

PARAPLEGIA: IMPLANTED PRAXIS24-FES SYSTEM FOR MULTI-FUNCTIONAL RESTORATION.

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ABSTRACT

Our aim is to develop a safe multi-functional implanted FES system for paraplegic individuals to enhance quality of life by allowing prolonged standing, increased mobility, lower extremity exercise, bladder control and pressure relief.

In 1991, our first FES 22 channel stimulator (Nucleus FES22, Cochlear Ltd, Lane Cove, N.S.W., Australia) was implanted in a T10-paraplegic male (CS; ASIA: A) who achieved closed-loop standing for over 1 hour. The knee angles were monitored by electrogoniometers, resulting in quadriceps stimulation time being less than 10%. Stance stability was assisted with the Andrews' Anterior Floor Reaction Orthosis. Using accelerometers for trunk inclination and acceleration, controlled stand-to-sit diminished slamming onto the seat.

In August 1998, a second T10-paraplegic male (FR; ASIA: A) was implanted with an updated 22-channel stimulator with telemetry (FES24-A, Neopraxis Pty Ltd, Lane Cove, N.S.W., Australia). 18 channels are connected to epineural electrodes on nerves for muscle activation and limb movements so allowing exercise and open-loop standing for 30 minutes. Over 7 months, the stimulation values for threshold and maximum muscle contractions have varied slightly in 13 nerves, and lowered in 5. Software for pressure relief, closed-loop standing and stepping is being developed. Three channels are connected bilaterally to electrodes positioned in sacral foramina epidurally on S2, 3 and 4 roots for bladder function (bowel and erection, if possible). Although not all of the bladder stimulation protocols are in place, stimulation of bilateral S3 & 4 has resulted in repeatable sustained voiding of up to 200+ ml with detrusor pressures of 40-70 cm water. One channel is connected to an epidural electrode (Pisces Quad, Medtronic Inc., Minneapolis, MN) for conus medularis modulation of spastic bladder and bowel reflexes. A belt-worn computer controls the multiple functions.

Keywords: Paraplegia. Multi-functional FES implanted stimulator. Standing. Bladder voiding.

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 disorders 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.

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 has been successful in conditioning his muscles and standing with surface applied FES (EMS+2, Rehabicare 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 µs 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 epineural stimulation were 10 thin flexible platinum cuffs (Flexi-Cuff) which 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 para-radicular (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 medularis 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 standardized sensor packs. Each sensor pack has a combination of 2 accelerometers and a rate gyroscope /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 will program 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.

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.

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/.

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.

DISCUSSION

We have demonstrated the possibility of a 7 1/2 year FES implant (Nucleus FES22 stimulator) 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 FES24-A system 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 will predict 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.

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ACKNOWLEDGEMENTS

This work was in part funded by Cochlear Ltd. and Neopraxis Pty. Ltd., Lane Cove, NSW, Australia, Neural Engineering Clinic Research Foundation, and by the Paralyzed Veteran of America SCRF grant #1246, and a Veterans Administration Research Grant. R. Davis' e-mail: rajdavis@midcoast.com