performed to grasp the catheter tip where it lies. Then, holding it, the catheter is pulled through to cannulate a portion of the canal. The catheter can then be threaded in the opposite direction to the cutdown area and the remaining angle incised.

Kahook Dual Blade

The Kahook dual blade® (KDB; New World Medical) was designed to perform a goniotomy and remove the TM and internal Schlemm's canal wall tissue of the treated area. The tip of the KDB has a special design that allows it to perforate the TM and the internal wall of Schlemm's canal. Once the KDB is correctly inserted in the canal, the instrument is advanced along the TM while the angulated metal at the tip of the instrument elevates the TM tissue and guides it towards the blades that are located at each side of the elevation. This allows cutting and removing the TM and inner Schlemm's canal tissue [20, 21]. The design of the KDB allows performing a precise incision without damaging the adjacent structures (Fig. 9.6).

Kahook Dual Blade Surgical Technique

As with all the ab interno angle surgery, positioning is an important step in this procedure: the microscope tilted, the head of the patient rotated away from the temporally positioned surgeon. A clear corneal incision is created (1.6 mm or bigger) close to the limbus and parallel to the iris. Cohesive viscoelastic is injected through the corneal incision to stabilize the AC. Bubbles need to be avoided in order to have a clear visualization of the angle structures. The KDB is introduced in the eye through the corneal incision and is advanced in the AC towards the nasal angle. Viscoelastic is placed on the corneal surface and then a gonioscopic lens is placed on the corneal surface to achieve direct visualization of the nasal angle. The tip of the KDB is inserted through the TM in Schlemm's canal. The surgeon makes a cut in the TM clockwise. Afterwards the surgeon returns to the original point of insertion and moves the blade counterclockwise in order to

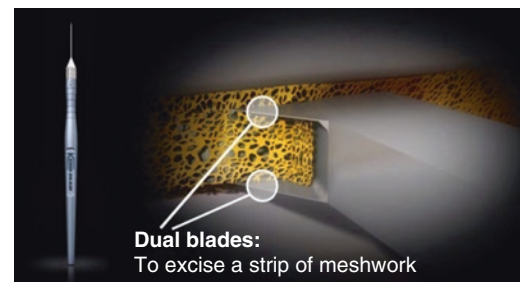

Fig. 9.6 The Kahook dual blade is designed to incise and remove the trabecular meshwork. (Courtesy of New World Medical, Rancho Cucamonga, CA, USA)

remove additional TM and inner Schlemm's canal wall tissue. The surgeon is able to remove this TM tissue out of the eye, since it remains in the instrument surface. Often, blood reflux is observed during the surgery, which confirms that Schlemm's canal has been unroofed.

Potential Modification of KDB: Viscoelastic Tamponade and Irrigation

As with most angle surgeries, there is reflux of blood into the AC at the time the canal is unroofed. The removal of tissue using the KDB makes the margins easily seen, and irrigation with the viscoelastic agent such as Healon® helps to tamponade the reflux of blood and can be seen clearing the episcleral venous veins around the limbus. The Healon® is left in the AC.

Trabectome/Goniotome

Trabeculotomy ab interno performed with Trabectome (NeoMedix) or the Goniotome (NeoMedix) is a technique that uses a bipolar electrode of 550 KHz to ablate the TM and the internal wall of Schlemm's canal. The ablation of tissue is mediated by plasma that ionizes and disintegrates the TM, dissipating the heat and minimizing surgical trauma [22–26].

The U.S. Food and Drug Administration cleared the Trabectome in 2004 for use in adults with open-angle glaucoma both phakic and pseudophakic. Outcomes of Trabectome have been published mainly for primary open-angle glaucoma and pseudoexfoliation glaucoma but also in pigmentary, uveitic, steroid-induced, and narrow-angle glaucoma [27–29]. Although studies include pediatric cases, there are no published outcomes of Trabectome in children. In general Trabectome has not found a place in the routine treatment of glaucoma in childhood, but there are some unique instances where the bipolar cutting electrode cautery applied to intraocular tissue in the AC (e.g., iridocorneal adhesions) has been helpful to create a better view of the angle without promoting bleeding from the iris, which would further obscure the view. The Goniotome is similar but is associated with irrigation and aspiration.

Trabectome/Goniotome Surgical Technique

Operative angle surgery positioning to allow adequate gonioscopic visualization of the nasal TM is again applied: the surgeon sitting temporally, the head of the patient rotated approximately 30° away from the surgeon, and the microscope inclined 40° towards the surgeon.

A 1.6–1.8 mm corneal incision is made close to the sclerocorneal limbus. Then the Trabectome is introduced through the corneal incision with active irrigation (AC maintainer) and a goniolens (a modified Swan-Jacob lens, Ocular Instruments, Bellingham, WA, USA) is placed on the corneal surface to allow visualization of the nasal angle. Then the triangular tip of the Trabectome is inserted in Schlemm's canal and the ablation of the TM tissue is performed in one direction; then the tip is turned and the other direction of the nasal angle is treated. Approximately 120°–180° of angle can be treated (Fig. 9.7).

The ablation is performed starting with 0.8 mW controlling the energy and aspiration rate through the pedal. The aspiration eliminates the remaining debrided tissue. The surgery is performed under continuous irrigation and after ablating the TM, the Trabectome is removed

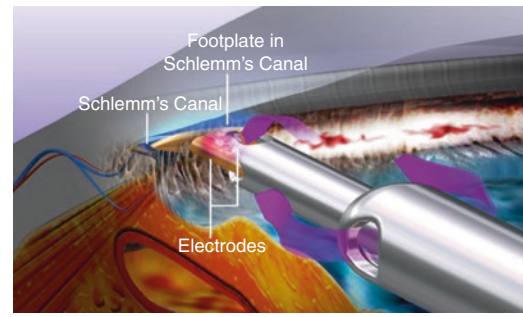

Fig. 9.7 Trabeculotomy ab interno with Trabectome uses a bipolar electrode to ablate the trabecular meshwork and the internal wall of Schlemm's canal. (Courtesy of NeoMedix, Tustin, CA, USA)

from the AC and viscoelastic is injected over the TM to minimize the postoperative hyphema. Then a 10-0 Vicryl® (Ethicon, Somerville, NJ, USA) or nylon corneal suture is placed and a bubble can be left in the AC as internal tamponade.

Potential Modification of Trabectome/ Goniotome: Goniosynechiolysis

The unique use of a bipolar electrode cautery tip to ablate tissue can be used to lyse iris adhesions to an anteriorly displaced Schwalbe line in Axenfeld-Riegers anomaly.

Ab Interno Angle Surgery: Postoperative Management

Postoperative management should be guided by treatment of the postoperative hyphema and inflammation. Each of these procedures results in a variable amount of bleeding and postoperative inflammation. Closure of the angle cleft by either peripheral anterior synechiae (PAS)—or, in some cases, iris strands—and membranes can result in less than satisfactory results. In general, postoperative medications are aimed at treating the postoperative bleeding. Steroids and often cycloplegia along with a topical antibiotic are used in the immediate postoperative period. Once the refluxed blood has cleared, pilocarpine 1% may help in pulling the iris away from the angle and assist in maintaining an open cleft.

Ab Interno Angle Surgery: Complications and Outcomes

The most common complication of ab interno angle surgery is intraoperative blood reflux and hyphema. Some patients following Trabectome can have recurrent spontaneous AC bleeding that can produce IOP spikes [29, 30]. Another complication is the formation of PAS in up to 24% of patients. Other uncommon but severe complications reported in adults are hypotony of <5 mmHg in 0.09% of cases, aqueous misdirection in 0.04%, cyclodyalisis 0.06%, and choroidal hemorrhage 0.01% [18, 24].

With respect to outcomes, Fellman et al. suggest that decompression and forceful irrigation of the AC to elicit an episcleral venous wave may indicate a functional collector channel system beyond Schlemm's canal and so be a predictor of angle surgery success [16].

Nevertheless, the fact remains that in children there is very little to no data regarding complications or outcomes from these newer procedures and devices. We are left to extrapolate from adult data along with the known pathophysiology of childhood glaucoma to access the risk and benefits of each of these surgical approaches.

Ab Interno Angle Surgery: Options After Failed Procedures

Depending on the time course, an unfavorable outcome following ab interno angle surgery may be approached in one of two ways after reexamining the amount of angle treated. The first option is to treat more angle if the first procedure did not treat 360°. If 360° were treated on the first procedure, we would then proceed with other surgical modalities. While this varies from region to region, for the most part either a GDD or a trabeculectomy with antimetabolite [31] are the procedures of choice following complete treatment of the angle.

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