

# Epidural Stimulation Surgery / T7, Italy

Patient Case Report  
#ES180037 / 3 Months

## Patient Overview

**Age:** 45

**Sex:** Female

**Nationality:** Italian

**Diagnosis on Admission:** Spinal cord Injury, T7

**Treatment Received:** Epidural Stimulation Surgery, Medtronic Restore Advance 16-electrode MRI Compatible Device. MSCs and hAFSCs 120 million.

**Date of Admission:** 06/07/2018

**Date of Discharge:** 09/08/2018

## Patient's Condition on Admission

Patient sustained fracture and bursting of T7 with 12mm rear wall displacement. Her MRI scan showed T7 fracture-dislocation with subsequent spinal cord contusion and myelomalacia. Patient has complete paraplegia with no residual motor or sensory functions below the injury level, but is independent in her daily activities. Patient suffers from neurogenic bladder and bowel.

## Previous Therapies and Treatments

Patient has participated in various rehabilitation programs, including ones for strengthening her upper extremities and improving ambulation and trunk control.

## Treatment Received

After a Spinal MRI scan and comprehensive blood work, patient underwent Laminectomy and implantation of the Epidural stimulation device on July 7, 2018. The surgery was completed without issue and no complications were reported during the postoperative hospital stay. Surgical wounds healed normally and no spinal cord or superficial wound infection was reported. Device Mapping and therapy were carried out after surgery for 35 days, then patient was discharged.

## Device Mapping and Therapy

Post-Surgical Care	Total Sessions	Sessions Per Week	Time (Hr) Per Session
Mapping	90	22	1
Physical Therapy	27	6	1
Occupational Therapy	-	-	-

## Cytotherapy

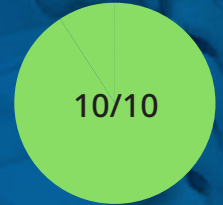
Type	Amount	Delivery Method	Number of Applications
MSCs	40 Million	IV Injection	1
hAFSCs	80 Million	Lumbar Puncture Injection	2

# Symptoms Improvement Post-Surgery

Abilities & Symptoms	Motor & Sensory Function (below injury level, before ES surgery)	Improvement Observed (35 days after admission)
<b>Motor Function</b>		
Standing with support	Not Possible	Yes
Stepping with support	Not Possible	Yes
Gross motor Skills	Not Present	Yes
Fine Motor skills	Not Applicable	Not Applicable
Balance	Poor	Yes
Coordination	Poor	Yes
Muscle Mass	Low	Yes
Stamina	Low	Yes
Fatigue	Present	Yes
Spasms	Present	Yes
Spasticity	Present	Yes
<b>Sensory Function</b>		
Neuropathic pain	Present	Present
Bladder Function	No	No
Bowel Function	No	No
Sweating Ability	No	No

Improvements are monitored in 15 targeted areas: 11 Motor areas and 4 Sensory areas. However, the number of targeted areas may vary depending on patient's condition prior to admission. If patient does not experience symptoms in certain Motor/Sensory functions, or is not impaired in a specific targeted area prior to surgery, it is excluded from the report (Not Applicable). If there is progress in any given area -- either mild, moderate, or significant -- it is measured and reported as positive ("Yes"). No improvement, the existence of pain or spasms, or an inability to perform a measured function is reported as "No".

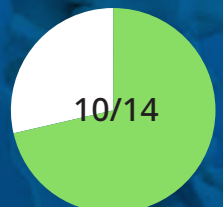
## Motor Functions



## Sensory Functions



## Overall Functions



## Results Interpretation

Since patient is paraplegic with normal upper limb function, improvement in Fine Motor Skills was considered "Not Applicable". Motor Function improved in 10 out of 10 targeted areas when the Epidural Stimulation device was switched on. Patient has not experienced any changes in Sensory Function, but more feedback will be collected after 3 months to note any improvements made by cytotherapy. Overall, improvements were recorded in 10 out of 14 targeted Motor and Sensory Function areas.

## Treatment Summary

After Epidural Stimulation surgery, patient received 90 Mapping sessions and 27 physical therapy sessions. Patient also received 120 million: 40 million MSCs and 80 million hAFSCs through one IV injection and two lumbar puncture injections, respectively. All three applications went well without adverse effects and no short-term or acute complications have been reported.

Mapping began two days after surgery and good voluntary muscle contraction was observed. Therapy was halted by a severe urinary tract infection and recurrent fever for which patient was treated with a prolonged course of IV antibiotics. She completely recovered towards the end of the post-surgical therapy (35 days).

After recovery, new Mapping sessions were begun and eventually voluntary muscle control started to come back, with standing and stepping training during the last week of the treatment.

Patient's Gross Motor Skills improved slightly. Patient is able to move her legs, and can move the left better than the right. Improvement was seen in hip flexion, but ankle flexion is observed in the left ankle only. Patient is able to lift her feet slightly.

Patient has good static sitting balance, but dynamic sitting balance requires minimal assistance. Patient has good static and dynamic standing balance with minimal support. Muscle mass has increased and endurance has improved. Two Mapping programs have reduced flexor spasms the patient experiences during sleep: one is conducted 2 hours before sleep and the other occurs overnight.

Patient is able to stand at the parallel bar and is able to lock both knees, but her left knee locks better than the right. Patient has good trunk control and is able to lock her hips while standing and bears weight equally on both legs. Patient uses a walking frame when taking assisted steps, but requires assistance with foot placement and is unable to lock her knees. Patient is able to coordinate both legs during her stepping exercises.

There was no noticeable improvement to her neurogenic bladder and bowel. Patient received cytotherapy, therefore we expect to see results in these areas within 3 months time. After 35 days, patient was discharged and will continue her physiotherapy back home.

## Three-Month Follow-Up Assessment

Abilities & Symptoms	Observations (3 months after discharge)
<b>Motor Functions</b>	
Standing with support	Mild Improvement
Stepping with support	Mild Improvement
Gross motor Skills	Mild Improvement
Fine Motor skills	N/A
Balance	No Change
Coordination	No Change
Muscle Mass	Mild Improvement
Fatigue	Moderate Improvement
Stamina	Moderate Improvement
Spasms	Slight Increase
Spasticity	Slight Increase

Abilities & Symptoms	Observations (3 months after discharge)
<b>Sensory Functions</b>	
Neuropathic pain	No change
Bladder Function	No change
Bowel Function	No change
Sweating Ability	Mild improvement

## Three-Month Follow-Up Summary

Follow-up call was conducted 3 months after discharge date. At this stage, patient was experiencing mild improvement during standing exercises and was able to lock both her knees without support. During her time at UAM, in her 35-day post-surgery rehabilitation, she could lock her left knee on her own, but required assistance locking her right knee. Patient also reported improvement during gait training and is able to lock her knees while taking assisted steps.

Patient's gross motor function has improved slightly as of the 3-month follow-up. She is now able to kick her lower legs up at a 30-degree angle. Patient's right leg is still weaker than her left leg, but she's seeing strength improvements in both legs. Patient's stamina has improved moderately and she is able to perform more difficult exercises than before with her therapist back home. Patient also noticed increased muscle mass in legs and increased core strength and feels more energetic throughout her day.

Patient's spasms and spasticity have increased slightly, and when she lies down she experiences stronger flexor spasms and trunk contractions. This increase could be due to patient's muscles getting stronger and/or an indication of neuroplasticity from Cytotherapy.

Patient's neuropathic pain and bladder and bowel functions have not changed. She has experienced mild improvement in sweating ability. Previously, patient was unable to sweat below her injury level, but now patient notices that during the night she can. More feedback will be collected on patient's progress in the 6-month follow-up call.



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