

An Implanted Upper Extremity Neuroprosthesis Utilizing Myoelectric Control

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Abstract

Neuroprostheses use electrical stimulation of paralyzed muscles to produce controlled limb movement. A first generation implanted neuroprosthesis for upper extremity function underwent a successful multi-center clinical trial and received FDA approval in 1997. We have now developed a family of second generation implanted neuroprosthetic systems. These systems provide control of grasp-release, forearm pronation, and elbow extension for individuals with cervical level spinal cord injury. The key feature of the advanced system is the capability to transmit data out of the body, allowing the use of implanted control sensors, 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 two C5/C6 spinal cord injured individuals, with plans for implementation in additional subjects in the future. The results from these two subjects demonstrate that myoelectric signals can be recorded from voluntary muscles in the presence of electrical stimulation of nearby muscles. Myoelectric signals can be used for both discrete and proportional control signals. The results to date are promising, and both subjects have demonstrated improved function using the implanted neuroprosthesis.

1 Introduction

Implanted neuroprostheses have been utilized for the restoration of hand function for mid-cervical level spinal cord injury (SCI). A first generation implanted neuroprosthesis was

developed in our laboratories, was successfully transferred to industry, and has been implemented successfully in over 200 patients worldwide [1-9]. The first generation neuroprosthesis has been demonstrated to provide improved pinch force, grasp and release ability and increased independence [6].

A second generation technology has been developed and clinical studies initiated to evaluate the function of an advanced neuroprosthesis for upper extremity control that extends the capabilities provided by the first generation system [10]. The functional specifications for the second generation neuroprosthesis were developed based on interviews with neuroprosthesis users and clinicians, and from our own clinical and technical experience. The key desired features included: elimination of external components wherever possible; provision of new functions such as elbow extension; enhancement of existing functions (especially finger extension); and improvement in the control method so that it was more natural. The technical requirements necessary to achieve the desired functional goals were: 1) an increased number of stimulus channels to allow stimulation of the finger intrinsic muscles, triceps and/or forearm pronator, 2) an implanted control source, 3) bi-directional transcutaneous communication, allowing sensor data to be transmitted outside of the body, and 4) reduction of all external cabling. Thus, our objectives were to:

- 1) Restore hand opening and grasp with a sufficient number of grasp configurations for users to manipulate and hold common objects encountered in their environment;
- 2) Expand effective arm movement over the workspace contained within the movement of the arm, and allow objects

to be fully oriented within this workspace;

- 3) Provide ease of control which is “natural” and integrated within the user’s movement strategies. The control should be ipsilateral to the arm receiving motor function, to allow possible enhancement using bilateral implementation;
- 4) Implement the above in a way that is biologically safe, easy for the user to operate, easy to don and to doff, cosmetically acceptable, transportable, reliable, and clinically effective. The implementation must be modular to allow individual elements to be replaced in the event of failure and to be upgraded in the event that future enhancements are developed. It should be deployable in the clinical environment by clinicians.

2 Methods

The second generation neuroprosthesis system provides control of grasp, forearm pronation and elbow extension for individuals who are paralyzed with cervical level spinal cord injury. A key feature of this system, shown in Figure 1, is the implantation of both the control and the stimulation source, thus freeing the user of most of the external technology, and adding function while making the system easier to use and more reliable. The implanted stimulator-telemeter (IST-12) consists of twelve stimulation channels and two channels of myoelectric signal (MES) recording acquisition. A single radio-frequency (RF) inductive link powers the system and transmits control commands and receives telemetered data.

The myoelectric signal is rectified, filtered and integrated within the IST-12 device. The value of the integrated signal is sampled at the end of the integrating window and the data can be transmitted to the external controller. Back telemetry is achieved using load-shift keying with circuit configuration modulation. The IST-12 has four programmable amplifier gains, from 200 to 4000, which can be controlled on a sample by sample basis.

An important aspect of the myoelectric recording circuit design is the ability to record MES in the presence of the large stimulus artifacts produced by twelve stimulating electrodes. Several measures were taken to minimize the influence of the stimulation

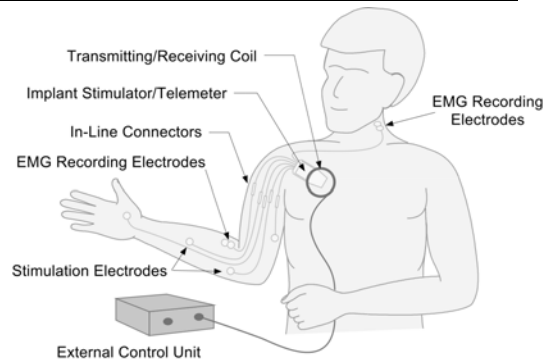


Figure 1: Drawing of the second generation neuroprosthetic system. The internal components include the implant stimulator/telemeter (IST-12), twelve stimulating electrodes and two recording electrodes. The external components include the external control unit and the transmit/receive coil. This system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

artifact on the recorded MES and to guarantee an artifact-free MES measurement time window. First, all stimulus pulses are grouped together at the beginning of each stimulus period so that their artifact is not spread throughout the stimulation sequence. Second, during the MES integration window, the stimulating electrode recharge current path is disconnected. Third, the MES integrator is enabled only during the MES window. Fourth, outside the MES window, the variable gain is set to the minimum value. Fifth, during stimulation, the front-end multiplexer entirely disconnects the MES processor from the MES electrodes. In-vivo studies in animals demonstrated the ability of this processing to eliminate stimulus artifact even when the recording electrodes are within a few centimeters of the stimulating electrode.

Two types of stimulating electrodes are used with the IST-12 neuroprosthesis. Epimysial electrodes consist of a platinum-iridium disk mounted in a silicone backing reinforced with Dacron. Epimysial electrodes are sewn onto the epimysium of the target muscle. The intramuscular electrode has a stainless steel stimulating area wound around the distal end of the lead. A prolene-barb on the tip of the electrode serves to anchor the electrode in the muscle. These electrodes are inserted into the muscle belly with an insertion tool. MES recording electrodes are bipolar epimysial electrodes surgically implanted on the fascia of the target muscle. They are made of two 4mm diameter Pt10Ir discs mounted on a medical

grade Dacron reinforced silicone backing. The discs are positioned 10mm apart.

3 Results

To date, two human subjects have been implanted with the IST-12 neuroprosthesis for hand-arm control.

Subject #1: This subject was implanted with the IST-12 in the right arm, which has grade 4 voluntary biceps function and grade 2 brachioradialis function. The left arm has C4 motor function voluntarily. Stimulating electrodes were placed on the muscles of the hand and forearm to provide grasp function, and on the pectoralis major and suprascapular nerve to provide shoulder function. MES recording electrodes were placed on the trapezius and brachioradialis. The subject is able to use the trapezius MES to control grasp opening and closing. The subject is able to use the neuroprosthesis for eating, a task for which he was completely dependent before surgery. Functional evaluations with this subject are ongoing.

Subject #2: Subject #2 has C6 motor function bilaterally. The IST-12 was implanted in the left arm as the first stage of a bilateral implementation. Stimulating electrodes were placed on the muscles of the forearm and hand for grasp, and on the triceps for reach. MES recording electrodes were placed on the extensor carpi radialis longus (ECRL - grade 4 strength voluntarily) and the platysma. The MES signal is used to proportionally control grasp opening and closing. The subject can use the neuroprosthesis for a variety of tasks, including eating, drinking, writing and embroidery. The subject is now using the neuroprosthesis at home.

4 Discussion and Conclusions

The use of myoelectric control in neuroprostheses allows considerable flexibility in the control algorithms that can be utilized. We have demonstrated that it is possible to record usable myoelectric signals from implanted recording electrodes even during stimulation of multiple muscles. We have successfully used myoelectric signals for both proportional and discrete control. The elimination of the need for an externally mounted control source is extremely desirable and makes system use much simpler. We are now proceeding toward the implementation of additional subjects with the IST-12 system for grasping and reaching.

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