1

CUTTING EDGE

Glaucoma

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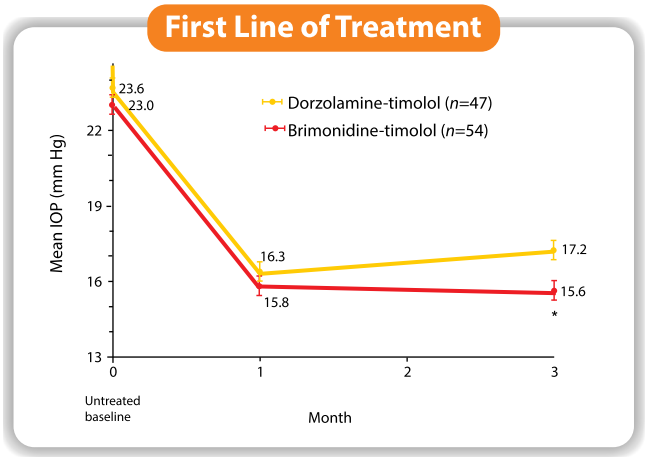
In Primary Open Angle Glaucoma & Ocular Hypertension

Rx BRIMOLOL

Brimonidine Tartrate 0.15% + Timolol Maleate 0.5%

Greater IOP Reduction Over Dorzolamide & Timolol Combination

First Line of Treatment



- Better IOP control upto 32% as compared to DTFC[1]
- DTFC caused more ocular stinging upon instillation[2]

No Washout Effect

Combined power, Greater benefits

1: Nixon etal, Current medical research and opinion Vol.25,iss,7,2009 • 2:Enyr etal, Current medical research and opinion,683-689

CUTTING **EDGE**
Glaucoma

Springer Healthcare Education

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Contents

Videos available online:

1. Nasal goniotomy technique, shown using locking forceps at the superior and inferior limbus, and a Barkan goniotomy lens modified with the addition of a handle, sitting on a cushion of viscoelastic applied to the cornea. A 25-gauge needle is used to enter the anterior chamber and to make a cleft to either side, while the assistant stabilizes the globe and rotates it to expose additional angle. Note that the needle entry is closed with a single buried10-0 polyglactin suture.
2. Nasal goniotomy technique without traction suture or assistant using modified Swan-Jacob lens. The anterior chamber is maintained with viscoelastic and a 25-gauge needle.
3. Nasal goniotomy without an assistant using a standard Swan-Jacob lens and a 25-gauge needle on viscoelastic.
4. ESM 1: Video that demonstrates technique of phaco-endocycloplasty and ECPL in pseudoexfoliation.

Step by step procedure for online viewing:

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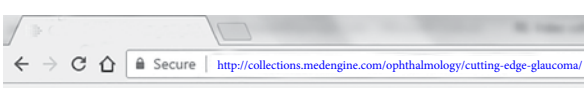

2. Web page of the issue will open on the screen.
3. View and read the PDF version and watch the videos online.
4. The PDF file can be downloaded too for offline reading.

Glaucoma Drainage Implants

Luigi Caretti, Lucio Buratto

Introduction

Glaucoma drainage devices (GDDs) or shunts were proposed by Molteno and coll in 1968 for the treatment of refractory glaucomas, meaning those cases at a high risk of failure following filter surgery or in cases in which surgery was already not successful.

Glaucoma drainage devices are devices designed to deviate the aqueous humor away from the anterior chamber (AC) to an external reservoir (bleb) in the subconjunctival space, where it forms a fibrous capsule that will be responsible for flow regulation. The formation of the fibrous capsule generally occurs 4–6 weeks after surgery.

These devices are available in different sizes, materials and shapes; they may be equipped (or not) with a valve that regulates the flow of aqueous humor that drains from the eye bulb and consequently regulates the intraocular pressure (IOP).

Over the past 40 years and especially in the last decade, new shapes of shunts and improvements in the surgical techniques have resulted in better efficacy with a lower rate of complications. These new devices are also easier to implant compared to the past and the indications have been modified. For all of these reasons, today, their clinical use has increased considerably.

However, despite these technical improvements, the IOP is often not predictable immediately after surgery and many patients need to continue using topical hypotonic therapy to maintain satisfactory pressure control.

In the past, some authors have suggested an association of the implants with antimetabolites; nevertheless, at the time of writing these have been nearly abandoned because in the literature, no evidence of their effective clinical use has been reported.

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Types of Drainage Implants

A number of GDDs are commercially-available; they differ in terms of type, shape and material. The implants consist of at least one plate and a tube. One of the main features that differentiates the various types of implant consists of the presence or absence of a valve fitted inside the implant. The devices with the 'valve' or with 'flow restriction' consent an exclusively unidirectional flow of liquid from the AC to the subconjunctival space with minimal activation pressure. On the other hand, the non-valved implants do not restrict the flow: these necessitate the intraand post-operative application of some additional maneuvers to prevent hypotonia (see successive paragraphs on the surgical technique). The GDDs by Ahmed (AGV; New World medical, Rancho Cucamonga, CA) (Fig. 1) and Krupin (production has been interrupted) are two examples of valved implants. Non-valved GDDs are produced by Molteno (IOP Inc., Costa Mesa, CA and Molteno Ophthalmic Ltd., Dunedin, New Zealand) (Figs. 2 and 3), Baelverdt (Abbott Medical Optics, Santa Ana, CA) (Fig. 4) and Eagle Vision (Eagle Viono Inc., Memphis, TN) (Fig. 5) (also see Table 1).

Fig. 1: Ahmed implant.

Fig. 2: Molteno implant (single plate).

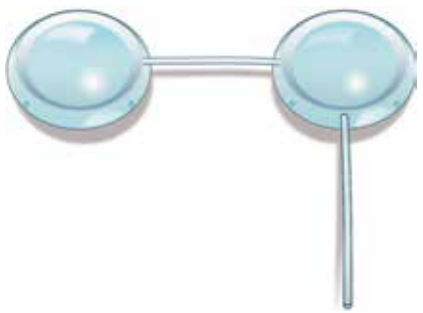


Fig. 3: Molteno implant (double plate).

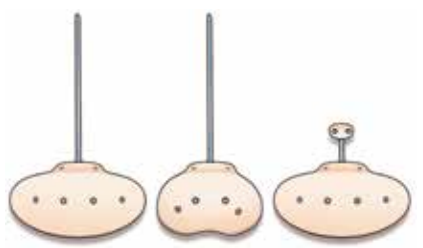


Fig. 4: Baelverdt implants.

Fig. 5: Eagle Vision implant.

Table 1: Commercially-available glaucoma drainage implants.

	Type of plate	Size range (mm²)	Type of material
Valved implants			
Ahmed	Single, double, for pars plana, pediatric	96–364	Polypropylene or silicone
Non-valved implants			
Baerveldt	Single, for pars plana	250–350	Silicone
Eagle vision	Single	365	Silicone
Molteno	Single, double, for microphthalmia	50–274	Polypropylene

Clinical Indications for the Use of Shunts

As mentioned previously, the GDDs were traditionally indicated for the treatment of refractory glaucoma, meaning cases in which filter surgery is associated with a high risk of failure (for example, neovascular or uveitic glaucoma), with a high rate of complications or in cases with previous failure of filter surgery for glaucoma. Moreover, the shunts appear to be effective in patients in which a previous intraocular surgery (vitreo-retinal or corneal) led to the formation of conjunctival scar tissues that reduce the amount of intact conjunctiva, precluding the trabeculectomy procedure or function. In recent years, the indications for these devices have expanded quite considerably, and now include congenital/juvenile glaucoma, traumatic glaucoma, glaucoma in the aphakic/pseudophakic eye, glaucoma post-keratoplasty, other secondary glaucomas (irido-corneal-endothelial syndrome, epithelial downgrowth). Moreover, in eyes with residual visual function, the shunts may be preferred over the cyclodestructive procedures that run a high risk of blindness and Phthisis bulbi (end-stage eye) (see Table 2). Lastly, in recent years these devices have been proposed as the elective procedure for cases of primary open-angle glaucoma: a number of

Table 2: Clinical indications for the glaucoma drainage implants.

• Previous failure of filtering surgery
• Patients in which filtering surgery is associated with a high risk of failure or complications
– Neovascular glaucoma
– Uveitic glaucoma
– Previous intraocular surgery (vitreo-retinal or corneal surgery) with the formation of conjunctival scarring that preclude trabeculectomy
• Eyes with residual useful function, for which the cyclodestructive procedures have a high risk of blindness and *Phthisis* bulbi (end-stage eye)
• Post-traumatic glaucoma
• Congenital/juvenile glaucoma
• Glaucoma in the aphakic/pseudophakic eye
• Post-keratoplasty glaucoma
• Other secondary glaucomas (irido-corneal-endothelial syndrome, epithelial downgrowth)

authors have suggested their use in the primary surgical management of non-complicated glaucoma—the most precocious cases—thanks to their better result predictability compared to the trabeculectomy with MMC and the lower incidence of complications (see results and complications below).

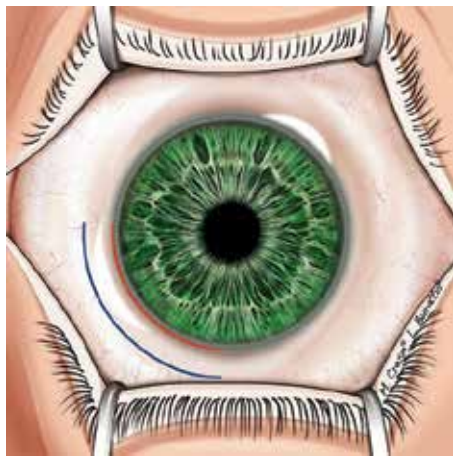
Preoperative Evaluation

It is essential that the surgeon performs a meticulous preoperative evaluation of the eye and devises an appropriate surgical plan to ensure the good outcome of the implant and minimize the risk of complications. First of all, the mobility of the conjunctiva must be examined to allow the surgeon to choose the best quadrant for the implant. In children affected by buphthalmos or in patients with vascular collagen disorders, the surgeon should attempt to identify thinned areas of the sclera where the implant should be avoided: under these clinical conditions, the surgeon must use certain techniques to anchor the plate of the device to the sclera to avoid possible perforations. The surgeon should examine the patient's cornea for marked peripheral gerontoxons or leukomas that could obstruct the visualization of the tube and cause problems with its insertion and correct positioning in the AC. Moreover, in the event of damage to the corneal endothelium, the implant in pars plana is preferable to the implant in AC. If the endothelial damage is evident (corneal insufficiency), and a clinically important cataract is observed, a triple procedure may be considered (phaco + IOL + GDD). The iris should be examined under high magnification to identify new blood vessels that may be treated with a preoperative intravitreal injection of anti-VEGF drugs to reduce the risk of intra- and post-operative bleeding. The depth of the AC must be measured to avoid exclude lesions to the cornea or the iris induced by the tube in the AC. The condition of the lens must also be considered: the tube can be positioned in the ciliary sulcus of pseudophakic eyes or in pars plana in aphakic eyes. It is extremely important that gonioscopy is performed on patients who are candidates for the GDD implant; this will identify neovessels in the camerular angle (in neovascular glaucoma) and peripheral anterior synechiae (frequently present in neovascular, uveitic and traumatic glaucoma). The surgeon must take note of the areas that are free from anterior peripheral synechiae as this will allow him to correctly choose the site for the implant. In the event of anterior peripheral synechiae of recent appearance, the tube can be positioned anterior to the synechiae. If synechiae are observed in an extremely anterior position, it may be necessary to perform an intraoperative iridectomy to facilitate the insertion of the tube. Alternately, the surgeon must plan the implant of the tube in the ciliary sulcus or in pars plana.

Surgical Technique

In most cases, the tube of the GDDs will be positioned in the AC. However, it can also be positioned in the ciliary sulcus of a pseudophakic patient or in pars plana in vitrectomized eyes. The implantation of GDDs in AC will be examined more in detail later. Each surgical step of this procedure requires maximum attention to achieve good results and reduce the post-operative complications. The first thing to do is to select the quadrant for the implant. Most of the GDDs

Fig. 6: Conjunctival incision (limbus-based flap). Once the surgeon has selected the site for the implant, the first maneuver in this type of procedure is to perform the conjunctival incision (peritomy or peritectomy). Westcott scissors are generally used for this procedure. We prefer to perform a capsule-conjunctival incision with the hinge at the limbus (*curved blue line* in the drawing) rather that the fornix-based flap (*curved red line* in the drawing). It must extend for 90–110° and be centered between the two rectus muscles (the distance is greater for the implant with two plates). The flap should include the conjunctiva and the Tenon because it should be a capsulo-conjunctival flap: this will ensure better closure and consequently a lower risk of exposing the implant. The advantages associated with the limbus-based flap are the excellent posterior exposure (the implantation of the plate is easier), the reduced risk of leakage from the scar in the limbal position, lower conjunctival retraction and preservation of the stem cells of the limbus. The disadvantages are that the suture is more complex (compared to the incision when the hinge is at the fornix), and the scar will be positioned above the plate of the shunt, with the consequent risk of dehiscence of the wound, leakage and epithelial downgrowth.



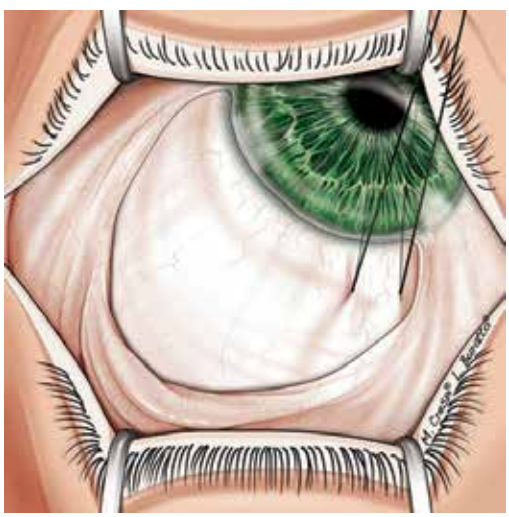


Fig. 7: Exposure of the quadrant for the implant. To create good exposure of the quadrant for positioning the shunt it is recommended to place of a scleral or corneal suture in silk 6.0 or 7.0 and then to tension the thread. The conjunctiva and the Tenon are detached, with the formation of a pouch. The surgeon should avoid an excessively wide dissection as the space created should not be greater than the diameter of the plate: there is a risk of acute post-operative hypotonia, particularly when non-valved shunts are used.

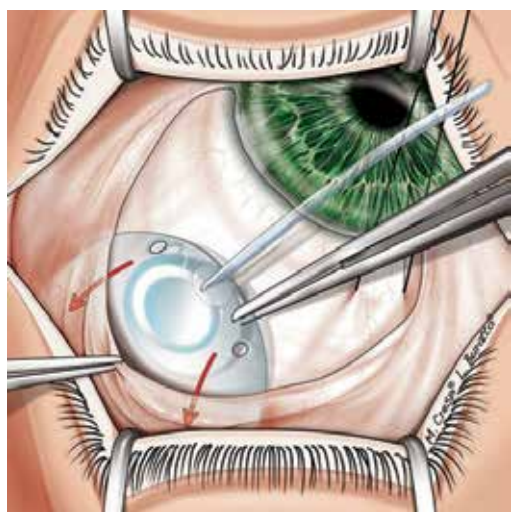


Fig. 8: Anchoring of the plate of the shunt to the sclera. The conjunctiva and the Tenon are retracted using forceps (or a retractor) to expose the bare sclera below. Now the surgeon proceeds by positioning the implant in the capsule-conjunctival pouch, between the two rectus muscles, so that the anterior edge lies approximately 8–10 mm posterior to the limbus.

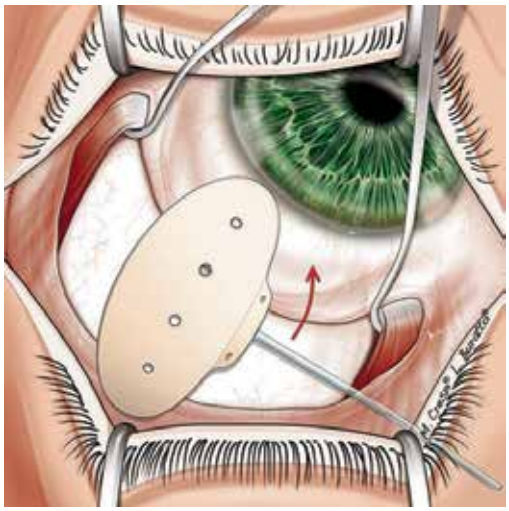


Fig. 9: Maneuvers to correctly position large shunts. The large implants (for example, the Baelverdt) should initially be inserted with the greater axis directed towards the apex of the eyeball and then rotated horizontally of approximately 90°, so that the tube is directed towards the AC, and the wings of the shunt slide under the rectus muscles (*red arrow* in the drawing). The surgeon should isolate the adjacent rectus muscles using a hook and mark the muscular insertion to allow correct positioning of the plate between or below the muscles.

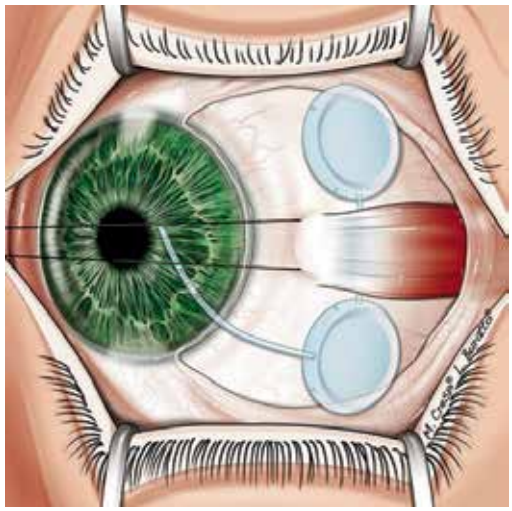
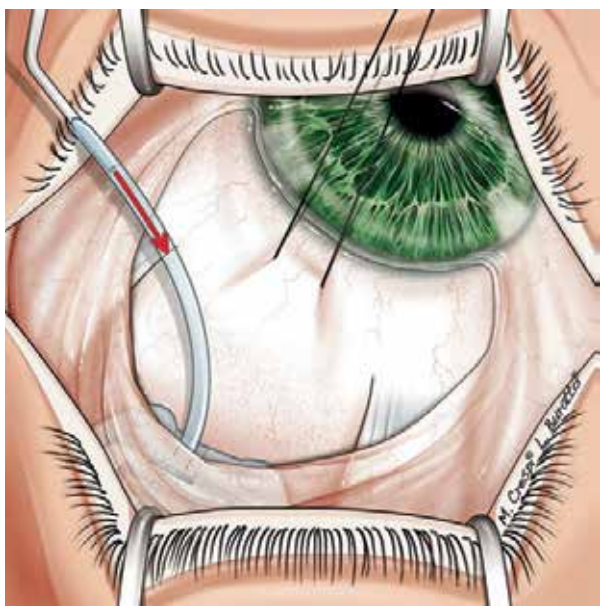


Fig. 10: Correct positioning of shunts with two plates. When shunts with two plates are inserted, one of the plates is positioned in one quadrant and the second plate is positioned in another quadrant. The connecting tube of the two plates can be positioned below or above the rectus muscle that separates the two quadrants.

Fig. 11: Control of the patency of the tube of the valved shunts (priming). When valved shunts are inserted, prior to anchoring it on the sclera, it is advisable to irrigate the drainage tube (priming) using a syringe filled with balanced saline solution (BSS) or sterile water with a 30G cannula; this can be used to control the correct movement of the internal valve (patency of the shunt); the valve can sometimes melt during the sterilization processes. The valve should not be touched with the forceps as it could be damaged producing a malfunction.



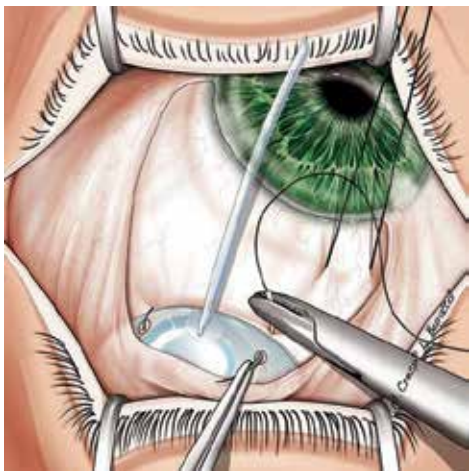


Fig. 12: Anchoring the shunt to the sclera. The plates of every type of shunt have small holes. Permanent/non-absorbable nylon 8.0, 9.0 or 10.0 sutures are passed through the holes and this consents firm anchoring to the sclera. As mentioned before, the surgeon should aim to anchor the anterior edge of the plate approximately 10 mm from the limbus. A spatulate needle is advisable as it reduces the risk of accidental scleral perforations. After passing the first suture, the surgeon must control that the GDD has been positioned correctly. Then, a second suture is passed through a second hole in the plate (there are normally two or three holes on each plate). It should be remembered that the knots must be recessed to avoid conjunctival erosion. It is also essential that the shunt is firmly anchored to the underlying sclera to prevent its postoperative migration in an anterior, posterior or lateral direction.

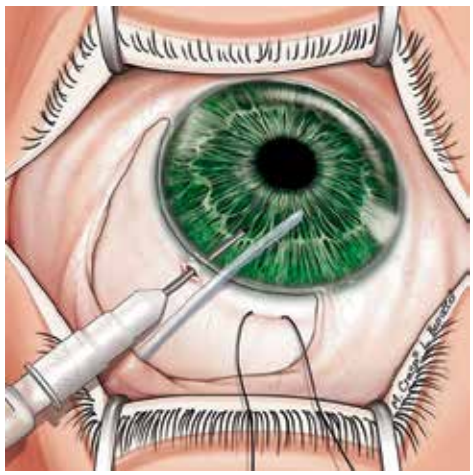
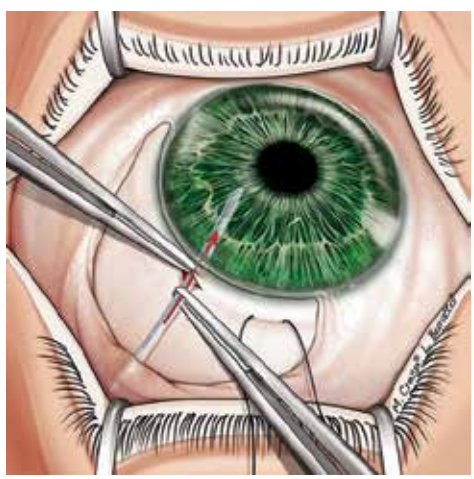


Fig. 13: Creation of a sclero-corneal opening. Now the surgeon makes a scleral incision, at about 1–1.5 mm from the limbus, with a 23G needle, that can be mounted on an insulin needle: the incision must be the right size to allow the insertion of the tube in the AC, it must be straight, positioned just above the iris and parallel to the iris itself. The needle is inserted immediately behind the limbus. It is important to stabilize the eye bulb with forceps when the surgical connection is being created and avoid lateral movements of the needle as this could induce hypotonia in the postoperative. Before the tube is insert in the AC, its distal portion must be cut with scissors to create a chamfered tip. It is extremely important to choose the incision site carefully: the tube must extend into the AC for approximately 2–3 mm, almost to the pupil margin. Its position should avoid the risk of any contact with the cornea or the iris, and the possible retraction that may cause the tube to exit the AC.

Fig. 14: Insertion of the chamfered tube in the AC. There will usually be no difficulty inserting a chamfered tube, with a 30°–45° bevel, into the AC. In order to facilitate the maneuver, the surgeon will normally use one or two toothless forceps.



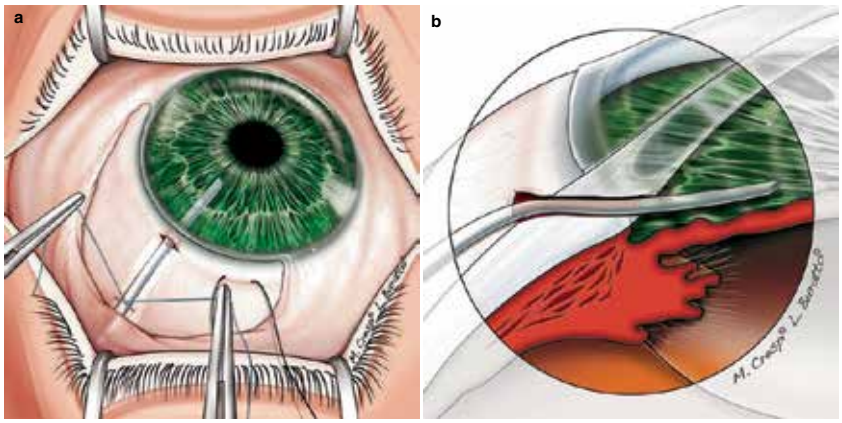


Fig. 15: (**a–b**) Correct positioning of the tube in the AC. Once the tube has been inserted, the surgeon must carefully control that it has been positioned correctly in the AC; contact with the cornea and the entrapment of the iris must be avoided. (**a**) Illustrates the correct position of the tube from above and (**b**) provides a side view of the tube in the correct position. The tube will now anchored to the sclera with a suture positioned just a few millimeters in front of the plate. The suture thread can be vicryl 8.0 or 10.0 (though some surgeons prefer nylon): the purpose of the suture is to stabilize the tube; it should not be excessively tight as this would obstruct the liquid flow in the valved shunts. If the tube is not positioned correctly, the surgeon should create a second paracentesis adjacent to the first and insert the tube through this second opening. The surgeon must pay attention to any leakage from the paracentesis: if leakage is observed, he must position a suture to maintain the intraoperative depth of the AC and reduce the dangerous risk of postoperative hyperfiltration and hypotonia.

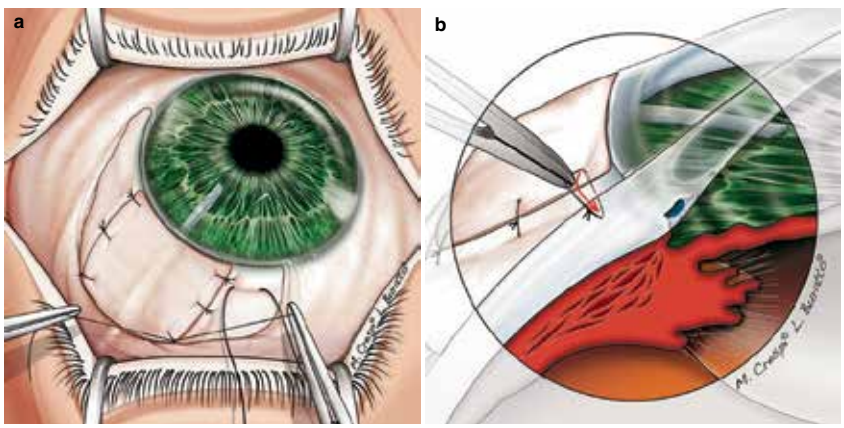


Fig. 16: (**a–b**) Covering the tube of the shunt. In recent years, many surgeons believe that the tube of the shunt must be covered with a patch or graft. This patch will reduce the incidence of conjunctival erosions, a dangerous and occasional occurrence. The patch is positioned to cover the extraocular portion of the tube of the shunt, from the plate to the insertion point in the AC. Single sutures in nylon 8.0 or 10.0 are used to anchor the patch to the bulb. Some surgeons prefer to use vicryl thread (see **a**). All sutures must be recessed in the scleral tissue to avoid late-onset erosion of the conjunctiva (see **b**). To avoid Dellen formation, the surgeon should thin the limbal edge of the patch prior to implanting it. Several materials can be used to cover the tube: scleral tissue, cornea, bovine pericardium, fascia lata and dura. However, the sclera and the cornea are the materials that are used more frequently and this can be sourced at the Eye Bank. Normally a patch measuring 6 × 6 mm or 4 × 6 mm will guarantee good cover. Some surgeons prefer corneal tissue (not suitable for keratoplasty) to the sclera. This is because the cornea is thinner than the sclera and will occupy a smaller volume. As an alternative, if the patch is not available, the surgeon can create a scleral flap that is not full depth: below this he can create the pass the tube with a 23G needle. The flap is then sutured with vicryl 10.0. However, this method would appear to be less secure than applying a patch.

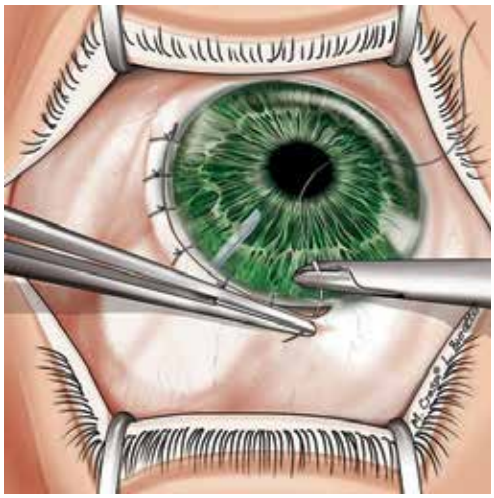


Fig. 17: Suture of the conjunctiva and the Tenon capsule. Final stages of the procedure. After having positioned the patch correctly above the tube of the shunt and sutured it, the surgeon must suture the conjunctiva and the Tenon capsule to cover everything completely. These two tissues must be stretched to cover the plate, the tube and the patch. An 8.0 vicryl suture—continuous or single—is normally used (as shown in figure). Everything the surgeon has done during the procedure should be controlled at the end of surgery: he should examine the position of the plate and the patch, and the correct position of the tube in the AC. Fluorescein drops or strips are useful when checking for leakage of the conjunctiva. Any continuous solutions of the conjunctiva must be closed and sutured with vicryl. Finally, a subconjunctival injection of an antibiotic-steroid combination is recommended.

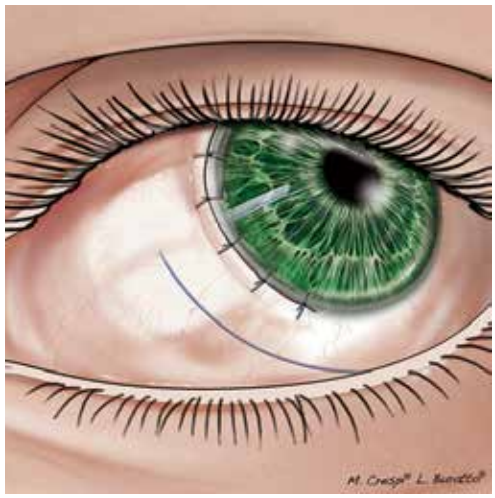


Fig. 18: Prolene stent in the inferotemporal quadrant of an eye with a non-valved implant Another system that reduces the flow of aqueous humor through non-valved implants is external occlusion of the tube (binding): this consists of a suture that is applied around the tube to reduce the size of the lumen. A non-resorbable 7.0 nylon suture with a slipknot or resorbable vicryl are usually used. Like the stent, the release or the resorption of the suture thread occur 4–6 weeks from surgery, the period necessary for the fibrous capsule to form around the implant. This technique is not particularly indicated for eyes affected by important preoperative hypertonia due to the long period required to normalize the IOP.

are positioned in a single quadrant, with the exception of the implants with two plates. When possible (due to the conditions of the conjunctiva, sclera, etc), the implant with a single plate should be positioned in the supero-temporal quadrant: this site consents the easiest access to implant the plate and leads to a lower rate of disturbance of ocular motility (see the paragraph on the complications below). With a silicone oil tamponade added to the eye, the implant is positioned in the temporal-inferior quadrant to prevent oil escaping; it is lighter than aqueous humor and will tend to rise.

Surgical Tips to Prevent Hypotonia with Non-valved Implants

When non-valved implants are used, two surgical maneuvers can be added to avoid hypotonia in the precocious post-operative period: both involve the use of suture thread that can be applied either inside or outside the tube of the implant.

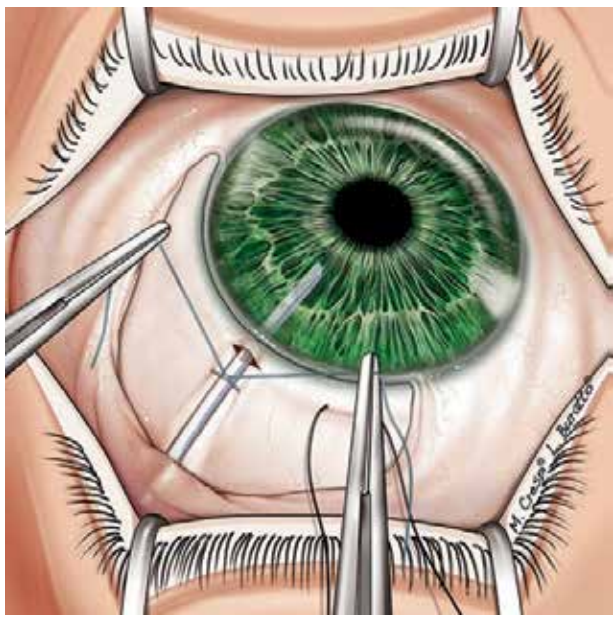


Fig. 19: External binding of the tube of the non-valved shunt with suture thread. Another system that reduces the flow of aqueous humor through non-valved implants is external occlusion of the tube (binding): this consists of a suture that is applied around the tube to reduce the size of the lumen. A non-resorbable 7.0 nylon suture with a slipknot or resorbable vicryl are usually used. Like the stent, the release or the resorption of the suture thread occur 4–6 weeks from surgery, the period necessary for the fibrous capsule to form around the implant. This technique is not particularly indicated for eyes affected by important preoperative hypertonia due to the long period required to normalize the IOP.

The first of these additional maneuvers involves positioning an obstruction inside the tube (stent): it consists of a prolene or 3.0, 4.0 or 5.0 nylon thread, positioned inside the tube's lumen. This will reduce the patency and consequently decrease the drainage of the aqueous humor: the thread acts as a temporary valve. The piece of thread is approximately 15–20 mm long; it is inserted in the tube for 6–10 mm through an opening on the tube close to the plate. The free end of the prolene or nylon thread that exits the tube is positioned in the subconjunctival space of the quadrant adjacent to the implant, close to the limbus. Once the fibrous capsule has formed around the plate (4–6 weeks from surgery), the suture can be removed under the slit lamp and topical anesthesia. At this point, the aqueous humor can drain freely into the fibrous capsule around the plate, with the capsule providing resistance to the flow. However, even though this technique is efficacious for preventing precocious postoperative hypotonia, it may be necessary to remove the suture immediately in the event of precocious postoperative hypertonia caused by occlusion of the tube. So there is again a risk of hypotonia, a reduction in the depth of the AC and the associated complications.

Results

Most of the published studies report a mean percentage of success with the four types of implant of approximately 70% (range 50–80%), with an average postoperative reduction in the IOP of at least 50% over the preoperative values 2 years from surgery: the variation of the range depends on the type of glaucoma and the type of implant chosen. Unfortunately, failures account for 10% per year, with a consequent 50% function of the drainage implant after 5 years. One-year results

of a comparative study for the Ahmed and Baerveldt implants did not clearly demonstrate any clear superiority of one over the other: even though the mean IOP was slightly higher in the eyes with the valved implant (Ahmed), this implant was associated with a lower incidence of precocious complications that are less severe than those observed with the Baerveldt implants. Recently an update with 5-year follow-up was published. It referred to an important study called 'Treatment Outcomes in the Tube Versus Trabeculectomy (TVT)". It reported that 5 years from surgery, IOP was a slightly greater (though not significant) when shunts were used compared to trabeculectomy: in the postoperative, both types of procedure are associated with a fairly similar reduction in the IOP and comparable use of a topical pressure-reducing therapy. GDDs have a greater success rate compared to the trabeculectomy procedure associated with MMC: the cumulative probability of failure during 5 years of follow-up has been reported as 29.8% for the GDDs and 46.9% for the trabeculectomy. By the same measure, the percentage of repeating surgery is greater for trabeculectomy. These important findings have driven numerous surgeons to increase the number of implant procedures performed and to propose this surgery in cases of simple, not complicated, chronic glaucoma. Barton et al concluded their study by stating that the Ahmed valves would appear to improve the predictability of the precocious postoperative control, and that the Baerveldt valves have a lower percentage of late encapsulation. The authors believe that the main obstruction to the diffusion of these devices in uncomplicated cases of glaucoma is the lack of data available on the long-term effects on the endothelium, an issue that has not been fully clarified. In conclusion, GDDs would appear to be associated with an efficacy that is comparable, and sometimes superior, to the trabeculectomy in the management of complicated glaucoma. Given that, traditionally, these devices were suggested for refractory cases of glaucoma, they have always been associated with poor results. Their use should be reviewed—something that is already happening to some degree—in the primary surgical management of uncomplicated glaucoma (the more precocious cases), even taking in consideration the greater predictability compared to the trabeculectomy with MMC, combined with a lower incidence of complications.

Complications

There are numerous possible complications associated with GDDs; the surgeon must necessarily construct a precise preoperative plan and have learned a meticulous technique (for all phases of the procedure) to achieve a valid result.

The complications are divided into:

- Intraoperative
- Precocious postoperative (within 3 months)
- Late onset postoperative (after 3 months)

Intraoperative Complications

One complication is the formation of 'button holes' or lacerations in the conjunctiva. These are observed more frequently in patients who were previously subjected to surgery that involved

manipulation of the conjunctiva. To suture the conjunctiva, many surgeons prefer to use a single filament of 9.0 vicryl because this thread has greater tensile strength and is equipped with an extremely fine needle that reduces the risk of button holes forming when used on a very thin conjunctiva. If the surgeon notices a tear during the surgery, it must be repaired with a 10.0 vicryl suture positioned with a fine needle. If the rupture cannot be closed, it is essential that the surgeon controls that the patch covers the entrance of tube into the AC and that there is no leakage through the conjunctival hole. If leakage is absent, the conjunctiva will heal at a later stage (thanks to the vascularization of the patch below). However, if leakage is observed, the implant must be removed, the conjunctival suture must be tightly sutured and the tube must be positioned in another quadrant. Other intraoperative complications are associated with the tube: it may be too short (the surgeon's error), its position may be excessively anterior or posterior causing it to touch the ocular structures (corneal endothelium, iris, crystalline) and this may lead to bleeding the AC in the case of an implant in eyes affected by iris rubeosis. This complication is often linked to acute hypotonia that appears during the insertion of the tube; it can be avoided by injecting VES into the AC prior to the procedure or by applying a maintainer. Scleral perforation is a serious complication that is rarely described. It occurs when the surgeon anchors the shunt to the sclera. He must pay maximum attention when inserting an implant into eyes affected by buphthalmos and in patients with vascular collagenopathies that may be associated with localized or widespread thinned areas. If scleral perforation is observed, the surgeon had to do an *in situ* cryopexy, followed by an attentive vitreoretinal follow-up examination.

Precocious Post-operative Complications

The complications are similar to those observed with other techniques, namely hypothalamy, hypotonia and associated consequences such as choroidal effusion and choroidal haemorrhage. Hypotonia with hypothalamy is possibly the most frequently observed complication. Hypotonia and associated consequences are observed most frequently with the nonvalved shunts. Precocious hypotonia is normally caused by leakage from the wound, inflammation, incomplete occlusion of the tube or excessively large drainage fissures with nonvalved implants. With the valved implants, hypotonia is observed less frequently and can be related to hyperfiltration. There may be leakage around the tube if the pathway that communicates with the AC is created with an excessively large needle or if it is widened unintentionally when the surgeon withdraws the needle. Consequently, as mentioned previously, it is important that the surgeon stabilizes the bulb with forceps when he creates the pathway and that he avoids any lateral movement of the needle. Hypotonia is treated conservatively for as long as it is observed in the AC: it may actually resolve spontaneously after just a few days. However, if the AC is lost or is very flat after 7–10 days, and there is contact with the endothelium, the AC must be reformed with the introduction of air or preferably cohesive, low resting molecular weight VES under the slit lamp. It is introduced using the paracentesis created during the procedure. If choroidal effusion is observed, it is usually treated with systemic corticosteroids and cycloplegics. In the event these measures are not successful, surgical revision may be necessary, possibly with the removal of the implant and drainage of the choroidal effusion.

Complications may also be linked to the presence of the tube, and these may also appear in the early postoperative period. The surgeon must take extra care to position the tube correctly in the AC: the tube must extend in the AC for approximately 2.5–3 mm. If the tube is excessively close to the cornea or if there is extensive contact, endothelial dysfunction may result: in this case, the tube must be repositioned. If there is contact with the peripheral cornea, the damage will usually be localized and the implant can be left in position. However, if the position of the tube is excessively posterior, it may touch the iris causing rubbing iritis, or if it touches the crystalline, a cataract might result. Iritis is a common occurrence. If it is mild, the tube can be left in position and the inflammation treated with low doses of topical steroids. In the event of severe iritis, the implant must be repositioned or replaced. The cause of the iritis may not always be identified; consequently, it must be treated like all iritis inflammations observed in glaucoma patients. The tube may occlude precociously due to the presence of blood, vitreous, fibrin exudate or iris entrapment with consequent ocular hypertonia: on occasion these can be treated with a delicate manual massage, with steroids, by washing with BSS or using the Nd:YAG; or it may be necessary to unblock the tube. Lastly, the tube may be withdrawn and moved in an anterior direction— this is indicated in children. Corneal edema (corneal swelling) may result from contact between the tube and the endothelium or persistent hypothalamy from hypotonia. The risk of this complication is reduced if valved implants and stents are used as the AC depth will be maintained more successfully. Even the implantation of the tube on pars plana will reduce the risk of this complication. If there is evident and irreversible corneal swelling, the tube must be repositioned, possibly in another quadrant, preferably prior to starting the keratoplasty. The keratoplasty procedure may be performed when the tube is being repositioned; the surgeon has the option of performing a perforating keratoplasty or an endothelial keratoplasty. As the endothelial keratoplasty requires air to be present in the AC, it may prove to be difficult as the tube may allow the air to escape more rapidly. In the 1–6 weeks postoperative, there may be hypotonia, most frequently observed between weeks 4–7; the IOP range lies between 30–50 mmHg. This condition has been reported for all types of drainage and is more frequently observed with the valved implants. The tube is not occluded by blood, vitreous, fibrin or the iris; hypertonia would appear to be associated with a pluri-compartmentalized bleb (containing many septums); these reduce the permeability of the aqueous humor through the conjunctiva. This complication is frequently observed with the smaller valved implants (in terms of filtration area) with a polypropylene plate (as opposed to silicone). The therapy options in the hypertensive phases are: IOP-reducing medical therapy, digital massage, needling of the bleb, with or without 5-fluorouracil and surgical excision of the bleb. Needling is performed under topical anesthesia at the slit lamp: it involves penetrating the conjunctiva with a 30G hypodermic needle 5–10 mm from the bleb and cutting the wall of the bleb with lateral movement. A small quantity (between ¼ and ½ cm^3) of aqueous humor is allowed to escape, but care must be taken to avoid losing the AC. This maneuver is considered successful when localized chemosis and a soft eye bulb are observed. The maneuver can be repeated once a week until the IOP has normalized. If these options are unsuccessful, the surgeon should consider the application of a new shunt or the cyclodestructive procedures. A malfunctioning valve, linked to the sterilization processes that may cause adhesion of the internal membranes, is a rare event. Nevertheless, prior to the definitive

anchoring of the eye bulb, the surgeon should always check the patency of the tube with BSS. Sometimes hypoema may be observed in eyes with neovascular glaucoma; it is normally of minor importance and resolves spontaneously. This complication is extremely rare since anti-VEGF drugs have been used in the preoperative period.

Late-onset Postoperative Complications

The most fearsome complication is the unsuccessful implant linked to fibrosis of the bleb. The Tenon capsule is the tissue responsible for the formation of the bleb. Several options have been proposed to prevent the onset of this phenomenon. Some authors inhibit the formation of fibrosis with a cocktail of NSAIDs, colchicine and topical adrenaline associated with systemic steroids, in the postoperative (1–6 weeks from surgery) as suggested by Molteno. As the antimetabolites have no effect in preventing the formation of fibrin, their use is not recommended. In the event hypertonia from fibrosis is observed, needling or the implantation of a second GDD in another quadrant may prove useful. In recent years, some authors have suggested the implantation of a shunt above the Tenon capsule; the reason for this procedure is to exclude the Tenon capsule from the bleb formation process, given that it is considered to be the main protagonist in this process. The positioning of a second GDD above the Tenon has also been suggested to prevent fibrosis above the plate. Erosion of the capsular-conjunctival tissue above the tube is a frequent consequence of conjunctival melting and can be associated with the inadequate preparation of the patch, its incorrect positioning or it may be assisted by the blockage of the tube. To reduce the increase in volume associated with the patch that can lead conjunctival erosion, some surgeons use a half-depth cornea as opposed to sclera or full-depth cornea. This will expose the tube and the plate of the shunt and may also occur in the event of a perfect surgical outcome. Erosion will be more frequent when the flap has its hinge at the limbus, as the incision will lie closer to the plate of the implant.

Sometimes the erosions can be associated with epithelial growth on the plate: this epithelial downgrowth can be extremely dangerous as it may prevent the scarring of the conjunctival wound. Exposure of the tube or the plate of the shunt are surgical emergencies that must be treated immediately to prevent endophthalmitis. If erosion is present, the bulb may become extremely hypotonic and consequently at a risk of endophthalmitis—a phenomenon observed more frequently in children. This tissue defect must be repaired by replacing the patch and bringing the conjunctiva forward. If this displacement of the conjunctiva is not sufficient, a conjunctival allograft removed from another quadrant may resolve the problem. And if the problem is still not solved with this procedure, the implant should be removed. A rare possible complication is the migration and the expulsion of the plate: this is associated with an excessively anterior position of the plate. If the patch is too thin or in an excessively anterior position, the bleb may protrude and this can lead to chronic Dellen or persistent ocular irritation. Strabismus may also appear. Changes in the equilibrium of the extrinsic muscles may lead to very serious diplopia; this is a frequent occurrence with implants in the inferior quadrants. It is also extremely frequent with the larger implants. This may limit the supero-version eye movements, given that the shunt is

frequently implanted in the superior quadrants; however, there will also be limits to the infero-version eye movements with inferior implants. These are the more frequent cause of diplopia and is extremely uncomfortable for the patients. Diplopia is observed more frequently when larger implants are used (despite the fact that these can lead to a better outcome on the IOP). The onset of pseudo-Brown syndrome and hyperopia have also been observed. These disturbances of the eye movements may appear in both the early and late post-operative period; they may be caused by the volume of the plate, scar tissue below the rectus muscles, entrapment of the oblique muscle or fibrotic retraction of the orbit fat (caused by accidental manipulation of the orbit fat). Diplopia induced by GDDs is sometimes difficult to treat with either prisms or surgery and sometimes it cannot even be resolved by removing the shunt. A meta-analysis on shunts dating 2008 highlighted the most serious long-term complication is corneal endothelium deficiency. The most frequent complication is the erosion of the conjunctiva above the GDD. This study also reported a 10% annual failure rate that is similar to the value for trabeculectomy. The TVT study with 5-year follow-up reported that despite the large number of complications, the majority are transitory and resolved spontaneously. Moreover, with respect to the trabeculectomy with MMC, there was a lower incidence of precocious complications. Both methods (GDD and trabeculectomy with MMC) are associated with a similar incidence of late-onset complications, repeated surgical procedures because of complications and a need for cataract surgery, all reasons that have driven a significant increase in the use of these devices.

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Non-penetrating Glaucoma Surgery (NPGS): Viscocanalostomy, Deep Sclerectomy and Canaloplasty

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Introduction

Non-penetrating glaucoma surgery (NPGS) is selectively used on the altered structures responsible for ocular hypertension. It is performed without penetrating the eye bulb; and different to other widely-used techniques, it is essentially extraocular surgery. In this way, the surgeon avoids the possible complications associated with penetrating surgery, such as trabeculectomy, still considered to be the gold-standard in the surgical treatment of open-angle glaucoma. In primary open-angle glaucoma and in some cases of secondary glaucoma, resistance to drainage of the aqueous humor is principally produced by the juxtacanalicular trabeculate and the internal wall of the Schlemm's canal: these are the two target structures of NPGS. The choice regarding which procedure to use in a patient affected by glaucoma must be taken on a case-by-case basis and it is extremely difficult to propose a standard treatment protocol. There are three types of procedure that are included in this group: viscocanalostomy, sclerectomy and more recently, canaloplasty. Canaloplasty is the procedure that in recent times is receiving greater consensus among the specialists of glaucoma surgery. And increasingly, this type of surgery is performed in combination with the cataract procedure (phacoemulsification).

Traditionally, NPGS is reserved for the following cases:

1. Closed-angle glaucoma compensated with miotics or other drugs;
2. Open-angle glaucoma compensated with two drugs (with a target pressure that is not excessively low);

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3. Glaucomas in which low ocular pressure is a serious complication following the filtering procedure.

Modern scientific literature reports that NPGS is a possible surgical option for all forms of open-angle glaucoma (primary or secondary), particularly in the early stages and with target pressures that are not excessively low (for example, glaucoma that is compensated with just one drug). Moreover, these techniques are indicated in uveitic glaucoma (given that they cause low grade post-operative inflammation), in glaucoma associated with severe myopia and with the Sturge-Weber syndrome, conditions that are at a risk of choroidal haemorrhage and consequently of post-operative hypotonia following filtering surgery. These techniques would also appear to be indicated in cases of glaucoma with severely altered or thinned conjunctiva in which a trabeculectomy with anti-mitotic drugs could be dangerous. The non-penetrating surgical techniques generally improve the safety profile of glaucoma surgery. There are absolute contraindications to NPGS in case of neovascular glaucoma and the irido-corneal-endothelial (ICE) syndrome relative contraindications include chronic closed angle glaucoma and eyes with extensive damage to the trabeculate (for example, post-trauma recession of the angle, previous laser trabeculoplasty treatments). Canaloplasty may be contraindicated in the event of previous procedures that preclude the incannulation of the Schlemm canal, or in eyes in which the distal aqueous humor outflow pathway has collapsed or contains obstructing scar tissue.

In the neovascular glaucoma, the extensive fibrovascular phenomena that block the filtration of the aqueous at the angle cannot be compensated by dilatating the Schlemm canal. In cases of chronic closed angle glaucoma, the advantages of NPGS are eliminated by the easy contact of the iris to the internal surface of the Descemet's window: consequently, intraoperatively there is an increased risk of the iris touching to the internal surface of the Descemet's window; and postoperatively, there is a reduced possibility of filtration; if the surgeon wishes to proceed with the viscocanalostomy procedure or a canaloplasty in the case of closed angle glaucoma, he must perform a basal iridectomy through a paracentesis or, alternately, a laser iridotomy, and prescribe miotic eye drops for the initial 3 or 4 weeks postoperative.

Viscocanalostomy

Viscocanalostomy is a non-perforating technique developed by Robert Stegman (Pretoria, South Africa) to avoid the problems associated with scarring.

The viscocanalostomy has two advantages over the trabeculectomy:

1. The elimination of the filtering bleb eliminates all of the problems associated with it, primarily the failure caused by the conjunctival, Tenonian and scleral scarring processes;
2. The fact that the AC has not been opened reduces the possibility of hypotonia, hypothalamy/athalamy, inflammation and cataract in the postoperative period.

The moderate popularity viscocanalostomy has achieved in recent years has meant that many surgeons have started using this technique, even in combination with phacoemulsification.

The literature available on viscocanalostomy, and the literature on the deep sclerectomy, was initially limited, though it has increased in recent years. Encouraging data have been

reported with inferior success percentage rates compared to trabeculectomy in the majority of cases. A careful analysis of the literature has shown that non-penetrating procedures (viscocanalostomy, deep sclerotomy, canaloplasty) consent good control of the IOP in the early postoperative period but they are also associated with a high percentage of late failures. Regarding the comparison of trabeculectomy with nonpenetrating glaucoma surgery, the literature reports contradictory results. While some authors have recently underlined how the use of the non-penetrating techniques (with or without phacoemulsification) have produced results that are comparable in terms of a reduction in the IOP, others have highlighted greater efficacy of the trabeculectomy with or without MMC compared to the non-penetrating techniques. Recent literature has reported a better safety profile of the non-penetrating techniques compared to trabeculectomy, while a superiority in terms of tonometric reduction has not been observed.

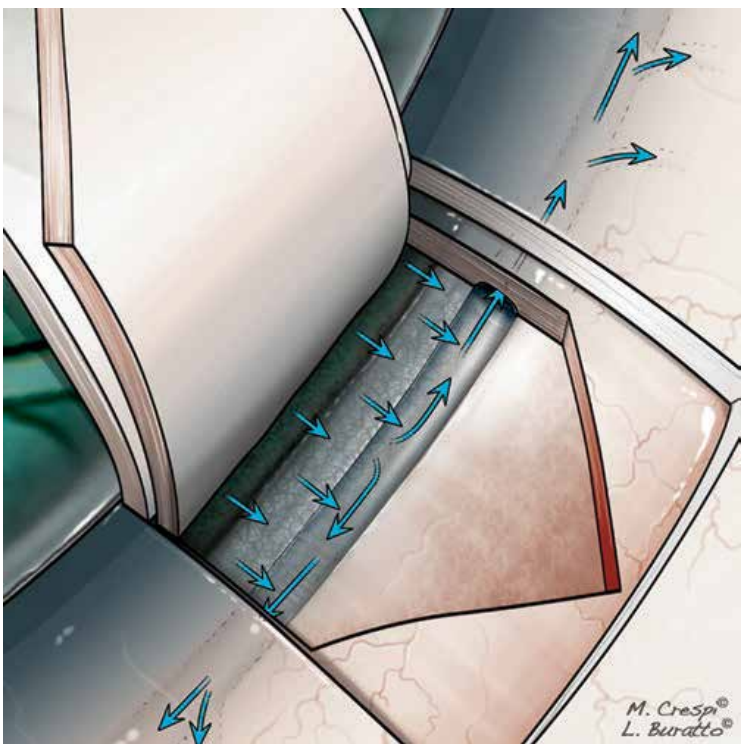

Fig. 1: Rational and presumed mechanism of action of the viscocanalostomy procedure. The viscocanalostomy aims to restore the physiological drainage pathway for the aqueous through the Schlemm canal and the venous collectors; filtration into the sub-Tenon space is excluded. This mechanism is possible with the creation of an intrascleral space, called a lake, into which the aqueous from the anterior chamber (AC) drains (seeps) through a specifically-created fine membrane: the Descemet's window, constructed of the anterior layers of the sclerocorneal trabeculate and the Descemet membrane. The aqueous is collected in the lake and from here passes directly to the cut ends of the Schlemm canal; the canal's lumen has already been incannulated and dilated with an injection of viscoelastic. The aqueous drains from the canal into the collector vessels and finally into the episcleral venous network. The aqueous collected in the lake may also drain into the underlying choroid, increasing the uveoscleral outflow pathway.

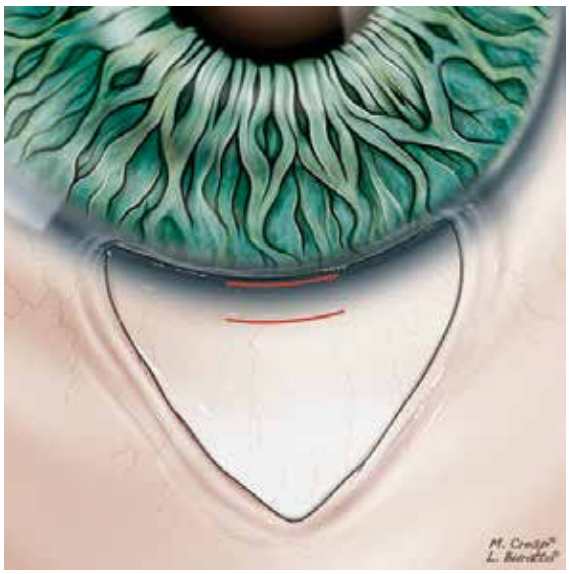

Fig. 2: Preparation of the scleral bed. Surgical technique: the surgeon exposes the eye bulb sufficiently using a traction suture or a Merocel sponge tip as illustrated for the trabeculectomy. The surgical procedure begins at 12 o'clock with the preparation of a conjunctival flap with fornix based, 8–9 mm wide (similar but slightly wider than the flap of the trabeculectomy) and includes the Tenon capsule. The surgical limbus must be identified as this is an important surgical landmark (*red lines*). To keep the surgical field relatively free from blood, the surgeon may request the continuous help of an assistant or he can place small fragments of sponge on the sclera and replace them frequently. The surgeon must reduce to a minimum the diathermy of the episcleral vessels; these must be protected as they are essential for the drainage of the aqueous humor. The main vessels must be identified and not damaged to prevent excessive bleeding. If diathermy is inevitable, it will be necessary to use reduced values and coagulate the individual vessels one-by-one. As an alternative to parsimonious cauterization, good hemostasis can be achieved by the topical application of ornipressin (L-ornithine 8-vasopressin, marketed with the name "POR & Ferring", Sandoz, Switzerland); this molecule is a vasoconstrictor free from any adrenergic action. When applied topically, it provokes a local ischemia that lasts for about 2 h. As an alternative, some surgeons apply a few drops of standard adrenaline.

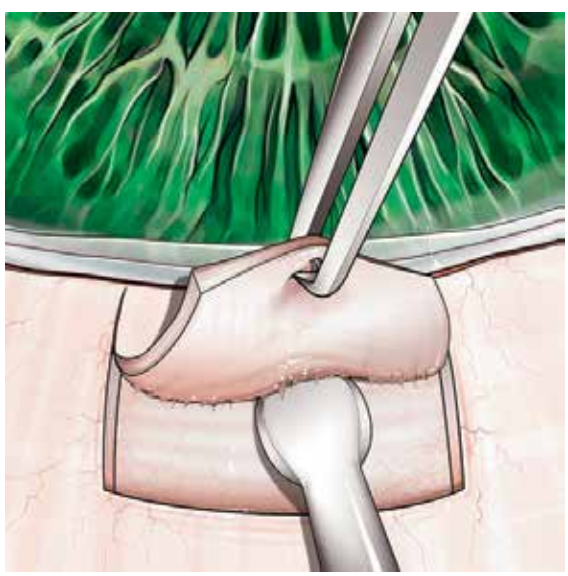

Fig. 3: Superficial scleral flap. When the surgeon has identified a suitable area, possibly lying between two venous collectors, he will create the superficial scleral flap that extends into clear cornea for about 1 mm. The flap can be created in a variety of shapes and sizes. Generally speaking, it has a parabolic shape and the dimensions can vary from between 5 × 5 to 4 × 3 mm for a thickness of approximately 200–250 μm. The dissection can be performed with standard bevel-up crescent knives or with a specially created Grieshaber bevel-up knives.

Fig. 4: Deep scleral flap. The preparation of the deep scleral flap is a crucial phase in the procedure: only the correct depth of the dissection plane will allow the surgeon to identify the Schlemm canal. The margins of the deep flap are cut approximately 0.5 mm inside the edges of the superficial flap, to guarantee better closure when the superficial flap is sutured at the end of surgery. Considering the variability of the scleral thickness between individual patients, it is difficult to establish the right depth of the dissection plane: the use of precalibrated blades is a relative contraindication in this phase of the surgery. The more appropriate approach is to reach the edge of the choroid: the *blue-gray* color must be visible through the residual scleral lamellas. To this end it is essential to work under maximum magnification with extremely low traumatizing instruments that will allow the surgeon to penetrate deeper or remain more superficially when creating the dissection plane with great precision (depending on the surgeon's requirements). If the dissection plane is correct, the surgeon proceeds forward and will automatically reach the point for identifying the Schlemm canal, that becomes 'unroofed' because it is part of the deep flap.

Fig. 5: Identification of the Schlemm canal. Once opened, the Schlemm canal appears as a *dark line*, positioned immediately in front of the scleral spur, represented visually by the concave line that anteriorly delimits the scleral bed. In front of the Schlemm canal, proceeding with the dissection in a centripetal direction, the surgeon identifies the sclera-corneal trabeculate, with its typical granular appearance.

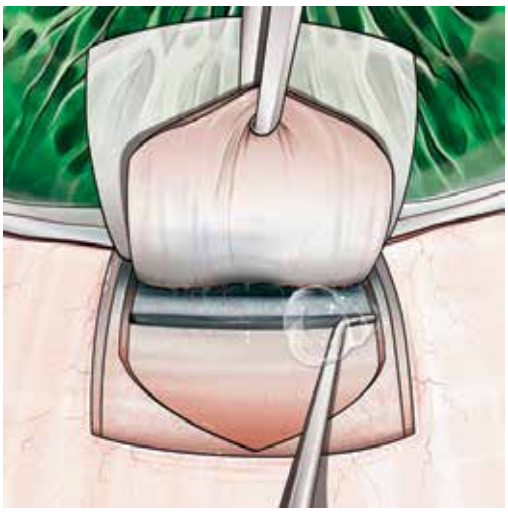

Fig. 6: Dilation of the Schlemm canal. Once the Schlemm canal has been identified and opened, the surgeon injects some high viscosity sodium hyaluronate inside (Healon GV). This maneuver is performed using a special Grieshaber cannula of external diameter 165 µm and internal lumen of diameter 90 µm. The surgeon must proceed with as little trauma to the structures as possible, allowing the cannula to penetrate just 0.5–1 mm. Simultaneously, the surgeon applies moderate traction on the deep flap. The viscoelastic must be injected slowly through the opening that has been created, avoiding that a sudden increase in the pressure inside the Schlemm canal ruptures the internal wall, inducing an undesired trabeculectomy. The viscoelastic mechanically dilates the lumen of the canal (that is pathologically reduced in primary open-angle glaucoma), increasing it from 25–30 to over 200 µm. Immediately after the injection, the surgeon will observe that the episcleral collectors will whiten as the viscoelastic passes through the lumen. To achieve maximum dilation on a greater portion of the circumference of the Schlemm, Stegmann suggests repeating this injection two or three times into both ends of the Schlemm. Now the surgeon can proceed with the successive phase, the creation of the Descemet's window.

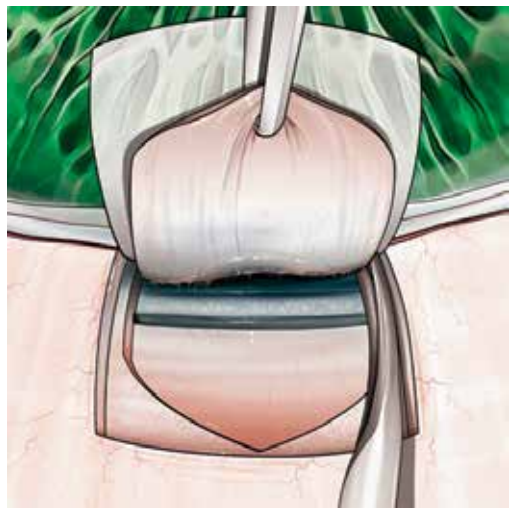

Fig. 7: Anteriorization of the sides of the deep scleral flap. A Descemet's window of suitable depth can only be created if, prior to applying pressure on the trabeculate with the sponge, the surgeon has anteriorized the sides of the deep scleral flap for about 1 mm in clear cornea. For this maneuver, Vannas scissors appear to be the ideal instrument to provide the best control during the cut: however, as these scissors are extremely sharp, there is a risk that they may perforate the underlying Descemet's membrane. Micro-scissors with blunt tips would appear to be more suitable for this maneuver.

In conclusion, thanks to the better safety profile and further improvements to the surgical technique, with or without phacoemulsification, these types of non-penetrating techniques are currently a valid surgical option, particularly in those cases where the target pressure is not excessively low.

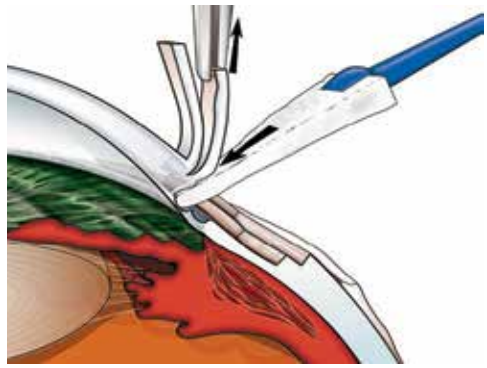

Fig. 8: Creation of the Descemet's window. First, a paracentesis is created at 2 o'clock: this will reduce the pressure in the anterior chamber (AC) and in the posterior chamber (PC); it will decrease the risk of perforation and consequently the prolapse of the iris through the window itself. The tonometric drop that follows the creation of the paracentesis will often eliminate the pressure gradient between the AC and the venous collectors, determining an inversion of the venous flow and blood reflux, that from the cut ends of the Schlemm canal slowly drains onto the exposed surface of the trabeculate. This sign gives us proof that the canal has been identified correctly. In the event of combined surgery, the paracentesis is used to allow the introduction of a second instrument in the AC. The Descemet's window is not created by dissection: the use of instruments that are even moderately sharp will considerably increase the risk of penetrating the AC. The window must be created using blunt instruments, using a sponge tip to exert mild pressure on the anterior edge of the trabeculate and simultaneously applying modest upward traction on the deep flap (*black arrow*). At this point, a reduced IOP will facilitate the success of the maneuver. The surgeon separates the Descemet membrane, that will remain attached to the sclera-corneal trabeculate from the corneal stroma that continues in the scleral tissue of the deep flap. The Descemet's membrane must be at least 500 µm long. Once the Descemet window has been created, in some patients it will already be possible to observe the percolation of aqueous across the Descemet membrane and the exposed portion of the trabeculate.

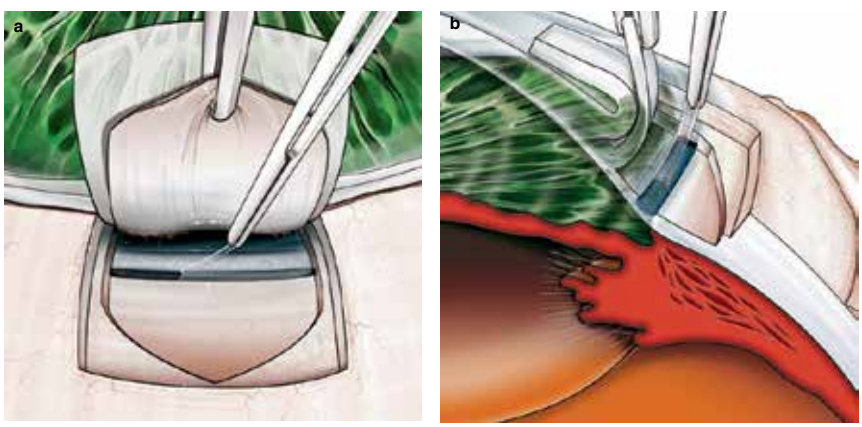

Fig. 9: Stripping the internal (deep) wall of the Schlemm canal. In the event percolation is insufficient or is absent, it will be necessary to remove the obstruction to this filtration: the obstruction will usually be the juxtacanalicular trabecular meshwork or rather the thin layer of connective tissue that separates the endothelium of the Schlemm canal from the remaining layers of the trabeculate. The juxtacanalicular trabecular meshwork is removed—along with the anterior wall of the Schlemm—with a delicate 'stripping' maneuver; at this point, the Descemet's window has been created in front of the Descemet membrane and behind the more internal layers of the trabeculate. The 'stripping' can be repeated several times using fine forceps until adequate percolation has been achieved. If necessary, light stripping can be associated using the bevel-up knife used for the inspection. Stripping of the canal's internal wall can be facilitated if the area is kept dry. Once the stripping of the internal wall of the Schlemm canal has been completed, the surgeon will observe an increase in filtration across the Descemet's window.

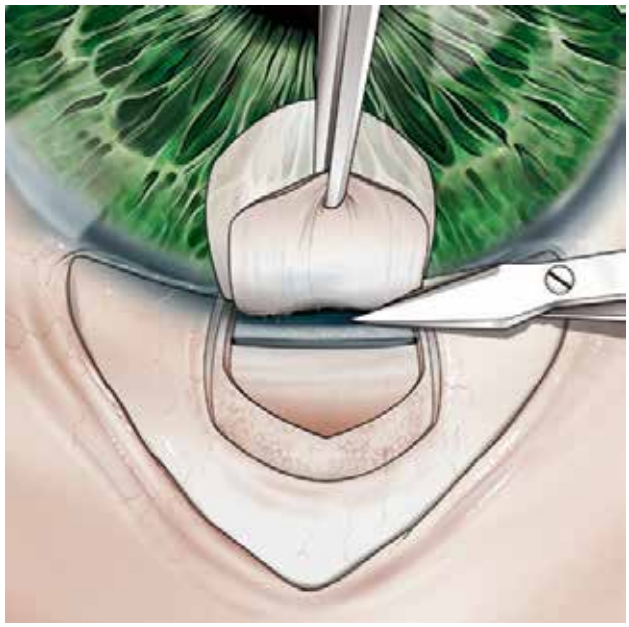

Fig. 10: Excision of the deep flap and suture. Once percolation of the aqueous has been achieved, the deep flap can be removed. Vannas scissors are used, again with the risk of inadvertently perforating the Descemet's window below with the sharp tips of the instrument. In this maneuver, it is essential to correctly position the sharp blades of the scissors in parallel with the Descemet window to cut the flap, keeping it distant from the window itself.

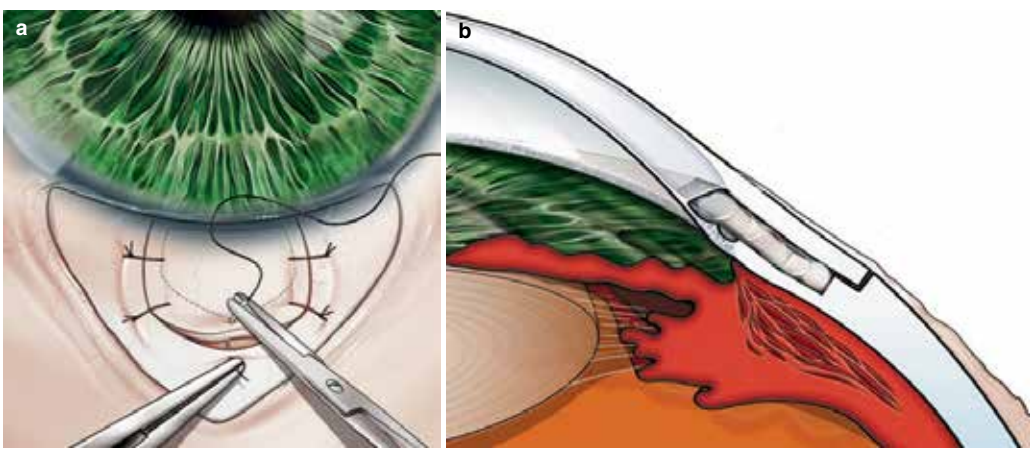

Fig. 11: Suture of the superficial flap. The superficial flap is sutured with 5 or 7 tight nylon 10–0 sutures to prevent aqueous filtering to the sub-Tenonian layer below; alternately, the surgeon can use 11–0 polyester sutures (MERSILENE®). It is essential that the suture provides good closure to prevent the bleb formation. High viscosity sodium hyaluronic can then be injected into the intrascleral lake with the objective of preventing the collapse and reduce scarring in the early postoperative period. Mersilene or nylon are also used for the closure of the conjunctiva, with two sutures applied on the sides of the conjunctival-capsular flap. Alternately, vicryl 8-0 can be used. Finally, a subconjunctival injection of a steroid-antibiotic combination can be performed in the inferior fornix.

Fig. 12: Single access phaco-viscocanalostomy. Combined phacoviscocanalostomy procedure: as with the phaco-trabeculectomy, in the combined phaco-viscocanalostomy procedure, the surgeon may opt for either a single or a double access. In the event the surgeon prefers the **single access** in the superior position at 12 o'clock, following creation of the superficial and deep flaps and identification the Schlemm canal, the viscocanalostomy is suspended temporarily: with the deep flap positioned on the scleral bed, the surgeon creates the tunnel as described below and performs the phacoemulsification. When this step has been completed, the surgeon resumes the viscocanalostomy. In practice, the surgeon begins the viscocanalostomy (having identified the Schlemm canal); the phaco procedure is performed (through a tunnel created below the superficial flap in the most anterior portion); finally, the surgeon creates the Descemet's window and the viscocanalostomy is concluded. Opting for a single access (at 12 o'clock), the tunnel created must also satisfy the requisites of the phaco procedure (intraoperative maintenance of the chamber depth, good closure of the incision at the end of the procedure) and those associated with the viscocanalostomy (that requires absolute integrity of the scleral flaps and the Descemet's window). The tunnel for the phacoemulsification is created following identification of the Schlemm canal, and prior to creating the Descemet's window. The fragile structure of the window could be damaged by the traumatic maneuvers of the phacoemulsifier. The most suitable location is the space that lies between the superficial flap and the deep flap (indicated in the figure). As the dissection for the deep flap extends approximately 1 mm into clear cornea, the tunnel will also lie in clear cornea. It is approximately 2 mm long with the width depending on the gauge of the tip fitted to the phaco handpiece. The principle advantage of the single access is logistics, as the surgeon will not have to change his position during the procedure. It is important to prevent the IOP rising excessively during phacoemulsification to avoid rupturing the filtration structures in the sclerectomy site with the consequent undesired sectorial perforation of the eye bulb. When the cataract procedure has been completed, the AC is filled with medium or low resting viscosity viscoelastic, and the glaucoma surgery can be resumed with the exposure and opening of the Schlemm canal. At this point, percolation of aqueous humor is usually observed in phakic eyes; however, following cataract surgery, only a marginal quantity of liquid will be observed. At the end of the phaco procedure, and once the residual viscoelastic has been removed, it is advisable to leave the eye in a condition of hypotonia to reduce the thrust of the iris on the Descemet's window. An injection of miotic into the AC will reduce the risk of iris prolapse in the event of a perforation of the Descemet's window (an event that would warrant a conversion to a trabeculectomy). Finally, the walls of the tunnel and the paracentesis are edemized.

Phaco-viscocanalostomy with a double access: in the event of phaco-viscocanalostomy with double or separate accesses, the surgeon can begin the procedure with a phaco in a temporal position, complete it and then proceed with the viscocanalostomy in a superior position. Alternately, in a similar way to a single access, the surgeon can begin with the viscocanalostomy in a superior position and continue with the preparation of the deep flap and the identification of the Schlemm canal, with the phaco performed in a temporal position and the viscocanalostomy completed superiorly.

Results

Available literature on viscocanalostomy and on the deep sclerectomy was initially scarce, though the quantity has increased in recent years. Regarding the viscocanalostomy (not combined with phaco), Stegmann reported a 3-year success rate of 82.7%. These figures refer to a relative young population of non-white patients (mean age 54 years), with a high preoperative IOP (47 mmHg). These results appear to be exceptional.

Encouraging results have also been reported in Europe and America with percentage success rates lower than the trabeculectomy in the majority of cases.

Compared to the trabeculectomy with NPGS (deep sclerectomy, viscocanalostomy, canaloplasty), the literature has reported contradictory findings. On this subject, as mentioned previously, some authors have recently underlined how the nonpenetrating techniques (with or without phacoemulsification) have similar outcomes in terms of a reduction in the IOP, while others have highlighted the greater efficacy of the trabeculectomy (with or without MMC) compared to the non-penetrating techniques (see also the results for the deep sclerectomy).

Complications

Intraoperative

The procedure (like the deep sclerectomy and canaloplasty) thins the wall of the eyebulb without opening the AC and will avoid a sudden drop in pressure that is traditionally observed with the classical filtering procedures. Consequently, complications associated with this drop in pressure are less frequent (intraoperative bleeding and post-operative detachment of the choroid).

The perforation of the Descemet's window is the most commonly observed intraoperative complication, particularly when the surgeon is learning the technique. If on the one hand, any microperforations can be ignored or even created intentionally to increase the percolation, on the other important solutions of continuity of the window necessitate the conversion to trabeculectomy (or phacotrabeculectomy). The two factors that condition the management of the perforation of the Descemet's window are the depth of the AC and an iris prolapse. In the event of tiny holes with no iris prolapse or loss of AC depth, the surgeon can continue the procedure without having to convert the technique.

The perforations with the reduction or the abolition of the AC depth, but without iris prolapse must be treated to prevent the iris prolapsing or anterior synechiae forming. The surgeon

then proceeds with the introduction of viscoelastic into the AC through a paracentesis, taking care to inject it below the perforated window to distance the iris. The surgeon should inject the smallest amount of viscoelastic to avoid postoperative hypertonia. Moreover, some authors suggest affixing an implant (scleral or corneal patch) on the perforation site to close the hole.

The perforation of the scleral bed, caused by an excessive depth of the dissection plane, in theory can have serious consequences, particularly if it causes bleeding of the ciliary bodies. Nevertheless, this is an extremely rare occurrence. The superficial flap is closed with several sutures (6–8) in 10.0 nylon, when the AC has reformed and the iris repositioned (if it had prolapsed).

In the event an iris prolapse accompanies a large Descemetic perforation, the surgeon should perform a peripheral iridectomy. The superficial flap must be sealed with sutures once the viscoelastic material has been introduced into the surgically-created scleral space to increase the resistance to drainage. Considering that the scleral space created reduces the resistance to drainage of the aqueous humor, it is extremely important that the superficial flap is completely watertight.

Post-operative

In the literature and from the experience of a number of surgeons, it emerges that the postoperative pathway prior to the viscocanalostomy shows an extremely low incidence of complications (see also the complications of the deep sclerectomy). Some complications appear early, others in the late postoperative period.

Redness (hypoema) was reported by a number of authors: it was normally mild and extended for less than 4 mm) but even in the more serious cases, it will reabsorb within three days.

The surgeon may detect pressure spikes in the initial postoperative period (with the pathogenesis probably correlated to Healon GV remaining in the Schlemm canal, though this is not completely clear). Leakage may be observed, associated with the incorrect placement of the sutures on the conjunctival flap. Hypotonia and associated consequences are extremely infrequent, even considering that the application of antimetabolites has no place in this surgery.

Postoperative hypertonia is not a frequent complication and should be managed differently based on the cause. There may be several causes:

- An incomplete surgical dissection of the deep flap: in this case, the surgical incision can be reviewed. Revision of the incision site may prove to be difficult and this is one of the reasons many surgeons prefer to intervene on a completely different site.
- Intrascleral hemorrhage: this will be resolved within a few days.
- Excessive viscoelastic in the AC (particularly after combined surgery or the re-formation of the AC following a microperforation): this will be resolved spontaneously within a few days.
- Rupture of the Descemet's window with iris prolapse secondary to hypertonia caused by rubbing the eye, Valsalva's maneuver etc. It is managed with miotics and the gonio-YAG laser on the prolapsed iris. If this is ineffective, the surgeon must proceed with an iridectomy.
- Formation of anterior synechiae at the site of the Descemet's window, often secondary to intraoperative microperforations.

- Steroid-induced hypertonia (during the first post-operative week). Even the formation of the filtering bleb (5% of cases according to Stegmann) is considered to be a sort of failure, even though this is normally associated with good tonometric control.

Deep Sclerectomy

The deep sclerectomy is a type of non-penetrating glaucoma surgery. It differs from viscocanalostomy and canalostomy mainly because its goal is to obtain the filtration of the aqueous humor into the intrascleral lake and from here into the sub-Tenon's space (and not to facilitate drainage through the dilation of the Schlemm canal with viscoelastic, as happens in the viscocanalostomy) (Fig. 13). Regarding the tonometric results from the deep sclerectomy, numerous studies

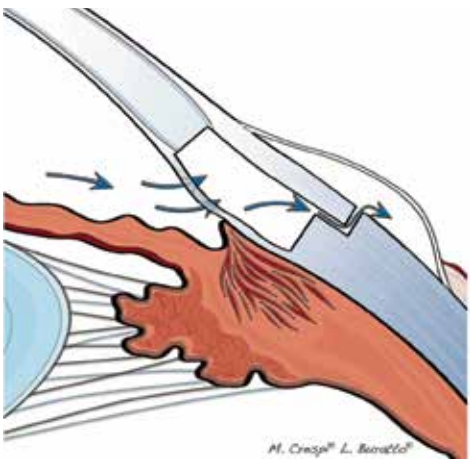

Fig. 13: Deep sclerectomy: possible filtration pathway for the aqueous humor. The procedure involves the removal of a portion of the sclera, including the part that covers the opened portion of the Schlemm canal, and a more anterior portion that lies immediately above the Descemet membrane. The endothelial wall of the canal itself is removed towards the corneo-scleral trabeculate. Therefore, there will be no fistula between the AC and the subconjunctival space. The Schlemm canal is expected to be in a slightly more scleral position with respect to the surgical limbus (Fig. 14). As with the viscocanalostomy, drainage is facilitated by the aqueous humor seeping through the thinned eye bulb wall in correspondence with the corneo-scleral trabeculate. The aqueous humor is collected in an intrascleral drainage chamber where it is transported by the uveoscleral discharge (*blue arrows*). The bleb almost appears to be almost an unintentional additional tool for reducing the IOP, transforming the procedure almost into a classical filtering surgery. As with the other glaucoma procedures, the deep sclerectomy can also be combined with phacoemulsification.

Fig. 14: Deep sclerectomy: schematic representation.

have demonstrated that the deep sclerectomy (as with the viscocanalostomy and canaloplasty), either when performed alone or in combination with phacoemulsification, can produce a satisfactory reduction in the IOP, with a greatly reduced percentage of complications compared to trabeculectomy. Many papers published in the literature—that have increased quite considerably over the last 8 years—support the efficacy of this technique, that has the same indications as the viscocanalostomy technique. Even though the efficacy of the deep sclerectomy is generally considered to be lower than the effectiveness of the trabeculectomy, additional techniques such as the intraoperative use of antimetabolites, implants and laser gonio-perforation would appear to increase the efficacy. In the past, the addition of collagen to the deep sclerectomy provided contrasting results and it is not possible to state definitely if it will really guarantee an improvement in the filtration.

Surgical Technique

As for the viscocanalostomy, the first phase of the procedure involves the appropriate exposure of the bulb and the preparation of the scleral bed: the conjunctiva and the Tenon capsule are generally cut at the limbus, creating a flap that is approximately 8 mm wide. Hemostasis of the episcleral vessels is performed by bipolar diathermy. It is important not to exaggerate with the settings used to avoid inducing an excessive scarring reaction, with possible retraction of the scleral tissue; however, it is not necessary to protect the venous collectors as in the viscocanalostomy, as they do not play an essential role in the mechanism of action of the deep sclerectomy.

The preparation of the superficial scleral flap more or less reiterates what has already been described for viscocanalostomy. The shape of the flap is usually quadrangular and measures approximately 4 × 4 mm; the surgeon can also prepare flaps that are slightly larger or slightly smaller.

The final phases of the procedure are the removal of the deep flap and suturing. The deep flap is removed using the same technique described for the viscocanalostomy. However, the suture of the superficial flap does not have to be watertight, it must allow sufficient filtering into the sub-Tenon space, similar to the trabeculectomy procedure. Two or three 10-0 nylon sutures are usually sufficient. The conjunctiva and the Tenon capsule are closed with two tobacco pouch sutures positioned at the two ends of the conjunctival flap (in 10-0 nylon or 8-0 vicryl).

The rational of the intraoperative use of antimetabolites is related to the surgical procedure goal: the drainage of the aqueous into the sub-Tenon space. This is the basic difference between the deep sclerectomy and the viscocanalostomy. The intraoperative use of the antimetabolites is justified by the presence of one or more risk factors for bleb failure. The antimetabolites 5-fluorouracil (5-FU) and mitomycin (MMC) can be used in the isolated deep sclerectomy. At the time of writing, there are no studies that precisely define the indications, the doses and the results obtained with MMC or 5-FU in the deep sclerectomy. The choice of the antimetabolite, its concentration and the time of application depend on the severity of risk factors associated. To achieve greater guarantee of water tightness, when an antimetabolite has been used it is

advisable to apply a continuous running suture along the entire length of the conjunctival flap (in 10-0 nylon or 8-0 vicryl) to include the conjunctiva and the Tenon capsule, in addition to two sutures positioned on the ends of the conjunctival flap.

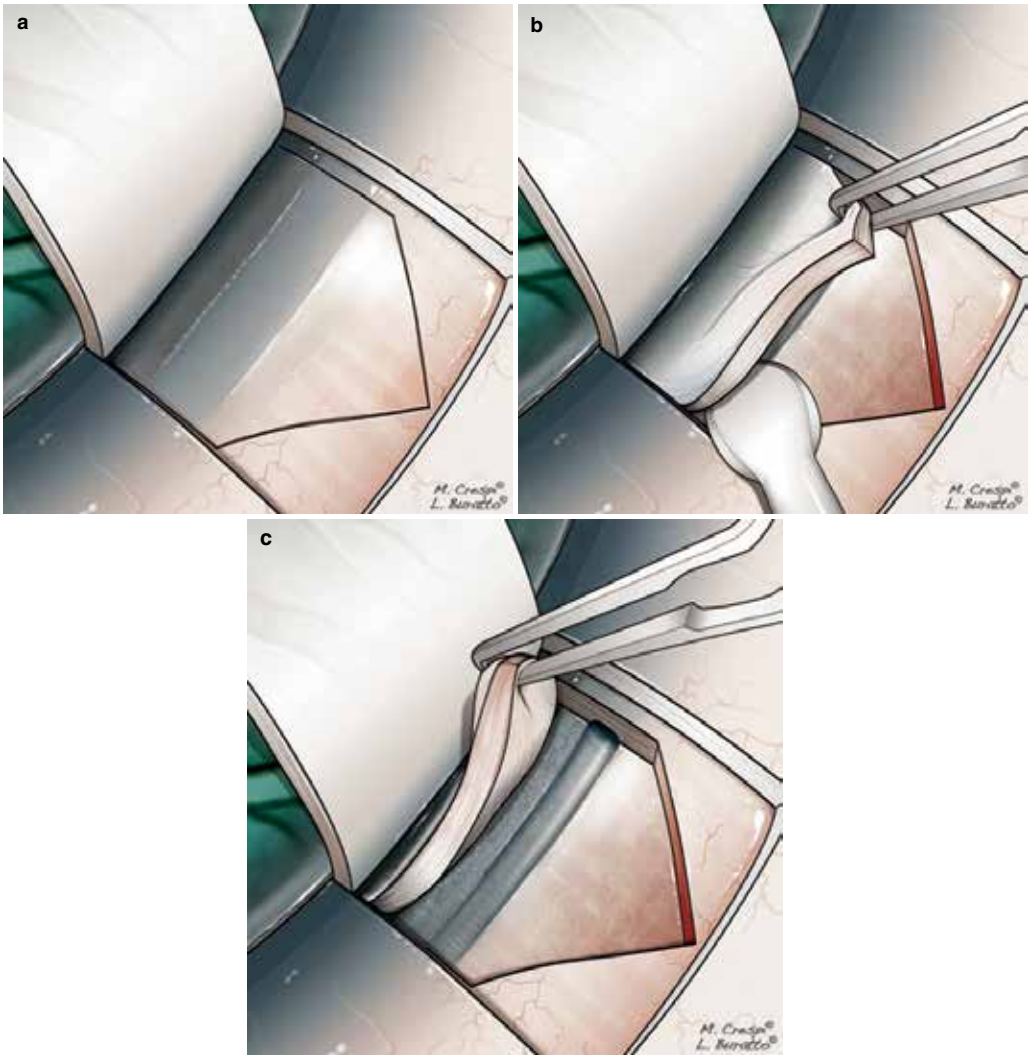

Fig. 15: Creation of the deep flap. The method used to create the deep flap is similar to that used to create the flap for the viscocanalostomy. The figure illustrates the pentagon-shaped deep flap before (**a**), during (**b**) and after (**c**) the dissection and the opening of the Schlemm canal. If the objective is to achieve greater filtration, a deep flap can be created with the side margins corresponding to those of the superficial flap. When the Schlemm canal has been identified and the posterior wall, that remains adhered to the inferior surface of the deep flap, has been removed, the Descemet's window can also be created in the deep sclerectomy. The process to create the Descemet's window is the same as the procedure described for the viscocanalostomy.

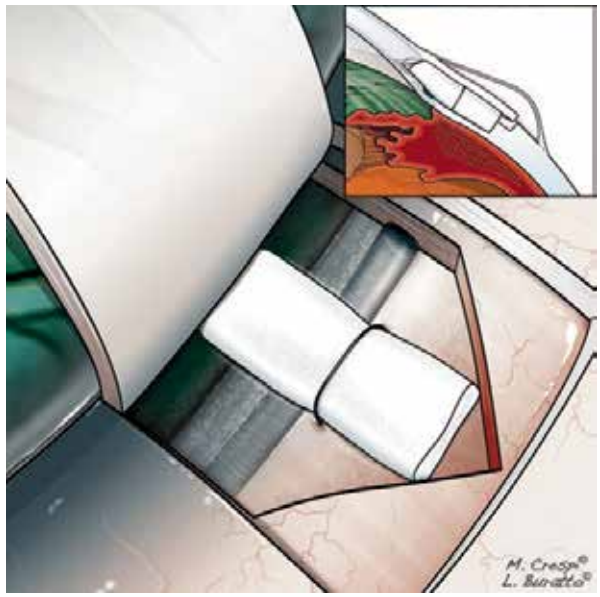

Fig. 16: Positioning of the inserts in the scleral lake. To ensure better filtration in the medium- and long-term postoperative period, the surgeon can position two inserts in the scleral lake following removal of the deep flap; this will facilitate maintenance of the intrascleral space and prevent occlusion by scar processes. An insert in collagen (AquaFlow, Staar Surgical AG, Ch-2560 Nidau, Switzerland) consists of a cylinder of lyophilized pig collagen (see the figure). This substance has a considerable degree of hydration and excellent biocompatibility. The cylinder is positioned radially at the bottom of the scleral lake, and is sutured with 10-0 nylon; the anterior tip of the cylinder should lie above the Descemet's window. The insert will be slowly re-absorbed over a period of about 6 months. The insert in reticulate hyaluronic acid (SK-Gel, Corneal, Paris, France) is a solid gel. The mechanism of action is correlated with maintenance of the space of the intrascleral lake. The insert is positioned on the bottom of the lake prior to suturing the superficial flap. According to the manufacturer, the insert will be reabsorbed within 3–6 months with decomposition delayed by the reticular agent. However, the insert in reticulate hyaluronic acid is not widely used.

The Combined Phaco-deep Sclerectomy Procedure

As for the viscocanalostomy, it is possible to perform the procedure in a superior position in correspondence to the sclerectomy, or in a temporal position; no significant differences in the tonometric results between the two techniques have been reported, even though some of the authors recommend a temporal incision.

Results

Numerous studies have demonstrated that the deep sclerectomy (and viscocanalostomy and canaloplasty), either when performed alone or in combination with the phacoemulsification, can result in a satisfactory reduction in the IOP, with a low complications rate compared to the trabeculectomy. Many of the papers published in the literature, that are increasing in number over the past 8 years, support the efficacy of this technique. Careful analysis of the literature, as mentioned previously, has shown that the non-penetrating surgical procedures (viscocanalostomy, deep sclerectomy, canaloplasty) are associated with a good control of the IOP in the early postoperative period but there is also a high percentage of late failures. Even though the efficacy of the deep sclerectomy is generally considered to be lower than the efficacy of the trabeculectomy,

additional techniques such as the intraoperative use of antimetabolites, implants and laser gonio perforation (see later) would appear to increase the efficacy. In the past, the addition of collagen to the deep sclerectomy provided contrasting results and it is not possible to state with certainty if it will guarantee an improvement in the filtration? In recent years, some meta-analyses have been published on the efficacy of non-penetrating surgery (isolated deep sclerectomy, with an insert of collagen, with an insert of hyaluronic acid, with antimetabolites, isolated viscocanalostomy) in the open-angle glaucoma: they report the success of these techniques, but with pressure results that have a lower validity when the target pressure is lower. As mentioned earlier, regarding the comparison between trabeculectomy and non-penetrating glaucoma surgery (with or without phacoemulsification), recent literature has reported contrasting results. However, while some authors have underlined how the use of non-penetrating techniques have produced comparable results in terms of IOP reduction, others highlighted greater efficacy of the trabeculectomy in comparison to the nonpenetrating techniques (see the results for viscocanalostomy): recent literature underlines the better safety profile of the nonpenetrating techniques, but does not state that these techniques produce better tonometric reduction than trabeculectomy. Consequently, thanks to greater safety and further improvements in the surgical technique, these nonpenetrating procedures, with or without phacoemulsification, are with no doubt a valid surgical option, particularly in cases in which the target pressure is not very low.

Complications

Intraoperative

The intraoperative complications can be comparable to those observed in viscocanalostomy and depend largely on the incorrect dissection of the deep flap.

Postoperative

As mentioned previously, the incidence of precocious postoperative complications following deep sclerectomy is greatly reduced compared to perforating glaucoma surgery. In the first post-operative month, the deep sclerectomy (and the same happens in the other NPGSs) causes less inflammation compared to the trabeculectomy because the AC is not opened and an iridectomy is not performed. On the other hand, even on the first postoperative, the eye frequently appears healthy and cases of hypotonia and/or reduction in the AC depth are extremely rare. This would suggest that visual rehabilitation is much more rapid.

The most frequent postoperative complication is hypoema; it will usually resolve spontaneously within a few days. In some extremely rare cases, the deep sclerectomy may be complicated by a ciliary block malignant glaucoma. Even in the combined procedure, a reduction in the precocious postoperative complications is observed: in particular, hypoema and an inflammatory reaction.

Another postoperative complication is the late failure of the procedure, with a IOP rise. The obstruction to the filtration can be internal or external.

YAG Laser Goniopuncture

Residual ocular hypertension may be observed at a variable time following the deep sclerectomy procedure. One of the possible causes is an obstruction to the drainage of the aqueous through the Descemet's window, in turn dependent on an intraoperative error (an excessively superficial dissection with insufficient percolation) or fibrosis of the window itself. In these cases, the filtration can be increased by perforating the Descemet's window from the inside using the YAG laser. YAG laser goniopuncture may be necessary in 40–50% of patients. The tonometric success following goniopuncture is above 80%. This procedure can be performed during the first postoperative period or 1 or 2 years later; as there are no studies that definitely demonstrate the efficacy, it is advisable to wait for at least 2 weeks postoperative to reduce the risks of ocular hypotony.

Canaloplasty

Conceptually, it is a variation of the viscocanalostomy technique with the addition of:

1. Dilatation of the canal using a catheter;
2. Placement of a permanent suture in the stretched Schlemm canal. The mechanism of action is different to penetrating surgery, because an alternative pathway for the drainage of the aqueous humor has not been created; however, the efficiency of the natural pathway (trabeculate) has been improved without interfering with the spaces that are normally not used for these purposes (subconjunctival space, a critical point for the failure of filtering surgery).

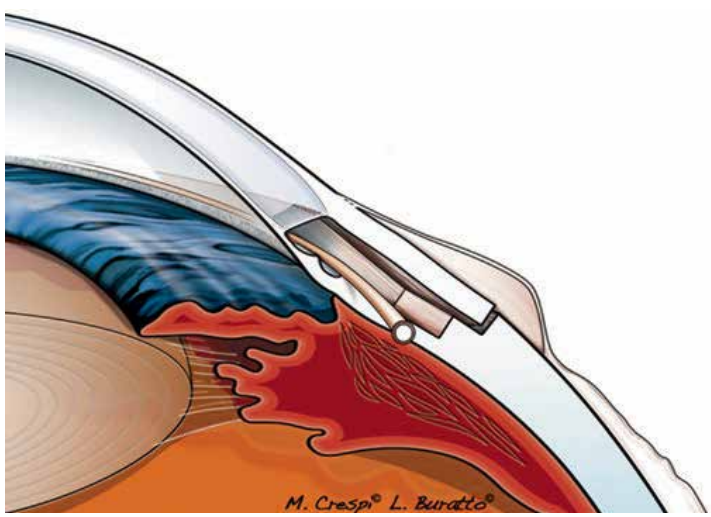

Fig. 17: Canaloplasty: schematic representation. Canaloplasty is a procedure developed to improve the drainage of aqueous humor and involves the insertion of a microcatheter inside the dilated Schlemm canal. The microcatheter will carry a single or double prolene thread inside the canal where it will be tensioned, in an attempt to stretch the juxtacanalicular portion of the trabeculate and improve the circumferential drainage capacity.

Recently, this technique would appear to be the elective non-penetrating procedure among glaucoma surgeons; canaloplasty is a technique that is indicated in open-angle glaucoma with a moderate-high pressure target. However as with other non-penetrating procedures, its use is contraindicated in certain forms of glaucoma – such as neovascular and obviously closed-angle glaucoma, in glaucoma secondary to trauma with recession of the angle, and in eyes in which the trabeculate received argon laser treatments or the trabeculectomy procedure. In theory the enormous advantage of the canaloplasty is the circumferential treatment of the Schlemm canal, without precluding the possibility of the intraoperative conversion to a trabeculectomy, if required (due to the probe being obstructed in the Schlemm canal, accidental perforation of the Schlemm canal, perforation of the endothelial window, etc.). The possible disadvantages are the difficulties with the external dissection (a step that is more complex and prolonged than other procedures on the camerular angle) and the conjunctival scarring that may increase the risk of failure of the successive trabeculectomy. This procedure does not create direct access to the collector channels and the tonometric reduction is limited to the resistance of the Schlemm canal and the episcleral vein pressure. Moreover, the long-term effects of the foreign body (prolene thread) in the Schlemm canal are not known. As with the other NPGS, this procedure can also be performed in combination with phacoemulsification, and results to date have been positive. Regarding the tonometric results, the available literature on canaloplasty still does not offer comprehensive information even though the technique would appear to be the most promising of those introduced recently.

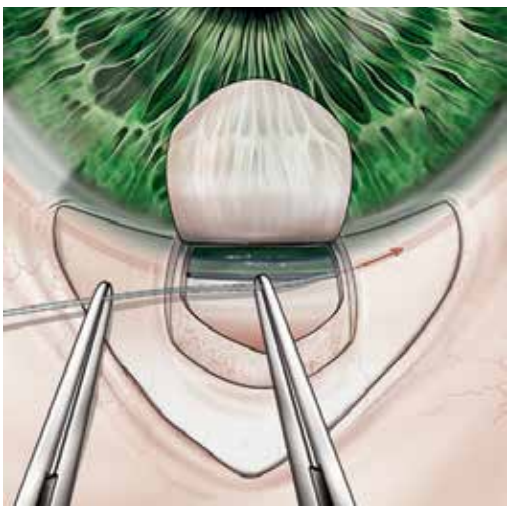

Fig. 18: Insertion of the microcatheter into the Schlemm canal.

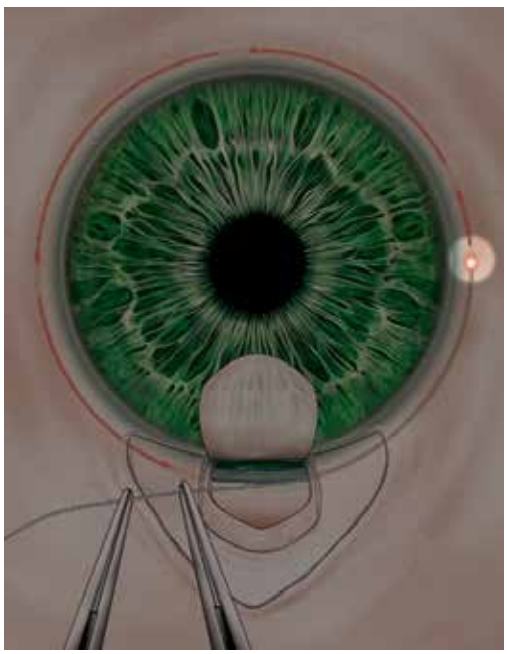

Fig. 19: Visualization of the fiber optic inside the Schlemm canal.

Surgical Technique

The first steps are the same as those for the viscocanalostomy: dissection of the conjunctiva with the base at the fornix, creation of a parabola-shaped superficial flap and the deep flap, paracentesis, removal of the deep flap to create the scleral lake.

These are followed by the dilatation of the Schlemm canal ostias with a dedicated cannula; these are found slightly posterior to the limbus,; the surgeon then introduces VES (Healon GV) into the ostias of the canal to facilitate the passage of the microcatheter.

The next phase of the procedure involves the insertion of a flexible microcatheter (in a direction indicated by the red arrow) into the Schlemm canal. The first microcatheter was produced by iScience Interventional, Menlo Park, CA. The surgeon can facilitate this maneuver catching the catheter with one or preferably two toothless forceps (tying or Duran forceps). The tip of the catheter has a diameter of 250 μm and an internal lumen of 200 μm. Through this the surgeon can inject the VES. The diameter of the Schlemm canal varies between 190 and 370 μm. Other commercially available microcatheters are: Glaucolight (DORC, The Netherlands) and Onalene (Onatec, Germany).

This device includes an optic fiber with an illuminated tip: considering the absence of direct vision, the tip illumination assists the correct insertion of the microcatheter. If the microscope light emission is reduced, it will be easy for the surgeon to follow the route of the optic fiber

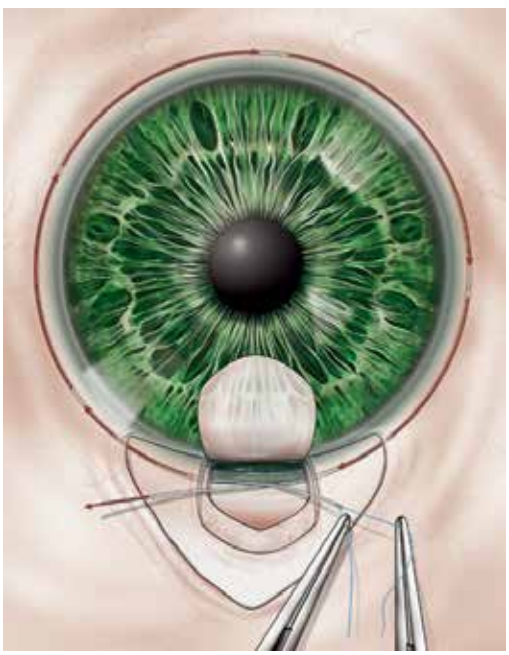

Fig. 20: Anchoring of the prolene 10.0 suture thread on one end of the microcatheter. Removal of the microcatheter.

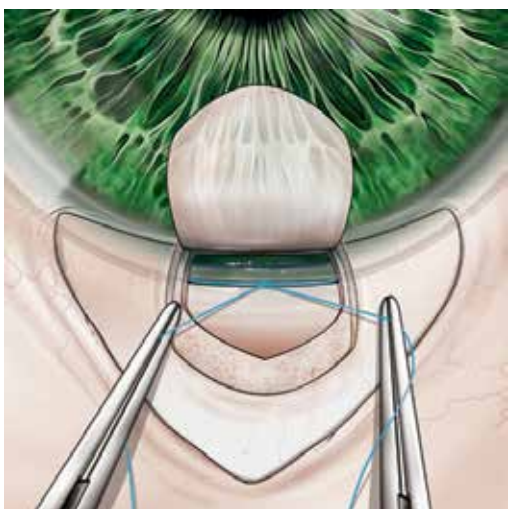

Fig. 21: Prolene suture.

(indicated by the red arrow) for 360° inside the Schlemm canal (transscleral illumination). During this maneuver, the surgeon must avoid going offline—into the AC on the one side and the suprachoroidal space through the large collector channels on the other. If the catheter is obstructed along its path, it can be withdrawn and another attempt to insert it into the canal can be made through the opposite ostia: this will normally be successful.

When the microcatheter is visible outside the distal ostium of the canal, the surgeon will anchor the 9.0 or 10.0 prolene thread to the terminal of the device, a 2.1.1 knot is recommended: it is important to create a small flat knot for each of the three passes. On the return route (red arrows), the surgeon must avoid damaging the Schlemm canal with the knot; he may wish to introduce a tiny quantity of VES through the microcatheter for the entire return phase (0.5 μL for every 2 h for the 360° −12 h of the Schlemm canal, corresponding to 1/8th turn of the Healon GV injector) as it will widen the canal, the viscoelastic will reduce the risk of damaging the canal.

Once the microcatheter has been withdrawn, the prolene 10.0 thread is released (usually a single thread, though a double thread may be used); the surgeon separates the two thread ends and positions the suture. The knot may have a 4.1.1 format that involves four passes; both suture ends are then raised and the knot is tightened. The knot is recessed close to either the right or the left ostia under appropriate tension. The surgeon then slowly performs the second and third passes.

Another elegant and extremely valid means for creating the knot is Siepser's 1.1.1 slipknot; in this case, the first maneuver is simple a pass, the second adjusts the final tension and the third closes the knot. In both cases, the tension given to the thread will be proportional to how much the Schlemm canal, and consequently the trabeculate, have been stretched. As the IOP in this eye will be very low, it is very easy to exceed with the thread tension; in extreme cases this may inadvertently create an undesired trabeculotomy. Correct suture tension is essential as this will determine the circumferential tension in the Schlemm canal and the trabeculate, responsible for restoration of natural drainage of the aqueous humor. Adjusting the tension of the prolene thread may reduce visual acuity (more than 12% patients initially lose 2 or more Snellen lines), linked to astigmatism induced by the closure of the suture; however, some authors believe that it is more linkly due to the sutures positioned on the superficial scleral flap. Astigmatism generally appears between 1 and 10 days postoperative and is generally resolved within 6–10 weeks. Once the tension in the prolene suture has been appropriately adjusted, the surgeon quickly closes the superficial flap and checks that there is no filtration (similar to viscocanalostomy). Finally, the conjunctiva is sutured with the standard method.

Results

The currently-available literature on canaloplasty does not yet provide us definitive informations because there are no long-term results available. Positive results for the combined canaloplasty/phacoemulsification procedure were reported by Shingleton in 2008.

Recent long-term studies have reported that canaloplasty on its own can significantly reduce the IOP in open-angle glaucoma, with a small percentage of serious postoperative complications

in the short- and long-term. However, these studies also demonstrate that this procedure can sometimes lead to a modest reduction in the IOP and consequently should be indicated only for those patients with mild perimetric alterations and a higher target pressure.

The use of MMC has proved to be safe and efficacious in the canaloplasty procedure proposed by some authors.

In a study by Grieshaber, the use of 10.0 prolene thread has proved to be slightly more efficacious in reducing the IOP compared to the use of 6.-0 prolene.

Complications

This surgical procedure requires the surgeon to have good manual skills. A brief description of the intra- and post-operative complications associated with the technique follows:

Intraoperative Complications

These may appear:

1. Due to lack of exposure of the canal
2. During the creation of the Descemet's window: (a) microperforation (b) macroperforation with or without iris prolapse
3. During insertion of the catheter and dilation of the canal:
   (a) Detachment of the Descemet's membrane;
   (b) Suprachoroidal pass

Post-operative Complications

1. Precocious (1–10 days post-surgery):
   (a) Increase in the IOP (the surgeon should exclude entrapment of the iris, angle closure, the formation of peripheral iris synechiae, the presence of residual viscoelastic in a combined procedure, hypoema, response to steroids)
   (b) Reduction of the visual acuity (more than 12% patients initially lose 2 or more Snellen lines) linked to the astigmatism induced by the closure of the sutures and resolves within 6–10 weeks
   (c) Hypoema: this is a very frequent complication and can be classed as physiological because it is caused by the reverse flow in the Schlemm canal (observed more frequently in patients previously subjected to ALT or SLT laser treatments)
   (d) Detachment of the Descemet membrane: this occurs when an excessive quantity of Healon GV has been injected
   (e) Hypotonia—this complication is almost always resolved spontaneously and rapidly.
2. Late onset (2–5 weeks):
   (a) Increase in the IOP due to insufficient trabecular filtration or micro/macro perforations that lead to iris prolapse.

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Angle Surgery: Goniotomy

David S. Walton, Elizabeth Hodapp

History

Otto Barkan performed the first goniotomy in 1935 on a 55-year-old man, and he reported a series of 11 adults in 1936 [1]. His procedure added direct visualization via a gonio lens to a technique described in 1893 by De Vincentiis. He reasoned that typical open-angle glaucoma was caused by an "impervious trabeculum" and that his procedure could restore "the physiologic function of Schlemm's (*sic*) canal" [1]. Long-term results in adults proved disappointing, but Barkan also applied the procedure with great success to congenital glaucoma, which was at the time virtually untreatable. He described the procedure as "intraocular microsurgery" that required detailed preoperative gonioscopy. Motivated by the importance of precise localization of the goniotomy incision in the trabecular meshwork, Barkan designed operating goniotomy lenses, a designated goniotomy knife, and a head-mounted binocular device that was arguably the first ophthalmic operating microscope [2].

Barkan published his first paper on goniotomy for congenital glaucoma in 1942 [3], and he discussed his surgical refinements and cumulative pediatric goniotomy results in San Francisco in November 1951, when he presented the Jackson Memorial Lecture at the 37th annual clinical congress of the American College of Surgeons [4]. Although the procedure remains much as described by Barkan, techniques and indications have evolved over the decades, and additional drainage angle procedures – collectively known as minimally invasive glaucoma surgery (MIGS) – have been developed. Goniotomy is now used in both primary and selected secondary glaucomas in children [5–7].

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Indications and Contraindications

Primary congenital glaucoma (PCG) is the most common indication for goniotomy. When chosen, it is generally performed as the initial procedure. Additional favorable diagnoses are listed in Table 1. Prophylactic goniotomy is sometimes performed in nonglaucomatous aniridic eyes with early angle closure to prevent further closure and secondary glaucoma [8].

A satisfactory view of the angle–which the surgeon can determine by doing intraoperative gonioscopy-is necessary to safely perform goniotomy. If corneal epithelial edema is present, the epithelium may be removed (described below). If the corneal stroma is not clear, another procedure, often a trabeculotomy *ab externo*, either partial (with a Harms trabeculotome) or 360° (with a suture or illuminated microcatheter), is generally a better choice.

Table 1: Some favorable diagnoses for goniotomy.

Primary congenital glaucoma (PCG)
Infantile and late onset better than neonatal onset
Previously controlled PCG
Glaucoma associated with non-acquired ocular anomalies
Aniridia with open-angle or limited angle closure[a]
Congenital iris hypoplasia (if open angle)
Congenital ectropion uveae (if open angle)
Glaucoma associated with non-acquired systemic disease or syndrome
Sturge-Weber syndrome (infantile onset)
Klippel-Trenaunay-Weber syndrome
Glaucoma associated with acquired condition
Uveitic glaucoma (if open angle)
Steroid-induced glaucoma
Glaucoma following cataract surgery
Infantile onset (if open angle)

[a]Surgery is extremely technically challenging and is viewed more as prophylaxis against glaucoma from angle closure rather than therapeutic as treatment once glaucoma has developed

Advantages and Disadvantages

Goniotomy is faster and less traumatic compared to trabeculotomy. Circumferential treatment (360°) is not possible with a single goniotomy, and there is a lower success with goniotomy compared to circumferential trabeculotomy [9]. However, the success rate for one goniotomy is high, and the shorter operating time limits the patient's anesthetic exposure. Unlike *ab externo* trabeculotomy, the surgical limbus including conjunctiva remains intact with goniotomy. And unlike *ab interno* trabeculotomy, there is minimal intraocular manipulation.

Disadvantages of goniotomy include the fact it is technically demanding and requires considerable surgical experience to master. Furthermore, special instrumentation along with specific patient and microscope positioning are necessary. All angle surgery, goniotomy or *ab interno* trabeculotomy, requires a clear view of the angle. So while there are specific advantages to goniotomy and *ab interno* angle surgery, it does affect patient selection. If epithelial debridement is required, the child may experience significant postoperative discomfort.

Preoperative Considerations and Preparation

In most hospitals and surgical centers, goniotomy is performed less frequently than other glaucoma procedures. It is essential that the operating room staff is informed of the necessary supplies, instruments (Table 2), and equipment in a timely fashion and that everything needed is in the operating room to allow an uninterrupted presurgical examination and successful goniotomy procedure. Preparation for an external trabeculotomy, described later in this chapter, is always advisable when planning for a goniotomy in case of an unsatisfactory view of the angle.

Table 2: Surgical instruments and supplies for goniotomy surgery.

Instruments
Operating microscope
Speculum (nasal or temporal depending on approach)
Operating gonioscopy lenses
Goniotomy knife or 23- or 25-g needle on a syringe
Fine tying forceps
Fine scissors
Needle holder appropriate for small needle
Optional instruments
Locking fixation forceps
Supplies
Balanced salt solution
Pilocarpine HCl 1%
Viscoelastic agent, Healon, or similar
10-0 absorbable suture (Vicryl, Ethicon, Somerville NJ, U.S.A.)
Antibiotic ointment
Eye pad
Eye shield-sized appropriately for patient
Optional supplies
30G irrigation cannula
#15 Bard-Parker® blade
70% isopropyl alcohol
Apraclonidine 0.5%

Depending on the specific clinical situation, glaucoma medications may be continued or discontinued. For example, if a patient's cloudy cornea cleared promptly with ocular hypotensive treatment, then the medication should not be stopped preoperatively so as to allow for a clear view of the surgical site. However, if the untreated intraocular pressure (IOP) level is crucial to surgical decision-making, then topical glaucoma medications are stopped 1 or 2 days before surgery. If acetazolamide is being taken, it is discontinued 12 h prior to surgery. Topical bacitracin/polymyxin ointment or other antibiotic may be administered to both eyes preoperatively at the discretion of the surgeon.

Operation

Intraoperative Preparation

Goniotomy, like all other surgical procedures, should be performed only by adequately trained individuals. The techniques of MIGS procedures, such as intraoperative gonioscopy and transcameral device placement, do translate to goniotomy. However, the nuances of goniotomy surgery, such as the ideal patient head and eye position, operating lens management, instrument selections, intraocular knife/needle management, and postoperative care, are best learned by direct observation and surgical assisting [10].

Prior to the operative procedure, an examination under anesthesia (EUA) of both eyes is performed. This operating room assessment includes tonometry, corneal diameter measurement, axial length determination if equipment is available, gonioscopy, handheld slit lamp examination, and fundoscopy (usually recommended only through an undilated pupil of a phakic eye, to avoid additional exposure of the crystalline lens during subsequent goniotomy surgery). With gonioscopy, the quality of the angle view is appraised, and the trabecular meshwork is studied to determine the site of the planned surgery.

The appropriate microscope position can be determined during the EUA, as can the best head position for the patient. In general, the light source should be about 40° from vertical, and the patient's head should be turned about 30° away from the surgeon [11, 12]. The surgeon sits facing the angle to be treated, and the assistant is seated opposite.

Apraclonidine HCl 0.5% may be administered as a drop during the EUA or on a microsurgical sponge to the limbus where the goniotomy will be performed to lessen reflux of blood during the expected period of hypotony that follows the withdrawal of the goniotomy knife or needle. Unlike brimonidine, apraclonidine rarely causes side effects in children [13]. Pilocarpine 1% or 2% is often instilled to constrict the pupil and decrease the risk of lens trauma. It should be instilled as soon as the decision to operate is made. If the pupil remains large at the time of surgery, intracameral acetylcholine may be administered immediately before the goniotomy.

Surgical Technique

If the view of the angle is limited by corneal epithelial edema and the surgeon has determined that goniotomy is still the best surgical choice, a segment of epithelium should be removed to create a

clear window. This can be done by applying absolute alcohol or 70% isopropyl alcohol on a sponge to about one-fourth of the cornea 180° away from the angle to be treated. As the initial surgery is usually done in the nasal angle, the temporal cornea is usually treated. Epithelial debridement should not be done in aniridic patients, and in all patients, one should scrupulously avoid the limbal stem cells when using alcohol. After about 10 s, residual alcohol should be thoroughly blotted. The epithelium is then debrided with a #15 Bard-Parker® blade (Aspen Surgical/Hill-Rom, Ashby-de-la-Zouch, Leicestershire, UK), taking care to avoid trauma to Bowman membrane [11, 12]. If removal of the epithelium is not desired or unlikely to improve the angle view, then convert to *ab externo* trabeculotomy, either segmental, using the Harms trabeculotome, or circumferential, using a suture or iScience fiber-optic filament (iScience Interventional, Menlo Park CA, USA).

The following description refers to goniotomy performed with a Barkan goniotomy lens and a standard Swan or Barkan non-irrigating goniotomy knife. Variations based on the choice of instrument and goniotomy lens are briefly described in the next section. In particular, many surgeons use a disposable needle (23 or 25 gauge) mounted on a syringe instead of a goniotomy knife. After preparation of the sterile surgical field and, if necessary, repositioning of the patient, the lashes are secured with tape or a surgical drape to prevent contact with the knife and to facilitate unimpeded suturing of the cornea. An appropriate lid speculum that will not interfere with the surgery is inserted.

Some surgeons will place locking forceps posteriorly on the vertical muscle insertions to allow the assistant to manipulate the eye without inducing corneal distortion and to facilitate entry of the goniotomy instrument through the cornea adjacent to the limbus. The selected magnification, device, and illumination source are adjusted to provide an optimal view of the angle. The operating gonio lens should leave about 2 mm of the exposed cornea to permit the comfortable entry of the knife (goniotomy knife or microvitreoretinal [MRV] blade) or needle (23 or 25 gauge) away from the gonio lens and to avoid elevating the gonio lens during the procedure. The surgeon's preferred surgical goniotomy lens is placed onto the cornea with either a balanced salt solution or viscoelastic under the lens acting as a fluid bridge. Some surgeons prefer to place a mound of viscoelastic either on the undersurface of the lens or onto the central cornea on which the gonio lens will sit. The goniotomy lens is usually held in place with the surgeon's nondominant hand.

The corneal incision is made with the knife or needle about 1 mm beyond the limbus and 180° from the center of the expected goniotomy incision. The assistant may need to use the forceps to gently move the eye toward the surgeon as counterpressure to facilitate entry. Once the knife is in the eye, the surgeon redirects his or her view from the limbus to the view through the operating gonio lens of the knife, which is passed across the anterior chamber (AC) under direct visualization, ideally over the iris rather than the central pupil opening.

The tip of the knife engages the middle to anterior trabecular meshwork, and the knife is passed in one direction as far as the corneal wound and view permit (Figs. 1 and 2). Then the knife returns to the middle and is passed in the other direction. Alternatively, the surgeon may engage the meshwork at one end of the site and make a single continuous incision. In either of these cases, the assistant may rotate the eye in the direction opposite to the direction of the surgeon's incision to allow more of the angle to be treated. The incision is superficial, and the surgeon should feel

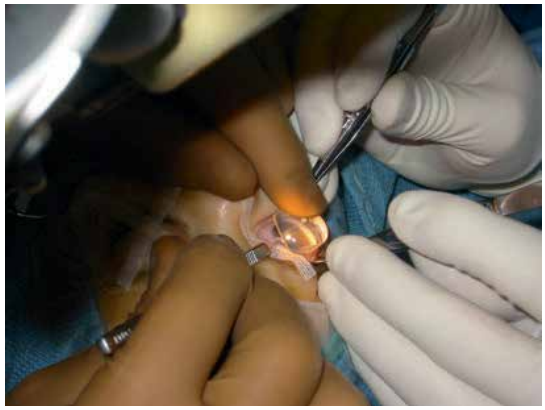

Fig. 1: Goniotomy in progress. The assistant stabilizes the globe using locking forceps on the vertical recti muscles, and the surgeon positions the gonio lens and performs the incision. The goniotomy is being performed at the temporal angle, so the surgeon works across the patient's nose. The surgeon in this photo is wearing surgical loupes, but most surgeons prefer to use the operating microscope which allows the assistant to view the angle and allows increased magnification if desired.

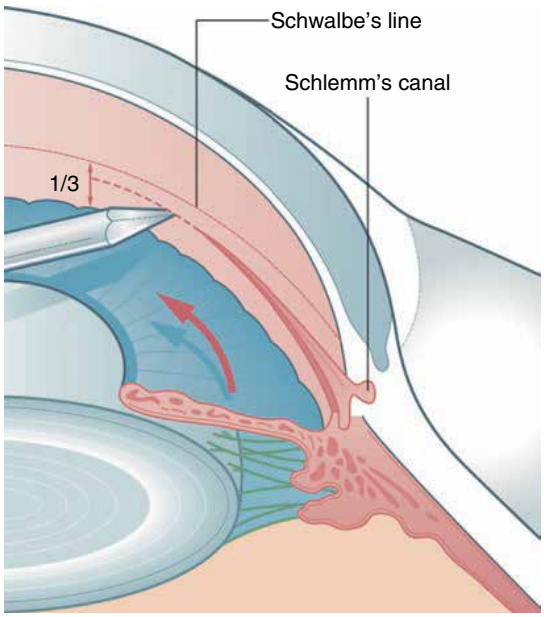

Fig. 2: Diagram of knife/needle engaging the anterior trabecular meshwork during goniotomy surgery. (From Chen and Walton [12], with permission).

Fig. 3: The goniotomy cleft is easily visible as a bright white line on the left, just above the iris insertion.

virtually no resistance. A distinct white line can usually be seen in the wake of the cutting instrument as it progresses circumferentially (Fig. 3). The knife is then withdrawn on a path over the iris, not over the pupil. The AC is deepened, and the corneal stroma around the incision is hydrated with balanced saline to maintain the IOP and discourage reflux bleeding into the AC. Typically no additional AC irrigation is done. Some surgeons use a filtered air bubble in the AC as well, to facilitate determination of the chamber integrity the following morning. If the corneal wound is not self-sealing, it is secured with a buried 10-0 vicryl suture, which is often necessary (children may rub the eye). A 10-0 nylon suture can also be used and removed at a subsequent EUA. The operated eye is protected with a patch and shield. Topical prednisolone acetate 1%, apraclonidine HCl 0.5%, and an antibiotic subconjunctival injection and/or ointment may be administered.

If bilateral surgery is being performed, the surgical instruments should be entirely replaced or re-sterilized, the operative team should rescrub, and the second eye should be prepped and draped in the usual sterile fashion.

Videos demonstrating the various techniques for goniotomy, type of lens, with or without assistant, and with or without viscoelastic, are included (Videos 1, 2, and 3).

Potential Modifications

Multiple variations to the procedure described above exist and include the following:

- Locking forceps may be placed at the tenon insertion superiorly and inferiorly rather than at the muscle insertions.
- The globe may be stabilized using traction sutures rather than locking forceps or not stabilized at all.
- An irrigating goniotomy knife attached to balanced salt solution may be used.
- A 23- or 25-gauge needle may be used instead of a goniotomy knife, and it may be attached to a syringe filled with either balanced salt solution or viscoelastic (Video 2).
- A 23-gauge MVR blade can be used instead of a goniotomy knife.
- Viscoelastic may be injected into the AC prior to passing the surgical instrument into the angle. If used, it must be thoroughly irrigated out at the end of the case.
- A Swan-Jacob goniolens or modified Swan Jacob goniolens (Ocular Instruments, Bellevue WA, U.S.A.), which is held by a handle, may be used and is generally placed onto the eye after the surgical instrument has passed across the pupil and the lens.
- A Glaukos lens with a clip (such as used in the placement of iStents) (Precision Lens, Bloomington MN, U.S.A.) can also be used, which allows lens movement.
- Atropine may be instilled at the end of the case to pull the lens posteriorly.
- Alternatively, pilocarpine may be instilled at the end of the case to pull the iris away from the incision and continued for a short time postoperatively.

Postoperative Management

Parents are advised to keep the infant/child's head elevated while sleeping to discourage additional blood reflux. Apraclonidine HCl 0.5% may be given twice daily for a few days when continued

postoperative reflux of blood is observed. If a corneal suture is present, topical antibiotics are administered daily for at least a week; ointment is often more soothing than drops. Topical steroid use varies among surgeons and often depends on the presence or absence of a hyphema. In a very quiet eye, topical corticosteroids may be used for as little as a week. Often they are used on a decreasing schedule for several weeks. Some surgeons treat the eye with pilocarpine, some with atropine, and some with neither.

Postoperatively, corneal clarity and intraocular pressures are assessed to ascertain the success of the procedure, which can take up to 4–6 weeks.

Complications

Hyphema is the most common complication of goniotomy. If bleeding occurs during the procedure, it may limit the amount of angle treated. Most postoperative hyphemas resolve spontaneously, although rarely a total hyphema complicated by increased IOP requires an AC washout or other procedure.

Injury to the iris and lens may occur, particularly if the AC shallows. This occurs very rarely if the surgeon has extensive experience and is unlikely to occur if an irrigating knife or a needle is used. AC shallowing can generally be avoided by use of intracameral viscoelastic.

An iridodialysis or cyclodialysis may be created if the incision is made too posteriorly. If the incision is made too deep, the surgical instrument may perforate the limbus. These complications are extremely unlikely if the surgeon is familiar with the anterior segment and angle structures, has a satisfactory view, and practices meticulous surgical technique.

Outcomes

The success rate of goniotomy depends on the severity of the angle abnormality or congenital anomaly. If PCG is present at birth, goniotomy success has been reported to be as low as 10% [14], although other reports are much less bleak. A review of 335 eyes of 210 patients with PCG who were treated with goniotomy in infancy found that 1 year after surgery, 71% of eyes were controlled with one procedure and 93.5% were controlled with one or more procedures. Following review of up to 30 years, 62 eyes relapsed (defined as progressive disease, the institution of medical therapy, or further surgery), but at 5 years, 93% were controlled without additional surgery. Eyes in which glaucoma was present at birth did worse than those whose symptoms appeared in the first 3 months of life (36% relapse compared to 15%) [15].

Good results have been reported following goniotomy in childhood uveitis. The specific definition of success varies among studies, but IOP control with one or more goniotomies and without other glaucoma surgery is about 70% [5, 6]. A small series (five patients) noted 100% success in patients with steroid-induced glaucoma [7]. Reported results vary in patients with Sturge-Weber syndrome. In a group of patients who received one or two goniotomies and were first operated at an average age of 4 months, the pressure was <22 without medication in 6 of 12 patients with follow-up of 2–12 years [16]. However, a review of 43 patients with glaucoma related to the Sturge-Weber syndrome found long-term failure in 98% (Walton DS, Yeung HH, unpublished data).

Options After Failed Surgery

If a single goniotomy does not control the patient's glaucoma, the procedure may be repeated in a different area of the drainage angle. (Fig. 1 shows a procedure on the temporal angle.) Goniotomy may interfere with circumferential trabeculotomy, but it does not preclude treatment of the untreated angle by either an *ab externo* or *ab interno* procedure.

If angle surgery is not successful, medical treatment is generally resumed. If necessary, a glaucoma drainage device may be placed or a trabeculectomy may be performed. Because the conjunctiva and sclera are not incised, goniotomy is unlikely to affect the success rates of these procedures, although good data are lacking.

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Intermediate Results of Phaco-endocycloplasty in an Exclusive Cohort of Angle Closure Glaucoma: Potential for Change

Vanita Pathak-Ray

Abstract

The objective of this study was to investigate the efficacy and safety of phaco-endocycloplasty in an exclusive cohort of primary angle closure disease/glaucoma. The study was interventional and noncomparative, carried out at a tertiary level eye care institute. All adult patients (> 18 years) with angle closure disease, who had controlled or uncontrolled intraocular pressure (IOP) and had visually significant cataract, requiring surgery, and had undergone phaco-endocycloplasty, performed for 180°–210° simultaneously with cataract surgery, were included. Primary outcome measure includes IOP, and secondary outcome measures include best corrected logMAR visual acuity (BCVA), anti-glaucoma medication (AGM) and complications. Thirty-two eyes of 28 patients were included. Median follow-up was 15 months (range 3–42 months, Q1 7.5, Q3 18, IQR 10.5). Median IOP pre-procedure (20.5 mmHg, range 11–46, Q1 16.75, Q3 31, IQR 14.25) decreased significantly postprocedure at last follow-up (IOP 16 mmHg, range 10–20, Q1 12, Q3 17.5, IQR 5.5) ($p < 0.001$). There was significant decrease in use of AGM (median 3 pre-procedure, range 1–5, Q1 2, Q3 3.25, IQR 1.25) at last follow-up (median 0) ($p < 0.001$) post-procedure. Median logMAR BCVA improved from 0.4 (Q1 0.3, Q3 0.625, IQR 0.325) to 0.05 (Q1 0, Q3 0.3, IQR 0.3) at last follow-up ($p < 0.001$). None of the patients had serious sight-threatening

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complications. This study indicates that phaco-endocycloplasty can effectively control IOP, significantly reducing need for AGM, without compromising safety, in angle closure glaucoma. When combined surgery is indicated, this conjunctiva-sparing procedure may be employed in the management of coexisting cataract and glaucoma prior to bleb-forming surgery.

Keywords: Endocycloplasty, Phacoendocycloplasty, Primary angle closure glaucoma, Endocyclophotocoagulation

Introduction

Glaucoma is the second leading cause of blindness, with primary open angle glaucoma (POAG) being the most common form worldwide; however, morbidity caused by primary angle closure glaucoma (PACG) is, in the least, the same as that of POAG [1].

In Asia, the prevalence of PACG can exceed that of POAG as it exists in a wide clinical spectrum [2]. Moreover, there is evidence that angle closure disease is more difficult to manage and is associated with more severe long-term visual morbidity in Asians than Caucasians [3].

Cataract and glaucoma frequently coexist, as both are diseases of advancing age; the presence of glaukomflecken, diffuse small white opacities in the anterior subcapsular region due to ischaemic necrosis of the lens epithelium, is virtually diagnostic of a past acute attack of angle closure [4, 5]. The chronic condition develops insidiously, the patient often being unaware of the ocular problem until relatively late in the disease process [6]. In either situation, laser peripheral iridotomy (LPI) is undertaken first, in an attempt to eliminate the element of relative pupillary block and deepen the anterior chamber [7]. However, occludability may not resolve post-LPI, when plateau iris syndrome (PIS) or a lens-related cause, or both are suspected.

The lens—due to its relatively anterior position, its thickness and increased lens rise [8–10]—plays an important role in the pathogenesis of PACG; its removal is thus advocated early, rather than late, even clear lens [11]. It has been shown that lens extraction alone significantly deepens the anterior chamber (AC), widens the anterior chamber angle and reduces IOP [12, 13]. However, this may be a rather simplistic view as there are multiple pathophysiological mechanisms causing angle closure and in PIS, there is evidence that the plateau may not resolve post-lens extraction alone [14]. There have been recent reports of endocycloplasty combined with lens extraction providing success in PIS [15] (Ahmed Ik, Podbielski D, Naqi A, *et al.* Endoscopic cycloplasty in angle closure glaucoma secondary to plateau iris. American Glaucoma Society Annual Meeting; March 5–8, 2009; San Diego, CA 2009) as well as in other aetiologies of angle closure [16].

The aim of this study was to explore the outcomes of phacoemulsification with PCIOL and endocycloplasty in all forms of primary angle closure disease, with or without synaechial angle closure.

Methods

Informed consent was obtained from all participants for the surgical procedure, and the study was approved by the ethics committee and review board (IRB) of the institute. It was conducted in accordance with the tenets as laid down by the Declaration of Helsinki.

A review of all subjects with angle closure disease, who had coexisting visually significant cataract and had undergone phaco-ECPL at a tertiary level academic practice, was done over the study period of May 2014–December 2016. We only considered subjects who had a documented post-surgical follow-up of at least 3 months.

Subjects with previous intraocular surgery or who had phaco-ECPL in complex refractory glaucomas (previous filtering surgery, corneal graft, retinal surgery, etc.) were excluded.

Relevant history for all subjects was recorded, and each subject underwent a comprehensive ophthalmic examination, including best corrected visual acuity (BCVA) assessment, slit-lamp biomicroscopy, intraocular pressure (IOP) assessment with Goldmann applanation tonometry (Zeiss SL 130 slit lamp with Goldmann style applanation tonometer AT 030), gonioscopy with Sussman 4-mirror under standard dark-room conditions, dilated stereo fundoscopy with +66D Volk lens (Volk Instruments, OH, U.S.A.). Visual fields were documented by the Humphrey field analyser (HFA).

Biometrics were obtained by Lenstar (Alcon, Fort Worth, TX, U.S.A.) and included axial length (AL), lens thickness (LT), central corneal thickness (CCT) and anterior chamber depth (ACD) measurements.

Surgical Procedure

Phaco-endocycloplasty (phaco-ECPL)

All surgeries were done by a single fellowship-trained surgeon and were performed in the operating room under regional anaesthesia; Inj. mannitol 20% (1–3 mg/Kg, Claris Otsuka, India) was administered pre-operatively, when indicated.

A clear corneal phaco was completed, and intraocular lens implant (IOL) was inserted in the bag, as per routine phaco surgery. Following this, a 20-gauge endoscope (Endo Optiks, Little Silver, NJ) was introduced through the phaco wound, after creating space in the sulcus with a cohesive viscoelastic and the ciliary processes (CP) were visualised. Delivery of laser was under direct vision, and it was aimed at the 'tail' of the ciliary process, in a modification of the endo-cyclophotocoagulation process called endocycloplasty (ECPL) [15, 16], wherein the ciliary body shrinks posteriorly, away from the iris (Fig. 1 and Electronic Supplementary Material 1—video demonstrating technique of ECPL). The end-point of whitening and shrinkage of ciliary body posteriorly determined the power of the laser delivered. Approximately 180°–210° were treated; laser energy was determined by shrinkage of CP and varied between 250 and 500 mw, with duration being constant at 2000 ms. 'Pops' were strictly avoided, and when encountered, it warranted an immediate reduction in power.

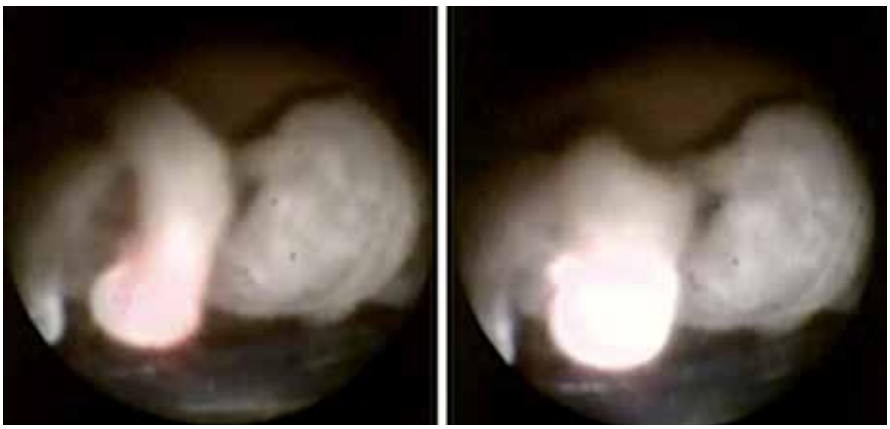


Fig. 1: *Left*: diode laser is aimed at the tail of the ciliary process. *Right*: whitening, contraction and retraction of ciliary body posteriorly post-laser, as ascertained by its height in relation to the ciliary process adjacent to it.

At the end of the procedure, viscoelastic was washed and sub-conjunctival steroid was administered (dexamethasone 2 mg).

Post-operatively all subjects were administered topical prednisolone acetate 1% (Predforte, Allergan, Irvine, CA, U.S.A.) for 4 weeks (in tapering dose) and moxifloxacin hydrochloride 0.5% (Vigamox, Alcon, Fort Worth, TX, U.S.A.) four times daily for 1 week, and if required, cycloplegic eye drops (homatropine hydrochloride 2%, Homide, Warren Excel, India) thrice daily were used for 1–2 weeks. All antiglaucoma medications were discontinued and reintroduced as per indication.

Primary outcome measure was IOP with complete success being defined as an IOP >5 and ≤ 18 mmHg without medication; qualified success was defined as meeting these criteria with medication. Failure to meet these criteria and/or requirement for reoperation (trabeculectomy or glaucoma drainage device or transscleral cyclophotocoagulation) was defined as failure of the phaco-endocycloplasty procedure.

Secondary outcome measures included logMAR best corrected visual acuity (BCVA), antiglaucoma medications (AGM) and major complications.

Data are presented as median, quartiles and interquartile range. Pre- and post-procedure IOP, AGM and BCVA were analysed using the Wilcoxon signed-rank test.

Results

During the study period of May 2014–December 2016, 32 eyes of 28 patients underwent phaco with endocycloplasty for primary angle closure disease alone, with at least 3-month follow-up. All subjects had primary angle closure with glaucoma which mostly ranged from moderate to severe.

Median age was 62.5 years (range 47–79). Median follow-up was 15 months (range 3–42 months, Q1 7.5, Q3 18, IQR 10.5). Nineteen eyes continued to demonstrate post-LPI occludability

(posterior trabecular meshwork not visible for 3 or more quadrants along with sine-wave sign) and were presumed to have plateau iris syndrome (PIS); however, not all of these had UBM-documented PIS. Fourteen eyes had peripheral anterior synaechiae (PAS) and synaechial angle closure ranging from less than 1 to all 4 quadrants. Glaucoma was advanced with mean MD (mean deviation) on 24-2 Humphrey visual field (Carl Zeiss, Dublin, CA) being 17.6 SD 11.5 (range 3.2 to 29.32) and visual field index (VFI) of 30% SD 37%. Table 1 lists the pre-operative characteristics, and post-operative results at last follow-up are shown in Table 2.

The median IOP pre-procedure decreased significantly post-procedure at last follow-up; there was also significant decrease in use of AGM. Mean pre- and post-operative IOP at different time intervals in phaco-ECPL is shown in Fig. 2. Median logMAR BCVA too improved significantly and none of the eyes lost vision. This was seen even when the cohort was analysed separately with respect to controlled (n = 16) and uncontrolled (n = 16) IOP (Tables 3 and 4).

Fibrinous uveitis was seen in six eyes post-operatively; all presented within 1 week, and most settled on conservative management. Only one such eye developed secondary pupillary block and had a repeat laser peripheral iridotomy. None of the eyes had cystoid macular oedema nor hypotony or any other notable complication. Subluxation or dislocation of IOL was also not seen.

Outcomes: complete success as per our definition was obtained in 75% eyes (n = 24); another 9.4% achieved qualified success (n = 3). Therefore, total success was seen in 84.4% eyes. Five eyes failed (15.6%); 2 eyes underwent trabeculectomy and have controlled IOP ever since. Two eyes had borderline IOP (22 mmHg without medication) at 3 months but were subsequently lost to follow-up.

Table 1: Pre-operative characteristics of patients undergoing phaco-endocycloplasty.

Pre-op characteristics	Median (Q1, Q3; IQR)
Age	62.5 (55.75, 70.5; 14.75)
Gender (female/male ratio)	9:5
Right versus left eye ratio	17:15
Axial length in mm	22.2 (21.9, 22.8; 0.8)
Anterior chamber depth in mm	2.6 (2.3, 2.9; 0.6)
Lens thickness in mm	4.7 (4.6, 4.7; 0.2)
Corneal thickness in microns	510.5 (493, 527.25; 34.25)
Lens position	5.0 (4.5, 5.2; 0.7)
Relative lens position	0.22 (0.21, 0.23; 0.02)

Table 2: Post-operative results at median 15 months of all patients undergoing phaco-ECPL.

Parameter	Pre-phaco-ECPL	Post-phaco-ECPL	*p*
Median IOP mmHg (quartiles, IQR)	20.5 (Q1 16.75, Q3 31, IQR 14.25)	16 (Q1 12, Q3 17.5, IQR 5.5)	< 0.001
Median AGM[a] (quartiles, IQR)	3 (Q1 2, Q3 3.25, IQR 1.25)	0	< 0.001
Median logMAR BCVA[b] (quartiles, IQR)	0.4 (Q1 0.3, Q3 0.625, IQR 0.325)	0.05(Q1 0, Q3 0.3, IQR 0.3)	< 0.001

[a]*AGM* anti-glaucoma medication
[b]*BCVA* best corrected visual acuity

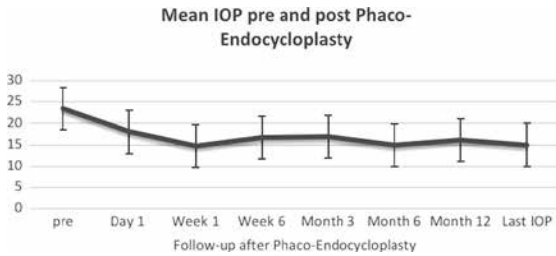
Table 3: Post-operative results of patients undergoing phaco-ECPL in controlled IOP (*n* = 16).

Parameter	Pre-phaco-ECPL	Post-phaco-ECPL	*p*
Median IOP mmHg (quartiles, IQR)	16.5 (Q1 15, Q3 18, IQR 3)	14 (Q1 12, Q3 16, IQR 4)	0.04
Median AGM[a] (quartiles, IQR)	3 (Q1 2, Q3 3, IQR 1)	0	< 0.001
Median logMAR BCVA[b] (quartiles, IQR)	0.4 (Q1 0.3, Q3 0.6, IQR 0.3)	0.0 (Q1 0, Q3 0.3, IQR 0.3)	0.001
[a]*AGM* anti-glaucoma medication [b]*BCVA* best corrected visual acuity			

Table 4: Post-operative results of patients undergoing phaco-ECPL in uncontrolled IOP (*n* = 16).

Parameter	Pre-phaco-ECPL	Post-phaco-ECPL	*p*
Median IOP mmHg (quartiles, IQR)	31 (Q1 23.5, Q3 36, IQR 12.5)	16 (Q1 13 Q3 17.75, IQR 4.75)	< 0.001
Median AGM[a] (quartiles, IQR)	3 (Q1 2.5, Q3 4, IQR 1.5)	0	< 0.001
Median logMAR BCVA[b] (quartiles, IQR)	0.5 (Q1 0.3, Q3 0.85, IQR 0.55)	0.2 (Q1 0, Q3 0.45, IQR 0.45)	0.007
[a]*AGM* anti-glaucoma medication [b]*BCVA* best corrected visual acuity			

Fig. 2: Mean pre- and post-operative IOP at different time intervals in phaco-ECPL.



Discussion

Trabeculectomy, since its first description in 1968 by Cairns [17], continues to occupy the foremost position in the surgical management of angle closure glaucoma, perhaps for lack of a suitable alternative. This is in contrast to the current day management of POAG where, with the advent of minimally invasive glaucoma surgical procedures (MIGS), several newer alternative approaches have been made available. MIGS has not only provided alternatives, but also options are available earlier on in the course of the disease, without compromising the conjunctiva [18].

Combined cataract and trabeculectomy (trab) is still the standard and preferred procedure in PACG in the presence of a visually significant cataract, especially when the IOP is uncontrolled, or the disease is progressing. Combining the two surgeries have several benefits-reduced morbidity and cost of surgery and visual rehabilitation in approximately 6–8 weeks. However, combined phaco-trab surgery is associated with much increased inflammation [19] (a cause for failure of

bleb) and a few unique vision-threatening complications like hypotony, shallowing of anterior chamber and bleb-related complications, including life-long risk of bleb-associated-endophthalmitis (BAE) [20].

A single-centre retrospective review from the 1990s showed that the 5-year risk of blebitis and that of BAE are 6.3% and 7.5%, respectively [21]. Also filtering bleb can fail at any time, from immediate post-op to as long as 20 years after surgery [22].

Thus, it becomes imperative to find newer, better and safer surgical solutions for PACG. One such modality is combining ECP with phaco, to control IOP whilst visually rehabilitating the patient. Our study has shown that phaco when combined with modified ECP, called endocycloplasty (ECPL), is successful in controlling IOP, reducing use of AGM whilst visually rehabilitating the patient in a few weeks. This effect was sustained in the intermediate term in all variants of angle closure, even those that had synaechial angle closure.

Studies with ECP hitherto have mainly been carried out in open angle or refractory glaucomas, and this approach has been moderately successful in POAG [23], pseudophakic and aphakic glaucoma [24], paediatric glaucomas [25] and even in refractory glaucomas [26]. Our success rate of 84.4% in angle closure glaucoma is comparable to those that are quoted in these studies; it could possibly have been higher if the two patients with borderline IOP without any antiglaucoma medication (22 mmHg) at 3 months had not been lost to follow-up and failed as per our IOP criterion.

Delivery of laser in ECPL in angle closure and these other types of glaucomas differ in as much as the tip of the ciliary process (CP) is targeted, rather than a continuous 'painting' of the ciliary body. This results in the contraction of the entire CP away from the angle, thereby widening the angle, if it is not synaechially closed. As persistence of plateau has been reported in PIS in eyes undergoing lensectomy alone (by Tran *et al.* [14]), we undertook intraoperative anterior segment optical coherence tomography (ASOCT) which confirmed this finding post phaco alone (Fig. 3, Left). The angle widened considerably at the end of combined phaco-ECPL surgery, and intra-operative ASOCT successfully demonstrated this effect (Fig. 3, Right).

If the angle was not synaechially shut, then endoscopic appearance of the angle also supported the findings of ASOCT (Fig. 4).

However, unlike Francis *et al.* [15] we did not restrict phaco-ECPL to PIS alone; on the contrary, we also included patients with synaechial angle closure, with or without PIS. Therefore, it

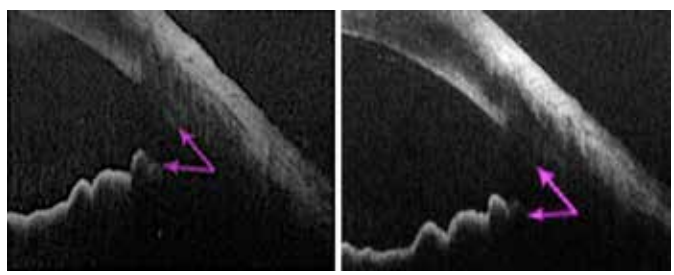


Fig. 3: Intra-operative ASOCT: *left*-angle recess before ECPL (after phaco) and *right*-after phaco-ECPL.

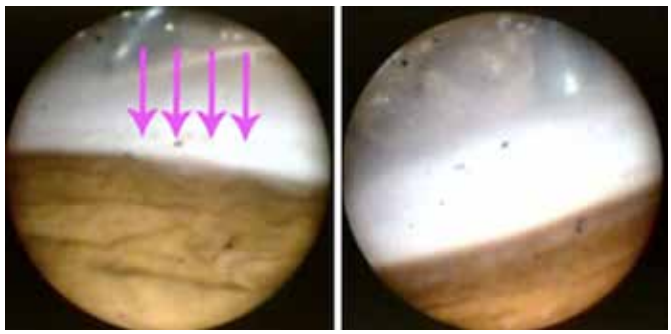


Fig. 4: *Left*-endoscopy pre-ECPL, post-phaco-except for 1 clock hour (*arrows*), the rest of the angle in the inferior 180° appears closed. *Right*-endoscopy post-phacoendocyclоplasty-scleral spur is visible throughout the inferior 180°.

is not only the angle-widening-with-restoration-of-anatomy effect that appears to be called into play, but also the cyclophotocoagulation per se appears to be quite effective.

This technique affords extremely precise laser ablation of the ciliary body, with reduced post-operative inflammation. Nonetheless, all patients received sub-conjunctival dexamethasone and we had very few eyes with fibrinous reaction postoperatively; one such eye had to undergo a laser peripheral iridotomy for secondary pupillary block. Post-operative phaco-ECPL eyes are generally very quiet, and recovery is very swift, with much speedier visual rehabilitation; moreover, conjunctiva remains unscathed should future filtration surgery become necessary (Electronic Supplementary Material 2-Figure demonstrating quiet eye at 1-week post-phaco-ECPL with unscathed conjunctiva).

As we target only 2–3 quadrants, risk of hypotony, and sequelae, is very low. In 5824 eyes, the ECP collaborative study group (Noecker RJ. Complications of endoscopic cyclophotocoagulation: ECP Collaborative Study Group. Paper presented at: The ASCRS Symposium on Cataract, IOL and Refractive Surgery: May 1, 2007 San Diego CA 2007) had also reported very low complication rates—notably hypotony in 0.12%, choroidal haemorrhage in 0.09%.

Such a procedure also helps to avoid damage to the zonules. Although zonules are not normally visible during the procedure, in one of the study eyes, pseudoexfoliation (PXE) deposits on the zonules made them discernible and even these weakened ones did not snap during delivery of laser (Electronic Supplementary Material 1-demonstrating ECPL in PXE also). This is also corroborated by the fact that in the median 15-month follow-up, we did not encounter any subluxation/dislocation of PCIOL, including the case with PXE. However, Wang *et al.* [27], aiming for emmetropia (using the Holladay 1 formula for the SN60WF IOL, Alcon), found a small myopic shift in relation to the change in effective lens position. Our eyes were shorter; we used the Hoffer Q formula for the majority of cases. However, IOL type was determined by the paying capacity of the patient and we did not aim for emmetropia. Target ametropia was between 0.25 and 1.0 dioptre, which we achieved for the majority of the patients.

On an average, we used only one-fourth of the total energy (500 mw), or less, when compared to transscleral cyclophotocoagulation. Hence, direct visualisation of ciliary processes for precise delivery of reduced laser energy also helps to avoid pain, excessive inflammation, hypotony,

phthisis and visual loss associated with transscleral delivery of the same [28]. It is surmised that in the latter, absorption across sclera is erratic and unpredictable, leading to the stated complications.

Furthermore, there is a recent report [29] of combining endoscopy-guided goniosynaechialysis (GS) with phaco-ECPL; the authors have had success with the procedure in a small series. We have tried GS in the past (none in this cohort) with severe protracted inflammation post-operatively which was difficult to control, and, in a few cases, it proved to be counterproductive too, with increase in PAS. Therefore, we do not favour this approach in the darker irides of South Asian eyes.

Overall phaco-ECPL is a very safe and effective procedure and as opposed to phaco-trabeculectomy, adds only about 5 to 10 min to the procedure of cataract extraction. It can be easily accomplished by an anterior segment surgeon who can expect hassle-free post-operative care, akin to phaco being performed alone.

Furthermore, laser can be repeated if required, and if it is not effective, it does not preclude, or compromise, future trabeculectomy.

This technology is readily available, but expense may be a consideration, especially in low-to-middle income countries. However, it should be considered as a one-time capital expenditure, just like a phaco machine. The possibility of acquiring an endoscope alone and coupling it with a pre-existing diode laser machine, if available, can also be contemplated, driving down expenditure.

Cost notwithstanding, when seen from the perspective of the patient, this freely available, relatively new technology not only improves their quality of life, with none or fewer anti-glaucoma medications, but also faster visual rehabilitation with fewer post-operative visits.

A small sample size and relatively short follow-up are some of the limitations of the study. However, the relatively small sample size is offset by inclusion of consecutive angle closure eyes that underwent phaco-ECPL. Furthermore, performance of phaco-endocycloplasty by one fellowship-trained glaucoma specialist ensured uniform protocol. Comparison with a cohort undergoing phaco alone is certainly desirable. However, our cohort of PACG had standard indications for combined surgery (either uncontrolled IOP, or progression in VF or IOP controlled with 3 or more medications, or non-affordability of medications) in the presence of visually significant cataract. Therefore, finding a comparable group of PACG subjects who underwent phaco alone was not possible. This, too, is a limitation of a retrospective study.

Conclusions

Phaco-endocycloplasty can effectively control IOP, significantly reducing need for anti-glaucoma medication in primary angle closure glaucoma also. Visual rehabilitation is early, without compromising safety, in this sub-group of glaucoma patients where high morbidity is anticipated following filtration surgery. When combined surgery is indicated, this conjunctiva-sparing procedure may be employed in the management of coexisting cataract and glaucoma prior to bleb-forming surgery. Comparison with phacoemulsification alone and larger-scale studies should be

conducted to explore its role as a minimally invasive procedure in all sub-types of angle closure glaucoma.

What was known:

- Endocyclophotocoagulation was hitherto moderately successful in POAG and refractory glaucomas.
- A slight modification in technique (endocycloplasty) combined with phaco has been recently described in plateau iris syndrome.
- Recent evidence suggests phaco-endocycloplasty is effective and safe in plateau iris syndrome.

What this paper adds:

- Phaco-endocycloplasty appears to be effective and safe in all variants of primary angle closure glaucoma, including those with synaechial closure.

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Compliance with ethical standards

Conflict of interest None relevant (Novartis, Allergan).

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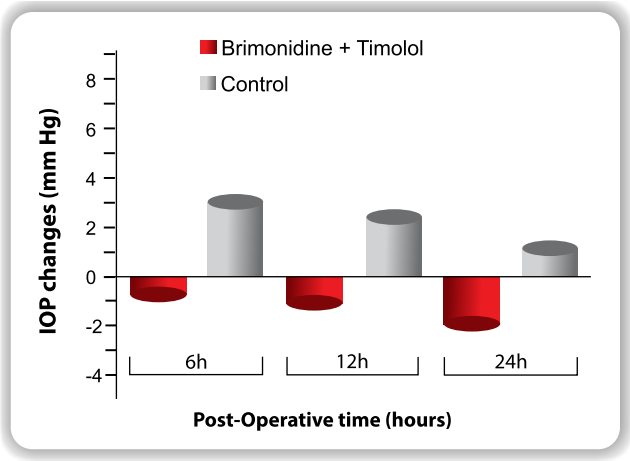
Notes:

To Control Post-operative IOP Spike

Rx BRIMOLOL

Brimonidine Tartrate 0.15% + Timolol Maleate 0.5%

Effectively Controls Post-operative IOP Spikes[1]



- Single administration - 24h IOP reduction[2]
- Effective in patients with pre existing glaucoma[2]
- Controls IOP elevation[3]

Combined power, Greater benefits

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