

Evidence Table

Clinical Area: Bioness NESS H200 for the upper extremity paralysis

Reference: Alon G, Levitt AF, McCarthy PA. Functional electrical stimulation (FES) may modify the poor prognosis of stroke survivors with severe motor loss of the upper extremity. *Am J Rehabil Med* 2008;87:627-636

Study Type: Randomized controlled trial.

Study Aim: To assess the effects of task-specific functional electrical stimulation (FES) program in patients with very low initial volitional motor control who were not expected to recover upper-extremity function.

Outcomes

- *Primary:* Improvement in function and volitional motor control.

Design

- *Number of subjects:* N= 26
- *Description of study population:* These were patients seen for a first time ischemic stroke in the hospital in Maryland. Their ages ranged from 42 to 85 years, 54% were men, 61.5% had right and 38.5% left upper extremity impairment.
- *Inclusion criteria:* Men and women 20-90 years of age, with a single unilateral ischemic stroke that occurred 2-4 weeks before the study, with paralysis/paresis of the upper limb, Fugl-Meyer score between 2 and 10, no clinical evidence of limited passive joint range of motion of the paralyzed upper limb, admitted to the hospital for at least one week, and actively engaged in physical and occupational therapy, forearm and hand size compatible with the use of the H-200 stimulation system, at least 60% of full finger flexion and extension response to stimulation, able and willing to participate in the 12-weeks study, adequate language function and signing of the consent.
- *Exclusion criteria:* Patients with pacemakers or defibrillators, unstable vital signs, active reflex sympathetic dystrophy, shoulder-hand syndrome, other residual motor weakness, inability to sit in a standard armless chair for 30 minutes, sensory aphasia, impaired communication, Mini Mental Status Examination core ≤ 2 , other co-morbid neurological disease, shoulder subluxation, unavailable care giver, or refusal to be videotaped.
- *Intervention:* All study participants were individually guided by physical and occupational therapists on how to exercise and promote motor retraining of the paralyzed muscles of the upper limb. The exercises were passive and active as well as task specific (grasping, holding and moving objects). These were adjusted to each patient and modified according to improvement. The exercises were practiced by the patient with the attending therapist in 30-minute sessions, two times a day, and 5 days a week during hospitalization. After discharge from the inpatient rehabilitation the patients were advised to practice 30 minutes twice daily without supervision. They also continued to receive in-home physical and occupational therapies 1-2 times per week. Those randomized to the FES group received electrical stimulation (ES) by means of the H-200 (Bioness, Inc). The initial duration of the stimulation sessions was 10 minutes each to be repeated 4 times a day (2 sessions with exercise and 2 for stimulation without exercise). The duration of the session increased by 5 minutes /day and by day 11 they had FES for 1 hour session to be repeated 4 times each day.

- *Source of outcome data:* Assessment of muscle tone, motion and function using the Box and Blocks (B&B) test, the light object lift subset of Jebson-Taylor (J-T) test, and video-based modified Fugl-Meyer test (mF-M) to measure volitional motor control, loss and recovery. These were recorded at baseline and after 4, 8, and 12 weeks of training.
- *Length of follow-up:* 12 weeks, the duration of therapy.

Validity:

- *Blinding?* No.
- *Appropriate randomization procedures?* Yes.
- *Appropriate comparison intervention (placebo or adequate dose of accepted intervention)?* Yes.
- *Treatment/control groups comparable at baseline?* Yes.
- *Other than intervention, was care/follow-up similar in each group?* Yes.
- *Adequate compliance with intervention?* Compliance could not be measured as the actual amount of time the patient exercised at home was not monitored.
- *Sufficient statistical power?* No.
- *Intention to treat analysis?* Follow-up was 100% complete.
- *Completeness of follow-up:* 100%.
- *Industry funding?* Yes, the study was supported in part by the manufacturer.

- **Conclusions regarding validity of methods:**

This small RCT had the advantage of comparing the standard therapy to standard therapy plus FES. However, the study was not blinded, and the home compliance of the patients to the treatment was not monitored, all of which are sources of bias. Moreover, it did not have sufficient power to detect significant differences between the study groups, and did not have an extended follow-up to determine the long-term outcomes of the therapy.

Results:

The tests used to evaluate the outcome measures were:

MF-M test: A modification of the Fugl-Meyer test (F-M_{Max} =66 points) to allow the clear video recording of movements. The maximum score of the modified test is 54 points. A total of 27 movement items was scored as follows: no visible movement =0; partial movement =1; and full range movement =2.

The B&B test: This includes a commercially available box divided by a partition and containing 150 blocks located on one side. The box is placed on a desk in front of the patient who is instructed to pick one block at a time and transfer it to the other side as fast as possible in 60 seconds. The test is repeated 3 times with each hand and the highest scores achieved are included as the final outcome measure.

The J-T light object lift test: Evaluates the ability to grasp, hold, and move and place large objects. The patient sits on a seat facing a desk on which are 5 empty aluminum cans which the he/she is asked to grasp each at a time, lift it over a 5-cm barrier and place it on the other side.

The time in seconds to lift and move all 5 cans is measured. The test is repeated 3 times with each hand and the fastest for each was recorded and included as the final outcome measure. The patient who is unable to perform or complete the test is given a score of 60 seconds.

Baseline values and outcomes at the end of therapy (12 months) in the two study groups

	FES (NESS H 200) group		Control group		P value (between 2 groups at 12 weeks)
	Baseline	12 weeks	Baseline	12 weeks	
mF-M score*	4.0 ± 2.4	24.2 ± 13.7	3.9 ± 2.6	14.5 ± 10.3	0.05
B&B test					
No of patients †	0	8	0	5	0.058
Group means		10.5 ± 12.0		2.5 ± 4.9	
J-T light object lift					
No of patients (%) ‡	0	6 (46%)	0	2 (15.4%)	0.12
Mean time:					
All participants		40.5 ± 22.8		52.9 ± 17.3	
Successful performance		17.7 ± 9.3		13.9 ± 1.3	

* The maximum score of the modified test is 54 points. A total of 27 movement items is scored as follows: no visible movement =0; partial movement =1; and full range movement =2

† No of patients who were able to transfer one or more blocks in 60 seconds

‡‡ No of patients who were able to grasp, lift, move and place the cans in 60 seconds.

Authors' Conclusions

The authors concluded that the addition FES to the exercises used in the study are likely to minimize motor loss, but may not significantly enhance the ability to use the upper limb after an ischemic stroke. They also concluded that patients with severe motor loss may need prolonged task specific FES training.

Reviewer's Conclusions

The study had the advantage of comparing the functional electrical stimulation using NESS H200 in addition to the standard therapy vs. standard therapy alone. However the study was too small, had insufficient power to detect statistically significant differences between the study groups, the trial was not blinded, and the compliance of the patients to therapy was not monitored. Moreover, the duration of the study was only 12 weeks which may be insufficient duration of recovery for some patients, and too short to determine the long-term duration of the improvement observed among some patients.