

A Pilot Study to Investigate the Effects of Electrical Stimulation on Recovery of Hand Function and Sensation in Subacute Stroke Patients

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■ ABSTRACT

Objectives. 1) To compare the effect of cyclic neuromuscular electrical stimulation (NMES) of the forearm and elbow extensor muscles with passive stretching exercises on hand function and sensation following stroke. 2) To inform sample size for a larger randomized controlled trial (RCT).

Materials and Methods. Twenty-two subjects with hemiplegia resulting from a stroke during the previous 12 months were randomly allocated into stimulation (treatment) and exercise (control) groups. Stimulation was applied to the elbow, and forearm extensor muscle groups of the hemiplegic arm for 12 weeks. Subjects in the control group were taught passive stretching exercises for the same period. The primary outcome measure was the Action Research Arm test (ARAT). Sensation was tested using two-point discrimination. Statistical analysis applied nonparametric analysis of covariance (ANCOVA).

Results. Statistically significant between-group differences in change in ARAT scores were shown between

the two groups after 12 weeks of treatment ($p = 0.003$) and following 12 further weeks without intervention ($p = 0.012$). There were no significant differences in sensation.

Conclusions. 1) A significant treatment effect of electrical stimulation over passive exercise has been demonstrated in a group of 22 subacute stroke patients, randomized into two equal groups and further work identified which may help to improve recovery of hand function and sensation following stroke. 2) A sample size of 24 subjects in each group has been estimated assuming a two-sided test significance level of 5% with 80% power, primary outcome variability $SD = 6.75$, a minimum difference of ten ARAT score units, and a 10% dropout rate. ■

KEY WORDS: electrical stimulation, hand, sensation, stroke

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INTRODUCTION

In the UK, over 100,000 people suffer a first stroke each year (1). Approximately half of all stroke patients starting rehabilitation have marked impairment of function of one arm and about 14% of these will regain useful function (2). The main

focus of therapy for patients is on recovery of motor function rather than any associated sensory deficits. However, impaired sensation is an important factor in disability following stroke.

Many studies have measured improved function following periods of electrical stimulation. However, most have had small subject samples and weak methodology.

Chae and Yu (3) found 11 studies conducted between 1960 and 2000, including four randomized controlled trials (RCTs) since 1998. Outcomes were often limited to measurement of impairment, with no indication of functional or quality of life changes. None followed up subjects after stimulation was stopped except Powell et al. (4) who found that the statistically significant improvement at the end of the treatment period was not maintained 24 weeks after treatment was stopped. However these studies show consistent benefits from stimulation in terms of passive and active range of movement, EMG activity, muscle strength, torque, and reduction in spasticity at the end of the study period.

Three recently published RCTs include a study of 44 chronic stroke subjects, matched for age, duration, and side of hemiplegia (5). The treatment group received transcutaneous electrical nerve stimulation (TENS) of forearm and elbow extensors and shoulder abductors. All subjects received physiotherapy treatment. Results showed significantly greater improvement in Fugl-Meyer scores in the treatment than the control group. This was not reflected in activities of daily living (ADL) measured by the Barthel Index and higher functioning subjects at the start of the study made greater improvements with stimulation.

Chae et al. (6) investigated 46 subjects recruited within 4 weeks of stroke. The treatment group received cyclic stimulation to the wrist extensors and the control group stimulation just above sensory threshold. There were greater reductions in impairment in the treatment group but not in the Functional Independence Measure (FIM) of ADL.

Similarly, Powell et al. (4) also investigated cyclic stimulation to the wrist extensors in 60 acute stroke patients randomized to stimulation and conventional treatment groups. Impairment of function was measured by the Action Research Arm test (ARAT) (7). Results showed significant

differences in changes between the two groups in wrist extension strength, total ARAT scores, and the grasp and grip subtests of ARAT, but no significant difference in total ARAT score 24 weeks after treatment had been discontinued in a subgroup that had retained some residual function at study entry.

These studies have concluded that motor control is improved by electrical stimulation, early intervention may be more effective and patients with some residual control are more likely to respond well. They also conclude that stimulation of several muscle groups to give a "functional" pattern of movement may be beneficial. Benefits were not always maintained when treatment was discontinued and reduction in impairment did not result in improvements in ADL.

A review by de Kroon (8) of six RCTs conducted between 1979 and 2000 also concluded that there appears to be a positive effect of electrical stimulation on motor control. However, due either to inadequate sample sizes and/or weak methodologies of the studies reviewed, it is not possible to draw any conclusions concerning its effects on functional ability or whether motor relearning is enhanced when stimulation is activated by voluntary movement.

Some physiotherapy treatments use sensory stimulation to improve movement but few attempts have been made to promote recovery of sensation directly following stroke. Results from studies conducted to date concerned with the effect of electrical stimulation on sensation have been inconclusive and the methodologies sometimes weak.

Yekutieli and Guttman (1993) (9) conducted a trial retraining sensation in 20 patients 2 or more years post stroke. Results showed statistically significant improvements in sensory function. Tests of motor function were not carried out although the authors suggest that harnessing any existing sensory recovery in early rehabilitation may result in improved hand function.

Baker et al. (1979) (10) used electrical stimulation to stimulate the forearm extensors in 16 subjects for 4 weeks. No changes in sensation were measured using the two-point discrimination test.

Dannenbaum (1988) (11) advocated retraining of hand sensation in stroke patients on the basis of a single case study in which electrical stimulation

was used to initiate sensory retraining in the tips of the thumb and first and second fingers.

Prada (1995) (12) found that electrical stimulation to the hemiplegic forearm triggered by movement of the unaffected arm resulted in significant improvement in awareness of the affected arm measured by the Rivermead Perceptual Assessment Battery and that this improvement was maintained.

Taylor et al. (1995) (13) conducted a retrospective analysis of 20 chronic stroke patients who had been referred for electrical stimulation treatment for the upper limb. These patients had restricted hand function, but were able to take the hand to the mouth. Stimulation was applied to the forearm extensors reciprocally with either the lumbrical muscles, finger flexors or a rest period. Outcome measures were the Jebsen-Taylor hand function test, grip strength, and static two-point discrimination for sensation. Fifteen patients improved their hand function score, two were unchanged, and three had reduced scores.

Tests of sensation were carried out on 11 of the original 20 subjects and of these seven showed improvement, four were unchanged, and none deteriorated. There was also a statistically significant difference in sensation between the affected and unaffected hands at the start of the study and no significant difference at the second measurement.

Only two of the six RCTs reviewed by de Kroon (4,6) applied cyclical neuromuscular electrical stimulation (NMES) to the treatment group and both were conducted in the acute stage (within 1 month) following stroke. It is difficult to assess during this stage the extent to which any improvement is caused by a particular treatment modality or to the natural process of recovery. Stimulation was applied to the wrist and finger extensors only in both studies. The other studies used TENS (5), positional feedback stimulation training (PFST) (14), or EMG-triggered stimulation (15,16). Although Sonde et al. (5) combined stimulation of shoulder, elbow, and wrist TENS was applied rather than cyclical NMES. None of the studies reviewed investigated the effects of NMES on both function and sensation, the study by Taylor et al. being only a retrospective analysis of these outcomes. Only one of the NMES studies used a functional outcome measure.

In this pilot study it was considered that simultaneous stimulation of elbow and wrist and finger

extension using cyclical NMES may produce a more functional movement than stimulation of wrist and finger extensors alone. Since sensory information and feedback is known to be an integral part of normal functional movement the effect of stimulation on both sensation and function was assessed.

Three previous studies (4-6) have performed follow up assessments to test any "carry over" effect of stimulation treatment but these were based on different treatment protocols and produced contradictory results. It is important from the point of view of treatment protocols to know the extent to which treatment effects last.

The objectives of this pilot study therefore were to investigate the effects of NMES of the wrist and elbow extensor muscles on recovery of hand function and sensation within a year following stroke, compared to passive stretching exercises and to gain information to design a larger RCT with adequate sample size and robust methodology. This evidence is essential to inform a clinical service for patients with regard to those most likely to benefit, the most appropriate muscle groups to stimulate, and the degree of motor relearning that may be achieved so that NMES can be more confidently recommended as an effective treatment within a rehabilitation program for patients following stroke.

METHOD

The study design was a randomized controlled pilot study.

Subjects

A consecutive sample of subjects was recruited from those referred for functional electrical stimulation (FES) treatment to the Department of Medical Physics, Salisbury District Hospital, UK. Ethical approval for the study was obtained from the Salisbury and South Wiltshire Local Research Ethics Committee.

Inclusion Criteria

Inclusion criteria were as follows: 1) recruitment between 1 and 12 months post first stroke resulting in hemiplegia; 2) medically stable; 3) at least 18 years of age with no upper age limit; 4) able to take the hemiplegic hand to the mouth; 5) evidence of sensory impairment tested by light touch

comparing hemiplegic and nonhemiplegic hands; 6) no previous pathology to the upper limb; 7) no cardiac pacemaker; 8) able to comply with assessment and treatment procedures; and 9) able to give informed consent.

Exclusion Criteria

Subjects were excluded if they demonstrated cognitive or psychiatric problems affecting ability to comply with assessment and treatment procedures, a history of cardiac problems, or an implanted cardiac pacemaker.

Interventions

Following recruitment, subjects were randomly assigned to stimulation (treatment) and passive stretching exercise (control) groups using computer-generated sealed allocation codes. Subjects who were already receiving therapy in addition to that provided by the study continued with their individual programs given by therapists experienced in the treatment of neurologic conditions. The content and amount of this additional therapy was not standardized.

NMES

Treatment Group

Stimulation was delivered to the treatment group by a two-channel stimulator (Microstim 2, Department of Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, Wiltshire, UK, CE approved) powered by a PP3 9V battery, using PALS self-adhesive electrodes. One channel was used to stimulate triceps brachialis to elicit elbow extension; cathode and anode were positioned over the upper and lower parts of the muscle belly. The second channel was used to elicit wrist and finger extension by stimulating extensor carpi radialis, extensor digitorum communis, and where possible, extensor pollicis longus. Cathode and anode were positioned on the dorsal aspect of the forearm, positioned to produce the most functional movement.

A digital photograph, retained with each subject's records and copied for the subject's reference at home, documented the electrode positions.

Stimulation of all muscle groups was synchronous with a duty cycle of 8 sec on and 8 sec off.

Stimulation output was ramped over 2 sec at the beginning and end of each cycle. Pulse width was 300 μ s and frequency 40 Hz. Stimulation output was adjusted to give full elbow, wrist, and finger extension without discomfort. The stimulation period was increased from 10 to 30 min twice a day over approximately 1 week.

Passive Extension Exercises

Subjects in the control group were taught passive extension exercises of the elbow wrist and fingers to be practiced for the same period each day. A trained therapist supervised treatment of subjects during their hospital stay. Upon discharge, treatment continued with the help of a caregiver or independently by the subject.

Subjects in both groups received 12 weeks of treatment followed by 12 weeks without treatment.

Outcome measures

The primary outcome measure was ARAT (7), a validated functional hand and arm test. It comprises four subtests of grasp, grip, pinch, and gross movement. A total score is calculated from individual scores for each task. The patient is seated at a table on which the forearms can be comfortably rested. The seat height must be the same at each assessment.

Patients can score from 0 to 3 points for each task as follows:

- unable to attempt task—0
- able to pick up object but not place it—1
- able to pick up object and place it with difficulty, or using unnecessary, abnormal movements—2
- able to place object easily and accurately using normal movement patterns—3

The first task in each category is the most difficult and if the patient is able to complete it he or she scores maximum points and progresses to the next category. If unable to complete the first task the patient progresses to the second, which is the easiest. If the patient cannot complete this he or she scores zero and moves on to the next category. If the patient can complete the easiest task he or she attempts the remaining tasks in the category and achieves a score according to how well the task is done. The maximum scores for each

category are grasp, 18; grip, 12; pinch, 18; gross movement, 9, making a total possible score of 57. In the grasp and pinch categories subjects have to reach to place objects at a level 37.5 cm above table height thus requiring at least 90 degrees of active shoulder flexion. In the grip category subjects place objects either on a shelf 6.5 cm above table height or at table height itself, requiring much less movement at the shoulder. Subjects attempt each category of the ARAT with the nonhemiplegic and hemiplegic upper limbs alternately.

Sensation was tested using static two-point discrimination (17) using blunt-ended pins 2, 4, 6, and 10 mm apart and a single pin to periodically verify response during assessment. Subjects were blindfolded and asked whether they felt one or two points when the hand was touched with the pins. Twenty-four discrete areas of the hand and fingers were tested and scored as follows:

- 0 = no sensation
- 1 = sensation, but no discrimination or ambiguous response
- 2 = accurate discrimination at 10 mm separation
- 3 = accurate discrimination at 6 mm
- 4 = accurate discrimination at 4 mm
- 5 = accurate discrimination at 2 mm

Assessments

All outcome measures were applied at the start of treatment (week 0), midway through the treatment period (week 6), at the end of the treatment period (week 12), and 12 weeks after completion of treatment (week 24).

Statistical Analysis

The characteristics of the two groups at baseline are described using summary statistics. ARAT and

sensation scores at 12 and 24 weeks are compared between groups in a regression model controlled for baseline scores (ANCOVA). Mean (SD) difference in ARAT and sensation between groups is presented with 95% confidence intervals.

RESULTS

Twenty-four subjects were recruited to the study. Two withdrew before completion, due to unrelated problems and were lost to follow-up. Data are presented for the 22 subjects who completed the study (Table 1).

Results of ARAT

Results of ARAT are presented as scores at weeks 0, 12, and 24 for each category in the test together with the statistical results using analysis of covariance (ANCOVA) at weeks 12 and 24. ANCOVA compares the differences in changes between the treatment and control groups adjusting for the differences in baseline scores between subjects (Table 2).

Total ARAT Scores

At the end of the 12-week treatment period all 11 subjects in the group receiving stimulation had improved total ARAT scores. In the control group 10 subjects had improved scores and one had a reduced score. A comparison with baseline scores showed that 12 weeks after treatment had stopped 10 of the stimulation group maintained improved scores and one was unchanged. In the control group all subjects maintained improved scores, but these were considerably smaller.

Nonparametric tests of covariance (ANCOVA) identified a significant between-group difference between the beginning and end of the treatment

Table 1. Demographic Data for All Subjects ($n = 22$)

Subjects	(a) Side of hemiplegia	(b) Mean age	(c) Male/female	(d) Mean time since stroke	(e) Infarct or hemorrhage
Treatment $n = 11$	5—right 6—left	68 (57–86) years	5—male 6—female	5.7 (1–12) months	10 infarct 1 hemorrhage
Control $n = 11$	5—right 6—left	71(57–87) years	5—male 6—female	8.5 (2–12) months	11 infarct
p values	$p > 0.5$	$p > 0.5$	$p > 0.5$	$p = 0.08$	$p > 0.5$

Note: p values for a, c, and e using Fisher exact test. p values for b and d using Mann–Whitney U -test.

Table 2. Action Research Arm Test. Total Scores and Scores for Each SubTest at Weeks 0, 12, and 24 and Analysis of Covariance (ANCOVA) with 95% Confidence Intervals (CI) Comparing the Difference in Changes Between Treatment and Control Groups Controlled for Baseline at Weeks 12 and 24

CATEGORY (maximum possible score)	Mean scores week 0	Adjusted mean week 12	Adjusted mean week 24	ANCOVA difference in means week 12	ANCOVA difference in means week 24
Total (57)					
Treatment n = 11	20.0	34.4	34.4	diff = 10.0	diff = 9.7
Control n = 11	14.3	24.4	24.7	CI 3.8 to 16.3 ($p = 0.003$)	CI 2.4 to 17.1 ($p = 0.012$)
	$p = 0.43$				
Grasp (18)	7.4	11.2	10.5	diff = 3.0	diff = 1.9
	4.6	8.2	8.6	CI 0.3 to 6.4 ($p = 0.074$)	CI -1.7 to 5.4 ($p = 0.278$)
	$p = 0.34$				
Grip (12)	4.6	8.0	8.3	diff = 2.8	diff = 2.8
	2.8	5.2	5.5	CI 1.1 to 4.6 ($p = 0.003$)	CI 0.6 to 4.9 ($p = 0.016$)
	$p = 0.26$				
Pinch (18)	2.7	8.6	8.8	diff = 4.1	diff = 4.6
	2.4	4.5	4.2	CI 1.1 to 7.1 ($p = 0.011$)	CI 1.4 to 7.8 ($p = 0.007$)
	$p = 0.65$				
Gross Mvt (9)	5.6	7.0	7.4	diff = 0.7	diff = 1.1
	4.6	6.3	6.3	CI 0.7 to 2.2 ($p = 0.313$)	CI -0.3 to 2.4 ($p = 0.108$)
	$p = 0.45$				

Note: p values obtained using Mann-Whitney U -test.

period, which was maintained at the end of the study (Fig. 1).

Grasp Scores

In the grasp category ten subjects in the stimulation group improved their scores and one was unchanged at the end of the treatment period. In the control group seven subjects improved and four remained unchanged. At the end of the study

nine subjects in the stimulation group had maintained their improved scores and two were unchanged. There were no significant between-group differences either at the end of the treatment or the whole study periods.

Grip Scores

Ten subjects in the stimulation group improved their scores at the end of the treatment period and one remained unchanged having scored maximum points at both assessments. In the control group six patients improved and five remained the same. At the end of the study the numbers in each group who had improved scores or remained unchanged were the same. Between-group differences in scores were significant both at the end of treatment and at the end of the study.

Pinch Scores

Ten out of 11 subjects showed an improvement in pinch category scores at the end of treatment and one was unchanged. This was maintained at the end of the study. In the control group scores improved in six subjects, were unchanged in two, and were worse in three subjects. At the end of the study these scores were unchanged except for

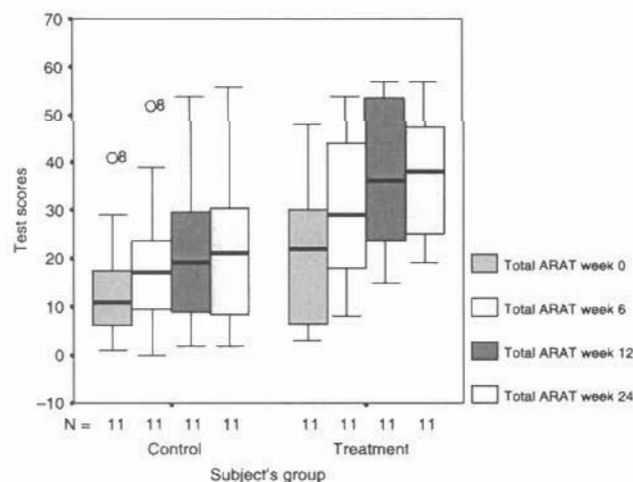


Figure 1. Action research arm test. Box plots showing total scores for treatment and control groups at weeks 0, 6, 12, and 24.

Table 3. Sensation Scores at Week 0 and Analysis of Covariance (ANCOVA) with 95% Confidence Intervals (CI) Comparing the Difference in Changes Between Treatment and Control Groups Controlled for Baseline at Weeks 12 and 24

Sensation	Mean score week 0	ANCOVA adjusted mean week 12	ANCOVA adjusted mean week 24	ANCOVA difference in means week 12	ANCOVA difference in means week 24
Treatment <i>n</i> = 11	36	49	51	diff = 2	diff = 4
Control <i>n</i> = 11	47 (<i>p</i> = 0.28)	47	47	CI -7 to 10 (<i>p</i> = 0.700)	CI -6 to 13 (<i>p</i> = 0.396)

one subject whose previous improvement had reduced. Between-group differences in scores at the end of the 12-week treatment period were significant as were those at the end of the study.

Gross Movement Scores

In the treatment group, gross movement scores at the end of the treatment period showed an improvement in seven subjects and no change in four subjects. This was maintained at the end of the study. Control group scores improved for five subjects during the treatment period with six subjects' scores remaining the same. At the end of the study four subjects had maintained improved scores, six were unchanged, and one was worse. Between-group differences were not significant at any stage of the study.

Sensation

Sensation scores at the end of the treatment period showed an improvement in eight subjects, no change in two, and deterioration in one subject in the treatment group. Although the same number of subjects improved, were unchanged, or had worse scores, the mean change in scores over the whole study period (0-24 weeks) was improved further. Control group scores improved for six subjects during the treatment period with three subjects' scores unchanged and two worse. This pattern remained unchanged at the end of the study (Table 3).

Between-group differences in scores at the end of the 12-week treatment period were not significant either at the end of treatment or at the end of the study (Fig. 2).

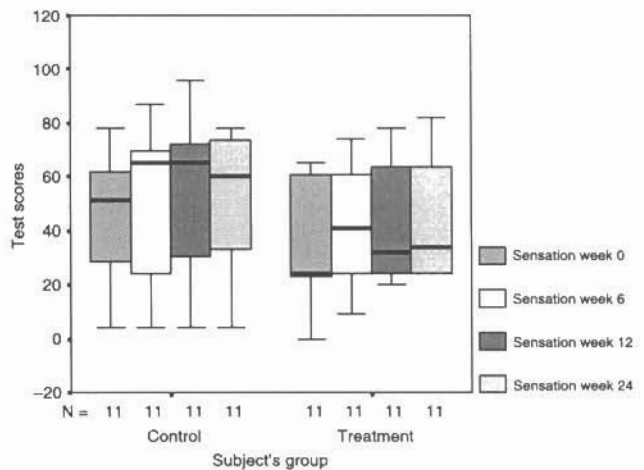


Figure 2. Sensation. Box plots showing two-point discrimination scores for sensation in treatment and control groups at weeks 0, 6, 12, and 24.

DISCUSSION

This study has demonstrated a significant clinical benefit of simultaneous electrical stimulation of the elbow, wrist, and finger extensors using a functional outcome measure, in subacute patients following stroke and has shown that this effect was maintained at 12 weeks postintervention. Previous randomized controlled studies using NMES (4,6) selected patients at an earlier, acute stage of recovery. Both studies applied stimulation to the wrist and finger extensors only and one (4) demonstrated improvements in total scores in the ARAT that were not maintained at 24 weeks. It is more difficult to attribute improvements in outcome in the acute stage to a particular treatment intervention rather than to natural recovery.

In the study reported here there was no correlation between baseline scores and changes in

scores at the end of the study, indicating that those subjects who had a lower level of function at the beginning of the study improved to as great an extent as those with higher initial scores. This differs from the findings of some other authors Powell (4), Sonde (5), and Popovic (18) who found that higher functioning subjects did better than those with lower levels of function at the beginning of the study.

The mean time since stroke in this study was almost 3 months less in the treatment group than in the control group so that natural recovery may have been a more influential factor in the improvement in the treatment group.

Another factor which may have affected the results was additional therapy being received by some subjects. Since this was not standardized with regard to either type or quantity it is difficult to know what effect it may have had on outcomes.

In the grasp subtest there were no significant differences in changes between the groups either at the end of the treatment period or the whole study period.

In order to complete this section of the test successfully a subject needs to be able to combine proximal control at the shoulder and elbow with sustained grasp of the object to be moved, in order to position it accurately. Most subjects found it difficult either to open the hand sufficiently and/or to sustain grasp of the larger objects. A number of subjects also had insufficient active range of movement at the shoulder to gain enough forward reach to complete the task.

In both the grip and pinch subtests there were significant differences in the changes between groups at the end of the treatment and study periods. The grip tasks required dexterity but less range of movement at the shoulder than the grasp section tasks. In the pinch category fine finger movement is needed as well as more than 90 degrees shoulder flexion. Subjects may have completed this more successfully than the grasp section as the objects to be placed are much smaller and lighter, requiring less active, sustained wrist and finger extension.

In the gross movement section there was no significant difference in the changes between the groups. This category would have been less influenced by stimulation treatment and improvements would largely have reflected improvement in

movement at the shoulder, possibly as a result of increased use of the limb.

The aim of combining stimulation of the wrist and finger extensors with elbow extension was to produce a more functional pattern and greater range of useful movement than can be achieved with stimulation of wrist and finger extension alone. Previous studies using NMES (4,6) have stimulated only the wrist and finger extensors. However, muscles at both the shoulder and shoulder girdle are also affected following stroke resulting in loss of range of movement and reduced proximal stability, contributing to reduced function. Future studies should consider adding stimulation of these muscles where appropriate not only to gain greater proximal stability and control of movement but also to facilitate motor relearning through achieving a more functional movement pattern. Classical motor learning studies (Schmidt) (19) have shown that positive feedback as well as repetition is important if tasks are to be learned. Therefore, neuromuscular stimulation should be applied so that the subject can successfully achieve meaningful functional tasks which incorporate use of the whole upper limb during reaching. This would be further assisted if a patient was able to trigger stimulation when he needs to perform a particular task and not merely as a repetitive exercise. The development of a simple triggering mechanism would potentially advance patient-controlled rehabilitation of the upper limb and maximize the potential for its functional use to perform everyday tasks.

Although the treatment group showed a significantly greater improvement in performance of ARAT than the control group, no assessment was made as to whether this resulted in meaningful functional improvement in activities of daily living. Future studies should therefore include a global functional outcome measure of relevance to the patient.

The mechanisms of the effects of electrical stimulation are unclear but may include improvement in muscle strength and motor control and a possible central effect on motor relearning. It has also been indicated that electrical stimulation may have an effect on sensory deficits (20) although the results of this study have been inconclusive.

The results of the two-point discrimination test showed no significant difference in changes in

sensation between the two groups, although slightly greater within-group changes occurred in the treatment group than the controls. This test is carried out on the palmar aspect of the hand which was not stimulated in the treatment group. It is likely therefore that any improvement in sensation in this group may have been due to increased use of the hand. In the control group however, passive stretching inevitably involved manual stimulation of the palmar surface of the hand and this may have had some effect in increasing awareness and sensation in that area. It may also be that the two-point discrimination test is not sensitive enough to detect change accurately. It is open to inconsistency in the application of the probes to the surface of the skin by the investigator and in this study a number of patients found it difficult to maintain concentration throughout the test. The effect of stimulation on recovery of sensation in the hand can therefore not be adequately assessed from this study and needs further investigation.

CONCLUSIONS

This study has shown that cyclic simultaneous electrical stimulation of the elbow and wrist extensors improves hand function and reduces upper limb disability in patients in the subacute stage following stroke, compared with self-administered passive exercises.

This improvement may be maintained for up to 3 months after treatment is stopped. Patients who have a lower level of function before treatment may gain similar improvements to those who have a higher pretreatment level of function. The effect on recovery of hand sensation is inconclusive. Further work should include stimulation of the shoulder where appropriate to maximize the potential function of the upper limb, development of a triggering device to enable use of stimulation during functional tasks, and monitoring patients' own functional objectives for treatment.

A sample size calculation has been made based on the primary outcome variable (ARAT). This is to underpin a full randomized controlled trial with the intent of establishing with greater precision the existence of a difference in ANCOVA-adjusted final ARAT total mean scores of at least ten units as a result of electrical stimulation intervention.

We assume the use of an ANCOVA to address the question at issue. We also assume a test significance level of 5%, 80% test power, and a pooled estimate of variability for the primary outcome variable derived from the current pilot study; SD = 6.75. The estimated sample is 24 subjects per group, adjusted upwards to allow for a possible 10% dropout rate. The sample size was obtained using the NQUERY ADVISOR software package.

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