



Update on aqueous shunts

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ABSTRACT

Medicare claims data and surveys of the American Glaucoma Society membership show that aqueous shunts are being increasingly utilized in the surgical management of glaucoma. New clinical trials data have identified differences in the efficacy and safety of shunts in common use. Recent studies have reported comparable results with trabeculectomy and aqueous shunts in similar patient groups. Intra-operative and postoperative complications may develop with aqueous shunt surgery related to the implantation of a foreign material. Several modifications in surgical technique have been directed toward improving surgical success, reducing complications, and optimizing efficiency and cost.

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1. Introduction

Glaucoma is a disease involving impaired outflow of aqueous humor through the anterior chamber angle. The increased resistance to aqueous outflow produces intraocular pressure (IOP) elevation that damages the optic nerve. The current treatment of glaucoma is directed toward decreasing IOP to prevent progressive glaucomatous optic nerve damage. Glaucoma surgery is typically performed when adequate IOP reduction cannot be achieved with maximally tolerated medical therapy and appropriate laser treatment. Trabeculectomy and aqueous shunt surgery are the most commonly performed incisional glaucoma procedures worldwide. Both operations create an alternative route for aqueous outflow, bypassing the high resistance pathway and providing IOP lowering. Trabeculectomy creates a scleral fistula that connects the anterior chamber and subconjunctival space resulting in the formation of a paralimbal filtering bleb. Aqueous shunts are implantable devices that allow drainage of aqueous humor more posteriorly.

Aqueous shunts share a common design consisting of a silicone tube that is inserted into the eye through a scleral fistula and shunts aqueous humor to an episcleral plate that is located in the equatorial region of the globe, typically centered between (and, in the case of some devices, extending under or over) two adjacent rectus muscles. Fibrous encapsulation of the equatorial plate produces a reservoir into which aqueous humor pools. The major resistance to aqueous outflow through these devices occurs across the fibrous

capsule around the equatorial plate (Minckler et al., 1987; Wilcox et al., 1994). Therefore, the final IOP that is achieved after aqueous shunt surgery is determined by capsular permeability and surface area (i.e. more permeable and larger surface-area capsules are associated with lower postoperative pressures).

Molteno pioneered the concept of wound-healing modulation to minimize the fibrous encapsulation of the equatorial explants in an effort to improve IOP control. He has advocated the combination of oral prednisone (or intramuscular methylprednisolone acetate), colchicine, and fluphenamic acid (a non-steroidal anti-inflammatory agent) with topical atropine sulfate, epinephrine hydrochloride, and dexamethasone (or betamethasone sodium phosphate), particularly for patients aged 18 months to 50 or 60 years in whom he regards the healing response most vigorous (Molteno et al., 1976; Molteno, 1980, 1987). However, because others have experienced or have been concerned about systemic side-effects, his antifibrosis regimen has not achieved widespread application (Brown and Cairns, 1983; Cairns, 1983). More recently, surgeons have attempted to minimize fibrovascular proliferation and thereby capsule thickness over the equatorial plate by applying mitomycin C (MMC), but this approach appears to be of limited benefit (Cantor et al., 1998; Costa et al., 2004). Shunts with larger equatorial plates produce greater IOP reduction, presumably by promoting a larger surface-area capsule around the plate for filtration (Heuer et al., 1992). However, there appears to be an upper limit beyond which an increase in plate size does not allow greater efficacy (Lloyd et al., 1994).

The equatorial plates of commercially-available aqueous shunts differ in the size, shape, and physical material composition. The material and surface characteristics of the equatorial plates may also influence the wound-healing response elicited by these

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devices. In rabbits, subconjunctival implantation of polypropylene induced more inflammatory reaction than silicone (Ayyala et al., 1999, 2000). Another recent study evaluated the surface topography of four commercially-available aqueous shunts and found a correlation in tissue culture to Tenon's capsule fibroblast adhesion to surface roughness as measured by three-dimensional white-light confocal microscopy (Choritz et al., 2010).

Aqueous shunts are "valved" or "non-valved", depending on whether a flow restriction mechanism limits aqueous humor flow. Non-valved shunts require a temporary restriction of flow by tube ligation or occlusion during surgical implantation. This maneuver allows a fibrovascular capsule to develop around the equatorial plate before aqueous humor outflow begins and reduces the risk of hypotony in the early postoperative period. Valved shunts have flow restrictors that are designed to lessen the likelihood of hypotony before plate encapsulation. Valved shunts do not require temporary flow restriction and offer the potential advantage of immediate postoperative IOP reduction. Table 1 reviews the advantages and disadvantages of commercially-available aqueous shunts (Schwartz et al., 2006).

2. Surgical trends

Medicare data and surveys of glaucoma specialists demonstrate an increase in the utilization of aqueous shunts and a concurrent decline in the popularity of trabeculectomy in recent years (Chen et al., 1997; Joshi et al., 2005; Ramulu et al., 2007). Concern about bleb-related complications, such as bleb leaks, blebitis, and bleb-related endophthalmitis (DeBry et al., 2002), has likely contributed to the expanded use of aqueous shunts as an alternative to trabeculectomy. Aqueous shunts were initially reserved for the treatment of eyes with glaucomas that had poor surgical prognoses with standard filtering surgery even with wound-healing modulation. However, an increasingly positive experience with these devices has prompted their implantation in glaucomas with better surgical prognoses (Jamil and Mills, 2007).

2.1. Medicare utilization data

Ramulu et al. (2007) examined trends in utilization of the most common glaucoma-related laser and surgical treatments for Medicare beneficiaries over the period 1995–2004. The numbers of procedures performed annually were tabulated with Current Procedural Terminology (CPT) codes. Trabeculectomies decreased by 43% and placement of aqueous shunts increased by 184% between 1995 and 2004. Commenting on those trends, Corcoran (2009) noted that in 1995, that there had been 23 times as many trabeculectomies as aqueous shunts, but by 2007 that ratio had changed to only three times more trabeculectomies.

2.2. Surveys of the American Glaucoma Society (AGS)

In late 1995, an anonymous survey of the AGS and Japanese Glaucoma Society memberships was conducted by Chen et al. (1997) to assess patterns of use of antifibrotic agents and aqueous shunts among glaucoma specialists. The survey presented ten clinical situations requiring glaucoma surgical intervention. For each clinical scenario, respondents were asked to estimate the percentage in which they would perform trabeculectomy alone, trabeculectomy with 5-fluorouracil (5-FU), trabeculectomy with MMC, or aqueous shunt implantation. Antifibrotic agents like 5-FU and MMC are routinely used as adjuncts to glaucoma filtering surgery to reduce scarring at the surgical site and increase the likelihood of surgical success. The majority of respondents preferred trabeculectomy with MMC for each of the clinical scenarios. In 2002 Joshi et al. (2005) redistributed the same survey to AGS members. Respondents still favored trabeculectomy with MMC for most clinical situations, but the percentage usage of aqueous shunts substantially increased; specifically, selection of aqueous shunts averaged 17.5% in 1995 and 29.4% in 2002.

3. Surgical results with different implants

Glaucoma surgeons have questioned the superiority of the commercially-available devices with respect to safety and efficacy. Several retrospective studies failed to detect a statistically significant difference of surgical outcomes among different aqueous shunt types (Ayyala et al., 2002; Nassiri et al., 2010; Smith et al., 1995; Syed et al., 2004; Tsai et al., 2003, 2006; Wang et al., 2004). The conclusions of these studies are limited by inherent biases of retrospective investigations. Recent prospective clinical trials have provided higher level medical evidence regarding popular currently utilized aqueous shunts (Barton et al., 2011; Budenz et al., 2011; Nassiri et al., 2010). Table 2 provides a summary of key elements of these randomized clinical trials.

3.1. Ahmed Glaucoma valve implant vs Molteno implant

Nassiri et al. (2010) reported the results of a prospective randomized study that compared the Ahmed glaucoma valve implant (New World Medical, Inc., Rancho Cucamonga, California, USA) and single-plate Molteno implant (Molteno Ophthalmic Limited, Dunedin, New Zealand) in 92 patients with refractory glaucoma. The rate of surgical failure (IOP > 21 mm Hg, IOP ≤ 5 mm Hg, phthisis bulbi, loss of light perception vision, removal of the implant, reoperation for glaucoma, or any devastating intra-operative or postoperative complication) was similar for both treatment groups after 2-year follow-up (16% Molteno group vs 18% Ahmed group). The Molteno group had a greater percentage drop in IOP from baseline at 2 years (49.7% Molteno group vs 41.9% Ahmed group, $p = 0.049$), but the mean number of glaucoma medications

Table 1
Advantages and disadvantages of commercially-available aqueous shunts.

Shunt Type	Commercially-available shunts	Advantages	Disadvantages
Non-valved	Baerveldt glaucoma implant, Molteno implant	Larger surface area of end plate(s) (Baerveldt glaucoma implant and Molteno double-plate implant) provides greater surface area that may increase IOP-reducing efficacy	Delayed functioning until encapsulation of plate occurs Greater risk of hypotony-related complications
Valved	Ahmed glaucoma valve	Allows immediate IOP reduction Valve minimizes risk of hypotony-related complications Ease of implantation	Higher rate of bleb encapsulation Smaller surface area of end plate may decrease IOP-reducing efficacy Valve malfunction can result in hypotony or obstructed outflow

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