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An Implanted Neuroprosthesis for Restoring Arm and Hand Function in People with High Level Tetraplegia

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Abstract

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Objective—To develop and apply an implanted neuroprosthesis to restore arm and hand function to individuals with high level tetraplegia

Design—Case study.

Setting—Clinical research laboratory.

Participants—Two individuals with spinal cord injuries at or above the C4 motor level.

Interventions—The individuals were each implanted with two stimulators (24 stimulation channels and 4 myoelectric recording channels total). Stimulating electrodes were placed in the shoulder and arm, including the first chronic application of spiral nerve cuff electrodes to activate a human limb. Myoelectric recording electrodes were placed in the head and neck areas.

Main Outcome Measures—The successful installation and operation of the neuroprosthesis, along with the electrode performance, range of motion, grasp strength, joint moments, and performance in activities of daily living.

Results—The neuroprosthesis system was successfully implanted in both individuals. Spiral nerve cuff electrodes were placed around upper extremity nerves and activated the intended muscles. In both individuals, the neuroprosthesis has functioned properly for at least 2.5 years post-implant. Hand, wrist, forearm, elbow and shoulder movements were achieved. A mobile arm support was needed to support the mass of the arm during functional activities. One individual was able to perform several activities of daily living with some limitations due to spasticity. The second individual was able to partially complete two activities of daily living.

Conclusions—Functional electrical stimulation is a feasible intervention for restoring arm and hand functions to individuals with high tetraplegia. Forces and movements were generated at the hand, wrist, elbow and shoulder that allowed the performance of activities of daily living, with some limitations requiring the use of a mobile arm support to assist the stimulated shoulder forces.

Keywords

Electrical stimulation; Tetraplegia; Implanted electrodes; Activities of daily living; Range of motion

Individuals with high cervical (C1-C4) spinal cord injury (SCI), a condition referred to as high tetraplegia, have extensive paralysis below the neck. Typically individuals with complete SCI at these levels are left with volitional control of the head, neck, and in some cases shoulder shrug with limited or no movement below. Individuals with high tetraplegia may be dependent on others for all aspects of care including activities of daily living (ADLs) and mobility. Unfortunately traditional rehabilitation programs result in minimal functional improvement¹. Our research group has been working for several years towards the deployment of an implantable neuroprosthesis for individuals with high cervical spinal cord injury^{2,3}. This report describes the system development surgical installation and functional outcomes in two individuals with high tetraplegia.

Neuroprostheses are systems that apply controlled electrical stimulation to paralyzed nerves and muscles to restore function. These systems can be used to restore different functions to

individuals with a variety of different neurological disorders, although many applications to date have been for individuals with spinal cord injuries⁴⁻⁹.

The application of functional electrical stimulation (FES) of paralyzed upper extremity muscles to restore lost shoulder and elbow function in high cervical SCI has been limited to research applications. Handa^{10,11} employed an FES system in an individual with C4 tetraplegia to restore movements by percutaneous stimulation, using stimulation patterns based on electromyographic (EMG) activity in able-bodied individuals. Pre-programmed sequences for different upper extremity activities were elicited by respiratory function (puff and sip). A mobile arm support was identified as the most important factor in successfully utilizing their FES system for functional tasks. Nathan¹² used voice controlled stimulation of surface electrodes in an elastic sleeve on the extremity, along with splinting and a sling. Betz^{13,14} depicted a system using percutaneous electrodes in the arm to provide function for an individual with motor complete C4 spinal cord injury. Control of arm movements was accomplished using voluntary action of the trapezius and levator scapulae of the contralateral shoulder. The workspace was limited to one location on a tray, so the objects had to be placed into the grasp of the recipient. No surface or percutaneous FES systems are currently available for functional use by people with high tetraplegia.

These studies have shown that it is feasible to use FES to restore meaningful function to individuals with high cervical SCI, and have taken initial steps toward the coordination of muscles and the development of user interfaces. However, surface and percutaneous FES interfaces are not optimal for a permanent neuroprosthesis because of electrode placement accuracy, durability of external connections, selectivity (surface electrodes often activate multiple muscles or have difficulty activating deeper muscles), and the hassles of donning and doffing. There have been significant advances in implanted FES technology, in user interfacing, and in the engineering and surgical techniques used to develop and deploy implanted neuroprostheses. The objective of this paper is to describe a systems integration effort over the past 10 years to systematically specify, develop, deploy, and evaluate an implanted neuroprosthesis for individuals with high tetraplegia. Specific innovations of this system include: the use of 24 channels of implanted stimulation to control hand, wrist, forearm, elbow, and shoulder movements and shoulder stability; the use of implanted EMG electrodes as a command interface for a high tetraplegia neuroprosthesis; and the first chronic application of spiral nerve cuff electrodes to control a human limb.

Methods

System design and implantation

Musculoskeletal Modeling—Musculoskeletal modeling is the mathematical description of the mechanical properties of a limb. Simulations performed with a musculoskeletal model are particularly useful for neuroprosthesis development because they allow many different muscle sets and control strategies to be examined *before* a neuroprosthesis is implemented. We have developed a sophisticated musculoskeletal model of the shoulder and arm^{15,16} and used simulations with this model¹⁷ to determine the optimal set of shoulder and elbow muscles required to perform a set of tasks important for providing some independence to individuals with high tetraplegia. These tasks included tabletop to mouth motions needed for

eating and grooming, and reaching in the coronal and scapular planes from the laptop to shoulder level¹⁷.

The simulations indicated that the muscles required to perform the selected set of functional movements included the triceps, biceps, deltoid, serratus anterior, infraspinatus, supraspinatus, latissimus dorsi, pectoralis major, pronator quadratus, and supinator. The simulations also indicated that the long head of the triceps should NOT be activated; that the biceps and brachialis should be independently activated; that the deltoid and teres minor (which share the axillary nerve) should be independently activated; that only the lower part of the serratus anterior should be activated; and that the infraspinatus and supraspinatus could be activated together without functional loss. Information obtained from simulations was combined with surgical considerations to determine the final muscle set and the location of nerve cuff electrodes on several peripheral nerves in the procedures described here.

Implantable Stimulation Components—This project used a 12-channel implantable stimulator-telemeter (IST-12)^{18,19} to apply the stimulation and to record EMG signals for a user interface. The IST-12 (Figure 1A) has a circuit hermetically sealed in a titanium capsule, a coil for power/communication, and leads for 12 stimulating electrodes and two bipolar EMG channels. The circuitry within the IST-12 provided an inductive link for receiving power and stimulation commands from the external control unit (ECU) and for transmitting EMG samples out to the ECU. EMG signals were filtered, amplified, rectified and integrated before the data was telemetered externally. The IST-12 delivers constant current, charge-balanced, biphasic pulses of varying amplitude (0 to 20 mA) and duration (0 to 255 μ sec), and can deliver the 12-16 Hz stimulation rate typical for FES upper extremity systems¹⁸.

Intramuscular electrodes (Figure 1B)^{20,21} were used in a number of muscles of the arm and hand (Table 1). These electrodes have demonstrated excellent durability in clinical applications (98.7% survival probability)²². In addition, spiral nerve cuff electrodes^{23,24} (Figure 1B) were used to activate several proximal arm nerves (Table 1). These spiral nerve cuff electrodes wrap around a nerve, and therefore can activate broad muscles or multiple synergistic muscles innervated by that nerve without spillover to other muscles²⁵. Nerve cuff electrodes are particularly appropriate for the proximal joints of the upper extremity because most of the nerves serve a single muscle or just a few synergistic muscles and are readily accessible in the region of the brachial plexus. Many of these proximal muscles have highly branched intramuscular innervation patterns that are not well suited for muscle-based electrodes. Many shoulder muscles also wrap along bony surfaces, making activation via the supplying peripheral nerve advantageous. Several of the nerve cuff electrodes included several contacts that could be independently activated, providing the possibility for selectively activating different muscles innervated by different fascicles within a single peripheral nerve trunk^{25,26}.

Two types of implanted EMG electrodes were used (Figure 1C). Epimysial EMG electrodes were used primarily for flat, superficial muscles (e.g., platysma), while intramuscular EMG electrodes²⁷ were typically used for larger, deeper muscles (e.g., trapezius).

The stimulation channels needed for proximal control and for hand and wrist function were provided through the use of two IST-12 devices, bringing the total capability to 24 stimulation channels and four EMG recording channels.

Command Sources—EMG signals were selected as the primary command source because recording electrodes could be readily implanted and because EMG signals have been used successfully as a command source in other neuroprosthetic systems¹⁸. The number of voluntary functions that can be used to command arm and hand function is limited in people with high tetraplegia. All of the available voluntary functions are located in the region of the neck and head and do not normally participate in arm control. Candidate muscles for good EMG signals in this population were limited to the platysma in the neck (used for grimacing), the trapezius, and the auricularis (used for ear wiggling). Surface EMG measurements were used to evaluate a subject's ability to independently control EMG signals from each of these sites. User interfaces such as three dimensional head orientation, neck muscle EMG signals, and facial EMG signals were also evaluated²⁸.

Candidate Selection—Approval to perform this study was obtained from our local institutional review board (IRB) and from the National Institute of Health Human Subjects Committee. An investigational device exemption for the implanted neuroprosthesis was also received from the FDA. Informed consent was obtained for each research participant.

Candidates for this study were individuals with spinal cord injuries of the first to fourth cervical vertebrae (C1-C4) resulting in complete motor paralysis in at least one upper extremity. Inclusion criteria included electrically excitable muscles, minimal upper extremity contractures, and general medically stability with good overall health. The candidate needed to be at least 18 years of age and six months post-injury.

Two high tetraplegia candidates were selected, but each had a different implementation pathway. The first subject participated in a percutaneous phase in which the nerve cuff electrodes were evaluated. The second subject received the neuroprosthesis 2½ years after the first subject. Since the nerve cuff electrodes had been used successfully in studies by that point^{25,26,29}, the percutaneous phase was eliminated and a reduced set of evaluations were done.

The first subject was a 48-year-old female who sustained a hemisection of the spinal cord at the C1-C2 level as a result of a gunshot wound, and was 11 years post-injury. Her right upper extremity was totally paralyzed, while her left upper extremity had diminished, but functional use (she was able to move her arm through a limited range of motion, and the high flexor tone in her hand allowed her to hold objects placed in her hand, including her wheelchair joystick control). Due to the high level of her injury, there was little to no denervation of the relevant upper extremity muscles, so that all the muscles of interest were able to be electrically activated.

The second subject was a 27-year old male with C3-level complete tetraplegia as a result of a motor vehicle accident, and was 13 months post-injury. All of the hand and arm muscles in

this subject were excitable with surface stimulation, with the exception of the left and right deltoid and supinator muscles.

Nerve cuff electrode testing

Recruitment and Selectivity—Spiral nerve cuff electrodes had not previously been implanted for chronic upper extremity applications, so these electrodes were studied extensively^{25,26}. An initial percutaneous phase in the first subject allowed us to determine which cuff contacts to connect to the implanted stimulator in subsequent surgeries.

Recruitment curves were used to characterize the relationship between stimulation level and muscle output²⁵. Surface and percutaneous EMG recordings were used to evaluate recruitment and selectivity of four of the six nerve cuff electrodes. Twitch recruitment curves were generated using monopolar stimulation. The thoracodorsal and long thoracic electrodes were not tested due to experiment time limitations.

Joint Moments—Tetanic stimulation (12.5 Hz) was used to measure isometric joint moments produced by stimulation through each contact on each nerve cuff electrode during each of the three sessions of the percutaneous phase and two sessions during the implanted stimulator phase for subject 1. The percutaneous phase was eliminated for subject 2, so these measurements were not done for this subject. Shoulder moments were measured while stimulating the axillary and suprascapular nerves and elbow moments were measured while stimulating the musculocutaneous and radial nerves. All tetanic trials were performed with a pulse amplitude of 0.8 mA. Four to five different pulse width values were chosen from the EMG recruitment curve to represent the full range of recruitment. Five repetitions were measured at each set of stimulation parameters and were presented in a random order with a rest period of at least 30 seconds between trials. A paired t-test was used to compare the output of different contacts on the same nerve cuff.

To measure shoulder moments, the subject was placed in a setup consisting of a six degree of freedom force and moment transducer^a attached to the endpoint of the humerus using a cast that fixed the elbow at 90°³⁰. A different setup was used to measure elbow moments, using a transducer consisting of a dual parallelogram linkage that was placed across the elbow³¹.

Functional pattern development

The functional activity of eating with a fork was selected as a task that incorporated a large set of the stimulated muscles. The functional stimulation patterns were initially divided into 'reaching' patterns and 'grasping' patterns. The initial functional 'reaching' pattern was computed using simulations with a sophisticated musculoskeletal model^{15,17}, which were then fine-tuned to accommodate the subject's detailed characteristics and/or to overcome positioning errors. A sample pattern is shown in Figure 2. The grasp patterns were developed from templates of the typical upper extremity neuroprosthesis systems³²,

^aSuppliers
JR3, Inc., 22 Harter Ave, Woodland CA 95776

including both ‘lateral’ and ‘palmar’ grasp patterns (Supplemental online content Figures S1 and S2).

Grasp strength

Grasp and pinch force was measured using a modified pinch meter^b with added metal bars to extend and enlarge the grasping surfaces of the meter³³.

Stimulated range of motion

The movements of the wrist, forearm, elbow, and shoulder were quantified by measuring the range of motion using standard techniques³⁴. A hand-held goniometer was used to measure the difference in joint angles during a rest position and the position obtained during maximal stimulation.

Mobile arm support

Neither of the subjects was able to support the weight of his or her arm with stimulation of their shoulder muscles alone. The ability of the first subject to abduct and externally rotate her shoulder was limited by spasticity and/or passive tightness in her shoulder. Since standard treatments did not sufficiently alleviate this issue, we have opted to use a mobile arm support to place her arm in a more functional position for the evaluations of control methods and stimulation patterns (Figure 3). The second subject had partial denervation of the deltoid, so a mobile arm support was necessary to help support the weight of the arm during functional tasks (Figure 3). Several different mobile arm supports^c were evaluated. Both of the mobile arm supports selected were passive devices that use rubber bands across a four-bar linkage to produce elevation force^{35,36}.

EMG control strategies

The EMG signals could be used either as proportional control signals (variable levels between a minimum and a maximum) or as state commands (on/off). The amplitude difference between the left and right platysma EMG signal was selected for the proportional control signal used to control the command axis for the stimulation patterns shown in Figure 2 (reach) & Supplemental online content Figures S1 and S2 (grasp). The other two EMG signals (trapezius and/or auricularis) were more suitable for state commands, and were used to select which motion (i.e., pronation/supination, wrist extension/flexion, shoulder elevation/depression, or shoulder abduction/adduction) was to be controlled at a given time. Two control strategies were investigated. One was serial control, in which the proportional command was used to control each joint sequentially (from proximal to distal). The other control strategy was proportional control over a stimulation pattern that had a ‘reach out’ phase (which included elbow extension, wrist extension, forearm pronation, and finger extension), followed by an ‘acquire’ phase (for finger and thumb flexion and extension), followed by a ‘bring to face’ phase (which included elbow flexion, wrist flexion, forearm supination, and finger flexion).

^bB & L Engineering, 1901 Carnegie Ave., Suite Q, Santa Ana, CA 92705

^cJAECO Orthopaedics, 214 Drexel, Hot Springs, AR 71901

Functional training

Several ADLs were selected by the subject and the research team for further evaluation. These activities included eating (with a fork and with ‘finger food’), hand shaking, nose scratching, nose wiping with a tissue, face washing, and teeth brushing. The ADL task was broken down into phases³⁷, and the subject was trained to perform each phase. This often involved modifying the stimulation parameters or the control parameters to identify the optimal combination for a particular task, and identifying the type of assistance required by the subject to complete the task phase. This assistance could range from physical support to complete independence³⁷. Task evaluation was done after the subject was trained on all the phases of the task.

Results

Surgery description

The first subject received her neuroprosthesis system in a set of three surgeries. The first surgery involved implanting four nerve cuff electrodes with the leads connected to percutaneous (i.e., through the skin) wires for external stimulation (Figures 4A and 4B). These nerves were:

- Radial nerve – four contacts on the cuff to potentially allow selective control of elbow, wrist, and finger extension.
- Musculocutaneous nerve – four contacts on the cuff to potentially allow selective control of elbow flexion and forearm supination (biceps, brachialis).
- Axillary nerve – single contact nerve stimulation for arm elevation (deltoid).
- Suprascapular nerve – single contact nerve stimulation for stabilizing the glenohumeral joint and control of humeral external rotation (supraspinatus, infraspinatus).

The nerve cuff electrodes were characterized for 16 weeks²⁵, after which the second surgery occurred.

In the second surgery, an IST-12 was placed in the subject’s abdomen, with 12 electrode leads going to electrodes that activated shoulder and upper arm muscles (see Table 1), and two EMG recording electrodes placed on voluntarily-controlled muscles to use as command signals. The percutaneous wires were disconnected from the nerve cuff electrodes. Since there were more cuff contacts than available stimulator channels, the contacts that provided the best muscle activation and selectivity were connected to the stimulator. This included two musculocutaneous nerve cuff contacts and three radial nerve cuff contacts. The axillary and suprascapular nerve cuff electrodes were also connected to the stimulator as single channels. Two additional nerve cuff electrodes were implanted in this surgery for single contact nerve stimulation. One was placed on the long thoracic nerve to activate the serratus anterior muscle and provide scapular abduction. The other nerve cuff electrode was placed on the thoracodorsal nerve to activate the latissimus dorsi muscle and provide arm adduction. Three intramuscular electrodes were also placed - one each in the rhomboids (for scapular adduction), and in the upper and lower pectoralis (for shoulder horizontal

adduction). Bipolar epimysial EMG electrodes were placed on the right platysma and the right auricularis.

In the third surgery, an IST-12 was placed in the subject's chest, along with 12 intramuscular electrodes placed in muscles of the hand and forearm and two bipolar epimysial EMG electrodes placed in the left platysma and left trapezius to provide additional command signals. The stimulation electrode locations were those that are typically used to produce hand grasps¹⁹. These include finger extensors and flexors; thumb extensor, flexor, and abductor; wrist flexor; and forearm supinator and pronator (Figure 4C; Table 1). Figure 4C is separated into two separate drawings for clarity in the supplemental online content (Figures S3 and S4).

The second subject received his neuroprosthesis in two surgeries. In the first surgery, an IST-12 was implanted in his abdomen along with six nerve cuff electrodes (radial, musculocutaneous, suprascapular, axillary, long thoracic, and thoracodorsal nerves). The radial nerve and musculocutaneous nerve cuff electrodes were multiple contact electrodes with individual leads for each contact. In order to optimize the 12 available channels on the IST-12, the lead for each contact was stimulated after the nerve cuff had been placed and the incision closed. The most functionally useful contacts were connected to the stimulator, while the others were capped. Previous work with nerve cuff electrodes indicated that their functional output at the time of surgery would be a good indicator of their functional output after the subject had recovered from surgery²⁵. In addition, two intramuscular stimulation electrodes (pectoralis), and two bipolar EMG recording electrodes (epimysial for the platysma & intramuscular for the trapezius) were implanted. It was observed in this surgery that the anterior portion of the subject's deltoid muscle was denervated.

In the second surgery, an IST-12 was implanted in the chest, along with 12 intramuscular stimulating electrodes and two bipolar EMG recording electrodes. The stimulating electrodes included eight for hand grasp, two for wrist extension/flexion, one for forearm pronation, and one for biceps (to complement the function of the musculocutaneous nerve cuff). The EMG recording electrodes were placed on the contralateral platysma (epimysial) and trapezius (intramuscular), so that the four EMG electrodes could be used as two pairs for control purposes (Table 1).

Post-surgical management

After each of the surgeries in which electrodes were placed in the proximal arm and shoulder, the arm was placed in a protective sling. After the surgeries in which electrodes were placed in the forearm and hand, the arm was placed in a bi-valve cast for 3 weeks. After the cast was removed, the electrodes were activated to identify their thresholds and maximum stimulation parameters. Initial exercise patterns were programmed into a portable ECU that the subject could take home and use to perform daily exercise routines to strengthen the muscles. The ECU also had a biofeedback light emitting diode (LED) display that allowed the subject to practice controlling the EMG signals.

Electrode performance

All twelve nerve cuff electrodes have continued to function properly for 7.5 years post-implant in the first subject and over 2.5 years post-implant in the second subject. The intramuscular electrodes also continue to function properly, consistent with other upper extremity applications²².

As has been reported previously, selectivity was seen on the multicontact cuffs (radial and musculocutaneous nerves) on the first subject²⁵. Not as much selectivity was seen with the second subject. All of the radial nerve cuff electrode contacts recruited the triceps first, with two of the electrodes also recruiting wrist extensors secondarily. Both of the musculocutaneous nerve cuff electrode contacts recruited the brachialis before the biceps.

Proximal joint moments

The shoulder abduction moments evoked by suprascapular and axillary nerve stimulation showed an initial increase (probably due to exercise) then showed a large increase on the last measurement date (Figure 5a). It is possible that the subject's spasticity had an effect on her recorded moments. These values were not significantly different from the model-predicted moments that were required to produce 45° abduction at the shoulder^{15,30}

Stimulation of the musculocutaneous nerve activated the biceps and brachialis, producing elbow flexion (Figure 5b). The moment evoked by stimulation through contacts 1 and 3 at the first and last sessions were not significantly different ($p > 0.7$, paired t-test). Contacts 2 and 4 were examined during the percutaneous phase only and were not connected to the implanted stimulator.

Radial nerve stimulation activated two muscles at the elbow: the triceps (causing extension) and the brachioradialis (causing flexion) (Figure 5c). Contact 1 evoked elbow extension throughout the study. Contacts 3 and 4 evoked elbow flexion throughout the study. Stimulation on contact 1 produced an increasing elbow extension over time and stimulation on contact 3 produced an increasing elbow flexion. Contact 4 was examined during the percutaneous phase only and was not connected to the implanted stimulator.

The elbow flexion and extension moments were sufficient for moving the arm to perform activities of daily living (see Table 2).

Grasp strength

Stimulated lateral pinch strength ranged from 11.6 – 25.5 N in the two subjects, which fits within the range seen in our other upper extremity neuroprosthesis studies^{4,33,38}.

Stimulated range of motion

The stimulated range of motion for the wrist, forearm, elbow, and shoulder of both subjects are shown in Table 3, along with normal ranges³⁴. Motions that were not tested are listed as 'NT'. Subject 2 wore a wrist splint, so no wrist movements were measured. Shoulder extension movements were limited by the wheelchair. External rotation was not activated in either of the subjects, and stimulated internal rotation could not be isolated in subject 1.

Functional activities

In both subjects, stimulation was successfully able to extend and flex the arm, open and close the hand, extend and flex the wrist, elevate and depress the shoulder, and abduct and adduct the shoulder (Figure 3). The first subject was also able to pronate and supinate the forearm, while the second subject could only pronate the forearm due to denervation of the supinator muscle. In this subject, supination was achieved by using gravity or by biceps activation for arm flexion.

Several ADL tasks were completed with the first subject. Six of the seven tasks selected by the subject involved bringing her hand to her face. The majority of the training time was spent on the ‘feeding with a fork’ task, since this task contained all of the phases used in all seven tasks, such as:

- Reaching out to an object placed in front of the subject
- Orienting the hand to acquire an object
- Acquiring the object
- Bringing the object near the face
- Orienting the hand or making fine movements near the face to accomplish the task
- Reaching back out to the starting location
- Releasing the object

A summary of the ADL tasks are shown in Table 2. The control strategy that worked the best was a hybrid of the two control strategies tested. The ‘reach out’ and ‘bring to face’ stimulation patterns would get the subject near the goal position. They then could switch to a fine control mode where they could add small movements to get closer to the goal position. For example, they could increase their forearm pronation or wrist extension if needed.

Training has been partially completed for two ADL tasks with the second subject; feeding with a fork, and moving chess pieces. Progress with this subject has been slower than the first subject due to medical and personal issues that limited his ability to visit the research lab. Training in ADL activities continues for both subjects, as alternate mobile arm supports and control strategies are evaluated.

Discussion

A 24-channel implantable neuroprosthesis system (two 12-channel stimulators), with four EMG recording channels, was successfully implanted in two individuals with high tetraplegia. Nerve cuff electrodes were used for the first time in the upper extremity, and they have continued to function properly for 7.5 years (subject 1) and over 2.5 years (subject 2), at the time of writing. Although an additional surgery was required for the first subject to allow us to evaluate the performance of the nerve cuff electrodes, we were able to eliminate that surgery in the second neuroprosthesis recipient. While there were no technical barriers to implanting the 24-channel system in one surgery, there was concern about the length of

the surgery and its effect on the patient, so it was decided that two separate surgeries would reduce the risk to the patient.

The subjects were able to use their implanted EMG electrodes for proportional and state control of joint movements at the hand, wrist, forearm, elbow, and shoulder. The implant recipients were able to accomplish the following movements: hand opening and closing, wrist extension and flexion, forearm pronation and supination, elbow extension and flexion, shoulder extension and flexion, shoulder horizontal abduction and adduction, and shoulder internal rotation.

While the technology functioned as designed, there were limitations in the clinical impact for these two subjects. One individual was able to perform several activities of daily living with some limitations due to spasticity. The second individual was able to partially complete two activities of daily living, but functional training has been limited by unrelated medical and personal issues. Neither subject was able to support the weight of the arm against gravity using only stimulation. While the musculoskeletal model indicated that the weight of the arm would be supported if 50% of the strength of the deltoid muscle was activated, each subject had physiological issues that affected the shoulder. One subject had significant denervation of the deltoid muscle that limited his strength and maximum shoulder abduction. The other subject had elevated tone due to spasticity in the pectoralis, subscapularis, and other muscles which opposed shoulder abduction movements. The ability to support the weight of the arm against gravity using FES will need to be evaluated in future subjects without muscle denervation or spasticity. However, a mobile arm support has been shown to be a useful adjunct to FES in individuals with limited shoulder abduction capability.

In comparison to the earlier surface and percutaneous approaches to a neuroprosthesis for people with high tetraplegia^{10–14}, the implanted neuroprosthesis presented here has several advantages. The nerve cuff electrode technology allowed the activation of many more shoulder muscles than the surface or percutaneous systems, and this activation was selective. The implanted technology has been shown to be durable^{18,22}, and is more easily donned and maintained than either surface or percutaneous systems. Having the control signal (EMG) implanted further reduced the system setup time. These factors, along with the small size of the battery-powered ECU, allowed the subjects to practice using their systems at home. We thus believe that the implanted system will be more effective and more readily accepted clinically than earlier systems.

Study limitations

Generalizability of the results is limited as this study describes a neuroprosthetic system that was implanted in two subjects with high tetraplegia.

Conclusions

A neuroprosthesis was implanted and function was evaluated in two subjects with high tetraplegia. The neuroprosthesis consisted of two implanted stimulators, each with 12 channels of stimulation and 2 EMG recording channels. Nerve cuff electrodes were used

successfully in the proximal muscles of the upper extremity for whole muscle stimulation and for selective activation of different muscles from a single nerve cuff. Appropriate joint movements were generated at each of the desired joints of the upper arm. Issues with excess shoulder adduction muscle tone and deltoid denervation necessitated the use of a mobile arm support. One subject was able to accomplish several activities of daily living, although assistance was often needed in acquiring an object. Training with these subjects continues, as the incorporation of different mobile arm supports, orientation sensors and feedback control may be able to overcome current limitations in function.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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We certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on us or on any organization with which we are associated AND, if applicable, we certify that all financial and material support for this research (eg, NIH or NHS grants) and work are clearly identified in the title page of the manuscript. (Hart, Bryden, Kilgore, Nemunaitis, Hoyer, Keith, Kirsch)

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Abbreviations

SCI	Spinal Cord Injury
C1-C4	Cervical levels 1 to 4
ADL	Activity of Daily Living
FES	Functional Electrical Stimulation
EMG	ElectroMyoGram
IST-12	Implantable Stimulator-Telemeter (12-channel)
IRB	Institutional Review Board
FDA	Food and Drug Administration
ECU	External Control Unit
NT	Not Tested

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Figure 1.

A) The IST-12 implantable stimulator-telemeter, with 12 stimulation channels and 2 EMG recording and telemetry channels. B) Intramuscular (bottom) and nerve cuff (top) stimulating electrodes. C) Epimysial (top) and Intramuscular (bottom) EMG electrodes.

Figure 2.
Stimulation patterns for the six arm muscles used in the reaching portion of the “eating” movement.

Figure 3.

a) Stimulated reaching controlled by neck EMG signals in first subject. b) Stimulated arm flexion and internal rotation controlled by neck EMG signals, allowing the first subject to

place a carrot in her mouth. A mobile arm support was used to overcome shoulder stiffness.
c) and d) Second subject extending and flexing arm while using a mobile arm support.

Figure 4.

A) X-ray showing 3 of the 4 nerve cuff electrodes implanted in the first surgery of the subject 1. B) Nerve cuff electrode placed around the suprascapular nerve. C) Diagram of dual 12-channel stimulator systems in the first subject.

Figure 5.

Arm moments for subject 1. a) Axillary and suprascapular nerve cuff electrodes. b) Four contacts of the musculocutaneous nerve cuff electrode. c) Four contacts of the radial nerve cuff electrode. Contacts that recruited the triceps caused elbow extension moments, while contacts that activated the brachioradialis caused elbow flexion moments. Contact 4 was only tested during the percutaneous phase and was not connected to the implanted stimulator.

Table 1

High Tetraplegia Dual-12-Channel-Stimulator Electrode Placement (IM=intramuscular, EP=epimysial, EMG=electromyographic signal, X=not implanted). Each muscle- based electrode is connected to a separate stimulator channel. There is one nerve cuff electrode for each nerve listed, with 1-4 contacts per electrode, and each contact is connected to a separate stimulator channel.

Upper Stimulator (Hand, Forearm)			Lower Stimulator (Shoulder, Upper Arm)		
Function - Muscle	Electrode Type		Function - Nerve/Muscle	Electrode Type	
	Subject 1	Subject 2		Subject 1	Subject 2
Finger Flexor - <i>Flexor Digitorum Profundus index</i>	IM	IM	Wrist Extensors - <i>Radial Nerve</i>	Cuff	X
Finger Flexor - <i>Flexor Digitorum Sublimis</i>	IM	IM	Elbow, Wrist & Finger Extensors - <i>Radial Nerve</i>	Cuff	Cuff
Finger Extensor - <i>3rd Dorsal Interosseous</i>	IM	X	Elbow, Wrist & Finger Extensors - <i>Radial Nerve</i>	X	Cuff
Finger Extensor - <i>2nd Dorsal Interosseous</i>	IM	IM	Elbow Extensor - <i>Radial Nerve</i>	Cuff	Cuff
Finger Extensor - <i>Extensor Digitorum Communis</i>	IM	IM	Elbow Extensor - <i>Radial Nerve</i>	X	Cuff
Thumb Flexor - <i>Adductor Pollicis</i>	IM	IM	Elbow Flexor - <i>Musculocutaneous Nerve</i>	Cuff	Cuff
Thumb Flexor - <i>Flexor Pollicis Longus</i>	IM	IM	Elbow Flexor - <i>Musculocutaneous Nerve</i>	Cuff	Cuff
Thumb Extensor - <i>Extensor Pollicis Longus</i>	IM	IM	Arm Abductor - <i>Axillary Nerve</i>	Cuff	Cuff
Thumb Abductor - <i>Abductor Pollicis Brevis</i>	IM	IM	Arm Adductor - <i>Thoracodorsal Nerve</i>	Cuff	Cuff
Wrist Flexor - <i>Palmaris Longus</i>	IM	X	Scapular Abductor - <i>Long Thoracic Nerve</i>	Cuff	Cuff
Wrist Flexor - <i>Flexor Carpi Radialis</i>	X	IM	Scapular Adductor - <i>Rhomboids</i>	IM	X
Wrist Extensor - <i>Extensor Carpi Radialis Longus</i>	X	IM	Shoulder Stabilizer - <i>Suprascapular Nerve</i>	Cuff	Cuff
Forearm Pronator - <i>Pronator Quadratus</i>	IM	IM	Shoulder Horizontal Flexor - <i>Upper Pectoralis</i>	IM	IM
Forearm Supinator - <i>Supinator</i>	IM	X	Shoulder Horizontal Flexor - <i>Lower Pectoralis</i>	IM	IM
Elbow Flexor - <i>Biceps</i>	X	IM	EMG Recording - <i>Right Platysma</i>	EP-EMG	EP-EMG
EMG Recording - <i>Left Platysma</i>	EP-EMG	IM-EMG	EMG Recording - <i>Right Upper Trapezius</i>	X	IM-EMG
EMG Recording - <i>Left Upper Trapezius</i>	EP-EMG	EP-EMG	EMG Recording - <i>Right Auricularis</i>	EP-EMG	X

Table 2

ADL Task Results for Subject 1.

Activity of Daily Living	Result & Comment
Feeding with a Fork	Success was dependent upon subject's spasticity level on the day of testing. Difficult to orient the fork to both acquire food and to reach the mouth.
Eating Finger Foods	Successful, but needed assistance acquiring the food due to hand stiffness
Scratching Nose	Successful
Wiping Nose with Tissue	Successful, but difficult to acquire the tissue from the tissue box
Washing Face with Washcloth	Somewhat successful, but needed help acquiring the washcloth and couldn't reach all of face
Brushing Teeth	Somewhat successful, but needed help acquiring the toothbrush and couldn't reach all of the teeth
Shaking Hands	Successful

Table 3

Stimulated range of motion for arm and shoulder muscles in two high tetraplegia subjects, along with normal active range of motion. NT = Not Tested.

Joint	Motion	Angles (degrees)		
		Subject 1	Subject 2	Normal
Shoulder	Extension / Flexion	NT / 74	NT / 47	60 / 180
Shoulder	Horizontal Adduction / Abduction	8 / 27	3 / 25	45 / 90
Shoulder	External / Internal Rotation	NT / NT	NT / 64	60 / 80
Elbow	Extension / Flexion	0 / 109	0 / 88	0 / 150
Forearm	Pronation / Supination	0 / 18	15 / 57	80 / 80
Wrist	Extension / Flexion	-10 / 18	NT / NT	70 / 80