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An Implanted Myoelectrically-Controlled Neuroprosthesis for Upper Extremity Function in Spinal Cord Injury

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Abstract— **A second generation implantable neuroprosthesis has been developed which provides improved control of grasp-release, forearm pronation, and elbow extension for individuals with cervical level spinal cord injury. In addition to the capacity to stimulate twelve muscles, the key technological feature of the advanced system is the capability to transmit data out of the body. This allows the use of myoelectric signal recording via implanted electrodes, thus minimizing the required external components. Clinical studies have been initiated with a second generation neuroprosthesis that consists of twelve stimulating electrodes, two myoelectric signal recording electrodes, an implanted stimulator-telemeter device and an external control unit and transmit/receive coil. This system has now been implemented in nine arms in seven C5/C6 spinal cord injured individuals. The results from these subjects demonstrate that myoelectric signals can be recorded from voluntary muscles in the presence of electrical stimulation of nearby muscles. The functional results show that the neuroprosthesis provides significantly increased pinch force and grasp function for each subject. All subjects have demonstrated increased independence and improved function in activities of daily living. We believe that these results indicate that implanted myoelectric control is a desirable option for neuroprostheses.**

I. INTRODUCTION

A second generation implantable neuroprosthesis has been developed which provides improved control of grasp and release, forearm pronation, and elbow extension for individuals with cervical level spinal cord injury. The primary feature of this neuroprosthesis is the capacity to record the myoelectric signal (MES) from two independent muscles, allowing users to control multiple functions using the signals from their voluntary musculature. Myoelectric control provides three significant advantages. First, the recording sensor is easy to develop as an implantable device, allowing the system have an implanted control source, thus reducing the external components that the user must wear. Second, the MES recording electrode can be used on a wide variety of muscles, making this method of control very adaptable to the capabilities of each subject. Finally, MES control signals can be obtained from weak or partially paralyzed muscles. Thus, MES control can potentially be obtained from almost any subject, as long as they retain voluntary control of at least one muscle. This greatly expands the applicability of this system to a wide range of disabling conditions.

II. METHODS

A. Neuroprosthesis Design

The second generation neuroprosthesis system consists of an implanted stimulator-telemeter (IST-12), implanted electrodes for stimulation and recording, an external control unit and a transcutaneous inductive link, as shown in Figure 1.

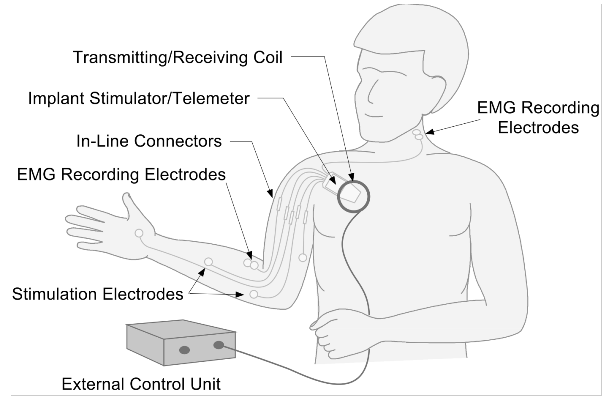

Figure 1. Drawing of the second generation neuroprosthetic system. The internal components include the implant stimulator/telemeter (IST-12), twelve stimulating electrodes and two recording electrodes. The external components include the external control unit and the transmit/receive coil. This system provides grasp/release, forearm pronation and elbow extension with myoelectric control.

The myoelectric signals are recorded via implanted electrodes, thus reducing the need for external components in order to obtain a control signal from the user. The signals are processed within the device and then transmitted out of

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the body via an inductive transcutaneous link. In addition, the IST-12 is capable of stimulating twelve different muscles independently.

The IST-12 is designed to rely on an external power supply and considerable external processing to relate the control signal (input) to the stimulus commands (output) to each electrode. This allows the size of the implanted components to remain small and provides the opportunity for considerable flexibility in designing and modifying the control algorithms and stimulation patterns. The external powering and processing are housed in an external control unit (ECU). The ECU is capable of recovering MES data, power supply data, internal settings and status from the IST-12, processing the recovered data using pre-programmed control algorithms, and transmitting the necessary stimulus commands back to the IST-12 device. Both power and bidirectional telemetry are provided through the same RF link so that the patient only needs to wear a single coil over the implanted device. The ECU uses a modular distributed architecture incorporating multiple microprocessors. Control applications are written on a desktop computer in a standard software package (Mathworks™ or Labview™) and downloaded to the ECU.

B. *Operation of the Neuroprosthesis*

The operation of the neuroprosthesis can be customized for each user. Typically, the user or caregiver turns the ECU on at the beginning of the day. This establishes RF communication between the ECU and the implant, allowing the MES from each muscle to be obtained. Generation of two successive high-level bursts of muscle activity from the shoulder (or neck) are used to activate the stimulation to the hand for grasp. The user selects the desired grasp pattern using bursts of activity from the same muscle. Once the pattern is selected, the user has direct proportional control of the degree of hand opening and closing through the MES activity level from their voluntary forearm musculature (either Br or ECRL). Strong contraction of this muscle results in hand closing and relaxation of the muscle results in hand opening. If the user desires to hold and object for a long period of time, he/she can initiate a “lock” command which disengages the grasp stimulation from control by the forearm MES. The lock command is initiated by holding the MES above a high threshold for two seconds. Once the hand is locked, it will remain closed until an unlock command is given. The unlock command can consist of two quick bursts of activity from the forearm (referred to as a “double-click”) or a quick burst of activity from the shoulder. The user can also independently activate other functions, such as elbow extension or forearm pronation, by producing a specific pattern of MES activity in the shoulder. For most users, this control algorithm allows the neuroprosthesis to be controlled without the need for any external switches.

C. *Measurement of Study Outcome*

Outcomes assessments were performed to measure the impact of the neuroprosthesis within the framework of the World Health Organization’s International Classification of Function (ICF) [1]. The domains of the ICF are: 1) body functions and structures, 2) activities, and 3) participation. Participants were evaluated prior to surgery and during rehabilitation following surgery (typically two to four months post implant-implantation).

Body Functions and Structures. The impact of the neuroprosthesis on body functions and structures was determined by evaluating the provision of joint movement and force generation, and the coordination of those forces into useful grasp patterns. Grasp and pinch force was measured using a modified pinch meter [2].

Activities. Activity performance can be divided into two categories: hand function and activities of daily living (ADL) function. Hand function was evaluated using the Grasp and Release Test (GRT) [2, 3]. This pick-and-place test 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 during a 30-second trial are recorded.

The impact of the neuroprosthesis on ADL performance was measured using the ADL Abilities Test (ADLAT). This test was developed specifically to measure differences in activity performance with and without a hand neuroprosthesis [4,5,6]. The test includes activities that are reasonable for individuals with tetraplegia to perform such as feeding, grooming, and writing. The test includes the participant’s subjective assessment of how he or she prefers to perform the activity (with or without the neuroprosthesis) and the therapist’s objective assessment of the overall quality of activity performance.

Participation. The impact of the neuroprosthesis on participation was determined using several measures: The ADL Habits Survey (ADLHS), The Neuroprosthesis Usage Survey [7], the Quality of Life Survey (Components of the Reintegration to Normal Living Index) [8,9], The Rosenberg Self Esteem Scale 10], the Mental Health Inventory [11], the Craig Handicap Assessment and Reporting Tool (CHART) and the Craig Hospital Inventory of Environmental Factors (CHIEF). Additionally, satisfaction with the neuroprosthesis was measured using the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) [12].

III. RESULTS

Seven subjects have been implanted with the IST-12 device, including two with bilateral systems. Four subjects have completed the functional testing, as described below. All subjects had either a C5 or C6 level spinal cord injury and were one to four years post-injury.

A. *Myoelectric Control*

It was possible to obtain a usable signal during stimulation in all subjects. Myoelectric signals can be recorded from implanted recording electrodes during stimulation of nearby muscles. For example, myoelectric signals could be recorded from the extensor carpi radialis longus during stimulation of the extensor digitorum where the stimulating and recording electrodes are within five cm of each other.

All subjects are able to control grasp opening and closing proportionally using one of their MES channels, typically the wrist extensor. Both of the subjects implemented with bilateral systems have demonstrated the ability to independently control each arm.

B. Functional Results

The study results to date indicate that every subject has shown improvement in all ICF domains. For the two subjects who were implemented bilaterally, each arm was studied separately in the two domains of body functions and activities.

Every subject improved significantly in their pinch force strength. In all cases, the pre-surgery pinch force was achieved by passive finger and thumb tone augmented with wrist extension. For most subjects, this pinch force is only useful for acquiring light objects, such as a piece of paper. With the neuroprosthesis turned on, pinch force typically doubled or tripled.

Every subject was able to at least double the number of objects they could manipulate in the grasp release test, as shown in Table 1. In four arms, subjects were able to complete all six tasks when using the neuroprosthesis, and a fifth could complete five of the six tasks.

Table 1. Grasp-Release Test Performance

(Number of Objects, Maximum = 6)

	Participant					
	1	2L	2R	4R	4L	6
Pre- Surgery Pinch	0	3	2	3	2	2
Post-Surgery, NP turned OFF	0	4	-	3	2	2
Post-Surgery, NP turned ON	5	6	-	6	6	6

The ability to perform activities of daily living has been assessed in each subject in unilateral activities. Every subject has demonstrated improvement in at least four activities, with one subject demonstrating improvement in 9/9 activities tested, as shown in Table 2. Improvement in these activities generally indicates that the subject can complete the task more independently with the neuroprosthesis than they can when the neuroprosthesis is turned off, although improvements in the quality of performance, ease of performance and time to complete the task are also possible. All six arms in the four subjects showed improved function in three tasks: eating with a fork, drinking from a glass and writing with a pen. These tasks have been shown to be some of the most common tasks for which subjects use their neuroprosthesis to accomplish in the home environment [7].

Table 2. Activities of Daily Living Performance Changes

("●" = Improved; "-" = Not Improved)

	Participant						
Activity	1	2L	2R	4R	4L	6	Number Improved/ Number Tested
Eating with a Fork	●	●	●	●	●	●	6/6
Drinking from a Glass	●	●	●	●	●	●	6/6
Writing	●	●	●	●	●	●	6/6
Using a Phone	-	●	-	●	-	-	2/6
Brushing Teeth	●	●			-	●	3/4
Using a Computer CD					-	-	0/2
Eating Finger Foods	●						1/1
Applying Lip Gloss		●					1/1
Applying Chapstick		●	●				2/2
Brushing Hair		●	●				2/2
Wiping Nose		●	●				2/2
Drinking from a Mug				●	●	●	3/3
Eating with a Spoon						●	1/1
Drinking from a Wineglass						●	1/1
Shaving with Electric Shaver						-	0/1
TOTAL TASKS IMPROVED	**5**	**9**	**6**	**5**	**4**	**7**	

IV. DISCUSSION

The results of this study show that a myoelectrically-controlled implantable neuroprosthesis provides significantly increased pinch force and grasp function for each subject. All subjects demonstrated increased independence and improved function in activities of daily living. We believe that these results indicate that implanted myoelectric control is a desirable option for neuroprostheses.

The IST-12 system provides some significant improvements over the first generation Freehand system [5,13]. The implanted myoelectric control provides subjects with multiple control options and eliminates the need to wear a joystick on the shoulder. The latter feature simplifies the donning of the device and may lead to higher usage rates long-term. The IST-12 system also provides stimulation to twelve different muscles, compared to eight for the Freehand system. For the subjects studied, these additional electrodes provided improved hand function through activation of the finger intrinsic muscles and wrist flexors and extensors. Control of elbow extension and shoulder position could also be provided. These additional motor functions allow subjects to attempt a broader range of functional tasks.

The use of myoelectric control in neuroprostheses allows considerable flexibility in the control algorithms that can be utilized. In this series of subjects, performance could be improved by customizing the control scheme for each subject. The ability of subjects to generate control signals varied, due in large part to the different pair of muscles used for each subject and probably due in part to differences in the innervation status of each muscle and differences in coordination. A principal consideration regarding the command control scheme was to make maximal use of voluntarily functioning muscles. Whenever possible, muscles that are synergists to the function to be provided serve as the control muscle in order to make the control scheme easier to learn. Specifically, in the case of C6 level

SCI, the wrist extensors, which are under voluntary control, are direct agonists to grasp closing. Therefore, by using the MES from the wrist extensor to proportionally control grasp closing, a very natural augmentation of the tenodesis function can be achieved. We have previously demonstrated that proportional MES control of grasp provides improved function over other forms of control [14]. All control signals are derived from ipsilateral muscles, thus enabling bilateral function to be provided in the future by implementing the system in the contralateral limb.

REFERENCES

[1] World Health Organization. International Classification of Functioning, Disability and Health (ICF). Geneva, Switzerland 2002.

[2] Wuolle, K.S.; Van Doren, C.L.; Thrope, G.B.; Keith, M.W.; Peckham, P.H.: Development of a Quantitative Hand Grasp and Release Test for Patients with Tetraplegia Using a Hand Neuroprosthesis. J. Hand Surg., 19A, pp. 209-218, 1994.

[3] Mulcahey MJ, Smith BT, Betz RR. Psychometric rigor of the grasp and release test for measuring functional limitation of persons with tetraplegia: a preliminary analysis. J Spinal Cord Med. 27, pp. 41–46, 2004.

[4] Stroh KC, Van Doren CL. An ADL test to assess hand function with tetraplegic patients. J Hand Ther. 7(1), pp. 47–48, 1994

[5] Kilgore, K.L., Peckham P.H., Keith M.W., Thrope G.B., Wuolle K.S., Bryden A.M., Hart R.L, An Implanted Upper Extremity Neuroprosthesis: A Five Patient Follow-up", J. Bone Joint Surg., 79A, pp. 533-541, 1997.

[6] Davis SE, Mulcahey MJ, Betz RR, Smith BT, Weiss AA: Outcomes of upper-extremity tendon transfers and functional electrical stimulation in an adolescent with C-5 tetraplegia, Am J Occup Ther, 51(4), pp. 307-312, 1997.

[7] Wuolle, K.S., Van Doren, C.L., Bryden, A.M., Peckham, P.H., Keith, M.W., Kilgore, K.L.. Patient Satisfaction and Usage of a Hand Neuroprosthesis, Archives of PM&R., 80, pp. 206-213, 1998.

[8] Wood-Dauphinee SL, Williams JI. "Assessment of global function: The Reintegration to Normal Living Index," Arch Phys Med Rehab 69, pp. 583-90, 1988.

[9] Wood-Dauphinee SL, Williams JI. "Reintegration to normal living as a proxy to quality of life," J Chron Dis 40, pp. 491-9, 1987.

[10] Piazza D, Holcombe J, Foote A, Penelope P, Love S, Daffin P. "Hope, social support and self-esteem of patients with spinal cord injuries," J Neurosci Nursing 23, pp. 224-30, 1991.

[11] Veit, C.T. & Ware, Jnr, J.E. (1983). The structure of psychological distress and well-being in general populations. Journal of Consulting and Clinical Psychology, 51, pp. 730-742, 1983.

[12] Demers L, Wessels R, Weiss-Lambrou R, Ska B, De Witte LP. Key dimensions of client satisfaction with assistive technology: a cross-validation of a Canadian measure in The Netherlands. J Rehabil Med. Jul;33(4), pp. 187-91, 2001.

[13] Peckham PH, Keith MW, Kilgore KL, Grill JH, Wuolle KS, Thrope GB, Gorman P, Hobby J, Mulcahey MJ, Carroll S, Hentz V, Wiegner A., Efficacy of an Implanted Neuroprosthesis for Restoring Hand Grasp in Tetraplegia: A Multicenter Study, Arch. Physical Medicine and Rehabilitation, 82, pp. 1380-8, 2001.

[14] Hart, R.L., Kilgore, K.L., Peckham, P.H.. A Comparison between Control Methods for Implanted FES Hand Grasp Systems. IEEE Trans. Rehab. Eng. 6(2), pp. 1-11, 1998.