Targeted Reinnervation to Improve Prosthesis Control in Transhumeral Amputees. A Report of Three Cases

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Targeted Reinnervation to Improve Prosthesis Control in Transhumeral Amputees

A Report of Three Cases

By Kristina D. O'Shaughnessy, MD, Gregory A. Dumanian, MD, Robert D. Lipschutz, CP, Laura A. Miller, PhD, CP,
Kathy Stubblefield, OTR, and Todd A. Kuiken, MD, PhD

Investigation performed at Northwestern University Feinberg School of Medicine, Northwestern Memorial Hospital, and Rehabilitation Institute of Chicago, Chicago, Illinois

Controlling an upper-limb prosthesis is challenging for transhumeral amputees. A central problem is the inability to move multiple prosthetic joints at the same time. With a body-powered prosthesis, an amputee uses shoulder motion to sequentially move the prosthetic elbow and lock it in place before switching to operation of the wrist, hand, or hook. With a myoelectric prosthesis, surface electromyographic signals from the residual biceps and triceps are used to control a motorized arm. Again, sequential control is required, as the biceps and triceps can only operate one joint at a time. The use of these prostheses rarely becomes intuitive. The patient is forced to use chest, shoulder girdle, or upper-arm muscles to move the prosthetic elbow, wrist, and hand in a slow, complex, and burdensome manner. Often, expensive prostheses are left untouched in the patient's closet because the sequence of movements that is required to effectively use the prosthetic arm actions does not occur in a workable time frame for the patient.

Use of a prosthetic arm will become more intuitive and facile if the nervous-system signals that formerly controlled arm movement can once again be used to direct the movement of the prosthesis. To date, most efforts at neural control have focused on brain-machine interface strategies in which electrodes implanted in the cerebral cortex[1,2] and on peripheral nerve interfaces make use of electrode arrays placed in the amputated nerves of the arm[3,4]. These systems face the challenges of weak signals, signal instability over time, potential infections from implanted devices, implant-device failure, and difficulties with extracting the electrical signals to detectors outside the body. The ideal interface between patient and prosthesis would not break, become infected, need a power source, or require repeated trips to the operating room.

Through the process of targeted reinnervation, we present a new method of achieving a functional neural-machine interface for individuals with amputations. Nerves amputated at the time of the initial injury are transferred to intact motor nerves still present in the residual limb. The target muscles are not biomechanically functional because they are no longer attached by tendons to a distal joint. The reinnervated muscle then serves as a biological amplifier of the amputated nerve signals[3,5]. Surface electrodes can record the electromyographic signals from these reinnervated muscles and provide additional control signals for the new prosthesis. Use of the prosthesis becomes intuitive because the nerves are controlling physiologically appropriate functions in the prosthesis. This system does not require any implanted hardware, and currently available myoelectric prostheses can be used with some modification[6]. Targeted reinnervation has been successfully performed in two patients who had a shoulder disarticulation amputation[7-9]. Here we present our experience in using multiple nerve transfers in three transhumeral-level amputees for the improved control of an upper-extremity prosthesis. Our three patients were informed that data concerning the cases would be submitted for publication, and they consented. In addition, the patient in Case 1 provided written consent for publication of the video supplement that is available with the electronic versions of this paper.

Surgical Technique

The goal of the nerve transfer is to take a nerve that formerly directed hand function and transfer that nerve to a muscle segment that otherwise has no function because of the amputation. The newly reinnervated muscle segment in turn bioamplifies the nerve signal that controls the activities of a

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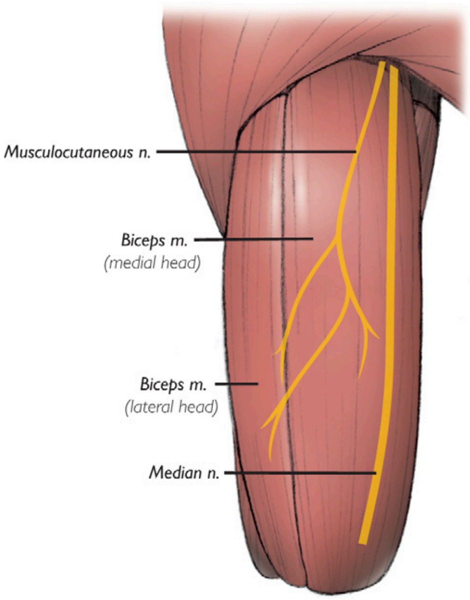

Fig. 1-A

Drawing of the musculature of the right arm from the anterior position.

myoelectric arm. In patients with transhumeral amputation, the median nerve is transferred to the medial head of the biceps for the purpose of operating hand-closing and the distal radial nerve is transferred to the motor nerve of the brachialis muscle to operate hand-opening. The intact lateral head of the biceps is still used to power prosthetic elbow flexion, and the triceps muscle is still used for prosthetic elbow extension.

For each of the three patients, full institutional review board approval and written informed consent were obtained for this experimental surgery. With the patient under general anesthesia and without muscle relaxation (so that motor nerves may be stimulated), an anterior incision is made directly over the muscle bellies of the biceps muscle, beginning just inferior to the lower edge of the deltoid muscle. Soft tissues are injected liberally with dilute epinephrine solution (1:500,000) in order to open tissue planes, increase the visual contrast between tissues, and improve hemostasis. Bipolar cautery is used for coagulation. The fascia overlying the muscle bellies is opened, and the interspace between the heads of the biceps is developed. Dissection of the area immediately inferior to the deltoid muscle between the heads of the biceps exposes the musculocutaneous nerve, the motor branches to the medial and lateral heads of the biceps, and the motor nerve to the brachialis muscle (Figs. 1-A, 1-B, and 1-C). With attention to the vascular supply of the medial head of the biceps muscle, the muscle segment is mobilized away from the humerus to expose the median nerve that runs parallel and inferior to the biceps. The muscle bellies are separated from each other for exposure of the brachial artery and the median nerve. The proximal and distal ends of the muscle bellies are not disturbed, so that the muscles will remain long and in the proper position to permit later detection of electromyographic signals. With this approach, the median nerve is superficial to the ulnar nerve. In the patient with a transhumeral amputation, only the anatomic position of the median and ulnar nerves will reveal their identity, as no muscle remains to be stimulated.

To facilitate the nerve transfers, the musculocutaneous nerve is dissected in such a way as to preserve the motor nerve innervating the lateral head of the biceps and to divide the motor nerve innervating the medial head of the biceps at a point 5 mm from its entry into the muscle substance; the proximal part of the motor nerve is mobilized and buried into the lateral head of the biceps to prevent reinnervation of the medial head. The continuation of the musculocutaneous nerve, which innervates the brachialis muscle, is divided just after the intact takeoff of the nerve to the lateral head in order to perform the radial nerve transfer, as will be described. The median nerve is cut back to healthy fascicles and sewn to the motor branch of the medial head of the biceps with use of 5-0 polypropylene suture (Prolene; Ethicon, Somerville, New Jersey). The suturing process incorporates some epimysium of the muscle belly itself so as to protect the small motor nerve from being torn. Median nerve fibers are thus abutted to transected medial biceps nerve fibers in a novel nerve transfer procedure in order to reinnervate the muscle.

A second lateral incision is made over the distal and lateral aspect of the residual limb. The interspace between the triceps and brachialis is developed to locate the septum between these muscles. The dissection is analogous to the harvest of a lateral arm flap. Continued dissection superiorly at a level just superficial to the periosteum of the humerus leads to the distal radial nerve where it lies in the humeral groove. The radial nerve is followed from this location out distally toward

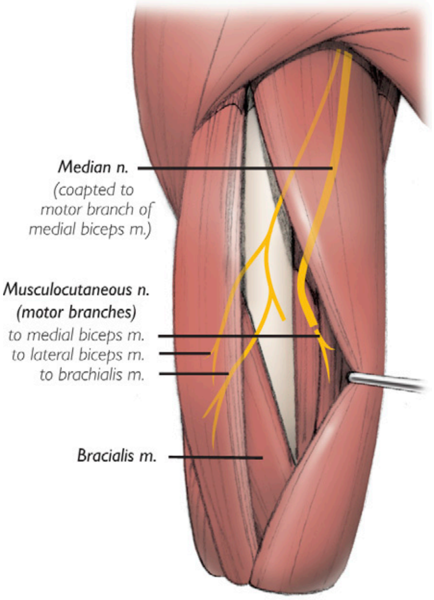

Fig. 1-B

Drawing of the biceps-splitting approach to the musculocutaneous nerve.

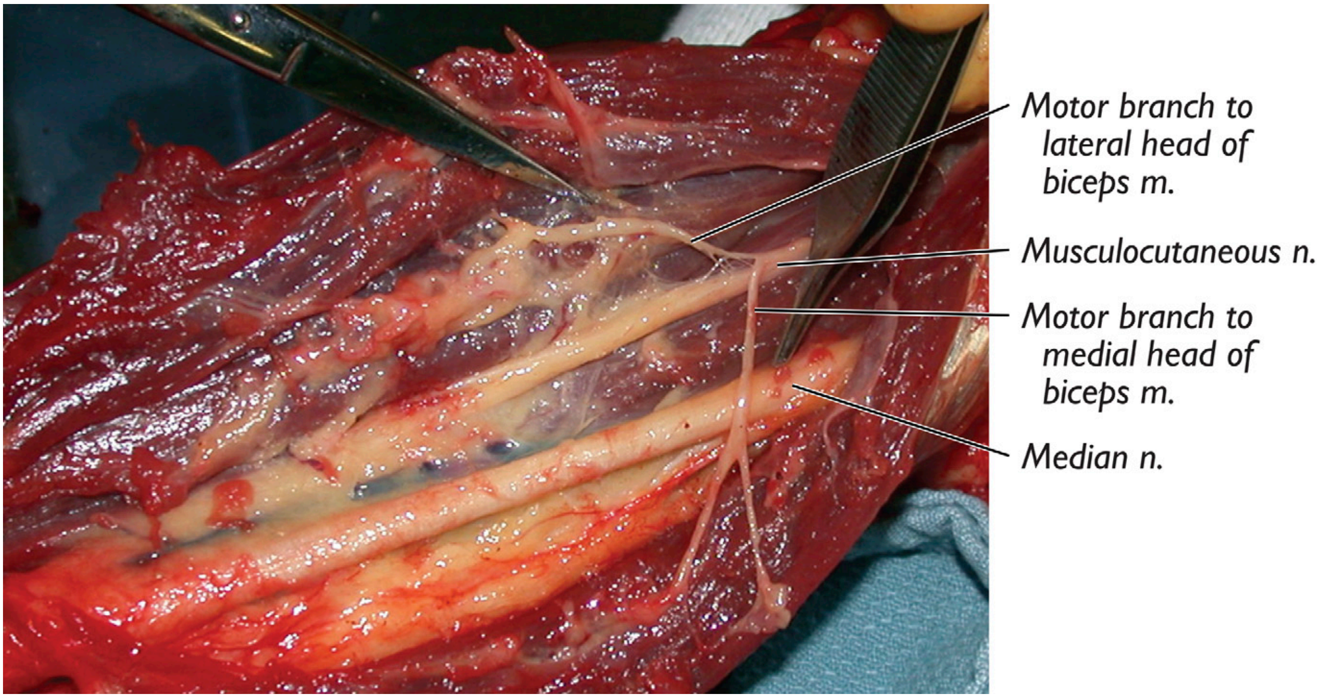

Fig. 1-C

Anatomic dissection of the same area with the heads of the biceps split. The motor branches of the medial and lateral heads of the biceps are well visualized, as is the median nerve.

the end of the amputation for the purpose of attaining additional length. Similarly to the median nerve, the radial nerve is cut back to healthy appearing fascicles. Aberrant innervation between the radial nerve and the brachialis muscle is sought and divided, thus ensuring that the target muscle regions are completely denervated. The motor nerve to the brachialis muscle is the continuation of the musculocutaneous nerve after the branches to the biceps muscle, and it is prepared during the earlier median nerve transfer. The motor nerve to the brachialis muscle and the distal radial nerve are mobilized to reach each other at the lateral border of the brachialis muscle and are then sewn in an end-to-end fashion with 5-0 Prolene suture (Fig. 2).

Attention is then paid to optimizing the surface electromyographic recordings. A 4 to 5-cm area of subcutaneous fat is thinned over all four muscle regions to decrease the separation between the epidermis and the muscle. This thinning maximizes the electromyographic amplitude over each muscle region of interest and minimizes electromyographic cross talk between muscle regions[10]. The lateral and distal aspect of the lateral head of the biceps is resected to better expose the brachialis muscle. In the patient in Case 2, a vascularized fascial flap was interposed between the two heads of the biceps muscle, thereby providing space between the muscle bellies and improving the separation of electromyographic signals from the medial and lateral heads of the biceps. Finally, the medial head of the biceps is tenodesed to the end of the amputation soft tissues to prevent lateral and proximal migration of the muscle belly.

The patients were admitted to the hospital overnight for observation and pain management. Subcutaneous drains were removed on the first postoperative day, and a lightly compressive dressing was applied.

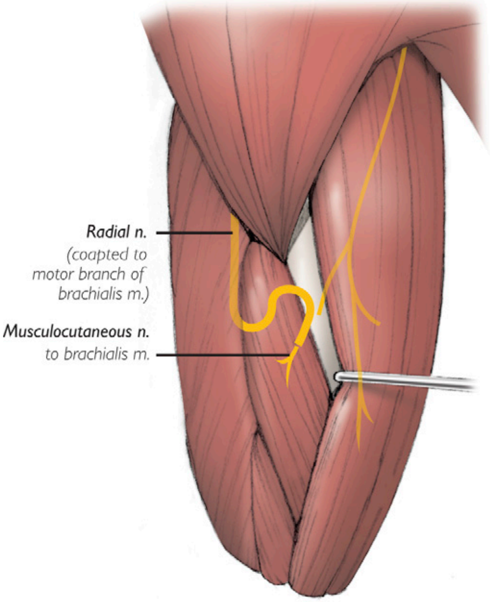

Fig. 2

Anterolateral view of the right arm, with a diagrammatic representation of the nerve transfer of the distal portion of the radial nerve to the motor nerve of the brachialis muscle.

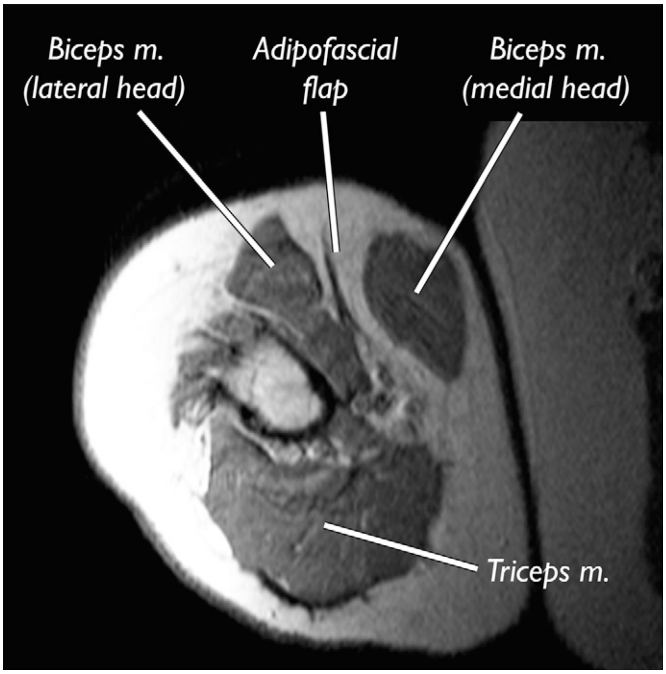

Fig. 3

T1-weighted magnetic resonance image showing the adipofascial flap transposition that was performed in the patient in Case 2.

Case Reports

Case 1. A forty-three-year-old right-hand-dominant man suffered a mutilating injury to the right elbow and forearm during a motor-vehicle accident in August 2002. He underwent an immediate transhumeral amputation. Initially, the patient was fit with a conventional transhumeral myoelectric prosthesis that included a flexible suction socket, a linear transducer, a motorized arm (Boston Digital Arm; Liberating Technologies, Holliston, Massachusetts), a motorized wrist rotator, and a powered hand (Otto Bock, Minneapolis, Minnesota). This prosthesis weighed approximately 2.3 kg and used two electrodes overlying the biceps and triceps to sequentially control the elbow and then the hand. Co-contraction of the biceps and triceps was used to switch from hand to elbow. Wrist rotation was controlled by a linear transducer in a slow-versus-fast pull scheme. The patient received thirty hours of training with this device; however, he had limited functional benefit. Approximately one year after the amputation, he elected to undergo multiple nerve transfers for improved control of the prosthesis. Muscle twitches were apparent four months after the transfer, indicating early muscle reinnervation. Strong, independent contractions of the brachialis muscle and the medial head of the biceps had developed by six months after the procedure. Electromyographic testing isolated signals from four different myoelectric sites: hand-closing from the medial head of the biceps, which was reinnervated by the median nerve; elbow flexion from the lateral head of the biceps; hand-opening from the reinnervated brachialis muscle; and elbow extension from the triceps. The patient was refit with the same prosthesis that had been modified with two additional electrodes for a total of four inputs and reprogrammed to allow simultaneous bidirectional control of the hand and elbow. The linear transducer was again used to control wrist rotation. The patient received twenty hours of training with the new prosthesis (see Appendix) and was followed for two years after the nerve-transfer procedure.

Case 2. A forty-nine-year-old right-hand- dominant man sustained a work-related crush injury of the right arm during a punch-press accident in April 2004, resulting in a long transhumeral amputation of the right arm. The original myoelectric prosthesis of this patient had the same components as the prosthesis of the patient in Case 1 but had a different control scheme. Two electrodes overlying the biceps and the triceps were used exclusively for control of elbow flexion and extension, so the patient did not learn to control the hand through use of the biceps and the triceps. The hand and wrist were controlled by a linear transducer in a slow-versus-fast pull scheme with mode selection accomplished via a bump selector switch mounted on the medial aspect of the humeral section. Training with the original prosthesis totaled twenty-seven hours over the course of several months, resulting in the limited functional benefit that is typical of a conventional transhumeral prosthesis. Nerve-transfer surgery was performed nine months after the original injury. In addition to the standard nerve transfers, the patient also had transposition of an adipofascial flap between the two heads of the biceps to provide more separation for later electromyographic signal detection. This inferiorly based fat flap was developed as an island perforator flap and was based on perforators that supplied the tissue at the level of the brachial artery. This tissue, originally superficial to the medial head of the biceps, was mobilized and passed posterior to the medial head of the biceps to rest between the two heads of the muscle. The patient first noticed muscle twitches 3.5 months after surgery, and strong, independent contractions developed by 5.5 months after the procedure. Electromyographic testing isolated signals to four different myoelectric sites. The experimental four-site myoelectric prosthesis retained all of the original components, again with the exception of two additional electrodes. The

TABLE I Box-and-Block Comparison Testing of Conventional Prosthesis Versus Modified Prosthesis*

	Patient in Case 1		Patient in Case 2	
	Conventional	Modified	Conventional	Modified
Trial 1	2	20	2	14
Trial 2	4	22	9	15
Trial 3	5	35	5	11
Average	3.6	25.6	5.3	13.3
% Improvement	611%		150%	

*Amounts listed represent number of blocks moved from one box to another in two minutes.

TABLE II Clothespin Relocation Comparison Testing of Conventional Prosthesis Versus Modified Prosthesis*

	Patient in Case 1		Patient in Case 2	
	Conventional	Modified	Conventional	Modified
Trial 1	105	45	94	36
Trial 2	70	25	84	92
Trial 3	52	32	99	34
Average	75.6	34	92.3	54
% Reduction	55%		41%	

*Numbers represent the amount of time (in seconds) required to move three clothespins from one beam to another.

patient received approximately eighteen hours of training with the experimental prosthesis. The patient in Case 2 has been followed continuously with in-office visits for over two years after the nerve-transfer procedure.

Case 3. A fifty-three-year-old right-hand- dominant man sustained a traumatic transhumeral amputation of the right arm just proximal to the elbow and a rotator cuff injury of the right shoulder during a train accident in January 2003. Within a month of the injury, arthroscopy of the right shoulder was performed, with subsequent removal of a loose body and subacromial decompression for impingement. The patient was fitted initially with a myoelectric prosthesis identical to that of the patient in Case 2. He underwent nerve-transfer surgery approximately one year after the amputation. The transfer of the median nerve to the biceps muscle proceeded smoothly, but the radial nerve appeared scarred and without healthy fascicles. The patient lost residual flexion of the lateral part of the biceps muscle for three months, and active contraction of this muscle segment only slowly returned. Muscle activity of the medial head of the biceps was detectable at seven months after the procedure but was not strong enough for control of the prosthesis. Distinct electromyographic signals could not be independently recorded from the radial nerve to the brachialis transfer site. Electromyographic testing was unable to isolate four different sites, and therefore the experimental myoelectric prosthesis could not be used.

Results

Two of the three patients (the patients in Case 1 and Case 2) had successful nerve transfers that were able to direct the experimental myoelectric prosthesis. Elbow flexion and extension were controlled with the native lateral head of the biceps and the triceps, respectively. The targeted reinnervation of the medial head of the biceps by the median nerve closed the prosthetic hand, while the radial nerve gave a signal to the brachialis to open the terminal device. Both patients were able to simultaneously operate the elbow and the hand with myoelectric control and the wrist with shoulder control. They reported operation of both the hand and elbow to be natural and easy.

The patient in Case 2 had a successful adipofascial flap transposition, creating ample distance between the lateral and medial heads of the biceps (Fig. 3). This muscle separation allowed for improved independent electromyographic signal measurement. The patient had delayed wound-healing of the anterior incision owing to the extra soft-tissue dissection necessary to create the fascial flap. One of the technical difficulties we encountered with reinnervation of the medial head of the biceps in this patient was muscle retraction, such that when the patient was asked to close his hand, the muscle belly of the medial head of the biceps would almost pull out of the socket. This patient experienced transient phantom limb pain for four months postoperatively.

For the two patients with successful reinnervation, a series of functional outcome tests showed substantial improvement in operation with use of the custom modified prosthesis compared with the conventional prosthesis. The so-called box-and-block test[11] is a validated objective measure of function during which the individual moves 1-in (2.5 cm) blocks from one box, over a divider, and into another box. This requires the use of the shoulder, the elbow, and the hand. The patient in Case 1 was 7.1 times faster with his four-input modified prosthesis, and the patient in Case 2 was 2.5 times faster (Table I). A clothespin test was also performed, wherein three clothespins are relocated from a horizontal beam to a vertical beam, thus requiring the additional use of the wrist. The patient in Case 1 was an average of 55% faster in this test, and the patient in Case 2 was 41% faster (Table II). The Assessment of Motor and Process Skills (AMPS) test is a validated single-subject tool[12]. It was used to quantify performance in selected activities of daily living tasks[13]. Motor and processing scores on the AMPS test improved markedly in both patients when they used the experimental prosthesis (Table III). Other activities of daily living, such as removing and putting on a long-sleeved front-buttoning shirt, placing three 1-lb (4.53-g) cans into a paper bag, and cutting meat with a knife and fork,

TABLE III Assessment of Motor and Process Skills (AMPS) Comparison Testing of Patients When Using Conventional Prosthesis Versus Modified Prosthesis*

	Patient in Case 1		Patient in Case 2	
	Motor Function	Processing Function	Motor Function	Processing Function
Conventional prosthesis	0.5	0.3	0.9	1.09
Modified prosthesis	1	1.1	1.56	1.43

*Numbers represent computer-tabulated scores reflecting motor and processing function with regard to activities of daily living. The higher the number, the more functional the patient is at performing activities of daily living.

TABLE IV Miscellaneous Activities of Daily Living (ADLs) Comparison Testing of Patients When Using Conventional Prosthesis Versus Modified Prosthesis*

	Patient in Case 1		Patient in Case 2	
Miscellaneous Activities of Daily Living	Conventional	Modified	Conventional	Modified
Cutting meat with a knife and fork	90	11	37	23
Place 3 objects onto tray and then transport the tray	74	37	126	53
Place 3 1-lb (4.53-g) cans into a bag with handles	69	26	66	27
Open and close a jar of peanut butter	14	8	45	8
Stir a spatula in a big bowl	32	3	12	19
Open an envelope with a tool	21	17	90	19
Wrap a package	28	97	152	275
Pull on both socks	76	28	64	79
Remove and put on a long-sleeved shirt	236	94	59	15

*Numbers represent the amount of time (in seconds) required to perform each listed activity.

were also assessed and compared between the conventional and modified prosthesis (Table IV). The speed of performing most of these activities of daily living increased; many activities-of-daily-living tasks more than doubled in speed. Some tasks, such as wrapping a package, took more time with the modified prosthesis than with the conventional prosthesis. For the task of wrapping a package, it was noted that both patients did the task almost entirely one-handed during the conventional testing but tried to incorporate the use of the new prosthesis in the repeat testing; thus the four-input modified prosthesis essentially was slower in this task than if the patients used no device.

Most importantly, both the patient in Case 1 and the patient in Case 2 preferred the function of the modified prosthesis compared with the previous system. Each described an improvement in the smoothness of the prosthetic arm motion and a much more natural feel. They reported that they could operate the hand and elbow just by thinking about it. Both patients used the prostheses on a regular basis and would be considered relatively heavy users. The patient in Case 1 used his final myoelectric prosthesis for three to ten hours per day, usually for three to five days per week. He stated that the device was heavy and difficult to don, which prevented him from using it more. The patient in Case 2 used his prosthesis for three to six hours per day, usually for four to five days per week. The patient in Case 1 returned to work within three months of injury. The patient in Case 2 did not return to his previous employment and has litigation pending.

The patient in Case 3 had evidence of reinnervation of the medial head of the biceps through electromyographic measurements, but the signal was not strong enough to be isolated from the electromyographic signal of the lateral head of the biceps with current signal processing techniques. Therefore, testing could not be completed with the experimental prosthesis.

Discussion

These cases illustrate a new paradigm for the creation of a neural-machine interface for patients with amputations. Motor-control signals that are still contained within cut nerves and that previously had traveled to the distal extremity can be accessed through the process of targeted reinnervation. The requirements for targeted reinnervation include a healthy residual motor nerve and a nearby functionless muscle segment still under active cortical control. Many patients with amputations theoretically could undergo this nerve-transfer procedure. For now, we have limited targeted reinnervation to patients with shoulder disarticulations and to patients with long transhumeral amputations. These patients have limited prosthetic options due to the severity of their injuries, and so the risk-to-benefit ratio of experimental surgery for these patients is favorable. In this report for transhumeral amputees, the surgery was successful in two of three patients. Our two patients demonstrated the ability to simultaneously move the prosthetic elbow and the prosthetic hand, and to do so in a completely intuitive manner. Targeted reinnervation surgery resulted in marked improvements in function and improved satisfaction with the prosthesis. The two patients in whom the procedure was successful were able to learn to use the new prosthesis with minimal training. None of the three patients had loss of function after the procedure. The patient in Case 2 had a transient increase in phantom limb pain that subsided after a few months. If targeted reinnervation had failed, the patients would still have retained the ability to fire the lateral head of the biceps to operate a myoelectric prosthesis with conventional control paradigms.

A key element to the success of targeted reinnervation is that the target muscles are hyper-reinnervated by the transferred nerves. The median and radial nerves contain many times the number of motor neurons that normally innervate the medial head of the biceps or brachialis muscle. This greatly improves the odds that any given muscle fiber will be reinnervated[5]. The transferred nerve must still have viable axons, however, which we believe was the problem for our patient in Case 3.

Quantification of prosthetic limb function is difficult with more proximal amputations. The success of targeted reinnervation was quantified with objective measurable improvement in function with use of validated tests such as the box-and-block test and the AMPS test. Simultaneous control of multiple arm functions was evident and observed in testing and for many activities-of-daily-living tasks. The improvement in speed while performing tasks, as seen with use of the experimental prosthesis, is due to having intuitive, simultaneous control of the arm, as opposed to the contrived control and the need to switch between control inputs that were seen with use of the conventional prosthesis. The improvements were not a function of the prosthesis itself, as the same device was used for conventional control and targeted reinnervation control. The difference was the control paradigm for the prosthesis.

The one unsuccessful procedure can be attributed to several factors. In retrospect, we believe that the lack of healthy fascicles seen in the radial nerve, the loss of active musculocutaneous nerve function for three months after the surgery, and the high-energy nature of the injury suggest a more proximal brachial plexus injury in addition to the amputation. It is difficult to diagnose a brachial plexus injury in the absence of an arm, but perhaps we missed the clue of the early rotator cuff surgery, which suggests an avulsive injury pattern. Future patients with an avulsion injury will be evaluated with cervical magnetic resonance imaging to detect possible nerve-root avulsion. The patient in Case 3 was also the oldest patient in our study. Age is a known cause of incomplete nerve recovery after nerve repair[14].

The ideal patient for this procedure is young and has a history of a sharp amputation at the distal transhumeral level. The subcutaneous tissues should be supple and easy to dissect. Thin subcutaneous tissues will allow for easier detection of the electromyographic signals from the musculature. Tinel signs denoting the distal end of the amputated nerves should be apparent near the end of the skin closure rather than proximally in the axilla.

Adequate electromyographic detection of the new targeted muscle segments is paramount in directing simultaneous function in the prosthetic limb. A key factor to successful targeted reinnervation involves optimization of the electromyographic recording. Electromyographic signal amplitude decreases as the distance between the electrode and the muscle increases[15]. Therefore, the greater the amount of subcutaneous tissues overlying the muscle of interest, the more attenuated will be the electromyographic amplitude. By surgically removing the bulk of subcutaneous fat in a 5-cm square area over each new targeted muscle at the level of the subdermal plexus, the distance between the muscle and the electrode can be decreased, causing a considerable increase in electromyographic amplitudes. Any unwanted electromyographic signal from a muscle adjacent to the muscle of interest can create electromyographic cross talk, which interferes with operation. Removal of subcutaneous fat places the surface electrodes as close as possible to the target muscle, thus allowing more focal recording and minimizing cross talk. Another way to reduce cross talk and improve electromyographic signal quality is to spatially separate the muscles. The adipofascial flap used in the patient in Case 2 separated the two heads of the biceps and led to improved electromyographic signal separation as compared with the signal separation results seen in the patient in Case 1.

We learned from managing the patient in Case 2 that reinnervated muscle segments that are not secured distally may migrate within the socket, making signal acquisition difficult. This work stresses the importance of myodesis at the time of the original amputation, thus keeping the muscles located in the proper position along the humerus and not allowing them to retract proximally. Anticipation of reinnervated muscle contractions can allow for proper intraoperative interventions, such as tenotomy of muscle insertions or distal myoplasties to prevent unwanted retraction or muscle movement posterior to the deltoid muscle or into the axilla, where signal detection is difficult.

In the future, through a greater understanding of the distribution of motor axons within fascicular groups, it may be possible to further subdivide electromyographic signals elicited by the peripheral nerves by splitting the nerves longitudinally along the inner epineurium and separating these groups of fascicles between viable muscle segments[16]. There is also considerable potential for further improvement of prosthesis control by extracting more information from these rich electromyographic signals with use of advanced computer algorithms. Pattern recognition techniques have allowed us to accurately decipher several different hand and wrist movements in the laboratory for more control over dexterity. We hope that greater knowledge and acceptance of targeted reinnervation will eventually change the current standard practice of cutting nerves back as proximally as possible at the time of amputation, as this practice may eliminate the possibility of a later transfer procedure.

In conclusion, with use of targeted muscle reinnervation, two additional control signals were created for direction of a prosthetic arm in transhumeral amputees. These signals allowed for simultaneous, intuitive control of the prosthetic hand and elbow. After targeted reinnervation surgery, our patients needed only minimal training to attain marked improvements in function with this new ability. To our knowledge, these are the first transhumeral amputation patients able to move two prosthetic joints simultaneously with use of physiological, intuitive control.

Appendix

eA A side-by-side comparison video of the patient in Case 1 performing the so-called box-and-block test while wearing the conventional prosthesis (video on left) and the modified prosthesis (video on right) is available with the electronic versions of this article, on our web site at jbjs.

org (go to the article citation and click on "Supplementary Material"). ■

Kristina D. O'Shaughnessy, MD
Gregory A. Dumanian, MD
Robert D. Lipschutz, CP
Laura A. Miller, PhD, CP
Kathy Stubblefield, OTR
Todd A. Kuiken, MD, PhD
Division of Plastic Surgery, Department of Surgery, Feinberg School of Medicine, Northwestern University, 675 North St. Clair Street, 19th Floor Galter, Suite 250, Chicago, IL 60611.
E-mail address for G.A. Dumanian: gdumania@nmh.org

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