Outcomes of Shunt Tube Coverage With Glycerol Preserved Cornea Versus Pericardium

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Abstract: Pericardium is a biomaterial widely used for covering the outflow tubes of glaucoma drainage devices. Recently, glycerol preserved cornea has been introduced as an alternative that offers durability and improved cosmesis because of its clarity. We retrospectively reviewed 262 patients in the University of Alabama Birmingham Glaucoma Service who underwent shunt procedures using either cornea tissue or pericardium to cover the tube. The primary outcome measure was the number of erosions of the covering material. Nine out of 101 (8.9%) patients in the pericardium covered group experienced an erosion compared with 3 out of 161 (1.9%) in the cornea covered group. A significant difference was reached with $P = 0.0125$. Median follow-up was 440 days for the cornea group and 331 days for the pericardium group. The type of glaucoma (primary open-angle glaucoma vs. secondary glaucoma) was not associated with the risk of erosion (odds ratio, 0.501; 95% confidence interval, 0.204-1.234). The median time to exposure was 252 days in the pericardium group and 440 days in the cornea group ($P = 0.0017$).

Key Words: glaucoma drainage implant, patch graft, cornea, pericardium, shunt tube, exposure

Glaucoma drainage implants (GDIs) have been increasingly used to treat difficult glaucoma cases, but carry the risk of corneal decompensation, tube exposure, tube migration, and infection, among other complications. The most frequent shunt-specific delayed complication is patch graft thinning with subsequent exposure of the subconjunctival portion of the shunt tube. It is a significant risk factor for endophthalmitis and revision with patch graft material has been recommended. Pericardial or glycerol-preserved corneal tissue as a primary covering material. Nine out of 101 patients in the pericardium covered group experienced an erosion compared with 3 out of 161 in the cornea covered group. A significant difference was reached with $P = 0.0125$. Median follow-up was 440 days for the cornea group and 331 days for the pericardium group. The type of glaucoma (primary open-angle glaucoma vs. secondary glaucoma) was not associated with the risk of erosion (odds ratio, 0.501; 95% confidence interval, 0.204-1.234). The median time to exposure was 252 days in the pericardium group and 440 days in the cornea group ($P = 0.0017$).

Several patch graft materials have been used. A glycerin-preserved free scleral graft was first described in 1987 as a novel material to cover shunt tubes. Since that time, multiple additional patch graft materials have been described, including pericardium, amniotic membrane, fascia lata, dura, and corneal tissue. Processed pericardial tissue (Tutoplast pericardium-IOP Inc., Costa Mesa, CA) is a commonly used patch graft material given its accessibility and long shelf life. More recently, glycerol preserved corneal tissue (GlycerolPlus Cornea; Global Sight Network, Birmingham, AL) has become available for shunt tube coverage, offering a similar 5-year shelf life. Use of cornea preserved in intermediate-term medium was first described in 1996 by Rojanapongpun and Ritch as a means to facilitate postoperative laser suture lysis. Others have also described the use of cornea, cryoprotected in glycerol and frozen, as a patch graft material to recover a GDI after an initial exposure. The purpose of this study is to retrospectively compare the incidence of erosion associated with the use of pericardial or glycerol-preserved corneal tissue as a primary means of covering GDIs.

MATERIALS AND METHODS

Institutional review board approval was obtained for this retrospective medical record review. Records of patients who underwent shunt tube placement by 1 of 3 glaucoma surgeons between August 2008 and August 2010 were reviewed from the University of Alabama Birmingham Glaucoma Service. Either an Ahmed (New World Medical Inc., Rancho Cucamonga, CA) or Baerveldt (Abbott Medical Optics Inc., Santa Ana, CA) shunt were placed in a similar fashion in the superotemporal quadrant and the tube was covered with pericardium or cornea at the discretion of the surgeon. The primary outcome was an exposure event. Eligibility criteria included patients 18 years and older undergoing initial shunt placement in the superotemporal quadrant. Exclusion criteria included patients under 18 years old, second shunt placement in the same eye, or inferonasal shunt placement. A subset analysis was carried out for shunts placed between August 2006 through July 2008 to reduce intersurgeon variability with regard to exposure rates.

In all cases, a fornix-based conjunctival peritomy was carried out and dissected posteriorly in the superotemporal quadrant. The shunt plate was secured to the sclera using either nylon or Vicryl suture. Placement under the respective superior and lateral rectus muscles was verified for Baerveldt shunts. The tube was trimmed to an appropriate length and inserted into the anterior chamber through a scleral fistula created with a 23-G needle. The patch material of choice was secured to the sclera over the extrasceral portion of the tube using interrupted 8-0 Vicryl sutures. The conjunctiva was reaproximated at the limbus with Vicryl suture taking care to completely cover the patch graft material. Pericardial tissue was used in either single or double thickness based on the appearance of the material at the time of surgery. Corneal tissue, provided as a full-thickness whole cornea, was rehydrated in a solution (0.75 mL) of gentamicin antibiotic (40 mg/mL) mixed.
with 30 mL of balanced salt solution, deep epithelialized and cut into split thickness with a #69 blade before placement. Approximately half of the corneal tissue was used to adequately cover the tube (Fig. 1). Postoperative drops consisted of a quinolone antibiotic and atropine for 1 week and a tapering dose of prednisolone acetate 1% (Allergan Inc., Irvine, CA) for 8 to 12 weeks. At follow-up examinations, the tube was carefully inspected for evidence of erosion through the conjunctiva.

Demographic and clinical characteristics were compared between patients with shunt tubes covered with pericardium tissue and those with shunt tubes covered with corneal tissue. The difference in means and medians between groups was assessed using the Student t test and the Wilcoxon rank-sum test, respectively. Categorical variables were examined by a χ2 test (the Fisher exact when expected cell counts were <5). Hazard ratios and associated 95% confidence intervals compared the erosion rate of the pericardium group with that of the corneal tissue group using Cox proportional hazards regression, adjusted for type of glaucoma.

RESULTS

There were 262 consecutive glaucoma patients who met eligibility criteria that were enrolled in the study. Of these, 101 patients had shunt tubes covered with pericardium and 161 with corneal tissue. Age, sex, race, and eye (right vs. left) were comparable between groups (Table 1). The patients in the pericardium group were more likely to report having primary open-angle glaucoma than those in the corneal group (48.5% vs. 36.0%, \(P = 0.0453\)). Patients in the pericardium group had a shorter follow-up time (surgery date to last visit) compared with patients in the corneal group (331 vs. 440 d, \(P = 0.0106\)) and a shorter time to surgery date to last visit; 252 vs. 440 d, \(P = 0.0017\).

The risk of erosion was 83% lower in the corneal group compared with the pericardium group (hazard ratios, 0.17; 95% confidence interval, 0.046-0.628; Table 2). Of the 3 patients whose shunt tubes were initially covered with corneal tissue and experienced erosion, all were re-covered with corneal tissue and have had no additional exposures. Of the 9 patients whose shunt tubes were initially covered with pericardium, 4 were re-covered with pericardium, and 2 out of those 4 experienced a second exposure event at 3 and 6 months, respectively. The Kaplan-Meier plot supports the finding of increased erosion rate among the pericardium group (Fig. 2). The greatest separation in survival of the patch graft material between groups occurred in the corneal tissue. Six of 16 eyes in the pericardium group (37.5%) experienced erosion, whereas no patients in the corneal group experienced erosion. Therefore, patients in the pericardium group with that of the corneal tissue group using Cox proportional hazards regression, adjusted for type of glaucoma.

DISCUSSION

The current study demonstrated a lower rate of erosion with GDI coverage with cornea compared with pericardium. To our knowledge, this is the first study to directly compare corneal tissue to pericardium as a primary means of GDI coverage. Previous studies have directly compared pericardium to other patch materials but not corneal tissue. Smith and colleagues retrospectively reviewed 64 eyes that underwent shunt tube surgery using donor dura mater (18 eyes), or pericardium (23 eyes) as a patch graft material. Six of 16 eyes in the pericardium group...
experienced patch thinning such that the suture securing the tube was visible through the conjunctiva, but no erosions developed. However, patch thinning developed at the same rate in the pericardium and sclera groups (26%) despite twice the length of follow-up in the sclera group (33 vs. 66 mo).

In another review, Raviv et al found that 5 of 44 eyes with pericardium patch grafts experienced thinning but no exposure with an average follow-up of 10.2 months. The current literature does not support different rates of erosion between glaucoma devices. The Ahmed Baerveldt Comparison study showed no significant difference in the incidence of erosion, with 2 of 249 (1%) patients with follow-up at 1 year experiencing tube exposure. Furthermore, a large meta-analysis of 38 studies by Stewart and colleagues demonstrated a 2.0 ± 2.6% incidence of shunt tube exposure with an average follow-up of 26.1 ± 3.3 months. There was no difference in rates of exposure with Ahmed, Baerveldt, or Molteno shunt tubes, though a multivariate analysis showed length of follow-up to be a risk factor for exposure (P = 0.001). In our study, the cornea group had a longer follow-up period than the pericardium group (440 vs. 331 d). However, the average follow-up period for the corneal group was identical to the average time to exposure, indicating that a longer follow-up period may be required to determine if corneal tissue melts at a similar rate as others but at a longer time to initial exposure event.

Recently, black race, diabetes mellitus, numerous glaucoma medications before shunt implantation, a history of multiple glaucoma laser procedures, and combination of an initial aqueous shunt implantation with another surgery were found to be associated with a worse outcome after exposure repair. The specific factors contributing to patch graft material melt are currently unknown but are thought to be due to either a mechanical or immune-mediated process. Compared with the looser, multidirectional structure of pericardium, the dense, regular collagenous structure of cornea may help prevent mechanical breakdown of the tissue.

The current study has several limitations. Because 2 of 3 surgeons in this study began using glycerol preserved corneal tissue exclusively in 2008 when it became available, multiple surgeons using dissimilar patch graft materials were reviewed. We attempted to control for this by analyzing a similar time period before the study period when all surgeons used the same patch material. This intersurgeon analysis indicates there was no difference in rate of tube erosion when all surgeons were using pericardial tissue so a surgeon specific difference is unlikely. Furthermore, pericardium was used with single thickness and a comparison with double layered tissue is not possible. Lankaranian and colleagues have shown that double thickness pericardium can also reduce GDI exposure. In their retrospective series, 5 of 31 (16%) GDIs covered with single thickness pericardium compared with 0 of 59 GDIs covered with double thickness pericardium developed erosion.

More quantitative measurement of the thickness of the patch graft material over time using a modality such as optical coherence tomography may also provide additional long-term data regarding thinning or eventual exposure.

In conclusion, this study indicates that GDI coverage with glycerol preserved corneal tissue compared with pericardium may significantly decrease the rate of an exposure event.

<table>
<thead>
<tr>
<th>% With Erosion</th>
<th>HR (95% CI)*</th>
<th>HR (95% CI)†</th>
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<tr>
<td>Yes</td>
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<tr>
<td>No</td>
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<td>0.15 (0.04-0.58)</td>
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<td>Referent</td>
<td>91.1</td>
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*Unadjusted.
†Adjusted for type of glaucoma.

**TABLE 2.** Hazard ratios (HR) and 95% confidence intervals (CI) for erosion event.

**FIGURE 2.** Kaplan-Meier curve demonstrating patch graft survival as a function of time.
event and provide a longer time to initial exposure event. Functional advantages, such as the ability to perform laser suture lysis, and improved cosmesis are further advantages in using corneal tissue.

REFERENCES


