Implanted FES for Upright Mobility in Pediatric Spinal Cord Injury: Collective Experience With Two Multi-Channel Systems

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Abstract
Ten subjects with spinal cord injury (SCI) underwent implantation of an 8-channel functional electrical stimulation (FES) system and three subjects with SCI underwent implantation of an 18-channel FES system. After training in the use of FES for upright mobility, subjects were tested in their ability to complete various upright mobility activities. The purpose of this paper is to share our experiences regarding muscle selection, stimulation patterns, muscle strengthening, mobility training, comparison to long leg braces, and accommodating growth.

1. INTRODUCTION
For individuals with motor complete thoracic level spinal cord injury (SCI), research has consistently demonstrated that it is possible to be upright and mobile about the wheelchair using functional electrical stimulation (FES). This has been demonstrated with as few as 4 channels of surface stimulation to as many as 18 channels using implantable technology.

For the last 20 years our research group has been investigating FES for upright mobility for children and adolescents with SCI. Our latest projects have included the implementation and evaluation of two multi-channel implantable FES systems. This paper is intended to share our collective experiences with these FES devices [1,2].

2. METHODS
2.1 CWRU 8-Channel Implant
Nine subjects with T1 to T11 paraplegia and one subject with C7 tetraplegia (mean age 13.4 ± 5.7 years) received the 8-channel Case Western Reserve University (CWRU) implanted FES system (NeuroControl Corporation, Valley View, Ohio). Surgically, the internal stimulator was placed subcutaneously in the right lower abdomen. Electrodes were placed bilaterally into the gluteus medius and maximus for hip abduction and extension, the posterior fibers of the adductor magnus for hip extension and adduction, and near the femoral nerve for knee extension.

Stimulation patterns were created using custom software and downloaded into a research grade external stimulator. A biphasic asymmetrical waveform with a current of 8-20 mA, a frequency of 20 Hz, and a pulse duration up to 200 µsec was provided. The external device communicated with the internal stimulator via a radio frequency antenna placed on the skin over the internal stimulator. Subjects controlled the system through a push button switch. Standing and walking were achieved through continuous stimulation to all implanted muscles, allowing a swing through gait pattern with forearm crutches or a walker. Solid ankle foot orthoses were worn by all subjects when using FES to prevent movement beyond neutral dorsiflexion in weight-bearing.

2.2 Praxis FES System
Three adolescents between 17 and 21 years of age with thoracic level SCI participated. The Praxis FES System (Cochlear Ltd, Lane Cove, NSW, Australia) consists of a 22-channel implant stimulator placed subcutaneously in the lower chest. Insulated stretchable leads were connected to 18 epineural electrodes to stimulate nerves in the lower limbs (Table 1). 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 were delivered to the implanted stimulator using a hand held personal computer that communicates with the internal stimulator via a transmit coil placed on the skin.

2.3 Mobility Training

Upright mobility was achieved through either continuous stimulation to the lower extremities for standing and bilateral swing-through gait (*CWRU* and Praxis) or through alternating extension and flexion for reciprocal gait using open loop control (Praxis). Transitions between sitting and standing were achieved by ramping stimulation up or down and were activated through the use of push button switches. For reciprocal gait with the Praxis System, swing was achieved through stimulation combinations of the iliopsoas, biceps femoris, and the tibialis anterior to create a flexor withdrawal response. Each step was initiated through a push button switch on the walker. Bilateral articulating ankle foot orthoses were worn for all upright mobility activities.

Table 1: Muscles stimulated bilaterally with the Praxis FES system during swing-through gait*, the stance phase of reciprocal gait #, and the swing phase of reciprocal gait ^.

<table>
<thead>
<tr>
<th>Muscle</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterior adductor magnus*</td>
<td>#</td>
</tr>
<tr>
<td>Biceps femoris – long head*</td>
<td>#</td>
</tr>
<tr>
<td>Gluteus maximus*</td>
<td>#</td>
</tr>
<tr>
<td>Gluteus medius, minimus, tensor fascia lata* # &amp;</td>
<td></td>
</tr>
<tr>
<td>Vastus lateralis, vastus intermedius* #</td>
<td></td>
</tr>
<tr>
<td>Vastus medialis, vastus lateralis*</td>
<td>#</td>
</tr>
<tr>
<td>Tibialis anterior, extensor digitorum longus ^</td>
<td></td>
</tr>
<tr>
<td>Iliopsoas ^</td>
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</tbody>
</table>

Two to four weeks post implantation of each system, subjects participated in 4 weeks of strengthening and conditioning of the implanted muscles followed by 8 to 22 weeks of training in upright mobility. 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, and swing-through (*CWRU* and Praxis systems) and reciprocal gait (Praxis system). Subjects were trained in standardized activities as well as activities of their choice.

3. RESULTS/DISCUSSION

The intent of this paper is not to report a direct comparison of two FES devices as these were two separate clinical trials, but rather to report our collective experience with implantable technology for upright mobility in children and adolescents with SCI.

3.1 System Performance

All 3 Praxis subjects and 9 of 10 subjects using the CWRU system could independently stand up from the wheelchair and could walk at least 6m using a swing through gait pattern. Other activities that could be performed included stand and reach, high transfer, and transfer to a bathroom stall.

Upright mobility with the CWRU system was compared to the use of long leg braces (LLB) for 7 subjects during 7 activities [3]. Subjects were able to complete 4 activities faster and 5 activities more independently with FES as compared to LLB. Transitions between sitting and standing were achieved faster and with more independence with FES. In addition, subjects reported preferring FES for the majority of activities. No activity required more time or more assistance to complete with FES as compared to LLB, demonstrating that FES is a realistic alternative for upright mobility for children with SCI.

Standing time was formally assessed for subjects with the Praxis system. Using open loop control, the maximum standing time for three subjects ranged from 5 to 45 minutes. Differences in subjects’ standing postures and upper extremity strength appeared to be factors in the length of standing time. While not formally assessed, subjects with the
CWRU system also showed a range of standing times with the highest time of approximately 45 minutes. Maximum stimulated muscle strength of the quadriceps was assessed for all subjects using an isokinetic dynamometer or a handheld dynamometer that was placed approximately 2 cm above the lateral malleolus to measure force. This measure was then divided by the weight. Following the training periods, force measured 1.75 ± 0.64 N/kg. In all subjects, stimulation levels for the quadriceps muscles during standing were titrated to a minimum value that would provide functional standing while minimizing muscle fatigue. For all, subjects, these values ranged from 26% to 100% of the saturation level determined for that muscle. Saturation was defined as the lowest amount of stimulation that could produce the maximal force.

3.2 Muscle Selection Considerations

Hip and knee extension were both important in achieving an upright posture for all subjects. Hip extension was obtained using at least 2 hip extensors in each subject, including the gluteus maximus, posterior fibers of adductor magnus, and long head of biceps femoris. Knee extension was achieved using the femoral nerve after proximal rectus femoris release or the vastus lateralis with the CWRU system and using individual heads of the vasti group for the Praxis system. All of these choices were able to provide sufficient knee extension force for standing. However, the Praxis system provides the ability to allow one head to rest while the other is active, potentially increasing standing time.

3.3 Accommodating Limb Growth

Six children with the CWRU FES system were still growing (between 7 and 14 years old) at the initiation of the study and therefore 3-5 centimeters of extra electrode leadwire was used to accommodate growth. The leadwires cross only the growth plate of the proximal femur. Thus the extra leadwire needed was estimated from the predicted growth from the proximal femoral growth plate which is reported to be about 30% of total femoral growth [4]. Average follow-up to date is 44 months with the longest follow-up being 60 months. Total femoral bone growth has averaged 5.6 cm. Of the 48 electrodes originally implanted (40 IM, 8 EP) in the growing lower extremity muscles, 42 (88%) continue to function at follow-up. Of the 6 electrodes that failed, five required replacement within the first few months after surgery before measurable growth occurred. These electrodes were successfully replaced. One electrode failed over 2 years after implant. Radiographs indicate that excess lead wire is still present. We hope to find further evidence as to the cause of failure during electrode replacement.

3.4 Consideration of Multi-Task Stimulation

Systems that provide multiple functions may be in more demand by users in the future. The ability to provide activities such as functional upright mobility, FES cycling, treadmill ambulation, weight training, and stair climbing may be attractive as the system would provide many options for exercise and mobility.

References


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