AN IMPLANTABLE FUNCTIONAL ELECTRICAL STIMULATION SYSTEM FOR UPRIGHT MOBILITY IN CHILDREN AND ADOLESCENTS WITH SPINAL CORD INJURY

Therese E. Johnston, Randal R. Betz, Brian T. Smith, MJ Mulcahey
Shriners Hospitals for Children, Philadelphia, PA

Abstract

The aim of this study was to compare the use of a completely implanted functional electrical stimulation (FES) system to long leg braces (LLB) for upright mobility in children and adolescents with spinal cord injury. Nine subjects underwent surgical implantation of an FES system, with electrodes placed to stimulate hip extension, abduction, and adduction, and knee extension. After receiving equal mobility training in the use of LLB and the FES system, subjects were tested in 8 upright mobility activities. Six subjects have completed data collection. Results indicate that the subjects completed 4 activities more quickly with FES than with LLB and were more independent in 2 activities. No subject required more time or assistance to complete any activity with FES. These results indicate that performance with an implanted FES system was comparable to or better than performance with LLB. In addition, FES may be advantageous for several important functional activities.

Introduction/Background

Individuals with paraplegia are commonly prescribed LLB when upright mobility is desired. User abandonment of LLB has been shown to be high due to issues such as poor fit into a wheelchair, bulkiness beneath clothing, and skin irritation.[1] FES may provide an alternative method of upright mobility while alleviating some of these issues.

The majority of the research on FES for upright mobility has provided stimulation to muscles using surface electrodes placed on the skin[2] or through percutaneous electrodes[3-5] implanted directly into the muscle, exiting at the skin surface. This research has shown that upright mobility with FES is feasible.[4-5] However, donning of multiple surface electrodes can be difficult and time consuming, and percutaneous electrodes require consistent maintenance. Due to this, completely implanted systems have begun to be studied primarily in adults.[6] There is no work published on these systems in a pediatric population.

Previous work in our lab[4] has shown that children and adolescents with paraplegia could perform as well with a percutaneous FES system as with LLB. In our desire to provide a more permanent system, we hypothesized in our current study that children and adolescents would be able to perform 8 upright mobility activities with a completely implanted FES system at least as well as with LLB.

Methods

Eight subjects with paraplegia (Table 1) who met the selection criteria (Table 2) and one subject with tetraplegia underwent surgical implantation of an 8 channel implanted lower extremity FES system (NeuroControl Corporation, Valley View, Ohio). The subject with tetraplegia had undergone upper extremity reconstruction to restore grasp and pinch so was included in the study. All subjects had previous experience with LLB and began the study with different levels of expertise with upright mobility. Changes were made in the type of LLB used only if it was felt by a physical therapist that the current type was inappropriate for the patient.

Table 1: Subject Profiles

SUBJECT	AGE (years)	LEVEL OF INJURY	BRACING USED
RF	13	T8	KAFO
JH	20	T1	HKAFO
CG	20	C7	RGO
LG	7	T7	RGO
LV	10	T11	HKAFO
JB	19	T7	KAFO
JS	8	T1	RGO
DP	9	T8	RGO
TC	8	T4	RGO

KAFO= knee ankle foot orthoses, HKAFO= hip knee ankle foot orthoses, RGO= reciprocating gait orthosis

Table 2: Selection Criteria

1)	intact lower motor neurons in targeted muscles
2)	no outstanding orthopedic issues
3)	flexion contractures <15º at the hip and knee and <10º at the ankle
4)	presence of neurological stability
5)	spasticity that does not interfere with standing
6)	6-20 years of age
7)	diagnosis of a motor complete thoracic SCI
8)	independence in basic activities of daily living

Surgically, the internal stimulator was placed into the subcutaneous fascia of the right lower quadrant of the 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. The first 5 subjects received a combination of intramuscular[7] and epimysial electrodes. The other 4 received all intramuscular electrodes. Following implantation, all electrodes were tunneled subcutaneously and attached to the internal stimulator. To prevent unwanted hip flexion with stimulation to the femoral nerve, a 1cm section of the proximal rectus femoris tendon was incised just distal to the separation of the main head and the reflected heads of its attachment to the pelvis. Subject TC underwent a different technique for knee extension, with an electrode being placed into the vastus lateralis without releasing the proximal rectus femoris. This procedure was chosen to determine if the vastus lateralis would be able to provide sufficient force for standing.

Post-operatively, subjects were immobilized up to 4 weeks to allow tissue encapsulation of the implanted electrodes. The subjects' hips were held in 20º of abduction and limited to a maximum of 20º of flexion. Strengthening exercises were then performed in supine and in standing for all implanted muscles for a total of 4 weeks.

Stimulation patterns were created using custom software and then downloaded into a research grade external stimulator[8] which each subject either placed on a walker or around the waist in a pouch. This external device communicated with the internal stimulator via a radio frequency signal transmitted through an antenna placed on the skin directly over the internal stimulator. Each subject controlled the FES system through a push button switch worn around the index finger or attached to the assistive device. Standing and walking were achieved through continuous stimulation to all implanted muscles, allowing a swing through gait pattern with forearm crutches or a walker. Several subjects could create a reciprocal pattern by using the trunk to advance each leg. Solid ankle foot orthoses were worn by all subjects when using FES to prevent movement beyond neutral dorsiflexion in weight-bearing.

All subjects were tested in 8 upright functional mobility activities after receiving equal training in the use of appropriate LLB and FES. Training time ranged from 3 to 8 weeks. The specific activities were chosen due to their relevance and appropriateness for the age group in the study. Five repeated measures were collected for each activity. Activities were scored based on completion time and on level of independence, using a 7-point scale based on the Functional Independence Measure (FIM). Immediately after testing, subjects were asked to identify which device was preferred for each activity. Six subjects have completed data collection.

A generalized linear model ANOVA with repeated measures was used to compare the completion times and the level of independence with FES and LLB for the 8 activities. A normalized rank transformation was performed to the data prior to the analysis. A p-value ≤ 0.05 was accepted to determine significance.

Results

Subjects were faster with FES for 4 activities (Table 3) and required less assistance (higher FIM score) with 2 activities (Table 4). In addition, two of the activities, stand & reach and high transfer, were scored based on their components, which included the sit to stand and stand to sit transitions. Analysis of these components showed that the subjects were able to stand up and sit down faster with FES and required less assistance to stand (Tables 5 and 6). Subjects reported preferring FES for 81% of the activities, LLB for 6%, and showed no preference for 13%.

Table 3: Mean time, in seconds, to complete activities

Activity	Mean FES time in sec	Mean LLB time in sec	p value
Donning	270.1(139)	439.0(155)	**0.0151**
Stand & reach	61.4 (22.7)	113.7 (49.5)	**0.0002**
High transfer	44.2 (14.2)	69.9 (24.6)	**0.0001**
Bathroom	25.4 (13.5)	36.0 (12.3)	**0.0085**
Floor to stand	35.8 (12.7)	39.9 (10.5)	0.3312
6-meter walk	35.5 (19.2)	28.8 (10.0)	0.2951
Stair ascent	18.2 (3.4)	18.2 (3.4)	0.5582
Stair descent	20.1 (3.8)	20.3 (5.5)	0.9267

Table 4: Mean FIM scores

Activity	Mean FES FIM	Mean LLB FIM	p value
Donning	6 (1.4)	4.2 (1.4)	**0.0042**
Stand & reach	5 (0.8)	4.5 (0.8)	0.0770
High transfer	4.4 (0.8)	4 (1.0)	0.1016
Bathroom	5 (0.8)	4.2 (0.9)	**0.0360**
Floor to stand	4.3 (0.8)	4.2 (0.9)	0.3632
6-meter walk	5.3 (0.8)	5.2 (0.9)	0.3632
Stair ascent	3.2 (1.8)	3 (1.9)	0.3632
Stair descent	3.3 (1.8)	3.3 (1.8)	0.3598

FIM scores: 1=total assistance, 2=maximal assistance, 3=moderate assistance, 4=minimal assistance, 5=supervision, 6=independent with equipment, 7=independent without equipment

Table 5: Mean time, in seconds, to complete components of activities involving sit to stand

Activity	Mean FES	Mean LLB	p value

	time	time	
High Reach			
Sit to stand	25.1 (9.4)	53.3(22.3)	**0.0016**
Reach	4.9 (2.5)	5.7 (2.2)	0.0780
Stand to sit	31.4(17.4)	54.8(29.2)	**0.0002**
High Transfer			
Sit to stand	25.0(11.1)	47.7(19.8)	**0.0005**
Pivot	13.0 (6.3)	12.8 (4.7)	0.9887
Stand to sit	6.2 (4.8)	9.5 (6.0)	**0.0119**

Table 6: Mean FIM scores for components

Activity	Mean FES FIM	Mean LLB FIM	p value
High Reach			
Sit to stand	5.2 (0.7)	4.3 (0.8)	**0.0376**
Reach	5.2 (0.7)	5 (0.8)	0.3632
Stand to sit	5 (0.8)	4.5 (0.8)	0.0770
High Transfer			
Sit to stand	5.1 (0.7)	4.5 (0.8)	**0.0271**
Pivot	5.1 (0.8)	4.7 (0.8)	0.0848
Stand to sit	4.4 (0.8)	4 (1.0)	0.1016

Discussion/Conclusions

With a completely implanted FES system, the subjects in this study were able to perform 8 upright mobility activities equal to or better than with LLB, as measured by timeliness and independence. Improvements were seen in several important areas, including system donning, maneuvering in an inaccessible bathroom, and 2 activities involving sit to stand. Clinically, these gains are very important as the subjects could more quickly and more independently don their FES system and stand up from the wheelchair. For the bathroom activity and the sit to stand components of the high reach and high transfer, subjects obtained mean FIM scores of 5 to 5.2, indicating supervision was required. The subjects obtained mean FIM scores of 4.2 to 4.4 for these same activities with LLB, indicating that minimal assistance was needed. This not only increases independence for the user, but also decreases the physical demand on the caregiver. Likewise, the subjects obtained a FIM score of 6 for donning FES and a FIM score of 4.2 for donning LLB, indicating that only FES could be donned without physical assistance from the caregiver.

Another important factor is that subjects preferred FES for the majority of the activities. Reasons given by the subjects included ease of standing up and sitting down with FES and not having to lock and unlock hip and knee joints during activities as required with LLB. KAFO users also preferred the stability around the pelvis provided by the FES. The younger subjects expressed preferring FES as it was lighter in weight, requiring less effort to lift the body to advance the legs.

The results of this study support our hypothesis that FES can provide at least equal function as LLB for the tested mobility activities. Future plans are to collect longer term follow-up data on the current subjects and to provide implanted FES systems to more children and adolescents with spinal cord injury.

References

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