

Challenges to clinical deployment of upper limb neuroprostheses

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Abstract—The technology for functional neuromuscular stimulation (FNS) as a means of providing upper limb function to people with tetraplegia has been under development by three clinical research groups for almost two decades. This paper presents the current status of the clinical trials of three FNS systems: a noninvasive system built into a cosmetic forearm splint, a 30-channel percutaneous system, and an 8-channel implantable system. The complexity of FNS systems and the unique characteristics of the individuals to whom they are applied combine to create many clinical and technical challenges that must be addressed before the devices can be deployed. The emerging challenges to widespread clinical introduction of FNS systems for hand and arm function are identified and analyzed. In addition to the demands of designing and conducting the clinical trials to satisfy regulatory requirements, the lack of knowledge,

skepticism, and complacency on the part of potential FNS recipients, as well as of rehabilitation professionals, must be overcome through education and careful consideration of economic and societal factors in the design of clinical systems.

Key words: FES, FNS, neuroprosthesis, technology assessment, tetraplegia.

INTRODUCTION

Approximately 60 percent of all traumatic spinal cord injuries (SCI) lead to some degree of tetraplegia (1). This is the most common cause of bilateral upper limb (UE) paralysis (2). While SCI results in multiple impairments including loss of sexual, bowel, bladder, and motor function, people with tetraplegia set restoration of grasp and release as a priority (3). Common methods of providing these functions are use of adaptive equipment, training in compensatory hand patterns, tendon transfer surgery, and orthotic management. Combinations of treatments are developed for each individual according to the level of voluntary function and personal preferences (4).

In the past 20 years, technology for functional neuromuscular stimulation (FNS) has been developed by three major clinical research groups as an alternative means of providing UE function to people with

This material is based upon work supported by the Rehabilitation Research and Development Service, Department of Veterans Affairs, Washington, DC 20420, and the Cleveland FES Center.

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tetraplegia (5–7). After demonstration of clinical feasibility, each of these systems is now entering a period of multicenter trials or broad application within a national clinical center. The rate of delivery of FNS systems of all types has increased rapidly in recent years. In particular, the cumulative number of implantable UE neuroprostheses deployed as investigational devices as of May 1995 is represented in **Figure 1**.

The complexity of FNS systems and the unique characteristics of the individuals to whom they are applied combine to create many medical and engineering challenges that must be addressed before the systems can be distributed clinically. The principal investigators from the three research groups, along with investigators participating in the clinical trials of their devices, have joined in this paper to assess the state of UE neural prostheses and to identify the factors that limit more extensive clinical deployment. The goal is to communicate the unaddressed clinical and technical issues to basic researchers who can address them at their most fundamental levels.

The clinical issues relate to invasiveness, complexity of systems, functionality, residual sensation, intact proximal control, and the etiologies of UE paralysis. Some of these issues arise as FNS systems move from the laboratory, where they are studied under ideal conditions, to the real world. While efficacy can be demonstrated clearly in the laboratory, showing effectiveness in the home and workplace is often more difficult. This task is further complicated by the variety of age and lifestyle factors represented in patients with UE paralysis.

FNS technology in its current state of development can introduce problems of its own. It requires specially trained engineering and medical staffs to install and maintain. While efforts are constantly underway to increase reliability of system components, data on long-term reliability are not yet available. This, together with the level of invasiveness or the inconvenience of donning and doffing an FNS system, can lead some candidates to hesitate to take advantage of the technology. Furthermore, FNS systems have been developed primarily for individuals with midcervical injuries, eliminating many interested candidates whose UE functional limitations have not yet been addressed. For example, people with high tetraplegia (at spinal level C4 and above) have received some attention in the laboratory, but systems to increase their function have not progressed to the stage of clinical deployment; simple systems for powered tenodesis grip for individuals with

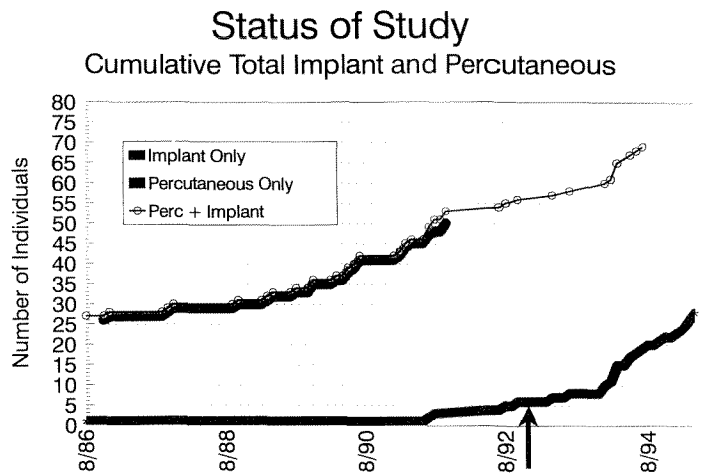


Figure 1.
Cumulative number of UE neuroprostheses in use.

lesions at C6 or lower have not been fully explored in deference to volitional tendon transfer surgery.

Candidates may not accept an FNS system because of poor cosmesis (e.g., the appearance of the external controllers or robotic quality of the stimulated motions); because they are complacent (they feel comfortable, safe, and happy with home and workplace adaptation, and with attendant care); because they may be waiting for the “cure” (and refuse any other intervention), or because they are afraid of the technology. Technophobia and complacency are also characteristics of many clinicians. Some see no need to change or improve the current standard of care and expend no time beyond their full clinical caseloads to learn new techniques. The developers of FNS systems must provide the appropriate educational experiences and materials to overcome technophobia and complacency in users and clinicians alike. The best methods to change these attitudes may be the successful demonstration of systems in the clinical environment, and the inclusion of users and clinicians in the design and development process.

Bringing about a change in the function of the hand is enormously challenging, given the complexity of the unimpaired system. Several deformities and disorders can be addressed with tendon transfers, electrical stimulation, or a combination of both methods. The anatomy of the surgically altered or FNS-driven hand may be fundamentally different from the system that existed before injury or before intervention. Using this new musculoskeletal system may require a change in the highly developed and sophisticated

control mechanisms that have evolved for optimal use of the normal hand. Hand function corresponds to a large area of cortex, suggesting that goals for motor prostheses and the strategies used to implement them may be limited to those within the compass of human-engineered systems. For example, when modified under surgical strategies that substitute muscles that are out of phase with the desired motions, the hand may be difficult or impossible to learn to use with the remaining neural circuitry.

Acceptance of FNS hand systems may depend largely on the degree of cognitive interaction they require. Users may find high levels of attention to their neuroprostheses an interference with social interaction. This may ultimately limit the usefulness of the systems, or lead to their abandonment. Feedback and sophisticated closed-loop control systems have the potential to improve performance of an FNS system, but in their current state are equally likely to encumber the patient and reduce use.

This paper describes three systems: a push-button operated, surface electrode system housed within a splint, a respiration-controlled percutaneous system, and an implanted system under control of voluntary muscles. The clinical and technical challenges addressed in the development of the systems, and the challenges remaining to their widespread use, are presented and discussed. A final section identifies issues related to the application of FNS that may be unique to children with SCI or cerebral palsy (CP).

NEUROPROSTHETIC SYSTEMS

A Hybrid Noninvasive System

A noninvasive UE neuroprosthesis has been under development at Ben Gurion University in Beer Sheva, Israel, to provide hand function to individuals with SCI, hemiplegia secondary to cerebrovascular accidents (CVA), or certain brain injuries that result in UE paralysis. All stimulation is delivered through surface electrodes, avoiding additional surgical procedures or implantation of electronic components. The challenges in developing an acceptable system of this type have primarily concerned issues of variability: 1) variability in the physical dimensions of the limb from patient to patient, 2) variability in positioning and repositioning the electrodes as the system is donned and doffed daily, and 3) variability in the stimulated responses of the underlying muscles.

One pair of surface electrodes over the finger and thumb flexors and a second pair over the extensors are sufficient to provide simple grasp and release movements in the laboratory. Such a system cannot be transferred to the home environment because of the time and expertise required to set up the system each day and the unpredictability of the grasp that results. The necessary expertise is found in only a small number of clinical laboratories throughout the world. In addition, the cosmetic appearance of such systems is generally unacceptable to potential users and detrimental to their self-image. The technical barriers to deployment of a surface stimulation system revolve around providing repeatable and cosmetically pleasing function with a simple system that is convenient to don and doff.

In a noninvasive system, mechanical splinting techniques are used to compensate for missing voluntary or stimulated muscle actions usually employed to stabilize the wrist. Partial or total denervation of certain muscles in the limb results in insufficient force generated to maintain the wrist in a functional position as the finger extensors or flexors are activated. Individuals with C5 level injuries generally exhibit a "deadband" of denervated muscles that usually encompasses the wrist extensors. In these people, stabilization of the wrist joint is achieved by an extension splint. Issues related to variability of electrode placement, cosmesis, and ease of donning and doffing were addressed by incorporating the stimulating electrodes into the splint itself. Recently, a company (NESS: Neuromuscular Electrical Stimulation Systems, Ltd., Raanana, Israel) was established to complete the development of a surface stimulation system based on this concept (**Figure 2**). Multicenter clinical trials of the system are now underway in the United States, Europe, and Israel.

The problems associated with electrode placement are central to the success of noninvasive technology. Difficulties increase with the complexity of the system as the number of stimulation channels increases. Several solutions to this problem have been developed, ranging from manually positioning electrodes according to simple skin landmarks, to a sophisticated automated process capable of positioning 12 bipolar surface electrodes over the hand and forearm in approximately 10 minutes. This is a computer-mediated procedure that automates the setup process and the calibration of threshold and saturation stimulation intensity levels for each channel. Users of the neuroprosthesis are able to set up and calibrate the system themselves in several minutes.

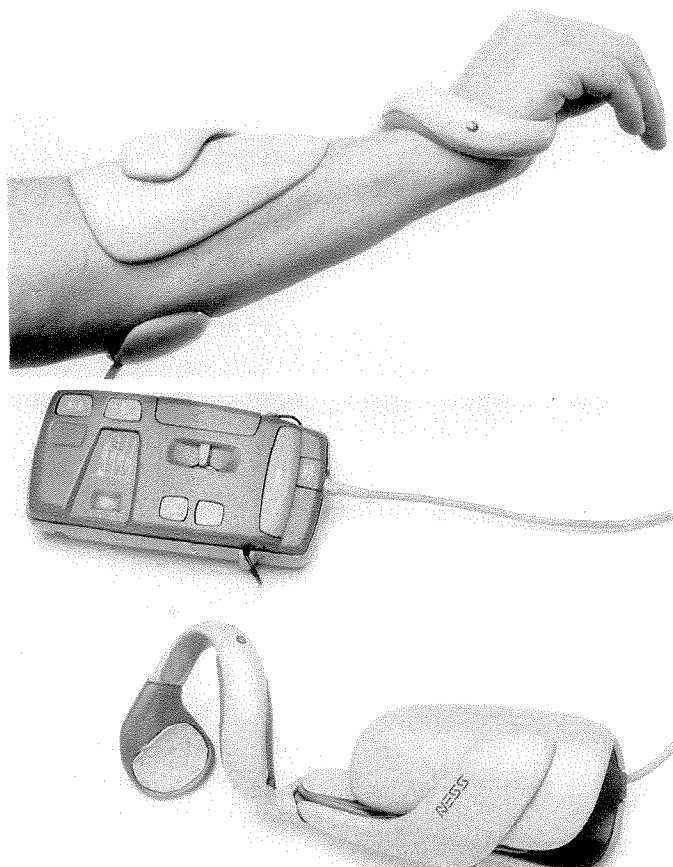


Figure 2. (Top) The "Handmaster" system is shown on a nonparalyzed limb. (Bottom) A noninvasive UE neuroprosthesis consists of an arm splint with built-in electrodes for surface stimulation, and a control unit. (Photo courtesy of NESS: Neuromuscular Electrical Stimulation Systems, Ltd., Raanana, Israel.)

Muscle responses to surface stimulation are particularly variable either because of the diversity in electrode placements possible as a system is donned, because of the relative movement between the electrode and muscle during limb movement, or because of changes in impedance of the electrode-skin interface. Careful design of the electrode system can minimize these variations. Criteria for identification of the motor points that emphasize robustness rather than high-gain placements can also lead to more stable systems. To avoid undesirable sensory effects of surface stimulation and to increase safety, a constant voltage stimulation was selected for unsupervised home use of the system. Since stimulating current decreases with increasing impedance, mistakes in setup or operation lead to lower

forces from the stimulated muscles, rather than pain or burns.

Time-dependent changes in neuromuscular physiology are important issues. Fatigue and spasticity in the electrically activated muscles of the individual with SCI or CVA can present problems, but they can be substantially reduced by conditioning the muscles with built-in therapeutic FES programs prior to using the system to perform activities of daily living (ADL). A wide range of ADL has been achieved using surface neuroprostheses: the Handmaster (Figure 2) for CVA, and for C5 and C6 quadriplegia; and the more complex system still under development for C4 quadriplegia.

The physical consequences of applying FNS to individuals with SCI or CVA remain to be investigated and understood thoroughly. Anecdotal reports indicate that one side effect of stimulation may be a therapeutic relaxation and improved range of motion.

A Percutaneous System in a Dedicated Clinical Center

In Japan, electrical stimulation via chronically indwelling percutaneous electrodes is being used both functionally for restoration of movement (functional electrical stimulation, or FES) and therapeutically to facilitate the return of volitional control or mediate the physical effects of paralysis (therapeutic electrical stimulation, or TES). The barriers to clinical deployment of this system addressed by its developers included: 1) the cost and availability of multichannel stimulators and percutaneous electrodes, 2) the establishment of a distribution system to apply FES and TES to patients as a clinical service, 3) the reliability of the percutaneous devices, and 4) the specification of customized patterns of stimulus intensities and timings to multiple muscles for complex movements involving the entire arm.

The availability and distribution of stimulation technology was provided by a unique partnership between civic, industrial, and medical communities. In 1991, the Japanese government, together with the University of Tohoku, established a clinic in the city of Sendai to focus exclusively on clinical applications of electrical stimulation. With government support, NEC corporation developed and produces programmable multichannel stimulation systems and electrodes. Their open-loop system, capable of delivering 30 channels of stimulation, is the technical platform for the clinical effort. The cost of the system is approximately \$10,000, including 15 electrodes, implantation, and associated

medical treatment. Of the 500 patients with SCI or CVA evaluated to date at the center, 115 received FES or TES systems. FES was administered to 23 patients and TES to the remaining 92, most of whom had CVA.

In a percutaneous system where leads may cross many tissue interfaces, especially the skin surface, electrodes are exposed to significant mechanical stresses. Reliability of these devices is essential for successful clinical application. The electrodes are of the Caldwell-Reswick type (8) and consist of a helical coil wound from a 19-strand stainless steel cable coated in Teflon® (Nippon Seisen Co. Ltd, Osaka, Japan). Each strand has a 25 micron surface of passivated SUS 316L hard wire, which is highly resistant to corrosion and breakage. The outermost diameter of the helically coiled electrode is 0.48 mm and the tip is deinsulated to allow current to flow to the tissue (**Figure 3**). Prior to implantation, the motor point of the muscle is identified electrically with a needle probe. A 21-gauge guide needle containing the electrode is introduced to the motor point along with the probe. When a desirable muscle contraction is obtained, the guide is withdrawn while a 20 Hz stimulus to the electrode is applied in order to provide pressure at the electrode tip. The electrode lead wire is subcutaneously passed to the electrode exit site at the desired point on the skin (**Figure 3**), using a tunnelling needle. One week after implantation, the electrodes are soldered to connectors, and stimulus parameters (thresholds and maximum stimulus voltages) are obtained for each muscle.

Electrode migration leading to failure in the desired muscle response occurred in about 2 percent of the electrodes within 2 weeks of implantation. An average of 1.3 percent of the electrodes broke within 6 months of implantation. Afterward, such mechanical failure was rarely observed. The remaining electrodes were functional throughout the FES or TES program. Maximum duration of use of the electrodes in an FES system by a volunteer with tetraplegia is almost 10 years, while the average duration of participation in the TES program approaches 2 years.

To control the position, speed, and power of upper limb joints, muscles must be activated with sophisticated stimulation patterns. EMG data collected with bipolar recording electrodes during stereotypical movements in nondisabled subjects are used to develop the stimulation patterns. Average EMG data during grasping motion include the activities of the wrist muscles as well as both the extrinsic and intrinsic finger muscles. Activities of the muscles around the shoulder have also

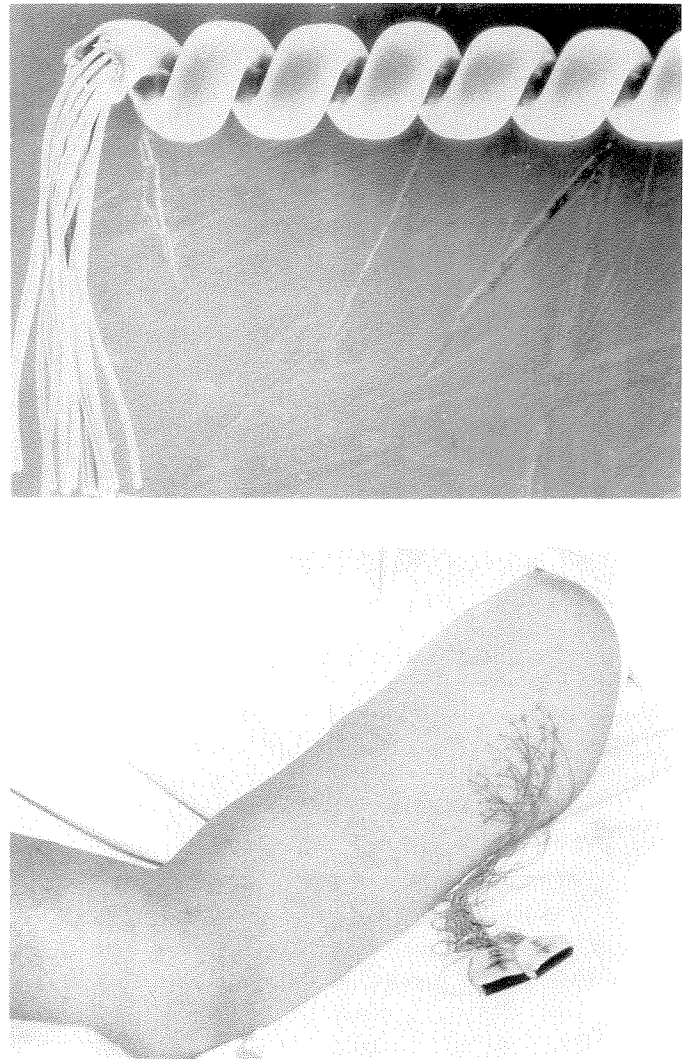


Figure 3.

(Top) The percutaneous electrode system used in Japan. The electrode lead is an insulated coil of fine multistranded wire and the stimulating end is deinsulated. (Bottom) Percutaneous leads emerge from the upper arm and are grouped on connectors.

been studied in order to define stimulation patterns for individuals with high tetraplegia or hemiplegia resulting from CVA. Based on these data, standard stimulation templates were created. Threshold and maximum voltages are determined individually for each muscle and combined with the stimulation templates to generate custom stimulation patterns automatically for each patient. These activation patterns are transferred to the multichannel portable system for later use.

This method has been used to coordinate intrinsic muscles such as the dorsal and palmar interosseus with the extrinsic muscles to extend the fingers and flex the

wrist simultaneously during release, and to flex the fingers and extend the wrist during object acquisition. In one patient with hemiplegia resulting from a stroke, this method was used to generate the appropriate stimulation template to control the hand, wrist, elbow, and shoulder simultaneously. Although he had intact sensation, the intramuscular stimulation resulted in no pain and afforded him enough proximal control to stabilize his arm in space.

Acceptance of the FES systems is due in part to an attempt to provide custom movements for very specific tasks that are important to the patients, rather than similar functions across all patients. For example, the patient with hemiplegia mentioned above was a sign painter before his CVA. FES provided him the ability to flex the elbow, while abducting and flexing the shoulder. Assuming this posture allowed him to stabilize his body against a wall or easel, freeing his uninvolved limb to paint. Other user-specific motions include a grasp to hold the joystick input to a motorized wheelchair, extending the index finger while flexing the other digits in order to use a computer keyboard, or holding a razor to shave. Command and control mechanisms are also customized for the individual. Control usually consists of voluntary switch closures. The sequence or duration of switch closures can select a motion or control its duration or velocity. For example, in systems for people with C4 level injuries, the duration of inspiration or expiration on a sip/puff switch controls the duration of the stimulation, allowing the individual to assume intermediate finger or elbow positions, rather than executing a preprogrammed motion to completion.

Paralysis can cause muscle atrophy, spasticity, and bone atrophy, as well as joint contracture, ossification, or subluxation. Electrical stimulation has therapeutic effects stemming from the activation of efferent and afferent pathways in patients with SCI and CVA that remain to be fully quantified. Efferent stimulation can result in strengthening and a reduction of atrophy within 2–3 months of application. Afferent stimulation can reduce spasticity by reciprocal inhibition of activity of antagonists. In Japan, FES has been used exclusively to provide functional movement of completely paralytic or seriously paretic extremities, while TES has been applied to more patients with moderate or mild dysfunctions in order to facilitate improvement. However, since FES and TES offer similar therapeutic effects, FES is often preferred by patients with paresis. The improvements in ADL through FES lead to increased motivation

toward all therapy, and the effects accompanying TES allow for further improvement in voluntary activities. In Japan, this combined effect is referred to as “Therapeutic FES.” FES and TES have targeted primarily motor paralysis and paresis following SCI and CVA, although they may be effective in other upper motor neuron disorders as well. It is expected that as the application potential becomes wider, the demand for FES and TES in clinical rehabilitation will increase and the impediments to deployment will be removed.

Implantable Systems With Surgical Enhancements

Case Western Reserve University (CWRU) has concentrated on resolving the issues related to clinical implementation of UE FNS systems by combining the technology with already proven clinical interventions such as tendon transfer surgery. Finding ways for FNS and surgical management to work in concert acknowledges a basic fact of clinical life: a paralyzed or paretic hand is always different from a normal extremity, that is, the “optimal” candidate for FNS does not exist. Individuals with upper motor neuron (UMN) lesions who present with supple, mobile hands without deformities and with a complete set of muscles that are innervated and respond well to stimulation are extremely rare. Individuals with C5 and C6 level injuries often exhibit lower motor neuron (LMN) damage resulting in a band of muscles that are unresponsive to stimulation, making alternative strategies to the isolated application of FNS necessary (9,10). Anatomic variations other than denervation patterns include contractures and scarring that frequently develop after injury or neurological insult. Any surgical or rehabilitation team that sets out to work with patients with cervical level SCI has to have a variety of techniques at its disposal.

The issues related to clinical implementation of upper limb FNS systems addressed by the group at CWRU include: 1) definition of surgical procedures to optimize or augment the efficacy of FNS, 2) establishment of patient selection criteria and implementation procedures for FNS systems, 3) development of implantable technology to obviate problems related to irreproducibility of surface responses or skin reactions to percutaneous interfaces, 4) identification of sources of complications, and 5) formulation of appropriate objective outcome measures.

Recently, emphasis has been placed on evaluating the first generation of implantable stimulators and electrodes controlled by a radio frequency link to an

external command processor. These systems reproduced the grasp patterns developed with percutaneous systems, but eliminated many of the drawbacks associated with the skin interface and external connections (11,12). Because stimulation alone was inadequate to address the needs of all patients with C5 or C6 level injuries in the percutaneous study, surgical options were incorporated into the clinical trials of the implantable system and deployed to collaborating centers along with FNS technology (13). The intermediate goal of surgery is to bring each individual to the highest functional level before adding FNS, providing each volunteer with a clinical benefit of participating in the study even if he or she eventually rejects the FNS system. Additional benefits of surgery are that it can compensate for denervation of prime movers by substituting another paralyzed but excitable muscle and then power it with FNS. Arthrodeses can help stabilize joints, and other procedures can improve the tenodesis action inherent in the C5–C6 hand by cross-connecting tendons to generate uniform movement of the digits. These procedures limit the degrees of freedom that need to be controlled and minimize the number of stimulating channels that need to be implanted.

The principal selection criteria for subjects to receive the implantable system are medical and neurological stability, which usually implies waiting 12 months from the time of original SCI. There are advantages to involving patients as soon after injury as possible, before contractures develop or they accept their current level of impairment as a way of life. Good sitting balance, voluntary proximal shoulder control, and an acceptable level of pharmacologically controlled spasticity are also required. Inclusion criteria and an algorithm for implementing FNS in conjunction with tendon transfers are summarized in **Figure 4**.

The implantable components of the system consist of a stimulator/receiver, eight leads with in-line connectors, and epimysial electrodes. Externally, a transmitting coil is taped to the skin above the stimulator/receiver, and a shoulder position transducer is attached to the contralateral shoulder each day (**Figure 5**). The amount of finger opening or closing is proportional to the contralateral shoulder position. The external components are cabled to a microprocessor-based controller that is carried behind the wheelchair. Locating the stimulator/receiver on the chest wall in a pacemaker position situates the in-line connectors in the upper arm. Seven epimysial electrodes are sutured to the motor points of the target muscles, while the eighth is placed

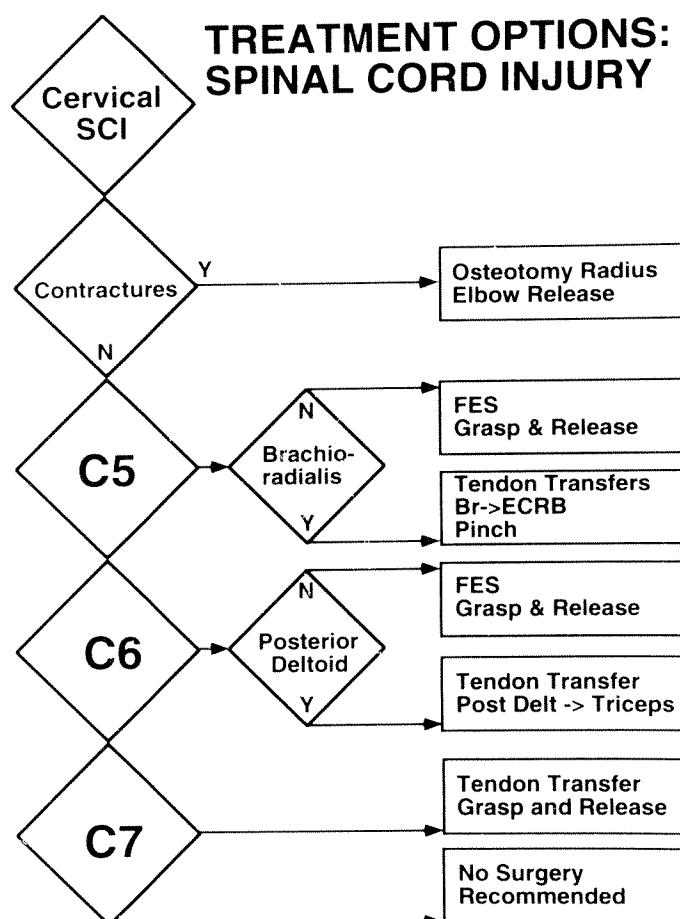


Figure 4. Flow chart of treatment options for cervical level spinal cord injury.

in a sensate area to provide feedback to the user about the state of the system. Leads are passed to the connector site in the upper arm. This design effectively separates the stimulator/receiver from the peripheral components and allows any part of the system to be replaced or upgraded without disturbing the others. Implementation of system takes 12 weeks (**Figure 6**), providing there are no complications.

The stimulation provides two prehension patterns. Palmar prehension involves touching the thumb in full extension and abduction against flexed fingers in order to contain large objects. Lateral prehension uses the thumb in flexion and neutral position (between abduction and adduction) against the flat aspect of the index finger, with the remaining fingers flexed behind it to stabilize it. This pattern accounts for 60–70 percent of the ADL activities of users of the system and provides the ability to grasp small objects and apply large forces with both the adductor muscle and flexor pollicis

FES System Components

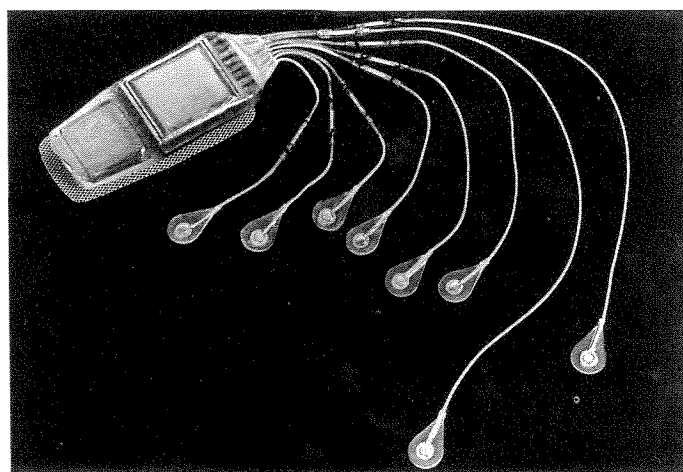
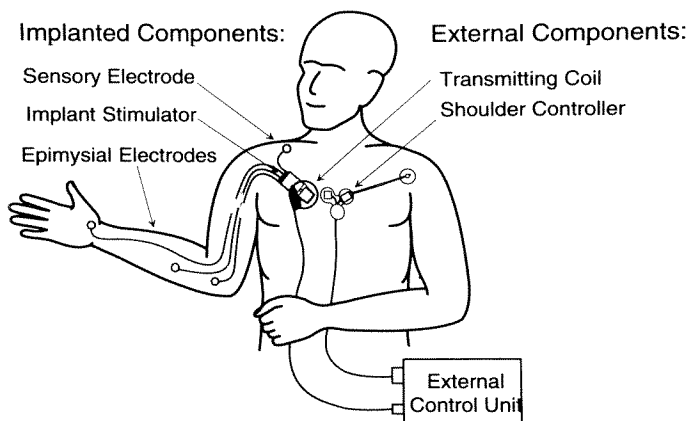


Figure 5. (Top) Schematic drawing of implantable CWRU/VA upper extremity neuroprosthesis. (Bottom) Internal components of the CWRU/VA system, including epimysial electrodes, in-line connectors, and implantable receiver-stimulator.

longus. The main advantage of FNS in this instance is the production of greater pinch force than with any of the tendon transfers available. With FNS, individuals can typically achieve grasp forces of 10 Newtons in lateral prehension and 5 Newtons in palmar prehension; with tenodesis action alone, grasp forces are generally less than 1 Newton.

The implantable system will remain clinically unproven until it is deployed in several centers with uniform results and acceptance. Because it is as important to train surgical, rehabilitation, and therapy teams as it is to develop good hardware and software, researchers at CWRU have standardized application procedures and established educational programs for

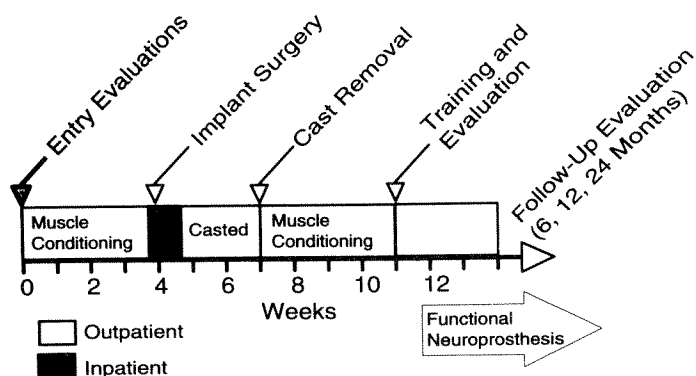


Figure 6. Implementation timeline for CWRU/VA UE neuroprosthesis.

satellite centers. Twenty-four surgeons have been qualified to screen, implant, and follow patients according to these protocols. A user-friendly programming system intended for the clinical environment without engineering support was also implemented. As a result of the efforts of the Cleveland FES Center, a private corporation (Neural Control Corporation, Cleveland, OH) was recently established to conduct the controlled multicenter clinical trials of the CWRU/VA system incorporating these elements.

In the multicenter trials currently underway, outcome measures are applied to quantify the ability to handle objects and the level of independence in ADLs with and without the system. Measures of quality of life are applied before and after installation of the system, and the outcomes will be extremely important for assessing its benefits. The device is intended for daily use. Reasons for not using the system have been lack of attendant support, proximal muscle weakness or contracture around the shoulder, or shoulder pain.

The possible medical complications are significant. While they have not presented themselves to date, the potential exists for a rate of infection as high as 20 percent, device failure in receiver or leads, evidence of rejection, tissue breakdown, fibrosis and scarring, and electrical safety issues (especially with a chest implanted device). Some surgical complications cannot be avoided; they are inherent in the nature of all surgery. Adhesion, muscle imbalance, and potential of iatrogenic nerve damage during exploration all have specific incidences. They will occur with implantable FNS systems regardless of the measures taken to minimize them. Other complications will be specific to the interface and include: lead breakage, changes in recruit-

ment properties or stimulated responses, localized infection at electrode, tissue erosion at a lead, or failure of encapsulation at the implant site. These complications may require further surgical interventions to rectify and should be anticipated.

The challenges that remain to implementing FNS clinically include 1) reducing the risk and minimizing the severity of surgical complications, 2) refining the design of the electrode to increase selectivity and ease of implantation, 3) providing additional channels of stimulation to reduce reliance on surgeries and allow control of more muscles, and 4) validating outcome criteria in order to determine the performance of the system quantitatively and in terms that are meaningful to clinicians and reimbursement agencies.

Pediatric Applications of UE FNS Technology

Children under the age of 15 may represent as much as 10 percent of all people with SCI in the United States, and teenagers are a group particularly at risk for injury (14). While many issues related to the application of FNS are common to all users (reliability, command input, and so forth), several factors are unique to the pediatric and adolescent populations. Researchers at the Philadelphia Unit of Shriners Hospitals for Crippled Children (SHCC) have been investigating UE applications of FNS in children with SCI and other neurologic impairments since 1989 and have participated in multicenter clinical trials of both percutaneous and implantable hand grasp systems. The challenges to clinical implementation of FNS technology in a pediatric setting include: 1) psychosocial issues related to home and school environments, 2) a lack of age-specific outcome measures, 3) reliable percutaneous electrodes and acceptable skin interfaces, 4) surgical techniques that minimize scarring and implant technology that accommodates growth, and 5) specialized control strategies to deal with primitive reflexes and other issues associated with dysfunctions more prevalent in children than SCI, such as CP.

At the present time, FNS technology is best suited to the needs of skeletally mature adolescents and young adults with SCI at the C5 and weak C6 levels. As part of a multicenter study with CWRU, percutaneous systems providing palmar and lateral grasps were placed in five adolescents with complete midcervical injuries at SHCC. Good grasp and release function was obtained in the laboratory, but the major barriers to daily use were attributable to the nature of the home and school environments (4). In several instances, having family

members attend to self-care needs was easier than using the system, while in others, personal assistance for basic support of the FNS system, such as donning and doffing the external components, was unavailable. Occasionally patients were unable or unwilling to use the systems at school due to restrictions imposed by school officials or their own self-consciousness.

Support in the school environment varied greatly among institutions; teachers and school officials were generally unfamiliar with SCI and uncomfortable around students with disabilities whether or not they were FNS users. Such difficulties were often compounded by introducing FNS at a time when families and users were dealing with issues related to adolescence in addition to an acquired disability. The psychosocial aspects of disability, adolescence, and assistive technology are critical areas for psychology, social service, and rehabilitation professionals to address if FNS is to be a viable option for young people.

Patients with C6 to C8 SCI are best served by tendon transfer surgery, with the possible exception of young children. Parents of pre-school and school age children may prefer FNS to surgery which can be perceived as irreversible and represents a complete and total acceptance of their child's disability. The efficacy and effectiveness of both surgery and FNS remain to be determined in children who are still growing. In this segment of the population, percutaneous systems may serve as valuable bridges until surgery or implantable FNS systems are strongly indicated or desired. Children with high tetraplegia may benefit most from FNS in the future. Many technical issues dealing with command and control input and stabilization of the proximal joints need to be addressed before practical systems can be delivered that minimize bracing or surgical reconstruction. Regardless of the target population, FNS systems will not be widely deployed until quantitative, reliable, specific, and sensitive outcome measures are applied in well controlled studies that prove their effectiveness. Age-specific assessments of need, opportunity, ability, and usage must be defined, or tests developed for the adult population need to be adapted and validated for children. This is a key issue critical to the success of FNS as applied to any age group.

In spite of the rapid advancement and obvious advantages of implantable technology, percutaneous systems will continue to play an important role in pediatric applications in the near future. They will be useful for therapeutic interventions, for temporary trials before installation of implantable systems, in acute

situations to prevent atrophy, or as alternatives to permanent procedures. However, the reliability of percutaneous electrodes in a pediatric population does not reflect the experience reported by the Japanese in adults (15). The devices exhibit a high rate of movement and breakage, which may be due to reasons that range from the activity level of the age group to the as yet unquantified effects of growth. While the skin interface does not become infected, there is often drainage that frequently requires the use of antibiotics. When percutaneous electrodes are removed, they are rarely extracted completely. The fragments remaining in the body can lead to sterile inflammatory granulomas. The engineering problems that need to be addressed to improve percutaneous electrodes include designing a smaller skin interface, minimizing breakage and movement, and avoiding lead fragments remaining in the body.

Implantable systems present other challenges. Body image and appearances are extremely important to teenagers, so new hardware or surgical techniques need to be developed to minimize the scars associated with implantable technologies. Location of the implant on the chest wall is especially undesirable for young girls who feel the need to dress in a manner acceptable to their peers: this often exposes the current implant site. Implantable leads currently available are of a fixed length, limiting their application to teens and young adults who are skeletally mature. Designing implantable systems appropriate for children is a significant technical undertaking. Basic studies regarding the stability of the motor point as a limb grows are needed to ensure that an electrode implanted in a child will remain effective as he or she grows to maturity. Leads which cross the shoulder and elbow will also need to accommodate up to 18 cm of growth if they are to be implanted without revision in the average 8-year-old boy. Finally, the physical sizes of the implants and external controllers need to be reduced for the pediatric patient.

Up to 98 percent of children with SCI will develop scoliosis. Two-thirds will develop a deformity severe enough to require surgery (16). Some of these can be controlled or prevented with a brace (thoracic-lumbar-sacral orthosis, or TLSO), which can also enhance the workspace by stabilizing the trunk. However, the TLSO may interfere with full movement of the limb or the mounting of transducers for command inputs to control the stimulation. Modifying command and control strategies to take such issues into account poses challenges to the technical and clinical members of the rehabilitation team working with FNS.

FNS may find its widest impact in children with CP, which is much more common than cervical level SCI in the pediatric population. Assisting motor function, preventing deformities, or modifying spasticity are potential applications of FNS that should be thoroughly investigated since they may have far-reaching advantages for these individuals. Children with hemiplegia who enjoy the use of one good limb may not benefit from the technology as much as those with spastic quadriplegia. However, spastic quadriplegia is frequently associated with sensory and cognitive deficits that present significant barriers to system implementation and use. Another subgroup within the CP population are children with athetosis, a condition in which there is a constant succession of slow, writhing, involuntary movements of the extremities. By mechanisms still poorly understood, stabilizing the proximal joints tends to afford these individuals better distal control. Children with either spastic or athetoid CP may develop considerable deformities if their limbs are not stretched or splinted consistently. The ability of FNS to address these issues should be a priority for further investigation.

Control of stimulation is a particular concern in pediatric applications of FNS, especially in children with CP. Damage to the cerebral cortex removes the natural inhibition of several obligatory primitive reflexes, such as the tonic neck, labyrinthine, and startle reflexes, which interfere with voluntary or stimulated movement. New command and control mechanisms need to be developed to compensate for these reflexes.

CONCLUSIONS

There are many recognized barriers to implementation of any new assistive technology. FNS systems are subject to the same forces as other assistive devices and should be held to the same standards as other medical technologies. Their eventual deployment in the clinical environment, prescription by rehabilitation professionals, and acceptance by consumers will depend on how well they address the challenges already acknowledged and met by devices in the medical market. Given the rapid rate of advancement in the electronics and material sciences, the largest challenges to the clinical deployment of UE FNS systems will lie in areas marked by the intersection of technology and biology. Societal, psychological, and economic issues will play increas-

ingly important roles in the success or failure of FNS in the upper limbs.

FNS systems are specialized examples of assistive technology. As such, they are subject to the same factors that influence the use and abandonment of other devices intended to augment the function of people with disabilities. Understanding the needs (17) and attitudes of the potential users of a technology and the psychological issues underlying their readiness to accept technical options is a prerequisite to the deployment of FNS systems, as it is for any assistive device (18).

Technical issues such as size, power consumption, ease of application, and reliability have already received considerable attention. However, even the smallest and most reliable systems require skilled surgeons to implant them, and the most sophisticated command and control schemes need a rehabilitation team trained in FNS to implement them in such a way as to best meet the needs of the individual. Developers of FNS systems need to be proactive in creating educational opportunities for medical professionals and rehabilitationists if widespread dissemination of the technology is to be successful. Whenever possible, prospective consumers should be included in the design process (19). Ultimately the cost of the systems, access to adequate training, and the extent to which systems meet the needs and expectations of their users will be among the critical determinants of the extent of clinical deployment.

Priorities and tasks will vary with the specific patient population and goals of the clinical application. For example, multijoint coordination and modification of spasticity or reflex patterns may be the most important obstacles to the development of useful FNS systems for individuals with high tetraplegia or CP, respectively. Other barriers, less technical in nature, will be common for all patient populations once FNS systems approach the stage of clinical deployment. The challenges currently facing the medical community for widespread dissemination of upper limb FNS are:

1. Overcoming inertia and complacency in patients and professionals satisfied with the current standard of care
2. Cultivating realistic sets of expectations of the technology and its alternatives in individuals waiting for "cures"
3. Dealing with skepticism rooted in earlier disappointments with other assistive devices or earlier attempts at applying FNS

4. Optimizing patient selection criteria and timing of intervention
5. Ensuring adequate personal assistance and social support to facilitate system use, as well as selecting potential users who are psychologically ready to accept assistive technology
6. Integrating FNS into educational curricula or training programs to certify healthcare professionals in its application
7. Identifying the risk/benefit ratio for specific patient populations
8. Performing well-controlled clinical outcome studies with sensitive and reliable measures designed to establish safety, efficacy, effectiveness, and value
9. Adapting command and control and implementation strategies without compromising the validity of clinical trials
10. Providing access to experimental technologies in clinical environments, and equal access to proven FNS systems in managed-care environments
11. Fulfilling the requirements of regulatory and reimbursing agencies.

Technologies or treatments competing with FNS, including neural regeneration surgery, drugs or cultured cell lines, acute interventions, and advances in traditional prosthetics and orthotics, will provide additional pressures. Participation by users currently involved in the development of FNS in other prospective clinical studies may compromise the effective administration of FNS or confound the results of outcome studies employing the technology.

Finding solutions to these challenges may require a change in the way most FNS research is conducted. Multidisciplinary teams of engineers, clinicians, and consumers should be enlisted to bring their talents and unique perspectives to bear on these issues. Traditional rehabilitation team boundaries will need to be expanded to include professionals such as sociologists, psychologists, educators, economists, and policy analysts well versed in the assessment of healthcare technology, as well as prospective users themselves.

ACKNOWLEDGMENTS

This paper arose from presentations at the Engineering Foundation Conference "Neural Prostheses: Motor Systems IV" on July 23-28, 1994 in Mt.

Sterling, Ohio. The conference was supported by grants from the National Institutes of Health, the Whitaker Foundation, the Paralyzed Veterans of America Spinal Cord Research Foundation, the National Science Foundation Grant No. BES-9319988, the University of Miami and the Bakken Research Centre. The Public Health Service participated in the support of this meeting under grant #1R13 HD/N631603-01 from the National Institute of Child Health and Human Development of the National Center for Medical Rehabilitation and Research, and the National Institute of Neurological Disorders and Stroke.

Dr. Triolo's work is supported by the Research and Development Service of the Department of Veterans Affairs and the Cleveland FES Center.

Dr. Handa acknowledges the support of the Ministry of Education, Science, and Culture of Japan and the Japan Research and Development Corporation.

Dr. Keith acknowledges the support of the Department of Veterans Affairs Rehabilitation Research and Development Service and the NIH Neural Prosthesis Program.

Dr. Betz acknowledges the support of Shriners Hospital for Crippled Children research grant #15954.

Ms. Carroll acknowledges the support of the Government Employees Medical Research Fund, the Anne Cullen Trust, Connibere Bequest and the Austin Hospital Medical Research Foundation.

The authors wish to acknowledge the help of Dr. Kevin Kilgore, Mr. Ron Hart, and Dr. Gerald Herbison in the preparation of this manuscript, as well as the services of Ms. Jeanne Teeter of the Cleveland FES Center and Ms. Laura Polacek of the Rehabilitation Engineering Center at MetroHealth Medical Center.

REFERENCES

- Falconer DP. Tendon transfers about the shoulder and elbow in the spinal cord injured patient. *Hand Clin* 1988;4:211-21.
- Lamb DW. Upper limb surgery in tetraplegia. *J Hand Surg* 1989;14:143-4.
- Hanson RW, Franklin MR. Sexual loss in relation to other functional losses for spinal cord injured males. *Arch Phys Med Rehabil* 1976;57:291-3.
- Mulcahey MJ, Smith BT, Betz RR, Triolo RJ, Peckham PH. Functional neuromuscular stimulation: outcomes in young people with tetraplegia. *J Am Paraplegia Soc* 1994;17:20-35.
- Nathan RH, Ohry A. Upper limb functions regained in quadriplegia: a hybrid computerized neuromuscular stimulation system. *Arch Phys Med Rehabil* 1990;71:415-21.
- Hoshimiya N, Naita A, Yajima M, et al. A multichannel FES system for the restoration of motor function in high spinal cord injury patients: a respiration-controlled system for multijoint UE. *IEEE Trans Biomed Eng* 1989;36(7):752-60.
- Keith MW, Peckham PH, Thrope GB, Buckett JR, Stroh KC, Menger V. Functional neuromuscular stimulation neuroprostheses for the tetraplegic hand. *Clin Orthop* 1988;233:25-33.
- Handa Y, Hoshimiya N, Iguchi Y, Oda T. Development of percutaneous intramuscular electrode for multichannel FES system. *IEEE Trans Biomed Eng* 1989;36:705-10.
- Peckham PH, Mortimer JT, Marsolais EB. Upper and lower motor neuron lesions in the upper extremity muscles of tetraplegics. *Paraplegia* 1976;14:115-21.
- Triolo RJ, Betz RR, Gardner ER, Mulcahey MJ. Application of functional neuromuscular stimulation to children with spinal cord injuries: candidate selection for upper and lower extremity research applications. *Paraplegia* 1994;32:824-43.
- Peckham PH, Keith MW, Freehafer AA. Restoration of functional control by electrical stimulation in the upper extremity of the quadriplegic patient. *J Bone Joint Surg* 1988;70(A):144-8.
- Keith MW, Peckham PH, Thrope GB, et al. Implantable functional neuromuscular stimulation in the tetraplegic hand. *J Hand Surg* 1989;14(A):524-30.
- Keith MW, Kilgore KL, Peckham PH, Wuolle KS, Creasey G, Lemay M. Tendon transfers and functional electrical stimulation for restoration of hand function in spinal cord injury. *J Hand Surg*. In press.
- Stover SL, Fine PR, eds. *Spinal cord injury: the facts and figures*. Birmingham, AL: University of Alabama, 1986.
- Smith BT, Betz RR, Mulcahey MJ, Triolo RJ. Reliability of percutaneous intramuscular electrodes for upper extremity FNS in adolescents with C5 tetraplegia. *Arch Phys Med Rehabil* 1994;75:939-45.
- Dearolf WW, Bety RR, Vogel LC, Levin J, Clancy M, Steel H. Scoliosis in spinal cord-injured patients. *J Ped Orthop* 1990;10:214-8.
- Phillips B, Zhao H. Predictors of assistive technology abandonment. *Assist Technol* 1993;5:36-45.
- Scherer MJ, McKee BG. But will the assistive technology device be used? In: *Proceedings of the 12th Annual RESNA Conference; 1989 June 25-30; New Orleans, LA*. Washington, DC: RESNA Press: 356-7.
- Scherer MJ. What consumers say most influences their assistive and educational technology use. In: *Proceedings of RESNA International '92; 1992 June 6-11; Toronto, ON*. Washington, DC: RESNA Press: 136-8.