

The effectiveness of Farabloc technology with Mirror Therapy in reducing phantom limb pain in individuals with a unilateral lower extremity vascular amputation

by

Helen Houston

April, 2012

Director of Thesis: Anne Dickerson

Major Department: Occupational Therapy, East Carolina University

Abstract

Objective: The objective of this study was to investigate the effectiveness of combining two interventions, Farabloc technology to eliminate electromagnetic fields and Mirror Therapy to assist in the sensory cortex reorganization, to decrease or eliminate phantom limb pain in vascular amputees.

Methods: Fourteen older adults with a unilateral vascular amputation participated in the study. Nine individuals started the intervention within 48 hours of surgery and were compared to five individuals who were approximately 18 months post-surgery. Measures of residual limb edema and temperature, phantom limb pain variables, activities of daily living and quality of life interference were completed pre and post intervention and 4 weeks after the end of therapy.

Results: All fourteen subjects reported an overall decrease in phantom limb pain using a visual analogue scale. For the acute group, wound healing and edema reduction decreased time to prosthetic fitting from 12 weeks to eight weeks, significant for improving functional ambulation, return to work and decreasing wheelchair mobility dependence. Activities of daily living and quality of life variables both showed significant differences.

Conclusion: Use of this combined treatment protocol shows promising results for not only acute amputee intervention, but also improved perception of pain and improved quality of life for amputees with chronic phantom limb pain. Implications for activities of daily living and quality of life are discussed.

The effectiveness of Farabloc technology with Mirror Therapy in reducing phantom limb pain in
individuals with a unilateral lower extremity vascular amputation

A Thesis

Presented to the Faculty of the Department of Occupational Therapy

East Carolina University

In Partial Fulfillment of the Requirements for the Degree

Post-professional Master's in Occupational Therapy

by

Helen Houston

April 2012

The effectiveness of Farabloc technology with Mirror Therapy in reducing phantom limb pain in
individuals with a unilateral lower extremity vascular amputation

by

Helen Houston

APPROVED BY:

DIRECTOR OF DISSERTATION/THESIS: _____

Anne Dickerson, PhD, OTR, FAOTA

COMMITTEE MEMBER: _____

Leonard Trujillo, PhD, OTR/L, FAOTA

COMMITTEE MEMBER: _____

Qiang Wu, PhD

CHAIR OF THE DEPARTMENT OF OCCUPATIONAL THERAPY

DEAN OF THE GRADUATE SCHOOL

Leonard Trujillo, PhD, OTR/L, FAOTA

Dr. Paul Gemperline, PhD

Table of Contents

| | |
|--|----|
| ABSTRACT..... | i |
| TITLE PAGE..... | iv |
| COPYRIGHT..... | v |
| SIGNATURE PAGE..... | vi |
| CHAPTER 1: Introduction..... | 1 |
| CHAPTER 2: Literature Review..... | 3 |
| Phantom Limb Pain..... | 3 |
| Farabloc technology..... | 13 |
| Mirror therapy..... | 19 |
| Summary..... | 23 |
| CHAPTER 3: Methods..... | 25 |
| Subjects..... | 25 |
| Design..... | 27 |
| Measurements..... | 29 |
| Procedure..... | 35 |
| Data Analysis..... | 39 |
| CHAPTER 4: Results..... | 40 |
| Discussion..... | 42 |
| Limitations..... | 52 |
| Summary and conclusions | 53 |
| REFERENCES..... | 56 |
| APPENDIX A: Institutional Review Board Approval..... | 66 |

| | |
|--|-----|
| APPENDIX B: Prosthesis Evaluation Questionnaire..... | 78 |
| APPENDIX C: Daily Log..... | 95 |
| APPENDIX D: Brief Pain Inventory - short form..... | 96 |
| APPENDIX E: Hubbard Scientific 6083 Liquid Crystal Temperature Strip.... | 97 |
| APPENDIX F: Log of Continuity Tester Measurements..... | 98 |
| APPENDIX G: Instructions to Therapists..... | 99 |
| APPENDIX H: Exercise Protocol for Mirror Therapy Exercises..... | 100 |
| APPENDIX I: Tables..... | 101 |

CHAPTER 1: Introduction

Phantom limb pain (PLP) is defined as painful sensations perceived in the missing portion of the amputated limb (Davis, 1993). It can be an extremely debilitating and complicated phenomenon limiting participation in daily life activities throughout the life of an individual with an amputation. Due to varied etiology, a variety of different treatment options have been explored to attempt to manage PLP. Yet, it continues to remain a challenging and disabling condition which continues to plague many amputees and at best, is difficult to treat.

The purpose of this study was to explore the effect of combining two therapies, Farabloc technology with Mirror Therapy, to explore the effect that this combined treatment protocol would have on PLP for acute compared to chronic, unilateral, lower extremity vascular above or below knee amputees.

According to the World Health Organization (WHO), “Electromagnetic fields (EMF) can affect the nervous systems of people exposed to them, resulting in adverse health consequences such as nerve stimulation” , whereas, “The absence of EMF can reduce persons chronic pain” (Nixdorf, 2012, p 1.). Farabloc technology (Farabloc Development Corporation, 2012)uses a fabric that is woven using 9.5% steel wire fibers consisting of iron, nickel, chromium and nylon, which has significant shielding effects on high frequency EMF (greater than 1MHz) (Bach & Clement, 2007). This washable fabric has an appearance similar to linen (Bach & Clement, 2007) and can be tailored into an amputee limb cover that is worn over the stump/ residual limb. It has been promoted and has been demonstrated to have a favorable effect on PLP in several studies (Bach, & Clement, 2007; Conine, Hershler, Alexander, & Crisp, 1993; Clement & Taunton, 2001; Halbert, Crotty, & Cameron, 2002; Zhang, Clement, & Taunton, 2000).

Mirror Therapy (Ramachandran, 1996) uses a mirror placed between the amputated and non-amputated limb, in which the non-amputated limb is observed while performing bilateral synchronous exercises, such that it appears that both limbs are intact. “The patient sits with a mirror facing the remaining leg, moves the remaining leg and watches the reflection in the mirror, so that it appears that both the good and the amputated leg are moving” (Helm, 2008). Mirror Therapy has been shown to significantly reduce PLP in individuals with an amputation (Chan et al., 2007; Flor, 2008; MacLachlan, McDonald, &Waloch, 2004; Ramachandran, 1996).

By combining Farabloc technology and Mirror Therapy, this study investigated whether PLP experienced by acute above/below knee amputees could be prevented or reduced in frequency, intensity or duration compared to chronic amputees. Farabloc and Mirror Therapy have been researched independently. This study is unique, as it utilizes the findings of the research done in these areas, as a combined intervention strategy.

As a primary provider of therapeutic interventions, occupational therapists’ focus would be on an individual’s functional participation in activities of everyday life. Living with chronic pain, such as PLP can be disabling and severely limit one’s quality of life as well as one’s ability to independently participate in everyday life tasks (Harrison, 2011). To maximize participation, occupational therapists need a treatment protocol to treat the effects of PLP in amputee clients. The objective of this study is to establish a viable treatment intervention protocol for this purpose.

CHAPTER 2: Literature Review

Phantom Limb Pain

More than 100,000 lower-limb amputations are performed each year in the United States, with many of these individuals facing secondary disabling pain conditions (Harness & Pinzur, 2001).

“The severity of the neurological injury associated with an amputation overrides all the other risk factors that influence the development of chronic pain syndromes” (Byrne, 2011, p. 1).

Definitions.

- Phantom limb pain (PLP) is defined as “painful sensations perceived in the missing portion of the amputated limb” (Davis, 1993, p. 79).
- Phantom limb sensations are “non-painful sensations perceived as emanating from the portion of the amputated limb that is missing” (Melzack, 1992, p. 121).
- Residual limb pain is perceived as “originating in the residual portion of the limb (i.e., the stump) (Davis, 1993, p. 79).

Phantom limb sensations remain a substantial and unpredictable problem in the amputee population (Ottaviani, Robert, Huh, & Jaffe, 2009). The sensations are experienced by up to 98% of all patients with limb amputations, and may be experienced as a warm or cold feeling, an itching sensation, pressure, and even a sense of position, shortly after losing a limb (Ramachandran & Hirstein, 1998). The focus in this study was on phantom limb pain.

Origins of Amputations. Amputations result from three major sources: congenital malformations, trauma and from diseases such as diabetes, peripheral vascular disease and neoplasms (Nikolajsen & Jensen, 2001). Improvised explosive devices used in Iraq and Afghanistan have led to an increased incidence in U.S. veterans returning home with limb loss

and subsequently increased phantom limb pain (PLP). A need for a simple, effective treatment for this debilitating disorder is more important than ever (Leskowitz, 2009).

Vascular Disease in the United States. Diabetes and resulting peripheral vascular disease is on the rise in the United States. In 2010, 8.3 percent or 25.8 million American adults had diabetes. Seven million of these are undiagnosed and 18.8 million people have been diagnosed with diabetes. According to the Centers for Disease Control and Prevention, diabetes is the seventh leading cause of death in the United States. It is also a leading cause for other chronic complications such as blindness, kidney failure, and lower extremity amputations (Prevention, 2011).

In 2010, North Carolina ranked 13th highest for adults diabetes prevalence in the nation. The national average was 8.3 percent, and the prevalence in North Carolina was 9.8 percent. In North Carolina, 643,000 adults had diagnosed diabetes and another 376,000 adults have pre-diabetes. Diabetes is more prevalent in ethnic minorities who live in the Northeastern and Southeastern portions of the state, with the highest prevalence seen in African Americans at 15.6 percent. One in every five African American adults, age 65 and older, has diabetes in North Carolina (North Carolina Diabetes Prevention and Control Program [NC DPH Diabetes], n.d.). The Amputee Coalition of America statistics report that dysvascular-related amputations account for eighty-two percent of limb loss, and lower-limb amputations account for ninety-seven percent of all amputations (“Amputee statistics by cause. Limb loss in the United States”, 2008).

History of phantom limb pain. Sensation post-amputation was first described by Ambroise Pare´ (1510 – 1590). He was a French military surgeon, who observed that many patients complained of severe pain in the missing limb after an amputation. Pare´ was the first to

characterize post-amputation syndrome and he proposed several different models to explain this post-amputation pain (Keil, 1990).

Other individuals were instrumental in providing important detailed descriptions of this post-amputation pain phenomenon throughout history: Charles Bell - 1830, Magendie - 1833, Rhone - 1842, Gueniot – 1861 (Nikolajsen & Jensen, 2001). A civil war physician, Silas Weir Mitchell in 1871, coined the phrase “phantom limb” to describe this phenomenon and noted that PLP is often resistant to standard medical and neurosurgical treatments for pain (Mitchell, 1871).

Almost all amputees experience phantom sensations after an amputation (whether these are painful or not). The non-painful sensations don't often pose a clinical problem and may provide the necessary proprioceptive feedback for these amputees to be able to use a prosthetic limb in a functional manner. In amputees with PLP however, the area distal to the residual limb becomes the site of severe pain and debility and once established this pain may be exceedingly difficult to eradicate or treat (Nikolajsen & Jensen, 2001). In the majority of cases, PLP onset is often experienced immediately upon awakening from anesthesia (Weeks & Tsao, 2010).

PLP Prevalence. There is a wide variety about the consensus of the prevalence of PLP, with rates ranging from 0.5% to 100% of persons with amputations. However using improved methods, more recent studies, have suggested that 90% of individuals, undergoing limb amputations will experience some degree of PLP (Chan et al., 2007).

In 75% of cases, PLP occurs within the first few days after an amputation (Nikolajsen & Jensen, 2001). PLP is described as shooting, stabbing, squeezing, throbbing or burning. It is primarily localized in the distal parts of the missing limb such as the toes, instep, top of foot and ankle in lower limb amputees (Nikolajsen, Ilkjaer, Kroner, Christensen, & Jensen, 1997).

In an important study by Sherman, Sherman and Parker, of 2694 amputees, 51% experienced phantom limb pain “severe” enough to hinder lifestyle on more than 6 days per month. Twenty-seven percent of this sample experienced PLP more than 15 hours each day and a further 21% reported daily pain over a 10 – 14 hour period. Sherman and his colleagues also found that 44% of amputees reported that their PLP had not diminished over a 30-year period (Sherman, Sherman, & Parker, 1984). This indicates that PLP is a significant, ongoing problem requiring intervention. Because PLP is such a persistent problem that interferes with daily function, it is an important problem for occupational therapists to address in order to maximize functional independence in their clients.

In a national survey of 914 persons with limb loss chronic, persistent pain was identified as leading to limitations in function, both physically and psychosocially (Ephraim, Wegener, Mackenzie, Dillingham, & Pezzin, 2005). This study noted that it is often not the underlying condition (i.e., the amputation) that primarily impairs the individual’s function, but rather the chronic pain that they experience. According to Mohamad, Ebrahimzadeh and Harris, 2009, amputees can have significant persistent symptoms that negatively influence their function, for as long as two decades post amputation. Early prosthesis use has been shown to reduce PLP by reorganizing the cortical patterns (Lotze, Grodd, Birbaumer, Erb, Huse, & Flor, 1999).

Theories of the origin of PLP. There are a variety of theories to explain PLP. In 1943, Livingston proposed the idea of “closed, self-sustaining, reverberating circuits” which are set up by chronic peripheral irritation or by the release of spinal cord cells from inhibitory control through the loss of afferent input. When these abnormal impulses reach the brain, they are experienced as painful. Furthermore, once these circuits are established, surgical removal of the peripheral source has no effect on them and, therefore, will not abolish the pain (Hill, 1999).

Melzack proposed the idea of the neuromatrix, a “network of neurons that extends throughout widespread areas of the brain, composing the anatomical substrate of the physical self” (Melzack, 1990, p. 91). Melzack believed that the primary components are genetically prewired, and experiences “add or delete, strengthen or weaken existing synapses” (Melzack, 1992, p. 124). His theory proposes that abnormal input to the neuromatrix following amputation alters the pattern generated by the neuromatrix and results in output which is experienced as a painful phantom. Abnormal input can either result from lack of normal sensory input following amputation or from high levels of input caused by excessive firing in damaged nerves. Following amputation, the neuromatrix no longer receives signals from the periphery that the limb is moving. The output from the neuromatrix includes the basic neuro-signature which has been modulated to include strong messages for the limb to move. This excessive output results in the report of a cramping type of pain, and an EMG spike of activity associated with this aspect of PLP (Hill, 1999).

Harris believed that a distorted cortical representation of a limb can result in discrepancies between motor intention, proprioception and vision, which lead to the affective sensation of pain (Harris, 1999), while Arnstein described an active sprouting of new neurons after an amputation, which leads to cortical remapping (Arnstein, 1997). Karl et al. noted a direct association between, greater neural plasticity and an increase in PLP (Karl, Birbaumer, Lutzenberger, Cohen, & Flor, 2001). Illusory body experiences, relate in some way to the re-mapping of the somatosensory cortex when the inputs from an amputated areas cease, allowing migration of neighboring somatosensory receptors sites into these “vacant areas”(Flor et al., 1995; Halligan, Zeman, & Berger, 1999; MacLachlan, McDonald, & Waloch, 2004). According to Manchikanti and Singh (2004) “the etiology and pathophysiological mechanisms of phantom

pain are not clearly defined. Peripheral and central neuronal mechanisms are both likely to occur” (p.366). There are a series of mechanisms that are involved in generating PLP which include the peripheral nerves, spinal cord and brain. The stimulation occurs initially in the periphery, which subsequently stimulates the spinal cord neurons, which in turn recruit cortical brain structures. The brain structures may be responsible for the sensation that characterizes certain PLP sensations (Nikolajsen & Jensen, 2001). Strange and sometimes painful phantom limb sensations can result from loss of afference to the brain (Bultitude&Rafal, 2009).

Based on these theories, early treatment to prevent or interrupt these pain circuits is essential in treating PLP because once these pathways are established they appear to be more difficult to abolish. The question remains whether by preventing these painful neural pathways from becoming established, PLP can be diminished or prevented altogether.

Neurological mechanisms involved in PLP. The neurological mechanisms underlying PLP have not been completely clarified. However, there is evidence of peripheral, spinal and central contributions. “It is likely that the initiating events for PLP, phantom limb sensation and stump pain start in the periphery, which generates a chain of events at the spinal and central nervous system level” (Chapman, 2011).

Peripheral factors. Peripheral factors indicate that PLP is significantly more frequent in those amputees with long-term pain, than those without persistent pain (Nikolajsen & Jensen, 2001). Pre-amputation pain has been thought to create a permanent imprint on the dorsal horn and in the central nervous system pain processing system (Morley-Forster, 2009). After nerves are cut in surgery, the formations of amputation neuromas frequently result. These masses develop in nerve tissue in a residual limb due to abnormal regrowth of the severed nerves. These neuromas show spontaneous and abnormal activity with mechanical or chemical stimulation and

are assumed to be the result of a novel expression or upregulation of sodium channels (Nikolajsen & Jensen, 2001). The amputated nerves within the neuroma are surrounded by irregularly sized sprouts that are not myelinated (Yuh, Fisher, Shields, & Ehrhardt, 1992). With mechanical or neurochemical stimulation, spontaneous and abnormal evoked activity is observed in nerve-end neuromas (Devor & Seltzer, 1999).

Dorsal root ganglion cells also undergo changes after nerves are completely cut. These cell bodies show similar abnormal activity and increased sensitivity to mechanical and neurochemical stimulation and switch from one sodium channel type to another (Waxman, 1999). From animal studies it has been shown that the sympathetic nervous system may also generate, and maintain PLP (Devor, Janig, & Michaelis, 1994).

Spinal plasticity. Spinal level factors involved in PLP are primarily due to deafferentation. These nerves receding from the amputated site are the result of the loss of large myelinated A-afferent nerve fiber input (“fast-pricking pain”) in the dorsal horn cells with an unopposed unmyelinated C-fiber input (“slow-burning pain”)(American Academy of Orthotics and Prosthetics, 2005). After nerve injury, there is an increase in excitability of the spinal cord neurons. C-fibres and A δ -afferents gain access to secondary pain signaling neurons. Experiments have found that the residual limb is much more sensitive to stimuli than that of the same region on the opposite limb. Sensitization of the dorsal horn neurons is mediated by release of glutamate. Glutamate is an excitatory neurotransmitter amino acid and tachykinins which are agents that act at the various neurokinin receptors. This process may manifest as mechanical hyperalgesia which is an increased sensitivity to pain, and expansion of peripheral receptive fields (Doubell, Mannion, & Woolf, 1999). The use of N-methyl-D-aspartate (NMDA) receptor blockade for relief of PLP supports the theory of central sensitization by peripheral nerve injury.

N-methyl-D-aspartate (NMDA antagonist) blocks the glutamate receptors in the central nervous system. Glutamate is an excitatory neurotransmitter which is thought to activate the central nervous system after noxious stimuli (American Academy of Orthotics and Prosthetics, 2005).

A recent study showed that the homunculus may actually stay intact after amputation and perhaps the remapping occurs at the levels of the spinal motor neurons (MacIver, Lloyd, Kelly, Roberts, & Nurmikko, 2008).

Cerebral reorganization. In adult monkeys, following amputation and deafferentation, there is a reorganization of the primary somatosensory cortex, subcortex and thalamus (Nikolajsen & Jensen, 2001). In humans, subcortical level changes, an unusually large thalamic stump representation and a similar reorganization has been observed. This is particularly true in individuals with PLP (Davis et al., 1998). “Somatosensory cortex reorganization has been concluded to be at least as important as events in the periphery” (Morley-Forster, 2009). Reduction in grey matter is found within the thalamus in amputees contralateral to side of amputation (Draganski et al., 2006). A linear relationship between pain and degree of reorganization has been observed using magnetoencephalographic techniques (Flor et al., 1998). During early studies, Melzack proposed that the reticular activating system plays an important role in PLP (Melzack, 1971). He proposed that when peripheral fibers are destroyed, thereby reducing input, inhibition is decreased and synchronous, self-sustaining activity develops at all neural levels. Thus, lack of input from the periphery following amputation will result in disinhibition not only at the spinal level, but also at the cortical level, which has been confirmed by more recent research (Hill, 1999). Individuals with an amputation are therefore at risk of hyperstimulation of these neural pathways, which may lead to PLP.

PLP treatments. Treatment of PLP after an amputation is challenging. A large variety of treatments have been suggested, however empirical data to support these treatments has been lacking, with the vast majority based on small sample sizes with no control groups. Although it is obvious that a series of changes which may play a role in the induction and maintenance of chronic PLP in the peripheral and central nervous system occur after nerve injury, without the underlying knowledge of the pathophysiological causes behind PLP, it is difficult to establish a clear, rational treatment regime (Nikolajsen & Jensen, 2001).

There are a variety of surgical, medical and non-medical techniques and protocols. Surgical intervention procedures however, carry a risk of further deafferentation, resulting in even more pain and should be avoided (Nikolajsen & Jensen, 2001). Medical interventions include tricyclic antidepressants (Kalso, Tasmuth, & Neuvonen, 1995), sodium channel blockers, and anticonvulsant drugs (Sindrup & Jensen, 1999). Non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol are considered to be ineffective in PLP by most practitioners (Nikolajsen & Jensen, 2001). Some amputees can benefit from opioids, with a limited risk of drug dependence (DelleMijn, 1999). Side effects associated with these pharmacological treatments are extensive. Tricyclic antidepressants may produce “sedation, confusion and anticholinergic side effects such as constipation, dry mouth, blurred vision, urinary hesitancy and orthostatic dizziness” (Simmons & Feldman, 2000, p. 1). They are contraindicated for use in individuals with heart disease, orthostatic hypotension or angle-closure glaucoma. Anticonvulsants have side effects such as dizziness, somnolence, headache, diarrhea, confusion, nausea and peripheral edema (Simmons & Feldman, 2000). Narcotic analgesics have side effects of nausea, sedation, constipation, respiratory depression and are controversial for treatment in that they are habit forming with chronic use (Lacy, Armstrong, Goldman, & Lance, 2010).

Capsaicin cream has been shown to have “poor compliance because of the need of frequent applications, an initial exacerbation of symptoms and frequent burning and redness at application site” (Simmons & Feldman, 2000, p. 3). Furthermore surveys suggest that although physicians believe treatments are effective (Sherman, Sherman, & Gall, 1980), fewer than 10% of patients with PLP receive lasting relief from prescribed medical treatments (Sherman et al., 1984).

Non-medical treatments include transcutaneous electrical nerve stimulation (TENS), vibration therapy, acupuncture, hypnosis, biofeedback and electroconvulsive therapy, although clear evidence of effect is limited. Electrical stimulation of the spinal cord, deep brain structures and motor cortex may relieve chronic neuropathic pain, including PLP; however the effect of treatment often decreases with time (Nikolajsen & Jensen, 2001). TENS, applied to the outer ear, was found in a placebo-controlled crossover design by Katz and Melzack, 1991 to reduce PLP; however its long-term effectiveness in alleviating PLP remains unknown. TENS applied to the contra-lateral limb was shown to reduce PLP, an effect which was maintained at a one-year follow-up (Giuffrida, Simpson, & Halligan, 2010). Sherman suggests that pain reductions after 1 year of treatment are comparable to placebo (Jensen, Wilson, & Rice, 2002). More recent treatments including local anesthesia, sympathectomy, dorsal root entry-zone lesions, cordotomy, neurostimulation methods, or pharmacologic interventions such as anticonvulsants, barbiturates, antidepressants, neuroleptics, and muscle relaxants have been beneficial only 30% of the time (Flor, 2002).

Two newer therapies have emerged. Farabloc technology and Mirror Therapy have been used effectively to treat PLP. Both therapies are without side effects and are drug-free alternatives to treating PLP.

Farabloc Technology Therapy

History of Farabloc. In 1978 Frieder Kempe designed a metallic fabric called Farabloc to help his father, an above knee amputee, deal with his PLP. Rudolf Kempe lost his leg in 1944 in the World War II battle of Monte Cassino. Frieder noted that his father's pain often seemed to be weather related (F. Kempe, personal communication, April 7, 2010).

The first publication of documented changes in pain perception associated with the weather was in the American Journal of Medical Sciences in 1887. This case report described a person with PLP who concluded that "approaching storms, dropping barometric pressure and rain were associated with increased pain complaint"(Shutty, Cunduff, &DeGood, 1992, p. 199). Individuals with PLP have been reported to be especially sensitive to weather changes (Harlfinger, 1991). Meteorological factors that contribute to changes in pain include temperature, barometric pressure, precipitation, humidity, thunderstorms, sunshine and increased ionization of the air (Harlfinger, 1991). Due to the fact that tendons, muscles, bones and scar tissue are of various densities, cold and damp may expand or contract them in different ways. Change in barometric pressure may also cause a transient "disequilibrium" in body pressure that may sensitize nerve endings and account for increased pain preceding changes in temperature or humidity (Jamison, 1996). Farabloc could be used to shield the high-frequency electromagnetic fields (EMF) that accompany such a change in the environment.

Frieder Kempe used the principles of the Faraday Cage developed by the 19th century British scientist Michael Faraday, to shield sensitive tissue, calm damaged nerve ends and stimulate blood circulation. The Faraday cage is used to protect sensitive MRI machines from the Earth's magnetic shifts. Farabloc in a similar manner, shields the human body from immediate shifts in the Earth's electromagnetic field. Published studies have shown that Farabloc relieves

pain, as measured by using the Visual Analogue Scale (VAS), comparing pain reports using Farabloc compared with a placebo fabric of identical color and texture (Bach & Clement, 2007).

Mechanisms involved in Farabloc therapy. Farabloc has been demonstrated to have external electromagnetic shielding properties (McDiarmid & Trudeau, 1998) and block electromagnetic fields (EMF) four times more effectively than placebo fabric (Clement & Taunton, 2001). Double layers of Farabloc are able to completely block high frequency EMF (greater than 1 MHz), such as radio waves (Zhang, Clement, & Taunton, 2000). The exact mechanism of action for Farabloc is unknown, however, it is theorized that the absence of EMF has an effect on damaged cells and subsequent pain (Clement & Taunton, 2001). Farabloc has no magnetostatic shielding properties (McDiarmid & Trudeau, 1998).

Farabloc has been shown to shield high frequency EMF, but not to shield low frequency EMF. Benefits of low frequency EMF have been demonstrated in orthopedic practice, in combination with controlled weight bearing, to stimulate ionic transfer across cell membranes in bone caniculi to facilitate healing (Pilla, 2002). Low frequency EMF exposure to human lymphocytes showed a reduction in cell membrane fluidity and an increase in superoxide dismutase (Bordiushkov et al., 2000). This suggests that low frequency EMF appeared to reduce permeability, while high frequency EMF increase permeability, with extreme cell membrane destruction the obvious result in ionizing radiation (Bach & Clement, 2007). Thus, Farabloc could reduce cell membrane permeability and promote healing in individuals with acute amputations.

Phantom limb treatments are based on the assumption that long-term PLP is due to functional or structural changes in the central nervous system, in response to noxious somatosensory input. "Peripheral factors may contribute to central changes and enhance map

reorganization” (Flor, 2008, p. 815). Amputated nerves have an increased excitability, or reduced threshold of stimulus (Gudin, 2004). An external mechanism to reduce this excitability, in the form of a Farabloc amputee limb cover, could be beneficial in reducing this noxious somatosensory input by reducing the high frequency EMF frequencies that over-stimulate these nerve pathways. Another possibility is that Farabloc may increase the blood supply of the residual limb, as indicated by the increased temperature perceived by users. Although the temperature of the residual limb with and without Farabloc has not been clinically measured, users report that an increase in temperature is perceived while using the Farabloc fabric, which may contribute to its pain relieving properties (Bach & Clement, 2007).

Published studies regarding the absence of EMF.

The absence of EMF as PLP treatment. In 1987 Bach conducted a study of 13 individuals with PLP and observed positive results. Two-thirds of the amputees reported a decrease in PLP, and some reported that they no longer required analgesics for pain. After 32 individuals were studied, 81.25% reported the Farabloc treatment success as “good” or “very good” (Bach, 1987). In this study, Farabloc was demonstrated to be an alternative or adjunct to oral medications.

In a sequential, controlled, double blind cross-over study on PLP in 1993, conducted by Conine et al., Farabloc fabric, wrapped around the post amputation stump was found to be statistically significant in reducing PLP, as compared to a placebo fabric. The greatest pain relief occurred during the period when double layers of Farabloc covered the stump of the amputated extremity. Nine of the 34 subjects reported pain relief of greater than 5 points on the VAS, while the average relief was measured at 3 points. Twenty-one of the thirty-four patients reported their greatest PLP relief during Farabloc intervention, with no adverse effects (Conine, Hershler, Alexander, & Crisp, 1993). The authors concluded that Farabloc therapy compared to placebo fabric demonstrated the ability to relieve PLP in the residual limb of amputees.

The effect of the absence of EMF with other diagnoses. In 2000 a randomized single-blind placebo-controlled crossover study using double layers of Farabloc fabric wrapped around the thigh post exercise produced similar results as these earlier studies. Zhang et al., exposed untrained subjects to eccentric exercises to produce delayed onset muscle soreness (DOMS) in the quadriceps. Farabloc technology therapy demonstrated significantly reduced pain, reduced strength loss and reduced serum inflammatory markers (malondialdehyde, creatine

phosphokinase, myoglobin, leukocytes and neutrophils), compared to placebo fabric (Zhang et al., 2000). Pain reduction of 3 points on the VAS was also found in this study.

Although the results of the study are unable to explain the exact mechanism in which the body's response alters muscle activity, by the use of Farabloc therapy, it is hypothesized that Farabloc shields the body from the effects of EMF and thereby stabilizes the muscle cell membrane and reduces release of these substances into the serum. The reduction in levels of leukocytes and neutrophils indicates a reduced inflammatory response, since white blood cells are known to increase with severe exercise and muscle damage (Clement & Taunton, 2001). The significant reduction in levels of malondialdehyde with the use of Farabloc is consistent with a decrease in lipid peroxidation and reduced cascade of free radical damage to cell membranes. The reduced elevation of creatine phosphokinase and myoglobin suggests that disruption of muscle cell membranes was lessened when Farabloc was used immediately after exercise. Farabloc is speculated to permit continued exposure to low frequency EMF, but effectively block high-frequency EMF which increased the cells' resistance to disruption. Changing the balance of the EMF toward lower frequencies may suppress free radical formation, by inhibition of iron-containing enzymes, limiting the potential cascade of lipid peroxidation that is characteristic of inflammation in delayed onset muscle soreness (DOMS) (Zhang et al., 2000). This study indicates that the use of Farabloc leads to a decrease in the blood markers for inflammation and cell destruction (Bach & Clement, 2007). These results suggest a substantial clinical reduction in post-exercise disability and limitation of muscle damage and neurological pain (Clement & Taunton, 2001).

In a study in 2007, by Bach and Clement, to investigate the effectiveness of Farabloc as an analgesic in primary fibromyalgia, quality of pain, quantity of pain and total paracetamol

dosage were significantly reduced in subjects that used Farabloc garments at night. The results of this study imply some alteration in somatic pain perception. This supports an analgesic effect with the use of Farabloc fabric when compared to placebo fabric for neurological pain (Bach & Clement, 2007).

In summary, in all of these studies, the absence of EMF - due to Farabloc, an electromagnetic shielding fabric, reduced pain in human subjects, who suffer from PLP, DOMS and fibromyalgia, when assessed in placebo-controlled cross-over designed studies. The exact mechanism behind these observations is still not known, however it is hypothesized that alteration in EMF may have biological effects secondary to stabilization of the cell membrane and enhancement of antioxidant properties. This could explain the reduced levels of anti-inflammatory markers in the DOMS study (Clement & Taunton, 2001). Alteration of EMF by shielding from high-frequency exposure could alter the permeability of the cell membrane, and the subsequent reduced transfer of ions may stabilize the cell's response to excess exercise. None of the studies reported any negative observations or side effects (Clement & Taunton, 2001).

Systematic reviews PLP interventions. In a systematic review by Halbert, Crotty and Cameron, 2002, regarding the optimal management of acute and chronic PLP, Farabloc research was only one of three studies to score the maximum of five points for a quality assessment. For late PLP (greater than 2 weeks post-operatively), this review agreed that there is evidence suggesting that Farabloc is an effective treatment (Halbert et al., 2002). These findings were echoed in a review by Stanndard, Kalso and Ballantyne, 2010, in which Farabloc was listed as an intervention, supported by evidence, for the management of PLP (Stannard, Kalso, & Ballantyne, 2010).

Mirror Therapy

History of Mirror Therapy. Mirror-box Therapy was initially introduced to treat upper extremity PLP by Dr. Vilayanur S. Ramachandran at the University of California, San Diego, in the early 1990s. Ramachandran was able to relieve PLP in 60% of his subjects in a study of ten subjects (Ramachandran & Rogers-Ramachandran, 1995).

In 2001, Herta, Flor and colleagues performed functional neuroimaging experiments to explore the neural reorganization that leads to PLP in upper extremity amputees, and discovered that Mirror Therapy can eliminate the remapping associated with PLP (Lotze, Flor, Grodd, Larbig, & Birbaumer, 2001). In this way it is theorized to “normalize the cortical reorganization in the brain” (Chapman, 2011). More recently, Jack Tsao et al. (2007) evaluated the effect of Mirror Therapy to treat PLP in lower extremity traumatic amputees (primarily due to blast injuries), in a randomized, sham-controlled trial of Mirror Therapy versus imagery therapy. Tsao reported that, “After four with four weeks of treatment, all patients using Mirror Therapy reported a decrease in pain” (Chan et al., 2007).

Although vascular amputations are more numerous, the majority of studies with Mirror Therapy have been conducted on amputees with lower extremity amputations due to traumatic amputations or with upper extremity amputations. Presently, there is little research on the use of Mirror Therapy with lower extremity amputees, due to vascular insufficiency or disease.

Theoretical Mechanisms involved in Mirror Therapy. According to Ramachandran, Mirror Therapy produces a modulation of pain pathways in the amputated limb through visually perceived movement of the amputated limb (Ramachandran & Rogers-Ramachandran, 1996). He explains that PLP may be induced by a conflict between visual feedback and proprioceptive representations of the amputated limb (Ramachandran & Hirstein, 1998). While periodic limb

movements during sleep and while awake do not activate central motor regions, normal descending motor information, retained and activated during purposeful “phantom limb movements” from the motor cortex is important in neutralizing the sensory (e.g. paresthesias and pain) and motor discomfort (urge to move) of the restless leg (Giummarra& Bradshaw, 2010). Simply imagining a motor sequence, which only activates the premotor regions, is insufficient to relieve motor discomfort (Skidmore, Drago, Foster, &Heilman, 2009). Intentional movement may also activate descending dopaminergic system in the striatum (Glasauer, 2001). This explains the need for purposeful physical movement, not just imagining the movements in order to obtain relief from motor discomfort. Thus the effectiveness of Mirror Therapy in reducing PLP with amputees might be explained by the theory that when a person performs or observes someone else’s performance, mirror neurons in the hemisphere of the brain that is contralateral to the amputated limb may be activated (Rossi, Tecchio, &Pasqualetti, 2002).

PLP has been associated with expansion of the amputated limb’s sensory or motor cortex map into nearby cortical structures. This reorganization appears to be both reversible and directly related to pain symptoms. The degree of pain reduction following rehabilitation correlated with normalization of the extent of primary sensory cortex. The ability to execute movements in the mirror suggests that the capability of the unaffected hemisphere to generate these postures can be transferred to the affected hemisphere if the affected motor system is provided with visual information that can replace, bypass or dominate the disturbance of kinesthesia (Bultitude&Rafal, 2009). Mirror therapy is thought to reverse this cortical remapping and thereby alleviate pain (Hanling, Wallace, Hollenbeck, Belnap, &Tulis, 2010). “Appropriate visual feedback (that matches the proprioceptive and motor feedback of a phantom sensation) can correct the mismatch between visual and proprioceptive and motor cues, thereby reducing

the symptoms of PLP” (Weeks & Tsao, 2010). Visual-kinesthetic feedback which combines observation and motor imagery has been shown to be beneficial to amputees experiencing PLP (Beaumont, Mercier, Michon, Malouin, & Jackson, 2011).

Published Mirror Therapy studies for lower extremity amputees. The first study to examine Mirror Therapy treatment in a person with a lower extremity amputation, who was reporting PLP, was conducted by MacLachlan, et al, 2004. This was an individual case study in which Mirror Therapy was used with a patient with PLP, who had been unable to obtain relief from other treatments or interventions. An increased sense of motor control of the phantom limb, and associated reduction in PLP, as previously reported with upper limb amputations, was observed. A “fading out” of therapist-mediated intervention was explicitly designed to encourage “ownership” of the treatment. Mirror Therapy exercises were directly supervised initially and the level of supervision was decreased as the subject demonstrated increased competency with demonstration of these exercises (MacLachlan, McDonald, & Waloch, 2004).

A landmark study was performed with 22 lower limb amputees by Tsao et al. (Chan et al., 2007). Patients were assigned to three groups: One that viewed a reflected image of their intact foot in a mirror, one that viewed a covered mirror, and one that was trained in mental visualization. Patients were instructed to attempt to move both their intact and amputated limbs or imagine performing the movements in the mental-visualization group. Under direct observation, patients performed their assigned therapy for 15 minutes daily for four weeks. The primary end point was the severity of pain after four weeks of therapy. The results indicated that pain intensity, as well as number, and duration of pain episodes decreased with Mirror Therapy. One hundred percent of patients in the Mirror Therapy group reported a decrease in pain, with a median change on the VAS of 24mm with a range of -54 to -13. Two patients had brief reactions

(< 2 minutes) of grief on viewing the reflected intact lower limb. In the covered-mirror group, only 17% indicated a decrease in pain, with 50% reporting worsening pain. In the mental-visualization group 33% reported a decrease in pain and 67% reported worsening pain. The mirror group differed significantly from the covered-mirror group and the mental-visualization group. PLP decreased in 89% who switched to the mirror therapy group after the four weeks.

This study provides support to Mirror Therapy being effective in reducing PLP in patients who had undergone amputation of lower limbs. It is suspected that this pain relief may be due to the activation of mirror neurons in the hemisphere of the brain that is contralateral to the amputated limb. These neurons fire when a person either performs an action or observes another person performing an action (Rossi et al., 2002). Alternatively, visual input of what appears to be movement of the amputated limb might reduce the activity of systems that perceive protopathic pain. Protopathic pain is described as sensing pain, pressure, heat, or cold in a nonspecific manner, usually without localizing the stimulus - used especially of certain sensory nerves (Henson, 1977). Although the underlying mechanism accounting for the success of this therapy remains to be fully elucidated, these results suggest that Mirror Therapy may be helpful in alleviating PLP in an amputated lower limb (Chan et al., 2007). In other studies, Mirror Therapy as a home program, has proven effective in decreasing PLP (MacLachlan, McDonald, & Waloch, 2004; Darnall, 2009).

PLP and Occupational Therapy. Occupational therapy intervention enables clients to maximize their independence during activities of daily living such as bathing, dressing, toileting, bathroom transfers, returning to work, and instrumental activities of daily living tasks such as cooking, cleaning, laundry, yard-work, money and medication management. If chronic pain impairs the client's ability to participate in activities that the client needs or wants to do,

decreasing the impact that this pain has on the client's participation, becomes important to the occupational therapist.

PLP can impact the roles, routines, habits and the self-concept of an individual with an amputation and negatively affect quality of life. Therapeutic techniques and modalities used by occupational therapists can decrease the effect that this chronic PLP has on the quality of life of our clients. By decreasing PLP, facilitating earlier prosthetic use and increasing functional participation in daily life activities, occupational therapists may help clients achieve their goals.

Summary.

From this research there is strong evidence that the absence of EMF, through the use of Farabloc, is effective in treating PLP, as well as other neurological types of pain. In other studies, Mirror Therapy research has been demonstrated to reduce PLP in upper as well as lower extremity amputees. The success of Farabloc appears to be due to the shielding of high-frequency EMF from entering the residual limb (an external process), while the effectiveness of Mirror Therapy appears to be due to the re-organization of the sensory-cortex (an internal process) and the pain relief is the “result of resolving the multisensory dissonance between visual and motor/proprioceptive systems” (Weeks & Tsao, 2010). Farabloc and motor imagery therapy were both identified as successful evidence-based nonpharmacologic therapies for PLP (Miller & Rodriquez, 2010). Once PLP pathways have been established they appear more difficult to eradicate and treat, therefore, it would seem critical to address the issue of PLP early in the process, soon after the amputation. Thus the purpose of this study was to investigate if the combined protocol using Farabloc and Mirror Therapy treatment, in the acute stages following surgery, would reduce the experience of PLP and increase the quality of life (QOL) for amputees

with an acute lower limb above or below knee amputation. The hypothesis is that a treatment protocol that targets external (peripheral) and internal (central) neuronal mechanisms simultaneously is likely to be able to reduce PLP more substantially than either treatments alone, particularly when used as an early intervention.

The primary research questions are:

What is the effectiveness of combining two interventions, Farabloc technology to eliminate electromagnetic fields and mirror therapy to assist in the sensory cortex reorganization, to decrease or eliminate phantom limb pain in above or below knee vascular amputees? The study also investigated whether 1) the intervention was effective with acute and chronic amputees and 2) whether improvement was maintained after intervention was discontinued.

Implications for activities of daily living and quality of life were measured as well as physical conditions of the amputee residual limb.

CHAPTER 3: Methods

Subjects

Sixteen subjects were recruited from January to July 2011 with all subjects completing the study requirements by September 2011. The subjects were recruited from a population of unilateral above or below knee vascular amputees. Eleven acute subjects were recruited from Vidant Medical Center, Greenville, NC and were identified with reference to the inclusion and exclusion criteria for this study. Five chronic subjects were recruited from the Eastern North Carolina Amputee Support Group and were included if they met inclusion criteria and were experiencing PLP. All subjects consented to participate. However, two subjects had medical complications that forced their elimination from the study, leaving nine subjects in the acute group.

Inclusion criteria. Adults 19 years of age or older, able to understand the use of a VAS, comprehend and write in English, with a minimum of 15cm of residual femur or tibia remaining over which an amputee limb cover could be placed. The only difference between the two groups was the time from amputation to beginning the study. Subjects in the acute group had surgery less than six weeks previously, while subjects in the chronic group had surgery more than six weeks previously.

Exclusion criteria. Individuals with bilateral lower extremity amputations; upper extremity amputations; guillotine amputations (delayed closure due to risk of infection), hip disarticulation amputations, foot, partial foot or toe amputations and individuals who were pending revision surgeries. Individuals were also excluded if they were involved in a compensation claim; had a diagnosis of neurological or psychological disorder that would interfere with the study; required dialysis; had a known uncontrolled systemic disease (i.e.,

cancer, lupus etc.); had a history of substance abuse or dependence; were unable to provide written consent and written authorization for use or release of health and research study information; had a prior history of vertebral disc disease/condition, sciatica or radiculopathy; were unable to follow study instructions or were unlikely to complete all required visits; were participating in another investigational drug or device study for phantom limb pain or had participated in these studies 30 days immediately prior to study enrollment; had any condition or situation that may have put the subject at significant risk, confounded the study results, or interfered significantly with the subject's participation in the study; subjects who were taking anti-convulsant/ neuropathic pain medications which exceeded maximum recommended daily dosages (e.g. pregabalin (Lyrica) 450mg/day, duloxetine (Cymbalta) 60 mg/day or gabapentin (Neurontin) levels 3600mg/day). Institution Review Board approval was received for this study and each subject signed consent before starting the study (Appendix A).

Demographics. Demographics were gathered in a brief pre-interview before doing any pretesting and are illustrated in Table 1. Sample group demographics represented the typical population of vascular amputee patients treated at Vidant Medical Center. Mean age for subjects was 59.43 years, SD = 9.96, range = 48 - 78, with the mean age for the acute group was 58.22 years, SD = 11.19, range = 48 – 78 years and mean age for the chronic group 61.60 years, SD = 7.92, range = 51-73 years. There was no statistically significant difference between the mean ages of the groups $t = .216$, $p = .832$. Seven of the sixteen were female and nine were males. The ethnicity of subjects included ten Caucasian, four African American and two of Hispanic origin. The subjects were evenly divided regarding the side of amputation (50% right and 50% left amputations), with five above knee amputations and eleven below knee amputations. Four subjects were working, three were on disability and nine were retired. The highest level of

education completed was high school for nine of the subjects and college for seven of the subjects, with six high school and five college graduates in the acute group, and three high school, with two college graduates in the chronic group. Average time from surgery until subjects began the study for the acute group was 35.5 hours, range = 26 – 48 hours, with the chronic group averaging 18.2 months since surgery, range = 8 – 28 months.

Design

This experimental pilot study used a repeated-measures design. There were two subject groups. Subjects were either assigned to the *acute* group if the amputation had occurred within six weeks of the beginning of the study or the *chronic* group if the amputation had occurred more than six weeks previously. All subjects were measured on the dependent variables, received the traditional amputee treatment protocol, as well as the experimental protocol combining Farabloc Therapy and Mirror Therapy for four weeks. The independent variable was the combined intervention therapy. Measurement of the dependent variables occurred at pre-treatment, immediately after the intervention (post-treatment) and after a four week period of no treatment (maintenance). There were multiple dependent variables that included: 1) physical measurements (e.g. edema, temperature of residual limb), 2) perception of phantom limb pain (e.g. intensity, frequency, duration, bothersomeness), 3) impact on the activities of daily living (e.g. self-care, walking ability, car transfers, low-chair transfers, sleep) and 4) well-being (e.g. satisfaction with how things worked out since amputation, mood and quality of life). Each of the dependent variables are explained below. For the variables that were the subject's perception, a visual analogue scale (VAS) was used. This unidimensional pain scale has been shown to be useful in the assessment of pain intensity (Hjermstad, et al., 2011).

Residual limb effects.

Edema: measured in centimeters (cm) around the widest part of the residual limb

Temperature amputee limb cover: measured in degrees Celsius (°C), temperature of residual limb covered with amputee limb cover

Temperature no cover: measured in degrees Celsius (°C), temperature of residual limb with no cover

PLP variables.

Intensity: Worst PLP daily, averaged over 4 weeks on a VAS in millimeters from

0 (no pain) to 10 (pain as bad as you can imagine)

Frequency: How often subjects experienced PLP over 4 weeks from

0 (never) to 6 (all the time)

Duration: How long each PLP episode lasts on a VAS in millimeters from

0 (I have none) to 6 (more than two days)

Bothersomeness: How bothersome PLP was over 4 weeks on a VAS in millimeters from

0 (extremely bothersome) to 100 (extremely mild)

ADL interference.

Self-care: the amount that PLP interferes with self-care tasks daily rated on a scale of

0 (Does not interfere) to 10 (Completely interferes)

Walking: the amount that PLP interferes with walking ability daily rated on a scale of

0 (Does not interfere) to 10 (Completely interferes)

Car transfer: ability to get in and out of car in the past four weeks using VAS, measured in millimeters from

0 (Cannot) to 100 (No Problem)

Low-chair transfer: ability to sit down and get up from chair with a low seat (e.g. an easy chair or deep sofa) in the past four weeks using VAS, measured in millimeters from

0 (Cannot) to 100 (No Problem)

Sleep: the amount that PLP interferes with sleep daily rated on a scale of

0 (Does not interfere) to 10 (Completely interferes)

Well-being.

Satisfaction: with how things have worked out since amputation, in the past four weeks using VAS, measured in millimeters from

0 (Extremely dissatisfied) to 100 (Extremely satisfied)

Mood : the amount that PLP interferes with mood daily, rated on a scale of

0 (Does not interfere) to 10 (Completely interferes)

QOL: Quality of Life in the past four weeks using VAS, measured in millimeters from

0 (Extremely dissatisfied) to 100 (Extremely satisfied)

Measurements There were three primary instruments used in this study. The Prosthetic Evaluation Questionnaire (PEQ) (Appendix B) which was completed at each of the three measurement periods. The Daily Log (Appendix C) and Brief Pain Inventory (BPI) (Appendix D) which were completed daily by each subject for eight weeks and were returned to the *Principal Investigator (PI)* after each four week period. Physical measurements were completed with each testing period to ascertain wound healing and included residual limb edema and temperature of residual limb.

Prosthesis Evaluation Questionnaire. The PEQ was developed to fill the need for a comprehensive self-report instrument for individuals with lower limb loss (Legro, 1998) and is widely used in rehabilitation health service research settings. The PEQ is divided into seven

Groups or topical sections, in order to categorize related issues, which include: Group 1 *Your Prosthesis/Amputee Limb Cover*, Group 2 *Specific Bodily Sensations*, Group 3 *Social and Emotional Aspects of Using a Prosthesis*(not be included in this study), Group 4 *Your Ability to Move Around*, Group 5 *Your Satisfaction with Particular Situations*, Group 6 *Your Ability to Do Your Daily Activities*, Group 7 *How Important Different Qualities of your Prosthesis/Amputee Limb Cover are to You*. The items in each Group include nine validated scales, with four included in this study: *Appearance, Residual Limb Health, Utility, and Well-Being*. There are also individual questions not combined into scale scores and include: *satisfaction, pain, transfer, prosthetic care, self-efficacy, and importance questions*.

Scoring. The PEQ is a self-administered questionnaire consisting of 82 items with a linear analog scale response format. The PEQ is composed of nine validated scales that are each comprised of multiple questions. The scales are computed from 42 items and include : *ambulation, appearance, frustration, perceived response, residual limb health, social burden, sounds, utility, well-being*. The forty remaining items pertain to other evaluation areas and are not grouped into to scales. The scales are not dependent on each other, making it possible to only use the scales pertinent to this study. A guide is provided which contains coding instructions for all the questions (“Prosthetic Evaluation Questionnaire Evaluation Guide”, 1998).

The linear visual analog scale format consists of a continuous numerical variable measured as the distance in millimeters from the left to endpoint of the line to the point at which the respondent's mark crosses the line. Each line is 100 mm long and is always measured from the left to right or from 0-100. All questions are worded so that a higher number will correspond with a more positive response. When a question is not applicable, it is coded "100" and or "nr" no response. Any question that is left blank is scored as a non-response and treated as missing.

To calculate the scale scores, the arithmetic mean is computed of all the questions answered by the respondent on that scale. A minimum of half the questions of a scale have to be answered, (i.e. not answered "nr") to be valid. For this study, the questions have been re-numbered from the original to make the questionnaire more usable.

Reliability. Two aspects of the PEQ's scale reliability were examined: internal consistency and temporal stability (Legro et al., 1998). The internal consistency of each scale was tested by computing a Cronbach's alpha and ranged from .73 to .89 for the 10 scales except for *Transfers*, which was .47 (Legro et al., 1998). The second reliability test determined the degree to which the scores were stable over time for subjects who had not experienced a change in health or prosthesis. The intra-class correlation (ICC) estimates for the mean scores of the first and second administration of the scales were calculated. The results ranged from $r = .79$ to $r = .90$ with two exceptions-*Perceived Responses* and *Frustration* (Legro et al., 1998).

Validity. The scales have been validated for internal consistency and temporal stability and are scored as a unit. To demonstrate whether the scales could differentiate between groups of people whose scale scores would be expected to be different, scores for the 10 scales were calculated for participants grouped by gender, age, presence or absence of co-morbidities, level of amputation, and years since the amputation. Statistical differences were found between men and women on two scales (Legro et al., 1998). Men reported significantly better for the variable *Ambulation* (70 versus 56 for women) and women reported a significantly greater *Social Burden* (34 versus 18). The scales of *Residual Limb Health* and *Frustration* have differed significantly across age groups such that younger patients identified more problems with their residual limbs and greater frustration, than participants who were 40 years or older (Legro et al., 1998). *Ambulation* scores differed significantly between those with and without co-morbidities such that those with no co-

morbidities reported better *Ambulation* (Legro et al., 1998). On the other hand, no statistically significant differences were noted due to amputation level or years since amputation, as indicated by correlations between $r = .49$ and $r = .61$ (Legro et al., 1998). In fact, the *Ambulation* scale was strongly correlated ($r = .61$) with the SF-36 subscale of physical function (Legro et al., 1998). The *Social Burden* scale of the PEQ demonstrated a strong negative correlation ($r = -.52$) with the social interaction score. This is as expected since a high *Social Burden* score indicates experiencing no social burden and a low score on the Sickness Impact Profile (SIP) subscale indicates no problem with social interactions (Bergner, Bobbitt, Carter, Gibson, 1981). Additionally, *Well-being* showed a moderate, negative correlation ($r = -.49$) with the total score on the Profile of Mood States – short form (POMS-sf) (Shacham, 1983). This is appropriate since a high score on the *Well-being* scale is a positive response and a low score on the POMS-sf indicates “low mental distress” (Legro et al., 1998, p. 935). Psychometric analysis supported the reliability and validity of the PEQ for evaluating the function of the prosthesis and the major health related quality of life domains. As questions on the PEQ are phrased within the past month, support from a recent study demonstrated that validity of the time frame (Broderick, Schneider, Schwartz, & Stone, 2010). Responses from the PEQ, should therefore be valid when compared to the two other assessments used in the study, the BPI and Daily Log.

Daily Log. The log included questions regarding adhering to the treatment protocol, the effect of PLP on sleep, duration of PLP episodes, as well as number of PLP episodes within 24 hours. Subjects were instructed to complete this log within one hour of waking up, daily for eight weeks. The Daily Log does not have standardized validity and reliability; however, such logs have been used elsewhere in research (Schumacher et al., 2002).

Brief Pain Inventory (BPI): Short Form. The BPI (Daut et al., 1983) was modeled after the McGill Pain Questionnaire (Melzack, 1975). The BPI is a 17 item patient self-rating scale assessing demographic data, use of medications, as well as sensory, and reactive components of pain. It identifies components of sensory pain including severity, location, chronicity and degree of relief due to therapy and reactive pain components including depression, suffering and perceived availability of relief. Pain ratings are performed daily which is a more accurate record of pain, when compared to scales in which recall periods are 3 days or longer (Broderick, Schneider, Schwartz, & Stone, 2010) .

Scoring. The BPI uses 0 to 10 numeric rating scales for item rating for simplicity, lack of ambiguity and cross-linguistic pain measurement. Subjects rate their pain at the time of responding to the questionnaire (pain now), and also at its worst, least, and average over the previous week. The ratings can also be made for the last 24 hours. Interference of function can be thought of as a reactive dimension. Because an effective intervention for pain control should demonstrate its effectiveness on more than a reduction in pain intensity alone, the BPI rates the degree to which pain interferes with mood, walking and other physical activity, work, social activity, relations with others, and sleep. The mean of these scores can be used as a pain interference score.

Validity. Validity of the relationship between the increased use of pain medications and high pain ratings was demonstrated for both narcotic ($\bar{x}=28.17$, $df=3$, $p<0.002$) and non-narcotic ($\bar{x}=23.75$, $df=3$, $p<0.002$) pain relievers (Fabry Registry, 2004-2010). Validity of the BPI was also supported by the moderate correlation between worst pain intensity ratings and ratings of interference with six areas of activity and mood ($r = .245$ to $.478$. $p<0.02$ for all but social relationships were $p<0.05$) (Fabry Registry, 2004-2010). There is a logical pattern in the

differences in inter-correlations among various pain and activity interference measures for different diseases.

Reliability. The BPI has demonstrated respectable test-retest item correlations; at least over short intervals (Daut, Cleeland, & Flannery, 1983). Evidence for the validity of the BPI comes from several studies using the instrument with cancer patients and patients with other diseases who had pain (Cleeland & Ryan, 1994). Expected differences in pain severity were found between groups of patients with pain who differed in the presence or absence of metastases. Ratings of pain interference with various activities increased as ratings of pain severity were higher. The proportion of patients receiving opioid analgesics increased with increased severity rating. The BPI has demonstrated over short intervals using test retest item correlation; worst pain, $r=.93$; usual pain, $r=.78$; pain now, $r=.59$ (Fabry Registry, 2004-2010). The correlations among the items differed in a logical way from one disease to another, suggesting that the BPI is sensitive to differences in pain characteristics associated with different diseases (Cleeland & Ryan, 1994).

Flexible Fabric Metric Tape Measure. This tape was used to examine wound healing properties and measure the edema of residual limb is an indicator of wound healing. Measurements were calculated in millimeters (mm), by obtaining a circumferential measurement at widest point of distal residual limb. Once each subject has been measured, the length from the end of the residual limb to the widest point of the residual limb was recorded, in order to ensure that the same circumferential measurement was documented with each measurement, for each subject.

Hubbard Scientific 6083 Liquid Crystal Temperature Strip (APPENDIX E). Skin temperature measurements were taken at all three measurement periods and included the

temperature of the residual limb both with and without coverings and the contralateral limb, as a baseline measurement. Measurements were taken in degrees Celsius.

Procedure

Institution Review Board (IRB) approval was sought and obtained from East Carolina University and Vidant Medical Center prior to beginning data collection. Potential subjects were identified by the Staff Research Assistant, at Vidant Medical Center, according to the inclusion and exclusion criteria. The Staff Research Assistant notified the principal investigator (PI) of these potential subjects. Individuals with acute amputations were on bed-rest per the current amputee protocol, when approached about the study. Individuals, who had amputation surgery more than six weeks earlier and complained of PLP, were also identified by the Staff Research Assistant, at the Eastern North Carolina Amputee Support Group. After completing the consent process, individuals were assigned to the appropriate group, acute or chronic, by the Staff Research Assistant.

Materials. The PI measured each subject's residual limb and fabricated two amputee limb covers using Farabloc technology, for each subject. Farabloc technology (Farabloc Development Corporation, 2012) uses a fabric that is woven using 9.5% steel wire fibers consisting of iron, nickel, chromium and nylon, which has significant shielding effects on high frequency EMF (greater than 1MHz) (Bach & Clement, 2007). This washable fabric has an appearance similar to linen (Bach & Clement, 2007) and can be tailored into an amputee limb cover that is worn over the stump/ residual limb. The dimensions for the Farabloc amputee limb cover was measured by the PI, using the distal circumference of the residual limb, and a proximal circumference a minimum of 15cm above this. The PI sewed two double layer cone-shaped amputee limb covers, with a three inch elastic section included within the covers

proximally to improve fit and Velcro closures proximally. These were worn over the stump dressing (4 x 4 gauze, dry dressing with liner to hold in place), and elastic shrinker, 23 hours/day for the acute group, and whenever the prosthesis was removed for the chronic group. Two were issued so that one could be worn while the other was hand-washed and air dried.

Pretesting. A Certified Prosthetist performed testing regarding the integrity and quality of the amputee limb cover material, prior to issuing product to the subject, to ensure that the amputee limb covers applied to subjects were functioning as anticipated. A continuity tester mini multi-meter was used to test the integrity of each amputee limb cover. The Certified Prosthetist measured the voltage that each amputee limb cover was conducting. All Farabloc amputee limb covers conducted electricity due to the metal fibers embedded within them, which demonstrated that the integrity of the fabric was intact. The PI kept a log (Appendix F) the readings obtained from each amputee limb cover. This testing occurred at pre-treatment and post-treatment.

Occupational therapy and physical therapy evaluations were initiated post-operation day one, per the standard acute amputee protocol. These evaluations include assessment of current functional level as well as education on the standard amputee treatment protocol. Chronic amputees completed this therapy at the time of their initial surgery. The education provided by therapists is described in an amputee booklet issued to all amputee patients. All subjects received this booklet, in which the care of residual limb, desensitization techniques for residual limb, instructions for donning stump-liner and stump shrinker, techniques and assistive devices for activities of daily living, mobility and functional transfers, durable medical equipment recommendations in preparation for discharge, as well as appropriate exercises for upper extremities and lower extremities are described. All subjects participating, regardless of group placement, met or exceeded standards of care.

Pre-treatment measures. For all the subjects in both groups, the PI administered the measurements prior to beginning the treatment protocol. For the acute subjects, this occurred within the first two days after amputation. For chronic subjects, upon consent, the PI administered measurements in their home, or at the prosthetist clinic. The measures included all the dependent variables described and were completed as appropriate in one session.

Intervention. Within 48 hours of surgery, the Certified Prosthetist provided two stump-liners and two stump shrinkers to all acute subjects per standard amputee treatment protocol. Chronic amputees were issued with stump liners and shrinkers on an ongoing basis, as needed, by a prosthetist. In addition all subjects received two Farabloc amputee limb covers. The amputee limb cover was placed over the stump-liner and stump shrinker.

For the acute subjects, the PI notified the assigned occupational therapists treating the subjects. Trained prior to the study on methods of intervention of Farabloc and Mirror Therapy protocols, these therapists followed the written instructions designed by the PI (Appendices G&H). The PI monitored the interventions to ensure the appropriate protocols were followed.

For the chronic group, the PI educated the subjects and family members on the Mirror Therapy and Farabloc protocol. The PI monitored the interventions telephonically by checking with chronic subjects and their families, to ensure the appropriate protocols were followed. The PI provided all subjects with an educational binder, with instructions regarding tasks that subjects were expected to perform daily throughout the duration of the study. The PI reviewed this material with each subject and required demonstration from each subject in order to verify comprehension. The PI provided each subject, with a 1/8" plexi-glass mirror (27 x 15") with instructions on how to perform the Mirror Therapy exercise protocol. The subject was asked for a demonstration of the Mirror Therapy exercise protocol to ensure there was an understanding.

The PI also provided instruction regarding how to don and care for the Farabloc amputee limb covers and provided printed instructions in an educational binder.

For the acute subjects, the hospital's discharge planners began the referral process to inpatient rehabilitation, or other discharge destinations as appropriate. Chronic subjects returned to their place of residence. The PI notified the appropriate therapist working with subjects in each setting about the subject's inclusion in this study. As appropriate, therapists assigned to follow up with the subjects were contacted. Each therapist was given verbal and written instructions via e-mail regarding the protocol and procedures, specifically regarding how to apply and care for Farabloc amputee limb covers and supervise subjects performing Mirror Therapy intervention. The PI monitored subjects and followed up with therapists in each setting to ensure that protocols for the study were adhered to. For chronic subjects who were living in their residences, the PI met with these subjects and their families after the Amputee Support Group monthly, or at the prosthetist's office.

Post-treatment Measures at four weeks. One week prior to the vascular clinic in which all acute subjects were seen four weeks post-surgery, the physician assistant notified the PI of the schedule for the acute subjects. Each subject was asked to bring their mirror, PLP documentation and amputee limb covers to this appointment. All dependent variables were measured by then PI. Testing regarding the integrity of the Farabloc amputee limb cover material was completed to ensure that the integrity of the fabric had remained intact. For the chronic subjects, the post-treatment measurements were done if they returned to the Eastern North Carolina Amputee Support Group, in the rehabilitation classroom at the end of the group, when all other members had left. The PI met the chronic subjects at the office of the prosthetist to conduct these measurements if the subject did not return to the Amputee Support Group. It was at this time that

the intervention was changed for all subjects. Subjects were instructed to continue with their Daily Log and BPI documentation as well as the standard treatment protocol. However, subjects were instructed not to use the Farabloc materials or perform Mirror Therapy intervention.

Maintenance measurements at eight weeks. The dependent variables were measured again for all subjects. Acute subjects attended the Amputee Clinic and the chronic subjects returned to the Amputee Support Group or their prosthetist's clinic. The PI collected the Daily Log and BPI documentation from the subject. Subjects were thanked for their participation and study materials were returned to subjects who requested their continued use.

Data analysis.

For each phase the mean and standard deviation was calculated for each variable, for all subjects. A complete block design analysis of variance was conducted for each variable with a .05 significance level. The week was the main effect and the individual was the blocking effect. The analysis was repeated for each group (acute and chronic) separately. An LSD post-hoc analysis was performed on all significant variables to compare the mean difference and standard error between time periods (pre-treatment to post-treatment, pre-treatment to maintenance and post-treatment to maintenance) using a significance level of .05 and 95% confidence interval.

CHAPTER 4: Results

Table 2 shows the results of the ANOVA for the combined subject groups. There were significant differences for all the variables (residual limb effects, phantom limb pain, ADL interference and Well-being), with the exception of the *temperature of the residual limb without the amputee limb cover* (control), *PLP duration* and *satisfaction*. These results suggest that the treatment was effective for subjects with chronic and acute amputations. However, when separating the two groups with separate ANOVAs, not all variables were significant, as seen in Table 3. Specifically the variables of *PLP intensity* ($p = .098$), *duration of PLP* ($p = .441$), *low chair transfers* ($p = .074$) and *satisfaction* ($p = .652$) for acute subjects were not significant. Variables of *edema* ($p = .983$), *residual limb temperature without amputee limb cover* ($p = .672$), *duration* ($p = .087$), *self-care* ($p = .160$), *walking ability* ($p = .219$), *car transfers* ($p = .301$), *low chair transfers* ($p = .162$) for chronic subjects were not significant. Marginally non-significant values for Well-being for the chronic group were also noted: *satisfaction* ($p = .054$), *mood* ($p = .055$), *QOL* ($p = .056$). All other variables were significant for both acute and chronic subjects.

Table 4 illustrates the post hoc analysis for the combined subject groups between the three time periods for all the significant variables for the combined group. A pattern of significant differences are evident from pre-treatment to post-treatment and from pre-treatment to maintenance for all significant variables (*edema, intensity of PLP, frequency of PLP, bothersomeness of PLP, PLP interference with self-care, walking, car transfers, low chair transfers, sleep, mood and quality of life*), with the exception of one variable, the *temperature of the residual limb with the amputee limb cover*. However, there are not significant differences between post-treatment and maintenance. This indicates that changes were more evident during the actual intervention of the Farabloc and mirror therapy. Exceptions to this pattern were noted

for residual limb *temperature with amputee limb cover*, which had significant differences from pre-treatment to maintenance as well as from post-treatment to maintenance.

Table 5 illustrates the post-hoc analyses of subjects in the acute and chronic groups across the three time periods. For the acute subjects, the same pattern emerged with significant differences from pre-treatment to post-treatment and from pre-treatment to maintenance, but not from post-treatment to maintenance for *edema, PLP frequency, and PLP bothersomeness, PLP interference with self-care, walking, car transfers, low chair transfers, sleep, mood and QOL*. For the chronic subjects, this pattern was shown for the variables of *PLP frequency, PLP bothersomeness* and PLP interference with *sleep*, suggesting that the intervention was effective as change stopped after discontinuation. This pattern indicates that significant differences are noted during the periods in which the treatment occurred but that significant differences were not noted during the period in which the treatment protocol was not being used.

A variation in this pattern was noted for the acute subjects, for the variable of *residual limb temperature with amputee limb cover*, in which there were significant differences from pre-treatment to maintenance and from post-treatment to maintenance (Table 5). Post-hoc analyses were not performed for the variables that were not significant in the initial ANOVA (e.g. *PLP intensity, PLP duration, PLP interference with car transfers, and satisfaction*) (see Table 3).

The variable of *residual limb temperature with amputee limb cover* for the chronic group also varied from the typical pattern and showed significant differences, for all time periods (see Table 5). *PLP intensity* was significantly different from pre-treatment to maintenance and from post-treatment to maintenance for the chronic subjects. Post-hoc analyses were not conducted the variables of *edema, residual limb temperature without a cover, PLP duration, PLP interference with self-care tasks, walking, car transfers, low chair transfers, satisfaction, mood or QOL*.

Table 6 illustrates the time from surgery until subjects were ready to be fitted with prosthesis. This was not a planned variable, but a real outcome measure for performance of clients. Chronic subjects were read to begin prosthetic fitting at 12 weeks post-surgery, whereas acute subjects (with the exception of two who had medical complications), were ready to begin prosthetic fitting at eight weeks. Wearing tolerance of prostheses increased from 0-2 hours pre-intervention to 8-12 hours per day for the chronic subjects. "For acute vascular amputee subjects, no prostheses are issued immediately after surgery (prior to intervention) per the vascular amputation protocol", Manalo, E., (personal communication, March 17, 2012), but after the intervention seven of the nine subjects were able to tolerate wearing prostheses between four and 10 hours per day. With the exception of the two with medical complications, all subjects in combined groups were able to use prosthesis after the intervention part-time (five subjects) or full-time (seven subjects) and return to work, for those working prior to surgery.

Table 7 illustrates an observation of residual limb temperatures. A mean difference of 1.18°C was noted for subjects in the combined group, between *residual limb temperature with amputee limb cover* versus *residual limb temperature without cover*. For the *residual limb temperature without amputee limb*, mean was 32.3°C, SD = 8.44, range = 30 to 33.5°C, with a confidence interval of [31.4, 33.1]. For the *residual limb temperature with amputee limb cover*, mean was 29°C, SD = 8.44, range = 29 to 34°C with a confidence interval of [24.13, 33.87], and were an average 1.18 °C cooler when wearing the amputee limb cover. This indicates a significant difference for the residual limb temperature with and without the amputee limb cover ($p < .001$).

Discussion

The purpose of this study was to investigate the effectiveness of combining two phantom limb pain treatments with vascular amputees, specifically, the absence of electromagnetic fields

using Farabloc technology (external source) and implementing Mirror Therapy as a method of sensory cortex reorganization (internal source) to reduce phantom limb pain. The results suggest that the combination of these therapies, significantly reduced PLP for both acute and chronic vascular amputees. For all fourteen subjects, there were significant differences noted from before to after treatment intervention and even after treatment stopped on the majority of the measurements, including physical measures, reported pain or discomfort, ADL performance and quality of life. No significant differences were noted for residual limb temperature without amputee limb cover, which acted as a control for each subject, PLP duration or satisfaction with how things had worked out since the amputation for the combined group. When analyzed further it was clear that there were differences between the two groups based on whether the individual was recovering from an acute amputation or their amputation was more remote. Overall, individuals with acute amputations having greater gains in residual limb healing, occupational performance measures, and well-being, while the individuals with chronic amputations, had greater gains in PLP intensity reduction.

An unexpected and significant result of this study was the decreased time from surgery until acute amputees were ready for prosthetic fitting. In accordance to typical vascular amputee protocols for this facility, (personal communication Manalo, E., 17 March, 2012) fitting of a prosthesis occurs around 12 weeks post amputation and this was true for 5 of the 5 chronic subjects. However, in this study, use of the two treatments appeared to reduce edema and accelerate wound healing so significantly, that all but two of the acute participants, seven of the nine acute amputees (78%), were ready for prosthetic fitting an average of four weeks early. The implications of this finding are considerable, as it could improve individual health outcomes as well as society outcomes in terms of cost. Currently the majority of amputee intervention is

provided by occupational therapists in acute or in-patient rehabilitation settings. Use a more effective treatment protocol to improve residual limb healing for acute amputees would decrease the time until acute amputees can become functional prosthetic users, improving functional independence, decreasing cost of services as well as reducing PLP for improving in quality of life outcomes.

Objective Measures

Edema. For the combined group there were significant differences with respect to residual limb edema. Although amputees are encouraged to exercise their residual limb, they are not always able to do so. With this study's protocol increased active motion of the residual limb was evident when subjects performed bilateral lower extremity movements during mirror therapy exercises. This increased active motion may explain some of the decreased edema noted with the use of this treatment protocol, as edema has been shown to decrease with active motion (Colditz, 2011).

As noted, *edema* decreased significantly for the acute group with the use of this treatment protocol. Although edema continued to decrease there was not a significant difference between post-treatment and maintenance. Significant changes were noted during periods in which the amputee limb cover was worn. Although it is not surprising that edema would decrease to some extent with this group, the marked decrease in edema that facilitated earlier prosthetic wear, was remarkable. A more likely explanation for the edema reduction may be the high frequency EMF shielding effects of the amputee limb cover. High frequency EMF increases cell permeability (Bach & Clement, 2007), so the absence of high frequency EMF provided by the amputee limb cover may mean that the cells are less permeable with a reduction in cell membrane fluidity and an increase in superoxide dismutase, which has anti-

inflammatory properties (Bordiushkov et al., 2000). This has been shown in other studies. Coupled with the increased exercise, the combination of these two therapies, have important implications for treatment.

Edema reduction was not anticipated for the chronic group, as wound healing was complete with this group. However, what was significant was the increased tolerance that the chronic group noted for wearing their prostheses. Logs of the subjects show that four of the five subjects reported an increase in their prosthetic wearing time and another was able to wear their prosthesis for the first time since surgery, 17 days after initiating treatment protocol. Chronic vascular amputees frequently struggle with prosthetic fitting and wearing, due to volume changes in the residual limb (Klute, Berg, Biggs, Pongnumkul, Popovic, & Curless, 2011). Farabloc can be incorporated into the socket of prostheses which may result in stabilization of residual limb volume, due to stabilization of muscle cell membranes (Clement & Taunton, 2001) and improved consistency with prosthesis wearing.

Residual limb temperature. *Temperature of residual limb with no cover* was the control for each subject to compare the *temperature of residual limb with the amputee limb cover*. Residual limb temperatures were an average of 1.18°C cooler for the combined group of subjects, when wearing the Farabloc amputee limb cover, than without the amputee limb cover. This reduction, could possibly be due to the shielding effects and absence of high frequency EMF, and appears to be associated with the reduction in PLP.

This suggests that the differences in temperature are related to the use of the Farabloc amputee limb cover, as all subjects used the same treatment protocol throughout the study. Since excessive heat and sweating of the residual limb within the socket of a prosthesis is the primary complaint for amputees and this decreases wearing time and QOL (Huff, Ledoux, Berge,

& Klute, 2008), these results suggest that fabrication of prosthesis sockets with the Farabloc fabric could lead to a decrease in temperature which may increase wearing times further and corresponding participation in life.

These results were not anticipated and the implication of the residual limb temperature reduction is not clear. The reduced inflammatory response, resulting in a reduction of leukocytes and neutrophils as blood markers for inflammation and cell destruction (Clement & Taunton, 2001) while wearing the amputee limb cover, may be one explanation for the temperature reduction. Despite this decrease in temperature, users perceived an increase in temperature while wearing the Farabloc amputee limb cover. These results are similar to another study in which users of Farabloc garments also perceived increased temperatures (Bach & Clement, 2007).

This is the first study using Farabloc technology in which the temperature of the residual limb with and without the cover was measured. Unfortunately, temperature readings with the use of the Hubbard Scientific 6083 Liquid Crystal Temperature Strip thermometer are not sufficiently sensitive. Improved accuracy of temperature readings would be required before clear associations could be made between residual limb temperatures and PLP reduction. Additionally wound bed temperature was not measured which might indicate wound healing. The initial results here warrant further investigation, and would be an interesting aspect of further research. Further continued research into lowering of residual limb temperatures with prosthesis use is needed to improve the QOL for these amputees.

PLP Subjective Measures

PLP Variables.

Intensity, Frequency, Duration and Bothersomeness of PLP. Significant decreases in phantom limb pain intensity, frequency and bothersomeness for the combined group were noted

during the treatment period and this reduction continued through the maintenance period, indicating a continued treatment effect. The long-term effects of this reduction require further investigation to establish whether these continued treatment effects are maintained. Individuals with vascular disorders from disease processes such as diabetes, frequently suffer from peripheral neuropathic pains for many months or years prior to an amputation (Health, 2011). Once neuropathic pain is established it is extremely difficult to eradicate (Nikolajsen & Jensen, 2001), therefore a treatment which was able to decrease the intensity of neuropathic pain prior to an amputation may lead to an even greater improvement in intensity, frequency and bothersomeness of PLP after amputation. The shielding properties of a Farabloc garment, such as those used in another study (Bach, 2007), may be useful in preventing this neuropathic pain.

Decreases were also noted in duration of phantom limb pain for the combined group; however these decreases were not statistically significant. The brevity of the treatment protocol period (four weeks) might have influenced this result. Further research is required to ascertain the optimal treatment period, as well as long-term maintenance results of this treatment protocol.

Overall, the significant decreases noted during the treatment period of PLP frequency and bothersomeness are important for the acute group in order to maximize their ability to participate in the rehabilitation process, which occurs within the first month after surgery. PLP intensity and duration did not significantly decrease for the acute group, however if reductions in the other two variables are noted, an overall improvement of participation can be anticipated, as demonstrated by this study.

Similarly, significant improvements were noted for PLP intensity, frequency and bothersomeness for the chronic group. These findings are promising, as all subjects in the chronic group agreed to participate in this study because they had PLP which interfered with

their function and QOL. Despite the time since surgery (an average of 18.2 months), these subjects were able to benefit from this treatment protocol in managing their PLP symptoms. This implies that occupational therapists can use this treatment protocol to help amputees deal with chronic PLP symptoms, which may continue to limit their participation with ADL tasks.

ADL Interference.

Significant reductions for the combined group were noted for PLP interference with self-care, walking ability, car transfers, low chair transfers and sleep. The mean value improved from pre-treatment to post-treatment and then again from post-treatment to maintenance, indicating a continuation of treatment effect for all categories of variables. PLP interference decreased significantly for all tasks for the acute group during the treatment and maintenance periods, with the exception of low chair transfers which was not significant for either the acute or chronic group, possibly due to a lack of power when the groups were divided. Low chair transfers represent a variety of different heights of surfaces, which can increase the difficulty of the transfer depending on the transfer performed e.g. transfer-board transitions as opposed to stand-pivot transfers, which may vary as subjects strength improved and have little to do with PLP interference. The differences noted with low-chair transfers may have been due to the lack of standardization of the term “low” which could represent a variety of heights of surfaces. This was a limitation of the PEQ evaluation tool. Despite this lack of standardization, significant improvements were noted for all ADL tasks. The use of a treatment protocol to increase acute amputee participation in ADL tasks is especially important for occupational therapists, as this is the population of amputees with whom the majority of occupational therapy interventions occur.

This treatment protocol appears to have had a more of an effect on reducing the interference of PLP on ADL tasks with the acute group, as compared to the chronic group.

Compensation techniques learned by the chronic amputees to adapt to their functional limitations, may be influential in limiting the effect that PLP interference has on ADL task performance, as chronic amputees have well established roles and routines.

Significant reductions were noted with PLP interference with sleep. The decrease in PLP interference with sleep for both groups is most encouraging. Amputees frequently report increased PLP symptoms at night and report sleep disturbances due to PLP, which influences all other ADL tasks and falls within the occupational therapy scope of practice (AOTA, 2009). A treatment protocol, in which occupational therapists can positively influence the amount that PLP interferes with sleep for all amputees, is important. These types of evidence-based treatment interventions are exactly what the occupational therapy profession needs to expand our toolboxes and maximize the functional outcomes of our clients.

Well-being.

Statistically significant improvements in mood and QOL were observed for the combined group during the treatment and maintenance periods. Post hoc comparisons for the acute group did not demonstrate statistically significant differences for satisfaction with how things had worked out since amputation. An explanation for the decreased satisfaction experienced by amputees in the acute group may be explained by the following, “Vascular amputees are frequently frustrated by the increased time required for wound healing and the resulting functional limitations of remaining at a wheelchair level for approximately three months, as opposed to using a lower extremity prosthesis immediately.” (Personal communication, Faulk, C., March 17, 2012). An area of further investigation would be to compare acute non-vascular amputees who are able to be fitted with early post-operative prostheses (E-P.O.P.), compared to vascular amputees who have to remain primarily at a wheelchair level of function due to wound

healing issues, because of their disease process. It is postulated that satisfaction improvements would be noted with amputees using an E-P.O.P. as opposed to amputees who remain at a wheelchair level of function. Subjects in the chronic group reported differences for satisfaction, mood and QOL during the treatment and maintenance periods, however these were marginally not statistically significant.

In conclusion, the results of this study are promising as they indicate significant differences for all categories of variables (residual limb, PLP, ADL interference and Well-being) for all subjects. The majority of these differences occurred during time period in which the treatment protocol was actively being used by subjects, which indicates that the differences noted were associated with the use of the treatment protocol. Despite the lack of discernible change during the maintenance period, the differences achieved from pre-treatment to post-treatment continued through the maintenance period for all significant variables. This demonstrates that differences noted with the implementation of the treatment protocol were not eradicated after the treatment protocol had ended.

A decrease in PLP leads to a subsequent increase in participation of daily life activities because pain and discomfort no longer limit participation. In fact, this was shown in the results. Specifically that both groups demonstrated significant improvements regarding reduction of PLP, increased participation in ADL tasks and a corresponding improvement in well-being. There does not appear to be a distinct advantage to using this treatment protocol with acute amputees as compared to chronic amputees. Both groups benefitted from the use of this treatment protocol. The implications of this study are that through the use of this treatment protocol, occupational therapists can have a positive influence in reducing PLP, reducing the

amount that PLP interferes with ADL tasks and improving Well-being, which would help our amputee clients meet their goals, to maximize functional independence and improve their QOL.

Implications of Functional Outcomes

As discussed, the implications for decreasing time from amputation surgery to initial fitting of the prosthesis for the acute participants in this group was an unexpected and very positive result. Equally unexpected and impressive was the impact of the treatment protocol on the individuals with amputations that had already been fitted with prosthesis, but were not wearing them due to discomfort and pain. The impact on the functional performance of these clients is significant as outlined in the following short descriptions.

A 73 year-old Caucasian male had pre-existing diabetic peripheral neuropathy prior to his amputation and spent the majority of his time on the couch. Prosthetic use was limited to two hours per day. After completing the treatment protocol, he is wearing his prosthesis ten hours per day. He has resumed yard work, going out to eat with his wife, and attending out-patient physical therapy sessions to improve his gait patterns.

Prior to the study, this 51 year-old Hispanic woman was incapacitated and remained in bed with PLP every 30 minutes. She was unable to tolerate wearing her prosthesis and the pain severely limited her quality of life, including participating in the care of a teenage daughter. Incredibly, within 17 days of beginning the protocol, she was tolerating wearing her prosthesis an average of 8 hours per day. She has return to important roles in her life, including that of mother, with significant improvement in her quality of life.

One participant was unable to use her prosthesis due to complications of wound healing; including negative pressure wound therapy and revision of the amputation to improve the shape of her residual limb. After the eight week study, this 63 year-old Caucasian female was able to

fit and wear her prosthesis during her waking hours (12 hours per day). She has returned to community participation tasks, particularly meaningful church attendance with significant quality of life improvement.

Finally, a 62 year-old African American male was only able to tolerate wearing his prosthesis for two hours per day due to phantom limb pain interfering with functional tasks. Since completing the study's protocols, he is able to tolerate wearing his prosthesis for 12 hours per day. This participant reports that he puts his prosthesis on in the morning when he gets up and takes it off at night when he goes to bed, with increased participation in occupational roles and routines greatly improved.

Limitations

Results of this study are limited primarily due to the small sample size, which decreases the ability to generalize the findings of this study to the larger population of vascular amputees. The variety of settings (acute, rehabilitation, home) in which the subjects used the treatment protocol, is also a limitation, as this increases the number of external influences which may have an effect on these results. The choice to use vascular amputees compared with traumatic amputees, also increases the co-morbidities involved in this study. However, the positive results of this study on subjects with more complex medical conditions - than might be typical of a traumatic amputation, leads to further support the outcomes. Clearly, the same protocols need to be applied to other amputee populations.

Another limitation was the relatively short length of time that individuals with acute amputations tend to remain in acute care and in-patient rehabilitation settings, in which the conditions can be closely monitored. Vidant Medical Center and Vidant Health serves 29 surrounding counties, therefore monitoring therapy conditions upon discharge from this facility

was challenging. The PI was diligent about educating therapists in an identical and systematic manner so that those who would directly work the clients in home-health, out-patient, or rehabilitation, were educated regarding the identified treatment protocols. Subjects were given written instructions, a home-exercise program to follow upon discharge and follow-up calls weekly by the PI, which assisted with compliance to the treatment protocol. It would seem that the strategies implemented were effective, as results were evident for both groups of subjects – even for a small sample.

A limitation may be that there was no control group of subjects without the Farabloc or not using the mirror therapy. This is a significant limitation. It is possible that the subjects improved simply because they were getting additional attention and motivated to improve. However, the physical changes of the residual limb as well as the significant improvements in the quality of life, particularly for the chronic group, seems to be more than can be expected from any placebo effect, making this unlikely.

Summary and Conclusions

This study aimed to ascertain the effectiveness of using a combined treatment protocol of eliminating electromagnetic fields by use of the Farabloc technology and the exercise program of Mirror Therapy. The main hypothesis was that the combined treatment protocol would have a more significant effect than either treatment in isolation. Decreasing edema and the discomfort due to phantom limb pain would improve the functional activities and quality of life of vascular amputees with lower extremity amputations. This was found to be true. A specific hypothesis question was whether the intervention effects would remain after a four-week period of no intervention (maintenance). Results varied between the acute and chronic subjects, but overall the changes were maintained, if not improved, for all subjects, suggesting that the combined

intervention of the two treatments has a biological impact that will remain once intervention is over. Further research will be needed to determine the ideal length of intervention.

Finally, the last hypothesis questioned the impact of the interventions on quality of life. All the quantitative measures suggested that the subject's quality of life was improved. However, the unexpected decrease of time between amputation and prosthetic fitting for those with acute amputations has major implications for recovery of functional tasks and quality of life. Even more significant was the resultant changes for the individuals with previous amputations, who were either not wearing their prosthesis or wearing them for very limited periods of time. For these five subjects, the increased tolerance and use of their prosthesis and the impact this will have on their return to functional participation in their activities of daily living, is substantial and noteworthy.

With the limitations of such a small sample, it will be critical to expand this study to a larger population, using a multi-site study, randomly selected from a variety of geographic areas increasing the reliability and generalizability of results. A double-blind cross-over design in which placebo amputee limb covers could be compared to Farabloc amputee limb covers would also be beneficial to decrease the placebo effect. Additionally, the use of the protocols with traumatic amputees and upper extremity amputees would be beneficial.

Results of this study could have far reaching impact. If research continues show the same results, an alternative treatment protocol to decrease the debilitating effects of PLP in amputees would be established. This protocol provides a cost-effective, drug-free alternative to current PLP treatments. This combined treatment protocol reduces PLP to the extent to which amputees can increase participation in their activities of everyday life and subsequently improve their QOL. Further, if the time between amputation and prosthetic fitting can be decreased, as it has in

this study, medical costs can be significantly reduced and function and quality of life for our older adults with vascular disorders can be improved.

REFERENCES

- American Academy of Orthotics and Prosthetics.(2005). Pain management for the lower-limb amputee.
- Amputee statistics by cause. Limb loss in the United States. (2008). Retrieved from http://www.amputee-coalition.org/fact_sheets/amp_stats_cause.html
- Amputee. (2009). In *The American Heritage® Dictionary of the English Language* (4th ed.)
- Arnstein, P. M. (1997). The neuroplastic phenomenon: a physiologic link between chronic pain and learning. *The Journal of Neuroscience Nursing*, 29, 179-186.
- Bach, G. L. (1987). Farabloc™ in the Treatment of Phantom Pain, Rheumatic Pain and Other Painful Symptoms.
- Bach, G. L., & Clement, D. B. (2007, March). . Efficacy of Farabloc as an analgesic in primary fibromyalgia, 26(3), 405-410. DOI: 10.1007/s10067-006-0494-9
- Bergner M, Bobbitt RA, Carter WB, Gilson BS. The Sickness Impact Profile: development and final revision of a health status measure. *Medical Care* 1981; 19:787-805.
- Beaumont, G., Mercier, C., Michon, P.-E., Malouin, F., & Jackson, P. L. (2011, February). Decreasing phantom limb pain through observation of action and imagery: a case series. *Pain Medicine*, 12(2), 289-299.
- Bordiushkov, I. N., Goroshinskaia, I. A., Frantsiiants, E. M., Tkacheva, G. N., Gorlo, E. I., & Neskubina, I. V. (2000, Jan-Feb). Structural-functional changes in lymphocyte and erythrocyte membranes after exposure to alternating magnetic field. *Vopr Med Khim*, 46(1), 72-80.
- Broderick, J. E., Schneider, S., Schwartz, J. E., & Stone, A. A. (2010, June 11). Interference with activities due to pain and fatigue. *Quality of Life Research*, 19(8), 1163-1170.
- Brodie, E. E., Whyte, A., & Waller, B. (2003, May 1). Increased motor control of a phantom leg in humans results from the visual feedback of a virtual leg. *Neuroscience letters*, 341(2), 167-169. DOI: 10.1016/S0304-3940(03)00160-5
- Bultitude, J. H., & Rafal, R. D. (2009, December 6). Derangement of body representation in complex regional pain syndrome: report of a case treated with mirror and prisms. *Experimental brain research*.
- Byrne, K. P. (2011, May). Survey of phantom limb pain, phantom sensation and stump pain in Cambodian and New Zealand amputees. *Pain Medicine*, 12(5), 794-798.

- Chan, B. L., Witt, R., Charrow, A. P., Magee, A., Howard, R., Pasquina, P. F., Heilman, K. M., & Tsao, J. W. (2007, November 22). Mirror Therapy for Phantom Limb Pain. *New England Journal of Medicine*, 357(21), 2206-2207.
- Chapman, S. (2011, January 12). Pain management in patients following limb amputation. *Nursing Standard*, 25(19), 35-40.
- Choudhury, A. (2009). *Statistical correlation*. Retrieved January 15th, 2012, from Experimental Resources.com: <http://www.experiment-resources.com/statistical-correlation.html>
- Cleeland, C. S., & Ryan, K. M. (1994, March). Pain Assessment: Global Use of the Brief Pain Inventory. *Annals, academy of medicine, Singapore*, 23(2), 129-138. Retrieved from http://www.painknowledge.org/physiciantools/opioid_toolkit/components/Cleeland_Article.pdf
- Clement, D. B., & Taunton, J. E. (2001, December). Alleviation of pain with the use of Farabloc, an electromagnetic shield: A review. *British Columbia Medical Journal*, 43(10), 573-577.
- Colditz, J. C. (2011). Therapist's management of the stiff hand. In T. M. Skirven, L. Osterman, J. M. Fedorczyk, & P. C. Amadia, *Rehabilitation of the hand and upper extremity, sixth edition* (pp. 1021 - 1029). Philadelphia, PA: Mosby, Inc.
- Conine, T. A., Hershler, C., Alexander, S. A., & Crisp, R. (1993). The Efficacy of Farabloc™ in the Treatment of Phantom Limb Pain. *Canadian Journal of Rehabilitation*, 6(3, 993), 155-161.
- Cramer, J., Rosenheck, R., Xu, W., Henderson, W., Thomas, J., & Charney, D. (2001). Detecting Improvement in Quality of Life and Symptomatology in Schizophrenia. *Schizophrenia Bulletin*, 27, 227-234. Retrieved from <http://schizophreniabulletin.oxfordjournals.org>
- Culver, A. (2009). *There is evidence showing mirror therapy to reduce phantom limb pain in adult clients with lower limb amputations*. Retrieved from <http://commons.pacificu.edu/otpf/6>
- Darnall, B. D. (2009, January). Self-Delivered Home-Based Mirror Therapy for Lower Limb Phantom Pain. *American journal of Physical Medicine and Rehabilitation*, 88(1), 78-81. DOI: 10.1097/PHM.0b013e318191105b
- Daut, R. L., Cleeland, C. S., & Flannery, R. C. (1983). Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases. *Pain*, 17, 197-210.
- Davis, K. D., Kiss, Z. H., Luo, L., Tasker, R. R., Lozano, A. M., & Drostovsky, J. O. (1998, January 22). Phantom sensations generated by thalamic microstimulation. *Nature*, 391, 385-387. DOI: 10.1038/34905

- Davis, R. W. (1993). Phantom sensation, phantom pain, and stump pain. *Archives of Physical Medicine and Rehabilitation*, 74, 79-91.
- DelleMijn, P. (1999). Are opioids effective in relieving neuropathic pain? *Pain*, 135, 453-462.
- Devor, M., & Seltzer, Z. (1999). Pathophysiology of damaged nerves in relation to chronic pain. (4th ed.). Retrieved from <http://www.sciencedirect.com>
- Devor, M., Janig, W., & Michaelis, M. (1994). Modulation of activity in dorsal root ganglion neurones by sympathetic activation in nerve-injured rats. *Journal of Neurophysiology*, 71(1), 38-47.
- Doubell, T. P., Mannion, R. J., & Woolf, C. J. (1999). The dorsal horn: state-dependent sensory processing, plasticity and the generation of pain. *Textbook of Pain*, 4th edition, 165-181.
- Draganski, B., Moser, T., Lummel, N., Ganssbauer, S., Bogdahn, U., Haas, F., & May, A. (2006). Decrease of thalamic gray matter following limb amputation. *Neuroimage*, 31, 951-957. DOI: 10.1016/j.neuroimage.2006.01.018
- E-hand.com. (n.d.). *Complications in Hand Surgery*. Retrieved March 11, 2012, from E-hand.com: <http://www.eatonhand.com/complic/text03.htm>
- Endolite USA. (n.d.). http://www.endolite.com/edu_glossary.php
- Ephraim, P. L., Wegener, S. T., Mackenzie, E. J., Dillingham, T. R., & Pezzin, L. E. (2005). Phantom pain, residual limb pain, and back pain in amputees: results of a national survey. *Archives of Physical Medicine and Rehabilitation*, 86, 1910-1919.
- Evans, F. J. (1974). The placebo response in pain reduction. *Advances in Neurology*, 4, 289-296.
- Fabry Registry. (2004-2010). Brief Pain Inventory. Retrieved from https://www.lsdregistry.net/fabryregistry/hcp/partic/assess/freg_hc_p_BPI.asp
- Farabloc. (1993). <http://www.farabloc.com/mUBC.html>
- Farabloc Development Corporation. (2012, February 29). *Farabloc Development Corporation*. Retrieved March 1, 2010, from Farabloc Development Corporation Web site: www.farabloc.com
- Flor, H. (2002). Phantom-limb pain: characteristics, causes, and treatment. *The Lancet Neurology*, 1, 182-189.
- Flor, H. (2008). Maladaptive plasticity, memory for pain and phantom limb pain: review and suggestions for new therapies. *Expert Review of Neurotherapeutics*, 8(5), 809-818.

- Flor, H., Elbert, T., Knecht, S., Wienbruch, C., Pantev, C., Birbaumer, N., Larbig, W., & Taub, E. (1995, June 8). Phantom-limb pain as a perceptual correlate of cortical reorganization following arm amputation. *Nature*, 375(6531), 482-484.
- Flor, H., Elbert, T., Muhn timer, W., Pantev, C., Wienbruch, C., & Taub, E. (1998). Cortical reorganization and phantom phenomena in congenital and traumatic upper-extremity amputees. *Experimental Brain Research*, 119, 205-212.
- Florence, S. L., & Kaas, J. H. (1995). Large-scale reorganization at multiple levels of the somatosensory pathways follows therapeutic amputation of the hand in monkeys. *Journal of Neuroscience*, 15, 8083-8095.
- Giuffrida, O., Simpson, L., & Halligan, P. W. (2010). Contralateral Stimulation, using TENS, of phantom limb pain: two confirmatory cases. *Pain Medicine*, 11(1), 133-141.
- Giummarra, M. J., & Bradshaw, J. L. (2010). The phantom of the night: restless leg syndrome in amputees. *Medical Hypotheses*, 76, 967-972. DOI: 10.1016/j.mehy.2009.12.009
- Glasauer, F. E. (2001). Restless legs syndrome. *Spinal Cord*, 39(3), 125-133.
- Gudin, J. A. (2004). Expanding our understanding of central sensitization. *Medscape Neurology & Neurosurgery*, 6(1).
- Halbert, J., Crotty, M., & Cameron, I. D. (2002, March/April). *Evidence for the Optimal Management of Acute and Chronic Phantom Pain: A Systematic Review*, 18(2), 84-92.
- Halligan, P. W., Zeman, A., & Berger, A. (1999, September 4). Phantoms in the brain - question the assumption that the adult brain is "hard wired". *British Medical Journal*, 319(7210), 587-588.
- Hanling, S. R., Wallace, S. C., Hollenbeck, K. J., Belnap, B. D., & Tulis, M. R. (2010, February). Pre-amputation mirror therapy may prevent development of phantom limb pain: a case series. *Anesthesia & Analgesia*, 110(2), 611-614.
- Harden, R. N., Houle, T. T., Green, S., Remble, T. A., Weinland, S. R., Colio, S., Lauzon, J., & Kuiken, T. (2005, March). Biofeedback in the treatment of phantom limb pain: A time-series analysis. *Applied Psychophysiology and Biofeedback*, 30(1), 83-93. DOI:10.1007/s10484-005-2177-8
- Hareendran, A., Doll, H., Wild, D., Moffatt, C., Musgrove, E., Wheatley, C., & Franks, P. (2007). The venous leg ulcer quality of life (VLU-QoL) questionnaire: development and psychometric validation. *Wound Repair and Regeneration*, 15, 465-473.
- Harlfinger, O. (1991). Weather-induced effects on pain perception. *Fortschr Medical Journal*, 109, 647-650.

- Harness, N., & Pinzur, N. S. (2001). Lower Extremity - Health Related Quality of Life in Patients with Dyvascular Transtibial Amputation. *Clinical Orthopaedics and Related Research*, 383, 204-207. DOI: 10.1097/00003086-20010200-00023
- Harris, A. J. (1999, October 23). Cortical origin of pathological pain. *The Lancet*, 354(9188), 1464-1466.
- Harrison, T. (2011, March). *Minnesota Medicine*. Retrieved February 29, 2012, from Minnesota Medical Association: <http://www.minnesotamedicine.com/tabid/3692/Default.aspx>
- Health, N. I. (2011, August 10). *Peripheral Neuropathy Fact Sheet*. Retrieved March 17, 2012, from National Institute of neurological disorders and stroke: http://www.ninds.nih.gov/disorders/peripheralneuropathy/detail_peripheralneuropathy.htm
- Helm, S., II (2008). Retrieved from <http://www.medicinenet.com/script/main/art.asp?articlekey=88097>
- Henson, R. A. (1977). Henry Head: his influence on the development of ideas on sensation. *British Medical Bulletin*, 33, doi: Retrieved from www.nejm.org
- Henson, R. A. (1977, May). Henry Head: his influence on the development of ideas on sensation. *British Medical Bulletin*, 33(2), 91-96.
- Hill, A. (1999). Phantom limb pain: A review of the literature on attributes and potential mechanisms. *Journal of Pain and Symptom Management*, 17(2), 125-142.
- Hjermstad, M., Fayers, P., Haugen, D., Caraceni, A., Hanks, G., Loge, J., et al. (2011, June). Studies Comparing Numerical Rating Scales, Verbal Rating Scales, and Visual Analogue Scales for Assessment of Pain Intensity in Adults: A Systematic Literature Review. *Journal of Pain and Symptom Management*, 41(6), 1073-1093.
- Huff, E., Ledoux, W., Berge, J., & Klute, G. (2008). Measuring Residual Limb Skin Temperatures at the Skin-Prosthesis Interface. *American Academy of Orthotists and Prosthetists*, 20(4), 170-173.
- Jamison, R. N. (1996). Influence of Weather on Report of Pain [Newsletter]. Boston, Massachusetts: International Association for the study of pain. Technical corner of IASP newsletter (<http://www.iasp-pain.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentID=2201>), Harvard Medical School.
- Jensen, T. S., Krebs, B., Nielsen, J., & Rasmussen, P. (1985). Immediate and long-term phantom pain in amputees: incidence, clinical characteristics, and relationship to pre-amputation pain. *Pain*, 21(3), 267-78.

- Jensen, T. S., Wilson, P. R., & Rice, A. S. (2002). Clinical Pain Management: Chronic Pain. Retrieved from <http://www.jfponline.com/Pages.asp?AID=7413&issue=March%202009>
- Kalso, E., Tasmuth, T., & Neuvonen, P. J. (1996). Amitriptyline effectively relieves neuropathic pain following treatment of breast cancer. *Pain*, *64*(2), 293-302.
- Karl, A., Birbaumer, N., Lutzenberger, W., Cohen, L. G., & Flor, H. (2001, May 15). Reorganization of Motor and Somatosensory Cortex in Upper Extremity Amputees with Phantom Limb Pain. *Journal of Neuroscience*, *21*(10), 3609-3618.
- Katz, J., & Melzack, R. (1991). Auricular transcutaneous electrical nerve stimulation (TENS) reduces phantom limb pain. *Journal of Pain and Symptom Management*, *6*, 73-83.
- Keil, G. (1990). Sogenannte Beschreibung des phantomschmerzes von Ambroise Pare. *Fortschritte der Medizin*, *108*, 62-66. Retrieved from <http://bj.oxfordjournals.org/cgi/content/full/87/1/10>
- Klute, G., Berg, J., Biggs, W., Pongnumkul, S., Popovic, C., & Curless, B. (2011, October). Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect on fit, activity, and limb volume. *Archives of Physical Medicine and Rehabilitation*, *92*(10), 1570 - 1575.
- Lacy, C. F., Armstrong, L. L., Goldman, M. P., & Lance, L. L. (Eds.). (2010). Lexi-Comp's Drug Information Handbook 2010-2011: A Comprehensive Resource for All Clinicians and Healthcare Professionals (19th ed.). Hudson, Ohio: Lexi-Comp, Inc..
- Legro, M. W., Reiber, G. D., Smith, D. G., Del Aguila, M., Larson, J., & Boone, D. (1998, August). Prosthesis Evaluation Questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. *Archives of Physical Medicine and Rehabilitation*, *79*, 931-938.
- Leskowitz, E. (2009, April). Energy medicine perspectives on phantom-limb pain. *Alternative and Complimentary Therapies*, *15*(2), 59-63. DOI: 10.1089/act.2009.15210
- Livingston, W. K. (1943). *Pain mechanisms: A Physiologic Interpretation of Causalgia and Its Related Status*. New York: Macmillan.
- Lotze, M., Flor, H., Grodd, W., Larbig, W., & Birbaumer, N. (2001). Phantom movements and pain. An fMRI study in upper limb amputees. *Brain*, *124*, 2268-2277.
- Lotze, M., Grodd, W., Birbaumer, N., Erb, M., Huse, E., & Flor, H. (1999). Does use of myoelectric prosthesis prevent cortical reorganization and phantom limb pain? *Nature Neuroscience*, *2*(6), 501-502.

- MacIver, K., Lloyd, D. M., Kelly, S., Roberts, N., & Nurmikko, T. (2008). Phantom limb pain, cortical reorganization and the therapeutic effect of mental imagery. *Brain a Journal of Neurology*, *131*, 2181-2191. DOI: 10.1093/brain/awn124
- MacLachlan, M., Desmond, D., & Horgan, O. (2003, January/February). Psychological correlates of illusory body experiences. *Journal of Rehabilitation Research & Development*, *40*(1), 59-66.
- MacLachlan, M., McDonald, D., & Waloch, J. (2004, July 22 - August 4). Mirror treatment of lower limb phantom pain: a case study. *Disability & Rehabilitation*, *26*(14-15), 901-904.
- Maihofner, C., Handwerker, H. O., Neundorfer, B., & Birklein, F. (2004). Cortical reorganization during recovery from complex regional pain syndrome. *Neurology*, *63*, 693-701.
- Manchikanti, L., & Singh, V. (2004). Managing Phantom Pain. *Pain Physician*, *7*, 365-375.
- McDiarmid, S., & Trudeau, M. (1998). A Study of the Electromagnetic Properties of Farabloc .
- McQuay, H. J., & Dickerson, A. H. (1990). Implications of nervous system plasticity for pain management. *Anaesthesia*, *45*, 101-102.
- Melzack, R. (1971). Phantom limb pain: implications for treatment of pathologic pain. *Anaesthesiology*, *35*, 409-419.
- Melzack, R. (1975). The McGill Pain Questionnaire: major properties and scoring methods. *Pain*, *1*(3), 277-299.
- Melzack, R. (1990). Phantom limbs and the concept of a neuromatrix. *Trends in Neurosciences*, *13*, 88-92.
- Melzack, R. (1992). Phantom limbs. *Science America*, *266*, 120-126.
- Miller, M. D., & Rodriguez, J. E. (2010, January). What is the best nonpharmacologic therapy for phantom limb pain? *Evidence-based Practice*, *13*(1), 7.
- Mitchell, S. W. (1871). Phantom limbs. *Lippincott's Magazine of Popular Literary Science*, *(8)*, 563-569.
- Mohamad, H., Ebrahimzadeh, M. H., & Hariri, S. (2009, June). Long-term outcomes of unilateral transtibial amputations. *Military Medicine*, *174*(6), 593-597.
- Morley-Forster, P. K. (2009, Dec). The vexing problem of post-amputation pain: what is the optimal perioperative pain management for below-knee amputation? *Canadian Journal of Anesthesia*, *56*(12), 908-913.
- Neuroma.(2007). In Merriam-Webster's Medical Dictionary.

- Nikolajsen, L., & Jensen, T. S. (2001). Phantom limb pain. *British Journal of Anaesthesia*, 87(1), 107-116.
- Nikolajsen, L., Ilkjaer, S., Kroner, K., Christensen, J. H., & Jensen, T. S. (1997). The influence of preamputation pain on postamputation stump and phantom pain. *Pain*, 72, 393-405.
- Nixdorf, D. (2012). *The Clinic*. Retrieved March 10, 2012, from Dr.Don Nixdorf, D.C.: <http://www.dnixdorf.com/the-clinic.html>
- North Carolina Diabetes Prevention and Control Program.(n.d.).*Impact of Diabetes*. Retrieved from <http://www.ncdiabetes.org/factsFigures/index.asp>
- Ottaviani, G., Robert, R. S., Huh, W. W., & Jaffe, N. (2009). Functional, psychological and professional outcomes in long-term survivors of lower-extremity osteosarcomas: amputation versus limb salvage. *Pediatric and Adolescent Osteosarcoma, cancer treatment and research*, 152, 421. DOI: 10.1007/978-1-4419-0284-9_23
- Parkes, C. M. (1973).Factors determining the persistence of phantom limb pain in the amputee. *Journal of Psychosomatic Research*, 17, 97-108.
- Pilla, A. A. (2002). Low-intensity electromagnetic and mechanical modulation of bone growth and repair: are they equivalent? *Journal of Orthopedic Science*, 7(3), 420-428.
- Prosthetic Evaluation Questionnaire Evaluation Guide. (1998). Retrieved from http://www.prs-research.org/Texts/PEQ_Evaluation_Guide.pdf
- Protopathic pain. (2009). In *The American Heritage® Dictionary of the English Language*. (4th ed.)
- Ramachandran, V. S., & Rogers-Ramachandran, D. (1996).Synaesthesia in phantom limbs induced with mirrors. *Proceedings of the Royal Society of Biological Sciences*, 263, 377-386.
- Ramachandran, V., &Hirstein, W. (1998).The perception of phantom limbs. *Brain*, 121, 1603-30.
- Rossi, S., Tecchio, F., &Pasqualetti, P. (2002).Somatosensory processing during movement observation in humans. *Clinical Neurophysiology*, 113, 16 - 24.
- Rossi, S., Tecchio, F., Pasqualetti, P., Olivelli, M., Pizzella, V., Romani, G. L., Passero, S., Rossini, P. M. (2002).Somatosensory processing during movement observation in humans. *Clinical Neurophysiology*, 113, 16-24.
- Schumacher, K. L., Koresawa, S., West, C., Dodd, M., Paul, S. M., Tripathy, D., Koo, P., &Miaskowski, C. (2002, October). The usefulness of a daily pain management diary for

- outpatients with cancer-related pain. *Oncology Nursing Forum*, 29, 1304-1313. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/12370700>
- Shacham S. A shortened version of the Profile of Mood States. *J Pers Assess* 1983;47:305-6.
- Sherman, A., & Sherman, C. J. (1983). Prevalence and characteristics of chronic phantom limb pain among American veterans. *American Journal of Physical Medicine*, 62, 227-238.
- Sherman, R. A. (1989). Stump and phantom limb pain. *Neurologic Clinics*, 7, 249-264.
- Sherman, R. A. (1994, January). Phantom limb pain. Mechanism-based management. *Clinics in Podiatric Medicine and Surgery*, 11(1), 106.
- Sherman, R. A. (1997). Phantom pain. Retrieved from <http://www.iasp-pain.org/AM/AMTemplate.cfm?Section=Home&CONTENTID=7591&TEMPLATE=/CM/ContentDisplay.cfm>
- Sherman, R. A., Sherman, C. J., & Parker, L. (1984). Chronic phantom and stump pain among American veterans: results of a survey. *Pain*, 18, 83-95.
- Sherman, R. A., Sherman, C. J., & Parker, L. (1984). Concurrent variation of burning phantom limb and stump pain with near surface blood flow in the stump. *Orthopedics*, 10, 395-401.
- Sherman, R., Sherman, C., & Gall, N. (1980). A survey of phantom limb pain treatment in the United States. *Pain*, 8, 85-89. DOI: 10.1016/0304-3959(80)90092-5
- Shutty, M. S., Cunduff, G., & DeGood, D. E. (1992). Pain complaint and the weather: weather sensitivity and symptom complaints in chronic pain patients. *Pain*, 49, 199-204.
- Simmons, Z., & Feldman, E. (2000, Summer). The pharmacological treatment of painful diabetic neuropathy. *Clinical Diabetes*, 18(3).
- Sindrup, S. H., & Jensen, T. S. (1999). Efficacy of pharmacological treatments of neuropathic pain: an update and effect related to mechanism of drug action. *Pain*, 83, 389-400.
- Skidmore, F. M., Drago, V., Foster, P. S., & Heilman, K. M. (2009). Bilateral restless legs affecting a phantom limb, treated with dopamine agonists. *Journal of Neurology, Neurosurgery and Psychiatry*, 5, 569-570.
- Stannard, C., Kalso, E., & Ballantyne, J. (2010). *Evidence-based Chronic Pain Management*. Hoboken, NJ, USA: Blackwell Publishing Ltd.
- The Free Dictionary.(n.d.). <http://www.thefreedictionary.com/phantom+limb+pain>

- Title of measure: The Brief Pain Inventory. (2007). Retrieved from http://www.rtog.org/pdf_document/QOL_PRO_Library/BriefPainInventory.pdf
- Wall, P. D., & Gutnick, M. (1974). Ongoing activity in peripheral nerves: The physiology and pharmacology of impulses originating from a neuroma. *Exploratory Neurology*, 43, 580-593.
- Waxman, S. G. (1999). The molecular pathophysiology of pain: abnormal expression of sodium channel genes and its contributions to hyperexcitability of primary sensory neurons. *Pain Supplement*, 6, 133-140.
- Weeks, S. R., & Tsao, J. W. (2010). Incorporation of another person's limb into body image relieves phantom limb pain: a case study. *Neurocase*, 16(6), 461-465.
- Wewers, M., Lowe, N., & Crichton, N. (1990). A critical review of visual analogue scales in the measurement of clinical phenomena. *Research in Nursing and Health*, 13, 227-236.
- World Health Organization. (2007). *Electromagnetic Fields: Extremely low frequency fields. Environmental health criteria monograph No. 238*. Geneva: WHO Press.
- Yuh, T. C., Fisher, D. J., Shields, R. K., & Ehrhardt, J. C. (1992). Phantom limb pain induced in amputee by strong magnetic fields. *Journal of Magnetic Resonance Imaging*, 2, 221-223. DOI: 10.1002/jmri.1880020216
- Zhang, J., Clement, D., & Taunton, J. (2000, January). The efficacy of Farabloc, an electromagnetic shield, in attenuating delayed-onset muscle soreness. *Clinical Journal of Sports Medicine*, 10(1), 15-21.
- contralateral limb. (2008). In The Free Dictionary. Retrieved from <http://www.thefreedictionary.com/contralateral>

APPENDIX A

IRB or IACUC approval letters - required if human subjects or animals are used

UNIVERSITY AND MEDICAL CENTER INSTITUTIONAL REVIEW BOARD
HUMAN BIOMEDICAL INTERNAL PROCESSING FORM
SUBMISSION FOR UMCIRB REVIEW
FULL AND EXPEDITED RESEARCH

Please note: For studies that involve greater than minimal risk, this application must be accompanied by a research protocol. For a template to assist in developing such a document, go to <http://www.ecu.edu/irb/TipsTools.html>.

DEMOGRAPHIC INFORMATION

Type of application: New Modification Date form was completed: 8/20/2010 UMCIRB #: HH2011

1. Title of proposed research (this title must match protocol, funding application and consent form):

The effectiveness of Farabloc technology with Mirror Therapy in reducing phantom limb pain in individuals with an acute lower extremity vascular amputation.

- a. PI Name, Degree(s) Name: Helen Houston, OTR/L, ECU graduate student
- b. Degrees/Credentials:
Bachelor of Science in Occupational Therapy completed in 1993. Presently enrolled in Masters of Science (post-professional) in Occupational Therapy, ECU.
- c. Affiliation: Faculty ECU Staff ECU Student UHS Employee/Agent Non-ECU/UHS
- d. Department, Section, School or College:
Department of Occupational Therapy, College of Allied Health Sciences, East Carolina University
Address: 305 Club Pines Drive, Greenville, NC, 27834
- e. E-mail address: [hhouston@vidanthealth.com](mailto:houston@vidanthealth.com) Telephone #: (252) 531-8993

2. Contact Person

- a. Name: Helen Houston
- b. Department, Section, School or College: Department of Occupational Therapy, ECU
- c. E-mail address: [hhouston@vidanthealth.com](mailto:houston@vidanthealth.com) Telephone #: (252) 531-8993

Note: You now should list all key personnel (which includes sub-investigators) on Question 34, along with their credentials, responsibilities and their signatures.

3. List all items related to this research study submitted for UMCIRB review and approval: Consent form, Institutional Approval for Research Form

4. SOURCE OF FUNDING

- No funding
- Institution or Department Sponsor, Name:
- Government Agency, Name:
- Grant: include 3 copies of the final grant application for full committee reviews or 1 copy for expedited reviews
- Private Agency, Name:
- Materials for study donated to Principal Investigator by Farabloc Development Corporation

5. Fund number for IRB fee collection (applies to all for-profit, private industry or pharmaceutical company sponsored projects): N/A

| Fund | Organization | Account | Program | Activity (optional) |
|------|--------------|---------|---------|---------------------|
| | | 73059 | | |

NOTE: The UMCIRB Conflict of Interest Disclosure Form needs to be submitted for expedited and full review.

6. CHECK ALL INSTITUTIONS OR SITES WHERE THIS RESEARCH STUDY WILL BE CONDUCTED:

- | | |
|---|--|
| <input type="checkbox"/> East Carolina University | <input type="checkbox"/> Beaufort County Hospital |
| <input checked="" type="checkbox"/> Vidant Medical Center | <input type="checkbox"/> Carteret General Hospital |
| <input type="checkbox"/> Heritage Hospital | <input type="checkbox"/> Boice-Willis Clinic |
| <input type="checkbox"/> Other | |

NOTE: Those research studies utilizing Pitt County Memorial Hospital resources, Brody School of Medicine resources or involving ionizing radiation should complete the Institutional Approval for Research Form.

7. CHECK THE FOLLOWING INVOLVED IN THIS STUDY:

Population Specifically Targeted

Methods/Procedures

- | | |
|--|--|
| <input type="checkbox"/> Normal volunteers | <input checked="" type="checkbox"/> Surveys / Questionnaires |
| <input checked="" type="checkbox"/> Adults (> 18 yrs old) | <input checked="" type="checkbox"/> Interviews |
| <input type="checkbox"/> Minors (< 18 yrs old) | <input checked="" type="checkbox"/> Standardized Written / Oral / Visual Tests |
| <input type="checkbox"/> Institutionalized Participants | <input type="checkbox"/> Videotaping / Voice Recording / Photography |
| <input type="checkbox"/> Students | <input type="checkbox"/> Deception |
| <input checked="" type="checkbox"/> Inpatient participants | <input checked="" type="checkbox"/> Randomization |
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Drugs |
| <input type="checkbox"/> Pregnant Participants | <input type="checkbox"/> Placebo (s) |
| <input type="checkbox"/> Participants of child bearing potential | <input checked="" type="checkbox"/> Medical Devices |
| <input type="checkbox"/> Embryos or fetuses | <input type="checkbox"/> Sterile Surgical / Invasive Procedures |
| <input type="checkbox"/> Neonates | <input type="checkbox"/> Non-sterile Invasive Procedures |
| <input type="checkbox"/> Wards of the State | <input type="checkbox"/> Surgical or otherwise discarded Tissue/Samples |
| <input type="checkbox"/> Minorities | <input type="checkbox"/> Autopsy or cadaver tissue |
| <input type="checkbox"/> Non-English speaking | <input type="checkbox"/> Therapeutic Radiation |
| <input type="checkbox"/> Desperately / Terminally Ill Participants | <input type="checkbox"/> Diagnostic Radiation |
| <input type="checkbox"/> Traumatized/Comatose Participants | <input type="checkbox"/> Banking of biological materials |
| <input type="checkbox"/> Communicable Disease | <input type="checkbox"/> Genetic testing |
| <input checked="" type="checkbox"/> Outpatient participants | <input type="checkbox"/> HIV Testing |
| <input type="checkbox"/> International research | <input type="checkbox"/> Registry / Database |
| <input type="checkbox"/> Cognitively or emotionally impaired | <input type="checkbox"/> Recombinant DNA / Gene Transfer Technology |

INVESTIGATIONAL TEST ITEMS

8. Does your proposal involve investigational drugs? No Yes
9. Does your proposal involve approved drugs for non-approved uses? No Yes
10. Does this proposal have an IND No Yes
- a. Name:
- b. Manufacturer:
- c. IND No:
- d. IND Filing date:
- e. Drug study phase:
11. Does your proposal involve investigational devices, instruments, machines? No Yes

12. Is this device exempt from the requirements of 21CFR812? No Yes
13. Does your proposal involve approved devices for non-approved uses? No Yes
14. Is this a significant risk (SR) device? No Yes
15. Does this proposal have an IDE? No Yes
- Name:
 - Manufacturer:
 - IDE No., device study type:
 - Device study phase:
 - Provide the FDA letter of SR/NSR designation or the sponsor letter of risk designation.
 - Attach a copy of the FDA approval letter of the IDE.

RESEARCH RISK AND LEVEL OF REVIEW REQUIRED

16. Research participants will be placed at as defined below:

- No more than minimal risk
 More than minimal risk

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR 46.102(i) The definition for prisoners differs and is located at 45 CFR 46

17. What level of review does your proposal require? Expedited Full

RESEARCH QUESTIONS

18. Subject Selection

- Describe how participants will be selected or recruited for the research, including enrollment procedure. All acute individuals that are scheduled for amputation will be considered for selection. Chronic amputees reporting phantom limb pain will also participate. If the individual meets the inclusion/exclusion criteria, the PI will be notified. The PI will speak to the potential subject, explaining all elements of the study and secure a consent form, if the individual agrees to participate. Enrollment will include signing of consent forms and explanation of risks and benefits of study.
- Identify the projected number of participants to be enrolled. 60 subjects
- Outline the inclusion and exclusion criteria for this research study.

Inclusion criteria: individuals who are 19 years of age or older, able to comprehend, read and write in English, and understand the use of a visual analogue scale. The study is targeting individuals who have undergone a recent (less than 6 weeks) unilateral, above or below knee amputation due of vascular insufficiency with a minimum of 15cm of residual femur or tibia remaining over which an amputee limb cover can be placed and chronic amputees (more than 6 weeks previously), who report phantom limb pain.

Exclusion criteria: individuals with one or more of the following types of amputations: bilateral lower extremity; upper extremity; guillotine (delayed closure due to risk of infection), hip disarticulation, foot, partial foot and toe amputation and individuals pending revision surgeries.

Individuals will also be excluded if they:

- are involved in a compensation claim;
- have a diagnosis of neurological or psychological disorder that would interfere with the study;
- require dialysis as this is often associated with an increase in cognitive deficits and fluctuating medical status;
- have a known uncontrolled systemic disease (i.e., cancer, lupus etc.);
- have current substance abuse or dependence;
- are unable to provide written consent and written authorization for use or release of health and research study information;
- have a prior history of vertebral disc disease/condition, sciatica or radiculopathy;
- are unable to follow study instructions and or are unlikely to complete all required visits;

- are participating in another investigational drug or device study for phantom limb pain or have participated in these studies 30 days immediately prior to study enrollment;
 - have any condition or situation that, in the investigator's opinion, may put the subject at significant risk, confound the study results, or interfere significantly with the subject's participation in the study.
 - are taking anti-seizure/ neuropathic pain medications which exceed maximum recommended daily dosages e.g. Lyrica 450mg/day, Cymbalta 60 mg/day or Neurontin levels 3600mg/day.
- c. Provide a justification for the sample size selected.
There will be two experimental groups of a minimum of five subjects each. For statistical analysis, there needs to be 30 subjects in each group, so the minimum of subjects needed for the study are 60 subjects who complete the study.
- d. Describe the safeguards in place to protect the rights and welfare of any vulnerable participants enrolled in this research study.
If there is a subject that is vulnerable, for example, not able to understand the purpose and process of the study due to cognitive deficits, the PI will not enroll them in the study. The exclusion criteria is extensive, in part to protect the subjects that have complex medical needs and therefore should not participate.

19. Are there any advertisements (public display in written, radio, or TV form) for participant recruitment?
 Yes No If yes, attach the advertisements to the processing form.

20. Does the research include any monetary inducements, compensation or reimbursement for participation in this research study?
 Yes No If yes, attach the payment schedule to the processing form or provide specific protocol reference.

21. Will the sponsor reimburse for any items or procedures or supply any items at no cost involved in this research study? Yes No If yes, attach written documentation of the items that will be reimbursed or supplied by the sponsor unless this information is specifically noted in the research protocol.

See Attachment

22. Are there any associated costs that participants will incur as a result of participating in this research study?
 Yes No If yes, describe these costs.

23. Risk Determination

Describe the research setting, listing any safeguards in place for participant safety.

Research will be initiated for the acute group, while amputees are inpatients in the acute care setting of Vidant Medical Center, or after six weeks for the chronic group. All subjects participating, regardless of group placement, will meet or exceed standards of care.

According to current amputee treatment protocol, all amputees receive occupational therapy or physical therapy evaluation and treatments, beginning on post-operation day one, per current treatment protocol. This protocol includes the evaluation of current functional level and education as usually addressed on the current amputee treatment protocol. The education is described in a booklet issued to all amputee patients. It explains the care of residual limb, desensitization techniques for residual limb, donning stump-liner and stump shrinker, activities of daily living, mobility and functional transfers, assessment for need of durable medical equipment or assistive devices in preparation for discharge, as well as appropriate exercises for upper extremity exercises and lower extremities. For subjects in the intervention groups, they will get additional occupational therapy intervention. This intervention has proven to be effective treatment, and does not have any known risks. As with any patient seen by therapists, any patient that shows illness or post-surgical complications will be brought to immediate attention of the medical staff.

24. Risk Determination

- a. Describe all foreseeable physical, psychological, economic, social, legal and dignitary risks to the participants, with steps outlined to minimize those risks. Risks should be described in terms of probability or likelihood, magnitude and duration when possible.

There are no foreseeable risks involved with this study, as all subjects will adhere to the traditional treatment protocol.

- b. Outline the mechanism for reporting adverse events or unanticipated risks to participants or others for this study. If any adverse events or unanticipated risks become evident, these will be reported to current participants via telephone contact and appropriate modifications will be made, with IRB approval, in order to continue with the study.
- c. Specifically address any risk associated with the use of placebo, if applicable.
N/A

25. Data/Safety Monitoring:

- a. Describe any additional data monitoring challenges when the principal investigator or another research team member is not directly involved in data collection or monitoring because they are not available on the research site.

Once participants have been discharged from the hospital they will be monitored by home-health, skilled nursing or outpatient therapists. These therapists will be contacted via telephonic means by the primary investigator and will receive written instructions via e-mail. These therapists will be educated regarding monitoring of participants compliance with the treatment protocol. The primary investigator will remain in telephonic contact with participants to ensure adherence to study protocols. At four, and eight weeks the primary investigator will meet with the participants to monitor safety and collect data. Subjects will meet with their physicians at four, and eight weeks for medical monitoring, per the current treatment protocol.

- b. Describe the data monitoring plan according to Good Clinical Practices (and Data Safety Monitoring Board/Committee, if applicable) to ensure safety of subjects.

All data will be stored in a locked location in the occupational therapy department at East Carolina University and the Occupational Therapy department at Vidant Medical Center, to ensure that participant confidentiality is adhered to. Data and personal participant identifiers will be separated.

26. Anticipated Benefits

- a. Describe the benefits of the research study to participants or others.
Participants of this study may benefit in that they may not develop phantom limb pain after amputation, or that it may be minimized due to this treatment protocol. If an effective combined protocol is developed due to the results of this study, others will benefit as they will not experience phantom limb pain or it may be able to be reduced due to this treatment intervention post-amputation surgery, thereby improving quality of life and potential to increase participation in activities of daily living.

27. Data Confidentiality and Subject Privacy

- a. Describe how confidentiality will be maintained by providing details about the storage facility, duration of storage, data destruction method, and persons with access to the data.

All data will be kept in a locked drawer within the PI's work office or within ECU's Department of Occupational Therapy thesis director's office. Data will be stored for three years and after this time data will be shredded using the professional shredding services provided at Pitt County Memorial Hospital. The only people with access to the data will be the PI, the thesis director, and the review committee. Results of the study will be shared with the sponsor.

- b. How will subject privacy be maintained during recruitment, data collection and data analysis?

All names will be eliminated from the documentation except for the consent form. An ID number will be assigned and used for identification.

- c. If the participants' data or samples will be used for future research, describe how their privacy will be protected. Only ID numbers will be used.

- d. Describe any additional safeguards in place to manage illegal, significantly intimate or potentially embarrassing information gathered in this research study.

There is no obvious intimate or embarrassing information that is being collected. Nevertheless, all will be adequately supervised and secured.

- e. Include steps to handle information that requires mandatory reporting to officials, for example physical abuse, emotional abuse or health problems.

The PI is an employee of Vidant Medical Center and will follow all mandatory reporting as required by the facility.

- f. If the research study involves HIV testing, describe the plans for pre/post-test counseling and other related considerations. N/A

28. Obtaining Consent or Parental Permission:

Describe the consent process, including members of the research team that will be obtaining informed consent from study participants.

- a. The PI will speak to the potential subject, explaining all elements of the study and secure a consent form, if the individual agrees to participate. Enrollment will include signing of consent forms and explanation of risks and benefits of study.
- b. Describe the setting in which the consent will be obtained.
Inpatient acute care setting at Vidant Medical Center and Eastern NC Amputee Support Group
- c. Describe the process to minimize undue influence and coercion during the consent process.
The risks and benefits of participating will be explained to individuals who meet inclusion/exclusion criteria, however all individuals will continue with traditional treatment protocol irrespective of whether they participate in this research study or not.
- d. Outline procedures for obtaining informed consent from participants with limited or low literacy.
One of the inclusion criteria for this study includes the ability to comprehend, read and write in English, and understand the use of a visual analogue scale. Subjects with limited or low literacy will thereby not be included as these skills are required to be able to complete the daily log and Brief Pain Inventory surveys daily.
- e. Describe the process for determining cognitive impairment or other conditions that may make a participant more vulnerable.
Due to the extensive exclusion criteria for this study, individuals with cognitive impairments or other conditions which may make a participant vulnerable will not be included in this study.
- f. Describe the process for identifying the legally authorized representative and the process to debrief and subsequently obtain consent from the study participant, when feasible.
Individuals that meet inclusion and exclusion criteria will be adults, without cognitive deficits and will be able to represent themselves, so legal representatives will not be applicable.

29. Assent Related Issues for children: NA

- a. Describe the assent processes given the range of ages intended for this research study.
- b. If a separate assent is not being used, how will assent be documented?
- c. How will custody changes during participation in the study be determined?
- d. Describe the processes as required for enrolling wards of the state if they are a target population for this study. Note: If a child becomes a ward of the state, the IRB must be notified immediately to seek advice on further protections that may be required.

30. Background

- a. The current state of knowledge surrounding the research questions to be addressed in this study.

Phantom limb pain (PLP) is an extremely debilitating and complicated phenomenon which can limit participation in daily life activities throughout the life of an individual with an amputation. The purpose of this study is to explore the effect of combining two therapies, Farabloc technology with Mirror Therapy, in order to decrease the experience of PLP for acute, unilateral, lower extremity vascular above or below knee amputees. Farabloc technology uses a fabric that is woven with fibers of extremely fine steel and nylon which has significant shielding effects on high frequency electromagnetic fields (greater than 1MHz) (Bach & Clement, 2007). When wrapped around a post amputation residual limb, Farabloc therapy has been demonstrated to have a favorable effect on PLP (Conine, Hershler, Alexander, & Crisp, 1993). Mirror Therapy uses a mirror placed between the amputated and non-amputated limb, in which the non-amputated limb is observed while performing bilateral synchronous exercises, such that it appears that both limbs are intact. Mirror Therapy has been shown to significantly reduce phantom limb pain in individuals with an amputation (Chan et al., 2007). By combining the two therapies, this study will investigate whether phantom limb pain experienced by acute above/below knee amputees can be prevented or reduced in frequency, intensity or duration compared with chronic amputees. This study is unique as a combined intervention strategy. The expectation is that the results of this study will provide a cost-effective, drug-free alternative to current phantom limb pain treatments and may prevent or

reduce phantom limb pain to the extent to which amputees could increase participation in their activities of everyday life.

References:

- Bach, G. L., & Clement, D. B. (2007, March). *Efficacy of Farabloc as an analgesic in primary fibromyalgia*, 26(3), 405-410.
- Chan, B. L., Witt, R., Charrow, A. P., Magee, A., Howard, R., Pasquina, P. F., Heilman, K. M., & Tsao, J. W. (2007, November 22). Mirror Therapy for Phantom Limb Pain. *New England Journal of Medicine*, 357(21), 2206-2207.
- Conine, T. A., Hershler, C., Alexander, S. A., & Crisp, R. (1993). The Efficacy of Farabloc™ in the Treatment of Phantom Limb Pain. *Canadian Journal of Rehabilitation*, 6(3, 993), 155-161.

b. Describe the uncertainty to be addressed by this research study (research question).

Once phantom limb pain pathways have been established they appear more difficult to eradicate and treat, therefore, it is critical to address the issue of phantom limb pain early in the process, soon after the amputation. There is strong evidence that Farabloc is effective in treating phantom limb pain and Mirror Therapy research has been demonstrated to reduce phantom limb pain in upper as well as lower extremity amputees, but they have only been studied separately. Thus, the purpose of this study is to investigate if the combined use of Farabloc and Mirror Therapy treatment protocol will reduce the experience of phantom limb pain and increase the quality of life for amputees with an acute lower limb above or below knee amputation. The hypothesis is that a treatment protocol that targets external (peripheral) and internal (central) neuronal mechanisms simultaneously is likely to be able to reduce phantom limb pain more substantially than either treatments alone, particularly when used as an early intervention.

The specific research questions will be:

By using a combined Farabloc Therapy and Mirror Therapy treatment protocol in the acute phase after surgery, can PLP be reduced or prevented in individuals who have a unilateral, above or below knee amputation when compared to the same treatment protocol used in chronic amputees (more than six weeks post-operatively)?

Will any intervention effects be maintained after a four week maintenance period?

Is a reduction in PLP associated with an increased in participation in activities of daily living, or an increased quality of life?

c. Describe the rationale for the type of research design chosen for this study.

A repeated-measures, experimental design has been chosen for this study. There are two experimental groups- with subjects assigned to the acute group if the amputation occurred less than six weeks previously and to the chronic group if the date of the amputation occurred more than six weeks previously. Both groups will receive the traditional amputee treatment protocol. Both groups will also receive the experimental protocol combining Farabloc Therapy and Mirror Therapy for four weeks. After the four week intervention, each subject received no experimental intervention for four weeks.

RESEARCH ABSTRACT

Phantom limb pain (PLP) is significant for amputees since its occurrence can be as high as 90% and is overwhelming and debilitating to those who experience it. Numerous treatment options have been studied, with some success. The purpose of this study will be to examine an effective treatment protocol to decrease PLP with acute amputation individuals using two relatively new and innovative therapies in combination. This study proposes combining two effective treatments 1) preventing the overstimulation of raw nerve endings from external sources, by providing an electromagnetic shielding fabric in the form of an amputee limb cover (Farabloc technology), and 2) reorganizing the sensory cortex internally, using Mirror Therapy, hypothesizing that this protocol will decrease or even prevent the experience of PLP in post-surgical lower extremity amputees by treating PLP limb pain from these two combined sources.

Key Personnel: Each key personnel must certify the following by signing below:

- a. I acknowledge my responsibilities in the conduct of this research study and have received adequate training to fulfill those responsibilities.
- b. I agree to follow the procedures for the conduct of this study as described in the IRB approved application.
- c. I agree to uphold the rights and welfare of all study participants.

| Name (Typed) | Degree, license, and/or certification | Responsibilities (Scope of Work) – select all that apply from list below | Date began service on this protocol | Date left service on this protocol | Date met Human Research Protections Education requirements | Signature |
|-----------------------|---------------------------------------|--|-------------------------------------|------------------------------------|--|-----------|
| Helen Houston | BScOT, OTR/L | Primary investigator: b,d,e,i,j,l,m,n,o | September 2010 | | July 2010 | |
| Anne Dickerson | PhD, OTR, FAOTA | Graduate student professor: e | | | | |
| Shane Coltrain | BS, CPO | Certified prosthetist: c,d,n | | | | |
| Susana Almeida-Peters | RN, BN | Research nurse: a,n | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

Responsibilities of key personnel:

| | |
|--|---|
| a. Screens potential participants | k. Administers IV Meds |
| b. Obtains Informed Consent** | l. Prepares Study initiation activities |
| c. Conducts physical exams | m. Enters patient data into electronic research records |
| d. Enters data on paper research records | n. Educates participants, families, or staff |
| e. Data management | o. Other: List other applicable duties |
| f. Collects specimens | |
| g. Dispenses medications | |
| h. Administers P.O. medications | 1. Sub-investigator |
| i. Addresses Regulatory issues | 2. Research Nurse |
| j. Communicates with IRB | 3. Graduate Research Assistant |

**For those individuals involved with obtaining informed consent, please provide a copy of their CV.

Confidentiality Statement
For Key Personnel Directly Involved in Research

All information pertaining to individuals participating as research participants in ECU or Affiliate research projects, including but not limited to names, addresses, and other identifying information, must be held in strictest confidence. Unauthorized disclosure of information related to research participants by staff constitutes serious misconduct, which is subject to disciplinary action, including termination. Under certain circumstances, unauthorized disclosure could result in criminal, civil, or judicial penalty. Research information cannot be disclosed to third parties other than those to which the participant agreed in the consent process and documented in the UMCIRB approved Informed Consent Form. This does not prevent disclosures required or permitted by state or federal law for the protection of human life or protection of children.

Acknowledgement

I have read and understand the above Confidentiality Statement and I agree to comply with all requirements for confidentiality.

Key Personnel Signature

Date

Note to Principal Investigator: A copy of this statement is to be signed by each key personnel who has access to confidential information covered by the IRB approved research project, including all sub-investigators and research/graduate assistants. DO NOT submit this original statement with the IRB application. All signed copies of this statement and the person's documentation certifying completion of educational training in human research protections must be maintained by the Principal Investigator for a period no less than three years after the end of IRB approval. During the research and for a minimum period of three years afterwards, the IRB may require the Principal Investigator to provide copies of this documentation. It is the Principal Investigator's responsibility to ensure that such documentation is available and current.

Principal Investigator (type name)

Principal Investigator Signature

Date of Signature

7. Maintain all study records for 3 (three) years after completion of the study at all sites or longer if required by a professional organization, sponsor, regulatory body or others.
8. Regard participant informed consent as an ongoing process.
9. Enroll participants only after obtaining ethically and legally effective informed consent, using only the most currently approved UMCIRB consent document, as required.
10. Obtain assent from children and parental permission prior to enrollment, as required.
11. Notify the UMCIRB if any relationships develop that may be considered a conflict of interest.
12. Abide by the UMCIRB Standard Operating Procedures, all applicable federal regulations, Good Clinical Practice, state laws, respective institutional policies to conduct this research study. Ethical standards include the Belmont Report and other professional standards for an individual research area.
13. To comply with regulatory reviews, data audits, and 3rd party observation for the consenting process by appropriate institutional regulatory officials.
14. Notify the UMCIRB prior to relocating (i.e., leaving ECU/UHS) to provide for the orderly study closure or to transfer the study to another investigator.

Signature Principal Investigator

Print

Date

APPENDIX B
Prosthesis Evaluation Questionnaire

Study Number _____
Date _____

Prosthesis
Evaluation
Questionnaire (modified)



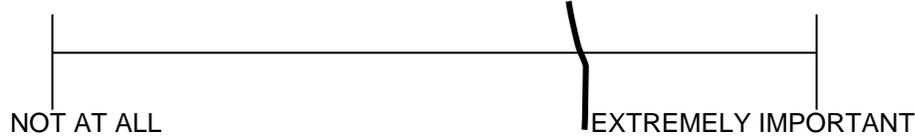
©1998, Prosthetics Research Study Seattle, WA, USA

Instructions

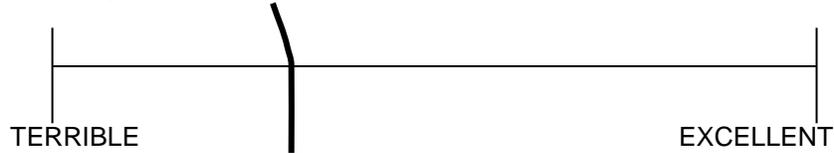
As you read each question, remember there is no right or wrong answer. Just think of YOUR OWN OPINION on the topic and make a mark THROUGH the line anywhere along the line from one end to the other to show us your opinion.

Example

How important is it to you to have coffee in the morning?



Over the past four weeks, rate your morning coffee.

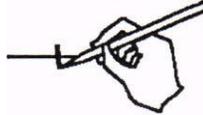


OR check I haven't drunk coffee in the morning in the past four weeks.

This example shows that the person who answered these questions feels that having coffee in the morning is important to him. He also thinks the coffee he has had lately has not been very good.

If he hadn't drunk any coffee in the last four weeks, he would have put a check by that statement instead of putting a mark on the line between TERRIBLE and EXCELLENT.

As in this example, make a mark across the line rather than using an X or an O.



Please answer all the questions.

Support for development of the PEQ was provided by the U.S. Department of Veterans Affairs.

Group 1

A. Over the past four weeks, rate the feel (such as the temperature and texture) of the amputee limb cover on your residual limb (stump).

WORST POSSIBLE BEST POSSIBLE

B. Over the past four weeks, rate the ease of putting on (donning) your amputee limb cover.

TERRIBLE EXCELLENT

C. Over the past four weeks, rate how your amputee limb cover has looked.

TERRIBLE EXCELLENT

D. Over the past four weeks, rate the damage done to your clothing by your amputee limb cover.

EXTENSIVE DAMAGE NONE

E. Over the past four weeks, rate how much you sweat inside your amputee limb cover.

EXTREME AMOUNT NOT AT ALL

F. Over the past four weeks, rate how smelly your amputee limb cover was at its worst.

EXTREMELY SMELLY NOT AT ALL

G. Over the past four weeks, rate how much of the time your residual limb was swollen to the point of changing the fit of your amputee limb cover.

ALL THE TIME NEVER

H. Over the past four weeks, rate any rash(es) that you got on your residual limb.

EXTREMELY BOTHERSOME NOT AT ALL

OR check ___ I had no rashes on my residual limb in the last month.

I. Over the past four weeks, rate any ingrown hairs (pimples) that were on your residual limb.

EXTREMELY BOTHERSOME NOT AT ALL

OR check ___ I had no ingrown hairs on my residual limb in the last month.

J. Over the past four weeks, rate any blisters or sores that you got on your residual limb.

EXTREMELY BOTHERSOME NOT AT ALL

OR check ___ I had no blisters or sores on my residual limb in the last month.

Group 4

This section is about YOUR ABILITY TO MOVE AROUND.

A. Over the past four weeks, rate your ability to get in and out of a car.

CANNOT _____ NO PROBLEM

B. Over the past four weeks, rate your ability to sit down and get up from a chair with a high seat (e.g., a dining chair, a kitchen chair, an office chair).

CANNOT _____ NO PROBLEM

C. Over the past four weeks, rate your ability to sit down and get up from a low or soft chair (e.g. an easy chair or deep sofa).

CANNOT _____ NO PROBLEM

D. Over the past four weeks, rate your ability to sit down and get up from the toilet.

CANNOT _____ NO PROBLEM

E. Over the past four weeks, rate your ability to bathe safely.

CANNOT _____ NO PROBLEM

Group 5

The following section asks about YOUR SATISFACTION WITH PARTICULAR SITUATIONS given that you have an amputation.

- A. Over the past four weeks, rate how satisfied you have been with your amputee limb cover.

EXTREMELY DISSATISFIED

EXTREMELY SATISFIED

- B. Over the past four weeks, rate how satisfied you have been with how things have worked out since your amputation.

EXTREMELY DISSATISFIED

EXTREMELY SATISFIED

- C. Over the past four weeks, how would you rate your quality of life?

WORST POSSIBLE LIFE

BEST POSSIBLE LIFE

Group 6

This next section asks you to rate your ability TO DO YOUR DAILY ACTIVITIES when you are having problems with your amputee limb cover.

A. When the fit of my amputee limb cover is poor, I will get...

NOTHING DONE EVERYTHING DONE

B. When the comfort of my amputee limb cover is poor, I will get...

NOTHING DONE EVERYTHING DONE

C. Without my amputee limb cover, I will get...

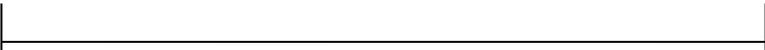
NOTHING DONE EVERYTHING DONE

Group 7

This last section asks you to rate HOW IMPORTANT different aspects (or qualities) of your amputee limb cover are to you.

A. How important is it that the weight of your amputee limb cover feels right?

NOT AT ALL EXTREMELY IMPORTANT



B. How important is the ease of putting on (donning) your amputee limb cover?

NOT AT ALL EXTREMELY IMPORTANT



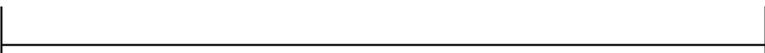
C. How important is the appearance of your amputee limb cover (how it looks)?

NOT AT ALL EXTREMELY IMPORTANT



D. How important is it that your amputee limb cover is durable (cannot be torn)?

NOT AT ALL EXTREMELY IMPORTANT



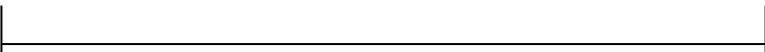
E. How bothersome is it when you sweat a lot inside your amputee limb cover?

EXTREMELY BOTHERSOME NOT AT ALL



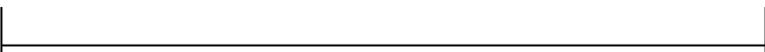
F. How bothersome to you is swelling in your residual limb (stump)?

EXTREMELY BOTHERSOME NOT AT ALL



G. How important is it to avoid having any ingrown hairs (pimples) on your residual limb (stump)?

NOT AT ALL EXTREMELY IMPORTANT



H. How bothersome is it to see people looking at you and your amputee limb cover?

EXTREMELY BOTHERSOME NOT AT ALL



Final Notes

A. If any of the following have happened in the past four weeks, please check off and give a brief description:

- a serious medical problem (yours)
- a noticeable change in pain
- a serious personal problem (yours)
- a serious problem in the family
- some other big change has occurred in your life

If you checked any of the five previous items, please give a brief description.

B. Please share with us anything else about you or your amputee limb cover that you think would be helpful for us to know (continue on the back of this page if you need more space).

THANK YOU VERY MUCH!

Acknowledgement: Roorda LD, Roebroek ME, Lankhorst GJ, van Tilburg T, Bouter LM. Measuring functional limitations in rising and sitting down: Development of a questionnaire. Arch Phys Med Rehabil 1996;77:663-669 for their influence on questions 4-J, 4-K, and 4-L.

PEQ Evaluation Guide:

http://www.prs-research.org/Texts/PEQ_Evaluation_Guide.pdf

Validated Scale Name for PEQ Questions (original numbering)

for each scale by page number and question letter

| | Original Numbers | Study Numbers |
|---------------------------|---|------------------------|
| Ambulation (AM) | 13A, 13B, 13C, 13D, 14E, 14F, 14G, 14H | None in this scale |
| Appearance (AP) | 3J, 3M, 3N, 4O, 4P | 1C, 1D, |
| Frustration (FR) | 10B, 10C | None in this scale |
| Perceived Response (PR) | 10A, 11D, 11E, 11G, 12H | None in this scale |
| Residual Limb Health (RL) | 4Q, 4R, 4S, 5T, 5U, 5V | 1E, 1F, 1G, 1H, 1I, 1J |
| Social Burden (SB) | 12I, 12J, 12K | None in this scale |
| Sounds (SO) | 3K, 3L | None in this scale |
| Utility (UT) | 1B, 1C, 1D, 2E, 2F, 2G, 2H, 2I | 1A, 1B |
| Well Being (WB) | 16C, 16D | 5B, 5C |

PEQ Question Modifications

Key: Green = Questions for this study

Purple = Original numbers of questions per scoring and analysis guide

Group 1:

| | | | | | | | | | |
|----|----|----|----|----|----|----|----|----|----|
| 1A | 1B | 1C | 1D | 1E | 1F | 1G | 1H | 1I | 1J |
| 2H | 2I | 3J | 3M | 4Q | 4R | 4S | 5T | 5U | 5V |

Group 2:

| | | | | | | |
|----|----|----|----|----|----|----|
| 2A | 2B | 2C | 2D | 2E | 2F | 2G |
| 6A | 6B | 6C | 7D | 7E | 7F | 7G |
| 2H | 2I | 2J | 2K | 2L | 2M | |
| 8H | 8I | 8J | 8K | 8L | 8M | |

No Group 3 questions

Group 4:

| | | | | |
|-----|-----|-----|-----|-----|
| 4A | 4B | 4C | 4D | 4E |
| 14I | 15J | 15K | 15L | 15M |

Group 5:

| | | |
|-----|-----|-----|
| 5A | 5B | 5C |
| 16A | 16C | 16D |

Group 6:

| | | |
|---------------|-----|-----|
| 6A | 6B | 6C |
| 18A (GROUP 6) | 18B | 18C |

Group 7:

| | | | | | | | |
|---------------|-----|-----|-----|-----|-----|-----|-----|
| 7A | 7B | 7C | 7D | 7E | 7F | 7G | 7H |
| 18A (GROUP 7) | 19B | 19C | 19E | 19F | 20G | 20H | 20I |

PEQ Guide for Scoring and Analysis

| Qu #: | Original Page/ Item #: | Scale or Single Question | Variable Name | Question Content | Scoring Code |
|-------|------------------------|----------------------------|---------------|--|--|
| 1A | 2H | Utility Scale | UTfeel | ...rate the feel of the amputee limb cover on your residual limb (stump) | 0 - 100 |
| 1B | 2I | Utility Scale | UTdon | ...rate the ease of putting on (donning) your amputee limb cover | 0 - 100 |
| 1C | 3J | Appearance Scale | APcovlook | ...rate how your amputee limb cover has looked | 0 - 100 |
| 1D | 3M | Appearance Scale | APdamagclo | ...rate the damage done to your clothing by your amputee limb cover | 0 - 100 |
| 1E | 4Q | Residual Limb Health Scale | RLsweat | ...rate how much you sweat inside your amputee limb cover | 0 - 100 |
| 1F | 4R | Residual Limb Health Scale | RLsmell | ...rate how smelly your amputee limb cover was at its worst | 0 - 100 |
| 1G | 4S | Residual Limb Health Scale | RLswollen | ...rate how much of the time your residual limb was swollen to the point of changing the fit of your amputee limb cover | 0 - 100 |
| 1H | 5T | Residual Limb Health Scale | RLrash | ...rate any rash(es) that you got on your residual limb_ Or check I had no rashes on my residual limb | 0 - 100 (if checked score 100) |
| 1I | 5U | Residual Limb Health Scale | RLhair | ...rate any ingrown hairs (pimples) that were on your residual limb _Or check I had no ingrown hairs on my residual limb | 0 - 100 (if checked score 100) |
| 1J | 5V | Residual Limb Health Scale | RLsore | ...rate any blisters or sores that you got on your residual limb _Or rate I had no blisters or sores on my residual limb | 0 - 100 (if checked score 100) |
| 2A | 6A | Pain Question | PAfrephsen | ...rate how often you have been aware of non-painful sensations in your phantom limb a. never...g. all the time or almost all the time. | a = 0 b=1 c=2 d=3 e=4 f=5 g=6 |
| 2B | 6B | Pain Question | PAintphsen | If you had non-painful sensations in your phantom limb during the past month, rate how intense they were on average _ Or check I did not have non-painful sensations in my phantom limb. | 0 - 100 If checked score as "nr" (no response) |
| 2C | 6C | Pain Question | PAbotphsen | ...how bothersome were these sensations in your phantom limb _ Or check I did not have non-painful sensations in my phantom limb | 0 - 100 If checked score as "nr" (no response) |
| 2D | 7D | Pain Question | PAfrephpa | ...rate how often you had pain in your phantom limb | a = 0 b=1 c=2 d=3 e=4 f=5 g=6 |

| | | | | | |
|----|-----|-------------------|-----------|--|--|
| | | | | a. never... g. all the time or almost all the time | |
| 2E | 7E | Pain Question | PAdurphpa | How long does your phantom limb pain usually last? a. I have none... g. more than two days | a = 0 b=1 c=2 d=3 e=4 f=5 g=6 |
| 2F | 7F | Pain Question | PAintphpa | If you had any pain in your phantom limb during the past month, rate how intense it was on average_ Or check I did not have any pain in my phantom limb | 0 - 100 If checked score as "nr" (no response) |
| 2G | 7G | Pain Question | PAbotphpa | ...how bothersome was the pain in your phantom limb_ Or check I did not have any pain in my phantom limb | 0 - 100 If checked score as "nr" (no response) |
| 2H | 8H | Pain Question | PAfrerlpa | ...rate how often you had pain in your residual limb. a.never...g. all the time or almost all the time | a = 0 b=1 c=2 d=3 e=4 f=5 g=6 |
| 2I | 8I | Pain Question | PAintrlpa | If you had any pain in your residual limb during the past month, rate how intense it was on average_Or check I did not have any pain in my residual limb | 0 - 100 If checked score as "nr" (no response) |
| 2J | 8J | Pain Question | PAbotrlpa | ...how bothersome was the pain in your residual limb_ Or check I did not have any pain in my residual limb | 0 - 100 If checked score as "nr" (no response) |
| 2K | 8K | Pain Question | PAfreolpa | ...rate how often you had pain in your other leg or foot a. never ... g. all the time or almost all the time | a = 0 b=1 c=2 d=3 e=4 f=5 g=6 |
| 2L | 8L | Pain Question | PAintolpa | If you had any pain in your other leg or foot during the past month, rate how intense it was on average _ Or check I had no pain in my other leg or foot | 0 - 100 If checked score as "nr" (no response) |
| 2M | 8M | Pain Question | PAbotolpa | ... how bothersome was the pain in your other leg or foot _ Or check I had no pain in my other leg or foot | 0 - 100 If checked score as "nr" (no response) |
| 4A | 14I | Transfer Question | TRcar | ...rate your ability to get in and out of a car | 0 - 100 |
| 4B | 15J | Transfer Question | TRhichair | ...rate your ability to sit down and get up from a chair with a high seat (e.g. a dining chair, a kitchen chair, an office chair) | 0 - 100 |
| 4C | 15K | Transfer Question | TRlochair | ... rate your ability to sit down and get up from a low or soft chair (e.g. an easy chair or deep sofa) | 0 - 100 |
| 4D | 15L | Transfer Question | TRtoilet | ... rate your ability to sit down and get up from the toilet | 0 - 100 |

| | | | | | |
|----|----------------|------------------------|------------|---|---------|
| 4E | 15M | Transfer Question | TRbath | ... rate your ability to shower or bathe safely | 0 - 100 |
| 5A | 16A | Satisfaction Question | SAsatpros | ... rate how satisfied you have been with your amputee limb cover | 0 - 100 |
| 5B | 16C | Well Being Scale | WBsincamp | ... rate how satisfied you have been with how things have worked out since your amputation | 0 - 100 |
| 5C | 16D | Well Being Scale | WBqol | ... how would you rate your quality of life | 0 - 100 |
| 6A | 18A (GROU P 6) | Self Efficacy Question | SEfitpoor | When the fit of my amputee limb cover is poor, I will get... | 0 - 100 |
| 6B | 18B | Self Efficacy Question | SEcomfpor | When the comfort of my amputee limb cover is poor, I will get... | 0 - 100 |
| 6C | 18C | Self Efficacy Question | SEnopros | Without my amputee limb cover, I will get... | 0 - 100 |
| 7A | 18A (GROU P 7) | Importance Question | IMimpwt | How important is it that the weight of your amputee limb cover feel right | 0 - 100 |
| 7B | 19B | Importance Question | IMimpdon | How important is the ease of putting on (donning) your amputee limb cover | 0 - 100 |
| 7C | 19C | Importance Question | IMimpapear | How important is the appearance of your amputee limb cover (how it looks) | 0 - 100 |
| 7D | 19E | Importance Question | IMimpcover | How important is it that your amputee limb cover is durable (cannot be torn) | 0 - 100 |
| 7E | 19F | Importance Question | IMsweatbot | How bothersome is it when you sweat a lot inside your amputee limb cover | 0 - 100 |
| 7F | 20G | Importance Question | IMswellbot | How bothersome to you is swelling in your residual limb (stump) | 0 - 100 |
| 7G | 20H | Importance Question | IMnohair | How important is it to avoid having any ingrown hairs (pimples) on your residual limb (stump) | 0 - 100 |
| 7H | 20I | Importance Question | IMlookubot | How bothersome is it to see people looking at you and your amputee limb cover | 0 - 100 |

APPENDIX C

Study participant number: _____

DAILY LOG

(For the past 24 hours = day + night).

Please complete this log within one hour of waking up daily.

Please also complete the Brief Pain Inventory at the same time as the log every day.

Thank you for helping other amputees!

| | | | | | | | | |
|---|-------|--|--|--|--|--|--|--|
| Questions to answer daily: | Date: | | | | | | | |
| Did phantom limb pain limit your sleep last night? | | | | | | | | |
| Number of phantom limb pain episodes in past 24 hours | | | | | | | | |
| How long did phantom limb pain episodes last (average) | | | | | | | | |
| Time stump shrinker was put on | | | | | | | | |
| Time amputee Limb Cover was put on | | | | | | | | |
| Mirror Therapy exercises performed for 15 minutes (Yes/ No) | | | | | | | | |
| Time stump shrinker was removed | | | | | | | | |
| Time amputee limb cover was removed | | | | | | | | |
| Other problems or information | | | | | | | | |

APPENDIX D

Brief Pain Inventory- short form

http://www.rtog.org/pdf_document/QOL_PRO_Library/BriefPainInventory.pdf

<http://prc.coh.org/pdf/BPI%20Short%20Version.pdf>

(https://www.lsdregistry.net/fabryregistry/hcp/partic/assess/freg_hc_p_bpi.asp)

APPENDIX E

Hubbard Scientific 6083 Liquid Crystal Temperature Strip



http://www.unbeatable.com/amed1178.html?utm_source=froogle4&utm_medium=cpc&utm_term=AMED1178&ci_src=14110944&ci_sku=AMED1178

APPENDIX F

Log of Continuity tester measurements

(performed on each amputee limb cover x 2)

Tested with multi-meter: <http://www.google.ca/search?hl=en&source=hp&q=mini+multimeter&aq=f&aqi=glg-m>

| Subject #: _____ | Voltage conducted prior to issue | Voltage conducted upon returned | Farabloc Fabric in working order? (Yes/No) | Other |
|------------------------------------|--|---------------------------------------|--|-------|
| Amputee limb cover # 1 Code: | | | | |
| Amputee limb cover # 2 Code: | | | | |

APPENDIX G

Instruction to therapists

Please note:

This patient is in a research study.

Subjects continue to follow the standardized treatment protocol for treatment: wash residual limb twice/day with antibacterial soap and water. Apply a piece of 4 x 4 gauze lengthways over incision. Don stump liner (panty-hose thickness) to hold gauze in place – no tape on the residual limb. Please continue to educate patients on putting on stump shrinker over liner with “four hands” and that shrinker needs to be smooth and evenly placed for even distribution of pressure. All subjects continue desensitization techniques to treat phantom limb pain (rubbing/ tapping end of residual limb as needed) and upper and lower extremity exercises – per amputee booklet issued from Vidant Medical Center. All subjects will be filling out a daily log to track pain, and completing the Brief Pain Inventory (in their binders).

Subjects are to continue with the above mentioned standardized treatment protocol and are being issued with two amputee limb covers and a plexi-glass mirror to continue with their Mirror Therapy exercises. After the above treatment protocol has been completed and the amputee has the shrinker on, the amputee limb cover is placed over the residual limb and fastened with the Velcro fastener (snug but loose enough that you can place two fingers underneath the cover). Subjects are to wear these 23 hours per day and swap to the second amputee limb cover when they take their morning bath and bath their residual limb. Please have them wash the amputee limb cover that they are taking off, at this time and place on a dry towel to air dry. Do NOT allow them to wring out the amputee limb cover as this could break the metal fibers which will prevent the treatment effects. All amputee limb covers have been tested for conductivity prior to issue to subjects.

Subjects also need to perform Mirror Therapy exercises for 15 minutes/day. Please supervise that they doing so correctly per the protocol below. Supervision is to be “faded-out”, as subjects learn to perform these exercises independently.

If you notice any adverse reactions, such as skin breakdown, red areas, dehiscence of the surgical incision site, please primary investigator.

APPENDIX H

Exercise protocol for Mirror Therapy exercises for lower extremity

Place mirror lengthways between legs, so that the non-amputated foot can be seen in the mirror. Subjects can perform exercises in long-sitting or seated. Subjects are to view the non-amputated leg, but to attempt to move both legs simultaneously. It will appear that they have two legs.

This may upset some amputees so please warn them of this reaction prior to viewing their lower extremities in the mirror.

Thank you for your assistance with this project.

The following 10 exercises were to be completed 10 times each

1. Slowly straighten knee and then bend your legs at the knee at the same time.
2. Slowly straighten and then bend your legs at the knee alternatively as if walking.
3. Point your feet upward, and then point your feet downwards at the same time.
4. Turn your sole in towards each other and then away from each other at the same time.
5. Move your feet around in a circle to the left and to the right.
6. Lift your feet off the ground in a walking movement.
7. Point your toes upwards and then downwards while trying to keep your ankle and foot still.
8. Clench and unclench your toes.
9. Spread your toes and then relax them.
10. Point up your big toes and point down the other toes, then reverse it so that your big toe is pointing down and your other toes are pointing up.

(Brodie, Whyte, & Waller, 2003) ;(MacLachlan et al., 2004) ;(Culver, 2009).

<bold>APPENDIX I bold>

APPENDIX I

Tables