

Thoracic Level Complete Paraplegia–Walking Performance, Training and Medical Benefits with the PARASTEP FES System

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Abstract

Goal: The paper discusses walking performance and the related patient-training of the non-invasive Parastep (also known as Parastep-1) Functional Electrical Stimulation System.

Regulatory status: The Parastep system was approved in 1993 by the FDA (USA) for walking by complete and near-complete paraplegics with upper-motor-neuron T1 to T12 spinal cord injuries, having no motor function and no sensation below their spinal cord lesion. The PARASTEP system was approved by U.S. Medicare and Medicaid for reimbursement in 2004.

Walking performance: In tests on 14 patients trained in walking with the Parastep system at Vicenza Rehabilitation Center, the patients averaged 444 meters per walk at 14.5 meters/minute. Several patients of the first author in the USA and of the second author in Italy have covered and documented one mile per walk. The first author experienced a 62 years old patient, 40 years post-injury, stand up stand up 6 minutes from start of training and take a few steps already on 3rd day.

Medical benefits: Medical benefits of Parastep use beyond those of walking include increase of blood flow at below the spinal cord lesion by an average of 56% (Tests performed at the University of Miami School of Medicine. The same University of Miami study reports positive improvements in several other physiological responses and in psychological measures. Improvements in bone density are also reported

Patient training: Although performance is a function of age, general health and time from injury to start of Parastep training, the training protocol is of major importance regardless of patient age, general health and time from injury. Therefore, training methodology is a major aspect of this paper.

Access is provided in several references below to videos on walking performance and training

Keywords: Parastep system; Rehabilitation; Paralysis; FES

Introduction

Although acute care management in SCI (spinal cord injury) has improve tremendously in the last 35 years, the major goal in SCI rehabilitation around the world is to obtain the maximum independence possible on a wheelchair. After the acute phase and following an intensive care rehabilitation, SCI activity below the level of injury is hardly considered and the vast majority of SCI subjects at discharge become sedentary on a wheelchair, and don't participate in physical activities [1]. Consequently, these individuals are more expose to the derived consequences of immobility [1-14]. Severe perpetuating degenerative effects may suddenly appear, starting with weight lost and followed by severe muscle waste or atrophy [2], flaccidity or spasticity [3], edema [4], decubitus ulcer [5], deep vein thrombosis [6], depression, osteoporosis [7], respiratory restrictive disorders [8], reduction in the cardio-pulmonary fitness [9,10], obesity and HDL reduction [11], fractures [12], chronic pain syndrome [13], recurrent UTI (urinary tract infection), sexual dysfunction and other secondary medical complications [14].

Today the cure of paralysis does not exist. Therefore, we need to create alternatives ways to reduce the burden of disability.

Research groups have found fertile territory to apply FES (functional electrical stimulation) in SCI subjects. From these pioneering experimental studies [15-18], some FES equipment has been developed with intent to bypass the area of the spinal cord injury by electrically stimulating certain paralysed peripheral nerves directly, regaining some artificial motor control, reconditioning paralyzed limbs to muscle fatigue, reactivating of paralysed muscle pump, conditioning of cardiopulmonary and circulatory systems through muscle stimulation in non-denervated SCI subjects.

The Parastep system [19-32], designed in Dr. Graupe's lab in Chicago, was the first and only walking system that gain approval from FDA [20] in the USA (1993) and covered by the US Medicare and Medicaid Authorities [21] in 2003 to be prescribed and used as walking aid for treatment in SCI individuals.

The Parastep (also known as Parastep-1) is based on the design by D Graupe et al. (see: US patents numbers [21-28] and related foreign patents). It was developed by Graupe and Kohn [19-21,29] between

1980 and 1994. The Parastep system, which is totally non-invasive, was described already in detail several papers and books [29-33]. Therefore, we shall only briefly summarize its major points in this paper.

This paper discusses and summarizes the walking performance and the related patient- training methodology of the Parastep functional electrical stimulation system (FES), also commercially known as Parastep-1.

The Parastep system is intended for independent indoor and outdoor walking by complete and near-complete paraplegics who sustained upper-motor-neuron thoracic-level (T1 to T12) spinal cord injuries (SCI), having no motor function and no sensation below their spinal cord lesion.

The Parastep's walking performance (average 444 meters/walk at average speed of 14.5 meters/minute) based on the current training methodology, as developed by Bazo [34], is given in ref. [31-37]. The medical and psychological benefits of FES walking, as tested on patients while using the PARASTEP system, were published in ref. [37-42]. It is noted that these results, while very important and certainly indicative, were based on a very short training and a far less rigorous patient training protocol than the one discussed below and that was used in ref. [31-36].

Performance and related medical and psychological benefits are a function of age, general health and time from injury to start of PARASTEP training. However, they are greatly influenced by patient training and lead to widely different outcomes in patients of similar age and general fitness [37-43]. Therefore, this paper outlines the principles of a training protocol and of its methodology [34,35] developed by Bazo, which resulted over the years in consistent outcomes far superior to others published or otherwise observed. The performance results that are presented below are based on this training protocol.

The paper provides access to YOUTUBE videos on walking performance by PARASTEP users as described above (having no motor function and no sensation below their thoracic-level SCI lesion) and on the training protocol that is discussed.

Research leading to the development of the PARASTEP system is further discussed in [8, 9, 43-47].

Brief System Description

The PARASTEP system is a totally non-invasive FES system [29]. It is designed to give the user full independence. Not only does the trained user walk with no need of being accompanied or otherwise supported/assisted by another person, but the user can don and doff the system with no assistance what-so-ever. The user dons six stimulation electrodes in the morning at positions easily remembered and doffs them when going to sleep or to shower. There is no bracing apart from a shoe-insert ankle-foot-orthosis (AFO) inserted into the user's shoes.

The Parastep main unit [29], which includes the stimulator and the microprocessor control of the system fits a pouch attached to the patient's belt or can be attached to the belt or pants without pouch. It weighs 7.6 ounces (216 grams) including batteries. It uses 4 AA rechargeable batteries, to be recharged daily (over-night), and which may be either incorporated in the main unit or held separately in the patient's pocket.

The purpose of the walker is not of weight-bearing, but of security and balance. It bears on the average below 5% of body weight.

However, at start of training, almost every patient would comment to me (DG): "Professor, I feel like I walk on air", since the patient has no sensation. Now, through changes in pressure on the arms while holding the walker, the patient learns to sense the ground and the position of his/her feet relative to the ground. This is the main purpose of the walker. It is also the reason why users must have use of their arms, thus excluding most cervical SCI patients.

The walker also houses (on its hand-bars) two finger-touch switches. These provide the user with easy (practically unnoticed by an observer) finger-touch switching activation of a computer (microprocessor) program to execute the sequence of controls to activate a right or a left step, including all muscles involved in the step and in related posture adjustment from the rising of a feet and until safe landing in preparation to either a next command (another step command or sit-down command) or to a stand phase. Hence, a single light and very brief finger touch that is almost unnoticed is needed for each step, while all adjustments, which involve sending electrical stimulation sequences of pulses of varying levels and durations to a multitude of stimulation electrodes is then performed by the microprocessor. The microprocessor thus simulates the natural sequence of firing of the groups of peripheral neurons involved in each step or in standing or in sit-down. It thus yields smooth rather than robotic movements that are close to the natural movements of an able-bodied non-paralyzed person.

The Parastep system (Figure 1) thus consists of the stimulator and control unit (Figure 1) and of 3 auxiliary units: (1) six stimulation noninvasive skin electrodes; (2) four-legged stability walker, and (3) shoe-insert AFOs. In addition there is wiring between units 1 and 2. There is also wiring from the main unit to auxiliary units (1) and (2). The latter can be eliminated if Bluetooth wireless is used.



Figure 1: The Parastep system.

The stimulation electrodes are each individually controlled by the microprocessor of the stimulator unit. They are placed on the patient's right and left biceps, right and left common peroneal muscle and at below the lesion on right and left para-spinals.

Stimulation is applied to the peripheral nerves in which it produces action potentials that can be shown to be identical to the action potentials in these nerves in a non-paralyzed person [29,30]. The Parastep's microchip coordinates the stimulation pulses being applied to the various motor-units so that they automatically simulate in time and in relative stimulation-level their distribution between the various motor-units in a non-paralyzed individual, for any given function (right-step, left-step, stand-up, sit-down, prolonged standing). Each

and every function of the above lasts over many stimulation pulses whose time-variation changes over the duration of even a quick step. The time-variations themselves differ also from electrode to electrode for that same function. These variations are all programmed into the microprocessor's microchip of the Parastep. They are thus automatically executed when a given function is selected and last until another function is selected by the Parastep's function finger-switch. The finger-switch selection of functions is hardly noticeable by an observer as its finger-touch becomes second-nature by a trained user (Figure 2).

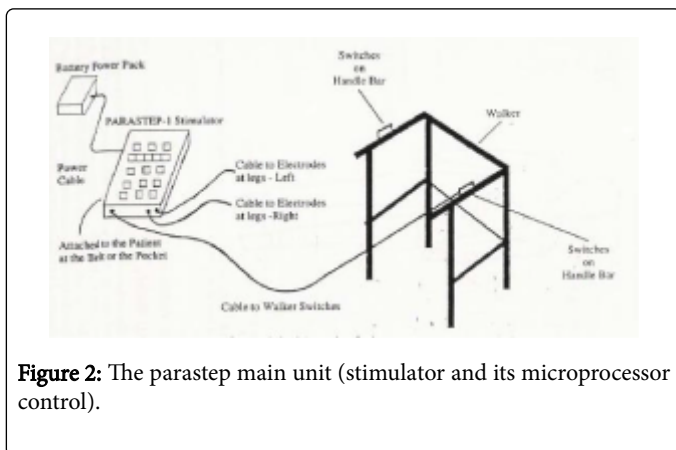


Figure 2: The parastep main unit (stimulator and its microprocessor control).

Further details of the system's hardware and its interconnections are given in various sources [29-32].

Patint-Training

Early training programs

The standing and walking kinematics in SCI subjects may differ between patients and this is related to SCI chronicity and impairments such as: reduced physical capacity, lack of muscle strength, motor control, trunk balance, motivation, presence of spasticity, flaccidity, muscle atrophy and degenerative muscle processes.

Initially every rehabilitation center came up with its own procedure to train Parastep users in walking. Cost and convenience of patients were obviously an important factor. Hence, training was attempted to be over a short period to fit the majority of patients.

Protocols varied in time and in detail from one center to another and where usually not published, nor are statistics on performance known.

The first detailed study on walking with the Parastep came from the University of Miami Cure Paralysis Program of the University of Miami School of Medicine, Miami, Florida [36,38-41]. Of their training methodology there are few details and they presumably followed the 1994 training principles of Graupe and Kohn [29]. In this Miami Project training was carried out in 32 sessions that lasted for 11-12 weeks. Typically, 3 walking trials were done in each session. The patients were allowed their own walking pace and duration [39,48-55].

The vicenza training protocol

On observing many patients in the Vicenza Rehabilitation Center in Italy, during their walking with the Parastep, it was decided to develop a new training methodology, now known as the Vicenza Parastep Training Method. It was hypothesized that physical capacity reduction in chronic SCI may contribute to deconditioning effects of the body in toto, reducing not only muscle strength but also coordination, mobility

and motivation. Consequently, the Parastep's SCI users in the Vicenza Center were trained to stand and walk against gravity only after participating in a well structured exercise and gait training program. The selected candidates were chronic SCI subjects ranging from C7/8 to T12 (average T6). The time from injury to the participation to the program was estimated 4.5 years (± 3.81), with a wide range between 10 months to 18 years.

The main goals of training are: (1) strengthen upper body muscles and condition the cardio-pulmonary and circulatory system; (2) maintaining lower extremities functional range of motion for standing and walking; (3) reversing muscle atrophy, stopping muscle degeneration and increasing muscle force and endurance through FES, and via repetitive (and increasing) weight-lifting exercise; (4) learning to walk through a task-oriented-approach, repetitive standing/walking exercise initially on flat surface follow by training on a treadmill; (5) Only then: Training progresses to walking on diverse terrain surfaces (slope, obstacles, including stairs), thus building up confidence in walking in the absence of direct feedback sensation from the FES stimulated paralyzed limbs.

Obviously, training towards the above mentioned goals cannot be rushed. It takes 4-5 months of daily (5 days per week) training/exercise. The training program consisted of the following:

Traditional physical therapy: Stretching, active and passive range of motion (ROM), standing (standing frame), trunk and balance exercise, breathing exercise, 3-5 times per week. All subjects should achieve control the trunk to prevent falling during long and short sitting periods. Traditional physical therapy and anti-spastic medication aim to achieve trunk, hip and knee within normal limits (WNL), at least 90° ankle dorsiflexion and full plantarflexion. Upper extremities must reach WNL.

Upper limb strengthening: Weight-lifting machines were utilized for deltoids, biceps, triceps, pectoral major, obliques, abdominals strengthening program. The initial workload used was 75% of the maximum weight resistance that the SCI subjects is capable to push against (10 repetitions are performed). 1-5 kg weight resistance is increased every 2-3 days, once the subject is able to exercise for 3 sets (1 set=10 reps). The SCI subjects were able to weight-lift at least up to 50 kg, over 3 sets (10 repetition each).

Upper limb arm-cranking: Subjects train at 65%-75% of the maximum heart rate age predicted (220-patient age) for 20-30 minutes. Workload resistance was between 25-50 Watts and gradually augmented from 0, three times per week, at constant cycling rate of 50 RPM. Once per week an interval training (gradually increased to the self-maximum workload ([0-100 Watts] per 10 minutes) was performed.

Paralysed limbs strengthening: Isokinetic machines and FES equipment are used to stimulate paralysed muscle, offering single joint and rotary movements. The muscles being stimulated are: gluteus (medius), hamstrings, quadriceps and adductors. Force resistance started at 10 Newtons (N) and gradually increased (at 10 N steps) to a maximum of 100-150 N per 30 minutes training time. The exercise protocol was considered appropriate when the exercised joint reaches at least 75% of full ROM per 30' of the exercise.

Vicenza FES walking program: All Parastep walkers are prescribed a carbon-fiber AFO (ankle-foot orthosis) with a patellar thrust acting as a ground reactive force brace, articulated at the ankle at 90°. Despite the effect of the FES neuro-prosthesis and the reconditioning training, the first scope of this orthosis (through the ground reaction force and patellar thrust), is to initially help the knee from bending. This permits

the use of low Parastep current intensity to prevent quadriceps muscle fatigue. The second objective is to achieve better alignment of the paralysed lower extremity through good stabilization of the ankle and knee. This allows the Parastep user to unload the upper body while standing and optimizing the effects of the Parastep system.

Initial training consisted of standing while maintaining body alignment in the upright position, SCI subjects were exercise to unload one upper limb at a time to the walker. This training follows walking on flat surface with walker support, 3-5 times per week in flat surface. The training strategies include modern approaches of motor learning such as task specificity training for standing, balancing and walking. When first learning the new motor skill (standing or walking), the movements of the Parastep users are extremely slow, vacillating, and poorly coordinated, trunk is flexed, major reactive forces are applied to the walker, the distance between the body and the walker are inappropriate. Each walking-trail is an attempt to achieve a target goal (i.e. secure step, trunk control, not falling, body re-alignment, correct distance achieve). At this stage, learning relies heavily on feedback to control each action. The unskilled Parastep user pauses between movements as visual information is evaluated and the movement is attempted again with a revised plan. At this stage the subjects are motor-learning but movements are not smooth. The Parastep users are then placed on a treadmill. Treadmill walking differs from surface walking on SCI subjects in the following aspects: The treadmill's running-band moves in a backward direction (with respect to the subject body), while the walker-support unit is securely fixed to the treadmill. Four conditions are necessary for forward transport of the SCI body on a treadmill:

- Adequate learning experience for the correct perception of body movement on a running band;
- Proper timing for transfer of body weight to the supporting limb;
- Proper timing for contralateral limb advancement (the Parastep subjects prepare and stimulate the unsupported hip-withdrawal reflex for leg advancement);
- Supporting aids (walker handles) to generate pulling forces by the upper extremities for controlling body movement and correctly keep the center of gravity and prevent falling.

Gradual but progressive speed and walking time increase (at 15-minute intervals).

Treadmill walking recreates 3D sensory inputs to allow loading of maximum or of desirable body weight without losing balance. This is essential to facilitate proper trunk posture and hip extension, integrating properly body systems above and below the level of injury to load or unload, to maximize the goal oriented task of standing, balancing and walking. The sequencing and timing of the movement thus becomes automatic, shifting from direct visual control to a more internalized form of control. The learned movement becomes smooth and coordinated in the treadmill, requiring little attention and facilitating walking under diverse surface conditions for longer periods of time at a self-preferred speed. SCI subjects can then adapt to slope, obstacles, including stairs, walking aids ameliorating energy consumption, attentional and navigational demands. The Parastep users were thus able to deambulate from a few minutes to 1 hour at a speed between 10 m/min to 20 m/min [33,34,53].

Walking Performance

Kern et al., Carraro et al., Camagnini et al., Protasi et al., and Bazo et al. [47-50], have highlighted the difficulties by SCI individuals in recovering paralysed muscles that are capable of generating force and endurance through FES in innervated SCI (spinal cord injured) patients and in denervated muscles. These difficulties were studied on the basis of muscle biopsies that were taken from the right and left vastus lateralis muscles at a single time point for each patient. The resulting specimens were then prepared either for light and/or electron microscopy (EM). These researchers thus shed light on the main factors inhibiting muscle recovery after an SCI.

The results have shown that, for innervated muscles in SCI patients, the time duration after injury that allows starting of effective response to stimulation, IS NOT the limiting factor but that limitation was a function of muscle composition and ultrastructure.

Biopsy results [35,47-50] indicate that stimulation can still be effective 18.39 ± 2.51 years from injury to biopsy, WITHOUT stimulation, in the innervated muscle myofibers that were tested (Vastus Lateralis). At this time duration post-injury, the muscle was shown to consist of 70% of the fiber as compared with 96% in normal same muscle. In contrast, stimulation is INEFFECTIVE in denervated muscles (Lower motor-neuron SCI at 0.85 to 7.4 ± 1 years post injury) where myofibers cover only 14%-40% of the. This study may help to explain the ability of a Buenos Aires patient, 40 years post injury¹, trained by the first author in Buenos Aires, discussed above, to start taking steps within 3 days of training [35].

Studies on 16 individuals (T4 to T11) at the Miami Project to Cure Paralysis of the Department of Neurological Surgery and the Department of Orthopedics and Rehabilitation, University of Miami School of Medicine show (Klose et al. [36]) that the group mean peak distance covered was 334 meters after 32 sessions of training over 11 weeks (ranging from 12 to 1707 meters) at group mean peak duration of 56 minutes (or 5.96 meters/min.).

A study on 14 SCI patients by H Cerrel Bazo et al. [37] at Centro di Neuroriabilitazione e Ricerca, Villa Margherita, Vicenza, Italy, employing the training methodology discussed in Section 5 below, average walking distance of 444.3 meters/walk at a speed of 14.5 meters (average maximum heart rate of 73.95 beat/min.). This was obviously achieved with far more training sessions.

The experience of these authors is that a fair percentage of the younger Parastep users (especially T-6 and lower) can and do exceed 1 mile/walk within about a year post-training. Figure 3 shows the finish line at the Capri Marathon, Italy, where two patients from the Vicenza program [34,35] are finishing a 1500 meters walk. Also, see Youtube videos [51,52], which show complete thoracic-level SCI patients walking outdoors with the Parastep and performing various daily living indoors and outdoors functions independently.

The Parastep was studied in several medical centers to provide benefits well beyond unaided walking ability indoors and outdoors and which benefits are often overlooked.

Studies performed at the Miami Project to Cure Paralysis of the Department of Neurological Surgery and the Department of Orthopedics and Rehabilitation, University of Miami School of Medicine. These were published in a special section of 5 papers in the Archives of Physical Medicine and Rehabilitation [34,36-39], and

¹ This patient did not continue training afterwards for reasons unrelated to the training program when the author left Buenos Aires, not due to any medical condition.

evaluate several medical benefits related to the use of the Parastep system and so did other studies [29-31,42], .

These studies relate to: (1) lower extremity blood flow, (2) heart rate, (3) time to fatigue at peak arm ergometry test, (4) oxygen uptake, (5) spasticity, (6) bone density, (7) physical self-concept scores, and (8) depression scores (Table 1). Note that the results reported do not yet relate to the training methodology.

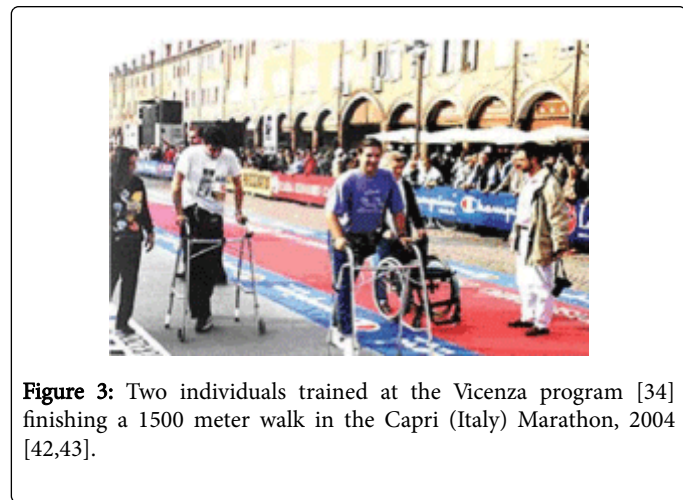


Figure 3: Two individuals trained at the Vicenza program [34] finishing a 1500 meter walk in the Capri (Italy) Marathon, 2004 [42,43].

Medical Benefits

Concerning bone mineral loss, Groah et al. [42] report that bone mineral density (BMD) loss in patients receiving conventional treatment but no FES (the control group), -1.88% over a 6-week test period , compared with -1.29% in patients under FES. At distal femur loss was -15.15% (no FES) against -7.4% with FES and at proximal tibia it was -17.4% against -12.31 with FES. It is unclear what FES training or exercise was involved in the patient undergoing FES, nor is it clear which FES system was used. Also, Groah [42] reports that Osteocalcin markedly decreased in the control group, while it remained stable in those receiving FES.

	Pre-FES Training (average)	Post-FES Training (average)	#of patients in In test/ref
Lower Extremity Blood Flow	417 ml/min	650 ml/min (improvement)	12 patients/Univ. Miami [38]
Heart Rate	70.1/min	63.2/min (imp.)	12 pat/Univ. Miami [39]
Time to Fatigue at Peak arm ergometry	15.3 min	19.2 min	15 pat/Univ. Miami [39]
Peak Workload Heart Rate (pk arm erg. Test)	188.5/min	183.1/min (imp.)	15 pat/Univ. Miami [39]
Oxygen Uptake (pk arm erg. Test)	20 ml/kg/min	23 ml/kg/min (imp.)	15 pat/Univ. Miami [39]

Spasticity	Occasional	None observed (imp.)	16 pat/ Reese Hosp [29,30]
Bone Density	Common	(No effect after 32 sessions)	16 pat/U Miami [41]
		Rate of loss decrease (imp)	26 pat/Nat Rehab Hosp Wsh DC [42]
Physical self concept (TSCS Scores)	43.2 (TSCS)	52 (TSCS) (imp)	15 pat/U Miami [40]
Depression Scores (BDI Scores)	8.8 (BDU)	5.4 (BDI) (imp.)	15 pat/U Miami [40]

Table 1: Medical and psychological effects of FES (parastep tests).

Conclusions

In this paper we tried to provide an updated review of what is till today the only FDA approved FES system and of a patient training methodology which lead to average walking performance as discussed. The results reported are clearly positive, both with respect to walking performance and with respect to medical and psychological benefits and need not be repeated here.

Looking towards what the future may hold, the authors believe that the Parastep system itself can easily be modernized. Specifically, even with no change of software what-so-ever, a modern microprocessor that is thousands of times faster while consuming less energy must replace the present one. This is a trivial change. Bluetooth wireless technology can easily and with no changes in anything else, replaces the wires from the main Parastep unit to the support walker.

Beyond this, the first author experimented on many patients with surface EMG (non-invasive) control. This involves both above lesion EMG control, to substitute the finger-touch switches that activate simulation sequences [28-30,32,42-47,54,55], and below-lesion response-EMG, to control automatically control the level of stimulation in the face of muscle fatigue [28-30,34,56,57]. This again can be accomplished via a wireless technology. It was not included in the commercial Parastep due to the additional training that is involved and the additional number of surface electrodes (to sense the EMG).

However, we are now at the dawn of a new era, the era of Brain-Computer Interface (BCI). Namely, control by deciphering thoughts and intentions from neuronal activity in the brain. BCI can be non-invasive, based on EEG. Impressive insight of the capabilities of BMI for applications related to FES and specifically to the computerized Parastep system is in the work of Pfurtscheller et al., at Graz Univ, Austria [58] and that coming from the group of Bing He at the University of Minnesota [59], both of which aiming at FES applications. This and progress in spinal cord regeneration will and must be the direction of the future².

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² The Parastep is manufactured and distributed by Sigmedics Inc., Fairborn, OH, which is owned by Worldwide Alliance for Locomotion and Kinetics (W.A.L.K.), a Nonprofit Foundation. The first author was founder, Chairman of the Board and Chief Scientist of Sigmedics (1987-1993). Presently, he is not associated with Sigmedics in any way. The patents on the Parastep have all expired by now. The second author is not associated with Sigmedics in any way.

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