

Paraplegia: Implantable Praxis24-FES System and External Sensors for Multi-Functional Restoration.

Ross Davis, Thierry Houdayer, Brian Andrews*, Andrew Barriskill**, Simon Parker**.

Neural Engineering Clinic, Augusta, Maine, U.S.A.

*Cybernetics, University of Reading

and National Spinal Injury Center at the Stoke Mandeville Hospital, U.K.

** Neopraxis Pty. Ltd., Lane Cove, N.S.W., Australia.

Abstract

Our aim is to develop a safe multi-functional, closed-loop controlled implantable FES system for paraplegic individuals to enhance quality of life by allowing prolonged standing, mobility, exercise, bladder voiding and pressure relief.

In 1991, a FES 22-channel stimulator (Nucleus FES-22, Cochlear Ltd., Lane Cove, N.S.W., Australia)

was implanted in a T10-paraplegic male (CS; ASIA: A) who achieved closed-loop standing for 1+ hour, with quadriceps stimulation time being less than 10%. Prolonged standing was obtained using the Floor Reaction Hybrid FES Orthosis (FRHO). Using accelerometers for trunk inclination and acceleration, controlled stand-to-sit can diminished seat slamming.

In August 1998, another T10-paraplegic male (FR; ASIA: A) was implanted with an updated 22-channel stimulator with telemetry (Praxis FES24-A, Neopraxis Pty. Ltd., Lane Cove, N.S.W., Australia). 18 channels/electrodes connect onto nerves for limb movements, allowing exercise and open-loop standing with an FRHO for 30 minutes. Three other channels connect bilaterally to electrodes in sacral foramina of S2-4 roots, allowing bladder voiding of 200+ml at pressures of 40-70 cm water. One channel is connected to an electrode (Medtronic Pisces Quad) for epidural conus medularis modulation of spastic bladder. A belt-worn computer ('Navigator') controls the multiple functions. An internal antenna wire broke after 8 month. A redesigned replacement is due to be implanted mid-2000, with subsequent clinical trials.

A new sensing system based on our prototype has been developed for closed-loop control comprising sensor packs that are located on the thighs, shanks and trunk. Each pack is capable of measuring 3-D acceleration (2x 2-D accelerometers), and 1-D angular velocity (rate gyroscope) and converts the sensor signal into digital values. The rate gyroscope can detect knee buckling up to 200 msec earlier than a Biometrics flexible goniometer or the accelerometers.

1. Introduction

The state of FES use in paraplegia has been reviewed, see for example, Kralj (1) and Davis (2).

Although considerable achievements have been made, there has yet to be developed a safe, practical FES system that is completely independent of the laboratory and is an energy efficient mobility aid for prolonged use at home and in the workplace. The reasons lies in the fact that FES is addressing complex problems requiring not only interdisciplinary knowledge from muscle and nerve physiology and electrical stimulation technology, but also implementation of biomechanical and control principles (3).

Other reasons that limit clinical application may also be significant, for example cost benefit considerations (especially for implanted systems). Spinal injury results in loss of multiple physiological systems, however, neural implants to date have been developed to only restore specific functions. An approach was proposed by the authors to develop a generic FES implant the functions or modes of which can be matched to an individual patient's requirements. In addition for bladder control, less invasive surgical procedures were proposed to avoid posterior conus rhizotomy, and sacral laminotomy in order to access the sacral nerve roots for stimulation. It is hoped that this system may offer more functions and less surgery to patients with a cost benefit. This new approach we call "Multi-Functional".

Our 22 channel FES implant is configured to restore control to the bladder (and possibly bowel), relieve pressure to ischial tissues and assist simple locomotor functions. In the latter we will focus on how the system can complement the use of a wheelchair and be helpful in overcoming obstacles to wheelchair access especially doorsteps and unadapted bathroom facilities. In addition, being able to stand up to reach objects and perform prolonged manual tasks would be convenient for many workplace and home situations.

2. Methods

Paraplegic Subjects: Subject CS is a 30 year-old T-10 (ASIA: A) paraplegic male who was injured in an ATV accident in August 1984. He is 1.78 m tall and weighs 100 kg and is married with three children, and works full time. After being implanted in November 1991 with the first Nucleus FES-22 stimulator /4,5/,

CS has been successful in conditioning his muscles and standing with FES /6,8,10/.

Subject FR is a 36 year old T-10 (ASIA: A) paraplegic male who was injured in a car accident in March 1996. He is 1.70 m tall, weighs 72 kg and is a widower with two children. FR had been successful in conditioning his muscles and standing with surface applied FES (EMS+2, Rehabilicare Inc., Tampa, FL) for 1 ½ years /8,10/.

Closed-Loop FES 22 Channel Implantable Stimulators: A] Nucleus FES22 stimulator: In 1991, subject CS was implanted with the Nucleus FES22 stimulator (Cochlear Ltd, Lane Cove, N.S.W., Australia) /4,5/. The radio frequency (RF) linked stimulator is capable of delivering a balanced biphasic pulse of 0-4.3 mA amplitude, at a 0-500 μ s pulse width and at 20-50 Hz. The controller provides three operations: 1] open-loop sit-to-stand, 2] closed-loop standing, 3] closed-loop stand-to-sit. To initiate standing up and sitting down, the subject can use a remote switch mounted on a hand glove. The sensors used for closed-loop control are: 1] an electrogoniometer across each knee (XM180, Biometrics Ltd., Gwent, UK), 2] two accelerometers (Analog Devices, Norwood, MA), each at right angles, located on the back at T-6 level /6-8/. A portable open-loop version is also available for muscle conditioning /6/.

B] Praxis FES24-A multi-functional stimulator: In August 1998, FR was implanted with an improved 22 channel RF linked Praxis FES24-A stimulator (Neopraxis Pty Ltd, Lane Cove, N.S.W., Australia). Eighteen channels are for stimulating individual nerves or branches for muscle contractions and limb movements, including exercise, pressure relief, standing and stepping. The electrodes implanted for epineurial stimulation were 10 thin flexible platinum cuffs (Flexi-Cuff) that were sized, cut and sutured closed with at least twice the diameter of encircled nerve. The other 8 electrodes were 3 mm diameter, platinum buttons which were placed on the epineurium. Each button has an attached Dacron mesh surround that was sutured to the adjacent connective tissue.

Three channels are for bilateral sacral root stimulation (S2- 4) for bladder control (bowel control and erection, if possible). The 3 pairs of linear pararadicular (LPR) electrodes (10mm long, solid platinum tubing of 1.0 mm diameter) were inserted into the external sacral foramina in a lateral direction to follow and stimulate the nerve roots epidurally. One further channel is connected to an epidural spinal cord stimulating electrode (Pisces Quad: Medtronic Inc., Minneapolis, MN) for conus medullaris modulation of spastic bladder and bowel reflexes. In April 1999, the FES24-A unit's connecting wire between the internal antenna and the IC module broke resulting from FR's bending at the waist. A single module (FES24-B) incorporating the antenna and IC is in production for a replacement.

The stimulation originates from an external, battery operated, belt worn controller (Navigator) which measures 15mm x 8mm x 3mm and is based on a Motorola 68332 micro-controller. The stimulation is delivered via an external RF linked antenna that is magnetically held to skin by an underlying magnet in the implant. The stimulation parameters are 6.0-8.0 mA, 25-500 μ sec pulse width, and frequency of up to 600Hz per electrode. The user has access to the different strategies via a menu driven protocol based on a simple LCD and keypad interface. A remote RF-linked button is being developed for finger control to compliment the keypad. The Navigator is capable of closed-loop control by connecting to its sensory ports to our developed sensor packs for control of sit-to-stand, prolonged standing, stand-to-sit and stepping. One function is to detect/predict a knee buckle during standing.

Each sensor pack has a combination of two 2-D accelerometers (ADXL202, Analog Devices) and a rate gyroscope (ENC-05D, Murata Co.) /9/. Five sensor packs will be used for subject FR; one will be placed above and below the knee, and one on the trunk for position changes. A Diagnostic Programming System computer programs the Navigator to insert and modify user parameters.

Subject Safety with Standing: Safety in the laboratory is achieved by using a trunk vest with shoulder straps connected to an overhead standing frame (Maine AntiGravity Systems, Portland, ME). The suspension system will provide enough slack for a 40° knee buckle with full weight support. A battery-operated winch can if necessary, lift the subject.

3. Results

Lower Extremity Paralyzed Muscle Conditioning: Subject CS is able to exercise his lower extremities both at home and at work using the Nucleus FES22 implanted system. The exercise protocol stimulates the right and left knee extensors and ankle plantar/dorsi flexors alternatively 4 sec ON/ 4 sec OFF, for a total of 20 minutes. After the muscles have been conditioned, dynamometric testing (isometric mode) has shown that implanted FES stimulation has produced bilateral knee extension torque of 45-55 Nm at 30° and 65 Nm at 60° of knee flexion. CS exercises 3 days a week.

Subject FR was able to exercise his lower extremities at home using a dual-channel surface stimulator for 1½ years prior to implantation. FR conditioned his quadriceps (by transcutaneous stimulation of the femoral nerves just below the groin) and ankle dorsi-flexion (by peroneal nerve stimulation) bilaterally daily for 20 minutes. At December 1997, muscle strength test by dynamometry (isometric mode) indicated that surface femoral nerve stimulation was capable of eliciting 50 Nm of knee extension at 30° and 45 Nm at 45° of knee flexion.

After implantation, FR has been exercising with the Praxis implanted system.

Closed-Loop FES Standing: For subject CS, Nucleus FES22 stimulation to the motor nerves of the quadriceps and gluteal muscles has resulted in uninterrupted standing of over 60 minutes. This has been achieved by using the bilateral knee-angle goniometer sensors with the Andrews' stabilizing Anterior Floor Reaction Orthosis (AFRO), which is an ankle-foot brace. With the knee goniometers sensing for a 10° buckle, the stimulator will come 'ON' to correct the buckle; usually this occurred between 3-8 % of the standing time. On recovery, the automatic switch 'OFF' occurs when knee flexion has returned to less than 5°. Otherwise, lower extremity muscle activation is not required to maintain the upright posture /6/.

For the year prior to his implantation, subject FR was able to stand without knee bracing using a combination of the Andrews' AFRO and closed-loop surface FES applied directly over the femoral nerves. By monitoring the knees, he would typically stand uninterrupted for 30 minutes, with up to 70 minutes. With training, FR has achieved the 'C' posture and can stand with the stimulation 'OFF' for more than 50% of the standing time.

Manual Tasks in the FES Standing Position: While standing, subjects CS and FR are able to perform a variety of one-handed tasks including reaching for and holding a 2.2 kg object at arm's length. These tasks were achieved while in the 'C' posture with no activation to the lower extremity muscles and balance maintained by the other upper extremity (Fig.1).

Stand-Sit Transition: An additional feedback system based on 2 accelerometers (each at right angles) and the knee goniometers controls the stand-sit transition to provide a "soft landing". The controller limits the angular velocity of the knees flexing while CS is sitting down /7/.

Sensor Pack Evaluations: When testing the sensor components placed on the pendulum, the rate gyroscope is more sensitive to motion than the accelerometers. Although the acceleration was the sum of gravity and a relative acceleration, the rate gyroscope gives a larger output. The accelerometer amplification cannot be increased significantly, since the sensor packs are to be able to work in the full range of motion of the limbs (sitting, standing and stepping motions).

Test results with buckling: A typical knee buckle of an able-bodied subject was recorded with five sensor signals from : a] the knee angle measured with the goniometer, b] the Z-acceleration of both sensor packs which is the direction perpendicular with gravity, but most sensitive for knee movement, and c] the two angular velocities measured with the rate gyroscopes. The rate gyroscopes give a significant signal the earliest in a knee buckle by 200 msec earlier than the goniometer or the accelerometers. There is some variation in the accelerometer and goniometer outputs,

but only in the later phase of the buckle is there a significant output. The sensor packs are being upgraded with more sensitive and stable components as well as shape.

Sacral Stimulation Bladder Responses: Using a preliminary stimulation strategy (5sec ON and 5 sec OFF, 20Hz), urodynamic pressure testing on FR following S2, 3 & 4 bilateral root stimulation has shown in 3 of 4 sessions of trials that only S3 & 4 combination can cause reproducible sustained bladder contraction. Detrusor pressures of 40-70 cm water were recorded. With the bladder catheter removed in 2 of the sessions, voiding was demonstrated (Fig.2).

4. Discussion

We have demonstrated the possibility of a 9 year FES implant (Nucleus FES22 simulator) with its control of complex stimulation patterns for strong limb movements including knee and hip extension and ankle dorsi/plantar flexion. For prolonged safe standing (30-60 minutes), the system requires an anterior foot-ankle stabilizing brace (AFRO) plus knee goniometers for the closed-loop system. Closed-loop control of stand-to-sit was demonstrated with knee goniometers and 2-D trunk accelerometer. With CS's approval, we plan to replace the partially working receiver/implant /5,6/, with the Praxis FES24 upgraded pulse generator so further control of the lower extremities can be obtained as well as bladder control.

In August 1998, we implanted the paraplegic subject FR with the Praxis24-A stimulator which will be linked to a new, more stable and less obtrusive sensor system for closed-loop control which replaces the Penny and Giles knee goniometers /9,11/ and has shown an earlier signal for incipient knee buckling. The latter will minimize disturbance to the patient whenever the control system suddenly responds to stabilize the leg during prolonged standing activities. Also, the stand-to-sit and sit-to-stand transitions are being re-designed to provide smoother motion with less upper extremity support. Because of the added stimulation sites, that is the 3 bilateral sacral roots (S2, 3 & 4) and the conus medullaris, this implant allows for multi-modal functional restoration, including bladder control.

5. References

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R. Davis' e-mail: rajdavis@midcoast.com

