Novel Regenerative Nanofibrous Bio-device for Dural Defect Repair

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CONGRESS OF NEUROLOGICAL SURGEONS
2011 ANNUAL MEETING
WASHINGTON, DC
OCTOBER 1-6, 2011

Introduction

Dural defect is a common problem following posterior fossa surgery and needs to be repaired timely so as to prevent the leakage of cerebrospinal fluid (CSF). Currently, there are a few alternatives to human dura mater; however, each has its respective shortcomings such as limited availability, risk of animal pathogens, and poor biocompatibility. To address these issues, we have recently developed a novel regenerative dural substitute (trade name: ReDura) by using the electrospinning technology.

Methods

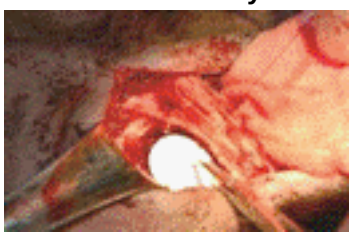
The ReDura products were fabricated from FDA approved medical-grade polyester materials by using our proprietary nanofabrication technology. The fabricated products were characterized with chemical and physical properties, microstructures, and cytotoxicity in vitro. The repairing effect of the substitutes for defective dural mater was tested with canine model. As a control, the commercially available SEAMDURA dural product (GUNZE Limited, Japan) is used.

Results

SEM imaging showed ReDuraTM mesh is composed of PLLA nanofibers in a three-dimensional network. The product owned adequate mechanical properties to avoid CSF. In the animal studies, for the group of the ReDuraTM products, new dural tissues formed along the scaffold and covered most areas of the defect one month after implantation; three-month post-implantation scaffold materials were completely degraded and a complete dura mater was generated to cover the full region of the defect. In contrary, for the group of the controls, scaffold material degraded slowly and remained most mass one month of operation, and the new brain tissue was partially formed on the scaffold three months after implantation.

Moreover, in the ReDuraTM group, adhesion of brain tissue to the implanted material was not observed; however, in the control group, a clear adhesion of material to brain tissue was seen. Histological studies confirmed the above findings.

Animal Study

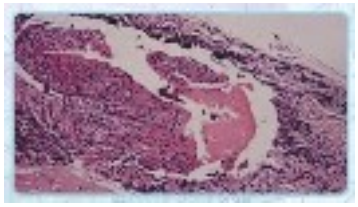


Surgical operation of ReDuraTM patch in a defective dura model

Degradation Comparison

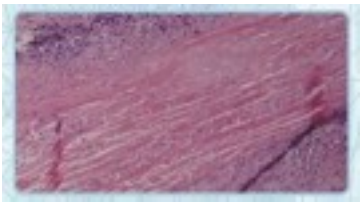
In ReDuraTM groups, new-born membrane took place in defects and scaffold materials degraded mostly (green arrows); however, in controls, partial dural was regrown with slow degradation of scaffold (blue arrows)

ReDura Group Histological Analysis



Scaffold degraded thoroughly as shown in fragment-shaped and discontinuously distributed implant debris

Control Group Histological Analysis



Fewer degradation was seen ; the implant maintained its original strip-shaped and loose structure

Conclusions

The novel nanofibrous dural substitute showed highly organized microstructure similar to native human dura matrix. The animal study shows the new dural product exhibited ideal repairing outcomes, such as excellent tissue biocompatibility, no leakage of CSF, fast degradation of the scaffold, and the superior anti-adhesion. The multicenter clinical trials of this new product are being conducted.

Learning Objectives

By the conclusion of this session, participants should be able to: 1) Describe the important of the novel nanofibrous dural substitute and 2) identify an effective treatment for the defective dural mater.