Clinical Experience of the NeuroControl Freehand System

P Taylor, J Esnouf,* 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 p.taylor@mpbe-sdh.demon.co.uk Web page www.mpbe-sdh.demon.co.uk.

Abstract *- This paper reports on the first nine tetraplegic subjects who have received the NeuroControl Free Hand System in Salisbury and have used it for more than one year. Outcome was assessed using a standardised hand function test called the Grasp Release Test (GRT), grip strength, two-point discrimination and Activities of Daily living Assessment. A questionnaire was also sent in a single mail shot to determine the user's opinions about the system.*

There were statistically significant increases in the number of types of task achieved and the number of repetitions of those tasks in the GRT. The system produced a functionally strong grasp where no grip strength at all was possible prior to implantation. 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. 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. 6 users felt more confident when using the system and 7 felt their quality of life had improved.

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

Keywords*: Free Hand System, Tetraplegia, FES, ADL, grip strength, user survey.*

1. Introduction

The NeuroControl Free Hand System[1, 2, 3, 4] 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 the first nine Freehand users in Salisbury.

2. Method

Prior to implantation, the muscles of the hand and forearm were conditioned using skin 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 was then commenced using the implant. After four weeks the shoulder controller was fitted and training in the use of the system commenced. Good independent function was usually achieved after a 2 to 4 weeks of practice.

3. Assessments

Outcome was assessed using a standardised hand function test called the Grasp Release Test[5]. 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 types of tasks performed and the number of times each task is repeated in 30 seconds were recorded.

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

Sensory ability was monitored using static two-point discrimination[6]. The medial and lateral side of each finger and thumb pulp was recorded.

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.

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.

4. Results

Out of the nine free hand users, eight were male while one was female. The mean age was 38.4 years with a mean time since injury of 10.1 years at the time of implantation. At the time of writing the total implant experience was 30 years. Four subjects had an international classification for the implanted side of O0, one of O1, two of OCu1 and 2 of OCu2.

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 was 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. Before being involved in the project, his bowel care was managed by the use of glycerine suppositories every two days and Senacot taken the night before. Retrospectively, he reported that loss of reflex activity began while using the external exercise stimulator. Repeated trials of periods when the implant was used and rest periods have confirmed the relationship between bowel activity and stimulation. Bowel emptying ceases after 3 to 4 days of use. We suspect an autonomic function disturbance, possibly raised sympathetic activity inhibiting sigmoid dumping. Beta-blockers were rejected due to the already low blood pressure. Following a literature review it was suggested that nicotine could be used as a colonic accelerator administered using patches. After an initially promising start when use of the system for exercise was possible, the subject became ill and was admitted to hospital for 10 days with symptoms consistent with a UTI. Use of the patches was discontinued and symptoms responded to antibiotics. No causal relation ship between the illness and the use of the patches has been established but is still under investigation.

4.1 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 GRT (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. At one year the number of types of task was 5.5 ($p=0.027$) with the system while without 1.2 ($p=0.028$) could be achieved. 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. The number of repetitions was increased at 1 year to 50.5 ($p=0.046$) with the system and 24.3 ($p=0.028$) unassisted. Improvement in tenodesis grip due to Brachioradialis transfer for wrist extension, 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 ($p=0.012$) Grip strength was maintained at one year showing a slight increase. The mean lateral, palmer and five finger grasp had increased to 15.2N, 10.4N and 14.7N respectively.

All subjects who had no sensory ability before implantation, all of who had C5 level lesions had no change in there sensory ability, as measured by static two point discrimination. However the subjects with C6 level injuries demonstrated some changes. 1 subject showed improved sensation in 6 areas of the hand, three of which had not demonstrated any sensory ability pre implantation. 2 other subjects showed improved sensation in five areas. However, one subject who had initially poorer sensation than the other subjects recorded a slight reduction in sensation in one area. To test the significance of the measurements the two point scores were ranked, i.e. no sensation = 0, 1pt = 1 …. 4mm = 7 etc. The hand scores for each subject pre op and at one year were then compared using the Wilcoxen Signed Rank Test. Three of the four subjects showed statistically significant improvements in sensory ability. The results suggest that where there is limited sensory

ability, use of the system may lead to a training effect in sensory ability.

Most of the selected ADL 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 a further 1.8 tasks. Carer assistance was eliminated from an average of 0.9 tasks while self-assist techniques (i.e. use of teeth etc.) were discontinued in 1.5 tasks indicating that they were performed in a more normal manner. On average, Freehand users preferred to use their system in 6.5 tasks each.

Questionnaire replies were received from 7 users of the system who had an average experience of 23 months use. All were current 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.

The questionnaire 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 or if the task was performed by their carer. 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. 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. 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.

5. Summary and discussion

Despite encountering problems, the use of the Freehand System has been very successful, giving useful hand function to a group of patients whom would not be able to achieve it in any other way. Seven of the nine subjects who are able to use the device, do so on a daily basis. One user stated that a short period of disuse due to equipment failure was “like being paralysed again” as it was so much part of his life that he took it for granted.

GRT: All subjects improved their score on the GRT indicating that the functionality of their grip had improved. Subjects who had active wrist extension did not improve their score for the lighter tasks but were able to achieve heavier tasks when the system was used. Subjects without voluntary wrist extension were not able to achieve any task without the system but could achieve most tasks when it was used. Some improvements were seen even without the system in those subjects whose voluntary wrist extension had been provided or improved by tendon transfer.

Grip strength: All subjects were able to grip with some force when the system was used. However, the grip provided is approximately 5% of maximum voluntary contraction for normals but this is an order of magnitude greater than was possible using a tenodesis grip.

ADL: The ADL results must be examined with some caution as they indicate what was possible rather than what was normal practice for the Free Hand user. Nevertheless most ADL goals were achieved and the use of the system preferred in over 80% of activities. Overall the system was most successful for activities that required a moderate amount of force. Activities that required a wide opening of the hand to acquire objects were less successful. While the system allowed new tasks to be performed, other tasks were performed without assistance or without adaptive devices for the first time. This represents an increase in independence for the Free Hand user.

Two point discrimination: Changes in two point discrimination following electrical stimulation have been reported in one other study. Eleven subjects who had had a stroke received electrical stimulation to improve wrist and finger extension using skin surface electrodes were reported to show improvements in two point discrimination after three months treatment[7]. While improvements in hand function were also reported with this group it is possible that the sensation of the stimulation may also have been a factor. The sensation experienced by Free Hand users due to the stimulation is considerably less than experienced in the other study so it is possible that this neuroplastic effect may be due to sensory input due to increased use of the hand.

User survey: Drawing conclusions from the data must be done with some caution. Not all users answered all questions, reducing the already small number. Although the questionnaire was administered through a third party and anonymously, it can not be ruled out that the answers given were not coloured by a desire to please, painting a rosier picture than experienced. However, the Freehand system was perceived as providing an increased ADL ability and all those that were able to, made 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 the perceived level of independence.

6. Conclusion

Seven of our nine subjects are current daily users of their systems and are able to achieve improved function. One subject is unable to use the system due to unforeseen problems related to the system and one due to a none related problem.

The system provides an active grasp with strength, enabling relatively heavy objects to be manipulated. This leads to a greater perceived level of independence and quality of life for its users, which could not be achieved by any other means.

Acknowledgements

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

Supplier

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. (1980) Controlled prehension and release in C5 quadriplegic elicited by functional electrical stimulation of the paralysed forearm musculature. *Ann. Biomed. Eng.* 8:369-388,

[2] Keith MW, Peckham PH Thrope GB, Stroh KC, Smith B Buckett JR, Kilgore KL, Jatich JW. (1989) Implantable functional neuromuscular stimulation in the tetraplegic hand. *J Hand Surg*;14A:524-30.

[3] Keith MW, Kilgore KL, Peckham PH, Wuolle KS, Creasey G, Lemay M. (1996) Tendon transfers and functional electrical stimulation for restoration of hand function in spinal cord injury. *J Hand Surg*;21A;89-99.

[4] Wuolle KS, Van Doren CL, Bryden AM, Peckham PH, Keith M, Kilgore KL, Grill J. (1999) Satisfaction with and usage of a hand neuroprosthesis. *Arch Phys Med Rehabil*;80:206-13.

[5] Wuolle KS, Van Doren CL, Thrope GB, Keith MW, Peckham PH. (1994) Development of a quantitative hand grasp and release test for participants with tetraplegia using a hand nueroprosthesis. *J Hand Surg*;19A:209-18.

[6] Lee Dellon, A. (1990) The sensational contributions of Erik Moberg. *J. Hand Surg*.; 15B: 14-24.

[7] Taylor PN, Burridge JH, Hagan SA, Swain IDS. (1995) Electrical stimulation exercises to improve hand function and sensation following chronic stroke. *Pro. 5th Vienna International Workshop on Functional Electrostimulation* ISBN 3-900928-03-7 pp359-362