Nicholas Theodore, MD, *Barrow Neurological Institute*
Domagoj Coric, MD, *Carolina Neurosurgery & Spine*
Patrick Hsieh, MD, *Keck Medicine of USC*
Kee Kim, MD, *UC Davis*

Abstract Title:
Neurologic Outcome following Implantation of a *Neuro-Spinal Scaffold*™ into the Lesion Cavity in Acute Thoracic Complete Spinal Cord Injury: Results of a Pilot Study

Introduction:
84% of patients with complete thoracic spinal cord injuries remain AIS A at 6 months. The Neuro-Spinal Scaffold is an investigational device that is implanted into an acutely injured spinal cord. Preclinically, scaffold implantation promoted tissue remodeling with preservation of spinal cord architecture at the site of scaffold implantation. This first-in-human study evaluates the effect of scaffold implantation on neurologic recovery in acute traumatic thoracic AIS A patients.

Methods:
Five patients with non-penetrating complete SCI between T3-T12/L1 were enrolled. Following spine stabilization, access to the injured spinal cord was achieved through myelotomy. The scaffold was implanted within the cavity at the epicenter of the spinal cord contusion. Patients receive frequent MRI scans and neurologic assessments for up to one year.

Results:
Scaffolds were implanted between 10 and 83 hours following injury. Patient #1 (T11) improved from AIS A to AIS C with a neurological level of L1 at one month with 3+ hip flexor and 2+ knee extensor function bilaterally at 6 months. At 6 months, Patient #2 (T7) had a sensory zone of partial preservation improvement from T7 to T12 and remains AIS A. Patient #3 (T4) improved from AIS A to AIS B at one month. Patients 4 (T3) and 5 (T8) are awaiting one month follow up. There have been no serious adverse events related to the investigational product or procedure.

Conclusions:
This study represents the first neurosurgical treatment of patients with complete SCI using myelotomy followed by implantation of a customized scaffold. In all cases, a contusion cavity was present and scaffold implantation was straightforward and safe. Two of the first three patients converted to incomplete status by one month. Six month data will be presented on all five patients. These encouraging results warrant further study.