

Use of Functional Electrical Stimulation to Improve Hand Function with Cervical Spinal Cord
Injury: A Case Study

by
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Injury: A Case Study

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Abstract

Spinal cord injuries paralyze many people in the United States each year. The injury location has an impact on the degree of residual function. For people with injuries to the cervical region, loss of hand function is typically observed. This inhibits ability to perform daily activities and results in loss of independence; therefore, restoration of hand function is an important area of study. Functional electrical stimulation applied to paralyzed nerves is an intervention implemented to promote neural health and strength. The NESS H200 is a stimulation device for the hands that is available commercially. This system was applied daily to upper extremities of a quadriplegic participant. Following treatment, no increase the grip or pinch force was observed and no change in the functional assessment was noted. When attempting to increase hand function, the NESS H200 may not be the most time or cost effective treatment for patients with similar injuries.

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List of Abbreviations

| | |
|-----|---|
| SCI | Spinal Cord Injury |
| CNS | Central Nervous System |
| AIS | The American Spinal Injury Association Impairment Scale |
| ADL | Activities of Daily Living |
| FES | Functional Electrical Stimulation |
| LMN | Lower Motor Neuron |
| FIM | The Functional Independence Measure |
| QIF | The Quadriplegia Index of Function |

Introduction

People engage in activities every day to which they devote little or no attention. These tasks such as walking, eating, or even simply wiggling the toes, are all possible thanks to the body's nervous system. However, every year in the U.S. more than ten thousand people experience traumatic spinal cord injury (SCI), are disabled, and in many cases are unable to perform these daily functions. (1-2)

The nervous system functions to process information that it collects about the body and its environment and generate an appropriate response that may involve sending signals to muscles to contract, glands to secrete, or to initiate a wide variety of other necessary functions. (1) These messages are sent via electrical signals transmitted by specialized cells of the nervous system called neurons. (1-2) Sensory information from the body is sent via sensory neurons to the spinal cord, a long and tubular structure, which then sends this information to the brain. (1-2) Similarly, the spinal cord relays information from the brain to effectors in the body via motor neurons. (1-2) The spinal cord also controls the simplest reaction called a reflex in which sensory input or feedback such as muscle or tendon stretch send signals to motor neurons of the spinal cord. These neurons then fire, signaling the muscle to contract. Together, the brain and the spinal cord constitute the central nervous system (CNS). The spinal cord is protected by a spinal column which consists of protective membranes called meninges, bones called vertebrae, and by muscular tissue. However, it may still sustain damage that, even when slight, can manifest itself as severe disability. (1-2) Even minor contusions can lead to what is called

the ischemic cascade, where insufficient blood flow leads to a vicious cycle of swelling, membrane damage, and cell death. (1)

The spinal cord is regionally named and consists of the cervical, thoracic, lumbar, and sacral regions (Appendix A). (1-2) The cervical spinal cord is located in the neck region and consists of eight segments and eight sets of spinal nerves that innervate the arms and neck. (1) These are abbreviated as C1 through C8. (2) Each region of skin (dermatome), organ, and muscle, connects at a particular level of the spinal cord, which allows for some degree of specificity when identifying the site of a spinal cord injury, as the symptoms of SCI depend on both the extent and location of the injury. (1-2) For this case, injuries sustained to the cervical region, particularly C5 are of interest.

Injuries are further classified by the extent of the damage, where a complete injury indicates no neurological function preserved below the injury site and an incomplete injury indicates some preservation of function. (1) The American Spinal Injury Association Impairment Scale (AIS) classifies injuries based on the evaluation of muscle strength and skin sensation. (1-2) Grade A is a complete injury where all other classifications are incomplete. (1-3) B is preservation of sensory but no motor function, C is preservation of sensory and some weak motor function, D is preservation of sensory and some stronger motor function of essential muscles, and grade E indicates normal sensory and motor function. (1-2) The less complete the injury is, the more likely it is to gain some recovery of function. (2) For those classified as a C, there is a 75 percent chance that the ability to walk (with or without assistive devices) will be regained. (1)

SCI usually results in loss of some or all movement and sensation below the injury level. (1) This type of injury when located high so all four limbs are paralyzed is known as tetraplegia (or quadriplegia). (2) Injuries sustained in the middle cervical regions still allow movement of the head and neck, but the hands, trunk, arms and legs will be paralyzed and/or numb. (1) Due to paralysis of the chest muscles, breathing may be difficult. (1) For C5 injuries, movement of the head, neck and shoulders is retained as is flexion of the elbow. (3) Patients can expect to achieve independent feeding with assistive devices, can be independent with an appropriate power wheelchair, but will need maximal assistance for transfers. (3-4)

Evidence suggests, patients with tetraplegia report that the most difficult aspect of their disability was loss of hand function. (5-6) Reduced dexterity in tetraplegic patients due to paralysis of the hands and arms can affect activities of daily living (ADL) as well as limiting vocational prospects. (7) Even a very small increase in hand function can result in increased ability to perform ADL and increase independence. (5) Though improving hand function is an area of great importance, the research is not consistent due to differences in functional ability with various levels of SCI, and it usually involves small sample sizes. (5) Though the majority of upper extremity function is regained in the first six months after injury (3) and some studies agree that early rehabilitation is vital to prevent functional loss, others have been successful with interventions starting in the chronic phase of recovery. (5) In select patients with cervical spinal injury, surgeries and functional electrical stimulation have been successful in regaining some function. (5, 8-10)

Functional electrical stimulation (FES) is a technology fairly recently developed and introduced commercially in 1990 (3) that stemmed from the knowledge that electricity stimulates muscle contraction. (7) This technology applies electrical currents to nervous tissue in an attempt to regain control over their functions and is being applied to patients with SCI. (3, 7, 11) The ultimate goal is to induce changes that promote muscular and nervous tissue health and allow function after the stimulation has ceased. (11) The application of FES has been utilized to improve functionality of the upper extremities but is only appropriate if the lower motor neuron (LMN) is not extensively damaged. (3-4, 7, 11) C5 level quadriplegia patients typically have some regions of the LMN intact and make viable candidates for FES. (7) Possible benefits to this type of intervention include the ability to grasp, hold, and release a variety of objects. (4,7) Such interventions have also been used to increase muscle size, treat osteoporosis, and control spasticity (7). The Bioness company provides a commercially available FES device with surface electrodes called the NESS H200 (Figure 1). (7, 11) The device supports the wrists and has five electrodes for the extensors and flexors of the thumb and fingers, and it has a control that stimulates various grasp and release patterns. (7-8, 11) A small scale study showed ability to perform three ADL (using a telephone, eating with a fork, and another ADL chosen by the subject) improved while utilizing the device after three weeks of at home training. (8) A different study concluded that the device is only effective on a limited subset of patients with C5 SCI. (9)



Figure 1: Study participant wearing the Bioness device

The Middle Tennessee State University Exercise Science Department has been successful in its unique research with spinal cord injuries and aquatic therapy. One participant has experienced the benefits of this therapy after sustaining spinal cord trauma of the C5 region during a skiing accident in 2012. His injury is classified as AIS C (incomplete), but function wise appears like a complete injury, though at the time of injury, it was noted that the spine was not severed, nor the meninges breached. To date, he has regained the ability to take steps both while on the underwater treadmill and above ground with a walker. However, due to the inability to grip, when doing above ground walking with crutches, his hands must be wrapped in wrist splints and then around the hand holds of the crutches by another person to provide support. This dependence due to

inadequate hand function has slowed the progress that can be made in regards to the functioning of the lower extremities and in regaining more independence.

Thesis Statement

The purpose of this study is to determine if function and hand strength can be improved by utilizing the NESS H200 in this case. This will be done by evaluating both strength and hand function on ADLs as well as changes in mobility based on the ability of the participant to use crutches. It is hypothesized that the FES will increase the force output of tested measures of strength by at least ten percent, and consequently, increase the functional measure score.

Methods

Before the device was used, all metal was removed from the wrist and hand. The electrodes were wet, and the orthosis (a stabilizer) was put on the wrist, making sure that the large electrode sat over the base of the thumb. The wing on top of the orthosis was completely closed (Figure 2). The system was controlled by a wireless unit that after being turned on allowed the training parameters to be entered. The participant had two devices, one for each hand, and utilized them with the stimulation intensity setting at eight, a relatively high intensity, for a duration of forty-five minutes to an hour. The devices have a personal operating mode and were used once every day at the participant's home. The "trigger" button on the device stimulated the grasp and release patterns via electrical stimulation and could be put in an exercise mode or a function mode for doing daily activities. The participant used devices consistently and met the criteria established in the protocol.

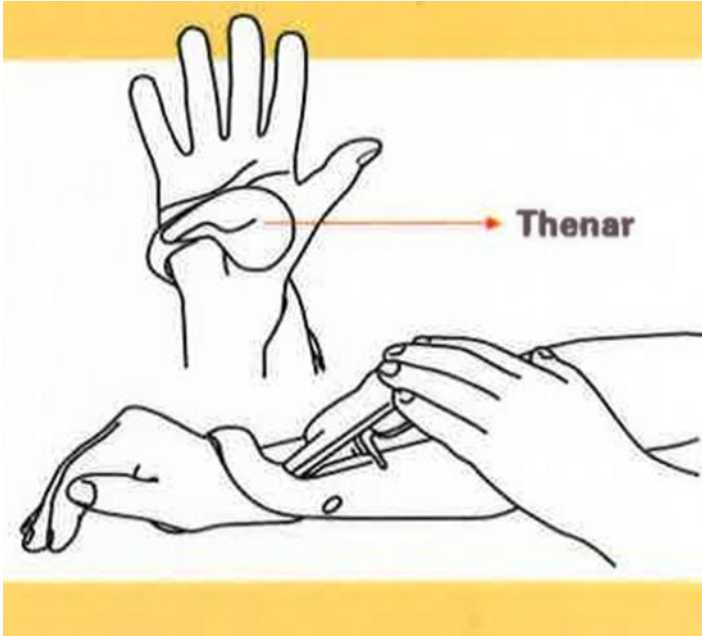


Figure 2: Proper use of the NESS H200 – large electrode over the base of the thumb, and upper wing being closed

Hand strength and function was evaluated over time. Strength was assessed using a dynamometer, which measures force to quantify incremental changes that cannot be detected during manual muscle testing. (6, 12) Dynamometers can be used to measure both grip and pinch strength, which is useful to detect improvements of the grip in quadriplegics. (6)

To test grip strength, the JAMAR Smedley-Type Lightweight Hand Dynamometer (Figure 3) was utilized.

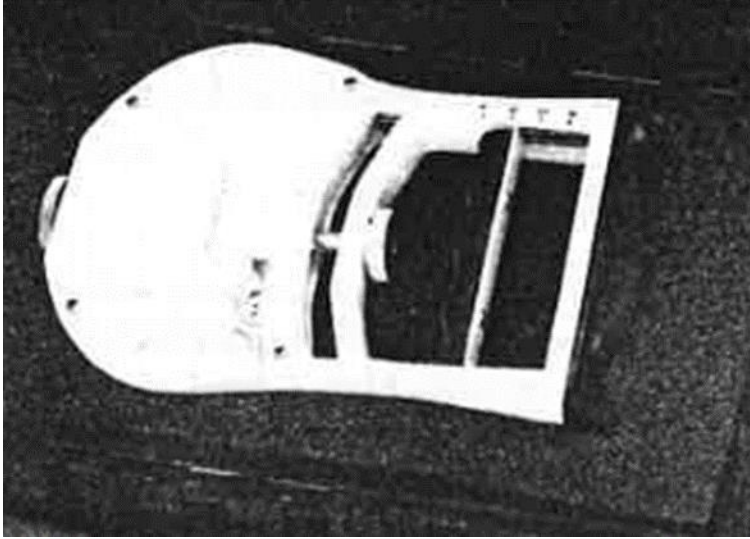


Figure 3: JAMAR Smedley-Type Lightweight Hand Dynamometer

To utilize the equipment, the participant sits in an upright position with the elbow forming a ninety degree angle and the wrist and forearm relaxed. (13) He then squeezes the dynamometer as hard as possible, and the amount of force produced is indicated on the dial. (13) In this case, upper extremity impairments related to tetraplegia limited the participant's ability to hold his arm in the standard position recommended for testing with this instrument. Therefore, support was provided to ensure the participant's arm position remained consistent over the course of testing, and the use other muscles to compensate for lack of hand strength was minimized. The grip force was tested twice each time in both the left and right hands, and the average was taken to represent the actual force reading for each hand. For males age 25 to 29, grip strength at the tenth percentile is 90 pounds of pressure in the right and 82 in the left hand. (13) However, even with the intervention, due to the nature of SCI, we did not expect the participant to reach these parameters, and were simply looking for changes from the baseline testing. To test pinch

strength, the Commander Muscle Tester (Figure 4) was used. The thumb was placed on one side of the device, and the two adjacent fingers were on the other. (14) Maximum pinch force was exerted and the output recorded. As with the grip strength test, the pinch strength was measured twice on each hand and the average of each was taken. Baseline measurements were taken before the intervention was implemented, and posttest measurements were taken upon the conclusion of the intervention. Two measurements were taken in-between to monitor progress.



Figure 4: J-Tech Commander Muscle Tester

Ultimately, the purpose of increased strength in the hand is the ability to apply any gain to daily tasks and to achieve more independence. There is a wide variety of measures that have been developed to evaluate function and ADL. (5) One of the most

commonly used assessments for SCI is the Functional Independence Measure (FIM). However, it has been argued that the measure is not sensitive enough to identify changes in patients with SCI and that some of the tasks are not feasible for a person with quadriplegia. (15) The Quadriplegic Index of Function (QIF) was developed specifically for people with tetraplegia and to be a measure more sensitive to change than the FIM. (6) The measure tests ten different areas such as transfers and grooming, and the ability to perform certain tasks in these areas is rated from 0 (dependent) to 4 (independent). (16) Each of the categories is weighted with the final score ranging from 0 to 100. Though scoring on the QIF is less specific than the FIM, (15) the feeding category of this assessment is able to assess changes not identified on the FIM. (6) The QIF has a high correlation with the overall FIM score (6) and was found to be reliable and a viable option for evaluating improvement in persons with quadriplegia in clinical studies and when monitoring program outcomes (16); thus it was selected as the ADL measure for this case study. The QIF was tested once at the start of the intervention and once at the end. The intervention was concluded in early May, three months from the beginning FES, which is adequate time to detect changes.

Results

To assess the effectiveness of the intervention, scores before and after FES were compared as well as those taken mid-intervention. Any trend in the data was compared to hand strength data taken yearly since 2013. Because a case study's sample size is one, statistical measures were not appropriate, and instead pinch and grip strength data was

analyzed graphically. When the full effort is being exerted, no more than a ten percent variation in strength is expected. (13)

Table 1: Pinch strength force outputs and averages in pounds both during and prior to the intervention.

| Date | Pinch R (1) | Pinch R (2) | Pinch R (Avg) | Pinch L (1) | Pinch L (2) | Pinch L (Avg) |
|----------------------|-------------|-------------|---------------|-------------|-------------|---------------|
| Feb. 2013 | 3.5 | 3 | 3.25 | 2.25 | 2.25 | 2.25 |
| Feb. 2014 | 3 | 3 | 3 | 2.25 | 2 | 2.13 |
| Jan. 2015 | 2 | 2.25 | 2.13 | 1.5 | 1.5 | 1.5 |
| Feb. 2016/ Week 0 | 2 | 2 | 2 | 1 | 1.5 | 1.25 |
| Week 6 | 2 | 2 | 2 | 2 | 2 | 2 |
| Week 9 | 2 | 2 | 2 | 2 | 1.5 | 1.75 |
| Week 12 | 2.5 | 2 | 2.25 | 3 | 2 | 2.5 |

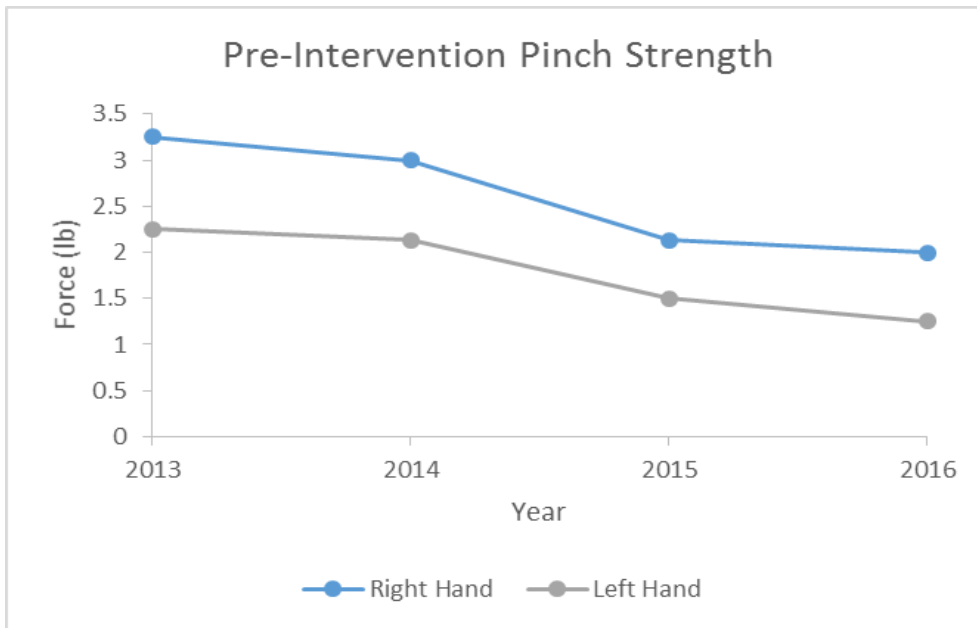


Figure 5: The graph shows pinch force data in pounds each year prior to the start of FES.

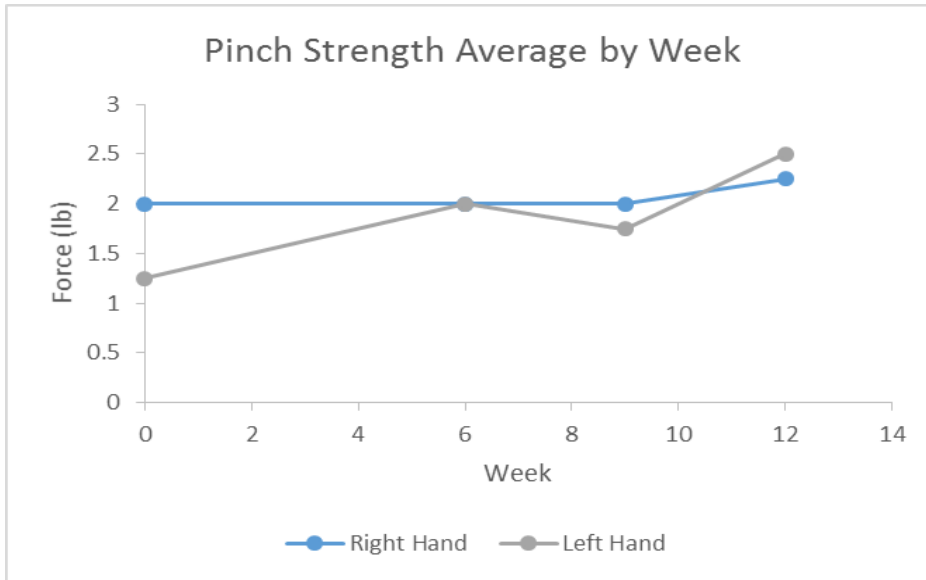


Figure 6: Changes in the average pounds of pinch force as detected by the J-Tech Commander Muscle Tester over the 12 week use of the NESS H200. Time zero is baseline testing done as included in figure 5.

Table 2: Grip strength force outputs and averages in pounds both during and prior to the intervention.

| Date | Grip R (1) | Grip R (2) | Grip R (Avg) | Grip L (1) | Grip L (2) | Grip L (Avg) |
|----------------------|------------|------------|--------------|------------|------------|--------------|
| Feb. 2013 | 4.5 | 3.5 | 4 | 4 | 5 | 4.5 |
| Feb. 2014 | 3 | 3 | 3 | 4.5 | 4.5 | 4.5 |
| Jan. 2015 | 2.5 | 1.5 | 2 | 3.5 | 2.5 | 3 |
| Feb. 2016/ Week 0 | 1.5 | 2.7 | 2.1 | 3 | 5 | 4 |
| Week 6 | 5 | 3 | 4 | 5 | 5 | 5 |
| Week 9 | 5.5 | 5.5 | 5.5 | 4.5 | 4 | 4.25 |
| Week 12 | 3.4 | 3.5 | 3.45 | 3 | 2.5 | 2.75 |

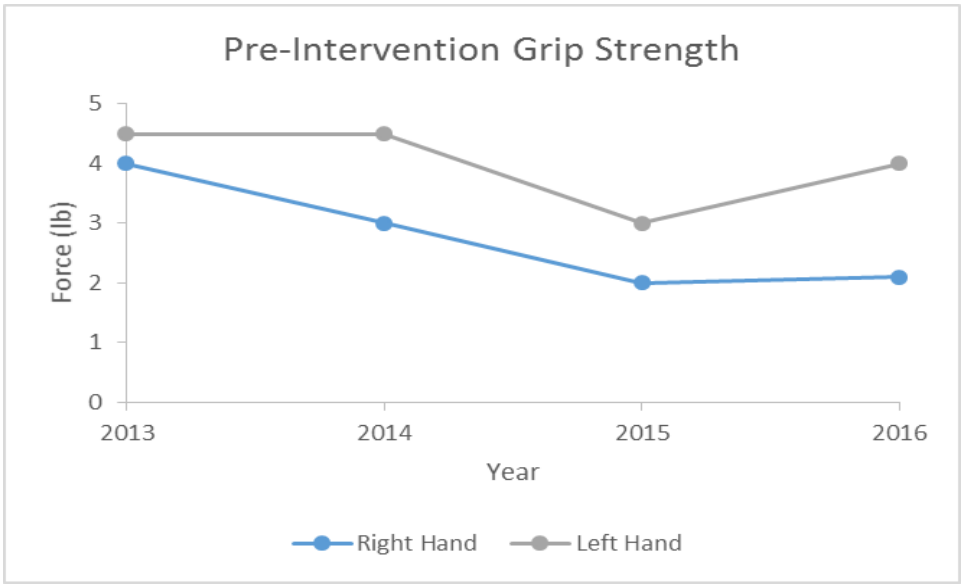


Figure 7: Yearly changes in generated grip force in pounds prior to the use of the FES intervention.

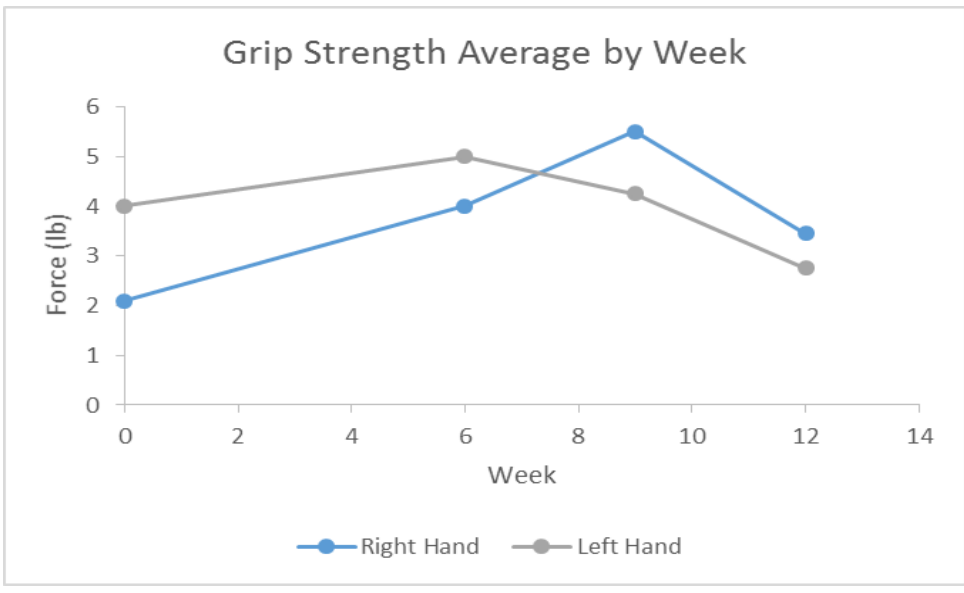


Figure 8: Changes in the average maximal grip force from baseline to the conclusion of the intervention as measured by the dynamometer.

Before the intervention with the NESS H200 began, the participant exhibited a QIF score of 52.83, and at the conclusion of the intervention the score was 56 which is a six percent change. Furthermore, by May the participant was able to take three steps while on crutches. From sit to stand, physical assistance was provided, but all steps were taken independently. Throughout the study, the type and degree of assistance remained unchanged, and the hands were still wrapped extensively and stabilized with splints to provide needed grip support (Figure 9).



Figure 9: Study participant standing crutches with the hands wrapped for support

In order better to understand what effects the Bioness was exerting, the participant was asked to report any changes he felt due to the intervention. In order to prevent bias reporting, he was not told the intention of the FES or given any positive or negative comments about his reporting. Over the course of the study, the reported effects of the Bioness stayed consistent. The FES made his hands feel “looser,” which was said in a positive manner, especially in the hours and days after the device was utilized. When first utilized, these loosening effects lasted an hour or two after use, but upon use every day these effects lasted longer. If a treatment was missed, the participant reported increased tightness of both hands once again. There was no mention of increased feelings of strength or of a greater ease when doing daily tasks.

Discussion

Prior to the intervention, the yearly strength data taken shows a slight decline in the pinch strength of both hands (figure 5). As illustrated in Figure 7, the grip strength of the right hand also exhibits a decline while in the left hand the values remained relatively constant. The declines could be due to a lack of stimulation from the nervous system, consequently leading to the atrophy of the muscles responsible for movement in the hand. However, because the decline is slight and no functional measures were taken, it is unclear as to whether such a decline would further inhibit the existing function.

If loss of strength was due to a lack of stimulation, the use of appropriate FES would theoretically slow or reverse this decline. This change in the pattern of strength loss should reflect greater hand function through the use of tenodesis grasp, which is a compensatory grip strategy implemented by C5-6 tetraplegics. A person with this level of

injury would be able to grip due to flexion of the fingers achieved by the extension of the wrist. (17) The effectiveness of this grip can be improved by increased support with adaptive devices, increased range of motion at the wrist, and increased muscular strength. (18) If, therefore, the NESS H200 was able to stimulate greater strength, then the tenodesis grip would be improved as well. If grip is weak or a large enough contraction is not achieved, then adaptive devices must be used to get the desired results. (17) For example, equipment such as splints can help make joints more stable to prevent injury or other issues.

Pinch strength of the right hand remained unchanged over the course of the intervention (figure 6). The amount of force exerted by the left hand pinch instead showed an increase from the start to the end of the trial. For grip strength, each hand exhibited opposite trends. Overall the force of grip by the right hand increased slightly while that of the left hand decreased slightly (figure 8). In both measures of strength, there appeared to be no consistent trend in the changes that occurred while utilizing the NESS H200. While recovery from this type injury is expected to consist of fluctuations, there is no continuity in the overall direction of strength. Neither hand appeared to be more responsive to FES than the other, as the pinch strength of the left hand exhibited an increase while grip strength of the right hand exhibited an increase instead. Furthermore, though the left hand increased its pinch strength, it decreased its grip strength. While pre-intervention measures consistently show a decline or a stasis of strength, the measures during the intervention show no such consistency. Therefore, it cannot be concluded given this protocol that the NESS H200 increases strength of the muscles responsible for

hand function. In most cases, however, there was either a slight increase in strength or a maintenance of strength over the course of the study, which may mean that while utilized consistently the NESS H200 could prevent the decline that was seen prior to its use. The overall changes in the negative direction prior to utilization of the NESS H200 were small, and occurred over the course of a year. Therefore, it is possible that the duration of testing was too short to show what, just like the grip strength of the left hand, may have been an eventual decline in function. The study duration, the loss of left hand grip strength, and the inconsistency of the data trends make it impossible to conclude with confidence that this NESS H200 may prevent this decline.

One of the functional measurements for the study, the QIF, further supports the lack of consistency seen in the strength data. The score exhibited only a six percent increase over the course of three months. This small change, however, is easily attributed to changes in question interpretation and feelings of the participant. For example, there is a significant difference in interpreting a wheelchair to vehicle transfer as moving from the wheelchair seat to the seat of the car instead of simply driving the wheelchair into the back of the vehicle. Furthermore, fluctuations so small could simply be due to the circumstances of the participant that particular day, such as how difficult it was to get dressed and in what type of garment. The QIF is designed to be sensitive to minor changes in function which causes a greater change in score as opposed to other more common tests. (16) Therefore, this correspondingly small change indicates that little to no functional gain was obtained as detectable by this measure. This result is not surprising given the very small changes in strength seen exhibited in figures 5 through 8.

The participant's description of the effects of the Bioness also seem to support these results. As stated, there was no mention of increased feelings of strength or ability to perform ADL. The only reported, detectable change was a temporary increased looseness of the hands. This was spoken of in a positive manner, and was probably more comfortable, however, these effects may have been counterintuitive. In order to grasp with a cervical spinal injury, additional tension in the muscles may have been useful as there would have been less tension to produce in order to effectively grip something. In fact, functional tenodesis grip requires some tightness of the finger flexors in order to be functional. (17) One of the hopeful goals of the intervention was an ability to grasp the crutches freely while in use, and "looser" hands would not necessarily aid in this goal. Regardless, the lack of increase in hand strength did not allow a safe grip to be obtained. While the participant was able to take three steps with the crutches, the hands were wrapped onto the handles and the wrists were also stabilized with adaptive equipment.

Overall, there were no issues with the protocol for the intervention. The devices can be safely utilized, and the only issue was the inconvenience and time required to utilize the device appropriately. Nevertheless, given this particular protocol, the NESS H200 was not successful at increasing strength of the hand such that functional gain was achieved. The study is limited in that it only consists of one participant, and because the nature of SCI is extremely varied, the results are not necessarily applicable to the entire population. However, this case exhibits a stage of recovery advanced for his injury level, and hand function began to be a limiting factor in training. In the future when working with patients with similar injuries, the very costly and time consuming treatment with the

Bioness device may not be a prudent course of action since the desired outcome was not achieved in this case. Furthermore, due to time constraints of the participant's residence in the area, the study could not be conducted over a long period of time, nor could further data be taken after secession of the daily FES. Had the study been conducted longer, the long term trend in data could have been used to determine if the NESS H200 prevents decline.

This Bioness Company advertises very different results than those achieved in this study, even though one of the many populations to which the device is being marketed are those with incomplete spinal cord injuries of the cervical spine. One of the advertised intentions of the FES system is to prevent the atrophy of muscles, which was not necessarily seen in this study. (19) Improving or maintaining range of motion is also listed as one of the benefits of the device, along with others, all for the purposes of more easily performing ADL. Furthermore, Bioness claims that the H200 may also reeducate the muscle so that they can function without the system. The brochure boasts 'Grasp onto Life,' (19: p.1) selling the concepts of freedom and independence, which may be successful in other situations, but not in this particular population subset whose restoration of hand function is a significant need. Unfortunately, given the measured parameters, it seems the company's claims may be too good to be true, though further study is needed. It was hypothesized that the Bioness device would increase strength by at least ten percent, which would result in an improvement in the functional measure (QIF) score. For this given methodology, the NESS H200 did not consistently result in

increases in pound of force generated by grip or pinch, and thus, the QIF score did not exhibit a substantial percent change.

References

1. Selzer ME, Dobkin BH. Spinal cord injury. New York: Demos Health; 2008.
2. Liverman CT, Altevogt BM, Joy JE. Spinal cord injury: progress, promise, and priorities. Washington DC: National Academies Press; 2005 July.
3. Bryce, TN. Spinal cord injury. New York: Demos Medical; 2010.
4. Formal CS, Cawley MF, Stiens SA. Spinal cord injury rehabilitation. 3. Functional outcomes. Arch Phys Med Rehabil. 1997 Mar;78(3 Suppl):S59-64.
5. Lu X, Battistuzzo CR, Zoghi M, Galea MP. Effects of training on upper limb function after cervical spinal cord injury: a systematic review. Clin Rehabil. 2015 Jan;29(1):3-13.
6. Tuijl JH, Janssen-Potten, YJ, Seelen HA. Evaluation of upper extremity motor function tests in tetraplegics. Spinal Cord. 2002 Feb;40(2):51-64.
7. Ragnarsson KT. Functional electrical stimulation after spinal cord injury: current use, therapeutic effects, and future directions. Spinal Cord. 2008 Apr;46(4):255-74.
8. Alon G, McBride K. Persons with C5 or C6 tetraplegia achieve selected functional gains using a neuroprosthesis. Arch Phys Med Rehabil. 2003 Jan;84(1):119-24.
9. Snoek GJ, IJzerman MJ, in 't Groen FA, Stoffers TS, Zilvold G. Use of the NESS handmaster to restore handfunction in tetraplegia: clinical experiences in ten patients. Spinal Cord. 2000 Apr;38(4):244-49.

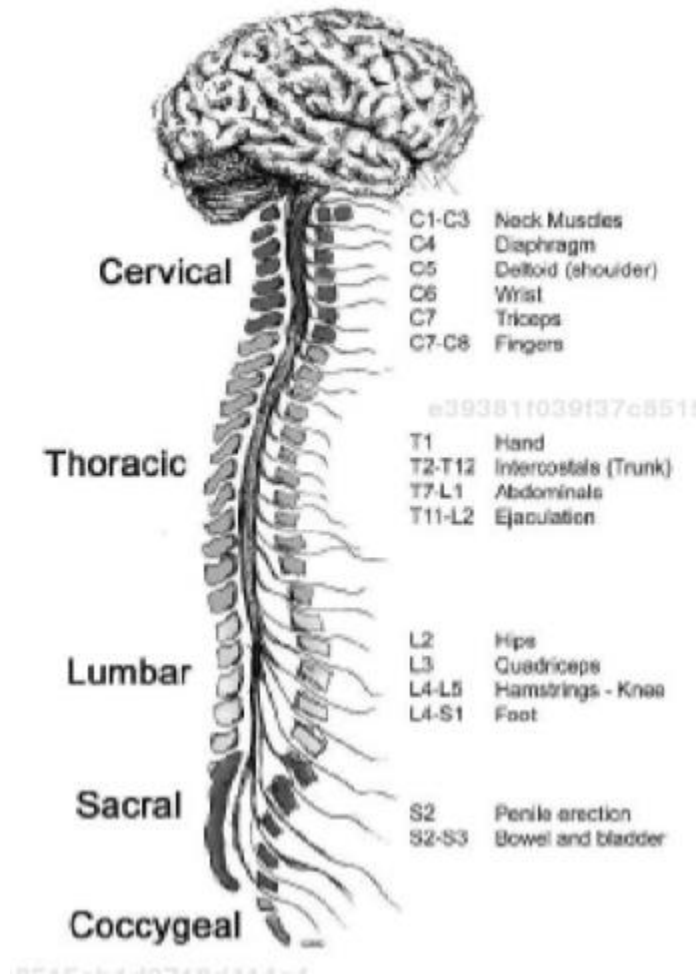
10. Gorman PH, Wuolle KS, Peckham PH, Heydrick D. Patient selection for an upper extremity neuroprosthesis in tetraplegic individuals. *Spinal Cord*. 1997 Sep;35(9):569-73.
11. Peckham PH, Knutson JS. Functional Electrical Stimulation for neuromuscular application. *Annu Rev Biomed Eng*. 2005;7:327-60.
12. Mulcahey M, Hutchinson D, Kozin S. Assessment of upper limb in tetraplegia: Considerations in evaluation and outcomes research. *J Rehabil Res Dev*. 2007;44(1):91-101.
13. Country Technology, Inc. Smedley-Type Lightweight Hand Dynamometer. Gays Mills, WI: Country Technology, Inc.
14. Livingston T, Bernardi D, and Carroll M. Commander Muscle Tester User's Manual. Midvale, UT: JTECH Medical; 2015.
15. Bryden AM, Sinnott KA, Mulcahey MJ. Innovative Strategies for Improving Upper Extremity Function in Tetraplegia and Considerations in Measuring Functional Outcomes. *Top Spinal Cord Inj Rehabil*. 2005;10(4):75-93.
16. Gresham GE, Labi ML, Dittmar SS, Hicks JT, Joyce SZ, Stehlik MA. The Quadriplegia Index of Function (QIF): sensitivity and reliability demonstrated in a study of thirty quadriplegic patients. *Paraplegia*. 1986 Feb;24(1):38-44.
17. Ford J, Duckworth B. Physical management for the quadriplegic patient. 2nd ed. Philadelphia: Davis; 1987.

18. Kohlmeyer KM, Hill JP, Yarkony GM, Jaeger RJ. Electrical stimulation and biofeedback effect on recovery of Tenodesis grasp: A controlled study . Archives of Physical Medicine & Rehabilitation . 1996Jul;77(7):702–6.
19. Bioness Inc. NESS H200 Wireless. Valencia, CA: Bioness Inc; 2013.

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Appendix A

Regions of the Spinal Cord and Spinal Nerves



Reference

Liverman CT, Altevogt BM, Joy JE. Spinal cord injury: progress, promise, and priorities.

Washington DC: National Academies Press; 2005 July. Figure 2-2, Functions controlled by nerves at different levels of the spine. Damage at a particular level usually impairs the functions controlled by all nerves at lower levels; p. 33.

Appendix B

IRB Approval



IRB

INSTITUTIONAL REVIEW BOARD

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IRBN008 - PROTOCOL APPROVAL NOTICE

Wednesday, April 1, 2016

Investigator(s): Sandra Stevens (PI), Don W. Morgan

Investigator(s)' Email(s): sstevens@mtsu.edu; don.morgan@mtsu.edu

Department: Health and Human Performance

Study Title: ***The effects of underwater treadmill training on mobility and function in adults with spinal cord injuries***

Protocol ID: **15-200**

Dear Investigator(s),

The above identified research proposal has been reviewed by the MTSU Institutional Review

Board (IRB) through the **FULL COMMITTEE REVIEW** mechanism under 45 CFR part 46. and

21 CFR part 56. This protocol was reviewed by the IRB at a convened meeting which meets

the HHS requirements on 4/1/15. The IRB has determined that this study poses minimal risk to

the participants or that you have satisfactorily worked to minimize the risks, and you have

satisfactorily addressed all of the concerns brought up during the review. A summary of the IRB

action and other particulars in regard to this protocol application is tabulated as shown below:

IRB Action APPROVED for one year

Date of expiration **4/1/2017**

Participant Size 10 (TEN)

Participant Pool **Adult diagnosed with a SCI, free from progressive medical condition**

Exceptions NONE

Restrictions 1. Signed informed consent for the collection of biological sample(s); (2) Patient records including full name, telephone numbers, street address, email address and photographic information MUST be stored securely in the designated location

Comments: This protocol was originally requested through the expedited process. It was referred to the full committee on 3/17/2015 by the primary reviewer in consultation with the secondary reviewer. Subsequently, the protocol approved by the IRB after clarifications and alterations to the protocol

Amendments **Date**

9/18/2015

Post-approval Amendments

1. Increase in training frequency to three times per week instead of previously approved two times has been granted

2. Change to the testing procedure to use wireless electromyography and electrical stimulation has been approved.

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3. Addition of a resistive exercise (refer to addendum request on file) to the protocol has been approved

This protocol can be continued for up to THREE years (**4/1/2018**) by obtaining a continuation approval prior to **4/1/2017**. Refer to the following schedule to plan your annual project reports and be aware that you may not receive a separate reminder to complete your continuing reviews. Failure in obtaining an approval for continuation will automatically result in cancellation of this protocol. Moreover, the completion of this study MUST be notified to the Office of Compliance by filing a final report in order to close-out the protocol.

Continuing Review Schedule:

Reporting Period Requisition Deadline IRB Comments

First year report 3/1/2016 The continuing review was completed through the expedited procedure in accordance with Category #9 sub classification 3: "Continuing review of research previously approved by the IRB at a convened meeting where NO ADDITIONAL RISKS OF THE RESEARCH HAVE BEEN IDENTIFIED" as defined further in 9.3a "the research project as a

whole involved no more than minimal risk."

Second year report 3/1/2017 INCOMPLETE

Final report 3/17/2018 INCOMPLETE

The investigator(s) indicated in this notification should read and abide by all of the post-approval conditions imposed with this approval. [Refer to the post-approval guidelines posted in the MTSU IRB's website](#). Any unanticipated harms to participants or adverse events must be reported to the Office of Compliance at (615) 494-8918 within 48 hours of the incident. Amendments to this protocol must be approved by the IRB. Inclusion of new researchers must also be approved by the Office of Compliance before they begin to work on the project.

All of the research-related records, which include signed consent forms, investigator information and other documents related to the study, must be retained by the PI or the faculty advisor (if the PI is a student) at the secure location mentioned in the protocol application. The data storage must be maintained for at least three (3) years after study completion. Subsequently, the researcher may destroy the data in a manner that maintains confidentiality and anonymity. IRB reserves the right to modify, change or cancel the terms of this letter without prior notice. Be advised that IRB also reserves the right to inspect or audit your records if needed.

Sincerely,

Institutional Review Board

Middle Tennessee State University

Quick Links:

[Click here](#) for a detailed list of the post-approval responsibilities.
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Appendix C

Photo Release

Permission to Use Photograph

Participant: Trent [redacted] *redacted*

I grant to MTSU, its representatives and employees the right to take photographs and videos of me and my property in connection with the underwater treadmill study. I authorize MTSU to use these in print and/or electronically for any lawful purpose, such as education, publicity, and illustration.

I have read and understand the above:

Signature *[Signature]* _____

Printed name *Trent* [redacted] _____
redacted