

# High vs. Low Electrical Stimulation Frequencies for Motor Recovery in Hemiplegia

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## High vs. Low Electrical Stimulation Frequencies for Motor Recovery in Hemiplegia

Stroke is the primary cause of serious, long-term disability in the United States (American Heart Association, 2004) and paralysis of the upper extremity can be the most debilitating of post-stroke sequelae, persisting for several weeks to months following onset.

Although exercise programs constitute an essential component of post-stroke rehabilitation, stroke survivors may not regain enough voluntary motor control in the upper extremity with traditional rehabilitation methods to fully and effectively grasp and manipulate objects. To address this shortcoming, newer and more technologically advanced rehabilitation methods have been investigated. In particular, the use of neuromuscular functional electrical stimulation (FES) has been shown to have positive effects in facilitating active movement and augmenting motor function following neurological impairment. FES is the application of a continuous current of electricity administered through a surface electrode at the nerve or motor point of a muscle to elicit a muscular contraction.

The application of FES as a therapeutic modality has the potential to increase voluntary movement, force production, strength, and functional skill abilities in the upper extremity; however, the specific stimulation protocol used can affect rehabilitation outcomes. Despite several clinical trials investigating FES, little work has been directed toward finding the optimal patterns of stimulation that could be effective in maximizing motor activity while simultaneously minimizing fatigue in the hemiplegic hand following stroke. If post-stroke individuals, assisted by electrical stimulation, could actively

perform effective hand movements and additionally experience reduced fatigue in those muscles, exercise regimens could be more effective and functional gains in task performance and manual skill could be realized.

During FES, stimulus frequency has the greatest influence on quality of muscle contraction and the development of fatigue. Normal physiological frequencies seen in muscles during voluntary contractions range between 10 and 30Hz. Higher rates of artificial stimulation (i.e., FES) are necessary to produce similar contractions but also tend to induce fatigue (Baker, Wederich, McNeal, Newsam, & Waters., 2000). A 20Hz stimulation program is within the physiological range and could produce low forces over longer periods of time; a 40Hz stimulation would maximize force production but maintain these forces for shorter periods.

*The purpose of this research is to compare the use of a low-frequency (20Hz) electrical stimulation retraining program with a high-frequency (40Hz) electrical stimulation treatment program to improve motor control in the affected hand of stroke survivors. The hypotheses are as follows:*

**Hypothesis #1:** Post-stroke individuals trained with a high (40Hz) electrical stimulation frequency program will

- a) exhibit a higher percentage change in grip strength in the hemiplegic hand following training when compared to post-stroke individuals trained with a low (20Hz) electrical stimulation frequency program,
- b) exhibit a higher percentage change in pinch strength in the hemiplegic hand following training when compared to post-stroke individuals trained with a low (20Hz) electrical stimulation frequency program,
- c) sustain an isometric force in the thenar muscles of the hemiplegic hand a longer percentage of time following training when compared to post-stroke individuals trained with a low (20Hz) electrical stimulation frequency program.

**Hypothesis #2:** Post-stroke individuals trained with a high (40Hz) electrical stimulation frequency program will show a higher percentage change in pretest-posttest scores when compared to post-stroke individuals trained with a low (20Hz) electrical stimulation frequency program on

- a) The Fugl-Meyer Battery and
- b) The Barthel Index.

#### Significance of Study

This study seeks to determine whether high or low electrical stimulation frequencies are more effective in maximizing motor return in hand function following stroke. This information will be extremely beneficial for the general public, for the participants directly involved in the study, and for other researchers investigating optimal methods of intervention for stroke survivors.

A therapeutic method or modality that will produce maximal rehabilitative benefits in a minimal amount of time is the consummate goal of most clinicians. Third party payers and insurers frequently limit the number of treatment sessions and their payment of therapy services such that treatment plans are now dictated by the reimbursement available rather than the needs of the patient. Electrical stimulation has been shown to be an effective modality to improve motor function following stroke. If gains in strength and function can be achieved quickly and effectively with electrical stimulation, patients would spend less time in an inpatient setting and reduce overall health care costs. In addition, if optimal function is restored, the need for caregivers or institutionalization is reduced, saving tax payer dollars and benefiting society as a whole.

The potential benefits to be gained by persons participating in this study are 1) to receive professional therapy services free of charge in treatment of upper extremity dysfunction as a result of stroke, 2) to reap the functional benefits of

a structured electrical stimulation program that has the potential to improve hand function, and 3) to increase overall activity at a physical, cognitive, psychological, and social level. Assisting stroke survivors in regaining motor function affords these persons increased independence in daily activities and again, reduces the need for family assistance or caregivers.

The information to be gained through this study has profound merit for academicians as well as basic and applied science researchers. This knowledge will be extremely useful in identifying effective treatment strategies, developing novel therapeutic devices, designing innovative rehabilitation instrumentation, electronics, or orthoses that assist paralyzed individuals in achieving active muscle contraction after neurological injury.

While current research supports the effectiveness of using electrical stimulation to enhance function following stroke, further scientific investigation should focus on the specific patterns of electrical stimulation that maximize motor return in the hand. Knowledge of these optimal strategies can lead to direct implementation in the rehabilitation setting and have a profound impact on changing clinical practice.

#### Limitations & Delimitations

This study has limitations. First, large numbers of participants may not be possible due to the numerous physical impairments present in the population being studied. Logistics of transportation and participation over several weeks may be difficult for these individuals. Second, while all efforts will be made to enroll a control group, the generalizability of the results may be limited if a control group is not used. This will affect internal validity and the ability to attribute changes (improved motor function) to the specific intervention

(electrical stimulation) may be restricted. Third, post-stroke individuals vary greatly in their motor presentation and functional abilities; groups will be matched as closely as possible, but this remains a limitation present whenever this population is studied. Finally, assignment to groups will be non-random due to matching of functional levels between the stroke survivors.

Some delimitations of the study exist due to 1) subjects only being obtained from the Austin, Texas, area, so generalizations cannot be made to other populations, 2) only those individuals whose native language is English will be eligible for participation, and 3) the level of education of individual participants will be uncontrollable, therefore may vary greatly.

Despite these limitations and delimitations, there remain salient reasons why the study should still be performed. First, research studies of this design have been successfully conducted on this population even though large individual differences in motor presentation exist. Differentiating factors will be clearly outlined and accounted for. These investigations continue to contribute new and usable information to the overall body of knowledge that ultimately impacts clinical practice. Second, information that provides insight into effective strategies for motor recovery in the hand following stroke is limited. This area of study can provide a scientific basis for promising interventions that may yield positive outcomes and fill the currently existing gaps in knowledge.

#### Definition of Terms

Operational definitions that will be used for the purposes of this study are as follows:

1. Electrical Stimulation – “The use of electrical current on the peripheral nervous system to contract a muscle either through direct activation of the

motorneurons in the peripheral nerve or indirectly through reflex recruitment” (Baker et al, 2000)

2. Fatigue (muscle fatigue) – “The condition of muscle tissue in which its response to stimulation is decreased or lost as a result of overactivity.” (Thomas, 1997).

3. Frequency – “Number of pulses per second (pps) used to describe pulsed electrical currents. The rate of oscillation or alternation in cycles per second of an alternating current, expressed in hertz (Hz)” (Baker et al, 2000).

4. Functional Electrical Stimulation – “The use of electrical stimulation of the peripheral nervous system to activate muscle contractions to assist in functional activities, such as walking or upper extremity prehension.” (Baker et al, 2000)

5. Hemiplegia – “Paralysis of one side of the body.” (Thomas, 1997).

### Related Literature

For several years, clinicians and researchers have used electrical stimulation to facilitate motor return following paralysis. The mechanisms behind this modality are straightforward: Through electrodes placed on the skin surface or percutaneously, electricity is conducted that stimulates the peripheral nervous system, causing a muscle or muscles to contract (Baker, Wederich, McNeal, Newsam, & Waters, 2000). Electrical stimulation is sometimes referred to as functional electrical stimulation, or FES. The challenge is that FES can be delivered in a number of ways, using variable or constant frequencies, short or long pulse durations, with ramping or without ramping, or using high or low intensities. The resultant movement will ultimately depend on the specific

parameters selected. Very often, the goal of electrical stimulation is to produce force from muscles that are not able to be activated as a result of illness, injury, or disease. However, because electrical stimulation produces muscular force through an artificial medium, the resulting motion is not as efficient or as effective as voluntarily induced movement. Often the onset of fatigue is rapid and greatly reduces the time spent in active muscle contraction or regimented exercise. Researchers continue to search for the patterns or frequencies of electrical stimulation that will produce the perfect balance of maximizing force while delaying the onset of fatigue. The ultimate goal of these efforts would be to produce movement through electrical stimulation that is as close to or more effective than physiological in the force produced and the fatigue response generated.

FES has been shown to be a viable modality in the treatment of motor deficits and paralysis following cerebral vascular accident (CVA) or stroke. Popovic, Popovic, Sinkjaer, Stefanovic, & Schwirtlich (2002) found that electrical stimulation combined with a voluntary exercise program was more effective in improving hand function in stroke survivors when compared to a group not receiving electrical stimulation. Electrical stimulation treatment has effectively reduced shoulder subluxation, a common condition following stroke where the humeral head is displaced anteriorly and caudally. FES intervention can result in reduced shoulder pain for the patient and increased muscle tone that reduces displacement of the humeral head at the glenohumeral joint (Handy, Salinas, Blanchard, & Aitken, 2003; Barreca, Wolf, Fasoli, & Bohannon, 2003). Similar results were obtained in the shoulder of recent poststroke patients by Wang, Chan, & Tsai (2000), however, the intervention

was found to be ineffective for those subjects whose insult had occurred over a year prior. Early research indicated that paralyzed lower extremity muscles were also receptive to electrical stimulation intervention when improvements in strength, range of motion, and active muscle contraction were seen following FES intervention (Liberson, Holmquest, Scott, & Dow, 1961). FES has also improved the gait kinematics in this clinical population as well (Binder-Macleod & Lee, 1997; Daly & Ruff, 2000). Electrical stimulation can be especially beneficial when conditions such as dense hemiplegia are present and traditional active-motor approaches may be difficult to implement (Gritsenko & Prochaska, 2004).

Suggestions have been made that the benefits of FES may go beyond the peripheral muscular level and that cortical activity may be stimulated during this type of intervention as well. Kimberley et al (2003) demonstrated increased cortical activation as measured by functional MRI during FES used to improve active finger extension in poststroke subjects. Additionally, event-related synchronization was seen in electroencephalogram (EEG) measures during wrist movements induced by FES in healthy subjects, suggesting that the cortical processes that regulate active voluntary movement are similar to the cortical activity seen during FES. Functional improvement and carry-over following FES intervention have been demonstrated, and cortical involvement has been suggested. Rushton (2002) proposed that synaptic modifications can be generated at the corticospinal-anterior horn level through FES combined with voluntary effort that could possibly result in permanent changes in muscle activation and function.

Studies that investigate the use of FES to restore hand function following stroke are few. Some investigators suggest that the inherent complexity of hand movements limit the amount of investigation in this area (Binder-Macleod & Lee, 1997). In some of the available research, subjects receiving electrical stimulation treatment showed notable improvements in fine motor abilities and grip strength following treatment when compared to controls receiving exercise only or no treatment at all (Kraft, Fitts, & Hammond, 1992). Similar results were seen in wrist and finger movement following implementation of an FES program (Chae et al, 1998). Carraugh, Light, Kim, Thigpen, and Behrman (2000) used electrical stimulation triggered by electromyographical (EMG) activity to improve hand function in poststroke subjects. When wrist and finger extension was initiated by subjects and reached a target EMG level, electrical stimulation was delivered that assisted the individual in completing the movement. The results indicated that participants in the treatment group achieved significantly higher gains on hand function tests and force generation measures following treatment when compared to a control group. EMG-triggered FES was also used by Chae, Fang, Walker, & Purmehdi (2001) in an active repetitive movement training program for the finger extensors of stroke survivors in which notable improvements in function were obtained. Improvements in self-care tasks have also been observed following treatment with EMG-triggered FES as well (Francisco et al, 1998). While the positive benefits of FES intervention following stroke are readily apparent, no investigation to date has examined the specific parameters of electrical stimulation that may contribute to optimal motor output (maximized force with minimized fatigue) in the hemiplegic hand.

When considering application of FES a few fundamental factors are present that will ultimately impact force output. First, the physiological changes that occur in paralyzed muscle will influence outcomes achieved with FES. Paralyzed muscle produces lower maximal forces and has a greater propensity for fatigue (Griffin, Thomas, & Godfrey, 2002; Farmer, Swash, Ingram, & Stephens, 1993). Second, the familiar motor unit “size principle” (Henneman, 1957) that refers to the orderly recruitment of motor units beginning with the smaller, slower types and progressing to the larger, faster units is reversed with electrical stimulation. Motor units are also recruited synchronously in the FES process rather than asynchronously as is the case in normal voluntary contractions. Because of these limitations, the movement induced by FES is not as efficient as self-initiated movement and higher frequencies of FES are needed to generate comparable contractions of the same magnitude (Baker, Wederich, McNeal, Newsam, & Waters, 2000). Third, individual tolerance to the electrical stimulation (pain and comfort level) will limit the intensity of FES that can be delivered.

Several studies have investigated how different electrical stimulation frequencies affect force output and muscle fatigue. Because paralyzed muscle is weakened and generates lower forces, higher frequencies may be needed to produce functional contractions. For example, Thomas, Bigland-Ritchie, & Johansson (1991) found that higher frequencies of stimulation are required to produce similar levels of force after a normal muscle has become fatigued, thus creating a rightward shift in the motor unit force frequency curve. This effect was found to be present in thumb musculature as well (Fuglevand, Macefield, & Bigland-Ritchie, 1999). In a study by Kraft, Fitts, & Hammond (1992) low-

intensity electrical stimulation treatment yielded gains in fine motor function, however, the higher-intensity EMG-triggered FES yielded the greatest motor gains. Similarly, increased muscle fatigue was seen in normal and paralyzed subjects following a regimen of intermittent low-frequency (20 Hz) FES when compared to a high-frequency (100 Hz) regimen. Force output at a higher constant frequency (30Hz) was greater in the adductor pollicis muscle when compared to the force output using a decreasing frequency pattern (progressive decrease from 30 Hz to 15 Hz) that incorporated lower frequencies (Fuglevand & Keen, 2003). Considering that motor unit firing rates have been shown to increase as fatigue progresses (Griffin, Garland, & Ivanova, 1998) higher frequencies may be needed to maintain force output during sustained contractions.

Lower frequencies of electrical stimulation may not elicit optimal responses in muscle tissue. The phenomenon of “low-frequency fatigue” was first described by Edwards, Hill, Jones, & Merton (1977). They observed that after intense muscle contractions, force loss persisted longer (hours to days) at low frequencies (20 Hz) as compared to high frequency (80 Hz) force loss, which usually recovered after several minutes. The existence of this phenomenon has been confirmed by several other researchers, however, the explanation for low frequency fatigue remains unclear. Westerblad & Allen (2002) suggest that the event may be due to changes in the proteins that regulate intracellular calcium. Several studies that have tested the effects of electrical stimulation and force output in the muscles of older adults suggest that low-frequency fatigue is present in this population as well, and that greater fatigue responses are seen in these individuals at lower frequencies (Allman & Rice, 2001). While low

frequencies may not be sufficient to elicit needed force from paralyzed muscle, these frequencies may inhibit force output and enhance the fatigue response through unknown mechanisms.

Another phenomenon that has been demonstrated during motor unit firing and which may play a role in force output and muscle fatigue is the presence of doublets. Doublets are the result of two action potentials that are generated with an interspike interval of less than 20 ms and produce greater forces than two single separate action potentials. Doublets were observed in voluntary fatiguing contractions of the triceps muscle (Griffin, Garland, & Ivanova, 1998) and may be a strategy to enhance force output during fatigue. When doublets were placed at the onset of an electrical stimulation train delivered to the thenar muscles, force output was enhanced in both paralyzed and normal subjects (Griffin, Thomas, & Godfrey, 2002). Although force output appears to be facilitated by doublets, reduction in the fatigue response when doublets are present has yielded inconsistent results. Binder-Macleod & Scott (2001) indicate that doublets reduced the fatigue response in normal quadriceps muscle, but no reduction was found when doublets were used in thenar muscle stimulation (Thomas, Griffin, Godfrey, Ribot-Cisar, & Butler, 2003).

Additional empirical research is needed to determine which parameters of electrical stimulation are most effective in maximizing force output and minimizing the fatigue response. In particular, determining whether high or low electrical stimulation frequencies are more effective in maximizing motor return in the hand following stroke remains a valid research question and should be investigated further. In consideration of the current research, it is hypothesized that higher stimulation frequencies may serve to maximize force output and

delay the onset of fatigue when used as a treatment regimen for paralyzed hand muscle following stroke. An investigation that can potentially elucidate this information will be extremely beneficial for the general public and for other researchers investigating optimal methods of electrical stimulation intervention for stroke survivors.

### Methods

*Subjects* - Persons who have sustained a stroke at least four months prior will be eligible to participate. Individuals whose stroke occurred more than eight years ago will not be included. Participants must be in good physical health without complicating medical conditions, as determined by their physician through the medical clearance form. A minimal amount of hand function will be required; criteria includes the ability to actively extend fingers approximately 15° and actively extend wrist 20°. Persons meeting these criteria must possess no contraindication for the application of electrical stimulation to their hands and forearms, including phlebitis, thrombophlebitis, varicose veins, cancerous lesions, epilepsy, implanted electronics, implanted surgical hardware, pacemakers, or transcerebral or carotid sinus electrode placement.

*Recruitment of Participants* Participants will be recruited for the study through three methods, 1) newspaper advertisement, 2) distribution of study information to staff and case managers at St. David's Rehabilitation in Austin, TX, and 3) direct contact of previously discharged stroke patients from Brackenridge Hospital in Austin, TX. Newspaper advertisements will be placed in the senior calendar section of the Austin Statesman, and hospital recruitment has been approved by key personnel in the respective organizations. Initial telephone interview will be conducted when the principal

investigator is first contacted by an interested party. Advertisement content and telephone script follow:

Newspaper Advertisement: Head: Stroke Survivors Wanted. Text: The University of Texas Department of Kinesiology is conducting a study investigating new rehabilitative methods to potentially improve hand function after stroke. If you or someone you know is a stroke survivor and you are interested in more details, please call Barbara Doucet, MHS, at 512-471-9228 or Lisa Griffin, PhD, at 512-471-2786.

Telephone Screening Interview Script: “Thank you for your interest in our study. My name is Barbara Doucet and I am a graduate student in the Department of Kinesiology here at The University of Texas working on my doctoral degree. My supervising professor is Dr. Lisa Griffin. We are looking for individuals who have suffered a stroke and are having difficulty in using their hand. I would like to ask you a few questions to see if you would be eligible to participate.” Questions that would be posed follow:

“How long ago did your stroke occur?”

“Did you participate in any rehabilitation therapies and for how long?”

“Have you been discharged from therapies?”

“Do you still see a physician for your stroke symptoms?”

“How would you describe the function of your hand right now?”

“Are you able to walk independently?”

“How would you describe your overall endurance? Do you tire easily?”

“Would you be able to participate in a therapy program four times per week for four weeks?”

“Do you have any other medical condition that might make participation in this study difficult for you? Do you have a pacemaker?”

“Thank you. Judging from your answers, I would like to meet you in person to further confirm that you are an appropriate candidate for our study. I would like you to come to the laboratory for an orientation/assessment session. Can we set up an appointment?” or

“Thank you for your time. Based on your answers, I’m sorry to say we would need subjects who fit a different profile, so you may not be eligible. However, I would like to keep your name on file and after our full review of candidates, you may be able to participate in this study or

other studies we'll be conducting in the future. Would that be acceptable to you?"

*Experimental Design* - The design of the current study is quasi-experimental if no control group is used. As mentioned previously, inclusion of a control group will depend on availability of subjects and time constraints. The study will not randomize assignment to groups. The two treatment groups will be matched for homogeneity. The independent variable being manipulated is the frequency of electrical stimulation that will be used. The first group will receive a low frequency stimulation program (20 Hz); the second group will receive a high frequency stimulation program (40 Hz). There are five dependent variables being measured. These include pretest-posttest measurements of grip strength, pinch strength, endurance of the thenar musculature, score on the Barthel Index, and score on the Fugl-Meyer Motor Assessment. This research can best be described as "applied" in that it is oriented toward solving a practical problem and testing a theory that may impact clinical practice. Outcome data will be reported numerically, so as such, the investigation will be quantitative.

*Pretesting/Instrumentation* - Participants will come to the Department of Kinesiology Neuromuscular Physiology laboratory for the initial screening and orientation session following the telephone interview. A detailed explanation of the project will be given to the participant and his/her family member, and any questions or concerns regarding the study will be addressed at this time. The participant will then review and sign The University of Texas Institutional Review Board consent form. Next, the participant will respond to a brief, twelve-item hand use questionnaire developed for use in this study. The principal investigator will administer the questionnaire and obtain information including personal demographics, medical history, current medications, activity level,

general hand use, surgical history concerning the upper extremities, occurrence of pain, and history of participation in rehabilitation programs.

*Test Administration* - The principal investigator will then administer two additional assessments, the Barthel Index, and the Fugl-Meyer Motor Assessment Scale. The Barthel Index is designed to assess functional skill performance in individuals with neuromuscular impairment. Questions can be answered by the individual or any other person familiar with the self-care performance of the participant. Inter-rater and test-retest reliability were found to be approximately 0.89 for the original instrument. Internal consistency improved for the revised edition (the edition that will be used in this study) to 0.90 at rehabilitation admission and 0.93 at rehabilitation discharge. Validity studies showed that scores on this battery agree with other measures of physical disability and compare to scores on other activities of daily living assessments (Asher, 1996). The Fugl-Meyer Motor Assessment Scale will be administered next. This instrument is a measure of motor function in the affected upper extremity and is designed to test sensorimotor function of post-stroke individuals. The Fugl-Meyer battery has been used extensively in clinical and research settings. Numerous researchers have concluded that the test is both reliable and valid, and compares favorably to other activities of daily living surveys (Dittmar & Gresham, 1997, p. 154). Scores on these two tests will be used as pretest scores and to assign participants of comparable functional level to treatment groups. See Table 1.

Prior to returning to the laboratory for further testing and direct intervention, each participant will obtain medical clearance from their personal physician

(Medical Clearance Form, Appendix B). Individuals that do not obtain medical clearance will not be allowed to participate in the study.

Upon returning to the laboratory for the second session, the individuals' grip strength, pinch strength, and motor endurance will be tested in the affected hand. Functional grip and pinch strength will be assessed using grip and pinch dynamometers (Jamar, Inc.) that are available commercially for these procedures. Three trials each will be taken for grip, lateral pinch, palmar pinch, and fingertip pinch. The average values obtained for each task will be used as pre-test values.

Specific endurance testing of the thenar muscles of the affected hand will be performed using a custom designed apparatus manufactured by the mechanical engineering department at The University of Texas. The device consists of a table-top apparatus that stabilizes the forearm in supination and thumb abduction using a thermoplastic splint. Participants will sit in a straight-back chair and the thumb will be positioned against a horizontal aluminum bar equipped with force transducers that measure thumb forces in both horizontal and vertical directions. Surface electrodes will be attached to the thenar group of muscles on the volar surface of the hand and will be used to collect surface electromyographic (EMG) activity. A computer monitor will be placed in front of the participants for visual feedback of EMG and force activity. Participants will be asked to perform three maximal voluntary contractions (MVCs); the average of these three trials will be used as the individually calculated pre-training MVC. To measure endurance limit, participants will be asked to hold a voluntary contraction of 45% MVC of thumb flexion/abduction for as long as possible. A target line will be provided so participants can receive continual

feedback in order to maintain the 45% contraction level. Endurance time at 45% MVC is approximately 5 minutes in able-bodied adults. The entire pretesting procedure will last approximately one hour.

*Rehabilitation Training Program* Two groups of ten participants each will receive in-home training 4 times a week for 4 weeks. The first group will receive electrical stimulation treatment with a low-level constant pattern of 20Hz elicited via a portable electrical stimulation unit (300PV Empi, Inc.). This frequency level should elicit a tetanized contraction and remain comfortable for the subject. The stimulation will be delivered initially at an intensity of 0.5 mA, which is indiscernible for most individuals. The intensity will be increased in 0.5 mA increments as tolerated by the participant until the highest comfortable intensity is achieved. Intensities will not exceed each individual's comfort level. The stimulation will be delivered in a pattern that will ramp up for 1 second, hold at 20Hz for 10 seconds, ramp down for 1 second, then rest for 10 seconds. This stimulation pattern will be administered to the hand flexor muscle group for approximately 20 minutes. Electrodes will then be repositioned and applied to the extensor muscle group. The same pattern of stimulation will then be administered to the extensor muscle group for approximately 20 minutes. The entire treatment will last approximately 40 minutes. This protocol is similar to those used in typical clinical applications.

The second group will receive a high-level constant frequency electrical stimulation pattern of 40 Hz. This frequency level should also elicit a tetanized contraction and remain comfortable for the participant. The stimulation will be delivered initially at an intensity of 0.5 mA, which is indistinguishable. The intensity will be increased in 0.5 mA increments as tolerated by the individual

until the highest comfortable intensity level is achieved. Intensities will not exceed comfort level. The stimulation will be delivered in a pattern that will ramp up for 1 second, hold at 40Hz for 5 seconds, ramp down for 1 second, then rest for 10 seconds. This stimulation pattern will be administered to the flexor muscle group for 10 minutes. Electrodes will then be repositioned and applied to the extensor muscle group. The same pattern of stimulation will then be administered to the extensor muscle group for 10 minutes. The entire treatment will last approximately 20 minutes. Again, this protocol is similar to those used in clinical applications, and is typically well tolerated by post-stroke individuals. The program will be administered to all subjects in both groups 4 times per week for 4 weeks.

*Posttesting* - Participants will be asked to return to the laboratory for a final session after the four weeks of electrical stimulation treatment. The same battery of tests and functional measures will be administered at that time. Compliance to Institutional Review Board Requirements. Figure 1 shows a complete flow chart of the study process.

*Analysis* - Descriptive statistics will be used to report measures of central tendency and variability for test scores of both groups. Mean and standard deviation scores will be used to describe performance on the Fugl-Meyer and Barthel Index by both groups, as well as performance on grip, pinch and thenar endurance tests. Outlier score limits will be determined a priori. Statistical tests will be conducted with and without outliers to determine differences.

Data that will address Hypothesis #1 will consist of grip strength, pinch strength, and endurance time. These values will be converted to percentages to

normalize the values and account for individual differences. The data are equal-interval/ratio data, which will incorporate the use of a parametric testing procedure. A one way repeated measures ANOVA will be used to analyze within and between group differences on the dependent measures of grip strength, pinch strength, and thenar endurance time. The one-way factor is the electrical stimulation frequency, which will have two levels: 20Hz and 40 Hz. An alpha level of 0.05 will be used with  $n_1 = 10$ , and  $n_2 = 10$ , and Bonferroni post hoc analysis will be performed to control for error across multiple dependent tests. An F statistic will be obtained and compared to critical values of F using an established F-ratio table. Power level will be set at 80% or  $\alpha = .20$ .

Data that will address Hypothesis #2 will be the pretest-posttest scores on the Fugl-Meyer and Barthel batteries. Because these tests use a rank-order scoring system, a nonparametric test will be used to compare differences, or change scores. Scores from the pretest administration and the posttest administration will be compared for each individual, and a change score will be obtained. This again will normalize the groups and equalize initial individual differences in test scores. The Mann-Whitney U-test will be used to compare pretest and posttest scores. This test is one of the more powerful nonparametric tests (Portney & Watkins, 2000) and will test the null hypothesis (that no difference in test scores exist between the 20Hz group and the 40Hz group). An alpha level of 0.05 will be used with  $n_1 = 10$ , and  $n_2 = 10$ . The U statistic will be obtained and compared to critical values of U. If the value of U is equal to or less than the table value, the difference will be statistically significant. All statistical recording and analysis will be conducted with the use of a computerized statistical package, SigmaStat.

All data will be recorded on computer and analyzed offline using Spike 2 for Windows (version 5) software package (Cambridge Electronic Design). The signals from the force transducer will be digitized at a sampling rate of 500 Hz. Flexion and adduction resultant forces will be calculated on-line for visual feedback to the subject. Surface EMG will be low-pass filtered at 1000 Hz and sampled at 2000 Hz. Surface EMG recordings will be digitized at a rate of 2,000 Hz.

#### *Human Subject Interactions*

Brackenridge Hospital Brain and Spine Center of Austin, Texas, (Dr. Thomas Caven, Director) will serve as one source for potential study subjects. A letter of support is appended. The Neuromuscular Physiology Laboratory will be collaborating with these professionals on various research-based projects. Permission will be obtained from organizational management or administrative representatives as required. A waiver of authorization form will be completed and approved by The University of Texas Institutional Review Board (IRB) in order to obtain names of former stroke patients previously treated at Brackenridge. Individual physician practices will also be contacted to obtain additional subjects if needed. The professional staff in these offices will be given flyers with study information and contact phone numbers of the principal investigator. Potential participants will voluntarily contact the principal investigator for more information if desired or interested in participating. Contact will also be made with organizers and leaders of stroke support groups within the city. Requests will be made to allow the principal investigator to attend the group, describe the study, and recruit individuals at that time. The staff at St. David's Hospital in Austin, Texas, will be briefed on the purpose and

design of the study as well. Flyers will be left with the staff and case managers to distribute to stroke subjects who are being discharged, as described earlier. For all interested parties, the purpose of the experiment will be fully explained and participation will be requested. For those consenting individuals, an initial screening interview will be conducted (see previously described script) over the telephone by the principal investigator. If the subject meets the study criteria based on the phone interview, he/she will be asked to attend the orientation/initial assessment session. Persons involved in the study will have to have been discharged from acute medical services and any inpatient and outpatient rehabilitation therapies. Individuals involved in this study will optimally be four months post stroke onset or longer.

Participants will be asked to discuss the appropriateness of this program with their personal physician and obtain a signed Medical Clearance Form (attached). Individual physicians will ensure that participants are of sound mind, able to sustain the rigors of the study, capable of giving consent to be involved, and able to understand the project requirements and perform project activities as directed. The form verifies that electrical stimulation procedures are a component of the study and that no medical conditions exist in the participant that would be contraindicated for receiving electrical stimulation.

Human subject involvement will occur throughout the course of the study with both stroke groups; the investigation will span approximately 9-12 months. Individuals from correctional facilities will not be included in this study. All participants will be adults over the age of 21, and no children will be involved due to this population being rarely affected by stroke. Subjects whose native language is not English will not be enrolled in the study. Assistance will

be provided to those who may be unable to read, or to those whose vision may be impaired due to stroke. For these circumstances, the consent form will be read by an outside party of the subjects' choice if needed.

Written consent will be obtained directly from the participants during the initial screening and orientation meeting. An informed consent document adhering to the requirements of The University of Texas IRB will be used. No minors will participate.

#### *Potential Risks*

Overall, very little risk is associated with this investigation. Dr. Lisa Griffin (supervising professor) has used the techniques of surface electrical stimulation extensively over the last decade with able-bodied and paralyzed individuals and has also previously received recent IRB approval from the University of Texas for the use of administering electrical stimulation to both younger and older adults (IRB #2003-09-0023). The principal investigator, Barbara Doucet, is a licensed occupational therapist with over 19 years experience in working with the stroke population and has been trained in the use of electrical stimulation for clinical intervention. In addition, she has worked for more than 15 years providing therapy to patients within their home through home health agencies. She is certified in CPR and basic life support.

Electrical muscular stimulation may be slightly uncomfortable for some subjects, but is generally tolerated well by most individuals. Occasionally, a tingling or slight stinging sensation will be reported. The FDA has reported instances of shock and topical burn at electrode sites with some electrical stimulation devices; however, this has never been reported with the Empi 300PV. Extreme care will be taken to obtain continual feedback from subjects

when determining appropriate stimulation intensity levels. Muscles will only be stimulated at intensities suitable for and within the comfort level of the subjects.

If motor improvement occurs following administration of FES during the study, there exists a risk of loss or decrease of these benefits upon discontinuation of FES. Previous research suggests that beneficial results may only be partially maintained following discontinuation of electrical stimulation (Rochester, Chandler, Johnson, Sutton, and Miller, 1995; Gurney, Robergs, Aisenbrey, Cordova, and McClanahan, 1998). Subjects will be encouraged to adopt an active hand exercise program to increase the potential of maintaining the positive motor benefits gained. Home exercise programs for the hand can be provided by the PI. In addition, subjects can discuss the use of a continued FES program with their treating physician.

Confidentiality of test results will be strictly maintained. Individual results of specific test batteries will be stored in a secure place, locked within the Neuromuscular Physiology Laboratory, and will only be used for the purposes of this study. Only graduate students and faculty members associated with this investigation will have access to individual scores. Data will be stored on computer hard drives that are password-protected and accessible only to the investigators. All data will be backed up on CDs that will be secured and locked within the laboratory. Reporting and publishing of the data will be done in a manner such that no individual is identifiable.

#### *Potential Benefits*

The potential benefits to be gained by persons participating in this study are  
1) to receive professional therapy services free of charge in treatment of upper

extremity dysfunction as a result of stroke, 2) to reap the functional benefits of a structured electrical stimulation program and a home exercise program that has the potential to improve hand function, 3) to increase overall activity at a physical, cognitive, psychological, and social level, 4) to interact with other individuals who have common limitations and challenges as a result of stroke, and 5) to contribute to the body of knowledge aimed at developing the most effective, efficient, and successful strategies to improve motor function following stroke. In this study, the potential benefit obtained in increasing movement and/or function in the upper extremity following the debilitating effects of stroke outweighs the risk associated with the experiment. Assisting stroke survivors in regaining motor function affords these persons increased independence in daily activities, reduces the need for caregivers, and thus decreases the burden to society of increasing numbers of institutionalized individuals.

The procedures associated with this study (assessment, measurement, and evaluation) will be conducted at the University of Austin Department of Kinesiology Neurophysiology Lab (BEL 546D). The rehabilitation programs will be administered at the participants' homes.

## Budget

### Direct Costs

Salary & Wages: The principal investigation will require assistance from a sophomore level student assistant to perform and complete the study

*Principal Investigator (1/2 FTE, Research assistant).....*\$11,484.00

*Undergraduate Research Assistant (1/2 FTE).....* 8,256.00

### Fringe Benefits

*Principal Investigator (1/2 FTE, Research assistant).....* 4,739.00

*Undergraduate Research Assistant (1/2 FTE).....* 3,407.00

Subtotal **27,886.00**

Consultant Costs: No consultants will be used

Capital Equipment: Capital equipment needed is as follows:

*Computer hardware and software.....* 2,000.00

*EMG Amplifier, Analog-Digital Converter.....* 5,000.00

*EMPI 300PV Portable Electrical Stimulators (2).....* 1,400.00

*Force Transducer, Amplifier.....* 2,500.00

*Dynamometer/ Pinch gauge kit .....* 299.00

*Barthel Index .....* 100.00

*Fugl-Meyer Battery.....* 150.00

Subtotal **11,449.00**

Expendable Equipment & Supplies: The following supplies will be required with the use of EMG and force data collection:

*Connectors, Cables .....* 500.00

*Disposable Electrodes .....* 750.00

*Prep Supplies: Alcohol pads, cotton, soap .....* 100.00

*Plain paper for copying, testing .....* 300.00

*Office supplies (pens, paper clips, etc.)* ..... 150.00

Subtotal **1,800.00**

Publication Costs: Fees associated with publication in journals or printing for poster/paper submissions to conferences.

*Publication and associated fees* ..... **350.00**

Travel: Costs associated with travel to conferences to present information from study. Includes conference fees, air/auto/hotel/meal expenses.

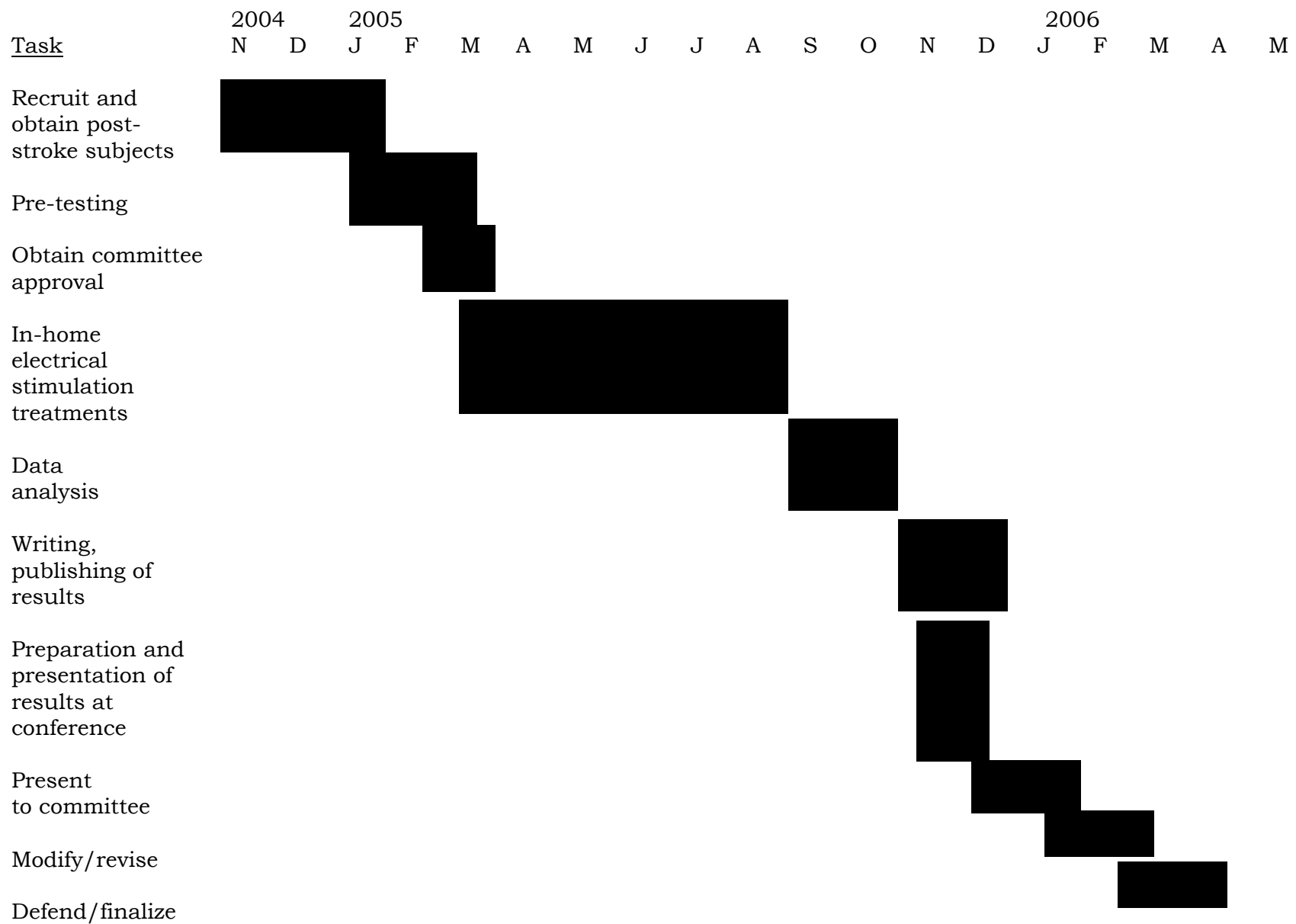
*Travel* ..... **2,000.00**

Computer Time: Additional computer time that may be necessary to print posters and produce documents not available with laboratory owned software.

*Computer Time* ..... **500.00**

Subcontracts/Agreements: No subcontracts or agreements will be tendered.

**GRAND TOTAL            \$43,985.00**



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Table 1  
Subject Demographics and Initial Clinical Characteristics

Subject	Gender	Age	Weeks Post CVA	Dominant Upper Extremity	Affected Upper Extremity	Fugl-Meyera <sup>a</sup>	Barthel <sup>b</sup>	Functional Use <sup>c</sup>
1	M	49	12	R	L	44	80	Assisted
2	F	61	15	R	L	30	50	Dependent
3	F	49	21	R	R	28	42	Dependent
4	M	63	13	R	L	50	84	Assisted
5	F	63	17	L	L	20	45	Dependent
6	F	50	25	R	L	50	85	Assisted
7	F	55	32	R	L	20	42	Dependent
8	M	67	22	R	R	18	30	Dependent
9	M	72	18	R	L	60	70	Assisted
10	F	59	16	R	L	54	82	Assisted

<sup>a</sup>Scores upper extremity volitional movements such as touching ear with affected hand, touching opposite knee with affected hand, grasping items, etc.: 0 = cannot be performed, 1= can be partially performed, 2 = can be performed fully and adequately; maximum score = 66 points

<sup>b</sup>Scores ability to perform daily functional tasks including bathing, feeding, dressing, etc.: (weighted items) 0 = unable to perform task, 1, 2, or 3 = attempts task but unsafe; 3, 5, or 8 = moderate help required; 4, 8, or 12 = minimal help required; 5, 10, or 15 = fully independent; maximum score = 100 points.

<sup>c</sup>Rating used to describe general level of assistance needed for affected hand function: Dependent = not able to use affected hand for function; Assisted = able to use affected hand for function with assistance; Independent = able to use affected hand independently.

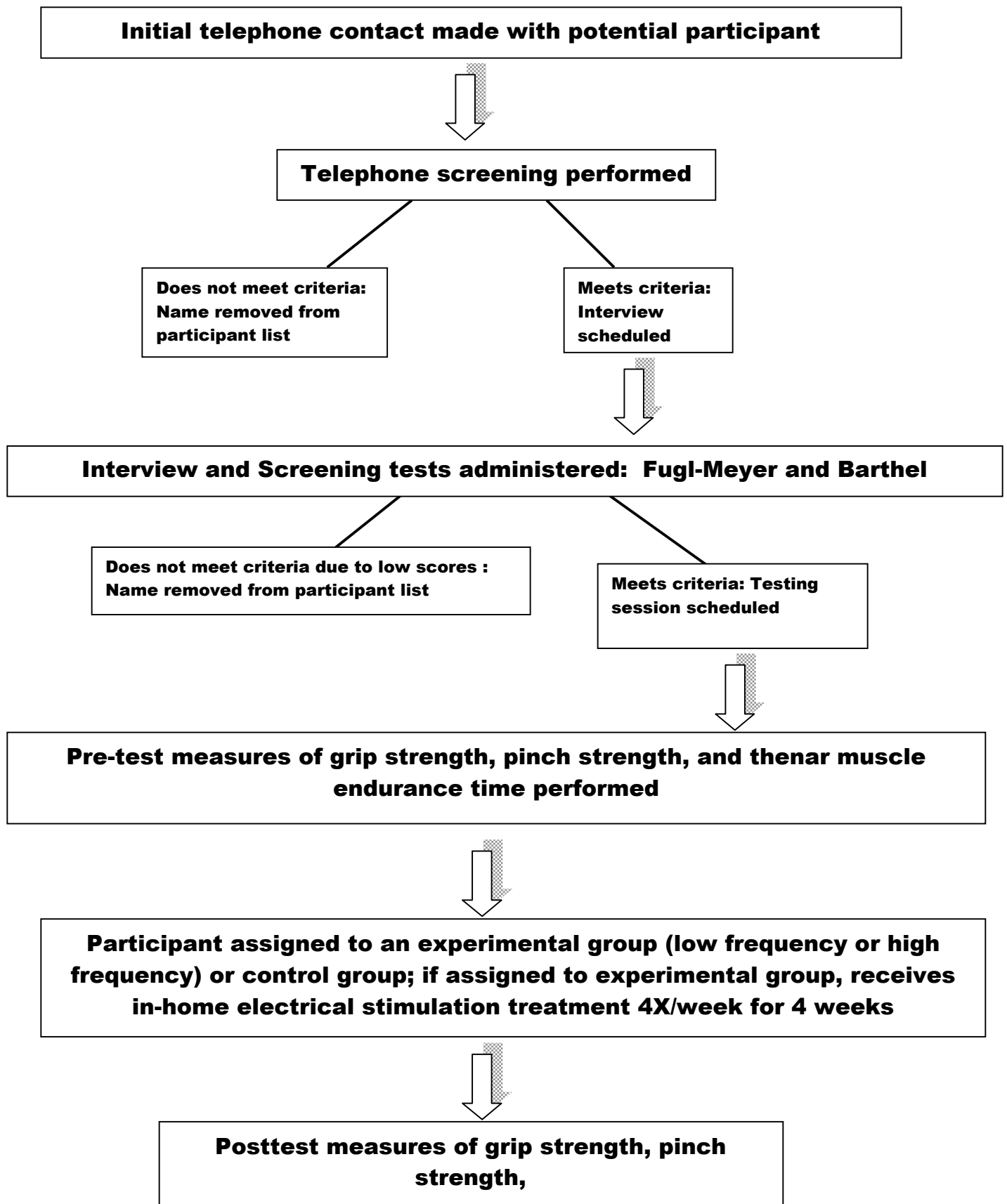


Figure 1: Flow chart of study process.

## Appendices

Appendix A: Pilot Study

Appendix B: Medical Clearance Form

Appendix C: Human Subject Consent Form

Appendix D: Human Subject IRB  
Application

Appendix E: IRB Compliance

Appendix F: Preliminary Outlines

Appendix G: Style Sheet

## Appendix A: Pilot Study

### Pilot Study

Pilot work was performed for this project over the course of approximately one year.

The custom designed force transducer device used in the study was built by the Mechanical Engineering Department at The University of Texas. Shortly after installation in our laboratory, the device was calibrated to ensure accuracy of measures. This was completed by attaching various weight gram measures to the transducer and recording the observed force. The equipment was deemed accurate in the measurement of force and data collection with human subjects began shortly afterward.

Specialized positioning equipment was designed for the study. A thermoplastic splint was constructed that immobilized the forearm in a supinated position. The splint was mounted onto a    inch thick laminated board and straps were attached and mounted adjacent to the splint. Holes were drilled in the mounting board and also in a large heavy table so that the board could be adjusted and positioned differently for a variety of experiments being performed in the laboratory. Long screws secured the splint board to the table. Subjects would sit in the straight-back chair with their forearm supported on the table and their forearm positioned and secured in the splint. The force transducer was constructed with a mobile arm such that the force interfaces could be aligned with the thumb and hand following positioning in the splint.

Preliminary data was collected by stimulating the thenar muscles of human subjects with differing frequencies. In addition, the fatigue response to the stimulation was also studied. The first investigation examined the fatigue response when thenar muscles were stimulated with an increasing frequency

pattern (20 Hz progressively increasing to 40 Hz) over the course of three minutes. The fatigue response induced by this pattern was compared to a constant frequency pattern administered at 20 Hz for the same duration. No significant differences were found in the fatigue responses of the two varying stimulation frequencies, suggesting that an increasing pattern did not delay the onset of fatigue.

Following data collection, numerous changes were made to the positioning procedures to ensure maximum accuracy of data obtained. A few subjects compensated with shoulder muscles when asked to specifically isolate movement to the thumb. For this reason, shoulder strapping was added so that the subject's shoulder could be secured and the hand/forearm would remain stable and movement would be restricted to the thumb muscles only. Thumb positioning against the force transducer required consistency between measures, so a procedure was incorporated to measure individual thumb length and record where anatomical landmarks aligned on the force transducer surface. This improved the consistency between measures taken on the same subjects on different days.

A second experiment was undertaken using the same equipment where electrical stimulation was delivered in a decreasing frequency pattern (40 Hz progressively decreasing to 20 Hz) over the course of three minutes, and comparing this to a constant 20 Hz pattern of the same duration. Once again, no significant differences were found in the fatigue response of the two patterns, again suggesting that a decreasing frequency stimulation did not delay the onset of fatigue either.

Following the completion of this study, positioning changes were again made since consistency of measures across days (maximum voluntary contractions, amplitude of M wave) was poor. Currently, a platform that allows for varying heights of the chair that the subject will be seated in is currently under construction. Subjects appear to require trunk stabilization during voluntary contractions, so additional strapping was ordered and a new positioning set up is being developed.

Performing the preliminary studies described above assisted us in determining optimal procedures and allowed laboratory personnel to familiarize themselves with the equipment and to gain experience in this type of data collection.

## Appendix B: Medical Clearance Form

## MEDICAL CLEARANCE FORM

Your patient, \_\_\_\_\_ is interested in participating in a research study being conducted by the Neuromuscular Physiology Laboratory at the University of Texas at Austin. The study is entitled “Functional Motor Recovery in the Hemiplegic Hand” and will investigate whether high or low frequencies of functional electrical stimulation (FES), applied to the affected forearm and hand of hemiplegic patients, will improve motor recovery. This project is being conducted by Barbara Doucet, MHS, OT, Clay Covington, B.S. and Lisa Griffin, PhD, in the Dept. of Kinesiology and Health Education. In order for the above named individual to become a subject in this project, we are seeking your medical clearance.

The study involves the provision of FES to the forearm and hand of post-stroke patients. This will be administered by the principal investigator in subjects’ homes. Individuals with swollen, infected, or inflamed areas (e.g. Phlebitis, thrombophlebitis, varicose veins and cancerous lesions) or pain syndromes affecting the hands and forearms will not be included in the study. Persons who have implanted electronics (e.g., pacemakers, defibrillators, transcerebral or carotid sinus electrode placement) or surgical hardware in the hands and forearms and those with epilepsy or who are pregnant are also not eligible to participate. Caution should be taken for individuals with heart problems or those who have a tendency to hemorrhage following trauma or fracture. Subjects must be of sound mind, capable of giving consent to be involved in the study, and in addition, must understand the project requirements and agree to perform project activities as directed.

Subjects enrolled in the study will come to the University of Texas Department of Kinesiology Neuromuscular Physiology Laboratory (BEL 546D) on two occasions. First, the subject will participate in an orientation/initial assessment session. During this time they will complete a short hand use questionnaire. Strength measures and fine motor accuracy tests will be taken from the hand, and we will evaluate the subject using three different tests that quantify movement limitations: The Barthel Index (Mahoney & Barthel, 1965), The Fugl-Meyer Motor Assessment (Fugl-Meyer et al., 1975), and the Test of the Hemiplegic Upper Extremity (Rancho Los Amigos Education and Research Center, 1975). This should take approximately 2 hours.

Subjects will then begin receiving specialized electrical stimulation treatments in their home four (4) times per week for four (4) weeks. We will be testing the difference between low-level frequency treatment (20 Hz), and higher-level frequency treatment (40Hz). Subjects will be assigned to either a low-level frequency group or a high-level frequency group.

The electrical stimulation treatment will consist of small electrodes being placed on the surface of the skin of the forearm and electricity being delivered to the muscles that control the hand. The specific device used in this study will be the 300PV portable electrical stimulation unit manufactured by Empi Corporation (<http://www.empi.com>). FES has been shown to help contract the paralyzed muscle and facilitate movement. Subjects in the low-level frequency group will have their muscles stimulated for 10 seconds at a time at a

frequency of 20 Hz followed by a rest period of 10 seconds after each stimulation. This will be applied to the flexor and extensor muscles of the forearm and the entire process should take about 20 minutes, 10 minutes for each of the two muscle groups. Subjects will undergo this treatment 4 times per week for four weeks at their home, scheduled at their convenience. Subjects in the higher-level frequency group will have their muscles stimulated for 5 seconds at a time at a frequency of 40 Hz followed by a rest period of 10 seconds after each stimulation. These subjects will receive FES for a total of 10 minutes, 5 minutes for each of the two muscle groups. The stimulation is not painful, although subjects may feel a “buzzing” or “tingling” sensation. Subjects will be able to tell the investigator which intensity of stimulation is most comfortable, and the investigator will set the level according to the subjects’ tolerance. The stimulation can be discontinued immediately at the subjects’ request. Visits to the home should last no longer than 30 minutes. Following the month of treatment, subjects will be asked to return to the Neuromuscular Physiology Laboratory for the final session where we will perform the same measures and tests as we did in the initial assessment session.

Functional electrical stimulation of the hand produces tingling-type sensations when administered. This may be uncomfortable for some individuals. The FDA has reported instances of shock and topical burn at electrode sites with some FES devices, however, this has never been reported with the Empi 300PV, and these situations are rare. If motor improvement occurs following administration of FES during the study, there exists a risk of loss or decrease of these benefits upon discontinuation of FES (following completion of the study). Subjects will be encouraged to adopt an active hand exercise program to increase the potential of maintaining the positive motor benefits gained.

## MEDICAL CLEARANCE

I \_\_\_\_\_, MD, have reviewed this medical clearance form and I give medical clearance for \_\_\_\_\_, a patient under my care, to participate as a subject in the “Functional Motor Recovery in the Hemiplegic Hand” research study being conducted by Barbara Doucet, MHS, OTR, and Lisa Griffin, PhD, of the University of Texas at Austin.

I am further aware that this individual will receive functional electrical stimulation (FES) as a rehabilitative modality during the course of the study and attest that the patient named above currently has no known medical condition(s) that would contraindicate application of FES to the affected forearm and hand.

\_\_\_\_\_  
Treating Physician

\_\_\_\_\_  
Date

## Appendix C: Human Subject Consent Form

***Informed Consent to Participate in Research***

**The University of Texas at Austin**

You are being asked to participate in a research study. This form provides you with information about the study. The Principal Investigator (the person in charge of this research) or his/her representative will also describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part. Your participation is entirely voluntary and you can refuse to participate without penalty or loss of benefits to which you are otherwise entitled.

**Title of Research Study:** Functional Motor Recovery in the Hemiplegic Hand

**Principal Investigator(s) (include faculty sponsor), UT affiliation, and Telephone Number(s):**

Barbara M. Doucet, graduate student, 512-471-9228; Lisa Griffin, PhD., Assistant Professor, 512-471-2786.

**Funding source:** University of Texas

**What is the purpose of this study?** Twenty (20) subjects who have suffered a stroke will be used to study return of movement in the affected arm and hand. The purpose of this project is to study which therapeutic methods work best when trying to recover motor function in the hand following stroke. This particular study will look at two methods of electrical stimulation treatment used to facilitate movement in the hand after stroke. The goal is to determine which method works best and to use this information to design specific activities for rehabilitation therapies that may help to restore overall movement and functional hand use.

**What will be done if you take part in this research study?** If you participate in this study, you will come to the University of Texas Department of Kinesiology Neuromuscular Physiology Laboratory (BEL 546D) on two occasions. First, you will attend an orientation session/initial assessment session. We will determine if you are eligible to participate at this first session. If you are eligible, you will complete a short hand use questionnaire, we will take strength and accuracy measures from your hand, and we will evaluate you using three different tests that quantify your current movement limitations. This should take approximately 2 hours. You will then begin receiving specialized electrical stimulation treatments in your home four (4) times per week for four (4) weeks. This will be administered by the principal investigator of this study, a licensed, certified, occupational therapist who has been trained in the use of this treatment. Visits to the home will be made at the subjects' convenience and should last no longer than 30 minutes. Following the

month of treatment, you will be asked to return to the Neuromuscular Physiology Laboratory for the final session where we will perform the same measures and tests as we did in the initial assessment session.

*Hand Use Questionnaire* – This is a short, two-page questionnaire that asks questions such as your name, gender, birthday, handedness, medical history, current medications, current physical activity level, any past hand injuries you may have sustained and if you experience any pain or problems with your hand.

*Strength Measures* - We measure the strength of the muscles in your hand and record the maximum forces you are able to produce. This will be done using electromyographical equipment that consists of surface electrodes placed on the skin.

*Accuracy Measures* - In addition, you will be asked to perform a hand function accuracy task that consists of following a target line on the computer screen by moving your thumb using varying levels of force. You will also be asked to hold a constant level force with your thumb as long as you can.

*Hand Function Tests* - The three evaluations that we will use to quantify your hand use are the Barthel Index, the Fugl-Meyer Assessment, and the Test of the Hemiplegic Upper Extremity. These tests will involve your answering a series of questions and the investigator taking measurements of your hand function.

*Home-based Electrical Stimulation Treatments* - We will be studying two methods of electrical stimulation that are very similar to what is currently used by many physical and occupational therapists. We will be testing the difference between low-level frequency treatment (20 Hz), and higher-level frequency treatment (40Hz). You will be assigned to either a low-level frequency group or a high-level frequency group. This electrical stimulation treatment will consist of small electrodes being placed on the surface of the skin of your forearm and electricity being delivered to your muscles that control your hand. The electrical current can help contract the muscle and produce movement. If you are a subject in the low-level frequency group, your muscle will be stimulated for 10 seconds at a time at a frequency of 20 Hz. You will have a rest period of 10 seconds after each stimulation. This will be done to your flexor and extensor muscles and the entire process should take about 20 minutes. You will undergo this treatment 4 times per week for four weeks at your home, scheduled at your convenience. If you are a subject in the higher-level frequency group, your muscle will be stimulated for 5 seconds at a time at a frequency of 40 Hz. You will have a rest period of 10 seconds after each stimulation. The stimulation does not hurt, although you may feel a “buzzing” or “tingling” sensation. You will be able to tell the investigator which intensity of stimulation is most comfortable for you, and she will set the level according to your request. The electrical stimulation program will be administered by the principal investigator, a trained rehabilitation therapist with over 19 years of clinical experience.

**What are the possible discomforts and risks?** Functional electrical stimulation of the hand produces tingling-type sensations when administered. This may be uncomfortable for

some individuals. The FDA has reported instances of shock and topical burn at electrode sites with some FES devices, however, this has never been reported with the Empi 300PV. Persons with swollen, infected, or inflamed areas (e.g. Phlebitis, thromophlebitis, varicose veins and cancerous lesions) or pain in the hands and forearms will not participate in this study. Persons who have implanted electronics (e.g. pacemakers, defibrillators, transcerebral or carotid sinus electrode placement) or surgical hardware in the hands and forearms, epilepsy and pregnant females are also not eligible to participate. Caution should be taken if you have heart problems or the tendency to hemorrhage following trauma. Participants are asked to discuss the appropriateness of this program with personal physician. A signed Medical Clearance Form must be obtained from your physician before you will be allowed to participate.

If motor improvement occurs following administration of FES during the study, there exists a risk of loss or decrease of these benefits upon discontinuation of FES. You will be encouraged to adopt an active hand exercise program to increase the potential of maintaining the positive motor benefits gained. Home exercise programs for the hand can be provided by the PI. In addition, you can discuss the use of a continued FES program with their treating physician.

No other discomfort or risks are expected, however, there may be risks that are unknown at this time. Overall risks involved in this study are minimal. If you wish to discuss the information above or any other risks you may experience, you may ask questions now or call the Principal Investigator listed on the front page of this form.

**What are the possible benefits to you or to others?**

There are potential benefits you may obtain by participating in this study. Electrical stimulation following stroke has been shown to have positive benefits and may potentially increase movement in specifically treated areas. Involvement in this study could improve muscle function that became impaired following your stroke and help to increase movement in your hand and arm. In addition, you will be receiving professional therapy services from a trained clinician at no cost.

**If you choose to take part in this study, will it cost you anything?** No.

**Will you receive compensation for your participation in this study?** Because there currently is only limited funding for this project, we are not able to compensate you for your time.

**What if you are injured because of the study?** As noted earlier, this study involves very little risk of injury or physical impairment; however, no treatment will be provided for research related injury and no payment can be provided in the event of a medical problem. Continuing medical care and/or hospitalization for research-related injuries will not be provided free of charge nor will financial compensation be available. No medical treatment will be provided or available in case of injury as a result of participation in this study.

**If you do not want to take part in this study, what other options are available to you?**

Participation in this study is entirely voluntary. You are free to refuse to be in the study, and your refusal will not influence current or future relationships with The University of Texas at Austin. Your participation or lack of participation will not affect the relationship between you and The University of Texas at Austin or your health care provider.

**How can you withdraw from this research study and who should I call if I have questions?**

If you wish to stop your participation in this research study for any reason, you should contact:

Barbara Doucet at (512) 471-9228 or Lisa Griffin, PhD, at (512) 471-278. You are free to withdraw your consent and stop participation in this research study at any time without penalty or loss of benefits for which you may be entitled. Throughout the study, the researchers will notify you of new information that may become available and that might affect your decision to remain in the study. In addition, if you have questions about your rights as a research participant, please contact Clarke A. Burnham, Ph.D., Chair, The University of Texas at Austin Institutional Review Board for the Protection of Human Subjects, 512/232-4383.

**How will your privacy and the confidentiality of your research records be protected?**

Authorized persons from The University of Texas at Austin and the Institutional Review Board have the legal right to review your research records and will protect the confidentiality of those records to the extent permitted by law. Otherwise, your research records will not be released without your consent unless required by law or a court order. If the results of this research are published or presented at scientific meetings, your identity will not be disclosed. All data will be stored on computer and backed up on disks. All disks will be coded so that no personally identifiable information will be visible. Disks will be kept in a secure place in the Neuromuscular Physiology Laboratory (Bellmont 546D) and will be accessed only for research purposes by the investigators and their colleagues. Data will be retained for future analysis.

**Will the researchers benefit from your participation in this study?** The researchers in this study will receive no benefit through your participation in this study beyond contributing to the motor behavior body of knowledge, and publishing and presenting the results.

**Signatures:**

**As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:**

---

**Signature and printed name of person obtaining consent**

**Date**

**You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.**

---

**Printed Name of Subject**

**Date**

---

**Signature of Subject**

**Date**

---

**Signature of Principal Investigator**

**Date**

## Appendix D: Human Subjects IRB Application

**The University of Texas at Austin  
IRB Application  
Use of Human Subjects**

Faculty, staff, students and/or employees who wish to engage in any research, demonstration, development, or other activity involving the use of human subjects must have review and approval of that activity by the Institutional Review Board, prior to initiation of the project. The Board is responsible for safeguarding the rights and welfare of subjects who participate in the research activity.

If you need further assistance in completing this form or need any other information regarding human subjects research please contact the Institutional Review Board at the Office of Research Support and Compliance at 471-8871 or by sending an Email to Daniel Y. Escareño at [Daniel.Escareno@mail.utexas.edu](mailto:Daniel.Escareno@mail.utexas.edu)

**Please Note: All fields in Part I through Part VII must be completed. Failure to answer all fields completely may result in delay of approval or your application being rejected.**

Date of Application: 02/06/04

Part I: Project Title and Type of Review

1. Project Title (Please note that if this project is funded and the grant title is different from this project, please include both the grant title and the project title):

**Project Title: Functional Motor Recovery in the Hemiplegic Hand IRB#2004-02-0029**

2. Please check the type of review you are requesting (**NOTE: CHECK ONLY ONE**):

☒ Full Board

☐ Expedited

Indicate the expedited category number claimed under 45 CFR 46.110: \_\_\_\_\_  
(<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm> - 46.110)

☐ \*Exempt

Indicate the exemption category number claimed under 45 CFR 46.101(b): \_\_\_\_\_  
(<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm> - 46.101)

(\*Exemption category 1 does apply to minors. Exemption category 2 only applies to minors for the use of educational tests and observation of public behavior with no intervention, but not for surveys or interviews. Exemption category 5 applies only to federal departments or agencies)

3. Has this application had prior IRB review? ☐ Yes ☒ No

If yes, which IRB? \_\_\_\_\_

(Please include a copy of that IRB's approval letter.)

**NOTE:** If this study is to be conducted for a period longer than one year, **it is the principal investigator's responsibility to renew prior to the anniversary date.** A continuing review must be submitted prior to the anniversary date of the studies approval date. Failure to renew will result in the study being suspended or possibly terminated. Please also note that any changes to your project must be formally submitted as an amendment and approved by the IRB **prior** to implementing the change.  
If this study is completed before its expiration date, please notify the IRB of its completion by submitting a Protocol Closure Report.

Part II: Principal Investigator's Information

4. The signature of the investigator(s) indicates agreement with the following:

I acknowledge the rights and welfare of the human subjects involved in this project. I acknowledge the responsibility to secure the informed consent of the subjects by explaining the procedures, in so far as possible, and by describing the risks and potential benefits of the project. I assure the IRB that all procedures performed in this project will be conducted in accordance with all federal regulations and university policies which govern research with human subjects.

**Principal Investigator's (PI) Information** All correspondence about the study will be sent to the PI's address below. Student PIs may wish to list a mailing address instead of a Department & Mail Code. **Your UT EID is the 'screen name' used to log in to UT Direct. Do not list your password or your social security number.**

Last Name: Doucet First Name: Barbara MI: M

UT EID: DOUCETBM Phone number: 512-471-9228

Department & Mail Code: KIN D3700

Email address: doucetb@mail.utexas.edu

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Position at UT: ☐ Faculty ☒ Student ☐ Staff

Project is: ☒ Dissertation ☐ Master's Thesis ☐ Class Project

☐ Und. Honors Thesis ☐ Other Research (Specify) \_\_\_\_\_

**Co-investigator #1**

Last Name: Covington First Name: Clay MI: \_\_\_\_\_

UT EID: clay0204 Phone number: 512-471-9228

\*Department & Mail Code: KIN D3700

Email address: clay0204@mail.utexas.edu

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Co-investigator #2**

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_ MI: \_\_\_\_\_

\*UT EID: \_\_\_\_\_ Phone number: \_\_\_\_\_

Email address: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Co-investigator #3**

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_ MI: \_\_\_\_\_

\*UT EID: \_\_\_\_\_ Phone number: \_\_\_\_\_

Email address: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

\*Student PIs may wish to list a mailing address instead of a Department & Mail Code.

5. If the PI is a student, he or she must have a faculty sponsor. The signature of the faculty sponsor indicates agreement with the following:

I have reviewed this proposal and will oversee the research project through its termination.

**Faculty Sponsor's**

Last Name: Griffin First Name: Lisa MI:       

UT EID: LG634 Phone number: 512-471-2786

Department & Mail Code: KIN D3700

Email address: L.griffin@mail.utexas.edu

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

6. **Departmental Review Chair (DRC)**

As Chair of the Departmental Review Chair, my signature testifies that I have reviewed and approved this application.

\_\_\_\_\_  
(Typed/printed name) (Signature) (Date)

7. **Institutional Review Board (IRB) FWA #00002030**

This protocol for the use of human subjects has been reviewed and approved by the University of Texas at Austin Institutional Review Board

\_\_\_\_\_  
(Clarke A. Burnham, Ph.D., IRB Chair) (Date)

Sections III through VII request brief answers on topics that you must cover in detail in your Research Proposal, consent forms, and other supporting documents. **By answering the questions below, you are not relieved of the responsibility to cover these issues in detail in your Research Proposal or any other supporting documents.**

Part III: Study population and Subject Participation

8. Will this study include:

- ☒ UT Students
- ☐ UT Faculty or Staff
- ☐ Mentally or psychologically impaired persons
- ☐ Children under the age of 18
- ☐ Prisoners
- ☒ Persons with a physical illness, injury, or disability
- ☐ Pregnant women or fetuses

9. If the participants are under the age of 18, indicate or state the rationale for their use.
- ☐ The purpose of the study is to understand developmental processes
  - ☐ The purpose of the study is to understand variables that influence education
  - ☐ Other (specify):
  - ☒ Does not apply
10. If the participants are either pregnant women, fetuses, mentally or psychologically impaired persons, prisoners, or persons with a physical illness, injury or disability, give a brief explanation of the need to use these particular individuals. **This study specifically investigates motor return in the upper extremity following stroke. In order to effectively study this behavior, persons who have suffered a stroke and display impaired motor return in the arm and hand are the population of interest.** ☐ Does not apply
11. If the participants are employees of The University of Texas at Austin are they directly supervised by the investigator? ☐ Yes ☐ No ☒ Does not apply
12. If the participants are students, is the investigator their instructor or advisor?  
☐ Yes ☐ No ☐ Some may be, but not selected on that basis ☒ Does not apply
13. Will you be asking the participants to provide any of the following on research forms or in response to research questions?
- ☒ Name ☐ Social Security number
  - ☒ Phone number or address ☒ Medical / Health information
  - ☐ Other information that may identify the subjects (specify):
  - ☐ Does not apply
14. If individuals with diseases or conditions are to be included and if the study involves a treatment for their disease or condition, please explain how that treatment will differ from standard care that they would ordinarily receive: **Individuals in the study will receive surface electrical muscular stimulation to investigate possible improvement in hand function. Application of this modality is similar to standard rehabilitative therapy that they might receive while in a rehabilitation setting.** ☐ Does not apply
15. If individuals with disease or conditions are to be included, is there a potential for direct benefit to these subjects? ☐ Does not apply ☐ No ☒ Yes, explain: **Subjects in this study will participate in evidence-based therapeutic interventions that could potentially improve hand function and optimize performance of daily functional tasks involving manual dexterity and fine motor control.**
16. How many subjects do you plan to enroll in your study? **20**  
(Please note: If the number changes, you will need to amend your study prior to increasing enrollment size)

17. How much time will be required of each subject? **Approximately 40-50 hours in total.**

18. What will be the age of your subjects? **Approximately 50- 80 years of age**

19. Gender of subjects: ☐ Males ☐ Females ☒ Both

If you are using only one gender population, please check one of the following:

☐ Only the gender selected has the condition

☐ Other, please specify:

20. If women of childbearing potential are to be included, will a pregnancy test be required?

☐ No - study poses no threat to fetus ☒ N/A

☐ Yes - please state who will pay for the test:

21. Does this study require that the subjects be recruited from a specific race/ethnicity?

☒ No

☐ Yes, please specify: ☐ Caucasian ☐ African-American ☐ Hispanic  
☐ Asian ☐ Native American ☐ Other:

Reason for selection (check one):

☐ The condition being studied occurs only in the selected group(s)

☐ Other, please specify:

22. Will this study involve:

Human use of radiation and radioactive materials? ☐ Yes ☒ No

Use of human tissue/body fluids ☐ Yes ☒ No

Genetic Testing ☐ Yes ☒ No

23. If you answered "Yes" to any of the questions in number 22, have you submitted the necessary forms to the Institutional Biosafety Committee and/or Environmental Health & Safety for review and approval?

☐ Yes

☐ Application is pending

☐ No (explain):

24. Is there a person (other than the Principal Investigator) or a group that will be responsible for reviewing adverse events and other issues related to the safety of the study?

☐ No

☒ Yes: Please describe your data safety monitoring procedure: **Participants will receive consent from treating physician**

25. Will the subjects be recorded with audio or video equipment? ☐ Yes ☒ No  
(Federal Regulations stipulate that studies involving the use of audio or video equipment must be reviewed at the Expedited level or higher)

Part IV: Financial / Material Support, Subject Compensation, and Incentives

26. Is there financial or material support for this study? ☐ Yes ☒ No
27. If you answered, "Yes," to question 27 please check below whether the support is Pending or has been Obtained:

<b>Source:</b>	<b>Private sponsor</b> (List company name: _____)	<input type="checkbox"/> Pending	<input type="checkbox"/> Obtained
	<b>DHHS</b> (If the project is DHHS funded, please provide a copy of the grant proposal)	<input type="checkbox"/> Pending	<input type="checkbox"/> Obtained
	<b>Other Federal Agency</b> (List Agency name: _____)	<input type="checkbox"/> Pending	<input type="checkbox"/> Obtained
	<b>UT Department, College, or UT</b>	<input type="checkbox"/> Pending	<input checked="" type="checkbox"/> Obtained
	<b>Other</b>	<input type="checkbox"/> Pending	<input type="checkbox"/> Obtained

28. Will the study provide reimbursement of the subjects' expenses?  
☒ No ☐ Yes, state amount: \$ \_\_\_\_\_
29. Will compensation be provided? ☐ Yes ☒ No  
If Yes select one of the following:  
☐ Pro-rated payment.  
Give amounts and schedule:  
  
☐ No pro-rated payment.  
Please explain:
30. If students from a class or set of classes are to be enrolled as research subjects, will they receive class credit or bonus points for participation?  
☐ Yes ☐ No ☒ N/A
- 30 a. If yes, have the alternative options for getting class credit been explained full to the student in the consent form or other material given to the students such as the course syllabus?  
☐ Yes ☐ No
31. Given the population which you will target, could monetary compensation unduly influence a subject to participate in this study or remain in this study when other factors in the subject's health or environment would keep the subject from doing so otherwise? ☒ No ☐ Yes, please explain:

32. If the study involves treating the subjects, will any of the drugs, devices, or treatment procedures be given to the subject free of charge? ☐ No ☐ N/A ☒ Yes, please explain: **Electrical stimulation procedures will be delivered free of charge**
33. Will any study interventions such as lab test, biopsies, or x-rays, etc. be performed that are additional to the routine work or therapy for these types of subjects?  
☐ N/A ☒ No ☐ Yes, please explain:
- 33a. Who or what agency will pay for the above tests/procedures?
34. Are there specific medications that must be used to meet the requirements of this protocol?  
☒ No ☐ Yes, please list the medications:
- 34a. Who or what agency will pay for the medications listed?
- 34b. Are you using a controlled substance(s) in this study?  
☒ No ☐ Yes, please list DEA number and expiration date:
35. Will any incentive (financial, gifts or other items of value) be given to persons who identify or refer subjects for enrollment?  
☒ No ☐ Yes, explain:

#### Part V: Informed Consent

36. An IRB may waive or alter some or all the requirements for informed consent if all of the \*four conditions apply. If you wish to request a waiver of the requirement for informed consent, explain the applicability of each of the requirements to your study (\*See Waiver of Informed Consent form on our website - <http://www.utexas.edu/research/rsc/humanresearch/forms>).
37. An IRB may waive the requirement for the investigator to obtain a signed written consent form from some or all subjects in lieu of a verbal consent if either of the \*two pairs of conditions apply. If you wish to request a waiver of the requirement for a signed consent form, explain the applicability of the two items in one of the two pairs of conditions to your study (\*See Waiver of Documentation of Consent form on our website - <http://www.utexas.edu/research/rsc/humanresearch/forms>).
38. If you are using an informed consent, answer the following questions about your informed consent document(s)
- 38a. Is the language in the document appropriately matched to the comprehension level of your intended subjects? ☒ Yes ☐ No
- 38b. Will the document be provided in language(s) other than English? ☐ Yes ☒ No
- 38c. Will you be providing subjects a copy of their consent document? ☒ Yes ☐ No
- 38d. Does your document in any way ask or imply that subjects are waiving any right or releasing you from any liability? ☐ Yes ☒ No
- 38e. Briefly explain who will provide informed consent (check all that apply):  
☒ The subject ☐ The subjects parent or guardian  
☒ Other, please explain: **Treating physician will also give consent**

38f. Who will obtain informed consent (check all that apply)?

☒ The PI or Co-investigators

☐ Graduate/Research Assistants (\*Note-Graduate/Research Assistants must be listed on The Documentation of Compliance with Educational Mandate for Conducting with Human Subjects)

☐ Other (please list):

Part VI: Conflict of Interest

**\*\* Conflict of Interest: A PI or Co-PI is said to have a conflict of interest whenever the researcher, spouse or dependent child of the researcher:**

- Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could directly or indirectly influence the value of the economic interest;
- Acts as an officer, director, or agent of the sponsor;
- Has any equity interest of 5% or more in the sponsoring entity
- Has received payments or other considerations from the sponsor of \$10,000 or more;
- Has identified him or her self for any other reason as having a conflicting interest.

39. Do you or does The University of Texas at Austin, hold a patent or license for any material, object, invention or process used in the study or do you intend to file a patent application at a later date?

☒ No

☐ Yes

40. If there is sponsor for the study, do you own equity or have a financial interest in the sponsoring entity, give presentations for or on behalf of the sponsor, serve as a consultant to the sponsor, or work in any capacity for the sponsor (such as board member, officer, etc.)?

☒ No

☐ Yes

41. Do any of the "Key Personnel" listed on this study, or listed on the Documentation of Compliance with Educational Mandate for Conducting Research with Human Subjects, have a conflict of interest associated with this study?

☒ No

☐ Yes

42. Do you have any other possible conflict of interest? ☒ No ☐ Yes, please explain:

Part VII: Location

43. This study will take place at:

☒ The University of Texas at Austin

Please list department, building, or site: **BEL 546D**

☒ Other

List location(s): **Individual homes of subjects**

(If the sites are agencies, school districts, etc., include permission letters that allow you to use subjects from the site and indicate the number of subjects per site.)

Part VIII: HIPAA Regulations: Use of Protected Health Information (PHI):

*Please read the definition of PHI below before answering.*

*PHI is defined under HIPAA as health information transmitted or maintained in any form or medium that:*

- Identifies or could be used to identify an individual;
- Is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and
- Relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual.

*Health-related information is considered PHI if (any of the following are true):*

- The researcher obtains it directly from a provider, health plan, health clearinghouse or employer (other than records relating solely to employment status);
- The records were created by any of the entities listed above and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR
- The researcher obtains it directly from the study subject in the course of providing treatment to the subject.

*Health-related information is not considered PHI if the researcher obtains it from:*

- Student records maintained by a school;
- Employee records maintained by an employer related to employment status; OR
- The research subject directly, if the research does NOT involve treatment.

As part of this study, do you:

- A. Collect PHI from subjects in the course of providing treatment/experimental care; or  
☐ No ☒ Yes
- B. Have access to PHI in the subjects' records?  
☒ No ☐ Yes

***If yes to A or B above, complete HIPAA FORM to show how you will satisfy HIPAA requirements for authorization to use PHI in research.***

## Appendix E: IRB Compliance



## Certificate of

This certificate is awarded to:

**Barbara M Doucet**

For the satisfactory completion of UT Austin's computer-based training program in the conduct of research with human subjects as approved by the Office of Research Support and Compliance at The University of Texas at Austin on June 12, 2004.

Dr. Lisa Leiden  
Director, Research Support & Compliance

## Appendix F: Preliminary Outlines

### First Stage Outline

#### High vs. Low Electrical Stimulation Frequencies for Motor Recovery in Hemiplegia

- I. Functional Electrical Stimulation (FES) is a viable modality in the treatment of stroke-related motor deficits
- II. Limited use of FES for hand re-training following stroke
- III. Muscle physiology will impact effects of FES
- IV. FES frequencies that maximize force production and minimize fatigue are yet to be identified

### Second Stage Outline

- I. Functional Electrical Stimulation (FES) is a viable modality in the treatment of stroke-related motor deficits
  - A. Combining FES and exercise produces positive rehabilitation outcomes
  - B. FES used extensively with positive results for shoulder subluxation rehabilitation
  - C. FES has widespread use with positive results for gait training following stroke
- II. Limited use of FES for hand re-training following stroke
  - A. Limited studies conducted without stimulation frequency as a variable
  - B. Stroke-related deficits that impact FES outcomes
- III. Muscle physiology impacts effects of FES
  - A. Factors present in normal muscle that influence FES outcomes
  - B. Factors present in paralyzed muscle that influence FES outcomes
  - C. Impact of motor unit “size principle” reversal with FES
- IV. FES frequencies that maximize force production and minimize fatigue are yet to be identified

- A. Electrical stimulation frequencies that have minimized fatigue in normal muscle
- B. “Muscle wisdom” hypothesis and its application to post-stroke FES
- C. Patterns of stimulation that maximize force-time integral in normal muscle

### Third Stage Outline

- I. Functional Electrical Stimulation (FES) is a viable modality in the treatment of stroke-related motor deficits
  - A. Studies indicate that FES combined with exercise shows greater gains than exercise or FES alone (Popovic et al., 2002; Barreca, Wolf, Fasoli, & Bohannon, 2003)
  - B. FES shown to be effective in reducing shoulder subluxation after stroke (Handy, Salinas, Blanchard, & Aitken; Wang, Chan, & Tsai, 2000; Chae & Yu, 2002)
  - C. FES produces improved gait kinematics following stroke (Daly & Ruff, 2000) as well as strengthening muscles, restoring range of motion, and stimulating muscle contractions (Liberson, Holmquest, Scott, & Dow, 1961).
  - D. Cortical fMRI indicates increased intensity during fine motor task following FES treatment (Kimberley et al, 2004).
- II. Limited studies investigating optimal parameters of FES for hand motor skill retraining following stroke
  - A. FES used for hand function following stroke yields higher outcomes than conventional therapies (Kraft, Fitts, & Hammond, 1992) and produces higher scores on selective outcome measures after training at 50Hz when compared to a control group (Carragee, Light, Kim, Thigpen, and Behrman, 2000).
  - B. Dense hemiplegia may limit application of both traditional and contemporary active-motor approaches (Chae et al., 1998; Gritsenko & Prochaska, 2004).
  - C. Fewer FES studies involving hand function due to complexity of movements as compared to lower extremities (Binder-Macleod & Lee, 1997).
- III. Paralytic and normal muscle physiology will impact effects of FES

A. Lower maximal forces and a greater propensity to fatigue present in paralyzed muscle (Griffin et al., 2002; Farmer et al., 1993).

B. Motor unit “size principle” shown to reverse with FES (Baker, Wederich, McNeal, Newsam, and Waters, 2000)

IV. FES frequencies that maximize force production and minimize fatigue are unclear

A. Higher frequencies of stimulation are required to produce similar levels of force after a muscle has become fatigued (Thomas, Bigland-Ritchie, & Johannson, 1991; Fuglevand, Macefield, & Bigland-Ritchie. 1999) and significantly more force is lost at low compared to high frequencies, a phenomenon known as ‘low-frequency fatigue’ (Edwards, Hill, Jones, & Merton, 1977; Westerblad, Duty, & Allen, 1993) and is greater in older adults (Allman & Rice, 2002).

B. More force is lost when stimulation frequencies are progressively reduced from 30-15 Hz than when constant stimulation frequency of 30 Hz was used (Fuglevand and Keen, 2003).

## Appendix G: Style Sheet

### Style

The style used for this proposal and all future manuscript development will be according to The American Psychological Association (APA) guidelines. I own the current edition of the APA style manual and will adhere to the formats prescribed therein.