Using FES Technology to Impact Outcomes and ADLs for the SCI population

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Paralyzed Veterans of America's Summit 2011 + Expo
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Cleveland FES Center

Advancing Technology, Enhancing Life

Developing technology that improves the quality of life of individuals with disabilities through the use of Functional Electrical Stimulation and enabling the transfer of the technology into clinical deployment.

Functional Electrical Stimulation (FES) is the application of electrical stimulation to restore function. FES can be applied for therapeutic purposes or for replacement of lost function.

Neural Prosthesis: A device that connects directly with the nervous system and uses FES to replace or supplement function.

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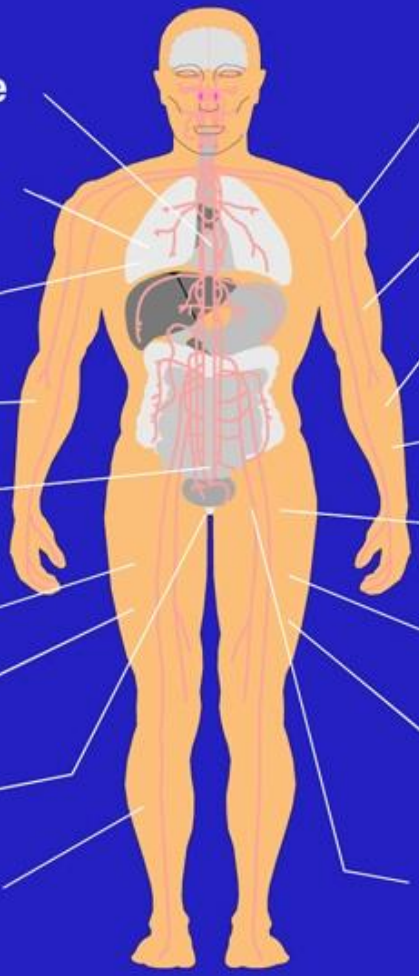
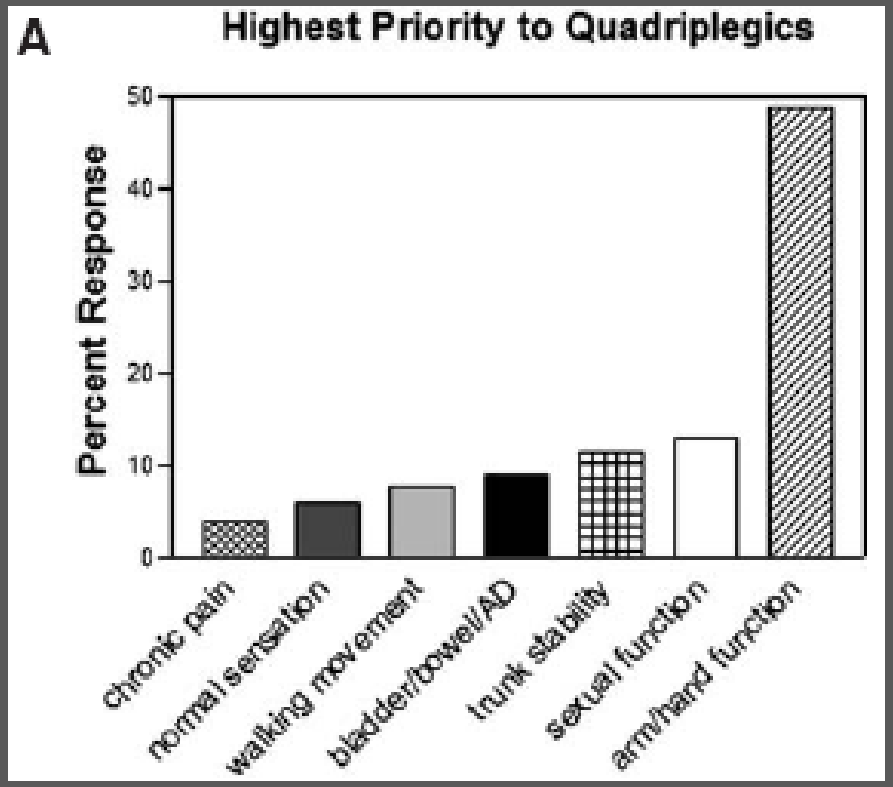
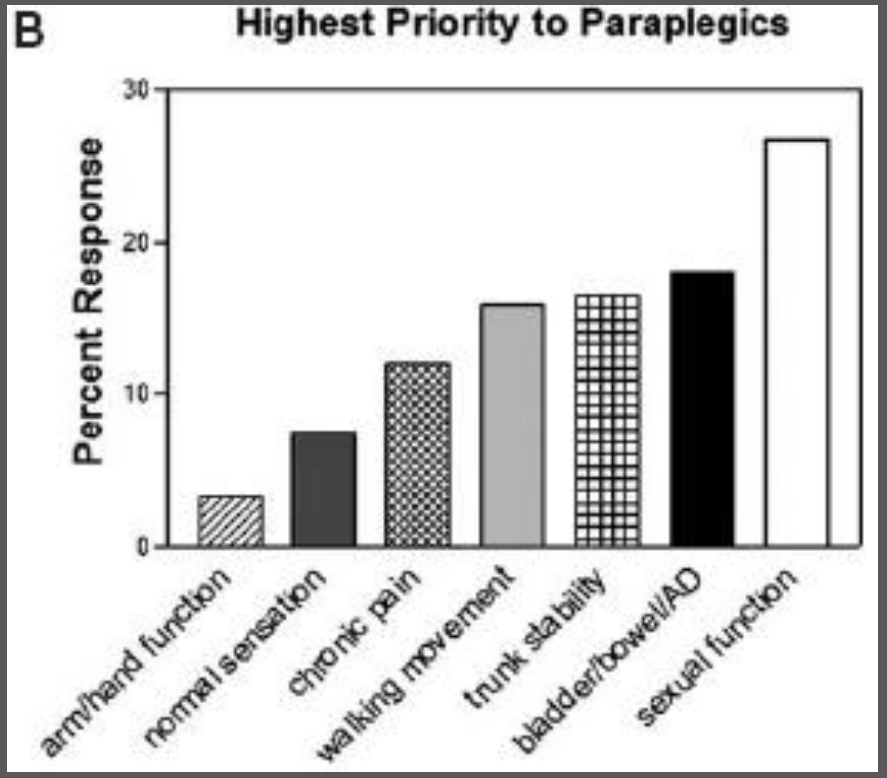
FES Applications in Spinal Cord Dysfunction



- Cardiovascular Exercise
- Breathing Assistance
- Cough Assistance
- Grasping & Reaching
- Bladder & Bowel Control
- Transfers & Standing
- Stepping and Walking
- Erection & Electroejaculation
- Improving Circulation
- Regaining Voluntary Function / Improving Movement Control
- Restoring Sensation
- Controlling Tremor
- Treating Weak Muscles
- Preventing / Treating Osteoporosis
- Preventing / Treating Contractures
- Controlling Spasticity
- Treating / Preventing Pressure Sores

Priorities of Individuals with SCI

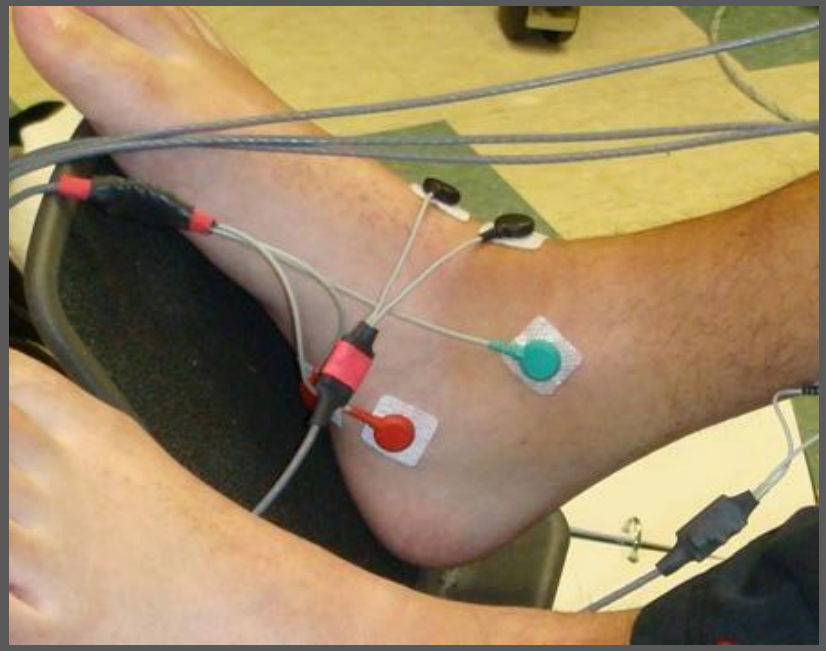




Anderson, K.D. (2004) *J. Neurotrauma*, 21: 1371-1383.

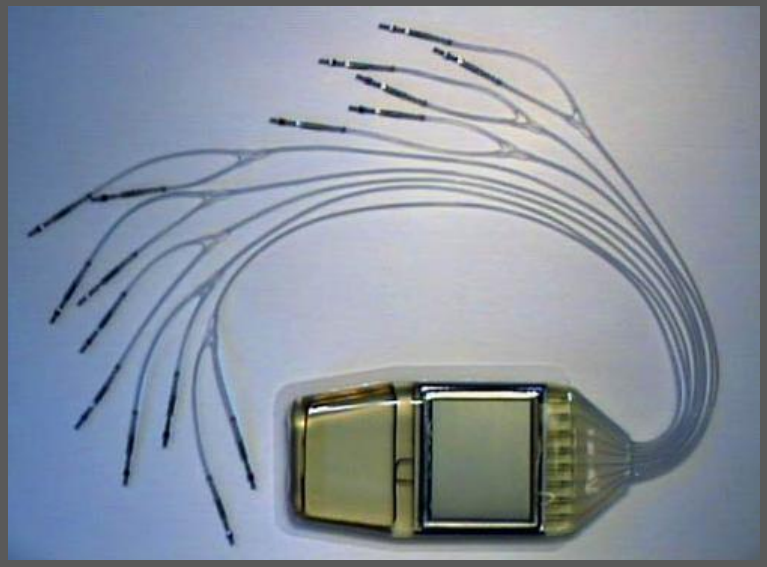
Enabling technology: External

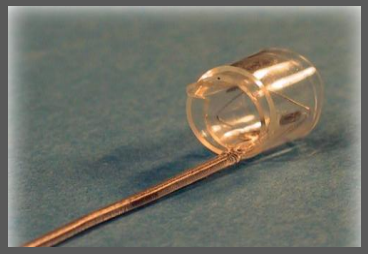
- **EMG**
- **Surface Stimulation**

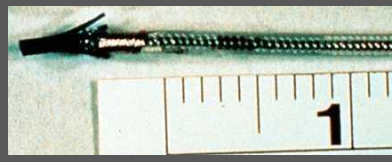


Enabling technology: Implanted

- **Implanted Stimulator-Telemeter (IST) : 'Pacemaker for the Body'**
  - 12 - 16 stimulus channels
  - up to 2 biosignal sensing (EMG) channels
- **Electrodes**
  - Intermuscular
  - Multicontact spiral cuffs
- **Universal External Control Unit**

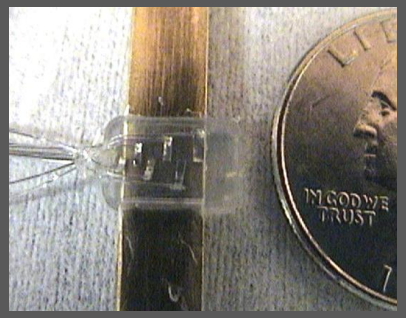




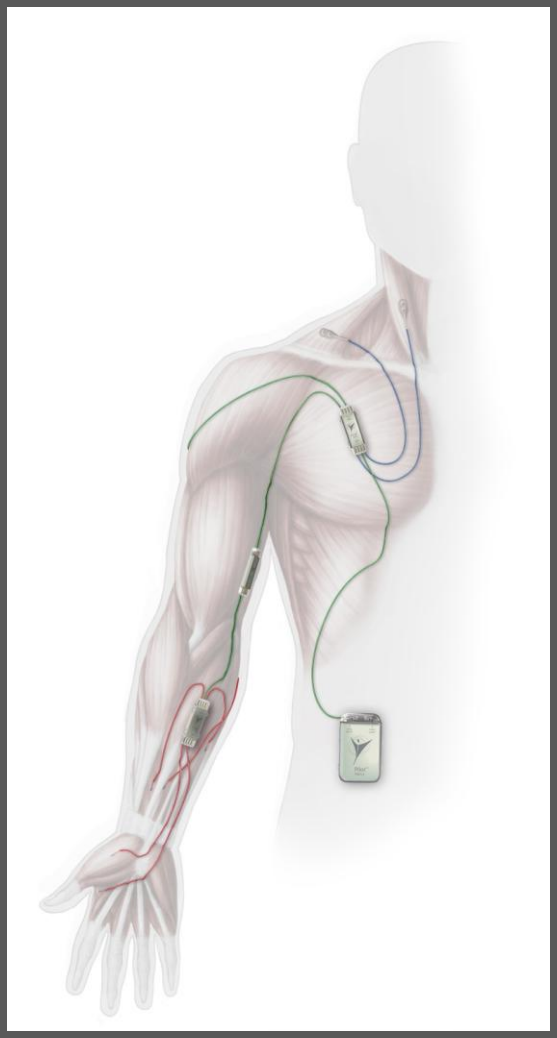


Enabling technology: Future

- **Flat Interface Nerve Electrodes (FINE)**



- **Network Neural Prosthesis**

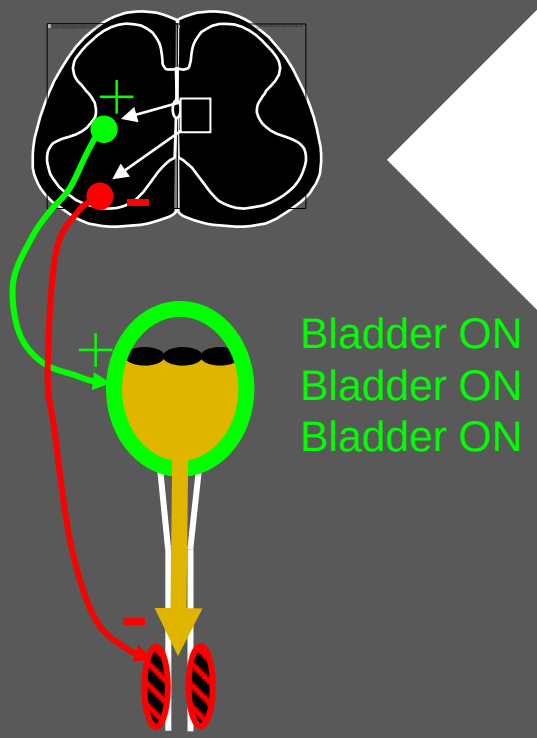


Clinical Applications

- Bladder Functions
- Pain Blocking Management
- Coughing
- Upper Extremity Function & Reaching
- Trunk & Posture Control
- Pressure Sore Prevention
- Standing & Transfer
- Stepping

No Bladder Control After Spinal Cord Injury (SCI)

Bladder Spasms
(hyper-reflexia)



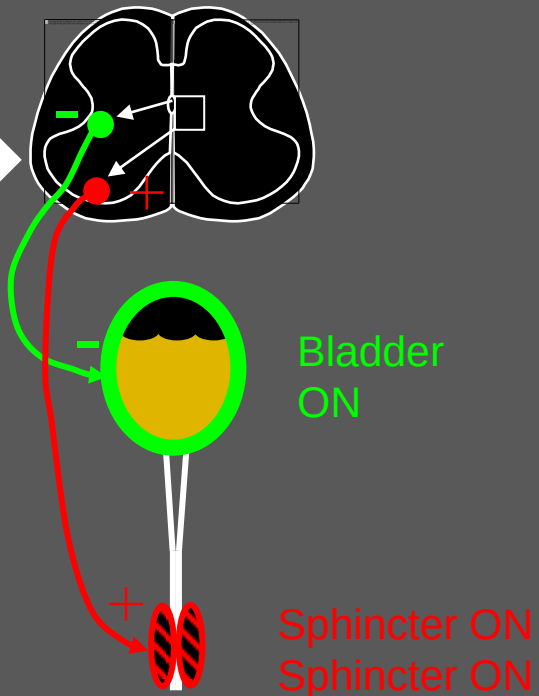
Bladder ON
Bladder ON
Bladder ON

Urine leaking, AD

Clinical Impact

- Significant health problems (UTI, AD)
- Profound social impact
- Decreased QOL
- Large medical costs
- Limited effective treatment options

Sphincter
Spasms
(dyssynergia)



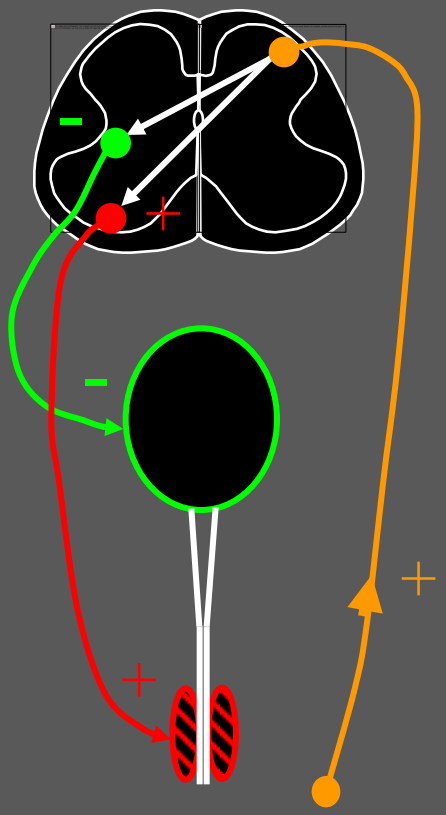
Bladder
ON

Sphincter ON
Sphincter ON

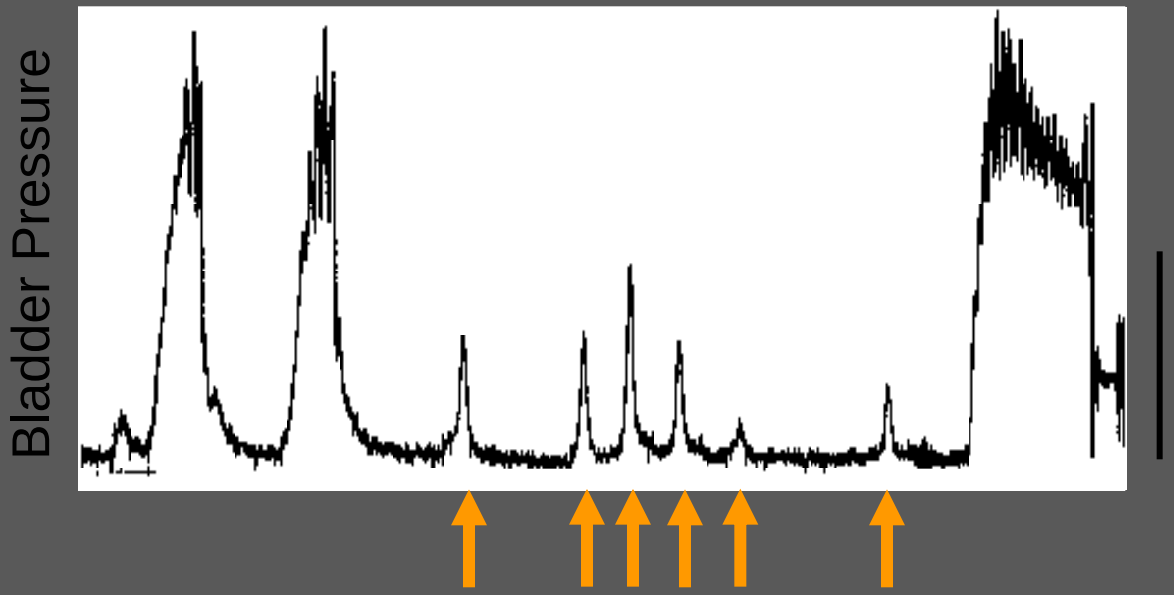
Prevents bladder emptying
Kidney problems, infections

Bladder Inhibition in Humans Using Sensory Nerve Stimulation

"Bladder Pacemakers"



Continence



Contractions abolished with nerve stimulation

Research Projects

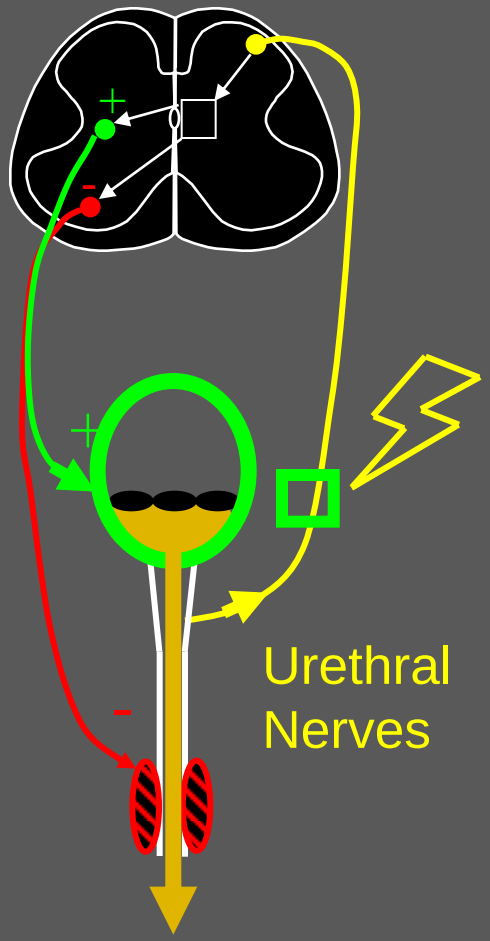
We are working to restore bladder function without nerve transections and develop less invasive methods

3 Approaches

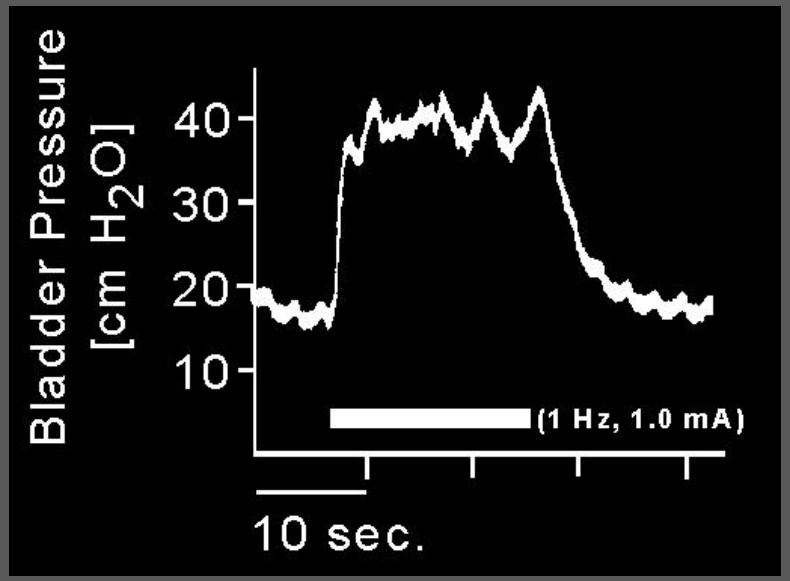
Urethral Nerve Stimulation
Interruption of Sphincter Reflexes
Sphincter Nerve Block

These approaches are in development
They are not currently available

Urethral Nerve Stimulation Generates Bladder Contractions and Voiding

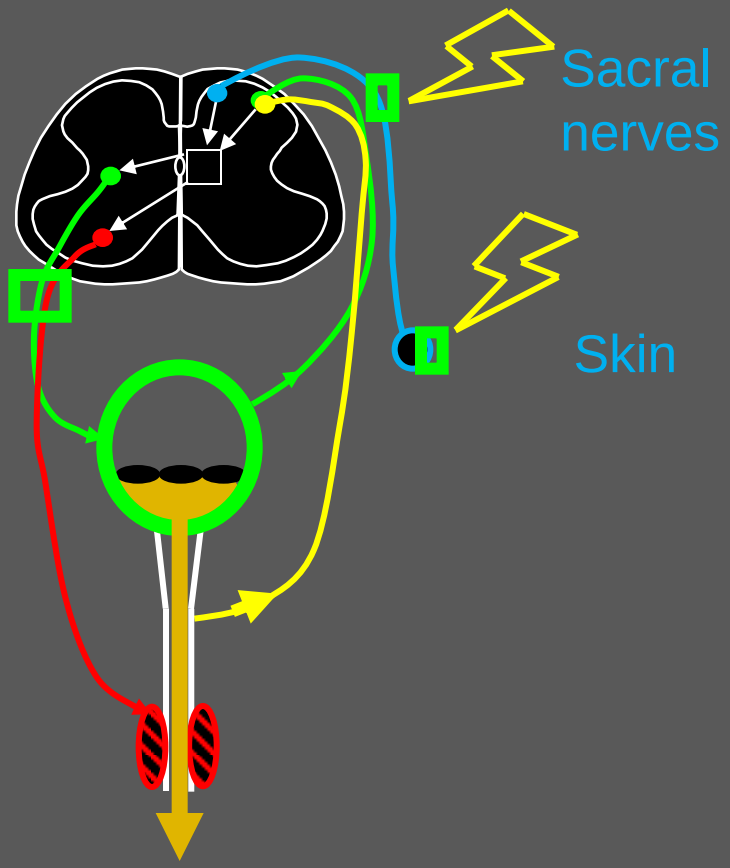


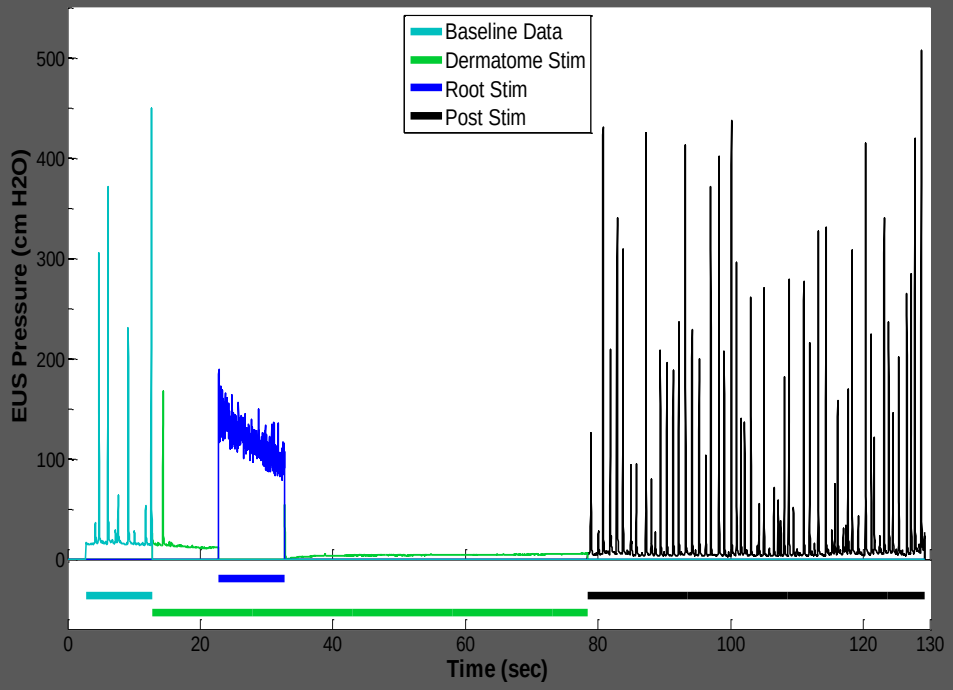
Takes advantage of natural nervous system



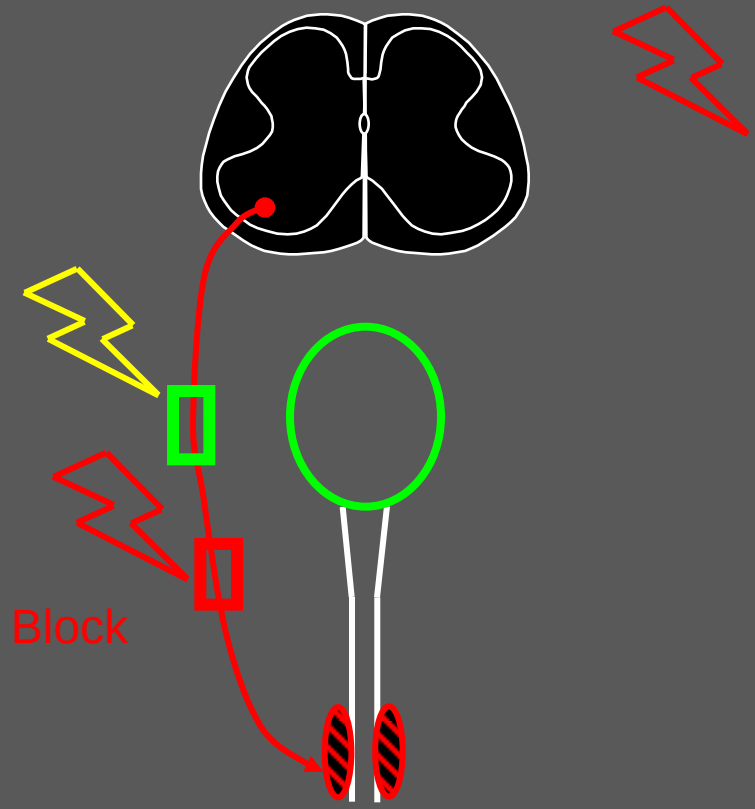
Interruption of Sphincter Reflexes

Sensory stimulation can interrupt or prevent sphincter reflexes





We Can Block Nerves Electrically



Specific stimulation can temporarily stop a nerve from working

Better than cutting the nerve

Immediate

- Nerve stops immediately

Complete

- No sphincter activity

Reversible

- Nerve recovers right away

Current Pain Management Options for SCI

Facts about Chronic Pain

- Pain is most common reason people seek medical care
- Over 75M Americans experience serious pain
- >50M suffer chronic nonalignant pain
- People with SCI can suffer extreme neuropathic pain

[American Pain Society, 2003]

Compensatory Treatments

- Pharmaceuticals
- Transcutaneous or Percutaneous electical nerve stimulation
- Intrathecal Analgesia Therapy
- Spinal Cord Stimulation

Pain Management with Nerve Blocking

- Develop a new method for blocking the conduction of nerve signals on peripheral nerves
- Use of high frequency alternating currents (HFAC)
- Produce a quick-acting and quick-reversing nerve conduction block

Nerve Blocking Benefits

- Utilizes novel electrical current waveform
- Delivered near the nerve
- Has no systemic effects
- Early experimental results show
  - Can be instantaneously started
  - Provides complete pain blockage
  - Reversible within milliseconds
  - Restores completely normal nerve activity

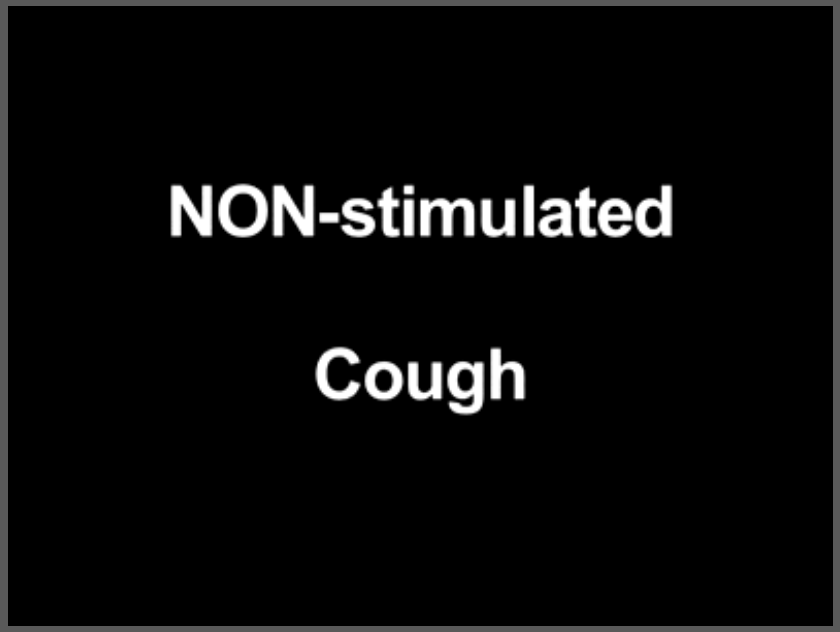
This research is currently being evaluated in humans for other conditions but in the pre-clinical stage for spinal cord injury.

Cough Restoration

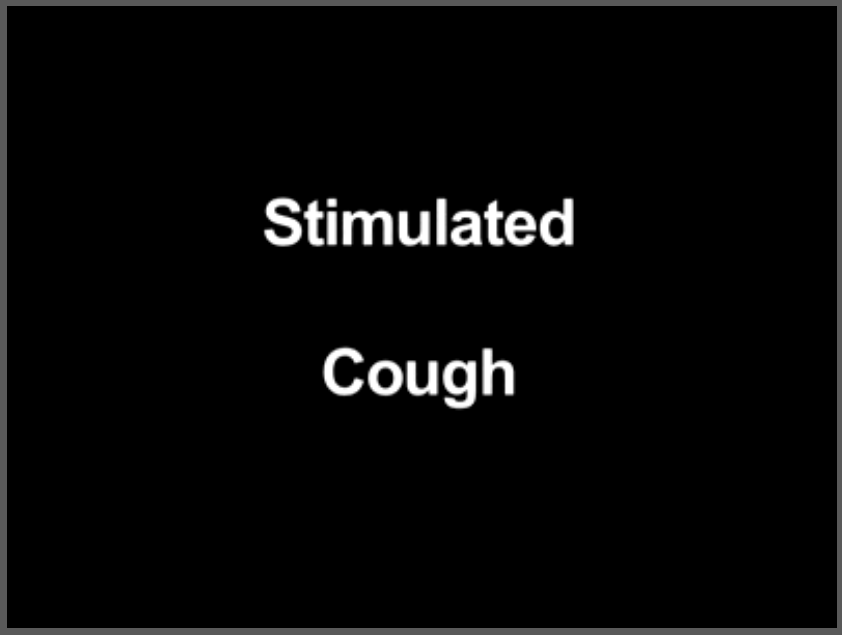
Objectives:
-Implement a more natural cough.
-Provide a system that can be independenctlyoperated by the user
-Customizable stimulation parameters
-Reduce the need for cargiver to provide secretion clearance
-Reduce the incidence of respiratory complications and associated illness and death

Candidates: individuals with cervical or high thoracic level SCI

Cough Restoration



Non-Stimulated Cough

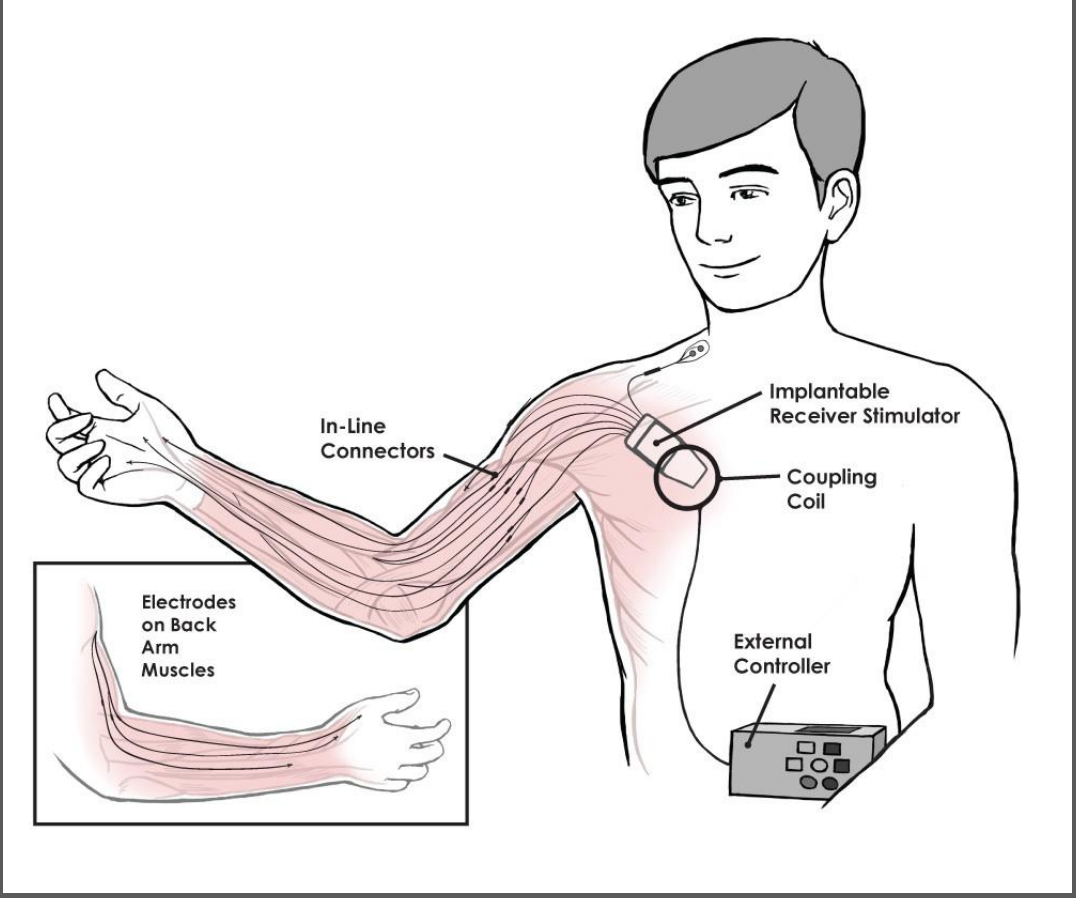


Stimulated Cough

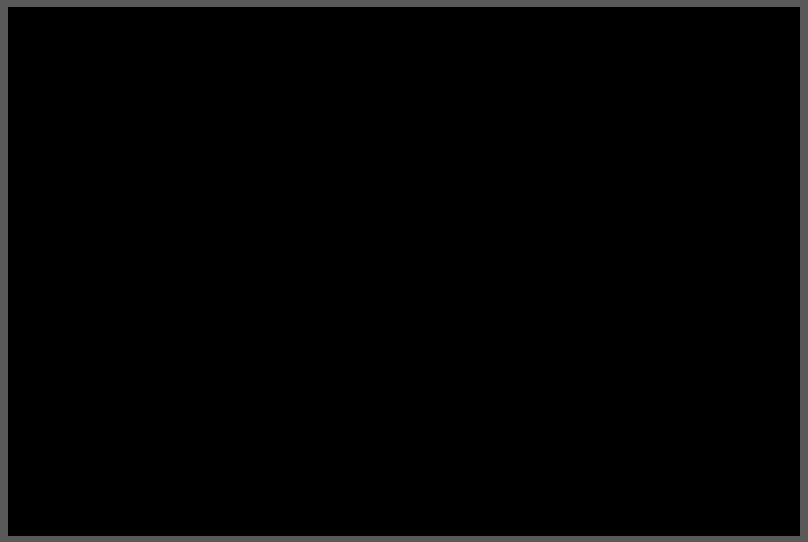
Upper Extremity

- Purpose: Provide hand grasp function for a variety of ADLs including:
  - Eating
  - Writing
  - Brushing teeth
  - Opening a wallet
  - Using a cell phone
- User controlled system contracting muscles in the shoulder, elbow and wrist

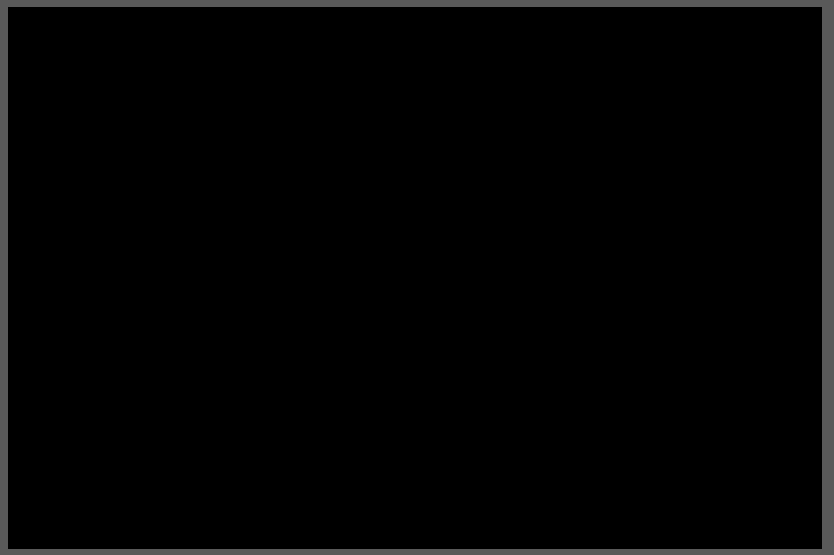
Upper Extremity



Upper Extremity



Participant using wrench without stimulation



Participant using wrench with stimulation

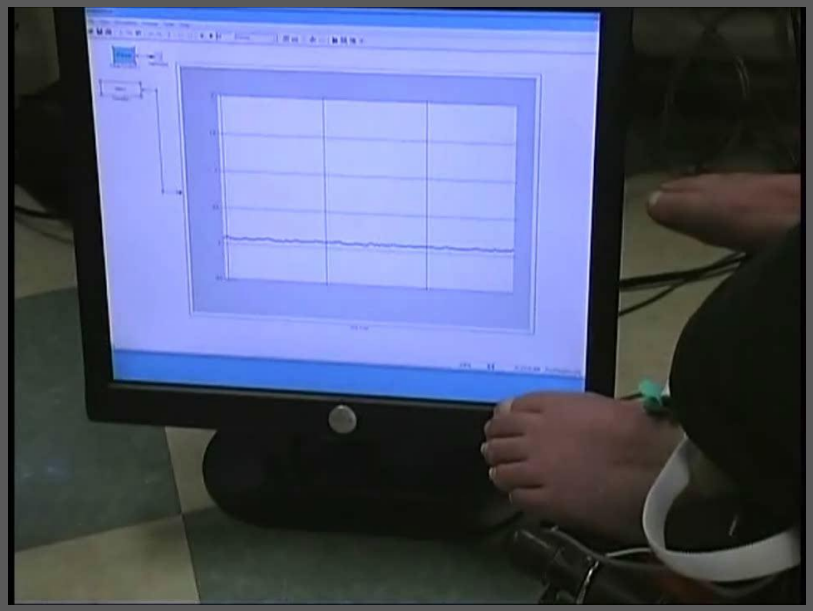
Upper Extremity

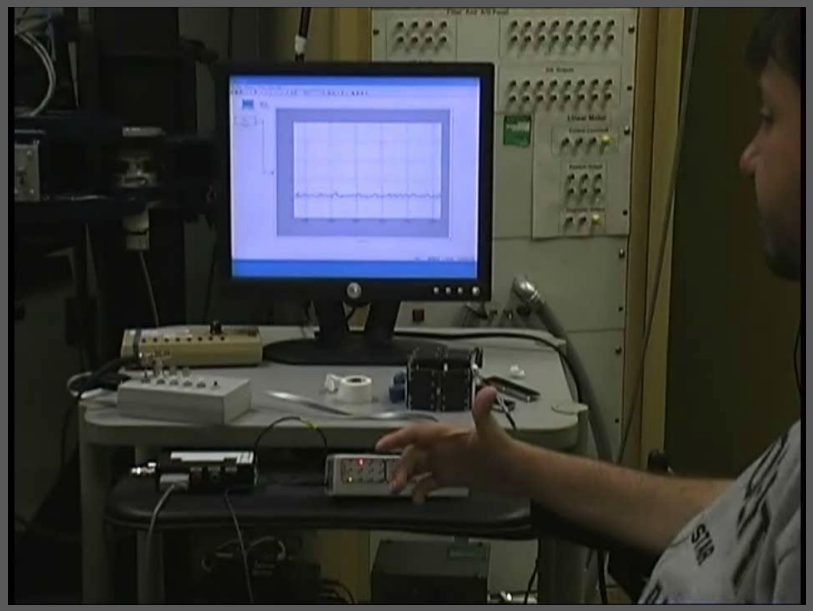
- Bilateral upper extremity stimulation user

EMG from Paralyzed Muscles

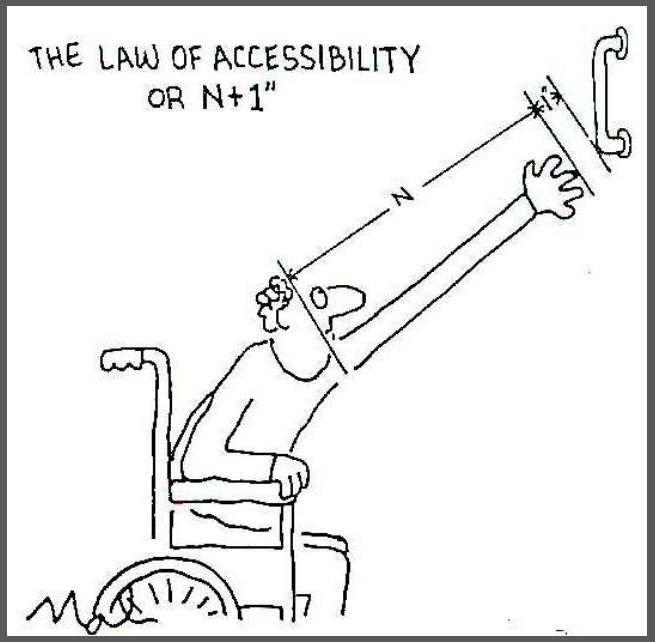
Muscle activity can be obtained below the injury level in individuals with **complete** injuries.

- Activity can be voluntarily controlled. With training, activity can be used to control FES systems or assistive devices.





Trunk Control & Posture

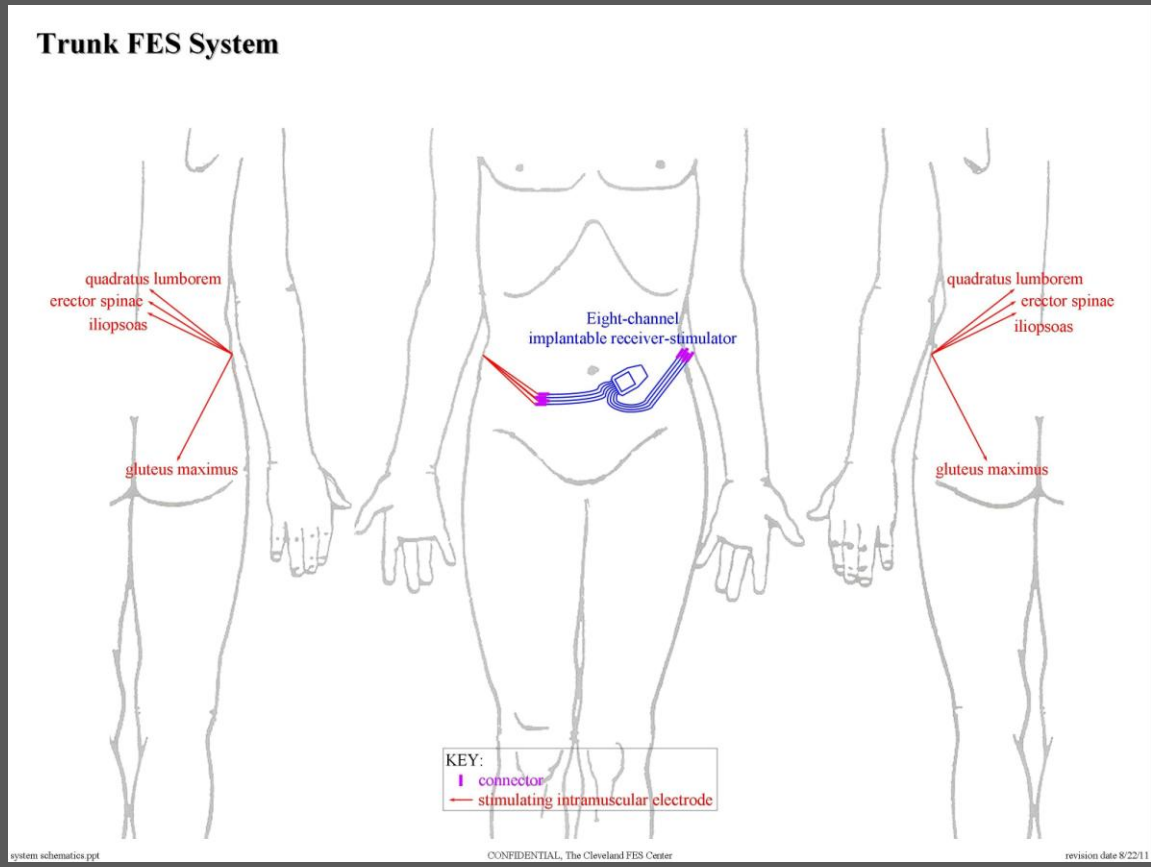


- Compensatory strategies
- Unimanual vs. bimanual
- Belts, straps, constraints

- Independent forward & lateral bending
- Turning in bed & transfer maneuver
- Reaching & completion of ADL
- Spinal alignment
- Pressure sore prevention

Trunk Only

- Targeted Muscles
  - Erector spinae
  - Quadratus Lumborum
  - Gluteus Maximus
  - Adductor Magnus
- Erector spinae provides more natural lumbar curve & anterior pelvice tilt ($\Delta = 20^{o}$)
- Workspace shifts forward & upward ($\Delta = 7cm$)



Trunk Control & Posture

Participant Info:

C4-5, ASIA A, 11 yrs post

No Electrical Stimulation

With Electrical Stimulation

Pressure Sore Prevention

Facts about Pressure Sores

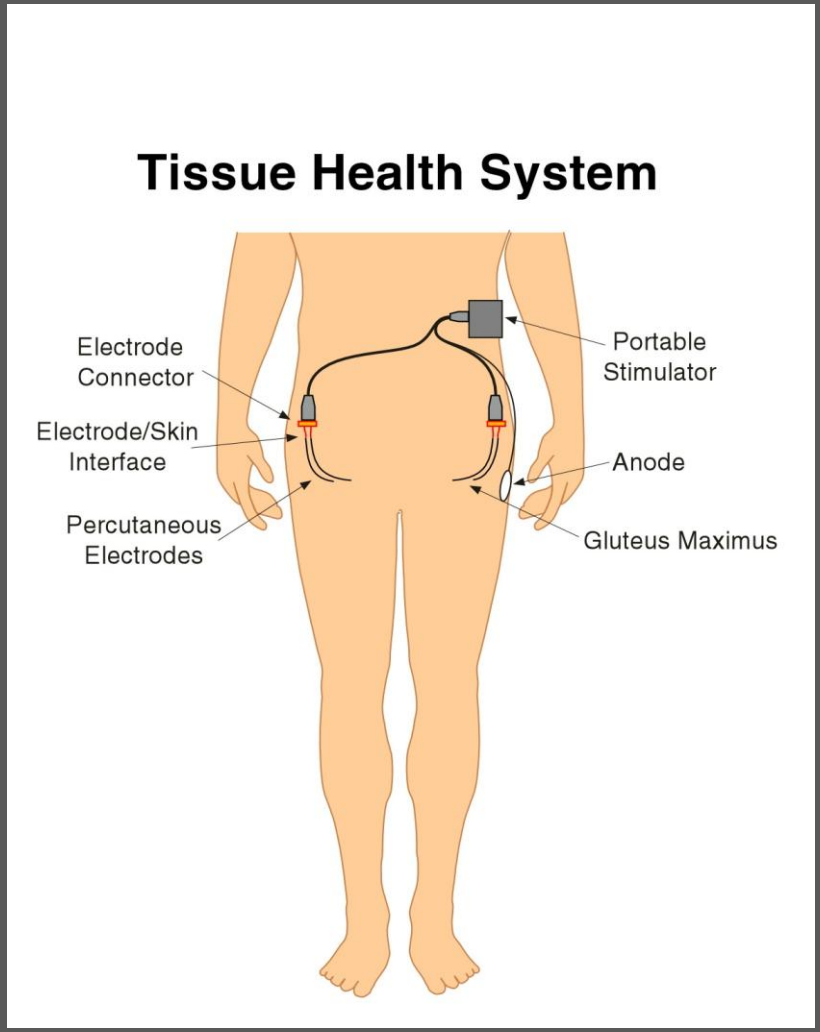
- Pressure Sores are still a major health issue
- Devastating impact on the quality of life
- Cause of frequent hospital admissions
- Long periods of bed rest
- Cost of care up to $100k per wound

Treatment Design

- Real-time static and dynamic evaluation of seating interface pressures
- Pressure mapping provides visual feedback
- Long term exercise of paralyzed gluteal muscles will improve the intrinsic health of the tissue at the seating interface.
- Dynamic weight shifting produced by the gluteal stimulation system will augment the efficacy of conventional pressure relief maneuvers

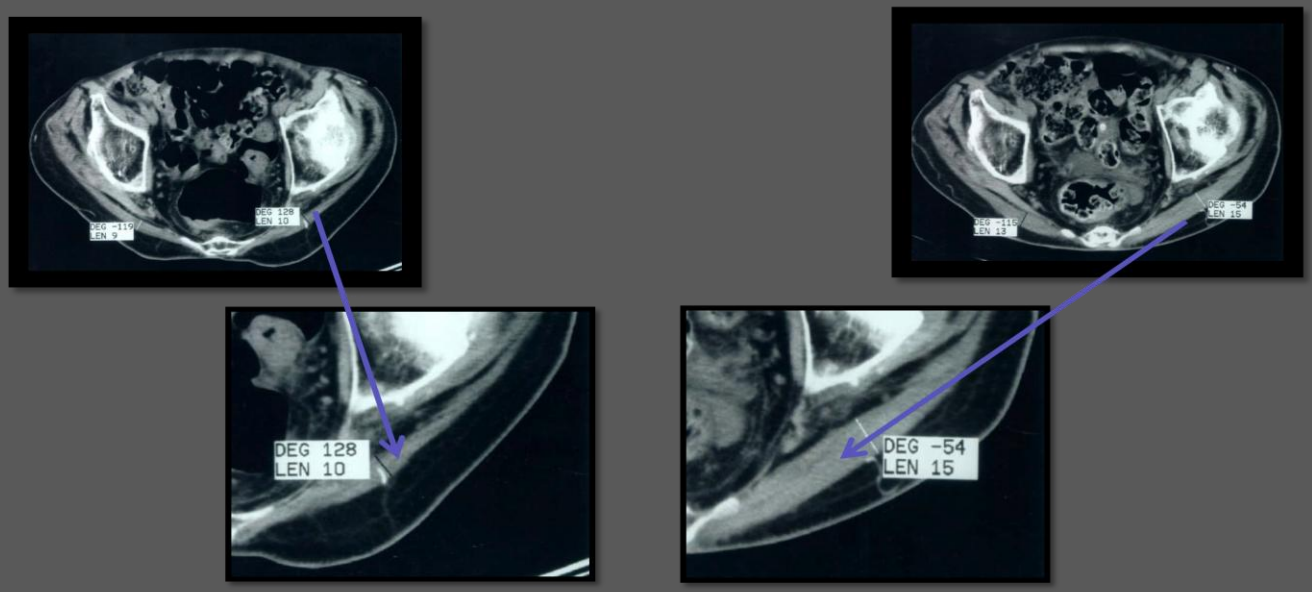
Pressure Sore Prevention Using NMES

- NMES provides at-risk individuals with a method for achieving an independent pressure relief regime
- Dynamic alternating bilateral stimulation (left/right) provides weight-shifting
- Used daily for a long period (over 6 months).



Pressure Sore Prevention

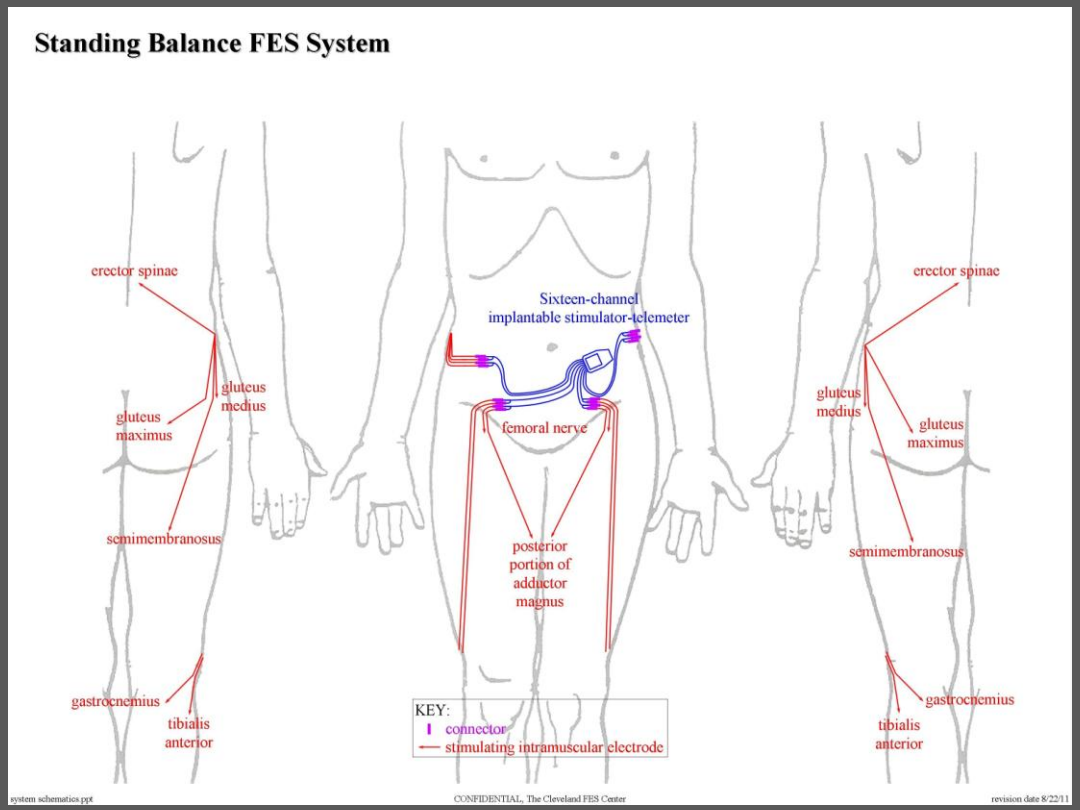
Changes in gluteal muscle thickness



Baseline Following stimulation

Transverse section through top of the head of the femur

Standing & Transfers



- Targeted Muscles
  - Erector spinae
  - Gluteus Maximus
  - Gluteus Medius
  - Adductor Magnus
  - Semimembranosus
  - Gastroenemius
  - Tibialis Anterior
  - Femoral Nerve

Standing & Transfers

Benefits

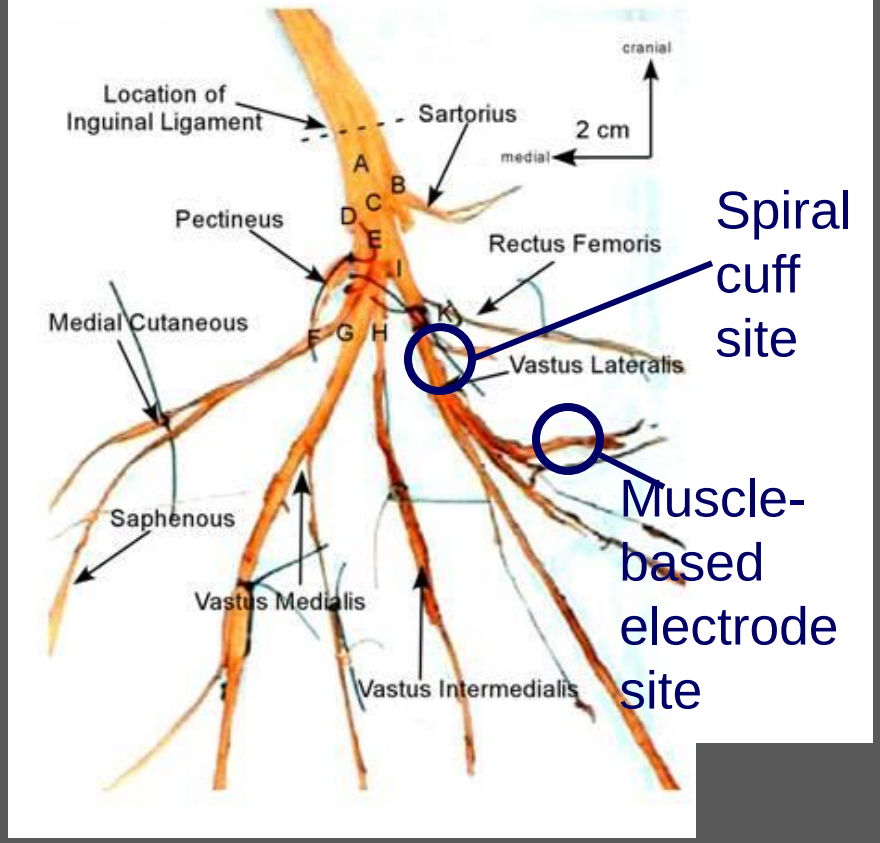
- Transfers to higher surfaces
- Reaching for objects overhead
- Additional environmental access
- Psychological benefits
- Physiological benefits

Limitations

- Standing duration
- No control for balance
- Requires some upper extremity support
- Invasive surgical procedure

Improving activation

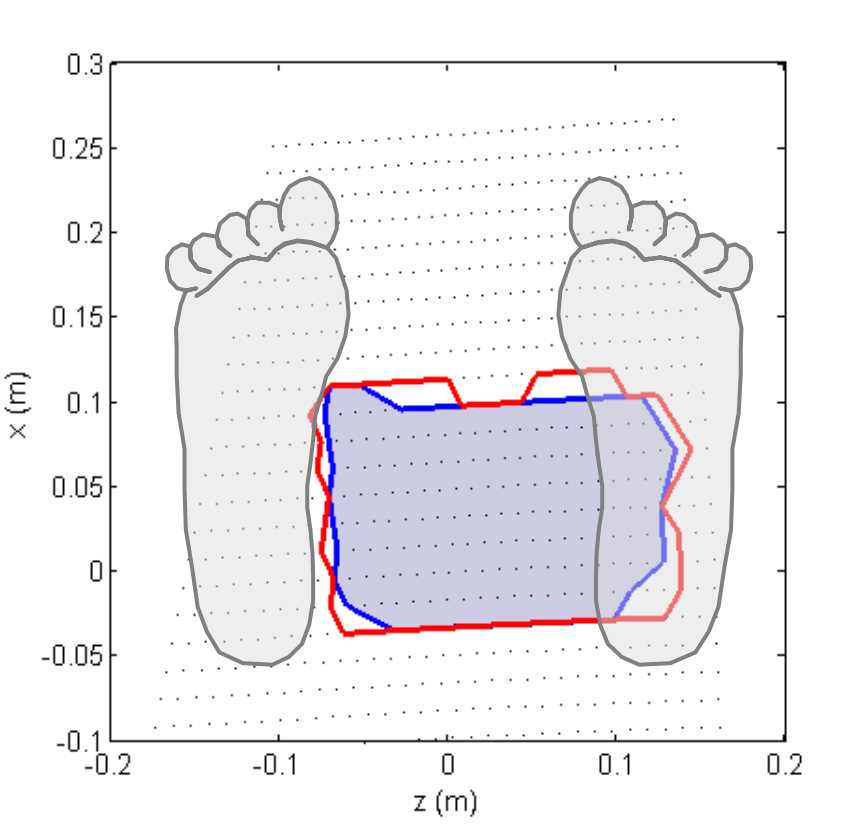
Femoral nerve



Nerve-based interfaces vs Muscle-based

- Full recruitment
- Redundancy
- Margin for fatigue
- Efficiency
  - Surgical access
  - Agonists & antagonists for additional function

Automatic Balance Control



Full Muscle Set (52 Channels)- shown in red. 16-channel muscle set shown in blue.

Channel 1/2	Gluteus Maximus
Channel 3/4	Gluteus Medius
Channel 5/6	Adductor Magnus
Channel 7/8	Semimembranosus
Channel 9/10	Vastus Lateralis
Channel 11/12	Plantarflexors
Channel 13/14	Tibialis Anterior
Channel 15/16	Erector Spinae

A 16-channel muscle set can have a stable region that is nearly as large as that for 52 channels!

Current Standing Studies

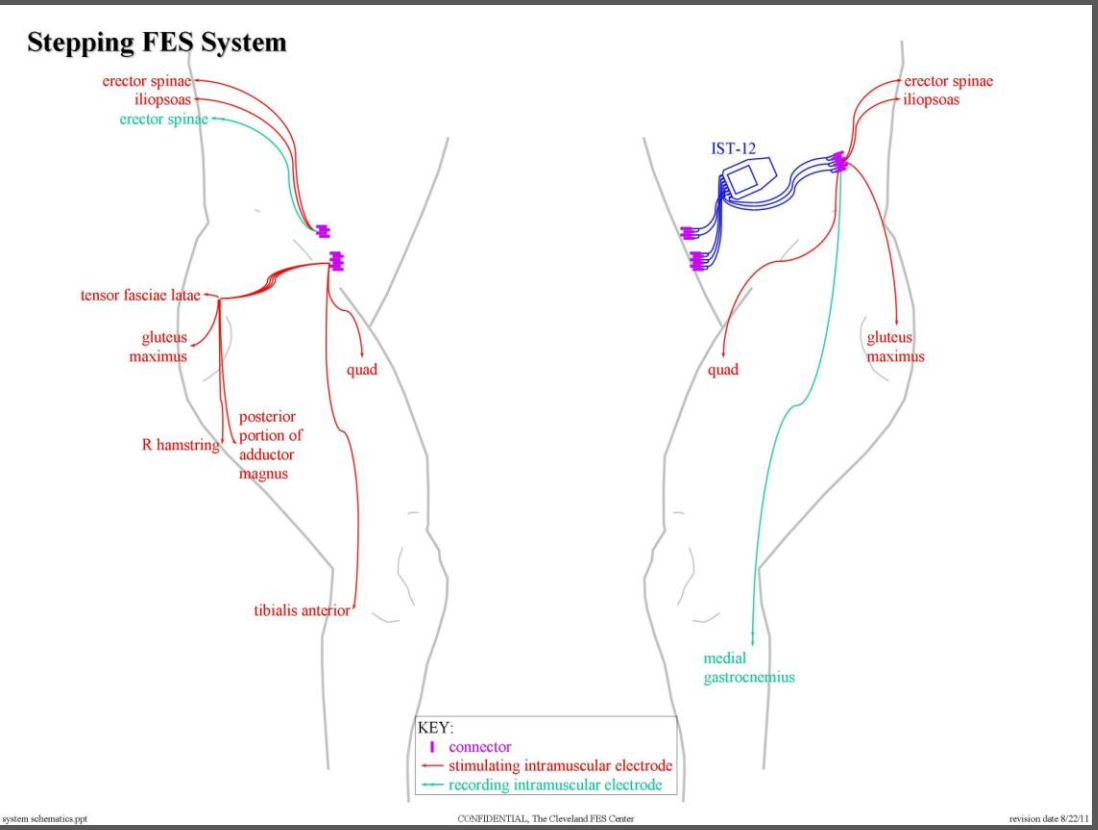
Balance Study

- Technology is IST-16, 16 channel stimulator
- Stimulate muscles that can help control for loss of balance both forward/backward and side to side
- Currently awaiting funding for this project

Nerve Cuff Study

- Technology is IST-16, 16 channel stimulator
- Uses the nerve cuff technology to provided improved stimulation of the quadriceps muscles
- Currently recruiting for this project.
- www.FESCenter.org

Stepping



Incomplete SCI

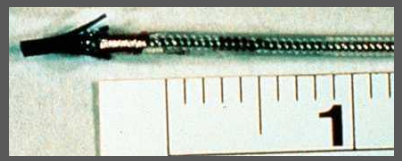
- Largest segment of SCI population
- Few channels

Complicating Issues

- Inter-subject variability
- Coordination with voluntary movements

Functional Goal

- Non/Physiological ambulators → Household/community ambulators



Intramuscular electrodes

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Pre & Post-Implant

Before: With no stimulation

After: With stimulation

EMG vs. switch

- EMG control is more consistent
- Stance times, symmetry & speed improved
- Dynamic stability to be determined

Current Stepping Studies

Stepping Study

- Technology is IST-12, 12 channel stimulator
- 2- channels for EMG control
- Stimulate muscles that participant does not have voluntary control
- Currently awaiting funding for this project

Considerations to Participating in any FES program

- Not all programs are appropriate for all populations
- Peripheral nerves damage
- Implanted vs external
- Time commitment
- Out of pocket cost and/or reimbursement
- Potentially dangerous if not used properly used

Quality of Life Impact

Acknowledgements

FUNDING

Website: www.FEScenter.org

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Investigators: P.H. Peckham, R. Triolo, J. Anderson, M. Audu, H. Hoyen, D. Durand, K. Gustafson, E. Hardin, R. Kirsch, R. Kobetic, G. Pinault, D. Tyler, K. Kilgore, K. Bogie, A. DiMarco, N. Bhadra

Staff of the FES Center

ALL RESEARCH VOLUNTEERS & THEIR FAMILIES

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