FUNCTIONAL ELECTRICAL STIMULATION

THE ANSWER OR A QUESTION
(To post SCI QL)

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ABSTRACT

KEY WORDS: Functional electrical stimulation (FES); Spinal cord injury (SCI); Quality of life (QL); Ambulation; Paraplegia.

PURPOSE:

This paper will evaluate the current status of FES, discuss the degree of relevance between research goals for this technology and SCI patients’ life quality needs and increase awareness of any dichotomies.

ARTICLE SELECTION:

The initial literature search was from the Internet (Medline, PubMed and WWW). Abstracts indicating functional electrical stimulation (FES) and functional rehabilitation of spinal cord injury (SCI) published since 1986 were identified. Articles found to be irrelevant to the current topic, or which were outdated, were rejected. For currency, the search was further limited to abstracts of studies published since 1992. Reprints of 80 articles from international sources were selected and 23 of these used as references for this article, in addition to selected information from FES research in progress in Augusta, Maine, in which the author is a participant.

RESULTS:

The research and development of functional electrical stimulation is a dynamic, exciting field of study that is growing exponentially. Technological advances in hardware reliability, refining software and miniaturization of components, together with new discoveries in materials and design are on-going. Most of the current focus for FES at is upon stimulated ambulation, with bladder control an ancillary benefit. At the same time the SCI patient, the recipient of this research, is rarely considered holistically. FES investigators seldom reference the literature regarding SCI quality of life criteria. Standing and stepping with FES is limited to one or two steps to turn and sit. Movement is slow and energy consuming and usually ankle orthoses and walking aids are needed. The literature suggests SCI patients place social needs, such as bladder control, considerably higher on the list of QL impacting situations than limited not-yet-functional ambulation. No QL studies to date have addressed the posibility and impact of functional ambulation.
**ETHICS**

**Consent:** All potential subjects from the author’s archive signed a standard Informed Consent form agreeing to publication and/or demonstration of any identifiable images or data.

**INTRODUCTION**

Increasing knowledge of the microbiology and physiology of neural tissues and advances in effective acute care and treatment of all levels of traumatic spinal cord injury (SCI) means long-term survival of people with potentially catastrophic disabilities. Twenty years ago the survival rate and life expectancy of SCI was measured in days, months or at most a few years because of acute and secondary complications. Now even high cervical cord lesion patients are surviving the initial trauma and are looking at years in a wheelchair, dependent upon others. These people have every reason to expect that, as medical advances have kept them alive, medicine can now provide the means for a quality life. The restoration and adaptation needed in order for these individuals to assume a quality, productive lifestyle is of paramount importance to the individual as well as to society. The more a person can survive independently and productively after SCI, the lower the cost to society as a whole in every way.

Treatment and rehabilitation options offered to SCI individuals are presently being addressed piecemeal by widely separated SCI centers in Europe, the USA, Japan and Australia, each developing unique protocols, more or less in isolation. There is only limited information exchange between these larger centers before publication of their research, when pooling of resources and sharing of ideas could speed progress. There is even less communication between major research centers and the rest of the medical community. As in other areas of research, there is competition to ‘be first’ in successful functional electrical stimulation (Alternatively called FES or FNS) ambulation. There are dozens of published studies on FES, yet relatively few studies, mostly European, covering the holistic needs of people with SCI. Patient perceptions of “quality life” (QL) after SCI are dismissed as insignificant compared to the “marketability” of focus of FES ambulation when appealing for funds to the public and private sectors.

- What is the purpose of FES? Is it the answer to the SCI patient’s dream of being perceived as a normal, functioning member of a community again? Or is this wonderful technology not really the whole answer? Does FES have the potential to significantly change the average SCI patient’s existence for the better? Is it likely to become, like Captain Picard’s mechanical heart, wholly independent and subliminal for life?
- Why pursue this technology when it is so expensive and apparently will only benefit a select few? When SCI FES, the Answer or a Question.
patients are already abandoning the technology for their wheelchairs for functional mobility.

- Why is selection and discrimination even necessary?
- Where will this technology be available? In larger city centers? Any rehabilitation center?

Is it not more important to consider a patient’s desire for QL and facilitate growth and adaptation to a new lifestyle, rather than constantly striving to regain what is lost?

- “In rehab. I was evaluated, dissected, tested, and judged by everyone on the staff. No-one ever asked me how I experienced what they were doing.” (Written correspondence to the National Committee of Medical Rehabilitation Research -- NCMMR -- field hearings on FES)
- “Focus should be placed on ... development of improved information management techniques to improve the effectiveness, integration, and delivery of rehabilitation treatment in multiple settings ...” (Testimony given at the NCMMR, Bethesda, field hearings on FES)

PHYSICAL THERAPIST INVOLVEMENT

Physical therapists (PTs) have been integrally involved in FES experimental programs from the beginning, including being involved in the design of selection and assessment tools. A PT spends considerable time with each SCI patient during every phase of selection, evaluation and training for FES. This places the PT in a unique position to be aware of QL issues in all areas of rehabilitation. An FES program demands a rigorous routine of physical rehabilitation, mental conditioning and education. PTs, working as part of the multi-disciplinary FES team, have been integral to the current paraplegic mobility successes reported in the literature.

At the earliest opportunity, after clinical medical stability has been achieved, a SCI patient is assessed as to the means of mobility that will eventually be possible or practical. The options for a thoracic SCI patient, in larger research centers, may range from “unlimited” FES ambulation to wheelchair mobility only, or any combination of these. Selection procedures for limb muscles’ implantation is a therapy-medical based procedure in which the extent of SCI, age, motivation and other psychological factors are assessed as well as indices testing of neurological, orthopaedic, cardiovascular, skeletal systems and Activities of Daily Living (ADLs) before the SCI patient is accepted for an FES program.²

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To effectively participate in patient selection and preparation, a physical therapist also needs insight and knowledge of all aspects of the FES program. Information needed includes:

- The potential, limits and expectations of the electromechanics and biomechanics of the FES hardware and software;
- The primary goals of the particular FES program;
- Implantation locations and techniques;
- The advantages and problems, mechanical and human, of FES.
- Knowledge of the physical and mental demands that each patient will have to meet in order to prepare for and participate in the program.

As much selection as possible is necessary before implantation. Because of the high financial, physical and mental costs, almost total involvement of the FES candidate is demanded. The degree of user participation causes necessary changes in lifestyle to accommodate the demands of the program. This commitment and decrease in free-time of the user, according to many studies, is a major factor in the high drop-out rate from FES studies of patients who initially eagerly agreed to participate. (Fig.1)²³

**FES PATIENT SELECTION**

Rushton et al, have identified 9 key selection factors for initial FES screening and selection for participation in a FES program:² (See table2)

- Static complete SCI at or below T3 of at least 2 years post injury;
- Age 16 to 55 years;
- No medical complications such as cardiac or respiratory conditions or autonomic dysreflexia;
- No joint contractures such as to hinder upright stance and balance;
- Mental competence such as to enable active participation in the program and learn necessary computer and other skills;
- No excessive hypertonia/spasticity;
- No known syringomyelia;
- No internal spinal fixation at or near any proposed implant site, including the stimulator unit;

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• Living situation so located that a patient is close enough to a hospital or clinic site to permit three visits per week for pre-FES implant evaluation and training, subsequent implantation and rehabilitation training;

Patient assessment for selection includes evaluation of all systems with tools common or unique to each individual center. The testing tools varied, but consistently the systems evaluated were:

• Motor and sensory neurology. This includes full body charting of voluntary muscle strength, joint proprioception, sensation to light touch and deep pressure and sensitivity to temperature.

• Lower extremities joints range of motion (ROM): Evaluations of passive ranges of hips, knees and ankles to ensure sufficient extension for erect posture, balance and function. Joint laxity was not usually considered a problem at initial assessment, but did cause later elimination of several patients in at least 4 studies reviewed.

• Spasticity was assessed using several different tools, including the Wartenburg Pendulum Test for a relaxation index. (Fig.2)

• Strength of both lower extremity (BLE) muscles was tested using peak generated moment during an electrically stimulated, 1 second, contractions of quadriceps with the knee at 90 degrees flexion. Stimulation strength and moment were noted when the moment readings stabilized. Fatigue testing was by repeated stimulation with the knee at 15 degrees for up to 50 contractions, or until the moment readings fell below 50% of initial value.

• Muscle bulk: Quadriceps, gluteal and lower leg muscle bulk are measured at 10 and 20 cm above the knee (AK); anterior superior iliac spine (ASIS) and greater trochanter; and 5 and 15 cm below the knee respectively.

• Bone density is usually assessed at the neck and diaphysis of the femur and lower lumbar vertebrae.

• Cardiac: Plethysmography is used to assess output and stroke volume, blood flow and pulse volume to the lower limbs.

• Muscle microscopic status is often evaluated by means of needle biopsy on vastus lateralis of the dominant leg for fibre typing and diameter.

• Psychological testing, using several tools to measure the anxiety and depression levels and other psychological factors.

Individual patient protocols are devised and implemented prior to implantation to maximize the potential of each patient and the beneficial effects of FES and to meet any required federal and grant demands as well as FES, the Answer or a Question.
maximizing patient success for the future funding of this procedure. Surveys of the literature suggest that only 5% to 12% of SCI may be suitable for neuroprostheses and fewer than half (average 3.3% of any group of selectees) of these to date have actually completed an FES rehabilitation program.

**FES MECHANICS**

FES technology and implantation techniques have been in the “research and development” phase of medicine for almost 15 years. The first implantations were done in 1986, but at that time computer technology was not as miniaturized and the microbiology of connective tissue and nerve was, by 1999 standards, poorly understood. These “first generation” implants were controlled manually by the user for control of flexor and extensor muscles with buttons on crutches or walker hand-grip and no internal feedback telemetry. Computers were bulky and slow, needing manual commands from the user to balance muscle action and movement. Usually the computer was pushed on a wheeled walker or cart while the paraplegic commanded about one step every 2 to 3 seconds. FES gait research is now using second and third-generation stimulators and electrodes. Smaller and smaller components are, thereby, less obvious when implanted, with more implant sites available. With the decreased size of implants, and increasing component reliability, long-term acceptance and use by patients becomes more probable.

The FES external receiving, monitoring, control unit, the hardware, together with the software, is collectively known as an External Control Unit (ECU); The implanted components, (stimulation and telemetry electrodes, connecting wires, stimulator and antenna) collectively are known as the neuroprosthesis. The neuroprosthesis is implanted in an operating room or similar sterile area on an out-patient basis. Anesthesia is not needed due to the upper motor neuron lesion. Various configurations of command and feedback control and stimulation are now possible. The whole neuroprosthetic system, employing multi-channel activation of paralyzed muscles and multi-joint position telemetry, weighs ounces and the ECU about 6 pounds. FES computers in use currently have almost unlimited memory capacity and fit into a small fanny pack. They generate and telemeter both command and feedback information, assessing the effects, accepting manual or verbal commands, adjusting stimulation and position appropriately. Feedback from implanted telemetry, external commands, or corrections from the user are processed with active computer-modification of programming such that eventually similar situations will produce similar responses without any active patient participation. The computer will function completely independently to modify muscle actions to appropriately effect the desired muscle stimulus for a desired movement.
essentially, instantly. At present, these systems are being designed for paraplegic situations, but it is envisioned that, before 2010, applications will provide functional hand grasp and release for cervical level SCI.²

FES hardware, software and design technology is evolving almost monthly. Bioengineers are constantly exploring new possibilities in wiring technology using new substances and components. New ever smaller stimulators, re-designed antennae; re-thinking intrinsic and extrinsic placement of components to minimize complications from component pressure and failure. While shrinking in size, components are increasingly more powerful and reliable, essential factors in safety and patient compliance and use in FES. The number of channels available for telemetry and stimulation functions now total more than 48, but current FES is being limited by hardware and other factors to 24 channels.³

Improvements and refinements are incorporated into models and tested before a single clinical trial in a selected subject. This single trial is assessed with components and protocols modified as indicated before being considered for use in a full study. As it is now being developed, FES can effectively mitigate four of the five major physical problems of which SCI patients complain. Reliability of components remains a major problem with hard connections breaking, implanted antennae wearing and loosening and stimulators malfunctioning. Reciprocal gait without orthoses requires 12 channels for minimum stimulation control of essential muscles and telemetry of joint angles and position. The more muscles that can be controlled and the more telemetry that can be assessed by the microprocessor, the safer and more functional will be the gait pattern.

Risk factors considered in the various selection processes, combined with the desire of investigators to have successful outcomes for this cutting-edge technology, limit the numbers of FES implantations available for follow-up study. This is expected to change more rapidly as new materials and techniques, being developed over the last 2 years, are implemented. Minimizing other risk factors, including the potential for patient non-compliance, must also be addressed. Unless technology is easy to manage, essentially subliminal, it will eventually be discarded by users as “too much trouble,” no matter how wonderful it seems to proponents. Acceptance is best when complexity of donning, use and maintenance is minimized. However, the more the ECU and neuroprosthesis operation is simplified and made user-friendly, the more complex the internal and external hardware and software must be, with built-in redundancy, to permit operation reliably for relatively long periods of time.⁴

FES, the Answer or a Question.
QUALITY OF LIFE

Being upright/standing and mobile has many beneficial physical, psychological and social effects for SCI individuals. Western Hemisphere culture is oriented to right-handed, healthy individuals of “average” height (Per the USA insurance actuarial tables data this means men, 5’8” and women 5’4”) or taller. Doors’ height and width, arrangement of furniture in rooms, malls stores, and displays are all designed for the “average.” Many United States public buildings are older, poorly adapted and marginally accessible to the mobility impaired. This in spite of the Americans With Disabilities Act (ADA). Anyone relying upon a wheeled means of transportation is literally and figuratively looked down upon by the majority of the rest of the population with potentially devastating physical and emotional consequences.

Many potentially life threatening secondary complications of SCI can be beneficially affected by attaining and maintaining upright stance and being vertically mobile for a significant part of each day.

Guest et al, in a combined, multi-faceted series of studies, demonstrated that just participation in an FES program significantly changed scores on a Physical Self Concept scale. They suggest that the standing training and exercise alone had played a key role in improved self concept and improved outlook on life.3

Quality assessments (QA) are being increasingly used in medicine to assure the efficacy and economy of treatment. Concepts may vary, but there seems to be agreement on the synthesis of objective and subjective dimensions, with new test instruments being developed and validated to measure the possible outcomes.5 With increasing demands upon financial resources and broadening treatment opportunities, it is important to tailor a rehabilitation program to individual patients’ needs in order to maximize benefits and monitor progress and outcomes. Built-in program flexibility allows for any patient-unique physical, social and psychological status changes. This is especially the case with SCI, where rehabilitation may be protracted, with needs and goals in flux and needing modification, especially in the acute and sub-acute stages. Because of the catastrophic nature of SCI, effective holistic rehabilitation may take years.6,7,8

Instruments and data used to evaluate patients’ opinions as to their quality of life include the SF-36, a self-administered Health Survey questionnaire of 36 items covering functional status, well-being and overall self-evaluation of health.9 This Swedish study is translated and validated by Sullivan and colleagues.10 Post et al used the Sickness Impact Profile (SIP68) to predict health status and life satisfaction of SCI patients. The SIP-68
comprises 68 questions on six levels reflecting the physical, mental and social dimensions of functional status. The sub- sets of SIPSOM, 29 items (Functional somatic autonomy and mobility control), SIPSY, 17 items (Psychological autonomy and communication), and SIPSOC, 22 items (Social behavior and mobility), are used to breakdown data into major components affecting the patient’s opinion of health and life satisfaction. For evaluation and study of long-term effects of SCI upon life quality, Krause used the Life Situation Questionnaire. This was developed in 1973 and expanded in 1985 to measure objective information on adjustment and life quality after SCI. It comprises seven scales of forty questions covering marital status, living arrangements, activities, recent medical history, employment, self-rated adjustment, and life satisfaction. 

Quality of life is a reflection of an individual’s ability to cope and adapt to a new life situation. This necessarily takes an uncertain time period because of the unique set of personal circumstances each patient brings to the equation. The FES selection and rehabilitation process is often initiated shortly after injury but, with the increasing emphasis on discharge from acute care and limited in-patient rehabilitation, much of the processing has to take place after discharge from a supporting institution. All studies report that, up to late middle age, the quality of life and adaptation for SCI patients tends to improve with time-distance from the onset of paresis. Other factors affecting patient perceptions of improved life quality include the positive support of a spouse or life-partner living with the patient, positive contacts with friends and relations, and satisfying employment which also improves the socio-economic status. The primary detracting factors from achieving a satisfactory degree of life happiness or life quality (LQ) are reported to be the number of secondary SCI-related medical and general health problems experienced by the individual and chronological age beyond age fifty. Although there is some disagreement in the literature, many investigators have found that education and the extent of an injury, level of SCI, or degree of disability, do not initially affect the outcomes of quality over time. These factors seem to play more of a role and influence the degree of impairment in everyday life beyond 10 years. Any improvement in LQ levels therefore is impossible unless the secondary problems and complications are addressed as fully as possible.

The sum of LQ variables, most of which are in the purview of the rehabilitation team, add up to overall functional health status (FHS). The secondary SCI complications are one of these variables. Other components of FHS are the intertwined psychological and social aspects of relationships, including family and friends’ relationships, success at a productive, enjoyable job and participation in pleasurable recreation activities.

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According to the Stockholm Spinal Cord Injury Study (SSCIS) database, SCI patients list their number one secondary complication problem as lack of bladder control -- the neurogenic bladder. Neurogenic or neuropathic pain is a close second. These two separate problems significantly interfere with all other independent functioning and activities. When they occur together they can prevent all other effective functioning.

A neurogenic bladder is defined as the uncontrolled hyper-response of the bladder muscle to the stretch reflex (filling bladder) with reflex relaxation of the sphincter leading to unexpected incontinence. This in spite of repeated self-catheterisations in an effort to remain socially acceptable. Recurrent urinary tract infections occur due to the need for frequent catherization as part of an effort to prevent incontinence and embarrassment. These infections can escalate and are the number one cause of death in chronic SCI.

Neurogenic pain is defined as pain of a burning, stabbing quality segmentally at or diffusely below the SCI level. Effective treatment of this pain is still a poorly understood challenge. Transcutaneous electrical nerve stimulation (TENS) and surgical intervention at the posterior horn have so far proved the most effective treatments as alternatives to globally clouding the brain with pain medications.

Other secondary SCI complications are:

- **Pressure sores**, defined as skin breakdown at bony pressure points such as the ischial tuberosities. As a prevention measure, these require diligent visualization of bony pressure points in some very difficult areas, frequent pressure releases and, if they occur, vigorous treatment, including skin grafting to prevent recurrence and/or infection;

- **Bone demineralization**, osteoporosis, with accompanying risks of pathological fractures;

- **Spasticity**, defined as a velocity-dependent increase of tonic stretch reflexes, increased tendon reflexes and other release phenomena such as increased flexor reflexes and flexor spasms;

- **Bowel function**, with constipation or incontinence;

- **Other relatively minor, but still important, complications are contractures, joint laxity with instability to the point of dislocation in some instances, excessive sweating, and respiratory problems. The last two problems are more commonly seen in upper cervical SCI in which the sympathetic nervous system is involved during trauma. Sexual dysfunction, including impotence, anejaculation, anorgasmia in men and diminished vaginal lubrication and anorgasmia in women and positioning problems for both sexes are important, especially to FES, the Answer or a Question.**
younger age groups. For obvious reasons, all secondary complications have strong negative associations with life quality. (Fig. 3)

MITIGATION OF SECONDARY SCI COMPLICATIONS WITH FES

The SCI person wants to be perceived as “normal.” Most SCI patients, when polled, placed control of function in order of importance as:

- Bladder control.
- Relief of symptoms such as neurogenic pain and severe spasticity.
- Independent, ambulatory/vertical mobility.
- Elimination of other complications such as pressure sores, degradation of bone density, etc.
- Sexual dysfunction.

1. Bladder Control: The number one complaint of SCI patients, bladder control/incontinence, has become a relatively easy FES goal to achieve. Newly redesigned (1999) cuff electrodes and stimulators are more reliable and consistent with more convenient patient control. The intrinsic and extrinsic units operate effectively on demand, giving patients a degree of freedom not previously possible. Because of the importance an SCI patient attaches to continence, it is now assumed that any FES implantation will include electrodes (4 or more) for bladder control.

2. Pain Relief: For most people available medications, including narcotics, are at best only minimally effective in the mitigation of neurogenic (neuropathic) pain. This is in part because an effective dosage would induce sleep and could be abused. Facet injections of anesthetic and injection of steroids at the fracture site are only effective 50% of the time. FES, with epidural electrodes at the conus medularis, usually bring pain levels down about 50%. Some patients have reported most relief from marijuana, but this is anecdotal, based upon an unpublished study in California in 1998.

3. Independent vertical mobility (Ambulation): Badj et al describe typical paraplegic gait as being very unstable and only possible for very selected individuals using a three-point technique of crutches, double leg swing through with arm support on crutches and rigid lower extremity orthoses. This is very strenuous, unsafe and unnatural appearing gait. With some effort and prolonged training, SCI patients can transform this to the slightly safer and more energy efficient reciprocal gait, but still needing orthoses and crutches. These are cumbersome to wear, are very energy demanding to use and time-consuming to don and doff. For all these reasons, most SCI
patients eventually discard orthoses and non FES efforts at ambulation. FES has enhanced this reciprocal gait potential using a minimum of four channel, externally applied, electrical stimulation (ES) but these still requiring the manual operation of controlling button signals from the hands on the crutches and therefore more co-ordination and significant risk. Orthoses reciprocal gait is slow, (average one step every 6 to 8 seconds) and consequently non-functional and tiring. FES assisted gait is more normal-appearing, a little faster and more stable, minimizing the unstable moment but this moment still being significantly longer than that of a normal person, up to 4 seconds as opposed to 1 second or less.14

During the past 3 to 4 years, an approach to paraplegic ambulation using external activation and training of spinal locomotor centers is developing:15 It has been found to be possible to stimulate complex bilateral muscle activation and stepping “ambulation” after SCI using surface electrical stimulation, release phenomena and the reflex increase in muscle tone.16,17 To achieve this, the individual is partially unloaded (up to 60%) in a support harness on a moving treadmill (Fig. 4) and trained in reciprocal gait. Manual patterning during training is necessary for learning to transition from the stance to swing phases of gait and is needed for 3 to 5 months for complete paraparesis and 2 to 6 weeks for incomplete paraparesis.18 FES surface stimulated gait is less modulated in amplitude and EMG activity is considerably less in both partial and complete paraparesis as compared to normally innervated muscle. This is thought to be due to impaired polysynaptic spinal reflexes in patients with spinal lesions. With increased muscle tone and exaggerated reflexes confirming previous investigators’ findings that alterations of the mechanical properties of tonically active muscle are mainly responsible for clinical spasticity. During training, EMG activity increases in stance-phase muscles while opposing muscle activation decreases, indicating that the isolated human spinal cord has the capacity to both generate and then “learn” locomotor patterns (Fig 5). Patients with partial paraparesis are able to translate this learned spinal pattern into locomotion on a level surface, off the treadmill, using a forearm crutch or cane. The more complex, complete lesions need the support of specialized orthoses and BUE support. Both groups benefit equally from the positive effects of standing and moving upon the cardiovascular and musculoskeletal systems, gaining improved overall cardiovascular endurance, decreased spasticity and decreased neurogenic pain.15

Kojima et al investigated the use of orthotic gait using the spinal cord learning techniques of partial unloading and patterning but without ES. They found that the lower limb EMG patterns of a paraplegic subject using FES, the Answer or a Question.
rigid exoskeletal support and forearm crutches (Fig. 6) produced modulated muscle activity in the lower limbs similar to that of stimulated gait but with more biomechanical features similar to the immature gait of an infant or older children with cerebral palsy (Fig. 7).

The rigorous program of strengthening for the antigravity muscles begins with cyclic stimulation in lying or sitting. At the same time balance and patterning are initiated on a treadmill using orthoses and partial unweighting with stimulation. This period may last several weeks, the average time for most SCI patients being 4 weeks. Once balance and strength and overall conditioning and co-ordination are satisfactory, stimulation using external electrodes, the neuroprosthesis and external components begin the learning phase of computer and patient. For most patients, FES gait cadence is slower than a normal person’s slow walk, but faster than unstimulated gait. Over time, as reported in the reviewed literature, a small percentage (1% to 2%) of patients have achieved a “normal” slow walk and even 1 or 2 stairs, but these are the exceptional few.

4. Other Complications: Some concerns with FES gait have been that it will harm the insensitive lower extremity structures, causing Charcot Joints, soft tissue injury or bony problems. In one study there were several bony and soft tissue injuries, such as strains and sprains and inflammatory joint changes with effusion, during the FES learning/training process but these were not serious and as easily treated as any other athletic injury with early detection and appropriate treatment during an adequate program of muscle conditioning and strengthening. Long-term studies of current technologies will obviously be needed. Some studies of physiological effects of the last 5 years suggest the possibility of improving mineralisation of bone, especially when FES gait is accompanied by the newest medications for osteoporosis. There are also some studies which indicate bone density is unaffected by the limited standing and movement currently possible. This discrepancy may be due to the length of time necessary for calcium metabolism and deposition versus the availability of bone density studies and the duration of those studies (weeks as opposed to years) on paralyzed limb bones. Problems such as pressure sores are significantly reduced due to the opportunities for pressure relief on bony prominences while up and about.

5. Sexual Dysfunction: Medication and mechanical devices are available for sexual dysfunction for males. FES stimulators and other medications are being evaluated for females.

6. A side benefit of FES gait is been an overall improvement in lower extremity thermo-regulation (The feet are warmer). This is thought to be due to the improved venous return from stimulated muscle action with FES, the Answer or a Question.
decreased homeostasis in the lower extremities.

CONCLUSIONS:

Ambulation for the sake of upright gait mobility is not the most important goal for most SCI patients. Being socially functional and acceptable is. The goal of FES, functional independent ambulation using implanted neuroprostheses, does coincide with the SCI needs and goals of being continent and preventing potentially life-threatening secondary complications. Stimulators can be used for voluntary bladder control as well as lower extremity muscle movement, but rarely is FES used alone for bladder control in an SCI patient who will go no farther in an FES research program. Other positive effects of the FES standing with limited walking are less tangible but equally important: FES patients experience increases of lower extremity inflow volume and reduced resting heart rate (they are more physically fit!), there is visibly increased muscle mass, which paraplegics find very satisfying after watching their legs shrink from muscle wasting; and spasticity is reduced. The possible benefits of increased bone density is still being debated and may take protracted, years-long, studies of long-term FES implants and their effects to resolve.

While FES has come a long way from the equipment and techniques of 15 years ago, it is still far from fulfilling all the expectations of SCI patients and claims of proponents to restore pre-injury gait and other activities and skills.

FES for the near future (5 to 10 years) must remain the domain of a select few candidates who are carefully screened and groomed and cultivated to ensure the success of the technology. Even with careful selection, 50% of FES implants fail or are discarded due to patient non-compliance or patient difficulty with device operation, or component failure, or any combination of a number of reasons as varied as the patients and their backgrounds. Synthetic mobility is still severely limited and a poor substitute for pre-injury walking. Computer controlled, electrically stimulated gait is difficult, slow and consumes an estimated, by O2 uptake tests, 6 times the normal effort to achieve. FES cannot at present replace a wheelchair for functional mobility. Of programs evaluated for this study, all investigators of FES gait begin with a pool of subjects numbered from dozens to hundreds which is quickly whittled down by selection and attrition in all studies to about 25% of the original number, from which test subjects are then selected. The final selections of subjects in these studies are fewer in number (from 1 to 12) than desirable for a satisfactory sampling and evaluation of the efficacy of the apparatus and/or technique under scrutiny.
and at best can only indicate trends. It is of note that all studies of the effects of SCI upon QL and other complicating factors affecting the possible outcomes of FES achieved up to 88% participation. This is 100% higher than the best general population norms for participation in similar questionnaire-based evaluations.

Recent advances in rat studies have indicated that, after inhibition of neurite growth inhibitors, it is possible to induce partial regeneration of the transected spinal cord. Also recently reported are studies of rats being directly “hard-wired” from the brain to respiratory muscles and learning to control breathing directly after anatomical neuron connections are surgically severed. Perhaps, rather than looking to FES for the entire solution to the problems of functional ambulation, and the patient’s dream of being “normal” once more, SCI patients and researchers answers will lie in a judicious marriage of medicine, microsurgery and technology, combining release of spinal reflexes with cutaneous stimulation, partial spinal cord regeneration, reflex stepping and FES with a highly customized rehabilitation program to address all the QL, mobility and control needs of upper motor neuron-damaged patients in general (CVA, ALS, MS) and all levels of traumatic SCI patients in particular. International Internet co-operation, sharing knowledge and protocols, by researchers at SCI centers could significantly speed progress toward the goals of restored direct upper motor control of all vital systems and truly insensible balance and ambulation at pre-injury effort levels.

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FES, the Answer or a Question.


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**APPENDIX A**

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**APPENDIX B**

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