THE STATUS OF NONINVASIVE FUNCTIONAL ELECTRICAL STIMULATION AND AMBULATION PERFORMANCE FOR THORACIC-LEVEL COMPLETE PARAPLEGICS

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Abstract—**This paper reviews of status of noninvasive (transcutaneous) functional electrical stimulation (FES) for the purpose of independent ambulation by spinal-cord injured (SCI) patients having complete thoracic-level spinal cord lesions, namely, patients having neither motor function nor sensation in their lower extremities.**

The paper reviews FES system design principles, criteria for patients admissibility to FES ambulation programs and training procedures. It provides data on ambulation performance and on subsequent medical benefits to patients who use a trascutaneous FES system. It also considers problems relating to system adoption and long term system use. Furthermore, the paper discusses regulatory approval and reimbursement aspects concerning the noninvasive FES systems for ambulation by paraplegics.

The paper also compares non-invasive FES as with implanted FES systems and with long-leg braced hybrid systems for ambulation purposes, thoracic level SCI patients.

Keywords—**Noninvasive FES, paraplegia, hybrid FES, Parastep, Ljubljana system, walking distances, circulation, spasticity, decubitus, psychological benefits, regulatory status**

I. INTRODUCTION

The first noninvasive (transcutanous) functional electrical stimulation (FES) in humans was reported in 1960 by Lieberson [1] and was applied to hemiplegic subject for correction of heel drop. Trascutaneous FES stimulator of thoracic-level paraplegic patients was first reported [2] by Kralj et al in 1980 to allow standing and the taking a few steps. 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 (see Graupe, et al., 1982 [3]; 1983 [4]). This design was subsequently implemented in the (now commercially available) Parastep system, which was approved by FDA in 1994 and which is to-date the only FDA-approved such ambulation system (Graupe and Kohn, 1994 [5]).

The early 1980's also saw the beginning of parallel work, based on implanted (invasive) FES systems for the same purpose of ambulation by thoracic-level paraplegics. The main groups working on such percutameous (implanted) FES systems were and still are those of Marolais, et al. (1983 [6]) and of Holle, et al. (1984 [7]).

The limitation of both the invasive and noninvasive FES ambulation systems to thoracic-level spinal cord injuries (SCI) is due to the fact that FES can lead to muscle contractions only when the SCI lesion is an upper motor-neuron lesion. Else, the motor neurons will not fire under stimulation and will not produce subsequent muscle contractions. Furthermore, whereas both cervical-level and thoracic-level SCI lesions are upper motor-neuron lesions as far as lower extremity functions are concerned, all the above systems are essentially limited to thoracic level paraplegia. Paralysis due to a cervical level lesion results quadraplegia, where arm-hand functions are lost. Hence, such patients cannot independently don system on, take it off or stand up to a support-walker safely by themselves or sit down safely without help, as is imperative for independent ambulation.

Work towards ambulation by paraplegics was also initiated already in the 1970's towards using long-leg-braced hybrid systems where ambulation was provided by FES underneath the long-leg braces (Tomovic, et al., 1973 [23]) (Solomonow et al., 1997 [8]). These systems are noninvasive (using transcutaneous FES), but the patients usually requires usually lengthy assistance in donning and doffing the system (the long-leg braces). Hence, hybrid long-leg-braced FES systems do not allow for patient-independent use of the system, as is the purpose of the other systems discussed above.

This paper will focus on the noninvasive FES. Since the Parastep FES system is presently the only one that is widely available and where considerable data exists on its ambulation performance and on its medical and psychological evaluations from several sources, particular attention will be on that FES system. No comparable data are yet available on other such systems. The paper will also discuss other noninvasive FES systems for standing and for ambulation, including hybrid FES-Long-Leg-Braced or FES-Body-Brace systems. Certain aspects of invasive percutaneous FES and of fully implanted FES will however, be considered for comparison purposes.

While this paper aims at considering and evaluating the state of the art of noninvasive FES systems for ambulation by paraplegics, we must comment that, obviously, the most complete and desirable approach to treating spinal cord injuries lies in spinal cord regeneration, on which considerably research is ongoing. However, there is presently no way to predict when regeneration will be applicable to treat human SCI patients. Therefore, a review of spinal regeneration is outside the scope of this paper.

FES is the transmission and the passing of neural-like information (not energy) from the FES system (say, from a microcomputer microchip, as in the Parastep FES system), in terms of properly shaped, directed, coordinated and controlled trains of computer-generated signals to appropriate groups of nerve fibers. These trains of signals trigger a train of natural action potential (AP) in these nerve fibers. The APs then trigger contractions in muscle fibers that are normally enervated by these nerve fibers. The information that is thus transmitted is a train of impulses of various amplitudes and rates that grossly simulates the natural triggering signals that would have been passed by an intact spinal cord in a healthy individual. This train of triggering signals (triggers), namely, the stimulus, is generated and shaped to achieve standing and ambulation over short distances by paraplegics who, in several cases can walk (with the Parastep FES system) a mile at a time.

II. SYSTEM DESIGN PRINCIPLES

2.1. The Parastep FES System

The system design given in this section is mainly based on the design of the Parastep FES system. Since this system is the only one that is widely available, since it is the only FDA-approved FES ambulation system and by its performance, it represents the present status of FES design. A discussion on different designs in other FES systems is briefly given towards the end of this Section. The Parastep system is described in further detail in (Graupe and Kohn, 1994 [5]; 1998 [9]). It is based on a single-microprocessor which is its main component. The microprocessor generates and shapes trains of stimulation pulses that are multiplexed and directed by the algorithm imbedded in that microcomputer to 6 output channels which are individually controlled by the microcomputer, in response to menu selection by the patient, to avoid robotic-like movements. Channel separation is performed by a timing program which is passed from the microcomputer to an array of microcomputer-controlled opto-isolators and then appropriately amplified thus providing the system's outputs to 12 surface electrodes that are attached to the skin at appropriate placements. These skin electrodes are self-adhesive and are reusable for 14 days. They are to be attached by the patient himself in the morning and removed each evening or as desired, at locations that the patient hs been taught to remember. The stimulator unit weighs 7.6 ounces (Fig. 3), excluding a battery pack of six AA 1.5 Volt rechargeable alkaline (or 8 rechargeable NiMH) batteries to allow at least 60 minutes of standing or walking.

Pulse durations are set to be of 120 to 150 microseconds. Higher durations are undesirable and unnecessary higher pulse width speeds up the rate of muscle fatigue and therefore reduces the maximal ambulation distance and the maximal time a patient can stand or walk via FES. It also causes body more electrical charge than needed to be applied than is and requires higher battery power and hence battery weight. Indeed, system weight is a factor in a body-borne system that MUST be as light and as compact as possible.

Inter-pulse frequency is set higher than the average pulse rate in the healthy individual, but still as low as possible (to 24 pulses per second). At lower frequencies muscle vibrations are observed that may affect the patient's balance when standing or walking. Higher frequencies also imply that a higher electrical charge enters the body, and requires higher battery power and heavier batteries. Furthermore higher pulse rates speed up the rate of muscle fatigue to reduce duration and range of ambulation. Both pulse widths and rates, while constant, can be adjusted if necessary.

Pulse amplitude shaping is a major aspect of the pulse shaping algorithm and it is the subject of four different menus within that algorithm. The menus are patient-selectable, through touch of finger-touch switches located on the Parastep's walker or on the Parastep's elbow-support canes. The menus are those for standing-up, for right step, for left step and for sitting down. Pulse-amplitude shaping is dynamic and varies per each of the six stimulation channels and per each menu as is the distribution of output signal to each output channel [5]; [11]. The time variation of the pulse amplitudes in each menu and per each channel is therefore unique and is based on considerations of the executions of the given menu's function (say, taking a right step), and of doing so safely, efficiently and smoothly.

The six simulation channels involved are to electrode pairs (two electrodes per channel, for a total of twelve electrodes) placed, as follows:

Over the right and the left quadriceps muscles, for leg extension; over the right and left common peroneal nerve, for hip flexion – through eliciting a hip flexion reflex, since direct stimulation at the vicinity of the hip is impractical; and over the right and the left paraspinal muscles or the gluteus maximus, (see Chapter 7 of [5]) for trunk stability., (to be placed approximately 1 inch below the level of the level of start of sensation, but not too close to the heart).

Alternatives to the peroneal placements are possible, (see Chapter 7 of [5]. These alternatives involve other branches of the sciatic nerve which trigger the hip flexion reflex. Paraspinal electrodes are not necessary for persons with good trunk stability, mostly when the SCI is at T-10 or below. We note that improved trunk stability affects not just patient safety, but helps to reduce fatigue, thus improving ambulation performance and appearance (which is not just an esthetic aspect but also a psychological one).

The number of channels (of electrode pairs) to be used is a matter of trade-off. Obviously, with more channels, then more muscle groups (at below the SCI lesion) can contract. However, when increasing the number of channels, say from 6 to 8, the patient must place (every morning) 16 electrodes instead of 12, and for a paraplegic patient this involves a lot of additional effort and time. Furthermore, the six channels

that are stimulated by the Parastep system, as discussed above are the ones that are the easiest to be reached by the user and the ones where there is the greatest tolerance in terms of error in placement's localization, while additional sites will require more care in exact placement. It is our experience that with more than 6 channels, most patients will soon stop using the system. Hence, human factor considerations imply to limit the system to the most important functions (channels), as far as performance is concerned. The resulting performance, as discussed later in this review (Section 5 below) appears to justify this choice and to result in a rather smooth walk, that can be viewed in a short movie , as in http://www.ece.uic.edu (click: faculty, then: Graupe, then : research, then open: movie), of a walk by a complete thoracic level paraplegic using the Parastep system.

The Parastep FES system uses a walker or (in a few cases) a pair of elbow-support (Canadian) canes. Walkers are employed in all other FES ambulation systems, invasive or not. Walkers (or elbow-support canes) serve mainly for balance. Walkers carry (in the Parastep system) only 5% or less of body weight in trained FES users during standing and are crucial during the standing-up mode. Their balancing role is due to the fact that complete SCI paraplegics have no sensation (in addition to having no motor functions below their lesion). Hence, indirect sensation coming through their arms and hands, while holding the walker's handle-bars, lets the users sense the ground to provide a certain psychological security. It thus allows the users to balance their body by slight shoulder and arm movements to better balance during standing and walking. The users are able to easily and rather naturally change direction of walking, at will, through shoulder positioning by which they turn their steps. One major function of the walker is during the stand-up phase from a seated position. The patient then gets up with the arms leaning on the walker. All theses reasons indicate the crucial role of walkers towards achieving independent standing and walking.

Menu-Selection finger-touch switches are located on the walker's handlebars for easy finger reach while normally holding the walker (or cane) They require only a light single and quick (short) finger touch, without changing hand position on the bars. Adaptation and learning of balancing and of menu selection (only two menus during walking; of right and of left step, activated at right or left handle-bar), is very easy and fast.

The patients have no sensation of the position of their feet during ambulation. Therefore, it is advisable that they wear shoe-insert AFO's (ankle-foot orthoses) to protect from ankle twisting [5], which can be inserted in any dress, tennis or walking shoes.

In contrast to other FES systems, the Parastep FES system employs fully computerized design (in terms of a single low power microchip), whose prime design goal is to maximize user independence and user friendliness in terms of ease of use and device compactness and lightness, while attempting to maximize ambulation performance. These are accomplished through the control and channel-synchronization software that is employed in the microcomputer chip and through the use of microcomputer-controlled optic isolation chips and consequently, of a single power amplifier for all channels. This also allows the Parastep to employ 6 rather than the usual 4 stimulation channels and to easily integrate them or increased weight, while facilitating full patient control of all channels. Furthermore, it facilitates considerable battery power savings. The additional two stimulation channels (at the paraspinals, for trunk stability) play a major role in enhancing standing time, ambulation distances and speeds as compared with four channel systems. Furthermore, in contrast to most other systems, the Parastep combines considerably lower pulse width and pulse frequency of the stimulation signals, with an additional effect on reducing muscle fatigue [5]. This allows further reduction in system's weight and longer battery life.

2.2. Other FES systems for standing and ambulation

The **Ljubljana FES system**, which is based on the work of Kralj et al [12], [13] is the only other transcutaneous FES system (but for the Parastep) for both standing and ambulation that has been used outside their inventors' laboratory. It stems from that group's earlier (1980) pioneering work on FES (related also to the still earlier 1960 work of Lieberson et al. [1] related to hemiplegia). A bench-model of the Ljubljana system was the first to demonstrate ambulation via FES by a complete thoracic-level paraplegic (1980 [2]). It is based on the same general principles and goals as the Parastep system, which are tracable to Lieberson 1960 work. It differs from the Parastep system in its control and in its channel coordination (to result in a bulkier system than the Parastep system). Its patient-borne version is usually a four channel system. Its signal generation is essentially a two-channel signal generator, such that the four channel system is a double two-channel system. The Ljubljana system is not commercially available (at least, not outside the use in research programs, mainly in Europe) and is presently not FDA-approved. No multi-patient ambulation-performance studies and statistics and no multi-patient medical evaluations or psychological evaluations were published on that system, at least not by outside users.

Another portable noninvasive FES system for standing and walking is the **Stanmore system** (Phillips et al., [14] 1993). It is purely a research tool, based on a bench-computer, for use in a laboratory (Phillips et al., [14] 1993).

There are several other transcutaneous FES systems for standing and ambulation, which are essentially all **bench-devices**, as developed in various research laboratories for use in their own research (see: D. Popovic et al., 1986 [15] and Mayagoitia, et al., 1993 [16]).

There are also several transcutaneous FES systems that are solely limited to standing tests (see: Jaeger, 1986 [17];

Kralj and Bajd, 1989 [18]; Taylor et al., – the Odstock standing system, 1993 [19]; Andrews and Bajd, 1984 [20]). These are obviously outside the scope of this paper.

Hybrid FES-Long-Leg-Brace or FES-Body-Brace systems, which combine trascutaneous FES with a long-leg brace or with a body brace for standing and ambulation by paraplegics, have been developed since the 1970's (Tomovic, et al., 1973 [21]; Solomonow, et al (the LSU system)., 1997 [8]; Andrews, 1993 [22]). These systems are also intended for upper-motor-neuron (thoracic level) LSI. They represent a regression from FES, since they gives up one major goals if FES-ambulation, namely, patient independence. Since hybrid systems use a body brace or a long-leg braces, they are far heavier and far more cumbersome than, say, the 10.5 ounce Parastep. They require 30 minutes to don and a long time to doff. The patient usually requires another person to assist in donning and doffing the system. This also affects patient compliance and regular use of the system, while the system's weight reduces ambulation distances (See: Cerrel-Bazo, et al., 1997 [23] and the LSU 1997 study [8] on the hybrid systems) and braces add to system's cost.

Implanted percutaneous FES systems are beyond the scope of the present review. However, for completeness, they are briefly discussed in Section 8 below, as is a fully-implanted FES system.

2.3. Comments on Invasive (Implanted) FES Systems

Although the focus of this review is the status of non-invasive FES, a few words on invasive method is necessary for completeness.

We already stated in Section 1 that research on implanted FES for standing and ambulation has been carried out in parallel with the work on transcutaneous non-invasive FES since the late 1970's and early 1980's. The first applications to thoracic-level complete traumatic paraplegic were reported for both approaches in the early 1980's (On noninvasive methods: Kralj, et al. 1980 [3]; Graupe et al.1982 [4]; Graupe, et al. 1983 [5]; and on implanted systems: Marsolais and Kobetic, 1983 [6]; Holle et al. 1984 [7]). Both approaches are based on the fundamentals user by Lieberson, et al. (1961 [2]). However, invasive methods, both percutaneous (Marsolais and Kobetic, 1983 [6]; Holle, et al. 1984 [7]) and of fully implanted systems (Davis, et al., 1994 [24]) always involve major surgery, in contrast to the non-invasive transcutaneous methods on which this review concentrates. Furthermore, until now all non-invasive methods encounter loss of contact of electrodes, wire breakage and sometimes even tear of nerve fibers. Such occurrences then require re-surgery. Fully implanted FES (Davis, et al. 1994 [24]) does not encounter infections, as happens with percutaneous methods (in fully implanted systems, a radio-frequency (RF) receiver is implanted that receives RF signals through the skin). All invasive systems require some kind of patient-control from a non-implanted device, as do noninvasive systems. They also require similar patient training and muscle strengthening to noninvasive FES. Implanted device requires no daily electrode placement and removal. However, with the Parastep system, electrode placement takes only 5 to 8 minutes for trained users and doffing takes 3 to 4 minutes. It is therefore not surprising that the Parastep system was the first and still the only FES system for standing and ambulation that received (1994) FDA approval and is commercially available. We note that there are presently about 1000 users of the Parastep and it is used both at home and at workplace. In contrast, there are presently only a few (a dozen or two) users of even the most advanced percutaneous system

The work on implanted FES resulted, however, in great advances in implantation techniques and materials whose importance exceeds FES for ambulation purposes. However, the difficulties above are still with us and surgery will always be required for implantation.

III. Patient admissibility and training

3.1, Patient selection criteria

The criteria for selecting a candidate suitable for to be trained to use an FES system, invasive or non-invasive, for standing and ambulation, are as follows [5]; [9], [11]:

(1) 3-4 months or as allowed by the neurosurgeon after recovery from surgery that follows the SCI.

(2) Traumatic complete SCI at the thoracic level of the spinal cord (having essentially no sensation or motor function below the SCI lesion). When some sensation exists, it should be such that the patient can tolerate the stimulation. Intact lumbar and sacral spinal cord (below T-12). Else person will not respond to stimulation. If a lesion exists exists below the T-12, then the patient usually lacks muscle tone in legs and has no spasticity.

(3) Stable ortho-neuro-metabolic system

(4) No history of long bone stress fractures, osteoporosis, or severe hip or knee joint disease. A bone density test is advisable in case of women over 40 and for patients who are many years (10 or more) post injury. (The author worked with a patient who 40 years post injury who was accepted to the FES ambulation program).

(5) Adequate trunk stability, at least once the paraspinals are stimulated, so that patient can keep upright while supported with arms on the walker.

(6) Adequate arm strength so that patient can get up to the walker. This is tested by having patient able to lift self up onto the walker and stay up for a few seconds.

No history of cardiac or respiratory problems.

(7) Sufficient finger control or voice control to select menus either by finger-touch or by speech commands.

(8) Patient should not be pregnant, since the effort involved in standing and ambulation via FES is much higher than in normal standing/ambulation.

(9) No severe scoliosis

(10)No morbid obesity.
(11)Certain skin diseases at stimulated sites should prevent stimulation at these sites
(12)No irreversible contractures.
(13)Motivation and desire to walk and commitment to complete the training process and to use the system daily.

Since the physical effort in ambulation via FES is at least 6 times that in normal walking, as indicated by oxygen intake tests [5], the cardiovascular status of the patient must be good. Patients with very low blood pressure may be subject to vertigo when using FES. Hence, when complaining of dizziness, they should be instructed to lie down and subsequent training should be rescheduled or postponed accordingly.

3.2 Patient training in Ambulation via FES

The experience of this author over 24 years of working with patients in the use of the Parastep FES system for standing and ambulation indicates that once a patient satisfies the criteria as above, the patient is able to stand and to ambulate if trained properly. Distances and speed vary widely. Even distances (and speeds) well below the averages mentioned in this paper may be major achievements for some patients, depending on their general health, level of lesion or age. The author worked with a 62 old T-3/T-4 complete paraplegic who spent 40 years in a wheel chair and who stood up in his first FES session and took 12 steps in his third one-hour session. Motivation is a major factor in progress and performance as is family/friends' and (and physician's) support. Treadmills are important for muscle strengthening exercises. The patient should have at least one strong arm chair with arm rests at an adequate height to be able to independently get up from onto the walker and then, to sit down independently from the walker.

Training programs vary as do their respective results. Certain Parastep training programs that involve 5-6 hours a day of supervised training, over 5 or 10 consecutive days. Other Parastep programs are of one hourly session every week or every two weeks for 12 months. A major Parastep programs is of three one-hour sessions per week over 11 weeks (Klose et al., 1997, [25] – the University of Miami program). Finally, there is an intensive Parastep program of 2 hours a day, five days a week over 4 months (Cerrel-Bazo et al., 1997 [23] – the Vicenza program, Italy). Since all these programs use the same FES system (the Parastep system), the performance results shed a light on their efficiency. However, they differ widely in cost and in the required commitment of time by the patient. Therefore, the decision on which kind of program to attend is usually not a matter of choice and of financial and other personal considerations. Obviously, the more intensive programs lead to the best performance. In all training programs, the patient must complement the supervised sessions with after-hour home exercise of; say at least 15 per day.

All training programs start with reconditioning and strengthening of the muscles involved, firstly and mostly the quadriceps muscles. Treadmill exercises in walking are often used, usually combined with heart rate blood pressure monitoring. It is psychologically most important to stand a patient up, even for 20-30 seconds (as long as is safe) already in the first session. This and early taking of 2 to 3 steps are great motivators. The first step should be taken after the patient can stand safely (with a walker) for about 3 minutes. Eventually, training and muscle strengthening should aim at standing for 10 minutes or more and at walking for as long as is possible. These sessions should start with treadmill standing and walking. At the last stages of training, patients should be taught to fall and to avoid an actual fall through proper use of walker. Patients must then proceed to learn to lift themselves up from the ground by themselves, to walk on rough ground and on reasonable slopes, to get in and out of a car unaided and to climb 1-2 stairs. The most advanced T-9 to T-12 patients can also train using elbow-support cane instead of walker support.

Above all, continuing to walk every day after end of training, (at least 45 minutes a day) is essential to maintain and improve performance with its resultant health benefits.

IV. Ambulation Performance and Medical Consequences

4.1 Ambulation Performance Data

Performance is influenced by the training program, but mostly by how rigorously the patient continues to actively stand and walk with the FES system after end of training. Improvements in performance will be very noticeable one or two years after end of formal training. Approximately 5% of the Parastep users known to the author (from several US training programs) can ambulate one mile per walk on occasions (usually one year or more after end of formal training). The author expects this to be the case also for the Vicenza (Italy) training program.

The Miami Project to Cure Paralysis of the University of Miami reports Average ambulation distances for Parastep users of 115 meters/walk at a mean pace of 5 m/minute, at the end of the training program of 33 sessions over 11 weeks (Klose et al., 1997 [25]) . For the Parastep training program of daily sessions over 4 months at the Centro di Rehabilitazione di Villa Margherita in Argugnano, Vicenza, Italy, an average distance of 444 meters per walk was reported, at a mean speed of 14.5 m/minute and with mean daily walk time of 90 minutes (Cerrel-Bazo, et al., 1997 [23]). These performance differences are very significant. Still, there is no reason to assume that persistent FES users in the 11 week program cannot do as well as those in the 4-month program at 1 year after end of training. However, continuous-use may be higher for patients whose

performance at end of training is considerably higher. This is the author's experience in his own (once weekly over 1 year program). The Vicenza program reports zero drop-out 14-39 months after end of training [23].. The author is not aware of other training program with similar results.

We comment that the averages above are for patients whose SCI lesion levels are more or less evenly distributed between T-1 and T-12. Usually, performance is better if the LSI lesion is lower (towards T-12). However, motivation, persistence often makes up for level of lesion. Still, patients who, for various medical or age reasons cannot walk more than 10 meters (per walk) at end of training, should still continue exercising, since benefits of FES exercise are more than just a matter of distance or speed, as is discussed below. Kralj et al. 1993 [13]) give general utilization statistics on their Ljubljana FES system, by its developers. However, these do not include performance data or medical or psychological patient evaluation on that system. The data given below on the Parastep system, are from independent centers (University of Miami Medical School, the Vicenza Rehabilitation Center, Italy), that are not connected with the system's manufacturers or its developers.

Table 1 (below) gives further ambulation performance data.

4.2. Medical and Psychological Consequences and Benefits

Ability to ambulate 10 meters or one mile is not the only benefit of ambulation via FES. By now several research groups have published medical and psychological evaluation data on patients who underwent ambulation training with the Parastep FES system. Below, we discuss the major such evaluation results:

(i). Lower-Extremity Blood Flow:

A study on Parastep users at the Miami Project (Nash et al., 1997 [26]) discussed earlier, involving 12 Parastep users, reports of an average increase of lower extremity blood inflow volume from 417 mL/min, to 650 mL/min. after 12 weeks (32 sessions) of Parastep training. It is noted that, after paralysis due to thoracic level SCI, blood flow to the lower extremities decreases considerably, with detrimental subsequent effects on kidney function and eventual cardiovascular effects. Dr. Cerrel-Bazo reported (verbally) to this author similar improvements (at the Vicenza program).

(ii) Other Cardiovascular Effects

The above twelve-patient study at the Miami Project [26] has shown that the average resting heart-beat of Parastep users decreased from 70.1 (prior to FES training) to 63.2 (post-training). Also, the Common Femoral Artery cross-section area increased from 0.36 sq.cm (pre-training) to 0.48 sq.cm (post FES training).

(iii). Physiological Responses to Peak Arm Ergometry

A 15-patient study on physiological responses by Parastep users (Jacobs, et al., 1997 [27]) to peak arm ergometry exercises have shown that average time to fatigue has improved from 15.3 min. pre-start of FES training to 19.2 min. after 33 sessions of training. Also, the peak workload increased from 48.1 Watts to 60 Watts. Oxygen uptake at peak arm ergometry increased from 20.02 mL/Kg/min pre-training to 23.01 mL/Kg/mim post-training, while the respiratory exchange ratio dropped from 1.26 pre-training to 1.18 post-training, to indicate improvement in all these parameters. The patients (12 men, 3 women) ranged in age from 21 to 45, in years from injury from 0.7 to 8.8 and in body weight from 53.6 Kg to 83.5 Kg.

(iv). Muscle Mass

A significant increase (10% to 22%) in thigh circumference was measured on Parastep users after 3 to 6 months of training at the University of Illinois/Michael Reese Hospital training program in Chicago [5].

(v). Spasticity

Spasticity is common to all SCI patients with upper-motor lesions. The authors experience in 19 years of observing well over 100 patients training with or using the Parastep system, almost all patients who complained of spasticity commented on either considerable or some improvement in spasticity. This improvement was usually observed after the first 2-3 training sessions. Usually, the higher the degree of spasticity, the greater was the improvement that was reported. This improvement was often reported as one of the reasons for participating in the FES program. The improvement in spasticity is important also due to the detrimental effect of medications (Baclofen, Valium, Lioresal), with respect to concentration and fatigue, noting that doses of such medication can often be reduced for FES users [5].

Ave. Speed	Ave. Distance m/walk	m/min
Approx 85 sessions daily over 4 months Vicenza (Cerrel-Bazo et al. [23])	444.3	14.5
32 sessions 3/week, 12 weeks Univ. of Miami (Klose et al. [25])	115	5.0

TABLE 1 AMBULATION PERFIRMANCE RESULTS (Parastep Users)
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

(vi). Bone Density

Practically all paraplegics suffer from reduced bone density. This happens right after injury and may be aggravated when the patient does not put weight on the legs whereas one of the Parastep patients in the author's program recorded a 50% bone density prior to training (but no bone injuries) with no improvement after one year, he continued to walk and reached one mile per walk. The only study published till now (Needham-Shropshire et al., 1997 [28]) does not show any improvement in bone density due to FES ambulation. However, this study refers to the end of 11 weeks of training. No study exists on patients who have consistently walked via FES for several years.

(vii). Pressure Ulcers (Decubitus Ulcers)

Almost all paraplegics suffer from decubitus ulcers However, all but one patient at the author's FES program (at Michel Reese Hospital, Chicago), had no occurrence of a new ulcer while regularly using FES. Improved blood circulation at below the lesion is most likely related to this [11]. The exception was due to a cut from a sharp object.

(viii). Psychological Effects - Self Concept Scores

A study on 14 Parastep users after 11 weeks of training at the Miami programs (Guest et al., 1997 [29]) compares Tennessee Self Concept Scale (TSCS) scores before the beginning of Parastep training and at the end of the 11 weeks. It shows that the average TSCS score improved in a statistically significant manner from 44.3 to 52.0. Furthermore, all patients with a score below 50 prior to FES-training have improved, whereas no patient with an initial score above 50 dropped to below 50.

(ix). Psychological Effects – Depression scores

The study [29] also reports on comparing Beck Depression Inventory (BDI) scores for measuring depression before and after 11 weeks of Parastep training. BDI scores of below 9 refer to no depression, scores below 18 to mild depression and scores from 18 to 29 point to moderate depression. The results of the study show that all 5 patients who were initially at mild or moderate depression score levels (one was initially even beyond the moderate range) improved significantly. The patient who was initially beyond the moderate depression range (namely, BDI score of 31) improved to 24 (mild depression range). One of the 2 patients, who were initially in the moderate range, improved to the low-mild range and the other to the no-depression range. All patients who were initially in the low depression range stayed in that range. The medical and psychological evaluation data are summarized in Table 2 below.

VI. Conclusion

This paper is concerned with the status of what non-invasive FES can already do for the thoracic level (complete) paraplegic patient in non-invasive FES, on how it performs and what its regulatory status is. Therefore, we did not review research that is presently in progress. Improvements and new avenues are always needed. Work on these is on-going. It is not yet part of the state of the art of what the user can get now.

We thus conclude that a totally non-invasive FES for independent standing and mobility is presently a reality today for complete upper-motor-neuron thoracic-level traumatic paraplegics. Furthermore, one such ambulation system, the Parastep FES system, is commercially available, having received FDA approval in 1994. It has also received (2002) approval for reimbursement by the Center for Medicare and Medicaid Services (CMS) that regulates Medicare and Medicaid reimbursements policies in the USA [30] and subsequently by practically all medical insurance companies in the USA. [cf. 31]. Training programs for that system exist in many hospitals and rehabilitation centers.

	Pre-FES-Training (Ave)	Post-FES-Training (Ave)	
Lower-extremity Blood Flow	417 mL/min	650 mL/min (improv.)	(Nash et al. [26]) 12 patient data/ U. of Miami
Heart Rate	70.1	63.2 (improv.)	(Nash et al. [26]) 12 patients/Miami
Time to fatigue (at peak arm ergometry test)	15.3min	19.2min (impr.)	(Jacobs et al. [27]) 15 patients/Miami
Peak Workload Heart Rate (pk arm ergom. test)	188.5	183.1 (impr.)	(Jacobs et al. [27) 15 patients/Miami
Oxyg. Uptake (pk Arm ergom. test)	20mL/Kg/min	23mL/Kg/min (improv.)	(Jacobs et al. [27]) 15 patients/Miami
Spasticity		usually improvement especially for very spastic pre-training	(Graupe, Kohn [5],[9], [11]) 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.[28])
Physical Self Concept (TSCS scores)	43.2 TSCS	52 TSCS (improv.)	(Guest et al. [29]) 15 patients/Miami
Depression Scores (BDI scores)	8.8 BDI	5.4 BDI (impr.)	(Guest et al. [29]) 15 patient data

TABLE 2. MEDICAL AND PSYCHOLOGICAL EVALUATION DATA (Parastep Users)

As was discussed above, upon completion of 4-months daily training, ambulation distances for the Parastep system were reported to average 444 meters per walk [23], or 115 m/walk in a 33-session 11-week program [25]. Medical benefits have been documented, in terms of greatly increased blood flow to the lower extremities [26], reduced spasticity [6], reduced incidence of decubiti [11], increased thigh-circumference [5] and of psychological benefits (improved self concept and depression scores) [29].

Still, even 10 years after FDA approval of such a noninvasive FES system and 2 years after reimbursement was approved by Medicare, Medicaid and by most insurers, there is great ignorance in the paraplegics community about the availability of such a system, and of its performance and benefits (see [32]: Kilgore, et al., 2001). In [32]., a statement by a patient is quoted (made in a recent symposium of prospective FES users, funded by the Whitaker Foundation), that "in 3 to 4 different rehabilitation facilities and (having) talked to over 200 patients… none of them ever mentioned FES". These indicates ignorance, regarding the role of FES in paraplegia, among physicians involved in caring for paraplegics and among the (physical and occupational) therapists and other related staff.

The consensus of the Symposium above (and which agrees with what this author repeatedly hears from patients), was that desire to stand upright independently and to ambulate even short distances, is the prime desire of paraplegics Still, long-term compliance and long-term use of FES is also a problem. However, the circulatory benefits and the other medical and psychological befits should play an important role, for patients, for physicians and for insurance companies involved in the care of paraplegics.

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