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Novel Surgical Procedure to Implant an Investigational Neuro-Spinal Scaffold Following Myelotomy for Treatment of Acute Traumatic Spinal Cord Injury: A Safety and Feasibility Study

Introduction:

The proprietary Neuro-Spinal Scaffold is a porous bioresorbable polymer implanted into the contusion epicenter of a spinal cord injury. A clinical study is underway to establish safety and feasibility of the Scaffold in acute thoracic SCI. The first two subjects have successfully undergone Scaffold placement and are being followed for safety.

Methods:

Following FDA IDE approval the first subject was enrolled and closely monitored for neurologic function. After a Data Safety Monitoring Board (DSMB) review of the first 2 months of safety data from this subject, enrollment was opened to a second subject. After DSMB review of all available safety data for both study subjects and FDA submission, it is anticipated that enrollment will open for three additional subjects.

Results:

The first subject, a 25-year-old male with a T11-12 fracture dislocation following a motocross accident resulting in an AIS A traumatic SCI, was enrolled in the study. The subject was treated with surgical decompression and spinal fusion. A 2mm diameter x 10mm length Scaffold was implanted directly the spinal cord through a myelotomy at the caudal extent of the contused area. At the 3 month follow up visit, the subject was an AIS C. The second subject, a 22-year-old female with a T6-T7 chance fracture AIS A acute SCI following a motorcycle accident, complicated by polytrauma, was enrolled. After T4-L2 spine stabilization, a 3mm diameter x 10mm length Scaffold was placed into the contusion epicenter. There were no procedural complications and to date, no reports of safety events related to either the Scaffold or the procedure.

Conclusions:

Preliminary results from this ongoing study demonstrate that the Neuro-Spinal Scaffold can be implanted into an acutely contused spinal cord following myelotomy.

This is the first human surgical implantation of its kind, offering the potential for a novel treatment of acute SCI.