

# Implanted Functional Electrical Stimulation for Upright Mobility in Paediatric Spinal Cord Injury: A Follow-up Report

Johnston TE, Smith BT, Betz RR, Mulcahey MJ

Shriners Hospitals for Children, 3551 North Broad Street, Philadelphia, PA 19140 USA

Email: btsmith@shrinenet.org

## Abstract

*Ten young people with thoracic level SCI, ages 7 to 20 years, received an 8-channel implanted lower extremity functional electrical stimulation (FES) system for standing and walking. Electrodes were placed for stimulation of hip and knee extensors, and for hip abduction and adduction. Standing and walking were achieved through constant stimulation to the implanted muscles, allowing a swing through gait pattern with an assistive device. After training with FES, subjects were tested in 3 upright mobility activities on an annual basis, which were scored based upon completion time and level of independence. Follow-up data were available for 7 of 10 subjects and spanned 1 to 5 years. Of the 21 activities tested (7 subjects x 3 activities), independence level with FES was improved or maintained in 15 cases (71%). For the 6 remaining cases (29%), moderate to minimal assistance was required at follow-up where no assistance was needed initially. Completion times were maintained or improved over follow-up in 17 of the 21 cases (81%). Perceived effort was rated as most reasonable (1) in 71% of the cases initially and in 62% of the cases at the latest follow-up.*

## 1 Introduction

Previous work in our laboratory [1][2][3] has shown that children with paraplegia could perform functional activities in at least an equal amount of time and with at least equal independence using a percutaneous or implanted FES system as compared LLB. Children were tested on common activities including a sit to stand transition, reaching items on a shelf, short distance ambulation (6 meters), ascending and descending stairs, and maneuvering in an inaccessible bathroom. The children preferred using the FES system for 62% of the activities, LLB for 27% of activities, and showed no preference for 11% of activities. The purpose of this paper is to report the results of our longer term follow-up with

the lower extremity neuroprosthesis to provide upright mobility in young people with motor complete thoracic level SCI [2].

## 2 Methods

As detailed in Table 1, nine subjects with T1 to T11 paraplegia and one subject with C7 tetraplegia (mean age  $13.4 \pm 5.7$  years) received an 8 channel implanted lower extremity 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.

Table 1: Subject Data

| SUBJECT | AGE (years) | LEVEL OF INJURY |
|---------|-------------|-----------------|
| 1       | 13          | T8              |
| 2       | 20          | T1              |
| 3       | 20          | C7              |
| 4       | 7           | T7              |
| 5       | 10          | T11             |
| 6       | 19          | T7              |
| 7       | 8           | T1              |
| 8       | 9           | T8              |
| 9       | 8           | T4              |
| 10      | 20          | T4              |

The first 5 subjects received a combination of intramuscular [4] and epimysial electrodes. The other 5 received all intramuscular electrodes. Following implantation, all electrodes were tunnelled 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. Subjects 9 and 10 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.

Stimulation patterns were created using custom software and downloaded into a research grade external stimulator [5]. 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.

Subjects were tested annually in 3 upright functional mobility activities (6 meter walk, Stand and Reach and High Transfer) after receiving training in the use of FES for those activities. 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). In addition, data were collected concerning perception of effort using a Likert scale. Eight subjects completed initial data collection and follow-up data is available for 7 of those 8.

### 3 Results

Follow-up data was obtained on 7 of the initial 10 subjects and ranged from 1 to 5 years. Five of the 7 subjects had at least 3 years follow-up.

Of the 7 subjects, 4 maintained or improved their independence level with FES on the 3 activities (Table 2). Of the three remaining subjects, ability on the high transfer was maintained. However, moderate to minimal assistance was needed at follow-up for the 6M walk and Stand and Reach activities that were performed without assistance initially. In total, performance was maintained or improved in 15 of 21 cases (71%). Similarly, completion times (Table 3) were maintained or reduced over follow-up in 17 of the 21 cases (81%). As shown in Table 4, perceived effort was rated as most reasonable (1) in 71% of the cases initially and in 62% of the cases at the latest follow-up.

**Table 2:** FIM scores for select activities after initial training (IT) and at latest follow-up (LF).

| Subject | Follow-up (yrs) | 6meter Walk |    | Stand & Reach |    | High Transfer |    |
|---------|-----------------|-------------|----|---------------|----|---------------|----|
|         |                 | IT          | LF | IT            | LF | IT            | LF |
| 1       | 5               | 6           | 6  | 6             | 6  | 6             | 6  |
| 4       | 4               | 6           | 4  | 6             | 3  | 4             | 4  |
| 3       | 4               | 4           | 4  | 4             | 4  | 4             | 4  |
| 7       | 3               | 6           | 4  | 5             | 4  | 4             | 4  |
| 9       | 3               | 5           | 5  | 5             | 5  | 3             | 5  |
| 10      | 2               | 5           | 6  | 5             | 6  | 5             | 6  |
| 8       | 1               | 5           | 4  | 5             | 4  | 4             | 4  |
| 2       | Initial only    | 5           |    | 4             |    | 5             |    |

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 3:** Time to completion (seconds) for select activities after initial training (IT) and at latest follow-up (LF). Average of 5 replications are in **bold** and the standard deviation is in italics.

| Subj | Follow-up (yrs) | 6meter Walk             |                         | Stand & Reach          |                         | High Transfer         |                       |
|------|-----------------|-------------------------|-------------------------|------------------------|-------------------------|-----------------------|-----------------------|
|      |                 | IT                      | LF                      | IT                     | LF                      | IT                    | LF                    |
| 1    | 5               | <b>9</b><br><i>0.5</i>  | <b>10</b><br><i>0.4</i> | <b>30</b><br><i>2</i>  | <b>48</b><br><i>4</i>   | <b>29</b><br><i>5</i> | <b>32</b><br><i>2</i> |
| 4    | 4               | <b>45</b><br><i>0.5</i> | <b>25</b><br><i>1</i>   | <b>52</b><br><i>5</i>  | <b>45</b><br><i>8</i>   | <b>45</b><br><i>1</i> | <b>40</b><br><i>5</i> |
| 3    | 4               | <b>67</b><br><i>6</i>   | <b>38</b><br><i>4</i>   | <b>39</b><br><i>3</i>  | <b>30</b><br><i>4</i>   | <b>37</b><br><i>1</i> | <b>32</b><br><i>1</i> |
| 7    | 3               | <b>43</b><br><i>3</i>   | <b>31</b><br><i>1</i>   | <b>54</b><br><i>3</i>  | <b>25</b><br><i>2</i>   | <b>33</b><br><i>2</i> | <b>27</b><br><i>1</i> |
| 9    | 3               | <b>41</b><br><i>5</i>   | <b>54</b><br><i>7</i>   | <b>48</b><br><i>4</i>  | <b>45</b><br><i>3</i>   | <b>42</b><br><i>3</i> | <b>41</b><br><i>3</i> |
| 10   | 2               | <b>11</b><br><i>0.5</i> | <b>11</b><br><i>0.4</i> | <b>53</b><br><i>3</i>  | <b>49</b><br><i>2</i>   | <b>31</b><br><i>3</i> | <b>27</b><br><i>1</i> |
| 8    | 1               | <b>26</b><br><i>1</i>   | <b>43</b><br><i>4</i>   | <b>106</b><br><i>9</i> | <b>106</b><br><i>17</i> | <b>67</b><br><i>4</i> | <b>51</b><br><i>5</i> |
| 2    | Initial only    | <b>24</b><br><i>1</i>   |                         | <b>68</b><br><i>4</i>  |                         | <b>58</b><br><i>3</i> |                       |

**Table 4:** Subjects' perception of effort is shown for the activities after initial training (IT) and at latest follow-up (LF). A 5-point Likert scale was used (1- reasonable effort; 5-too much effort).

| Subject | Follow-up (yrs) | 6M Walk |    | Stand & Reach |    | High Transfer |    |
|---------|-----------------|---------|----|---------------|----|---------------|----|
|         |                 | IT      | LF | IT            | LF | IT            | LF |
| 1       | 5               | 3       | 1  | 2             | 2  | 3             | 2  |
| 4       | 4               | 1       | 3  | 1             | 1  | 2             | 2  |
| 3       | 4               | 3       | 2  | 2             | 1  | 1             | 2  |
| 7       | 3               | 1       | 1  | 1             | 1  | 1             | 1  |
| 9       | 3               | 1       | 4  | 1             | 1  | 1             | 1  |
| 10      | 2               | 1       | 1  | 1             | 3  | 1             | 1  |
| 8       | 1               | 1       | 1  | 1             | 1  | 1             | 1  |
| 2       | Initial only    | 1       |    | 1             |    | 2             |    |

#### 4 Discussion and Conclusions

In this study, we followed the ability of seven young people with SCI to use their FES system for three relevant mobility activities. Performance level and time to completion on those activities was maintained or improved in most cases over a 1 to 5 year follow-up period. In addition, the perceived effort was scored as most reasonable (score of 1 on a 5 point Likert scale) in nearly the same number of cases at follow-up (13) as initially (15).

Technically, the FES components continued to operate throughout the follow-up period. On the annual visits, stimulated muscle performance was characterized and slight alterations to the stimulation parameters were made as necessary. Anecdotally, it seemed that there was a direct relationship between the amount of time the children used the FES system for the tested activities at home and their performance of those same activities at follow-up (i.e. greater use at home resulted in maintenance or improvement in performance in the lab). Subjects also reported performing other activities with the FES system at home including getting into an airplane, getting into a sports utility vehicle, and standing to don pants.

#### References

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