

Comparison of Locally Sourced Pericardium and Other Conventional Patch Graft Materials in a Glaucoma Drainage Device Surgery

Shruti Aggarwal¹, Candice Kremer², Stephanie Engelhard³, Sandra Johnson⁴

ABSTRACT

Purpose: Our study aimed to compare the outcomes and costs of various patch graft materials used in the setting of glaucoma drainage device (GDD) surgeries: conventional Tutoplast® pericardium (TP), locally-obtained Lifenet® pericardium (LP), and tissue-banked corneal (CP) and scleral (SP) patches.

Design: Retrospective observational study.

Subjects: One hundred and ninety-five eyes of 185 patients who underwent glaucoma device surgery with patch grafts were included.

Materials and methods: Patient records were reviewed for demographics and surgical data including age at the time of GDD surgery, race, sex, eye, history of diabetes or immunologic disease, glaucoma diagnosis, length of follow-up, pre- and postoperative intraocular pressure (IOP), type and location of GDD, patch type, and tube-related complications.

Main outcome measures: The primary outcome measures were rates of patch graft-related complications including conjunctival dehiscence with and without tube exposure. Secondary outcome measures were IOP control achieved and cost of patch graft materials.

Results: Mean follow-up for all eyes was 17.1 months. Overall, conjunctival dehiscence without tube exposure occurred in four eyes (2.1%); tube exposure was seen in six eyes (3.1%). The mean time to exposure was 3.3 months (range 1–8 months). The rate of tube exposure was 2.3% of eyes with TP grafts, 10.7% of eyes with CP grafts, 2.8% of eyes with SP grafts, and 0% of eyes with LP grafts. There was no significant difference in rates of tube exposure rates by graft material ($p = 0.26$). Multivariate logistic regression analysis with adjustment for patch type, age, sex, implant type, and location revealed no significant risk factors for tube exposure. Univariate logistic regression was then performed on the same risk factors as well as diabetes, prior and concurrent ocular surgery, and showed no significance.

Conclusion: Our preliminary, short-term results show that locally sourced patch graft material can be a cost-effective alternative to traditionally used patch grafts without an increase in tube exposure rates. To further determine the efficacy of the different patch graft materials, longer-term comparative prospective trials are needed. Longer prospective studies are needed to compare the long-term safety and rate of tube exposures in these locally obtained patch graft materials.

Keywords: Anti-glaucomatous valve, Corneal patch graft, Glaucoma drainage devices, Glaucoma surgery, Sclera patch graft.

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INTRODUCTION

Glaucoma drainage device (GDD) implantation is a well-established surgery to lower intraocular pressure (IOP) by diverting aqueous humor from the anterior chamber to an external reservoir. Although the concept of GDDs was introduced over a century ago in 1906,¹ they were popularized in 1976 by Molteno et al.² Since then, both the device design and surgical techniques have evolved to improve clinical outcomes and decrease complications.^{3,4} Traditionally, these surgeries were performed after failed trabeculectomy or in complex glaucomas such as neovascular, uveitic, and traumatic.⁴ With studies showing good long-term IOP lowering, possibly less postoperative complications vs traditional filtering procedures, and success in pediatric and complicated glaucomas, the utilization of GDD surgery, both as primary procedure and as second surgery has increased significantly over the past decade.^{5–7}

A GDD is composed of two components—a plate and a tube. The tube runs along the sclera to enter the anterior chamber. Direct contact between the tube and conjunctiva can lead to conjunctival erosion over time.⁸ The subsequent tube exposure is a serious complication as it can lead to endophthalmitis.⁹ Biologic patch grafts are used to cover the tube and prevent its erosion through

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the conjunctiva. Various patch graft materials have been used, such as donor sclera, cornea, dura mater, and pericardium. Each patch graft material is associated with risks and benefits when evaluated by availability, price, and efficacy. The decision to use a particular

patch graft may be based on surgeon preference, patch thickness, availability, cosmesis, and cost.¹⁰

In January 2015, the Center for Medicare and Medicaid Service bundled the patch graft component with the glaucoma implant code, thereby making it important to include price and availability considerations when evaluating the utility of patch graft materials.¹¹

With healthcare costs becoming a growing concern, it is crucial for healthcare providers to keep the quality of care high while reducing costs when possible. As members of an accountable care organization (ACO), physicians at our institution aim to look for cost-effective measures. We use a pericardium patch graft from a local tissue company, which has a lower cost relative to other patch graft materials.

Our study aimed to compare the preliminary outcomes of locally sourced pericardial patch graft relative to other conventional patch grafts including tissue-banked corneal and scleral patches and pericardium products from a national tissue bank in the setting of GDD surgeries.

MATERIALS AND METHODS

This was a retrospective, observational study of patients who were implanted with GDDs over 4 years (September 2102 to November 2016) at a single center, the Department of Ophthalmology at the University of Virginia. The study was approved by the institutional review board of the University of Virginia and was conducted in accordance with the principles of the Declaration of Helsinki. The requirement for written informed consent was waived due to the retrospective nature of the study.

The inclusion criterion included age over 18 years undergoing GDD surgery with patch graft with a minimum of 6 months follow-up. One hundred and ninety-five eyes of 185 patients were identified from the electronic medical record. Drainage devices included 132 Ahmed Glaucoma Valves (New World Medicine, Inc., Rancho Cucamonga, CA, USA) and 63 Baerveldt implants (Advanced Medical Optics, Inc., Santa Ana, CA, USA). Ahmed glaucoma valves in the study included Model FP-7 ($n = 127$) and Model M4 ($n = 5$). All implanted Baerveldt implants were the 350 model. Eyes were categorized by the type of patch graft used. Patch graft materials included conventional irradiated Tutoplast® pericardium (TP) (IOP Ophthalmics, Costa Mesa, CA, USA), locally obtained LifeNet® pericardium (LP) (LifeNet Health®, Virginia Beach, VA, USA), tissue-banked corneal patches (CP), and scleral patches (SP). Figure 1 shows the LP in place 1-year postoperatively. All the surgeries using LP were done by a single surgeon using a limbus-based approach.

Patient records were reviewed for demographic information and surgical data including age at the time of GDD surgery, race sex, eye, diabetes history, immunologic disease history, glaucoma diagnosis, length of follow-up, pre- and postoperative IOP, type and location of GDD, conjunctival patch type, and complications including tube exposure and conjunctival dehiscence. The primary outcome measures were rate and risk factors for patch graft-related complications including conjunctival dehiscence with and without tube exposure. Conjunctival dehiscence was described as any breakdown of the conjunctiva over the tube or plate or limbus. Secondary outcome measures were IOP control achieved and cost of patch graft materials.

Data are reported as mean \pm standard deviation. Descriptive statistics were used to describe the data. A comparison of the rates of exposure was analyzed using the ANOVA test. Univariate analysis was performed to assess if various factors such as age, sex,

type of implant, the location of implant, diabetes, concurrent, and prior ocular surgeries were associated with an increased exposure rate. A multivariate logistic regression model adjusted for each of the above-mentioned factors was used to assess the association between patch type and exposure rate. Significance was set at $p \leq 0.05$.

RESULTS

Demographics and patient characteristics are shown in Table 1. One hundred and ninety-five eyes of 185 patients were included in the study. Mean age was 64.1 ± 16.5 years (54.9% male; 45.1% female). Of 195 eyes undergoing GDD surgeries, the patch graft materials were TP ($n = 43$, 22.1%), LP ($n = 53$, 27.2%), CP ($n = 28$, 14.4%), and SP ($n = 71$, 36.4%). Mean preoperative IOP across all groups was 28.4 ± 12.6 mm Hg, while mean postoperative IOP was 14.4 ± 6.1 mm Hg, representing a significant IOP decrease ($p = 0.0$). Mean follow-up for all eyes was 17.1 months (range 6–30 months), with no significant difference in follow-up times among the different groups.

Overall, conjunctival dehiscence without tube exposure occurred in four eyes (2.1%). There were six tube exposures (3.1%). Other tube-related complications were tube malpositioning (1.0%) requiring repositioning and one tube blockage (0.5%) requiring tube revision. Patient characteristics, surgical indications and characteristics, and complications by patch graft material are shown in Table 2.

Among eyes with tube exposure, the mean age was 68.8 years (range 51–86 years). Four of six tube exposures occurred in open-angle glaucoma, and one each occurred in neovascular and pseudoexfoliation glaucoma. Mean follow-up in these six cases was 21 months. The mean time to exposure was 3.3 months (range 1–8 months). Four exposures occurred in Ahmed FP7 implants, and two occurred in Baerveldt 350 implants. Two of six exposures occurred in eyes with inferiorly located implants.

Tube exposure occurred in 2.3% of eyes with TP grafts, 10.7% of eyes with CP grafts, 2.8% of eyes with SP grafts, and 0% of eyes with LP grafts. Tube exposure rate by patch graft material is shown in Figure 2. ANOVA showed that there was no significant difference in rates of tube exposure rates by graft material used ($p = 0.26$, $R^2 = 0.02$). Multivariate logistic regression analysis with adjustment for patch type, age, sex, implant type, and location revealed no significant risk factors for tube exposure. Univariate logistic regression was then performed on the same risk factors as well as diabetes, prior and concurrent ocular surgery, and continued to show no significance.

DISCUSSION

Complications associated with the GDD surgery as reported by the American Academy of Ophthalmology, include hypotony both in the immediate and late postsurgical period, high IOP and clinical failure with excessive capsular fibrosis around the plate and tube, tube-related complications—malposition, blockage, and exposure; and conjunctival retraction, dehiscence, and scarring.^{12,13} Tube exposure is a well-known complication, which prompts urgent surgical intervention. It can lead to symptoms of ocular irritation, focal injection, pain, and light sensitivity. It leads to hypotony, inflammation, corneal decompensation, and infection leading to endophthalmitis.^{9,14,15}

The reported rate of tube exposure is very variable and ranges from 2 to 7%; with the mean time to tube exposure ranging from

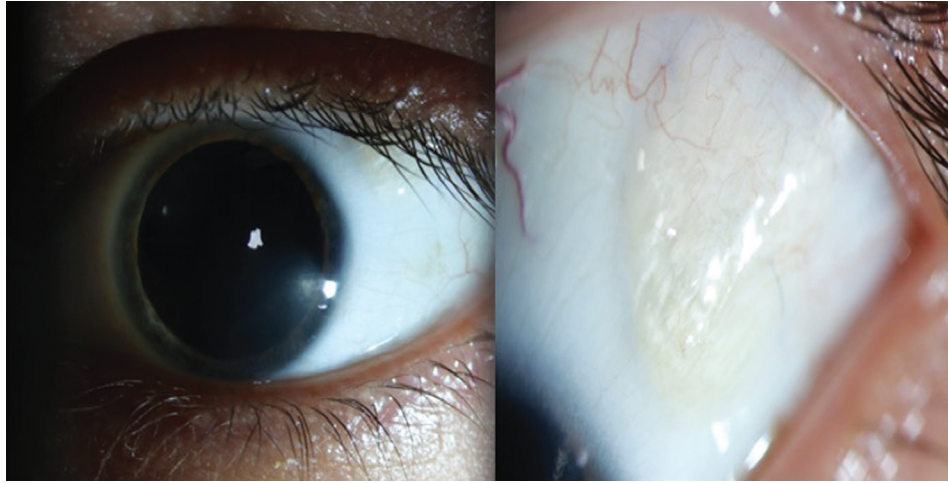


Fig. 1: Slit lamp biomicroscopy photograph showing LifeNet pericardium patch graft in place 1 year postoperatively

Table 1: Details of demographics and patient characteristics

Demographics and patient characteristics	Tutoplast® pericardium (n = 43 eyes) (22.1%)	Tissue-banked corneal patch (n = 28 eyes) (14.4%)	Scleral patch (n = 71 eyes) (36.4%)	Lifenet® pericardium (n = 53 eyes) (27.2%)	All (n = 195 eyes) (100%)
Age (years)					
Mean ± SD	59.4 ± 14.5	57.8 ± 16.2	73.0 ± 13.3	59.3 ± 17.4	64.1 ± 16.5
Sex (%)					
Male	26 (60.5)	19 (67.9)	36 (50.7)	27 (50.9)	107 (54.9)
Female	17 (39.5)	9 (32.1)	35 (49.3)	26 (49.1)	88 (45.1)
Ethnicity					
African American	16 (37.2)	9 (32.1)	18 (25.4)	16 (30.2)	58 (29.7)
Caucasian	20 (46.5)	15 (53.6)	49 (69.0)	29 (54.7)	113 (57.9)
Hispanic	3 (7.0)	0 (0)	1 (1.4)	5 (9.4)	9 (4.6)
Other	4 (9.3)	4 (14.3)	3 (4.2)	3 (5.7)	15 (7.7)
Eye					
Right	27 (62.8)	11 (39.3)	31 (43.6)	26 (49.1)	95 (48.7)
Left	16 (37.2)	17 (60.7)	40 (56.3)	27 (50.9)	100 (51.3)

SD, standard deviation

as short as 4 weeks to up to 5 years after surgery.^{16–21} In a large meta-analysis study, the incidence of tube exposure was reported to be $2.0 \pm 2.6\%$, with an average exposure rate per month of $0.09 \pm 0.14\%$.²² Netland et al.²³ reported tube exposure at a mean of 1.43 ± 1.5 years. Our data agree with the literature; the tube exposure rate in our patient population was 3.1%, the rate of conjunctival dehiscence without tube exposure was 2.1%. The mean onset of tube exposure was at 3.3 months of follow-up, the range being 1–8 months.

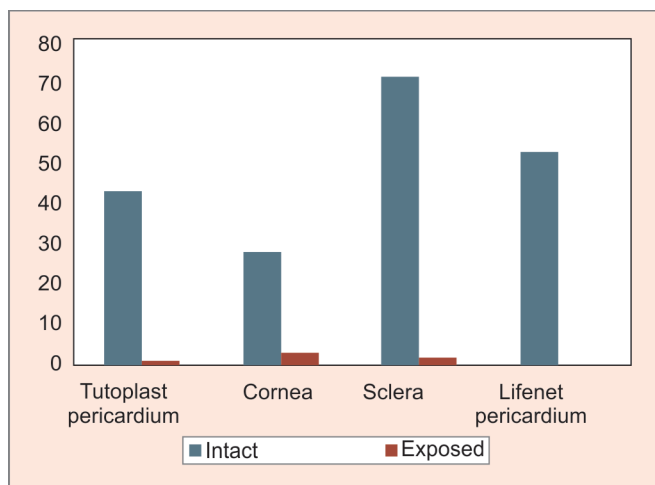
Various mechanisms for tube exposure have been postulated, including both high-grade and low-grade inflammation leading to rapid and slow gradual tube exposure, respectively.²⁰ Direct contact between tube and conjunctiva is shown to be an important mechanism for conjunctival erosion.⁸ In an attempt to decrease the contact and prevent tube erosion while reinforcing overlying conjunctiva, Freedman described the successful use of full-thickness, glycerin preserved, full-thickness scleral patch graft in 16 patients undergoing GDD surgery in 1987.²⁴ Since then, use of many different patch graft materials has been described.²⁵ Commonly used commercially available grafts include sclera; partial and full-thickness cornea, fascia lata, and pericardium.

We reviewed the outcomes of the patch graft materials used for GDD surgery at our institution—banked donor sclera, donor cornea, Tutoplast pericardium, and locally sourced pericardium and found no significant difference in the tube exposure rate among the four groups. Multiple other studies have also compared the rate of tube exposure using the different patch graft materials. Muir et al.²⁶ compared eye bank sclera, Tutoplast sclera, and pericardium. Smith et al.²⁰ compared eye bank sclera, dura, and pericardium; while Zalta²⁷ looked at erosion rates in donor dura and sclera. None of those studies found a significant increase in tube exposure in any particular type of patch graft material.

Considerations while choosing appropriate graft are the location of the implant, thickness, size, longevity of graft material, ease of manipulation, past patch erosions, and cosmetic outcomes.^{10,25} Cost of the graft is important to consider. The cost of the patch graft depends on the type of tissue, harvesting and processing costs, and shipping costs. At our institute, the average cost of these grafts is \$295–\$415 for banked cornea, \$250 for banked sclera, and \$275 for Tutoplast pericardium. As a part of being an ACO, we have tried a more cost-effective alternative to conventional patch grafts. LifeNet® pericardium (LP) (LifeNet Health®, Virginia

Table 2: Indications and complications

	<i>Tutoplast® pericardium</i> (n = 43 eyes) (22.1%)	<i>Tissue-banked corneal patch</i> (n = 28 eyes) (14.4%)	<i>Scleral patch</i> (n = 71 eyes) (36.4%)	<i>Lifenet® pericardium</i> (n = 53 eyes) (27.2%)	<i>All</i> (n = 195 eyes) (100%)
<i>Patient characteristics</i>					
Diabetes					
Yes	17 (39.5)	12 (42.9)	10 (14.1)	25 (47.2)	64 (32.8)
No	26 (60.5)	16 (57.1)	61 (85.9)	28 (52.8)	131 (67.2)
Prior surgeries					
Scleral buckle	2 (4.7)	1 (3.6)	2 (2.8)	4 (7.5)	9 (4.6)
Trabeculectomy	5 (11.6)	11 (39.3)	36 (50.7)	10 (18.9)	62 (31.8)
<i>Indications for surgery (glaucoma diagnosis)</i>					
Open-angle	12 (27.9)	10 (35.7)	47 (66.2)	21 (39.6)	90 (46.2)
Neovascular	11 (25.6)	5 (17.9)	2 (2.8)	18 (34.0)	36 (18.5)
Angle-closure	4 (9.3)	2 (7.1)	7 (9.9)	3 (5.7)	16 (8.2)
Traumatic	4 (9.3)	2 (7.1)	2 (2.8)	1 (1.9)	9 (4.6)
Uveitic	10 (23.3)	3 (10.7)	0 (0)	5 (9.4)	18 (9.2)
Pseudoexfoliation	2 (4.7)	0 (0)	11 (15.5)	0 (0)	13 (6.7)
Congenital	0 (0)	5 (17.9)	2 (2.8)	0 (0)	7 (3.6)
Aphakic	0 (0)	1 (3.6)	0 (0)	5 (9.4)	6 (3.1)
<i>Surgical characteristics</i>					
Glaucoma implant type (%)					
Ahmed FP7	41 (95.3)	26 (92.9)	8 (11.3)	52 (98.1)	127 (65.1)
Ahmed M4	2 (4.7)	2 (7.1)	0 (0)	1 (1.9)	5 (2.6)
Baerveldt	0 (0)	0 (0)	63 (88.7)	0 (0)	63 (32.3)
Implant location (%)					
Superior	42 (97.7)	23 (82.1)	61 (85.9)	50 (94.3)	176 (90.3)
Inferior	1 (2.3)	5 (17.9)	10 (14.1)	3 (5.7)	19 (9.7)
<i>Complications</i>					
Tube exposure					
Yes	1 (2.3)	3 (10.7)	2 (2.8)	0 (0)	6 (3.1)
No	42 (97.7)	25 (89.3)	69 (97.2)	53 (100)	189 (96.9)
Conjunctival dehiscence					
Yes	2 (4.7)	0 (0)	1 (1.4)	1 (1.9)	4 (2.1)
No	41 (95.3)	28 (100)	70 (98.6)	52 (98.1)	191 (97.9)

**Fig. 2:** Bar graph showing tube exposure in the different patch graft groups

Beach, VA, USA) is a pericardial patch graft obtained from a local company. The average cost of LP is \$105.75. Consideration of cost has become a prominent issue given the rising cost of health care and the recent changes in the billing codes for GDD surgery. What used to be two separate codes—GDD implantation and scleral re-enforcement with patch graft, is now a bundled payment code.¹¹

In addition to assessing whether the type of patch graft used influenced tube exposure, we also assessed other risk factors that may be associated with increased tube exposure. In the literature, various risk factors for tube exposure have been identified; the most important being younger age at the time of surgery,²³ ocular inflammation,²³ concomitant ocular surgery,²⁸ number or prior ocular surgeries,¹⁶ and inferior quadrant positing of the implant.^{29,30} Role of systemic conditions such as diabetes, hypertension, and rheumatologic conditions remains controversial.^{23,26,27,31} In our study, we performed univariate logistic regression analysis for factors including age, sex, type of implant, location of implant, diabetes, concurrent and prior ocular surgeries to assess for association with tube exposure. We did not find any of these

associated with an increased rate of tube exposure in the number of cases reviewed. This may be due to the small number of patients with tube exposure making it not possible to establish a statistical significance; a much larger number of patients with exposure would help to establish any significant risk factors.

While our study shows promising preliminary results on the use of the local tissue bank graft (LP), it does have limitations. This is a retrospective study and suffers from the limitations of a retrospective chart review. Also, the data are accumulated from the different surgeons and hence there is a possible bias based on surgeon technique, tissue handling, and patient population. We have follow-up data for at least 6 months; however, as complications have been shown as late as 5 years after surgery, we need a longer follow-up time to determine the long-term safety of locally sourced pericardial tissue vs other patch graft materials. Another important consideration is that while comparative, our study is not a non-inferiority study. Given an incidence rate of 2–5% of tube exposure rate reported in the literature and our results, power analysis shows that for a power of 80%, alpha of 0.05, assuming no >5% exposure rate over the baseline 5% exposure rate, we would need a minimum of 382 patients in each arm of the patch graft type group, which is challenging in a single institution-based study.

To conclude, our preliminary study shows that locally sourced patch graft material is a cost-effective alternative to commercial patch grafts with good short-term results without an increased rate of complications. Further, prospective studies with longer follow-ups and larger sample sizes are needed to further determine the comparative efficacy of different patch materials.

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