Webinar title: Direct Nerve Stimulation
What is it really and what is the potential?

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Want to Ask a Question?
The information presented in this webinar is not meant to replace the advice from a medical professional. You should consult a health care professional familiar with your specific case, concerns and condition.

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www.NeurotechNetwork.org

Helping people regain life thru neurotechnology

www.themiamiproject.org

The Miami Project is dedicated to finding more effective treatments and, ultimately, a cure for paralysis resulting from spinal cord injury.

Focusing on education of and advocacy to access neurotechnology devices, therapies and treatments for people living with impairments, their care-givers and medical professionals.
Objectives

- Understanding the Human Nervous System
- Introduce various purposes of stimulation to a nerve
- Differentiate implanted from external stimulation
- Technology applications
  - Peripheral
  - Brain
  - Spinal Cord
- Resources to learn more
The Human Nervous System

Central Nervous System
- Brain
- Spinal cord

Peripheral Nervous System
- Autonomic division
  - Regulates internal environment.
  - Carries information from the CNS to organs, blood vessels and glands.
- Somatic division
  - Carries information to the CNS from the senses and from the CNS to the skeletal muscles.

Sympathetic (Aroused the body)
Parasympathetic (Calms after arousal)
The Human Nervous System

The major components and functions of the nervous system

**Central Nervous System**
- The central nervous system (CNS) consists of the brain and spinal cord and is responsible for integrating, processing, and coordinating sensory data and motor commands.

**Peripheral Nervous System**
- The peripheral nervous system (PNS) includes all the neural tissue outside the CNS.

1. **Receptors** are sensory structures that detect changes in the internal or external environment.
2. **Somatic sensory receptors** provide position, touch, pressure, pain, and temperature sensations.
3. **Special sensory receptors** provide sensations of smell, taste, vision, balance, and hearing.
4. **Visceral sensory receptors** monitor internal organs.

**Information processing** includes the integration and distribution of information in the CNS.

4. **The motor division** of the PNS carries motor commands from the CNS to peripheral tissues and systems.
5. **The somatic nervous system (SNS)** controls skeletal muscle contractions.
6. **The autonomic nervous system (ANS)** provides automatic regulation of smooth muscle, cardiac muscle, glands, and adipose tissue.

**Effectors** are target organs whose activities change in response to neural commands.

- **Skeletal muscle**
  - Smooth muscle
  - Cardiac muscle
  - Glands
  - Adipose tissue
Purposes of Nerve Stimulation

- **Promote Plasticity**
  - Peripheral
  - Brain
  - Spinal Cord

- **Modulation**
  - Control Pain
  - Suppression tremors or seizures
  - Obesity
  - Bladder

- **Movement**
  - Augment rehabilitation
  - FES
  - Regulate
## Implanted vs External

<table>
<thead>
<tr>
<th></th>
<th>Benefits</th>
<th>Risks</th>
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<tbody>
<tr>
<td><strong>External Stimulation</strong></td>
<td>low clinical risk</td>
<td>burning of skin</td>
</tr>
<tr>
<td></td>
<td>easy to implement</td>
<td>stimulate a large muscle group rather than targeted</td>
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<tr>
<td></td>
<td>lower cost</td>
<td>difficult to duplicate/compliance</td>
</tr>
<tr>
<td><strong>Implanted Stimulation</strong></td>
<td>targeted stimulation</td>
<td>surgery</td>
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<tr>
<td></td>
<td>Consistency</td>
<td>infection</td>
</tr>
<tr>
<td></td>
<td>ease of use</td>
<td>scar tissue</td>
</tr>
<tr>
<td></td>
<td>mobile</td>
<td>higher cost</td>
</tr>
<tr>
<td></td>
<td></td>
<td>complex</td>
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## Stimulation of Peripheral Nerves

<table>
<thead>
<tr>
<th></th>
<th>Commercial</th>
<th>Investigative</th>
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<tbody>
<tr>
<td>Facial Muscles</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Swallowing</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sleep Apnea</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Stroke/SCI Recovery Upper Extremity</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Bladder Management</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Nerve Repair*</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Pain Management*</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Gait for Drop Foot</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
PENS
Percutaneous Neuromodulation Systems

Algotec
www.algotec-ltd.com

Biowave
www.biowave.com

SPR Therapeutics
www.sprtherapeutics.com
Stimulation of the Brain

TMS & rTMS
Transcranial Magnetic Stimulation

DBS
Deep Brain Stimulation

BCI & BMI
Brain Computer Interface
Brain Machine Interface

tDSCS
Transcranial Direct Current Stimulation
Stimulation of the Brain - External

TMS – *Transcranial Magnetic Stimulation*
- Magnetic stimulation on outside of brain
- Magnetic pulses produce changes in neuron activity

TDCS – *Transcranial Direct Current Stimulation*
- Direct Current stimulation on outside of brain
- Low level current between anode & cathode to produce changes in neuron activity
Stimulation of the Brain - Internal

- Implanted electrodes in brain
- Stimulate abnormal signals or affect cells and chemicals in the brain
- Various targets of the brain. Most common is subthalamic nucleus (STN) or globus pallidus interna (GPI)
Stimulation of the Brain: Commercial

- Medtronic Activa DBS - www.medtronic.com
- Boston Scientific Vercise - www.bostonscientific.com
- St. Jude Medical Brio - www.sjm.com
- Aleva Neurotherapeutics – www.aleva-neuro.com

- Fisher Wallace Stimulator – www.fisherwallace.com
- Halo Neuroscience – www.haloneuro.com

Non-FDA Approved:
- TCT Research Ltd www.trans-cranial.com
- Cognitive Kit Cognitivekit.com
- Brain Stimulator theBrainStimulator.net
- Thync – thync.com
- Foc.us – www.foc.us

- NeuroStar TMS Therapy® System - www.neuronetics.com
- eNeura: Spring TMS - www.eneura.com
- Magstim - www.magstim.com
- Cefaly - www.cefaly.us
- Nexstim – www.nexstim.com
- Brainsway – www.brainsway.com
- Rio Grand Neurosciences – riograndneuroscience.com
Stimulation of the Brain: Investigational

Noted Published Studies
• Stroke Rehabilitation – rTMS, tDCS
• Incomplete SCI rTMS, tDCS
• Parkinson’s disease – rTMS
• ALS – rTMS
• Chronic Pain – DBS
• Tourette’s – DBS
• Huntington’s – DBS
• MS - DBS
• Psychiatric - DBS

Cervel Neurotech rTMS
www.cervel.com

Soterix Medical 1 × 1 tDCS Platforms
www.soterixmedical.com
Stimulation of the Brain: Investigational

Battelle & Ohio State University
NeuroBridge
ClinicalTrials.gov Identifier:
NCT01997125

Brain Gate Brown University
MultiCenter
ClinicalTrials.gov Identifier:
NCT00912041

University of Pittsburgh
ClinicalTrials.gov Identifier: -
NCT01894802, NCT01364480
Stimulation of the Spinal Cord

- Cervical spinal cord
- Thoracolumbar spinal cord
- Intrathecal
SCS - Spinal Cord Stimulation

Medtronic: Restore Sensor
www.tamethepain.com

Boston Scientific: Precision Spectra
www.controlyourpain.com

St. Jude Medical: Eon
www.poweroveryourpain.com

StimWave: Freedom-4
www.stimwave.com

Nevro: Senza
www.nevro.com

Nuvectra: Algovita
www.nuvectramed.com
Epidural Stimulation

- 16-electrode array implanted over the L1-S1 spinal cord segments
- Creates sensory input to the spinal cord, which may alter the threshold for motor circuitry activation

Source: Harkema et al 2011, Lancet
Noted Clinical Trials

• **Epi Stim to Facilitate Standing and Stepping, NCT02339233**
  - The overall aim is to assess whether task specific locomotor training and spinal cord electrical stimulation (SCES) can induce neural reorganization of the functionally isolated human spinal cord to improve standing and stepping in individuals with functionally complete SCI.
  - Univ. Louisville; Cervical and Thoracic SCI

• **Epi Stim to Recover Cardiovascular Function, NCT02037620**
  - This study is designed to use epidural spinal cord stimulation to improve cardiovascular and respiratory function.
  - Univ. Louisville; Cervical SCI

Source: [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)
Noted Clinical Trials

- **Spinal Cord Neuromodulation for SCI, NCT02313194**
  - This study is designed to assess the strategy of using spinal cord stimulation to improve the ability to move arms and hands in spinal cord injured humans.
  - **UCLA; Cervical SCI**

- **Stimulation with Wire Leads to Restore Cough, NCT01659541**
  - The overall aim is to assess the efficacy of spinal cord stimulation to restore effective cough in individuals with chronic cervical SCI.
  - **Case Western Reserve Univ.; Cervical SCI**

Source: [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)
Noted Clinical Trials – Non-Invasive

• Transcutaneous Electrical Spinal Stimulation for Lower Limbs, NCT01949285
  • The aim is to assess whether non-invasive spinal cord electrical stimulation can be used to measure spared function in individuals with non-ambulatory SCI and if it is a useful rehabilitation tool.
  • UCLA, NeuroEnabling Tech.; Cervical and Thoracic SCI

• Restoring Arm and Hand Function with Non-Invasive Spinal Stimulation, NCT01906424
  • This study is designed to assess the strategy of non-invasive spinal cord stimulation to improve the ability to move arms and hands in spinal cord injured humans.
  • UCLA, NeuroEnabling Tech.; Cervical SCI

Source: www.ClinicalTrials.gov
Considerations for Participating in any Clinical Trial

- Know your rights & risks: Informed Consent, Read the fine print
- Understand your commitments
- Manage your expectations
- Beware – of “trials” that are unapproved, even in the US – just because a US doctor is doing it does not mean it is legitimate
- Do your research – get a second or third opinion from a research center or hospital
- Never pay for experimental treatments
- Expect Follow Up
- Refer to ClinicalTrials.gov (https://clinicaltrials.gov/ct2/about-studies/learn)
Additional Resources

• Search Terms [ClinicalTrials.gov](http://ClinicalTrials.gov)
  - “spinal cord injury”, “tetraplegia”, “paraplegia”
  AND
  - “stimulation”, “spinal cord stimulation”, “epidural”, “neuromodulation”, “brain interface”, “TMS”, “tDCS”

• Miami Project: [www.themiamiproject.org](http://www.themiamiproject.org)
  - Link study for treatment of pain & AD for SCI using DBS

• Neurotech Network Condition Fact Sheets: [www.NeurotechNetwork.org](http://www.NeurotechNetwork.org)
  including spinal cord injury, brain injury, stroke, multiple sclerosis, Parkinson’s and more
Kim Anderson-Erisman PhD, Director Of Education, University Of Miami & Miami Project To Cure Paralysis

Jennifer French, MBA, Executive Director, Neurotech Network

Next Webinar is October 13, 2016: Pain and Spasticity Management