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Clinical study

Evaluation of the use of BioGlue® in neurosurgical procedures

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Summary *Objective:* Post-operative cerebrospinal fluid (CSF) fistula following neurosurgery is associated with increased morbidity and mortality. This prospective study evaluates the efficacy of a new bioadhesive – *BioGlue*, as a dural sealant in preventing CSF fistula. The complications associated with its use are investigated and the literature regarding dural closure reviewed. *Methods: BioGlue* was applied to the dura mater as a sealant in 210 patients undergoing 216 neurosurgical procedures over a period of 22 months at the Royal Melbourne Hospital. It was used where watertight closure of the dura mater could not be ensured by primary suture alone and for reconstruction of the sellar floor following transsphenoidal adenohypophysectomy. It was used in 114 supratentorial (52.7%), 53 infratentorial (24.5%) craniotomies, 41 (18.9%) transsphenoidal adenohypophysectomies and 8 spinal (3.7%) procedures. The incidence of CSF fistula as a complication of surgery with intradural exposure was analysed. *Results:* The incidence of CSF fistula post-operatively was significantly low. Two patients (0.93%), both having undergone posterior fossa craniotomy – for evacuation of a cerebellar haematoma and redo excision of a metastasis respectively and both complicated by hydrocephalus, developed CSF fistula. There were no complications associated with the use of *BioGlue*. *Conclusion: BioGlue* reduced the incidence of complications associated with neurosurgery. It is an effective adjunct in dural closure to prevent CSF fistula with enhanced bonding properties and is simple to use. In this study there were no complications associated with its use.

Keywords: bilge, cerebrospinal fluid fistula, dural closure, fibrin sealant

INTRODUCTION

Problems related to CSF dynamics and infection, remain one of the major causes of neurosurgical morbidity and mortality, normally requiring re-operation. The rate of post-operative CSF fistula in surgery where intradural exploration is undertaken, is reported as being as high as 10% in supratentorial tumour surgery, 4% for transsphenoidal procedures, 5% in acoustic neuroma surgery, 8–32% in posterior fossa surgery and 5% in spinal procedures.[1–5] These figures include subgaleal CSF collections. Post-operative CSF fistula may be complicated by meningitis, encephalitis, low-pressure headaches, chronic subdural haematomas and effusions, pseudomeningocoele, arachnoiditis, dural-cutaneous fistula, pain and pneumocephalus. A watertight dural closure minimises the risk of these complications. Numerous surgical techniques to achieve this have been described – many of which include the use of various tissue adhesives.[6–13] These substances have properties of polymerisation, enabling them to be used as adhesives, sealants or as haemostatic agents. Their role is to augment but not replace the suture techniques used by surgeons. These adhesives can be comprised of both natural and synthetic substances and there are now many in use, including cyanoacrylate, albumin-based compounds, collagen-based compounds, glutaraldehyde glues and hydrogels. Fibrin sealants, however, are most commonly used.

BioGlue® surgical adhesive (Cryolife, Inc., Kennesaw, GA, USA) is a combination of bovine albumin and glutaraldehyde that confers enhanced bonding properties.[7,14] Its use has already been well established in cardiothoracic surgery for aortic and bronchopulmonary fistula surgery.[1416] This is the first study of its use in neurosurgery, besides a technical note describing its application in reconstruction of the sellar floor following transsphenoidal pituitary surgery.[17]

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MATERIALS AND METHODS

This was a prospective study conducted over a period of 22 months (January 2001–October 2002) at the Royal Melbourne Hospital. The aim of the study was to analyse the safety and efficacy of *BioGlue* in ensuring the integrity of dural repairs and in reconstruction of the sella floor. It was used primarily as an adjunct to ensure watertight dural closure thus preventing CSF fistula whenever a clearly watertight primary closure with 5/0 Prolene® suture material alone could not be achieved and in the opinion of the surgeon there remained a risk of post-operative CSF fistula. Autologous pericranial or fascial grafts were harvested to augment dural closure whenever complete approximation of dural edges could not be achieved. All large pericranial grafts, approximately greater than 1 cm^2, were sutured in place and the seams covered with *BioGlue*. Often grafts for smaller dural defects were simply overlain and glued in place. The *BioGlue* was introduced using the applicator (Fig. 1) under direct vision, incrementally and as required, once the mixing tip had been primed, thereby ensuring the *BioGlue* components were appropriately combined. The 10 cm extender tip was used in the transsphenoidal cases and the standard length tip used in all others.

Two hundred and ten patients, fulfilling the criteria and undergoing 216 neurosurgical procedures were recruited into the study. Their ages ranged from 16 to 86 years (mean 53.8 years). There was an equal sex distribution with 111 male (52.3%) and 105 female (48.6%) patients. One hundred and fourteen patients (52.7%) underwent supratentorial craniotomies, 53 (24.5%) infra tentorial craniotomies, 41 (18.9%) transsphenoidal hypophysectomies and 8 (3.7%) spinal operations. Six patients had repeat craniotomies for cerebral gliomas, 4–14 months after their initial operation at which *BioGlue* was used. A breakdown of the operative procedures in which *BioGlue* was used is outlined (Table 1). The mean amount of *BioGlue* applied was 6.6 ml (range 5–10 ml). One hundred and three (48%) patients had post-operative CT or

Fig. 1 Assembled *BioGlue* delivery "gun" device with prefilled adhesive cartridge in place and applicator tip extension connected.

MRI imaging performed during the first to fifth post-operative day and the mean post-operative hospital stay was 6 days (range 3–40 days). CSF fistula as a complication of surgery with intradural exploration was analysed. Patients were reviewed daily post-operatively and then followed up routinely as outpatients, by the authors at 6 weeks and thereafter as clinically indicated.

RESULTS

Of the 216 neurosurgical procedures in which *BioGlue* was used, 214 (99.0%) developed no complications related to CSF fistula. Post-surgical CSF fistula occurred in 2 cases (0.93%). Both were associated with hydrocephalus and both were successfully managed conservatively. One sixty year-old male, who had previously received both radiotherapy and chemotherapy, underwent a redo-craniotomy for excision of a recurrent cerebellar metastasis (primary small cell carcinoma of lung). He developed a percutaneous CSF leak on the 3rd post-operative day that was complicated by meningitis and managed using a two-week course of intravenous antibiotics and 9 days of lumbar CSF diversion. This was the only patient in the series requiring lumbar CSF drainage. The second patient was another 60-years-old male who underwent insertion of a ventriculostomy drain and a posterior fossa craniotomy for a hypertensive cerebellar haematoma and obstructive hydrocephalus. He developed a transient CSF leak on the 3rd post-operative day when his ventriculostomy drainage pressures were increased. This settled spontaneously without being complicated by meningitis. There were no other infective complications in this series. Six patients had repeat craniotomies for excision of cerebral gliomas, 4–14 months (median 10 months) after their initial operation at which *BioGlue* was used. In each case the dura was found to have sealed. Extradural remnants of *BioGlue* were noted in the 4 patients whose initial surgery was less than 6 months previous.

No adverse reactions or complications related to the use of *BioGlue* were noted – none of the patients developing seizures, allergic reactions or granuloma formation. There was no contrast enhancement seen on post-operative MRI and CT imaging. The median follow-up period was 288 days (range 11–648 days) and there was no mortality in this series.

DISCUSSION

BioGlue is an admixture of bovine serum albumin (45%) and glutaraldehyde (10%). The bovine serum comes from North American cattle herds that are free from transmissible bovine spongiform encephalopathy. It is purified by heat precipitation, chromatography and then gamma-irradiation. The two solutions are dispensed in a predefined ratio and mixed in a special appli-

Table 1

1. Acoustic Neuroma	19 (8.8%)
a. Middle fossa	3 (15.8%)
b. Retromastoid	16 (84.2%)
2. Arachnoid cyst	4 (1.9%)
3. Astrocytoma and GBM	32 (14.8%)
a. Supratentorial	30 (93.8%)
b. Infratentorial	2 (6.3%)
4. Meningioma	31 (14.4%)
a. Falcine	2 (6.5%)
b. Cavernoussinus	4 (12.9%)
c. Cerebellopontine angle	4 (12.9%)
d. Tentorial	1 (3.2%)
e. Petroclival	5 (16.1%)
f. Tuberculum sellae	1 (3.2%)
g. Sphenoid wing	1 (3.2%)
h. Olfactory groove	2 (6.5%)
i. Biparietal	1 (3.2%)
j. Parasagittal	1 (3.2%)
k. Frontal	2 (6.5%)
l. Parietal	2 (6.5%)
m. Sphenoid plaque	1 (3.2%)
n. Temporal	4 (12.9%)
5. Pineocytoma	1 (0.5%)
6. Metastases	11 (5.1%)
a. Supratentorial	7 (63.6%)
Temporal	2
Parietal	5
b. Infratentorial	4[a] (36.4%)
7. Haemangioblastoma (posterior fossa)	5 (2.3%)
8. Ventricular tumors	2 (0.9%)
a. 4th Ventricle-choroid plexus papilloma	1 (50%)
b. 3rd Ventricle	1 (50%)
9. Haematoma evacuation	5 (2.3%)
a. Supratentorial	1 (20%)
b. Infratentorial	4[a] (80%)
10. Microvascular decompression	22 (10.2%)
a. Trigeminal	16 (72.7%)
b. Facial	3 (13.6%)
c. Division of Glossopharyngeal	3 (13.6%)
11. Transsphenoidal adenectomy	41 (19.0%)
12. Craniotomy for Pituitary tumor	6 (2.8%)
a. Recurrent	4
b. Residual	1
c. Large tumor	1
13. Melanoma	1 (0.5%)
14. Temporal lobectomy for epilepsy	3 (1.4%)
15. Optic nerve glioma	1 (0.5%)
16. Evacuation of Subdural haematoma	4 (1.9%)
17. I/O Intracranial pressure monitor	1 (0.5%)
18. CRW frame biopsy of Corpus callosum tumor	1 (0.5%)
19. Spontaneous CSF rhinorrhoea	1 (0.5%)
20. Cranitomy for clipping of aneurysm	16 (7.40%)
a. MCA	6
b. ACom A	3
c. PcomA	2
d. ICA	1
e. Vertebrobasilar	1
f. Multiple-	3
21. Spine	8 (3.70%)
a. Lumbar laminectomy for E/O Schwannoma	1
b. Hemilaminectomy for disc excision	1
c. Decompressive lumbar laminectomy	1
d. Syringopleural shunt	1
e. Excision of lumbar intradural disc	1
f. PLIF	1
g. Cervical laminectomy	1
h. Thoracic laminectomy	1
22. A.C. Fossa reconstruction for spont. CSF rhinorrhea	1 (0.5%)

[a] The two categories in which the 2 cases of CSF fistula occurred as outlined in Results.

cator through to the tip where cross linkage occurs. The advantage of *BioGlue* is that the bi-functional glutaraldehyde molecule covalently bond the bovine serum albumin molecules to each other, as well as to lysine in proteins on the cell surface and in proteins in the extracellular matrix. This reaction is spontaneous, increasing tensile and shear strength independently of the coagulation status of the patient, the albumin providing an extensive flexible network of bonds. Polymerisation commences within 20–30 s and reaches full bonding strength in 2 min – allowing it to form a mechanical seal at the site of application.

BioGlue has been used in cardiothoracic surgery as an adjunct for sealing vascular anastomoses and in bronchopleural fistula repairs.[14–16] Bovine studies have shown that it is able to provide a tensile strength in transected aortas of 847 ± 127 g/cm^2 with a shear strength of 256 ± 46 g/cm^2. Animal laboratory studies have also demonstrated that at up to 2 months post-operatively, it does not induce a chronic inflammatory response.[14] Rarely, however, specimens showed a minor chronic granulomatous response as in foreign body reactions but neither fibrosis nor multinucleated giant cells were seen.[14] These findings correlated with our clinical experience in this series.

The integrity of the dura mater is paramount in preventing CSF fistula and ensuing complications; inter alia meningitis, encephalitis, low-pressure headaches, chronic subdural haematomas and effusions, pseudomeningocoele, arachnoiditis, dural-cutaneous fistula, chronic pain and pneumocephalus. During neurosurgical procedures the dura mater is often intentionally opened in order to provide access. It may also be accidentally torn, retract due to desiccation or diathermy since opened, or be compromised by tumour invasion. Lacerating densely adherent dura mater in elderly patients when opening a craniotomy or during technically difficult spinal procedures occurs not infrequently. In some instances the dural closure just requires straightforward resuturing. However, patching with various graft materials and reinforcement with substances that can provide a watertight seal until the dura is able to unite, is frequently necessary.

The incidence of CSF fistula in posterior fossa surgery is generally higher and clinically more significant. Diathermy of the dural edges for haemostasis and desiccation during protracted procedures under the operating microscope and theatre lights, causes retraction and shrinkage of the dura – the edges becoming impossible to oppose using sutures alone. Frequently dural substitutes are necessary to achieve a watertight seal. Various techniques to achieve this have been suggested. Fisher et al. in a technical note advised a special technique of dural closure for midline posterior fossa surgery[18] and Ogungbo and Nath[4] described a technique of dural repair following retromastoid craniectomies that avoids excessive packing of mastoid air cell with bone wax and the risk of sigmoid sinus thrombosis and granuloma formation. For retrosigmoid craniotomies, we consider a watertight dural seal to be essential and routinely use a pericranial graft sutured into the defect that we reinforce with *BioGlue*. The use of autologous fibrin sealant in acoustic schwannoma surgery is, however, controversial and a retrospective study of 492 acoustic neuroma surgeries by Lebowitz et al. demonstrated that there was no decreased incidence of CSF fistula with the use of fibrin glues.[12] The incidence of CSF fistula in acoustic neuroma surgery varies from 6.6% to as high as 35.6% with an incidence of meningitis between 2.2% and 14%.[3,19–21]

CSF fistula may complicate transsphenoidal surgery with an incidence reported at 2.7–6.4%.[22] Many techniques have been described to avoid this complication, including intrasellar and intrasphenoidal placement of autologous fat, fascia lata or muscle grafts, reconstruction of the sella floor with autologous bone, polyester-silicone dural substitute and fibrin glue or Synthes® mini fragment plates and packing off the sphenoid sinus.[2325] Lumbar CSF diversion is frequently used to augment repairs in such settings.[5] Kelly et al. advocated the use of a two layered collagen sponge for small defects obviating the need for fat graft, fibrin glue and lumbar CSF drainage.[26] We have developed and published a simple but successful technique, utilising *BioGlue* in the reconstruction of the sellar floor and for repair of CSF fistula following transsphenoidal pituitary surgery.[17]

In skull base surgery, abnormally large dural defects are often created due to extensive bone invasion by tumour. Surgery can also be complicated by previous irradiation resulting in poor vascularity and tissue necrosis. Such defects are furthermore difficult to repair due to restricted access and fragility of the dura. Once again various techniques have been described – all with limited success.[12,27–29] We have found *BioGlue* to be a useful adjunct in sealing the dural closure following extensive skull base resections, avoiding the necessity for spinal drainage.

Dural tears complicate 4–8% of spinal neurosurgical procedures[30] potentially causing arachnoiditis, meningitis, pseudo meningocoele, nerve root herniation, cutaneous fistulas and chronic pain.[2,8,13] Normally, dural tears are repaired with 4-0 to 6-0 monofilament polypropylene using various suture techniques, including that described by Adams.[31] Re-operating on the lumbar spine, in particular, increases the chance of dural tears with CSF leak. Levy and Sonntag[2] designed a titanium clip with corrugated jaws that can be applied with a standard aneurysm clip applicator. Marks and Koscuba[32] recommended the use of arcuate-legged titanium non-penetrating staples for closure of spinal dura. These clips are MRI compatible, easy to use and can be used for closure of dura in thoracolumbar spine and following transoral surgery. Vaquero et al. demonstrated that when fibrin glue was used in epidural space following laminectomy, it minimises scar formation for at least two weeks post-operatively[33] concluding that it should be considered in spinal surgery when early reoperation is contemplated. We have used *BioGlue* to reinforce the dural closure in 8 patients, none of whom subsequently had a CSF leak.

The materials commonly used to augment and seal dural closures once the edges have been approximated with sutures – with or without the aid of a graft, are fibrin glue and cyanoacrylate. Two kinds of fibrin glue are currently available. The first, autologous cryo-preserved fibrin glue produced from single donor plasma in combination with bovine thrombin, carries lower risk of transmittable diseases. The second is derived from pooled human plasma containing human lyophilised fibrinogen, human factor XIII, bovine aprotinin, human lyophilised thrombin and $CaCl_2$. The latter is considered superior to the single donor type as it contains a higher concentration of fibrinogen. These components mimic the final step of the coagulation cascade.

All donated plasma and bovine tissue undergoes rigorous virus screening and purification and thus far, despite the risk, there has been no proven case of viral transmission associated with use of commercially available fibrin sealant.[7] Recently, Stechison[10] has described and recommended the use of fibrin glue from autologous blood, as this minimises the risk of blood-born diseases and can be prepared within 5 min. Cain et al.[8] concluded that the dural defects repaired with fibrin glue were twice as strong as those repaired with sutures alone between day 1 and day 3. The strength diminishes between post-operative day 4–7, by which time, it is enough, the dural edges unite. Shaffrey et al. (1990) demonstrated in a study on 134 neurosurgical patients that fibrin glue augmentation of dural closure was extremely effective in situations where specific dural defects were identified intra-operatively and repaired.[34]

Fibrin glues are biodegradable and biocompatible and have been used in many surgical specialties, including neurosurgery,

where they are used primarily for prevention of CSF fistula. They are also utilised for achieving haemostasis, in cranioplasties using autologous bone fragments and for anastomoses of nerves and vessels. However, in order to increase clot stability, fibrin sealants frequently contain antifibrinolytic substances like aprotinin or synthetic Tranexamic acid. The latter has been shown to cause seizures in animal models.[19]

Cyanoacrylates are bacteriostatic but are associated with tissue inflammation (both acute and chronic) and tissue necrosis and therefore recommended for superficial use only.[7] Although Tse et al. recommended the use of cyanoacrylate in orbital surgery[35] it is considered to be unsuitable for this purpose as it has been shown to cause cytotoxicity leading to meningeal necrosis, astrocytosis, vascular wall degeneration, superficial cortical necrosis and marked inflammatory reaction.[8]

Due to its enhanced bonding properties *BioGlue* is able to adhere to synthetic graft material, although a wet surgical field may impair adhesion. It also acts a mechanical barrier and hence has an additional haemostatic effect. Our post-operative radiological imaging demonstrated that it did not enhance following injection of intravenous contrast media.

It should be added that at present there is some doubt as to the possibility of a neurotoxic effect of *BioGlue*. We would thus caution against its use subdurally until further studies to evaluate this have been completed.

CONCLUSION

The results presented in this study indicate that *BioGlue* is an effective and safe bioadhesive comparing favourably with previous studies investigating fibrin glue and cyanoacrylate. Its utility in neurosurgical practice for achieving watertight dural closure can be recommended.

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