Initial Experiences with Upright Mobility using the Praxis Multi-Functional Implanted FES System

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Introduction

As evidence of the effectiveness of functional electrical stimulation (FES) for different applications continues to emerge for the population with spinal cord injury (SCI), there will be a concomitant demand for a single FES device that can efficiently provide multiple functions. Multi-functional FES devices may decrease the amount of implanted material, reduce surgical time and the number of surgical procedures and allow for easy co-ordination between stimulated functions. The Praxis FES System (Neopraxis Pty. Ltd., Lane Cove, NSW, Australia) was developed due to the desire to provide a safe multifunctional FES system that could be used by people with paraplegia outside of the laboratory environment. Research with an earlier generation of the device demonstrated that two subjects could stand continuously for up to 60 minutes and perform a reaching task.[1] Early bladder results with one subject showed that stimulation to the S3 and S4 nerve roots was able to achieve bladder contractions and voiding, demonstrating the potential of the bladder component.[1]

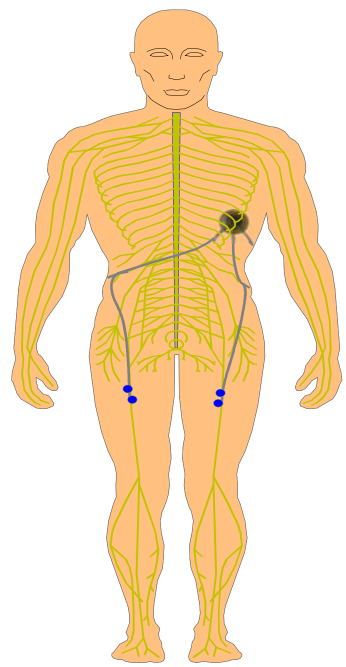

Figure 1 Approximate location of the implanted stimulator, leads and electrodes of the Praxis FES system.

The main aim of the current study is to determine the effectiveness of the Praxis FES System to provide standing and stepping ability and bladder and bowel management for individuals with motor complete thoracic level spinal cord injuries. This paper will focus on the upright mobility aspect of the Praxis FES System.

Methods

Three males with paraplegia, ages 18, 21 and 21 years, have undergone surgical implantation of the Praxis FES System. The Praxis FES System (Figure 1) consists of a 22-channel implant stimulator placed subcutaneously in the lower chest and connected through insulated stretchable leads to 18 epineural electrodes that stimulate nerves in the lower limbs (Table 1).

Muscle(s)
Posterior adductor magnus
Biceps femoris – long head
Gluteus maximus
Gluteus medius, minimus, and tensor fascia lata
Vastus lateralis and vastus intermedius
Vastus medialis and vastus lateralis
Tibialis anterior and extensor digitorum longus
Gastrocnemius, soleus, and flexor hallucis longus
Iliopsoas

Table 1: Muscles implanted bilaterally

Four additional electrodes are placed near sacral nerve roots and the conus medullaris for bladder stimulation and neuromodulation respectively. The available stimulation parameters are 0.2-8.3 mA amplitude, 25-600 μsec pulse duration, and 2-500Hz pulse frequency per channel. Stimulation patterns are delivered to the implanted stimulator using a hand held pocket personal computer that communicates with the internal stimulator via a transmit coil placed on the skin. Sensor packs can be attached externally to the lower limbs and the trunk to enable joint position feedback for closed loop control of lower extremity stimulation.

Upright mobility is currently achieved through either continuous stimulation to the lower extremities for standing and bilateral swing through gait or through alternating extension and flexion for reciprocal walking using open loop control. Transitions between sitting and standing are achieved by ramping stimulation up or down and are activated through the use of push button switches. For reciprocal gait, swing is achieved through stimulation to the iliopsoas and/or the tibialis anterior to create a flexor withdrawal response. Currently, bilateral ankle foot orthoses are worn for all upright mobility activities.

Four weeks post implantation of the Praxis FES System, subjects participated in 4 weeks of strengthening and conditioning of the implanted muscles followed by 22 weeks of upright mobility training for subject 1 and 17 weeks for subject 2. Upright mobility training focused on programming of the upright mobility strategies and training on their functional use. Goals included achievement of the transitions between sitting and standing, swing through and/or reciprocal gait with a walker or crutches, and prolonged standing. Additional training goals include advanced activities, such as ascending and descending stairs and achievement of subject specific goals.

Following training, data were collected for a variety of mobility activities. Completion times and level of independence based upon the Functional Independence Measure (FIM) were recorded. Maximum isometric strength of the quadriceps muscles was assessed using an isokinetic dynamometer prior to and after strengthening and following training.

Results

Activity	Subject 1	Subject 2
Sit to stand	12.9 ± 0.3	13.5 ± 2.7
Stand to sit	11.8 ± 1.2	15.0 ± 1.7
6 m walk	32.4 ± 3.5	9.1 ± 0.8
Inaccessible bathroom transfer	42.0 ± 0.4	34.7 ± 2.4
Timed up and go	114.7 ± 11.2	48.7 ± 4.1
Ascending 3 stairs	Not tested	13.2 ± 1.4
Descending 3 stairs	Not tested	15.9 ± 1.5
6-min walk	39.3 ± 5.71 m	215.1 ± 39.3 m
Functional Standing Test	968.3 ± 390.44 (16.1 ± 6.5 min)	2048.7 ± 374.4 (34.1 ± 6.2 min)

Table 2: Time in seconds (distance for 6-min walk) to complete mobility activities

Subject 1 is able to stand from his wheelchair and ambulate up to 285 feet (87 m) with a swing through gait pattern using a walker. Distance is typically limited by lower extremity fatigue. He can increase the stimulation to each lower extremity while standing through the use of the push buttons on the walker. This enables him to continue standing after signs of fatigue occur. Reciprocal gait has been attempted with this subject using a withdrawal reflex to initiate swing, as the iliopsoas muscles are not yet implanted. The withdrawal reflex is obtained by increasing the stimulation to the common peroneal nerve. With this pattern, subject 1 has ambulated up to 20 feet (6 m) with minimal assistance for proper weight shifting. He has also demonstrated the ability to stand with open loop stimulation for up to 25 minutes. Subject 1 has completed post-training data collection (Table 2) and is able to perform all activities with supervision (FIM score of 5) except for ascending and descending stairs. Subject 1 is not yet able to ascend and descend stairs safely so the activity was not tested.

Subject 2 is able to stand up from his wheelchair and ambulate up to 730 feet (223 m) using a bilateral swing through gait pattern and forearm crutches. Reciprocal gait for this subject is achieved using both the psoas muscles and a withdrawal reflex to achieve swing and he is able to ambulate up to 75 feet (23 m) using this pattern. Using open loop stimulation, subject 2 can stand for just over 40 minutes while performing one-handed reaching tasks. Subject 2 has completed data collection post training (Table 2). He is able to perform all activities without physical assistance with a FIM score of 5 (supervision) for ascending and descending stairs and a FIM score of 6 (independent with assistive devices) for all other activities.

Subject 3 is in the surgical phase of the study and has undergone implantation of 12 of the 18 lower extremity electrodes.

Isometric strength of the quadriceps muscles improved following exercise and again following upright mobility training for both subjects 1 and 2. Figure 2 presents the force values normalized to body weight.

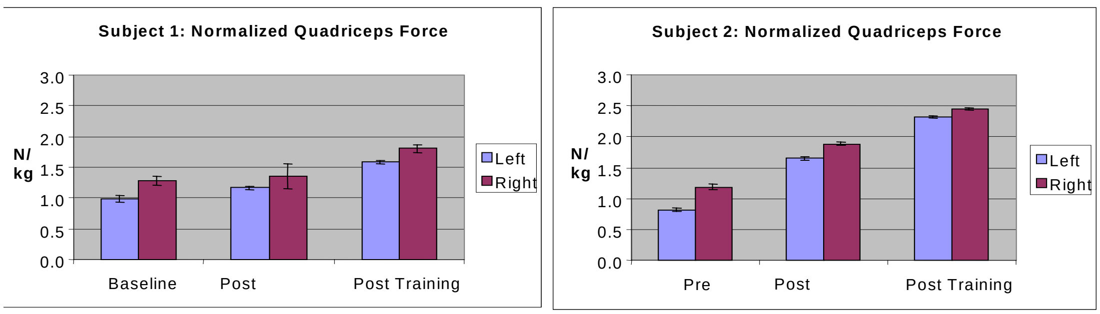

Figure 2: Isometric quadriceps force

Discussion

Both subjects have demonstrated the ability to safely stand, walk, and perform functional upright activities with the Praxis FES System using continuous stimulation and open loop control, demonstrating initial feasibility of the system for upright mobility. Functional independence results are comparable to those obtained in our previous study using an 8-channel FES system for upright mobility in children and adolescents with paraplegia.[2] In addition, the Praxis subjects demonstrated that FES could be used for standing and walking over a longer duration than was tested for the subjects using the 8-channel system.

One goal of the Praxis FES System is to increase standing time over what typically has been achieved with FES. Currently, further increases in walking distance for subject 1 and standing time for subject 2 are limited by lower extremity fatigue, primarily with the quadriceps muscles. Several possibilities are being investigated to extend standing time. One potential method is through closed loop control using sensor packs placed externally on the trunk, thigh and calf. Changes in joint position and/or angular velocity will then cause the external stimulator to increase or decrease the stimulation current delivered to each muscle. A second option is to alternate stimulation between two channels to the quadriceps muscles as opposed to providing continuous stimulation through both channels. A third option is to evaluate the effects of other muscles during standing, such as the gastrocnemius muscle, which may assist in maintaining an extension moment at the knee. Any of these options may be feasible either alone or in combination in order to extend functional standing time.

Longer term follow-up data will be collected with these first two Praxis subjects to determine the stability of the electrodes and the functional results over time. Both subjects had identified personal goals at the beginning of the study and their satisfaction with using FES for these activities will also be assessed after they have had the opportunity to try these activities at home.

References

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[2]Johnston TE, Betz RR, Smith BT, Mulcahey MJ. Implanted functional electrical stimulation: an alternative for standing and walking in pediatric spinal cord injury. Spinal Cord. 2003; 4:144-152