Clinical Experience of the NeuroControl Freehand System

J Esnouf,* P Taylor, J Hobby**

Department of Medical Physics and Biomedical Engineering, *The Duke of Cornwall Spinal Treatment Centre, **The Odstock Centre for Burns, Plastic and Maxillo-Facial Surgery, Salisbury District Hospital, Salisbury, Wiltshire SP2 8BJ. Tel. 01722 429 121, Fax. 01722 425 263. E-mail j.esnouf@mpbe-sdh.demon.co.uk Web page www.mpbe-sdh.demon.co.uk.

6th IPEM Clinical FES Meeting April 12,13 2000 University of Surrey.

Introduction

The NeuroControl Free Hand System from Cleveland Ohio, is an implanted FES device intended for the restoration of hand function in C5 and C6 level tetraplegics. The subject controls the device by movement of the opposite shoulder, using a skin surface mounted position detector. The strength of the grasp is proportional to the distance moved by the shoulder. Both palmar and lateral grasps are possible, selected by pressing a button on the shoulder controller. This paper reports on the first nine Freehand users in Salisbury.

Method

Prior to implantation, the muscles of the hand and forearm are conditioned using surface electrical stimulation for a period of 4 to 8 weeks. Following the 6 hour operation, the arm was in plaster for three weeks. Muscle training is then commenced using the implant. After four weeks the shoulder controller is fitted and training in the use of the system commenced. Good independent function was usually achieved after a 2 to 4 weeks of practice.

Assessments

Outcome was assessed using a standardised hand function test called the Grasp Release Test. It consists of the following 6 tasks:

· Picking up wooden pegs and dropping them in a box.
· Picking up wooden cubes and dropping them in a box.
· Lifting a 250gm weight and placing it on a box.
· Lifting a videotape and placing it on a box.
· Lifting a plastic cylinder the same dimensions as a small juice can and placing it on a box.
· Gripping and pushing down a plunger.

This device is intended to simulate the act of stabbing with a fork and is calibrated to the standard baked potato. The number of times each task is repeated in 30 seconds is recorded.

Grip strength is measured using a modified Gaymar dynamometer. Three grips are recorded, a lateral grasp, a Palmer grasp and a five finger grasp. ADL

(Activities of Daily Living) is assessed by patient goals. The subject chooses eight activities that they can not perform or wish to improve, prior to receiving the implant. Tasks are scored to record the amount of assistance or aids required in the set up, performance, and take down stages of each task. A questionnaire was also sent in a single mail shot to determine the user opinions about the system.

Sensory ability was monitored using static two-point discrimination. The medial and lateral side of each finger and thumb pulp was recorded.

Outcome measure assessments are made prior to receiving the implant and after 1 year of functional use of the system. Additionally, the GRT and grip strength measurements were made at the end of the training period. ADL re-assessments were only made at the post training stage. Statistical significance was shown using the Wilcoxon signed rank test.

Results

Two subjects discontinued using the system. The first developed a lesion of the post interosseus nerve as it passes under the supinator, after three months of system use. The lesion, which prevented finger, thumb and wrist extension, was of unknown origin but is not thought to be directly related to the system. The second subject reported problems with bowel motility, experienced after 2 to 4 days of use, leading to severe constipation. 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.

System users:

There were statistically significant increases in the number of types of task achieved and the number of repetitions of those tasks in the grasp release test. Subjects could perform on average 5.1 types of task (max 6) post implant with the system compared with 1.4 ($p=0.010$) pre implantation and 1.5 ($p=0.011$) post implantation without the implant. Subjects could perform on average 37.4 repetitions post implant with the system compared with 12.7 ($p=0.028$) pre implantation and 20.2 ($p=0.046$) post implantation without the implant. Improvement in tenodesis grip of the C6 subjects post op, lead to an improvement in the tasks requiring little force when the system was not used.

The system produced a functionally strong grasp where no grip strength at all was possible prior to implantation. Four subjects had sufficient tenodesis grip to produce a

measurable grip pre implant. They had a mean lateral, Palmer and five finger grasp of 0.93 N, 0.96N and 1.04N respectively. This was not significantly changed post implantation when the implant was not used in this sub group. With the implant post implantation the mean lateral, palmer and five finger grasp had increased to 11.2N, 9.5N and 10.4N respectively, all changes shown to be significant (p=0.012)

Three of the four subjects who had sensory ability prior to implant showed improvements in two-point discrimination.

Most of the selected tasks were achieved in the Activities of Daily Living Assessment indicating a significant improvement in independence. Out of eight selected tasks, on average 3.8 new tasks could be performed by each Free Hand System user with adaptive equipment being eliminated from 1.8 tasks. Carer assistance was eliminated from an average of 0.9 tasks while self-assist techniques were discontinued in 1.5 tasks indicating that they were performed in a more normal manner. On average, Free Hand users preferred to use their system in 6.5 tasks each.

Seven of the subjects are currently daily users of the device. Some problems had been experienced with equipment reliability and skin allergy to the tape used to secure external components. The system did not significantly alter the amount of carer time required, although two subjects believed the burden on family members was lessened. Six users felt more confident when using the system and seven felt their quality of life had improved.

Conclusion

The Free Hand system can significantly improve the functional ability and perceived level of independence of C5 and C6 lesion tetraplegics.

Acknowledgements

Thanks to Jonathan Norton of University College for assistance with the questionnaire. Thanks also to the INSPIRE Foundation who funded this work.