ESTABLISHING AND FULFILLING CRITERIA FOR PRACTICAL FNS SYSTEMS

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INTRODUCTION

After many years of major effort by several groups [1,2,4,5,8,15,16] the feasibility of using electrical stimulation to provide walking in the complete paraplegic subject has been proven[11]. What remains, however, is establishment of the practicality of this treatment. This paper attempts to set criteria for this practicality and suggests methods of meeting these criteria.

Despite our inclination to think otherwise, functional neuromuscular stimulation (FNS) is merely another rehabilitation tool and no matter how dramatic it may at times appear, it must pass the same functional tests faced by all rehabilitation techniques. The impaired individual will judge the actual level of function achieved, the ease of use, amount of metabolic energy consumed and cosmesis. Acceptance of the device will depend on a net positive balance.

CRITERIA FOR PRACTICAL FNS SYSTEMS

Function provided

An acceptable FNS system for the complete paraplegic should provide the following capability using only forearm crutches: standing for one hour with no break, fast walking at a speed between 1.0 and 1.5 m/sec for 150 meters (approximately one block), walking 2000 meters (approximately one mile) at 1.0 m/sec, getting up from a low chair, getting up from a fall, walking on ramps and uneven surfaces, negotiating steps and escalators, exercise and recreational activities. If this range of function can be provided reliably and repeatably, we believe most potential users will undergo the complex implant and training process to acquire the system.

Providing for protection from injury is also an important quality of the FNS system. There obviously must be electrical safety, but there must also be safety in the forces generated and in the long-term use by a subject. While there has been no evidence of Charcot type joint degeneration yet noted, experience with meningomyelocele patients and diabetic neuropathy patients functioning in a similar manner to the spinal-cord injured indicates a need for concern. Even though external bracing is unnecessary for FNS walking, some means of protection must be provided to restrict inversion and eversion at the ankle and to provide attachment for the necessary feedback devices.

If this level of function can be provided reliably and repeatably while meeting the other criteria, we believe that most potential users will accept the implantation and training process needed to acquire the system.

Ease of Use

Ease of use has proved to be a significant problem with FNS devices in the past. In our work with the functional electrical peroneal assist (FEPA) device[7] in the 1970's, we found major problems with electrode placement and wire breakage to the point that most subjects rejected the system in favor of a non-electrical ankle-foot orthosis. This led to the development by Rancho Los Amigos of the Neuromuscular Assist (NMA)[17] but added the requirement of surgical implantation. The device was generally well-accepted for its ease of use, however in most cases it proved to be not cost effective when compared with a simple AFO[7]. In our current 32-channel FNS system for restoring

functional tasks, the paraplegic subjects regularly encounter difficulties in connecting their percutaneous electrodes to the portable computer-controlled muscle stimulator.

Minimizing both donning and upkeep of the FNS system is a high priority. Experience in our clinical work at Cleveland's Highland View Hospital with the flexor hinge splint in rehabilitation of the quadriplegic hand indicated that if over three minutes were needed to don the device, after thorough training, the patient eventually discarded it. It would appear, therefore, that we had best make donning time and upkeep time minimal. Practical FNS systems should require no more than five minutes for donning. They should require checking and maintainence no more than once a month.

Another important aspect of ease of use is the control interface. Early systems utilized simple footswitches to initiate stimulation. We have used a ring on the index finger activated by the thumb. Visual feedback is used in all cases. A practical FNS system must have a simple interactive, responsive control system. It must incorporate non-visual feedback but in a nonobjectionable and reliable way. It must not only control walking and climbing but also must allow acceptable positioning in small spaces.

The length of training needed to use an FNS system must appear reasonable to the subject. Since we have been both developing the system and training the subjects to use it at the same time, it is difficult to estimate the current training period. Obviously, sufficient time is required for strengthening bones prior to intense stimulation in order to prevent fracture. A training period of no more than two to three months following implantation of the full system, depending on the initial state of the bones, is desirable.

Energy Expenditure

Energy studies done at Rancho Los Amigos[6] indicate that an individual will not continue to use mobility methods requiring more than 50% of his maximum aerobic capacity (MAP).

Cosmesis

The system must allow the subject to appear as a normal human. Subjects must be able to wear clothes similar to normals without major modification. The system must not make abnormal sounds or have an unusual appearance that draws attention to the subject.

FULFILLMENT OF CRITERIA

Function provided

Techniques enabling the full range of functional tasks are being addressed by our group in current ongoing research. This includes development of better percutaneous electrodes for the system development phase and of totally implantable electrodes for the permanent systems. Control of stimulation will be improved with methods which will reduce muscle fatigue and provide better control of joint motions to allow movement which is better coordinated and less costly of energy. Hardware will be improved with better subject-to-system and system-to-subject interfaces; reliable and accurate feedback transducers; miniaturization of external hardware and its modification to incorporate sensors and control algorithms.

At present five subjects have walked distances ranging from 15 to 250 meters with a rolling walker and one subject has been able to walk 30 meters with axillary crutches. Problems with trunk and hip stability prevent forearm crutches from replacing the walker. Programming of various functional tasks such as standing, walking at 1.0 m/sec, climbing and descending steps[3] have been successfully accomplished (Figures 1a-d).

Better hip flexion is needed for faster walking and consistent step climbing. A technique for implantation of the iliopsoas has been developed to provide this flexion. Also a new version of the percutaneous electrode has been devloped which includes an

anchoring device and a prolene core. These are to prevent early movement of the electrode away from the nerve and to reduce breakage of the electrode from body motion.

A totally implantable permanent sytem has been developed and has been implemented in the upper extremity. The size of the percutaneous stimulator box has been reduced to about one third and the number of channels has been increased from 32 to 48. A new subject-to-system interface has been created with a multi-dimensional joy stick added to the control ring. This allows the individual immediate access to groups of functions and also allows proportional signals to be given. New pressure transducers have been identified and are being tested.

Ease of Use

The current percutaneous system under development in our laboratory[7] requires connection of the electrodes to the stimulator each day. Hygienic care of the electrode sites requires 12-15 minutes daily. It takes the average subject 15 minutes to connect and 5 minutes to disconnect from the stimulator. In addition hardware failures such as broken cables, pins or connectors are often discovered at the time of connection, adding to the time requirement for preparation for walking.

In order to simplify the connection process, and to provide for implementation of the planned feedback devices, we have developed a body suit similar to the type used by skaters or dancers. The suit is made of a stretchable firm fabric and covers the legs and lower trunk. It will incorporate all surface wiring and connectors. After donning the suit, the subject will need only to join the connectors on his/her percutaneous electrodes to the connectors on the suit; and to plug the belt-carried, portable microprocessor-controlled stimulator into the connector on the suit. Currently our system also uses six surface electrodes placed on the lower back. These electrodes and their connecting wires to the stimulator will also be incorporated into the suit. When feedback devices are added the additional cables needed to join them to the computer/stimulator will be added.

The ultimate form of our FNS system will be a fully implanted one, where the stimulator and all electrodes will be surgically implanted. Such a system will use radio frequency signal control from an external unit. When that generation of the system has been achieved the garment will be reduced to a belt which will contain antennae for sending signals to the implanted devices and for receiving signals from feedback transducers located elsewhere on the body. The belt will also carry the batteries for the system and the necessary connectors for the external controller.

A lightweight ankle-foot orthosis[13] has been developed to provide mediolateral stability at the ankle and to prevent inversion/eversion. Incorporated into the foot section of this brace is a sorbothane pad for energy absorption with footswitches which trigger the muscle stimulator upon foot contact with the ground. Pressure sensors have been developed but they do not give reliable data.

Training for all subjects includes both increasing muscle strength and endurance and improving their cardiovascular condition as well as practice in the use of the FNS system. Muscle strength and endurance training begins as soon as the muscles are implanted. Subjects are encouraged to stimulate their implanted muscles for two to three hours each day, using portable stimulators. Exercise programs are designed to provide sufficient rest between contractions to allow the muscles to contract for at least an hour. As muscle endurance improves, the ratio between on-time and off-time is increased.

Torques produced by the quadriceps are monitored weekly using a Cybex II system. When peak quads torque is equal or greater than 25-30 foot-pounds subjects progress to standing in parallel bars with constant stimulation of the knee and hip and trunk extensors. Although initially poor, the subjects' ability to walk improves rapidly as their

cardiovascular status improves and they learn to coordinate their upper limb and upper trunk function with the lower half of the body. There is little difference in the respnse of subjects with lesions between T-4 and T-11[10].

Maintainence of muscle strength and endurance and of cardiovascular fitness is necessary for all subjects. We recommend gait practice three times per week and daily stimulation exercise for two hours. Problems with subject compliance, however, mean that this level of exercise is not always achieved.

Energy Expenditure

Current energy cost evaluation of our percutaneous FNS system is shown below:

Speed of FNS walking	Energy cost per distance
.18 m/sec	4.2 times normal
.20 "	3.0 " "
.35 "	2.5 " "
.56 "	2.2 " "

Reduction in energy cost/distance with increasing speeds of FNS walking indicates that when speeds greater than 1.0 m/sec are reached the energy costs will be acceptable. Much of the energy cost is spent in standing which should be greatly reduced with the introduction of closed-loop control of the spine, hip, knee and ankle.

Cosmesis

Constant attention is kept on the appearance of the system. The size of the controller/stimulator has been reduced to 25x21x9 cm and the body suit will conceal unsightly wiring. The ankle-foot orthosis has been designed to be inconspicuous.

The feasibility of using functional electrical stimulation to provide walking in the complete paraplegic subject has been demonstrated. For the system to be practical it must provide a sufficient level of additional function while exhibiting ease of use, acceptable energy cost and cosmetic appearance. Much work is currently underway to insure practicality for large numbers of paralyzed individuals within the next few years.

ACKNOWLEDGEMENTS

This work has been supported by the Rehabilitation Research and Development Service of the Veterans Administration, Shriners Hospitals for Crippled Children, and the Spinal Cord Society.

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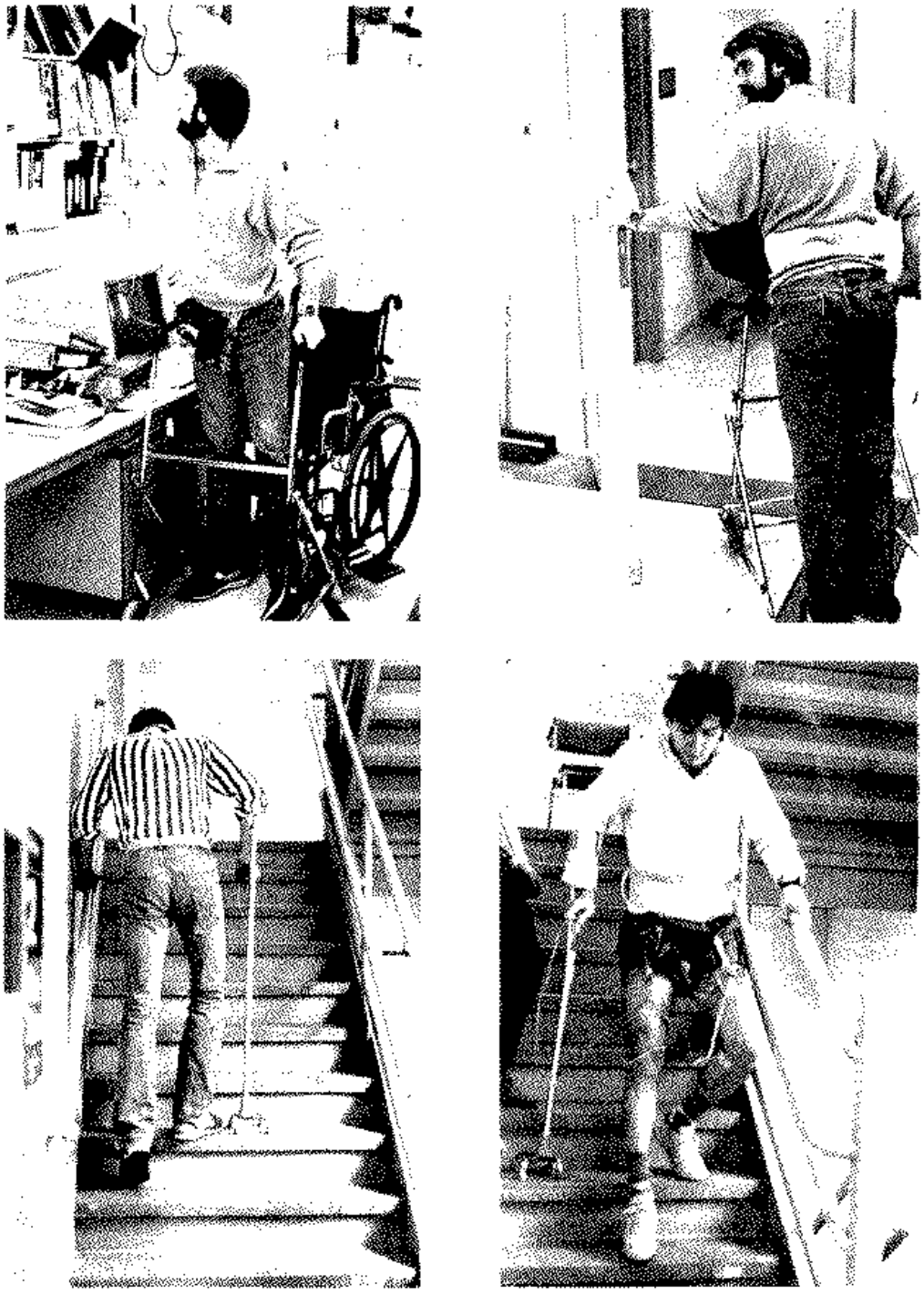

Figure 1A (upper left): Paraplegic subject DJ (T-11) reaching.
Figure 1B (upper right): Paraplegic subject DJ (T-11) opening door.
Figure 1C (lower left): Paraplegic subject DJ (T-11) ascending stairs.
Figure 1D (lower right): Paraplegic Subject BK (T-8/9) descending stairs.