Current Status and Future Prospects for Upper and Lower Extremity Motor System Neuroprostheses

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■ **ABSTRACT**

This paper reviews the current state of the art and identifies the major challenges facing the future development and clinical application of neuroprostheses to provide limb movement. It gives insight into the current status of functional electrical stimulation (FES) for motor control, identifies problems, and proposes possible directions of development in cervical cord injury, thoracic spinal cord injury, and stroke. For upper extremity function, existing clinical applications are covered, major problems are identified, and possible future trends are highlighted. The discussion on lower extremity applications describes current and possible future solutions of the major impediments to the development of FES systems for individuals with paraplegia after spinal cord injury and surface and implantable setups for stroke survivors with hemiplegia. Particular attention is given to sensor issues and requirements for walking with FES after stroke. ■

KEY WORDS: functional electrical stimulation, functional neuromuscular stimulation, neuroprosthesis, paraplegia, tetraplegia, spinal cord injury, stroke.

Introduction

Neuromuscular stimulation for motion can be applied for therapeutic or functional purposes. The therapeutic uses include many clinical interventions from simple exercises for muscle conditioning through motor relearning. The current presentation is focused only on functional uses of electrical stimulation as a prosthesis or orthosis to replace or augment the function of the damaged neuromuscular system, that is, the application of electrical stimulation as a motor system neuroprosthesis.

In 1961, Liberson and his colleagues (1) reported the first clinical application of Functional Electrical Stimulation (FES). They restored the drop foot on the affected side of an individual with hemiplegia by stimulating the peroneal nerve. This is the starting point for all FES research in providing motion to a paralyzed extremity. During the past four decades, there has been much research, from basic science to clinical applications, building on this fundamental idea. Many other FES subsystems have also been developed, including electrodes, stimulators, sensors, control algorithms, man–machine interfaces, mechanical braces, and so on. The purpose of this paper is to summarize the present status of the field,

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to identify the major problems that remain to be solved, and to present future trends in the development of advanced motor control neuroprostheses.

UPPER EXTREMITY NEUROPROSTHESES

Summary of FES for Paralyzed Upper Extremity

FES for the paralyzed extremities in upper motor neuron disorders has rapidly developed in parallel with advances in computer technology. Restoration of motor function of the paralyzed upper extremities is particularly difficult due to the fact that individuals with tetraplegia exhibit total paralysis of the upper extremities as well as the trunk and lower extremities. Therefore, torso stability and residual voluntary function for controlling the FES stimulator are low.

In 1976, a FES workshop was held at Pomona, California. Based on this workshop, "Functional Electrical Stimulation: Applications in Neural Prostheses" was published the next year (2). At the time, there were a few clinical applications for the paralyzed upper extremities mentioned in this book. Vodovnik (3) reported hand opening in hemiplegia. Peckham (4) reported restoration of finger extension and flexion in high-level spinal cord injury. Both were reports of laboratory-based trials.

A quarter of a century has passed since then. Now there are several FES systems available around the world for clinical use at home and in the community. Peckham and his colleagues (5) have developed a motor system neuroprosthesis for the paralyzed hand of individuals with C5 and C6 tetraplegia. They designed and conducted the initial field testing of a totally implantable, eight-stimulus channel FES system known commercially as "FreeHand" (Neural Control Corp., Cleveland, OH) (6). Handa and Hoshimiya succeeded in controlling paralyzed elbow and hand movements in volunteers with C4 and C5 level injuries by using an EMG-based multichannel FES system (7). They produced a commercially available portable FES system with 30 stimulus outputs designed for use with percutaneous intramuscular electrodes (8). Nathan controlled the paralyzed upper extremity of individuals with C4 tetraplegia by using a 24-channel FES system with surface electrodes (9). He and his colleagues produced a sophisticated surface system known as "Handmaster" (NESS Ltd., Ra'anana, Israel) that included an integrated wrist extension orthosis for persons with C5 tetraplegia or hemiplegia (10). Prochazka and his colleagues also developed the surface stimulation system known as the "Bionic Glove" for individuals with C6 tetraplegia (11). There are also several other projects around the world that are aiming at development of FES systems for upper extremity function after spinal cord injury or stroke.

Current Clinical Issues

Clinical applications of FES for upper extremity function can be divided into two categories according to the nature of the upper motor neuron dysfunction: cervical cord injury (CCI) and stroke. Each etiology presents unique challenges to the neuroprosthesis designer and clinician.

The approach to applying FES after CCI is different depending on the level of injury. Individuals with C4 complete tetraplegia have the highest level CCI possible without being ventilator dependent and relying on a respirator for breathing. Only the function of the fourth cervical nerve and above are intact. Individuals with injuries at this level lose total function of the upper extremities, except for shoulder elevation. FES systems for this population must control the finger, thumb, wrist, elbow, and shoulder joints. Thirty channels of stimulation, the maximum number of outputs available in any existing system, may not be enough to control full and precise motion of all of these joints. In many cases, electrical stimulation fails to induce good contraction of the shoulder muscles, because associated peripheral innervating neurons were injured at the spinal cord or anterior root at the time of the original trauma. For the purpose of compensating for lost shoulder function, balanced forearm orthoses (BFO) or arm slings have been used with mixed results. Patients show little voluntary residual function, limited primarily to shoulder elevation, head movement, voice, and respiration. This greatly complicates the FES algorithms for controlling many joints with few command sources. The function of the entire upper extremity, from the posture of the proximal arm through reaching, hand opening, and grasping, have to be produced by FES. While several such trials on systems for high tetraplegia are taking place in laboratories around the world, FES systems

for independent home use have not been realized yet for this population.

Individuals with C5 tetraplegia can flex, extend, abduct the shoulder, and flex the elbow in addition to the function exhibited by people with C4 level injuries. They can use gravity to extend the elbow by externally rotating the arm while in the sitting position. These facts indicate that basic reaching ability is still intact. The target joints for FES therefore are the wrist, fingers, and thumb for grasp and release. Individuals with this functional level are good candidates for FES because many command sources are available and control algorithms can be quite simple. The surgical restoration of hand function in C5 tetraplegia is difficult because there are very few possible sources for tendon transfer. However, combination of FES and hand surgery is effective if the wrist extensors show no response to electrical stimulation.

FES control for C6 tetraplegia is much easier than for C4 and C5 level injuries. Patients have the ability to open the grasping hand by using dynamic tenodesis action. The main purpose of FES in persons with this level of function is to produce grasping power. However, many surgical alternatives exist to achieve the same ends and FES is perceived to be competitive to hand surgery. Many hand surgeons may contend that surgery alone provides sufficient function for individuals with C6 CCI. Certainly, present man–machine interfaces used with FES cannot provide the direct and rapid motion of the hand that surgery can produce. If more sophisticated and responsive man–machine interfaces, such as the electroencephalogram (EEG) control could be developed in the near future, many clinicians and consumers with lower level injuries might be more accepting of FES-based interventions (see Scott and Haugland contribution to this issue).

The FES approach to the hemiplegic hand is a different story. Stroke survivors with hemiplegia can perform virtually all activities of daily living (ADL) with the unaffected hand. The main purpose of conventional rehabilitation is switching hand function from the affected to the unaffected side. Present FES systems produce simple hand grasp or combined reaching-opening-grasping motions. In the latter case, shoulder, elbow, wrist, finger, and thumb joints have to be controlled by FES. Patients are forced to use their unaffected hand as a command input to the FES stimulator. However, persons with hemiplegia are eager to use both hands at the same time, if possible. If FES could produce a sophisticated man–machine interface for bilateral hand use, hemiplegia would become a major target of FES.

Major Problems Remaining to be Solved

While locomotion is an automatic movement, reaching, opening, and grasping are intentional movements. Requirements for motion planning and command inputs to control the motion are different. In other words, the man–machine interface for the upper extremity has to be designed for quick transfer of the user's will.

Upper extremity FES systems are more readily available throughout the world now than they have been at any time in the past. Consumers of neuroprostheses have access to several options for providing hand grasp. However, many individuals are not satisfied with their system interfaces. Consumers want to use FES systems in a natural manner to position their arms in space to where and when they want and to reproduce the hand grasp responsively and how they did prior to injury. Developing an improved man–machine interface might help realize these hopes. Direct translation from EEG to command control is one potential approach. It might also be necessary to restore sensory function such as position sense, touch, pressure, pain, temperature, and so on to make a major leap in the performance and acceptability of upper extremity neuroprostheses.

Restoration of the upper extremity function in C4 tetraplegia is still in laboratory trials. The technology for controlling each of the upper extremity joints has already been developed. The principal problem remaining is trajectory planning or the motion algorithm for controlling multiple joints at the same time with very few residual volitional command inputs.

Muscle fatigue, induced by reversed recruitment of electrical stimulation, is still a major problem. It is a common issue in every FES application. Fatigability of target muscles will be improved by daily electrical stimulation as an exercise. Grasping for writing or eating will be prolonged gradually. Intermittent rest during FES control is effective for supplying oxygen to stimulated muscles and also effective for washing out metabolic byproducts through blood circulation. Issues related to muscle fatigue may not

be as significant an impediment to the progress of FES for upper extremity applications as it appears to be for the lower extremity.

Future Trends of the Upper Extremity Neuroprostheses

There are three kinds of FES systems, categorized by the type of electrode: surface systems, percutaneous systems, and total implanted systems. All of these systems will exist in the near future.

The surface system is the most common and easiest to use. Commercially available systems are designed for C5 and C6 quadriplegia and hemiplegia. There is a possibility that surface systems specialized for each disorder may be developed. Percutaneous systems can produce fine hand movement in individuals with C4, C5, and C6 tetraplegia and still has value in research and clinical trials. The major trend in upper extremity neuroprostheses will be toward totally implantable systems because consumers are eager for it. They want to be free from the maintenance of percutaneous electrode interfaces and from attaching surface electrodes and the associated cabling. In addition, several new technologies such as the Bion microstimulator (Advanced Bionics, Sylmar, CA) are being developed that may eliminate the need for lead wires and can simplify implant surgery (12). Some hand surgeons speculate that such devices may be effective in the field of FES-related tendon transfer surgery. Partial or local use of microstimulators will enlarge the clinical application into various other disorders.

All of these FES systems require man–machine interfaces. Usually they need residual function to generate command inputs such as shoulder movements, voice, head tilting, EMG, and so on. They rely on indirect control commands to the stimulator. EEG may represent a good possibility for direct command input. However, at present, the relationship between EEG and intentional motion has not been clear. Further progress in the neuroscience and signal processing of the EEG is necessary. While EEG control may be a long-term goal, a short-term goal of man–machine interface would be improvement of the conventional techniques utilizing residual voluntary function.

Planning or motion algorithms for controlling multiple joint systems will become more sophisticated as closed-loop feedback with implantable sensors is introduced. In reaching tasks, the feedforward component contributes to fast movements of the arm, whereas visual feedback controls fine positioning. Feedback from implantable angle sensors or position sensors will make the reaching task with FES more precise. In the grasping task, the shape of the hand is controlled by visual feedback. Adequate grasping power will be obtained by a closed-loop feedback system with implanted pressure sensors. Information obtained from peripheral sensory nerves might also contribute a useful feedback signal.

The ultimate goals of developing advanced upper extremity neuroprostheses will not be achieved in the near future. However, progress of associated technologies will accelerate development of this field. Good collaborations among clinicians, researchers and system users is fundamental for the advancement of FES research.

LOWER EXTREMITY NEUROPROSTHESES

Motor Neuroprostheses for SCI

Numerous clinicians and researchers have invested their intellectual and financial resources to achieve advances in lower extremity applications of FES to restore or improve standing and walking abilities in adults with complete or partial thoracic spinal cord injury (SCI), head trauma, or stroke. The purpose of FES assistance in all these etiologies is not the same.

FES in complete SCI, by using complex approaches and devices, provides the limited functions of standing up, standing, sitting, simple walking, or cycling. At present, FES walking appears to be a promising form of exercise, like a sport activity, rather than an alternative to wheelchair locomotion. The principal functional goal of neuroprostheses in lower extremity hemiplegia is different. In ambulatory populations, FES can improve the general appearance, symmetry, energy efficiency, and safety of gait, while allowing users to navigate various surfaces including uneven surfaces, ramps, curves, and stairs.

The approaches and devices to assist in these populations vary from technically simple one-channel devices to complex multichannel microprocessor and computer-based devices. The early four-channel surface stimulation system for SCI lesions

introduced in the 1970s by Ljubljana researchers (13,14), was successfully transferred to clinical practice, implemented in various centers around the globe, lately brought back as the Parastep System (Sigmedics, Inc., Northfield, IL) and as such approved by the US Food and Drug Administration (15). The inherent limitation of this approach is the biomechanical role of the rectus femoris muscle as it is active during surface stimulation of the quadriceps muscle, and thus compromising standing stability by flexing the hip. Furthermore, each method of eliciting the swing phase of gait brings associated limitations. The flexion withdrawal reflex habituates gradually (13), is not always strong and repeatable, and can be jerky and inconsistent. The stimulation of the mixed peroneal nerve triggers simultaneous hip and knee flexor muscle responses, and ankle dorsiflexion. Surface stimulation of the calf muscles results in efferently provoked ankle plantar flexion and knee flexion, and also afferently elicited flexion withdrawal response (16), which is probably why this second technique is not widely used. As the third method, and least known approach, the swing phase of walking can be efficiently influenced also through cutaneous stimulation of selected (L-3,4) dermatomes (17).

These stimulation systems are in general simple, but need some kind of technological innovation to be practical, such as the electrode trousers made for cosmonauts by the Vienna group (18). Fatigue remains a major limiting concern. Changing the posture and thus using various active muscle groups can increase endurance. However, a limited number of candidates can benefit from this approach, and today there are probably few if any individuals with SCI practicing posture switching. Furthermore, the closed loop control of knee extensors can provide a minimal, but adequate level of stimulation of the knee (19). Current sensors to detect knee joint buckling, including strain gauge or potentiometer angle acquisition, are definitely suitable for therapeutic use, but less suitable for everyday home application. Current technology brings advanced hardware, which can incorporate complex algorithms and produce online adjustment of stimulus parameters. Speaking only about one-channel stimulation on the quadriceps muscle, there are still unused choices of parameters (amplitude, width, and frequency) for real-time adaptation to recruit muscle in a more physiologic manner.

One possible strategy for dealing with rapid fatigue is also the hybrid system [for example, reciprocating gait orthosis (20)]. Such passive mechanical hip-knee-ankle-foot orthoses in combination with FES are not easy to don and doff, but when fitted offer prolonged standing, as well as stepping, with minimal effort (21).

All the systems mentioned so far are noninvasive, so there is minimal medical risk to the applicant and users can change their minds about using the system without inconvenience. From a technical point of view, they are fairly simple, and the skilled physiotherapist can become familiar with the basics of these techniques in a reasonable time. These methods bring indispensable therapeutic as well as limited ambulatory value. Although it would be nice to see a demonstration of current microstimulator technology in this application (12), the quadriceps muscle area and mass probably prevent such a solution.

Further, there have been in the past an admirably large financial and scientific investment into percutaneous systems in the US (22) and Japan (23,24). These sophisticated systems have allowed individuals with paraplegia to advance with a walker at nearly normal walking speeds (0.7 m/s). However, this excellent achievement has not yet extended beyond laboratory demonstration. Installing and maintaining systems consisting of a large number of percutaneous intramuscular electrodes becomes impractical or impossible in the clinical or even the home setting. It is also not surprising that stability of the highly nonlinear double or triple inverted pendulum of the body, or automatic postural corrections, cannot be provided satisfactorily even with such systems. From the chronic implantation point of view, completely implantable stimulation would be much more desirable. However, the inherent complexity of total implant and internal wiring is not decreased if compared to a percutaneous system, although the apparent complexity perceived by the user is greatly reduced. From a statistical point of view, as the number of elements in the system increases to achieve more and more clinical functions, the risk of system failure also increases in the absence of redundancy or other safeguards. Even large systems do not necessarily imply redundancy, which might be an advantage in the case of partial system failure. With the introduction of implanted sensors and processing of EMG, the reliability of the system

may be further eroded. Further, the Signal-to-Noise (S/N) ratio of these sensors is not always good enough to enable automatic closed loop control, limiting the control approach to a small number of discrete states. In our opinion, the functional outcome currently achieved by fully implanted lower extremity systems for thoracic level injuries is relatively low compared to the investment and the risk involved.

The next emerging and so far insufficiently exploited approach is via lumbar anterior-root electrical stimulation (25). Several highlights and drawbacks are inherent in this approach. Successful application of sacral root stimulators for bladder control and the knowledge obtained in that application made this technology interesting also for a neuroprosthesis to control lower extremity motion. The motor control requires very few connections compared to direct nerve or muscle stimulation. The inherent disadvantage is that, due to the anatomy of muscle innervation from the spinal roots, there is inevitably present muscle coactivation, as excitation is spread simultaneously among several axons. Some selective actions can be obtained by very careful choice of stimulus intensity parameters. In this way, standing, cycling, and short distance walking has been demonstrated (25). The Praxis24 system (Cochlear, Inc., Lane Cove, NSW, Australia) (26) for multimodal restoration merges stimulation of bladder and individual nerves or branches for muscle contractions and limb movements. The logical next step involves the stimulation for motion and bladder via sacral roots. Concerns involve low selectivity of activation and in the surgical field placement of electrodes at lumbar laminectomy.

Motor Neuroprostheses for Hemiplegia

In the population with partial lower motor neuron motion disorder following stroke, multiple sclerosis, cerebral palsy, or head injury, a number of gait deficits can be efficiently corrected with FES. Due to its high numbers, the hemiplegic population deserves special attention. Sufficient muscle function must still be intact to enable the subject to stand and walk. Ten to twenty percent of stroke survivors after a period of physiotherapy show drop foot and inability to dorsiflex the foot during the swing phase of gait, loss of normal knee flexion, inability to push off, or spasticity of the calf muscles (27).

Evolution of stimulation for hemiplegia started with hard-wired, single-channel, surface electrode-based drop foot stimulators, followed by multichannel, implanted, and microprocessor-based implanted devices. At present, even the simplest single-channel devices incorporate several clinically useful features such as triggering via a heel-switch worn on either paretic or nonparetic side, stimulation delay, or ramp up and ramp down time adjustment (28). Ramping can be very important to subjects with calf spasticity. Foot or hand switches, stimulator, and electrodes are most frequently all connected with wires.

Hard-wired surface drop foot stimulators with two or more channels (29) have proven to be suitable for the first phase of treatment, while they might be replaced with single or dual-channel devices for home use (30–32). Permanent daily home use of multiple surface electrodes is not efficient due to difficulties with electrode placement (33). Such FES systems are practical during evaluation prior to the use of implanted devices.

Individuals with hemiplegia exhibit preserved sensation, which usually results in discomfort with surface electrode stimulation. There are also difficulties experienced by subjects in correctly placing the stimulation electrodes, poor reproducibility of muscle contraction, limited accessibility to deep muscles, and poor muscle selectivity. For long-term drop foot correction, implanted stimulation eliminates the difficulties associated with the placement of the electrodes. The early implants, 20 years ago (34), had problems with reliability and material biocompatibility, as well as with a relatively complex surgical procedure for the implantation of the device. Two incisions were made, one on medial apex of the thigh for receiver implantation, and another on the lateral leg below the knee to expose the common peroneal nerve (34). Today, better materials incorporating smaller and more compact implant assemblies carrying the receiver circuit and metal fixation loops (electrodes) simplify the required surgical procedure (35).

Groups in Ljubljana (36,37), Enschede (38), and Aalborg (39) have developed new models of implantable devices based on a microcontroller core. The devices in general do not use a processor in the implant circuitry itself, but rather in the external and programmer module (40,41). The fact that a minimal set of two channels is needed to have a

chance of independent postsurgery dorsiflexion and eversion balancing seems to be accepted by all these designs (36). This exceeds limitations encountered with one-channel foot drop implant showing frequently excessive inversion or eversion. The problem arises from initial incorrect positioning or subsequent movement of electrodes relative to the branch of the common peroneal nerve (42).

Furthermore, in another later design, the nerve cuff electrode was fitted to a common peroneal nerve above the knee, eliminating implanted wire leads crossing the joints and thus increasing reliability (39). Due to activation redundancy in the nerve above the knee, a 12-polar cuff is required to provide sufficient selectivity among dorsiflexors and everters, and dorsiflexors and inverters.

Sensors for Hemiplegic Gait

The characteristics of sensors for detecting walking phases and their reliability is a continuing nagging problem in all foot drop stimulation systems. Sensors for applications after stroke have been investigated much more in detail than sensors for application after paraplegia or tetraplegia (43).

Original mechanical on-off switches carry problems due to deformation or sticking of contacts and breakage of solder joints. Force sensitive resistors (FSR) are also prone to solder joint breakage in addition to resistance change with age and use. The stimulator electronics can track and minimize these drawbacks. Even the best contact sensor is not suitable for implantation, calling for alternative gait sensors, which might be some other type of artificial gait sensor or "natural" sensor.

In the pool of artificial sensors are accelerometers, gyroscopes, goniometers, and tilt sensors. Use of accelerometers (44) has been much appreciated as miniaturized sensing elements suitable for incorporation in the implant housing have become available. Integrated accelerometers (45) would be highly reliable, but exhibit an absolute error significantly larger than the error reported for potentiometer-based recordings (46). Furthermore, joint angle, limb acceleration, as well as joint movement artifacts, are all merged in one output signal, yielding only a degraded estimation of the shank segment orientation. Sensor integration with additional gyroscopes was verified in a study (47) and found suitable only for applications where the subject was almost stationary. Individuals on crutches could possibly benefit from such sensing, while the users of foot drop system can not. Judging from the name, the tilt sensors seem to be promising (48). Here, gravitational acceleration or external inertial forces (as in true accelerometers) cause mass movement, only the sensing is different. Problems mentioned above for accelerometers still remain. When searching for reliable sensors, one might use also the existing signal shape to enhance gait phase recognition (48). This approach, in combination with a tilt sensor, produced walking with a foot drop stimulation system that was as fast as with an ankle foot orthoses.

The application of knee goniometers is impractical even for laboratory settings. As a second option, nobody has verified in practice the use of the elegant implantable Hall magnetic sensors, similar to those used in Freehand system, as a knee goniometer (6).

One very elegant solution to the problems with sensors is the use of the natural body sensing mechanism (49). Recordings of electroneurogram (ENG) cuff electrodes from the sural nerve include also undesired EMG artifacts from lower leg muscles as well as stimulation artifacts when used in combination with the peroneal stimulator. The S/N ratio of ENG is very low and also not in direct relation to foot pressure, but rather dependent on slip. Intensive signal processing beyond the current miniature hardware capability is necessary to extract useful signals, which would be to some degree a substitute for a heel switch. Significant enhancement and miniaturization of all elements in the signal chain is emerging to make this pioneering work ready for out-of-laboratory use. The EMG as a signal source as examined in early days in single-channel devices was not confirmed to be a reliable trigger.

CONCLUSIONS

The final therapy goal for individuals with spinal cord injury (at cervical and thoracic levels) must be regeneration of nervous systems of the spinal cord. There have been many medical researchers who tried to solve this difficult issue. Unfortunately, no one has succeeded in finding a solution during the last century. Conventional rehabilitation could not answer how to use the paralyzed extremities for assistance in ADL movements. The current purpose of therapeutic exercise is limited to strengthening residual functions. FES systems can only reconstruct lost movements to a limited degree. This is the moti-

vation for the scientists who are engaged in FES research.

Compared with the situation 40 years ago, we are now standing at a considerably better point, where we can use the benefits of evolution in various fields of science. The solution of recent issues concerning upper extremity neuroprostheses must be encouraged through development of new technologies.

In the hemiplegic population, there remain unanswered questions of when therapeutic relearning ends, of being present even among chronic stroke survivors, and when the neuroprosthetic needs begin.

After solving issues of reliability, implant circuitry and sensors, closed loop systems (50,51) will improve performance of lower extremity systems by correcting the stimulated response based on knowledge of the output, and this represents the next step in systems designed for hemiplegia and spinal cord injury.

Nerve blocking to eliminate spasticity or other unwanted activity should be widely examined and incorporated into general stimulation systems (52).

Despite some brilliant technical demonstrations, general circulation and commercialization of FES technology in the field of hemiplegia are poor. Medtronic, Inc. (Minneapolis, MN) was active as an early producer of FES implants, but other producers are small businesses of local nature. These cannot provide reliable functional devices, long-term technical support, and inclusion of such assistive devices in various countries (53).

New ideas (12,23,54) generate numerous possible neuroprosthesis applications, however, simple, solvable clinical problems should be approached to offer decent payoff in a reasonable time, rather than focusing exclusively on the most difficult issues such as locomotion after complete paraplegia (12).

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■ COMMENTARY

In review of current lower extremity neuroprosthesis, the author should note that implantable systems with highly selective muscle activation have been implemented in a number of individuals with spinal cord injury. These systems have been shown to have highly reliable components without complications and with minimal risks (56). It is also worth noting that the development of implanted systems has been based on discoveries made with percutaneous approaches, and that large financial and scientific investment in these systems is starting to pay off in both upper and lower extremity neuroprostheses. The lower extremity system provides practical limited mobility in the vicinity of a wheelchair in persons with paraplegia and is in clinical trial (56). While it is true that walking systems are used mostly for exercise, it should also be noted that implanted systems are being developed with (57) and without (58) bracing that can provide limited but practical walking at home and in the community. The hybrid systems address the limited range of motion of braces by electromechanical control of joints, muscle fatigue, and stability concerns when using FES only. In addition, the multichannel implanted hybrid systems will provide an opportunity at many centers for closed loop development with brace mounted sensors.

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■ COMMENTARY

This paper meets its objectives well, making mention of both the difficulties and the benefits associated with limb neuroprostheses. From the users' perspective, the difficulties will determine whether these devices are accepted as viable longer-term options; many challenges still exist. Experiences with disabled children have identified much better acceptance when technologies are introduced early in the rehabilitation process, and a similar effect occurs among disabled adults. However, this is often not clinically possible, as indications for a prosthesis include stability of the neurologic condition, which may not be reached for many months. Among those with spinal cord injuries, only a minority of the potential beneficiaries can commit the necessary time and effort to achieve the muscle conditioning essential to use the prosthesis. Introduction of neuromuscular stimulation (NMS) early in the rehabilitation period will help retain muscle condition, and should facilitate acceptance of a neuroprosthesis. However, organizational logistics, staff time, and equipment costs will preclude this in many clinical institutions. Clinical experience with NMS, including several neuroprostheses, has identified several difficulties not well explored in the paper. The use of closed loop and feedforward control is necessary to increase speed of response and to enhance the system efficiency. This is particularly so for standing and stepping systems, as delays between generating the electric currents and the motor response will compound the problem. Improved skill can reduce these problems, but a transition, from a series of consecutive steps to ''walking'' requires much greater control. This is less of a problem for upper limb neuroprostheses, in which the

complexity of the movement is reduced. I am very concerned about the risks of inducing overuse injuries to the upper limb joints of paraplegics who undertake NMS standing and stepping programs. The majority of paraplegics experience shoulder pain, due to excessive loading on these small joints. It can be very disabling, impeding independent function. To change a person from fully independent to requiring assistance for mobility and transfers, all for the sake of using the legs for weight-bearing activity, is irresponsible and inexcusable. These problems should in no way impede further research and development of these systems. Continuing research into reducing the losses associated with neurologic disorders is likely to increase the demands for neuroprostheses. Therefore, although FES research will occur independently to research for a cure for spinal cord injury, both will benefit from close associations.

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■ COMMENTARY

My response is limited to upper extremity systems only. I believe the authors are correct when they identify C4 spinal cord injury and hemiplegia as the most probable near-future applications of FES. I would also agree that developing the algorithms to control multiple joint movements is a major issue, especially if we are to provide function for C4 and higher spinal cord injuries. However, I would not identify 'natural' control and muscle fatigue as major problems remaining to be solved. First, 'natural' control, if defined in the ultimate as the restoration of the original connection between the motor cortex and the hand, is certainly desirable, but not necessary, for progress in the field. Control is an important area of research, and new control schemes are needed for high level spinal cord injury and hemiplegia, but I do not believe that natural control is a requirement for consumer acceptance. Second, muscle fatigue, which is a common problem in lower extremity applications, is essentially a nonissue for muscles of the hand and forearm. A consistent program of muscle conditioning can eliminate fatigue problems in grasp.

I believe that there are three other major impediments to improving the function provided by neuroprosthetic systems that were not identified by the authors. First, denervation remains an important factor in spinal cord injury. Although reconstructive surgical procedures can be used to overcome some of the muscle force deficits produced by denervation in C5 and C6 level spinal cord injury, it is a more difficult issue in higher level spinal cord injury where denervation commonly affects critical muscles such as the biceps and brachialis. We need to determine methods for developing or maintaining muscle innervation. Second, it will be difficult to produce fine control of the hand unless the joints can be maintained in a supple state. We will need to work together with surgeons and therapists to ensure that the joints of disabled individuals are not allowed to develop detrimental passive properties. Third, if we are to apply FES to other diseases such as stroke, multiple sclerosis, and cerebral palsy, we need to develop methods of controlling spasticity. We must have some method of relaxing antagonistic muscles that contract involuntarily.

Two trends that I expect in the near future are: early postinjury intervention and multifunction FES systems. At present, implanted FES systems are considered an option only after the injury has stabilized. This view considers implanted systems as a ``last resort''. Instead, implanted FES systems have the potential to be used for early muscle conditioning of paralyzed and voluntary muscles. Training the patient to utilize electrically stimulated muscles for function soon after injury is a good idea and should be pursued.

The second trend, which is already beginning, is the use of multifunction systems, that is, systems that provide function to more than one extremity or organ system. For example, providing cervical level spinal cord injury individuals with the ability to use both hands, to stand for transfers and pressure relief, and to have control over both bladder and bowel functions is a logical progression for FES technology. When we can no longer divide up IFESS sessions into ``upper extremity'' and ``lower extremity'' applications, then we will know that we have made some progress!

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