

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

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Introduction

Extradural bony decompression and fixation is the current standard of care for acute spinal cord injury (SCI). A novel treatment being explored to manage acute SCI includes myelotomy followed by implantation of a biodegradable scaffold within the necrotic lesion. The investigational *Neuro-Spinal Scaffold* has been shown preclinically to preserve the macroscopic architecture of the spinal cord and facilitate microscopic neural regeneration. A clinical study is underway to establish safety and feasibility of the *Neuro-Spinal Scaffold* in acute thoracic complete SCI. The first five patients have successfully undergone scaffold implantation and are being followed for safety.

Methods

Pilot Study of Clinical Safety and Feasibility of the PLGA Poly-L-Lysine Scaffold for the Treatment of Complete (AIS A) Traumatic Acute Spinal Cord Injury (NCT02138110)

The purpose of this study is to evaluate whether the Scaffold is safe and feasible for the treatment of complete functional SCI and gather preliminary evidence of clinical effectiveness.

Key Inclusion Criteria:

- AIS A (T3-T12/L1)
- 18-65 years of age
- Nonpenetrating contusion injury no less than 4 mm diameter by MRI
- within 4 days of injury

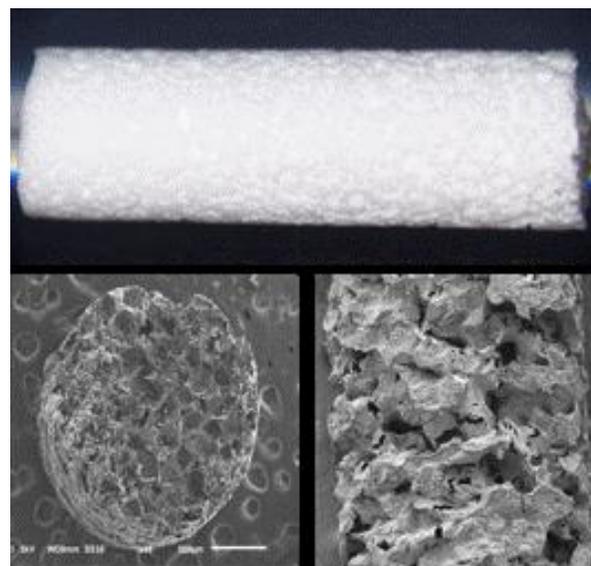
Key Exclusion Criteria:

- Incomplete SCI
- SCI associated with TBI
- Significant spinal conditions other than lesion to be treated

Results

Patient demographics at time of Scaffold Implantation

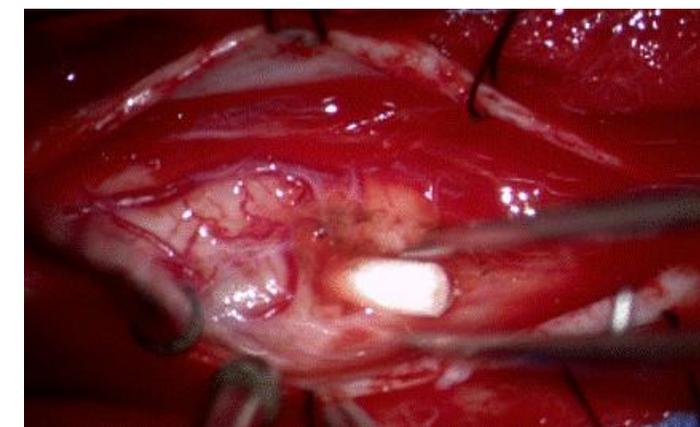
Patient Number	Neurological Level of Injury	Time to Implant (hrs)
1	T11	10
2	T7	46
3	T4	83
4	T3	53
5	T8	69



Structure of porous, biodegradable Scaffold

Representative Surgical Procedure:

- Perform midline durotomy
- Perform myelotomy (midline or DREZ)
- Gentle saline irrigation of contusion to remove necrotic tissue
- Implant scaffold within cavity
- Close dura in water-tight fashion (running suture or duraplasty)



Scaffold implantation within cavity (top). Intraoperative ultrasound image of the Scaffold implanted in the spinal cord (bottom).

Conclusion

The *Neuro-Spinal Scaffold* has been safely implanted acutely in five patients. In all cases, access to the lesion was achieved via myelotomy and gentle irrigation of the necrotic epicenter allowed for scaffold placement in the cavity. There have not been any serious adverse events that were deemed device-related to date. Preliminary results show that two of the three patients who have undergone clinical evaluation have converted from complete to incomplete SCI. This study represents a novel treatment approach to acute SCI that has potential to redefine standard of care.