EPIDURAL STIMULATION
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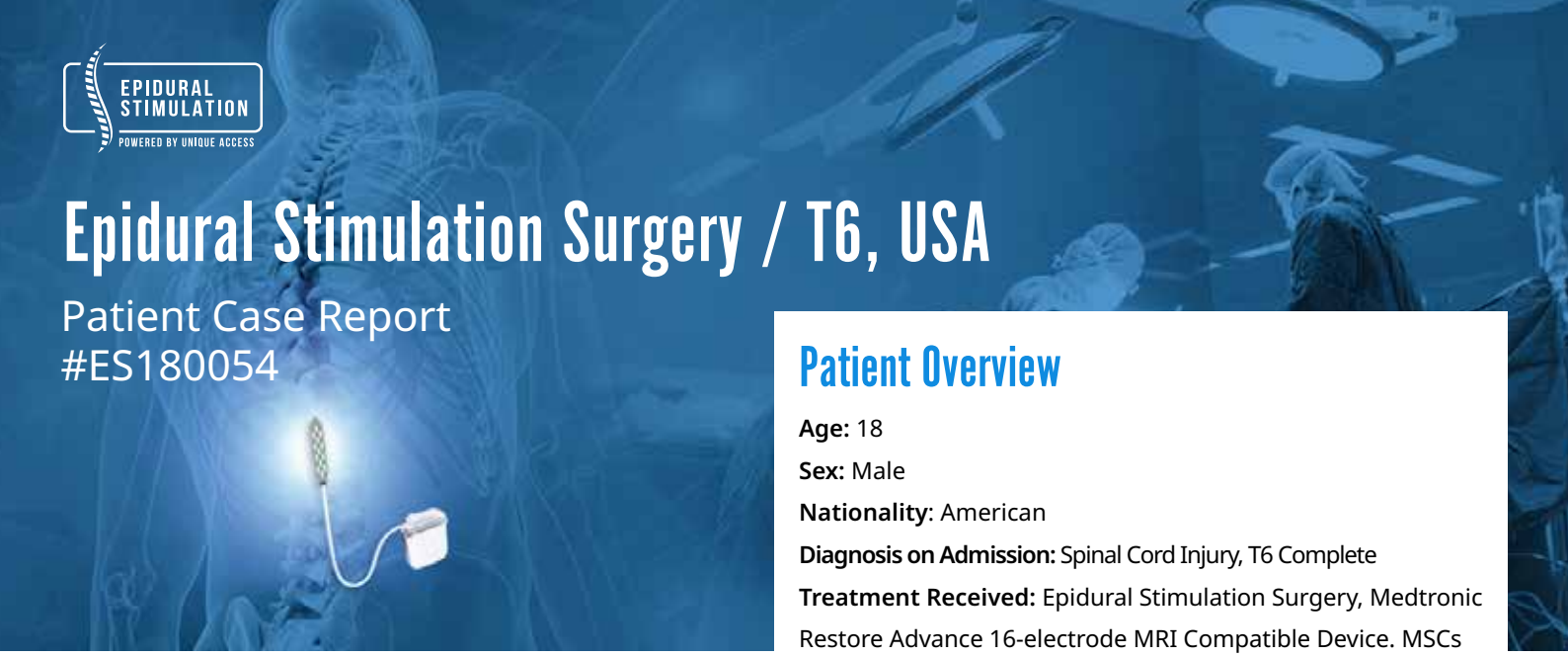
Epidural Stimulation Surgery / T6, USA

Patient Case Report
#ES180054



Patient Overview

Age: 18

Sex: Male

Nationality: American

Diagnosis on Admission: Spinal Cord Injury, T6 Complete

Treatment Received: Epidural Stimulation Surgery, Medtronic Restore Advance 16-electrode MRI Compatible Device. MSCs and hAFSCs 150 million.

Date of Admission: 30/09/2018

Date of Discharge: 01/11/2018

Patient's Condition on Admission

Patient sustained a traumatic spinal cord injury at T6 level in November, 2012. Patient's MRI scan showed T6-7 myelomalacia and T6-9 syringomyelia. He has complete loss of motor and sensory functions below the injury level. He suffers from neurogenic bladder and bowel, and slight spasticity; he does not suffer from neuropathic pain. He is independent in his daily activities.

Previous Therapies and Treatments

Patient was admitted in UW- Madison Children's hospital for 6 weeks and then transferred to Froedtert Hospital (Milwaukee, USA) for another 4 weeks of rehabilitation.

Treatment Received

After a Spinal MRI scan, EMG, and comprehensive blood work, patient underwent Laminectomy, Syringostomy, and implantation of the Epidural Stimulation device on October 1, 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, then patient was discharged.

Device Mapping and Therapy

Post-Surgical Care	Total Sessions	Sessions Per Week	Time (Hr) Per Session
Mapping	124	31	1
Physical Therapy	35	7	1
Occupational Therapy	-	-	-

Cytotherapy

Type	Amount	Delivery Method	Number of Applications
MSCs	40 Million	IV Injection	1
hAFSCs	40 Million	Lumbar Puncture Injection	1
hAFSCs	70 Million	Intraspinal Injection	1

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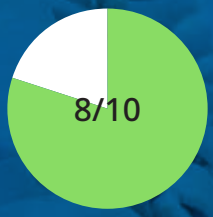
Symptoms Improvement Post-Surgery

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 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	No	No
Spasticity	No	No
Sensory Function		
Neuropathic pain	Not Applicable	Not Applicable
Bladder Function	No	No
Bowel Function	No	No
Autonomic Functions		
Bowel Control	No	Yes
Sweating Ability	No	No
Orthostatic Hypotension	Not Applicable	Not Applicable

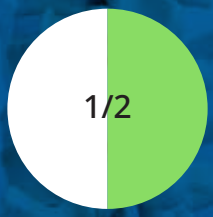
Improvements are monitored in 17 targeted areas: 11 Motor areas, 3 Sensory areas and 3 Autonomic areas. However, the number of targeted areas may vary depending on patient's condition prior to admission. If patient does not experience symptoms in certain Motor/Sensory functions, or is not impaired in 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

Autonomic Function



Overall Functions

Results Interpretation

Fine Motor Skills were excluded from this case report since patient is paraplegic, therefore 10 out of 11 Motor Function areas were measured. Motor Function improved in 8 out of 10 targeted areas when the Epidural Stimulation device was switched on.

Patient does not suffer from neuropathic pain, therefore 2 out of 3 Sensory Function areas were measured. Patient has not experienced any changes in those two Sensory Function areas, but more feedback will be collected after 3 months to note any improvements made by cytotherapy.

Patient does not suffer from Orthostatic hypotension, therefore 2 out of 3 Autonomic Function areas were measured. Patient's Bowel Control improved when the Epidural Stimulation device was switched on. Overall, improvements were recorded in 9 out of 14 targeted Motor, Sensory, and Autonomic Function areas.

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Treatment Summary

After Epidural Stimulation surgery, patient received 124 Mapping sessions and 35 Physical Therapy sessions. Patient also received 150 million: 40 million MSCs via one IV injection, and 110 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 moderately. Patient is able to isolate movement in both ankles during ankle flexion, and he had good improvement in hip and knee flexion. Knee extension was improved in both kicking out and pushing out, however patient's left leg works better than his right leg. Patient has fair trunk control.

Patient has good static sitting balance, but does not exhibit dynamic sitting balance. When patient is standing during physical therapy sessions, he has poor static standing balance.

Patient is able to stand at the parallel bars with minimal assistance from physiotherapists. At certain times, requires assistance locking his knees while standing and is unable to keep them locked. He is able to lock his right knee better than his left knee. Patient has good trunk control while standing, but he bears weight more on the right side of his body than the left and requires assistance locking his hips.

Patient is able to take assisted steps with the support of a walking frame. During stepping exercises, patient is able to lift his leg up, but requires assistance in foot placement and with locking his hips and knees. Patient has good trunk control and fair coordination when alternating steps.

Muscle mass and endurance were improved upon discharge. Patient reported that spasms and spasticity increased after receiving stem cell injections, but they decreased when therapists provided the overnight program. Feedback will be collected in 3 months time to see whether spasms and/or spasticity have decreased.

During mapping sessions, patient was put on a bowel program. It helped reduce the amount of time the patient spends emptying his bowel, from 45-60 minutes to 20-30 minutes daily, a significant improvement in quality of life.

There was no noticeable improvement to his neurogenic bladder and bowel.

Patient received cytotherapy, therefore we expect to see results in these areas within 6 months time. After 35 days, patient was discharged and will continue physiotherapy back home.

For more information please contact:

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

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

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

epiduralstimulationnow

@SCIbreakthrough