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Effect of Lower Extremity Sensory Amplitude Electrical Stimulation on Motor Recovery and Function after Stroke: a Pilot Study

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**EFFECT OF LOWER EXTREMITY SENSORY AMPLITUDE ELECTRICAL
STIMULATION ON MOTOR RECOVERY AND FUNCTION AFTER STROKE:
A PILOT STUDY**

By

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ABSTRACT

BACKGROUND AND PURPOSE : Post-stroke sensory dysfunction has been observed in more than 50-60% of all patients and negatively impacts motor control. Afferent input through sensory amplitude electrical stimulation (SES) has been associated with increased cortical excitability and plasticity, having a positive impact on the generation of skilled movement and function. The purpose of this study was to investigate the effect of lower extremity SES on motor and sensory recovery and function after first stroke for adult patients undergoing acute rehabilitation.

METHODS: This study is part of an ongoing double blind, randomized controlled trial. Inclusion criteria: admitted to inpatient rehabilitation with first stroke, medically stable, sensory and/or motor dysfunction, and scored ≥ 26 on the Montreal Cognitive Assessment Score. Exclusion criteria: pre-morbid neurologic or balance disorders and a projected length of stay less than 6 days. The experimental group received SES and control group received sham stimulation over the peroneal nerve for 60 minutes daily prior to physical therapy. Both interventions were provided six days/week throughout the rehabilitation stay; subjects received an average of 12 treatments. Outcome measures included the Fugl-Meyer lower extremity sensory assessment, Lower Extremity Motricity Index (LEMI), Berg Balance Scale (BBS), gait speed, and the Functional Independence Measure (FIM).

RESULTS: Forty-four patients were screened over six months: three patients met inclusion/exclusion criteria and consented to participate. Two females, one in the control group and one in the experimental group; and one male in the control group were recruited with an average age of 62.7, all with subcortical stroke. Subject one was seven days post-stroke, subjects two and three were five days post-stroke. Subjects in both groups showed meaningful improvement on LEMI and BBS . Only those in the control group showed meaningful improvement on the FIM. Fugl-Meyer was normal for all subjects at baseline. Gait speed could not be assessed due to subjects' inability to complete the test upon initial evaluation. The experimental subject showed the greatest amount of change in the LEMI compared to the control group.

CONCLUSION : Due to a small sample size the results cannot be generalized to all who have experienced stroke. Additional research and subjects are necessary to gain a better understanding of how peripheral sensory stimulation can affect sensory recovery and functional gain following acute stroke.

The undersigned certify that they have read, and recommended approval of the research project entitled...

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STIMULATION ON MOTOR RECOVERY AND FUNCTION AFTER STROKE:
A PILOT STUDY**

submitted by

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Rebecca Nelson

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In partial fulfillment of the requirements for the Doctor of Physical Therapy Program


Primary Advisor  Date 5/1/14

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CHAPTER I: INTRODUCTION AND LITERATURE REVIEW

Stroke is the number one cause of long-term severe disability among adults in the United States.¹ Stroke costs the United States \$36.5 billion annually, including the cost of health care services, medications, and lost productivity.² Effects of stroke include impaired strength, sensation, balance, and cognition. All of these impairments may have a negative impact on an individual's mobility, activities of daily living (ADL's), and ability to function independently at home and in the community. Furthermore, these deficits can decrease quality of life and limit full participation in life roles. It is also important to note that according to the Centers for Disease Control, 34% of people hospitalized for stroke were under the age of 65 in 2009.³ This only adds to the urgency associated with the identification of effective interventions for these individuals given their life expectancy and long-term goals related to work and family life. As such, there is a need to explore further intervention options with the potential to mitigate the impairments and functional limitations associated with stroke. In addition, by improving outcomes after stroke, individuals may also require fewer services, medications, and decrease their loss of productivity.

As noted above, one of the residual impairments commonly observed after stroke is post-stroke sensory dysfunction which has been documented in 50-60% of all stroke patients.^{4,5} This is significant because sensory input is important for the generation of skilled movement, and impaired sensation may contribute to limitations in function.⁶ Another concern is the ability to maintain balance, which may be significantly affected when sensory loss is present. Specifically, balance deficits that could be associated with

sensory loss include increased postural sway during quiet stance, uneven weight bearing and decreased ability to weight shift in standing.⁷

A variety of interventions can be used in order to regain sensory function after stroke including sensory discrimination, vibration, thermal stimulation, stereognosis and electrical stimulation.^{8,9,10} Electrical stimulation can be given in many forms, including transcutaneous electrical nerve stimulation (TENS), neuromuscular electrical stimulation (NMES) or sensory level electrical stimulation (SES), which is the focus of our literature review and study.

In conjunction with “typical” rehabilitation after stroke as well as when used by itself, afferent input has been associated with increased corticomotorneuronal excitability and plasticity in the primary motor, secondary motor, and somatosensory areas of the cortex.¹¹ As such, sensory input through electrical stimulation has the potential to enhance recovery and function following stroke. The benefits of electrical stimulation at the sensory level may include improved sensation, proprioception, and motor output all leading to improved functional mobility. With sensory re-training through sensory electrical stimulation the theory is that the portions of the brain affected by the neurologic insult will be re-organized in order to promote functional recovery.

The somatosensory cortex has direct connections to the primary motor, premotor, and parietal cortices which help modulate neuronal activity. According to current research it has been found that sensory level electrical stimulation can elicit cortical reorganization in the somatosensory cortex but also in the motor cortex of patients with chronic stroke.¹² Unmasking of pre-existing connections is one possible mechanism

explaining the reorganization.^{12,13} In addition, some authors state that neurons connect to a larger region than their assumed region of influence which may help to impact synaptic changes based on activity through long-term potentiation or depression.¹³ Another mechanism for growth is of course the formation of new neural connections and the formation of new synapses.

Multiple studies have shown that SES impacts cortical excitability and plasticity.^{6,11,14} One such study evaluated use-dependent plasticity in patients with chronic stroke.¹⁴ In conjunction with motor training, somatosensory stimulation was applied to either the upper extremity via the ulnar, median and radial nerve or to the lower extremity via the tibial, superficial peroneal and sural nerves. The researchers found that there was a significant increase in use-dependent plasticity, as measured by Transcranial Magnetic Stimulation (TMS), as well as TMS evoked thumb movements after upper extremity stimulation but not lower extremity stimulation. Another study used SES, thumb movements and the subsequent blood flow to the associated areas of the brain to demonstrate cortical excitability.¹¹ The researchers evaluated the perfusion signal and the change in blood oxygenation level (BOLD) response in various parts of the brain through Functional Magnetic Resonance Imaging (fMRI). Stimulation was applied for 2 hours above the perceptual level but without eliciting a visible muscle twitch and motor tasks consisted of visually paced, voluntary thumb movements, measured by fMRI. The 3 regions of interest included the primary motor cortex (M1), primary somatosensory cortex (S1) and dorsal premotor cortex (PMd). The researchers found that there was an increase in task-related blood flow which lasted significantly longer than the treatment

and had the greatest influence in the somatosensory and motor cortices related to the thumb with median nerve stimulation only, when compared with stimulation over the deltoid muscle and no stimulation groups. These studies suggest that a period of somatosensory stimulation increases the excitability of the motor cortices as well as the sensory cortices and can be beneficial for motor re-training and motor learning. Studies of behaviorally induced neural plasticity suggest that changes in cortical maps or cortical organization are specific to the trained task, the stimulated nerve and related body locations.⁶ For example, if the peroneal nerve is stimulated it will not enhance upper extremity function, just as lower extremity tasks will not improve upper extremity function.

Upper Extremity

Although limited, much of the research involving sensory level electrical stimulation to date has been conducted on the upper extremity and is focused on the relationship between sensory input and improvements in motor output. Many of the results are positive and suggest that sensory stimulation may be a viable option to help improve function following stroke.

For example, one randomized control trial recruited 28 right-handed subjects with acute or subacute stroke to participate in either 2 hours of peripheral sensory stimulation (PSS) or 2 hours of sham treatment to the median and ulnar nerves simultaneously.¹⁵ The PSS group received stimulation at an intensity level high enough to evoke paresthesia with no visible muscle contraction or report of pain. The sham group was still receiving stimulation but it was turned down to a level of minimal perception. The researchers used

the Action Research Arm Test (ARAT) and pinch strength test before and after each treatment to evaluate the functional progress the participants were making. They found that there was no significant increase in ARAT scores but there was an increase in lateral and tip pinch strength. The PSS group had a significantly higher gain in pinch strength than the sham group and it is important to note that the increase in strength was correlated with the intensity of the stimulus given. The best explanation of the lack of change in ARAT scores is most likely due to the fact that most of the patients had “normal” scores prior to beginning any stimulation intervention therefore yielding a ceiling effect. The authors of this study suggested that the increase in pinch strength immediately after stimulation may be due to an increase in excitability in the motor cortices.¹⁵

In a similar study, researchers recruited 8 subjects who were classified as having a chronic stroke.¹⁶ Each subject participated in two different sessions separated by at least 24 hours in which they received two hours of median nerve stimulation (MNS) and two hours of a control intervention. The stimulus intensity was similar to that of the previous study with the MNS group intensity at a level to produce paresthesia and the control group immediately below the level required to cause paresthesia. After both sessions the subjects maximal pinch strength was measured five times and an average was calculated. The researchers found that pinch strength was significantly increased after the MNS sessions but not after the control sessions. It is also important to mention that two of the patients reported that they could “write better and hold object and play cards more accurately” and this feeling lasted for about 24 hours. These findings indicate that even

with short sessions of sensory level stimulation some immediate return of function may be observed in subacute and chronic stroke survivors.¹⁶

Many studies that further demonstrate the efficacy of sensory level stimulation for patients with chronic stroke utilize the Jebsen-Taylor Hand Function Test (JTHFT) also known as the Jebsen-Taylor Test (JTT). This test has been shown to have good reliability and validity, and has normative data available for gender and various ages. The benefit it brings is that it includes tasks that mimic activities of daily living (ADL's), giving the researchers and clinicians an insight into overall levels of function.^{12,16,17,18} In one study, researchers analyzed the effects of somatosensory stimulation on the JTHFT when applied to the paretic limb.¹² The 9 patients included in the study participated in 3 different experimental interventions: 2 hours of stimulation to the paretic hand via the median, ulnar and radial nerves, the paretic leg via the peroneal, sural and tibial nerves and no stimulation. The authors found that there was significant improvement in the JTHFT time but only for the upper extremity stimulation condition. The researchers also stated that the improvements lasted less than 24 hours and that the greatest improvement was shown in the subjects with the greatest impairments. In response to this they raised the hypothesis that "this intervention strategy may be useful in people with poorer function and residual hand weakness that makes motor training too difficult."^{12 (p.353)}

In another study the participants were either placed in the treatment or sham group, with the stimulation kept at a sensory level and applied to the ulnar and median nerves for 2 hours.¹⁷ Sham or sensory stimulation was always preceded and followed by the JTHFT and cortical excitability monitoring. The researchers found that there was a

significant intervention effect in favor of peripheral nerve stimulation for JTHFT time at both one hour post-treatment and 24 hours post treatment. The authors also found a significant effect for decreased intracortical inhibition for the condition of peripheral stimulation with training compared to no stimulation as well as an increase in intracortical facilitation.¹⁷ The significance of this study continues to reiterate the concept that motor performance as well as motor learning can be significantly influenced by sensory input.

Researchers have also evaluated functional performance after stimulation through the kinematics of the hand.¹⁹ Twelve patients with chronic stroke were randomly assigned to either a group that received somatosensory stimulation or a group that participated in 2 hours of idle time. All subjects participated in both groups at different times throughout the experiment. The somatosensory stimulation group received electrical stimulation to the median nerve at an intensity that elicited paresthesia or above the sensory threshold. Each session was separated by one week and kinematic motion analysis of index finger tapping, hand tapping and reach to grasp movements were evaluated prior to and following both intervention conditions. It was found that the frequency of finger and hand tapping movements as well as peak velocity of the wrist during reach-to-grasp movements were increased in the somatosensory stimulation group. There was no difference between groups for change in peak wrist position or amplitude of wrist or finger tapping. The authors of this study, like many of those previously mentioned, addressed the suggestion that this increase in dexterity was due to the excitation of the cortex associated with the hand and wrist motions and the nerve being

stimulated which, in turn, may promote an increase in function and decrease in disability.¹⁹

The research conducted about sensory level stimulation has generated mixed results in regard to the appropriate level of stimulation. In one randomized controlled trial the authors examined the effects that somatosensory stimulation can have on the activities in the JTT for patients with chronic stroke that have primarily cortical involvement in the region of the middle cerebral artery (MCA) which holds significance as the main artery supplying blood to the somatosensory cortex.¹⁸ Eleven patients were assigned to receive 2 hours of median nerve stimulation at either subsensory (not high enough to elicit paresthesia) or suprasensory (high enough to cause paresthesia in the median nerve distribution without the presence of pain). Each subject participated in both the subsensory and the suprasensory interventions, separated by at least 60 days to avoid any carry-over. The authors found that there was improvement in the JTT in both groups but the increase was only significantly different in the suprasensory group, indicating that stimulation to the median nerve at a suprasensory level can enhance motor function.¹⁸

In contrast to these findings, another study found that there was a significant increase in function for subjects receiving subsensory stimulation.²⁰ This study recruited twenty-two participants who had experienced a single ischemic stroke no more than two months prior to the start of the study. The stimulation was kept at similar intensities compared with other research studies within both suprasensory and subsensory intensity groups. These participants received the stimulation 3 times per week for 1 month or a total of 12 visits and were always immediately followed by the JTT and once per week by

outpatient rehabilitation. After 12 sessions of stimulation the researchers found that there was an increase in JTT score for both groups but it was significantly higher in the subsensory group. At one month the subsensory group continued to show a greater degree of improvement with their scores being $43 \pm 4.5\%$ above baseline and the suprasensory group being $25 \pm 6.2\%$ greater than baseline. This difference diminished, and at 2 and 3 months there was no significant difference between groups. The authors also note that the greatest improvements were observed in those individuals who had the lowest JTT scores at baseline. The main differences between the two studies cited here are the chronicity of stroke and frequency of the stimulation. The researchers felt that the finding that subsensory stimulation was more effective requires additional investigation because it does not coincide with other research. More studies may be able to help determine the best parameters needed to facilitate the most beneficial treatment.²⁰

Few studies have investigated the benefit of sensory level stimulation on the upper and lower extremities together. One example is a study by Peurala, et al. which investigated the impact of sensory level stimulation on functional recovery of the paretic upper or lower limb in patients with chronic stroke.¹³ Outcome measures included the Modified Motor Assessment Scale (MMAS), 10 meter walk test, paretic limb function which was measured in the UE through picking up a pencil, pinch, and wrist extension and in the LE through toe flexion & extension and the ability to lift the paretic leg over the healthy leg, as well as sensation which was measured through a visual analog scale as well as somatosensory evoked potentials (SEPs). Fifty-nine subjects participated and they were given electrical stimulation below their sensory threshold via a sock or glove

electrode for 20 minutes daily, for a period of 3 weeks. The MMAS is an outcome measure that evaluates gross motor activities such as transitioning supine to side lying and walking as well as upper arm function, hand movements and advances hand activities. The researchers found there were significant improvements in MMAS in both the upper and lower extremity stimulated groups as well as significant improvement in gait speed in the upper extremity group but not the lower extremity group.¹³ It is also valuable to note that for the outcome of paretic limb function the subjects rated themselves as follows: 22/32 rated their hand function as improved and 12/19 rated their foot function as improved which equates to 67% of all participants reporting that their paretic limb was “better” at the end of the treatments. Upper extremity sensation, as rated by a visual analog scale, increased significantly but the increase in lower extremity sensation was not statistically significant. This study helps to further illustrate that even sub-sensory electrical stimulation can help to not only improve sensory input and processing but also improve motor output and functional recovery.¹³

Lower Extremity

Recent studies examining the use of electrical stimulation as a means of providing sensory input in order to influence motor output in the lower extremity have generated mixed results. Many of these studies have researched the effects of electrical stimulation on the lower extremities in regards to motor output, spasticity reduction, and sensation. In a randomized controlled trial by Yan et al. the researchers evaluated the effectiveness of transcutaneous electrical stimulation (TENS) applied to acupuncture points on muscle function.²¹ 62 subjects were recruited following acute stroke and randomly assigned to

one of 3 groups: TENS and standard rehabilitation, placebo stimulation and standard rehabilitation or just standard rehabilitation. The TENS parameters were 0.2 ms pulses at 100 Hz constantly to 3 acupuncture points on the lower extremity with the placebo stimulation set at the same level but the circuit disconnected and this was delivered 60 minutes per session 5 times per week for a total of 3 weeks. The researchers found that there was a significant decrease in plantar flexor spasticity and an increase in isometric ankle strength in the TENS vs. control group but no difference in TUG score between groups.²¹

Yavuzer, Oken, Atay, and Stam evaluated the effects of sensory amplitude electrical stimulation of the paretic leg on motor recovery and gait mechanics of patients with stroke.⁸ They studied 30 patients six months post-stroke without voluntary ankle dorsiflexion. Fifteen subjects were placed in the electrical stimulation group and 15 in the placebo group. Both groups participated in a conventional stroke rehabilitation program 5 days a week for 4 weeks. The electrical stimulation group received 30 minutes of sensory level electrical stimulation to the paretic leg without muscle contraction 5 days a week for 4 weeks. Brunnstrom stages improved significantly in both groups. 58% of the electrical stimulation group and 56% of the placebo group gained voluntary dorsiflexion. Gait kinematics improved in both groups. The differences between groups in active dorsiflexion and gait kinematics were not significant. This study may have been limited by the short duration of the sensory stimulation sessions.⁸

Additional studies have looked at the role of task-specific training combined with afferent input and their effects on motor and sensory output. In a larger study by Ng and

Hui-Chan the purpose was to investigate whether combining electrically induced sensory inputs through transcutaneous electrical nerve stimulation (TENS) with task-related training (TRT) in a home-based program would augment voluntary motor output in chronic stroke survivors better than either treatment alone or no treatment.²² This study included 88 patients with stroke who were randomly assigned to receive either TENS alone, TENS+TRT, placebo TENS+TRT, or no treatment. They were all seen five days a week for four weeks. The TENS group received 60 minutes of TENS while the TENS+TRT and placebo TENS+TRT got 60 minutes of TENS then 60 minutes of TRT. The control group had no treatment. Ankle plantarflexor spasticity was measured by the Composite Spasticity Scale which has been shown to be reliable and valid in people with stroke.²² Peak torques of maximum isometric voluntary contraction of ankle dorsiflexors and plantarflexors were recorded with a load cell mounted on a custom-built foot frame. Gait velocity was measured with a 4.6 m long instrumented carpet (GAITRite). Results indicated that in chronic stroke, combined TENS+TRT decreased plantarflexor spasticity, improved dorsiflexor and plantarflexor strength, and increased gait velocity significantly more than TENS alone, placebo+TRT, or no treatment.²²

In summary, the majority of research on this topic has been conducted in the upper extremity with individuals with chronic stroke. Current studies also include significant variability in regard to electrode placement, stimulation parameters, and the incorporation of active practice in conjunction with the stimulation. Typically upper extremity stimulation is placed over the median nerve and seems to get the most specific results in regard to hand function whereas the peroneal nerve is most often targeted in

lower extremity studies. The length of time the electrical stimulation was used varied throughout the research. The majority of the studies involving upper extremity stimulation typically utilize 2 hours of stimulation and two of the lower extremity studies utilized 60 minutes of therapy, but positive results have been shown at as low as 20-30 minutes of stimulation. Factors that may impact the length of stimulation range from caregiver support to level of arousal and/or cognition, all which may vary depending on level of acuity. There is a lack of information on how sensory level electrical stimulation may affect sensory and motor recovery in the acute stages of stroke as well as whether electrical stimulation may be more beneficial when used for longer periods of time. There have also been mixed results in regard to sensory and motor output in the lower extremity as some studies have shown no difference in proprioception. The study by Yavuzer used SES on the lower extremity which resulted in voluntary dorsiflexion, when a voluntary contraction was not present prior to the initiation of treatment while other studies have shown no significant difference in LE function or sensation at the end of treatments. Given the limited research on the use of electrical stimulation in the lower extremity post-stroke and on patients in the acute phase, the purpose of this research is to investigate the effect of lower extremity sensory amplitude (sub-motor threshold level) electrical stimulation on motor and sensory recovery and function after first stroke for adult patients undergoing acute rehabilitation. Please refer to Table 1 for a description of the different types of stimulation used in various research studies and the range of timeframes in which it was applied.

Table 1. Summary of Parameters Use By Previous Researchers for Electrical Stimulation Following Stroke.

Study & Type	Electrode Location	Time/Frequency	Parameters	Intensity
<i>Upper Extremity</i>				
<i>Conforto, et al. 2002 Case series</i> ¹⁶	median nerve	2 sessions (separated by at least 24 hours): 2 hours SES or 2 hours of control stimulation	SES: trains of stim delivered at 1Hz consisting of 5 pulses of 1ms delivered at 10Hz	SES: paresthesia; no muscle contraction Control SES: below paresthesia
<i>Conforto, et al. 2007 Case series cross-over design</i> ¹⁸	median nerve	2 sessions (separated by at least 60 days): 2 hours SES or 2 hours of control stimulation	SES: trains of stim delivered at 1Hz consisting of 5 pulses of 1ms delivered at 10Hz	SES: paresthesia; no muscle contraction Control SES: below paresthesia
<i>Conforto, et al. 2010 RCT</i> ²⁰	median nerve	12 sessions (provided 3x per week for 1 month) for 2 hours prior to motor training in addition to conventional rehab; 2 hours SES or 2 hours control stimulation	SES: trains of stim delivered at 1Hz consisting of 5 pulses of 1ms delivered at 10Hz	SES: paresthesia; no muscle contraction Control SES: below paresthesia

<i>Celnik, et al. 2007 Randomized crossover study¹⁷</i>	ulnar and median nerves	Participants all received: 1. 2 hours SES for ulnar and median nerves 2. 2 hours sham stim 3. subset also received 2 hours asynchronous stim (switching between ulnar and median nerves every 15 min)	SES: trains of stim delivered at 1Hz consisting of 5 pulses of 1ms delivered at 10Hz	SES: paresthesia; no muscle contraction Control SES: below paresthesia
<i>Klaiput, et al. 2009 RCT¹⁵</i>	ulnar and median nerves	2 hours SES or 2 hours sham	SES: trains of stim delivered at 1Hz consisting of 5 pulses of 1ms delivered at 10Hz for 500ms with 50% duty cycle Sham SES: same	SES: paresthesia; no muscle contraction Sham SES: level of minimal perception
<i>Koesler, et al. 2008 Randomized crossover design¹⁹</i>	median nerve	Sessions separated by at least 1 week; 2 hours SES or 2 hours idle time	SES: trains of stim delivered at 1Hz consisting of 5 pulses of 1ms delivered at 10Hz	SES: strong paresthesia with no pain or visible muscle contraction
<i>Peurala, et al. 2002 Quasi-experiment al¹³</i>	affected hand or foot using a glove/sock electrode	daily for 20 min over 3 weeks	SES: monophasic constant current twin pulses at 50Hz	SES: below sensory threshold

<i>Sawaki, et al. 2006 Case Series, Random cross-over Design¹⁴</i>	1. ulnar, median and radial nerves 2. tibial, superficial peroneal and sural nerves	3 different randomly ordered sessions separated by at least 24 hours: 1. 2 hours UE stim, 2. 2 hours LE stim or 3. 2 hours idle time	SES: trains of stim delivered at 1Hz consisting of 5 pulses of 1ms delivered at 10Hz	Intensity was adjusted to elicit compound muscle action potentials up to 100 μ V measured by electromyographic electrodes
<i>Wu, et al. 2006 Randomized cross-over design¹²</i>	1. ulnar, median and radial nerves 2. tibial, superficial peroneal and sural nerves	3 different randomly ordered sessions separated by at least 24 hours: 1. 2 hours UE stim, 2. 2 hours LE stim or 3. 2 hours idle time	SES: 5 continuous single pulses at 10Hz over 500ms, 50% duty cycle	2-3 times above perceptual level with no visible muscle twitch
Lower Extremity				
<i>Yan, et al²¹</i>	3 acupuncture points on the lower extremity	60 minutes per session 5 times per week for a total of 3 weeks	TENS: 0.2 ms pulses	100Hz
<i>Yavuzer, et al. 2007⁸</i>	common peroneal nerve	Conventional rehab: 5 days per week, 2-5 hours per day for 4 weeks SES: 30 min 4 times per week Sham: set the same but not turned on	35Hz pulse width of 240 μ s, duty cycle of 10s on/10s off, asymmetric biphasic rectangular wave	240 μ s

<p><i>Ng, et al. 2007²²</i> <i>RCT</i></p>	<p>4 acupuncture points on affected leg: (ST 36) below tibial tuberosity and lateral aspect of tibialis anterior, (LV 3) dorsum of the foot between 1st and 2nd metatarsals, (GB 34) anteroinferior aspect of capitulum of the fibula and (UB 60) the depressed area lateral to the tendon of the calcaneus, posterior to the lateral malleolus</p>	<p>1. TENS group: received 60 min TENS</p> <p>2. TENS+TRT group: 60 min TENS followed by 60 min of task related training (TRT)</p> <p>3. PLBO+TRT group: 60 min of sham TENS followed by 60 min TRT</p> <p>4. Control: no treatment</p>	<p>TENS: 100Hz, 0.2ms square pulses</p>	<p>2-3 times sensory threshold</p>
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CHAPTER II: METHODS

IRB Statement

In compliance with St. Catherine University's and Allina's Institutional Review Boards (IRB), each subject was verbally informed of the testing procedures and any potential risks associated with said procedures before giving written consent to participate in this study.

Study Design

This study was a prospective, double blind, randomized controlled trial.

Subjects

All subjects were patients at Courage Kenny Rehabilitation Institute. Subjects were included in this study if they were being admitted for their first ever stroke, were medically stable as determined by their primary rehabilitation physician, and had motor and/or sensory deficits in the lower extremity that were identified during the initial physical therapy (PT) examination. Subjects were excluded if they had any other known pre-morbid neurological or balance disorders, if their projected length of stay as determined by the admitting physical therapist was less than six days, or if they had a prior stroke. Additionally, participants needed to pass a screen of their cognition by scoring greater than or equal to 26 on the Montreal Cognitive Assessment (MoCA). A score of 26 or higher is considered to be "normal" for cognitive abilities.²³ Forty four subjects were screened for inclusion in this study. As shown in Figure 1 twenty four subjects were excluded based on an insufficient MoCA score, 13 were excluded due to the fact that they had a pre-existing neurological condition, 2 subjects had an insufficient

length of stay, and 2 subjects had not experienced a stroke. Three subjects, 2 females and 1 male, met the inclusion criteria and were admitted to the study. Each subject included in the study had experienced a sub-cortical stroke and was on average 5.7 ± 1.2 days post-stroke. The average age of the participants was 62.7 ± 6.03 years.

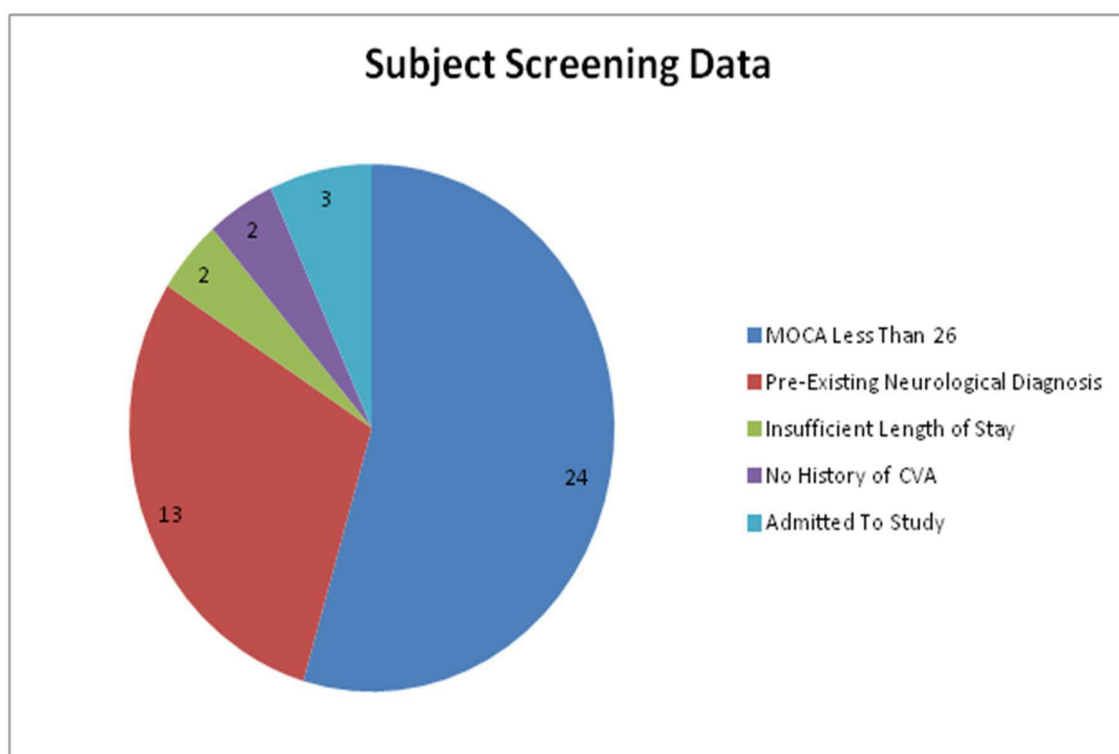


Figure 1. Subject screening data for all who were included and excluded from this study.

Testing procedures

Subjects were assigned sequential numbers as they entered the study and were placed randomly into the experimental group or control group based on groupings supplied by a random number generator. Beginning on the third day of each subject's inpatient rehabilitation stay they received either sensory amplitude electrical stimulation or sham sensory amplitude electrical stimulation depending on group assignment in addition to their usual physical therapy treatment. Stimulation or sham stimulation was

applied by a researcher who was aware of group assignments, but was not involved in any aspect of outcome measurement. The experimental group received sensory amplitude electrical stimulation to the peroneal nerve at a pulse width of 300 micro seconds and a frequency of 10 hertz for 60 minutes prior to each day's physical therapy session. Intensity was increased until a visible muscle twitch was elicited, then decreased to a level where the muscle twitch was no longer present, but strong paresthesias were reported by the subject without pain. The parameters used for sensory amplitude electrical stimulation in this study were chosen based on the parameters used in studies that had shown neuroplastic change and improved motor function associated with SES in the upper extremities in subjects with stroke.^{12,14,15,16,17,18,19,20} The control group received sham stimulation. The electrodes were placed over the peroneal nerve and intensity was increased until a visible muscle twitch was elicited, but then intensity was turned down to 0 and the electrodes were left in place for 60 minutes prior to the subject's physical therapy session. In summary, the electrical stimulation or sham stimulation was applied starting on the third day, one time per day for 60 minutes prior to their typical physical therapy intervention, Monday through Saturday, for the subject's entire length of stay. The average number of intervention sessions for participants was 12.3.

Outcome Measures

Data was collected on the following outcome measures upon admittance to and completion of the study by testers and treating therapists who were all blinded to the group assignments of the subjects: Fugl-Meyer lower extremity sensory assessment, Lower Extremity Motricity Index, Berg Balance Scale, gait speed, and the Functional

Independence Measure. Each of these outcome measures incorporate either sensory function or motor performance of the lower extremities, and were used to measure change over time in both the control and experimental groups. Lower extremity sensation and proprioception were measured using the Fugl-Meyer lower extremity sensory assessment, which is a subscale of the Fugl-Meyer Assessment of Motor Recovery after Stroke. Light touch sensation and proprioception are categorized as absent, impaired, or normal and are scored on a 3-point ordinal scale (0-2).²⁴ In an effort to maintain consistency across researchers, a script was used for the administration of this assessment so each subject received the same instructions for each test. Also, researchers blinded to group assignment were the only ones to administer the Fugl-Meyer, treating therapists did not participate in the administration of this outcome measure. This assessment was chosen for its excellent inter-rater and test-retest reliability, along with its excellent responsiveness.²⁵

Lower extremity muscle strength was assessed using the Lower Extremity Motricity Index. The Lower Extremity Motricity Index has previously been found to be a reliable outcome measure for assessing strength in patients with stroke, with a Cronbach's alpha of 0.77 for inter-rater reliability.²⁶ This outcome measure tests the strength of hip flexors, knee extensors, and ankle dorsiflexors. The grading scale for Motricity Index ranges from zero to 33. The total score is determined by taking the sum of the three muscle tests and adding one. There is a total possible score of 100. All Pearson's statistical correlations exceeded 0.77 when the Motricity Index was compared to dynamometry and were found to be significant with a p-value less than 0.001.

Cameron et al. found this outcome measure to have high criterion validity when compared to objective measures such as hand-held dynamometry.²⁷

The Berg Balance Scale (BBS) was used to measure the ability to balance in each of the subjects. It was administered by the treating therapist upon admission and discharge. The BBS consists of 14 different balancing tasks and is scored on a 5-point ordinal scale (0-4), making the maximum possible score 56, with a higher score indicating better balance and a decreased fall risk.²⁸ The Berg Balance Scale was initially developed to assess fall risk in the elderly population.²⁹ It has been tested and found to be valid and reliable in patients who have had a stroke.²⁹ For stroke patients, there was found to be inter-rater reliability with ICC of 0.98 and ICC of 0.99 for test-retest reliability.²⁹ Stevenson found that the minimal detectable change (MDC) for patients with acute stroke was 6.9 points within a 95% confidence interval. This is an estimate of the change in score that clinicians need to see in order to conclude that true change was observed in a particular patient.²⁸

The Functional Independence Measure (FIM) is used to measure a person's level of independence with various functional tasks and abilities.³⁰ This measure contains 18 total items made up of 13 motor tasks and 5 cognitive tasks. Each task is rated on a 7 point ordinal scale ranging from complete dependence to complete independence and scores range from the lowest score of 18 to the highest possible score of 126. A higher score indicates a higher level of function. Several studies have found the FIM to be an accurate predictor of functional outcomes for patients who have had strokes.^{30,31,32} A cross sectional, retrospective study conducted by Stineman et al. found that the FIM had

good to excellent internal consistency of items as measured by a Cronbach's Alpha of 0.86-0.97, which was consistent across a variety of patient diagnoses.³¹ Minimal Clinically Important Difference (MCID) was found to be 22 points for the total FIM score, 17 points for the motor section, and 3 points on the cognitive section in order to detect a meaningful change.³²

The final outcome measure used in this research was gait speed. It is known that gait speed is a valid measure of measuring walking ability.³³ It has been found that gait speed is moderately to strongly correlated with paretic lower extremity muscle function and has also been noted to be strongly correlated to energy expenditure and energy cost of walking.^{34,35,36,37} The Minimal Detectable Change (MDC) of 0.30m/s is necessary for a single patient to show genuine change. Fulk and Echternach also found that test-retest reliability for gait speed was good with an ICC of 0.862.³³

CHAPTER III: RESULTS

All outcome measures were assessed for each subject on an individual basis in order to determine meaningful change over the length of stay. For all of the following data, subjects 1 and 3 were allocated to the control group, and subject 2 was the sole representative of the experimental group.

Fugl-Meyer

Each participant had fully intact lower extremity sensation and proprioception upon entrance to the study as measured by the Fugl-Meyer sensory assessment. No changes occurred throughout their lengths of stay.

Lower Extremity Motricity Index

As shown in Figure 2, subject one improved by 11 points over the course of rehabilitation, beginning with a score of 58 and ending with a score of 69. Subject two improved by 22 points, beginning with a score of 39 and ending with a score of 61. Subject three exhibited no improvement over time, starting and ending at a score of 42.

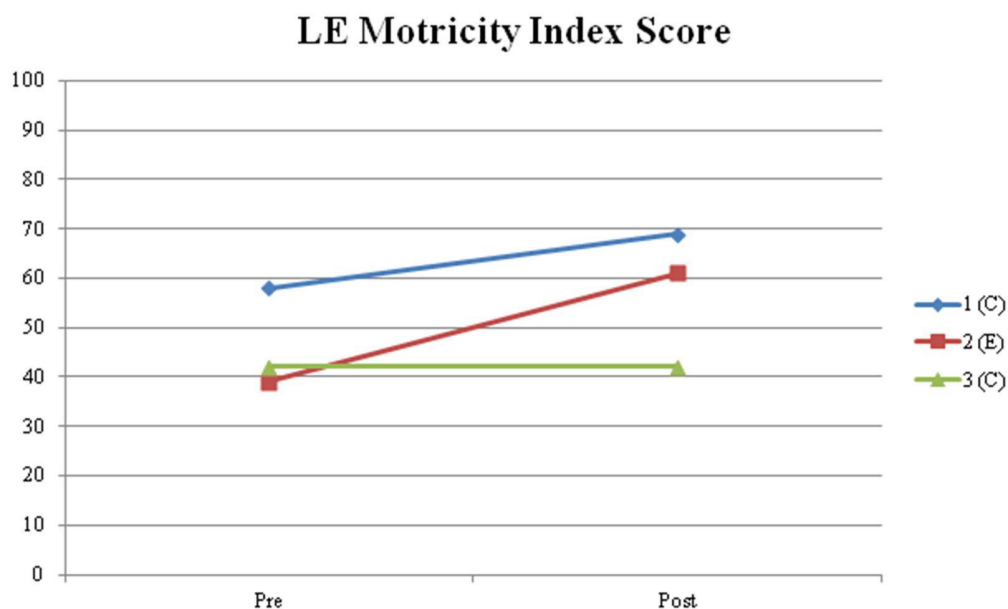


Figure 2. Change in Lower Extremity Motricity Index scores for each subject from pre-intervention to post intervention.

Berg Balance Scale

Figure 3 illustrates the changes in Berg Balance scores over the course of each subject's rehabilitation. Subject one improved from 17 to 40 over the course of rehabilitation, a total change score of 23. Subject 2 improved from 20 to 45, a change score of 25. Last, subject 3 improved from 4 to 34, for a total change score of 30. All of these scores indicate meaningful change over time when compared to the minimum detectable change score of 7 in acute stroke patients.

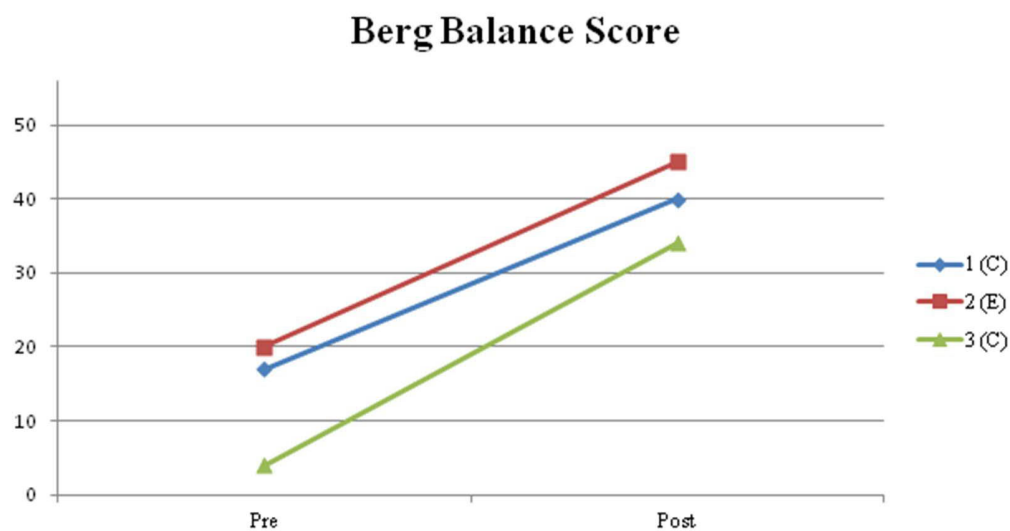


Figure 3. Change in Berg Balance scores for each subject from pre-intervention to post-intervention.

Functional Independence Measure

Figure 4 shows the changes in FIM scores over time for each subject. Subject one improved from 66 to 90, a change of 24 points. Subject 2 improved from 76 to 94, a change of 18 points. Subject 3 improved from 66 to 95, a change of 29 points. Subjects 1 and 3 showed meaningful improvement when compared to the MCID score of 22.

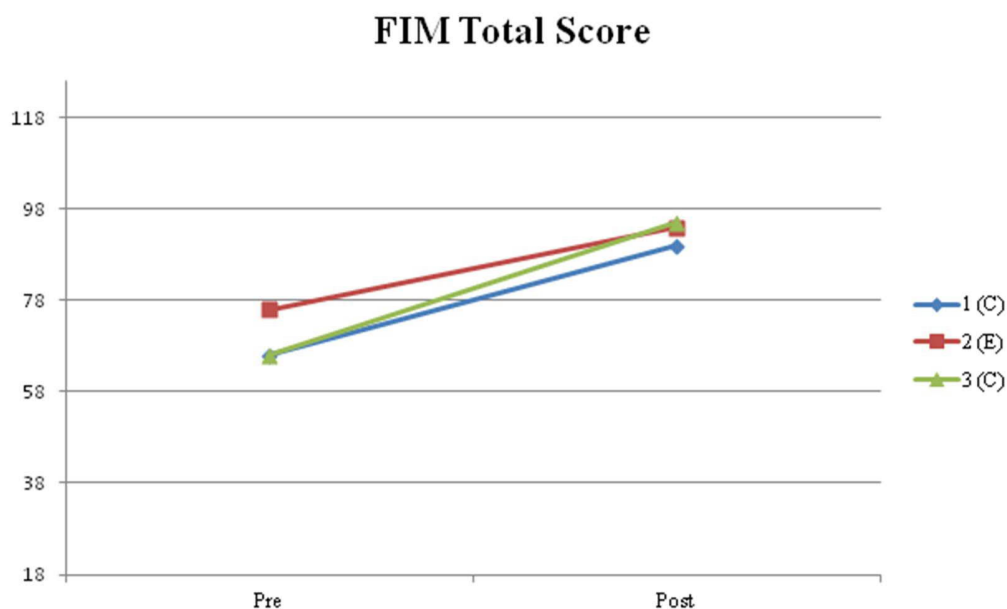


Figure 4. Change in Functional Independence Measure scores for each subject from pre-intervention to post intervention.

Gait speed

All subjects included in this study were non-ambulatory upon admission to the study, so this outcome measure was unable to be used to show change over time.

Statistical Analysis

No formal statistical analysis was performed due to the insufficient sample size.

CHAPTER IV: DISCUSSION

The experimental subject showed the greatest gains in strength as measured by the Lower Extremity Motricity Index. This is the most interesting finding as the one person who was in the experimental group demonstrated the largest increase in the scale measuring motor output. This increase in gross motor function is consistent with increased lower extremity motor output following SES as previously reported by Yavuzer et al. and Yan et al.^{8,21} As in the pilot data described here, Yan et al reported that TENS plus standard rehabilitation was superior when compared to standard rehabilitation alone or standard rehabilitation plus sham stimulation for acute stroke subjects. In addition, as in this study, this previous literature also reported increases in ankle dorsiflexor strength for those subjects receiving the stimulation. Although it cannot yet be determined if the increase in strength observed in this study is statistically significant when compared to the control group, these results may potentially extend the results from the previous studies. Additionally, it has been suggested that subjects, such as the one in the experimental group, who start at a lower level of motor function make the greatest motoric gains following sensory amplitude electrical stimulation.¹⁶

The potential impact of SES on sensory recovery could not be examined as each subject had fully intact sensation at baseline as measured by the Fugl-Meyer Sensory Assessment. The subjects had all experienced subcortical strokes; thus, one would not expect to observe significant sensory deficits. As such, it remains unknown if the response to SES for the subjects in the present study was affected by the lack of sensory deficits. Although the measurement of sensation for these subjects was irrelevant, it is

still a vital measure. This holds true based on the study conducted by Peurala et al in which 59 subjects received electrical stimulation below their sensory threshold for 20 minutes daily, for a period of 3 weeks. Upper extremity sensation, as rated by a visual analog scale, was found to have increased significantly but the increase in lower extremity sensation was not statistically significant. Also, in previous literature, it has been discussed that 50-60% of all people who have survived stroke will have sensory impairments.^{4,5} Therefore, researchers should continue to include sensation outcome measures in future studies for the assessment of individuals who present with sensory deficits.

Gait speed has been used in previous research studies as a measure of functional performance and is a part of the typical battery of tests utilized at Courage Kenny Rehabilitation Institute. Upon initial evaluation, all subjects were non-ambulatory, therefore no change in gait speed could be shown over time in this sample. This represents the difficulty in performing a study with patients in a more acute stage of stroke. Although the measure of gait speed has been shown to be valid for patients with stroke, if they are not yet ambulatory, as these subjects, it cannot be used to show improvement because there would be no baseline score to improve from. Finding a different outcome measure to use is important when considering a population in an acute stage. An outcome measure focused on functional mobility following stroke such as the Postural Assessment Scale for Stroke Patients (PASS) is a possible alternative to gait speed for measuring functional performance since it can be used with patients who are non-ambulatory.

As in some previous research, all subjects in the present study received standard physical therapy rehabilitation in addition to receiving either actual electrical stimulation or sham electrical stimulation. Effects of electrical stimulation (TENS) alone on recovery have been examined by Ng and Hui-Chan and the results showed that the group that received TENS alone demonstrated less functional recovery than the group that received electrical stimulation and rehabilitation, in this case task-related training. Therefore, standard physical therapy rehabilitation appears to be a crucial part of functional recovery, especially in the acute phase of stroke.

Previous studies also included outcome measures such as gait speed and the Berg Balance Scale. The current research study included these outcome measures based on this previously conducted research, as these measures have been found to be valid and reliable in people who have experienced strokes. Although we did not find any differences between groups, previous studies have also failed to find significant differences between groups with similar outcome measures like the Timed Up and Go.²¹ In the current literature review, previous studies did not include the Berg Balance Scale, but the Berg is still an appropriate measure for this study because it has normative data for stroke patients and examines static and dynamic balance.

In previous studies conducted on the use of SES for functional recovery following stroke the electrical stimulation was typically applied for 30 to 60 minutes, therefore this study also used 60 minutes per day prior to physical therapy as our treatment time.^{8,21,22} Yan et al. applied SES to patients for 60 minutes, 5 times per week for 3 weeks.²¹ Yavuzer et al. applied the SES for 30 minute sessions, 4 times per week for 4 weeks.⁸

Both of these studies yielded increased motor recovery as compared to the standard rehabilitation alone or standard rehabilitation with sham SES groups. Other authors suggest that treatment sessions longer than 60 minutes are needed in order for neuroplastic changes to occur from the sensory input.^{15,16,17,18,19,20} These authors studied the recovery of the upper extremity. It is unclear if it is more beneficial to apply the SES for longer periods of time, for a fewer number of days or to apply shorter bouts of SES over a longer period of time. Both scenarios have shown increased motor output and increased functional recovery when paired with standard physical therapy rehabilitation. It may also not be feasible in the clinical setting to apply electrical stimulation for longer than 60 minutes prior to physical therapy sessions.

Another difference between our study and existing research is the number of days subjects received the SES and physical therapy. Previous literature has provided subjects with at least two weeks of treatment, and some studies up to four weeks. The average number of days of treatment subjects in this study received was 12.4 days, which is shorter than previously published literature. This could suggest that greater gains in ankle dorsiflexor strength and functional recovery could be seen if the subjects' received more consecutive days of SES or sham SES and standard physical therapy rehabilitation, especially in the acute phase following stroke. By starting SES in the acute stage of recovery the patient's may be able to experience the positive effects of SES for a longer period of time.

A notable difference between the present study and previous literature is that the subjects in this study did not receive TENS as the type of electrical stimulation. Subjects

received only sensory amplitude stimulation. There is less existing literature applying SES to the lower extremity as compared to the research involving TENS. In our literature review we found that two studies utilized TENS and only one used SES. This could suggest that TENS is the preferred type of electrical stimulation when attempting to facilitate recovery in patients who have experienced a stroke. Additionally, TENS units may be easier to transport, apply, and use as compared to larger units used for SES.

Existing literature surrounding recovery of the paretic upper extremity appears to generally be more positive than that which investigates recovery of the involved lower extremity. This could be due to the location of stroke in the brain and the way it aligns with the homunculus. For example, the area of the brain supplied by the middle cerebral artery (MCA) aligns with the upper extremity, face, and speech related areas, which would be more involved with greater deficits if the MCA distribution were to be affected by a stroke. This may also impact the way the sensory input coming into the brain is perceived and interpreted, as well as the ability to respond to the sensory input based on the affected areas.

The gap in previous literature that was being investigated in the current study was the acute phase of rehabilitation following stroke and recovery of the involved lower extremity. Previous research has focused on recovery of the involved upper extremity in chronic stroke survivors. In the past, there have been mixed results when applying sensory level electrical stimulation to increase motor output in the lower extremity.

Limitations

The main limitation of this study is due to the small sample size. With a small sample size, there is a subsequent lack of statistical power, and therefore, the results are not able to be generalized to a greater population. All subjects showed meaningful improvement in at least one outcome measure, however these motor gains could also be attributed to the fact that each subject received standard inpatient rehabilitation physical therapy intervention. It is also important to consider the fact that because these subjects were in the very acute phase of stroke recovery, some of their improvement could be related to neurologic recovery. The inclusion and exclusion criteria were also limiting factors for this study. Over 50% of subjects screened were excluded from the study based on the results from their MoCA. Also, most existing research up to this point has focused on the effects of sensory amplitude electrical stimulation on motor and sensory recovery in the sub-acute and chronic stages of stroke. Because this study was focused on the acute stage of rehabilitation, there were more exclusions based on medical complexity and cognitive impairment.

Recommendations for Future Research

After performing a literature review and gathering data on the few patients included in this study, we recommend that there be further research conducted in the area of sensory level electrical stimulation on patients who are in the acute stage following stroke. We also recommend that there needs to be a larger sample size in order to generalize these findings to the greater population of stroke survivors. By modifying our inclusion and exclusion criteria future researchers may be able to gain a larger sample

size and recruit more patients with both sensory and motor deficits. An alternative cognitive screening tool may also be a viable option in order to gain a larger sample population while still ensuring participants are cognitively aware of and able to provide informed consent.

CHAPTER V: CONCLUSION

In conclusion, there is a lack of existing research on the effects of sensory amplitude electrical stimulation and functional recovery of the involved lower extremity in the acute phase of rehabilitation following stroke. All subjects in the experimental and control groups improved ankle dorsiflexor strength, Berg Balance score, and Functional Independence Measure (FIM) total score. These findings indicate that the use of SES may influence recovery of patients who have experienced stroke in the acute stage, and this area warrants further research to determine the full extent to which this modality affects recovery post stroke.

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