

Biosynthetic Materials Facilitate Effective Neurosurgical Closure

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STATEMENT OF PURPOSE: Numerous neurosurgical procedures result in the perforation or resection of the dura mater. While multiple dural substitutes exist to facilitate dural repair, an ideal implantable solution facilitating optimal handling, suturability, and biocompatibility has yet to be developed. Novel resorbable, biosynthetic materials have demonstrated significant promise as an implantable surgical material. The primary aim of the present study was to examine the safety and efficacy of a novel biosynthetic dural substitute compared to existing xenogenic and synthetic dural substitutes in a clinically-relevant animal model.

METHODS: Unilateral osteoplastic craniotomies were performed in 4.0 kg New Zealand white rabbits. Circular dural defects were then microsurgically created in the exposed dura. Induced dural defects were repaired utilizing: resorbable biosynthetic (CERAFIX™ Dura Substitute, Acera Surgical, Inc.), xenogenic collagen (DuraGen Plus®, Integra Lifescience, Inc.), or synthetic multi-laminate (Ethisorb™ Dura Substitute, Codman, Inc.) dural substitutes. All implants were applied in an onlay fashion and tacked in place using non-tension sutures. Following recovery animals were monitored for signs of CSF leakage, infection, and behavioral / neurological impairment. Four week post-operatively all animals were euthanized and repair sites were harvested for histological and histomorphometric evaluation.

RESULTS: Novel biosynthetic materials promoted effective closure and repair of dural defects comparable to gold-standard xenogenic collagen products and superior to synthetic multi-laminate products. Intraoperatively, biosynthetic materials demonstrated marked compliance, strength, and suturability and enabled successful closure of induced defects. Post-operatively, no incidents of infection, CSF leak, or neurological injury were observed as a result of implantation of the electrospun material. Histological analysis demonstrated effective tissue integration and neoduralization with biosynthetic materials equivalent to xenogenic collagen and superior to synthetic multi-laminate products.

CONCLUSIONS: Novel resorbable biosynthetic material offers a viable and effective alternative to gold-standard xenogenic collagen matrices in neurosurgical repair of dural defects.

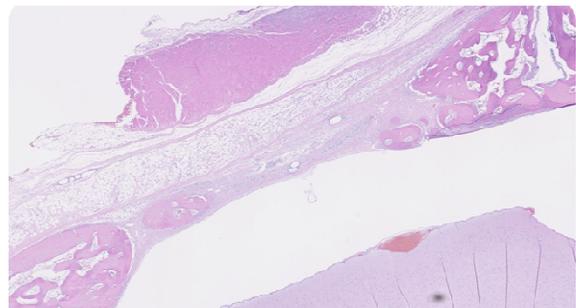
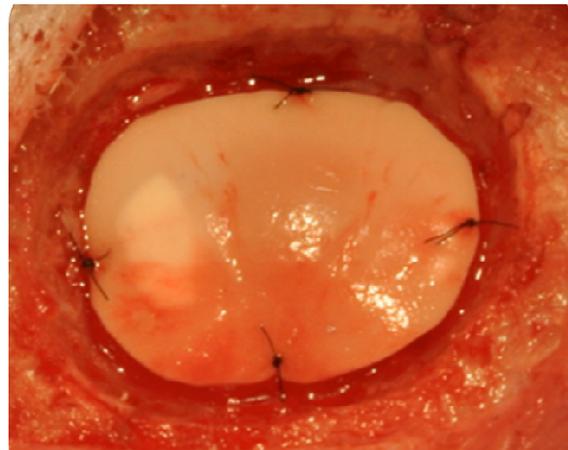


Figure 1. (Top) Novel electrospun biosynthetic material, Cerafix™ Dura Substitute, offers a compliant and suturable material for closure of induced dural defects; (Middle) Cerafix™ implanted in rabbit duraplasty model using interrupted sutures, (Bottom) Effective dural repair as evidence by H+E stain facilitated by biosynthetic material.