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Original Article

The functional impact of the Freehand System on tetraplegic hand function. Clinical Results

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Study Design: A B design with subjects acting as their own control when the device is turned off.
Objective: Evaluation of the efficacy of the NeuroControl Freehand System.
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. Its use was assessed using the Grasp Relies Test (GRT), Activities of Daily Living (ADL), Grip strength and two-point discrimination.
Results: Seven out of nine subjects are currently daily users of the device. 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. 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 ADL assessment indicating a significant improvement in independence.
Conclusion: The Freehand system can significantly improve the functional ability of C5 and C6 lesion tetraplegics.
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Keywords: freehand; FES; function; ADL; two point discrimination; grip strength

Introduction

The NeuroControl Freehand System[1–5] from Cleveland, Ohio, USA, is an implanted FES device intended for the restoration of hand function in C5 and C6 level tetraplegics. The device consists of an active receiver/stimulator which is placed in 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 a connector site in the upper arm. Here they are joined to epimyseal electrode leads, passed under the skin from the forearm and hand. Power and control signals are passed through the skin to the receiver/stimulator from a skin mounted coil. The subject controls the device by movement of the opposite shoulder, using a skin surface mounted position detector. Hand opening, closing and strength of the grasp are proportional to the distance moved by the shoulder. Both palmar and lateral grasps are possible, selected by pressing a button on the shoulder controller. Tendon transfer surgery is used to augment the system, typically Brachioradialis to Extensor Carpi Radialis for voluntary wrist extension and Posterior Deltoid to Triceps for elbow extension.

This paper reports the first nine Freehand users in Salisbury. A report of the surgical implementation of the system with the same nine subjects has been published elsewhere.[6]

Method

The purpose of the clinical assessments was to demonstrate the efficacy of the Freehand system both in terms of standardised measures such as a hand function test and grip strength but also to demonstrate its usefulness in every-day life by an ADL assessment. Sensory ability was also collected to monitor any possible nerve damage due to the procedure.

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Outcome measures
The Grasp Release Test (GRT) was devised by the Cleveland group to quantify changes in hand function following receiving the implant.[7] It consists of six tasks, three requiring a lateral pinch and three manipulated with a palmar grasp. They are as follows:

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

Before the main test a pre-test was used to determine whether it was possible for the subject to perform each task. The main part of the test was completed. It was repeated three times. The order of tasks was randomised to prevent bias due to fatigue. The repetitions that could be achieved with the number of errors in 30 s were recorded for each task.

Grip strength was measured using a modified pinch meter. Three grips were recorded, a lateral grasp, a palmar grasp and a five finger grasp.

Activities of Daily Living (ADL) were assessed by patient goals. Before receiving the implant the subject chose eight activities that they could not perform or wished to improve. Tasks were scored to record the amount of assistance or aids required in the set up, performance, and take down stages of each task.

Sensory ability was monitored using static two-point discrimination.[8] The medial and lateral side of each finger and thumb pulp were recorded.

Outcome measure assessments were 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, approximately 3 months post surgery. ADL re-assessments were only made at the post-training stage.

Analysis
Continuous data variables were analysed using Wilcoxon signed rank tests. Statistical significant change was assumed at $P<0.05$.

Ethics
The local ethics committee approved this study and signed informed consent was obtained from each participant.

Results

Out of the nine freehand 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 (Table 1) for the implanted side of O0, one of O1, two of OCu1 and two of Ocu2.

Two subjects discontinued using the system. The first developed a lesion of the posterior interosseus nerve as it passes under the supinator, after 3 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 2 days and Senakot 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 relationship between the illness and the use of the patches has been established but is still under investigation.

GRT results
Grasp Release Test results are presented comparing test scores pre-implantation with scores with and

Table 1 International classification for tendon transfer surgery

Motor score	*Meaning*	*Subjects*
0	No voluntary muscles MRC scale 4 or better below the elbow	4
1	Brachioradialis (BR)	3
2	BR and Extensor Carpi Radialis Longus (ECRL)	2
Sensory score		
O	(Ocular) eye sight only	5
OCu	Eye sight and sensory ability	4

without the implant at the post-training stage ($n=8$) and at 1 year post training ($n=6$) (Table 2). At 1 year the cohort is reduced to six. Subject 3 was unable to use his system following a posterior interosseus nerve lesion and subject 5 had continuing problems controlling the device. GRT results at the post-training stage are sown in Figures 1–4. All subjects who had completed the training stage showed improvements in GRT score when the system was used. Subjects could perform on average 5.1 types of task (maximum 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 1 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. There were also significant changes in the total number of task repetitions performed. 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.

Two subjects (1 and 5) showed increased scores in some tasks without the implant. This was due to improved tenodesis grip following Brachioradialis (BR) to Extensor Carpi Radialis Brevis (ECRB) tendon transfer. One subject showed a slight decline in GRT score when using the system for the block test as this task was easier to perform with a tenodesis grasp than with the system. Two subjects showed a decline in the block test without the system. However, both subjects had an effective tenodesis grasp prior to implant and achieved high scores both with and without the implant. The decline may therefore be considered insignificant.

Comparing the individual tasks, five of the six tasks at the post-training stage were performed significantly better post-implantation when the system was used in comparison with pre-op performance (Table 2). The exception is the block task, which was approaching significance at the 0.05 level. Improvement in tenodesis

Table 2 Grasp release test

Task	Pre-op Mean $n=8$	Post-op NS Mean $n=8$	Post-op S Mean $n=8$	1 year NS Mean $n=6$	1 year S Mean $n=6$	Pre-op/ post-training S $P=$	Post-training NS/S $P=$	Pre-op/ 1 year S $P=$	1 year NS/S $P=$
Weight	0.0	0.0	6.6	0.0	8.0	0.018	0.018	0.068	0.068
Fork	0.0	0.0	5.7	0.0	7.5	0.018	0.018	0.027	0.027
Can	1.0	2.5	4.6	3.4	7.9	0.043	0.08	0.043	0.104
Tape	1.2	1.8	3.5	1.7	3.9	0.027	0.044	0.068	0.273
Block	5.4	8.6	8.1	8.4	11.0	0.068	0.889	0.028	0.686
Peg	5.1	7.3	9.1	4.0	12.2	0.017	0.325	0.027	0.168
Total no of repititions	12.7	20.2	37.4	24.3	50.5	0.028	0.046	0.028	0.028
Mean no. task types	1.4	1.5	5.1	1.2	5.5	0.010	0.011	0.027	0.028

Summary of GRT results. NS = no system, S = with system

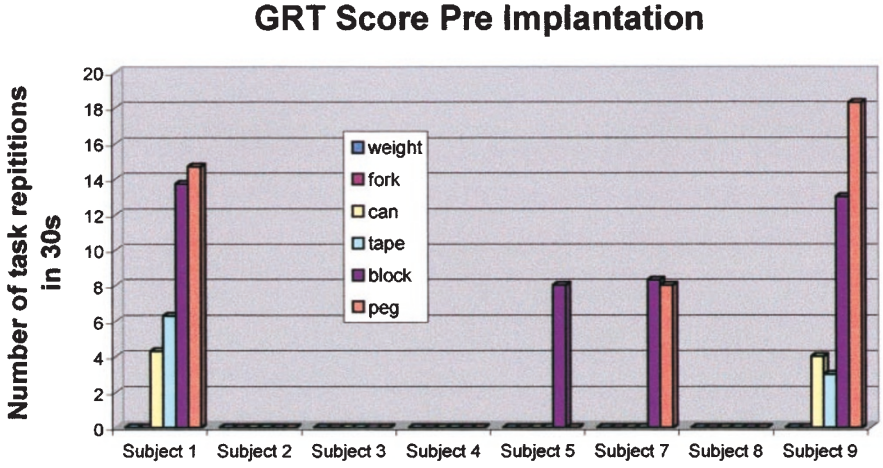

Figure 1 This figure illustrates the ability some voluntary wrist extension gives. While only two subjects had ECRL MRC score of 4 or more before surgery, subjects 5 and 7 also had some weak wrist extension

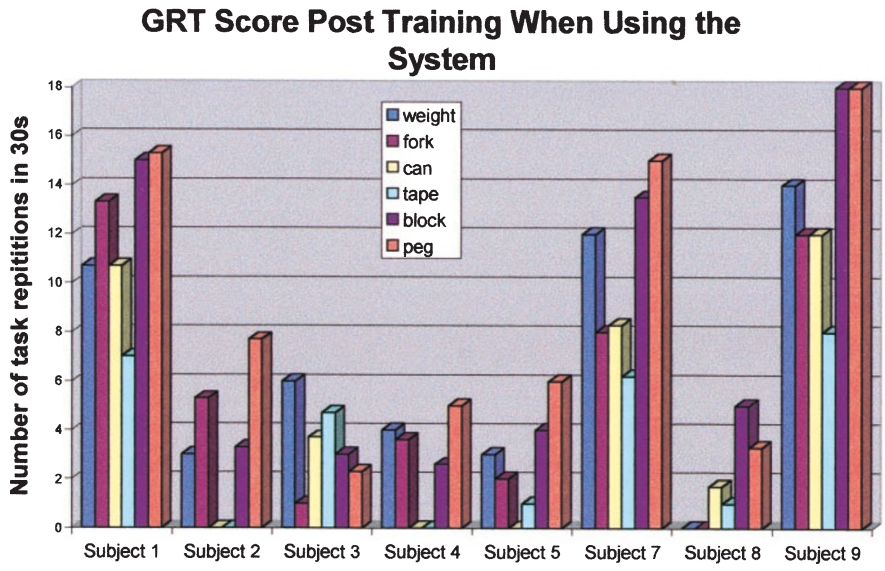

Figure 2 This figure illustrates the subject's GRT ability with the system. For those subjects without wrist extension this represents the total gain in function

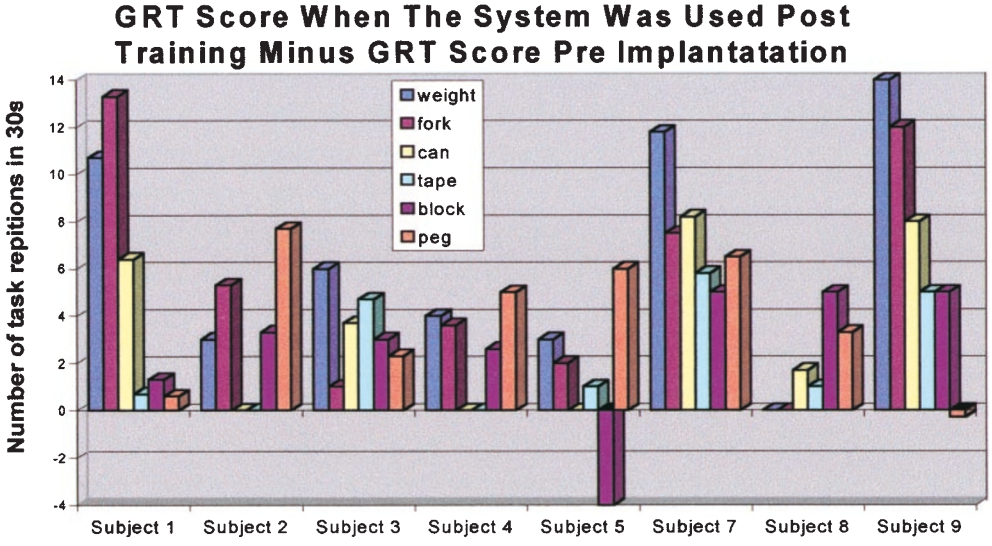

Figure 3 This figure represents the change in ability compared with the subject's ability prior to implantation

grip of the C6 subjects post-op led to an improvement in the tasks requiring little force when the system was not used. This led to the changes seen in comparison to using the system being non-statistically significant in two of the six tasks although again a trend towards a significant change is present for the can task. Overall performance improved at 1 year in all tasks when the system was used. However, the reduced number of subjects gave fewer statistically significant results.

Overall, the C5 subjects were unable to complete any of the tasks without the system while they could complete most tasks with the system. The C6 subjects could complete some of the tasks involving light objects or little force pre-implantation but could complete all tasks and usually more repetitions with the system.

Grip strength

Grip strength measurements are presented comparing the lateral, palmar and five finger grasp strengths pre-implant with those with and without the implant at the end of training stage and at 1 year. Four subjects had sufficient tenodesis grip to produce a measurable grip pre-implant. They had a mean lateral, palmar and five finger grasp of 0.93N, 0.96N and 1.04N respectively.

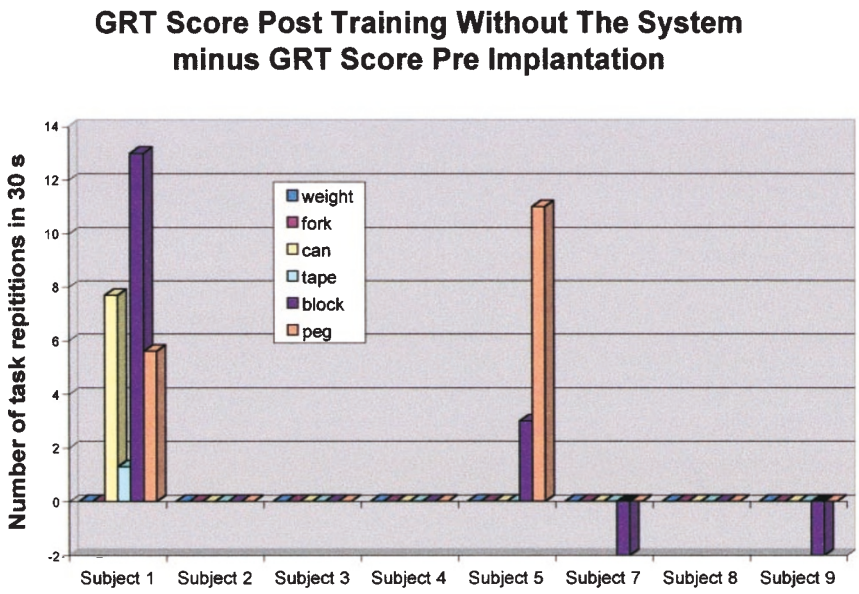

Figure 4 This figure demonstrates that four subjects demonstrated a change in GRT function even when the system was not used. In subjects 1 and 5 this may be due to improved tenodesis grasp while in subjects 7 and 9 it may be due to reduced wrist flexion following Br to ECRL tendon transfer

Table 3 Static two-point discrimination

			Subject 1		*Subject 5*		*Subject 7*		*Subject 9*	
Area	Dermatone	Nerve	Pre-op	1 year	Pre-op	1 year	Pre-op	1 year	Pre-op	1 year
thumb 1	C6	Median	15	15	6	6	1pt	1pt	1pt	10
thumb 2	C6	Median	1pt	15	8	4	15	1pt	6	4
index 3	C6	Median	15	10	8	6	1pt	1pt	15	10
index 4	C7	Median	15	8	12	6	1pt	1pt	10	10
mid 5	C7	Median	15	15	12	10	npt	npt	1pt	15
mid 6	C8	Median	npt	1pt	15	10	npt	npt	12	10
ring 7	C8	Median	npt	1pt	15	15	npt	npt	1pt	1pt
ring 8	C8	Ulnar	npt	1pt	15	15	npt	npt	1pt	1pt
little 9	C8	Ulnar	npt	npt	15	15	npt	npt	1pt	1pt
little 10	C8	Ulnar	npt	npt	15	15	npt	npt	1pt	1pt
$P=$				0.024		0.041		0.317		0.039

Numbers 4 to 15 = the minimum point separation (mm) recognised as two individual points. 1pt = sensation but no two point discrimination. npt = no sensation

This was not significantly changed post-implantation when the implant was not used in this subgroup. With the implant post-implantation the mean lateral, palmar and five finger grasp of all eight subjects had increased to 11.2N, 9.5N and 10.4N respectively, all changes shown to be significant ($P=0.012$) level using the Wilcoxon signed rank test. Grip strength was maintained at 1 year showing a slight increase. The mean lateral, palmar and five finger grasp had increased to 15.2N, 10.4N and 14.7N respectively.

ADL

The most commonly chosen tasks were writing with a pen, using a fork or knife, drinking from a cup and using the telephone. Almost all ADL tasks were achieved at the end of the training period, post implantation. Out of the 64 chosen tasks, on average 3.8 new tasks could be performed by each Freehand 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, Freehand users preferred to use their system in 6.5 tasks out of the eight original chosen tasks.

Two point discrimination test

All subjects who had no sensory ability before implantation, all of who had C5 level lesions had no change in their sensory ability as measured by two

point discrimination. However, the subjects with C6 level injuries demonstrated some changes (Table 3). Subject 1 showed improved sensation in six areas of the hand, three of which had not demonstrated any sensory ability pre-implantation. Subject 9 had five areas of improved sensory ability as did subject 5. Subject 7, however, who had initially poorer sensation than subjects 1, 5 and 9 recorded a slight reduction in sensation in one area. To test the significance of the measurements the two point scores were ranked, ie npt = 0, 1pt = 1, 15 mm = 2, 10 mm = 3, 8 mm = 4, 6 mm = 5, 4 mm = 6 and 2 mm = 7. The hand scores for each subject pre-op and at 1 year where then compared using the Wilcoxon Signed Rank Test. Subjects 1, 5 and 9 showed statistically significant changes. While it can not be ruled out that these changes were due to the gradual change in the subjects' neurological condition, as the subjects were 14, 12, 19 and 12 years post-injury at implantation it is reasonable to assume they were in a stable condition. The results suggest that where there is limited sensory ability, increased hand activity may lead to a training effect in sensory ability.

Discussion

GRT
All subjects improved their score on the GRT indicating that the functional ability 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, where possible, their 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 Freehand 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 Freehand user.[9]

Two point discrimination
Changes in two point discrimination following electrical stimulation have been reported in one other study where 11 subjects who had had a stroke received electrical stimulation to improve wrist and finger extension using skin surface electrodes.[10] While improvements in hand function were reported with this group it is possible that the sensation of the stimulation may also have been a factor. The sensation experienced by Freehand 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. This may be similar to the improvement seen in stereognosis seen in cerebral palsy patients following tendon transfer surgery which has resulted in improved hand function.[1,12]

Conclusion

Seven of our nine subjects are current daily users of their systems and are able to achieve improved function. The system provides an active grasp with strength, enabling relatively heavy objects to be manipulated. This leads to greater independence and quality of life for its users, which could not be achieved by any other means.

Acknowledgements

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Supplier

The Freehand System is CE marked and FDA approved and is available from The NeuroControl Corporation, 8333 Rockside Road, Valley View, Ohio 44125, USA. Tel. 001 216 912 0101.

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