Pattern of use and user satisfaction of Neuro Control Freehand system

P Taylor^{*1}, J Esnouf² and J Hobby³

¹Department of Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ, UK; ²The Duke of Cornwall Spinal Treatment Centre, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ, UK; ³The Odstock Centre for Burns, Plastic and Maxillo-Facial Surgery, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ, UK

Objectives: Evaluation of the use and acceptability of the Neuro Control Freehand system.

Study design: A questionnaire was sent in a single mail shot to users of the system. Administration was by a 3rd party with anonymous returns.

Setting: A supra regional spinal unit in the UK.

Methods: The Freehand system is an implanted Functional Electrical Stimulation (FES) device for restoration of lateral and palmar grasps following C5 or C6 tetraplegia.

Results: Replies were received from seven users of the system who had an average experience of 23 months use. All used the system daily and had increased their range of activities of daily living skills. Some problems had been experienced with equipment reliability and skin allergy to the tape used to secure external components. Six users felt more confident when using the system and seven felt their quality of life had improved.

Conclusion: The Freehand system provides increased function that is considered by its users to be of benefit.

Sponsorship: This study was funded by the charity INSPIRE.

Spinal Cord (2001) 39, 156–160

Keywords: Freehand; FES; tetraplegia; ADL; user satisfaction survey

Introduction

The NeuroControl Freehand System is an implanted FES (functional electrical stimulation) device intended for the restoration of hand function in C5 and C6 level tetraplegics. The device was developed at the Case Western Reserve University, Cleveland, Ohio, USA by Hunter Peckam.^{1–4} It consists of an active receiver/stimulator that is placed inside the chest wall in a similar way to a cardiac pace maker. Eight leads come from the receiver/stimulator and pass under the skin to the hand and forearm where they are terminated by epimysial electrodes, sutured to the surface of each target muscle. Power and control signals are passed through the skin to the receiver/stimulator from a skin mounted coil. The user controls the device by movement of the opposite shoulder, using a skin surface mounted position detector known as a shoulder controller. To open the hand, the user might retract his shoulder. To close the hand the shoulder would be brought forward, the tightness of the grasp being proportional to the distance moved by the shoulder. If the user wishes to lock their hand in a fixed position, to hold a knife or pen for example, a quick elevation or depression movement of

the shoulder is made. Using a technique known as velocity threshold switching, the system interprets the faster movement as a command to maintain the present stimulation levels until the lock signal is given again.

Two grips are possible with the system. The first is a lateral grasp where the fingers are first closed and the thumb brought down against the side of the index finger. This grasp is used for holding small objects such as a pen or fork. The second is a palmar grasp where the thumb is brought into abduction to allow the hand to close around larger objects such as a glass or bottle. The user selects which grasp they wish to use by pressing a switch, mounted with the shoulder controller. The same switch is also used to turn the system on and off.

In 1994 Salisbury joined the multi-centre international clinical trial of the system for USA's Food and Drug Administration, and was the first centre in Europe to use the device. The team, based around the Duke of Cornwall Spinal Treatment Centre, was already experienced in tendon transfer surgery and the clinical application of FES in paraplegia and stroke. In the autumn of 1998 we sent by post a purpose designed questionnaire to nine Freehand users. The questionnaire attempted to ascertain the pattern of usage of the device, whether there had been any change in the users' ADL skills and their opinions about the device and the service that they received.

*Correspondence: P Taylor, Department of Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, Wiltshire SP2 8BJ, UK

Method

The questionnaire was delivered through a third party, the Implanted Devices Group at University College London and replies were anonymous. A stamped addressed envelope was supplied for returning the questionnaire. Multiple choice questions were used wherever possible, although there was opportunity for the users to add their own responses where they were not covered by the given choices.

Analysis

As the numbers are small, no formal statistical analysis has been used. The number of responses to each question are reported.

Results

Eight Freehand users returned the questionnaire, one of whom were not currently using the system (see section on *Physiological Problems*). The ninth subject was also known to be not using the device. This was due to a lesion of the post interosseus nerve as it passes under the supinator, sustained after 3 months use of the system. The lesion, which prevented finger, thumb and wrist extension, was of unknown origin but is not thought to be directly related to the system. Not all the subjects answered all questions and where this is the case, the number who answered the question is given (Table 1).

The system had been used for an average time of 23 months. User 2 was in full time employment while users 3, 4 and 5 were in part time employment. All used a powered wheelchair both inside and outside the house except user 4 who used a manual chair all the time and users 2 and 3 who sometimes used a manual chair inside the house.

Care

All users had care from outside agencies (mean 11.5 h a day, range 3–24 h) and four users also had additional care from family members (mean 3.4 h a

day range 2–5 h). No users claimed any reduction in outside care but two users claimed that the care given by family members had decreased.

The system

Seven of the users reported that the external components of the system took about 5 min to put on each day while one reported that it took 10 min. Only in two cases was this done by the same carer each day indicating the need to train more than one carer in the set up of the system. Most users reported no significant problems fitting the external equipment, although two users had problems locating the coil and three locating the shoulder controller. One user had persistent problems maintaining the position through the day due to the adhesive tape used becoming detached. This was reported as an occasional problem by five other users. Four users had experienced problems with skin allergy to the tape or double sided adhesive rings used to hold the components to the skin. Two users reported that the system made transfers more difficult.

Three users had never had to stop using the system because of system failure. The longest time that the five users were without use of the system was 10 days for one user, 7 days for two, 3 days for one and 1 day for one (Tables 2 and 3).

Table 2 System reliability

	How many times have you experienced problems with any of the following components?			
	0	1	2–4	5+
Coil	3	0	4	1
ECU	4	0	4	0
Shoulder controller	2	1	3	2
Implant	6	2	0	0
	How would you rate the reliability of the system?			
	Very reliable	Moderately reliable	Reliable	Unreliable
	2	5	1	0

Table 1 Patient details

User	Age	Sex	Level	Time since injury (months)	Cause of injury	Time since implant (month)	Side Implanted	Hand dominance Prior to injury	Now
1	43	m	C4/5	43	Fall	17	L	L	L
2	46	m	C5/6	155	Fall	53	R	R	R
3	39	m	C5	240	RTA	16	R	R	R
4	31	m	C5/6	149	RTA	8	R	R	R
5	48	f	C5/6	156	RTA	20	L	R	L
6	37	m	C5	430	RTA	23	R	R	R
7	40	m	C4/5	57	Horse riding	34	R	R	R
8	33	m	C5/6	73	RTA	15	R	R	R

RTA: road traffic accident

Table 3 System acceptability

<i>Strongly agree</i>	<i>The system has a good cosmetic appearance when worn</i>				<i>Strongly disagree</i>
	<i>Agree</i>	<i>Indifferent</i>	<i>Disagree</i>		
0	4	2	1		1
<i>Strongly agree</i>	<i>The sensation from the implanted electrodes is comfortable</i>				<i>Strongly disagree</i>
	<i>Agree</i>	<i>Indifferent</i>	<i>Disagree</i>		
4	4	0	0		0
<i>Very good</i>	<i>What do you think of the appearance of your implanted hand?</i>				<i>Poor</i>
	<i>Good</i>	<i>OK</i>	<i>Not good</i>		
4	2	2	0		0
<i>Greatly improved</i>	<i>Has the appearance of your hand changed since receiving the implant?</i>				<i>A great deterioration</i>
	<i>Improved</i>	<i>No change</i>	<i>Deterioration</i>		
5	3	0	0		0

Table 4 Confidence

	<i>Has your confidence changed since implant in the following situations?</i>				
	<i>Greatly improved</i>	<i>Improved</i>	<i>No change</i>	<i>Deteriorated</i>	<i>Greatly deteriorated</i>
Home	4	2	2	0	0
Social	2	4	2	0	0
Work	1	1	2	0	0

Physiological problems

Two users suffered from fatigue when using the system at first but this ceased to be a problem once they had used it for a while. User 5 reported sweating while using the system for exercise. This was thought to be due to autonomic dysreflexia and stopped once the amount of time spent exercising was reduced. User 1 reported problems with bowel motility, experienced after 2–4 days of use leading to severe constipation. Again this was thought to be due to autonomic nervous system disturbance and as yet the problem remains unsolved preventing the subject from using the system.

Use of the system

All seven of those using the system used it every day. The average daily use of the system was estimated to be 6 h while the average period the external components of the system were worn was 11 h. All users used the system at home, while six out of seven used it in social situations, five using it for eating out. Four users used it for work, study or shopping (Table 4).

The questionnaire (Table 5) listed 29 activities of daily living (ADL) tasks that were thought might be improved by use of the system. Users were asked if they could perform each task with or without the system if the task was performed by their carer. Additionally, they were asked to state their preference

for the method of performing each task. On average, of the seven users who answered this question, they were able to perform 11.3 new tasks from the list of 29 ADL tasks offered. Only four users expressed their preference as to which way they performed each task but chose to use the system in an additional 4.5 tasks which previously they had performed without the system. Other activities the system was used for included, playing pool, sweeping the floor, using the TV remote control, applying make up, removing and replacing spectacles, cooking and making toast. Tasks that were considered the most important, facilitated by the system, were those where a strong grasp was required such as writing, using a knife, opening a door, cleaning teeth, shaving and using the telephone.

The users were asked if there were any activities that they could not do following receiving the implant. User 5 reported that she was unable to use her tenodesis grip to pick up small objects, as her thumb was unstable. Subject 6 reported that he was unable to use his right hand to steer his powered chair, due to tightness in his fingers.

Service

All users either agreed or strongly agreed that; they were given sufficient information about the system and operation prior to implantation; that they were given adequate training to use the system and that the problems they had experienced had been dealt with promptly (Table 6).

Discussion

Drawing conclusions from this data must be done with some caution. Not all users answered all questions, reducing the already small number further. Although the questionnaire was administered through a third party and anonymously, it cannot be ruled out that the answers given were not coloured by a desire to please, painting a rosier picture than experienced. Additionally, the Salisbury team, who devised suitable questions

Table 5 Tasks

	<i>Can you do the following tasks?</i>				
	<i>Without the system</i> (n = 7)	<i>With the system</i> (n = 7)	<i>Carer performs task</i> (n = 7)	<i>Not tried</i> (n = 7)	<i>Prefer to use system</i> (n = 4)
Can you use a table knife to cut your food?	0	4	4	0	3
Can you use a table fork to eat?	3	5	0	1	3
Can you use a spoon to eat?	4	7	0	0	4
Can you pick up and eat a biscuit?	5	7	0	0	1
Can you pick up and eat a sandwich?	4	5	1	1	1
Can you pick up and eat an apple?	3	4	3	0	0
Can you drink from a straight glass without a handle?	2	3	4	0	2
Can you drink from a wineglass?	3	6	2	0	2
Can you drink from a mug with a handle?	2	4	2	0	2
Can you drink a hot drink?	2	3	3	0	1
Can you write with a biro?	2	7	1	0	2
Can you write with a felt tip pen?	2	7	1	0	2
Can you pick up and move sheets of paper?	3	7	0	0	4
Can you use an electric toothbrush?	1	3	2	3	0
Can you use an ordinary toothbrush?	3	3	2	1	3
Can you use an electric razor?	3	4	1	1	0
Can you use a hairbrush?	3	5	1	1	0
Can you insert a videotape?	2	4	2	1	3
Can you insert an audiotape?	3	3	2	2	2
Can you insert a CD?	3	4	2	1	0
Can you use a push button telephone?	4	6	1	0	2
Can you pick up a telephone receiver?	3	5	1	1	1
Can you use a round door handle?	0	3	3	1	2
Can you use a level door handle?	4	7	1	0	2
Can you take a book from a bookshelf?	1	4	3	0	3
Can you take a tin or can from shelf?	1	3	4	1	2
Can you use kitchen knives?	0	3	3	4	3
Can you lift and move saucepans?	0	2	4	2	2
Can you take food from a refrigerator?	2	3	3	2	2

Table 6 General

	<i>Do you agree with the following statements?</i>				
	<i>Strongly agree</i>	<i>Agree</i>	<i>Indifferent</i>	<i>Disagree</i>	<i>Strongly disagree</i>
I am glad that I have the system	5	3	0	0	0
I would recommend the system to another person	5	1	2	0	0
The system allows me more independence	5	1	1	1	0
I feel more confident when I use the system	3	4	1	1	0
I am less of a burden on others since I received the implant	4	2	1	1	0
The implant has improved my quality of life	4	2	2	0	0

based on their clinical experience of the Freehand system, wrote the questionnaire and did the data analysis.

Care

The system did not significantly alter the amount of carer time required, although two subjects believed the burden on family members was lessened. This might be expected, as the system appears to have little impact on many aspects of personal care.

The system

The external components of the system are relatively easy to set up each time although minor problems were reported. One subject had difficulty maintaining the positions of the external components throughout the day. Four subjects had skin allergy problems to the tape used to secure these components, indicating that this is an aspect of the device, which needs improving. All users had experienced some equipment failure at some point. The commonest failures were with the transmitter coil and shoulder controller. Spare coils are

now given as standard. Despite these problems all subjects found the reliability of the system acceptable.

System acceptability

Six users were happy with or indifferent to the cosmetic appearance of the system while two were less than satisfied. All users felt that the appearance of their hand had improved since receiving the implant and all thought the appearance acceptable. The sensation of stimulation was completely acceptable.

Confidence

Five users felt that their confidence at home, and six in social situations was improved by using the system.

Physiological effects

Two physiological effects were reported, both of which may be related to autonomic nervous system dysfunction. Significant autonomic dysreflexia is now considered a contraindication to selection for the device.

System usage

All users who were able to use the system used it every day. The most common situation for its use was in the home and social activities. All users who worked used it in their work place. On average an additional 11.3 tasks out of a possible 29 tasks could be performed when the system was used. It must be remembered that some of the 29 tasks could be performed previously, particularly by users with some voluntary wrist extension. The tasks for which use of the system made the biggest difference were generally those which required a moderate amount of strength in the grasp such as cutting food with a knife, writing, using a door handle and drinking from a handled mug or wine glass. Tasks where a wide grasp is required such as drinking from a glass or eating an apple were less affected by use by the system. The most important uses for the system were considered to be those related to eating, cooking and writing. Two users reported activities that were more difficult since receiving the implant, steering a powered wheelchair and a reduction in the effectiveness of their tenodesis grip due to an unstable carpo-metacarpal joint. This joint has since been stabilised by an arthrodesis.

General

All users were glad that they had received the implant although two were indifferent about recommending it

to other tetraplegics. Six users felt that the system gave them greater independence and that their quality of life had been improved. Seven felt more confident when using the system, while seven felt they were less of a burden on others.

Service

All users were satisfied by the level of service received.

Conclusion

The Freehand system provides an increase in ADL ability for C5 and C6 spinal lesion level tetraplegics and those that are able to make daily use of this ability. The system, in its present form is acceptable to the users, although there have been some problems with equipment reliability. Although no reduction in paid carer time was reported, it would appear that the system is beneficial to quality of life and perceived level of independence.

Acknowledgements

Thanks are due to all at The Neuro Control Corporation for their support throughout this work. Thanks also to Jonathan Norton of University College for assistance with the questionnaire. Special acknowledgement must be given to Jack Gardner, Robert Morgan and the INSPIRE Foundation without whom this work would not have taken place. The Freehand system is CE marked and FDA approved and is available from The Neuro Control Corporation, 8333 Rockside Road, Valley View, Ohio 44125, USA Tel. 001 216 912 0101.

References

- 1 Peckham PH, Mortimer JT, Marsolais EB. Controlled prehension and release in C5 quadriplegic elicited by functional electrical stimulation of the paralysed forearm musculature. *Ann Biomed Eng* 1980; **8**: 369–388.
- 2 Keith MW *et al.* Implantable functional neuromuscular stimulation in the tetraplegic hand. *J Hand Surg* 1989; **14A**: 524–530.
- 3 Keith MW *et al.* Tendon transfers and functional electrical stimulation for restoration of hand function in spinal cord injury. *J Hand Surg* 1996; **21A**: 89–99.
- 4 Wuolle KS *et al.* Satisfaction with and usage of a hand neuroprosthesis. *Arch Phys Med Rehabil* 1999; **80**: 206–213.