Walking by Complete Thoracic-Level SCI Patients Via FES: Present Status and System Improvements

Daniel Graupe

Daniel Graupe, PhD, Professor, 651 South Morgan Street, Room 1117, University of Illinois, Chicago, IL 60607 EMAIL: graupe@ece.uic.edu, Web Address: www.ece.uic.edu/~graupe

Abstract

The paper discusses present data on walking performance and on medical outcome results relating to use of the Parastep transcutaneous FES system, the first to receive FDA approval (1994) and to be commercially available. It also discusses modifications to improve system performance and to delay onset of muscle fatigue. These improvements go beyond a particular FES system and may be worthwhile in FES applications beyond those for ambulation.

1 Introduction

Ambulation by thoracic-level traumatic paraplegics was first realized by Kralj et al. (1980) [1]. The first system to demonstrate walking over distances exceeding 100 m/walk on the average for trained patients and to receive FDA approval (1994) [2] was the transcutaneous Parastep system, developed by Graupe and Kate Kohn (1982 – 1990) [3], [4], to maximize patient independence and range/duration of walking. Subsequently, this system became commercially available and it received approval for reimbursement (cost of equipment and of training) by Medicare and Medicaid in the USA (2003) [5] and later by several leading US medical insurers. Noting the wide availability of the Parastep system, multi-patient performance and related medical outcomes were evaluated independently in several rehabilitation centers for the same system, as published in [6], [7], [8], [9], [10], [11]. The users require no assistance during walking or for donning (7-10 minutes) and doffing (3-5 minutes) of the system. Since that time several possible improvements to that system and to other FES systems were proposed. Below we summarize both the published evaluations and the proposed improvements.

2. Evaluations: Walking Performance and Medical Outcomes

FES training outcomes are usually better if started soon after the SCI injury, though in one case a T3/4 complete paraplegic who was 40 years post-injury stood up with the Parastep 6 minutes after start of first stimulation and took 3-4 steps in the third training session, during a training session held in Buenos Aires at the invitation of and in presence of members the Neurosurgery Department of the University of Buenos Aires.

Average walking distances of 444 m/walk at average speed of 14.5 m/sec were reported (for 14 patients) in [7], at the end of 4 months of Parastep training (5 days per week) at the Villa Margherita Neurorehabilitation and Research Center in Vicenza, Italy (average for 14 patients in the study). Average distances of 115 m/walk at average speeds of 5.0 m/sec were reported in [6] after 33 sessions of Parastep training at the University of Miami Project to Cure Paralysis (16 patients).

The differences in performance are mainly due to difference in training methods and noting the practical constraints on training in US facilities in general. The training at the Vicenza center, as designed by Dr. H. Cerrel-Bazo, requires first a rigorous preparatory program that is concerned with attempting to overcome derivative effects of paralysis, including rigidity, contractures, metabolic fatigue, energy inefficiency, bad posture, and lack of motivation. It proceeds with FES activated auxiliary muscle strengthening with bicycle exercise, treadmill walking and foot-borne weight exercise. After start of actual walking training and throughout the walking training, the preparatory program and auxiliary muscle strengthening are continued. The 33 sessions at the Miami program is constrained by practical limitations common in US rehabilitation centers which cannot usually provide for (sometimes lengthy) preparatory
Data on medical and psychological outcomes for patients in the Miami, at the end of the 33 sessions (11 weeks) of training with the Parastep were published in [8], [9], [10], [11]. These show a 56% improvement (end of 33 training sessions vs. start of training) in lower-extremity blood flow [9], from 417 ml/min to 650 ml/min. Also reported are 11.3% reduced heart rate heat-rate [8], 25.5% increased time to fatigue [9] and improvements in oxygen and in heart-rate at peak-work-load [9]. As might be expected, no change in bone density was measured at 11 weeks after start of training [10], while later follow-up data is unknown to us. Concerning psychological measures, the average Physical Self-Concept TSCS scores were improved by 12% [10] and the BDI depression score was reduced by 38.6% [11].

3 Proposed System Improvements

The proposed system improvement below are intended to serve to enhance patient independence and to improve standing/walking performance.

3.1 Stochastic Modulation of the FES Stimuli:

This is a mere software modification and was published already in [12]. Although tested on only one patient (T9 complete SCI), more than 250 test-runs were performed, in a double blind manner. These were motivated by mathematical principles on improved stability of nonlinear system via stochastic modulation of the control inputs that are applied [13] and by the observation that in arrival time of action potential in the absence of SCI varies randomly around some mean value [14]. Our initial tests, reported in [12] have shown a 36.6% improvement in rate of muscle fatigue in the quadriceps at a 42 m.sec. average pulse interval modulated by white noise at 10 m.sec. standard deviation, as compared with stimuli at 42 m.sec pulse interval with no modulation. All other parameters where held exactly constant and no difference was observed between Gaussian and uniformly distributed white noise modulation [15]. If this improvement can be further confirmed in many more patients, one should consider it for other FES applications.

3.2 Closed-Loop Control of Stimuli Amplitude via Response-EMG

In complete thoracic level (or cervical level) paraplegia, no meaningful EMG exists below the level of the lesion. However, when FES is applied at the lower extremities, it produces action potential in the peripheral nerves that undergo stimulation [4]. Hence, EMG is generated in response to the stimulation, to be termed as response-EMG [4]. This EMG is measurable at the stimulation sites. Since the FES stimulus lasts only (in the case of the Parastep) some 100-150 microseconds, whereas the interval between adjacent stimuli is of the order of 40 milliseconds and whereas the response EMG lasts many milliseconds after the application of the stimulus, there is more than adequate time to measure the response EMG at the stimulation site without interfering with the stimulus itself. Adequate delayed gating thus allows using the stimulation electrodes also as EMG measuring electrodes [15]. This can provide feedback for closed loop control of stimulation levels. Allowing to automatically adjust levels (or pulse-widths) with the progression of muscle fatigue, in order to recruit related neurons that have not yet been stimulated.

3.3 Wireless Link Between Walker and Stimulator

Walker–support (or at least cane-support) is essential in walking with the Parastep and other FES systems. Though only approximately 5% of body weight is borne by the walker, the walker is necessary for standing-up from a seated position and for sitting down, it is a safety-net during walking and last but not least, it provides a sensation feedback to allow the user (who has no sensation below the lesion) to sense the ground through his arms (that are above the lesion). Also, finger-touch controls for selection menus for stimulation sequences and coordination between them at different stimulation sites throughout the execution of left or right step, are placed on the walker, such that a slight finger-touch, performed almost instinctively by the patient while walking (and hardly noticed by others), will change menus from right step to left step or to sit-down.. Presently, communication between the menu-switching controls on the hand-bars of the walker (or in some cases, on canes) and the body-borne (pocket-borne) stimulator unit, is
by wire. Hence, is tied to the walker and requires one particular walker. We recently designed a removable finger-switch module that can be placed on the hand-bars of any walker or cane, which communicates with the body-borne stimulator by wireless signals. These are coded to avoid wireless interference that may lead to undesirable steps or to missing steps.

4 Discussion and Conclusions

This paper attempted to show that FES for walking is a viable reality, as indicated by performance data and medical outcome evaluations. It is not only FDA approved, but it also received US Medicare and Medicaid approval for reimbursement of cost and training. The paper also discusses system improvements which, though easy to implement, have been overlooked despite their potential to improve performance and patient independence.

References


