

Implanted Functional Electrical Stimulation for Upright Mobility in Pediatric Spinal Cord Injury

Introduction

The ability to walk short distances and perform activities in standing are often goals of people with spinal cord injuries, and physiological and psychological benefits have been shown.^{1,2,3} Long leg braces (LLB) are typically prescribed for those who desire upright mobility and have the physical ability to use LLB. Users frequently abandon the use of LLB (30-71%) due to issues including poor fit into a wheelchair, bulkiness beneath clothing, skin irritation, and difficulty in donning.^{2,4} A potential alternative to LLB is implanted functional electrical stimulation (FES). In addition to addressing the more common reasons for abandonment of LLB, FES may provide benefits of enhanced functional upright abilities by allowing a quicker transition from sitting to standing with greater independence. It is important to note however that the goal of FES is not to eliminate the need for a wheelchair.

FES Systems for Upright Mobility

Our laboratory has conducted research on two implanted systems for upright mobility, one with eight channels (NeuroControl Corporation, Valley View, OH) available for muscle stimulation⁵ and one with 22 channels (Cochlear Ltd, Lane Cove, NSW, Australia).⁶ The 8-channel system was implanted in nine children and adolescents and the 22-channel system was implanted in three adolescents/young adults. Both systems provided stimulation for upright mobility (Figure 1); however the 22-channel system also provided stimulation for bladder and bowel function. Two of the three subjects using this system received electrodes for bladder and bowel management.

For individuals with SCI to be eligible for an implanted FES system, the lower motor neurons to the targeted mus-

cles must be intact in order to obtain a stimulated response. Therefore individuals with low thoracic or lumbar injuries may not qualify for these systems.⁷

Surgical Implantation

Each system included an internal control unit, implanted beneath the skin over the abdomen or lower rib cage (Figure 2). Electrodes were placed near the motor point of the muscle or adjacent to the nerve branch to the muscle. For the 8-channel system, electrodes were placed using a percutaneous approach, in which electrodes were placed using a series of cannulas, thus requiring only a small incision. For the 22-channel system, larger incisions were made to access the nerve branches to the targeted muscles. For both systems, leads were then passed beneath the skin to connect to the internal control unit.

Five subjects with the 8-channel system were growing children at the time of the surgical implantation. To accommodate for growth of the pelvis and proximal femur, extra lead wire was placed for each electrode in an S-shape along the path to the stimulator.⁸

External Control Unit

To operate each system, a radio frequency antenna was placed on the skin over the implanted control unit to allow an external controller to communicate with the internal components. The external controller for the 8-channel system was approximately the size of a standard cell phone, while the controller for the 22-channel system was a pocket computer. Users placed the external controller on a belt, pants pocket, or on the assistive device. Both systems were simple to activate, allowing the user to activate the system through a push button or by tapping on the computer screen.



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Figure 1: A subject stands with his FES system to use a vending machine. The external control unit is placed on his belt.



Figure 2: X-ray of the implanted 22-channel FES system. The internal control unit is located near the left lower ribcage. Circular electrodes were placed adjacent to the nerve branches and passed beneath the skin to connect to the internal control unit.

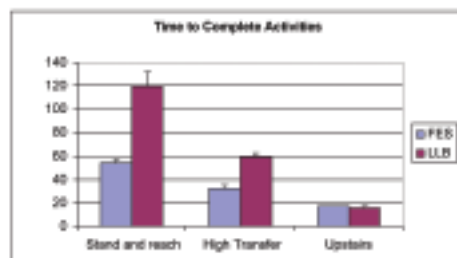


Figure 3: Results for an eight year old boy with T1 paraplegia using a walker as an assistive device. Two activities (standing to reach an object and transferring to a higher surface) involved transitions from sitting to standing, and he was able to complete these activities faster with FES than with LLB. He required a comparable amount of time to ascend stairs with FES and LLB. These results are typical of other children in the study. Time to complete activities is measured in seconds.

FES for Upright Mobility

The first use of implanted FES for upright mobility in our laboratory involved stimulation to eight lower extremity muscles, including the quadriceps muscles via the femoral nerve for knee extension, the gluteus medius for hip abduction, the gluteus maximus for hip extension, and the posterior head of the adductor magnus for hip extension and adduction. All muscles were activated continuously to allow standing or walking. In this study, the use of FES for upright mobility was compared to the use of traditional LLB during eight short duration activities for nine children and adolescents with paraplegia. Subjects completed the activities with FES at least as fast as they did with LLB and were faster during activities involving transitions between sitting and standing (Figure 3). With LLB, users must first lock the knees into extension prior to standing. With FES, the knees can begin in flexion and stimulation ramps up during standing, potentially reducing the effort of the upper extremities. In addition to being faster with some activities with FES, the younger children also gained greater independence for several activities, requiring minimal physical assistance with LLB and only supervision with FES.

The 8-channel system allowed users to walk by swinging both legs together while using an assistive device to support the body weight during the swing. A reciprocal pattern with FES is another option and the subsequent 22-channel system provided this ability. With this system, 18 electrodes were designated for lower extremity stimulation, providing use of muscles to flex and extend the hip, knee, and ankle. This provided the ability to create stance and swing with users activating a step through push buttons on the assistive device. With this device, additional testing was performed to examine activities of longer duration than with the 8-channel system, including a six minute walk and maximum standing time. Two of the three subjects could perform the six minute walk, walking $39.3 \pm 5.7m$ (subject 1) and $215.1 \pm 9.3m$ (subject 2) during that time. Maximum standing time for the three subjects ranged from two minutes, two seconds to 40 minutes, 33 seconds.

Conclusions

These implanted FES systems provided subjects with an alternative means for upright mobility. Functionally, subjects were faster and more independent with FES than they were with LLB during upright mobility activities. Overall, the results of this study suggest that implanted FES systems are a realistic alternative for children and adolescents with paraplegia.

References

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Prescribing information: AVONEX®

Presentations: Lyophilised powder for injection for IM administration containing a 30µg dose (6 million IU) of Interferon beta-1a per vial. Solution for injection in a pre-filled syringe of 0.5ml for IM administration containing 30µg dose (6 million IU) of Interferon beta-1a. **Indications:** For the treatment of ambulatory patients with relapsing multiple sclerosis characterised by at least 2 recurrent attacks of neurologic dysfunction (relapses) over the preceding 3-year period without evidence of continuous progression between relapses. AVONEX® slows the progression of disability and decreases the frequency of relapses. AVONEX® is also indicated for the treatment of patients who have experienced a single demyelinating event with an active inflammatory process if it is severe enough to warrant treatment with intravenous corticosteroids, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis (see SPC for further information). Treatment should be discontinued in patients who develop chronic progressive multiple sclerosis. **Dosage and Administration:** The recommended dosage of AVONEX® in the treatment of relapsing MS is 30µg injected IM once a week. AVONEX® lyophilised powder presentation should be reconstituted with the solvent supplied. Treatment should be initiated under supervision of a physician experienced in the treatment of the disease. An antipyretic analgesic is advised to decrease the flu-like symptoms associated with AVONEX® administration. AVONEX® should not be used in children. **Contraindications:** Hypersensitivity to natural or recombinant interferon beta or any of the excipients; pregnant women; nursing mothers; patients with severe depressive disorders and/or suicidal ideation; epileptic patients with a history of seizures not adequately controlled by treatment. **Precautions:** **CNS:** AVONEX® should be used with caution in patients with depression or other mood disorders. Patients should be advised to immediately report any signs of depression or suicidal ideation to their prescribing physician. Patients exhibiting depression should be closely monitored, treated appropriately, and cessation of AVONEX® considered. AVONEX® should be used cautiously in patients with pre-existing seizure disorder. New seizures should be fully investigated and treated with appropriate anti-convulsant therapy prior to resuming AVONEX®. **Pregnancy and lactation:** Fertile women should take appropriate contraceptive measures. **General:** AVONEX® should be used with caution in patients with cardiac disease, severe renal or hepatic failure or severe myelosuppression, and these patients should be closely monitored. Routine periodic blood chemistry and haematology tests are recommended during treatment with AVONEX®. Laboratory abnormalities may also occur which do not usually require treatment. **Drug interactions:** No formal interaction studies have been conducted with AVONEX® in humans. Clinical studies indicate that corticosteroids or ACTH can be given during relapses. Caution should be exercised in combining AVONEX® with medicinal products with a narrow therapeutic index and dependent on hepatic cytochrome P450 for clearance. **Side effects:** The most commonly reported symptoms are of the flu-like syndrome: muscle ache, fever, chills, asthenia, headache and nausea. Other less common events include: **Body as a whole:** anorexia, hypersensitivity reactions, weight loss, weight gain, severe allergic reactions (anaphylactic reactions or anaphylactic shock), syncope. **Skin and appendages:** alopecia, angioneurotic oedema, injection site reaction including pain, pruritus, rash, urticaria. **Digestive system:** diarrhoea, hepatitis, liver function test abnormalities, vomiting. **Cardiovascular system:** chest pain, palpitations, tachycardia, and vasodilatation and rarely arrhythmia, cardiomyopathy, congestive heart failure. **Haematological system:** thrombocytopenia and rare cases of pancytopenia. **Reproductive system:** metrorrhagia and/or menorrhagia. **Nervous system:** anxiety, dizziness, insomnia, paraesthesia, seizures, depression, suicide (see Precautions). Transient neurological symptoms that mimic MS exacerbations may occur following injections. **Musculoskeletal system:** arthralgia, pain, transient hypertonia and/or severe muscular weakness. **Respiratory system:** dyspnoea. Autoimmune disorders, central nervous system disorders and laboratory abnormalities have been reported with interferons. Rare cases of arthritis, hypo- and hyperthyroidism, lupus erythematosus syndrome, confusion, emotional lability, psychosis, migraine and very rare cases of autoimmune hepatitis have been reported with AVONEX®. For further information regarding adverse events please refer to the Summary of Product Characteristics. **Preclinical Safety:** Fertility and developmental studies with a related form of Interferon beta-1a in Rhesus monkeys show anovulatory and abortifacient effects at high doses. No teratogenic effects or effects on foetal development were observed. **Legal Classification:** POM. **Pack Size and NHS Price:** Box containing four injections £654. Reimbursed through High Tech Scheme in Ireland. **Package Quantities:** Lyophilised Powder: 1 box containing four trays. Each tray contains a 3ml glass vial with BIO-SET device containing a 30µg dose of Interferon beta-1a per vial, a 1ml pre-filled glass syringe of solvent and one needle. Pre-filled syringe: 1 box containing four trays. Each tray contains a 1 ml pre-filled syringe made of glass containing 0.5ml of solution (30µg dose of Interferon beta-1a) and one needle. **Product Licence Numbers:** EU/1/97/033/002-003. **Product Licence Holder:** Biogen Idec Ltd., 5 Roxborough Way, Foundation Park, Maidenhead, Berkshire SL6 3UD, United Kingdom. Date of last revision of Prescribing Information: 9 December 2005. Please refer to the Summary of Product Characteristics for further information.

Information about adverse event reporting can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Biogen Idec Ltd., on 08000 286639.

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