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Abstract for 2015 AANS

First Human Implantation of a Polymer Scaffold for Traumatic Spinal Cord Injury: A Clinical Pilot Study for Safety and Feasibility

Introduction:

The Neuro-Spinal Scaffold, is a proprietary, porous bioresorbable polymer scaffold which acts by appositional healing to spare white matter, decrease post-traumatic cysts, and normalize intraparenchymal tissue pressure in preclinical animal models of spinal cord contusion injury. We successfully implanted the first Neuro-Spinal Scaffold in a spinal cord injury patient.

Methods:

Following FDA approval for an Investigational Device Exemption (IDE), a 25-year-old male with a T11-12 fracture dislocation following a motorcross accident resulting in an ASIA A traumatic spinal cord injury (tSCI) was enrolled in the study. The patient was treated with acute (less than 8 hrs post-injury) surgical decompression and spinal fusion. In addition, a 2mm x 10mm Neuro-Spinal Scaffold was placed in the spinal cord parenchyma at T12 to test it's safety and feasibility.

Results:

The patient underwent a successful T11-12 decompression and T10-L1 posterior fusion. The scaffold was implanted directly into the dorsal columns of the spinal cord through a myelotomy at the caudal extent of the contused area. The patient's ASIA score and sensory level (T12) did not acutely improve or deteriorate following this novel surgery. There were no procedural complications related to the scaffold implantation.

Conclusions:

While longer term follow up and investigation will be required, we demonstrated that a polymer scaffold can be safely implanted into an acutely contused spinal cord. This is the first human surgical implantation of its kind and future studies will focus similar scaffolds impregnated with stem cells aimed at improving function following tSCI.