

## Implanted neuroprosthesis for assisting arm and hand function after stroke: A case study

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**Abstract**—Loss of arm and hand function is common after stroke. An implantable, 12-channel, electromyogram (EMG)-controlled functional electrical stimulation neuroprosthesis (NP) may be a viable assistive device for upper-limb hemiplegia. In this study, a research participant 4.8 yr poststroke underwent presurgical screening, surgical installation of the NP, training, and assessment of upper-limb impairment, activity limitation, and satisfaction over a 2.3 yr period. The NP increased active range of finger extension from 3 to 96 degrees, increased lateral pinch force from 16 to 29 N, increased the number of objects from 1 to 4 out of 6 that the participant could grasp and place in a Grasp-Release Test, and increased the Arm Motor Abilities Test score by 0.3 points. The upper-limb Fugl-Meyer score increased from 27 at baseline to 36 by the end of the study. The participant reported using the NP at home 3–4 d/wk, up to 3 h/d for exercise and household tasks. The effectiveness of the NP to assist with activities of daily living was dependent on the degree of flexor tone, which varied with task and level of fatigue. The EMG-based control strategy was not successfully implemented; button presses were used instead. Further advancements in technology may improve ease of use and address limitations caused by muscle spasticity.

**Key words:** assistive device, FES, functional electrical stimulation, hemiplegia, implant, medical device, neuroprosthesis, rehabilitation, stroke rehabilitation, upper limb.

## INTRODUCTION

Approximately 15 to 30 percent of stroke survivors never regain hand function and therefore remain significantly dependent on caregivers for activities of daily living (ADLs) [1]. Poststroke upper-limb motor impairment is often characterized by both extensor paresis and involuntary flexor contractions, making it difficult for individuals

**Abbreviations:** ADL = activity of daily living, AMAT = Arm Motor Abilities Test, AROM = active range of motion, CRPS = complex regional pain syndrome, DI = dorsal interosseous, EDC = extensor digitorum communis, EMG = electromyogram, EPL = extensor pollicis longus, FDP = flexor digitorum profundus, FES = functional electrical stimulation, FMA = Fugl-Meyer Assessment, GRT = Grasp-Release Test, IST = implantable stimulator-telemeter, NP = neuroprosthesis, PIP = proximal interphalangeal, RF = radio frequency, ROM = range of motion, SS = supraspinatus.

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to open the affected hand and to control arm and hand muscles independently. Compensatory strategies and disuse of the affected arm and hand often lead to “learned non-use” [2].

An implantable functional electrical stimulation (FES) system (neuroprosthesis [NP]) can activate upper-limb muscles and produce movements that have enabled tetraplegic spinal cord injury patients to perform some ADLs independently [3–5]. Such an NP may be a viable solution for stroke patients who do not regain arm and hand function with other rehabilitation techniques. An NP may also allow more intensive and longer term therapeutic input directly related to practical skill acquisition than is possible with conventional therapies.

Implanted NPs offer several advantages over transcutaneous electrical stimulation systems. With an implanted NP, more and deeper muscles can be activated with greater selectivity and may thereby provide control of more joints and produce more useful movement patterns. With surface stimulation systems, adding more electrodes means more external hardware and a more cumbersome donning procedure that needs to be repeated daily. Stimulation from surface electrodes can also be uncomfortable because sensory receptors in the skin are activated, and the amount of contractile force produced with surface electrodes can be inconsistent because of movement of the target muscles under the skin relative to the electrodes as the stimulated limb moves [6].

This article describes the first individual with post-stroke hemiplegia to receive a 12-channel, implanted NP for assisting arm and hand function. The purpose of the project was to evaluate the feasibility of the NP as an assistive device for upper-limb function in a stroke patient. This research was performed at an academic medical center with approval from its institutional review board. The participant gave written informed consent prior to any study procedures.

## METHODS

### Participant

The participant was a 57 yr-old female, 4 yr and 10 mo after a stroke caused by arteriovenous malformation rupture with subsequent hemiparesis of her left side. Four months after her stroke, she had a tonic-clonic seizure during which she sustained a left humeral head fracture that triggered an episode of complex regional pain syndrome

(CRPS) that affected her left shoulder and hand for 3 mo. She was on antispasticity and antiseizure medications. She had not had a seizure for approximately 1 yr prior to our NP intervention.

Prior to NP intervention, she presented with left side upper-limb hemiparesis characterized by weak active extension of the elbow (grade 1/5 on the Medical Research Council scale), wrist (2-/5), fingers (1/5), and thumb (2/5) (**Table 1**). Active flexion was also weak but slightly stronger (4/5) at the elbow, wrist, fingers, and thumb. She had impaired but not absent proprioception of finger flexion/extension and impaired cutaneous sensation at the fingertips. She had shoulder subluxation (1 fingerbreadth) and an anterior shoulder contracture that mildly limited the passive range of shoulder flexion but that was resolved with several weeks of passive range of motion (ROM) exercise prior to NP intervention. She had no shoulder, arm, or hand pain. Mild to moderate levels of muscle hypertonia (modified Ashworth scale [7]) were noted in the elbow flexors (1+) and extensors (1), wrist flexors (1), and finger flexors (2) when passively ranged while the participant was relaxed (**Table 1**). She ambulated independently using a straight cane.

The inclusion criteria were >6 mo poststroke, upper-limb hemiparesis resulting in functional deficits of the arm and/or hand, sufficient active shoulder elbow movement to bring the paretic hand to the face and to different spots on a table while seated, functional passive ROM of the wrist and fingers, ability to follow three-stage commands, ability to recall three items after 30 min, caregiver support, and functional hand and arm movement in response to surface stimulation under various conditions of rest and activity of the arm and hand. Four candidates were assessed and excluded before the participant was enrolled. She lived more than 200 mi away from the medical center; therefore, surgical planning, problem-solving, fine tuning, training, and assessments were accomplished during multiple 1 to 3 d visits over approximately 2.3 yr (**Table 2**).

### Neuroprosthesis System

The NP consisted of an implantable stimulator-telemeter (IST), 12 intramuscular stimulating electrodes, 2 epimysial electromyogram (EMG)-recording electrodes, and an external control unit, which have been described in detail elsewhere [4,8–9]. The IST produced 12 independent channels of electrical stimulation (charge-balanced biphasic current pulses) and recorded,

**Table 1.**

Motor impairment and activity limitation scores before and after neuroprosthesis (NP) implementation.

| Instrument                               | Pre-NP   | Postrevision Surgery |            |
|--|----------|----------------------|------------|
|  | Baseline | 10 Mo                | 22 Mo      |
| <b>Modified Ashworth Scale Score/MRC</b> |          |                      |            |
| Shoulder Abductors                       | 0/2–     | 0/—                  | 0/3–       |
| Shoulder Adductors                       | 0/—      | 0/—                  | 0/—        |
| Shoulder External Rot                    | 0/—      | 0/—                  | 0/—        |
| Shoulder Internal Rot                    | 1/—      | 0/—                  | 0/—        |
| Elbow Flexors                            | 1+/4–    | 1+/-                 | 1+/3       |
| Elbow Extensors                          | 1/1      | 0/—                  | 0/4        |
| Supinators                               | 0/4–     | 0/—                  | 0/3        |
| Pronators                                | 0/3+     | 0/—                  | 0/3+       |
| Wrist Flexors                            | 1/4–     | 1/—                  | 0/3+       |
| Wrist Extensors                          | 0/2–     | 0/—                  | 0/3        |
| Index MP Flexors                         | 0/—      | 0/—                  | 0/—        |
| Index MP Extensors                       | 0/—      | 0/—                  | 0/—        |
| Index PIP Flexors                        | 2/4      | 2/—                  | 2/3+       |
| Index PIP Extensors                      | 0/1      | 0/—                  | 0/3+       |
| Thumb MP Flexors                         | 0/4–     | 0/—                  | 0/3        |
| Thumb MP Extensors                       | 0/2      | 0/—                  | 0/2+       |
| <b>FMA (max = 66)</b>                    | 27       | 24                   | 36         |
| <b>AROM (degrees)</b>                    |          |                      |            |
| Shoulder Flx                             | 54       | 44                   | 41         |
| Shoulder Abd                             | 62       | 53                   | 67         |
| Elbow Ext                                | 110      | 120                  | 165        |
| Elbow Flx                                | 124      | 78                   | 113        |
| Wrist Ext                                | 40       | 30                   | 35         |
| Wrist Flx                                | 70       | 85                   | 72         |
| Finger AROM                              | 4        | 5/131*               | 3/96*      |
| <b>Pinch Force (N)†</b>                  |          |                      |            |
| Lateral                                  | 20.0     | —                    | 16.0/28.9* |
| Palmar                                   | 13.8     | —                    | 17.3/16.4* |
| <b>GRT†</b>                              |          |                      |            |
| Peg                                      | 2.7      | —                    | 0/2.7*     |
| Paper Weight (264 g)                     | 0        | —                    | 0/0*       |
| Fork Plunger                             | 3.7      | —                    | 0/1.3*     |
| Block (2.5 cm)                           | 5.7      | —                    | 4.7/3.0*   |
| Can (d = 5.4 cm)                         | 0        | —                    | 0/1.7*     |
| VHS Tape                                 | 0        | —                    | 0/0*       |
| AMAT (max = 5.0)                         | 1.6      | —                    | 1.9/2.2*   |

\*With NP.

†Average of 3 trials.

— = not measured, Abd = abduction, AMAT = Arm Motor Abilities Test, AROM = active range of motion, d = diameter, Ext = extension, Flx = flexion, FMA = Fugl-Meyer Assessment, GRT = Grasp-Release Test, max = maximum, MP = metacarpophalangeal, MRC = Medical Research Council, PIP = proximal interphalangeal, Rot = rotators.

processed, and transmitted 2 independent channels of EMG signal to the external control unit. The external control unit (15.2 × 7.6 × 4.4 cm; 0.45 kg) recovered

**Table 2.**

Time sequence of events.

| Time Relative to NP Surgery (mo) | Time Relative to Revision Surgery (mo) | Event   |
|----------------------------------|--|---|
| –2                               |  | Baseline assessments                                |
| 0                                |  | NP surgery  |
| <1                               |  | Exercise stimulation pattern started                |
| 2                                |  | Functional stimulation and EMG-control started      |
| 4                                |  | Electrode malfunction noted                         |
| 6                                | 0                                      | Revision surgery                                    |
|                                  | <1                                     | Exercise stimulation pattern started                |
|                                  | 2                                      | NP training   |
|                                  | 10                                     | Replaced EMG with button press control; assessments |
|                                  | 22                                     | Assessments   |

EMG = electromyogram, NP = neuroprosthesis.

radio frequency (RF) coil placed externally over the IST and transmitted power and stimulus commands for each electrode back to the IST based on subject-specific EMG control algorithms [4] and/or button presses.

### Screening, Surgical Planning, and Surgical Procedure

The goal of the NP for the participant in this study was to improve upper-limb function by reducing shoulder subluxation and by assisting elbow extension, hand opening, and hand closing. During presurgical screening visits, surface and percutaneous stimulating electrodes were used to determine whether muscle contractions and hand movements could be elicited to compensate for paresis and spasticity. To screen for prohibitive levels of flexor hypertonia (which may worsen with increased effort to assist the stimulation [10–12]), we verified that stimulated hand opening did not appreciably diminish when this participant attempted to volitionally open the hand or reach forward. Surface and percutaneous EMG-recording electrodes were also used during screening visits to determine whether the participant could adequately produce and terminate EMG signals for NP control. Key criteria for selecting muscles as EMG sources included the ability to consistently produce either sustained EMG signals or EMG bursts, to produce and terminate signals during reaching, and to isolate the signal from nearby voluntary

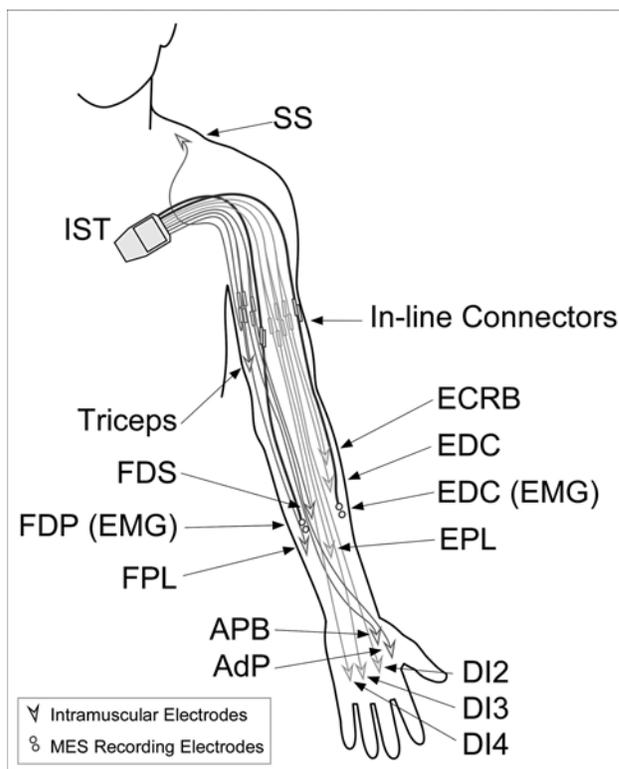
muscles [4]. Although it was desirable that the control muscles have synergistic action with the movement being produced by the NP, that was not a requirement.

Based on the participant's motor deficits and the responses to stimulation, the following 12 muscles were chosen for implantation: extensor digitorum communis (EDC); dorsal interosseous (DI) 2, 3, and 4; extensor pollicis longus (EPL); extensor carpi radialis brevis; abductor pollicis brevis; adductor pollicis; flexor digitorum superficialis; flexor pollicis longus; triceps; and supraspinatus (SS). The participant could consistently produce bursts of EMG signal from the EDC and could initiate and terminate strong sustained EMG signals from the flexor digitorum profundus (FDP) that were independent of EDC activity. There were no technical reasons for ruling out the possibility of using EMG signals from a muscle that is being stimulated [8]. Therefore, the planned EMG control strategy was to trigger finger and thumb extensor stimulation with EDC bursts and to modulate finger and thumb flexor stimulation with FDP activity. The surgical plan is shown in **Figure 1**. The participant used a surface stimulator several hours a day for 4 wk before surgery to condition her SS, triceps, and forearm muscles in preparation for surgery. General medical and surgical preoperative clearance was performed prior to NP implantation.

The surgery was performed in an operating room with the participant under general anesthesia. The stimulating and EMG-recording electrodes and IST were implanted according to procedures described in detail elsewhere [4,13–14]. Muscle identities were confirmed intraoperatively with a surgeon's stimulator. Before closing all incisions, to verify that the device was working properly, the surgeon used an external control unit and RF coil to communicate with the IST to produce muscle contractions through each stimulating electrode and to receive signals from the EMG electrodes. The surgery lasted approximately 4 h. There were no postsurgical complications, and the participant was discharged from the hospital 3 d later.

### Postsurgical Course

Thermoplastic splints were used to immobilize the elbow at 90° and the hand in an intrinsic-plus posture for 3 wk to allow electrode encapsulation. After the splints were removed, the proper function of each stimulating and EMG-recording electrode was verified and the NP was programmed to deliver stimulation to the muscles in



**Figure 1.**

Surgical plan. AdP = adductor pollicis, APB = abductor pollicis brevis, DI = dorsal interosseous, ECRB = extensor carpi radialis brevis, EDC = extensor digitorum communis, EMG = electromyogram, EPL = extensor pollicis longus, FDP = flexor digitorum profundus, FDS = flexor digitorum superficialis, FPL = flexor pollicis longus, IST = implantable stimulator-telemeter, MES = myoelectric signal, SS = supraspinatus.

a cyclic (on/off) pattern. The participant was instructed to use this exercise stimulation up to 8 h per day (during sleep if possible) in order to build and maintain muscle strength and fatigue resistance in preparation for functional use of the NP.

At 2 mo postsurgery, lateral and palmar pinch stimulation patterns were created and programmed for functional use [15]. An EMG control strategy was programmed that required a burst of EMG signal from the FDP to trigger a stimulation ramp to close the hand and a burst of EMG signal from the EDC electrode to trigger a stimulation ramp to open the hand. Triceps stimulation, which reduced shoulder subluxation, was programmed to turn on with hand opening and off with hand closing; SS stimulation turned on with hand closing and off with hand opening.

This was to help mitigate muscle fatigue while keeping shoulder subluxation reduced. The triceps and SS could also be turned off if desired with buttons on the external control unit. With training from an occupational therapist (approximately 6 h over 3 d), the participant used the NP to practice hand-positioning strategies, tabletop pick-and-place tasks, and bilateral tasks before returning home.

At 4 mo postsurgery, the EPL electrode was no longer functioning because of a failure in the output stage for that channel in the IST, which was verified in a subsequent revision surgery. The revision surgery to restore EPL stimulation was done approximately 6 mo after the initial surgery. This involved disconnecting the EPL electrode from the IST at the lateral brachial connector site (**Figure 1**), verifying that the EPL electrode retained continuity and function, and reconnecting it to the IST channel that was stimulating DI4. The electrode to DI4 was disconnected from the IST and capped. Loss of DI4 stimulation was expected to have the least effect on the stimulation patterns compared with any other electrode.

Three weeks after the revision surgery, the participant began stimulating her hand with an exercise pattern. Two months after the revision surgery, the participant returned for adjustments to the stimulation patterns and NP training. An occupational therapist trained the participant on several bimanual tasks, many of which required the stimulated hand to hold or stabilize an object while the unaffected hand manipulated the object (e.g., applying toothpaste to a toothbrush, peeling a potato, filling a cup from a faucet, and using a fork and knife). The participant and occupational therapist also compiled a list of ADL tasks centered around the participant's goals to be practiced with the NP each day at home. The participant returned at 10 and 22 mo postrevision surgery for outcome assessments.

### Outcome Assessments

Outcomes were assessed by investigator observation and participant reports, clinical measures of arm and hand impairment and activity limitation, and a 41-item NP Satisfaction and Usage Questionnaire. The questionnaire was sent to the participant 2 wk before her final assessment visit and asked her to compare her arm and hand function before and after the intervention, compare her function with and without the NP, report on the usability of the NP, rate the impact of the NP on her life, and describe her use of it.

The clinical measurements of arm and hand impairment were made at baseline and at 10 and 22 mo postrevision surgery. These measures included the modified Ashworth scale of muscle spasticity [7]; upper-limb Fugl-Meyer Assessment (FMA, max score = 66) [16]; goniometric measurements [17] of active ROM (AROM) at the shoulder, elbow, and wrist; electrogoniometric measurement of finger AROM [18]; pinch meter measurements of lateral and palmar pinch force [19–20]; the Grasp-Release Test (GRT) [19]; and the Arm Motor Abilities Test (AMAT, max score = 5) [21]. For each of these measurements there was one member of the research team who made the measurement at each assessment time point, keeping all testing conditions as similar as possible each time.

The 6-point modified Ashworth scale (0 to 4, including 1+) was used to rate the resistance to joint translation when the examiner rotated the joint passively through its range and the participant remained relaxed. For the FMA, the participant was asked to perform specific coordinated and isolated shoulder, elbow, wrist, and hand movements. Each movement was rated by a therapist using a 3-point ordinal scale and summed to produce an overall score, the maximum of which is 66. For the electrogoniometer measurements, the participant was cued to attempt to maximally open her hand for several seconds and then close it for several seconds, repeating this three times. The metacarpophalangeal and proximal interphalangeal (PIP) joint angles of the index finger were added together as a composite measure of finger flexion [22], and the average AROM (difference in finger flexion during maximum open and close) over the three repetitions was calculated. The score for the GRT is the number of times the participant could grasp, manipulate, and release an object in 30 s. There were six objects of different size and weight. The AMAT score is an average across 9 different compound ADL tasks composed of 1 to 3 component tasks, each of which was scored by a therapist using a 0 to 5 ordinal scale: 0 = no attempt to use affected limb, 1 = attempt to use affected limb but it does not participate functionally, 2 = affected limb is used only as a helper or stabilizer, 3 = affected limb is used slowly or within synergy patterns, 4 = affected limb use almost normal, 5 = normal use. The follow-up assessments of finger AROM, pinch force, GRT, and AMAT were done with and without the NP on.

## RESULTS

### Observations and Participant Reports

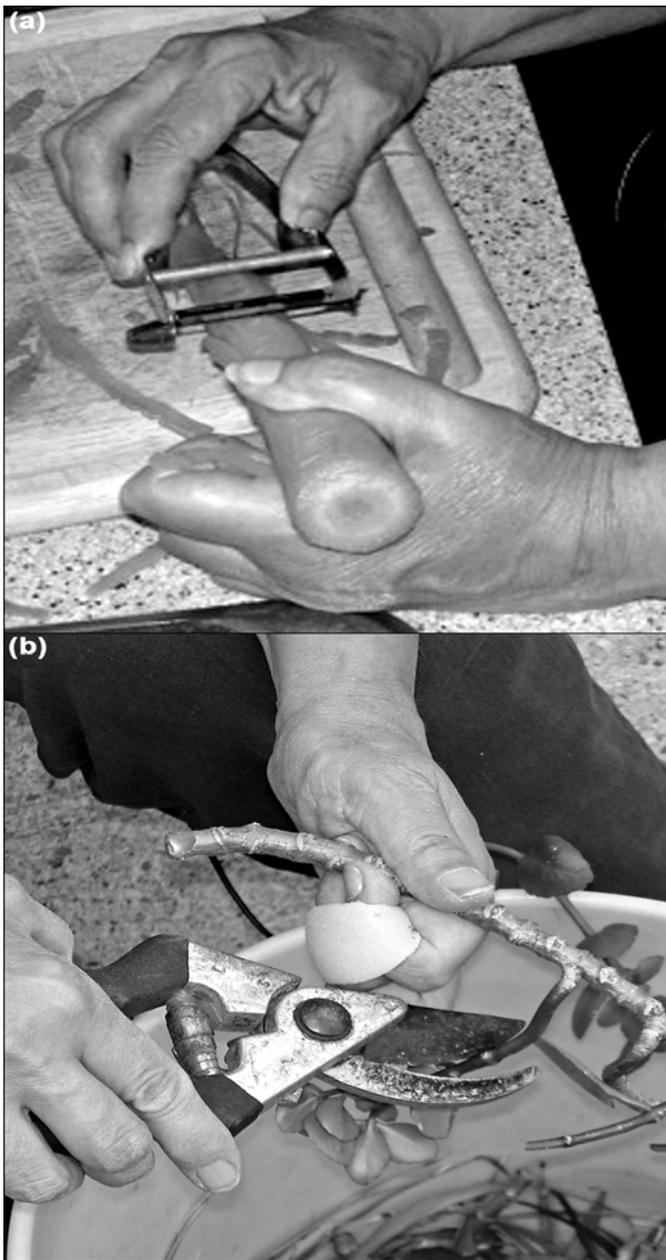
With practice, the participant was able to use the NP to perform several bimanual tasks in the laboratory. This success came with several complications. The NP did not produce sufficient extension of the index PIP joint during the open phase of the palmar pattern. To achieve full extension of the index PIP joint, “buddy taping” was used to couple the index and long fingers at the middle phalanges and was also used during assessments. Often, several seconds of rest were needed to allow for subsidence of flexor tone after the participant exerted effort to close the hand before the hand would fully open again with stimulation. Also, the degree of flexor tone varied with level of fatigue and amount of effort required to achieve the task and caused changes in the amount of hand opening achieved with the NP. Weakness and lack of motor control of proximal arm muscles made it difficult for the participant to position her hand well for different tasks. The participant was able to improve her performance by passively placing her arm where necessary for function, by learning to consciously relax flexors, and by taking rest breaks for muscles to relax between task repetitions.

Shoulder subluxation was effectively reduced with stimulation of either the triceps or SS. Triceps stimulation also produced elbow extension but not with enough force to allow unsupported reach; however, it was adequate to counteract elbow flexion tone and keep her arm extended and useful for some tasks. The participant preferred to have the ability to turn SS and triceps on and off with button presses rather than having them automatically turn on and off during the hand stimulation pattern. She used the SS and triceps stimulation frequently.

The EMG control strategy failed to provide easy-to-use NP control for this participant. Attempts to volitionally open her hand did not produce adequate EMG signal from the EDC-recording electrode. However, she could generate a strong EMG signal from the FDP-recording electrode by attempting to close her hand. An FDP-only control strategy was initially tried in which the EMG signal from the FDP would proportionally modulate hand opening and closing, but the increase in flexor tone limited the finger extension that could be achieved with electrical stimulation. Other FDP-only control strategies were tried but were not consistently effective. Because attempts to extend the wrist produced discernable EMG

signal from the EDC-recording electrode, an EMG control strategy was tried that used a quick wrist extension to trigger stimulated hand opening and a quick finger flexion to trigger stimulated hand closing. The participant demonstrated some success in the laboratory with this strategy and used it, albeit with difficulty, over a period of 14 mo. At the 10 mo postrevision visit, the EMG control strategy was replaced with push-button control for the following reasons: (1) inadvertent “open” commands were frequent in spite of methods to reject them (e.g., adjusting EMG thresholds, using multiple thresholds, adjusting window lengths, triggering based on differences between EDC and FDP EMG amplitudes, requiring single or double twitches rather than sustained contractions, etc.), (2) the effort required to generate EMG signals produced flexor spasticity that made extensor stimulation less effective in opening the hand, (3) it was difficult to incorporate the EMG control strategy into tasks, and (4) modifications of the EMG control algorithm and alternative EMG control strategies to address these limitations were unsuccessful. In place of the EMG strategy, successive presses of a large button opened and closed the hand (i.e., ramped the stimulation intensity to flexors and extensors up and down). The button was cabled to the external control unit and could be mounted wherever it was convenient for a given task. The change in control strategy resulted in a much improved hand opening pattern.

Between 2 and 10 mo postrevision surgery, the participant reported using the NP for exercise and function 1 to 2 h per day and for assistance with eating about every third meal. She reported success using the NP to help with closing zippers and cutting vegetables during meal preparation, but that her performance varied from day to day. She also reported that after using the NP in exercise mode for a while her hand felt looser and her ability to use her hand improved. She remarked that her grip strength without the NP had increased as well. Between her 10 and 22 mo visit, she reported using the NP almost daily, finding a “whole range of things in the kitchen” for which she was using the NP, such as cutting and peeling vegetables (**Figure 2(a)**). She also reported using the NP for gardening (e.g., trimming flower gardens, **Figure 2(b)**) and using the NP during gym sessions to grasp handles on the equipment. Though she regularly tried using the NP during meals, she reported finding it very difficult to use for eating and was frustrated by weak flexion of the fourth and fifth fingers. She also remarked that the external



**Figure 2.** Participant using neuroprosthesis (NP) at home for **(a)** meal preparation and **(b)** gardening tasks. NP allows impaired (left) hand to be used as an effective support to allow bimanual tasks that were not otherwise possible.

control unit was cumbersome to wear (i.e., in a fanny pack or a camera bag over her shoulder) and that the NP might be easier to incorporate into daily tasks if the external control unit were smaller.

### Quantitative Assessment of Impairment and Activity Limitation

Quantitative outcomes are summarized in **Table 1**. There were no notable changes in degree of muscle spasticity as measured with modified Ashworth scores. Overall, upper-limb motor impairment as measured by the FMA improved from a score of 27 at baseline to 36 at 22 mo, a magnitude of change that is considered to be clinically significant [23]. The increase in score occurred mainly in the shoulder/elbow subsection of the assessment. Upper-limb AROM from baseline to 22 mo follow-up remained largely unchanged with the exception of an increase in active (volitional) elbow extension from 110° to 165°. The FES-generated ROM of the index finger was 131° and 96° at 10 and 22 mo follow-up, respectively, compared with no appreciable finger AROM during the electrogoniometer trials when the NP was off. Likewise, the changes in pinch force from baseline were negligible without the NP. With the NP, the lateral pinch force nearly doubled; yet, the palmar pinch force did not change with the NP. On the GRT, the participant was able to perform the task with three of the six objects at baseline. At 22 mo, she could perform the task with only one object with the NP turned off, but with the NP, she could do the task with four of the six objects. While the NP improved the participant's ability to acquire and grasp objects, she still had significant difficulty positioning her hand around the larger and heavier objects in the GRT to grip them securely. The participant's AMAT score improved from 1.6 at baseline to 1.9 without the NP and to 2.2 with the NP at 22 mo follow-up.

### Satisfaction and Usage Questionnaire

In the questionnaire, the participant agreed that (1) if given the opportunity to do it over again, she would have the NP implanted; (2) she had benefited from the NP; (3) she felt more confident performing activities with the NP than without it; (4) she could do some tasks faster with the NP than without it; and (5) the NP made a positive impact on her life. She commented that the NP has shown her what is possible to do with her arm and hand, that she is more willing to try tasks with the NP on than without it, and that she can perform certain tasks better with the NP than without it. She listed cooking, gardening, and reading as the tasks for which she had found the NP to be the most important, commenting that the NP is "a great help with gardening." However, she disagreed with the statement that the NP had made a positive

impact in her actual homemaking or home maintenance and was neutral toward the statement that the NP had improved her quality of life. Her most frequent complaints against the NP were (1) it did not provide her enough functionality to do some of the tasks she wanted to do because of inadequate grip; (2) she found the external control unit to be bulky and heavy, sometimes upsetting her balance; and (3) it was difficult for her to position the control button so that it was not activated inadvertently. She reported using the NP for functional tasks 3 to 4 d per week on average and commented that she continues to attempt to use it every day if she is feeling well. She reported that she can use the NP up to about 3 h per day, but that within that time period her hand becomes tight and then does not function as well. When that occurs, she lets the NP run in exercise mode (cyclic stimulation), which loosens up her hand, then she switches back to functional mode. The participant described the NP as adding “limited functionality”; yet it “still provides me with the potential to perform functions that I cannot do without the system.”

### Adverse Events

The participant experienced several transient health issues throughout the course of the study that affected her progress. These included neurogenic bladder; insomnia; severe knee pain that required arthroscopic surgery; CRPS symptoms (treated with prednisone); multiple falls (one of which resulted in hairline fractures at the bases of the long and ring fingers of her paretic hand); and episodes of disorientation, shakiness, blurry vision, and lethargy (treated by her neurologist adjusting antiseizure medication). These issues as well as the fact that she did not live locally affected her participation in the study, her progress with the NP, and her performance on the assessments. All of these medical complications were part of her health condition prior to the study and were not considered to have worsened after NP intervention. After her 22 mo follow-up, the participant fell, fractured her left clavicle, and subsequently underwent open reduction and internal fixation. She subsequently had several minor seizures. Magnetic resonance imaging was determined to be medically indicated by her neurologist and was performed without consequence to the device or participant.

## DISCUSSION

Improvements in NP technology made it feasible to implement a multichannel, implantable NP in a stroke patient for the first time. Compared with its predecessor [3], the NP used in this study had 4 more stimulation channels plus 2-channel implanted EMG-recording capability, two-way RF telemetry technology, and a much smaller and lighter external control unit. In spite of these advances, this case study highlights yet additional technology improvements that might increase the degree of success in the future, including (1) increasing the number of EMG-recording channels and thereby the number of EMG-control strategy/algorithm options and the chances that one will work well; (2) adding implantable sensors (e.g., joint and limb position) that can be incorporated into the control strategy and/or provide feedback control (i.e., to automatically adjust stimulation if the desired movement is not achieved); (3) increasing the number of stimulating channels and thereby improving stimulation patterns and muscle recruitment; (4) adding the capability of nerve stimulation to improve muscle recruitment; (5) miniaturizing or eliminating (i.e., implanting) the external control unit (i.e., fewer external components); and (6) developing an intramuscular EMG-recording electrode, which might improve the precision with which the recording electrodes can be placed within the voluntarily active compartments of paretic muscles. Also, advances in surgical techniques and/or intraoperative testing are needed to ensure optimal placement of stimulating and EMG-recording electrodes.

The earliest studies of NPs in hemiplegia reported cases in which the participants' voluntary effort to control the paretic limb produced tremors and spasticity [24–25]. Similarly, our own previous work with surface and percutaneous stimulation found that electrical stimulation was effective at producing the desired hand movement when the participant was relaxed, but that stimulated finger extension was reduced if the participant attempted to assist the stimulation or when stimulation followed voluntary flexion [10–12]. In this study, we attempted to avoid the problem of flexor spasticity by enrolling a participant who did not exhibit these characteristics during screening procedures. Presurgical testing indicated that this participant would not have the degree of muscle tone that we observed in previous research participants; nevertheless, her flexor tone did reduce the effectiveness of extensor stimulation and thereby diminished her performance with the NP. A

more comprehensive screening protocol and testing of EMG control strategies in concert with surface or percutaneous stimulation would aid participant selection by providing a better prediction of the effects of muscle tone and the outcome of an implanted NP. It may also be possible to train participants to perform tasks in such a way that reduces the likelihood of spasticity interfering and to train participants to relax tight muscles. Future NP systems may be able to control spasticity by incorporating new neurotechnology that blocks undesirable neural activity, such as a quick-acting, quick-reversing, high-frequency nerve-conduction block [26].

In this case study, comorbidities and proximity issues made it difficult to provide optimal NP training. Ideally, a stroke survivor receiving the NP would participate in a 6 or 12 wk training regimen that would entail working with an occupational therapist in the laboratory two or three times a week and using the NP at home daily. This would allow participants to overcome learned nonuse by practicing in their home environment the strategies they learned in the laboratory and then returning to the laboratory to work on correcting problems encountered at home and to learn new tasks. This training sequence was not possible for this participant; she lived too far from the medical center to attend visits on such a schedule. An extended training period would also allow the participant to learn to use the NP in a more systematic fashion, starting with a simple control strategy and a single stimulation pattern and achieving a certain level of proficiency before progressing to more advanced control strategies and additional stimulation patterns. Careful screening for significant medical history is important to reduce the likelihood of health issues impeding progress and affecting outcome assessments. The participant in this study had many personal, social, and physical characteristics that are critical to success: excellent social support, cognitively intact, willing and able to endure surgeries, willing to follow through with complex interactions, interested in learning about the technology, and willing to work over long periods of time, all with no guarantee of success.

## CONCLUSIONS

For the first time, a stroke patient received an implanted, 12-channel NP to assist upper-limb function. The NP enabled the participant to perform some bimanual tasks in the laboratory and home setting. Even with-

out the NP, the participant's overall upper-limb motor impairment improved by 9 points, as assessed by FMA score; this improvement may in part be attributed to a carryover effect of NP usage. Flexor spasticity reduced the effectiveness of the NP to assist in performing tasks, especially if the tasks required the participant to exert much effort to position the hand appropriately for the task in the workspace. This made it difficult for the participant to integrate the NP into ADLs at home, though she faithfully used the NP to exercise her hand and practice tasks. Further advancements in technology are needed to increase the likelihood of stroke survivors fully integrating the NP into their ADLs. This study has clarified obstacles that remain to be addressed and represents a landmark step toward the development of advanced enabling technology to benefit many thousands of stroke survivors in the future.

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