STEM CELL THERAPY FOR SPINAL CORD INJURY

Patient treatment results at BioXcellerator

Scientific Direction Board
BioXcellerator

bio cellerator Medicina Regenerativa Y Células Madre	**STEM CELL THERAPY FOR SPINAL CORD INJURY. Patient treatment results at Bioxcellerator**

Contents

Figures

Introduction

Spinal Cord Injury -SCI- is a damage on spinal nerves, body's central and most important nerve bundle, because of backbone trauma. SCI is often called a “broken neck” or “broken back”.

Most SCI patients treated at Bioxcellerator were caused by trauma that resulted in fractured or squeezed vertebrae or bones in the back, damaging axons; the long nerve cell "wires" that pass-through vertebrae, carrying signals between the brain and body. Stem cell therapy facilitates the natural repair of nerve tissue in spinal cord and nerve roots.

SCI is classified by injury level and severity:

- Injury level is determined by the lowest point on the spinal cord where sensory feeling and motor movement diminish or disappear. Trauma or SCI can occur in a segment of the cervical, thoracic, or lumbosacral cord.
- SCI severity is subclassified into 2 grades:
  - ***Complete injury:*** so severe that almost all feeling (sensory function), and movement control ability (motor function) are lost below the SCI area.
  - ***Incomplete injury:*** some sensory or motor function remains below the SCI area. There are many degrees of incomplete injury.

Mesenchymal Stem Cells (MSCs) therapy can potentially support the microenvironment to improve the health status of SCI patients, by modulating the inflammatory response, increasing vascularity, and promoting the body’s natural repair process.

Demographic and clinical data

Bioxcellerator treated 32 SCI patients with MSCs therapy between 2019 and 2021. These charts show the baseline clinical characteristics of those patients.

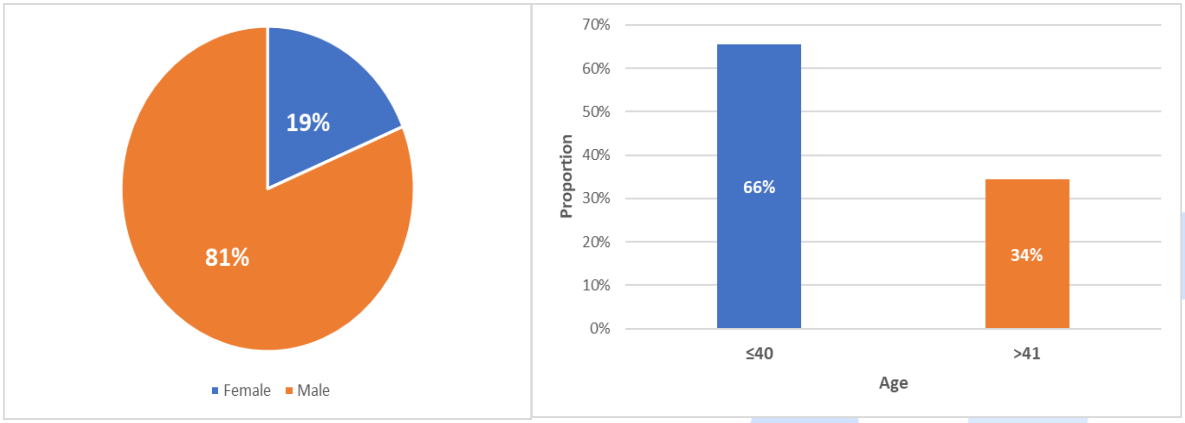


Figure 1. Distribution of patients treated with MSCs by gender and age.

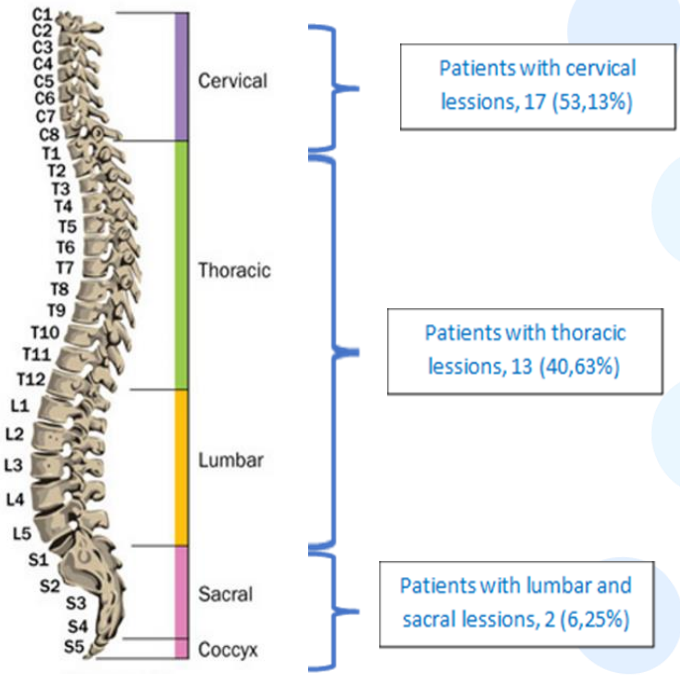


Figure 2. Distribution of patients treated with MSCs by injury level

Treatment data

The clinical treatment protocol for SCI patients, includes 4 visits to our clinic for MSCs therapy and clinical follow-up.

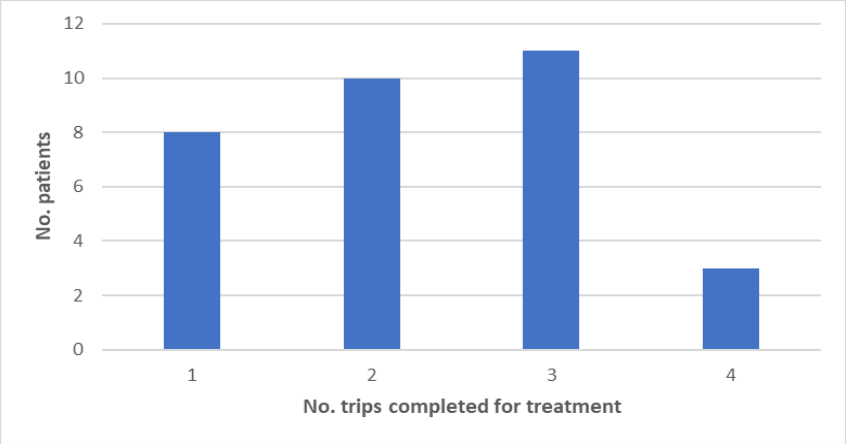


Figure 3. Number of visits to Bioxcellerator clinic by SCI patients as of December 2021.

Outcome findings

Progression disease or improvement of SCI patients is evaluated with the American Spinal Injury Association (ASIA) scale, a widely accepted standard for evaluating motor and sensory function as well as injury severity. Bioxcellerator physicians use this scale to assess a patient's progress on each visit to the clinic for Mesenchymal Stem Cells (from Wharton's Jelly) therapy.

Measurement of upper- and lower-extremity strength is scored from 0 (completely paralyzed limb) to 5 (active movement and full range of motion against maximal resistance) for each limb. Deep and superficial sensation is also evaluated. Scores for each component and each limb (upper and lower) range from 0 to 100; with higher scores corresponding to improved recovery.

Findings based on the ASIA scale are classified as follows:

- **Grade A:** The impairment is complete. There is no motor or sensory function left below the level of injury.
- **Grade B:** The impairment is incomplete. Sensory function, but not motor function, is preserved below the neurologic level (the first normal level above the level of injury) and some sensation is preserved in the sacral segments S4 and S5.
- **Grade C:** The impairment is incomplete. Motor function is preserved below the neurologic level, but more than half of the key muscles below that level have a muscle grade less than 3 (not strong enough to move against gravity).

- **Grade D**: The impairment is incomplete. Motor function is preserved below the neurologic level, and at least half of the key muscles below that level have a muscle grade of 3 or more (strong enough to move against gravity).
- **Grade E:** The patient's functions are normal. All motor and sensory functions are unhindered.

According to the ASIA results, most of our patients (79%) presented complete SCI (Grade A), followed by grade B incomplete injury (14%).

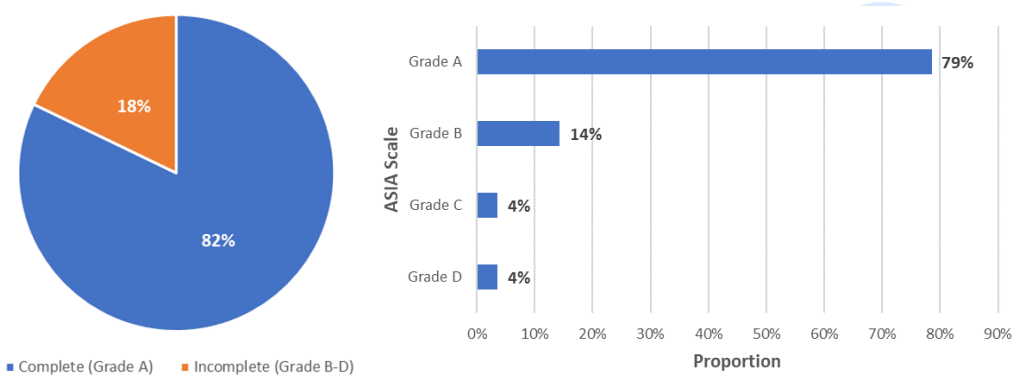


Figure 4. Distribution of patients treated with MSCs by ASIA scale (Impairment Scale for Traumatic SCI).

Key sensory points are bilaterally tested using “pin prick” and “light touch”.

"Pin prick" type sensitivity

Based on sensitivity score, the improvement in “pin prick” was evident from the third treatment visit, going from a median of 46 points to 54 points, with an increase of 8 points (17.3%) on the overall punctuation, for all body segments. This indicates that for an improvement in deep sensitivity in SCI patients, is required a minimum of three stem cell treatment-visits.

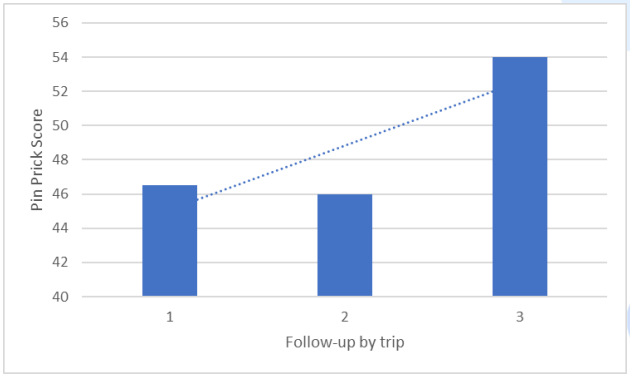


Figure 5. ASIA "pin prick” type sensitivity at three therapy and follow-up visits.

"Light touch" type sensitivity

There was no significant increase of the score in superficial-type sensitivity or "light touch" in any of the stem cell treatment visits. This seems to indicate that improvement in sensitivity may be better seen at a 'coarse' than in 'fine' sensitivity. However, several of our SCI patients had not completed their treatment visits, so improvement levels might change when more data becomes available.

ASIA motor score on limbs evaluation

Our results show an improvement in motor function in SCI patients treated with MSCs, going from a base median of 12 to 18 points at the third visit, with an increase of 6 points (50%) on the overall punctuation. This indicates that for an improvement in motor function in SCI patients, is required a minimum of two stem cell treatment-visits.

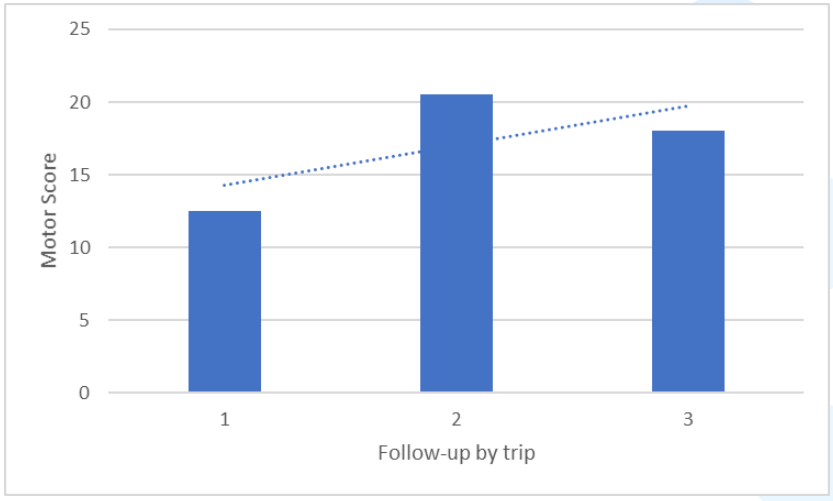


Figure 6. ASIA motor score on limb's evaluation after three MSCs therapies and follow-up visits.

Other significant findings

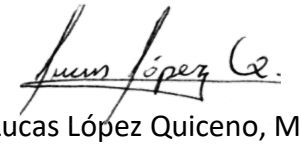
Our data evidenced that the SCI patients who complete a protocol of four treatment visits, significantly improve their sensory level, strength and mobility of their hands and can-do activities such as putting on and taking off their shirt, combing their hair, brushing their teeth, and eating alone.

However, SCI patients with incomplete protocols of two treatment visits have reported improvement in their energy levels, greater sleep conciliation and control of abdominal muscles, and less need for pain medication.

Some of our SCI patients have also reported a progressive and gradual increase in muscle strength in their arms and legs, and greater ease of muscle movement, and a decrease in spasms and stiffness.

In addition, some SCI patients have reported a reduction in the severity of their neuropathy by up to 75%, along with less neuropathic pain. Other patients with complete SCI have reported improvement of anal and urinary sphincters control.

This report was prepared by Scientific Direction Board from internal data sources on January 25, 2022.



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