Implanted Neuroprostheses to Improve Standing, Walking and Seated Mobility after SCI

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Basic standing system

Technology
- Muscle-based electrodes
- 8-channel stimulator

Muscle selection
- Knee extension
- 2X Hip extension
- Trunk extension

Clinical outcomes
- Recruitment stability
- Component reliability
- Strength & endurance
- BW distribution
- Standing times
- Usage patterns
- Perceptions of health
- Satisfaction
- Effort and assistance
**System operation**

**Intimate & convenient**
- Self-contained with no special equipment
- Continuously available & unobtrusive
- Easy doffing/donning
- Menu-driven selection & activation

**Potential Benefits**
- Reaching for objects overhead
- Transfers to higher surfaces
- Environmental access
- Psychological & physiological benefits

**Limitations**
- Standing duration
- No control of balance
- Requires upper extremity effort
- Invasive surgical procedure
Clinical results

• 15 recipients of original 8-channel implanted system from 1996 to 2010
  – Gender: 14 M, 1 F
  – BMI: 18 – 32
  – Injury level:
    5 low cervical
    10 mid-thoracic
  – AIS Classification:
    10 A, 4 B, 1 C
  – MPI @ implant:
    13 – 202 (avg: 72.6)

• Follow-up more than 1 year later (mean 13 ± 4 mos)

Triolo et al.
APMR 93(5), 2012
System performance

- All able to stand, transfer & reach overhead
- Component reliability ~ 90%
- Knee extension strength & endurance maintained
- Minimal UE effort required for balance
  ~ 90% to 77% Body Weight supported by legs
- Functionally relevant standing times
  Mean: ~ 15 to 27 min.
  Median: ~ 4 to 3 min.

- Use shifted from maintenance exercise to functional standing
  ~ 40% of days
  ~ 1hr per day
• Technical performance maintained for more > 1 year
  – Strength, Endurance, Standing Time & BW Distribution statistically unchanged, but highly variable
• The system appears to be safe & reliable
• Use was regular and incorporated into daily routines
  – Amount of usage consistent over time
  – Patterns of usage changed
• No clear relationship between time post-injury, or level of injury
Technical challenges

BW support & standing times related to height and weight, NOT time-post-injury or injury level.

*How can we make outcomes more consistent?*

Systems are unresponsive to disturbances & balance is maintained by the arms.

*Can we modulate stimulation AUTOMATICALLY and reduce reliance on the UEs?*

John Callahan
1951 - 2010
Enabling technologies

- 12 & 16 channel Implanted Stimulator-Telemeter (IST)
  - EMG recording capability
- IM recording electrodes
- Nerve-based stimulating electrodes
  - Multi-contact cuffs
Brute force

More complete activation
More muscle fibers recruited
More force generated

Gustafson et al.
JRRD 46(7), 2009
53 yrs. T6 AIS A
7 yrs. post-injury
8-CH system user
Max stand time: 4.5 min.

Replace muscle-based electrodes with multi-contact spiral cuffs on the femoral nerves

Nerve cuffs improve performance & accelerate progress

More complete activation
More muscle fibers recruited
More force generated
Sinusoidal oscillations of independent motor unit pools at pulse parameters optimized for multiple spiral nerve cuff contacts

Avg. $\sim 20$ Nm

Fisher et al.
Jou Neural Eng & Rehab 10(25), 2013
A matter of balance

- Biologically Inspired Controllers
  - Center of Mass (COM) Acceleration
    - Maps body acceleration to muscle activation
    - Simulates short-latency vestibular reflexes
  - Joint Angle Feedback
    - Maps joint angle to muscle activation
    - Simulates longer-latency proprioceptive reflexes
- Upper extremity controller
  - Simulates user interactions with a walker or support device
  - Compensates for errors and reduced muscle set
  - Controller output = UE effort
  - Control should reduce UE effort

- 43 - 56% reduction in UE effort with controllers active
- COM acceleration control 3x to 5x more tolerant to noise and error

Nataraj et al.
IEEE TNSRE 18(6), 2010; JRRD 49(2), 2012
Significant reduction in UE effort with controller vs. continuous stimulation for applied disturbances

Nataraj et al.
JRRD 46(2), 2012
**Implications**

- **Selective activation** of independent motor unit pools with multi-contact nerve cuffs can **prolong joint moment production**.
  - Performance during standing and other functional activities needs to be determined

- **Feedback control** can **reduce UE loading** required to maintain balance.
  - Practical issues related to controller tuning, sensor mounting, etc. need to be addressed

- Methods to implement & evaluate **reactive stepping** and **posture setting** remain to be developed.
Walking

Incomplete SCI
- Largest segment of SCI population
- Few channels $\rightarrow$ large gain

Complicating Issues
- Inter-subject variability
- Natural recovery
- Coordinating stimulation with voluntary movements
- Compensatory mechanisms

Outcomes
- Addressing focal gait deficits with stimulation can improve walking one full ambulatory category

Hardin et al.
JRRD 44(3), 2007
Approach

• Maximize voluntary function with over ground gait training
• Identify major deficits
• Customize muscle set & stimulation patterns
• Implant stimulating & recording electrodes
  – Incorporate implanted stimulation into gait training

Household amubulator with AFOs

Weaker left side

Muscle set:

Left
Iliopsoas
Glut Max
TA
Quadriceps
TFL
PostAd
Hamstring
Glut Med

Right
Iliopsoas
Glut Max (2)
TA
*Gastroc
*RF

36 sessions of gait training with implanted system

* - Recording electrodes
With & without assist

T1 motor/C5 sensory AIS D

Volitional only
(2 years post injury)

Stimulation-assisted
(9 months post implant)

Neurotherapeutic vs. neuroprosthetic effect?
- **Voluntary** 6 minute walking distance improved
- **Additional** 20% gain when using FES during walking
- **Maximum** distance increased 3X with FES assistance
- **Gait symmetry & double stance time** improved

*Bailey et al.*
*JRRD 47(1), 2009*
EMG control

- Volitional R Gastrox activity (push off) triggers R Swing
- Peak R Quad EMG (weight acceptance) triggers L Swing
- Algorithm adapts trigger thresholds and scales stimulation patterns
- Allows variable speed & step length and integration with voluntary function

Potential to reinforce desired muscle coordination patterns
Implications

- Customized stimulation programs can facilitate ambulation after incomplete SCI
  - Exceeds maximal voluntary function achieved via conventional rehabilitation & training
  - Individual variation & sensation
- Over ground gait training with stimulation can enhance voluntary walking performance
  - Neurotherapeutic effect
- Appropriately timed stimulation enables function beyond voluntary capacity
  - Neuroprosthetic effect
- Coordinating stimulation with residual voluntary function can enable variation of speed and stride length and reinforce active voluntary muscle control
Seated posture

Core Trunk/Hip Paralysis

- Necessitates compensatory strategies
- Limits workspace and environmental interactions
- Restricts tasks to unimanual vs. bimanual
- Requires belts, straps, & adapted seating systems
- Results in kyphotic postures that can increase interface & internal pressures
- Contributes to rotator cuff injuries

Track 1: 1:30 – 3:00
Basic trunk system

**Technology**
- Muscle or nerve based electrodes
- 8 or 16 channel implanted stimulators

**Muscle selection**
- Trunk stabilization
  - Lumbar paraspinals
  - Quadratus lumborum
- Hip extension
  - Gluteus maximus
  - Semimembranosis
  - Posterior Adductor
- Knee extension
  - VL, VI, VM
- Others
  - Iliopsoas
  - Gluteus medius
  - Triceps surae
  - Tibialis anterior
Effects on posture

Continuous activation of hip and trunk muscles:

- Normalizes head & shoulder position
- Reduces posterior pelvic tilt and kyphotic postures
- Restores vertebral alignment and scapular symmetry
- Redistributes interface pressures
- Improves pulmonary function

- Enables return to erect sitting from full forward flexion
- Facilitates bed turning by coupling the hips and shoulders

Triolo et al. APMR 90(2), 2009
Wu et al., PM&R Journal, 2013 (in press)
Effects on function

- Extends sagittal reach distance
- Expands bimanual work volume
- Shifts work space forward and upward
- Improves stability during internal & external disturbances
- Increases ability to exert forces on the environment
  - On average 46% improvement over volition alone (up to 15 additional pounds)

Kukke et al. IEEE TNSRE 12(2), 2004
Triolo et al. APMR, 2013 (in press)
Return to erect

Controller OFF

Controller ON

C7 AIS C
Continuous sub-maximal stimulation to the hip and trunk muscles can:

- **Fraction Effective Force** (ratio of tangential to total hand rim force) in most subjects (mean = 15.41%)

- **Peak Force** for most subjects (mean = 18.92%) with **no increase in shoulder moment**

Stiffening the torso can make level propulsion at comfortable speeds more efficient.

Effects disappear for more challenging tasks like ramps & sprints.

Triolo et al. APMR, 2013 (in press)
Implications

• Activating core trunk & hip muscles can positively impact seated posture
  – Anterior pelvic tilt, postural alignment normalized

• Stimulating the hip & trunk muscles can improve seated function
  – Active sitting stability, Bimanual reach & Level propulsion

• Activating the hip & trunk muscles can enable return to erect sitting and other maneuvers
  – Outcomes may be related to stimulated strength & most pronounced in higher level injuries

• Modulating stimulation via simple controllers may improve & expand functional benefits
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Additional Resources:
APT Center:  http://www.aptcenter.research.va.gov
FES Center:  http://fescenter.org