Glycerin-preserved Human-donor Corneoscleral Patch Grafts for Glaucoma Drainage Devices

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Precis: Glycerin-preserved, human-donor, corneoscleral patch grafts are effective and safe for glaucoma drainage device (GDD) implantation, and they are comparable to previously reported materials. It can be preserved with the sterile technique for up to 12 months.

Purpose: To evaluate the efficacy and safety of glycerin-preserved human donor corneoscleral tissue as the patch graft for GDD implantation.

Patients and Methods: This was a retrospective noncomparative study from the medical records of 102 eyes from 102 glaucoma patients who underwent GDD implantation by or under supervision of a single surgeon (N.K.) at the Department of Ophthalmology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand between January 2006 and December 2016. The glycerin-preserved human-donor corneoscleral tissue was used as the patch graft to cover the tube portion of GDD over the sclera. The primary outcome measure was the occurrence of patch graft-related complications.

Results: There were 64 males and 38 females with the mean age of 52.8±18.5 years. The underlying diseases included failed filtration surgery with primary open-angle glaucoma 32 eyes and primary angle-closure glaucoma 15 eyes, congenital glaucoma 3 eyes and secondary glaucoma 52 eyes. The mean of ocular surgeries before GDD implantation was 2.3±1.1. Patch graft–related complications included tube exposure in 4 eyes (3.9%) and wound leakage in 4 eyes (3.9%). Eyes with tube exposure underwent regrafting 3 eyes and tube reposition 1 eye. Eyes with wound leaking resolved spontaneously 2 eyes and underwent conjunctival resuturing 2 eyes. The 5-year survival rate of the corneoscleral graft was 95.7%. There was no recurrence of graft-related complications after surgical procedure to correct the complications. Postoperatively, the mean of intraocular pressure (IOP) and antiglaucoma medications decreased significantly from 27.4±9.8 mm Hg and 3.8±0.93 to 13.8±6.4 mm Hg (P<0.001) and 1.6±1.5 (P<0.001) at the last visit, respectively. The mean follow-up time was 59.9 months (range, 1 to 144.7 mo).

Conclusion: The glycerin-preserved human-donor corneoscleral tissue using as the patch graft was a safe alternative for GDD tube coverage. The patch graft–related complications was comparable to other materials.

Key Words: glaucoma drainage device, glaucoma surgery, glaucoma, patch graft, tube exposure

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BACKGROUND

Glaucoma drainage device (GDD) implantation has become more popular for the surgical management of primary and refractory glaucomas.1–3 GDD implantation outcomes, which are the reduction in intraocular pressure (IOP) and a lower rate of early postoperative complications, are comparable to those of trabeculectomy, which is currently the gold standard surgical treatment.2,3 Patch graft materials are commonly used in GDD implantation to cover the anterior portion of the tube before it enters the eye.4 Patch grafts are used to prevent tube-related complications, which have been reported as common complications related to the GDD procedure. Studies have shown that tube erosion occurs in 1% to 5% cases of GDD implantation at the 5-year follow-up.5–7 The reported patch graft materials include the human-donor sclera, cornea, dura mater, sclera, and bovine pericardium.4–10 GDD implantation in Siriraj Hospital has been performed using a glycerin-preserved human-donor corneoscleral graft for over 10 years. The corneoscleral rim was obtained from the fresh, human-donor corneal button leftover in Optisol GS after the clear corneal graft was used for penetrating keratoplasty. It was preserved in glycerin using the sterile technique and kept in the medical refrigerator. The idea of using the corneoscleral graft was motivated by its advantages of cost-effectiveness, cosmetic appearance, and efficacy over the conventional heterologous human preserved scleral graft.

This study was conducted to review the long-term efficacy and safety of glycerin-preserved human-donor corneoscleral tissues as patch grafts for GDD implantation.

PATIENTS AND METHODS

This retrospective, noncomparative study was conducted at the Department of Ophthalmology, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand. The medical records of patients who underwent GDD implantation between January 2006 and December 2016 were reviewed. The study protocol was approved by the Siriraj Institutional Review Board, Faculty of Medicine, Siriraj Hospital, Mahidol University. This study complied with all of the principles set forth in the Declaration of Helsinki (1964) and its subsequent amendments. The inclusion criteria were glaucoma patients who had GDD implantation with all of the principles set forth in the Declaration of Helsinki (1964) and its subsequent amendments. The inclusion criteria were glaucoma patients who had GDD implantation surgery with a fornix-based conjunctival flap technique using glycerin-preserved human-donor corneoscleral graft. The procedure was carried out by or under the supervision of a single surgeon (N.K.). Exclusion criteria...
were glaucoma patients who underwent GDD implantation surgery with other methods. Glycerin-preserved human donor corneoscleral tissue was used as the patch graft material. The corneoscleral rim was the remaining tissue of the heterologous human-donor corneal button, obtained from the International Eye Bank of Thailand after the clear corneal graft was used for penetrating keratoplasty. It was preserved in glycerin using the sterile technique and kept in the medical refrigerator for no longer than 12 months.

**Corneoscleral Graft Preparation and Preservation**

After the donor corneal button was removed from the transporting media (Optisol GS), the donor central clear cornea was excised for keratoplasty. The remaining corneoscleral rim was placed in a 10-mL sterile container containing 5 mL of 95% sterile glycerin. The specimen container was closed, sealed, and stored under refrigeration at 4 to 8°C for no longer than 12 months. When needed for GDD implantation, the container was opened under sterile conditions, and the corneoscleral rim in glycerin was decanted. The corneoscleral rim was rinsed with a balanced salt solution to remove the glycerin, and it was placed in a gentamicin solution (80 mg in balanced salt solution 10 mL) for 10 to 15 minutes.

**Surgical Technique**

Following retrobulbar anesthesia with 2% marcaine and 1% xilocaine without adrenaline (1:1), patients were prepped and draped using the usual sterile technique. A fornix-based conjunctival peritomy was performed in the superotemporal quadrant for 4 clock’s hours. After the superior rectus and lateral rectus muscles were identified, the 350 mm² Baerveldt (BG 101-350) GDD (Johnson and Johnson, Santa Ana, CA) was implanted under them. In most cases, the tubes were inserted into the anterior chamber. In eyes with high peripheral anterior synchiae or pseudophakia with deep sulci, the tubes were inserted into the sulcus posterior to the iris. A 23-G needle was advanced into the eye through the sclera. The tube was shortened, beveled up, lined in an S curve, and inserted 1.5 to 3 mm posterior to the limbus to the iris. A 23-G needle was advanced into the eye through the sclera. The tube was shortened, beveled up, lined in an S curve, and inserted 1.5 to 3 mm posterior to the limbus to the eye at ~12 clock’s hours. A 9.0 nylon suture was used to secure the plate and the tube onto the sclera. The corneoscleral rim was cut to 6×8 mm² and soaked in a gentamicin solution (40 mg/mL) for 10 to 15 minutes.

**RESULTS**

A total of 102 eyes from 102 consecutive patients were included in the study. There were 64 men and 38 women with a mean age of 52.8 ± 18.5 years. The common underlying causes included failed filtration surgery with primary open angle glaucoma 32 eyes and with primary angle-closure glaucoma 15 eyes, congenital glaucoma 3 eyes and secondary glaucoma 52 eyes. The mean number of ocular surgeries before GDD implantation was 2.3 ± 1.1. The tube was inserted into the anterior chamber in 75 eyes. The eye with high peripheral anterior synchiae or pseudophakia with deep sulci, the tubes were inserted into the sulcus posterior to the iris. A 23-G needle was advanced into the eye through the sclera. The tube was shortened, beveled up, lined in an S curve, and inserted 1.5 to 3 mm posterior to the limbus to the eye at ~12 clock’s hours. A 9.0 nylon suture was used to secure the plate and the tube onto the sclera. The corneoscleral rim was cut to

![FIGURE 1](https://example.com/figure1.png)

**FIGURE 1.** The Kaplan-Meier survival curve summarizes patch graft survival. Corneoscleral graft failure was defined as tube exposure. The 5-year survival rate of patch graft was 95.7%. Figure 1 can be viewed in color online at www.glaucomajournal.com.
the corneoscleral graft was 95.7%. Eyes with wound leaking resolved spontaneously in 2 eyes, and the conjunctiva was resutured in 2 eyes. There was no recurrence of graft-related complications after the surgical procedure to correct the complication. The overall postoperative complications, both related and unrelated to the corneoscleral graft, are summarized in Supplemental Table 2 (Supplemental Digital Content 1, http://links.lww.com/IJG/A449). The leading complications unrelated to the patch graft were ocular hypotony in 20 eyes (19.6%), corneal decompensation in 10 eyes (9.8%), choroidal detachment 9 eyes (8.8%), and cataract 7 eyes (6.8%). Among 10 eyes with corneal decompensation, 1 eye had preexisting corneal decompensation due to complicated cataract surgery and subsequent multiple ocular surgeries. Two eyes developed endophthalmitis ~2 and 3 years after implantation without any evidence of external causes. One of these was HIV positive. Both eyes finally underwent enucleation. The mean follow-up period was 59.9 months (range, 1 to 144.7 mo) (Supplemental Table 3, Supplemental Digital Content 1, http://links.lww.com/IJG/A449).

DISCUSSION

This study demonstrates that glycerin-preserved human-donor corneoscleral tissue is safe and effective as a patch graft for GDD implantation. As GDD implantation has been used globally, the prevention of complications is of concern. The erosion of the patch graft, which can lead to exposure of the device in GDD surgery, has been reported as one of the major postoperative complications that require surgical intervention for correcting that.10 The eyes with tube exposure could increase the risk of infection, the dysfunction of the GDD implantation, and repeated conjunctival erosions.11,12 Various surgical methods and materials have been used to prevent tube erosion. The tube can be inserted under a partial-thickness scleral flap, as a surgical technique, to get it covered. On the other hand, creating a partial-thickness scleral flap can be surgically challenging, especially for cases with thin scleras or a history of multiple previous surgeries. The use of the glycerin-preserved donor sclera was first reported in the 1980s for covering the tube of GDDs.4 Many materials have been used as GDD-covering grafts, including the autologous sclera,13 preserved cornea,14,15 preserved sclera,16 pericardium,17 fascia lata,18 dura mater,19 amniotic membranes,20,21 buccal mucous membrane,22 and recently the fresh, heterologous human-donor corneoscleral rim.23 The use of these materials can reduce the rate of tube erosion. Currently, the heterologous human-donor sclera is usually used after keratoplasty because it is cost-effective and biocompatible.23,24 The second commonly used material is bovine pericardium, which has a better shelf life and greater availability; however, it is more expensive than the other materials.17,25,26 We report the use of glycerin-preserved human-donor corneoscleral tissue obtained from the fresh, human-donor corneal button left after the clear corneal graft was used for penetrating keratoplasty. It was preserved in glycerin using the sterile technique and kept in a medical refrigerator. The idea of using the corneoscleral graft was motivated by its advantages of cost-effectiveness, cosmetic appearance, and efficacy over the conventional heterologous human preserved scleral graft. Our study used glycerin-preserved corneoscleral grafts instead of fresh corneoscleral grafts because they can be preserved longer, without increasing the risk of bacterial reactivation.10,11 With a human-donor scleral patch graft, the incidence of implant erosion has been estimated as ~1% per year.6,24,27,28 In a large meta-analysis, the incidence of tube exposure was determined to be ~2.0 ± 2.6% after an average follow-up of 26.1 ± 3.3 months.29 The incidence of tube erosion after using the bovine pericardium as a patch graft varied from 2.0% to 8.9%,6,12,30,31 The incidence of tube exposure can be reduced by using a double layer of bovine pericardium.17 The reported rate of tube erosion using human donor sclera as a patch graft was 3.18% to 26% with a mean follow-up period of 6 to 24 months.32,27 Tsoukanas et al23 reported a 1.6% incidence of tube or plate erosion using fresh, human-donor corneoscleral rim as a patch graft after a follow-up of 18.2 ± 15.4 months. In our study, the incidence of tube exposure was 3.9% after a mean follow-up of 59.9 months. The higher incidence of tube exposure in our study compared with the previous study may be due to the significantly longer follow-up period in our study. The average period from surgery to tube exposure has been reported to be between 23 and 31 months.17,27 In our study, tube exposure occurred after a mean period of 11.3 months (range, 0.25 to 24 months), which was sooner than in previous reports. This incidence may be related to early wound leakage and conjunctival retraction. The mechanism for patch graft melting has been suspected to involve immune-mediated inflammation, and excessive tension which can be defined as the mechanical friction of tissues, decreased perfusion, and ischemic conjunctiva.24,27,32 We hypothesized that all 4 cases of patch graft melting in our series may have been due to mechanical friction resulting in conjunctival retraction, graft exposure, and melting. Immediate intervention is required in cases of tube erosion. We removed the melting patch graft, repositioned the tube more posteriorly, and fixed the tube in a flat position over the underlying sclera to reduce mechanical friction, followed by a regrafting with the new glycerin-preserved corneoscleral tissue. There was no recurrence of tube exposure or subsequent intraocular infection in any of the cases. The overall rate of postoperative complications in our study was similar to that in several reports.7,33 The most common complication found in our study was ocular hypotony (19.6%) which was comparable to the observation from previous studies (36.6% within 6 mo and 9.7% thereafter).34 However, our research did not record the time ocular hypotony occurred. Among the ocular hypotonic eyes, 9 developed choroidal detachment. Most cases of ocular hypotony resolved spontaneously; 4 eyes had tube ligation and 4 eyes underwent anterior chamber reformation with a viscoelastic substance. Eyes with corneal decompensation were scheduled for penetrating keratoplasty. The eyes with tube occlusion or tubes touching the cornea underwent tube repositioning. In 2 eyes with chronic endophthalmitis, we could not find any relationship between the patch graft and the late endophthalmitis. Although we included eyes with neovascular glaucoma, the overall incidence of hyphema was only 2.9%. This may have resulted from the effective management of ocular ischemia prior to GDD implantation with panretinal photocoagulation and antivasular endothelial growth factor injection. This also implied that hyphema was not a common complication, and it may not be related to GDD implantation. A child with GDD plate exposure underwent GDD removal and endoscopic cyclocryocoagulation. The overall success rate in terms of IOP control (IOP <21 mm Hg with or without topical antiglaucoma medication) in our series was 84.3%,
and it was better than what was reported by the American Academy of Ophthalmology, which stated a 10% failure per year for GDDs. The mean IOP was below 17 mm Hg throughout the follow-up period until the last visit. One of the important concerns of the glycerin-preserved human-donor corneoscleral tissue was pathogen transmission. The donor human corneas exclusively obtained from the International Eye Bank of Thailand were routinely tested, and donor corneoscleral tissue was pathogen transmission. The donor corneoscleral rims were also routinely cultured after keratoplasty. Tsoukanas et al., including the anterior aspect of the patch donors with transmitted viral pathogens (anti-HIV-1, anti-HIV-2, or combination test, hepatitis B surface antigen, anti-HCV, and VDRL) were excluded.36,37 Donor corneoscleral rims were also routinely cultured after keratoplasty. In any case, when there was an abnormal result, the glycerin-preserved human-donor corneoscleral tissue was destroyed. In this study, we did not routinely culture the corneoscleral tissue at the time it was used as the patch graft. Our study can confirm the advantages of corneoscleral tissues as patch grafts for GDD implantation as reported by Tsoukanas et al., including the anterior aspect of the patch graft, a part of the cornea that improved cosmesis and the visualization of the anterior part of the tube. This feature allowed postoperative modification of the tube such as cutting the ligating suture with laser suture lysis or a needle, and additional fenestration through the patch graft and conjunctiva for early IOP reduction. Our study had several limitations; because of the retrospective nature of our case series there were missing data, including the times of occurrence of complications and the details of the interventions for correcting the complications.

In conclusion, glycerin-preserved human-donor corneoscleral tissue is a viable alternative patch graft material for GDD implantation. Prospective, randomized, comparative studies should be conducted to compare the efficacy and complications of glycerin-preserved human-donor corneoscleral tissues and other materials during long-term follow-up.

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