Abstract

In this investigation, an implantable 8 channel functional electrical stimulation (FES) system (NeuroControl Corporation, Valley View, OH) was implanted in 9 growing children with spinal cord injuries (SCI) ranging in age from 7 to 14 years. For 6 children with thoracic level injuries, the stimulator was placed in the lower extremities to provide upright mobility and for 3 children with C5 SCI, the stimulator was placed in the upper extremity to provide hand grasp and release. In both applications extra lead was used to connect the internal stimulator to each electrode in order to accommodate limb growth. The amount of extra lead needed was determined based on each child’s skeletal age. To date, average follow-up is 19 months during which time an average of 2.7 cm of femoral or humeral/ulnar bone growth has occurred. Of 61 electrodes exposed to growth, data suggest that 1 (1.6%) electrode may have failed due to growth.

Introduction/Background

The implantable FES system manufactured by NeuroControl Corporation (NCC) [1] is commercially available to provide stimulated hand function for individuals with C5 SCI [2,3] and has been used experimentally to provide stimulated upright mobility for individuals with thoracic level SCI. [4,5] With the NCC system, 8 implanted electrodes are placed in targeted muscles; the corresponding electrode leads are routed subcutaneously and are connected via an in-line connection to an eight-channel implanted stimulator. [1] An external control unit supplies power and stimulation parameters to the internal stimulator by way of a radio frequency signal. The user controls stimulated hand grasp with contralateral shoulder shrug sensed by an external position sensor. For standing, a simple on/off switch is used to initiate and deactivate stimulation.

While the NCC implantable FES system has been implemented with both adults [2,5] and skeletally mature adolescents with SCI [3], growing children have not yet been recipients of this device due to the unknown effect of limb growth on the performance of the internal components. Recent results of animal studies at our institution suggest that motor responses could be maintained with growth using the implanted electrodes of the NCC system [6] and that excess electrode lead can unravel with growth such that electrodes will remain in position and provide a stable motor response [7]. These positive results using an animal model were the catalyst to implement the NCC FES system in growing children with SCI.

Methods

The NCC implantable FES system was implanted in 9 skeletally immature children with SCI (3 upper extremity and 6 lower extremity systems) ranging in age from 7 to 14 years (Table 1). Generally, epimysial (EP) electrodes [2] were used for superficial muscles and intramuscular (IM) electrodes [8] were used for deeper muscles. For each child, the amount of expected upper or lower limb growth contributed by individual growth plates was determined from growth charts [9,10] based on skeletal age calculated using the Greulich-Pyle Method. [11]

Table 1: List of study participants. LE- lower extremity system; UE – upper extremity system.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Implant Location</th>
<th>Birth Age* (years)</th>
<th>Bone Age* (years)</th>
<th>Level of Injury</th>
</tr>
</thead>
<tbody>
<tr>
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<td>T10</td>
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<tr>
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<td>LE</td>
<td>11</td>
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<td>T11</td>
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<td>LE</td>
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<td>AM</td>
<td>UE</td>
<td>15</td>
<td>15</td>
<td>C5</td>
</tr>
</tbody>
</table>

*At start of study

The amount of excess lead was then determined based on the number of growth plates spanned by the lead wire connecting the individual electrodes to the central internal stimulator. For the upper extremity application, the stimulator is in the upper chest so that electrodes in forearm muscles (finger and thumb extensors and flexors) cross the humeral and proximal radial growth plates and electrodes in the hand muscles (thumb abductor and adductor) additionally cross the distal radial growth plate. For the lower extremity application, the lead wire must accommodate growth of...
the proximal femur only, since the stimulator is in the abdominal region and the electrodes are placed in muscles of the upper leg (hip and knee extensors and hip abductor). For both applications, anywhere from 4 to 10 cm of extra lead wire was used per electrode and was distributed along the lead pathway in several places in an “S” shape (Figure 1).

![Figure 1: Radiograph showing placement of excess lead in the arm for subject JC.](image)

Measures

Yearly evaluations included radiographs to measure lead unwinding and bone growth, measures of stimulated muscle strength (5 point Manual Muscle Test scale) and the functional abilities of the child while using the FES device scored using the 7 point scale of the functional independence measure (FIM). An electrode failure was defined as a grade 1 stimulated muscle strength for the hip abductors and extensors and less than grade 4 stimulated muscle strength for the knee extensors. For the upper extremity system, electrode failure was considered a stimulated muscle strength of less than grade 3. Also, an electrode was considered to have failed, regardless of the target muscle, if a 2-point drop in muscle force was realized on the Manual Muscle Test scale.

Results

Lower Extremity System

For the 6 subjects with lower extremity systems, average follow-up to date is 19 months with the longest follow-up being 36 months. Total femoral growth has averaged 2.7 cm. To date, four subjects have achieved less than 25% of expected growth, 1 subject 37% of expected growth and the oldest subject (RF) 75% of expected growth. Of the 53 electrodes implanted (45 IM, 8 EP) in the lower extremity muscles, 48 (91%) continue to function at follow-up. The 5 electrodes that failed did so an average of 121 days after implant. Four of these failures came from one subject (LV). Lead unwinding has not yet been observed. At their latest follow-up points, 5 of 6 subjects were able to achieve a FIM score of 5 or 6 when using the FES system for stand and reach, a 6 meter swing through walk with crutches, or transfer to an inaccessible bathroom stall. One subject (LV) has not yet had one of his failed electrodes replaced and has been unable to achieve a standing position as a result.

Upper Extremity System

For the upper extremity subjects, one subject (RD) was lost to follow-up because of system removal at 6 months post implant due to an infection and one subject (AM) has not exhibited any bone growth at 18 months post implant. For subject JC, approximately 2.7 cm of total upper limb bone growth was measured over the course of 16 months. Six of 8 electrodes have maintained functional stimulated responses over that period. Of the two failed electrodes, one failed within 2 months after implant and the second at 16 months post implant.

Lead unwinding on the order of limb growth was quantified in subject JC. Using a cartography wheel, 1.2 cm of lead unwinding in the upper arm was measured from tracings taken from X-ray, comparable to the 1.4 cm of humeral bone growth. In addition, for the two electrodes in hand muscles, lead unwinding on the order of ulnar bone growth (1.3 cm) was calculated (Figure 2). Of the two failed electrodes, one exhibited a 0.6 cm decrease in excess lead so that by 16 months post implant the amount of extra lead close to the electrode tip was depleted. The second electrode appeared to have ample excess lead.

Hand function using FES was consistent throughout follow-up and represented an improvement over voluntary upper extremity function. At the 6 and 16 month follow-up points, the FES system provided a functional pinch force (about 15 Newtons) greater than that which could be achieved with tenodesis pinch (1.3 Newtons) and the FES system improved function (9 point improvement in FIM score over upper extremity function without FES). Functional gains were realized primarily in eating and grooming.
Discussion/Conclusions
Overall, of the 61 electrodes exposed to growth (7 subjects), 54 (88.5%) have maintained their stimulated motor responses in the presence of 2-3 cm of limb growth over an average follow-up period of 16 months. Six electrodes (9.8%) failed within 4 months of implantation and 4 of those 6 were from 1 lower extremity subject. These failures are likely not due to growth since in each case ample extra lead was evident by radiograph and very small amounts of growth occurred before failure (about 0.3 cm estimated from interpolation of one year growth post implant). These failures are more likely due to poor initial electrode placement. One electrode (1.6%) is suspected of failing due to growth. In this case the electrode failed after several centimeters of growth had occurred (16 months after implant) and the excess lead for that electrode appeared to have been exhausted close to the tip likely placing tension on the electrode. Several centimeters of additional lead perhaps could have prevented this failure.

By using excess lead to accommodate growth, these children have been provided with implantable FES systems 3 to 10 years sooner than would otherwise be indicated. Each subject will be followed annually until skeletal maturity is reached.

References

Acknowledgments: This study is funded by Shriners Hospitals for Children Grant #8530. Therese Johnston is gratefully acknowledged for performing manual muscle testing.