Functional Outcomes after Implantation of a Myoelectrically-Controlled Neuroprosthesis in People with Tetraplegia

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Disclosures

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Learning Objectives:

At the conclusion of this activity, the participant will be able to:

• Identify appropriate surgical procedures for restoring arm and hand function in people with tetraplegia
• Recognize the importance of characterizing paralysis by differentiating between upper motor and lower motor neuron damage
• Identify appropriate outcome measures to determine the effects of UE reconstructive surgery within the domains of the International Classification of Functioning, Disability and Health (ICF)
• Be able to evaluate and recommend appropriate interventions for improving arm and hand function in people at all levels of tetraplegia
The Cleveland FES Center

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The Importance of Upper Extremity Function

“...the greatest potential for improvement of quality of life lies in rehabilitation and maximal restoration of upper extremity function.” Waters (1996)

The return of arm and hand function is the highest priority among tetraplegics as compared to other functions such as sexual function, trunk stability or walking. Anderson (2004)

77% of tetraplegics expected an important or very important improvement in QOL if their hand function improved. Snoek (2004)


Innovation

1: the introduction of something new
2: a new idea, method, or device: novelty

UE Reconstructive Procedures

Functional Electrical Stimulation (FES)
SCI - Phases of [Recovery]

- **Acute** — The first days / weeks following injury. The main goal during this time is to save the person’s life (medical stabilization, spine stabilization...)

- **Rehabilitation** — Can start as early as a couple of weeks post-injury. The main goal during this phase is to strengthen and improve function in preparation for living life with SCI

- **Post-Rehabilitation** — Can start as early as six weeks to two months post-injury. The main goal is to assimilate back into life with SCI
International Classification for Surgery of the Hand in Tetraplegia (ICSHT)

- Introduced specifically for surgical planning in the upper limb in tetraplegia
- Includes motor and sensory portion
  - Muscles – grade 4 or higher
  - Sensory – static 2 pt. discrimination - thumb
    - O – Occular, > 10 mm static 2 pt.
    - Cu – Cutaneous, < 10 mm static 2 pt


ASIA Classification
(Grade 3 MMT)

C5 - Elbow Flexors
C6 - Wrist Extensors
C7 - Elbow Extensors
C8 - Finger Flexors
T1 – Finger Abductors

ICSHT
(Grade 4 MMT)

Group 0 - No muscles for transfer
Group 1 - Brachioradialis
Group 2 – ECRL
Group 3 – ECRB
Group 4 – Pronator Teres
Group 5 – FCR
Group 6 – EDC
Group 7 – Extensor Pollicis Longus
Group 8 - Partial Digital Flexors
Group 9 - Lacks only intrinsics
Group X - Exceptions

C5

C6

C7

C8
Restoring Function: *Philosophy*

- Maximize existing function
  - Muscle strengthening
  - ADL training

- Complement voluntary function
  - Reconstructive procedures
  - Functional electrical stimulation (FES)
Types of Reconstructive Procedures:

- **Neuroprosthesis** – a system using functional electrical stimulation for the performance of functional activities
- **Tendon transfer** - Surgical procedure by which a tendon is incised at its insertion and placed at an anatomical site distant from the original insertion. The tendon remains attached at the point of origin and takes over the function of a muscle inactivated by trauma or disease.
- **Tenodesis** - The surgical anchoring of a tendon, as to a bone
- **Tenotomy** (tendon lengthening )- A surgical procedure that cuts the tendon of a contracted muscle to allow lengthening
Types of Reconstructive Procedures

- **Arthrodesis** - The surgical fixation of a joint to promote bone fusion
- **Capsulodesis** - The surgical fixation of a joint capsule to promote joint stability
- **Radial Osteotomy** – The surgical repositioning of the radius to correct for fixed supination contracture
- **Hybrid Approach**
Electrical Stimulation for Providing Function after Spinal Cord Injury
**Therapeutic Applications**
To improve or restore function, a form of neuromuscular retraining, with the goal of returning the person to performing activities without stimulation

**Functional Applications**
A neuroprosthesis, combining stimulation with the performance of functional activities

Implantable Stimulator and Telemetry System (C5-C6)
Implantable Stimulator and Telemetry System
(C4 and higher)

Hand, Arm, Shoulder
External Controllers, Implantable Stimulators

IST-12
Controlling the System
Candidate Selection

• Cervical level SCI (typically C5, C6)
• Intact lower motor neuron
• Motivated, desire for improved function
• Good family support / resources
• Ability to cope with post-operative course
Pre-Surgery Preparation

- Maximization of voluntary function
  - Range of motion
  - Strength
  - Function
- Education / increase awareness
  - surgical procedure
  - benefits
  - post-operative protocols
- Strengthening of paralyzed muscles to be implanted
- Collection of baseline data
Surgery

- General anesthesia
- Generally a 4-6 hour procedure
- Inpatient stay – approximately 2-3 nights
Post-Operative Course

• Immobilization 3-4 weeks
• Cast removal
  • Electrode profiling
  • Exercise grasp programming
• Exercise regimen – minimum of 4 weeks
• Rehabilitation Phase I – (one week)
  • Functional grasp and control programming
  • ADL training
  • Data collection
• Rehabilitation Phase II – (one week)
  • Grasp and control refinement
  • Additional ADL training and data collection
Drinking from a glass with the neuroprosthesis compared to without
Applying lip balm with the neuroprosthesis
Functional Activities
Functional Activities
Functional Activities
Outcome Measurement: Application of the WHO International Classification of Functioning, Disability and Health (ICF)
International Classification of Functioning Disability and Health (ICF)  
WHO 2001

- Health Condition
  - Body Functions and Structures
  - Activity
  - Participation
  - Environmental Factors
  - Personal Factors
Participant Demographics

- 14 Participants (17 arms implanted)
  - 11 C5/C6 Tetraplegia (14 arms)
  - 2 High Tetraplegia (2 arms)
  - 1 Stroke (1 arm)
- Females 4/14 (5/17 arms)
- Average Age at Implantation – 37 years (26-56)
- Cause of Injury
  - MVA 8/13
  - Swimming / Diving 2/13
  - Violence 1/13
  - Other 2/13
- Average Time to Implantation after Injury – 6 years (1-21)
Grasp Strength

- Measured as part of the Grasp and Release Test
- Measured pre-surgery and post-implantation during rehabilitation
- Measurements made for the following patterns of prehension:
  - Lateral
  - Palmar
  - Palmar (Five Finger)
Changes in Grasp Strength

Lateral Grasp Strength

Palmar Grasp Strength

p = 0.000

p = 0.000

p = 0.027
Grasp and Release Test

• Grasp strength measurements
• Pick and place test of object acquisition
  • Pass / Fail
  • Main Test
• Administered:
  • pre-surgery
  • post-implantation


Grasp Release Test Performance

# Objects

# Participants who Pass

Pre-Surgery
Post-Surgery NP Off
Post-Surgery NP On
Capabilities of the Upper Extremity (CUE)

- Measures upper extremity function in people with tetraplegia
- Questionnaire format
- Separates hand function from shoulder/elbow

1. Totally limited, can't do it at all
2. Extremely limited
3. Very limited
4. Moderately limited
5. Some limitation
6. A little limited
7. Not at all limited

Changes in CUE Responses: Neuroprosthesis On vs. Pre-Surgery

![Graph showing changes in CUE responses with different tasks and percentage of improvement, same, or worse.]

- Pinch and Hold Key
- Grasp and Hold Hammer
- Raise Arm over Head, Arm Straight
- Raise 5 lb. Object Overhead, Both Arms
- Pushing Heavy Object on Table Away
- Pick Up Small Object
- Press Button with Index Finger
- Sliding Heavy Object on Table Toward
- Pushing Light Object on Table Away
- Curl Wrist Upwards, Palm Down
- Pick Up Large Jar or Open Lid
- Sliding Light Object on Table Toward
- Push-up Weight Shift
- Turn Palm Downward, Elbow at Side
- Reach Forward at Arm Level
- Reach, Touch Floor, Sit Back Up
- Manipulate Objects

Legend:
- Green: Improve
- Yellow: Same
- Red: Worse
ADL Abilities Test

• Compares the ability to perform ADL with and without the neuroprosthesis
• Provides an ADL training program
• Participants are trained in at least four ADL
• Tasks are divided into phases and scored for
  • Amount of assistance required
  • Preference
  • Quality


Activities Tested

• Standard Activities:
  Eating, Drinking, Writing, Computer Disc, Phone, Brush Teeth

• Additional Participant Selected Activities
  Brushing Hair, Eating Sandwich, Cards, Drinking from a Wine Glass, Cross-stitch, etc.
Changes in ADL Performance

Everybody improved in eating with a utensil and writing

92% of participants improved in 3 or more activities
Five problems identified and further rated:

**SATISFACTION**

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<th>2</th>
<th>3</th>
<th>4</th>
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<th>6</th>
<th>7</th>
<th>8</th>
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<tbody>
<tr>
<td>Not satisfied at all</td>
<td>Extremely satisfied</td>
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**PERFORMANCE**

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<td>Not able to do it</td>
<td>Able to do it extremely well</td>
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Total Score = \[
\frac{\text{Total performance or satisfaction scores}}{\text{# of Problems}}
\]
COPM

67% improved 2 or more steps in performance

Median 3 (0-6.5)

89% improved 2 or more steps in satisfaction

Median 4.6 (1-7.3)
Craig Handicap Assessment & Reporting Technique (CHART)

- Developed to measure the WHO dimensions of participation
- Dimensions:
  - Cognition
  - Physical independence
  - Mobility
  - Occupation
  - Social integration
  - Economic self-sufficiency

Changes in CHART Responses

Physical Independence

Mobility

Occupation

Social

Increase  Same  Decrease
Usage Data

Two participants don the system every day. All but one participant donned the system more than half of the time.
High Tetraplegia Outcomes
Activities for High Tetraplegia

- Shaking hands - successful
- Scratching nose - successful
- Wiping nose – successful with assistance
- Eat finger foods – successful with assistance
- Eat with utensil – successful with assistance
- Wash / wipe face – successful with assistance
- Brush teeth – successful with assistance
No one measure provides the complete picture. As long as you are measuring across all domains of the ICF you can be reasonably sure to capture what is important.
Case Study

- 25 year-old male
- Cause of Injury - MVA
- 1 ½ years post-injury
- Air Force Veteran, service-connected
- Married, 1 child
- Looking to improve arm and hand function
Level of Injury

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<td>O:2</td>
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What muscles are functional for his right UE?
- Deltoid
- Biceps
- Brachialis
- Brachioradialis
- Shoulder abduction
- Elbow flexion

What muscles are functional for his left UE?
- Deltoid
- Biceps
- Brachialis
- Brachioradialis
- ECRL
- Shoulder abduction
- Elbow flexion
- Wrist ext
Level of Injury

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What movements can be restored in his right UE?

- Elbow Extension (PD-Triceps)
- Wrist Extension (Br-ECRB)

What movements can be restored in his left UE?

- Elbow Extension (PD-Triceps)
- Thumb Pinch (Br-FPL)

Bilateral surgery performed on the same day – August 2004
Immobilization Phase

- Bilateral arms immobilized for three weeks
  - Elbows at (nearly) full extension
  - R wrist positioned in extension
  - L wrist at neutral, thumb in flexion
- Inpatient at VA Hospital during immobilization phase
Tendon Transfer
Rehabilitation Phase

• Casts removed at three weeks post-op
• Inpatient at VA for two weeks
• Protective Splints Fabricated
  • Elbow extension
    • Dynamic flexion-block splints – daytime
    • Static elbow extension splints - night-time
  • R wrist cock-up splint
  • L modified thumb spica
• Splints are removed during therapy only
Tendon Transfer Rehabilitation Phase

- Outpatient therapy for six weeks
- Protective splints discontinued during day
- Protective splints used at night-time and during strenuous activities
- Progressive resistance exercises
- Complication –
  - Infection – graft material of right PD-Triceps
  - Revision Surgery – removal of graft material, revision of transfer, IV antibiotics
Functional Gains

• Right UE
  • Full elbow extension in gravity-reduced plane
  • Active wrist extension, tenodesis grasp
  • Increased independence in ADL with AE

• Left UE
  • Full elbow extension against gravity
  • Active thumb flexion – stronger thumb pinch
  • Increased independence in ADL, reduced AE
Functional Electrical Stimulation Phase

Right UE: All paralyzed muscles responded to electrical stimulation

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<tr>
<td>Thumb Opening</td>
<td>EPL, AbPB, APL</td>
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<tr>
<td>Finger Flexion</td>
<td>FDP, FDS</td>
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<tr>
<td>Finger Extension</td>
<td>EDC, 2\textsuperscript{nd} – 3\textsuperscript{rd} DI</td>
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<td>ECU to ECRB</td>
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System implanted In December 2005
**Functional Electrical Stimulation Phase**

**Left UE:** All paralyzed muscles responded to electrical stimulation

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System implanted in April 2006
FES Rehabilitation

- Immobilization – three weeks
- At cast removal, implanted neuroprosthesis programmed for exercise
- After 4 weeks of exercise, 1 week inpatient stay for programming and functional training
- Participant returns home to use neuroprothesis in home environment
- After 1 month, participant returns for additional programming (if needed), functional training and data collection.
- Continued follow-up visits at 6 months, 1 year and annually
Bilateral Hand Function
Questions?

Thank You!
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