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Original Article

Implantation of the Freehand System® during initial rehabilitation using minimally invasive techniques

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Study design: Series of four single subjects with and without intervention design.
Objectives: To describe a minimally invasive surgical technique used to implant the Freehand System® during initial spinal cord injury (SCI) rehabilitation and to report rehabilitation outcomes of four recently injured adolescents using the Freehand System®.
Setting: Nonprofit children's hospital specializing in orthopedic and SCI care.
Methods: Four subjects with C5 tetraplegia between 13 and 16 years of age and between 9 and 16 weeks following traumatic SCI underwent implantation of the Freehand System® using minimally invasive surgical techniques. Outcomes on muscle strength, pinch force, hand function, performance of activities of daily living and satisfaction with and without the Freehand System® were collected.
Results: Each subject was successfully implanted with the Freehand System® without perioperative complications and employed the Freehand System® during therapy services and *ad lib* on the rehabilitation floor. At the last follow-up, every subject remained a motor candidate for the Freehand System®. With the Freehand System®, average lateral and palmar pinch force was 1.8 and 1.6 kg respectively; average pinch force without functional electrical stimulation (FES) was 0.29 kg. With the Freehand System®, three subjects improved their rate of performance on The Upper Extremity Capabilities Questionnaire. All subjects increased their level of independence on The Quadriplegia Index of Function. On the Canadian Occupational Performance Measure (COPM) with the Freehand System®, average performance and satisfaction scores improved for every patient. Three of the four subjects continued to use the system at home.
Conclusion: This case series demonstrates that the Freehand System® can vastly improve hand function and performance of rehabilitation activities within days after a minimally invasive implant procedure during initial SCI rehabilitation. Satisfaction with the Freehand System® beyond initial rehabilitation is evidenced by continued use at home.
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Keywords: functional electrical stimulation; spinal cord injury; tetraplegia

Introduction

The Freehand System®[1,2] (formally manufactured by NeuroControl Corporation, Valley View, OH, USA) is an eight-channel functional electrical stimulation (FES) system designed to stimulate paralyzed muscles of the hand and arm to provide hand function for persons with C5–C6 spinal cord injury (SCI) (motor groups 0–2 of International Classification for Surgery of the Hand in Tetraplegia Classification (ICSHT). With this system, implanted electrodes are placed in paralyzed forearm and hand muscles; the electrode leads are routed in a proximal direction subcutaneously through the arm and are connected via an in-line connection to an eight-channel implanted stimulator placed in the chest. An external control unit supplies power and stimulation parameters to the internal stimulator by way of a radiofrequency signal (Figure 1). The user controls stimulation to the hand with contralateral shoulder shrug sensed by an external position sensor. A quick movement of the shoulder allows the user to maintain grasp of an object without keeping the elevated shoulder position by locking the hand in a desired position. Typically, the Freehand System® is combined with

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surgical reconstruction[3–6] to reverse the deformities of the hand in an effort to provide an efficient, balanced hand grasp and release. Keeping with the principles of surgical reconstruction set forth by the Moberg Society in 1986,[7] implantation of the Freehand System® has been performed on adults who are at least 1 year after injury and when neurological stability is present.

Over the past decade, the Freehand System® has undergone a multicenter clinical trial (1993–1997) and was approved by the United States Food and Drug Administration (1997). It has gained acceptance by experts in the field of upper extremity reconstruction in tetraplegia[3] and has demonstrated effectiveness for enhancing function of persons with tetraplegia worldwide.[3,6,8–10] Our institution has been offering the Freehand System® since its inception, first as part of the clinical trial, and following FDA approval, as part of our clinical services. Most recently, we have implanted four Freehand Systems® during initial rehabilitation using a minimally invasive approach. Our decision to implant the Freehand System® earlier than 1 year postinjury was motivated by the superior outcomes in function demonstrated by those with chronic SCI after receiving the device,[3] the challenges of reconstructing hand deformities due to long-term paralysis[4] and most importantly, by patients' requests for the Freehand System® prior to the first anniversary of their injuries. While the Freehand System® is no longer manufactured, prototypes of second-generation FES systems are undergoing human trials. The purpose of this paper is to describe the minimally invasive surgical technique used to implant the Freehand System®, and to report rehabilitation outcomes of four recently injured adolescents using the FES. Results of this study provide insight into the clinical usefulness of FES and hence, important applications of future FES systems.

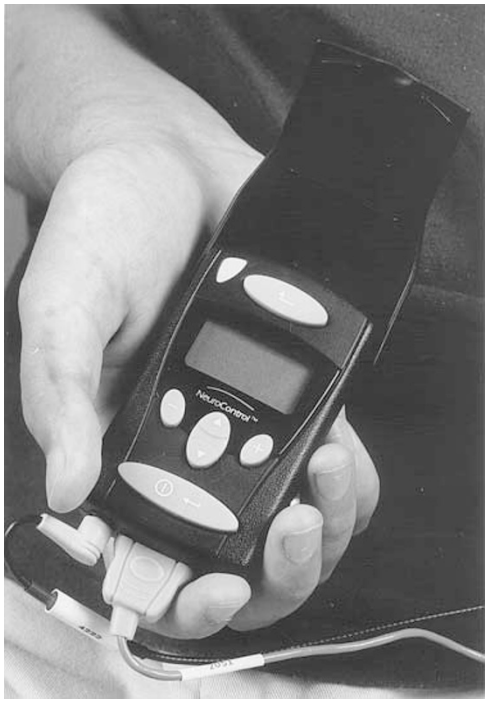

Figure 1 The external universal control box contains client-specific grasp patterns

Methods

Participants

This was a case series consisting of four subjects, using a 'with and without' intervention study design. Four adolescents with newly acquired tetraplegia were implanted with the Freehand System.® As shown in Table 1, at the time of implant, each subject was classified as ASIA C5 and ICSHT group 0 and therefore had less than a grade 3 radial wrist extension strength; Subject 2 had an asymmetrical presentation with a C4 motor level of his non-FES side. Length of time between date of injury and date of implant ranged between 6 and 16 weeks. With the exception of Subject 3, the Freehand System® was implanted to the preinjury dominant extremity. Each subject provided written informed consent.

Table 1 Characteristics of subjects

	Level of injury at time of implant					
Subjects		*ASIA*	*ICSHT*	*Cause of injury*	*Age at injury (years)*	*Length of time between date of injury and date of freehand implant (weeks)*
	Right	C5	0			
1	Left	C5	0	Diving	13	9
	Right	C4	0			
2	Left	C5	0	Diving	15	11
	Right	C5	0			
3[a]	Left	C5	0	Snowboard	16	16
	Right	C5	0			
4	Left	C5	0	Diving	16	6

[a]Patient had brachioradialis to wrist extension transfer

Freehand System® implantation

For each subject, the following muscles were implanted with intramuscular electrodes: extensor digitorum profundus, extensor pollicis longus, abductor pollicis longus, flexor digitorum profundus, flexor pollicis longus (FPL), adductor pollicis, and oppoenuns pollicis. Unlike traditional applications of the Freehand System®,[4] multiple tendon transfers and soft-tissue procedures were not performed. Rather, only the FPL split tendon transfer[11] was performed to provide thumb stability for pinch, and in Subject 3 the brachioradialis was transferred to the radial wrist extensors. The remaining subjects used their residual wrist extensors to stabilize their hands during stimulated finger and thumb flexion; stimulated flexion was programmed to allow for sufficient grasp without overpowering volitional wrist extension.

Minimally invasive surgical technique

Each subject was positioned supine on the operating table. Usually, Monitored Anesthetic Care (MAC) with light sedation was used. The subjects were prepped and draped over the upper extremity, shoulder, and hemithorax, and the proposed incisions were drawn. Percutaneous probing of the muscles was performed with 25-gauge by 6-in needle to assess the muscles' response to stimulation and to locate an optimal point for electrode insertion. This assessment was performed using pulse sequence stimulation of 16 Hz and 20 mA varying the pulse width based on the muscles' response. Once an optimal muscle response was elicited, verification of the motor point was made by increasing the pulse width to produce a full contraction of the muscle (Figure 2a,b).

Electrode implantation was performed in a distal to proximal direction. After verifying motor points for the muscles, a 3–4-mm skin incision was made for insertion of a Memberg Intramuscular™ electrode probe. The intramuscular probe was inserted to reconfirm the motor point and verify accurate electrode placement (Figure 3). A 4-in cannula was placed over the probe to create a reproducible channel to enable the actual electrode access to the motor point (Figure 4). Following withdrawal of the probe, the cannula remained to guide electrode insertion. Next, the electrode was placed through the cannula and inserted into the motor point (Figure 5a–c); once the electrode 'locked' into the muscle, the cannula was removed (Figure 5d).

Several methods such as a tendon passer and a neurosurgery shunt passer were used to pass the electrode leads in a proximal direction within the subcutaneous tissue to the connector site located in the proximal arm. Typically, electrodes were routed via small (3–4 mm) incisions, which were made throughout the forearm to assist in passage.

After all electrodes were implanted and passed to the connector site in the proximal arm, a 4-cm incision centered over the outline of the stimulator on the skin was made and a subcutaneous pocket was created to insert the stimulator (Figure 6). Once the stimulator was placed in the chest, the attached leads were passed via a Scanlon Tunneler™ to the connection site in the proximal arm. The stimulator was then sutured in place and the electrode leads from the muscles were connected to the leads from the stimulator. Once all leads were connected, the antenna in a sterile arthroscope plastic covering was placed over the implant. Stimulated responses of each electrode were performed to verify electrode placement and muscle response.

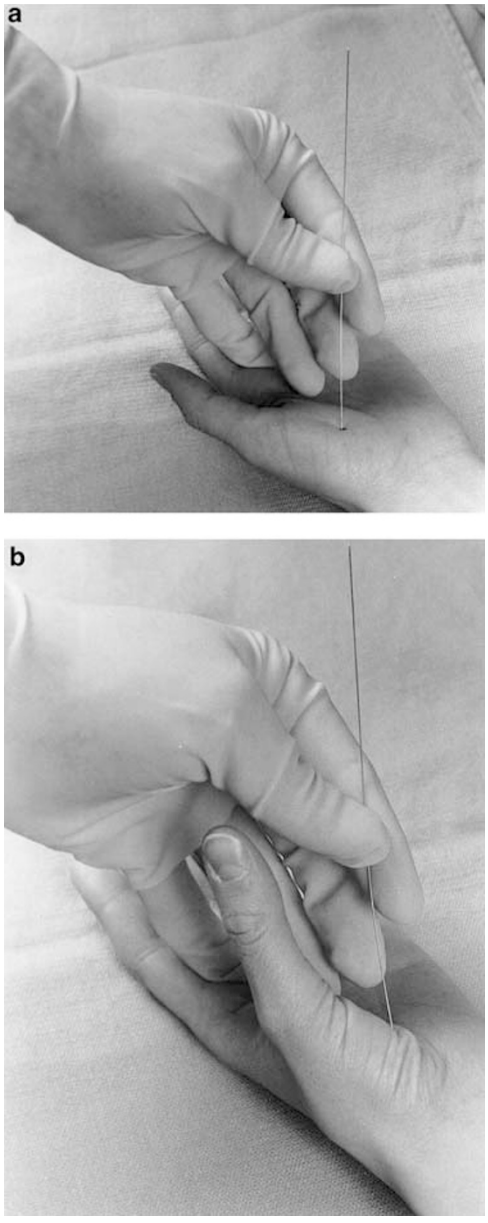

Figure 2 A thin probe is inserted to identify motor points for optimal electrode placement, in this case for the abductor pollicus brevis (**a**). Stimulation of the probe confirms motor point (**b**)

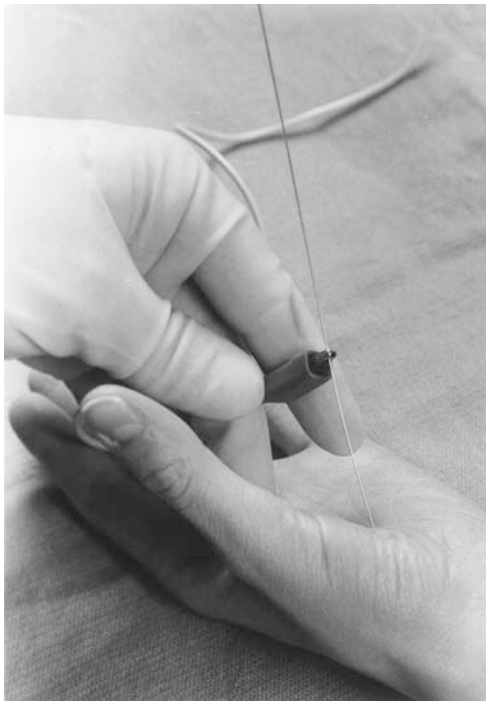

Figure 3 The intramuscular probe is placed to prepare for electrode insertion

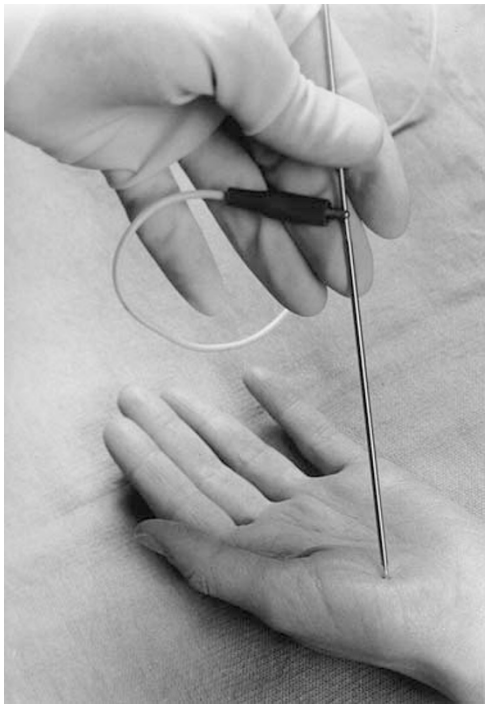

Figure 4 A cannula is placed over the probe; the probe is removed to allow access for implantation of the electrode

Following verification of each electrode, all incisions were irrigated, and primary closure of all incisions was performed.

Postoperatively, a soft dressing was applied for 2–4 days. With the exception of Subject 3, who was immobilized for 3 weeks with a splint secondary to the brachioradialis to wrist extensor transfer, subjects started exercising using their Freehand System® within the week of implantation.

Outcome measures

Evaluation of the Freehand System® was performed at discharge from initial rehabilitation (between 3 and 8 weeks following implantation) and again during regularly scheduled follow-up appointments. Upper extremity muscle strength, hand function, performance of activities of daily living (ADL) and satisfaction with the Freehand System® were evaluated.

Voluntary muscle strength of upper extremity muscles were measured on a scale between 0 (no strength) and 5 (normal) according to the guidelines of Daniels and Worthington.[12] Lateral and palmar stimulated pinch force and natural tenodesis pinch force was measured using a pinch gauge modified by an extension handle for tetraplegic grip. Upper extremity capacity was measured using the Upper Extremity Capabilities Questionnaire (UEC).[13] The UEC is a 17-item questionnaire that requires subjects to rate their ability to use their arms for a variety of activities that typify function of persons with tetraplegia. The first 11 questions focus on shoulder and reaching activities; questions 12–17 focus on hand function and object manipulation. Using the ordinal scale shown in Table 2, subjects rated each question under FES and non-FES conditions for their implanted side.

Performance of ADL was evaluated with the Quadriplegia Index of Function (QIF).[14] The QIF consists of two distinct areas of assessment. One area is composed of specific ADL that rates actual performance of the activity on a scale between '0' and '4' where '0' represents complete dependency and '4' represents complete independence. A score of a '1' and '2' denote the need for help and supervision by another person, respectively. A score of '3' reflects the need for adaptive equipment but no reliance on another person. The second area of QIF consists of a questionnaire designed to assess a person's understanding of consequences of SCI (such as dysreflexia, skin) and personal care concerns. For this study, the latter area of assessment was not conducted.

Satisfaction with the Freehand System® was measured with the Canadian Occupational Performance Measure (COPM).[15,16] The COPM is a tool designed to measure changes in client-perceived performance of and satisfaction with self-identified goals. In this study, goals were identified through informal interviews between the occupational therapist and subject during regular rehabilitation sessions. During these sessions, explanations based on past experience and published reports were

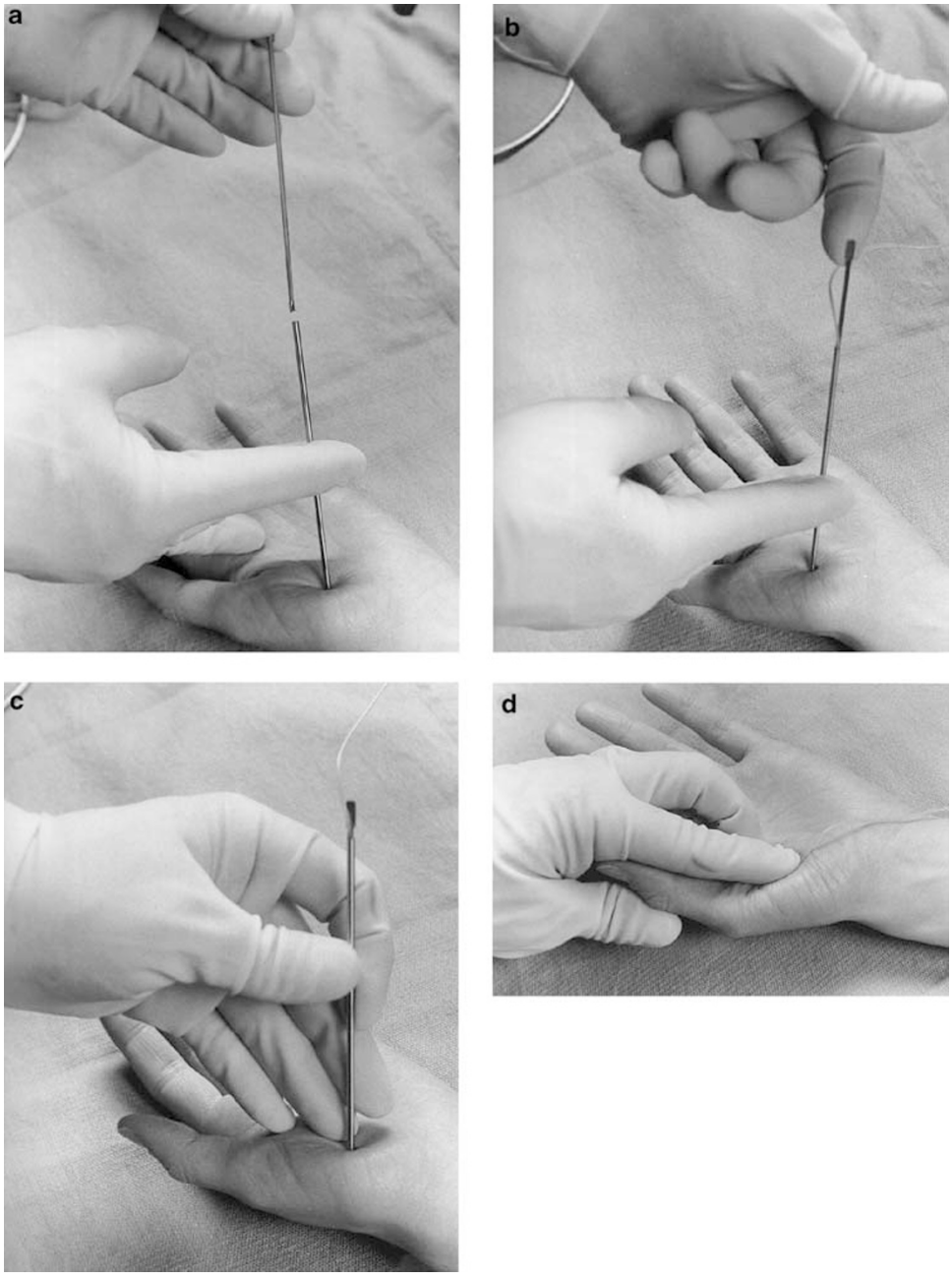

Figure 5 The hollow cannula acts as a guide to insert the electrode (**a**). The electrode is gently inserted into the cannula (**b, c**) and once in the muscle, the cannula is removed (**d**)

provided about the expected outcomes of the Freehand System.® Clarification on and understanding of their goals were solidified by viewing videotapes of people using the Freehand System® and creating opportunity for the subjects and their parents to talk with other people who had previously underwent Freehand System® implantation. For each goal, performance and satisfaction were rated by the subject using a 10-point ordinal scale where one was negative (cannot perform, not satisfied) and 10 was positive (performs very well, very satisfied). Open-ended questions were used to further evaluate subjects' experiences of early implantation of the Freehand System® and satisfaction with its outcomes.

Results

The minimally invasive approach to the Freehand System® implantation successfully restored hand function for each subject with minimal incisions (Figure 7a,b). There were no perioperative complications associated with the surgery. As important, subjects began Freehand System® use between 2 and 5 days after implantation and completed their initial SCI rehabilita-

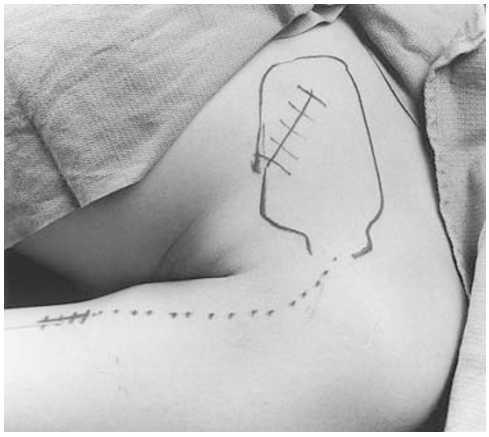

Figure 6 The stimulator is implanted via a pocket incision in the chest. The electrodes from the stimulator are pathed subcutaneously under the dotted line to be connected in the proximal arm to the leads from distal electrodes

Table 2 Rating scale for the upper extremity capability questionnaire

Score	*Description*
1	Totally limited, cannot do at all
2	Extremely limited
3	Very limited
4	Moderately limited
5	Some limitation
6	A little limited
7	Not at all limited

tion, integrating Freehand System® function into therapy and ad lib activities, without extensions to their in-patient status. Subject 3's use of the system and discharge was delayed by 3 weeks due to immobilization and retraining of the brachioradialis to wrist extension transfer. Three subjects have been followed for at least 12 months and Subject 4 has been followed for 6 months.

Muscle strength

No subject gained significant strength in any key muscle on their Freehand limb that would enable them to have active grasp via tendon transfers; hence, at the last follow-up, each subject remained a motor candidate for Freehand implementation. Also, cutaneous sensation as measured by two-point discrimination according to ICSHT was unchanged. As shown in Table 3, Subjects 1 and 4 showed strength changes in muscles distal to the zone of partial preservation on their non-Freehand System® extremity.

Pinch force

The mean of three trials of stimulated lateral and palmar pinch and natural tenodesis pinch was calculated and corrected within two decimals based on calibration of the modified extension handle. As shown in Table 4,

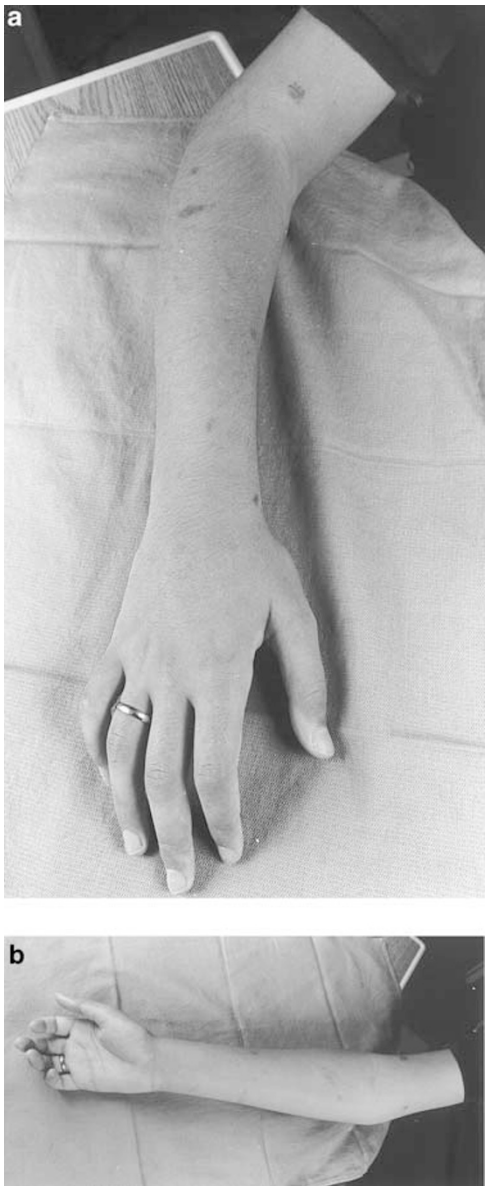

Figure 7 Healing incisions of dorsal (**a**) and volar (**b**) electrode implantation and passing sites approximately 3 months after implantation

while using the Freehand System® each subject realized significant improvement in pinch force. The average stimulated lateral and palmar pinch force was 1.8 and 1.6 kg, respectively. Before FES implantation, there was no measurable tenodesis pinch force at baseline for any subject. However at their last follow-up, Subject 1 produced 0.67 kg of force using natural tenodesis and Subject 3 produced 0.05 kg of force. Without the Freehand System®, the others produce no measurable pinch force.

Upper extremity capacity

As anticipated, the Freehand System® had no adverse impact on shoulder and elbow activities as measured by

Table 3 Strength of key muscles on non-freehand extremity

	1			*2*		*3*		*4*	
	Base	*3*	*12*	*Base*	*12*	*Base*	*12*	*Base*	*6*
Biceps	4	5	5	3	4	4	4	4	4
Brachioradialis	3	2+	4	1	2	3	3	1	2
ECR	2	3	3	1	1	1	1	2	2
Supinator	2	3	4	3	3	3+	3+	2+	4
Pronator	0	0	0	0	0	0	0	0	0
Finger ext.	0	0	3	0	0	0	0	0	0
Thumb ext.	0	0	3+	0	0	0	0	0	2
Finger flex.	0	0	3	0	0	0	0	0	0
Thumb flex	0	0	3	0	0	0	0	0	0
Other	0	0	3+	0	0	0	0	0	0

Table 4 Mean pinch force (kg) for each subject at last follow-up

Subjects	*1*	*2*	*3*	*4*
Lateral	2.8	0.82	1.9	1.7
Palmar	2.8	1.5	1.5	0.70
Natural tenodesis	0.67	0	0.05	0

Natural tenodesis reflects non-FES function

the first set of questions on the UEC; subjects rated each of the first 11 questions as 'totally to moderately limited' with and without the Freehand System®. However, on the last set of questions addressing hand function and object manipulation, the Freehand System® improved scores. As shown in Table 5, without the Freehand System®, three subjects (1, 3, 4) rated their ability to perform each of the activities between 'totally limited' to 'moderately limited.' With the Freehand System®, each of these subjects improved their rating; with FES Subject 1 rating the ability for every question as 'not limited at all'. The smallest gains were realized by Subject 2, who continued to rate the abilities with the Freehand System® between 'totally limited' and 'very limited'.

Quadriplegia index of function
The QIF was administered to Subjects 2–4. Subject 1 refused this assessment. With the Freehand System®, all subjects increased their level of independence. As shown in Table 6, activities in which most improvement was realized were particularly suited for the Freehand System® use: feeding, bladder management, and grooming. The scores of the three activities that are best suited for FES are also shown. Total scores are provided to illustrate overall improvements.

Canadian occupational performance measure
The COPM was administered to Subjects 1–3. Subject 4 refused this assessment. As shown in Figure 8a and b, subjects rated their performance better and had greater satisfaction when using the Freehand System®.

Open-ended questions
All subjects would repeat implantation of the Freehand System® during their initial rehabilitation. Three of the four subjects continue to use their system routinely; Subjects 2 and 4 daily, and Subject 1 several times a week. Subject 3 reports infrequent use due to the difficulty in maintaining the position sensor while propelling his manual chair.

Discussion

During their initial rehabilitation, four adolescents with newly acquired traumatic tetraplegia were implanted with the Freehand System® using minimally invasive surgical techniques. Each adolescent was trained in how to employ the Freehand System® for ADL during regular occupational therapy sessions and *ad lib* while on the rehabilitation unit. Also, they returned to home with the device within their anticipated discharge date. With the Freehand System®, three subjects improved on unilateral hand function tasks and continue to use their systems at home.

A critical consideration in the recommendation for early Freehand System® implantation is the prediction of neurologic recovery. In this study, the only patients considered for implantation were those with ASIA A injuries with wrist extension strength less than grade 3. While each subject gained some strength in elbow and wrist muscles, gains were not sufficient enough to move them from Freehand System® candidacy to active tendon transfer candidacy for grasp and pinch. Thus, each subject continues to meet the motor candidate criteria for the Freehand System®, ASIA C5 or weak C6 (wrist extension grade 3 or less). Data in the literature suggest that if a muscle has a 0 muscle grade at 2 months, it is unlikely that it will achieve a grade 3.[17,18] Lack of sensation in the nerve root deratome also suggests that recovery of motor function will unlikely

Table 5 Results of upper extremity capabilities test

		1 Totally limited	*2 Extremely limited*	*3 Very limited*	*4 Moderately limited*	*5 Some limits*	*6 Little limits*	*7 No limits*
Think about grasping and holding an object, like a hammer, in your hand	Without Freehand	2, 3, 4			1			
	With Freehand			2		3		1, 4
Think about picking up a small object such as a paper clip.. with the tips of your thumb and first two fingers	Without Freehand	1, 2, 3, 4						
	With Freehand			2			3	1, 4
Think about pinching and holding an object between your thumb and the side of your index finger…	Without Freehand	2, 3, 4	1					
	With Freehand			2			3	1, 4
Think about grasping a large object like the lid of a 2 pound jar…	Without Freehand	1, 2, 3, 4						
	With Freehand	2				3, 4		1
Think about using your finger to manipulate objects such as a coin….	Without Freehand	2, 3, 4			1			
	With Freehand	2				3		1, 4
Think about pressing something with the tip of your index finger…	Without Freehand	1, 2, 3, 4						
	With Freehand	2						1, 3, 4

Table 6 Results of QIF

		QIF score			
		Total score	*Feeding (0–24)*	*Grooming (0–12)*	*Bladder (0–28)*
	Without FES	17.38	1	0	0
2	With FES	25.7	2.25	3	2
	Without FES	19.87	3.75	2	0
3	With FES	43.5	15.75	12	14
	Without FES	19	1.5	0	0
4	With FES	30.9	10.5	5	7

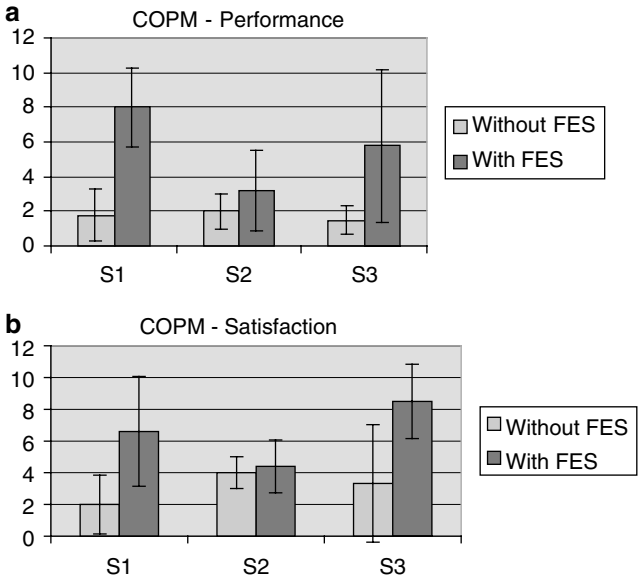

Figure 8 Performance (**a**) and satisfaction scores (**b**) of COPM activities with and without Freehand System®. As shown with the Freehand System®, there was a significant increase in performance and satisfaction for each subject: S1 = Subject 1, S2 = Subject 2; S3 = Subject 3

occur in that nerve root. An interesting and unanticipated finding was the strength improvements of two subjects in the contralateral extremity beyond the zone of partial preservation. While these changes may be unrelated to electrical stimulation produced by the Freehand System®, recent work by McDonald *et al*[19] draws attention to the findings. Recovery for both subjects was not related to recovery of lower motor neuron damage since all of the muscles were tested pre-Freehand System® and were found to be excitable, but paralyzed. On the other hand, one could pose the argument that FES prevented recovery on the implanted side and also, one cannot dismiss the possibility that these findings are coincidental. Additional experience with chronic stimulation early after SCI may provide further understanding into our findings.

The percutaneous (minimally invasive) technique is appealing to the patient. The use of a removable intramuscular electrode as opposed to the original Freehand Systems® epimyseal electrode, which requires

suturing onto the muscle through open incisions, has made this approach possible. The scarring for the patient is minimal, no permanent changes are done to their extremity, and should they get neurological recovery, the system can be easily removed or just not used.

Pinch force results were anticipated and comparable to previous reports on the outcomes of the Freehand System®.[3,6] The difference between this report and previous reports is timing; provision of stimulated pinch force early in rehabilitation provided a means for these subjects to perform ADL without adaptive equipment and therefore more spontaneously and with more independence. Because of the newness of their injuries, the subjects' hands were supple and, for two subjects, did not generate any measurable force from passive tenodesis until between 6- and 12-month follow-up; two other subjects never developed sufficient flexor tone to generate force. As important, but often underestimated, was the ease of achieving full hand opening with stimulation to the finger and thumb extensors. In contrast to stimulation to the hand with chronic paralysis and joint tightness, that often results in intrinsic-minus posturing and other posturing, stimulation to the extensors in these four subjects provide full opening allowing acquisition of larger objects. We believe this outcome was due to the fact that the hands were supple and without contractures and tightness.

In combination, the UEC and COPM provide insight into the capability of the Freehand System®. With FES, each of the subjects, with the exception of Subject 2, rated their abilities and satisfaction better. Despite good functionality of the Freehand System®, Subject 2 experienced a difficult rehabilitation course complicated by severe biceps spasticity, shoulder weakness on his non-Freehand side and nutritional challenges. He was also at a disadvantage due to the nature of his asymmetry and inability to use his non-FES arm (C4 level) as an assist. Subsequent to his last follow-up appointment, he showed small but clinically significant gains in elbow flexion on his non-Freehand System® side and underwent bilateral biceps to triceps, transfers and a brachioradialis to radial wrist extensors transfer and a Moberg tenodesis on his non-Freehand side. He is now able to use both upper extremities during activities and appreciates the functionality of the Freehand System® as evidenced by his use at home. This subject's experience indicates the importance of proximal muscle strength and its relationship to performance of activities. We are now undertaking a study correlation between proximal muscle strength and ADL performance in 25 Freehand System® recipients.

At our institution, the COPM is routinely used as an outcome measure. Application with the subjects in this study highlighted the challenges of applying this assessment to persons with new injuries. Subject 4 refused the COPM after several sessions of goal setting; he was not interested in establishing goals such as eating, writing, and brushing his teeth, but rather focused on the goal of walking. The other three subjects required considerable coaching and support in the goal-setting process due to the difficulty in articulating goals they perceived as simple, every day tasks. While the COPM may not be the assessment of choice in acute SCI due to the individuals' inability to preview goals as a person with a disability, it did provide insight into these adolescents' opinions of the Freehand System® for the activities they deemed most important at that time in their recovery.

This series of single subjects demonstrates the feasibility of a minimally invasive surgical technique for implantation of the Freehand System®. In this study, rehabilitation lengths of stay were not extended due to Freehand System® implantation. Follow-up studies suggest that for those with ASIA A injuries with wrist extension strength of less than grade 3, the intervention continues to be indicated and provides superior function in ADL and self-identified activities when compared to non-FES function. Clearly, there is justification to forge ahead with newer generations of FES systems for hand function and larger comparative and longitudinal studies.

Despite overwhelming positive experiences of early implantation, patients' decision to devote several days during the already overwhelming acute rehabilitation period to the implantation and rehabilitation of the Freehand System® was not an easy one. The acute rehabilitation period following an SCI is filled with life-altering decisions, adjustments, stresses, and learning; among others things, learning how to make the most of a set of limited movements to accomplish everyday tasks. Equally compelling are the insurance-driven financial and time constraints that frame the rehabilitation period. All of these variables deserve further attention.

This case series demonstrates that FES can vastly improve hand function within days after a minimally invasive implant procedure and that it is feasible to accomplish this within an acute rehabilitation period. Further study is warranted to determine how the restoration of hand function early in rehabilitation process facilitates recovery and community re-entry and what impact if any, it may have on financial considerations. Research is also needed to compare the benefits of FES over alternative options.

Acknowledgements

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