

# A Comparison of Treatment Approaches to Improve Upper Extremity Function in Patients Post CVA: A Pilot Study

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## ABSTRACT

The purpose of this study was to determine if electrostimulation neuroprosthesis (Bioness – Ness H200®) when combined with conventional treatment is more effective in improving upper extremity (UE) function in patients post-stroke than conventional treatment alone. The research was designed to compare post-stroke rehabilitation between clients who used Bioness- Ness H200® in conjunction with conventional therapy and those who were treated with traditional methods alone. This study is a quasi-experimental design using systematic random assignment.

## INTRODUCTION & RELEVANCE OF STUDY

- According to the National Stroke Association, stroke is the leading cause of serious long-term disability in adults ("Impact of stroke," 2012).
- In Lee County from 2010 to 2012, there were 7,173 reported hospitalizations as a result of stroke ("Hospitalizations from stroke," 2012).
- Addresses a gap in current stroke research by conducting an upper extremity, Bioness Ness-H200® specific study within an inpatient rehabilitation hospital.
- Contributes to the body of research that utilizes the Bioness Ness-H200®, yet it is not endorsed by the device manufacturer, Bioness Inc.

## BIONESS NESS-H200®

- "The H200 Wireless System uses functional electrical stimulation (FES) to activate the nerves that control the muscles in the hand and forearm" (Bioness Inc.)
- Use of device may help restore function (grasp, release, open/close hand), assist with circulation, ROM, muscle spasms, and muscle atrophy (Bioness Inc.)
- Muscles activated: Extensor Digitorum, Extensor Pollicis Brevis, Flexor Digitorum Superficialis, Flexor Pollicis Longus, and Thenar muscles (Page et al 2009)



## MEASURE: ACTION RESEARCH ARM TEST (ARAT)

- Founded on the assumption that most upper extremity activities of daily function are comprised of grasp, grip, pinch, and gross movements of extension/flexion at the elbow and shoulder.
- Consists of 19 items grouped into 4 subtests:
  - Grasp (6)
  - Grip (4)
  - Pinch (6)
  - Gross movement (3)
- Each item scored on a four point ordinal scale from 0 (cannot perform) to 3 (performs normally in less than 5 seconds)
- Total scores range from 0 to 57
- Higher scores indicate greater UE function
- High inter-rater reliability: 0.98
- Can be completed in 8 to 10 minutes (van der Lee, 2001)



## METHODOLOGY

### Study Design:

- Quasi-experimental design
- Systematic random assignment
- Single-blind: Students were blind to treatment group assignment

### Inclusion Criteria:

- Cognitive ability to give informed consent and understand a command
- Diagnosis of ischemic or hemorrhagic CVA as ascertained from neuro-images or written medical reports
- Functional upper extremity PROM
- First onset of CVA
- Inability to achieve full reach and open hand when upper extremity is unsupported
- Able to tolerate three hours of daily therapy five times per week

### Exclusion Criteria:

- Shoulder or hand pain (acute or chronic)
- Contraindications of using Bioness Ness-H200®
- Un-resolvable language barrier

### Treatment Groups:

- Control group received two, 45 minute conventional therapy sessions daily.
- Experimental group received two conventional therapy sessions daily and wore the Bioness Ness-H200® device during one of the 45 minute sessions.

### Procedure:

1. ARAT inter-rater reliability for student researchers was determined (0.998)
2. Therapist obtained informed consent, completed chart review and participant information sheet, and fit the Bioness Ness-H200® for participants in the experimental group.
3. Students administered pre-test (ARAT)
4. Therapists conducted appropriate treatment session per assigned treatment group
5. Students administered post-test (ARAT)
6. Students conducted data analysis

## PARTICIPANTS

Demographic Data		
	Bioness	Conventional
Gender		
Females	1	3
Males	2	0
Age		
	49	72
	67	77
	92	80
Ethnicity		
White/Causian	1	3
Black	1	0
Hispanic	1	0
CVA Type		
Ischemic	2	3
Hemmoragic	1	0
Affected Side		
Left	3	2
Right	0	1

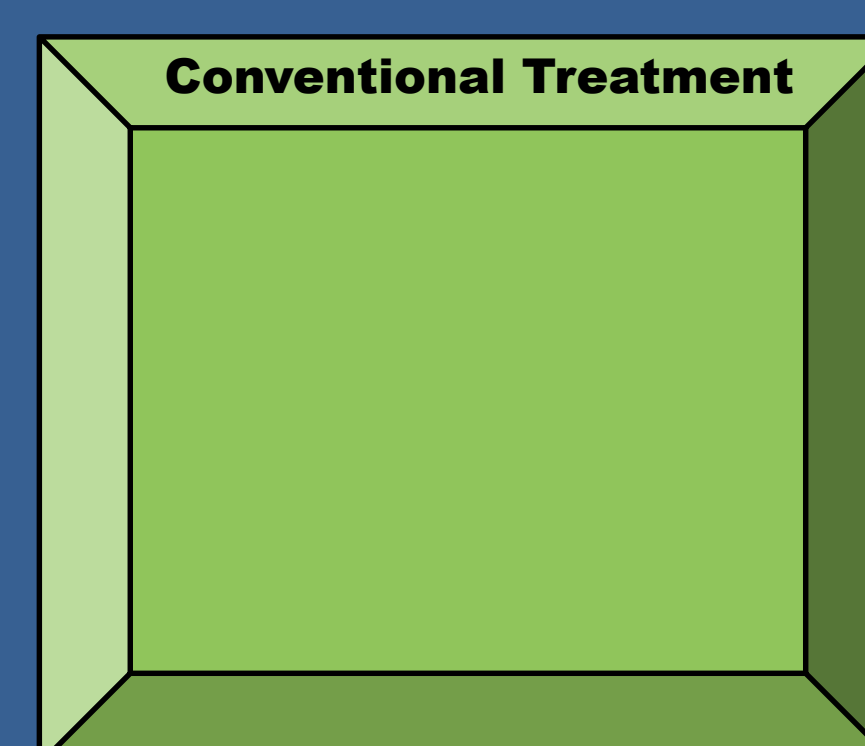
### Sample size: 6

- 32 Chart reviews were conducted
- 9 Individuals enrolled in the study
- 3 Participants were unable to complete the study

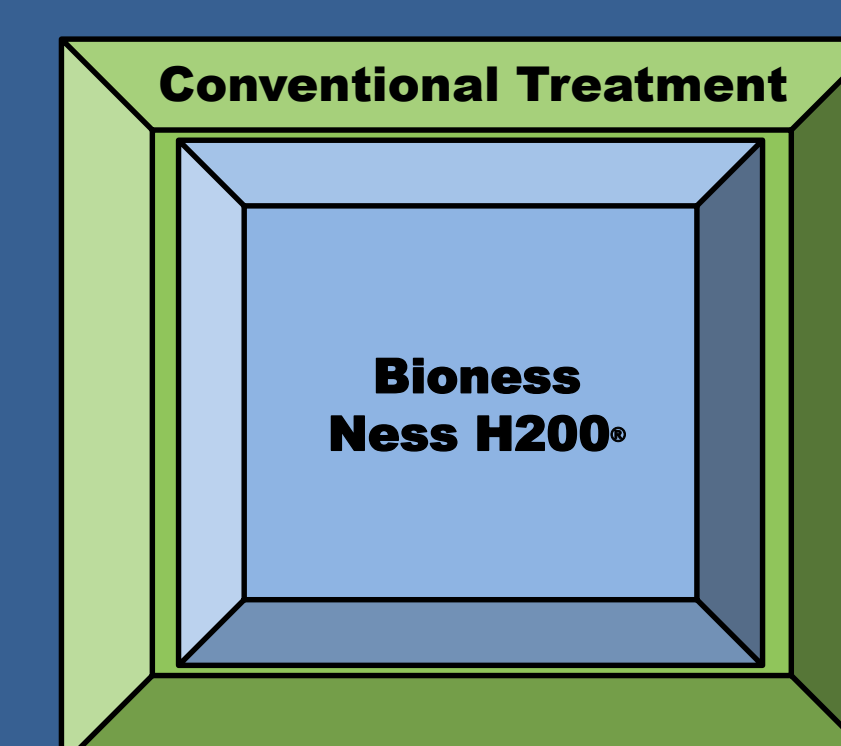
## Comparison of Treatment Days

Experimental	Control
12	7
14	6
16	7
Average Number of Days/Participant	
14	6.66

## TREATMENT GROUPS



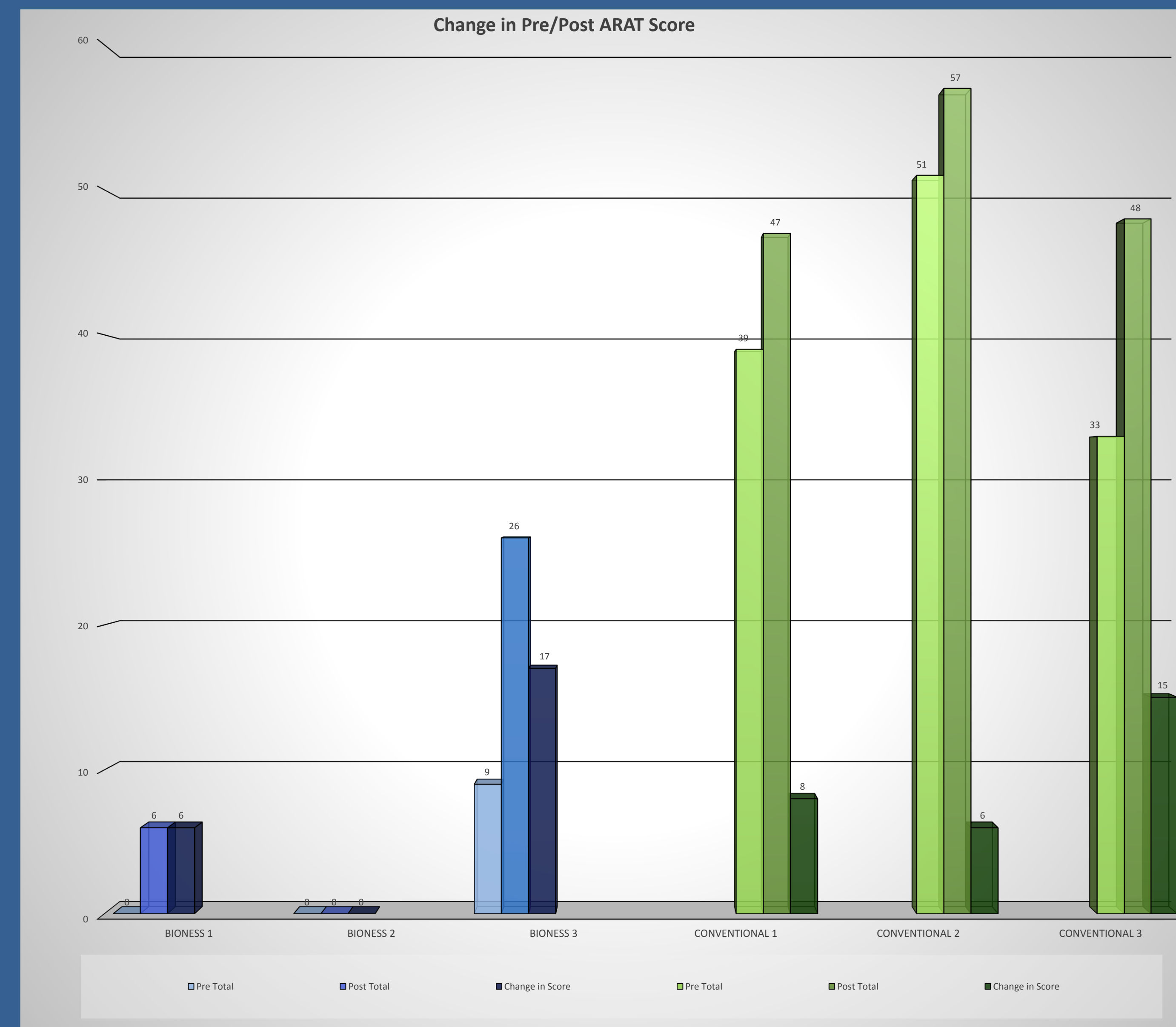
Control Group



Experimental Group

## RESULTS

- Due to the small sample size, descriptive statistics and a graphical display are used to show results.
- According to pre- and post- intervention ARAT scores, 5 of 6 participants who completed the study displayed an increase in performance on the ARAT. One participant showed no change.



## DISCUSSION

Due to the small sample size, the results of this pilot study are inconclusive. Factors and limitations contributing to inconclusiveness of the study include: the small sample size, variations in treatment administration, disparities in functional levels of the two treatment groups upon entering the study, mechanical complications with the electrostimulation neuroprosthesis (Bioness Ness-H200®), and inability to achieve ideal fit of the device for all patients. Despite these limitations, the strengths of this study include: a single-blind study design, high inter-rater reliability on ARAT scoring (.998), pre-study device training by a Bioness Inc. representative for the therapists, occurrence in a clinical setting instead of a laboratory, licensed therapists facilitating treatment, and the study was not endorsed or funded by the device manufacturer, Bioness Inc.

Replication of the study should aim to obtain a larger sample size, provide an ideal fit of the Bioness – Ness H200®, use a more reliable device with fewer mechanical malfunctions, improve data collection sheets to obtain more accurate information about time spent in therapy, and ensure consistent adherence to the treatment protocol.



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