Evidence Table

Clinical Area: **Bioness NESS H200 for the upper extremity paralysis.**
Reference: **Alon G, Levitt AF, McCarthy PA. Functional electrical stimulation enhancement of upper extremity functional recovery during stroke rehabilitation: A pilot study. *Neurorehabil Neural Repair* 2007;21:207-215.**

Study Type: Randomized controlled trial.
Study Aim: To assess whether functional electrical stimulation (FES) with task-specific training would enhance recovery of the upper-extremity function when stared early after inpatient rehabilitation and continued for 12 weeks.

Outcomes

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

Design

- *Number of subjects:* N= 15
- *Description of study population:* These were patients with a first time ischemic stroke seen in a hospital in Maryland. 53% were men, 73.3% had right and 26.7% left upper extremity impairment. The stroke to start of study duration ranged from 11 to 29 days.
- *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 paresis of the upper limb, Fugl-Meyer score between 11 and 40, 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 $\leq$2, other co-morbid neurological disease, shoulder sublaxation, unavailable care giver, or refusal to be videotaped.
- *Intervention:* All participants began standard rehabilitation with 3 hours daily physical, occupational and speech therapies within 1-2 days of admission. They 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-min 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 min twice daily without supervision. They also continued to receive in-home physical/occupational therapy 1-2 times per week. Those randomized to the FES group received electrical stimulation (ES) by means of the H-200 (Bioness, Inc). They started the stimulation sessions at 10 minutes/session and repeated it 4 times (2 sessions for exercise and

2 for stimulation without exercise). The duration of the session increased by 5 minutes /day. 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-Tylor (J-T) test, and video-based mF-M score 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, the study 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 is 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 s 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 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 is 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 12 months in the two study groups

	FES (NESS H 200) group N=7		Control group N=8		P value (between 2 groups at 12 weeks)
	Baseline	12 weeks	Baseline	12 weeks	
mF-M score	23.9 ± 7.4	49.0 ± 5.1	21.9± 7.5	40.6± 8.2	0.042
B&B test*					
Group means	5.9 ± 6	42.3 ± 16.6	5.3 ± 6.2	26.3 ± 11	0.049
J-T light object lift**					
Task Time (sec)	47.5 ±21.3	6.7± 2.9	50.9 ±17.6	11.8 ± 5.4	0.049

* At baseline 3/7 of the FES group and 2/8 of the controls were unable to transfer any block with the paretic limb After 12 months all patients in the two groups were able to perform the test with the paretic hand.

** At baseline 2/7 of the FES group and 1/8 of the controls were able to perform the J-T test with the paretic limb After 12 months all patients in the two groups were able to perform the test with the paretic hand

Adverse events:

There were no reports of any adverse events as recurrent stroke, TIA, cardiac symptoms, shoulder sublaxation, reflex sympathetic dystrophy or skin damage.

Authors' Conclusions

The authors concluded patients with mild /moderate paresis in the upper extremity who begin early task-oriented training together with FES may have better functional recovery than those who receive task oriented training alone.

Reviewer's Conclusions

The study had the advantage of comparing the functional electrical stimulation using Ness H200 in addition to task-oriented training vs. task-oriented training alone. However, it was too small, unblinded, and was conducted among a selected group of patients with more favorable prognosis. Moreover, and the compliance of the patients to therapy was not monitored, and the study had no extended follow-up after the end of therapy to determine the durability of the improvement observed.