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

2015 Annual AANS Meeting
Poster # 31137

Alexander E. Ropper, MD 1
Randall Hlubek, MD 1
Jill Danielson, RN 1
Lou Vaickus, MD 2
Kristin Neff 2
Thomas R. Ulich, MD 2
Nicholas Theodore, MD 1

1. Division of Neurological Surgery, Barrow Neurological Institute, St. Joseph’s Hospital and Medical Center. Phoenix, AZ.
2. In Vivo Therapeutics Corporation. Cambridge, MA.
Disclosures

• The presenting author, AER, has no financial disclosures.

• LV, KN and TRU are employees of In Vivo Therapeutics Corp. and have a financial interest in the company.
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 an acute spinal cord injury patient.
Methods

• Following FDA approval for an Investigational Device Exemption (IDE), IRB approval and informed consent, a 25-year-old male with a T11-12 fracture dislocation following a motocross accident resulting in an AIS 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 from T10-L1.
• A 2mm x 10mm Neuro-Spinal Scaffold was placed into a cavity created by the contusion in the spinal cord parenchyma at T12.
• The goal of the study was to test safety and feasibility.
Preoperative CT scans
Preoperative T2 MRI
Results

• A cystic and hemorrhagic cavity was encountered in the center of the spinal cord at T12.
• A myelotomy was performed at the caudal end of the contused area via a left dorsal root entry zone approach.
• Gentle irrigation and suction cleared the necrotic tissue and blood from the injured parenchyma.
• After opening into the cavity, the spinal cord lost its tension and the pulsatility of the cord returned indicating resumption of circulation.
• The scaffold was then implanted directly into the cavity.
• The patient’s AIS score and sensory level (T11) did not acutely improve or deteriorate following this novel surgery.
• There were no procedural complications related to the scaffold implantation.
3 month follow up

Pre-Surgery

3-Month Visit

Summary

- 10 point sensory improvement
- 2 segment neurological level of injury improvement (T11 → L1)
- 8 point motor improvement
- DAP (deep anal pressure) at 3 mo: YES
- VAC (voluntary anal contraction) at 3 mo: YES
- Improved. AIS A → AIS C
Summary

• While longer follow up and investigation will be required, we demonstrated that a biopolymer scaffold can be safely implanted into an acutely contused spinal cord.

• This was the first human surgical implantation of its kind.

• Future studies will focus on the use of similar scaffolds impregnated with stem cells aimed at improving function following traumatic spinal cord injury.