Performance and patient training in walkinng with fes by thoracic-level paraplegics

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Abstract

Below is a discussion of an FDA-approved noninvasive Functional Electrical Stimulation (FES) System for ambulation by traumatic T1 to T12 paraplegics having no sensation and no motor function below their spinal cord injury (SCI). The system's ambulation training, its ambulation performance evaluation and its medical evaluation are summarized.

Key words: FES (functional electrical stimulation), paraplegia, thoracic SCI, training, walking performance, medical evaluation.

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The paper discusses an FDA-approved (1994) noninvasive FES system for ambulation by thoracic-level paraplegics [3] and evaluates its performance and its medical and psychological benefits. The system that is discussed (known as the Parastep FES System), is also approved by Medicare and Medicaid for reimbursement of equipment cost and of training cost [1]. It allows paraplegics with complete traumatic T1-T12 paraplegia (having no sensation or motor function below the SCI lesion) and who are trained in its used to walk short distances. Walking distances vary with intensity of training protocol from an average of 115 meters per walk after a 32-session 3 months training program to 450 meters/walk average after a 4-months daily training program. The system allows full patient independence in standing, walking, and in donning/ doffing the system. Among the medical benefits beyond mobility, most important is the improvement in blood flow at below the lesion by 50-60% average, to near normal pre-injury levels. The Parastep system is based on principles stemming from 1791 Luigi Galvani's work on exciting a frog's leg [4]. Noninvasive (transcutaneous) functional electrical stimulation (FES, or FNS: functional neuromuscular stimulation) in humans was reported in 1960 by Lieberson [14] and was applied to hemiplegic subject to correct heel-drop. Trascutaneous FES stimulator of thoracic-level paraplegic patients was first reportedby Kralj et al (1980) to allow standing and the taking a few steps [6]. Graupe et al. have extended Lieberson's and Kralj's earlier noninvasive FES systems to a patient-borne patient-controlled FES system for thoracic-level complete paraplegics (with upper motor-neuron paraplegia), aiming at maximizing patient's independence in ambulation and in the control of the system [7,8]. This design was subsequently implemented in the (now commercially available) Parastep system, which was approved by FDA in 1994 [3] and which still is the only FDA-approved such ambulation system [5], is the subject of the present discussion and performance evaluation. It employs 12 surface electrodes at 6 sites (quadriceps, common peroneal n. and paraspinals at right and left side each. The stimulation signals to each stimulation site are designed to maximize standing/ walking time. They are coordinated in time and amplitude throughout stimulation by a microcomputer that resides in the patient-borne system, in terms of 3 menus (stand, right step, left step). These menus are selectable by a single finger touch and the full time-evolution of the simuli throughout each menu resides on the above microcomputer.

	Ave. Distance m/walk	Ave speed m/sec
Approx 85 sessions daily over 4 months Vicenza (Cerrel-Bazo et al. [12]): 14 patients	444.3	14.5
32 sessions 3/week, 12 weeks Univ. of Miami (Klose et al. [13]): 16 patients (13 male, 3 female)	115	5.0

Table 1. Ambulation performance results (parastep users)

	Pre-FES-Training (Ave)	Post-FES-Training (Ave)	
Lower-extremity Blood Flow	417 mL/min	650 mL/min (improv.)	(Nash et al. [14) 12 patient data/ U. of Miami
Heart Rate	70.1	63.2 (improv.)	(Nash et al. [14]) 12 patients/Miami
Time to fatigue (at peak arm ergometry test)	15.3min	19.2min (impr.)	(Jacobs et al. [15]) 15 patients/Miami
Peak Workload Heart Rate (pk arm ergom. test)	188.5	183.1 (impr.)	(Jacobs et al. [15] 15 patients/Miami
Oxyg. Uptake (pk Arm ergom. test)	20mL/Kg/min	23mL/Kg/min (improv.)	(Jacobs et al. [15]) 15 patients/Miami
Spasticity	usually improvement especially for very spastic pre-training		(Graupe, Kohn [3],[9], [116]) Michael Reese Hospital, Chicago
Bone Density	No follow-up data except for 11 weeks after start of training, where no significant change was reported		(Needham-Shropshire et al.[17)
Physical Self Concept (TSCS scores)	43.2 TSCS	52 TSCS (improv.)	(Guest et al. [18]) 15 patients/Miami
Depression Scores (BDI scores)	8.8 BDI	5.4 BDI (impr.)	(Guest et al. [18]) 15 patient data

Table 2. Medical and psychological evaluation data (Parastep Users)
TSCS: Tennessee Self Concept Scale score BDI: Beck Depression Inventory score

We note that parallel work on FES, based on implanted (invasive) FES systems also began in the 1980's, for the same purpose of ambulation by thoracic-level paraplegics. The main groups working on percutaneous (implanted) FES systems were and still are those of Marsolais, et al. [16] and of Holle, et al. [10].

System and training

The system (Fig. 1), which is known as the Parastep system, is limited to upper motor-neuron paralysis, to exclude patients with lumbar-level lesions. It also requires full upper-extremity function to exclude patients with cervical-level lesions. It is reported in detail in [5].

Figure 1*: Parastep I Users, trained at Vicenza's Villa Margherita Neurorehabilitation and Research Center (direction of Dr. H. Cerrel-Bazo), shown at the finish of 1.5 kilometer walk in Carpi, Italy, part of the city's "Marathon Run" celebration.*

Walker-support, that usually carries only 5% of body weight, is required for balance and for safe and independent stand-up and sit-down. Since the patients have no sensation, the only information (but for visual) that they have on their ground contact comes from sensation of pressure through the walker on their arms. They claim that they "feel like walking on air".

Since the system is noninvasive, patients may don the system each morning and diff it in the evening. Donning and doffing times are 5-10 minutes and can be done by the patients themselves.

Patient-training should start within a few years after injury for best outcome. However, in one case, a 62-years old male T3/4 complete paraplegic, 40-years post-injury, trained by one of the authors (DG), was able to stand up (for approximately 2 minutes) within 6 minutes of start of training and to take his first 3 steps 3 days later [15].

A rigorous muscle-strengthening procedure for both upper body and lower extremities is most essential for adequate training. The results that are summarized in the next section may serve to illustrate this aspect.

Results

Ambulation performance, concerning average walking distances (meters/walk) were reported in [2] and [12] and are given in Table 1 below. These relate to two different training methods, one, at Vicenza, Italy [2], of 4 months of daily training, including considerable muscle-strengthening routines using treadmill exercises, the second [12], at the University of Miami school of Medicine, being of 11 weeks of training (3 one-hour sessions per week).

Comment

For most USA patients, 4 -months training programs as in Vicenza are impractical. On completing a 32 session program, performance may reach that of a 4-month program in 6-12 months if patients continue ambulating at least 30 Min./day

Results of medical and psychological evaluations were published in [5,6,9,11,15,17,18], and are summarized in Table 2 below. A 15 minute movie (T9 and T10 complete traumatic SCI paraplegics) is accessible in [19].

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References

[1] Centers for Medicare and Medicaid, Code K0600 (Parastep-I equipment acquisition), and Code 97116 (physical training services with Parastep-I): http://www.cms.hhs.gov/coverage 2003.

[2] Cerrel-Bazo HA, Rizetto A, Pauletto D, Lucca L, Caldana L: Session 91, Paper 66, Proc. Eighth World Congress of the International Rehabilitation Medicine Association, Kyoto, Japan, 1997.

[3] FDA approval P900038, http://www.fda.gov/cdrh/pma94.html, April 20, 1994.

[4] Galvani L, Commentary on the effects of Electricity on Muscular Motion, Proc. Bologna Acad and Inst of Sciences and Arts, 1791.

[5] Graupe D, Kohn KH: Functional Electrical Stimulation for Ambulation by Paraplegics, Krieger Publishing Co., Malabar, FL, 1994.

[6] Graupe D, Kohn KH: Neurol Res 1997; 19: 323-333.

[7] Graupe D, Kralj A, Kohn K., Proc IFAC Symp. Prosthet. Control, Columbus, OH, 1982.

[8] Graupe D., Kohn, KH, Basseas S., Naccarato E., Proc. IEEE Frontiers of Eng. & Comp. in Health Care, Columbus, OH, 1983.

[9] Guest RL, Klose KJ, Needham-Shropshire BM, Jacobs PL, Arch Phys Med and Rehab 1997; 78: 804-807.

[10] Holle J, Frey M, Gruber H, Stohr H, Thoma H: Orthopedics 1984; 84: 145-160.

[11] Jacobs PL, Nash MS, Klose KJ, Guest RS, Needham-Shrpshire BM, Green BA, Arch Phys Med Rehab 1997; 78: 794-798.

[12] Klose KJ, Jacobs PL, Broton J, Guest S, Needham-Shopshire BM, Lebwohl N, Nash MS, Green BA: Arch Phys Med Rehab 1997; 78: 789-793.

[13] Kraly A, Bajd T, Turk R: Med Prog Technol 1980; 7: 3.

[14] Lieberson WT, Holmquest HJ, Scott D, Dow C: Arch Phys Med Rehab 1961; 42:101.

[15] Lotersztain H, La Nacion (daily), page 3, Dec. 24, Buenos Aires, 1997.

[16] Marsolais E, Kobetic R: Clin Orthop 1983; 175: 30-36.

[17] Nash MS, Jacobs PL, Montalvo PM, Klose KJ, Guest RS, Needham-Shropshire BM: Arch Phys Med Rehab 1997; 78: 808-814.

[18] Needham-Shropshire BM, Broton GJ, Klose KJ, Lebwohl N, Guest RS, Jacobs PL: Arch Phys Med Rehab 1997; 78: 799-803.

[19] www.ece.uic.edu/~graupe, 1994.