

Introduction

Leakage of cerebrospinal fluid (CSF) can lead to fistula formation, pseudomeningocele, neurological injury, infection and death. CSF leaks increase operative time and hospital stays. Currently, no methods of dural closure yield consistently reliable results. We tested a new fibrin dressing (NFD) that does not contain a collagen or cellulose backing in a CSF leak model. The carrier for the dressing is a mat of dextran nanofibers that dissolves immediately on contact with blood, leaving behind only a tenacious, translucent fibrin clot.

Methods

The cranium of 6 adult sheep was exposed and four craniotomy sites were created connecting 2 14mm burr holes. A 12-14mm durotomy was created and CSF leak was confirmed. The durotomy was then closed with a running 6-0 silk suture. Following closure a Valsalva maneuver was performed (20cm water for 15 seconds). If the durotomy leaked CSF the NFD was applied for 3 minutes. After 5 more minutes a Valsalva maneuver was performed again and observed with loupe magnification by 3 investigators. If CSF leak continued, a second dressing was applied in the same manner. If two NFD dressings did not control the CSF leak the site was considered a failure of treatment.

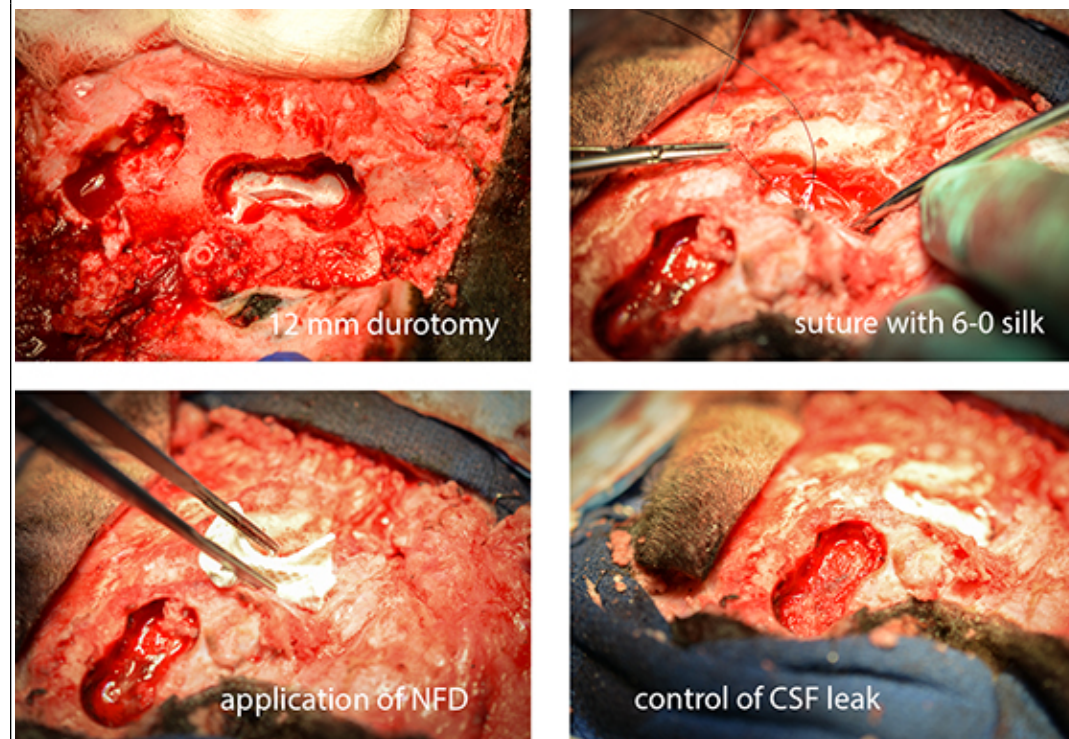
Results

Suture alone controlled CSF leak in 3 of 23 (13%) durotomies (95%CI (2.78,33.6%)). The NFD controlled CSF leak in all 20 (100%) remaining durotomies (95% CI (83.2%, 100%)), demonstrating that suture+NFD is superior to suture alone ($p < 0.0001$). Three injuries required 2 dressing applications. NFD stopped CSF leak even in presence of dura torn by suture and cerebral herniation.

Conclusions

The NFD was a useful adjunct to suture repair in this durotomy model. The NFD was able to control CSF leak even when the dura could not be approximated with suture. A parallel study of lumbar durotomies in a caprine model treated with the NFD showed no pseudomeningocele or histologic evidence of abnormal inflammation or fibrosis after 30 days of survival indicating the safety of the dressing. This highly efficacious dressing is able to seal femoral artery bleeding in coagulopathic swine (U.S. Army model, Ref 1), and is currently in clinical trials for use on bleeding cancellous bone in spine surgery (Ref 2 & 3). The dressing adheres strongly to tissue and is simple to use with no preparation necessary. Our pre-clinical studies show that this dressing controls CSF leaks from cranial and spinal dura and is useful as an autonomous, translucent patch that adheres tenaciously to the dura, allowing the surgeon to continue to work with impunity from dislodgement and recurrent leak.

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Demonstration of creation of durotomy and control of CSF leak by NFD

Learning Objectives

Surgeons should be able to describe the importance of the NFD in controlling CSF leak.

References

1. Floyd CT et al. Salmon thrombin-fibrinogen dressing allows greater survival and preserves distal blood flow compared to standard kaolin gauze in coagulopathic swine with a standardized femoral artery injury. 2012. J Spec Ops Medicine, 12(2):16-26.
2. Floyd CT et al. Hemostasis and safety of a novel fibrin dressing vs standard gauze in bleeding cancellous bone in a caprine spine surgery model. Proceedings of the Scoliosis Research Society 50th Annual Meeting, p 219, 2015
3. Craig N et al. Safety and performance study of a novel fibrin dressing for cancellous bone bleeding. Eur Spine J 25 (Suppl3): S345, 2016.



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