

Functional Electrical Stimulation

Electrical activation of nerves and muscles can be separated into two categories: therapeutic intervention and functional restoration. Therapeutic intervention is used to modify an existing condition so that as a result of temporary or intermittent stimulation there is a persistent effect producing a desired goal that extends beyond the actual delivery of the electrical stimulus. Functional restoration, also known as functional electrical stimulation (FES) or function neuromuscular stimulation (FNS), involves the user wearing a device, called a neuroprosthesis, to achieve a particular function. Examples of therapeutic intervention are the electrical stimulation of paralysed muscle to prevent bedsores and to improve cardiovascular fitness. Another example is the stimulation of the broken ends of a fractured bone to promote healing. Examples of FES are standing and walking after spinal cord injury (SCI), and restoration of bowel and bladder control and erection and ejaculation after SCI.

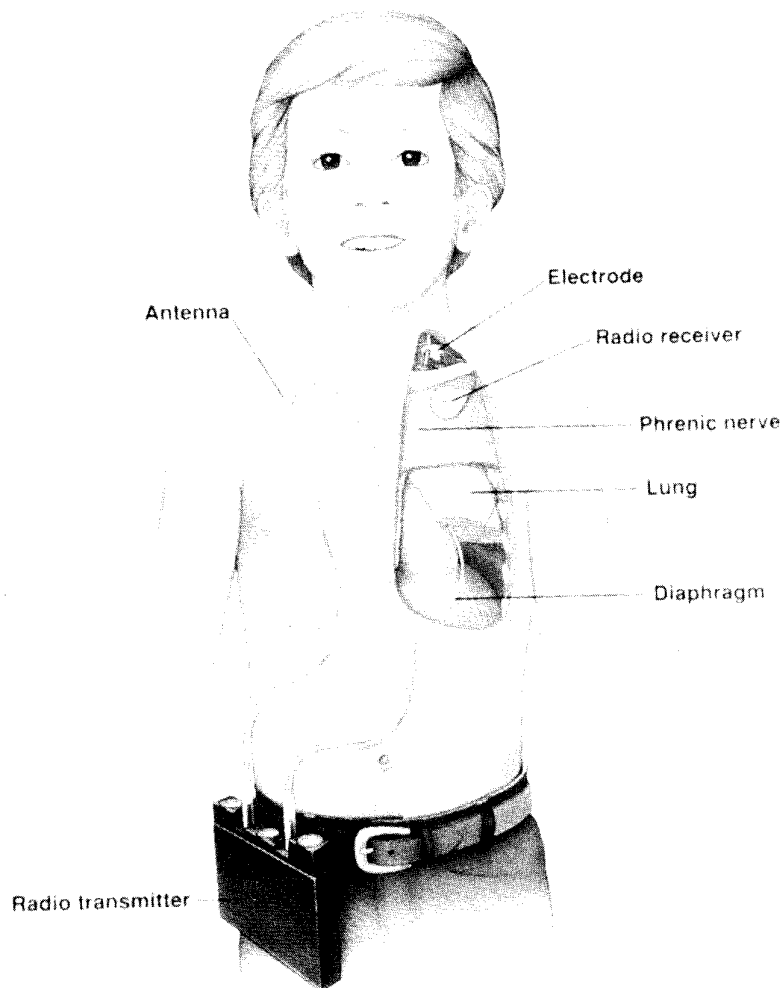
The majority of patients requiring and able to benefit from FES are those with SCI. These patients tend to be young adults who are otherwise healthy. Lifestyle factors put them at greatest risk; the most common causes of SCI being motor vehicle accidents, falls and industrial accidents. To restore movement, motor nerves supplying muscles are stimulated, rather than directly stimulating the muscles themselves. The reasons for this are that a saving of approximately 100 times in stimulating current amplitude may be made and muscle fatigue may be reduced if the nerves are stimulated. Nerve fibres individually supply many muscle fibres and the fibres are bundled closely together in a nerve, so greater effect may be achieved by stimulating these fibres rather than attempting to stimulate all the individual fibres in a muscle that are spread over a much larger volume. This requires that the nerves themselves are intact, as well as the muscles. The cell bodies of motor nerves form the anterior horn cells of the spinal cord. They are frequently injured in SCI, causing a lower motor neurone lesion, and so rendering their corresponding muscles unsuitable for FES.

Electrical Activation of the Nerve

Stimulation of the nerve occurs when a current flowing through the nerve raises the membrane potential above threshold. The current is provided via a pair of electrodes that may be implanted or on the skin surface. Two electrode arrangements are used. A pair of small electrodes may be placed near the nerve (bipolar stimulation) or a large reference (indifferent) electrode may be placed at a distance from the nerve with a smaller, closer active electrode (monopolar stimulation). A smaller stimulation threshold current results if the closer electrode is the cathode as it more readily depolarises the outside surface of the nerve fibre membranes that are positively polarised. Bipolar stimulation allows a more precise direction of the stimulation current. Monopolar stimulation allows fewer electrodes, when several nerves are being stimulated, as only one reference electrode is required. The magnitude of a muscle contraction may be increased by increasing the stimulus amplitude or pulse width, or by increasing the pulse repetition frequency. Typical stimulus frequencies vary from 12 – 15 Hz. At low stimulus amplitudes larger diameter fibres fire first with smaller, higher threshold fibres being brought in as the stimulus amplitude increases. This is the opposite order to natural stimulation where smaller diameter fibres fire at low levels of contraction and larger fibres come into play as the contraction strength

increases. In FES charge balanced pulses are used, ie the pulses reverse polarity so that the charge flowing in each direction is equal. This prevents ionisation of the electrode material with subsequent deposition in the tissues. Current, rather than voltage, controlled stimulators are used as impedance may increase as a surface electrode becomes detached or an implanted electrode is surrounded by a sheath of fibrous tissue. Under these circumstances the stimulating current would decrease with a constant voltage stimulator and the muscle contraction would diminish in strength. Although surface electrodes are simpler, cheaper and easier to place, fully implanted electrodes and stimulators are more reliable and offer more precise stimulation of required muscles with less pain.

Example of an FES phrenic pacing system



Diaphragm Pacing

Of those people who sustain a high cervical chord injury, a substantial number require some form of mechanical ventilation of their lungs initially. Most will be able breathe spontaneously with recovery, but 25% will remain dependent upon some form of ventilation support for the remainder of their lives. Most of these injuries occur in young, otherwise healthy people with a life expectancy of 20 years or more, assuming

they have access to appropriate medical care. The people who remain dependent on ventilators generally are also tetraplaegic (quadriplaegic) so that they have multiple disabilities. They require a tracheostomy, constant attendant care and suffer difficulty with speech, physical discomfort, reduced sense of smell, and anxiety due to fear of disconnection and maintenance of a relationship with care-givers. Mechanical ventilators are bulky with cumbersome attached tubing and require an external power source to re-charge batteries.

Phrenic nerve pacers were designed by Dr William Glenn at Yale University in the 1960's to drive the diaphragm in suitable patients. In the early 1980's the first commercial phrenic nerve pacers were introduced and are now manufactured by two American, one Austrian and one Finnish company. They have now been implanted in about 1,000 patients world-wide. Suitable patients are those with an intact phrenic nerve motor neuron pool in their cervical spinal cord on both sides. This can be checked by measuring the phrenic nerve conduction velocity and the diaphragm muscle compound action potential. To do this the phrenic nerves are stimulated by needle or surface electrodes in the neck and the diaphragm muscle electromyogram (EMG) is recorded from electrodes placed low on the chest at the front.

The devices consist of a receiver and electrode system for each side, that are implanted in the chest or the neck, and an external controller, transmitter and aerial. The electrodes may be monopolar, bipolar or quadripolar. The Finnish quadripolar system consists of two bipolar electrodes that reverse polarity so that four different areas of the diaphragm are stimulated. The lower effective stimulation rate for each muscle group reduces fatigue and allows a more rapid transformation of muscle fibres to more fatigue resistant, slow twitch, Type 1 fibres. Some electrode systems have a moulded silicone rubber backing shaped as a trough into which the phrenic nerve is placed.

The controller is strapped to the patient with the aerials adhering to the skin over the receiver implanted into the anterior chest wall. The controller is powered by a rechargeable battery and the transmitted power also powers the receiver. The controller can be programmed so that respiratory rates in the range 5 – 60 breaths per minute, pulse intervals from 25 – 170 ms and pulse widths of 0.1 – 1.0 ms are possible. Stimulating currents for each electrode are usually in the range from 0.5 to 2 mA.

The electrodes may be implanted into the neck, which is surgically easier but leaves the electrodes more vulnerable to displacement, or into the upper chest. After implantation there is a training period of up to 6 weeks during which the diaphragm is strengthened and transformed to fatigue resistant muscle and the patient is weaned off the mechanical ventilator. The cost of the devices is about US\$60k, excluding the costs of surgery.

Benefits of phrenic nerve pacing are as follows:

- Increased mobility – easier bed-to-chair transfers and transport outside the home
- Improved speech
- Improved sense of well being and health. More normal breathing and tracheostomy closure in some patients.

- Reduced anxiety and embarrassment – elimination of fear of ventilator disconnection, elimination of ventilator tubing, elimination of ventilator noise
- Improved comfort
- Reduced volume of respiratory secretions
- Reduced incidence of respiratory tract infections
- Reduced level of required nursing care
- Reduced overall costs – reduction or elimination of ventilator supplies

Complications of phrenic nerve pacing are:

- Technical malfunction – external components (battery failure, breakage of antenna wires), implanted components (receiver failure, electrode malfunction, breakage of implanted connecting wires)
- Infection – receiver site, electrode site
- Mechanical injury to the phrenic nerve – directly due to surgery, late injury due to scar formation and/or tension on the nerve
- Reduction in ventilation due to altered respiratory system mechanics – increased airway resistance, reduction in lung compliance
- Upper airway obstruction after tracheostomy closure
- Paradoxical movement of the upper rib cage, particularly in children

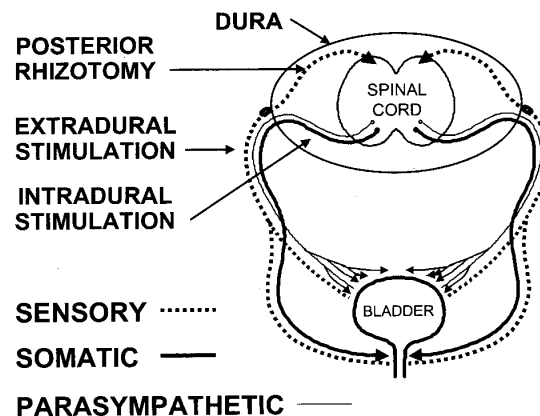


Fig 1. Location of electrodes and rhizotomy. Extradural electrodes are currently approved for use in the United States; intradural electrodes have been used in other countries. Rhizotomy is most reliably done at the conus medullaris, although it has also been done at the cauda equina.

Restoration of Bladder, Bowel and Sexual Function

Voluntary control and conscious sensation of all these functions are lost in SCI; the degree of loss depending on the completeness of the cord transection. The bladder, lower bowel wall, internal sphincters and erectile tissue receive parasympathetic (autonomic) innervation from the sacral segments of the cord. The consciously controlled external bladder and anal sphincters and the pelvic floor muscles are also supplied by similar sacral segments of the cord. Sympathetic (autonomic) innervation, particularly important for ejaculation, is derived from the thoracolumbar segments of the spinal cord and travels downwards in the sympathetic trunks in front of the spine.

Commonly the detrusor muscles of the bladder wall that empty the bladder and the bladder sphincter muscles that prevent micturition (urination) are both in spasm. At high volumes the detrusor muscles win causing incontinence. However the bladder fails to empty completely making the patient prone to bladder infections and calculi (stones). The constant high pressure in the bladder causes back pressure on the kidneys and reflux of urine leading to kidney failure and kidney infections.

The anal sphincter is also in spasm most of the time preventing defaecation so that manual evacuation of the anus is necessary. From time-to-time unwanted reflex defaecation occurs.

Reflex erection may occur but is usually poorly sustained. Reflex ejaculation is difficult to achieve and may be accompanied by autonomic dysreflexia, whose worst feature is an increase in blood pressure that may be dangerously high.

The sacral spinal motor nerves that provide voluntary control of the sphincters are very close to the parasympathetic nerves controlling the bladder detrusor muscle. Thus it is impossible to stimulate one without stimulating the other. However the detrusor muscle relaxes more slowly than the sphincter muscle, so by giving a series of rapid bursts of stimulation, both the detrusor and sphincter muscles contract, but only the sphincter muscle relaxes between bursts, allowing urine to flow. This technique was first developed by Brindley in London. The technique allows urine to flow at desired times but does not prevent reflex or overflow incontinence. Some improvement to urinary incontinence can be made by cutting the posterior (sensory) sacral nerve roots of the spinal cord. This interrupts the voiding reflex that relies on sensation of the degree of distension of the bladder being passed back to the spinal cord through the posterior nerve roots. Cutting of these roots is known as posterior rhizotomy.

The advantages of posterior rhizotomy are:

- Abolition of uninhibited reflex bladder contractions, increasing bladder capacity and abolishing reflex incontinence
- Restoration of bladder compliance (ability of the bladder to expand with minimum tension in its wall) thereby protecting the kidneys from excess back pressure
- Abolition of reflex contraction of the sphincter, reducing uncoordinated detrusor and sphincter contractions
- Abolition of autonomic dysreflexic attacks triggered by the bladder or rectum

The disadvantages of posterior rhizotomy are:

- Loss of reflex erection and ejaculation if still present. Alternatively erection can be produced by prostaglandin injection, by external vacuum or by penile implants. Ejaculation can be produced by rectal electro-stimulation.
- Loss of reflex micturition, although sacral plexus (nerve roots) stimulation is more effective

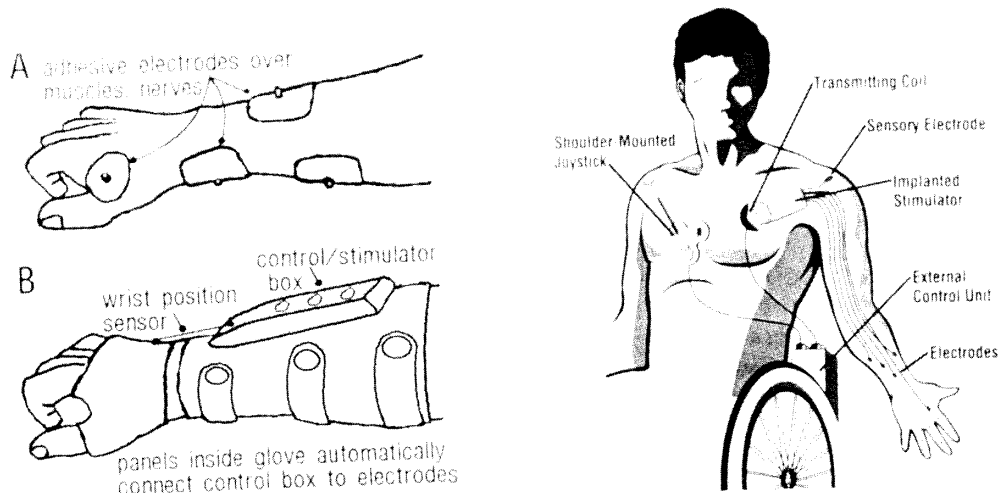
- Loss of reflex defaecation, although this can also be replaced by sacral plexus stimulation.
- Loss of perineal and sexual sensation if this is still present.

Electrodes are placed inside the sacral portion of the spinal cord canal on the S2 – 4 nerve roots. They may be placed inside or outside the dura, the tissue sheet covering the brain and spinal cord. If placed inside the dura it is possible to avoid stimulating the posterior nerve roots, making a posterior rhizotomy unnecessary. However the operation is more difficult with more side effects and has not been approved by the Food and Drug Administration of the USA, so is only performed in Europe. Leads are tunnelled to a radio receiver-stimulator placed under the skin of the abdomen. The patient uses a radio transmitter to initiate micturition. About 50% of patients are also able to defaecate with the stimulator and report a lower incidence of faecal incontinence.

About 60% of males with these implants report erections on stimulation, however ejaculation cannot be produced in this way. Ejaculation of semen into the urethra can be produced by stimulating an electrode placed in the rectum. The semen must then be massaged out of the urethra or retrieved with a catheter placed in the urethra to use it in artificial insemination.

It has been estimated that these devices lead to a savings in cost of care of US\$5,988 per patient per year in the USA, with a range of US\$2,194 to US\$10,909, and would pay for themselves in about 5 to 7 years.

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



Restoration of Upper Limb Function in Tetraplaegia (Quadriplaegia)

FES has concentrated on restoring grasp with the hand and release in patients with C5 and C6 injuries. If the injury occurs below this level, tendon transfer of functioning muscles is used to re-create the ability to grasp objects. Above this level there are not enough functioning muscles for this to be possible. At injury levels above C4 it is difficult to stabilise the arm.

Both implantable and external systems have been developed. External systems have been developed in Israel and Canada and a fully implanted system in Cleveland, USA. The Cleveland system is a multichannel stimulator and receiver unit and electrodes are placed on the surface of the muscles or within the muscle belly so as to stimulate the nerves entering the muscle. It is designed to produce movement of the fingers, thumb, wrist and elbow.

Two types of grasp are used: key grip and palmar prehension and their corresponding releases. Key grip (lateral prehension) is the movement in which the thumb contacts the side of the flexed index finger. This enables the person to hold small objects such as a spoon or a pen. Palmar prehension is the movement in which the index and long fingers touch the thumb. This movement is used to grip larger objects such as a glass or cup. A combination of muscles is used to achieve these two grasps, including the thumb abductor, adductor, long thumb flexor and long thumb extensor and both finger flexors (flexor digitorum profundus and superficialis) and the finger extensors (extensor digitorum communis and extensor indicis). The receiver stimulator unit is implanted under the pectoral muscles and the electrode leads run under the skin (subcutaneously). Tendon transfer can also be used if some of the above muscles have been denervated.

Control of the unit is via an external device with a radio link. The external unit is operated by the opposite shoulder or by wrist flexion and extension on the same side. Wrist flexion or shoulder retraction causes full hand opening. Wrist extension or shoulder protraction causes grasp. The movement is proportional to the patient's controlling movement. The grasp can be locked and unlocked by a rapid shoulder movement or by wrist movement. Feedback of grasp strength is provided by electrical stimulation of the skin just below the clavicle (collar bone). Gradual muscle conditioning is required to increase the strength of the stimulated muscles over a period of 4 weeks. About 120 implants have been done to date.

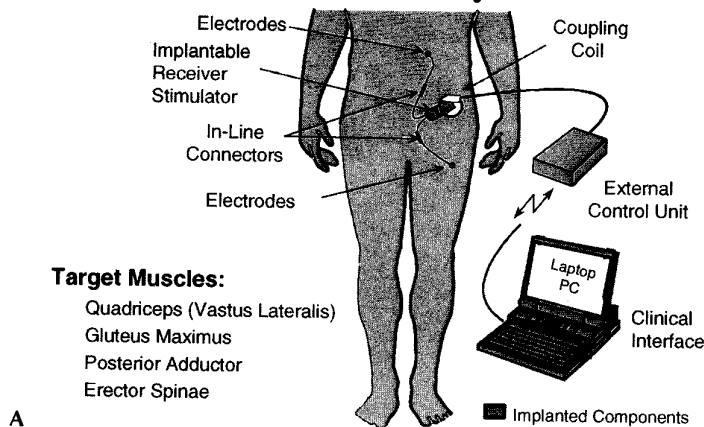
Research into future devices in Cleveland is concentrating on control of all the finger joints, decreasing the size of the devices and providing finer finger control. Feedback of force and position is being explored. Instead of using existing movements to work controls on the external controller, direct wiring of electrical sensors into the patient's controlling muscles is being investigated. In both Europe and Cleveland researchers are also exploring using EEG (electroencephalogram) signals from the patient, mainly beta waves, to control devices.

Restoration of Lower Limb Function

Systems used with patients have included stationary bikes for exercise, transfer systems to enable the patient to move between a wheelchair and a bed, transfer systems between standing and sitting and walking aids. The first systems were external devices enabling walking and were developed in the 1970's in Lubljana, Slovenia by Kralj and Bajd. The initial devices only used two surface stimulation channels for each leg to produce standing and walking. Patients used a rolling walker frame or crutches for support. Buttons on these supports were used to control stimulation. One pair of electrodes was placed on each leg over the quadriceps muscles on the front of the thigh. A second pair of electrodes is placed to stimulate

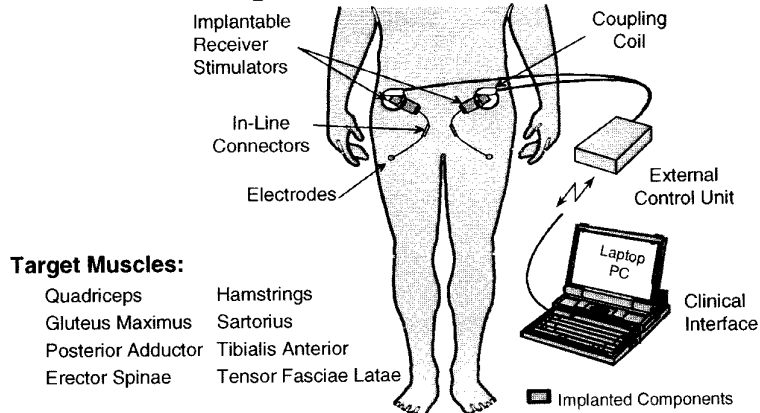
either the sural, peroneal or saphenous nerves of the foot. Standing is achieved by simultaneously activating both quadriceps. A stride is produced by maintaining activation of the quadriceps of the stance limb while initiating a flexion withdrawal reflex in the contralateral (opposite) limb. A flexion withdrawal reflex is flexion of the hip, knee and ankle in response to a noxious stimulus. In this case the noxious stimulus comes from the electrodes on the foot stimulating one of the nerves there. This reflex takes place entirely in the nerve cells in the isolated, lower part of the spinal cord. To complete the reaching phase of the stride, the quadriceps of the swinging leg are activated, straightening the knee, while the hip continues to flex. The stimulus producing the flexion reflex is then removed, leaving the user in double-limb support with both quadriceps activated. The quadriceps is then switched off on the rear limb and a flexion withdrawal reflex commenced on that limb to complete the cycle. Some people have been able to walk at one quarter of their normal speed and ascend a curb or step. Trunk extension is maintained by allowing the spine to adopt an exaggerated backwards arch. The reflex habituates (diminishes with repetition) so there is a limit to the number of steps that can be taken in sequence before the patient must rest. Systems activating the quadriceps only are used for simple standing and transferring from wheelchair to chair or bed.

Standing Transfer System



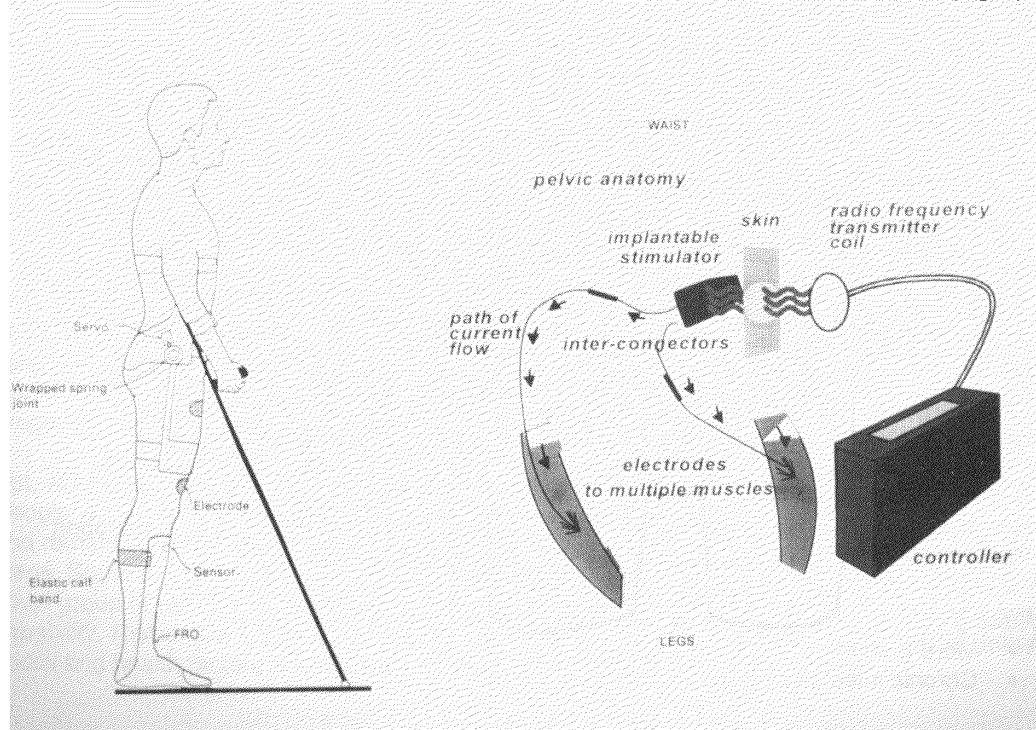
Implanted systems for standing and stepping have been developed in Cleveland, USA and other centres. Similar principles are used but with more stimulation channels so that up to 48 muscles may be stimulated. This gives better control and the implantation frees the patient from cabling. Braces are necessary and the patient must still use a walking frame or crutches. The receiver stimulator connected to the electrodes often receives its power from the transmitted signal from the external controller.

Dual Implant Mobility System



Other conditions must be considered in using these devices. These are the range of motion the patient has, this often being reduced by contracture deformities. Spasticity can interfere with movement. Joint instability with paralysis can lead to damage. Peripheral nerve damage or damage to the motor neurones in the spinal cord can make systems impracticable.

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



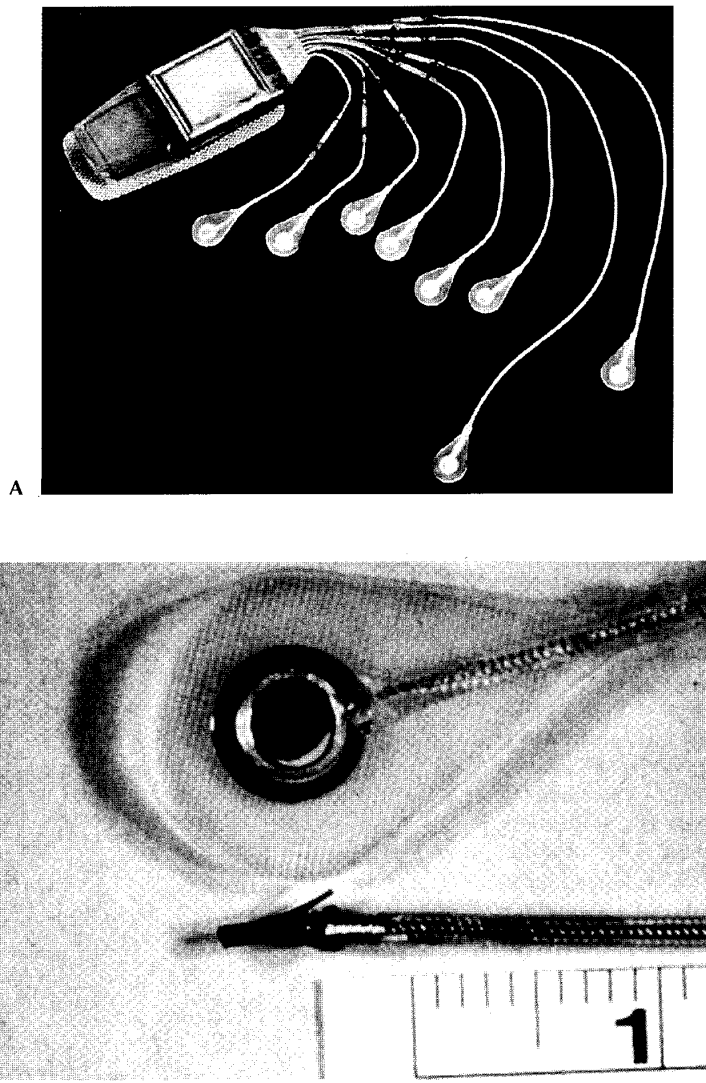


Fig 3. Implanted components of the Case Western Reserve University/Veterans Affairs (CWRU/VA) lower extremity functional neuromuscular systems: (A) Eight-channel implanted receiver-stimulator with in-lead connectors and eight epimysial electrodes, (B) close-up of epimysial (upper) and surgically implanted intramuscular electrodes (lower).

Advanced FES Stimulator for Enhanced Mobility

The Praxis FES device is part of the next generation of devices designed to aid mobility and other functions for people with partial or complete paralysis in their limbs. It is also able to provide bladder control and improve bowel control in some patients. It can also be programmed to provide periodic muscle stimulation to promote circulation in the lower limbs to reduce the incidence of pressure sores. These last two functions are most important as bladder infections, as a result of loss of normal function, and pressure sores are the two biggest problems in patients with spinal cord injuries.

The system consists of external and implanted systems. A controller (the “Navigator”) powers and controls an implanted stimulator through coils under the skin and adjacent, on the skin surface. The surface coil is held in position by magnetics in both the surface and implanted coils, in the same way as the Cochlear hearing device. The implanted device has the capability of 24 stimulation channels. Normally nine electrodes are implanted in each lower limb adjacent to motor nerves where they enter their respective muscles (motor points). Three electrodes activate the quadriceps muscles in the front of the thighs, two activate the hamstrings at the back of the thighs, two the tibialis anterior muscle at the front of the legs and the triceps surae in the calves (flexing and extending the ankle), and two the gluteal muscles in the buttocks. These muscles are used for mobility, general exercise and to promote circulation to prevent pressure sores.

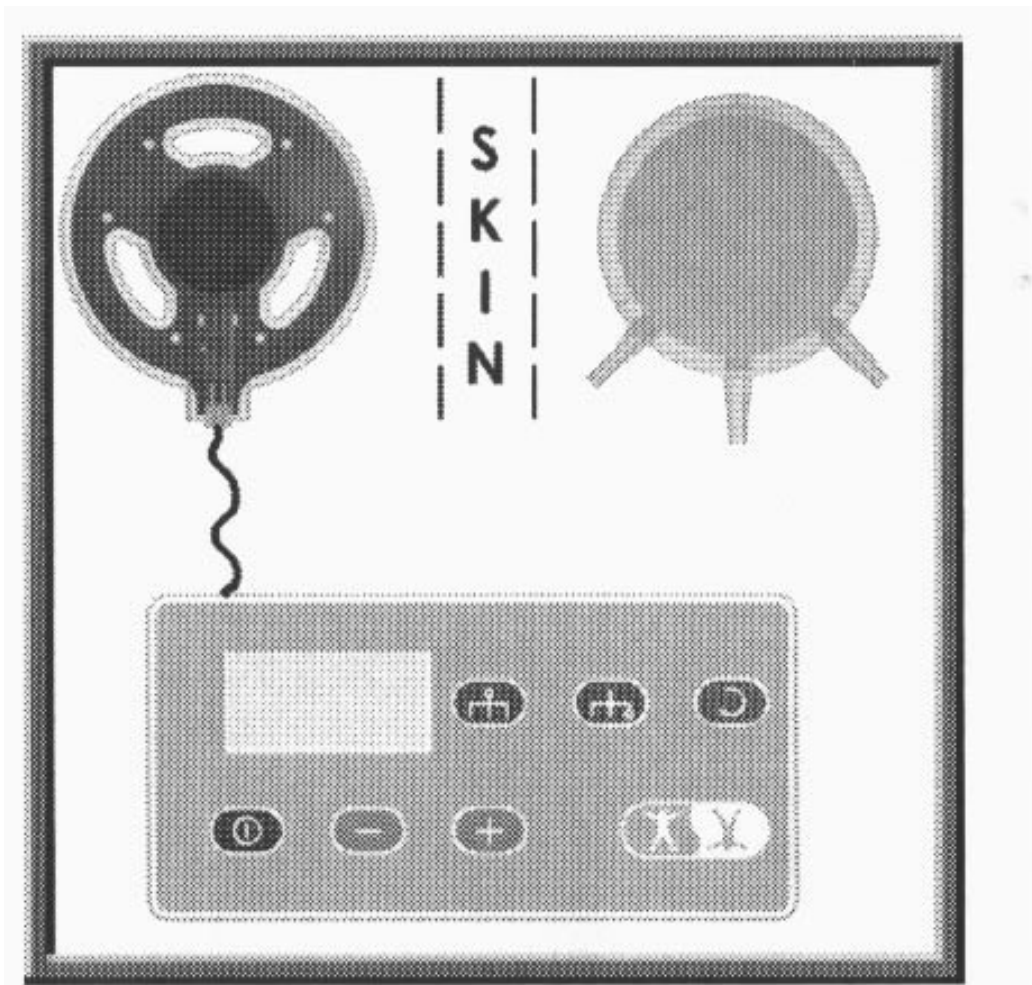


Figure 4 The Praxis FES consisting of an implanted stimulator (top right), a communicating coil (top left) and an external control and power supply (bottom).

Three additional electrodes are implanted on each side of the sacrum adjacent to sacral nerve roots (S2, S3 and S4). These are stimulated in a pulsatile fashion to allow voiding, contracting both the sphincter and detrusor muscles, then allowing the sphincter to relax more quickly than the detrusor. A fourth electrode is implanted over

the conus medullaris at the T12 level. It is hoped that this will allow modulation of the bladder nerves to provide better bladder function.



Figure 5 The external controller and power supply (Navigator) of the Praxis system, showing the push-buttons and the LCD display (top right).

The external Navigator is powered by 'AA' batteries that have a life of 8 hours. It can store up to 8 software strategies that can be activated by the user from a simple keypad with the aid of a two-line LCD display of menus. Positional information concerning the trunk, thighs and legs (shanks) comes from microprocessor-controlled sensor packs that are strapped to the trunk, thighs and legs. These each contain a gyroscope and two 2-D accelerometers. The sensor packs derive their power from the Navigator and are connected to it by cables. It is hoped that the use of these sensors will avoid the need for the patient to think through each movement and will also enable the patients to walk without the aid of crutches or a walking frame. Clinical trials are presently in progress through out the world.

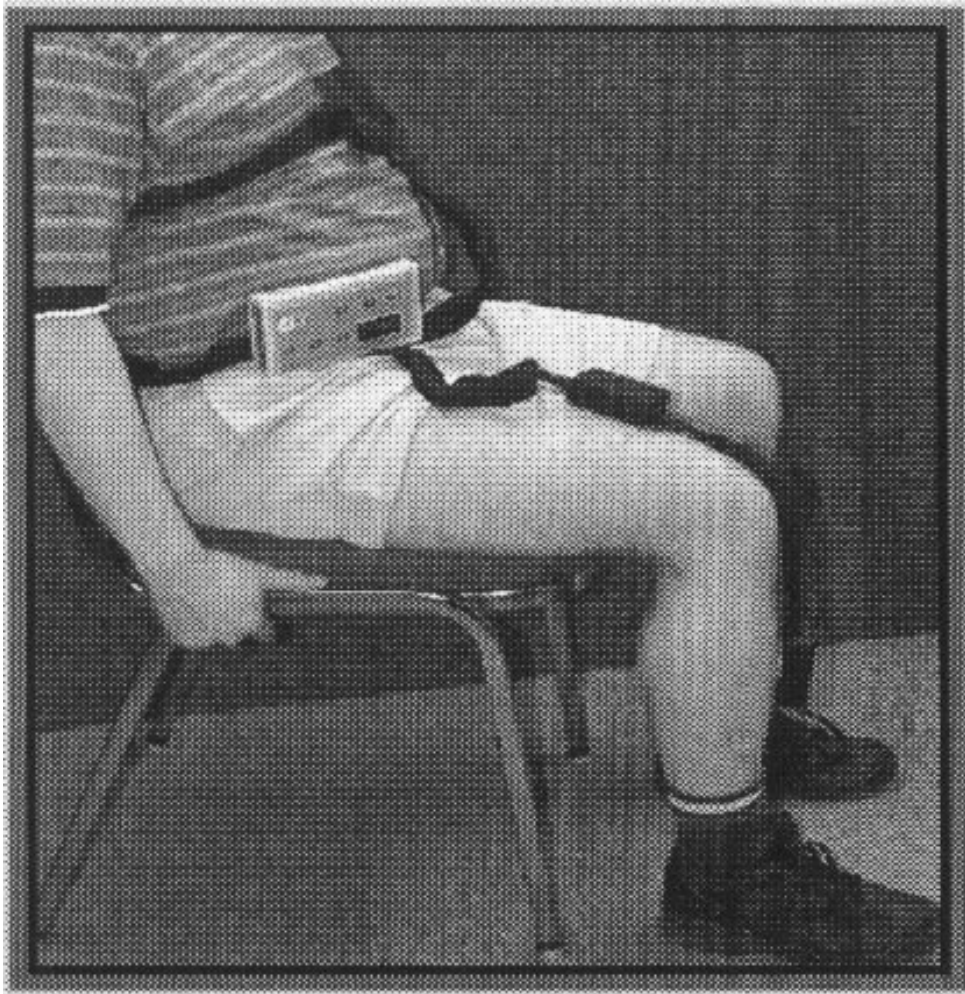


Figure 6The complete Praxis external system showing the Navigator controller worn on a belt and sensors with gyroscopes and accelerometers attached to the body, front of the thigh and the front of the shin.

The implanted device is the same as in the Cochlear hearing device. It is implanted under the skin above the left costal margin. It uses the same radio frequency data protocol as the Cochlear. It is able to transmit back to the Navigator the impedance of all electrodes. It provides charge balanced pulses up to 8mA peak amplitude and with widths from 25 to 500 μ s. The repetition frequency can range up to 14.4 kHz.

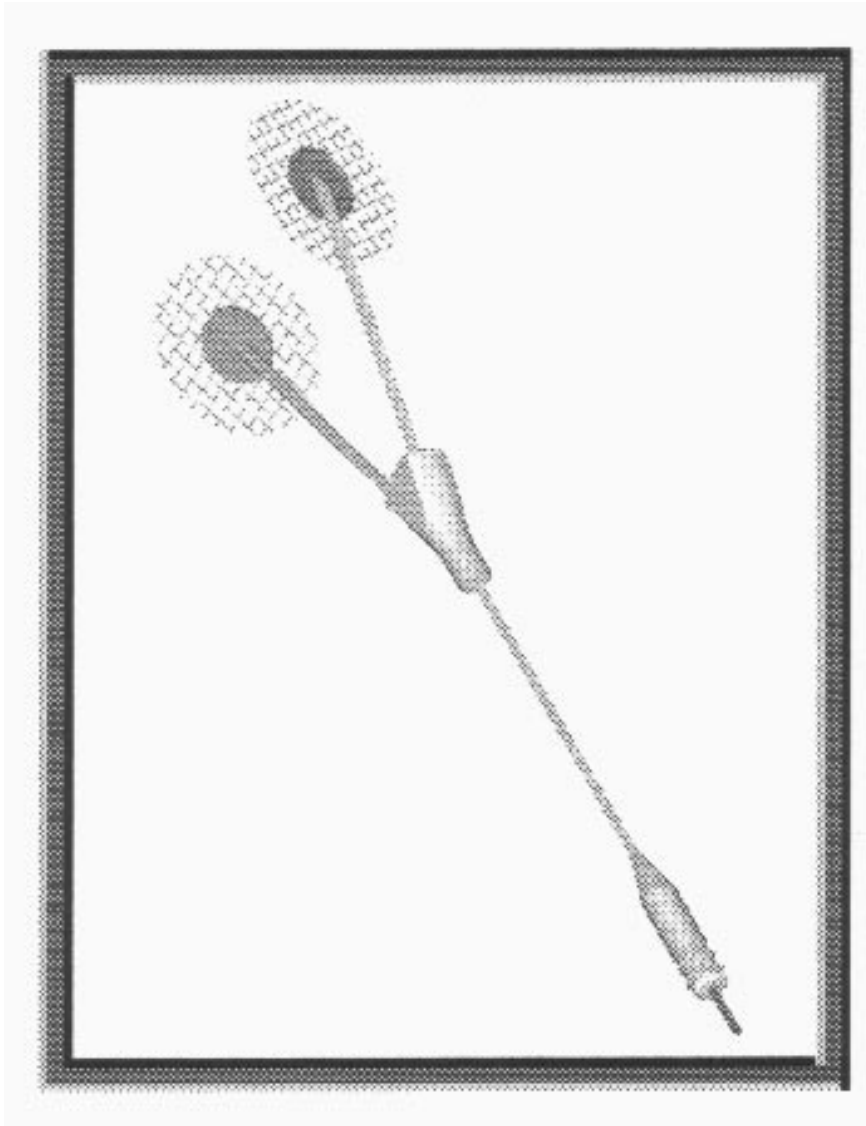


Figure 7 Muscle electrodes implanted either side of the nerve to the stimulated muscle, usually directly on the muscle itself.

Peripheral nerves are stimulated with button electrodes of 3 mm diameter Pt mesh which are sutured in place. The electrodes inserted into the spinal foramina (nerve root canals) are a platinum tube with a suture collar and stiffening stylet. A special tool is used to insert them. Extension leads with sealed terminal connectors are used to connect the implanted stimulator to the electrodes.

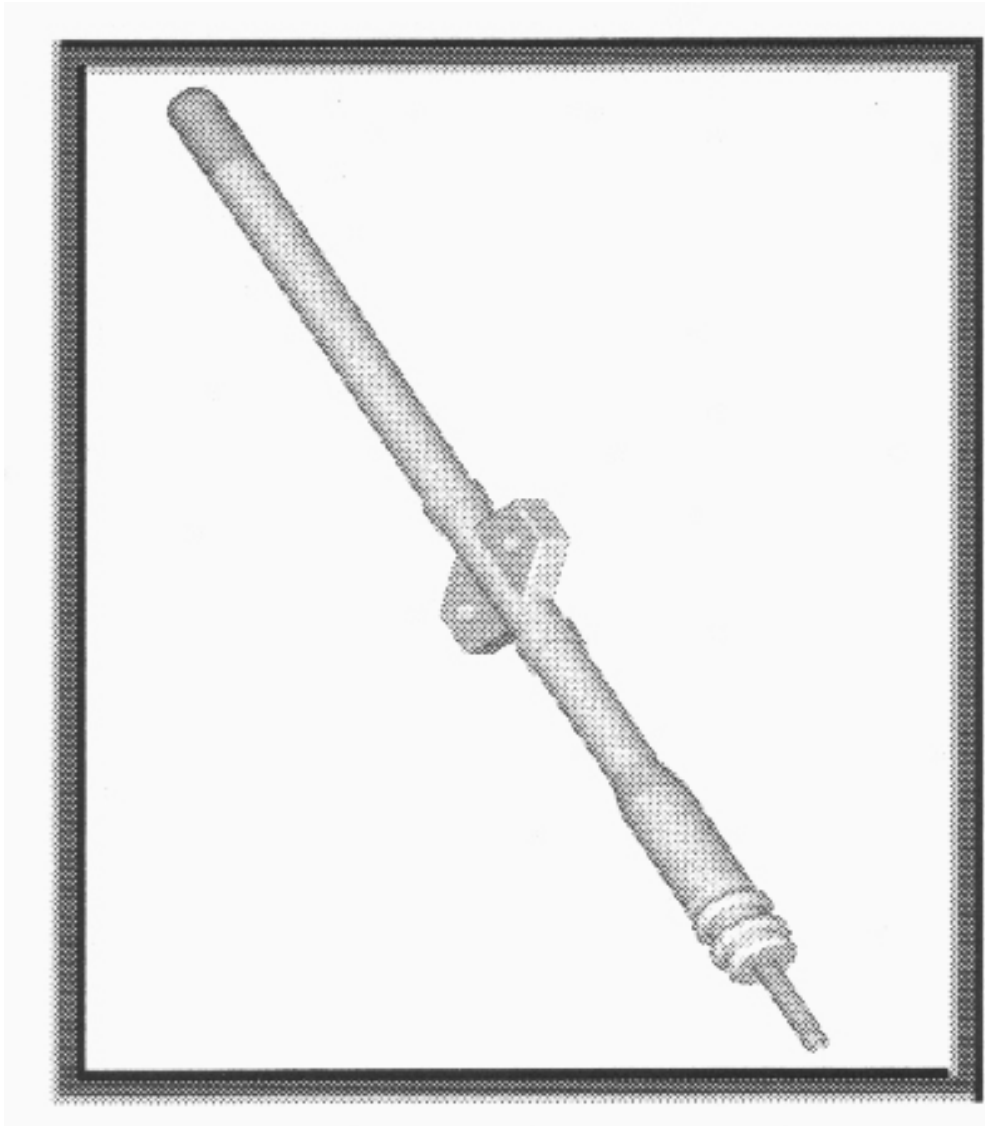


Figure 8 Platinum tubular electrode implanted into the sacral foramina (nerve root canals) for bladder control.

Before the system is implanted, the patient is fitted with a training system that uses surface (skin) electrodes. This allows the patients to increase their muscle strength and become familiar with the device before the implantation is performed.

Future Trends

Research is currently underway to process and use signal from EEG recordings of the motor cortex to directly control FES devices, so that a patient only needs to think about a movement to actually perform the action.

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