IMPLEMENTING A SIMPLE FNS STANDING PROTOCOL IN A CLINICAL SETTING

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ABSTRACT

A simple two-channel protocol for standing was implemented on a limited trial basis at three spinal cord injury centers that did not have extensive experience in electrical stimulation for standing and/or walking. Two patients were studied at each center for a total of six patients. The results indicated that standing could successfully be achieved. Whether this technology would be useful outside a clinical setting or whether actual functional benefit can be ultimately derived by users of this technology remains to be seen.

KEY WORDS: Spinal cord injury, paraplegia, standing, electrical stimulation, physical therapy.

INTRODUCTION

Various forms of electrical stimulation have been used to produce contraction of upper motor neuron paralyzed skeletal muscle in spinal cord injured patients. These contractions can induce movement of both the upper and lower extremities (for reviews and representative papers, see [2,6,7,8,10,12,13,16]). These applications have been referred to as functional neuromuscular stimulation (FNS), functional electrical stimulation (FNS), motor system neural prostheses, electronic orthoses, and other similar terms. FNS is presently viewed as an emerging technology in the area of health care [4].

This research was directed at a select population of thoracic spinal cord injured individuals to test the hypothesis that it is possible to use bilateral electrical stimulation of the quadriceps to produce transient periods of standing in a clinical setting without extensive research intervention. Over fifteen years of experience with this type of system has been obtained in Ljubljana, Yugoslavia, and over eight years of similar work has been done at the Pritzker Institute of Medical Engineering and Rehabilitation Institute of Chicago. While the preliminary data (collected in research intensive environments) is encouraging, the exact clinical protocol for widespread use of such a system

in both large model spinal cord centers and smaller rehabilitation facilities remains loosely defined.

This research expands clinical investigation and evaluation of this system to three other rehabilitation centers. The purpose of this study was to indicate the practicality and potential usefulness of this system outside of the research environment in which it was developed. It was also to determine what deficiencies exist in the system or the proposed application protocol. We hypothesized that a two-channel stimulation system for transient periods of standing can successfully be used by clinicians in clinical settings without extensive previous experience with the technology of FNS or research experience with FNS. This hypothesis was tested by evaluating a protocol for muscle restrengthening and standing by functional electrical stimulation, in a select population of paraplegic individuals, at three different centers in the US. Centers participating in the multi-center evaluation had a minimum of one physician and one physical therapist develop expertise in using the protocol, and had two patients participate.

This study was restricted only to the feasibility of using a single protocol to produce transient periods of standing in a clinical outpatient situation under the supervision of a clinician. It did not study the extension of this technique to the patient's daily life. It is premature to extend the existing protocol to unsupervised standing by patients until additional clinical evaluation of the existing protocol is accomplished. This is the first published report concerning the results of this study.

METHODS

Centers and Equipment Provided: In the initial phase of this study, fifteen centers were invited to participate. Eight centers agreed to participate. Due to funding difficulties, only three centers actually participated. Two subjects participated at each center. Participating centers were furnished with the following materials:

- *Patient Information Booklets*
- *MD/PT Technical Booklets*
- *Patient Video Tape (describe project and informed consent)*
- *MD/PT Video Tape (supplement technical book)*
- *Stimulators (standing and exercise)*
- *Accessories (electrodes, wires, straps etc)*
- *Protocol Forms*

Subject Criteria: The acceptance criteria for research participants was:

1. Lesion level T4-T12
2. Months post-injury 2-48
3. Upper motor neuron paralysis of quadriceps
4. Prescribed KAFO or able to stand in training KAFO
5. No severe intractable complications (chronic UTI, repeated decubiti, psychological problems etc)

Protocol: The protocol outline was as follows:

1. Selection of research subjects and informed consent procedures (1 visit: MD+PT).
2. Document intake status (1 visit: MD+PT)
3. Subject training for restrengthening (1-2 visits: PT)
4. Subject stimulates at home (1 month: 1-2 PT phone calls)
5. Subject recheck, replace batteries (1 visit: PT)
6. Subject stimulates at home (1 month: 1-2 PT phone calls)
7. Subject recheck, replace batteries, stand in KAFO,first standing by FNS (1 visit: MD+PT)
8. Standing training (4-8 visits: PT)
9. Document exit status (1 visit: MD+PT)

   (Note: each visit was estimated to be between 45 minutes and one hour. Participation by MD and PT as indicated.)

Muscle Restrengthening: The initial phase of participating was a stimulation protocol designed to restrengthen paralyzed muscles. Subjects were allowed to stimulate themselves at home after they were thoroughly instructed and made aware of the proper protocol to follow. At a minimum, this entailed one hour spent with the investigator and includes demonstration of techniques by both investigator and subject, and a period of questions. Follow-up phone calls or visits were made to monitor patient compliance. The stimulators used are locally designed and constructed for research purposes in our laboratory and have been previously described [10]. Since the optimal procedure for muscle restrengthening is not yet known, we are utilizing a 1:1 duty cycle of stimulation on/off with the quadriceps being alternately stimulated. Since the quadriceps is the most important muscle group in this study, our primary emphasis is on this muscle. The typical procedure for restrengthening is to have the subject recumbent, elevate the knees about 25 to 30 cm, and stimulate the quadriceps, alternating right and left.

Standing: Once subjects demonstrated their capability to stand in the clinic by knee-ankle-foot orthoses (KAFO) and familiarity with the stimulation protocol feasibility of standing by FNS was investigated . The main point of this part of the program is to gather data on the utility of and the problems associated with standing by FNS in a clinical setting. While it might appear that this technique would be eagerly anticipated by paraplegic individuals and their care providers, this must be supported with data and experience. Concern with this issue is justified by the rejection rate of knee-ankle-foot orthoses. It is important that as many subjects as possible be evaluated in this regard.

Standing by FNS can be achieved by a minimum of two channels of stimulation and this simplicity is clinically attractive. The knee joints are stabilized by bilateral quadriceps stimulation and upon assuming upright posture, the hips are kept in hyperextension, the so-called "C-curve" posture. The ankle joints are essentially unstable, and this necessitates reliance on external balance aids such as parallel bars or walkers.

Our stimulator design concept was similar to that of the Ljubljana group [2,7], however, our unit has been designed for standing only, to reduce the number of control

knobs and switches. The stimulator assumes the sitting mode on power up and the command sequence is a toggling between the sitting and standing modes. A time delay between the actuation of the command button and the onset of stimulation allows the subject to position his hands to assist with standing. Auditory feedback allows better synchronization of upper body action with the gradual onset of stimulation. The stimulator has been previously described [10].

To effect standing, the POSTURAL CHANGE button on the right of the front panel is depressed. A two-second delay occurs while the patient prepares for standing, an audible warning is sounded and the stimulation begins. Pulse width is increased linearly over the first two seconds to 0.40 ms. This causes a smooth onset of quadriceps contraction and transition to a standing posture. To sit, the POSTURAL CHANGE button is again depressed. A two-second delay occurs, the audible warning is sounded and the stimulation pulse width is decreased over the next two seconds to effect a smooth transition to a seated posture.

Measurement: Three methods were used to evaluate the standing with FNS. The first method was a written questionnaire completed by the patient, to determine the extent to which standing was previously achieved by the patient and its perceived benefits (it is our experience that patients with previous experience with standing, usually with KAFOs, do better with FNS). The second method was monitoring of total standing time and number of times standing was achieved by FNS in visits to the clinic. The third was written evaluation by the physician and therapist of the standing actually obtained by FNS.

The data collection instruments consisted of four forms:

1) Patient Questionnaire (4 pages): This form is completed by the patient prior to participation in this study. It is intended to document the patient's assessment of their ability to stand, and their perception of the need and benefits of standing.
2) Patient Intake Form (5 pages): This form is completed by the clinician and is intended to document the condition of the patient (especially with respect to the lower extremities and the muscles to be stimulated) prior to participation.
3) Record of Stimulation (2 pages): This form is completed by the clinician during the study. In particular, the time the patient stood by FNS and the number of times the patient stood by FNS are recorded here. This is the most important quantitative measurement in this study.
4) End of Study Form (3 pages): This form is completed by the clinician at the end of the study. It rechecks the information obtained in the intake evaluation to determine if there has been a change.

Included for measurement before and after stimulation were thigh circumference (measured at mid thigh) and manual muscle grading of quadriceps contraction induced by electrical stimulation.

RESULTS

An extensive amount of data were collected in this study. Since this is the first preliminary report, emphasis will be placed on the quantitative measurements.

The characteristics of the participants in this study are given in table 1 below. These are comparable to previous studies.

SUBJ#	SEX	LEVEL	AGE	KAFO
1	M	T5	33	Y
2	M	T4	30	Y
3	F	T8	30	Y
4	F	T6	26	Y
5	M	T7	33	Y
6	M	T5	26	Y

TABLE 1: Characteristics of subjects.

The changes in subject's thigh circumference in response to electrical stimulation of the quadriceps is summarized in table 2 below. There was not a statistically significant increase in mean circumference pre- versus post- as determined by a t-test.

SUBJ#	R-PRE	L-PRE	R-POST	L-POST
1	19.50	19.50	20.25	20.00
2	21.50	21.50	22.50	22.50
3	21.00	21.00	21.50	21.50
4	19.00	19.00	20.50	20.50
5	52.00	51.00	52.00	51.50
6	44.00	44.30	44.00	44.00

TABLE 2: Thigh circumference measured at mid thigh in cm.

The change in the manually graded muscle test in response to electrical stimulation is given in table 3 below. All legs showed an improvement of at least one half grade, except when the response was already graded at maximal in the pre- case.

SUBJ#	R-PRE	L-PRE	R-POST	L-POST
1	4+	4+	5	5

2	4+	5	5	5
3	4-	3	4+	4+
4	3	3	4-	4-
5	3+	3	4+	4
6	4-	4-	5	5

TABLE 3: Manual muscle grade for knee extension in response to electrical stimulation.

The table below gives the number of attempts made at standing, the average time stood per attempt and the maximum standing time observed.

SUBJ#	#ATTEMPTS	AVG TIME	MAX TIME
1		2.0	2.0
2		2.0	2.0
3	10	3.9	7.0
4	7	1.6	2.0
5	5	0.95	2.0
6	9	4.2	5.0

TABLE 4: Summary of standing times.

In the subjective comments recorded by clinicians, no major problems were discovered.

DISCUSSION

The enthusiasm of researchers for the future of FNS must be tempered with the reality that no commercial systems are presently available in the United States to provide upper or lower extremity function in the spinal cord injured patient. The numbers of patients who have used this technology is relatively small. Furthermore, usage has been confined to research-intensive rather than clinical environments. Further the actual desire for and priority given to such systems by spinal cord injured patients is still not clear [9].

It is particularly appropriate to focus on standing. Standing is thought to help [1,3,11]: **1)** prevent contracture by serving as a type of range of motion exercise at the hips and ankle, **2)** prevent osteoporosis by loading the long bones of the legs, **3)** improve the position of the internal organs and perhaps aid bowel and bladder function, **4)** reduce the chance of decubitus ulcers by relieving pressure, **5)** increase functional ability to reach while standing and **6)** contribute a psychological benefit by enhancing

personal esteem. Proposed methods for mobilization must provide reliable standing function.

The results of this study should not be applied to arguments advocating the abandonment of bracing technology. It is clear that bracing will continue to be the treatment of choice in a number of patients. Braces serve a large population of spinal cord injured persons, but there are problems associated with their use, and a high user rejection rate exists (e.g.[5]). It is likely that external bracing technology has reached, or is near, its limits. This is not so with FNS technology, which is just emerging. Enthusiasm for FNS must be tempered with the precautionary note that no data exist concerning the feasibility of using FNS clinically on a large scale without significant research support.

Restoration of mobility in spinal cord injury is an extremely difficult problem [15]. This problem is compounded by individual variations in residual muscle function at particular levels of injury [14]. Demonstrations of restoring mobility by FNS have been confined to a small number of centers with carefully selected and highly motivated patients. The data from this study could be interpreted to support the view that improvements still are needed in the standing protocol.

The next stages in the implementation of this protocol on a clinical basis would be a larger multi-center evaluation of this protocol. Such a research study might involve ten other centers, preferably those without a strong established research base in this application of electrical stimulation. This study would be intended to determine if, in fact, comparable results can be obtained by other users and whether the protocol can in fact be transferred to daily use by patients in their lives to achieve useful functions.

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