



Evaluation of Use of a Protein-Based Bioadhesive in Neurosurgical Procedures

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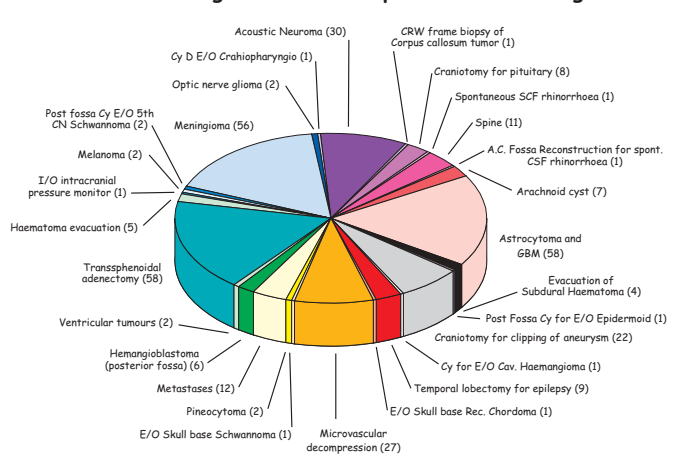
Introduction

Postoperative cerebrospinal fluid (CSF) fistula following neurosurgery is associated with increased morbidity and mortality. This prospective study evaluates the efficacy of a new bioadhesive, BioGlue Surgical Adhesive ("BioGlue," CryoLife, Inc., Kennesaw, GA) 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 333 patients undergoing 333 neurosurgical procedures over a period of 31 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 184 supratentorial (55.25%), 80 infratentorial craniotomies (24.02%), 58 transsphenoidal adenohypophysectomies (17.41%) and 11 spinal procedures (3.30%). The incidence of CSF fistula as a complication of surgery with intradural exposure was analysed.

Chart demonstrating breakdown of procedures utilizing BioGlue

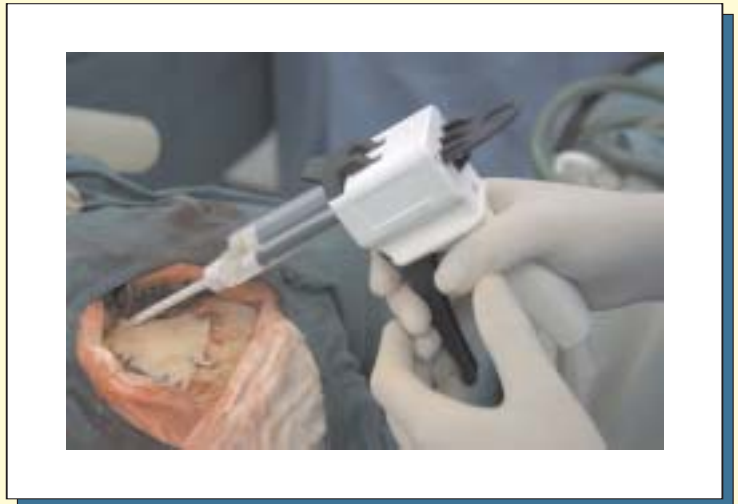


Results

Two patients (0.6%) in this cohort who had undergone posterior fossa craniotomy developed a CSF fistula. One procedure was for evacuation of a cerebellar haematoma and the other was for redo excision of a metastasis. Both procedures were complicated by hydrocephalus. There were no adverse reactions or complications associated with the use of BioGlue. BioGlue did not interfere with post-operative imaging studies

Conclusion

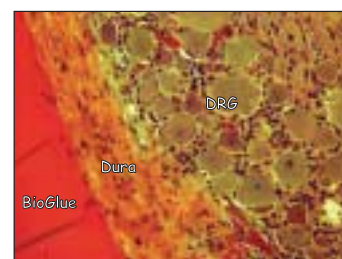
Compared to published historical data, BioGlue reduced the incidence of postoperative CSF leakage complications in neurosurgery procedures. BioGlue is an effective adjunct in dural closure to prevent CSF fistula with enhanced bonding properties. It is simple to use and in this study there were no complications associated with its use.



Technique

BioGlue 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. Autologous pericranial or fascial grafts were harvested to augment dural closure if complete approximation of dural edges could not be achieved. All large pericranial grafts were sutured loosely in place and the seams covered with BioGlue, while often grafts for smaller dural defects were simply overlain and glued in place. The BioGlue was introduced using the applicator under direct vision, incrementally and as required once the mixing tip had been primed, thereby ensuring the BioGlue components were appropriately combined.

Post operative histological appearance



BioGlue on dorsal root ganglia. No evidence of granuloma formation or fibrosis.

Study #ACAW-0105: A Pilot Study to Determine the Effect of the Test Article on Non-Exposed Dorsal Root Ganglia in Sheep (CryoLife, Inc., Data On File).



BioGlue at 2 years in an aortic dissection sheep model (H&E stain). No evidence of granuloma formation or fibrosis.

Williams CP, Tren JLV, DeSouza M, Schuster K, Lenz S, Marra S, Gilley J, Simonetti V, DeRassi AJ, Hewitt CW. Histopathology of tissue remodeling of thoracic aorta repaired with an adhesive protein hydrogel - a prospective study. Experimental Biology 2003, April, 2003, San Diego, CA.



BioGlue at 2 years (staining for Type 1 collagen). Was applied to an aortic jump graft (Dacron) in a sheep model (same area as above slide). No evidence of granuloma formation or fibrosis.

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Reconstruction of the Sellar Floor Using BioGlue Surgical Adhesive Following Transsphenoidal Procedures

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Objective

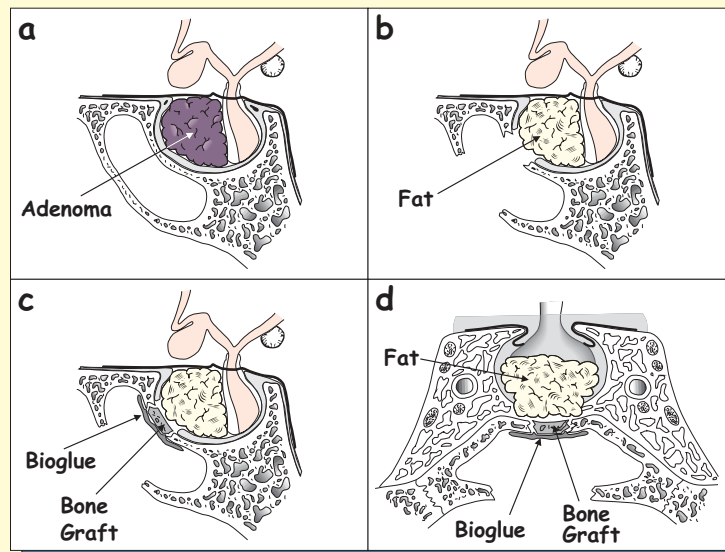
Cerebrospinal fluid rhinorrhea, pneumocephalus and meningitis are serious complications following transsphenoidal excision of sellar, suprasellar and parasellar lesions. This study evaluates the use of a new bioadhesive, BioGlue Surgical Adhesive ("BioGlue," CryoLife Inc., Kennesaw, GA) as an adjunct in reconstructing the sellar floor and preventing CSF fistula and investigates the possible complications associated with its use.

Methods

Between January 2001 and July 2003, BioGlue was used to help reconstruct the sellar floor after endonasal transsphenoidal procedures in 58 patients (56 pituitary adenoma, 1 meningioma and 1 Rathke's cyst) at our facility. All 58 patients underwent endonasal transeptal submucosal transsphenoidal resection of sellar region tumors using microsurgical techniques. In all cases, the resection cavity was packed with autologous abdominal fat graft. The anterior wall of the pituitary fossa was reconstructed with a customised fragment of bone taken from the sphenoid. This fragment was reinforced and secured in place with BioGlue. All of the patients had similar selection criteria, pre-operative evaluation and post-operative management.

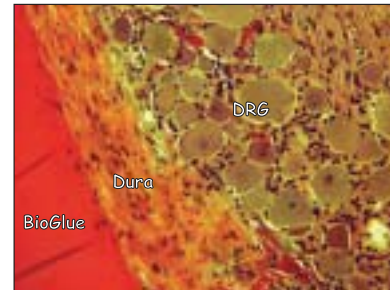
Technique

All 58 patients underwent endonasal transeptal submucosal transsphenoidal resection of sellar region tumours using microsurgical techniques. A subarachnoid lumbar drain was inserted preoperatively in selected cases with macroadenomas extending into the suprasellar cisterns to assist intraoperative descent of the diaphragma sella. The drain was removed at end of procedure if a defect was not identified in the arachnoid during the procedure. However, if a CSF leak was observed during tumour resection, lumbar CSF diversion was continued for 24-72 hours post-operatively.



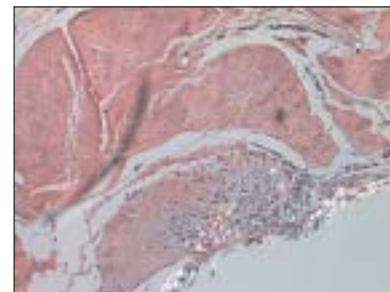
In all cases, regardless of whether a CSF leak was identified, the resection cavity was packed lightly with autologous abdominal fat graft. The anterior wall of the pituitary fossa was then reconstructed with a customised fragment of bone taken from the sphenoid or nasal septum. While this fragment was being held in position with a bayonet forceps against the floor of the pituitary fossa, from within the sphenoid sinus, it was reinforced and secured in place with BioGlue. This was introduced via a malleable plastic 10cm extender tip under direct vision, incrementally and as required once the mixing tip had been primed ensuring the BioGlue components had been appropriately mixed. The quantity of BioGlue used varied between 5-10ml. The nasal cavity was then packed with iodine impregnated ribbon gauze (BIPP) that was removed after 48 hours.

Post operative histological appearance



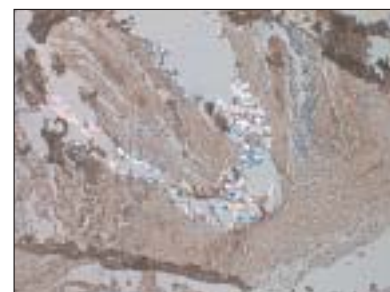
BioGlue on dorsal root ganglia. No evidence of granuloma formation or fibrosis.

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BioGlue at 2 years in an aortic dissection sheep model (H&E stain). No evidence of granuloma formation or fibrosis.

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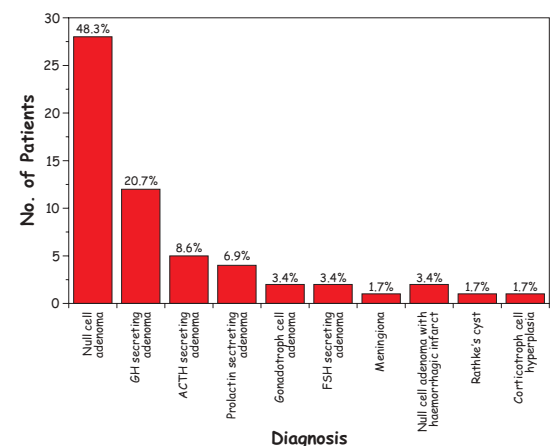
Results

Follow-up ranged from 40 days to 890 days with a median of 298 days. There were no occurrences of postoperative CSF rhinorrhea, allergic rhinitis, meningitis, pneumocranium, granulomas or other complications associated with the use of BioGlue.

Conclusions

This technique of reconstruction of sellar floor using BioGlue is simple and time efficient in preventing CSF fistula formation following transsphenoidal procedures for sellar region lesions.

Table: Pathological diagnoses of 58 patients where BioGlue was used for sellar floor reconstruction



Reference: Journal of Clinical Neuroscience. 10(1), 92-94, 2003