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Introduction

This book has been written for persons with spinal cord injury or multiple sclerosis, their families, and the health care professionals who work with them. The book contains information on the use of functional electrical stimulation (FES) to maximize health and function for people with these spinal cord dysfunctions.

Although this book is specifically for people living in the United States, residents of other countries will likely find it useful because the information was gathered from medical and rehabilitation experts across the world. The material is current as of spring 1995. We expect to provide supplements periodically as new developments occur. See the order form on the last page.

How to use this book

This book is divided into five parts. The tabbed divider between each part provides information about how to use the part.

If you don't know much about FES and need to learn about how it works, what the options are, and how to select a treatment to explore, start with *Part 1. Learning about FES*. This section provides an overview of FES and then describes each type of application or treatment that is currently available. Focus on SCI-1 through SCI-18 if you have a spinal cord injury, or MS-1 through MS-18 if you have multiple sclerosis. The guidelines (page 65) for selecting FES programs at specific clinics or with a specific health care provider may also be useful. The glossary should help you with any unfamiliar terms used in the book. Terms appearing in bold type are explained in the glossary starting on page 191.

If you already know quite a bit about FES, but need to know where you can go to get treatment, start with *Part 2. Where to get FES*. These descriptions of FES programs are listed by location so that you can identify the options in your local area*. If you want to look for a particular type of FES program, then use the index at the end of the book. It will direct you to any programs in *Part 2* that match your criteria. Before making any decisions, you may want to review the selection guidelines at the end of *Part 1* on page 65.

If you can't find all the information you need in *Parts 1 or 2*, turn to *Part 3. More resources on FES.* This section includes a bibliography for additional reading, a directory of some FES product manufacturers, and listings of other organizations that may be helpful in your search for information about FES.

You can always use the index in *Part 5* to find appropriate information in any section of the book. Don't forget to use the glossary in *Part 4* - sometimes your definitions of terms may be somewhat different from those used in the book. Even professionals who work with FES may use words differently since they have been trained in different fields - for example, neurosurgery, physical therapy, biomedical engineering. There is no standard terminology today in the FES field.

Remember - electrical stimulation is a medical technology that should be undertaken only under the guidance and supervision of a trained health care professional!

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PART 1. LEARNING ABOUT FES

What is FES?

Spinal cord injury (SCI) or multiple sclerosis (MS) can produce total or partial paralysis. The person who has one of these conditions may be unable to move parts of his or her body. Breathing, blood circulation, bladder and bowel function may also be affected. In the last 30 years, medical scientists and engineers have invented methods and devices to assist with these problems. One technique is called **functional electrical stimulation (FES**) (pronounced "ef-ee-es".) Because FES can be applied to many different physical problems, any person with SCI or MS may want to investigate FES as a treatment option.

FES is a method of applying low level electrical currents to the body to restore or improve function. A heart pacemaker is one example of an FES system. Other types of FES may restore lost abilities such as standing or grasping. Also, FES may assist with some secondary problems of paralysis such as poor blood circulation or slow wound healing. When used in these ways, the treatment may simply be called electrical stimulation or ES.

It is important to understand that ***FES is not a cure*** for spinal cord injury or multiple sclerosis. FES is an assistive device. For people with a **complete spinal lesion**, FES provides benefits only when the system is operating. When the system is turned off, the benefits will disappear. People with an **incomplete spinal lesion** or multiple sclerosis may be able to use FES to recall some amount of voluntary muscle function, so that when the FES system is turned off, the user may still receive benefits. This is a therapeutic benefit of FES. ***FES itself does not reverse paralysis***. Finally, people with certain types of nerve damage cannot be helped by FES. Despite the limitations, one of the exciting things about FES is that improvements in function are possible for people of any age and any duration, level, or completeness of injury. Many FES techniques are still experimental. Yet, they hold real promise for helping people with paralysis. For some individuals, FES can improve physical and emotional health in ways that cannot be achieved with other methods available today.

The nervous system

Movement and feeling in the human body depend on natural electrical currents that flow through nerves connecting the brain with the limbs. At the bottom of the skull, the brain joins a long bundle of nerves called the spinal cord. Along the spine, smaller nerve bundles branch out from the spinal cord to the head, arms, trunk, and legs. We call the brain and spinal cord the **central nervous system.** We call the branching nerves that supply the arms, legs, and other parts of the body the **peripheral nervous system**. We call the nerve bundles branching out from the spinal cord **spinal nerve roots**.

The natural electricity in the body carries signals back and forth between the central and peripheral nervous systems. When we decide to make a movement, signals start in the brain and travel to the limbs. The signals carry the electrical commands that cause voluntary muscles to contract. We call these commands motor signals. Other signals go in the opposite direction. They start at a limb, the trunk, or the head and carry electrical messages about touch, pressure or pain back to the brain. We call these sensory signals.

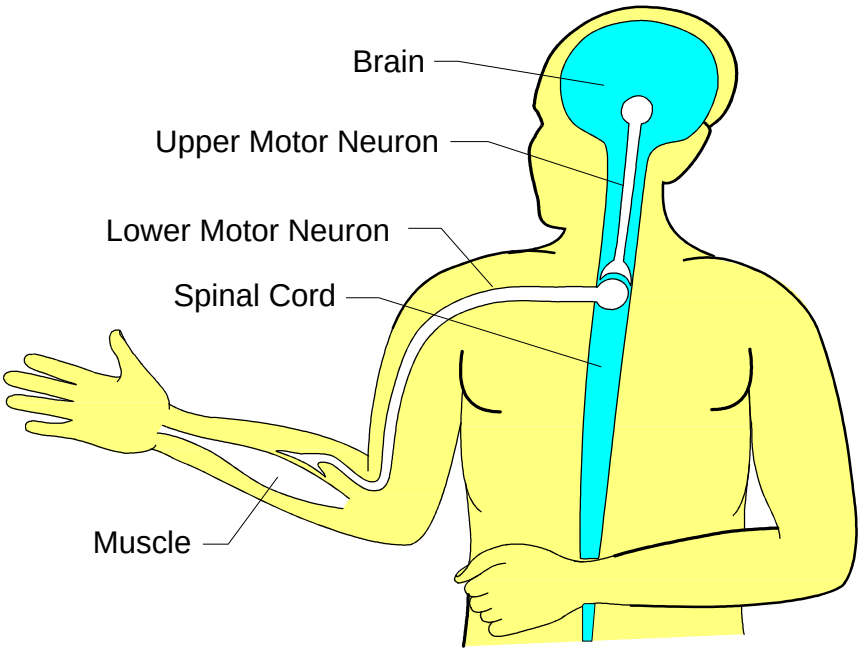
Why does paralysis occur?

Injury or disease in the nervous system can interrupt the normal communication between the central and peripheral nervous systems. The result may be muscle weakness or paralysis. This can happen when there is damage at any point between the brain and a muscle. Such damage points may be in

- the brain itself
- the spinal cord
- the spinal nerve root (a bundle of nerves that branch out from the spinal cord)
- the peripheral nerve
- the muscle.

Injury or disease in the nervous system harms nerve cells. The **central nervous system** may be affected -- brain cells or spinal cord cells are damaged. Or, the peripheral nervous system may be affected -- **spinal nerve roots** or peripheral nerves are damaged. Peripheral nerve damage is called **denervation**. Often an injury to the spinal cord (central nervous system) can also affect the peripheral nerves that lead out from the cord. The picture below shows the difference between the **upper motor neurons** and **lower motor neurons** of the nervous system. Most types of FES are not beneficial when the lower motor neuron is damaged. A clinician can perform simple tests of muscle function to check for lower motor neuron damage or denervation.

The Nervous System



How does FES overcome paralysis and its related problems?

When there is damage only to the **central nervous system**, the muscle and its nerve supply remain healthy. The reason they don't work is that they are cut off from the command signals coming from the brain. FES applied near the muscle or nerve can substitute artificial electrical signals for the missing normal motor signals. The artificial impulses make the muscle contract.

Things are different when there is also **denervation**. When that happens, the nerve-muscle connection is broken. Stimulating the nerve with FES pulses will not make the muscle contract. Electrical pulses applied to the nerve or muscle will face the same barrier faced by the normal

signals from the brain. This happens in peripheral nerve disorders or injuries, in diseases of the nerve-muscle junction, and in muscle diseases. Recently, researchers have started to design special stimulation equipment to activate denervated muscle directly and bypass the damaged peripheral nerve. The biggest problem is that the muscle **fatigues** and gets weak very quickly.

Multiple sclerosis (MS) also produces problems in transmission of nerve signals. While SCI is caused by a physical insult, MS is caused by degrading of the natural insulation on nerves. Depending on where this happens, the symptoms can vary from weakness and numbness to eye problems and dizziness.

The ideal solution to neurological problems such as these is **regeneration**. It involves causing the central nervous system to grow new neurons to replace the ones that are injured or sick. Scientists who are working on this problem are doing basic research about how cells and nerves grow. They are studying cells and animals to learn more about nerve cell growth in humans. Some experiments are looking at the possible benefits of electrical stimulation applied very shortly after injury to the spinal cord. We all hope that someday FES won't be needed anymore because regeneration will have solved the problem of paralysis. But, that day is many years in the future.

Today, we have more than a dozen applications of FES to improve health and function, such as for improving circulation, and for moving muscles. When FES is used to move parts of the body, it may also be called FNS or **functional neuromuscular stimulation**. Such FES/FNS applications include:

- cardiovascular exercise
- breathing assist
- grasping and reaching
- transfers and standing
- stepping and walking
- bladder and bowel function.

Sometimes the primary purpose of FES does not involve moving muscles. Then, it may be called simply electrical stimulation (ES), TENS (**transcutaneous electrical nerve stimulation**) or **electrotherapy**. In such cases, the primary purpose may be to prevent or treat problems that arise because of SCI or MS. These problems are called *secondary complications* and they include:

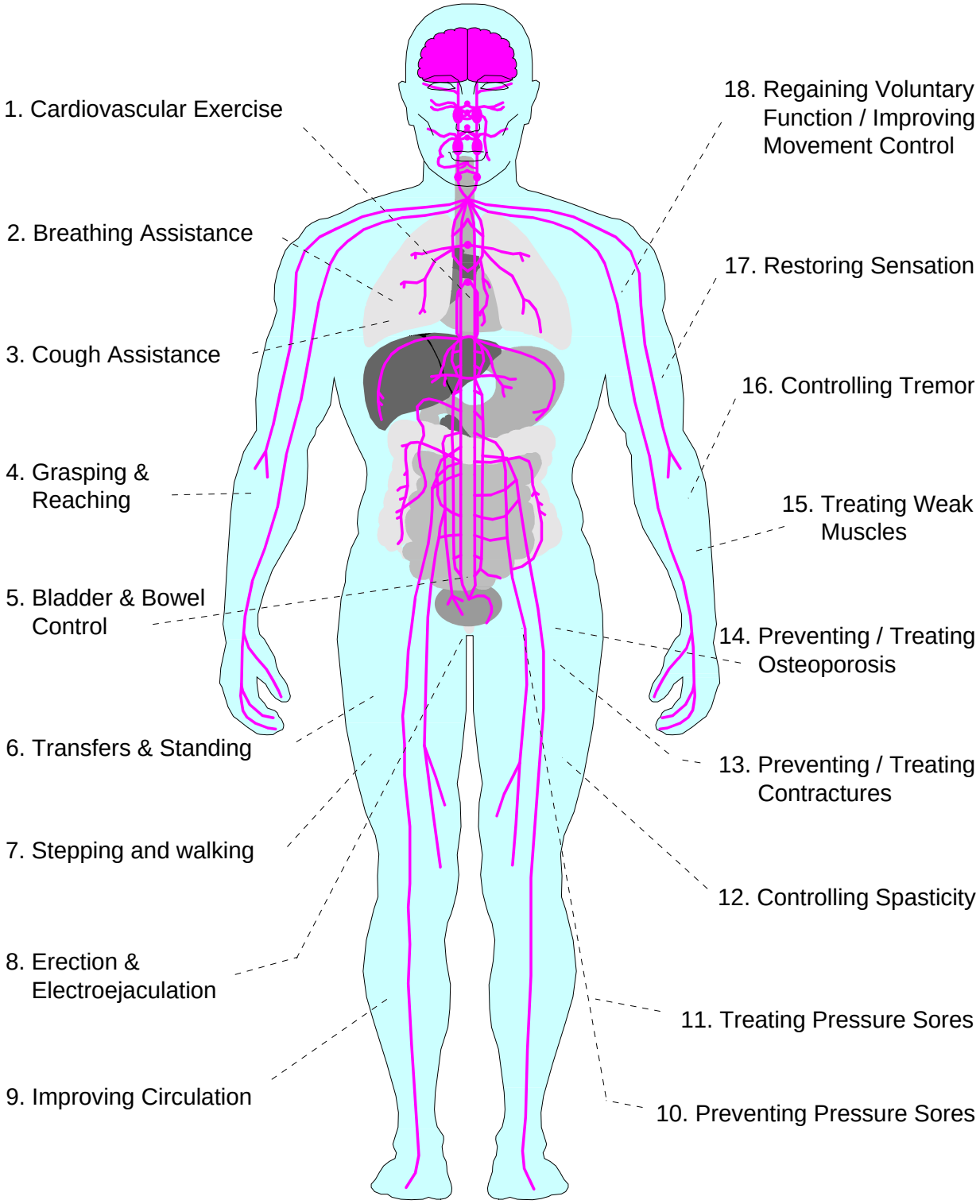
- male sexual dysfunction (inability to have an erection or ejaculate)
- blood clots (**deep venous thrombosis**)
- **pressure sores**
- **spasticity** (uncontrolled contraction of muscles that causes stiff awkward movement)
- contractures (joints that cannot open fully)
- loss of bone mineral (**osteoporosis**)
- weakening and shrinking of muscles due to inactivity (**atrophy**)
- **tremor** (shaking that occurs continuously or whenever a voluntary movement is made).

When FES is used for these problems, two effects can occur. One is muscle contraction and the second is electrical current in the affected tissues, without muscle contraction. These effects are sometimes called **therapeutic electrical stimulation**.

Together with heart pacemakers, electrical stimulation (ES) devices for pain control are the most widely available ES devices. Because so much information is already available, this book does not deal specifically with ES for pain. Neurologists, doctors who specialize in the nervous system, often prescribe ES for pain that cannot be treated otherwise. Pain control may include many other treatment methods such as medication, psychological therapy, and acupuncture.

The picture below shows 18 different ways that FES can be used to help someone with a spinal cord dysfunction.

FES Applications in Spinal Cord Dysfunction



How is FES Applied to the Human Body?

How does FES technology work?

The main components of an FES system are the electrodes, the stimulator, and sensors or switches. When FES is being used to move muscles, current pulses in the electrodes cause the weakened or paralyzed muscles to contract. In other applications, currents in the electrodes may simply produce electrical currents in the tissues without moving any muscles. The stimulator controls the strength and timing of the low-level pulses that flow to the electrodes. The sensors or switches control the starting and stopping of the pulses supplied by the stimulator.

Electrodes

Electrodes may be applied to the skin daily or they may be implanted in the body. Skin **surface electrodes** are made of a flexible material such as rubber that conducts electricity. Tiny electrical currents are sent through the electrode to the skin and the tissues beneath the skin. Some surface electrodes are applied with a conductive gel. Others are self adhesive. Both types may be reusable. Surface electrodes are widely used in therapeutic electrical stimulation for rehabilitation of injury or weakness. It is convenient to simply apply electrodes to the skin surface. But, daily application of the electrodes can be time consuming. Stretchable garments with electrodes already mounted in appropriate locations have been developed by several manufacturers to simplify the process.

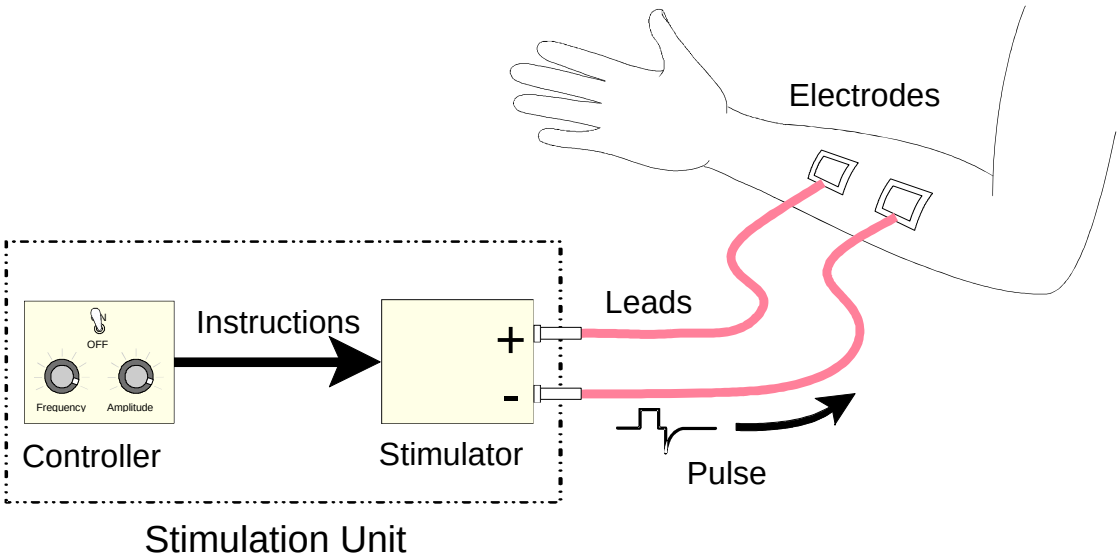
Surface electrodes have some drawbacks. Because they are separated by skin and fat from the underlying muscles and nerves, surface electrodes cannot make individual muscles active. Instead, they stimulate groups of muscles. Therefore the desired action may be more difficult to achieve. Also, the muscle stimulation may vary from day to day because of differences in placement of the electrodes. Sometimes, the skin may be irritated or burned by the electrode gel or the electrical current itself. In people who retain feeling, there is a possibility of discomfort because the stimulation may accidentally activate pain nerve fibers. Researchers are developing new stimulation equipment that avoids pain nerve activation.

Implanted electrodes are located inside the body and avoid the need for daily application. They provide selective stimulation of particular muscles with lower current levels. But, a drawback is the need for surgery to place the electrodes or replace them if necessary. They are also more expensive to produce. Implanted electrodes may be fine wire coils inserted in muscles (**intramuscular electrodes**), flat metal foils placed against the spinal cord or muscle surfaces (**epimysial electrodes**), or soft cuffs of rubber and metal foil that surround nerves (**nerve electrodes**).

Leads, Stimulators and Sensors

Electrodes are connected to a stimulator by insulated wires called **leads**. The stimulator sends electrical pulses through the leads and to the electrodes where the electrical charge is delivered to the nerve, muscle or other tissue. Most stimulators are external units that can be as small as a calculator or as large as a computer workstation. Usually, a stimulator has a computer controller built into it. Each stimulation **channel** sends pulses to one or more electrodes.

A Basic Electrical Stimulation System



More advanced systems have implanted electrodes and also may have implanted stimulators. Implanted electrodes and their leads can be completely inside the body or the leads may pass through the skin (**percutaneous** leads) and connect to an external stimulator. The surgery for implanting an FES stimulator is similar to that used in implanting a heart pacemaker. The electrodes are connected to the stimulator inside the body. The stimulator has a built-in radio receiver that receives command signals from an external control unit. *See the pictures on pages 11, 14, 17, 27, and 41 for examples of different FES system components.*

Sensors are electronic or mechanical devices that measure some feature of the environment and send information about it back to the stimulator-controller. The controller uses the information to adjust the stimulation. Sensors include the switches that the FES user operates to start and stop the system. Some systems also have switches that allow the user to select from a menu of choices. Some sensors are built into braces or shoes to detect the angle at a joint or the pressure when weight transfers onto a foot. These are all man-made, or artificial, sensors. Researchers are also working on using natural sensors by recording signals from the sensory nerves in the body using special types of electrodes.

One of the important senses we use in movement and posture is **proprioception**. This means knowing where the parts of our bodies are. For example, natural sensors in the area of the knee joint tell you the position of your leg even when you cannot see it. In complete SCI, the sensory nerve pathways are interrupted and cannot convey information about limb position to the brain. Some FES systems use an angle sensor to get information on limb position. This electronic device is strapped to the limb, it measures joint angle, and sends that information to the controller. The controller then adjusts the stimulation levels according to the desired task.

To be truly practical, an FES system needs to correct for changes in the environment and day-to-day changes in the user's body. This requires a **feedback** method that can adjust the stimulation so that it accomplishes the desired movement. Examples of adjustment goals are to give the best grasp force for a particular object or the best walking step length for a particular floor

surface. Some forms of feedback are already built into FES devices. For example, some FES walking systems use pressure sensors in the shoes that signal the controller when a step is completed. Feedback information may also be used as an "alarm" signal to alert the user that his FES system needs attention. An example would be a bladder sensor that notes when the bladder is full and signals the user of a FES bladder system to activate the stimulation and empty the bladder.

Feedback information, whether it comes from artificial or natural sensors, has many benefits. It can make the FES user aware of the FES system's status and how well it is performing. It can help the control system to adjust to changing conditions. That adjustment may reduce muscle **fatigue**. FES exercise can push muscles to their limit even sooner than would occur with normal muscle contractions. The resulting fatigue is an ongoing problem with some types of FES. FES systems with feedback also require less attention from the users. Developing such systems is an important goal.

Factors that determine what an FES system can do
♦ the number of electrodes
♦ the type of electrodes (some can activate specific muscles better than others)
♦ how many separate channels the stimulator has (one channel may control several electrodes)
♦ the number and complexity of patterns of stimulation stored in the controller
♦ feedback designs in the controller
♦ the characteristics of the sensors or switches

What FES systems are available?

As with any medical technology, FES methods must be demonstrated in the laboratory years before they can be available to the consumer. Today, a newspaper or television show may report a laboratory breakthrough in FES. That does not mean that tomorrow your doctor can prescribe a new FES exercise system for you. Years of work by scientists, physicians, therapists and engineers are needed to develop today's breakthrough into a practical device.

In the United States, the process of testing and approval of medical devices is governed by a regulatory agency called the Food and Drug Administration (FDA). Gaining FDA approval can take many years. Devices have to be tested on larger and larger groups of subjects* to gather enough information to show if they are safe and effective. Today, many FES devices are investigational - they are still being tested and improved. This means that they are not commercially available and that doctors cannot simply prescribe them for a medically eligible person. Only research subjects who participate in FDA-approved studies have access to investigational devices. And, the locations where they are available are limited to the research sites.

Even if an FES system is approved by the FDA, it doesn't mean every doctor believes that it is the best alternative to other available treatments. It may take many years for clinicians to reach a "consensus" and recommend the FES system over other alternatives, thereby identifying it as **accepted practice**. Some clinicians, however, might never choose to prescribe the system.

* When a person participates in a research project, we refer to her or him as a "subject." When a person with a disability is receiving medical or surgical care, we refer to her or him as a "patient." Sometimes we refer to the person with a disability as a "consumer" of an FES product or service.

The development of FES systems can be divided into four progressive stages as shown in the table on page 9: basic research, clinical feasibility studies, multicenter clinical trials, and regulatory approval. **Basic research** includes testing using animals and computers. **Clinical feasibility studies** are the first tests of a system, involving only a small number of human subjects. Usually, such tests are conducted at a single location. In some studies there are no costs to the subjects.

In the third stage of development, researchers conduct **multicenter clinical trials.** They collect the same type of information at all the participating clinics and involve many more subjects. Such studies are designed to gather information about the safety and effectiveness of new devices. All testing on human subjects in the United States is governed by investigational device exemptions (IDE) that are granted by the FDA. Naturally, other countries have their own regulations for approval of medical devices. Often, devices are approved in other countries before they receive FDA approval. Each facility that offers an investigational device is monitored by its own Institutional Review Board (IRB). The IRB makes sure that subjects are fully informed about any risks or benefits of the system that is being tested by ensuring that the subject signs an accurate **informed consent** form.

When multicenter trials produce satisfactory results, the device is approved by FDA and can then be distributed commercially. If a new device is very similar to a device already approved by the FDA, the manufacturer may be granted approval without having to conduct multicenter trials. At this stage, the FES application has achieved **regulatory approval**. It is commercially available, and may be covered by some insurance carriers. *However, it is always up to a patient's doctor to determine if a particular device or treatment is suitable for that patient.*

Some FES systems are commercially available only outside the US. The tables in this part of the book indicate that those systems have achieved regulatory approval and shows in which countries they are available. The FDA is usually more strict than the regulatory agencies of other countries. As a result, the same device may be investigational in the US but approved elsewhere.

Even if an FES device is FDA-approved and commercially available, many factors affect how widely it will be used. These include how complex it is to select the people to use the system, how easy it is to use, its appearance and cost, how long the user must train to use it effectively, and how well it compares to other available alternatives. There may be a shortage of doctors and therapists who know how to select people, apply the system, and train the users. Third party payers like Medicare or private insurance companies may be reluctant to provide reimbursement. Some FES applications may never be widely available because of the small numbers of people who can benefit and the complexity of the treatment.

The table on page 9 shows the development stage and availability (limited, restricted or wide) of FES systems. The key that precedes the table provides a detailed explanation of the terms used in the table. Each of the numbered rows names an FES application. Each column heading names a stage of development or a degree of availability. In the box where a row and column meet, we show the activity that exists today for the application named at the left of the row. SCI refers to spinal cord injury. MS refers to multiple sclerosis. For example, on line 5, bladder and bowel control, "SCI, MS" under the column headed "feasibility studies" indicates that small FDA-approved studies are underway with people who have SCI or MS. Under the column headed "regulatory approval, non-US", "SCI, MS" indicates that systems are approved and commercially available outside the US for people with SCI or MS. The table also indicates that the availability of this type of system is "restricted" for people with SCI or MS, meaning that there are only a few places in the US providing this type of FES.

Applications may have activity in more than one stage, usually indicating that alternative techniques are being investigated. See the corresponding numbered sections, beginning on page 10, for a description of each application (for example, SCI-3 for information on FES for cough assistance). SCI applications are grouped together. MS applications follow them. See *Part 2, WHERE TO GET FES*, for information about specific FES programs that provide people with devices and training.

While FES may help many people in the future, today many FES applications are still experimental. This becomes clear when you page through the SCI and MS applications on the following pages. Anything that is not in the column headed regulatory approval is experimental, or investigational. Even for most of the approved FES applications today, there is no general agreement within the medical community that they are the preferred treatment. Education about and training of health care providers in FES methods will help to make them more widely available to interested consumers. Be sure to let your clinicians know that this book and other resources are available to rehabilitation professionals who seek education and training about FES.

Key to Table (Page 9):
Development Stage of FES Systems and
Clinical Availability of FES Systems

Development Stage

- **Basic Research**: Usually means computer modeling or animal experimentation.
- **Clinical Research**:

Feasibility Study: Study to prove that the treatment is effective and safe for a small number of individuals, typically up to 20.

Multicenter trial: Identical studies conducted at multiple clinics with a sizable total number of individuals, typically 50 -100. The goal is collection of data on safety and effectiveness that will be adequate for regulatory approval.

- **Regulatory Approval**: The FDA, in the US, has reviewed the data of multicenter trials and agrees that the documentation and data support the manufacturer's claims of safety and effectiveness. This does not mean that all clinicians agree that the treatment is safe and effective and preferred over other alternatives. In other countries, the counterpart agency to FDA has reviewed results of clinical studies and granted approval for marketing of the device.

Clinical Availability (includes availability in clinical research centers as part of feasibility or multicenter studies, may or may not be approved by FDA)

- **Restricted**: Available in only a few (1-6 centers in the US) specialized rehabilitation centers or clinics serving persons with SCI or MS. Personnel require extensive training to provide this treatment.
- **Limited**: Available in some, but not all, rehabilitation centers or clinics serving persons with SCI or MS. Personnel require specialized training to provide this treatment.
- **Wide / Extensive**: Available in most rehabilitation centers serving persons with SCI or MS. Personnel may require training but it is readily available.

A note on development stage and availability in countries other than the United States:

In each specific application section of this chapter, we have included a small table describing the status of FES systems for that application. We have indicated specific types of systems as being in basic research, clinical research or approved practice stages. Unless a country is specified, we are referring to the US.

Table of Applications

What FES Applications Can Benefit People with Spinal Cord Injury?

The picture on page 4 and the table on page 9 name 18 applications of FES that have been used in people with spinal cord dysfunction. The sections that follow explain how each application works, its purpose, status (availability) and cost, who is eligible, time needed for treatment, and expected results or outcomes.

For each application, the status information is presented in a small table similar to the table on page 9. The table indicates that the availability of the application may vary from a single location where feasibility studies are underway to many clinics where an approved treatment and device can be obtained. See Part 2. WHERE TO GET FES for specific details about where particular FES treatments are available.

For each application there are also medical eligibility requirements. In addition, there are factors which would disqualify a candidate. Many of these disqualifying factors apply to almost all uses of FES. They include:

- Heart rhythm or high blood pressure problems
- Implanted pacing devices
- Possible blood clots
- Some types of tumors
- Pregnancy
- Unhealed wounds
- Tendency for worsening of **autonomic dysreflexia** with FES.

People who have any of the conditions listed above should **not** use FES.

SCI-1. FES systems for cardiovascular exercise

What is the purpose?

- Increase endurance and physical fitness.
- Improve heart and lung function.
- Maintain and increase muscle bulk.
- Help to reduce secondary complications such as **decubitus ulcers**, colds, and urinary tract infections.

What are non-FES alternatives?

To develop and maintain physical fitness, people with paraplegia can do sports involving the arms such as swimming, wheelchair tennis, and wheelchair racing.

People with paraplegia, or quadriplegia from C-5 to C-8 levels, or incomplete quadriplegia can do arm-cranking exercise or various wheelchair sports to develop greater aerobic capacity. But, like in any exercise, overuse of the arms can lead to arm or shoulder strain, and injury. Long-term changes may include **osteoarthritis** or **tendonitis**.

People with quadriplegia at levels above C-5 may be able to use adapted equipment to move their limbs, but they have no non-FES exercise option for increasing cardiovascular endurance.

How do the FES systems work?

Stationary exercise bicycle or ergometer
In a typical system, the user sits in a specially fitted chair that allows the legs to be positioned on pedals. A stimulator activates 6 surface electrodes applied over leg muscles to produce a pedaling motion. A computerized control unit tracks the stimulation applied to the leg muscles and coordinates it with position and resistance readings taken from the pedals. The goal is 35 - 50 revolutions per minute. The controller keeps the prescribed resistance and stops the exercise when the muscles are fatigued.

Example of an FES bicycle ergometer

STATUS OF FES SYSTEMS FOR CARDIOVASCULAR EXERCISE			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
	• Rowing ergometer • Modified bicycle as mobility aid		• Computer-controlled FES exercise bicycle; several styles available

Who is medically eligible?

Persons who fulfill all the following requirements:

- Only **upper motor neuron** lesions.
- Joints that can move throughout the range needed for the bicycling or other motion.
- Skin sensation that can tolerate surface electrodes.
- No abnormalities in x-ray of legs.
- Good general health.
- Emotionally stable and realistic.

People who were injured more than 5 years ago will need special assessment before starting an exercise program. They can have a large loss of muscle mass, **contractures**, and brittle bones. People over 40 years of age will need additional evaluation for possible heart problems.

People with the following conditions are disqualified:

- History of leg fractures.
- Severe **spasticity**.
- **Contractures**.
- Severe **osteoporosis** (thin, weakened bones).
- See additional disqualifying factors on page 10.

How long does the treatment take?

Exercise is not a treatment but rather a part of daily life. In past years, doctors' recommendations for physical fitness included

- Exercise at 70% of maximum heart rate for your age,
- 30-60 minutes each session,
- At least three times a week.

In recent years, they have found that the same health benefits can be obtained from less strenuous exercise provided it is done regularly.

Participation in an FES exercise program typically involves:

- Thorough medical checkup.
- Physical therapy and conditioning to strengthen leg muscles (3 times/week - 10-20 weeks).
- Personal exercise program in community, home or other location as part of your regular activities.
- Medical follow-up every 36 exercise sessions.

What does it cost?

Most insurance programs will pay for the medical work-up and the initial training to reach a specific goal. They are reluctant to pay for the exercise system itself. There are several manufacturers of FES bicycle ergometers -- the price of a complete home system ranged from $10,000 to $15,000 in 1999.

What can I realistically expect today?

With consistent exercise, about two thirds of FES exercise system users can expect

- Improved cardiovascular health.
- Improved fitness.
- Increased leg muscle strength.
- Increased leg muscle bulk.

About half to two-thirds of users feel better about their appearance. More than a quarter of users experience less swelling of the legs. Some users report decreased secondary complications. Despite all these possible benefits, it is important to remember that a person with complete SCI will not regain voluntary control of the legs by using an FES bicycle system.

Some FES exercise users report increases in

- Employment opportunities.
- Participation in social activities.
- Efficiency in activities of daily living.

FES exercise can increase pain in some people. This pain has caused people to stop FES exercise. Newer equipment is designed to reduce pain from stimulation.

Supportive family and friends are a big help to the exercise system user in following a regular exercise program.

See SCI-14 *FES for preventing or treating osteoporosis* for information about bicycle exercisers and improving bone strength.

What may be available in the future?

Research has been conducted on an exercise system that uses an adapted rowing exercise machine and surface FES. A commercial stimulator is set to activate leg muscles at a rate that the user can control. The user rows with the arms voluntarily while keeping in time with the electrically-controlled leg muscle action. Researchers have also developed prototypes of FES bicycle-like systems to serve as a wheelchair alternative. These systems may function as a combined mobility and exercise aid.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-2. FES systems for breathing assistance

What is the purpose?

- Activate the diaphragm and/or chest muscles to produce breathing.
- Reduce the need for a ventilator. Provide more freedom.
- Provide more consistency of ventilation.

What are non-FES alternatives?

- Ventilator.
- Continuous, positive nasal air pressure device (CPAP)
- Pneumobelt, a corset that inflates and deflates to assist movement of the diaphragm.

How do the FES systems work?

Diaphragm muscle stimulation

In a typical system, called a phrenic pacer, cuff electrodes are surgically implanted around the phrenic nerves in the neck or chest. The phrenic nerves (one on each side) control the movement of the diaphragm, the large muscle that separates the chest from the abdomen. A stimulator-receiver (pacer) connected to the cuff electrodes is implanted under the skin just below the rib cage. An external antenna-transmitter is taped onto the abdomen just above the implanted pacer unit.

When the phrenic nerve is stimulated, the diaphragm moves downward (towards the feet), expanding the chest cavity and pulling air into the lungs. When the stimulation is turned off, the diaphragm relaxes, moves up, and air leaves the lungs.

Intercostal muscle stimulation

Muscles other than the diaphragm play a role in breathing too. Researchers are testing an FES device that activates the muscles between the ribs (intercostal muscles) to expand the lungs. This device involves a single electrode implanted on the surface of the spinal cord in the upper back. Studies indicate that it may provide sufficient ventilation when used in addition to a one-sided phrenic nerve pacer.

Example of an FES phrenic pacing system

STATUS OF FES FOR BREATHING ASSISTANCE			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
•	• Intercostal muscle pacer • Systems with electrodes implanted in the diaphragm for pacing		• Phrenic nerve stimulator to pace diaphragm

Who is medically eligible?

Phrenic nerve pacer
People who have:

- SCI at levels C-1 to C-3.
- Undamaged lower motor neuron to diaphragm.
- Normal diaphragm and lungs.

People may be disqualified if they have SCI at C-4 or C-3 level, since this may result in phrenic nerve damage. See additional disqualifying factors on page 10.

Intercostal muscle pacer
A person who has only one healthy phrenic nerve may have inadequate air supply when using a phrenic pacer. Early tests show that combining phrenic nerve pacing with spinal cord pacing of the intercostal muscles may provide adequate ventilation for such individuals.

How long does the fitting and training take?

Following the surgical implantation of a phrenic pacer, the patient remains in the hospital for daily training of the diaphragm muscles. At the start of this period, the FES device may be used for only a few hours a day. The time using the FES device is gradually increased. A person with quadriplegia may need as long as 3 - 4 months to build tolerance to using a phrenic nerve pacer full-time. Other types of systems would probably follow a similar course.

What does it cost?

Phrenic nerve pacers cost about $50,000 - 75,000. This includes the device, the surgery to implant it, and costs for hospitalization during training. Cost information is not available on the research systems under development.

What can I realistically expect today?

People who can adapt to phrenic nerve pacing or intercostal muscle pacing can expect that their breathing system will be more cosmetic, or less noticeable than with a ventilator. They will have more freedom to move around without the interference of ventilator tubing. They may not need to use a ventilator except as a backup if there is a problem with the phrenic or intercostal pacer. Speaking will be more natural because they will not need to use a tracheostomy tube for breathing. They will also be able to smell more normally. Most patients report that generally they feel much better during pacing than during mechanical ventilation.

What may be available in the future?

Some individuals using phrenic pacers have been able to have their tracheostomy stoma permanently closed. More studies are needed to describe the user training and nighttime monitoring protocols needed to achieve this goal for more individuals. In new developments, clinical studies of a diaphragm stimulation system are just beginning to test whether electrodes implanted directly in the diaphragm muscle with laparoscopic surgery (“Band-Aid” surgery) are effective.

See page 65, “What Should I Know When Choosing an FES Product or Service?”

SCI-3. FES systems for cough assistance

What is the purpose?

Provide independent ability to cough and clear lung secretions.

What are non-FES alternatives?

- Positioning that helps gravity to drain lung secretions.
- If secretions are heavy, suctioning.
- “Assisted cough” (or “quad” cough) can be provided by a therapist or attendant. He or she manually compresses the abdomen while the person controls the opening and closing of the upper airway.

- Mechanical negative pressure devices applied to the mouth and nose.

How does the FES system work?

In one type of system, surface electrodes are placed on the abdomen. They are controlled with a battery-powered stimulator. Stimulation is triggered for about 1 second, producing strong, brief contraction of the abdominal muscles, which causes a cough.

Investigators are studying a commercially available magnetic stimulator as an alternative to electrical stimulation to restore cough. The magnetic stimulator functions by sending out a short magnetic pulse from a coil that is placed on the skin over the lower thoracic spine. This pulse induces an electrical current in the underlying tissue causing a contraction of the abdominal muscles. Studies in animals have shown that implanted spinal cord stimulation can also produce cough, but this technique would require surgery.

STATUS OF FES SYSTEMS FOR COUGH ASSIST

Basic research	Clinical research	Multicenter trials	Regulatory approval
• Spinal cord stimulation	• Functional magnetic stimulation	• Surface electrode system (Available commercially outside of the US)	

Who is medically eligible?

People with

- Cervical level SCI.
- Mid to upper thoracic level injury and impaired abdominal muscles.

FES cough assist devices may interfere with other implanted devices such as heart pacemakers or drug infusion pumps. People with incomplete SCI may be unable to tolerate the skin sensation of the surface electrode device. See additional disqualifying factors on page 10.

How long does the fitting and training take?

People may need some training to learn to coordinate their voluntary activity with the electrically assisted cough. No more details are available yet.

What does it cost?

Outside of the United States, surface electrode systems are available for under $500.
What can I realistically expect today? How effective a cough is in removing airway secretions depends on how fast it moves air out of the lungs. Surface stimulation of the abdominal muscles can boost peak air flows up to 30% in a person with SCI. The effectiveness will depend on the volume and thickness of the individual's airway secretions.

The ability to cough on demand will allow the person with SCI to clear his or her breathing passages at any time. This may reduce the number of lung infections, shortness of breath, and dependence on trained assistants.

What may be available in the future?

The manufacturer of the surface electrode FES coughing system is hopeful that approval from the Food and Drug Administration to distribute the system in the United States will be obtained in a few years.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-4. FES systems for grasping and reaching

What is the purpose?

- Increase the number of activities that can be performed.
- Increase the ease and security of doing certain activities.
- Decrease the need for personal assistance.
- Decrease the need for other adaptive equipment such as splints, braces, or customized tools.

What are non-FES alternatives?

- Splints (orthoses) covering either the forearm or the wrist.
- Surgical tendon transfers, possibly together with other surgical procedures that fuse or stabilize joints.
- Combination of splints and muscle or tendon transfers.
- Reliance on someone else to do activities.

How do the FES systems work?

An FES grasping system activates the muscles that control the fingers and thumb. A reaching system also activates the muscles that control the elbow. Electrodes may be the surface type or they may be implanted on nerves or muscles. Depending on the particular type of system, the user controls the stimulation by either shoulder or wrist movements, voice, or breathing in a set pattern. Control by shoulder or wrist movements works through a joystick-type device that is mounted across a joint, such as the shoulder. For most systems, a personal assistant is needed to help you put the system on.

Depending on which muscles are activated, FES hand grasp systems can provide some or all the following types of grasp:

- *Key pinch* as you would use to hold a thin object such as a key or pencil.
- *Three-jaw-chuck grasp*, also called palmar or cylindrical grasp, as you would use to hold a glass or a book.
- *Parallel extension grip* as you would use to hold a hand of cards.

These different grips are achieved by differently coordinated actions of the finger and thumb muscles. The patterns are tuned for each user by the rehabilitation team and with some systems, can be further adjusted by the user. The patterns are stored in the controller, which is mounted on the wheelchair or on the user's arm.

With a system that includes muscles for elbow control, the user may also be able to reach out in one or more directions. Again, the electronic patterns that coordinate all the activated muscles to achieve reaching are stored in the controller.

Examples of FES hand grasp systems: surface electrodes (left) and implanted electrodes/stimulator (right)

Some systems have features that give the user feedback about how the system is operating. A user may get confirmation of the system's settings through tones or beeps, or a screen display. Another form of feedback to the user can be provided by a **sensory electrode**. It is implanted in the skin of the upper chest or back, and it provides a tapping sensation to indicate how the system is working. See SCI-17 *FES for sensation* for more information about sensory electrodes.

In addition to nerve and muscle locations, the surface of the spinal cord is a site where electrical stimulation may be applied. Called **spinal cord stimulation** (SCS) or dorsal column stimulation, this method is usually used to treat pain and spasticity. In some people, especially those with incomplete injuries, it also improves hand and arm function. See SCI-12 for further information.

STATUS OF FES SYSTEMS FOR GRASPING AND REACHING			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
• Implantable sensors for control • Feedback to prevent slip	• Reaching systems • 12 channels, surface electrodes, voice control (Israel)	• Glove, 3 channels, surface electrodes, controlled by voluntary wrist action (Canada, US) • 2 channels, surface electrodes built into close-fitting splint, controlled by user-operated push button (Israel, Europe, US) • 30 channels, percutaneous electrodes, control by breathing pattern (Japan) • 8 channels, implanted electrodes and stimulator; RF controlled under direction of voluntary shoulder action	

Who is medically eligible?

Candidates for FES grasping and reaching systems are persons with quadriplegia due to traumatic SCI with injury at C4/C5/C6/C7 levels. The various FES systems have somewhat differing requirements. In general, the potential user needs to have:

- A stabilized condition, at least 6 months following injury.
- Fingers and thumb that bend and straighten in response to electrical stimulation.
- Good trunk stability in the wheelchair or other seating system.
- An optimistic and motivated attitude.
- Acceptance of technology.
- Good support from family and friends.
- Note: Surgical procedures may be used to bring a person into the candidate group.

To use a system with a shoulder-mounted joystick, the person needs to have enough voluntary shoulder control to allow positioning the hand for function and operating command switches. To use the glove system, the person needs voluntary wrist extension against gravity.

Persons are not eligible if they have:

- Uncontrolled spasticity.
- Extreme sensitivity to skin stimulation.
- Infection, skin breakdown.
- Diabetes, but not all cases.
- Chronic kidney, heart or lung disease, demand pacemaker, hand contractures.
- See additional disqualifying factors on page 10.

How long does fitting and training take?

When a person begins the process of being fitted with an FES system, there will be an initial period of muscle conditioning. The person does surface FES exercise of the arm and hand muscles for at least several hours a day. This is an important process that reverses some of the weakening that occurred with disuse. This conditioning phase may take from 1 to 3 months.

A system with surface electrodes may require three to four visits for initial training and fitting of the device. Adjustments are done when needed and users may be seen every 3 months for follow-up. Participation in the multicenter clinical trial of the arm splint/surface electrode system requires a 6-month commitment.

If the system includes implanted electrodes, the next step will be implantation. After that, the system is tuned to the individual and both the user and personal assistant are trained to operate it independently. In clinical research studies, subjects may require fitting, training and tuning of the system over as long as 1 - 3 years. When systems achieve regulatory approval, that time should decrease.

What does it cost?

- The surface electrode system being tested in Canada costs around $2,000. Disposable electrodes cost $250-500 per year. The glove may be replaced (using the same controller) for $300.
- The 30-channel percutaneous system available in Japan costs $15,000.
- The 8-channel implanted system, under multicenter trials in the US, costs about $50,000 including the device, surgery and training.
- Participation in clinical trials of systems may involve no monetary cost to research subjects. However, participation may take much time away from other activities.

What can I realistically expect today?

FES hand grasp systems can provide one or more basic hand grasps. They do **not** restore the fine finger control that a person had before his or her injury. You can expect an FES grasp and reach system to increase your independence by enabling you to do activities of daily living yourself or with less assistance. Examples are eating, grooming, writing, telephoning and operating a computer. With the glove system, people have been able to use it for washing dishes and for using tools such as screw-drivers and paintbrushes. People who have used FES for grasping say they feel more self-sufficient and independent. People with SCI at C5 level can expect a greater improvement than those with SCI at C6 level.

Electrical stimulation of arm and hand muscles can decrease spasticity and the formation of contractures. In some cases, it can also improve voluntary movement. FES of the paralyzed hand can improve grip strength.

What may be available in the future?

Basic research is underway to develop implantable sensors to control the systems and feedback methods that will prevent a grasped item from slipping out of the user's hand. Also, researchers are studying methods to adjust for some amount of muscle fatigue. Another experimental area is increasing the workspace in which the FES-activated hand can operate. This type of FES system will activate muscles that control the elbow to move the hand. Some researchers plan to work on the exciting possibility of controlling both hands with one FES system and providing more types of hand grasps.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-5. FES systems for bladder and bowel control

What is the purpose?

- Provide a reliable method for emptying the bladder.
- Reduce urinary tract infections.
- Reduce bladder accidents.
- Reduce constipation.
- Provide a reliable method for emptying the rectum.
- Reduce bowel accidents.

What are non-FES alternatives?

Bladder management includes use of temporary or permanent catheters, or condom catheters which are attached to leg bags or bed bags. Or, the bladder may be periodically drained by intermittent catheterization. Surgical procedures may relieve obstructions, and on rare occasions, divert the urine stream. A frequent complication of all these methods is urinary tract infection, which must be treated with antibiotics. Some other drugs may also help to reduce bladder problems.

Bowel management involves eating a diet with more fiber, using stool softeners and suppositories, and digital stimulation of the rectum. Bowel emptying usually takes one half to two hours on each occasion and may require help from a personal assistant.

How do the FES systems work?

Many different approaches are in use today. In the most widely tested implanted system, developed in Britain, electrodes are placed on the anterior sacral **spinal nerve roots,** which control bladder and bowel contraction. (The sacral area is where the end of the spine joins the pelvis.) The user controls the electrodes with an external controller that transmits radiofrequency (RF) signals to an implanted stimulator. Different selections on the external controller will produce emptying of the bladder or of the bowel.

During implantation of an anterior sacral root stimulator, the surgeon usually cuts the posterior nerve roots that carry sensation. This procedure is called **rhizotomy** and it prevents reflexes from interfering with the desired bladder function. However, this procedure also prevents a man from having reflex erection of the penis (see section SCI-8). Rhizotomy has another negative effect in people who have incomplete injuries -- it eliminates sensation in the sacral area. This may decrease bowel and sexual function.

Another system uses an electrode inserted alongside one of the sacral nerves. These nerves contain both sensory and motor fibers. Doctors believe that the stimulation of the sensory nerves interferes with spasticity, which is often the cause of voiding problems. This type of interference is called **neuromodulation**. (See sections SCI-12 and MS-12, *FES for controlling spasticity*.) Built into the electrode are several conductors. Stimulation can be adjusted among them to get the most benefit. First, the system is tested with a percutaneous (through the skin) lead and an external stimulator. If voiding problems are reduced, the user tries the system at home for about a week. Then, stimulation is stopped. If urinary control becomes difficult again, it shows that the FES system provided improvement. Then, a permanent electrode and stimulator can be implanted. Adjustment of the stimulation settings may be necessary during the first 6 months. This system has helped people with a range of disabling conditions, and is also used for pelvic pain that does not respond to other treatments.

Another location where electrical stimulation may be delivered is the surface of the spinal cord. Called **spinal cord stimulation** (SCS) or dorsal column stimulation, this method is usually used to treat pain and spasticity. In some people, especially those with incomplete injuries, it also improves bladder function and may be implanted for that purpose. See section SCI-12, *FES for controlling spasticity*, for further information.

Most bowel problems in spinal cord injury are related to the inability to voluntarily empty the bowels. This frequently leads to constipation. Rarely, it may happen that a person with spinal cord injury cannot contain his or her stool, despite medical care of the problem. This is called fecal incontinence. For this condition, an FES system has been developed to keep the rectum closed. The system requires a surgical procedure that transfers a leg muscle (gracilis) to be a loop around the rectum. Then, an electrode to that muscle and a stimulator are implanted in the body. During an 8-week training period, the muscle is gradually conditioned until it can remain contracted all the

time. When the person wants to defecate, he or she turns the stimulation off with a small magnet placed against the skin over the stimulator. The method is called **dynamic graciloplasty**.

Pelvic floor stimulation is another method that can help correct problems with bladder or bowel function. Stimulation is applied to the supportive muscles of the pelvis that help control urination and defecation. Probes or catheters that contain electrodes are inserted into the rectum, vagina, or urethra. The treatment protocols vary, but usually stimulation is applied for a certain period every day. This method strengthens the muscles and improves sensation and control. Another method to improve bladder and bowel function uses surface electrodes placed over the penile nerve (male)/ vaginal area (female), or over the anal sphincter. In addition, some clinicians have reported that electrodes placed on the skin over the abdomen can improve bowel management for persons with paralysis.

The wide variety of stimulation techniques that are available for improving bladder and bowel control reflect the complexity of the problem. A proper evaluation is key to determining which techniques, if any, are most appropriate.

STATUS OF FES SYSTEMS FOR BLADDER AND BOWEL CONTROL

Basic research	Clinical research	Multicenter trials	Regulatory Approval
• 6 channels, anterior sacral root stimulator, percutaneous leads with external controller • Direct bladder stimulation • Pudendal nerve stimulation	• 3 channel, anterior sacral root stimulator, totally implanted (Multicenter trials of British system expected to begin in US in 1996. Available commercially in Europe, Asia, Far East) • Pelvic floor stimulation • Penile nerve/ vaginal/ anal stimulation with surface electrodes	• Sacral nerve stimulator, 1 channel, totally implanted. (Considered investigational in the US, but available commercially in Europe) • Dynamic graciloplasty, 1 channel, totally implanted (Considered investigational in the US, but available commercially in Europe)	• SCS, 1 channel, totally implanted with battery or RF power (Unlabeled use except when prescribed for pain control) • Pelvic floor stimulation • Anterior sacral root stimulator (Europe, Asia, Far East) • Sacral nerve stimulator (Europe) • Dynamic Graciloplasty (Europe)

Who is medically eligible?

Many people with SCI can manage their bladder and bowel function with existing medical techniques. Because of that, doctors are testing most stimulation devices only on people who have complications of bladder and bowel function. If these devices receive FDA approval, people without complications will have access to them in the future also.

Candidates for an anterior sacral root stimulator must be:

- More than one year post injury.
- Have a complete spinal cord injury.
- Have bladder and bowel response to electrical stimulation.
- Be emotionally stable and realistic.

A person may be disqualified because of:

- **Denervation**.
- Underlying bladder or bowel disease.

- Substance abuse.
- See additional disqualifying factors on page 10.

Candidates for the other types of systems described would include those with incomplete SCI.

What does it cost?
The British anterior sacral root stimulator costs from $13,000 to $20,000 including surgery and training. For spinal cord stimulator treatment, the medical evaluation, the device and surgical implantation cost about $18,000. Prices for other types of implanted systems are comparable. The cost of pelvic floor stimulation is less than the cost of implanted stimulators, but varies depending on the particular method. At this time, it is difficult to determine what charges will apply for those devices considered investigational.

What can I realistically expect?
People who have used a sacral anterior root implant system for bowel and bladder control report:

- Fewer urinary tract infections.
- Many fewer bladder and bowel accidents.
- Shorter times to empty their bowels.
- Greater ease and convenience in bladder, and usually bowel, emptying.
- Greater comfort and confidence in controlling bladder and bowel functions.

With a reliable method for fully emptying the bladder that is used on a consistent schedule, the user may be able to retrain the bladder muscle. When the bladder is overfilled and not emptied promptly the muscle can stretch so much that it becomes ineffective when it tries to expel urine. Thus, urine is retained, increasing the chance of infection. FES used to empty the bladder may help to prevent these problems.

The anterior sacral root stimulator can also produce penile erection, although it is unlikely that it would be prescribed for that purpose (see section SCI-8, *FES for erection and electroejaculation*).

What may be available in the future?
Clinical feasibility tests are expected to begin during 1996 on an anterior sacral root stimulator that uses a new pattern of stimulation. It has been designed to produce more effective bowel emptying. Investigators are also comparing other methods of bladder activation, such as stimulating the pudendal nerve that controls the bladder sphincter (the muscle fibers that keep the bladder closed and prevent urine release) and surface stimulation of the bladder itself. These techniques may require less invasive surgery than those involving anterior sacral root stimulation. Researchers are developing sensors that can be combined with a FES system to alert the user when his bladder is full and requires emptying.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-6. FES systems for transfers and standing

What is the purpose?

- Reduce the need for personal assistance.
- Increase mobility and independence.
- Reduce the need for bracing.
- Increase home, workplace, and leisure capability.

What are non-FES alternatives?

To transfer, people with SCI may require assistance from one or more helpers. To stand, they may use

- Standing frames.
- Wheelchairs with standing appliances.
- Stand-up wheelchairs.
- Long-leg braces.

How do the FES systems work?

An FES system for transfer and standing activates major muscles of the legs and pelvis through internal or external electrodes. Any FES system for stepping and walking can also be used for standing- see SCI-7 for more information. In a standing system, electrodes may be placed internally in or on the muscles -- or externally, on the skin over the muscle. These muscles stiffen the knee and hip joints to support standing. The simpler FES systems use fewer electrodes -- from 2 to 6.

Some systems, called hybrid systems or **hybrid orthoses**, add bracing to FES. These braces (orthoses) range from very small to very large. Small ankle-foot orthoses (AFO) prevent ankle twisting. Large hip-knee-ankle-foot orthoses (HKAFO) extend from the feet to the ribs These large braces provide support and balance, reducing the amount of FES used and producing less muscle fatigue than FES-only systems. In systems that use bracing, FES is typically used during transitions, such as from sitting to standing.

Another location where electrical stimulation may be delivered is the surface of the spinal cord. Called **spinal cord stimulation** (SCS), this method is usually used to treat pain and spasticity. In some people, especially those with incomplete injuries, it also improves transfers and standing. See section SCI-12, *FES for controlling spasticity*, for further information.

STATUS OF FES TRANSFER AND STANDING SYSTEMS

Basic research	Clinical research	Multicenter trials	Regulatory approval
	• Various systems: 2 - 48 channels, external or implanted electrodes, bracing ranging from none to HKAFOs		• 6 channels, surface electrodes, often used with AFOs (Approved in 1994) • 4 - 6 channels, surface electrodes, no bracing (Slovenia)

Who is medically eligible?

Candidates for lower extremity transfer and standing systems need to have:

- Little or no peripheral nerve damage or joint damage.
- Good general health.
- No current substance abuse.
- Flexible joints (only minor **contractures**).
- Upper extremities intact and strong.
- At least age 14 (or with fully grown bones).
- Optimistic and motivated attitude.
- Acceptance of technology.

The following conditions would disqualify a person:

- Chronic infective disease.

- History of transient ischemic attacks (minor strokes).
- Chronic kidney, heart or lung disease.
- Poor skin condition in electrode areas.
- Allergy to adhesive materials.
- Low tolerance to pain.
- Amputation, impairment or weakness of upper extremities.
- See additional disqualifying factors on page 10.

The great majority of users of FES transfer and standing systems will be people with thoracic (T) spinal cord injuries, either incomplete or complete, between T-4 and T-12. There will also be some people with incomplete cervical (C) injuries who will be able to use such systems.

What does it cost?

- Surface electrode systems without bracing cost about $15,000 including training.
- Hybrid systems (surface electrodes plus HKAFOs) cost from $30,000 - $40,000 including training.
- Participation in clinical trials of implanted, percutaneous or surface electrode systems may carry no monetary cost to research subjects. However, participation may take much time away from other activities.

How long does the fitting and training take?

When a person begins the process of being fitted with an FES system, there is an initial period of muscle conditioning. The first activity is FES exercise of the leg muscles while seated. This is an important process that reverses some of the weakening and loss of bulk that occurred with disuse. The conditioning phase may take from 1 to 3 months.

- Fitting and training with surface electrodes takes from 4 to 6 months.
- Fitting and training with implanted muscle electrodes is still in the clinical research phase. Length of treatment time varies with the individual's condition. Time ranges from as little as 6 months to as much as 2 years.

What can I realistically expect today?

You may be able to stand with FES for exercise as part of your daily routine. You will need some type of appliance -- walker, wheelchair frame attachment, etc. -- to provide support and balance. You may be able to use FES in your daily activities at home or work. All current systems require you to exert a lot of physical energy, mainly with the arms and shoulders. If you have paralysis on one side (called **hemiplegia**) or incomplete paralysis you can expect improved transfers and standing with FES. You will depend less on braces or a personal assistant.

FES of the lower body has valuable health benefits. Because using FES demands so much energy, consistent users improve their cardiovascular capability. FES may reduce spasticity of leg muscles and increase strength in remaining voluntary muscles. Some regular users of FES standing systems report reduced pressure sore problems and fewer urinary tract infections.

FES also has benefits for bones. In paralysis, when muscles are inactive and do not put stresses on the bones, the bones lose mineral content. They become thinner and weaker -- this is called osteoporosis. People who use FES standing and walking systems are putting stress on their bones. Some studies have shown that standing with FES can stop loss of bone mineral and slow the progress of osteoporosis.

What may be available in the future?

The next advance will probably be totally-implanted, 8-channel FES systems. Researchers predict that FES users will be able to control transfers and standing with a beeper-sized, miniature controller, attached to a belt.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-7. FES systems for stepping and walking

What is the purpose?

- Increase mobility and independence.
- Provide a supplement to the wheelchair.
- Reduce the need for bracing or walking aids.
- Increase home, workplace, and leisure capability.

What are non-FES alternatives?

- Some people with SCI have stood and taken a few steps using the Vannini-Rizzoli stabilizing limb orthosis. These are knee-high boots with built-in braces. The boots provide limited balance.

- Some people with lower thoracic and lumbar level SCI have successfully used **long-leg braces** for stepping. They "swing through" or "swing to" and use elbow crutches or a walker for additional support and balance. Long leg braces require a very strong upper body and good balance, including some hip and abdominal control.
- Some people with SCI have used braces that extend from the lower chest to the feet (HKAFO) to walk. One type of HKAFO is the reciprocating gait orthosis (RGO) and another is the hip guidance orthoses (HGO). These braces provide pelvis and hip support in addition to the functions of long-leg braces. HKAFOs do not require as much upper body power as long-leg braces and can be put on or taken off in less than 5 minutes by most people with paraplegia. However, some RGO users find them too bulky and heavy. Properly fitting RGOs must be hand made and fitted for each individual. Rehabilitation and training to use an RGO takes a minimum of 4 months.

How do the FES systems work?

An FES system for stepping and walking activates major muscles of the legs and pelvis through internal or external electrodes. Electrodes may be placed internally in or on the muscle -- or externally, on the skin over the muscle.

The minimum system uses four channels. Activation of both thigh muscles (quadriceps) locks the knees during standing. Stimulating the common peroneal nerve on one side and switching off quadriceps stimulation on that side together produce bending, or flexion, of that leg. This flexion combined with movement of the upper body and use of the arms for support allows the user to take a step. This is called the swing phase of the gait cycle.

If the FES system has six channels, much better performance is possible. One channel on each side is devoted to activating the hip extensors, muscles that keep the hip joint from bending.

The user voluntarily commands the FES stimulator through switches or a miniature joystick. Some type of walking aid -- walker, crutches, or canes -- provides support and balance.

Researchers have suggested systems for restoring walking with up to 48 channels. These systems have either **percutaneous** or totally implanted electrodes. Their main advantage is their ability to selectively activate different muscle groups. This type of muscle control can produce movement that is much more like walking than taking one step at a time.

With the command switch, the user selects from the pre-programmed patterns stored in the stimulator. Possible functions include standing, walking, side-stepping, back-stepping, stair climbing and stair descending. Remember that as the technology of any device becomes more complex, the possibility of technical problems increases.

The systems that use FES together with HKAFOs are called **hybrid orthoses**. Electrodes (usually surface type) activate leg and hip muscles to initiate walking. This reduces the energy demand on the upper body.

Examples of FES systems for stepping and walking: hybrid orthosis with surface electrodes (left) and implanted electrodes/stimulator (right)

FES systems for stepping and walking use stimulation levels that will be high enough to produce muscle contractions even when muscles are **fatigued**. This is a safety measure taken to ensure that the user's legs will not buckle when the muscles tire. If bracing is used together with FES, the stimulation levels can be lower because the brace can provide support against buckling. Since stimulation levels are lower, muscles do not fatigue as quickly. In addition, if the FES part of the system should fail, the brace will prevent the user from falling.

One type of brace used in hybrid systems is the RGO, which some people feel is too bulky and heavy. To overcome these problems, one experimental system uses a two-part brace: the leg sections are worn all the time and the trunk section can be removed to simplify some activities. The leg sections use **feedback** control to provide muscle stimulation only when needed, thus delaying

muscle fatigue. Braces offer good locations for mounting the **sensors** that provide the feedback information.

Another location where electrical stimulation may be delivered is the surface of the spinal cord. Called **spinal cord stimulation** (SCS) or dorsal column stimulation, this method is usually used to treat pain and spasticity. In some people, especially those with incomplete injuries, it also improves stepping and walking. See section SCI-12, *FES for controlling spasticity*, for further information.

STATUS OF FES STEPPING AND WALKING SYSTEMS			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
	• Various systems: 2 - 48 channels; surface, percutaneous, or implanted electrodes; bracing ranging from none to HKAFOs (US, Canada)		• 6 channels, surface electrodes, sometimes used with bracing • 2 - 6 channels, surface, hybrid exercise systems using commercial braces and muscle stimulators (in combination-unlabeled use) • 4-channel, surface electrodes, no bracing (Slovenia) • 30 channels, percutaneous electrodes (Japan)

Who is medically eligible?

Candidates for FES stepping and walking systems need to have:

- Little or no peripheral nerve damage or joint damage.
- Limited **osteoporosis**.
- Flexible joints (only minor **contractures**).
- Good general health.
- No current substance abuse.
- At least age 14 (or with fully grown bones).
- Optimistic and motivated attitude.
- Acceptance of technology.
- Ability to control balance and upper body posture with arms and an external support (parallel bars, walker, crutches).

The following conditions would disqualify a person:

- More than moderate spasticity.
- Chronic infectious disease.
- History of transient ischemic attacks (minor strokes).
- Chronic severe kidney, heart or lung disease.
- Poor skin condition in electrode areas.
- Allergy to adhesive materials.
- Low tolerance to pain.
- See additional disqualifying factors on page 10.

The great majority of users of FES standing and walking systems will be people with thoracic (T) spinal cord injuries, either incomplete or complete, between C-7 and T-12. There will also be some people with incomplete cervical (C) injuries who will be able to use such systems.

What does it cost?

- Surface electrode systems without bracing cost about $15,000 including training.
- Surface electrode systems with HKAFO braces (hybrid orthoses) cost between $30,000 and $40,000 including training.
- Participation in clinical trials of some systems carries no cost to research subjects. However, there is a large time commitment.

How long does fitting and training take?

When a person begins the process of being fitted with an FES system, there is an initial period of muscle conditioning. The first activity is FES exercise of the leg muscles while seated. This is an important process that reverses some of the weakening and loss of bulk that occurred with disuse. The conditioning phase may take from 1 to 3 months.

- Fitting and training with surface electrodes takes from 3 to 6 months.
- Fitting and training with intramuscular electrodes is still in the clinical research phase. Length of treatment time varies with the individual user's condition. Time ranges from as little as 6 months to as much as 2 years.
- The more complex the activities -- for example, going up and down stairs -- the longer the training will take.

What can I realistically expect today?

Many users report that FES of the lower body has valuable health benefits. Because using the systems can demand so much energy, consistent users of some systems improve their cardiovascular capability. For some users, FES reduces spasticity of leg muscles and increases strength in remaining voluntary muscles. Regular users of FES standing systems report reduced pressure sore problems and urinary tract infections.

FES also has benefits for bones. In paralysis, when muscles are inactive and do not put stresses on the bones, the bones lose mineral content. They become thinner and weaker -- this is called osteoporosis. People who use FES standing and walking systems are putting stress on their bones. Some studies have shown that standing with FES can stop loss of bone mineral and slow the progress of osteoporosis.

But, what about the walking? People with incomplete SCI can experience great improvement. People with complete SCI who meet the entrance criteria will be able to stand up independently and remain standing for periods as long as one hour. They will probably be able to take single steps. Some of them will be able to take a series of steps, and some will progress to walking. A small group of users may also master climbing up and down stairs, depending on the FES system's capability. Remember that not everyone will benefit from an FES system. Many physical, mental, social and health factors will influence the outcome.

Some of today's FES walking systems are useful for limited activities at home or at work. At the same time, **hybrid orthoses** have allowed particularly athletic people with paraplegia to walk several miles. Some systems have a great deal of external equipment. All systems require excessive energy output. Walking with FES stresses the cardiovascular system as much as running does in an able-bodied person. If you have paralysis on one side only (called **hemiplegia**) or incomplete paralysis, you can expect improved standing and walking with FES. You will depend less on braces or walking aids. You may be able to use FES daily at home, work or leisure activities.

What may be available in the future?

Walking is very individual. Not surprisingly, each person using an FES walking system requires different fitting and programming. Also, programming needs to be adjusted over time as muscles

respond to regular use. If electrodes should move or fail, stimulation patterns will again need to be modified. Today's FES walking systems have very little built-in feedback to help adjust for fatiguing muscles or changes in the walking surface. Basic research is underway to develop both the sensors and the computer programs to provide this kind of automatic adjustment.

The next advance will probably be totally-implanted, 8-channel FES systems. Researchers predict that FES users will be able to control stepping and walking with a beeper-sized, miniature controller, attached to a belt.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-8. FES for erection and electroejaculation

What is the purpose?

- Produce erection of the penis.
- Produce ejaculation to collect sperm for artificial insemination.

What are non-FES alternatives?

In men with SCI at T-9 or above erection can sometimes be produced by:

- Masturbation.
- Stimulation with a vibrator.
- Use of a suction device.
- Injection of drugs into the penis.
- Implantation of penile prosthesis.

About 65% of these men can ejaculate with masturbation or vibromassage. This may or may not be accompanied by erection. Men with injuries at T-5/6 or above may experience sudden high blood pressure, slow heartbeat, sweating and severe headache with ejaculation. This is called **autonomic dysreflexia**. They should consult with their doctors before attempting ejaculation at home.

For men with SCI *below* T-10, only injection, suction and penile prosthesis can be used to produce an erection. In these men, the nerves that activate the spinal cord to produce ejaculation are damaged and vibromassage will have no effect.

How do the FES systems work?

Erection

The implanted anterior sacral root stimulator described in section SCI 5, *FES for bladder and bowel control*, can produce erection as well as enhance bladder and bowel function. However, it would probably not be implanted for the sole purpose of providing erection. After the device is implanted, the doctor will test the effect of stimulating the different nerve roots that have been equipped with electrodes. In most men, one particular pair will produce erection without bladder contraction. The FES controller will be tuned with a setting for erection.

Most men, however, will use one of the alternatives to FES listed above, if their primary goal is to achieve an erection.

Electroejaculation

The doctor inserts an electrode probe into the man's rectum and electrically stimulates the nerves that control ejaculation. Men with incomplete SCI may need local, spinal or even general anesthesia because of the strong stinging sensation. A nurse or a second doctor collects the sperm. In some men whose sperm goes into the bladder, the doctor or nurse will collect it from there with a catheter. A gynecologist uses the sperm to inseminate the man's partner.

STATUS OF FES FOR ERECTION & ELECTROEJACULATION			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
		• About 50 clinics in the US and Canada offer electroejaculation procedures for SCI men, but this is still an experimental procedure in North America.	• Electroejaculation is available in many European countries • Anterior sacral root stimulator for erection (Europe, Asia, Far East with multicenter trials to begin in the US in 1996)

Who is medically eligible?

Men with

- Any level SCI for electroejaculation.
- SCI above T-12 for erection.
- 6 months post injury.

Men are usually ineligible if they have

- Heart rhythm or high blood pressure problems.
- Implanted pacing devices.
- Possible blood clots.
- Some types of tumors.
- Tendency for worsening of **autonomic dysreflexia** with FES.

How long does the treatment take?

- See section SCI-5 for details of the implanted stimulator that can produce erection. Use of this FES system for penile erection can be done whenever and wherever the man chooses.
- Electroejaculation treatments should be timed with the man's partner's most fertile time each month. A single session takes about 45 minutes plus travel time.

What does it cost?

- See section SCI-5 for details on cost of the implanted FES system for erection.
- Electroejaculation treatment costs about $400 per session excluding anesthesia. In some cases, insurance will cover the cost, but this is still considered to be an experimental procedure in North America.

What can I realistically expect?

Erection

In several studies, about 65% of men using the implanted device described in section SCI-5 achieved full erections. A smaller group achieved partial erections. The device is usually implanted to improve bladder function and would not likely be implanted only to restore erection.

Electroejaculation

Electroejaculation is successful in nearly all men with SCI but only 70% will have adequate numbers of sperm to induce a pregnancy. An important issue is the potency of the sperm that is collected. Because of changes caused by SCI, sperm tends to be much less potent than sperm from able-bodied men. Doctors may recommend actions that can improve the quality of sperm.

When a couple is trying to conceive a child, the woman's fertility is as important as the man's. When you undertake electroejaculation, make sure that you also have experienced fertility doctors on your medical team. Between 30% and 50% of couples who try artificial insemination are successful. New methods of artificial insemination may increase the success rate.

What may be available in the future?

Researchers are trying to learn more about sexual dysfunction after spinal cord injury. They need more information about the factors that make sperm different post-injury to understand the effect on fertility. Advances are also being made in insemination and in-vitro fertilization techniques. These types of studies may drive further research into electrical stimulation devices to correct male sexual dysfunction. Even though the electroejaculation techniques available today are inconvenient and have been around for many years without much innovation, they appear to be effective.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-9. FES for improving circulation

What is the purpose?

- Reduce formation of blood clots (deep venous thrombosis).
- Reduce swelling of limbs.
- Reduce chance of pressure sores.

What are non-FES alternatives?

- Re-positioning of limbs to increase blood flow.
- Wearing elastic stockings to prevent clot formation in the lower legs.
- Use of anticoagulant drugs. These can be a problem during the first three months after SCI because they tend to reduce the amount of oxygen that reaches the spinal cord. Also, they may cause bruises after minor injuries and they may increase the tendency to bleed if they are taken for a long time.

How do the FES systems work?

Surface electrodes are used to apply stimulation to the muscles. The muscle contraction pumps blood back to the heart, especially from the deep veins. This can help to reduce the formation of blood clots. Also, blood flow may be increased in the stimulated muscles. This is important because better circulation improves the nutrition and clean-up of wastes from tissues.

Surface electrode systems used to change or shift pressure on the buttocks (See section SCI-10) may also improve circulation of blood in that area.

FES used for exercise or walking can also improve circulation (see sections SCI-1 and SCI-7).

STATUS OF FES FOR IMPROVING CIRCULATION			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**

	• Surface FES systems		• Physical therapy treatment using FES with surface electrodes

Who is medically eligible?

Any person who is at risk for clot formation and who should not use anticoagulant drugs. Development of clots in deep veins occurs in many people with SCI in the first 3 months following injury. See disqualifying factors on page 10.

How long does the treatment take?

Therapeutic treatments may last from 10 to 30 minutes, several times a day.

What does it cost?

There is no standard and it is difficult to state a cost. Physical therapy sessions generally cost around $80 each. Once a physical therapist instructs a patient, much of the treatment can be done at home with a rented or purchased stimulator. Stimulator rental costs about $80 per month. Stimulator purchase can range from $65 to $4000, depending on the technical features of the device. Electrodes and supplies may cost $1,000 per year.

What can I realistically expect?

One study made a three-way comparison: 1) treatment with FES, 2) no treatment, and 3) treatment with blood thinners (low dose heparin). FES and heparin together produced a decrease in incidence of blood clots, compared to no treatment, or treatment with only heparin.

See page 65, “What Should I Know When Choosing an FES Product or Service?”

SCI-10. FES for preventing pressure sores

What is the purpose?

- Prevent formation of pressure sores.

What are non-FES alternatives?

- Maintain good health through diet and exercise; avoid smoking
- Use a properly designed and fitted seating system.
- Change position frequently while lying in bed.
- Lift the buttocks from the wheelchair while seated.
- When a red area on the skin does not disappear within 30 minutes after relieving all pressure, lie on stomach or side for 24 hours or until redness is completely gone.

How does the FES system work?

Researchers are working on several systems that could be used by people seated in a wheelchair. These systems deliver electrical stimulation to the buttock muscles. Effects are:

- During FES muscle contraction, distribution of pressure over the buttock and thigh muscles rather than concentration on the “sit bones”.
- Increased blood and lymph flow that delivers nutrients and removes waste from the tissue.
- A more permanent increase in tissue bulk may occur with regular use. This maintains healthy tissue and helps to prevent pressure sores.

STATUS OF FES FOR PREVENTING PRESSURE SORES

Basic research	Clinical research	Multicenter trials	Regulatory approval
	• Various FES systems using surface and implanted electrodes		

Who is medically eligible?

People who have

- Difficulty raising their buttocks from the wheelchair seat by using their arms for weight shifts.
- Recurring pressure sores.
- No allergy or excessive skin sensitivity.
- See additional disqualifying factors on page 10.

How long does the treatment take?

If an FES system for preventing pressure sores were developed, using it would be part of a regular daily routine. The user would likely go through an initial conditioning and training period.

What does it cost?

Since there are no systems currently available specifically designed to prevent pressure sores, it is difficult to specify a cost. We know that today, physical therapy sessions using surface electrodes generally cost around $80 each. Muscle stimulator rental costs about $80 per month. Stimulator purchase can range from $700 to $2000, depending on the technical features of the device. Electrodes and supplies may cost $1,000 per year.

What can I realistically expect today?

Regular use of FES to activate buttock muscles that have nerve supply from the spinal cord may help to prevent pressure sores. People who use FES exercise, standing and walking systems report fewer problems with pressure sores. See SCI-1, SCI-6, SCI-7, and SCI-15 for more information.

What may be available in the future?

Researchers are designing projects to measure quantities important to the health of body tissues and how FES may affect those quantities. If results are favorable, they may contribute to FES systems for pressure sore prevention.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-11. FES for treating pressure sores

What is the purpose?

- Speed the healing of pressure sores.

What are non-FES alternatives?

- Relieving all pressure on the area of skin breakdown.
- Gels or baths that contain growth factors and other formulations
- Suction pumps to drain the wound
- Devices to pressurize the wound
- Antibiotics if there is infection.
- In extreme cases, surgery which may involve various types of grafts.

How does the FES system work?

Researchers believe that electrical stimulation (ES) may help pressure sores to heal in several ways. ES increases the amount of oxygen in the tissue around the wound and reduces the number of bacteria in the wound. Both effects contribute directly to healing. Indirectly, the improved blood circulation produced by ES boosts the nutrition and waste removal in the tissues (See SCI-9).

It is no surprise that ES also creates electrical currents in the tissue. Normal tissue has natural electrical currents (different from nerve signals) flowing in it. These currents assist in healing of wounds. When there is spinal cord injury, neurological disorder, or degeneration (as in the elderly), these currents are reduced or missing. Surface electrode stimulation can partially replace natural electrical currents in tissue and assist in wound healing.

STATUS OF FES FOR TREATING PRESSURE SORES			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
• Studies of electrical properties of wounded tissue	• Various systems using surface electrodes	• Various systems using surface electrodes	• Physical therapy treatment with surface ES systems (Unlabeled use in the USA).

Who is medically eligible?

People who have superficial and minimally infected wounds have the best chance for healing. This is true both with and without ES. If there is a pocket of infection under the skin or infection of bone, surgery may be needed. See disqualifying factors on page 7.

How long does the treatment take?

Healing of pressure sores is usually a lengthy process, and ES has been shown to speed it up.

What does it cost?

The most important variables are the health of the individual and the extent of the pressure sore. Costs will vary widely with the person's condition and whether or not surgery is needed.

What can I realistically expect?

Healing of pressure sores in people with SCI can take a long time. ES treatment can speed the healing process.

What may be available in the future?

Researchers are conducting studies to better understand the electrical properties of healthy and wounded tissue. This should help to determine more effective stimulation patterns.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-12. FES for controlling spasticity

What is the purpose?

FES can be used to reduce **spasticity**. Spasticity is the abnormal, involuntary contraction of muscles, causing stiff and awkward movements sometimes called spasms. For some individuals, spasticity may be helpful for standing activities or transfers.

What are non-FES alternatives?

- Various lying, seated, and standing positions can reduce spasticity.
- Very localized spasticity may be treated by heat or cold.
- Stretching and passive range of motion exercises (individual, therapist, or caregiver moves limbs through a range of motion) may temporarily reduce spasticity. This will also help prevent contractures.
- Oral medication can reduce spasticity, primarily baclofen, dantrolene (Dantrium), diazepam (Valium), and tizandine (Zanaflex).
- Intrathecal medication (baclofen or morphine) can reduce spasticity if oral medications are not successful.
- Nerve block injections (phenol or botulinum toxin) can decrease spasticity in a localized area.
- Surgery can be used to release tendons, cut nerve roots, or cut the spinal cord to decrease spasticity.

How do the FES systems work?

When FES is applied specifically to counteract spasticity, surface electrodes are applied to the spastic muscles or to their antagonists. Each muscle has a counterpart muscle that moves the limb in the opposite direction -- this is called the antagonist.

Spasticity usually occurs in several muscles at once. Some studies have shown that the most effective treatments are those where FES is applied to all the muscles of a limb. Physical therapy treatment may also be given during the same period. In one study, 30 out of 32 patients experienced relaxation of their spastic legs after 6 weeks of FES and physical therapy. For 35 minutes a day, they received alternate stimulation of the hamstrings and quadriceps (agonist and antagonist).

Another method for reducing spasticity is applying FES to skin areas called dermatomes. A dermatome is an area in which all the sensory nerve receptors belong to the same spinal cord level. Since particular muscle groups have their motor nerves at specific spinal cord levels, the dermatome that is stimulated is chosen to have the same spinal cord level as the spastic muscle group. This type of stimulation is known as **dermatomal stimulation**.

The use of implanted electrodes or stimulators also may reduce spasticity. Such electrodes may be implanted in muscles, over nerves, or on the spinal cord. In **spinal cord stimulation** (SCS), low levels of stimulation are delivered continuously. A single cable leading to a multiple electrode provides stimulation that has a general effect on many motor nerves. Thus, an SCS device for controlling spasticity might have beneficial effects on bladder function, arm movement, standing, and leg movement. An individual's level of SCI will determine exactly where on the spinal cord the surgeon places the electrode array.

Implanted spinal cord stimulators, also called dorsal column stimulators, may be battery-powered or controlled by radiofrequency waves passing through the skin. Similar to heart pacemakers, the battery-powered units require replacement after several years. Both types of device are turned on and off by the patient. Typically, users operate their stimulators most of the day. When the devices are turned off, the benefits quickly fade.

Doctors believe that dermatomal, SCS, and sacral nerve stimulation work by a method called **neuromodulation**. It seems to depend on stimulation of sensory nerves reducing the spasticity of related motor nerves.

STATUS OF FES FOR CONTROLLING SPASTICITY

Basic research	Clinical research	Multicenter trials	Regulatory approval
	• Various surface and implanted electrode systems • Dermatomal (skin) stimulation		• Physical therapy treatment using FES with surface electrodes • Implanted spinal cord stimulation (SCS) (unlabeled use, except if implanted to relieve pain)

Who is medically eligible?

For dermatomal stimulation, physical therapy treatment with surface stimulation or SCS, people with incomplete or complete spinal cord injury.

See disqualifying factors on page 10.

How long does the treatment take?

When FES is used only for spasticity control, treatment time will depend on which of the many methods your doctor or therapist is using. One study used 20-minute sessions twice a day .

For SCS, some doctors implant the electrode and stimulator in a single surgery. Others do a one-week trial with an electrode whose wire comes through the skin (**percutaneous** lead) and can be implanted in a short out-patient procedure. The lead is connected to an external stimulator. If that system provides benefit, the doctor will implant the stimulator during a short hospital stay of several days. During that time, the doctor and therapist will determine the most beneficial stimulation settings.

What does it cost?

There is no standard treatment. However, a typical therapist charges about $80 per session. A muscle stimulator costs about $80 per month for rental. Purchase of such a stimulator costs from $700 to $2000, depending on its special features. Electrodes and supplies may cost $1,000 per year. Once a person learns how to use the stimulator, he or she can carry out treatment at home.

A spinal cord stimulator, surgery to implant it, and tuning the device to provide the most benefit cost about $18,000.

What can I realistically expect?

Some people experience a reduction in spasticity from just enough stimulation intensity to create a “tingling” sensation. Others have better relief when FES produces a muscle contraction or moves a limb. People who use FES daily for exercise, hand function or walking report that their spasticity is suppressed 24-hours a day. Regular use of FES may help to reduce spasticity but it will not eliminate the problem.

For more information about exercise, grasping, standing, and walking systems, see sections SCI-1, SCI-4, SCI-6, and SCI-7.

If spasticity is reduced over a long period, then there may be a reduction in contractures also. See section SCI-13, *FES for preventing or treating contractures.*

See page 65, “What Should I Know When Choosing an FES Product or Service?”

SCI-13. FES for preventing or treating contractures

What is the purpose?

- Maintain full range of joint motion (ability to move limbs to all normal angles).
- Regain lost range of motion (ROM).

What are non-FES alternatives?

Many standard physical therapy techniques are available, including:

- Use of splints or braces.
- Passive joint ROM by therapist or caregiver, or by positioning one’s own body.

- Exercise against resistance (for example, lifting weights), if the muscles are strong enough to take the joint through a full ROM.
- Use of heat may assist in gaining joint ROM if it is combined with other treatments like positioning (see section SCI-12).
- If spasticity is causing contractures, then decreasing spasticity will maintain ROM (see section SCI-12).

How does the FES system work?

Skin surface electrodes and portable, battery-powered stimulators are used. The muscle contraction must be strong enough to move the joint through the available ROM and "tug" a bit at the end of the range.

Occasionally, implanted electrodes and stimulators have been used for reducing contractures as an intermediate step to implementing a complete grasping, standing, or walking system. See sections SCI-4, SCI-6, and SCI-7 for more information.

STATUS OF FES TO PREVENT OR TREAT CONTRACTURES			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
			• Physical therapy treatment using FES with surface electrodes

Who is medically eligible?

FES to prevent and treat contractures is suitable for most people with SCI. See disqualifying factors on page 10.

How long does the treatment take?

Therapeutic treatments may last from 10 to 30 minutes, possibly as frequently as several times a day.

What does it cost?

As there is no standard physical therapy treatment for contractures, it is difficult to state a cost. A typical therapist charges about $80 per session. A muscle stimulator costs about $80 per month for rental. Purchase of such a stimulator costs from $65 to $4000, depending on its special features. Electrodes and supplies may cost $1,000 per year. Once a person learns how to use the stimulator, he or she can carry out some treatments at home.

What can I realistically expect?

- Physical therapy with FES may reduce contractures.
- Regular use of FES exercise, grasping, standing, or walking systems may help to prevent contractures. In some cases, FES can improve joint ROM more than standard rehabilitation. See sections SCI-1, SCI-4, SCI-6, and SCI-7 for more information.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-14. FES for preventing or treating osteoporosis

What is the purpose?

Stop the weakening of bone in people who are immobilized due to SCI.

In healthy people, bone tissue is kept strong by the constant stresses placed on bones in everyday activity. In normal bone there is an ongoing process of death and regrowth of cells. Stresses on bone cause new bone cells to grow and minerals to be deposited in bone. When a person is immobilized, the stresses on bone, cartilage, ligaments and tendons are severely reduced. When such a person can no longer stand, and the legs don't bear weight, there is very little stress on the leg bones. As a result, growth of bone cells and deposit of minerals in leg bones are reduced. Bone mass or mineral density is reduced and the bones become more porous, a condition called **osteoporosis**.

What are non-FES alternatives?

Standing with

- Standing frame.
- Bracing.
- Standing attachment on wheelchair.
- Stand-up wheelchair.

Some people who use these devices experience fractures of their osteoporotic bones.

How do the FES systems work?

Standing and walking with FES (see sections SCI-6 and SCI-7) can stress the leg bones in ways that may help to prevent bone loss. This is most effective in the months immediately following SCI. For people who have had SCI for years, the data is not conclusive. Some studies indicate FES walking systems can help to reverse osteoporosis to some degree; other studies have not found any significant changes in bone density.

FES bicycle exercise does not increase bone density. Some researchers have tested a modified bicycle exerciser designed to do this. The new machine mimics the forces that affect the feet and legs during walking.

Muscle stimulation exercise routines that generate 40% of maximal voluntary muscle contraction have been reported to aid in bone strengthening.

STATUS OF FES FOR PREVENTING OR TREATING OSTEOPOROSIS

Basic research	Clinical research	Multicenter trials	Regulatory Approval
	• Standing/walking systems • Modified bicycle exerciser • Surface muscle stimulation		

Who is medically eligible?

- See sections SCI-1, SCI-6, and SCI-7.
- See disqualifying factors on page 10.

How long does the treatment take?

Bone loss begins immediately after spinal cord injury. Most of the loss has occurred by about one year. Some researchers suggest that immediate rehabilitation with weight bearing may help to prevent this early loss.

Benefits of regular bone-stressing exercise have been shown in one study after 4 months of three sessions per week. No further bone was lost. But, bone mineral density did not increase. Osteoporosis was stopped but it was not reversed. In another study, after daily use of an FES walking system for 6-12 months, bone mineral density increased in paraplegic subjects but not to the level of a normal person. In this case, osteoporosis was somewhat reversed. In another study, 32 training sessions with an FES walking system did not effect bone mineral density.

What does it cost?

See sections SCI-6 and SCI-7 for the cost of standing or walking systems. The cost for a modified bicycle ergometer would be similar to that of a standard FES bicycle ergometer - see section SCI-1. The cost of a small portable muscle stimulator would be from $65 to $4000, depending on its special features. Electrodes and supplies may cost $1,000 per year.

What can I realistically expect?

Using FES to stress bones seems promising for stopping the progress of osteoporosis. However, the effect may vary with the length of time since SCI, the location of the bones in the body, and the duration of the treatment. Further research is needed to understand what factors are important in stopping and reversing the weakening of bone after SCI. A note of caution: some people who use FES systems for exercise or standing and walking have had fractures of their osteoporotic bones. A medical evaluation prior to starting FES is critical.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-15. FES for treating weak, atrophied muscles

What is the purpose?

- Strengthen weak muscles.
- Increase bulk of shrunken (atrophied) muscles.

What are non-FES alternatives?

When muscles are totally paralyzed, there is no other way than FES to activate them. When muscles are partially paralyzed, voluntary exercise can help to maintain some level of strength.

How do the FES systems work?

In the general practice of physical therapy, electrical stimulation (ES) with surface electrodes is used to treat various problems of muscles and bones. Often, these problems result from injuries such as fractures or dislocations. ES may be used to help maintain muscle condition, to increase the range of movement (see section SCI-13), and to assist weak muscles.

Any type of electrode or muscle stimulator may be used. Some muscle stimulators for paralyzed people are packaged with customized electrode garments to make it easier to set up and connect the electrodes. FES or ES activates the weak or paralyzed muscle. Even though these systems are simple, they should only be used with appropriate instruction from a clinician.

Example of typical FES surface electrode system used in physical therapy

The muscle response to stimulation will depend on the type of weakness or paralysis. Muscle that is weak because of inactivity but is still under voluntary control will become stronger and bulkier (**hypertrophy**). Muscle that is paralyzed due to an **upper motor neuron** lesion will become bulkier but voluntary strength will not improve. However, the strength during FES will increase. Muscle that is paralyzed due to a **lower motor neuron** lesion (**denervated**) may become bulkier, but voluntary strength will not improve and strength during FES will probably not improve.

FES systems for cardiovascular exercise, grasping, standing and stepping (see sections SCI-1, SCI-4, SCI-6, and SCI-7) may also make muscles stronger and larger. A crucial factor is whether or not the stimulation regimen stresses the muscle.

STATUS OF FES FOR INCREASING STRENGTH AND BULK OF PARALYZED MUSCLES			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
	• Special stimulators designed for denervated muscle		• Physical therapy treatment using FES with surface electrodes • Specialized FES systems with electrode garments

Who is medically eligible?

Generally, FES will only work for the extended periods of time necessary to convert the paralyzed muscle into a stronger muscle if there is no **denervation** -- loss of nerve supply between the spinal cord and the muscle. For specialized physical therapy treatment with surface electrodes, persons should have

- Good skin condition.
- No allergy to adhesives or gels used with surface electrodes.
- See disqualifying factors on page 10.

How long does the treatment take?

Like any kind of exercise, muscle exercise for maintaining strength and bulk needs to be done as part of a regular daily routine. Suggested exercise times will vary with the therapist and the patient's condition. Initial sessions will be under the guidance of a therapist with later sessions completed independently.

What does it cost?

Specialized physical therapy treatment with muscle stimulators costs around $80 for each session with a therapist. Purchase of a home model stimulator costs $700 - $2000 and rental costs about $80 per month. Electrodes and supplies may cost $1,000 per year. Custom muscle stimulation systems that include electrode garments can cost several thousand dollars. They may provide long term savings by reducing the cost of supplies. Third party payers usually do not pay for this treatment if the condition causing the atrophy is permanent as in central nervous system paralysis.

What can I realistically expect?

Consistent exercise may result in increased muscle bulk and strength. Side benefits may include improved circulation and reduced risk of pressure sores. As with any physical therapy treatment, an improvement in daily function or well being should result from FES/ES (for example, independent standing, or transfers for people with partial paralysis).

What may be available in the future?

Because denervated muscle is missing a nerve supply, traditional muscle stimulators are not effective. Although it is possible to stimulate the muscle directly, this requires very high currents and the muscle fatigues quickly. New stimulators are being designed to get around these problems.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

SCI-16. FES for controlling tremor

Not used in SCI. See section MS-16 for information about use of FES for controlling tremor in multiple sclerosis.

SCI-17. FES for sensation

What is the purpose?

Sensory substitution is the use of one sense to receive information normally received by another sense. In SCI, normal sensory receptors may be present in the skin, muscles, and joints but the spinal injury prevents the sensory signals from reaching the brain. Certain FES systems can provide a substitute for the missing or impaired sensation. Substitute sensory feedback can make the use of FES systems more natural and easier to learn.

What are non-FES alternatives?

FES users with impaired sensation can sense when they need to make adjustments to their systems by using visual feedback. For example, if a user of an FES grasp system sees a held object slipping out of the hand, he or she may be able to adjust the stimulation to grasp the object more firmly. Also, if an FES system has the capability, the user may be able to trigger a change from one to another pre-programmed stimulation pattern when he or she sees that it is needed.

How do the FES systems work?

Besides the electrodes used to activate muscles, some FES systems have another kind of electrode known as a **sensory electrode**. Typically, the electrode is placed where the user has skin sensation. **Electrotactile stimulation** involves activating the sensory electrode in a certain pattern so that the user feels a tickling sensation that represents coded information. The information may relate to forces that the user is exerting on an object but cannot feel due to impaired sensation. Or the information may relate to FES stimulator settings. For example, signals about grasp force may be sent to the sensory electrode. At the beginning, this type of substitute sensation may seem unrelated to muscle force in the fingers, because the sensation is so far away from the fingers. With practice, the user can learn to reinterpret the skin sensation as an indicator of grasp force. However, it may take months to achieve this.

STATUS OF FES FOR SENSATION

Basic research	Clinical research	Multicenter trials	Regulatory Approval
• Single skin electrode and electrode arrays for substitute sensory stimulation	• Skin electrode arrays for substitute sensory stimulation	• Substitute sensory electrode in grasping systems	

Who is medically eligible?

See section SCI-4 for grasping systems. See disqualifying factors on page 10.

How long does the treatment take?

See section SCI-4 grasping systems. Most aspects of FES for restoring sensation are in such basic research stages that we cannot talk about treatment times yet.

What does it cost?

See section SCI-4 *FES grasping systems*.

What can I realistically expect?

At the present time, only one FES hand-grasp system provides sensory information to the user. This information is about the stimulator settings rather than about quantities that are felt at the fingers or hand.

What may be available in the future?

Researchers are studying single electrodes and electrode arrays as ways of providing the FES system user with more complex sensory information. Examples would be positions of the fingers, force exerted by the fingers, and surface texture. Sensory information can also be provided as a feedback signal to the stimulation system (rather than the user) to provide more natural control of the stimulation parameters. For more information see page 5, “How does FES technology work?”

See page 65, “What Should I Know When Choosing an FES Product or Service?”

SCI-18. FES for regaining voluntary function

What is the purpose?

When the spinal cord has suffered a complete injury, lost neural function will not be regained. FES devices can be used to replace some of those lost functions in those SCI patients who are medically eligible. However, if an injury is incomplete -- meaning that there are still some nerve pathways that go from the brain to the peripheral nerves -- there is a possibility that some or all of the lost function can be regained.

What are non-FES alternatives?

- Voluntary exercise.
- **Biofeedback**. Electronic devices give users information about how their bodies function. The information may be sounds, or lines on a computer screen that are produced from signals obtained from a pickup (or sensor electrode on the body). In this way, the user can recognize very small muscle movements (too small to be noticed) and may begin to exert conscious control over them. Biofeedback has been used before FES to help establish conscious control of muscles. Afterwards, FES is used to strengthen those muscles. Biofeedback may also be used to establish better voluntary control following gains achieved with FES.

How do the FES systems work?

Various FES devices may help an individual to regain voluntary function. Movement practice with FES can assist the weak remaining function in the person with an incomplete injury. With FES exercise, weakened muscles can become stronger. As they grow stronger, they can respond better to the weak nerve signals. In time, they may produce a noticeable movement. At first, such a movement may be too small to be useful. Later, it may become functional. Biofeedback, alone or with FES, may be valuable in converting the small movement to a functional one.

Spinal cord stimulation (SCS), also called dorsal column stimulation, applies electrical pulses directly to the spinal cord. In some people, this produces a general improvement in coordination and strength. See section SCI-12, *FES for controlling spasticity*, for more information on SCS.

STATUS OF FES FOR REGAINING VOLUNTARY FUNCTION			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
• Various stimulation systems	• Various stimulation systems; some with biofeedback		• Various surface stimulation systems; some with biofeedback

Many different FES devices may be useful in restoring voluntary function to the person with SCI. See sections SCI-1 through SCI-17. Benefits have been reported with use of a simple two-channel surface electrode stimulator, providing continuous pulses during sleep.

Who is medically eligible?

People who have

- **Innervated** muscle (active nerve cells going to muscle fibers).
- Enough nerve cells remaining to permit “strengthening”. If only a few nerve cells remain, it will not be possible to improve muscle function.

See sections SCI-1 through SCI-17, for the specific function of interest. See disqualifying factors on page 10. See the discussion in SCI-15 regarding **denervation**.

How long does the treatment take?

This is perhaps the most unpredictable area of FES application. It may take months or it may take years for voluntary function to return, if it returns at all.

What does it cost?

See sections SCI-1 through SCI 17.

What can I realistically expect?

In some cases, with sufficient physical therapy and FES, the injured person can regain function. How much is regained will depend on the particular injury. Each case is different.

What FES Applications Can Benefit People with Multiple Sclerosis?

Multiple sclerosis (MS) is usually managed with medical and drug care. FES is rarely used. Therefore, there is not as much information about FES in people with MS as there is in people with spinal cord injury (SCI).

MS is classified into types according to how the disease changes over time, or progresses. About half of people with MS have what is called relapsing-remitting MS. They have attacks of neural problems (such as double vision, weakness, or poor coordination) which then subside. In some people, the symptoms may completely disappear after an attack. But, in others some neural difficulty remains after an attack. Over the course of many attacks, the person's neurological condition becomes progressively worse.

Selecting people with MS to receive FES systems is difficult because MS is often a progressive condition. That makes it hard to judge if FES is bringing any improvement. The person's condition may be changing during a period of FES treatment. This would make it impossible to properly evaluate the treatment. To avoid this, doctors are careful to select people with stable conditions, early in the course of their disease. Once FES treatment has begun, a change in condition may require modifications to the FES systems. Changes may, in some cases, exclude the use of FES systems.

Another problem is that people with MS have increased skin sensation and find surface stimulation uncomfortable. Researchers are developing stimulation techniques that may provide more comfortable stimulation for the future.

The picture on page 4 names 18 applications of FES, some of which have been used in people with MS. The stage of development of the applications varies from basic research to regulatory approval (see table on page 9). Just because a treatment is approved does not mean it will be widely available. When a device and treatment are approved in the US, it means that the Food and Drug Administration (FDA) has determined it to be safe and effective. In other countries, agencies similar to the FDA grant approval according to their own guidelines, which often differ from the FDA's. The doctor and therapist who provide you with your regular care may not know about a particular treatment. If they do know about it, they may not have the training necessary to give that treatment. This book and other resources are available to help rehabilitation professionals who seek education and training about FES.

One of the few approved uses of FES in people with MS is for control of pain. This treatment uses **spinal cord stimulation** (SCS), also called dorsal column stimulation. When SCS is used for other goals, such as improving voluntary control of movement or improving bladder control, it is called an **unlabelled use**.

The sections that follow explain how each application works, its purpose, availability and cost, who is eligible, time of treatment, and expected outcomes. See Part 2. WHERE TO GET FES for specific details about locations where treatment is available.

For each application there are medical eligibility requirements. In addition, there are factors which would probably disqualify a candidate. Many of these disqualifying factors apply to almost all uses of FES.
The disqualifying factors include:

- Poor skin condition.

- Allergy to electrode gels or adhesives.
- Heart rhythm or high blood pressure problems.
- Implanted pacing devices.
- Possible blood clots.
- Some types of tumors.
- Pregnancy.
- Unhealed wounds.
- Chronic infective disease.
- History of transient ischemic attacks (minor strokes).
- Chronic severe kidney, heart or lung disease.

People who have any of the above conditions should **not** use FES.

The sections below provide information on the current use of FES in MS. Even if a particular type of FES is not used in MS treatment today, learning about how it is used in spinal cord injury may be helpful for the future. Refer to sections SCI-1 through SCI-18 for information about FES in persons with spinal cord injury.

MS-1. FES systems for cardiovascular exercise

Currently, FES systems to improve cardiovascular health are not designed for use by persons with MS, although there are reports that people with MS are using the systems. For further information see SCI-1, *FES for cardiovascular exercise.*

MS-2. FES systems for breathing assistance

Not used in MS at present.

MS-3. FES systems for cough assistance

A person with MS and very weak abdominal muscles might benefit from an FES cough assist device. Such devices have not been tested in people with MS. For further information see SCI - 3, *FES for cough assist.*

MS-4. FES systems for grasping and reaching

Specialized systems for grasping and reaching have not been designed for people with MS. FES systems implanted to control pain or spasticity in people with MS have improved hand and arm function in some people. Also, FES has been tested for improving strength and coordination in people with MS. Some users of **spinal cord stimulation** (SCS) showed improved hand strength and they could move their hands faster. See sections MS-12, *FES systems for controlling spasticity* and MS-18, *FES systems for improving control of movement*.

MS-5. FES systems for bladder and bowel control

What is the purpose?

- Provide a reliable method for emptying the bladder.
- Reduce bladder accidents.
- Reduce urinary tract infections.
- Provide a reliable method for emptying the rectum.
- Reduce constipation.
- Reduce bowel accidents.

What are non-FES alternatives?

Bladder management includes

- A regular toilet routine.
- Exercising weak pelvic floor muscles.
- Use of condom and leg bags (men).
- Intermittent or permanent catheterization.

In addition, some drugs help to reduce bladder problems.

It is important not to reduce fluid intake. People might think that would make it easier to manage needing to urinate frequently. But, reduced fluid intake is not good for you. It may cause infection and dehydration. It contributes to constipation.

Loss of bowel control is rarely a problem in MS. But, where bowel control is a problem the exact cause must be identified and can sometimes be helped by FES. Constipation is a more common problem. In that case, bowel management involves eating a diet with more fiber, and using stool softeners and suppositories when needed.

How do the FES systems work?

In an anterior sacral nerve root stimulator, electrodes are implanted on the spinal nerve roots that control bladder and bowel contraction. The user controls the electrodes with either an external stimulator or an external controller that runs an implanted stimulator. This will be dictated by which type of electrodes (totally implanted or with percutaneous leads) are used. Different selections on the external controller will produce contraction of the bladder or bowel muscles.

Another system uses an electrode inserted alongside one of the sacral nerves. These nerves contain both sensory and motor fibers. Doctors believe that the stimulation of the sensory nerves interferes with spasticity, which is often the cause of voiding problems. This type of interference is called **neuromodulation**. (See sections SCI/MS-12, *FES for controlling spasticity*.) Built into the electrode are several conductors. Stimulation can be adjusted among them to get the most benefit. First, the system is tested with a percutaneous (through the skin) lead and an external stimulator. If voiding problems are reduced, the user tries the system at home for about a week. Then, stimulation is stopped. If urinary control becomes difficult again, it shows that the FES system provided improvement. Then, a permanent electrode and stimulator can be implanted. Adjustment of the stimulation settings may be necessary during the first six months. This system has also helped people with pelvic pain that does not respond to other treatments.

Another method that has been used to control bladder function is **spinal cord stimulation** (SCS) (see section MS-18, *FES systems for improving control of movement*).

Pelvic floor stimulation is another method that can help correct problems with bladder or bowel function. Stimulation is applied to the supportive muscles of the pelvis that help control urination

and defecation. Probes or catheters that contain electrodes are inserted into the rectum, vagina, or urethra. The treatment protocols vary, but usually stimulation is applied for a certain period every day. This method strengthens the muscles and improves sensation and control. For treating constipation, sometimes, surface electrodes applied to the skin of the abdomen, thigh or the anus can be used.

The wide variety of stimulation techniques that are available for improving bladder and bowel control reflect the complexity of the problem. A proper evaluation is key to determining which techniques, if any, are most appropriate.

STATUS OF FES SYSTEMS FOR BLADDER AND BOWEL CONTROL

Basic research	Clinical research	Multicenter trials	Regulatory Approval
	• 3 channel, anterior sacral root stimulator, totally implanted (Multicenter trials of British system expected to begin in US in 1996. Available commercially in Europe, Asia, Far East) • Pelvic floor stimulation with various types of electrodes	• Sacral nerve stimulator, 1 channel, totally implanted. (Considered investigational in the US, but available commercially in Europe)	• SCS, 1 channel, totally implanted with battery or RF power (Unlabeled use except when prescribed for pain control) • Pelvic floor stimulation • Anterior sacral root stimulator (Europe, Asia, Far East) • Sacral nerve stimulator (Europe)

Who is medically eligible?

A person with MS who

- May need to urinate frequently.
- Cannot contain urine voluntarily (incontinence).
- Has bladder and bowel response to electrical stimulation.
- Is emotionally stable and realistic.

A person may be disqualified because of:

- Denervation.
- Underlying bladder or bowel disease.
- Substance abuse.
- See additional disqualifying factors on page 47.

What does it cost?

The British anterior sacral root stimulator costs from $13,000- $20,000, including surgery. It is only available in the US as an investigational device. For SCS treatment, the medical evaluation, the device, and surgical implantation cost about $18,000. The cost of pelvic floor stimulation is less than the cost of implanted stimulators, but varies depending on the particular method.

How long does the treatment take?

Preliminary assessment to determine if you are medically eligible for implanted bladder/bowel devices may take several months. Lengthy tests of the urinary tract and colon may be needed. If implantation surgery is necessary, it will involve a hospital stay of up to one week.

What can I realistically expect?

Only a few dozen people with MS have received the anterior sacral root stimulator. Their experience is similar to that of the people with SCI who received the same device. In one study, more than half of the users found it to be good or satisfactory for emptying the bladder. See section SCI-5 for additional information.

The anterior sacral root stimulator can also produce penile erection, although it is unlikely that it would be prescribed for that purpose only (see section MS-8, *FES for erection and electroejaculation*).

Spinal cord stimulation produced improvement on nerve tests and urine flow tests in 42% of 40 people with MS. An even larger group, 77%, felt that implantation of the SCS improved their bladder control.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

MS-6. FES systems for transfers and standing

Systems for transfers and standing have not been designed for people with MS. Some systems for people with SCI are being modified for use in people with MS. See section SCI-6, *FES systems for transfers and standing*.

FES systems implanted to control pain or spasticity in people with MS have improved transfers and stepping in some of those patients. FES delivered at the surface of the spinal cord, **spinal cord stimulation**, has been tested for improving strength and coordination in people with MS. See sections MS-7, *FES systems for stepping and walking*; MS-12, *FES systems for controlling spasticity;* and MS-18 *FES systems for improving control of movement*.

MS-7. FES systems for stepping and walking

What is the purpose?

- Increase mobility and independence.
- Improve muscle coordination.
- Improve muscle power.
- Increase home, workplace, and leisure capability.

What are non-FES alternatives?

- Braces.
- Anti-spasticity drug treatment.

How do the FES systems work?

Surface FES systems have been designed to help with walking by lifting the toe or the whole foot during a step. Such systems may help those who have footdrop. This is a condition where the toe drags on the ground as a step is taken. During walking, the FES system produces a short burst of stimulation timed by a trigger switch usually placed under the heel or toe.

Spinal cord stimulation (SCS), also called dorsal column stimulation, may improve a person's ability to stand and take steps. See section MS-18, *FES systems for improving control of movement*, for details about this implanted stimulation system.

STATUS OF FES STEPPING AND WALKING SYSTEMS			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
	• Various surface electrode systems • Surface electrode system with feedback		• Surface electrode systems with foot switch (US, Europe, other regions) • Spinal cord stimulation (SCS) (unlabelled use except if implanted to relieve pain)

Who is medically eligible?

People with

- Little or no peripheral nerve damage or joint damage.
- No current substance abuse.
- Flexible joints (only minor contractures).
- Optimistic and motivated attitude.
- Acceptance of technology.
- See disqualifying factors on page 47.

What does it cost?

- A foot drop system with surface electrodes costs $300-$1,500.
- Surface electrode systems without bracing cost about $15,000 including training.

How long does fitting and training take?

- Fitting and training with a footdrop system takes 1 - 2 days.
- Fitting and training with the spinal cord stimulator may take about a month.
- Fitting and training with a surface electrode walking system is still under development.

What can I realistically expect?

Only a small number of people with MS have been treated with FES. Doctors disagree on the value of FES for this population. Some doctors feel SCS should be used as soon as possible in the weakened person with MS. Others observed that there were no benefits of SCS two years after implantation. Some of these failures were probably the result of faulty equipment in the early devices (1970s to mid 1980s).

FES has valuable health benefits in some people. Because using the systems demands so much energy, consistent users improve their cardiovascular capability. When FES is used for weight bearing activity, it can help to increase bone strength. See section MS-14, *FES for osteoporosis*. Regular SCI users of FES standing systems report reduced pressure sore problems and urinary tract infections.

What may be available in the future?

A surface FES system for standing and walking in SCI is being modified for use in people with MS. The specific goals of motion control in people with MS change constantly. For FES to work with the person's voluntary movement, feedback is needed to adjust the stimulation levels. The goal is to create automatic minute-to-minute changes in the FES pulses.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

MS-8. FES for erection and electroejaculation

What is the purpose?

- Produce erection of the penis.
- Produce ejaculation to collect sperm for artificial insemination.

What are non-FES alternatives?

- Masturbation.
- Stimulation with a vibrator.
- Use of a suction device.
- Injection of drugs into the penis.
- Penile prosthesis.

How do the FES systems work?

Erection
The bladder and bowel device described in section MS-5 (anterior sacral root stimulator) can also produce erection, although it would probably not be prescribed solely for that purpose. After the device is implanted, the doctor will test the effect of stimulating the different nerve roots that have been equipped with electrodes. In most men, one particular pair will produce erection without bladder contraction. The FES controller will be tuned with a setting for erection.

Most men with MS will choose one of the above non-FES alternatives if the primary goal is to achieve erection.

Electroejaculation
The doctor inserts a probe into the man's rectum and electrically stimulates the nerves that control ejaculation. The individual may need local or general anesthesia because of the discomfort, particularly if he retains sensation in the rectum and lower abdomen. A nurse or a second doctor collects the sperm. In some men whose sperm goes into the bladder, the doctor or nurse will collect it from there. A gynecologist uses the sperm to inseminate the man's partner.

STATUS OF FES FOR ELECTROEJACULATION

Basic research	Clinical research	Multicenter trials	Regulatory approval
		• About 50 clinics in the US and Canada offer electroejaculation procedures, still considered experimental in North America.	• Electroejaculation (many European countries)

Who is medically eligible?

Men with MS who cannot achieve ejaculation by other methods.
See disqualifying factors on page 10.

How long does the treatment take?

Electroejaculation treatments should be timed with the man's partner's most fertile time each month. A single session takes about 45 minutes plus travel time.

What does it cost?

Electroejaculation treatment costs about $400 per session plus anesthesia charges. In some cases, insurance will cover the cost, but this is still considered to be an experimental procedure in North America.

What can I realistically expect?

Electroejaculation has been successful in a few men with MS.

An important issue is the potency of the sperm that is collected. Also, when a couple is trying to conceive a child, the woman's fertility is as important as the man's. When you undertake electroejaculation, make sure that you also have experienced fertility doctors on your medical team. Between 30% and 50% of couples who try artificial insemination are successful. New methods of artificial insemination may increase the success rate.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

MS-9. FES for improving circulation

Currently, customized FES systems to improve circulation are not designed for use by persons with MS. Still, it is possible that these and generic muscle stimulation systems may be beneficial. For further information see SCI-9, *FES for improving circulation.*

MS-10. FES for preventing pressure sores

What is the purpose?

Prevent formation of pressure sores.

What are non-FES alternatives?

- Maintain good health through diet and exercise; avoid smoking
- Use a properly designed and fitted seating system.
- Change position frequently while lying in bed.
- Lift the buttocks from the wheelchair while seated.
- When a red area on the skin does not disappear within 30 minutes after relieving all pressure, lie on stomach or side for 24 hours or until redness is completely gone.

How do the FES systems work?

Researchers are working on several systems that could be used by people seated in a wheelchair. These systems deliver electrical stimulation to the buttock muscles. People with MS may have a level of sensation that makes use of such systems very uncomfortable. See SCI-10, *FES for preventing pressure sores*, for further information.

STATUS OF FES FOR PREVENTING PRESSURE SORES

Basic research	Clinical research	Multicenter trials	Regulatory approval
	• Various prevention systems using surface electrodes		

Who is medically eligible?

For surface electrode FES treatment, the person with MS should have

- Otherwise good general health.
- No allergy or excessive skin sensitivity.
- See disqualifying factors on page 47.

How long does the treatment take?

If an FES system for preventing pressure sores were developed, using it would be part of a regular daily routine.

What does it cost?

Using FES to prevent pressure sores may be done in a variety of ways by different doctors and therapists. There is no standard and it is difficult to state a cost. Physical therapy sessions generally cost around $80 each. Once a physical therapist instructs a patient, much of the FES can be done at home with a rented or purchased stimulator.

What can I realistically expect?

Regular use of FES to activate buttock muscles that have nerve supply from the spinal cord may help to prevent pressure sores.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

MS-11. FES for treating pressure sores

What is the purpose?

Speed the healing of pressure sores.

What are non-FES alternatives?

- Relieving all pressure on the area of skin breakdown.
- Gels or baths that contain growth factors and other formulations
- Suction pumps to drain the wound
- Devices to pressurize the wound.
- Antibiotics if there is infection.
- In extreme cases, surgery which may involve various types of grafts.

How do the FES systems work?

Researchers believe that electrical stimulation (ES) may help pressure sores to heal in several ways. ES increases the amount of oxygen in the tissue around the wound and reduces the number of bacteria in the wound. Both effects contribute directly to healing. Indirectly, the improved blood circulation produced by ES boosts the nutrition and waste removal in the tissues (See sections MS-9 and SCI-9, *FES for improving circulation*).

It is no surprise that ES also creates electrical currents in the tissue. Normal tissue has natural electrical currents (different from nerve signals) flowing in it. These currents assist in healing of wounds. When there is neurological disease, or degeneration (as in the elderly), these currents are reduced or missing. Surface electrode stimulation can be used to substitute for the electrical currents in tissue and to assist in wound healing.

STATUS OF FES FOR TREATING PRESSURE SORES

Basic research	Clinical research	Multicenter trials	Regulatory approval
• Studies of electrical properties of wounded tissue	• Various systems using surface electrodes	• Various systems using surface electrodes	• Physical therapy treatment using FES with surface electrodes (Unlabeled use in the USA).

Who is medically eligible?

People who have superficial and minimally infected wounds have the best chance for healing. This is true both with and without ES. If there is a pocket of infection under the skin or infection of bone, surgery may be needed. See disqualifying factors on page 47.

How long does the treatment take?

Healing of pressure sores is usually a lengthy process, and ES has been shown to speed it up.

What does it cost?

The most important variables are the health of the individual and the extent of the pressure sore. Costs will vary widely with the person's condition and whether or not surgery is needed.

What can I realistically expect?

Healing of pressure sores in people with MS can take a long time. ES treatment can speed the healing process.

What may be available in the future?

Researchers are conducting studies to better understand the electrical properties of healthy and wounded tissue. This should help to determine more effective stimulation patterns.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

MS-12. FES for controlling spasticity

What is the purpose?

FES can be used to reduce **spasticity**. Spasticity is the abnormal, involuntary contraction of muscles, sometimes called spasms. It interferes with voluntary movements, causing them to be stiff and awkward. Spasticity may contribute to fatigue and pain.

What are non-FES alternatives?

- Various lying, seated, and standing positions can reduce spasticity.
- Very localized spasms can be treated by heat or cold.
- Stretching and passive range of motion exercises (individual, therapist, caregiver or robotic device moves limbs through a full range of motion) can reduce spasticity. This will also help to prevent contractures.
- Medication can reduce spasticity.
- In extreme cases, surgery may be used to control spasticity

How do the FES systems work?

Several methods of reducing spasticity use skin surface electrodes. People with MS who have intense skin sensation may not be able to use these FES methods.

When FES is used specifically to counteract spasticity, surface electrodes are applied to the spastic muscles or to their antagonists. Each muscle has a counterpart muscle that moves the joint in the opposite direction -- this is called the antagonist.

Spasticity usually occurs in several muscles at once. Some studies have shown that the most effective treatments are those where FES is applied to all the muscles of a limb. Physical therapy treatment may also be given during the same period.

Another method for reducing spasticity is applying FES to skin areas called dermatomes. A **dermatome** is an area in which all the sensory nerve receptors belong to the same spinal cord level. Particular muscle groups also have their motor nerves at specific spinal cord levels. The dermatome that is stimulated is chosen to have the same spinal cord level as the spastic muscle group.

The use of implanted electrodes or stimulators also may reduce spasticity. Such electrodes may be implanted in muscles, over nerves, or on the spinal cord. In **spinal cord stimulation** (SCS), also called dorsal column stimulation, low levels of stimulation are delivered continuously. A single cable leading to a multiple electrode provides stimulation that has a general effect on many motor nerves. Thus, an SCS device for controlling spasticity might have beneficial effects on bladder function, arm movement, standing, and leg movement.

Implanted SCS stimulators may be battery-powered or controlled by radiofrequency waves passing through the skin. Similar to heart pacemakers, the battery-powered units require replacement after several years. Both types of devices are turned on and off by the patient. Typically, users operate their stimulators most of the day. When the devices are turned off, the benefits quickly fade.

Doctors believe that dermatomal, SCS, and sacral nerve stimulation work by a method called **neuromodulation**. It seems to depend on stimulation of sensory nerves reducing the spasticity of related motor nerves.

Grasping, standing and walking systems may help to reduce spasticity. See sections MS-4, MS-6, and MS-7.

STATUS OF FES FOR CONTROLLING SPASTICITY

Basic research	Clinical research	Multicenter trials	Regulatory approval
	• Various surface and implanted electrode systems • Dermatomal stimulation		• Physical therapy treatment using FES with surface electrodes • SCS, 1 channel, totally implanted, with battery or RF control. (unlabeled use except when implanted to control pain or spasms)

Who is medically eligible?

People with MS who have spasticity that cannot be controlled by medical methods. For surface electrode FES treatment, the person with MS should have

- Otherwise good general health.
- No allergy or excessive skin sensitivity.
- See disqualifying factors on page 47.

How long does the treatment take?

When FES is used only for spasticity control, treatment time will depend on which of the many methods your doctor or therapist is using. One study used 20-minute sessions twice a day.

For SCS, some doctors implant the electrode and stimulator in a single surgery. Others do a one-week trial with an electrode whose wire comes through the skin (**percutaneous** lead) and can be implanted in a short out-patient procedure. The lead is connected to an external stimulator. If that system provides benefit, the doctor will implant the stimulator during a short hospital stay of several days. During that time, the doctor and therapist will determine the most beneficial stimulation settings.

What does it cost?

- As treatment with surface electrodes is adjusted to each individual, costs of therapy will vary. Therapists typically charge $80 per session. Stimulators can be rented for $80 per month or purchased for $700 - $2000, depending on the specific features of the device.
- For SCS treatment, the medical evaluation, the device, and surgical implantation cost about $18,000.

What can I realistically expect?

Researchers who have used surface FES or SCS to treat spasticity in people with MS have found a variety of results. In addition to reduced spasticity, some people with MS have experienced improved grasping, standing, walking and bladder function. This occurs because the reduction in spasticity removes interference with these movement functions. Spasticity can be decreased but it will not be eliminated with the use of FES.

When there was a benefit following FES treatment, in some cases it disappeared within days or years. However, in other cases it persisted for up to 4 years. Perhaps, the natural progress of the MS wiped out the improvement in some people. This is an area where much more basic and clinical research is needed to know what we can expect of FES.

If spasticity is reduced over a long period, then there will be a reduction in contractures also. See the next section.

See page 65, “What Should I Know When Choosing an FES Product or Service?”

MS-13. FES for preventing or treating contractures

What is the purpose?

- Maintain full range of joint motion (ability to move limbs to all normal angles).
- Regain lost range of motion (ROM).

What are non-FES alternatives?

Many standard physical therapy techniques are available, including:

- Use of splints or braces.
- Positioning and stretching.
- Passive joint ROM exercise by therapist or caregiver, or by positioning one's own body.
- Exercise against resistance (for example, lifting weights), if the muscles are strong enough to take the joint through a full ROM.
- Use of heat may assist in gaining joint ROM if it is combined with other treatments like positioning.
- If spasticity is causing contractures, then decreasing spasticity will maintain ROM (see previous section).

How does the FES system work?

Skin surface electrodes and portable, battery-powered stimulators are used. The muscle contraction must be strong enough to move the joint through the available ROM and "tug" a bit at the end of the range.

In the general practice of physical therapy, FES with surface electrodes is used to treat a variety of muscle problems. Often, these relate to injuries such as fractures or dislocations. FES is used to produce low levels of contraction. This maintains muscle condition, increases the range of movement, and assists weak muscles.

STATUS OF FES TO PREVENT OR TREAT CONTRACTURES			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
			• Physical therapy treatment using FES with surface electrodes

Who is medically eligible?

FES to prevent and treat contractures is suitable for most people with MS. See disqualifying factors on page 47.

How long does the treatment take?

Therapeutic treatments may last from 10 to 30 minutes. They may be given several times a week, or several times a day, depending on the condition.

What does it cost?

As there is no standard physical therapy treatment for contractures, it is difficult to specify a cost. A typical therapist may charge $80 per session. Stimulators can be rented for $80 per month or purchased for $65 - $3000, depending on the specific features of the device.

What can I realistically expect?

Contractures are often caused by spasticity. If spasticity can be reduced, contractures will also be reduced. See previous section.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

MS-14. FES for preventing or treating osteoporosis

What is the purpose?

Stop the weakening of bone in people who are immobilized due to MS.

In healthy people, bone tissue is kept strong by the constant stresses placed on bones in everyday activity. In normal bone there is an ongoing process of death and regrowth of cells. Stresses on bone cause new bone cells to grow and minerals to be deposited in bone. When a person is immobilized, the stresses on bone, cartilage, ligaments and tendons are severely reduced. When such a person can no longer stand, and the legs don't bear weight, there is very little stress on the leg bones. As a result, growth of bone cells and deposit of minerals in leg bones are reduced. Bone mass or mineral density is reduced and the bones become more porous, a condition called **osteoporosis**.

What are non-FES alternatives?

Standing with

- Standing frame.
- Bracing.
- Standing attachment on wheelchair.
- Stand-up wheelchair.

Some people who use these devices experience fractures of their osteoporotic bones. Also, some people who use FES systems for exercise or standing and walking have fractures of their osteoporotic bones.

How do the FES systems work?

Standing and walking with FES (see section MS-6, *FES systems for transfers and standing* and MS-7*, FES systems for stepping and walking*) may stress the leg bones in ways that prevent loss of bone mineral.

Muscle stimulation exercise routines that generate 40% of maximal voluntary muscle contraction have been reported to aid in bone strengthening.

Researchers have tested a modified bicycle ergometer to increase bone density for people with SCI. See section SCI-14, *FES systems for preventing or treating osteoporosis.*

STATUS OF FES FOR PREVENTING OR TREATING OSTEOPOROSIS			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
	• Standing/walking systems • Surface muscle stimulation		

Who is medically eligible?

- See sections MS-6, MS-7.
- See disqualifying factors on page 47.

How long does the treatment take?

There have been no studies documenting the length of treatment for people with MS.

What does it cost?

The cost of a small portable stimulator would be in the range of $65 to $3000. Annual cost of supplies is about $1,000. See section MS-6, *FES systems for transfers and standing* and MS-7, *FES systems for stepping and walking.*

What can I realistically expect today?

Using FES to stress bones seems promising for stopping the progress of osteoporosis. However, the effect may vary with the length of time of immobilization, the location of the bones in the body, and the duration of treatment. Further research is needed to understand what factors are important in stopping and reversing the weakening of bone in MS.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

MS-15. FES for treating weak, atrophied muscles

What is the purpose?

- Strengthen weak muscles for specific movement functions. (See sections MS-4, 6, and 7, *FES systems for grasping and reaching, for transfers and standing, for stepping and walking.*)
- Increase bulk of shrunken (**atrophied**) muscles.

What are non-FES alternatives?

- When muscles are totally paralyzed, there is no other way than FES to activate them.
- When muscles are partially paralyzed, voluntary exercise can help to maintain some level of strength.

How do the FES systems work?

In the general practice of physical therapy, electrical stimulation (ES) with surface electrodes is used to treat a variety of problems of the muscles or bones. These problems often result from injuries such as fractures or dislocations. Similar methods may be used to treat people with weak muscles due to MS.

Any type of implanted or surface electrode FES system may be used (see section MS-12, *FES for controlling spasticity* for information about **spinal cord stimulation** (SCS)). Some muscle stimulators for paralyzed people are packaged with customized electrode garments to make it easier to set up and connect the electrodes. FES or ES activates the weak or paralyzed muscle. Even though these systems are simple, they should only be used with appropriate instruction from a health care provider. A consistent exercise program may produce increases in strength and in muscle size.

In a partially paralyzed muscle, the portion of the muscle that is weak because of inactivity but still has a nerve supply will become stronger and bulkier (**hypertrophy**). The portion of the muscle that

is paralyzed due to neural damage will become bulkier but voluntary strength will not improve. However, the strength during FES will increase.

FES systems for cardiovascular exercise, grasping, standing and stepping (see sections SCI-1, MS-4, MS-6, and MS-7) may also make muscles stronger and larger. A crucial factor is whether or not the stimulation routine stresses the muscle.

STATUS OF FES FOR PREVENTING OR TREATING WEAK, ATROPHIED MUSCLES

Basic research	Clinical research	Multicenter trials	Regulatory approval
	• Specialized stimulators designed for denervated muscle		• Physical therapy treatment using FES with surface electrodes • Specialized systems with electrode garments

Who is medically eligible?

- Generally, FES will only work for the extended periods of time necessary to convert the paralyzed muscle into a stronger muscle if there is no **denervation** -- loss of nerve supply between the spinal cord and the muscle.
- See disqualifying factors on page 47.

How long does the treatment take?

Like any kind of exercise, muscle exercise for maintaining strength and bulk needs to be done as part of a regular daily routine. Suggested exercise times will vary with the therapist and the patient's condition. Initial sessions will be under the guidance of a therapist. Later sessions can be carried out independently.

What does it cost?

- See sections SCI-1, MS-4, MS-6, and MS-7 for details of exercise, grasping, standing and walking systems that also reduce atrophy.
- Specialized physical therapy treatment with muscle stimulators costs around $80 for each session with a therapist. Purchase of a home model stimulator costs $700 - $2,000 and rental costs about $80 per month. Electrodes and supplies may cost $1,000 per year.
- Custom muscle stimulation systems that include electrode garments can cost several thousand dollars but may provide long term savings by reducing the cost of supplies.

What can I realistically expect today?

MS patients with mild to moderate dysfunction will gain the most benefit from surface stimulation. Changes may include improved endurance, strength, coordination, joint movement, and walking. Consistent exercise may increase muscle bulk and strength. Side benefits may include improved circulation and reduced risk of pressure sores.

What may be available in the future?

Because denervated muscle is missing a nerve supply, traditional muscle stimulators are not effective. Although it is possible to stimulate the muscle directly, this requires very high currents and the muscle fatigues quickly. New stimulators are being designed to get around these problems.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

MS-16. FES for controlling tremor

Tremor is shaking that occurs continuously or whenever voluntary movement is made. Poor muscle coordination and balance (ataxia), another symptom of MS, may also be helped by FES. However, this is a very specialized type of treatment that requires frequent adjustment of stimulation.

What is the purpose?

Reduce and control tremor that interferes with everyday tasks.

What are non-FES alternatives?

- Bracing.
- Drug treatment.
- Brain surgery to remove the thalamus, the area of the brain that produces tremor.

How does the system work?

In one type of system, surface electrodes are built into a glove or armband. The timing of FES pulses is tuned so that the FES movement and the tremor movement cancel each other out. This is done by a type of **feedback control**.

In another type of system, called deep brain stimulation, a tiny electrode is implanted deep in the thalamus area of the brain and attached to a pacemaker-like stimulator implanted under the skin of the chest. When the individual with tremor activates the system using a hand-held magnet, the pacemaker sends a signal to the electrode that acts to short-circuit the abnormal nerve impulses that cause the tremor. This type of therapy is FDA-approved for people with Parkinson's disease or essential tremor, but studies are needed to test its effectiveness for people with MS.

STATUS OF FES FOR CONTROLLING TREMOR			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
	• Surface electrode system fitted into a glove or armband, with feedback (Canada) • Deep brain stimulation		

Who is medically eligible?

People with MS and tremor. See disqualifying factors on page 47.

How long does the treatment take?

The treatment takes place whenever the individual experiences uncontrollable tremor and turns on the stimulation. Set-up, testing and training will vary, depending on the type of system. The deep brain stimulation involves inpatient surgery and a recovery period. Periodic adjustments can be accomplished in outpatient visits.

What does it cost?

The glove or armband system costs about $2000. Annual supplies and maintenance cost about $500. Deep brain stimulation costs average about $50,000 including surgery and training.

What can I realistically expect?

Forearm tremor was decreased by more than 50% in three of the five people with MS who tested the surface electrode glove system. However, the stimulation caused discomfort and muscle ache

in two of the five subjects. The first multicenter trials of the glove device are expected to begin in 2000.

In a study of 15 individuals with MS who received deep brain stimulators, all experienced a reduction in their hand and arm tremor on one side of their body and all developed a tolerance to the stimulation that required repeated re-programming of the stimulator to maintain the benefit.

What may be available in the future?

Researchers developing the glove device are studying ways to control tremor in more than one plane of movement using multiple feedback sensors. This may assist with combined pronation-supination and flexion-extension tremors.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

MS-17. FES for sensation

There are no FES systems to compensate for impaired sensation that are specifically designed for use in MS. See section SCI-17, *FES for Sensation* for more information.

MS-18. FES systems for improving control of movement

People with MS often have enough muscle strength for daily activities. But, they may lack muscle control and coordination.

What is the purpose?

- Improve muscle coordination.
- Improve muscle power.
- Increase home, workplace, and leisure capability.

What are non-FES alternatives?

- Braces.
- Drug treatment.

How does the FES system work?

The method called **spinal cord stimulation** (SCS) was discovered when a person with MS was fitted with a stimulator to control pain. It seemed to improve control of movement.

In SCS, flat electrodes are surgically placed on the spinal cord, usually in the upper back. The procedure can be done by passing the electrodes through a special needle. A fine wire connects the internal electrode to an external stimulator with a **percutaneous** lead. If the system produces benefits, a miniature stimulator is then implanted within a week or two. Such a stimulator can be operated for short periods or at a low level all the time. When it is successful, the FES seems to affect all movement functions and bladder function also. This method is also called **dorsal column stimulation**.

Surface electrode systems for standing and walking may also provide improved movement control. See section MS-7.

STATUS OF FES SYSTEMS FOR IMPROVING MOVEMENT			
Basic research	**Clinical research**	**Multicenter trials**	**Regulatory approval**
			• SCS, 1 channel, totally implanted, with battery or RF control. (unlabeled use except when implanted to control pain or spasms)

Who is medically eligible?

People with

- Little or no peripheral nerve damage or joint damage.
- No current substance abuse.
- Flexible joints (only minor contractures).
- Optimistic and motivated attitude.
- Acceptance of technology.
- For disqualifying conditions, see 47.

What does it cost?

For SCS treatment, the medical evaluation, the device, and surgical implantation cost about $18,000.

How long does fitting and training take?

Fitting and training with the spinal cord stimulator may take about a month.

What can I realistically expect today?

Only a small number of people with MS have been treated with FES. Doctors disagree on the value of FES for this population. Some doctors feel SCS should be used as soon as possible in the person with MS who has a relapsing-remitting pattern of symptoms (see page 47). Others observed that there were no benefits of SCS two years after implantation. Some users of SCS experienced improved hand strength and the ability to move their hands faster.

See page 65, "What Should I Know When Choosing an FES Product or Service?"

What Should I Know When Choosing an FES Product or Service?

How will participation in an FES program affect me?

Typically, when you receive an FES system, a specially trained rehabilitation team will work to ensure that the system is doing its job. The team may include physicians, surgeons, therapists, engineers, and technicians. If the FES system is complex, you may need to spend much time with the team members. You may need to receive implants, be fitted with devices, and train to independently use the devices safely and effectively.

Each individual has personal goals for adding FES to his or her life. Also, medically, each person is different. If you are interested in exploring FES, you will want to talk with a physician or therapist who is experienced in FES treatment. Ask that person what you can realistically expect from the particular FES system that is available now. This is important because many FES devices are still being developed. Some people may want the devices that are available today and may be

willing to accept their limitations. But, others may prefer to wait until the technology is more fully developed.

FES systems may require either no surgery, simple surgery, or complex surgery. Your medical condition and personal feelings about surgery will be important factors in determining whether or not you receive a particular FES system. Even if a system seems ideal, some individuals with normal or heightened sensation may not be able to tolerate the stimulation.

Today, many FES systems are not covered by insurance. The main reason is that they are not yet approved by FDA. People are concerned that even when systems receive approval, the health care system may not cover FES devices. Because FES is a new technology in the medical marketplace, much education is needed for funding agencies, insurance companies, medical technology investors, and consumers. Only by knowing the risks, benefits, and costs can we evaluate FES as a health care option. This is especially true for the consumer so that he or she does not develop false hopes about FES. As an interested consumer, you can help to educate yourself and others.

What questions should I ask?

Choosing an FES product or service can be complicated because there are many factors to consider. FES treatment is usually very specialized. That means it is offered by only a limited number of health care providers. And, that means that insurance companies have little experience with it. Therefore, what is covered will usually be decided on a case-by-case basis. The insurance company will require supporting documentation that clearly shows the benefit of this treatment over more traditional ones. Since there is little agreement in the medical community about FES, such documentation may be difficult to produce. Usually, the manufacturer of a device can supply documentation to insurance companies to back its claims.

Much of the FES treatment available is in research programs. These usually cost little or nothing. But they may take much of your time in travel and long testing sessions. On the other hand, if you are so inclined, you can be more than a “subject” - you can be part of a research team.

Since many FES treatments are new, it is often helpful to know how many people have been successfully treated with the system you are considering, how many reached their goals, and whether they continue to use the FES system. Here are some guidelines to help you in choosing an FES product or program:

DO check out the credentials of any FES service provider or product manufacturer.

- How long have they been in business?
- How many satisfied customers or clients have they served?
- Are they accredited by a professional organization or review board? For example, the Commission on the Accreditation of Rehabilitation Facilities (CARF) sets minimal standards for facilities. Certain rehabilitation professions require their practitioners to maintain licensure credentials that are monitored by a professional review board.
- For a company or clinic, has the Better Business Bureau received complaints about them? (Look up the local number in your Yellow Pages.) For a health care professional, has a medical review board received complaints?

DON’T rely on the provider’s or manufacturer’s claims.

- Ask for names and phone numbers of clients who have received FES treatment and speak with them.
- Tour the facility.
- Arrange for demonstrations.

DO obtain, in advance, a written good faith estimate of all costs that you may incur.

- Check out your insurance coverage immediately.
- Beware of hidden costs such as supplies and equipment that you must purchase for home use, and transportation and accommodation expenses.

DON'T become carried away by your emotions. Be as realistic as possible about the benefits you may receive and the risks you will be exposed to.

DO obtain a written statement that describes your treatment plan. It should include:

- Initial evaluation.
- Treatment goals.
- Frequency and length of treatments.
- When the treatment will be terminated.
- Any follow-on activities that will be needed to maintain the benefits of treatment.

DO find out if use of FES will require permanent or irreversible surgery. Doctors who implant FES systems are constantly developing better surgical procedures. Ask if the surgery can be broken into short sessions. Ask if any of it can be done on an outpatient basis. Ask about the risks of surgery. Discuss the proposed treatment plan with health care providers whom you trust.

DO explore all the alternatives to FES. More traditional treatment plans may be just as effective, and less expensive.

You may decide to volunteer for an experimental FES project. If you do, make sure that you completely understand your commitment to the project. Ask how the FES treatment may affect other assistive technologies that you already use or may use in the future. Ask about the risks and benefits of the treatment. This should be detailed in a document called an **Informed Consent**. The researchers are required to write out these details and explain them to you. They will ask you to sign the document to show that you understand it.

If you choose to participate in a research project, find out in advance what expenses are involved and who will be paying them. Ask how much time you need to be at the research clinic, and how that will affect your daily activities. Ask what FES, if any, will be available to you when the project is over, or when you stop being an active participant.

FES holds great potential to improve the health, well-being, and quality of life of many people. As you would in considering any elective treatment, learn all you can about FES. If you are satisfied that the application is safe, that it may help you, and that you can fit it into your life -- go for it.

PART 2. WHERE TO GET FES

This section is currently not available on the on-line version on this website, but will be soon. You may find the on-line directory through the FES Information Center at website at http://feswww.fes.cwru.edu/info/ Please look under FES Resource Library.

United States Listings

Other Countries

PART 3. MORE RESOURCES ON FES

This section is currently not available on the on-line version on this website, but will be soon. You may find the on-line directory through the FES Information Center at website at http://feswww.fes.cwru.edu/info/ Please look under FES Resource Library.

Suggested Reading on FES

Information and Referral Centers

Professional Organizations

Manufacturers of Electrical Stimulation Equipment

PART 4. GLOSSARY

This section is currently not available on the on-line version on this website, but will be soon. You may find the on-line directory through the FES Information Center at website at http://feswww.fes.cwru.edu/info/ Please look under FES Resource Library.

PART 5. INDEX

This section is currently not available on the on-line version on this website, but will be soon. You may find the on-line directory through the FES Information Center at website at http://feswww.fes.cwru.edu/info/ Please look under FES Resource Library.

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