Functional Results Following Implantation of an Upper Extremity Neuroprosthesis Utilizing Myoelectric Control

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Abstract:
A second-generation implantable neuroprosthesis has been developed for individuals with cervical level spinal cord injury. The user generates myoelectric signals from muscles under voluntary control to activate stimulation to the paralyzed muscles in the arm. This results in functional grasp patterns including activation of shoulder and scapular muscles. The system has been implanted in 10 participants (13 arms) with C5-C7 motor level SCI. The International Classification of Functioning, Disability and Health (ICF) was used to structure measurement of functional outcomes. The impact of the neuroprosthesis on the ICF domain of body functions and structures is demonstrated by median grasp strength of 4.18 lbs. (1.74-6.27) with the neuroprosthesis compared to 1.48 lbs (0.70-5.23) without the neuroprosthesis. Performance of activities of daily living improved in a median of 76% of activities tested (33%-100%). Within the domain of participation, participants are performing more activities in their homes and communities using the neuroprosthesis. These results indicate that implanted myoelectric control is an effective control option for neuroprostheses and for restoring function to individuals with cervical level spinal cord injury.

INTRODUCTION: Traumatic cervical spinal cord injury (SCI) can result in tetraplegia with severely compromised upper extremity function in addition to paralysis of the trunk and lower extremities. Of the approximately 11,000 new SCIs that occur each year in the United States, 56% result in complete or incomplete tetraplegia. This type of injury typically happens to individuals younger than 40 years. The impact of the injury transcends the damage to body functions and structures and affects the person’s ability to perform functional activities and participate in the life roles that were assumed prior to the SCI. The severity of this type of injury, its occurrence in the young, and the fact that people with SCI are living longer in the presence of compromised function increase the importance of restoring upper extremity function where possible and measuring outcomes of this restoration. This paper focuses on measuring the functional impact of a myoelectrically controlled neuroprosthesis for people with C5 and C6 tetraplegia.

As options for improving upper extremity function after tetraplegia have increased as a result of advancing science and technology, it becomes increasingly important to use a common language or approach for measuring
outcomes. The International Classification of Functioning, Disability and Health (ICF) is a theoretical framework developed by the World Health Organization that can guide the measurement of outcomes across all domains of health. Attention is needed in choosing appropriate outcome measures that detect the often subtle, yet significant, functional gains that affect all aspects of human function from the basics of movement to participation in life in a personally meaningful way.

**METHODS:** A second-generation implantable neuroprosthesis has been developed for individuals with cervical level spinal cord injury. The user generates myoelectric signals from muscles under voluntary control to activate stimulation to the paralyzed muscles in the arm. This results in functional grasp patterns including activation of shoulder and scapular muscles. The system has been implanted in 10 participants (13 arms) with C3-C7 motor level SCI.

Resulting functional outcomes have been measured within the ICF domains. Several measures are used in each domain, however, only key measures are included in this paper.

**Body Functions and Structures**

**Grasp Strength** - Grasp strength was measured with and without the neuroprosthesis using a modified pinch meter. The meter was modified to better accommodate a tetraplegic hand by providing a larger base upon which to pinch. Three trials of grasping were tested for each of the following grasp patterns: lateral, palmar and five finger.

**Activities**

**Object Acquisition** – The Grasp and Release Test (GRT)²,³ is a pick-and-place test that requires the participant to unilaterally acquire, move, and release six objects varying in weight and size. The number of objects that the participant can successfully manipulate with and without the neuroprosthesis was measured.

**Activity of Daily Living Performance** – The ADL Abilities Test was developed by researchers at the Cleveland FES Center to measure differences in activity performance with and without a hand neuroprosthesis.⁴ The test includes activities that are reasonable for individuals with tetraplegia to perform such as feeding, grooming, and writing. The activities are broken down into phases, and each phase is scored for the amount of assistance the participant requires, including physical assistance, supervision, orthotic assistance, adaptive equipment, self-assistance, or no assistance (independent).

**Participation**

The Craig Handicap Assessment and Reporting Technique (CHART)⁵ is the only instrument developed specifically for individuals with SCI that is currently available to measure community reintegration. The CHART was administered prior to neuroprosthesis implantation and one-year post-surgery.

Satisfaction with the neuroprosthesis was measured with the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST), a structured and standardized measure to evaluate user satisfaction with a wide range of technology devices⁶.

**RESULTS:**
Figure 1 shows the differences in grasp strength (pre-surgery, post-surgery with the neuroprosthesis off and post-surgery with the neuroprosthesis on). Grasp strength increased significantly with the neuroprosthesis on as compared to off for both lateral and palmar prehension (p < 0.0001). Additionally, a significant increase in strength was seen between pre-surgery and post-surgery with the neuroprosthesis turned off for palmar prehension (p = 0.027).

Figure 2 shows the ability for participants to grasp and release objects prior to surgery, post-surgery with the neuroprosthesis turned off and with the neuroprosthesis turned on. There is a maximum of six objects. Most of the participants could successfully move two of the six objects prior to surgery. These were typically the lightest two objects, the peg and the block. Three participants increased the number of objects they could acquire post-surgery with the neuroprosthesis turned off. All of the participants could move at least five or all six of the objects with the neuroprosthesis turned on.

Activity of daily living performance improved with the neuroprosthesis for 76% of the tasks tested. All participants improved in the tasks of eating with a utensil and writing. The improvements per participant ranged from 33% - 100% with the neuroprosthesis. Table 1 shows the activities tested.

Table 1. Activity of Daily Living Performance Changes

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of Participants</th>
<th>Number Improved/Number Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eating with a Fork</td>
<td>12/12</td>
<td>12/12</td>
</tr>
<tr>
<td>Drinking from a Glass</td>
<td>8/12</td>
<td>8/12</td>
</tr>
<tr>
<td>Writing</td>
<td>12/12</td>
<td>12/12</td>
</tr>
<tr>
<td>Using a Phone</td>
<td>5/11</td>
<td>5/11</td>
</tr>
<tr>
<td>Brushing Teeth</td>
<td>5/7</td>
<td>5/7</td>
</tr>
<tr>
<td>Using a Computer CD</td>
<td>4/8</td>
<td>4/8</td>
</tr>
<tr>
<td>Drinking from a Mug</td>
<td>4/4</td>
<td>4/4</td>
</tr>
<tr>
<td>Other Assorted tasks</td>
<td>2/2</td>
<td>2/2</td>
</tr>
<tr>
<td>Total Tasks Improved</td>
<td>56 54 26 66 88 1 1 59</td>
<td></td>
</tr>
</tbody>
</table>

Data from the CHART is still being analyzed. Preliminary data of satisfaction with the neuroprosthesis as measured by the QUEST shows high satisfaction across the twelve items (figure 3). Likert response categories range from 1 – not satisfied at all to 5 – very satisfied.
CONCLUSION:
Preliminary data shows that this latest generation neuroprosthesis incorporating myoelectric control improves function in people with tetraplegia. With the neuroprosthesis, participants have stronger grasp and perform activities more independently. Additionally, the participants are satisfied with the function and related services of the neuroprosthesis.

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