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Case Report

An implantable upper extremity neuroprosthesis in a growing child with a C5 spinal cord injury

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Objectives: To implement a functional electrical stimulation (FES) hand neuroprosthesis called the Freehand System in a growing child with spinal cord injury (SCI) using extra lead wire to accommodate limb growth, and to evaluate the performance of the Freehand System during the subject's maturation.
Setting: Pediatric orthopedic hospital specializing in SCI rehabilitation.
Subject: Ten-year-old female patient with a C5 level SCI.
Method: The Freehand System was implanted. Eight electrodes were implanted to targeted forearm and hand muscles to provide grasp and release function. The lead wire associated with each electrode was pathed subcutaneously up the arm with 4 cm of extra lead distributed throughout the path to accommodate expected limb growth. All leads were attached to a stimulator placed in the upper chest. Measures of lead unwinding, limb growth, stimulated muscle strength, and hand function were made at 6 and 16 months after implant.
Results: By 16 months post implant, the upper limb growth plates were closed and humeral and radial bone growth combined was 2.7 cm from the time of surgery. For all eight leads, lead unwinding in the upper arm was approximately 1.2 cm and was comparable to humeral bone growth (1.4 cm). Lead unwinding in the lower arm was also measurable for the two electrodes in hand muscles. Six of eight electrodes maintained grade 3 or better stimulated muscle strength throughout the growth period according to a manual muscle test. Of the two other electrodes, one appeared to have lost function due to depletion of excess lead. However, hand function with FES was comparable at 6 and 16 months post implant suggesting that growth did not negatively impact performance with the FES system. Hand function with FES was improved over voluntary hand function as well. Using the Freehand System, a pinch force of approximately 15 N was achieved compared to 1.3 N of voluntary tenodesis pinch force. Scores on the Functional Independence Measure (FIM) increased by 9 points when FES was used as compared to voluntary function. Improvements occurred primarily in eating and grooming. Independence in writing was achieved only with FES.
Conclusions: For this child, hand function with the Freehand System was sustained over the growth period and was a significant functional improvement over voluntary hand function. By using excess lead wire, the Freehand System was successfully implemented before skeletal maturity, affording the child improved hand function earlier than would be otherwise indicated.
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Introduction

The Freehand System (NeuroControl Corporation, Valley View, OH, USA) is a commercially available eight-channel functional electrical stimulation (FES) system designed to stimulate paralyzed muscles of the hand and arm to provide hand function for skeletally mature individuals with C5 spinal cord injury (SCI). With this system, implanted electrodes are placed in selected forearm and hand muscles; the electrode leads are routed subcutaneously along the arm and are connected via an in-line connection to an eight-channel

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implanted stimulator placed in the chest.[1] An external control unit supplies power and stimulation parameters to the internal stimulator by way of a radio frequency signal. The user controls stimulation of hand grasp with contralateral shoulder shrug sensed by an external position sensor[1]

While the Freehand System has been implemented with both adults[2] and skeletally mature adolescents with SCI,[3,4] 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. At our institution, recent results using a canine model suggest that motor responses can be maintained with growth using the implanted electrodes of the Freehand System[5] and that excess electrode lead can unravel with growth such that electrodes will remain in position and provide a stable motor response.[6] These positive results with growing animals were the catalyst to implement the Freehand System in a growing child with SCI using excess lead wire to accommodate limb growth.

Case report

Subject
The subject is a 10-year-old female with a C5 SCI who is classified as motor group 1 according to the International Classification for Surgery of the Hand in Tetraplegia. She was 10 months post injury at the time of Freehand System implantation. Before the intervention she was able to perform simple activities with a dorsal wrist splint and cuff. She was unable to perform more difficult tasks such as drinking from a cup or using utensils independently to eat. Other than the fact that the subject was skeletally immature, she was considered an appropriate candidate for the Freehand System based on her level of motor function.[2] Informed consent was obtained from the child and family. An Investigational Device Exemption was obtained from the United States Food and Drug Administration for this study.

Excess lead calculations
Pre-operatively, skeletal age was determined by left-hand radiograph to be 13 years using the Greulich-Pyle method.[7] From the skeletal age, growth charts[8] were used to determine the maximum remaining bone growth expected across each upper extremity joint. Knowing the expected growth across each joint, we calculated the amount of excess lead required based on the position of each electrode (ie by the number of joints crossed by each electrode lead). For a female at a skeletal age of 13 years, approximately 1.5 cm of growth would be expected across the wrist (distal radial growth plate), about 0.1 cm across the elbow (proximal radial growth plate plus distal humeral growth plate) and 1.4 cm across the shoulder (proximal humeral growth plate).[7] Because the electrode leads are pathed along the arm starting from the upper chest, an electrode positioned in a muscle in the forearm or hand would be exposed to growth of both the humeral and proximal radial growth plates. An electrode in a muscle in the hand would additionally be exposed to growth from the distal radial growth plate. Thus, for this subject, a forearm muscle electrode required approximately 1.5 cm of excess lead and a hand muscle electrode required about 3 cm of excess lead.

Implantation of Freehand System
The implementation of the system included implantation of electrodes with excess lead wire and the stimulator as well as several surgical procedures to enhance the effectiveness of the system. The following muscles were implanted with surgically implanted intramuscular electrodes:[9] adductor pollicis (AdP), flexor digitorum profundus and flexor pollicis longus (FPL). Epimysial electrodes were implanted to the following muscles: abductor pollicis brevis (AbPB), extensor digitorum communis, extensor pollicis longus, pronator quadratus and abductor pollicis longus (AbPL). For each electrode, once the optimal position of the electrode within or along the muscle was determined, the length of the electrode lead pathway was measured with about 4 cm of excess lead added to accommodate growth. Figure 1 shows the placement of excess lead in the upper arm. The excess lead was distributed in an ‘S’ shape along the pathway.

Surgical procedures included transfer of the brachioradialis and abductor pollicis longus tendons to the radial wrist extensors, a flexor pollicis longus tendon split, fusion of the metacarpophalangeal joint of the thumb and deltoid to triceps tendon transfer. These procedures are designed to facilitate the application of the Freehand System and are typically employed with the application of the system in adults and adolescents.[2,3]

To allow for proper healing of the tendon transfers, the arm was casted for 4 weeks following surgery with the hand in the intrinsic plus position, the elbow in 10° of flexion and the wrist in 20° of extension.[10] Following cast removal, the child underwent both a 4-week stimulated exercise program to hypertrophy forearm and hand muscles and traditional rehabilitation for transfer re-training involving the brachioradialis and deltoid muscles.[10] The child was then trained to use the Freehand System for daily activities such as eating, brushing teeth, and writing. She was subsequently discharged to home to use the Freehand System as desired. Throughout the follow up period, the stimulated grasps were refined as necessary to produce the greatest grasp and pinch forces possible while allowing the child to maintain a functional wrist position without the use of a splint.

Outcome measures
At 2, 6 and 16 months post implant, stimulated strength of the individual muscles was assessed using

Figure 1 Radiograph of the upper arm taken 1 day after Freehand system implantation. Note the extra lead wire placed in the upper limb

the 5 level manual muscle test (MMT) scale. At 6 and 16 months post implant measures were taken of stimulated pinch force. In addition, the Grasp and Release Test (GRT)[11] and the Functional Independence Measure (FIM) were administered. Bone growth was determined by finding the difference between the length of the bones (for the humerus and radius) between the pre-operative and 16 month post-operative radiographs. Lead unwinding was quantified by tracing the path of each electrode in both the upper arm and forearm/hand from the radiograph onto transparency. Then a cartography wheel was traced along the lead path to determine lead length within the fixed area. The difference in lead length between the pre-operative and 16 month postoperative radiographs determined the amount of lead unwinding. For each electrode lead, unwinding was determined for the upper arm (defined as the path from the connection to the stimulator lead to the end of the humerus) and the forearm and hand (defined as the path from the electrode tip to the end of the humerus).

Results

By 16 months post surgery, 2.7 cm of right upper limb growth was measured: 1.4 cm of humeral growth and 1.3 cm of radial/ulnar growth. At that time the child's growth plates were closed as determined by radiograph. Approximately 1.2 cm of unwinding was measured in the upper arm from all of the leads, comparable to the measured 1.4 cm of humeral growth (Figure 2). For the electrodes implanted in the AdP and AbPB (Figure 3) muscles of the hand, additional lead extension in the hand and forearm of 1.3 cm and 0.8 cm was measured, respectively, comparable to the 1.3 cm of radial/ulnar growth to which these leads were exposed. For the electrodes implanted in the forearm muscles, only for the lead correspondiing to the FPL muscle was there measurable lead extension (0.6 cm). For the forearm muscles, the general lack of unwinding of extra lead in the forearm was not unexpected since those leads were exposed primarily to growth of the humerus which was accommodated by the unwinding of extra upper arm lead.

Of the eight implanted electrodes, six generated the same stimulated muscle strength (grade 3 or 4) at each follow-up point. One electrode, implanted in the AbPL muscle, was repositioned 3 months after surgery (before substantial growth) due to a decrease in generated muscle force (from grade 2+ to grade 1). Following the revision, grade 2 muscle force was recovered and maintained until the 16-month follow-up point (following growth) at which time the electrode stimulated an adjacent muscle, the extensor pollicis longus. A second electrode implanted into the FPL muscle provided grade 3 muscle strength until the 16-month point at which time it excited another muscle innervated by the median nerve, the flexor pollicis brevis.

A review of the radiographs showed that for the AbPL electrode, ample excess lead was available throughout the lead path. For the FPL electrode, there was a 0.6 cm decrease in the amount of extra lead closest to the electrode tip so that by 16 months post implant it appeared that the excess lead was exhausted possibly placing stress on the electrode. Stimulation through these electrodes was discontinued and the grasp patterns reprogrammed after these changes were measured.

Stimulated pinch force was 14.2 N at 6 months follow-up and 15.5 N at 16 months follow-up. Voluntarily, approximately 1.3 N of pinch force could be achieved at these follow-up points. On the GRT, only the two lightest objects could be manipulated voluntarily at 6 and 16 month's follow-up whereas with FES grasp, the lightest and heaviest objects could be manipulated successfully at those points (five of the six objects on the test). The child's FIM score was 52 without FES at both follow-up points and increased

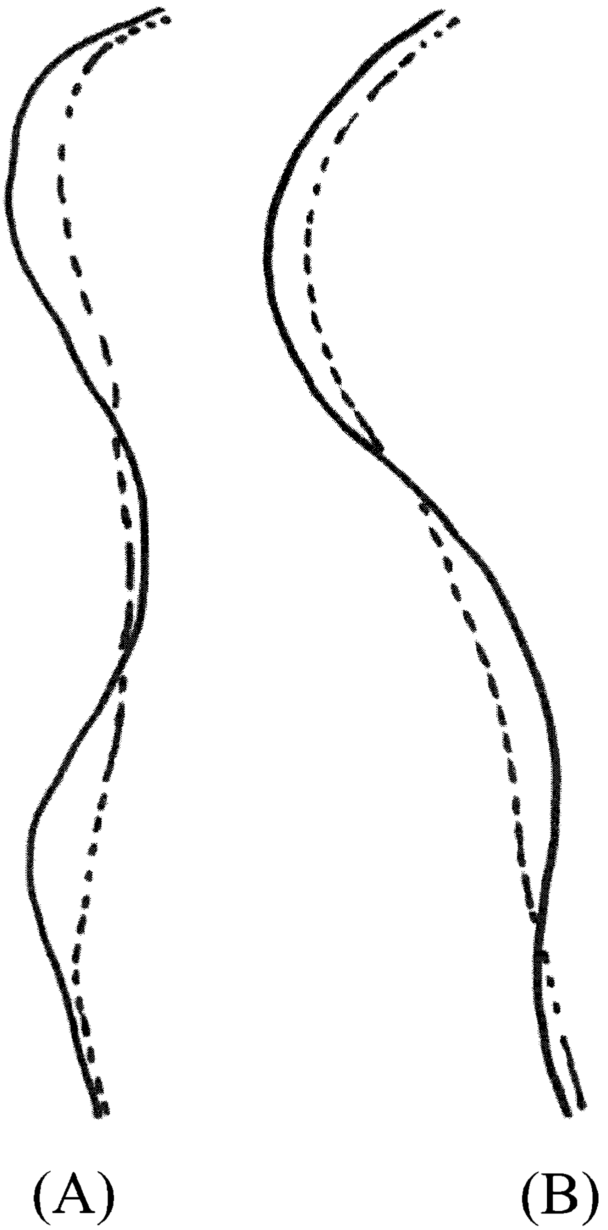

Figure 2 Tracings taken from radiograph of the lateral (**A**) and medial (**B**) lead paths in the upper limb. Because leads were pathed in the upper arm in pairs of 4, each tracing represent four sets of superimposed lead wires. The solid lines are the lead paths just after implant and the dashed lines show the lead paths after growth was completed. For both the medial and lateral lead sets, the decrease in lead length after growth was measured to be 1.2 cm, comparable to the measured humeral growth of 1.4 cm

with FES to 59 and 63 at 6 and 16 months post-surgery, respectively. Primary improvements were realized in eating (+2) and grooming (+5). In both cases the child went from being dependent on a caregiver to being independent in the tasks. Also, the child was typically dependent on a caregiver to assist with positioning a pen in her hand for writing. With

Figure 3 Tracings of the excess lead close to the tip of the electrode to the AbPB muscle taken from radiographs immediately after implant (**A**) and after growth (**B**). The 1.3 cm reduction in the excess lead measured in the area closest to the electrode tip following growth matches the measured radial bone growth

FES grasp, she was able to acquire the pen herself so that writing became an independent task.

Discussion

For this 10-year-old child, FES grasp and release abilities provided significant improvement over voluntary tenodesis function, comparable to that reported in adults[2] and adolescents[3] Hand function using the Freehand System was maintained in the presence of 2.7 cm of upper limb growth. Lead extension was measurable and, for each electrode lead, on the order of the bone growth to which it was exposed.

In this case we were able to employ FES to improve hand function for a 10-year-old child, 16 months earlier than would have been indicated due to growth. For a child with a C5 SCI, the ability to provide more independent hand function at an earlier age may have a profound positive impact on various aspects of development through improved social interactions, the ability to participate in school and complete assignments, and in the performance of hygiene tasks.[12,15] For tasks such as writing and grooming, this child was independent of a caregiver only when using FES.

Importantly, the Freehand System was implemented 16 months sooner after injury as well (at 10 months post injury). Potential issues associated with longer term spinal cord injuries such as tendon tightness of the finger flexors or supination contractures can hamper effectiveness of stimulated grasps and may be avoided with earlier application of the Freehand System.[12]

Measured upper limb growth (2.7 cm) was comparable to that predicted (3 cm) based on growth charts.[8] While this child's chronological age was 10 years, she was 13 years old skeletally so that relatively small amounts of excess lead were required. Since substantial limb growth is expected in younger children, the accurate prediction of expected growth is critical to estimate the required amount of implanted lead wire. For example, a male child at a bone age of 7 years would require 14 cm of extra lead for an electrode in the forearm to accommodate growth to skeletal maturity. Lead wire placement will also become more challenging as these larger amounts of excess lead wire will be required in a smaller arm.

Based on the sustained stimulated pinch force and FIM score, the loss of the desired muscle responses from two electrodes did not deter from the hand function provided by the Freehand System. Without stimulation to the AbPL muscle (which was intended to provide additional wrist extension force by way of the transfer of the AbPL tendon to the radial wrist extensors), the child maintained adequate wrist position with voluntary effort from the transfer of the brachioradialis muscle to the radial wrist extensors which was performed during the original surgery. A strong stimulated response from the adductor pollicis muscle compensated for the loss of the distal thumb flexion of the FPL muscle.

We suspect that growth was a factor in the changed response of the electrode to the FPL muscle but not the AbPL. At the time of their respective response changes, the FPL electrode had no excess lead left closest to its tip while the AbPL electrode had ample redundant lead. Further, the AbPL electrode first lost its response within the first months after implant when growth was minimal suggesting that this electrode position was very discrete. Conversely, the change in the response of the FPL electrode appeared to correspond to the depletion of excess lead. We speculate that several additional centimeters of lead could have prevented this situation.

To our knowledge, this is the first report of an implantable stimulation system for limb function in a growing child. Various stimulation devices such as cardiac pacemakers,[14] diaphragmatic pacing systems,[15] and cochlear implants[16,17] have been investigated in growing animal models and in some instances, implemented clinically with children. As in this case report, these studies have shown that using redundant lead wire, in some cases housed within biocompatible pouches,[16,17] is effective in accommodating small amounts of growth on the order of several centimeters so that system performance remains stable.

Conclusion

For this child, hand function with the Freehand System was sustained over the growth period and was a significant functional improvement over voluntary hand function. By using excess lead wire, the Freehand System was successfully implemented before skeletal maturity, affording the child improved hand function earlier than would be otherwise indicated.

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