INSPIRE study

https://clinicaltrials.gov/ct2/show/NCT02138110

INSPIRE was a prospective, open-label, multicenter, single-arm study. Eligible patients had traumatic nonpenetrating spinal cord injury (SCI) with a visible contusion on MRI, American Spinal Injury Association Impairment Scale A classification, neurological level of injury at T2-T12, and requirement for open spine surgery ≤96 hours postinjury.

Nineteen patients underwent Neuro-Spinal Scaffold [NSS] implantation. Three patients had early death determined by investigators to be unrelated to the NSS or its implantation procedure. Seven of 16 evaluable patients (44%) had improvement of ≥1 AIS grade at 6 months (primary end point) to AIS B (n = 5) or AIS C (n = 2). Three patients with AIS B at 6 months had further neurological improvement to AIS C by 12 (n = 2) and 24 (n = 1) months, respectively; none have deteriorated per latest available follow-up. No unanticipated or serious adverse device effects were reported.

In this small group of patients with complete thoracic SCI, acute NSS implantation within the spinal cord appeared to be safe with no long-term neurological issues identified during the 24-month follow-up. Patients remain stable, with additional AIS conversions observed in some patients at 12 months and beyond. These data further support the safety and probable benefit of NSS implantation in this patient population [1)]

Acute traumatic spinal cord injury (SCI) is a devastating event with far-reaching physical, emotional, and economic consequences for patients, families, and society at large. Timely delivery of specialized care has reduced mortality; however, long-term neurological recovery continues to be limited. In recent years, a number of exciting neuroprotective and regenerative strategies have emerged and have come under active investigation in clinical trials, and several more are coming down the translational pipeline. Among ongoing trials are RISCIS (riluzole), INSPIRE study (Neuro-Spinal Scaffold), MASC (minocycline), and SPRING (VX-210). Microstructural MRI techniques have improved our ability to image the injured spinal cord at high resolution. This innovation, combined with serum and cerebrospinal fluid (CSF) analysis, holds the promise of providing a quantitative biomarker readout of spinal cord neural tissue injury, which may improve prognostication and facilitate stratification of patients for enrollment into clinical trials. Given evidence of the effectiveness of early surgical decompression and growing recognition of the concept that “time is spine,” infrastructural changes at a systems level are being implemented in many regions around the world to provide a streamlined process for transfer of patients with acute SCI to a specialized unit. With the continued aging of the population, central cord syndrome is soon expected to become the most common form of acute traumatic SCI; characterization of the pathophysiology, natural history, and optimal treatment of these injuries is hence a key public health priority. Collaborative international efforts have led to the development of clinical practice guidelines for traumatic SCI based on robust evaluation of current evidence [2)].

1)

Kim KD, Lee KS, Coric D, Harrop JS, Theodore N, Toselli RM. Acute Implantation of a Bioresorbable Polymer Scaffold in Patients With Complete Thoracic Spinal Cord Injury: 24-Month Follow-up From the INSPIRE Study. Neurosurgery. 2022 Apr 22. doi: 10.1227/neu.0000000000001932. Epub ahead of

print. PMID: 35442254.
2)
Badhiwala JH, Ahuja CS, Fehlings MG. Time is spine: a review of translational advances in spinal cord injury. J Neurosurg Spine. 2018 Dec 20;30(1):1-18. doi: 10.3171/2018.9.SPINE18682. Review. PubMed PMID: 30611186.