EPIDURAL STIMULATION
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Epidural Stimulation Surgery / C5, Lithuania

Patient Case Report
#ES180018/ 1 Year

Patient Overview

Age: 29

Sex: Male

Nationality: Lithuanian

Diagnosis on Admission: Spinal Cord Injury, C5 Complete Paraplegia

Treatment Received: Epidural Stimulation Surgery, Medtronic Restore Advance 16-electrode MRI Compatible Device. 20 million MSCs and 100 million hAFSCs.

Date of Admission: 01/04/2018

Date of Discharge: 09/05/2018

Patient's Condition on Admission

The patient sustained a traumatic C5 spinal cord injury, characterized by incomplete quadriplegia and complete paraplegia on June 4, 2017. Patient has limited hand and arm Sensory and Motor functions, but no voluntary Motor function in his lower limbs. He suffers from neurogenic bladder and bowel but does not suffer from significant spasms, spasticity, or neuropathic pain.

Previous Therapies and Treatments

Patient underwent tracheostomy and the tracheal tube was removed in September 2017. Patient received spinal decompression surgery at C5 and the Aesculap "Spine System Evolution" titanium implant. Patient has been receiving therapy from the rehabilitation hospital in Lithuania.

Treatment Received

After a Spinal MRI scan, EMG, and comprehensive blood work, the patient underwent Laminectomy and implantation of the Epidural Stimulation device at T12-L1 level, and intraspinal injection at C5-C6 levels on April 2, 2018.
The surgery was completed without significant adverse events and no serious 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, the patient was discharged.

Device Mapping and Therapy

Post-Surgical Care	Total Sessions	Sessions Per Week	Time (Hr) Per Session
Mapping	104	26	1
Physical Therapy	30	8	1
Occupational Therapy	15	4	1

Cytotherapy

Type	Amount	Delivery Method	Number of Applications
MSCs	20 Million	IV Injection	1
hAFSCs	30 Million	Lumbar Puncture Injection	1
hAFSCs	70 Million	Intraspinal Injection	1

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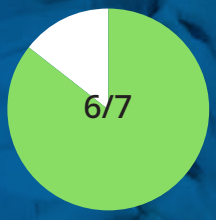
Symptoms Improvement Post-Surgery

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

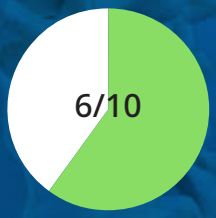
Improvements are monitored in 15 targeted areas: 11 Motor areas and 4 Sensory areas. However, the number of targeted areas may vary depending on patient's condition prior to admission. If patient does not experience symptoms in certain Motor/Sensory functions, or is not impaired in a specific targeted 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

Stepping exercises were not conducted with this patient, therefore "Stepping" and "Coordination" are excluded from the report. Patient does not suffer from spasms or spasticity, so they are also excluded from the report. As a result, only 7 out of 11 Motor Function areas were measured, and there were improvements in 6 out of those 7 targeted areas when the Epidural Stimulation device was switched on.

Patient does not suffer from neuropathic pain, therefore only 3 out of 4 Sensory Function areas were measured. Patient has not experienced any improvements in the three measured Sensory Function areas, but more feedback will be collected after 6 months to note any improvements made by cytotherapy. Overall, improvements were observed in 6 out of 10 targeted Motor and Sensory Function areas.

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Treatment Summary

After Epidural Stimulation surgery, the patient received 104 Mapping sessions, 30 Physical Therapy sessions and 15 Occupational Therapy sessions. Patient also received 20 million MSCs via one IV injection, and 100 million hAFSCs via one lumbar puncture injection and one intraspinal injection. All three applications went well without adverse effects and no short-term or acute complications have been reported.

Patient's Gross Motor Skills improved significantly, exhibited by knee and hip flexion with a full range of motion. However, ankle flexion was possible in only the patient's right foot. Improvement was also observed in knee extension (kicking out), with the patient's right leg extending better than the left leg, but without full range in either leg. Patient is able to push both legs outwards and demonstrated fair trunk control while sitting.

Patient has fair static sitting balance with no back support needed and is able to sit up straight. Patient also demonstrated dynamic sitting balance but loses balance when reaching out at an extended distance. Patient does not have static standing balance and required maximum assistance when changing position from sitting to standing, requiring a hoist for support.

Patient is able to stand with the support of a hoist and requires assistance in locking knees and hips in both legs while standing. Patient has no trunk control while standing and is able to support only 50-70% of his weight on his legs when upright. Overall improvements in standing are very mild, but more feedback will be collected in 6 months time to see if any further improvements in standing have been made.

Due to the inability to stand effectively, stepping exercises were not conducted with this patient in his immediate post-surgery rehabilitation. However, a stepping program has been created so that the patient is able to practise stepping during his physical therapy sessions back home.

Patient does not suffer from spasms or spasticity, but a program has been created to facilitate a small amount of spasms in order to tone up his very flaccid muscles, which is necessary in order for the patient to carry out physical therapy. Muscle mass and endurance were improved upon discharge.

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

Ability	Improvement Assessment 1 Year After Discharge from UAM
Motor Functions	
Standing with support	Mild improvement
Stepping with support	Not Applicable
Gross motor Skills	Moderate Improvement
Fine Motor skills	Same as before
Balance	Mild improvement
Coordination	Not Applicable
Muscle Mass	Worse than before
Fatigue	Moderate Improvement
Stamina	Mild improvement
Spasms	Not Applicable
Spasticity	Not Applicable

Ability	Improvement Assessment 1 Year After Discharge from UAM
Sensory Functions	
Neuropathic pain	Not Applicable
Bladder Function	No change
Bowel Function	No change
Sweating Ability	No change

Six-Month and One-Year Follow-Up Summaries

One year after the Epidural Stimulation device was implanted and cytotherapy, the patient has been performing 10 hours of physical therapy per week.

Patient's Gross Motor Functions have improved moderately. The patient is still able to flex and extend his right ankle, hips, and knees. The programs provided by UAM for Gross Motor Functions are still working very well. Patient feels stronger and is able to carry out more repetitions of kicking out his legs. From a scale of 1-to-5 with "1" being worse than before surgery and "5" being significantly improved from the surgery, the patient rates his Gross Motor Functions somewhere between 3-4.

Patient is still practising standing exercises and is able to stand without switching on the Epidural Stimulation device, but that requires support. When the stimulator is switched on, the patient is able to stand bearing weight equally on either leg, but he reports that he does not use the stimulator often. The patient is still not able to take steps or conduct gait training. Mild improvement was seen in patient's static and dynamic sitting balance.

Patient reports that he has observed a decrease in his muscle mass, but has experienced a slight reduction in fatigue. We recommend this patient to come back for more mapping sessions to improve his stepping exercises. The patient should also increase the amount of physical therapy he conducts per week, and switch on the Epidural Stimulation device more often in order to gain muscle mass and improve more.

For more information please contact:

UNIQUE ACCESS MEDICAL

Thailand office:

111 Naradhiwas Rajanagarindra 7 Alley,
Khwaeng Thung Maha Mek, Khet Sathon,
Krung Thep Maha Nakhon 10120,
Bangkok, Thailand

https://uniqueaccess.com
https://epiduralstimulationnow.com

Telephone:

+66 (0) 2 287 2056 TH
+1 888-557-5988 Toll Free USA
+61 2 8310 7389 AUS
+44 20 3868 1498 UK

E-Mail:

info@epiduralstimulationnow.com

epiduralstimulationnow

@SCIbreakthrough