Neuro-Spinal Scaffold

The INSPIRE study 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)]

The NSS was implanted into the epicenter of the postirrigation intramedullary spinal cord contusion cavity with the intention of providing structural support to the injured spinal cord parenchyma. The primary efficacy endpoint was the proportion of patients who had an improvement of ≥ 1 AIS grade (i.e., conversion from complete paraplegia to incomplete paraplegia) at the 6-month follow-up visit. A preset objective performance criterion established for the study was defined as an AIS grade conversion rate of ≥ 25%. Secondary endpoints included change in neurological level of injury (NLI). This analysis reports on data through 6-month follow-up assessments.

Nineteen patients underwent NSS implantation. There were 3 early withdrawals due to death, which were all determined by investigators to be unrelated to the NSS or the implantation procedure. Seven of 16 patients (43.8%) who completed the 6-month follow-up visit had conversion of neurological status (AIS grade A to grade B [n = 5] or C [n = 2]). Five patients showed improvement in NLI of 1 to 2 levels compared with preimplantation assessment, 3 patients showed no change, and 8 patients showed deterioration of 1 to 4 levels. There were no unanticipated or serious adverse device effects or serious adverse events related to the NSS or the implantation procedure as determined by investigators.

In this first-in-human study, implantation of the NSS within the spinal cord appeared to be safe in the setting of surgical decompression and stabilization for complete (AIS grade A) thoracic SCI. It was associated with a 6-month AIS grade conversion rate that exceeded historical controls. The INSPIRE study data demonstrate that the potential benefits of the NSS outweigh the risks in this patient population and support further clinical investigation in a randomized controlled trial.Clinical trial registration no.: NCT02138110 (clinicaltrials.gov) [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)
Kim KD, Lee KS, Coric D, Chang JJ, Harrop JS, Theodore N, Toselli RM. A study of probable benefit of a bioresorbable polymer scaffold for safety and neurological recovery in patients with complete thoracic spinal cord injury: 6-month results from the INSPIRE study. J Neurosurg Spine. 2021 Feb 5:1-10. doi: 10.3171/2020.8.SPINE191507. Epub ahead of print. PMID: 33545674.