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STANDING, EXERCISE AND TRANSFERS WITH AN IMPLANTABLE FUNCTIONAL ELECTRICAL STIMULATION (FES) SYSTEM

***Information About Research Participation
for Individuals with Spinal Cord Injury***



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Overview

What is a research study?

- A research study is a scientific investigation that examines and answers questions about how something works. Studies that include investigational devices for human use are registered with the Food and Drug Administration (FDA) and have participants who volunteer to be part of the research study.

What are the goals of this research project?

- To prove the safety, effectiveness and functionality of a surgically-implanted functional electrical stimulation (FES) system that allows selected individuals with a spinal cord injury to exercise, stand, and pivot transfer
- To transfer the technology to other rehabilitation sites for more people to gain access to the system

What is Functional Electrical Stimulation (FES)?

- FES is a rehabilitative technique using low-level electrical current to enhance the function of paralyzed muscles
- FES is not a cure for spinal cord injury (SCI)

How does FES work?

- A device sends small electrical currents through electrodes to excite the nerves and cause the muscles to contract
- The device and electrodes can be external to the body (surface of the skin) or internal (implanted directly in contact with the muscles). This study involves a surgically-implanted system much like a heart pacemaker.

What are the benefits of FES?

- FES may improve the overall health of persons with SCI by:
 - Exercising lower extremity muscles
 - Increasing cardiovascular fitness
 - Reducing osteoporosis and medical complications associated with immobility (i.e. spasticity, pressure sores)

Who is a candidate for this study?

(additional inclusion & exclusion criteria listed on Page 8)

- Minimum age 18 years old
- Spinal Cord Injury levels C6-T12
- Intact lower motor neurons (presence of spasticity in legs)
- At least six months post injury
- No current major mental illness, chemical dependency, or medical complications
- Willingness to comply with terms for participation

What is involved in being a research participant?

- 18 months time commitment
- Understand and sign the informed consent forms
- No cost for implantable FES system or surgical procedure/hospital stay
- Follow pre-surgical routines (evaluation, exercise, and stimulation)
- Undergo surgery and recovery (10 days in-hospital stay)
- Follow training and exercise routines (as specified by research team)
- Participate in system testing (pre-discharge, training, and 3, 6, 12 month follow-up)

What are the components to the FES standing system (shown in Figure 1)?

- Surgically implanted device that receives information from a control unit worn on a waist belt and sends the electrical stimulation to the electrodes (implantable receiver/stimulator)
- Surgically implanted electrodes
- External control unit (ECU), coupling coil and ring-mounted command switch
- AC power adapter/battery charger with auxiliary battery pack
- Laptop computer with clinical software
- Walker and ankle foot orthoses

Overview (continued)

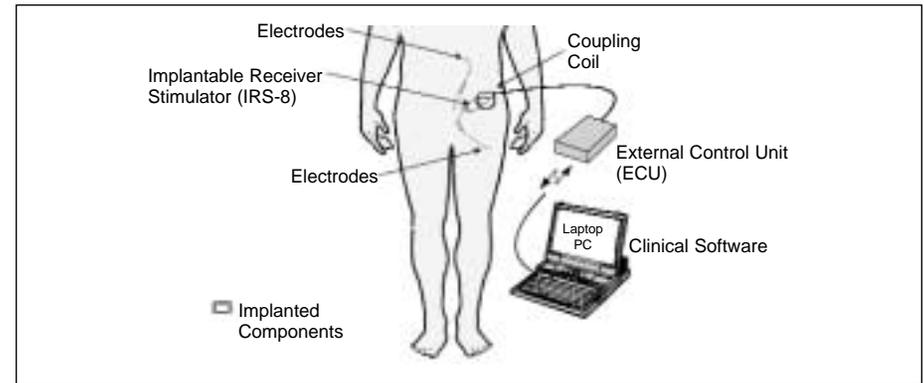


Figure 1: Components of the FES standing system.

Background

If the damage resulting from a spinal cord injury affects only the central nervous system and the muscle and other nerves remain healthy, then the intact peripheral nerves (branching nerves that supply the arms and legs) can be excited with an electric current, causing the muscle fibers to contract. Functional electrical stimulation (FES) refers to the activation of muscles to obtain a coordinated and useful movement from an otherwise paralyzed limb.

FES offers advantages over other assistive devices for standing or transfers including easy application, increased versatility, and prevention of muscle atrophy by using the body's own power^{1,2}. Standing with FES allows users to reach objects from high shelves, gain entry to places inaccessible from the wheelchair,

and participate in social or work situations on eye level with their peers. FES not only provides the ability to stand, it can also facilitate an assisted transfer by raising, supporting and lowering an individual under the power of his or her own stimulated muscles³.

FES can positively impact the overall health of persons with SCI. Long periods of immobility can cause degenerative changes of almost every major organ system including the bones and joints, bowel and bladder, heart, lungs and skin. Long-term follow-up of FES system users has revealed decreases in spasticity⁴ and increased muscle bulk, which may reduce the risk of developing pressure sores. Exercise with FES may also improve cardiovascular fitness⁵ and reduce osteoporosis⁶.

History of the Implantable FES System

Investigators at Case Western Reserve University (CWRU) and the Louis Stokes VA Medical Center in Cleveland (VA) developed an implantable FES system to provide active hand grasp and release to individuals with C5/C6 level tetraplegia⁷. The device received Food and Drug Administration (FDA) approval in August

of 1997, and to date has been implanted in more than 200 individuals. The implanted components have proven to be safe, effective and reliable in one participant for more than ten years. Application of the CWRU/VA system in the lower extremity for standing and transfers is another use for this proven technology.

Description of FES Standing System Components

The components of the FES standing system that are placed inside the body during surgery are shown in **Figure 2**. The system consists of an implanted device (implantable receiver/stimulator) that receives information from an externally worn control unit (ECU) and sends the electrical stimulation to eight electrodes (one electrode to one muscle). There are two types of electrodes: epimysial electrodes lay on the surface of the muscle and intramuscular electrodes are embedded in the fibers of the muscle. **Figure 3** is a x-ray showing the placement of the internal components.

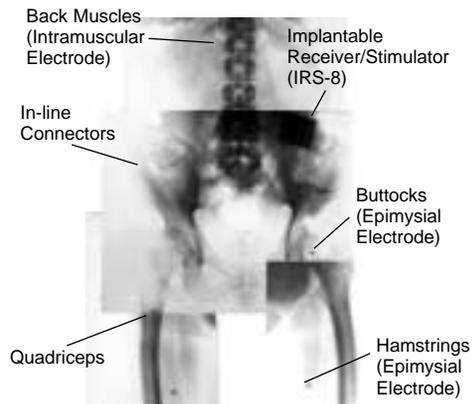


Figure 3: X-ray of the FES standing system

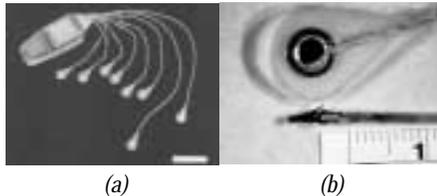


Figure 2: Implantable components of the FES standing system (not to scale). a) The eight-channel implanted receiver-stimulator (IRS-8) and epimysial electrodes b) Close-up of epimysial (top) and intramuscular (lower) electrodes.

The 8-channel implantable receiver/stimulator (IRS-8) contains no batteries. The external control unit (ECU) powers and instructs the IRS-8 via radio frequency signals. Buttons mounted on the ECU (or on a ring-mounted command switch worn on the index finger) allow the user to select and activate the standing or exercise patterns of electrical stimulation. Ankle foot orthoses and a walker are also provided to system users. The external components of the standing transfer system are depicted in **Figure 4** and consist of the ECU, coupling coil, and ring-mounted command switch. An AC power adapter/battery charger and auxiliary battery pack are also provided. Together with a laptop computer and the internal components in **Figure 2**, these external components comprise the entire standing system being evaluated in this study.



Figure 4: External components of the FES standing system, including the external control unit (ECU), coupling coil, and ring-mounted command switch.

Complete instructions on how to use the ECU for standing and exercises will be described during the training periods of the study. Stimulation for standing begins by pressing a button on the ECU, which is worn on a belt at your waist. Pressing the button activates the pattern for standing, which begins with a “beep”. A three-second delay allows you to prepare to stand by repositioning your body at the edge of the wheelchair and placing your hands on an assistive device (parallel bars or a walker). A second “beep” is heard immediately before the stimulation begins. A final “beep” signals the end of the maneuver, allowing you to adjust your standing position while constant stimulation is maintained. Pressing the button again reverses the sequence.

Participant Inclusion and Exclusion Criteria

The Cleveland FES Center and its affiliates (Case Western Reserve University, Louis Stokes VA Medical Center in Cleveland and MetroHealth Medical Center) do not discriminate against

anyone in employment, educational programs, activities or admissions based on race, gender, religion, national origin, age, marital status, or handicap.

The inclusion criteria for the study are as follows:

1. Skeletal maturity and ability to understand and sign the informed consents (age greater than 18 years)
2. Low cervical or thoracic spinal cord injuries (C6-T12).
3. ASIA Impairment Scale A (complete motor and sensory deficits) or B (sensory sparing) for mid- to low-thoracic injuries (T4-T12) or ASIA Impairment Scale A, B or C (motor and sensory sparing) for low-cervical/high-thoracic injuries (C6-T4).
4. Time post injury greater than six months (neurological and emotional stability).
5. Intact lower motor neurons (intact peripheral nerves).
6. Absence of acute or chronic psychological problems or chemical dependency.
7. Range of motion within normal limits (no greater than five degree flexion limitation at the hip, 10 degrees at the knee, and ability to attain neutral ankle position).
8. Full coverage of the acetabulum and minimal knee and ankle laxity.
9. No acute orthopaedic problems (scoliosis, dislocations, etc.).
10. No acute medical complications (cardiac abnormalities, skin breakdowns, uncontrolled seizures, immunological/pulmonary/renal/circulatory compromise, etc.).
11. Adequate social support and stability
12. Willingness to comply with follow-up procedures.

Criteria for exclusion include the following:

1. Pacemaker
2. Cardiac arrhythmia
3. Pregnancy
4. Severe contractures of any major joint of upper or lower extremities
5. Seizure disorder
6. Obesity
7. Untreated substance abuse
8. Immunodeficiency
9. Frequent urinary tract infections
10. Presence of decubitus ulcers



The Terms for Participation

The educational component of the informed consent process takes place continuously over a period of months between initial contact and the implant procedure. Potential participants and their families or caregivers interact one-on-one with members of the research team as all procedures and potential risks and benefits are thoroughly explained. Candidates also have the opportunity to meet and confer privately with current study participants who can offer first-hand accounts of their involvement in the program. Participation

in the project and receipt of the implanted FES standing system will be free of charge. Although the results of this study may appear in scientific publications, patient records will remain confidential at all times and participants will not be identified by name or in any other manner (without his or her permission) that might violate his or her privacy.

If an invitation to participate in the study is extended, volunteers will be asked to sign Informed Consent Forms and agree to the following:

TERMS OF PARTICIPATION

If I am accepted as a research participant and I continue to be in good health, I will be expected to participate in the study for 18 months. I am responsible for the use of the standing system for exercise, standing and transfers, as recommended by the research team. I am responsible for providing feedback to the research team regarding the system, reporting any system problems immediately, maintaining a log of use and exercise, reporting any dental or medical procedures, and following all of the protocols of the research project (including testing, training, and evaluations). I am also responsible for seeking immediate medical treatment for any health problem that may be related to my FES system including a local or systemic infection. If I am unable to continue my responsibilities, I may be asked to leave the study. Special considerations for any of the above mentioned items will be given when the research team deems appropriate.

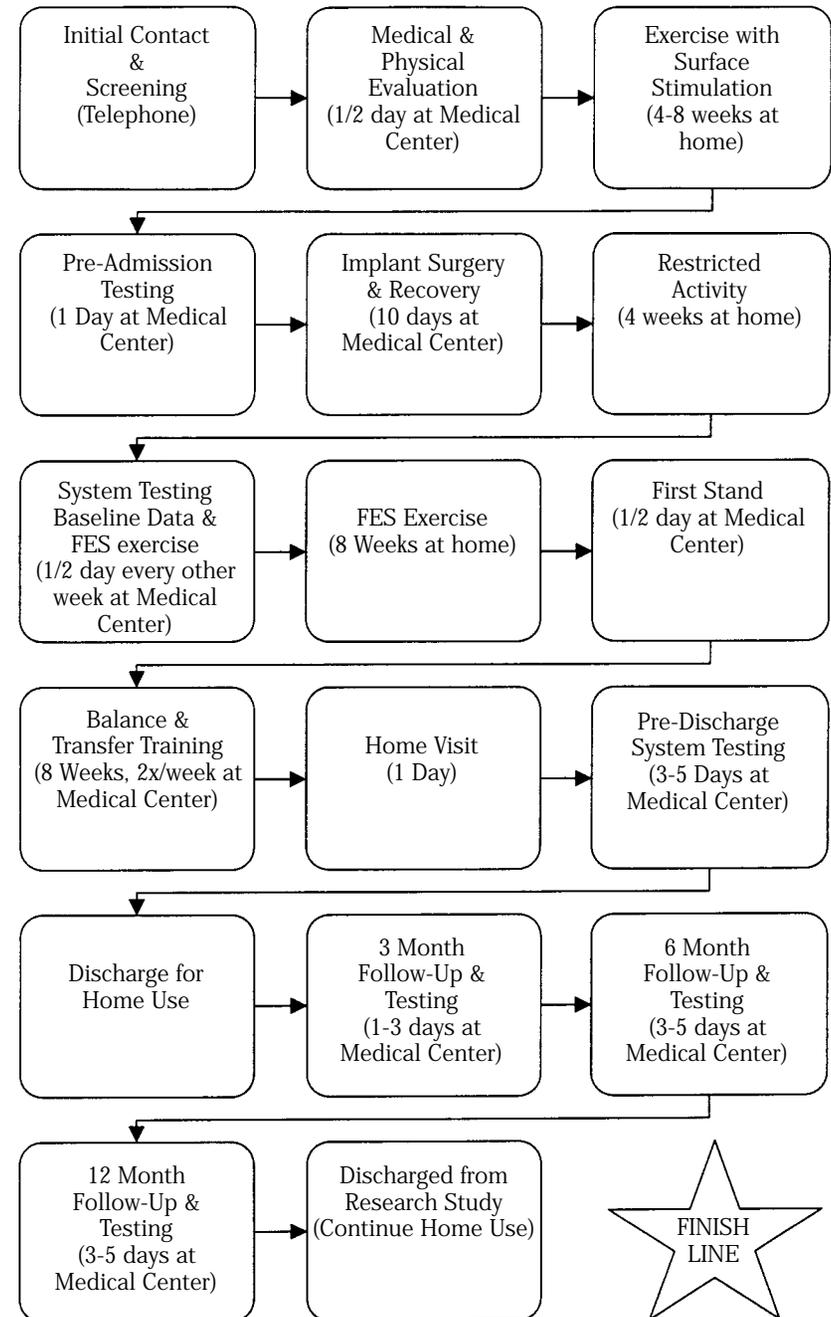
I understand that this research study is currently funded through grants. I understand that the grants are subject to renewal and if they are not renewed, the study may be terminated.

In agreeing to participate, I understand that I am free to withdraw from the study at any time, for any reason, without being required to provide an explanation. My decision to participate in the study will in no way interfere with any future therapy or benefits to which I am entitled, or any other medical treatment prescribed by my attending physician. I understand that the system will not interfere with any future developments addressing spinal cord injury, and that I may have the system removed.

I have read the terms of participation, along with the consent forms, and discussed the contents and implications with the research team. I have had my questions answered in a satisfactory manner.

Participation Outline and Timeline

The following highlights the key steps of study participation:



Participation Outline & Timeline (continued)

Steps involved in participating in this research study:

- Once contact has been initiated, a telephone interview answers background questions for participant screening purposes.
- A Clinical Review Board reviews the potential candidate's information.
- If approved by the Clinical Review Board, the potential candidate undergoes a thorough medical and psychological screening before being accepted into the project. A complete medical history is obtained and a physical examination is performed to identify any conditions that would contraindicate participation.
- The research team renders a decision. If no exclusion criteria exist, the team extends an invitation of participation into the research study. If the potential candidate accepts the invitation and terms of participation, he/she officially becomes enrolled in the study, through the informed consent process.
- Participant begins exercising the target muscles through surface stimulation and continues for at least six weeks, or until the surgical procedure.
- Approximately two weeks before the surgery, the participant goes through pre-admission testing. Although blood loss during the procedure is minimal, a transfusion may become necessary. If the participant chooses, he/she may donate blood prior to the surgery (please ask about further details).
- The participant undergoes the surgery. The surgery is performed at either MetroHealth Medical Center or the Louis Stokes VA Medical Center in Cleveland. The procedure lasts for approximately 8 hours, consists of 13 incisions and is separated into three stages. The target muscles for the electrodes include of the following:
 - Quadriceps (vastus lateralis)
 - Back Muscles (erector spinae; levels L1-L3)
 - Buttocks (gluteus maximus)
 - Hamstrings (semimembranosus or adductor magnus)
- The participant remains in the hospital for approximately 10 days of recovery. This gives the incisions time to heal and protect the electrodes.

If the surgery is performed at MetroHealth Medical Center, the participant stays at the General Clinical Research Center (GCRC). The GCRC is funded by the National Institute of Health (NIH) and is a fully staffed hospital floor available for patients undergoing experimental procedures requiring medical observation. The GCRC at MetroHealth has experience in the treatment and care of patients with spinal cord injuries, as well as recipients of implantable FES devices.

If the surgery is performed at Louis Stokes VA Medical Center in Cleveland, specialists on the SCI unit provide post-operative care.
- The participant must restrict activities after discharge, for 4 weeks post-discharge.
- The electrodes are tested for threshold values (lowest level of stimulation that the muscles respond) and exercise patterns are set 6 weeks post-surgery. The exercises continue for 8 weeks.
- The participant performs his/her first stand, after being trained by the physical therapist to accommodate a wheelchair and environmental conditions.
- The research team visits the participant's home to determine any unusual environment conditions that should be addressed during the training.
- Several types of tests, including x-rays, strength & endurance, transfers at various heights, etc., are performed before discharge and at intervals during the following year (3, 6, and 12 months).

The Surgical Procedure

The stages of the surgery are shown in **Figure 5**. In stage one, epimysial electrodes are placed in the quadriceps and the leads are routed under the skin to connector sites (where the electrode leads will connect with the IRS-8) on the abdomen. During stage two, intramuscular electrodes are placed in the back muscles and epimysial electrodes are placed in the buttocks and hamstrings. Six electrode leads are routed to side incision sites. During the final stage, the six leads from

the two side sites are routed to and join the quadriceps leads at the connector sites. The IRS-8 is placed into the left side of the lower torso, oriented with the leads towards the body's midline and the implant leads are connected to the electrode leads. The upper four channels connect to the muscles on the right side of the body and the lower channels connect to the left side, preventing wires from crossing each other.

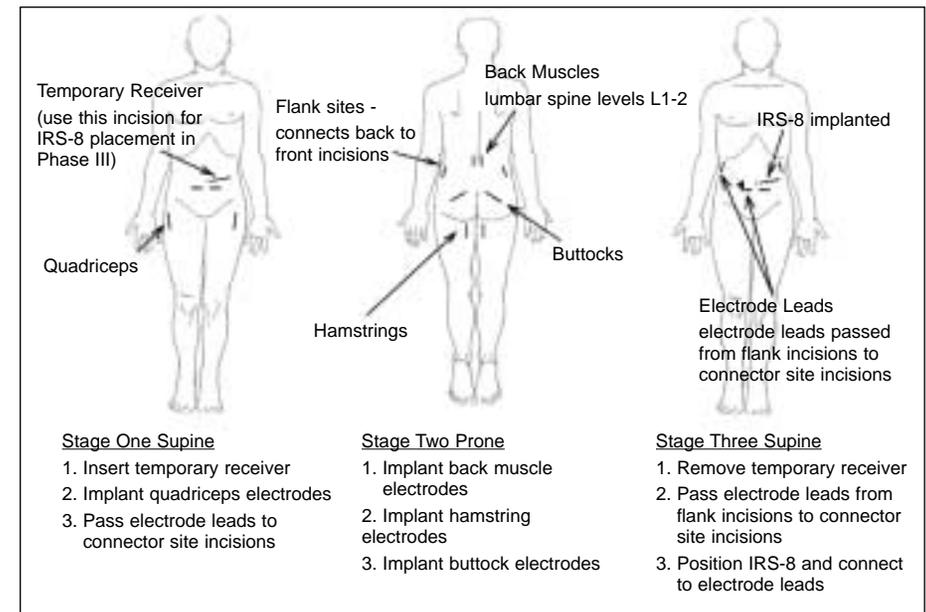


Figure 5: Incisions and surgical stages for installing the FES standing system

Risks Associated with the FES Standing System and Surgery

The usual discomforts and inconveniences of being hospitalized and having surgery are part of participation in this study. In addition, participants are expected to come to MetroHealth Medical Center, the Cleveland VA Medical Center or their local participating center on a weekly basis for post-operative rehabilitation and training for several months after the implant. After that time, travel will be minimized. Routine testing and check ups will occur at three, six and 12 months post discharge with the FES system. While most tests are shorter, some may take as long as several hours. When using the FES system at home, participants will need to respond to telephone interviews or home and work site visits by the research staff.

The following are known risks associated with this investigation and the precautions taken to minimize them:

Surgery - There are associated risks with any surgical procedure and the use of anesthesia. To minimize this risk, complete monitoring will be performed by a qualified anesthesiologist during the operation to assure safety.

Infection - There is the risk that the implanted device could become infected. To reduce the likelihood of infection, special steps for implanting artificial devices (including extensive cleaning of the surgical area prior to the operation, antibiotic medication prior to the operation and the procedure will be done in an operating room which is set-up for doing joint replacement operations) will be taken. If an infection occurs, further antibiotics will be prescribed. If this is unsuccessful, the device may have to be removed in a second surgery.

Device Malfunction - There is the risk that the implanted device could fail to operate properly. This may happen due to failure of the device itself or failure of the electrodes and leads. Manufacturing procedures have been set up to reduce the chance of malfunction. If failure should occur, the investigators will analyze the failure and replace the faulty component. This would require a second surgery.

Device Rejection - There is a chance that the body might reject the device. To reduce the possibility of a foreign body reaction, all materials used in the implant have been thoroughly tested for biocompatibility. They are approved for human usage and have been employed in other implanted devices such as heart pacemakers. Still, some unknown process could cause a rejection reaction. If this were to

happen, the subject would be counseled regarding the nature of the problem and the device would be removed.

Tissue Erosion - The skin and tissue over the implanted material could be eroded from repeated rubbing and abrasion, exposing the device or causing part of the implant or lead to protrude through the skin. The device and leads are designed to avoid such erosion. If the tissue were to erode, subjects would be counseled regarding the nature of the problem. If requested by the implant recipient, the entire device could be removed at that time, or repositioned in a surgical revision.

Scarring - Tissue around the device or electrodes could become excessively scarred from the surgical procedure or the presence of the electrode. It is also possible that scarring might be induced as a result of electrical currents in the tissue over a long period of time. These changes would show up with changes in the function of the device. If such scarring interfered with the function of the implanted devices or presented a safety problem, the electrode or stimulator could be removed or replaced.

Other Risks - As with any use of electricity, there is a risk of an electrical burn. The stimulators are designed to prevent any current flow at levels that might cause tissue damage. In this way the risk of electrical burn will be minimized. With extremely low probability, there is a risk of heart or nervous system problems (irregular heartbeat, blood pressure, or autonomic dysreflexia). Careful monitoring can further minimize these risks. In addition, there is a risk of falling and the possibility of bone fracture while exercising or standing with FES. There have been no occasions of injuries resulting from falls while standing or transferring in the preliminary studies leading to this investigation. Procedures to reduce the risk will include close supervision of initial attempts at standing by a qualified member of the research staff and detailed instructions and training in proper safety precautions. Extensive functional training, including home visits to identify potentially dangerous situations and maximize safe and effective use of the system, is included in the implementation protocol. Unsupervised use will be permitted only after completing the required course of rehabilitation and training. Participants will perform at home only those exercises or maneuvers that have been specifically approved by the research staff. Another risk is sprain or joint deterioration resulting from overuse, especially in the absence of sensation in the extremities. After daily use of the system for one year, x-rays and a bone scan of the knees, hips and ankle joints may be done to check for possible damage.

Frequently Asked Questions and Answers

What does the FES standing system cost?

Because this is a research project, the only cost to you is time (including travel time). There is no cost for the FES standing system, the surgery, the hospital stay or the training/testing materials and time.

What if I have muscle spasms?

Spasms are desirable, as they usually indicate that the muscles can be stimulated and will respond to FES. Severe or absent spasms may be a problem.

What precautions will I need to take with this system?

The precautions you need to take with the implantable FES system are minor. However, you should consult with your physician before any medical or dental tests or procedures. You will need to remove the external components of the system before you bathe or shower.

What are the rates of infection or body rejection of the system?

To date, for the participants receiving this FES system for the purposes of standing, there have been no incidences of infection or body rejection.

What happens if the project loses funding?

If this should happen, the project will be terminated and no further electrical stimulation would be done. All of the implanted components will remain in place unless you desire them to be removed. In this instance, the internal components will be removed in another surgical operation. Otherwise, you will be able to receive follow-up examinations as long as the resources are available.

If new technology develops and I want to explore those options, can I have the system removed?

You may withdraw from the research study at any time, for any reason, without being required to provide an explanation. Your decision to participate will in no way interfere with any future therapy or developments addressing spinal cord injury. You may have the system removed at any time, through another surgical operation.

What type of relationship will exist after the required time involvement?

The research team will periodically call to ask how you are using the system and how it is working. If you have a medical or dental procedure performed, we ask that you contact us. Please inform your doctor that you have an implanted FES system.

Is there a system for walking?

A second implant procedure consisting of an additional 8-channel receiver/stimulator and electrodes can be performed, for qualified participants, after completion of the described standing research study protocol. This additional system provides stepping capabilities for short distances.

Is this system available outside of the Cleveland FES Center?

The implantable FES system for standing, as described in this informational brochure, is only available through participation in the research study conducted through the Cleveland FES Center and with its affiliates.

Glossary

Adductor Magnus - muscle located on the inner back part of the thigh; secondary muscle option for the hamstring epimysial electrodes.

Central nervous system - one of two main divisions of the human nervous system consisting of the brain and spinal cord.

Coupling coil - a small circular device that is placed on the skin over the IRS-8 and is connected to the ECU. This coil is what connects ("couples") the ECU to the IRS-8.

Epimysial electrode - electrodes that are fixed to the surface of a muscle. The epimysial electrodes are made of platinum disks with Dacron®-reinforced elastomer skirts.

Erector Spinae - a series of muscles in the lower back that helps resist the action of bending forward; location for the intramuscular electrodes.

External control unit (ECU) - a device that is worn around the waist and contains the power and information that is sent to the IRS-8. Buttons on the ECU are pressed by the user to control the system.

Functional electrical stimulation (FES) - a rehabilitative technique where low-level electrical current is applied to enhance the function of paralyzed muscles.

Gluteus Maximus - the largest muscle in the buttock region that receives epimysial electrodes. This muscle assists the body in the motion of rising to a standing position.

Hamstrings - The group of three muscles on the back portion of the thigh.

Implantable receiver/stimulator (IRS-8) - small electrical device that is surgically implanted into the lower left abdomen of the recipient. The device receives power and information from the external control unit and sends it to the eight electrodes.

Intramuscular electrode - electrodes that are placed within the muscle tissue. A polypropylene barbing mechanism holds the intramuscular electrode in place.

Muscle atrophy - a decrease in the size of the muscle resulting from a wasting away of tissue, usually caused from a lack of use.

Peripheral nervous system - one of the two main divisions of the human nervous system including the sensory and motor nerves that branch to the organs and limbs of the body.

Semimembranosus - the hamstring muscle on the back portion of the thigh that is the target site for an epimysial electrode.

Quadriceps - A group of four muscles that cover the front portion of the thigh.

Vastus Lateralis - the strongest muscle in the group of quadriceps that is the target site for epimysial electrode.



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