Surgical management of Glaucoma: Glaucoma Drainage Implants

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LOLA IDOWU MD
ASSOCIATE PROFESSOR OF OPHTHALMOLOGY
DIRECTOR, GLAUCOMA SERVICES
UNIVERSITY OF MISSISSIPPI MEDICAL CENTER, JACKSON, MS
Also Called

- Aqueous Drainage Devices
- Setons
- Shunts (tube shunts)
- Implants
Introduction

Why Implants?

Trabeculectomies

- are not perfect operations and there is a significant failure rate
- Even with adjunctive antimetabolites inadequate pressure control often occurs in eyes with refractory glaucoma
Why do filters fail?

- Scarring of the internal ostium
- Intrascleral fibrosis
- Episcleral membrane or fibrosis
- Excessive encapsulation or Tenon’s cyst

To “keep the filter open” a variety of foreign materials were tried:
  - First solid filaments as wicks
  - Then hollow tubes as shunts

The open end becomes the “effective sclerostomy”. Scarring occurs around the tube at the entry site and the lumen remained open, maintaining an open connection to the externally located bleb.
### Historical Perspective

<table>
<thead>
<tr>
<th>Period</th>
<th>Description</th>
<th>Materials Used</th>
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<tbody>
<tr>
<td>1907 - 1965</td>
<td>Translimbal Setons</td>
<td>Horsehair - Rollet 1907, Silk, Gold, Tantalum, Plastic, Glass</td>
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<tr>
<td>1906 - 1949</td>
<td>Cyclodialysis cleft implants:</td>
<td>Platinum, Horsehair, Supramid, Polyethylene, Gelatin film, Magnesium foil</td>
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<td>1967 - 1974</td>
<td>Anterior Chamber shunt to a distal site:</td>
<td>A.C. tube to the lacrimal sac, A.C. tube (silicone) to superior temporal vein, A.C. tube (collagen) to intrascleral vortex vein</td>
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Molteno

Late 1960’s

First to attach the anterior tube to a “bleb promoting episcleral device”

- Recognized that for effective filtration it was necessary to maintain a bleb in addition to a fistula
- Attached a tube to an acrylic episcleral plate which worked to maintain a bleb cavity
- The plate and the overlying encapsulation tissue created an aqueous reservoir preventing scarring around the distal end of the tube
Glaucoma Drainage Devices

**Type**

**Valved**
- Ahmed
- Joseph
- Krupin
- Optimed

**Nonvalved**
- Baerveldt
- Molteno
- Shocket

**Episceral Plate**

- Single and double plate
- Encircling band
- Single-plate or encircling band
- Single matrix of conductive resistor
- Single-plate
- Single and double plate
- Encircling band

*Figure 2. Glaucoma implant devices tested, from left to right: Baerveldt Implant, Krupin Eye Valve, OptiMed Glaucoma Pressure Regulator, Joseph Valve, and the Ahmed Glaucoma Valve Implant.*
Molteno Glaucoma Implant

- Non valved
- Longest tract record
- >30 years of clinical experience
- Used world wide
- Seven different models
- Two staged procedure or single staged with temporary tube occlusion
Baerveldt Implant

- Non-valved
- Barium impregnated silicone
- Three models, 2 sizes
  - BAERVELEDT® 250 mm² BG103-250 Implant
  - BAERVELEDT® 350 mm² BG101-350 Implant
  - BAERVELEDT® 350 mm² Pars Plana BG102-350 Implant (with Hoffmann elbow)
- “Wings” that extend under recti muscles
- Increased incidence of strabismus/diplopia
- Added fenestrations to create lower profile
- Largest single quadrant implant, lowest IOP
- Needs temporary tube occlusion
Ahmed Glaucoma Valve Implant

- Valved
- Single plate
- Silicone tube connected to a silicone sheath valve held in a polypropylene silicone body
- Four Models: FP7, FP8, S2, S3.
- Two sizes: Adult and pediatric
- Valve mechanism: 2 thin silicone elastomer membranes which allows 1-way flow
- IOP 6-10mmHg on first day
- High profile
Krupin Implant

- Introduced in 1976, first valved implant
- Originally used as a translimbal device
- Later was attached to a single silicone plate
- Made of silicon and shaped like a disk
- The valve is a simple slit that is designed to open at an IOP of 11mmHg and close at 9mmHg
- No longer commercially available
Schocket Shunt and Joseph Implant:

Anterior chamber tube shunted to an encircling band

**Schocket Shunt**
- Silicone tube and a #20 encircling band
- Can constructed on site - time consuming but materials readily available
- Surgical technique - time consuming, similar to a scleral buckle
- Needs temporary tube occlusion

**Joseph Implant**
- One piece tube and plate implant
- Encircling band
- Valved
- Implantation similar to a Shocket

*FIGURE 1: Joseph and Schocket implants. The Joseph tube contains a longitudinal slit for aqueous drainage near its attachment to the outer surface of the silicone band. The Schocket tube inserts into a groove on the inner surface of the encircling band.*
Mechanism of Action

- Capsule formed around plate forming bleb by fibroblastic activity
- Aqueous flows through the tube to the encapsulated bleb, diffuses across the capsule wall and is eventually picked up by capillaries in the external vascular layer and drained from the orbit
- The resistance to outflow is in the capsule wall
- Aqueous drainage proportional to bleb size and inversely proportional to capsule thickness
Hypertensive Phase

- Several weeks after initiation of flow
- Secondary to inflammation in tissues around the bleb induced by the onset of aqueous flow
  - Is less prevalent in non-valved implants where aqueous access to the plate is delayed
- It slowly resolves over several months if anticipated and properly managed
- Often requires the temporary use of antiglaucoma medications- start as soon as possible.
  - High IOPs/intrableb pressure induce cytokines which increase fibroblastic activity leading to thicker capsules
Glaucoma Drainage Implant: How well do they work?
TVT study: Design

- Multicenter randomized clinical trial comparing the safety and efficacy of tube shunt surgery to trabeculectomy with mitomycin C (MMC) in patients with previous ocular surgery
- 212 patients (17 clinical centers)
- Prior cataract and/or glaucoma surgery
- Randomly assigned to Baerveldt 350-mm² glaucoma implant or trabeculectomy with MMC (0.4 mg/mL for 4 minutes)
TVT study: Results

- Both procedures produced a sustained IOP reduction to the low teens throughout 5 years of follow-up.
- Tube shunt surgery required more glaucoma medications than trabeculectomy with MMC during the first 2 years, but use of drops equalized with longer follow-up.
- Trabeculectomy with MMC had a higher failure rate.
- Trabeculectomy with MMC had a higher rate of reoperation.
- Vision loss occurred at a similar rate with both procedures.
- Early postoperative complications developed more frequently after trabeculectomy with MMC relative to tube shunt surgery, but both procedures had similar rates of late postoperative and serious complications.
ABC and AVB studies: Design

- Multicenter randomized clinical trials comparing outcomes of the Ahmed Glaucoma Valve and Baerveldt glaucoma implant
- Patients with refractory glaucoma requiring tube shunt surgery were randomized to receive an Ahmed implant (model FP-7) or a Baerveldt 350-mm² implant
  - ABC Study - 276 patients (16 clinical centers)
  - AVB Study - 238 patients (7 clinical centers)

- Outcome measures
  - visual acuity (VA)
  - IOP
  - surgical complications
  - use of adjunctive medical therapy
  - failure (IOP>21 mm Hg or not reduced >20% from baseline, IOP<5 mm Hg
  - additional glaucoma surgery
  - removal of the shunt, or loss of light perception vision
ABC and AVB studies: Results

3 years of follow-up - similar results

- Ahmed implantation produced a greater IOP reduction in immediate postoperative period, but Baerveldt implantation resulted lower IOPs long term.
- Fewer glaucoma medications were required long term after placement of a Baerveldt implant compared with an Ahmed implant.
- The Baerveldt implant demonstrated a higher rate of surgical success relative to the Ahmed implant.
- Serious postoperative complications occurred more frequently after Baerveldt implantation than Ahmed implantation. (43% Ahmed group vs. 58% Baerveldt, p=0.016)
- Vision loss occurred at a similar rate with the Ahmed and Baerveldt implants.
Clinical considerations: Indications

Historically tube shunt surgery reserved for:

- Conjunctival scarring
- Neovascular glaucoma
- Post penetrating keratoplasty
- Refractory infantile glaucoma (post trabeculotomy)
- Aphakia
- Anterior chamber IOL
- Uveitic glaucoma
- Epithelial downgrowth
- Refractory secondary glaucomas
Clinical considerations: Indications

- Currently many more surgeons are performing tube shunt surgery earlier in disease course, some even as the primary procedure
  - Age
  - Conjunctiva (healthy or not)
  - Co-morbidities
  - Social issues
Clinical considerations: Contraindications

- Active Rubeosis (relative)
- Active Fibrovascularization (relative)
- Active Severe Uveitis (relative)
- Tight orbit
- Connective tissue disease (presence of scleral disease)
- No Light Perception
- Technically Impossible

Red hot eye
Clinical considerations: Implant Choice

- Single or two staged
- Single or multiple quadrant surgery: try to see the future
- Encircling element or plate
- Valved vs. nonvalved
- Need for temporary tube occlusion, ligature sutures or intubation sutures
- Scleral flap or donor cornea/sclera/pericardium
- Experience
Surgical Technique

- Careful conjunctival dissection
- Open and expose quadrant
- Position and secure the episcleral plate
Occlude the tube (if non valved)
Insert tube into the anterior chamber
Patch graft
Close conjunctiva
Complications: Intraoperative

- Bleeding
- Conjunctival buttonhole
- Scleral perforation
- Tube placement too posterior
- Tube misdirection in anterior chamber
- Tube length (too long or short)
- Flat anterior chamber
- Suprachoroidal hemorrhage
Complications: Early post-op

(commonly due to hypotony)

- Large or kissing choroidal detachments
- Suprachoroidal hemorrhage
- Flat anterior chamber
- Corneal decompensation
- Cataract
- Tube corneal touch
- Maculopathy
- Disc swelling
- Tube lens touch
- Tube blockage: iris, lens, vitreous, fibrovascular membrane, blood
Complications: Later

- Tube retraction
- Strabismus/diplopia
- Corneal decompensation
- Corneal graft failure
- Corneal epitheliopathy
- Cataract
- Uveitis exacerbation
- Iris neovascularization
- Maculopathy
- Disc swelling
Complications: Later

- Tube erosion through sclera and conjunctiva
- External tube blockage
- Recurrent hyphema
- Excessive encapsulation causing increased IOP
- Endophthalmitis
- Sterile hypopyon
- Phthisis
- Implant extrusion
Summary

- Glaucoma drainage implant surgery is a proven effective option for the treatment of refractory glaucoma.
- Newer implant designs and the surgical technique have decreased the incidence and severity of post operative complications while increasing efficacy.
References


https://www.molteno.com/pages/13/Product


References


Thank you