THE PRAXIS FES SYSTEM FOR FUNCTIONAL RESTORATION IN PARAPLEGIA.

Ross Davis, Andrew Barriskill*, Zoran Milijasevic*, Thierry Houdayer, Brian Andrews**. Neural Engineering Clinic, Augusta, Maine, U.S.A. *Neopraxis Pty. Ltd., Lane Cove, N.S.W., Australia. ** National Spinal Injury Center at the Stoke Mandeville Hospital, U.K.

Abstract

Neopraxis Pty. Ltd. (Lane Cove, N.S.W., Australia) is manufacturing the new implantable Praxis FES System to provide multiple benefits to suitable paraplegic users: Bladder Control, Upright Functional Mobility, Pressure Relief and Lower Extremity Exercise. The implant achieves these functions through epineural stimulation of nerves in the legs, the medial lumbar region, the sacrum and the conus medullaris. A body worn controller, the Navigator, transcutaneously powers and controls an implanted Stimulator via a magnetically held Transmit Coil/Antenna. The Stimulator is connected to 22 Electrodes by flexible and stretchable insulated leads. Sensor Packs attached to each thigh, shank and the trunk, provide the Navigator's software Strategies with real time information on the position of the lower extremities and the trunk. The Stimulator provides real time data telemetry functions including the ability to measure the impedance of the current path through each electrode and the ability to transmit voltage measurements from each electrode.

Introduction

The authors aim has been to develop a generic FES implant for the restoration of function in spinal cord injured (SCI) paraplegic individuals, the functions or modes of which can be matched to an individual's requirements: Upright Functional Mobility, Pressure Relief and Lower Extremity Exercise, Bladder Control (1-4). 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 (3,4). It is hoped that this system will offer more functions and less surgery to patients with a cost-benefit ratio. We call this new approach "Multi-Functional".

To assist simple locomotor functions, 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 (2-4).

Method

A] **Controller** ('Navigator'): A body-worn controller transcutaneously powers and controls the implanted Stimulator via a Transmit Coil (Fig. 1). The Coil is held in place on the skin surface over the Stimulator by magnetic force. This battery-powered Controller runs software Strategies designed to provide the user with a variety of functions. A touch sensitive LCD and remote control units provide simple menu driven operation of the FES system.

Figure 1.

B] **Sensor Packs,** (Fig.2) attached to each thigh, shank and the trunk, provide the Navigator's software Strategies with real time information on the position of the lower extremities and the trunk. Each microprocessor controlled Sensor Pack contains a miniature rate gyroscope and two 2-dimensional accelerometers. The Sensor Packs derive their power from the Navigator avoiding the need for additional batteries.

Figure 2.

C] The **FES24-B Stimulator** is the primary implanted component and is placed subcutaneously above the left costal margin. The FES24-B provides 22 stimulation channels and two-monopolar case Electrodes. The FES24-B utilizes a CIC3 integrated circuit (which is used in Cochlear Ltd.'s Nucleus 24 implants). The "CIC3" integrated circuit implements a high-speed radio-frequency data protocol. It can operate in common ground stimulation mode (all non stimulating Electrodes are placed in parallel to provide the current return path) or monopolar mode (a case mounted electrode provides the current return path). The Stimulator provides real time data telemetry functions including the ability to measure the impedance of the current path through each electrode and the ability to transmit voltage measurements from each electrode. The FES24-B Stimulator provides up to 8mA of charge-balanced stimulation current via a biphasic waveform. Pulse widths can be varied from 25μsec up to 500μsec. The total pulse rate can range up to 14,400 pulses per second.

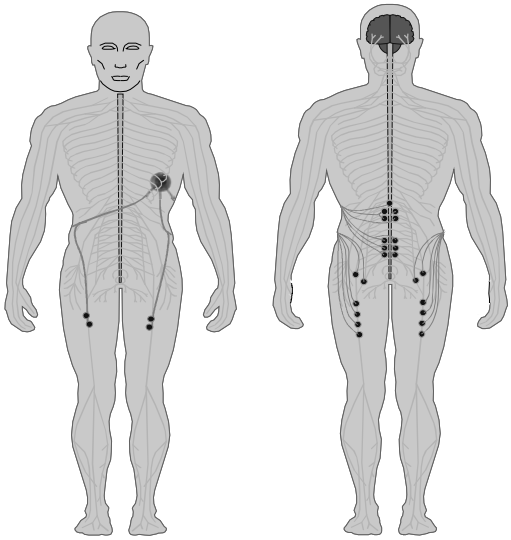

Figure 3.

D] **Leads and Electrodes:** The implanted Stimulator is connected to 22 Electrodes (Fig.3) by highly flexible and stretchable insulated leads. Eight Electrodes are implanted in each lower extremity adjacent to motor nerves. Two Electrodes activate the quadriceps, two the hamstrings, two the ankle and two the gluteal muscles. These Electrodes facilitate the system's mobility, exercise and pressure relief functions. Two electrodes are implanted unilaterally in the medial lumbar region to activate the psoas muscle for hip flexion. Three additional Electrodes are implanted bilaterally adjacent to three sacral roots (S2, S3 and S4). These Electrodes facilitate the system's bladder control function. Pulsatile voiding is produced by periodically stimulating the sacral roots causing the bladder's detrusor muscle and sphincter to contract and then allowing the sphincter to relax at its faster rate. The final Electrode is implanted epidurally directly over the conus medullaris at the T12-L1 level. This Electrode provides a neuromodulation function to assist with a reflexive bladder. It is anticipated that this technique may reduce the need to perform a posterior rhizotomy.

E] **Pre-surgical Subject Training**: The Praxis system includes a FES surface stimulator (Fig. 4), the *ExoStim*, which is intended to provide pre-surgical training of subjects in order to condition muscles and familiarize patients with FES training. The *ExoStim* is controlled by the Navigator and allows simple lower extremity software Strategies to be utilized prior to surgical implantation. The *ExoStim* is powered by 'AA' batteries and can deliver up to 200mA of biphasic stimulation to 8 channels with pulse-by-pulse control of the stimulation parameters. The *ExoStim* has extensive built in status detection capabilities including over voltage detection, pulse-by-pulse compliance checking, battery status monitoring and stimulation pad impedance.

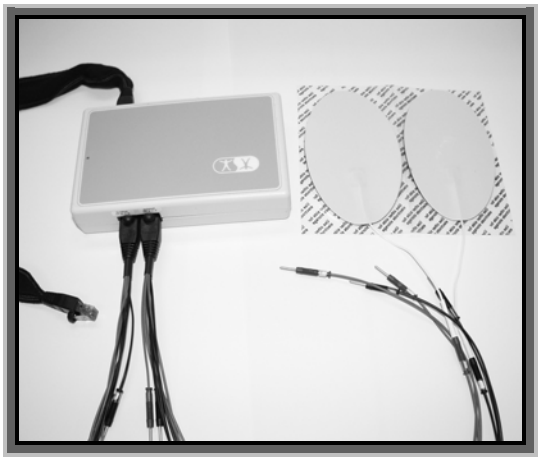

Figure 4

Clinical Results

Subject F.R, a 35 yr. old paraplegic male (F.R.: T10; ASIA: A), was implanted with an initial version of the Praxis system (FES24-A stimulator) in August

1998. This earlier implanted stimulator suffered breakage of its antenna coil after 8 months of operation. Redesign work has overcome this problem by inclusion of the stimulator's antenna coil within the FES24-B stimulator's rigid polymer housing.

A] **Exercise and standing**

For the year prior to his implantation, F.R. was able to stand without knee bracing using a combination of the Andrews' Anterior Floor Reaction Orthosis (5) and closed-loop skin surface FES applied directly over the femoral nerves. With closed-loop control of stimulation, he would typically stand uninterrupted for 30 minutes, and up to 70 minutes. With training, F.R. has achieved the 'C' posture and can stand with the stimulation 'OFF' for more than 50% of the standing time. In December 1997, muscle strength test done on the Biodex dynamometer (isometric mode) showed that surface stimulation of the right quadriceps (femoral nerve) was capable of eliciting 50 Nm of knee extension at 30° of knee flexion and 45 Nm at 45° (11,12).

After implantation of the Praxis FES 24-A system in August, 1998, subject F.R., carried out an FES exercise routine, which stimulated 3 separate sequences (quadriceps group, buttocks and posterior thigh group, and ankle group), each initially running for 5 minutes and extending to 15 minutes over a two-week period. Each muscle in the sequence would be stimulated sequentially for 4 sec on and off. FR found that daily stimulation decreased his muscle spasms and spasticity level.

When standing with the implanted system, he was able to perform a variety of one-handed tasks including reaching for and holding a 2.2 kg object at arm's length (Fig 6). These tasks were achieved while in the 'C' posture with closed-loop activation to the lower extremity muscles and balance maintained by the other upper extremity (12).

B] **Bladder Results**

On September 4th 1998, with urodynamic testing, F.R.'s sacral roots (S3 & 4) were bilaterally stimulated intermittently. On 3 occasions F.R.'s bladder contracted with recorded pressures of between 45 and 50 cm of water. On December 14th 1998, urodynamic testing again showed consistent results from S3 & 4 sacral root stimulation producing 3 sustained bladder contractions with pressures of 40-55 cm water and urination with each stimulation pattern (5 sec on / 5 sec off, 20 Hz, 8 bursts). On April 2nd 1999, urodynamic testing was repeated with 2 bladder reflex activations from each pattern of stimulation (5 sec on / 5 sec off, 20 Hz, 8-14 bursts). Pressures of 50-70 cm water were recorded.

A Clinical Trial of the new Praxis24-B system will commence early in 2001.

Conclusion

In the developing field of FES and implantable neural prosthetic devices, there has been a need for reliable and safe, multi-channel implantable stimulating systems to restore function in neurologically impaired patients. In paraplegic individuals, the stimulating systems' functions should be designed to modulate spasticity and precisely activate individual muscles for joint movement and control of bladder and bowel functions. The more channels available, the more nerves can be activated and the more modes of functionality can be restored. Our contribution to this aim has been continuous since 1983, and the Praxis FES System (3,4), its FES24-B stimulator, Navigator body worn controller and the connected Sensor Packs for sensing of joint and body position in the paraplegic subjects (4) provides the hope for a new rehabilitation aid for restoration of function in spinal cord injury paraplegia.

References

1. Davis R, MacFarland W, Emmons S. Initial Results of the Nucleus FES-22-Implanted Stimulator for Limb Movement in Paraplegia. Stereotact. Funct. Neurosurg. 1994; 63:192-197.

2.Davis R, Houdayer T, Andrews B, Emmons S, Patrick P. Paraplegia: Prolonged Closed-Loop Standing with Implanted Nucleus FES-22 Stimulator and Andrews Foot-Ankle Orthosis. Stereotact. Funct. Neurosurg. 1997; 69:281-287.

3 Davis R, Houdayer T, Andrews B, Barriskill A. Prolonged Closed-Loop Functional Electrical Stimulation and Andrews Ankle-Foot Orthosis. Artif. Organs, 1999; 23: 418-420.

4. Davis R, Houdayer T, Andrews B, Barriskill A, Parker S. Paraplegia: Implantable Praxis24-FES System and External Sensors for Multi-Functional Restoration. Proc. 5th Ann Conf Int Funct Electr Stim Soc, Aalborg, Denmark, June 18-21,2000; pp 35-38.

5. Andrews et al. Hybrid FES Orthosis Incorporating Closed Loop Control and Sensory Feedback. J.Biomed Eng, 1988; 10: 189-195.

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R. Davis' e-mail: rosdavis@qsilver.net