

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 three subjects 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 * Non-penetrating 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

Table 1: Subject demographics at time of scaffold implantation

| Subject Number | Neurological Level of Injury | Time to Scaffold Implant (hr) |
|----------------|------------------------------|-------------------------------|
| 1 | T11 | 10 |
| 2 | T7 | 46 |
| 3 | T4 | 83 |

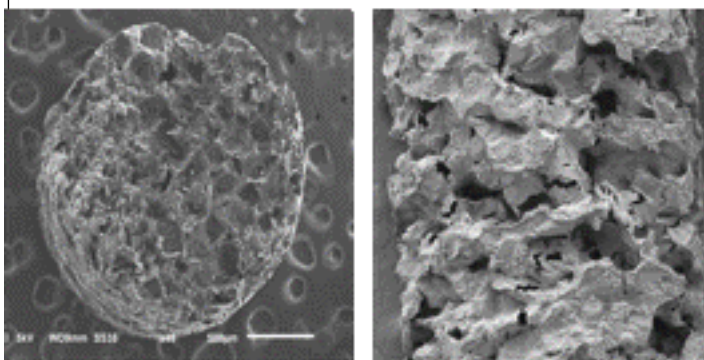
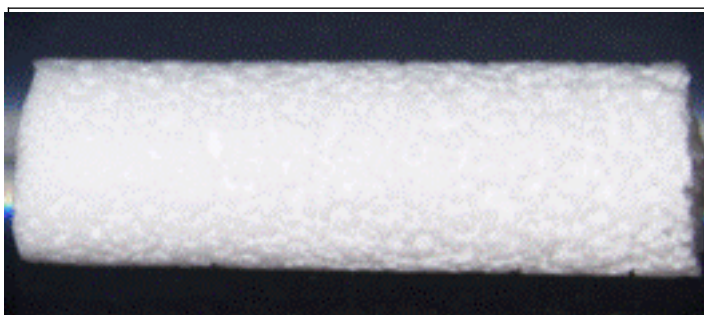


Fig. 1: Structure of porous, biodegradable scaffold

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)

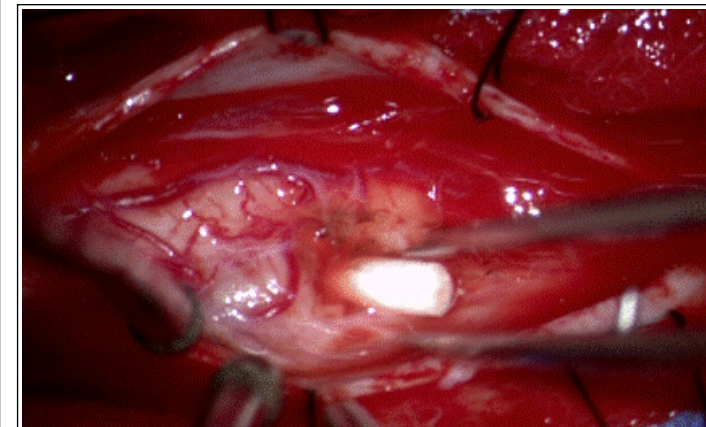


Fig. 2: Scaffold implantation within cavity



Fig. 3: Intraoperative ultrasound image of the scaffold implanted in the spinal cord

Conclusion

The Neuro-Spinal Scaffold has been safely implanted acutely in three subjects. 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 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.