Glaucoma Drainage Devices in Children

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15.1 Introduction

Childhood glaucomas represent a diagnostic and therapeutic challenge for both ophthalmologists and glaucoma specialists, not only because achieving intraocular pressure (IOP) control is difficult but also because some patients may still have poor vision in spite of successful IOP control due to amblyopia, corneal opacities, and/or uncorrected high myopia and astigmatism. Medical treatment is only used adjunctively to reduce intraocular pressure (IOP), but the mainstay of treatment is surgical management [1, 2]. All cases of primary congenital glaucoma require surgical treatment, and although angular surgery (goniotomy or trabeculotomy) has been the preferred first procedure, glaucoma drainage devises (GDD) have a leading role in refractory cases and are even preferred as a first surgical effort in selected cases where other surgeries are contraindicated or unlikely to succeed (i.e., when there is significant conjunctival scarring) [3–10]. Furthermore it has been found that 20% of children with glaucoma often require two or more surgical procedures for an adequate IOP control, and GDD are frequently used in the second or third surgical attempt [3].

The Molteno Glaucoma implant (MGI) (IOP Inc., Costa Mesa, CA, USA) was the first GDD used in children in 1973, followed by the Baerveldt glaucoma implant (BGI) (Pharmacia and Upjohn Inc., Kalamazoo, MI, USA) and the Ahmed glaucoma valve (AGV) (New World Medical, Inc., Rancho Cucamonga, CA, USA), the latest, being currently the most used GDD in children [4].

15.2 Ahmed Glaucoma Valve

The AGV was approved by the US Food and Drug Administration for glaucoma surgery in 1993. It is a tube-shunt device with unidirectional flow and a restrictive mechanism that has the advantage of decreasing early postoperative hypotony, by opening only when the pressure surpasses 8 mmHg. Retrospective studies on AGV in children reveal a 28–49% in IOP reduction [4, 6–13].

15.2.1 Ahmed Valve Models

Four Ahmed glaucoma valve models have been used in children: the non-flexible polypropylene S-2 and S-3 and the flexible silicon FP7 and FP8.

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The S-3 model was originally designed for children under 12 years of age. It has a smaller single plate than the S-2 model (width, 9.6 mm vs. 13.0 mm; length, 10.0 mm vs. 16.0 mm; surface area, 96.0 mm^2 vs. 184.0 mm^2), but the tube dimensions remain the same. The FP7 and FP8 models are the equivalent to de S-2 and S-3 models in size, respectively, but the single plate is made of silicon instead of polypropylene, which in theory reduces the formation of fibrous tissue, hence encapsulation, allowing a higher success rate, although there is contradictory evidence in this matter [14–29].

Currently, ultrasonic biometry of the eye size is essential in deciding the implant's model; the S-3 and the FP8 models should be used when the eye's axial length is smaller than 20.5 mm, independently from the patient's age. Sometimes though, in newborns with very large globes but with normal size orbits, there may not be enough space to fit in an adult size implant, so an S-3 or FP8 model must be placed to attempt an initial IOP control; in these cases, valve replacement at a later age is sometimes necessary to obtain long-term IOP control.

15.3 Molteno Glaucoma Drainage Device

The Molteno glaucoma drainage device (MGI) was the first glaucoma device to offer drainage to a posterior bleb, away from the limbus, although the first surgeries did have the implant at the limbus. With more than 30 years of mostly positive experience and extensive long-term research, the newest Molteno 3 offers improved surgical time, a better material, a lower profile, and possibly better results regarding IOP control.

The use of MGI in pediatric glaucomas has very good reported rates of success but still necessitates close follow-up in order to detect any possible complication. Early hypotony is very common during the first 6 months of surgery, so the use of a tube ligature is mandatory; we believe this is a sound recommendation for children, because the pressure ridge might not sufficiently avoid hypotony for most children due to their activities [30–32].

15.4 Baerveldt Glaucoma Implant

The Baerveldt glaucoma implant (BGI) was developed as an alternative, larger surface-area implant with a softer, radio-opaque material. The principle of this non-valved device is similar to the MGI, but it incorporates four fenestrations on its body, designed to let fibrous tissue grow through them and limit bleb size and secondary strabismus.

As with all glaucoma devices, it is designed to have the tube inserted into the anterior chamber, but it is possible to insert the tube behind the iris or through pars plana, a version with a Hoffman elbow is available for this purpose. The available sizes are 250 and 350 mm^2, and there seems to be no significant difference in terms of IOP control in the long term, so individual criteria for each eye should be used to choose the best model [30, 32–36].

15.5 Surgical Techniques for Valved and Non-valved Devices

There are many variations in the surgical technique to implant a glaucoma device, many which require the opening of a scleral flap and a patch of various materials to cover the tube. We prefer the scleral tunnel technique described by Dr. Felix Gil-Carrasco, as it has proven to decrease significantly the risk of tube extrusion and requires no additional tissue to be used as a patch [1, 17, 21].

Small children have to be operated under general anesthesia. An examination under anesthesia is made before starting the surgery, in which IOP must be measured during induction. Special attention must be put on the conjunctiva and the angle to better plan the implantation of the valve and the tube. Some older children in whom general anesthesia is contraindicated may be operated under sedation and topical anesthesia.

Before beginning, we strongly suggest removing all talcum powder from the surgical gloves with a wet gauze. The valve's tube must be primed with balanced salt solution or viscoelastic material; this is particularly important for the AGV or it might not work at all.

Additional topical anesthesia and sub-Tenon lidocaine help reduce the risk of vagal reflexes from any manipulation of the extraocular muscles. A fornix-based conjunctival flap is performed in the superior temporal quadrant of the eye (if it is the second valve implanted, the superior nasal quadrant is used), followed by careful dissection of Tenon's capsule to create a pocket and adequate cautery of episcleral vessels, when needed. The valve's plate is then inserted under the conjunctiva/Tenon flap and firmly secured to the sclera using 7-0 silk suture; 8 mm posterior to the limbus if an MGI, BGI, or an S2 AGV model is used; and at 9 mm from the limbus when using the FP7 model (if the valve is placed in the superior nasal quadrant, sometimes it must be fixed 1 or 2 mm nearer to the limbus).

A scleral tunnel is then performed using a 23G needle folded in a "Z" shape, starting at 4 mm posterior to the limbus and rectifying its direction abruptly at the limbus to enter the anterior chamber parallel to the iris plane: The needle must be mounted on a viscoelastic syringe to be able to reform the anterior chamber; as we remove the needle from the eye, viscoelastic material must be injected into the tunnel. The silicon tube is then trimmed to create a 30–45° bevel which must be facing up; the tube is then inserted into the scleral tunnel. The conjunctiva/Tenon is then closed at the limbus with 8-0 polyglactin (Vicryl; Ethicon Ltd) inverted sutures.

The tube must be ligated when using either an MGI or BGI, using an absorbable 7-0 or 8-0 Vicryl suture. If there is need for early filtration in cases of advanced glaucomas, an AGV might be the better alternative, but a venting slit in the tube anterior to the ligature can provide some filtration for the first 3–4 weeks until the suture is released.

If a graft patch is to be placed, the tunnel might not need to be so long, so insertion of the tube becomes easier, but the patch must be secured using absorbable sutures, and then the conjunctiva should perfectly cover the patch and be fixed water-tightly to the limbus [4–8, 10–16, 37, 38].

The technique just described does not vary much from that used in adult patients, with the exemption that absorbable sutures are used to close the conjunctiva in children. So, what is "special" about inserting a valve in a child's eye? Well, children with primary congenital glaucoma tend to have large corneas and thin scleras, and limbal structures may be distorted beyond recognition. If the globes are larger but the orbits aren't, the space between these two structures might be smaller, making it more challenging to implant the valve.

Extraocular muscles may be thin and elongated and may not stretch properly, making it difficult to rotate the eye inferiorly to be able to work in the superior temporal quadrant; traction sutures may be used to aid us with this problem, but they will induce folding of the flexible sclera, making the construction of the tunnel and the insertion of the tube very difficult.

As mentioned before, the sclera is thinner, making the suture of the valve's plate a risky step; furthermore, sometimes, the plate must be placed more posteriorly than the usual 8–9 mm because the apparent position of the limbus is usually more anterior than its real position (where we'd find the angle structures); if this is the case, the plate must be fixed to the sclera 10–11 mm posterior to the apparent position of the limbus. For the same reason, the scleral tunnel must also be 1 or 2 mm longer, initiating it 6 mm from the apparent position of the limbus; the abrupt change in the direction of the limbus must also be done a bit posteriorly, to ensure the tube enters the anterior chamber through the trabecular meshwork.

Secondary glaucomas in children present in an eye that had had a normal development, so the globe's size and scleral thickness is usually similar to that of an adult. Sometimes secondary glaucomas have abnormal angles and corneal opacities, making surgeries more challenging. When operating on eyes with pseudophakia or aphakia, one must be prepared to perform an

anterior vitrectomy, when necessary, to remove any remaining vitreous from the anterior chamber and prevent it from blocking the tube [39]. It is not uncommon to have to remove inflammatory membranes, anterior or posterior synechiae, so it is always wise to have extra viscoelastic material, anterior vitrector, retinal forceps, and microincision scissors on hand.

Postoperative care includes 1% prednisolone acetate every 2 h during the daytime in the first week and tapered weekly over 1 month. Antibiotic drops must be installed four times a day until the absorbable sutures fall off (2–4 weeks).

When using one of the non-valved implants, the IOP might be very elevated until the ligature is released, so aqueous suppressants might be needed to maintain an IOP below 30, or even better below 20, for the 3–5 weeks needed for the ligature to loosen.

15.6 Success Rate of the Three Implants

Success rate reported in the literature is sometimes difficult to compare because often different definitions of success are used, plus "glaucoma in children" encompasses various entities with different pathophysiologies and risk factors that can influence a surgery's success. Most studies consider success when postoperative IOP lies between 6 and 21 mmHg, without complications that require further surgeries or the loss of light perception. Furthermore, up to 45% of the children in whom valves are implanted have undergone previous glaucoma surgeries before the AGV implantation, thus modifying its success potential.

Having said that, cumulative probabilities of success reported in literature are around 63–97%, 45–86%, 51–87%, 41–45%, and 33–56% at 1, 2, 3, 4, and 5 years, respectively. The mean time to failure in refractory pediatric glaucoma reported in different studies is 19–29 months.

After a second implantation, more commonly reported with AGV, IOP lowers further; the cumulative probability of success reported in the literature is 86–93% in 1 year, 86–89% in 2 years, and 53–69% in 5 years. A third implantation of an AGV or a 250 BGI or a Molteno 3 is possible in the inferior temporal or nasal quadrants, but because this is rarely performed, there is no available data as to its success rate [18].

Vision tends to improve or remain stable in most children after implanting an AGV and seems to be a bit more blurry with non-valved implants. This may be due to the period of elevated IOP before the ligature gets loose. Most patients with one or two GDD will need one or more glaucoma medications at some point after surgery to maintain an adequate IOP control, but the number of needed medications seems to be lower with BGI. Some may even require additional, more aggressive glaucoma surgeries, such as cyclodestructive procedures.

Having more than two previous glaucoma surgeries and intraoperative complications are recognized predictors for failure. This reflects on the importance of having as much experience as possible in GDD implantation in adult eyes before daring to operate on children, and on choosing the right time to perform the implant, even considering primary insertion on selected cases. Hispanic ethnicity and female sex have been suggested to be risk factors for failure, but the underlying reason is yet unknown.

All studies show that success rates for GDD decline over time; the pediatric population needs a longer valve survival, so efforts to find medications or surgical procedures that prolong such survival are essential.

15.7 Complications

Trans-surgical complications from AGV are similar to those found in adults and include hyphema and lens touch with subsequent cataract formation. However, there are two tube-related postsurgical complications that are quite unique to the pediatric population: retraction of the tube into the scleral tunnel due to the globes' growth, especially in unsuccessful cases where high IOP continues to cause buphthalmos and, on the other hand, plate migration secondary to the shrinkage of the sclera and globe after IOP reduction, with the tube advancing into the anterior chamber,

often closer to the corneal endothelium. Siliconplate FP7 AGV has posterior holes through which fibrous tissue can grow, fixating the valve further and making migration less likely, although it can still happen due to eye growth.

Other postoperative complications are similar in children and in adults, but incidences may vary. Some complications require additional surgeries to correct them, which in children represents another challenge as it implies another round of general anesthesia. Postoperative complications include tube block with iris or vitreous, hypotony, shallow anterior chamber, hypertensive phase, tube malposition with tube-corneal touch, decreased endothelial cell density, cosmetically large blebs, bleb encapsulation, strabismus, tube or valve's plate extrusion, and endophthalmitis. Choroidal detachments are very rare in children and tend to disappear very quickly [21, 22, 25, 33].

Corneal decompensation is more common in children, and it's secondary to tube-corneal touch; it is related to the higher flexibility of tissues and the continuous remodeling that occurs as the child grows. Loss of resistance around the tube's entrance to the anterior chamber explains the anterior displacement of the tube's tip frequently observed in children. The greater incidence of dyscoria observed in children might be due to the enlargement of the entrance of the tunnel into the anterior chamber [5].

Extrusion is a common long-term complication observed in tubes implanted using patches, with an incidence of 5.6% in children to 2.5% in adults. The scleral tunnel technique reduces extrusion risk to around 0.4–1.5% [21, 24].

15.8 Adjunctive Therapy

Glaucoma-filtering surgeries and tube-shunt procedures fail due to excessive fibrosis, either by creating a large encapsulated bleb that inhibits fluid exchange or, specifically in GDD, by fibrovascular ingrowth into the valve's chamber that virtually shuts it down, leading to failure of the procedure in both cases. The fibrous tissue response following a GDD implant is more extreme in the pediatric population, especially in patients with previous surgical interventions on the conjunctiva; for this reason, attempts to regulate and control the healing process of blebs are constantly being made. The possible benefit of using silicone plates instead of polypropylene plates has been mentioned previously in this chapter.

Mitomycin C is an antimetabolite that inhibits fibroblast proliferation and collagen synthesis. It is widely used intraoperatively or postoperatively in glaucoma-filtering surgeries in adults. There are controversial results on the use of mitomycin C associated to GDD in children; some studies have found an increased success rate, while others show a decreased survival rate. Furthermore, its use in children is much more restricted as devastating complications such as late-onset bleb-related endophthalmitis or tube erosion occur more frequently than in the adult population due to the lower scleral rigidity in children [28].

Bevacizumab (Avastin, Genentech Inc., San Francisco, CA, USA) is a recombinant antibody that binds to all isoforms of vascular endothelial growth factor (VEGF) and has been used as an off-label drug in ophthalmology to treat many retinal pathologies (proliferative diabetic retinopathy, neovascular age-related macular degeneration, macular edema), and recently it has gained some turf as an adjunctive therapeutic agent in glaucoma surgeries. Bevacizumab may be injected at the end of the surgery at a dose of 2.5 mg between the conjunctiva and Tenon's capsule, next to or on top of the valve's plate. A second dose 1 week later, which is recommended in adults, is not advised in children, since it would require another round of general anesthesia [23].

Antiangiogenic agents like Bevacizumab and antimetabolites such as mitomycin C have been used intraoperatively in children as an attempt to enhance valve survival, with a reported success rate of 80–90% for mitomycin C and 80% for subconjunctival bevacizumab but with a safer profile for the second one. Further research is needed to find a plate material or an adjunctive safe therapeutic agent that prevents bleb encapsulation and fibrovascular ingrowth, thus ensuring a better success rate for GDD [29].

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