**TITLE:** Five Year Follow up of Chronic Spinal Cord Injury Patients Receiving Autologous Bone Marrow-Derived Mesenchymal Stem Cell Therapy Combined With Physical Therapy.

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**ABSTRACT:**

**Background:** Spinal cord injuries (SCI) cause sensory loss and motor paralysis. They are normally treated with physical therapy, but most patients fail to recover due to limited neural regeneration. Here we describe a strategy in which treatment with autologous adherent bone marrow cells is combined with physical therapy to improve motor and sensory functions in early stage chronic SCI patients.

**Subjects and Methods:** In a phase I/II controlled single-blind clinical trial (clinicaltrials.gov identifier: NCT00816803), 70 chronic cervical and thoracic SCI patients with injury durations of at least 12 months were treated with either intrathecal injection(s) of autologous adherent bone marrow cells combined with physical therapy or with physical therapy alone. Patients were evaluated with clinical and neurological examinations using the American Spinal Injury Association (ASIA) Impairment Scale (AIS), electrophysiological somatosensory-evoked potential, magnetic resonance imaging (MRI), and functional independence measurements. Chronic cervical and thoracic SCI patients (15 AIS A and 35 AIS B) treated with autologous adherent bone marrow cells combined with physical therapy showed functional improvements over patients in the control group (10 AIS A and 10 AIS B) treated with physical therapy alone, and there were no long-term cell therapy-related side effects.

**Follow-up:** Patients were assessed every months for five years after completing cell therapy.

**Results and Conclusions:** At 18 months post-treatment, 23 of the 50 cell therapy-treated cases (46%) showed sustained functional improvement. Compared to those patients with cervical injuries, a higher rate of functional improvement was achieved in thoracic SCI patients with shorter durations of injury and smaller cord lesions. Therefore, when combined with physical therapy, autologous adherent bone marrow cell therapy appears to be a safe and promising therapy for patients with chronic SCI of traumatic origin. Randomized controlled multicenter trials are warranted. None of the patients showed loss of improvements or development of late complications related to cellular therapy.

**Keywords:** stem cell therapy, mesenchymal stem cells, spinal cord injury