Review article

Artificial drainage devices for glaucoma surgery: an overview

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Abstract

Artificial drainage devices (ADD) create an alternative pathway for aqueous drainage from the anterior chamber of an eye through a tube to the subconjunctival bleb connected to an equatorial plate under the conjunctiva. The ADDs, both valved and non-valved, are available for end stage or refractory glaucoma. Currently, some of these devices, particularly the Express shunt, are recommended for the primary treatment of glaucoma. In this article, we highlight various ADDs, their indications and contraindications, surgical techniques and associated complications.

Key-words: Artificial drainage devices, glaucoma, recent advances

Introduction

Artificial drainage devices (ADD) create an alternative pathway for aqueous drainage from the anterior chamber of an eye through a tube to the sub-conjunctival bleb connected to an equatorial plate under the conjunctiva. ADDs are indicated for patients with neo-vascular glaucoma, glaucoma with uveitis, secondary glaucoma following penetrating keratoplasty, retinal detachment surgery, cataract surgery and failed filtration surgery (Lieberman et al, 1990). A variety of materials have been used to facilitate aqueous drainage from the anterior chamber, including silk thread, glass, platinum, teflon, cartilage, and autologous lacrimal canaliculus (Melamed & Fiore, 1990). These early implants were associated with high complication rates, excessive scar formation near the limbus, seton migration and conjunctival erosion. Molteno introduced the implant consisting of a long silicon tube attached to a large end plate placed 9-10 mm posterior to the limbus. The modern implants are based on this concept of Molteno (Molteno et al 1976). This article outlines various drainage devices, surgical techniques and complications following ADD insertion.

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Description of ADD

Currently, the ADDs are divided into three categories: those with no resistance, those with resistance and those with variable resistance to aqueous outflow.

ADDs with no resistance

These implants consist of a silicon tube connected to an end plate placed sub conjunctively which acts as surface for bleb formation. Molteno implants are of two types: single plate and double plate. A single plate Molteno implant is a silicon tube with external diameter of 0.63 mm and internal diameter of 0.30 mm connected to the upper surface of a polypropylene plate (Molteno et al 1969; Lloyd et al 1992). The double plate implant consists of two plates one of which is attached to silicon tube in the anterior chamber while the second connects the two plates forming a surface area of 270 mm^2 (Molteno 1981).

The Baerveldt implant consists of a silicon tube attached to a barium impregnated silicon plate with a surface area of 200 mm^2, 350 mm^2 or 500 mm^2 .The advantage of the Baerveldt implant is that it has a large surface area plate that can be implanted through a one-quadrant conjunctival incision (Lloyd et al 1994). The Schocket implant is a cheap and easily assembled implant which includes a silastic tube used for NLD intubation. This tube is connected to a 360° encircling silicon band, like that used in retinal detachment surgery. The disadvantage of this implant is that the surgical procedure of implantation is cumbersome and lengthy (Schocket et al 1982; Schocket et al 1985).

ADDs with set resistance

To avoid early post operative complication such as excessive drainage and hypotony, the concept of a one-way valve that opens at predetermined IOP was introduced by Krupin and associates (Krupin et al 1976). The Ahmed glaucoma valve (AGV) has lowest incidence of hypotony amongst all valved devices. The AGV consists of a silicon tube attached to a silicon sheet valve held in a polypropylene body (Coleman et al 1995). The valve consists of a thin silicon elastomer membrane which creates a venturi-shaped chamber. Because the inlet is wider than the outlet, a pressure gradient between the anterior chamber and the bleb is created which enables the valve to open in response to pressure differential, as described by Bernouillis principle. The valve is designed to open at an IOP of 8 mm of Hg or more. The Optimed implant is made up of a silicon tube with PMMA plate. The flow is restricted by the presence of an element in the rectangular box situated at the end of the tube with in the plate.

ADDs with variable resistance

These are modified Molteno and Baerveldt implants. These devices include a tissue resistance mechanism that limits the aqueous flow. However, since the tissue apposition force is variable, IOP levels remain unpredictable.

The Molteno implant with a pressure ridge is a dual chamber, single plate implant with a V-shaped pressure ridge on the upper surface of the plate which encloses an area of 10.5 mm^2 around the opening of silicon tube (Molteno 1990; Freedman 1992). The pressure ridge and the overlying Tenon's capsule regulate the flow of aqueous into the main bleb cavity during the early post-operative period, thereby decreasing excessive filtration and hypotony. But in our experience, these complications are not effectively prevented by the pressure ridge mechanism. The Baerveldt bioseal is a flap that overhangs the silicon tube as it opens on the end plate. The apposition of bioseal elements to the sclera with absorbable sutures provides early resistance, which limits the aqueous flow beneath the device.

Pathophysiology

After implantation of the ADD, there is formation of a fibrous capsule around the end plate over a period of several weeks. The fibroblasts do not adhere to the silicone or polypropylene material of the plate. This is an important feature which allows success of drainage implant. The aqueous humor passes out of the anterior chamber and collects in the space between the end plate and non-adherent fibrous capsule. Aqueous flow then passes through the fibrous capsule via passive diffusion and is absorbed by periocular lymphatics. The fibrous capsule is the main site of resistance to aqueous outflow. Therefore, the success of drainage surgery is dependent on capsular thickness and surface area of encapsulation. The thinner is the capsule and larger the surface area of encapsulation, the lower will be the intraocular pressure. A large plate will have an increased surface area of encapsulation and greater intra-ocular pressure (IOP) reduction. Heuer and colleagues achieved a higher success rate and a better IOP reduction with the double plate implant due to its increased surface area (Heuer et al 1992).

Comparison of various ADDs

Baerveldt vs Ahmed glaucoma valve

The Ahmed and Baerveldt drainage implants show competitive IOP lowering potential with good success rates. At 1 year follow up, both devices have similar IOP control rates and success end points (Tsai et al 2003; Syed et al 2004). Similar results were seen in an Asian population, as described by Wang et al (Wang et al 2004). The Ahmed implant has a higher hypertensive phase with raised IOP after 1-2 months of implant and high rate of bleb encapsulation as shown by Tsai JC et al and Syed HM et al in two different studies (Tsai et al 2003; Syed et al 2004). Syed et al demonstrated a higher hypotony rate for Baerveldt implants (Syed et al 2004).

Baerveldt vs double plate Molteno implant

Smith et al compared 18 eyes with a Baerveldt implant and 19 eyes with a double plate Molteno (Smith et al 1995). Both the implants had a relatively good and similar IOP reduction (> 44%), good success rates and better visual outcomes after one year. The Baerveldt implant was associated with slightly more risk of AC shallowing and the Molteno was associated with an increased incidence of corneal graft failure.

Ahmed vs double plate Molteno

A retrospective study done by Ayyala RS showed a better IOP reduction with the double plate molteno as compared to the Ahmed glaucoma valve at 12 and 18 months of follow up (Ayyala et al 2002). The chances of a hypertensive phase were greater with the Ahmed implant than the double plate Molteno, but ultimately, the success rate by the end of 2 years was similar in both the groups.

Ahmed vs Krupin eye valve with disc vs Double Plate Molteno

Yagira et al performed a non-randomized retrospective study of patients who received the double plate Molteno (27 patients), Krupin eye valve with disc (13 patients) and Ahmed glaucoma valve (13 patients) (Taglia et al 2002). The double plate Molteno produced a greater reduction in IOP but with a higher rate of hypotony.

Indications

Artificial drainage devices are associated with serious intraoperative and post operative complications, hence these are reserved for patients with refractory and intractable glaucoma. Glaucoma drainage devices are indicated for patients with neovascular glaucoma, glaucoma with uveitis, secondary glaucoma following penetrating keratoplasty, retinal detachment surgery, cataract surgery, refractory infantile glaucoma, and failed filtration surgery. The patients with aphakia who need contact lenses may require an ADD (Lieberman & Ewing, 1990). Additionally, patients with bad surface diseases like pemphigus are alsocandidates indication for ADD. In most cases, trabeculectomy with antimitotics such as Mitomycin-C and 5- Fluorouracil should be attempted before ADD is used.

Contraindications

ADDs are associated with various postoperative complications so are contraindicated in noncompliant patients. The drainage devices are not recommended for patients with poor endothelial function.

Surgical technique

The surgical technique is the same for most implants. A fornix based conjunctival flap is made in the superotemporal or superonasal quadrant with two relaxing incisions. The superotemporal quadrant is preferred because a supero-nasal approach may induce postoperative strabismus (Prata et al 1993). A partial thickness rectangular scleral flap is created as large as possible so that the tube is covered. The draining part of the implant is placed in the sub-Tenon's space and the anterior portion is sutured to the sclera approximately 7 mm posterior to the limbus.

The silicon tube is radially placed across scleral flap and excess tube is trimmed so as to overlap the limbus by 2 mm. A 23 gauge needle is used to enter the anterior chamber and the tube is inserted through this opening. The scleral flap is sutured with 10-0 nylon. The conjunctiva is attached back around the limbus. Due to larger dimensions, Baerveldt and Schocket implants require dissection in one or more than one quadrant. A scleral patch graft from donor tissue may be placed over the tube to avoid post-operative erosion of tube as a modification of original technique (Minckler et al 1988).

Post-operative period

Hypotensive phase

After surgery this phase lasts from day 1 to 4 weeks. During this phase the bleb looks to be diffuse and thick valved with few engorged blood vessels. The IOP is low and varies from 2-3 mm of Hg to 10-12 mm of Hg.

Hypertensive phase

Beginning 3-6 weeks after surgery, it can last for 4-6 months. The bleb appears inflamed; dome shaped and may be associated with a raised IOP of 30 mmHg or greater. The Ahmed glaucoma valve has increased incidence of hypertensive phase when compared to Baerveldt implant and the double plate Molteno as shown in many studies. The increased incidence can be explained because of increased surface area of these two implants. The difference may also be due to the different bio-materials used in various implants.

Stable phase

After the hypertensive phase there is stabilization of IOP in the mid to high teens. The bleb appears as a thick-valved, dome-shaped, elevated area overlying the end plate with no associated inflammation.

Complications

Intraoperative complications

Globe perforation and uveal tissue exposure can occur while fixing the implant or while dissecting the sclera, especially in previously operated eyes which have thin sclera. Intra-operative complications can be vitreous loss, ciliary body bleeding while inserting the tube. If the incision is large there can be leakage around the implant. There can also be hyphema, supra-choroidal hemorrhage or expulsion, and vitreous hemorrhage.

Post operative complications

The tube vs trabeculectomy study done by Gedde and associates compared the efficacy and the clinical outcomes of nonvalved ADDs vs trabeculectomy with mitomycin-C (Gedde et al 2007a; Gedde et al 2007b). He reported a similar rate of intraoperative complications in the two groups. At one year follow up, patients who had a tube shunt device were less likely to develop post-operative complications (p=0.001), lower incidence of failure, and more likely to take anti glaucoma medications. Gedde and associates also found that the presence of intra-operative or post-operative complications did not increase the risk of failure.

One of the major post-operative complications of ADD is shallow anterior chamber secondary to wound leak, overfiltration, and choroidal effusion. The incidence of over-filtration is higher in non-valved implants. To address this complication, ligatures can be placed around the external portion of the tube or the internal lumen can be occluded. An 8-0 suture can be tied around intraocular portion of the tube and cut after one week with an argon laser. Alternatively, releasable sutures with one end of the suture placed on the cornea can also be used (Sayyad et al 1991). Hypotony from overfiltration usually can be left as such unless there is a flat anterior chamber with lens-cornea touch. In this case, the anterior chamber should be reformed with a viscoelastic agent. In recalcitrant cases, one needs to repeat the procedure. Choroidal effusions can be managed conservatively with steroids orally or topically. Large effusions require surgical drainage.

Increase in intraocular pressure

Raised intraocular pressure may be encountered in the early post operative period, and can be due to fibrin, vitreous, an iris plug occluding the lumen, or a tight external ligature. The techniques which have been reported to open the occlusion include irrigation of the tube with saline through paracentesis or use of Nd-YAG Laser for vitreous incarceration or Nd-YLF. A tight suture can be severed with an argon laser. A late increase in intraocular pressure can be due to a thick fibrous capsule. Raised intraocular pressure can also be the result of topical steroids used during the postoperative period (Mermoud & Salmon, 1993).

Ocular motility disturbances may occur following large plate implant, which manifest as diplopia and strabismus. When implanted in inferonasal quadrants, larger plates can interrupt extra ocular movements. It can be corrected by a replacement with a smaller design, transfer to another quadrants, or, in persistent cases, removal of the implant.

The intraocular portion of the tube may touch the cornea leading to corneal edema and decompensation. The tube-cornea touch can be minimised by using a scleral patch graft instead of a scleral flap. Alternatively, the tube can be repositioned (Freedman, 1987). Retraction of the tube may occur as a result of inadequate anchoring of the tube to episclera. Late erosion of tube may also occur. Epithelial ingrowth is uncommon, but may occur in tubes inserted closer to limbus. A sterile hypopyon has also been reported. Other late complications include choroidal effusion, choroidal hemorrhage, retinal detachment, endophthalmitis and phthsis bulbi.

Endophthalmitis as a result of drainage device implantation is not very common; the incidence is less than 2% (Al Torbak et al 2005). Early postoperative endophthalmitis may be associated with host flora while late onset endophthalmitis is more common in thin-walled and leaky blebs that allow trans-conjuctival migration of bacteria (Gedde et al 2001). Diminution of vision may be seen secondary to suprachoroidal hemorrhage, corneal edema, cataract, band shaped keratopathy and cystoid macular edema. Due to the high risk of complications, the US Food and Drug Administration has classified these devices as Category 3, presenting a potential unreasonable risk requiring the highest level of regulation (Krawczyk 1995).

Recent advances in ADDs

Recently, many advances have been made in the field of ADDs with respect to materials, design, and technique of implantation. All implants share the common goal of shunting aqueous humor out of the anterior chamber and bypassing the trabecular meshwork to increase outflow and lower the IOP. Some recently introduced implants are described below.

Ex-Press shunt (Stainless steel)

The Express shunt is the latest development in the treatment of difficult glaucoma cases. It consists of a 3 mm long stainless steel tube with a central hollow lumen that is 400 micrometers in external diameter and 50 micrometers internally. The bleb formation starts immediately and micro cysts within the bleb can often be seen within the first or second post-operative day. Additionally, surgery with the Express is less time consuming than with a larger shunt and, if it fails, a more extensive shunt procedure can be planned later. The Ex-Press shunt was initially designed to implant near the limbus through sclera into the anterior chamber. The external plate of the shunt was placed under the conjunctival flap thereby producing a filtering bleb near the entrance of Ex-Press shunt. This led to a number of postoperative complications including hypotony, choroidal detachment and suprachoroidal hemorrhage (Wamsley et al 2004). To overcome these complications, the Ex-Press shunt is implanted under the scleral flap which reduces the overall complication rate (Wamsley et al 2004; Dahan & Carmichael, 2005).

Gold micro shunt (GMS)

This device uses a 24 carat gold plate which is implanted into the suprachoroidal space. It is a biocompatible and inert material. The IOP reduction is achieved by the presence of opening and closing holes in the gold microshunt. The outflow is titrated with the help of 790 nm Titanium sapphire laser (Ozdamar et al 2003).

Artificial nano drainage implant (ANDI)

ANDIs are a biomedical device with a characteristic design that increases its success rate. It is a serpentine microchannel made of poly dimethyl siloxane (PDMS). The microchannel regulates the forward flow by friction. The special serpentine design increases the length of channel thereby creating a larger pressure differential over a smaller area. It also decreases the chances of infection by impending bacteria movement up the device (Barth et al 2011).

Sutureless ADD surgery (Fibrin glue assisted)

The fibrin glue assisted surgical technique is similar to the Vicryl suture technique but instead of sutures, Tisseel fibrin glue is applied to the silicon tube to facilitate adherence to the underlying sclera. The Tisseel glue considerably reduces the postoperative conjunctival inflammation and decreases the time of surgery with no adverse effect on IOP control (Kahook & Noecker, 2006).

Glaukos iStent

It is a Titanium device which is placed inside the Schlemm's canal, thereby allowing the aqueous humor to flow directly into the canal and bypassing the trabecular meshwork (Spiegel & Kobuch, 2002). The advantage of this implant is that it is free from bleb related complications. It is implanted through a clear corneal incision under topical anaesthesia.

Eyepass glaucoma implant

It is a Y-shaped stent made of silicon. The Eyepass directly shunts aqueous humor from the anterior chamber into the Schemm's canal bypassing the trabecular meshwork. The arms of the Y-shaped implant facilitate the flow of aqueous in both the clockwise and counter clockwise direction (Karmel 2004; Daly 2004).The rate of complications is also reduced. More studies and long term follow up is required to determine the safety and utility of this implant and any additional advantage over the currently used ADDs.

Aquaflow glaucoma implant

A non-penetrating deep sclerectomy along with the aqua flow collagen glaucoma implant has shown significantly lower post operative complications and better outcomes when compared to conventional trabeculectomy (Mermoud et al 1999). The Aquaflow glaucoma implant is a 5 mm × 4 mm in length. The collagen implant is inserted under the scleral flap after a deep sclerectomy. It swells to double its original size after absorption of eye fluids, and the implant takes 6 to 9 months to dissolve. The normal time for surgical scar healing is less than the life of this device. Once the aqua flow is dissolved, a channel remains to allow the aqueous flow to exit from the desired location, thereby maintaining the reduced IOP. Since the surgeon does not enter the anterior chamber, the chances of cataract formation are also reduced.

Future perspective

Currently, an aqueous shunt is in clinical trials which will include the formation of a thinner capsule and have greater hydraulic conductivity. It is based on the hypothesis that changing the geometrical design of the commonly used shunt devices from a plate design to a cylindrical shape will reduce the tension on the capsule surrounding the implant (Wilcox & Minckler, 1994). In experiments on rabbits, the cylindrical design produced a thinner bleb as compared to the Baerveldt implant with an 8 times increase in hydraulic conductivity as measured by perfusion experiments (Wilcox et al 2000). The goals of new designs are to produce easier- to-use implants with fewer complications, and more predictable IOP control. Currently, none of the available implants provide predictable resistance to fluid outflow.

Conclusion

Artificial drainage devices have been successfully used to treat glaucoma in refractory cases but due to high rates of complications, they are reserved for cases of recalcitrant glaucoma. In developing countries with illiteracy and poor follow-up trabeculectomy with Mitomycin-C remains the treatment of choice.

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