Evidence Table

Clinical Area: **Bioness NESS H200 for the upper extremity paralysis**
Reference: **Ring H, and Nechama Rosenthal. Controlled study of neuroprosthetic functional electrical stimulation in sub-acute post-stroke rehabilitation. *J Rehabil Med* 2005;37:32-36**

Study Type: Quasi randomized controlled trial.
Study Aim: To assess the effects of daily neuroprosthetic (NESS Handmaster) functional electrical stimulation in sub-acute stroke.

Outcomes

- *Primary:* Reduction in spasticity, improved function and movement, change in pain and hand edema, and adverse events.

Design

- *Number of subjects:* N= 22
- *Description of study population:* These were patients admitted to a day hospital for post cerebrovascular accident (CVA) rehabilitation. The mean age was around 55 years, mean time post CVA was 3.6 months, 72.7% were men, 50% had right and 50% left hemiparesis.
- *Inclusion criteria:* 3-6 months status post single non-hemorrhagic CVA, moderate to severe hemiparesis, cognitive adequate to follow multistep commands, and agreement to sign an informed consent.
- *Exclusion criteria:* Patients with pacemakers, uncontrolled seizure disorders, joint instability or structural impairment, in the involved limb, severe neglect, severe aphasia, or unstable medical disorders.
- *Intervention:* The participants were categorized in 2 groups: those with no active voluntary motion and the fingers and wrist (Type I), and those with active partial range of motion (type II). Patients in both groups underwent baseline goniometric measurements, assessment of muscle tone, and functional use of the hand, as well as upper limb pain and edema. They were then randomized to a treatment group using a neuroprothesis (NESS Handmaster) or a control group. All patients in both group received similar rehabilitation programs using standard physical and occupational therapies. Those in the neuroprothesis group were fitted with the Handmaster upper limb system and provided with a protocol for home use. The use of the system was started at 10 minutes twice a day, progressed to up to 50 minutes 3 times a day over the first 2 weeks, and remained at that level to the end of the 6-week study.
- *Source of outcome data*: Assessment of muscle tone, motion function, pain, and edema at six weeks after therapy.
- *Length of follow-up*: There was no long-term follow-up after the 6 weeks of therapy.

Validity:

- *Blinding?* The clinician who made all the clinical evaluations was blinded to the treatment group. Pain and edema were graded by the patients themselves and evaluated by therapist.
- *Appropriate randomization procedures?* No, patients were assigned to the treatment or control group on an alternating basis.

- *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?* The authors did not provide figures but indicated that there was a high level of compliance.
- *Sufficient statistical power?* No
- *Intention to treat analysis?* Follow-up was 100% complete.
- *Completeness of follow-up:* 100%
- *Industry funding?* The devices were supplied by the manufacturer.

- **Conclusions regarding validity of methods:**

This was a small inappropriately-randomized study. It had the advantage of including a comparison group, and blinding of the provider who evaluated the patients clinically. However, it was too small, and the authors did not discuss if they performed any power calculations.

Results

Spasticity

	P for improvement vs. control
Type I* neuroprothesis patients	
Shoulder	0.05
Finger	0.04
Type II** neuroprothesis patients	
Shoulder	0.03
Wrist	0.04
Finger	0.01
Thumb	0.04

The difference was statistically insignificant for the other joints

*Type I: Those with no active voluntary motion and the fingers and wrist
**Type II those with active partial range of motion

Active motion

	P for improvement vs. control
Type I patients	No significant difference vs. control
Type II patients	
Shoulder flexion	0.03 (28^o increase vs. 1^o loss)
Wrist extension	0.02 (17^o increase vs. 2^o loss)
Wrist flexion	0.04 (21^o increase vs. 5^o increase)

Functional tests

Percentage change in spasticity (Modified Ashworth scale)
And scores in functional hand test in the two study groups

	Handmaster %	Control %	P value
Reduction in spasticity			
Type I	27	10	0.0457
Type II	60	4	0.0293
Box and Blocks	50	2	0.0143
Jebson-Tylor Light Weight Object Placement	36	9	0.0261
Jebson-Tylor Heavy Weight Object placement	39	16	0.0105

Pain and hand edema

Numbers were too small to compare.

Adverse effects and compliance

No adverse effects were reported in any of the two groups.

Authors' Conclusions

The authors concluded that the addition of daily home neuroprosthetic activation to the standard outpatient rehabilitation improves upper limb outcomes.

Reviewer's Conclusions

The study had the advantage of comparing the functional electrical stimulation using Handmaster in addition to the standard therapy to standard therapy alone; however the study was too small, had inappropriate randomization, and no extended follow-up to determine if the improvement observed would persist.