Technological Advancements in Rehabilitation: Independent Standing & Short Distance Walking for the Spinal Cord Injured

An Overview of The Parastep® System

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I. Executive Summary

The purpose of this paper is to introduce and describe The Parastep System, a new rehabilitation technology for people who have sustained a spinal cord injury. The Parastep is a microcomputer controlled system which emits low levels of electrical currents through surface applied skin electrodes to the paralyzed limbs of upper-motor-neuron injured paraplegics and some quadriplegics. The stimulation evokes a muscle response in the lower extremities which allows users to independently stand and walk short distances.

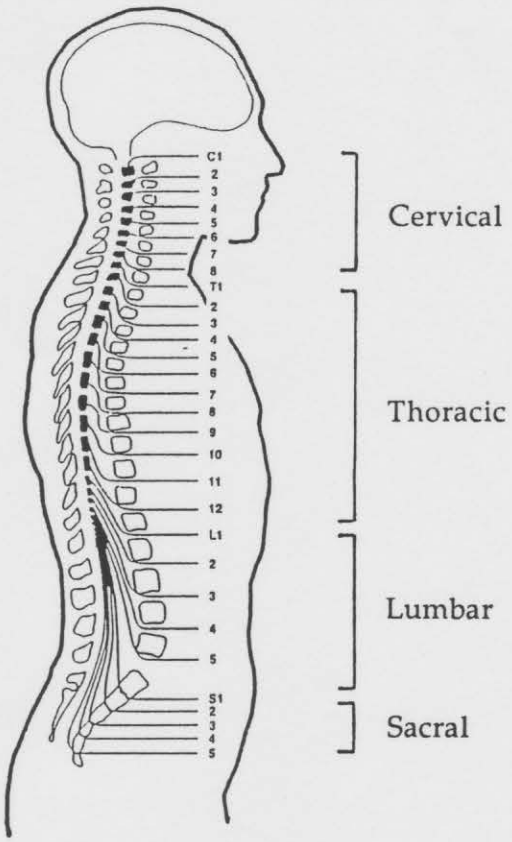
This paper will discuss the devastating effects of spinal cord injury, provide a historical overview of the use of functional electrical stimulation as an effective rehabilitation modality for the spinal cord injured, and describe The Parastep System, including patient management protocols and the short- and long-term benefits of System use. It will demonstrate that The Parastep System is a cost effective therapy which should be covered by third party payors to help restore independence, mobility and function to those disabled by a spinal cord injury.

II. Spinal Cord Injury

Definition

A spinal cord injury is a traumatic lesion to the spinal cord and the associated nerves. Thirty-one spinal nerves originate from the spinal cord: 8 cervical, 12 thoracic, 5 lumbar, 5 sacral and 1 coccygeal.[1] An injury can result in varying degrees of neurologic impairment (muscle paralysis and/or loss of sensation), depending on where and to what extent the spinal cord is injured. Generally, the higher the injury is to the cord, the more extensive the impairment. Quadriplegics have varying degrees of motor and/or sensory dysfunction in both the lower and upper extremities. This is usually the result of an injury or trauma to one of the eight cervical segments of the spinal cord. Paraplegics have motor and/or sensory loss affecting the lower extremities only, which is the result of an injury or trauma to the thoracic, lumbar, or sacral regions of the spinal cord. (See Exhibit 1.)

Exhibit 1: The Spinal Cord



Demographics

Spinal cord injury can occur in a number of different ways. The major causes are motor vehicle accidents (48%), falls (21%), acts of violence (15%) and injuries resulting from recreational sporting activities (14%).[2]

Spinal cord injury is a tragedy that primarily affects young adults. Sixty-one percent of all injuries occur between the ages of 16 and 30. The average (mean) age at injury is 29.7 years, the median age of injury is 25 years and the most frequently occurring age at injury is 19 years.[3]

The overwhelming majority of spinal cord injured patients are male (82%). The male-to-female ratio is approximately 4-to-1.[4] While the reason for such an imbalance can only be speculated, it is generally accepted that young males are more often involved in high risk activities than are their female counterparts.

The majority of spinal cord injured individuals are employed in the competitive labor market or are students at the time of injury.[5]

Prevalence and Incidence

It is estimated that there are 225,000 to 250,000 people with spinal cord injuries in the U.S. today with an estimated 8,000 to 10,000 new cases occurring annually.[6]

III. Medical Consequences of Spinal Cord Injury

The physical and emotional changes that result from spinal cord injury are traumatic and profound. The loss of motor strength in the legs and the consequent loss of mobility, function and ability to ambulate are the most observable and traumatic features of a spinal cord injury. The injury, however, results in more than just a physical disability. Spinal cord injury changes, often suddenly and irreversibly, an individual's quality of life and affects the way people view themselves. The injury has emotional and psychological effects including depression, loss of morale, self-esteem and self-image. And, in addition to the emotional and physical adjustments to paralysis, people who have suffered a spinal cord injury have a host of other secondary medical complications including: [7-8]

- Muscular atrophy in the lower limbs resulting in reduced muscle mass and strength
- Loss of bone mineral content, which can result in osteoporosis
- Frequent occurrences of decubitus ulcers and skin breakdown problems
- Increased incidence of urinary tract infections and other urinary and bladder problems
- Muscle spasticity
- Impaired circulation
- Reduced capacity of the heart and lungs

A spinal cord injury, therefore, has enormous physical, emotional and economic consequences. Optimization of function, and the prevention and/or management of the secondary medical complications which accompany a spinal cord injury, is of the utmost importance for both the individual, his family and for society.

IV. Rehabilitation Treatment Alternatives

Current methods of functional mobility rehabilitation for individuals with spinal cord injury have focused on the wheelchair. But use of the wheelchair is not without problems. Two of the major problems associated with the wheelchair are environmental barriers and decubitus ulcers or pressure sores. Another major limitation is that traditional wheelchairs do not enable standing, and even the newer standing wheelchairs do not enable ambulation.

Ambulation after spinal cord injury has traditionally relied on long leg braces (LLBs), knee-ankle-foot-orthoses (KAFOs), or reciprocating gait orthoses (RGOs). Studies, however, of paraplegics who were prescribed long leg braces indicate a high rejection rate for these devices. [9-12] Many paraplegics fail to use them once discharged from the rehabilitation setting. In fact, a recent study has shown that only 26% of the people who were prescribed braces continued to use them for any purpose, with only 4% using them as their sole means of mobility.[12] Reasons for the high rejection rate include difficulties in donning and doffing the braces, cosmetic concerns and the significant energy expenditure required for walking. It should also be mentioned that these orthoses are passive devices which mechanically support an individual's musculature. The user does not actively use his or her own leg muscles for ambulation.

Current rehabilitation modalities have provided limited benefits to the spinal cord injured in terms of independence, mobility, function and long term health consequences. The Parastep System is a new rehabilitation technology with the potential to change this scenario.

V. A New Rehabilitation Technology: Functional Electrical Stimulation

The Parastep System is a microcomputer controlled functional electrical stimulation (FES) system that enables independent, unbraced standing and short distance walking by upper-motor-neuron injured paraplegics and some incomplete quadriplegics.

Functional Electrical Stimulation

Functional Electrical Stimulation (FES) is a technology which uses low-levels of electrical current to restore the loss of motor or sensory function, or to reverse the progress of a disabling condition.[13] It is used in more than two dozen medical applications to produce a specific outcome. FES has been used for cardiac pacing, to alleviate pain, improve bladder control, reduce epileptic seizures, prevent the progress of scoliosis, promote bone growth, improve blood circulation in various parts of the body, control respiration and stimulate the auditory nerve and visual cortex.[14]

The first application of FES to a paraplegic patient was reported by Kantrowitz in 1963. Kantrowitz attached electrodes to a paraplegic subject, and, by applying electrical current that stimulated the muscles under the skin, he was able to get his subject to walk several steps.[14] Research conducted since then by numerous researchers* has demonstrated that the application of electrical pulses of the appropriate amplitude, pulse width and frequency can enable paraplegics to stand and take steps. However, the FES systems used for research purposes were often large and usually required the presence of a physician or a physical therapist to individually activate the patient's steps; or, in some cases, more invasive techniques such as the use of subcutaneous (implantable) electrodes were used.

In 1981 Daniel Graupe, Ph.D., Professor of Electrical Engineering and Computer Science and Adjunct Professor of Physical Medicine and Rehabilitation at the University of Chicago, in conjunction with Kate Kohn, M.D., Clinical Professor at the University of Illinois Medical School and Chairperson, Department of Physical Medicine and

* Key researchers in the use of functional electrical stimulation for ambulation include the University of Ljubljana, Ljubljana, Yugoslavia (Kralj); Rancho Los Amigos University, Downey, California (McNeil/Waters); Case Western Reserve University, Cleveland, Ohio (Marsolais/Peckham); Wright State University, Dayton, Ohio (Petrofsky); and the Pritzker Institute, Chicago, Illinois (Yarkony/Jaeger). [15]

Rehabilitation, Michael Reese Medical Center, established an FES research clinic for independent ambulation. The Parastep is the result of ten years of their research with paralyzed subjects at Michael Reese Medical Center in Chicago (now Humana Hospital – Michael Reese). Their goal was to develop an FES system that could be totally controlled by the user and which would be practical for use outside of the clinical laboratory.

Consequently, Dr. Graupe designed the Parastep so that it is totally controlled by the user and is easy to operate, activate and control. A minimum amount of training is therefore required for independent home use. He miniaturized the stimulator unit, which made it possible to move the Parastep outside of the clinic into the home or work environment. The battery operated stimulator unit is small, lightweight and portable. Weighing only 7.6 ounces, it is usually worn clipped to the user's belt. Dr. Graupe also eliminated the need for supporting leg braces, which makes the Parastep easy and quick to don and doff and improves the cosmesis of the system, which is an important feature for users. Finally, the Parastep was designed with a variety of safety features built in, so that there is minimal risk to users. These design features have allowed the Parastep to move beyond the clinical laboratory to help restore mobility and enhance functional ability for the spinal cord injured on a daily basis.

A Premarket Approval Application (PMA) for the Parastep has been submitted to the U.S. Food and Drug Administration. Sigmedics expects approval within the next 12 months. Until the system is approved, its use is considered investigational in the U.S. The Parastep has met the provisions of the Medical Devices Regulations of the Health and Welfare Bureau of Canada, Health Protection Branch, and the U.S. Food and Drug Administration has also approved export of the system to Canada.

VI. The Parastep® System

The Parastep System is a comprehensive approach to enable standing and short distance walking. The system consists of professional physical therapy training/support services and product components.

Physical Therapy Services

Physical therapy is a key element of The Parastep System. Thirty-two sessions of physical therapy, including instruction on system use and gait training, are provided to users at no charge when they purchase a system.

The physical therapy sessions are provided by specially trained physical therapists at rehabilitation institutions across the country. Sigmedics has established a comprehensive training and education program for rehabilitation professionals (physiatrists, neurologists and physical therapists), including rigorous protocols for patient selection, patient education/training, and patient follow-up.

Product Components

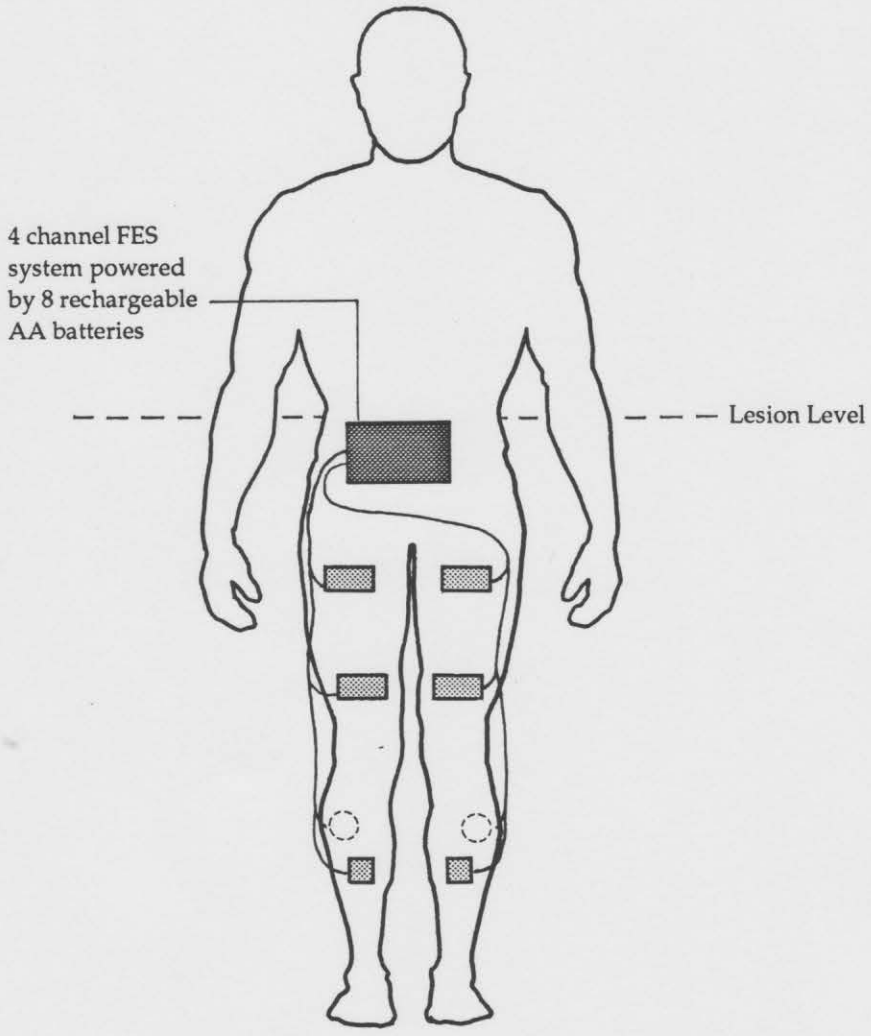
The Parastep System consists of a microcomputer controlled neuromuscular stimulator, a battery pack with recharger, surface applied electrodes, power and electrode cables, a control and stability walker with surface mounted control switches, and the Paratester™, a diagnostic unit for testing system components.

Exhibit 2: The Parastep System

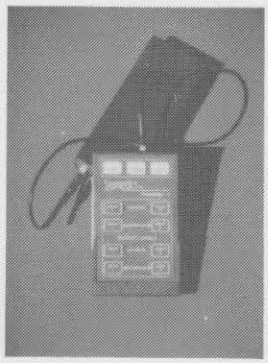
A T7 paraplegic standing with The Parastep System

The neuromuscular stimulator generates sequences of electrical impulses. These impulses are passed to the target peripheral nerves through surface applied skin electrodes, placed on the quadriceps muscles and over the peroneal nerves on the lower legs. Stimulation of the quadriceps muscles causes contraction which results in knee extension, allowing the user to stand. Stimulation of the peroneal nerve in the lower leg initiates a reflex contraction of the hip muscle to flex the hip, which allows the knee to bend, producing a step and allowing the user to walk.

Exhibit 3: The Parastep System – Operational Schematic

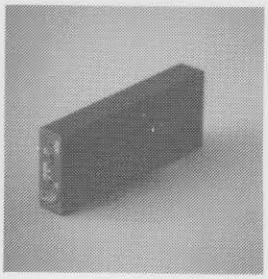


Each of the components of the system will now be discussed in turn.



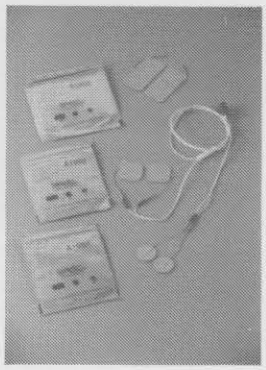
Neuromuscular Electrical Stimulator

The stimulator unit houses the microcomputer and associated electronics which generate the electrical impulses that stimulate the user's legs. It has four* stimulation channels: two for the quadriceps muscles and two for the calf muscles. The unit is lightweight (7.6 oz.) and is usually worn clipped to the user's belt. Users set levels of stimulation, increase or decrease levels of stimulation and activate commands for standing and stepping through a user-friendly key pad on the front of the stimulator unit or through switches mounted on the walker. The stimulation level is displayed by a 10-segment LED (light emitting diode) display located on the side of the stimulator unit.



Battery Pack

The stimulator is powered by a rechargeable battery pack which contains eight AA nickel cadmium batteries. The battery pack is attached to the stimulator unit with a power cable and then is usually placed in the user's pocket. A low battery level indicator is built in, to warn users when recharging is necessary. A normal charge provides for approximately 2 1/2 hours of continuous use.



Electrodes and Lead Cables

Stimulation signals generated by the stimulator unit are sent by two cables to eight self-adhering, surface skin electrodes that are applied to the user's legs. One cable connects to four electrodes on the right leg, and one cable connects to four electrodes on the left leg.

Two electrodes are applied to the quadriceps muscles (i.e., on the upper thigh) of each leg, and two electrodes are placed on the lower leg: one over the peroneal nerve (underneath the knee bend, just behind the head of the fibula) and one over the shin (lateral to the upper third of the tibia, over the anterior tibialis muscle). (See Exhibit 3, page 11.) Some variation in electrode placement may be necessary for each user to produce the most effective steps.

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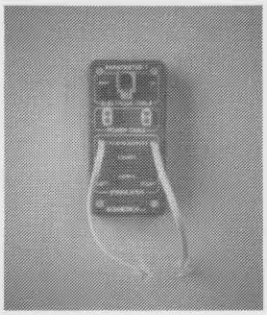
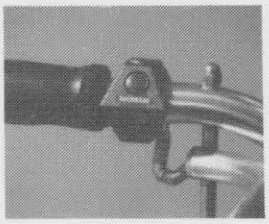
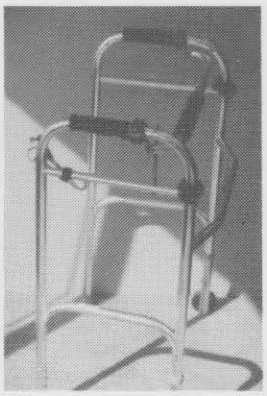
* A six-channel Parastep stimulator unit is also commercially available. The extra two channels are prescribed for patients requiring additional trunk balance and control.



The Paratester™

The Paratester is a diagnostic tool for pretesting system components. The tester checks and alerts the user of possible malfunctions in the stimulator, and electrode and power cables.





Control and Stability Walker

A specially designed walker is utilized to compensate for the user's lack of balance. It provides support and stability while standing and walking. After presetting the initial levels of stimulation to be applied to the legs on the face panel (keypad) of the stimulator and attaching the walker cable to the stimulator unit, the user can operate all commands (stand, step, sit, increase/decrease levels of stimulus) through finger switches mounted on the handle bars of the walker (see photo above).

Technical Service and User Support

The acquisition of The Parastep System gives a spinal cord injured individual a life long capability to stand independently, take steps and walk short distances. Sigmedics is committed to providing the clinical and user support required to ensure compliance and to maximize user performance with the system. The company has a staff of experienced clinicians who have developed a comprehensive clinical and user support program including:

- Ongoing, onsite education and training of rehabilitation professionals (physiatrists, neurologists, physical therapists) in system use, patient selection, and patient education and training
- Complete package of patient education materials and user manuals
- The *Parastep Update,* a quarterly newsletter for clinicians and users which provides updates on product technology and techniques on system use
- A nation-wide user support network including quarterly user group meetings sponsored by Sigmedics, in conjunction with participating rehabilitation institutions. These group meetings provide participants with the opportunity to share their experiences in using the Parastep and to obtain information and techniques for maximizing their functional use of the system
- Toll-free telephone access for technical, clinical and user inquiries. The technical service and user support operation is directed by a Sigmedics employee who has been a Parastep user for eight years and has a thorough knowledge and understanding of both the product technology and user issues and concerns

User Selection Criteria

Upper-motor-neuron injured individuals with adequate trunk control are candidates for The Parastep System. The most suitable candidates have thoracic injuries T4 to T12. But individuals with thoracic injuries T1 to T3 and incomplete cervical injuries C5 to C8 may also be acceptable candidates. (See Exhibit 1, page 3.) Candidates for The Parastep System should have stable ortho-neuro-metabolic systems, intact lower motor units (L1 and below) and no history of long bone fractures, severe osteoporosis, hip or knee joint disease. In addition, candidates must satisfy the clinical and functional criteria outlined in Exhibit 4 (below).

Exhibit 4: Clinical and Functional Criteria for Parastep Use

Clinical Criteria:	*Functional Criteria:*
1. *Motivation* Does the patient demonstrate and express appropriate motivation and commitment to the therapeutic program?	1. *Force Generation – Hip and Knee Torque* Does the patient demonstrate sufficient muscular force with FES at the hip and knee required for function?
2. *Musculo-skeletal Integrity* Is adequate muscle and joint stability available for weight bearing at upper and lower extremities?	2. *Cardiopulmonary Reserve* Does the patient respond to upright positions and stepping with adequate hemodynamic and ventilatory response?
3. *Articular Excursions* Is sufficient range of motion available at all extremity articulations?	3. *Independent Transfers* Is the patient independent in all transfers?
4. *Motor Excitability* Does the patient demonstrate appropriate muscle contractile response to Functional Electrical Stimulation (FES)?	4. *Standing Tolerance* Does the patient demonstrate adequate tolerance to perform standing activities?
5. *Controlled Spasticity* Is motor hyper activity sufficiently controlled to allow safe independent upright stance?	5. *Balance and Trunk Control* Does the patient demonstrate adequate balance and control skills to maintain an upright supported posture independently?
6. *Cognition* Does the patient demonstrate adequate faculties and learning capability to successfully employ The Parastep System?	6. *Grasp* Does the patient demonstrate adequate hand finger control to manipulate system controls?
7. *Sensation* Does sensory perception of electrical stimulus allow sufficient levels required for muscular contraction?	

Individuals with the following conditions are not appropriate candidates for The Parastep System:

- Cardiovascular disease
- Pulmonary insufficiency
- Pregnancy
- Epilepsy
- Severe scoliosis
- Severe spasticity
- Severe osteoporosis
- Irreversible contractures
- Skin disease at stimulation sites
- Morbid obesity
- Vision or hearing impairments, which could interfere with training

Sigmedics estimates that 40% of the spinal cord injured population could be candidates for The Parastep System.

Physical Therapy Protocols

Comprehensive physical therapy protocols have also been established for rehabilitation professionals. The goal of physical therapy is independent use of The Parastep System to stand and ambulate short distances with a walker. User selection, education and training, will occur under the direction and supervision of a physical therapist specifically trained by Sigmedics on the use of The Parastep System. Thirty-two sessions of physical therapy will be provided to Parastep users and will cover the following:

Safety:

- Patient Instruction
- Equipment Check and Maintenance Instruction
- Fall Prevention Instruction
- Terrain and Surfaces Instruction

Physiology:

- Improve Strength
- Improve Endurance
- Improve Balance

Utility:

- Self Initiated Powered Muscular Contraction
- Powered Sit-Stand-Sit
- Upright Weight Shift (Lateral)
- One Leg Stance
- Walker Advance
- Stepping and Foot Placement
- Upright Weight Shift (Forward)
- Alternating Gait
- Independent use in Activities of Daily Living

Clinical training is conducted 2 to 3 times per week. Unsupervised physical conditioning sessions are prescribed, to be performed daily at home, to improve the strength and endurance of the lower extremities. Patient information, treatment records and functional measures will be collected at each training session, consolidated into a progress report, and will be forwarded periodically to third party payors, upon request.

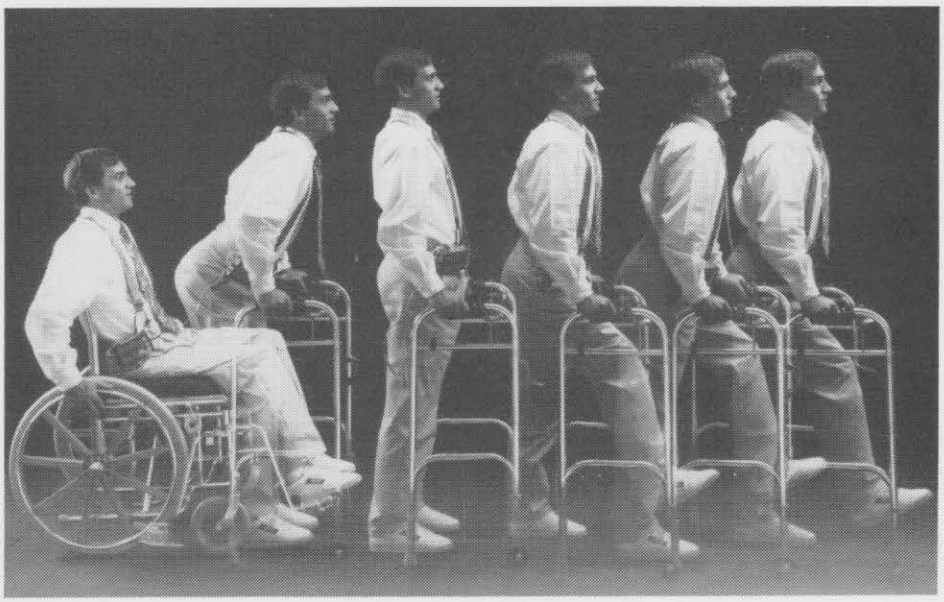
VIII. Clinical Results

The Parastep System affords appropriately selected spinal cord injured individuals the opportunity to independently stand and take steps. This functional enhancement results in a variety of physiological, psychological and functional benefits which will vary for each person depending upon the individual's objectives and the degree and frequency of Parastep use.

Functional Outcomes

The most immediate benefit of The Parastep System is its ability to help restore function to the spinal cord injured individual. The Parastep enables users to stand and walk short distances independently without long leg braces, at home or in the workplace. In some cases, The Parastep can help users perform some of the activities of daily living which require standing, that were previously not possible for those solely confined to wheelchairs.

Exhibit 5: The Parastep System in Use



A T7 – complete paraplegic standing and walking with The Parastep System

Physiological Outcomes

Beyond improvements in function and mobility, there are a host of other potential physiological benefits associated with Parastep use which may be realized over time.

It has long been accepted in the rehabilitation field that prolonged immobilization of the body has extensive deleterious physiological and psychological consequences. The benefits of standing after spinal cord injury have been well documented in the medical literature. Standing – even if only passive standing – has been demonstrated to prevent, reverse, or improve many of the adverse effects of prolonged immobilization.[16-19]

In addition, the use of FES with spinal cord patients has also been shown to have a number of beneficial therapeutic effects.[20] Consequently, Sigmedics expects that The Parastep System, which enables individuals to stand and to ambulate with the assistance of FES, may likewise help alleviate many of the chronic health problems associated with immobilization due to spinal cord injury.

It is expected that long-term use of FES via The Parastep System should help:

- Prevent muscle atrophy and increase muscle bulk and strength in the lower extremities [21-26]
- Retard osteoporosis and prevent contractures by loading the long bones of the legs, and help maintain or increase the range of motion [27-32]
- Reduce the incidence of decubitus ulcers by relieving pressure, and increasing blood flow and muscle bulk [33-38]
- Improve the position of the internal organs which may aid bowel and bladder function and may help reduce the incidence of urinary tract infections [39-42]
- Improve circulation in the paralyzed limbs [43-44]
- Improve cardiovascular health [45-47]
- Reduce spasticity [48-50,54]

Sigmedics is initiating research efforts at several rehabilitation institutions across the country to substantiate the physiological benefits associated with use of The Parastep System.

Prevention of Muscular Atrophy and Increased Lower Limb Strength and Bulk

The most widely apparent changes produced by paralysis and subsequent immobilization occur in the muscles. Prolonged immobilization results in severe muscular atrophy. This loss of muscle mass causes a decrease in muscle strength and endurance. Studies have shown that immobilized muscle loses 3% of its original strength per day of immobility.[51] In cases of prolonged immobilization, the muscle may lose up to 35% of its mass. If the muscle is totally denervated, it can lose up to 95% of its original mass.[52]

Reversal of disuse atrophy, and increases in muscle strength and size as a result of FES have been well documented in spinal cord injured patients.[21-26] The increases are directly related to the frequency and intensity of FES-induced muscle contractions.

Reduced Potential for Osteoporosis

Osteoporosis is an increase in the porosity of the bones due to disuse and poor circulation. It is a common condition of paraplegics. Studies have shown that the most useful therapy for the prevention of immobilization osteoporosis is weight bearing or exercises designed to simulate weight bearing. As FES use via The Parastep System allows for unbraced weight bearing on the long bones of the legs, it should help maintain bone mineral content and therefore retard the development of osteoporosis.[27-32,40]

Prevention of Contractures and Improvements in Joint Range of Motion

Muscles that are immobilized and remain in a shortened or fixed position become contracted. One of the primary functions of physical therapists when working with spinal cord injured patients, is to perform range of motion exercises on paralyzed limbs, to prevent serious and chronic contractures. An FES system, like the Parastep, for standing and walking enables users to bear their own weight on their legs and actively utilize their own muscles to take steps, thereby increasing (enhancing) joint range of motion, which should help prevent contractures.[27-32]

Prevention of Decubitus Ulcers

Most spinal cord injured patients spend a great deal of time in the seated position and are therefore at a high risk for decubitus or pressure ulcers. The prevention and treatment of these ulcers requires pressure relief that may be accomplished by postural changes. Pressure relief must be frequent, sufficient and preferably self-initiated. Standing clearly provides pressure relief to the seated individual by shifting the pressure to the long bones of the legs. It allows for a more sustained period of relief to the sacral and ischial high pressure areas of the buttocks than can be achieved by wheelchair push-ups. Standing and walking, therefore, should help prevent pressure sores ,which is a major physiological benefit for users and a potential economic benefit to third party payors.[33-38] (A discussion of the economic benefits follows in Section IX.)

Reduced Risk of Urinary Tract Infections

The most frequent complication for the spinal cord injured after the initial medical/rehabilitation period is urinary tract infection. Incidence numbers range from 50% in the first post-injury year to 77% of the population in year 15. Clearly this represents both a serious danger and a significant risk factor in the management of spinal cord injury.[53] And, the associated medical and hospitalization costs are quite substantial.

Hypercalciuria is an excessive quantity of calcium in the urine. The hypercalciuria associated with immobilization is thought to be due to the reduced axial weight bearing on the long bone of the skeletal system causing loss of large amounts of bone calcium which is excreted in the urine. Hypercalciuria has been demonstrated to be associated with an increased risk of renal and urinary tract calculi and infections, particularly in the spinal cord injured, which can lead to progressive deterioration of the renal function if the infection ascends.

A study conducted by Kaplan indicated that ambulation significantly decreased hypercalciuria and modified calcium balance in a positive direction. His study suggested that early ambulation will probably prevent bone loss, calcium stones in the genitourinary tract and other sequellae of negative calcium balance.[40] Abramson also compared the incidence of urinary calculi in ambulating vs. non-ambulating spinal cord injured patients. He found that ambulatory patients had a lower incidence of urinary calculi when compared to nonambulatory patients.[41] In addition, research conducted by Freeman suggested that weight bearing within 18 months of injury could significantly reduce the incidence of urinary calculi.[41]

Another study has shown the effect of the upright posture on bladder pressure.[41] The investigators demonstrated that bladder pressure was increased by 14-25cm H_2O in the upright posture (90°) as compared to the supine (on the back) position. The increase in bladder pressure seen in the upright posture is attributed to the weight of the other internal organs on the bladder. The increase in bladder pressure during standing has implications for improved drainage of the bladder, particularly in patients with poor bladder function.

Consequently, it is expected The Parastep System, which enables an upright posture, weight bearing and the ability to ambulate several times daily, should help reduce the risk of urinary tract infections and help improve bladder function.

Improved Cardiovascular Health

Immobilization or confinement to a wheelchair reduces circulation and cardiovascular function. An FES system for short distance walking, like the Parastep, enables paraplegics to stand and walk under their own muscle power which improves their overall circulation. By offering individuals an opportunity to ambulate on a daily basis, it can help improve their cardiovascular function.[45-47]

Reduction of Spasticity

Spasticity or hypertension of muscles is a common problem associated with spinal cord injury and other neuromuscular disorders. Muscle spasticity causes stiff and awkward movements. It is frequently treated with habit-forming drugs which have severe side effects and can result in dependency problems. Odeen and Knutsson studied the effects of weight loading and muscle stretch on spasticity in nine paraplegics.[54] All patients had been injured at least three years prior to the study and their spasticity hindered such activities as dressing and transferring. The investigators found that muscle stretch by weight load in standing was able to reduce spasticity 26-32% depending on the flexion of the feet.

Several clinical programs have also demonstrated overall reduction in spasticity as a result of extended use of FES.[48-50] This is a promising finding which could lower the pharmacological requirements of patients suffering from spasticity.

Psychological Outcomes

It has long been reported that the upright position has an impact on the self-esteem, self-image and morale of the immobilized individual. The assumption and maintenance of upright posture is such a common occurrence among human beings that it is perhaps the most universally accepted measure of normality.

If a person cannot stand he is classified as not being normal and may find it difficult to interact with the able bodied population on an equal footing. "Pretending to be disabled is easy. When you can't look someone in the eye, you become his inferior; when you have wheels you must be an object, like a luggage cart." [55]

Depression is a typical response to spinal cord injury, and it can have disastrous effects on the individual, psychologically as well as physically. Due to the catastrophic nature of this injury, there is an extremely high incidence of suicide among the spinal cord injured.

The Parastep offers this population tremendous psychological benefits. It gives the spinal cord injured the freedom to independently stand and walk short distances. It provides an alternative to the wheelchair and gives users a new perspective on the environment. Many clinical programs have documented improvements in morale, self-image and self-esteem by individuals who have utilized The Parastep System or other experimental FES ambulation devices.[56-58]

Sample comments by both users and clinicians regarding the functional, physiological and psychological benefits of The Parastep System are provided in Exhibit 6 (following page).

Exhibit 6: Selected Clinician and User Comments

Clinician Perspectives:

"The benefits of stimulating these muscle groups, standing and gaiting for short distances are tremendous. Better circulation, strengthening of weakened muscles and increased girth in the size of muscles are physically and psychologically beneficial."

"Walking short distances with the Parastep is literally the first step toward a new kind of independence for people with spinal cord injuries."
Myrtice Atrice, Physical Therapist
Shepherd Spinal Center
Atlanta, Georgia

"It (the Parastep) allows the spinal cord injured patient to move about as never before. It allows them to move around at home or in an office and do things independently that wouldn't be possible from a wheelchair.

"People who are in wheelchairs suffer loss of bone density and are prone to fractures. Standing and weight bearing helps maintain bone density and increase muscle mass. It's also beneficial for the heart and lungs, and it helps reduce the skin problems that can occur from sitting too much."
Edward Chaplin, M.D., Medical Director
Scripps Memorial Hospitals
Rehabilitation Center
Encinitas, California

"The first system I've seen that will actually enable the paraplegic to walk outside the laboratory."

"It's the first realistic beginning we've had in 20 years since FES was first started."
Amie Jackson, M.D.
Associate Professor of Physiatry
Spain Rehabilitation Center
University of Alabama - Birmingham

"It's exciting to see his response – his eyes light up. It's kind of unbelievable if you read about it (the Parastep), but when you actually are working with it and you can see the results, it's really gratifying."
Amy Steed, Physical Therapist
Scripps Memorial Hospitals
Rehabilitation Center
Encinitas, California

User Perspectives:

"I've used the Parastep for standing and walking around the house and for functional activities such as opening up the refrigerator door, getting a tray of ice cubes and having a drink of water."

"I suppose with some more work there are other tasks I could do using the system, such as changing a light bulb or even painting portions of a room."
Carl Larson
Parastep User
Shepherd Spinal Center
Atlanta, Georgia

"I have the standing unit at home. Being able to get into a cabinet to get a casserole dish is really nice. (And) from a health standpoint, getting those muscles fired up is important. It's good to know you're staying in shape."
Kristi Wickiser
Parastep User
Craig Hospital
Englewood, Colorado

"It's a big psychological boost to be on my feet."
Leah Patterson
Parastep User
Spain Rehabilitation Center
University of Alabama - Birmingham

"The first time I stood up, I felt seven feet tall. It means so much to me. It gives you hope."
Darrell Banks
Parastep User
Spain Rehabilitation Center
University of Alabama - Birmingham

"I used long leg braces, but they weren't feasible because of the weight. With (the Parastep) electrodes, you stick them on and you're ready to go."

"Just to be able to get up and walk on your own ... it feels so good."
Aric Fine
Parastep User
Spain Rehabilitation Center
Univ. of Alabama-Birmingham

"My son talked more in the first 24 hours after he stood up for the first time with the Parastep than he had in the last two years. He came out of his shell."
Vicki Fink, LVN
Mother of a Parastep User
Scripps Memorial Hospitals
Rehabilitation Center
Encinitas, California

"The Parastep won't be a substitute for all the activities I did before my injury, but it does give me a new sense of self ... it helps me make my life as functional as possible now, with a great deal of hope for the future."
Craig Prudian
Parastep User
Humana Hospital - Michael Reese
Chicago, Illinois

IX. System Economics

Therapy Costs

The Parastep System is the first commercially viable product which enables independent, unbraced standing and short distance walking for some of the spinal cord injured. There are no other FES systems for ambulation on the market. A variety of FES assisted exercise devices are available commercially, but none of these enable standing and ambulation. As was mentioned in Section IV, ambulation after spinal cord injury has been accomplished with passive orthotic devices such as long leg braces (LLBs), knee-ankle-foot orthoses (KAFOs) and reciprocating gait orthoses (RGOs). The user does not utilize his or her own muscles to effect standing; rather, these devices mechanically support the user's legs with an external bracing system which is more cumbersome, more difficult to don and doff and definitely more visible than The Parastep System. These factors have resulted in a high rejection rate for these devices among users.

The Parastep System, then, is distinguished from all other commercially available products in its practicality, functionality, and potential physiological and psychological benefits. As Exhibit 7 (below) demonstrates, the cost of the Parastep (including both product costs and the related physical therapy) compares favorably with other rehabilitation technologies that are covered by the U.S. insurance industry.

Exhibit 7: Cost of Therapy Comparisons

Therapeutic Values	The Parastep System	FES Assisted Cycle Ergometers	Standing Frames	Standing Wheelchairs	LLBs/ KAFOs	RGOs	Orthotic Boots
Function							
Ability to Stand	•		•	•	•	•	•
Ability to Ambulate	•				•	•	•
Utility							
User Controlled	•	•	•	•	•	•	•
Ease of Donning & Doffing	•		•	•			
Lightweight & Compact	•					•	
Appearance/Cosmesis	•						
Portability	•				•	•	•
Useable in Multiple Environments	•			•	•	•	•
Physiology							
Active Muscle Contractions	•	•					
Prevents Muscle Atrophy	•	•					
Increases Muscle Bulk & Strengthens Lower Extremities	•	•					
Therapy Costs (Product & Therapy Fees)	$10,000-$15,000	$21,000-$24,000	$1,200-$8,000	$4,100-$14,000	$13,000-$23,000	$36,000-$40,000	$11,000-$24,000

Long-Term Cost Effectiveness

While the impact of spinal cord injury on the individual in terms of health, employment and personal economics is inestimable, the economic costs to society, including direct costs for hospitalization, medical and rehabilitation services and the indirect costs for loss of earnings and wages, was estimated in 1977 to be nearly 3 billion dollars.[59] Improvement in the long-term management of spinal cord injury, therefore, is of immense importance for the individual, his family and for society as a whole.

The Parastep System promises to be a valuable rehabilitation tool for improving health among the spinal cord injured. It has the potential to reduce the lifelong medical complications, and consequently the costs, facing the SCI community and their insurers.

People with SCI are at a higher risk for hospital admissions, excessively long hospital stays and greater use of emergency medical services than the non-disabled population. There is consensus among the rehabilitation community that high use of hospital and emergency room services is not only costly, but also disruptive of work, education, interpersonal relationships and destructive of independent living goals.[60]

A survey conducted by the Paralysis Society of America to estimate direct costs associated with SCI showed that 29% of SCI persons who have been injured at least three years, were hospitalized at least once in the year prior to the survey; and, on average, individuals with SCI will spend about six days more each year in a hospital compared to the non-disabled population.[61] As Exhibit 8 (below) illustrates, a spinal cord injured person will spend $5,206 more per year for hospital and medical services than their non-disabled counterparts, and they can expect to incur annual costs in excess of $14,000 on an ongoing basis through their post-rehabilitation lives.

Exhibit 8: Annual Incremental Costs Over Non-disabled Population [61]
(1988 Dollars)

Hospitalization		$ 2,958
Medical Practitioners		2,248
Subtotal (Medical Services)	$ 5,206	
Personal Assistance & Institutional Care		6,269
Prescription Drugs		113
Nonprescription Drugs		1,686
Adaptive Equipment		861
Total		$ 14,135

Hospitalization is a direct result of secondary complications peculiar to SCI. The most frequent secondary complications are urinary tract infections, pressure sores, spasticity, contractures, general infections and abnormal renal function. (See Exhibit 9, below).

Exhibit 9: Secondary Medical Complications of SCI [62]

Percentage of Patients Developing Secondary Medical Complications			
	Years Post Injury		
	5	10	15
Urinary tract infections	57.2%	75.9%	76.9%
Pressure sores	19.0	26.9	41.2
Spasticity	38.3	35.3	27.9
Contractures	4.4	5.0	11.6
Infection (chills and fever)	14.7	17.4	14.3
Abnormal renal function	2.7	10.2	18.8

Treatment of these secondary complications is costly. The increased cost of hospitalization due to pressure sores in patients with SCI has been calculated periodically, most recently in a study presented in 1988. Based on per day costs at the presenter's Model Spinal Cord Injury System it was calculated that the average cost of treating a pressure sore was $58,000 for hospital stay expenses alone.[63-64]

Urinary tract infections are another common problem in SCI. It is not uncommon to expect one to two urinary tract infections per year, even in well managed SCI cases, and for treatment costs to approach $7,000 per incidence.[65]

As was discussed in Section VIII (pages 19 to 22), the medical literature suggests that an FES ambulation system like The Parastep System may help reduce the incidence of both pressure sores and urinary tract infections and, therefore, the costs born by insurers for these medical complications. Even if The Parastep System eliminated only one occurrence of either a pressure sore or a urinary tract infection, these cost savings alone would more than justify the expense to acquire the system.

Sigmedics will be undertaking studies in conjunction with several rehabilitation institutions across the country to further quantify the cost savings associated with long-term use of The Parastep System.

X. Insurance Coverage Considerations

The Parastep System has the potential to help restore independence and functional ability to the spinal cord injured. It is cost effective compared to other commercially available rehabilitation products, and it has the potential to yield long-term cost savings to the health care system by helping to reduce the incidence of some of the costly secondary medical complications associated with a spinal cord injury. It follows, therefore, that The Parastep System should be favorably accepted and covered by insurance carriers, and made available to selected candidates who would benefit from it. Sigmedics has developed strict selection criteria, and training and follow-up protocols to control the distribution of the system to appropriately selected candidates committed to long-term compliance to the Parastep ambulation restoration program.

The Parastep System will be available only through a physician's prescription. The individual's physician, in conjunction with his or her physical therapist, will make the candidacy determination based on protocols and onsite training provided by Sigmedics. Candidate evaluation will consist of the following components:

- Medical evaluation:
  - Review of the individual's medical history
  - Performance of general physical examination and psychological evaluation/assessment
  - Discussion of the Parastep program, including clinical goals and objectives, patient expectations and required commitment on behalf of the user
- Physical therapy evaluation:
  - A complete examination to assess joint range of motion, degree of spasticity, presence of spinal reflexes, residual sensory and motor function
- Electrical stimulation evaluation:
  - Performed by the physical therapist to determine muscle response to electrical stimulation, to establish the degree of neurosensory deficit and to assess patient tolerance to prescribed levels of electrical stimulation
- Radiological examination:
  - Complete x-rays of the lower extremities to indicate the degree of osteoporosis, fractures and/or heterotopic ossification. A/P and lateral views of the femur, tibia/fibula, hips, knees and ankle joints are recommended

In addition, a comprehensive hematology assessment (SMAC 20/CBC) and cardiopulmonary assessment, as well as any other tests, should be conducted, if indicated based on the patient's past medical history.

If the results of the medical evaluation are positive and there are no precluding conditions or contraindications, the individual will be qualified as a candidate. The physician will submit a letter of medical necessity and a prescription and request payment authorization from the individual's insurer. Thirty-two (32) sessions of physical therapy will then be provided to the user to ensure that he or she becomes a functional independent ambulator with The Parastep System. Progress reports from training sessions will be sent to the insurer upon request to document the individual's progress and functional status. The physician and/or physical therapist will conduct an annual follow-up visit with users to check health status and compliance with system use.

FES restored ambulation represents a major breakthrough in the management and rehabilitation of the spinal cord injured. Sigmedics is looking forward to working with third party payors to develop universally acceptable coverage and reimbursement guidelines for The Parastep System so that independence, mobility and functional ability can be restored to those permanently disabled by a spinal cord injury.

XI. References

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