Glycerol preserved cornea vs pericardium:
Outcomes of glaucoma drainage device surgery

C.A. Curcio, PhD; E. Wigton, MD; J. Swanner, MD; W. Joiner, MD; A. Feldman, MS; G. McGwin, MA, PhD; C. Huisingh, MPH; C.A. Girkin, MD, MSPH

Outcomes of shunt tube coverage with glycerol preserved cornea versus pericardium

Glaucoma drainage implant surgery can be complicated by patch graft erosion

- Glaucoma drainage implants (GDIs) are used in difficult cases, often as revisions to primary procedures
- Risks: corneal decompensation, tube exposure, tube migration, infection
- Patch graft thinning is a delayed complication
  - Exposure of the subconjunctival portion of the shunt tube increases risk for endophthalmitis
- Surgical goals of revision with patch graft: re-cover exposed part of the GDI, prevent repeat exposure

GDI patch graft materials include cornea

- Many biomaterials available for grafts
  - Glycerol-preserved sclera (1987), pericardium, amniotic membrane, fascia lata, dura, cornea
- Processed pericardium (Tutoplast® - IOP, Inc) popular due to accessibility, long shelf life, price
- Clear cornea is favorable, because it facilitates postoperative lysis suture by laser
- Glycerol preserved cornea (GlycerolPlus Cornea™; Global Sight Network) with 5-year shelf life
Glycerol preserved cornea

- Glycerol
  - Hygroscopic, dehydrating, de-cellularizing agent
  - Acellular cornea serves as scaffold for procedures not requiring viable cells
- J.H. King studies (1956-1984) added molecular sieves to further dehydrate glycerol
- Formulation for GDI patch grafts by Florida Lions Eye Bank for Bascom Palmer surgeons

Purpose of current study

- Retrospective comparison of tube erosion incidence associated with the use of pericardium or glycerol preserved cornea to cover primary GDIs

Retrospective study design

- Patients with GDI by 1 of 3 surgeons 9/1/2008 - 7/31/2010
- University of Alabama at Birmingham Glaucoma Service
- Ahmed or Baerveldt GDI in superotemporal quadrant
- Pericardium or cornea at surgeon’s discretion
- Exclusion: <18 yr old, 2nd GDI in same eye, inferonasal placement
- 1° outcome: exposure event
- A subset analysis reduced inter-surgeon variability

Statistical analysis

- Demographic and clinical characteristics, pericardium group vs cornea group
- Student’s t-test (means), Wilcoxon rank sum test (medians)
- Categorical variables: chi-square test or Fisher’s exact for small sample
- Hazard ratios (HR) and associated 95% confidence intervals (CIs) using Cox proportional hazards regression, adjusted for type of glaucoma
Surgical methods and clinical follow-up

- GDI implanted using standard of care methods
- Pericardium: single or double thickness, surgeon’s discretion
- Cornea preparation
  - Rehydrate (gentamicin in BSS)
  - De-epithelialize
  - Split horizontally with a blade
- ~1/2 cornea covered a GDI tube
- Postoperative drops: quinolone antibiotic and atropine for 1 wk, tapering dose of prednisolone acetate 1% for 8-12 wk
- GDI were inspected for evidence of erosion through the conjunctiva at follow-up
- All grafts were clear at 4 wk

Patient demographics

- 262 consecutive glaucoma patients were eligible
- 101 patients with pericardium, 161 with cornea
- Age, sex, race, and eye (OS vs OD) were comparable between groups
- Relative to the cornea group, patients in the pericardium group were more likely to have
  - Primary open angle glaucoma (48.5% vs. 36.0%, p=0.0453)
  - Shorter follow-up (331 days vs 440 days, p=0.0106)
  - Shorter time to event (surgery date to exposure date) (252 vs 440 day, p=0.0017)

Risk of erosion is 83% lower in cornea group

Table 2. Hazard ratios and 95% confidence intervals for erosion event

<table>
<thead>
<tr>
<th></th>
<th>% with erosion event</th>
<th>HR (95% CI)1</th>
<th>HR (95% CI)1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>98.1</td>
<td>0.17 (0.05-0.63)</td>
</tr>
<tr>
<td>Corneal</td>
<td>No</td>
<td>91.1</td>
<td>Referent</td>
</tr>
<tr>
<td>Pericardium</td>
<td>8.9</td>
<td>Referent</td>
<td>Referent</td>
</tr>
</tbody>
</table>

1: Adjusted for type of glaucoma

Fewer erosions requiring GDI revisions in cornea group

- 3/161 patients with GDI initially covered with cornea experienced erosion
  - All re-covered with cornea, no additional exposures
- 9/101 patients with GDI initially covered with pericardium experienced erosion
  - 4 were re-covered with pericardium
  - 2 second exposures (3 and 6 mo)
Longer time to erosion in cornea group

- Greatest difference in graft survival occurred in the first 100 days post-operatively
- Uniform failure rate in the pericardium group to ~300 days post-op, then levels off

Sub-analysis for between-surgeon exposure rates

- Before 8/2008, all three surgeons used pericardium for GDI; Surgeon 2 switched
- Analysis including 2006-2008: no significant difference in the exposure rate for individual surgeon (p=0.7611)

First to compare cornea and pericardium as a 1° means of GDI coverage

- Consistent with retrospective reports of pericardium thinning with and without erosion
  - Smith 2002 - 6/16 eyes, ≥24 mo; shorter time to erosion than sclera
  - Raviv 1998 – 5/44 eyes, ≤10.2 mo
  - Lankaranian 2008 – 5/84 eyes, mean 18.2 mo
- No evidence for differences between GDI types
- Longer follow-up needed to witness corneal erosions

Factors underlying risk for exposure

- Risk factors are black race, diabetes mellitus, numerous glaucoma medications, a history of multiple glaucoma laser procedures, and combination of an initial GDI with another surgery (Huddleston 2011)
- Factors contributing to patch graft failure may include mechanical or immune-mediated process
- Compared to looser, multi-directional structure of pericardium, the dense, regular collagenous structure of cornea may help prevent mechanical breakdown of the tissue (Singh 2008)
Limitations of this study

• Retrospective design
• Multiple time periods to assess between-surgeon variability
• Pericardium included both single and double thickness
• Qualitative – patch thinning may be quantifiable with optical coherence tomography

Summary

• Tube exposures, while uncommon, can be devastating to the eye
• Multiple materials have been used to cover shunts
• Compared to pericardium, glycerol preserved cornea provides fewer exposures and a longer time to exposure
  – Cosmetic and functional advantages
  – 5 yr shelf life
  – Affordable cost for initial implant
  – Reduced future costs due to fewer revisions

Implications of results for eye banking

• Glaucoma is a widely prevalent cause of vision loss for which more GDI surgery is expected
  – >16,000 Medicare-reimbursed procedures in 2007
  – Screening initiatives in susceptible populations, overall aging, data from clinical trials (Tube vs Trab, ABC) expands range of suitable patients
• An emerging medical need which eye banks can help fill using medically eligible tissues not suitable for optical keratoplasty (9,471 in 2010)

Thank you for your attention!