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INSPIRE Neuro-Spinal Scaffold™ : An Implantable Alternative to Stem-Cell Therapy for Endogenous Repair in Spinal Cord Injury

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To the Editor,

We have read with great interest the article by Jeong et al.³⁾. The depth with which the current state of stem cell therapy for spinal cord injury (SCI) was explored was vastly appreciated, given that implications of SCI include significant impairment of patients' overall quality of life and well-being. Astoundingly, first year costs after injury associated with SCI are estimated at an average of \$1044197 for individuals with C1–C4 tetraplegia and \$754524 for those with C5–C8 tetraplegia (after all medical costs and personal needs associated with SCI are considered). Over the course of their lifetime, an individual who develops High tetraplegia before the age of 25 will incur, on average, almost \$5000000 in direct costs due to SCI⁵⁾. Clearly, the stakes associated with SCI are high, and adult stem cells as well as mesenchymal stem cells must continue to be explored for their potential to yield therapeutic outcomes in those suffering from SCI²⁾.

As noted by Jeong et al.³⁾, various regenerative strategies involving scaffolds, cytokines, and other modulatory factors are coming through the pipeline that may augment the effects of stem cell therapies. However, combinations of stem cells with

various scaffolds (poly lactic-co-glycolic acid, collagen, chitosan, gelatin), trophic factors (neurotrophin 3, brain-derived neurotrophic factor, cyclic AMP, fibroblast growth factor), and lithium, as denoted by Jeong et al.³⁾, have failed to demonstrate clear synergistic effects.

Despite these disappointing results, several clinical trials are in the works involving translational therapeutic strategies that are stem-cell independent. Of particular note (as Jeong et al.³⁾ briefly describe combined stem cell-poly lactic-co-glycolic acid scaffold techniques) is the INSPIRE (Neuro-Spinal Scaffold™) technology, an implantable poly lactic-co-glycolic acid polymer scaffold that is thought to promote endogenous repair in SCI²⁾. Developed by InVivo Therapeutics Corp., this porous bioresorbable scaffold conjugated to poly-L-lysine is thought to promote healing while minimizing cyst formation and stabilizing intraparenchymal pressure¹⁾. In animal hemisection models, this scaffold has been shown to promote recovery. A current study evaluating the safety and effectiveness of the Neuro-Spinal Scaffold for recovery in SCI between vertebral level T2-T12 (InVivo Study of Probable Benefit of the Neuro-Spinal Scaffold™ for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Inju-

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ry) has already reported a positive case study. When implanted into the spinal cord (via a dorsal root entry zone myelotomy) of the first patient (a 25-year-old male who had sustained a T11 American Spinal Injury Association Impairment Scale (AIS) grade A traumatic spinal cord injury), there were no procedural complications or safety issues to report. Additionally, at 3 months postoperative follow-up, his neurological examination had improved to L1 AIS grade C incomplete injury^{4,6}. A later study begun in May 2019 by InVivo Therapeutics is comparing Probable Benefit of the Neuro-Spinal Scaffold™ in Subjects With Complete Thoracic AIS A Spinal Cord Injury as Compared to Standard of Care (INSPIRE 2). Ultimately, if stem cells continue to yield marginal results, as noted by Jeong et al.³ in the recent installment of the *Journal of Korean Neurosurgical Society*, scaffold technology could provide the answers we are seeking in SCI therapeutics. The Neuro-Spinal Scaffold™ appears to be safe and has already demonstrated in primate models that it can promote appositional healing, spare white matter, decrease post-traumatic cyst formation, and normalize intraparenchymal tissue pressure¹.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

INFORMED CONSENT

This type of study does not require informed consent.

AUTHOR CONTRIBUTIONS

Conceptualization : NB

Data curation : NB

Formal analysis : NB

Funding acquisition : NB

Methodology : NB

Project administration : NB

Visualization : NB

Writing - original draft : NB

Writing - review & editing : NB

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