Bovine Pericardium for Dural Grafts: Clinical Results in 35 Patients

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OBJECTIVE: The United States Food and Drug Administration has recently approved the marketing of bovine pericardium as a dural graft material, but literature reports of this use are limited. Bovine pericardium has been widely used for grafts in cardiac surgery and seems to have suitable properties for use as a dural graft. We report the use of glutaraldehyde-processed bovine pericardium for dural grafts in 35 patients undergoing cranial and craniospinal operations with the objective of providing a clinical assessment of this material and technique.

METHODS: This report is a retrospective analysis of 35 patients. All available records were reviewed and information regarding the indication for grafting, graft size, complications, and outcome were collected and analyzed for all patients.

RESULTS: Indications for grafting included meningioma resection, posterior fossa craniotomy, Chiari decompression, dural-based metastases, and trauma. Outcomes were good or excellent in 32 patients; the three fair or poor outcomes were not related to surgical closure. In no patient was the dural graft a significant factor in outcome. Bovine pericardium was found to be easily sutured to be watertight using standard suture material. The material is relatively inexpensive and requires no additional incision. It has low antigenicity and toxicity, good strength, and minimal elasticity.

CONCLUSION: In this clinical assessment, bovine pericardium was found to be an excellent dural graft material.
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Key words: Bovine pericardium, Craniotomy, Dura mater, Graft, Meningioma

Despite 100 years of experimentation, the search for an ideal dural substitute still continues. Considerations for a substitute material include antigenicity, toxicity, strength, elasticity, suturability, availability, and expense. Abbe (1) described the first dural graft in 1895, using rubber sheeting to fill a dural defect. Two years later, Beach (4) reported using gold foil as a dural substitute. A wide range of materials have subsequently been used as dural grafts, most commonly autologous tissues such as fascia lata (34) and pericranium, homologous tissues such as lyophilized or freeze-dried cadaveric dura (8, 23, 30), and synthetic materials such as metallic foil (29), Silastic (36), fibrin, polyethylene film (7, 15, 38), and collagen sponge (20, 27). Lyophilized cadaveric dura is probably most widely used, but is expensive, sometimes difficult to obtain, and has been reported to transmit Creutzfeldt-Jakob disease (24, 25, 28, 33, 37).

Prompted by recent difficulty in obtaining lyophilized dura mater, we have been using processed bovine pericardium (BP) for dural grafts. BP has been used extensively in cardiac surgery for valves and patch grafts (5, 11) and seems to have suitable properties for use as a dural graft. The U.S. Food and Drug Administration (FDA) has recently approved the marketing of glutaraldehyde-processed BP for use as dural graft material. We report the clinical results in 35 patients who underwent dural grafting with BP as part of a variety of neurosurgical procedures.

PATIENTS AND MATERIALS

Between July 1993 and July 1995, placement of BP dural grafts was performed on 35 patients as part of their cranial or craniospinal operations. The clinical characteristics of these patients are described in *Table 1*. The material used was commercially available glutaraldehyde-processed BP (Dura-Guard; Biovascular, Inc., St. Paul, MN). In all cases, the material was prepared for implantation according to the manufacturer's instructions using standard sterile surgical technique. The size of the graft was selected based on the largest dimension of the dural defect, allowing it to be trimmed for appropriate placement. It was rehydrated in either saline or antibiotic irrigation fluid and sutured into place in a watertight fashion using running 4-0 Nurolon suture.

TABLE 1. Clinical Characteristics of 35 Patients with Bovine Pericardium Dural Grafts[a]

Patient No.	Age (yr)/ Sex	Diagnosis	Surgery	BP Graft Size (cm)	Complications	Outcome[b]
1	54/M	Occipital meningioma, SSS involved	Bilateral occipital crani, resection	4 × 4	None	Excellent
2	80/F	Foramen magnum meningioma	Far lateral approach, resection	4 × 4	None	Excellent
3	71/M	Posterior fossa meningioma	Suboccipital crani, resection	6 × 8	None	Excellent
4	63/M	Chiari I malformation	Suboccipital/C1 decompression, duraplasty	4 × 4	None	Excellent
5	50/M	CPA meningioma	Combined approach, resection	4 × 4	Pneumonia, meningitis	Good
6	57/M	Foramen magnum meningioma	Far lateral approach, resection	4 × 4	CSF leak, meningitis, wound infection	Good
7	76/M	Trigeminal neuralgia	Suboccipital crani, MVD	6 × 8[c]	None	Excellent
8	76/M	Trigeminal neuralgia	Suboccipital crani, MVD	8 × 14[c]	None	Excellent
9	50/M	Recurrent parietal meningioma	Redo crani, resection	6 × 8	None	Excellent
10	80/M	Frontotemporal meningioma	Crani, resection	6 × 8	None	Excellent
11	56/M	Occipital cranial/dura prostate metastasis	Craniectomy, resection bone and dura	4 × 4	None	Excellent
12	45/M	Recurrent olfactory groove meningioma	Transfronto-nasal-orbital approach, resection	6 × 8	None	Excellent
13	16/M	Cerebellar malignant astrocytoma	Suboccipital crani, partial resection	4 × 4	None	Excellent
14	74/M	Parieto-occipital large meningioma	Crani, resection	6 × 8	None	Excellent
15	60/F	Temporal meningioma	Frontotemporal crani, resection	4 × 4	None	Excellent
16	26/M	Brain stem cavernous malformation	PF crani, resection brain stem CM	4 × 4	None	Good
17	34/F	Large frontal meningioma	Crani, resection	6 × 8	None	Excellent
18	64/F	Grade 4 SAH, PICA aneurysm	Far lateral approach, aneurysm clipping	6 × 8	Vasospasm, pneumonia	Poor
19	40/F	Cerebellar cavernous malformation, ICH	Suboccipital crani, resection hematoma, and CM	4 × 4	None	Excellent
20	65/F	Trigeminal neuralgia	Suboccipital crani, MVD	4 × 4	None	Excellent
21	47/F	Chiari malformation	Suboccipital/C1 decompression, duraplasty	4 × 4	CSF leak, pseudomeningocele	Good
22	54/F	Frontotemporal dura-based lung CA metastasis	Crani, resection tumor and dura	6 × 8	None	Excellent
23	31/F	Large pineal tumor	Suboccipital crani resection of tumor	4 × 4	Hydrocephalus	Fair
24	50/F	Chiari malformation	Suboccipital/C1 decompression, duraplasty	4 × 4	None	Excellent
25	9/M	Depressed cranial fracture, dural tear	Elevation of fracture, dural repair	4 × 4	None	Excellent
26	7/M	Medulloblastoma	PF crani, resection of tumor	4 × 4	None	Excellent
27	1/M	SDH, brain swelling	Crani, evacuation, SDH, dural graft	4 × 4	Hydrocephalus, wound infection	Fair
28	50/F	Frontal large meningioma	Crani, resection	6 × 8	None	Excellent
29	6 mo/M	Medulloblastoma	PF craniotomy, resection	6 × 8	None	Excellent
30	15/M	Chiari I malformation	Suboccipital/C1 decompression, duraplasty	4 × 4	None	Excellent
31	13/F	Chiari II malformation and syrinx	Suboccipital/C1 decompression, duraplasty	4 × 4	None	Excellent
32	76/M	Trigeminal neuralgia	Suboccipital crani, MVD	4 × 4	None	Excellent
33	43/F	Posterior fossa meningioma	PF crani, resection	4 × 4	None	Excellent
34	42/M	Temporal/cranial base meningioma	Crani, resection	6 × 8	None	Good
35	26/M	Cerebellar AVM	PF crani, resection	4 × 4	None	Excellent

[a] AVM, arteriovenous malformation; CM, cerebellar malformation; BP, bovine pericardium; PF, posterior fossa; SAH, subarachnoid hemorrhage; PICA, posterior inferior cerebellar artery; SDH, subdural hematoma; MVD, microvascular decompression; CPA, cerebellopontine angle; CA, carcinoma; ICH, intracerebral hematoma; SSS, superior sagittal sinus; crani, craniotomy.

[b] Excellent, no deficit, normal mentation and employment; Good, mild deficit but normal mentation and employment; Fair, disabling deficit but able to care for self; Poor, severe neurological deficit requiring assistance in all daily activities.

[c] Used instead of next smaller size because of availability.

The most common indication for dural graft placement, occurring in 14 patients, was meningioma resection resulting in a dural defect. This was followed by posterior fossa craniotomies for a variety of pathological conditions that required graft placement for dural closure (12 patients). Other indications included decompression of Chiari malformations with relaxing duraplasty (5), penetrating and blunt trauma (2), and dura-based metastases (2).

RESULTS

Clinical outcomes and complications are shown in *Table 1*. Thirty-two patients had excellent or good outcomes after surgery. Two patients, one with a large malignant meningioma in the pineal region and one a victim of child abuse with severe brain injury, had fair outcomes. The single poor outcome was in an elderly woman with a Grade 4 subarachnoid hemorrhage from a posterior inferior cerebellar artery aneurysm complicated by vertebrobasilar vasospasm. In no patient was the dural graft a significant factor in the outcome. Two patients developed postoperative wound infections. One was a superficial wound infection in an infant with contaminated traumatic scalp lacerations that resolved with antibiotics and local care (Patient 27). This complication was not thought to be related to the dural graft or to the surgery in general. One patient who had a cerebrospinal fluid leak that caused partial wound dehiscence and subsequently developed a wound infection and meningitis, underwent a second exploration of his posterior fossa wound (Patient 6). A small fenestration was found in an area of thinned dura approximately 1 cm distant from the graft and was repaired. The dural graft appeared to be intact and no cerebrospinal fluid leakage was seen through or around the graft including with a Valsalva maneuver. The smallest size piece of graft material could be used in the majority of patients. In 22 patients (63%), a 4 × 4 cm piece was used. In 12 patients (34%), 6 × 8 cm grafts were used; one 8 × 14 cm piece was used (3%). No complication could be directly attributed to the dural graft material. Late postoperative computed tomographic scans obtained 6 and 12 months after surgery in three and two patients, respectively, showed no evidence of calcification.

DISCUSSION

An ideal material for dural graft should be easily obtained, be strong yet easily shaped and sutured, have low antigenicity and tissue toxicity, and be inexpensive. A wide variety of both biological and synthetic materials have been used for grafts, yet few meet all these requirements. Lyophilized cadaveric human dura mater (Tutoplast; Sierra Medical, Phoenix, AZ) has been widely used for over 3 decades as an alternative to autologous tissue (8, 9). This material has been associated, however, with transmission of Creutzfeldt-Jakob disease (24, 25, 28, 33, 37). Pieces of this material are also frequently of inconsistent thickness and may be more difficult to handle than either BP (21) or synthetic materials.

There has been much interest in synthetic materials because of the theoretical advantages of uniform production and absence of risk of infection. Most of the materials tried, however, have been rejected because of excessive local tissue reaction, which can result in irritation of the underlying brain, excessive scar formation or encapsulation of the graft, meningitic symptoms, or hemorrhage (2, 10, 14, 26, 31, 35). Some degree of adhesion formation can also be seen with autologous grafts. Recently, collagen sponge has been reported to be a favorable dural substitute (27), although it is not approved by the FDA for that purpose. In a study of collagen sponge used as dural grafts in 459 patients, CSF leak and wound infection rates were comparable to 637 patients in whom it was not used (27). Specimens were obtained in 102 patients for histological study which showed no evidence of foreign body reaction or hemorrhage. It should be noted that this collagen sponge is not a true synthetic material but is prepared from bovine tendons. Although some concern about potential transmission of bovine spongiform encephalopathy with bovine preparations has been raised in Great Britain, there has been no evidence of transmission to humans and the potential concern seems limited to Great Britain and western Europe (5, 19).

Although BP is generally considered nonreactive in cardiac use, at least one patient has been reported with a severe inflammatory epicardial reaction to a BP graft (32). A comparison of BP dural graft and native dura in rabbits showed minimal or no adhesion formation between dura and underlying cortex at both macroscopic and histological evaluation and no significant difference between BP and native dura (unpublished data, independent laboratory study for Biovascular, Inc.).

BP can be considered another type of collagen implant material, because it consists of a mesh of collagen fibers after the degradable proteins have been removed. It can be easily prepared and supplied in large quantities and is relatively inexpensive. The material has structural properties well suited for use as a dural graft. It comes in sheets of uniform thickness (0.41 mm ± 0.02), has good tensile strength (685 g/mm^2) with slight elasticity (30%), but is supple and easy to cut, manipulate, and suture (unpublished data, Biovascular, Inc.). There has been one published report comparing lyophilized BP with lyophilized human dura that demonstrated equally low rates of infection and absent immune response in both, but superior workability, thickness, and flexibility of the pericardium patches (21).

The BP used in this series was not prepared by the lyophilization technique, which is a freeze-drying process that may have some disadvantages with regard to ice crystal formation and tissue hardening. This BP is processed with a dilute glutaraldehyde solution which cross-links the native collagen. Glutaraldehyde preparation renders the material biocompatible as well as improving strength and durability (12, 16). The product is stored in sterile water and 1% propylene oxide, which allows use of a short (3 min) saline rinse before implantation. Proprietary processing steps reduce residual glutaraldehyde in the pericardium below levels of detection and minimizes its potential for mineralization after implantation (Bio-Vascular, Inc., personal communication).

One major concern with cardiovascular use of BP has been development of calcification seen in both laboratory studies (17, 18) and cardiac patients (6). In one series of 1193 implanted BP cardiac valves, the incidence of calcification was 0.1% per patient-year (6). Despite this concern, there has been widespread use of BP grafts in cardiac surgery for many years with good results (3, 6). Calcification is a greater concern with cardiac grafts

because of the thromboembolic risk than it is with dural grafts. Until recently, much of the BP used for cardiac bioprostheses has been either lyophilized or tanned for preparation. There is evidence, however, that glutaraldehyde-treated BP exhibits less tendency for calcium accumulation (13). It has also been suggested that the greater porosity of BP compared to lyophilized dura mater allows better migration of fibroblasts into the graft, which reduces subsequent calcification (21). One recent study demonstrated that calcification of BP implants was inhibited by dilantin, possibly because of its anti-vitamin D effect (22). The frequent use of dilantin in neurosurgery patients may thus have additional beneficial effects in those receiving BP dural grafts.

In these times of cost-consciousness and increasing budgetary constraint, the cost of various implants must also be considered. The hospital costs of the BP grafts were \$145 for 4 × 4 cm, \$245 for 6 × 8 cm, and \$310 for 8 × 14 cm grafts. This contrasts with Tutoplast dura mater, which costs from \$325 for 4 × 5 cm grafts to \$845 for a 7 × 8 cm piece. Autologous fascia lata has no material price, of course, but any additional operating time must be considered on the basis of cost as well as medical considerations. At the University of New Mexico Hospital, for example, operating room charges are \$666 per hour, plus \$345/h for anesthesia. If harvesting a fascia lata graft takes an additional 20 minutes, that results in an additional \$337 cost. Collagen sponge (Bicol; Codman & Shurtleff, Randolph, MA) costs only \$34 for a 3 × 4 inch sheet, but it is not FDA approved for dural grafts and does not provide watertight closure.

Although available for some time and widely used in cardiac surgery, the recent FDA approval to allow marketing of BP as a dural graft will increase awareness of this material among neurosurgeons. Glutaraldehyde-processed BP seems to be a safe, suitable, and cost-effective material for dural grafts. Although associated with microscopic calcification, this does not seem to be an important consideration in dural application. Its low immunogenicity, excellent strength and suturing characteristics, and easy availability make it superior to other available dural graft materials.

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COMMENTS

The authors present a series of 35 patients who underwent supra- and infratentorial craniotomies associated with dural defects requiring dural grafting. The majority of the operations were performed for meningioma resection and various posterior fossa lesions. The dura defects were covered with bovine pericardium (BP) grafts, recently approved for this use by the Food and Drug Administration. Of the 35 patients, 32 had good or excellent outcomes. The three fair to poor outcomes were not related to the use of the BP grafts. The authors conclude that the BP dural grafts are not only a much cheaper substitute for the cadaveric grafts but they also compare favorably with the cadaveric grafts in terms of low antigenicity and toxicity, good strength, and minimal elasticity.

A series of 35 patients is sufficiently large, in my opinion, to convince me at least that BP dura grafts can be used safely in place of the human cadaveric grafts. In this age of cost cutting, such a change in technique would be most welcome by those watching for the cost effectiveness of our work.

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The authors report the use of BP for dural grafts in a series of 35 patients who underwent a variety of cranial and craniospinal operations. The most common indication for the use of this graft material was meningioma resection (14 patients). Thirty-two patients had excellent or good outcomes after surgery, 2 had fair outcomes, and 1 had a poor outcome. The authors state that the dural graft was not a significant factor in outcome in any patient. Two patients developed postoperative infections that apparently were unrelated to use of the graft material.

In their discussion, the authors comment on some of the disadvantages of the use of cadaveric human dura (Tutoplast), including the rarely reported transmission of Creutzfeldt-Jakob disease, high cost, inconsistent thickness, and difficulty in obtaining the material. They fail to mention the rare immune response to this material that has been reported by us and by others (1). (The authors imply that Tutoplast is processed by lyophilization. It is actually processed by dehydration using acetone, hydrogen peroxide, and sodium hydroxide [1].) They discuss the merits of BP including its uniform thickness, strength, flexibility, low immunogenicity, and lower cost relative to cadaveric dura mater. At our institution, we have also used BP in 40 patients who underwent neurosurgical procedures over a 1-year period with good result (unpublished data) and would agree with the author's conclusions. The only morbidity that may be related to the graft material occurred in a 64-year-old man who underwent a suboccipital craniotomy for resection of a cerebellar arteriovenous malformation and in whom closure of the dura was facilitated with a bovine pericardial graft. Two weeks after surgery, he complained of persistent nausea and headache and a lumbar puncture revealed 48% eosinophilia. He recovered uneventfully. This may represent an immune-type response similar to our previous report (1).

Although their numbers are relatively small, the authors show that BP is safe and has distinct advantages over other materials used for dural closure in neurosurgical procedures. This article should be of interest to readers of this Journal and should raise awareness of this graft material among neurosurgeons.

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1. Alleyne CH Jr, Barrow DL: Immune response in hosts with cadaveric dural grafts: Report of 2 cases. **J Neurosurg** 81:610–613, 1994.

The authors report their use of glutaraldehyde-treated BP (Peri-Guard) as a dural substitute in 35 patients who underwent cranial and craniospinal procedures during the last 2 years. There are no histological, cytological, or immunological data to support the claims of "low antigenicity" and "low toxicity." Indeed, the favorable response of mammalian cerebral cortex (rabbit) to this material is from an unpublished investigation. Nevertheless, "no complication could be directly attributed to the dural graft" and thus this report does document the apparent early safe use of this material as a dural substitute in the authors' 2-year experience.

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