Carolyn E. Horne. COMPLEMENTARY PAIN INTERVENTION PILOT STUDY IN THE ACUTE HOSPITALIZATION PHASE AFTER LOWER EXTREMITY AMPUTATION SURGERY. (Under the direction of Dr. Martha Engelke) College of Nursing, April, 2014.

The national prevalence of limb loss is approximately 1.7 million people. Leading causes of this type of loss are diabetes and peripheral vascular disease. Diabetics are more likely than non-diabetics to have an amputation. Sixty percent of non-traumatic amputations occur in diabetics. Although preventive care measures are improving for diabetics, the epidemiological rate of increase in diabetes will continue over the next thirty years. The rate increase is projected to have an equal increase in the amputation rate. Along with amputation, comes a pain sequela that becomes chronic in nature. Pain management after amputation requires a specific regimen of pain control for the amputee. Primary pain management in the acute hospitalization phase focuses on pharmacologic management. To date, no studies have examined a complementary intervention along with pharmacologic measures immediately after surgery.

The purpose of this study was to investigate the feasibility and efficacy of a desensitization protocol in the immediate postoperative period for patients who had a major lower limb amputation, along with the impact of demographic factors, clinical factors and treatment fidelity on pain level, use of pain medication, anxiety and depression. Roy's Adaptation Theory and Melzack's Neuromatrix Theory of Pain provide the framework for this study.

Using a prospective repeated measure design with convenience sampling, data was collected from twelve patients after lower limb amputation surgery in a large medical facility in the southeastern United States.

This study found that in the acute hospital setting after amputation surgery continuous, intermittent and neuropathic pain is present. Total pain intensity mean scores decreased during repeated measurement periods for each pain type. Several correlations were noted in this study. Continuous pain and intermittent pain showed a significant correlation during all time periods of the study. By the last day of the study, present pain, SF-MPQ-2 total score, continuous pain, intermittent pain and neuropathic pain showed a strong correlation with medication dosing. A number of other strong correlations were noted among the measures. Feasibility of the desensitization protocol showed that all participants felt the protocol was easy to use. The majority felt it helped their pain. During self-administration of desensitization the participants recorded each intervention with a numerical pain score before and after intervention. During postoperative days two through five, a large effect size was noted in paired comparisons of pain for each day that reached statistical significance.

This study supports previous studies that multiple types of pain are present after amputation surgery. Overall, pain intensity scores decreased during the study. Desensitization was supported as being feasible and efficacious as a complementary therapy for this sample. Nurses provide pain control measures to patients daily. Finding ways to modulate the pain using self-administer techniques such as used in this study provides improved patient outcomes. Further studies need to be conducted in a larger sample on complementary pain measures.

COMPLEMENTARY PAIN INTERVENTION PILOT STUDY IN THE ACUTE
HOSPITALIZATION PHASE AFTER LOWER EXTREMITY AMPUTATION SURGERY

A Dissertation

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by

Carolyn E. Horne

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COMPLEMENTARY PAIN INTERVENTION PILOT STUDY IN THE ACUTE

HOSPITALIZATION PHASE AFTER LOWER EXTREMITY AMPUTATION SURGERY

by

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DEDICATION

In memory of my mother and father, Louise M. Ervin and James G. Ervin, you made me who I am today. Mom, I followed in your footsteps becoming a nurse. I found that this career fulfills me as a person and brings joy in helping others. I watched your dedication, empathy and kindness with patients and became a better person because of it. Dad, with your hard work and dedication to career and family, you set the example that helped me finish this work.

Finally, this work is dedicated to all people who have suffered from limb loss. The pain and suffering experienced by all deserves more attention. This work is a starting point in my quest to continuously help each of you with the pain experience.

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To my good friends, Millie Shinn and Shane Coltrain, who have both sustained limb loss, you were always there to lend a helping hand. You have both shared so much knowledge and insight about limb loss, prosthetics and the struggles each amputee has to overcome. I am ever so appreciative of the assistance and friendship during my studies.

Finally to my family, you have watched me persevere during this time. Steve, you have been my supporter and encourager. Sarah and Christina, you have given of your time so I could complete my studies. I want to thank you for letting me fulfill my dream.

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CHAPTER 1: INTRODUCTION

Prevalence of limb loss in the United States is approximately 1.7 million people.

(Ziegler-Graham, MacKenzie, Ephraim, Travison & Brookmeyer, 2008). Limb loss occurs as a

result of dysvascular disease, trauma, cancer and congenital anomalies. Diabetes and peripheral

arterial disease are the two prominent conditions causing the majority of limb loss. Diabetic

limb loss usually results from one of the following causes: foot infection, foot trauma or

peripheral arterial disease. Despite the cause, amputation surgery causes multidimensional pain

for the individual that may end up in a chronic state. A majority of amputees live with pain for

their entire lives.

Background and Significance

Pain associated with amputation surgery is complex. In addition to postoperative pain,

patients experience residual limb pain (RLP) and phantom limb pain (PLP). Pain experienced

after amputation can continue years beyond the surgery, resulting in a chronic pain state (Ehde &

Smith, 2004; Fritz, Chaitow, Hymel, 2007; Galloway, Buckenmaier & Polomano, 2011). The

Institute of Medicine's (IOM) recent report on *Relieving Pain In America* (2011) reports 116

million adult Americans living with chronic pain. Chronic pain in the United States costs $635

billion per year (IOM, 2011). Pain is a public health problem recognized by the IOM with a call

to adopt population-level strategies in treating this health problem. Amputees are one of the

populations represented in the IOM Report.

Diabetes accounts for 60% of the non-traumatic amputations done yearly (CDC, 2011).

The primary amputation site for diabetics is the lower extremity (CDC, 2011). Age adjusted

rates for people with diabetes that have a major lower extremity amputation is 5.5 per 1,000

diabetics, which is 28 times higher than those without diabetes (NLLIC, 2008). Prevalence of

diabetes is rising in the United States. The CDC (2011) reported that the disease affected 25.8 million people in 2010 with 18.8 million diagnosed cases and another 7 million undiagnosed. Epidemiological projection is that the rate of amputations will double by 2050 due to diabetic causes (Ziegler-Graham et al., 2008).

In a recent study, Li, Burrows, Gregg, Albright and Geiss (2012) found that the rate of amputation was decreasing in the diabetic population. The reason behind this decrease was not due to a decrease in the rate of diabetes but improved preventive care. The authors found that amputation rates among diabetics who were forty years or older decreased from 11.2/1000 to 3.9/1000. Although this is a significant change, the authors noted that lower extremity amputations are much higher in the diabetic population when compared to people without diabetes. Rates are particularly high for those greater than or equal to 75 years old, African Americans and men. Even though the study reported improvement in rates of lower extremity amputation, it did not take into account the projection of the epidemiological rate of diabetes or those who are undiagnosed. Ziegler-Graham et al. (2008) anticipate that the rate of amputation will increase due to improved measures to detect diabetes at an earlier stage over the next thirty years. Diabetic lower extremity amputation will not be solved by preventive care. The association of the disease and outcome may be slowed, but amputations will continue to be a concern for the future.

Another major dysvascular condition that ends in primary amputation is peripheral arterial disease (PAD). Peripheral arterial disease affects 3-6% of the population over age 55 (Gregg et al., 2004; McCollum & Raza, 2004). Prevalence of PAD increases with age with an escalation of up to 20% at 70 years of age (Hirsch et al., 2006). Severe PAD leads to lower extremity limb amputation due to infection and tissue loss from lack of adequate blood flow.

Diabetes can be the cause of PAD, but not in all cases. Those that have diabetes and PAD are at greatest risk for limb loss (McCollum & Raza, 2004). PAD is increasing in our nation due to an increase in the elderly population (McCollum & Raza, 2004). The symptoms of PAD sometimes go unrecognized and undiagnosed until it is too late to salvage the limb. Only 10% of people with PAD have intermittent claudication, which is the classic symptom for the disease (Hirsch et al., 2001). One study found up to 63% of the participants that tested positive for PAD by ankle brachial indices had no claudication symptoms (McDermott, Fried, Simonsick, Ling & Guralnik, 2000).

People with diabetes and/or peripheral arterial disease that have an amputation deal with acute and chronic pain. Chronic pain occurs in 72% to 80% of amputees (Ehde et al., 2000; Hanley et al., 2007; Richardson, Glenn, Horgan & Nurmikko, 2007). There is some evidence that severe acute pain in the postoperative period is related to increased chronic pain (Dunworthy, Krenzischek, Pasero, Rathmell & Polomano, 2008). Chronic pain causes suffering, inability to perform activities of daily living, inability to participate in rehabilitation, psychological strain and sometimes a dysfunctional home environment due to the role strain from the constant presence of pain (Bosmans, et al., 2007; Dudgeon, Gerrard, Jensen, Rhodes & Tyler, 2002; Ehde et al., 2000; Ellis, 2002). Therefore, minimizing acute pain in the post-operative period may have long-term positive benefits. Although there is some evidence to support this, few non-pharmacological interventions have been tested in the post-operative period. In particular, there is a dearth of literature on interventions targeting phantom pain and residual limb pain in the acute setting.

In a recent analysis of pain management options for neuropathic pain, Knotkova, Cruciani, Tronnier and Rasche (2012) found that a limited number of control studies have been

done to assess drug efficacy in this type of pain. They also found that of the limited studies available, inadequate methodology was used. After review of the literature, the authors concluded that since neuropathic pain is chronic in a majority of amputees that pharmacologic treatment does not provide adequate relief and supportive treatments must be used to enhance the treatment regimen.

The pain experience encompasses both physiological responses and psychological processes. Craig (2006) described pain and emotion as reciprocal influences. Although pain management is focused primarily on the sensory aspect of the physiological responses and is reported via pain scales, there is little to no attention placed on the affective component of pain. Craig (2006) noted that pain management is largely one-dimensional due to the lack of treating both the sensory and affective component of pain.   Two of the basic emotions experienced in pain processes are anxiety and depression.

Anxiety is a psychological response to pain often experienced in the new amputee. Studies have reported rates of anxiety after amputation to be from 17.6% to 37% (Atherton & Robertson, 2006; Desmond & MacLachlan, 2006; Coffey, Gallagher, Horgan, Desmond, MacLachlan, 2009; Hawamdeh, Othman & Ibrahim, 2008; Singh et al., 2009).   A correlation exists between pain and anxiety. The greater the amount of anxiety then the worse the postoperative pain experienced (Craig, 2006). Acute pain, such as that found in the immediate postoperative period, generates anxiety, as well as, when there is a change in the pain level (Craig, 2006). Not only can anxiety change the level of pain, but it can also cause physical decompensation (Craig, 2006).   The pain-anxiety-tension cycle can lead to physical decline from the pain by causing muscle tension at the site of injury which results in vasoconstriction,

ischemia and release of enzymes stimulating the pain pathway (Keefe & Gil, 1986). The anxiety heightens the pain leading to a prolonged cycle of pain.

Anxiety does not occur as the only affective disorder in the amputee. Depression is often present. Depression related to amputation has been reported in a number of studies, with rates reported from 13.4%, to as high as 41.7% (Atherton & Robertson, 2006; Cansever, Uzun, Yildiz, Ates & Atesalp, 2003; Darnell et al., 2005; Desmond & MacLachlan, 2006; Coffey et al., 2009; Hawamdeh et al., 2008; Singh, Hunter & Philip, 2007). Craig (2006) discussed that both positive and negative moods are capable of altering pain. Depression, a common negative reaction to the process of amputation, can alter pain tolerance. Most studies linking depression and amputation pain have been conducted after the patient is in a chronic phase of pain (Castillo, Mackenzie, Wegener & Bosse, 2006; Desmond & MacLachlan, 2006; Whyte & Niven, 2001). In studies done on chronic amputation pain there are mixed reports as to whether pain and depression have a synergistic effect. Desmond and MacLachlan (2006) found significant differences between types of amputation pain and depression. Castillo et al. (2006) found that high levels of depression post discharge were related to chronic pain in the lower extremity amputee. Whyte and Niven (2001) found that the depression might be related to the disability and not necessarily the pain. No studies were found studying depression in the acute postoperative setting relating to the pain experience.

Statement of the Problem

Pain management in the amputee is a difficult task due to the multidimensional aspects of pain and affective disorders that contribute to the total pain experience. Craig (2006) noted the inability of the health care practitioner to adequately assess for both the sensory and affective processes of pain due to limited tools for assessment. Treating the complexity of amputation

pain with interventions for both sensory and affective qualities is imperative to help prevent a chronic, debilitating pain in the future. At present, pain management in the acute phase after amputation is normally treated by opioids. Additional pain management in the form of complementary therapies need to be incorporated into pain control measures for the amputee.

Desensitization, a non-invasive, complementary therapy is a technique, similar to massage, that is found in instructional texts for interdisciplinary health care students. It is purported to decrease pain and help with adjustment to body image (Huang & Kuiken, 2004). However, no studies have been conducted to verify this information. Studies using the complementary therapy of desensitization are needed in order to substantiate practice. Since no established protocol was found in textbooks or practice settings, this pilot study will test a protocol developed by the author and evaluate its feasibility, efficacy and effect on pain after amputation surgery.

Physiological Mechanisms of Pain after Amputation

In order to understand the theory related to this study, knowing the physiologic mechanisms causing amputation pain is necessary.

Pain after amputation surgery is not only caused by the stress of surgery but is related to the induced injury of the tissues from the actual procedure. Pain after surgery is acute and should not be long lasting. Damage to the peripheral nervous system caused by the amputation procedure may lead to a chronic pain syndrome (Fritz et al., 2007). If pain in the acute phase is not optimally managed, the patient's outcome may be a chronic pain syndrome. Galloway, Buckenmaier & Polomano (2011) reported that unresolved acute pain leads to chronic pain in the amputee. Ehde and Smith (2004) also discussed how pain after amputation can transition to a

chronic state and limit quality of life and functional ability. Daniel (2008) stated that inadequate postoperative management of pain increases the risk of chronic pain.

Pain Pathway after Amputation

Firing of the nociceptors causes pain after amputation surgery. The skin possesses more nociceptors than muscle, bone or visceral tissue (Fritz et al., 2007) Chemicals are released at the site as a response to the injury of surgery. In the case of amputation it is tissue and nerve injury due to the severing of the limb that causes firing of millions of these nociceptors. The action potential of the nerve sends signals to the dorsal root ganglion of the spinal column where the pain gate is opened and transmission occurs through the ascending tract to the medulla and thalamus (Meyer, Ringkamp, Campbell & Raja, 2006; Nikolajsen & Jensen, 2006). Two types of fibers exist in the spinothalmic tract that transmits the signals from nociceptors. The pain sent from the nociceptors is transmitted along small or A-delta fibers, which are rapid transmitting fibers. The A-delta fibers respond to signals of weaker intensity. The C-fibers are large diameter, slow transmitting pathways that respond to signals of greater intensity or magnitude. The C-fibers synapse at the dorsal horn sending the signal through an ascending pathway (Galloway et al., 2011). If pain is not managed properly in the acute care setting then the C-fibers cause a constant firing and dorsal horn excitability. The stimulation of C-fibers is accomplished through rubbing which results in decreased sharp pain sensation (Fritz et al., 2007).

Transmission through the ascending path travels to the medulla and thalamus and then to the somatosensory parts of the brain. Simultaneously a descending pathway is activated during initial pain sensation. The descending pathway is an inhibitory pathway that should prevent some of the pain signals from being sent to the brain (Galloway et al., 2011). It is through the

ascending and descending pathways that the individual perceives pain. Treatment is aimed at reducing the excitation of the ascending pathway and increasing the inhibitory system of the descending pathway (Galloway et al., 2011).

Acute to Chronic Pain Transition

The transition point from acute to chronic pain is critical. Sensitization with changes in the peripheral or central nervous system causes this transition (Galloway et al., 2011). The inflammatory process that occurs with the healing of the tissues causes a reduced threshold at the periphery for nociceptors. The results are a prolonged and heightened response to pain manifesting as hyperalgesia or an extreme sensitivity to pain caused by neuronal hyper-reactivity. It can also cause allodynia or pain from stimuli that are not typically painful, such as light touch. (Galloway et al., 2011; Meyer et al., 2006; Nikolajsen & Jensen, 2006).

Neurons in the dorsal horn of the central nervous system become sensitized with the constant transmission of painful stimuli occurring from C-fiber stimulation. This process is called central sensitization. (Meyer et al., 2006; Nikolajsen & Jensen, 2006) During this process changes occur in receptors and neuron structures leading to an overactive pathway transmission to pain and sensation. The threshold to block painful stimuli from transmission to the brain lowers. The outcome is pain that transitions from an acute state to a chronic state (Daniel, 2008; Galloway et al., 2011).

A second change that occurs during central sensitization is independent firing of neurons from the periphery without a stimulus.   Firing without a stimulus is called wind-up. Firing of the peripheral neurons sends a continuous signal through the pathway thus lowering pain inhibition even further. The central nervous system forms a maladaptive pattern of processing pain at this point. The neuron structure and pain processing mechanism are redefined in this

maladaptive firing and are unable to inhibit the pain. The restructuring is called neuroplasticity.

Results are a chronic pain state including phantom limb pain (Galloway et al., 2011).

During this transition the pain has been largely uncontrolled. The dorsal horn has to be desensitized to increase the pain threshold and inhibit transmission. Pain caused by neuroplasticity and wind-up are resistant to analgesics (Galloway et al., 2011). The need for pain management in this type of pain is through alternative management strategies (Galloway et al., 2011).

Theoretical Frameworks

The nursing theory used in this study is Roy's Adaptation Model, which will help structure the variables surrounding amputation pain, treatment and the neuromatrix theory of pain. The neuromatrix theory also will provide a framework for understanding how the intervention works with the amputation pain pathway.

Roy's Adaptation Model

Roy's Adaptation Model is the guiding nursing framework for this study. An assumption of this theory is that individuals have the ability to accept input, control the input and form a responsive output (Roy, 2009). In new amputees a positive response would be adaptation to a life without a limb and without pain. Unfortunately, amputees struggle with pain and pain interferes with daily life. Pain is the primary input in the immediate postoperative period eliciting the need for an adaptive response. If pain is uncontrolled, it may become chronic and negative adaptation will be the outcome (Hanley et al., 2007). Macrae, Powell & Bruce (2008) report that the incidence of chronic pain after lower limb amputation surgery occurs in 50 – 85% of patients which shows that at present inadequate pain control of the amputation patient is an on-going problem.

Input (Stimulus). Roy (2009) describes a focal stimulus as the immediate input that the system experiences. In an amputee, the focal stimulus is pain within an acute setting. The experienced pain may be heightened by other stimuli. Roy (2009) refers to contextual stimuli as all other stimuli that enhance the focal stimulus. Contextual stimuli influence how the individual deals with the focal stimulus (Roy, 2009). Contextual stimuli aggravating the pain experience for the amputee can include patient characteristics, clinical characteristics, prior pain experience, anxiety and depression. Patient characteristics that may contribute to the pain experience are age, gender, race and educational level. Clinical characteristics may also affect pain and include surgical procedure, underlying disease cause, comorbid conditions and anesthesia used during the procedure. Pain experienced prior to the surgery can also contribute to the amount of pain experienced after the amputation. Anxiety and depression are common experiences related to surgery. The amount of anxiety and depression of an amputee may lead to heightened states of pain in the postoperative period resulting in a chronic pain state (Castillo, et al., 2006).

Coping Strategies (Adaptation). Coping or controlling of the pain is important after amputation. Roy (2009) divides coping processes into subsystems of cognator and regulator for the individual. Coping processes for the amputee in the acute setting primarily relate to effective pain control following surgery. The cognator and regulator system of the human body carry out life processes. The result of the system can be integrated, compensatory or compromised. The amputee's ability to deal with the stimulus of pain in an integrated and compensatory manner will lead to a positive response. Constructive changes show when adaptation has occurred. If the system fails to effectively deal with the changes then a compromised state will occur. The response will act as a feedback to the system seeking a homeostatic level (Roy, 2009). The two systems make up the total experience of pain sensation by the individual.

The regulator system as described by Roy (2009) follows the physiological responses of the pain pathway noted earlier. The regulator system is the neural, chemical and endocrine responses the pain elicits internally. Roy describes the regulatory actions as primarily autonomic in nature, although some can be imposed externally. After amputation, the effect of surgical separation of the tissue, bone and nerves starts the process of the regulator system causing pain.

The cognator subsystem uses four channels which are; emotion, perceptual and information processing, learning and judgment (Roy, 2009). It is through the perceptual and information processing channel that Roy says attention, coding and memory are linked to the stimulus. The channel of learning deals with imitation, reinforcement and insight. Judgment is comprised of problem solving and decision-making. Roy explains emotions as the person's relief from anxiety or affective circumstances. In the amputation patient in the acute setting, the pain after arousal from surgery enacts the processes of attention, coding and memory linking it to past pain experiences. In essence, this is why someone can rate his or her pain scale comparatively. The person has had prior experience with pain and possibly surgery and has learned about pain after this experience. Judgment of the pain experience is seen when the individual decides on the course of action to take. Often this results in needing some form of pain relief, i.e. asking for pain medication. Emotion, as Roy describes in her model, centers on affective feelings, one being anxiety. Emotions for some one sustaining limb loss heightens the pain experience. The four channels of the cognator system are used during pain processing in the amputation patient. Roy (2009) sees the pain experience as part of the sensory adaptation of the individual. Therefore, a stimulus causes the sensation of pain. This is easily related to the amputation of surgery. But, what is not understood is pain caused when there is no sensory input, as that caused from a phantom limb.

Behaviors (Outcome). Processing of the input or stimuli through coping processes results in a behavioral response. Behaviors can be internal or external (Roy, 2009). External pain behaviors may be observed, such as an elevated heart rate. Internal behaviors are more prevalent in amputation pain. The internal regulator system is automatically trying to deal with the pain. It is only when this system fails that behavior changes. This occurs immediately after the amputation. The physiological distress of neuropathic pain and residual limb pain are prominent sensations needing adaptive coping. Nurses must assess internal and external behavior in order to help with adaptation.

The outcome of adaptation can be integrated, compensatory or compromised (Roy, 2009). Integrated adaptation occurs when the person meets basic human needs such as, oxygenation, food and water. Compensatory adaptation occurs when coping is needed to establish holism again. Compromised adaptation occurs when a failure of integration and/or compensation occurs (Roy, 2009). In the acute postoperative period, the amputee is in a compensatory state trying to seek ways of controlling the pain. If the person is successful with pain control, then an integrated and compensatory state occurs and the person has adapted. If this is not effective, then adaptation is compromised. Prolongation of a compromised state during the pain experience will result in a poor patient outcome (Roy, 2009). The result of compromised adaptation is chronic pain.

Neuromatrix Theory

As discussed in Roy's theory, the subsystem of the regulator and cognator, explain the response to the sensation of pain caused by the amputation surgery. What is not clear is what happens when there is no sensory input. The lack of sensory input from a phantom limb is

difficult to explain due to there being no neural, hormonal or chemical inputs to evoke this type of pain.

Explanation related to coding for phantom limb pain is addressed in the work of Dr. Melzack's Neuromatrix Theory. Melzack (1999) suggests that phantom limb pain does not follow the traditional physiological response. A belief in this theory is that a neural process of the brain makes the phantom pain seem real to the individual in the absent of any type of input. Melzack also based this theory on the body having a genetically predisposed brain process that through the course of living has been modified.

Melzack (1999) describes a matrix of neurons extending through the body that produces repeatable nerve impulse patterns. This matrix is formed genetically but through life the patterns may be transformed. He describes this as the neuromatrix with patterning or loops in the thalamus, cortical and limbic regions of the brain that process the inputs cyclically. This process produces an output he terms the neurosignature. Unlike Roy, Melzack believes that the pain is more than sensory. He believes the pain experience upsets the brain's homeostasis causing stress, which leads to activation of the hypothalmic-pituitary-adrenal pathway. This results in release of adrenocorticotropic hormone (ACTH), which in turns acts on the adrenals to release cortisol. If pain is not modulated then cortisol can be produced excessively, leading to a chronic pain state.

According to Melzack (1999), the hyperactivity of constantly firing neurons from severed tissues produces a referred pain pattern that is distinct in areas without nerves. It is through the constant barrage of neuron firing and genetically predetermined neurosignature of pain that the brain reacts to the phantom pain experience. Melzack (2001) states that in order for this internal coding to be reestablished, restructuring has to occur. The primary way to stop an established

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and innate pain pathway in the body is by establishing a new pathway through stimuli at the site (Melzack, 2001).

Research Questions

Specific questions that will be addressed in this study are:

(1) What are the demographic (age, gender, ethnicity, education level) and clinical characteristics (type of amputation, reason for amputation, pre-amputation pain management) of the lower limb amputee patients in the study?

(2) a. What are the patterns of pain quality, total pain, type of pain, pain management (opioid use), anxiety and depression in the immediate post-operative period on postoperative day (POD) 2, 4 and 6?

b. What are the relationships among pain quality, total pain, type of pain, pain management, anxiety, and depression in the immediate post-operative period on POD 2, POD 4 and POD 6?

(3) a. What is the acceptability and feasibility of a desensitization intervention (recruitment, retention, patient acceptance, ease of use) for lower limb amputees in the post-operative period?

b. How does the desensitization intervention affect self-reported short-term pain in lower limb amputees during the immediate post-operative period?

Definition of Terms

Conceptual Definitions.

For the purposes of this study the following terms are conceptually defined as:

Amputee includes any male or female that is 18 years of age or greater that has a lower extremity amputation at the transfemoral, transtibial or knee disarticulation level.

Lower limb amputation is the process of removing a limb by division through the long bone of the leg or through the knee (Browker, 2004).

Pain is the sensory, affective, behavioral and cognitive personal experience resulting from induction of noxious stimuli (Roy, 2009).

Acute pain is pain that is short in duration and has an identifiable cause with an expected time course (Roy, 2009).

Chronic pain is pain that persists and does not have a predictable time limit that may or may not have an identifiable cause with an expected time course (Roy, 2009).

Neuropathic pain is the sensory experience in the missing area after removal of a body part. It is also called phantom pain (Middleton, 2003).

Nonneuropathic pain or nociceptive pain is pain resulting from physiological activation of the peripheral and central nervous system that actual tissue injury (Haanpää & Treede, 2010).

Depression is a change in mental mood that is accompanied by feeling down with a loss of interest in normal activity, feelings of low self esteem, lack of sleep, poor appetite, diminished energy, and lack of concentration (World Health Organization, 2014).

Anxiety is a transitory and unpleasant emotional response that is preceded by a perceived threat leading to tension and apprehension (Daniel, 2008)

Operational Definitions.

Anxiety and depression were operationalized in this study by completion of the Hospital Anxiety and Depression Scale (HADS), consisting of 14 questions measured on a four-point rating scale from 0 to 3 being answered. The participants rated two subscales with 7 questions for anxiety and 7 questions for depression.

Neuropathic pain and nonneuropathic pain were measured by the completion of the Short Form McGill Pain Questionnaire-2 (SF-MPQ-2) consisting of 22 items measured on an eleven-point scale from 0 to 10. The questionnaire is subdivided into four scales; continuous, intermittent, neuropathic and affective descriptors. Nonneuropathic pain consists of the two subscales of continuous and intermittent pain measured by this instrument.

Conceptual Model

In the conceptual model for this study, Roy's Adaptation Model is used as a basis for construction for the proposed research. The input is made up of the focal stimulus of amputation pain with the contextual stimuli represented by patient characteristics, clinical characteristics, pre-intervention pain control, anxiety and depression. Coping (adaptation) strategies for the amputee is done through the use of available pain management. All patients receive a prescribed regime of medication for their pain after surgery, usually consisting of an opioid. Roy (2009) discusses pain compensation as a complex biological and behavioral process that is difficult to manage within the context in which it occurs. Because of this difficulty, Roy (2009) feels that a person experiencing pain often loses the ability to compensate and becomes compromised in trying to adapt. Roy (2009) identifies nurses as the healthcare professional that can assist the person with pain adaptation. Although, Roy does feel nursing often bypasses the need for more than one intervention to help with pain adaptation. In assisting with this adaptation, a complementary therapy, desensitization, is proposed for pain relief. Through the use of both pharmacologic therapy and desensitization, the outcome for the patient may be a decrease in the level of neuropathic and non-neuropathic pain, as well as, reduced anxiety and depression which will lead to a compensated state for the new amputee. See Figure 1.

Figure 1. Acute Amputation Pain Management Model
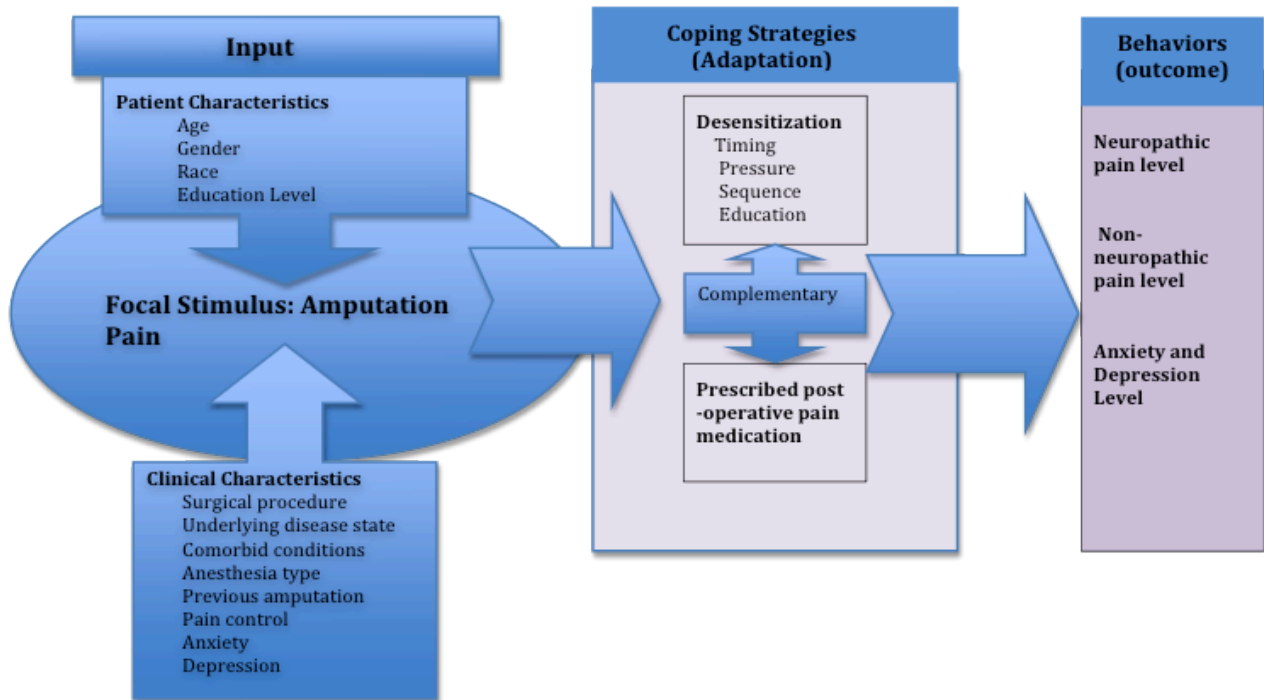
Model based on Roy's Adaptation Model (2009).

Summary

Currently 1.7 million people live with limb loss. The majority of these individuals have received an amputation due to a dysvascular cause with diabetes being the leader of lower limb amputation. Individuals diagnosed with diabetes are escalating with 18 million currently diagnosed and another 5.9 million that are undiagnosed. Of total amputations done, 60% occur in the diabetic population.

Pain is a major outcome of those having an amputation. The pain is multidimensional and difficult to treat. Pain not only has a physiological cause but also an affective component. The new amputee is typically treated with standard pharmacologic pain medication as a result of an assessment completed on a numerical pain scale. The affective components of pain are not assessed and therefore left untreated. The lack of treatment of the holistic biobehavioral process of the pain experience in the amputee leads to a chronic state of pain that has long lasting effects on functionality, recovery and daily productivity (Huang & Kuiken, 2004).

In order to treat all aspects of amputation pain, effective treatment must be employed. Research on pain lacks the use of complementary therapies that can accompany the pharmacologic regime. Desensitization is a complementary therapy that has been discussed as a possible treatment for this population but has gone unresearched as an adjunct in pain management despite it being taught in didactic classes for professional health care personnel. Furthermore, no research has used complementary therapies in the time period immediately following amputation surgery.

CHAPTER 2: REVIEW OF THE LITERATURE

The purpose of this pilot study is to examine the efficacy and feasibility of a desensitization protocol on pain management of the postoperative amputation patient in the acute care setting. This chapter is a review of the pertinent literature relevant to the variables in the conceptual model.   The chapter will include three main categories represented by pain as the focal input, contextual input, and coping strategies. Contextual input variables include patient characteristics, clinical characteristics and pre-surgical control of pain, anxiety level and depression level. Variables representative of coping strategies after surgery include pain medication regimen and the intervention of desensitization. Finally the chapter will conclude with an explanation of Roy's Adaptation Model and Melzack's Neuromatrix theory as the theoretical basis of this study.

Focal Stimulus: Pain

Pain is the immediate response following amputation surgery. It is this focal stimulus that elicits the individual to seek strategies to resolve the pain in order to reestablish a homeostatic state of being. The pain experienced after amputation often prevents the patient from developing suitable strategies to cope with the pain. Two types of pain are experienced by the amputee, residual limb pain and phantom limb pain or neuropathic pain. The amputee does not usually experience just one of these types of pain. Both pain types are reported in the amputee beginning in the immediate postoperative period (Flor, 2002; Nikolajsen & Jensen, 2001; Wiffen et al, 2006). Bloomquist (2001) and Richardson (2008) describe amputation pain as complex and multidimensional, making it difficult to treat.

Phantom Limb or Neuropathic Pain

Phantom limb pain (PLP) is the sensory experience of pain in the missing limb after removal (Middleton, 2003). Haanpää and Treede (2010) describe this neuropathic type of pain as a direct result of a lesion or a disease that has direct affect on the peripheral and central nervous systems. Studies on phantom limb pain have mainly focused on prevalence and descriptors of the pain.

Prevalence. Studies measuring the prevalence of phantom limb or neuropathic pain have reported ranges from 63% to 85.6% in the literature (Clark, Bowling, Jepson & Rajbhandari, 2013; Ehde et al., 2000; Ephraim, Wegener, MacKenzie, Dillingham & Pezzin, 2005; Gallagher, Allen & MacLachlan, 2001; Hanley et al., 2006a; Jensen et al., 2002; Kern, Busch, Muller, Kohl & Birklein, 2012; Probstner, Thuler, Ishikawa & Alvarenga, 2010; Richardson et al., 2007: Smith et al., 1999). The mean time since amputation ranged from 4 years to 18 years (Ehde et al., 2000; Ephraim et al., 2005; Hanley et al., 2006a; Smith et al., 1999). Studies on prevalence of PLP have taken place after respondents have reached a chronic pain state.

Two studies were longitudinal (Bosmans, Geertzen, Post, van der Schans & Dijkstra, 2010; Castillo et al., 2006). Bosmans et al. looked at PLP over a three and a half year period of time. The study used a repeated measures design with surveys given at five days postoperative, 1 ½ years, 2 ½ years and 3 ½ years. Included in the sample (n = 85) were both upper and lower limb amputees. The authors found that PLP in lower extremity amputees decreased over the first 2 ½ years, but then started increasing again at the 3 ½ year mark. Limitations of the study included attrition rate of the sample and lack of instrument reliability and validity. The initial sample started out with an n = 225 and due to attrition over half of the sample was lost to follow-

up. The instruments used were the only ones available in the Dutch language and had not been tested for reliability and validity.

Castillo et al. (2006) used secondary data from a national study to look at prevalence of chronic pain seven years after lower limb amputation due to trauma. Several predictors of chronic pain were found to be statistically significant in the sample (n = 397). These predictors were; less than a high school and college education, low self-efficacy and high alcohol use. The study also showed high pain intensity starting at three months post discharge. They found that only 22.9% of the sample was pain free after seven years. The chronic pain was associated with the experience of PLP. The study was limited by secondary data and confounding variables.

Ephraim et al. (2005) performed a cross sectional study of a national sample (n = 914) through the Amputee Coalition of America (ACA) over a two year period using a telephone survey. The authors measured prevalence, intensity and bothersomeness of pain with a convenience sample. Ninety-five percent of the sample reported pain in the previous month. Mean time since amputation in the total sample was four years. Phantom pain was more prevalent (79.9%) than residual pain (67.7%). The phantom pain was usually severe (7-10 on a 1-10 scale) and extremely bothersome. The authors concluded that chronic pain after amputation was a problem.

In a study by Smith et al. (1999) frequency, intensity, bothersomeness and treatment were measured in a sample of 92 amputees. They found 63.3% experienced PLP. The majority of participants reported their phantom pain as severe in intensity but only mildly bothersome. The majority of participants (63.3%) had not used any prescription medication for relief of this type of pain. Of those participants that did take medication, 35.5% took medicine on a daily basis.

The study is limited by generalizability since the population was primarily white (84%), educated (51%) above high school level and male (84%).

Hanley, Ehde, Campbell, Osborn and Smith (2006b) looked at similar variables with PLP, as did Ephraim. Pain prevalence, intensity and severity along with prevalence of treatments used by the participants. The study was conducted as a secondary analysis of a larger study. In the lower extremity amputee sample (n = 255) the prevalence of pain was 72%. Phantom limb severity on the average was rated as a 5.1 on a 1-10 scale. Pain intensity was moderate for 26% and severe for 31% of the sample. In reporting treatment, it was found that 53% of the sample had never used any treatment for their PLP. At the time of the study, 43% were currently using treatment of medications and non-pharmacologic modalities. Respondents that used treatment reported higher phantom pain levels in the previous three months and experienced higher levels of disability. The main treatment used was pharmacologic therapy of opioids with acetaminophen (22%) being the most frequently used. Physical therapy was the main non-pharmacologic therapy used (16%). Massage had been used in the past by 48% of the respondents and was considered moderately to extremely helpful. The authors concluded that more research is needed on effective treatments for phantom pain.

In a recent study by Kern et al. (2012), 537 participants in Germany were surveyed by questionnaire about PLP. Of the 74% that suffered from PLP, a majority (42%) had never been informed about PLP. Most patients went untreated when they experienced this type of pain. Those that were treated averaged seeing three health care professionals before intervention was done. Limitations of the study were convenience sampling using a mailed questionnaire and also support for the study by a prosthetic company.

Descriptors. Researchers have studied amputee's description of phantom pain to become familiar with the characteristics of this type of pain (Clark et al., 2013; Bosmans et al., 2007; Dudgeon et al., 2002; Dudgeon et al., 2005; Ehde et al., 2000; Jensen, Smith, Ehde & Robinson, 2001; Mortimer, Steedman, McMillan, Martin & Ravey, 2002; Richardson et al. 2007; Smith et al., 1999; Warms, Marshall, Hoffman & Tyler, 2005). Several of the studies were qualitative (Bosmans et al., 2007; Mortimer et al., 2002; Warms et al., 2005), one study used a mixed method design (Dudgeon et al., 2005) and the rest of the studies were quantitative.

One qualitative study used a phenomenological approach to describe chronic pain experienced in disabled individuals (Dudgeon et al., 2002). Three groups of disabled individuals were interviewed with one of these groups being amputees. The sample consisted of nine participants with 3 participants in each group. Themes arising from the study were that pain is a mystery, pain is plural and pain is personal. The entire sample said pain was a mystery and they had to be a self-advocate with medical personnel to get treatment for this pain by giving direction to the physician or nurse to help them. Limitations of the study are sample size with only three participants for each disability and results were not specified per disability.

Dudgeon et al. (2005) several years later used a mixed method sample to describe pain among the disabled. The qualitative sample used the same three disabled groups with a sample of 28 participants. Nine of the participants had lower limb amputations. The phenomenological approach of this study found that descriptors of pain from the amputation group included squeezing and pinching for musculoskeletal pain while zinging, buzzing and knotted were the descriptors for neurologic pain. Dudgeon et al. used a modified McGill Pain questionnaire with 24 descriptors to quantitatively measure frequency of descriptors used per group. Each group was analyzed for frequency. The authors suggested using a set of the top fifteen words. The top

fifteen descriptors for the amputee group were: sharp, tingling, shooting, stabbing, throbbing, aching, shocking, piercing, cramping, tiring-exhausting, stinging, nagging, tight, hot-burning and radiating. One strength of this study compared to Dudgeon's previous study was that results were specific per disability.

Mortimer, Steedman, McMillan, Martin and Ravey (2002) found similar findings in regards to descriptive words used by patient's experiencing phantom limb pain. In this focus group designed study, pain was described as shooting, shocking, sticking, stabbing, burning, cramping and crushing. The authors found that people living with this type of pain were not educated nor were they able to articulate information about the treatment. In Warms et al. (2005) a secondary analysis of comments written in the margins of a pain survey were explored. Amputees were a subset of the sample. The overarching theme was the need to speak with others about the experience of pain. The respondents lived with pain daily without adequate information from health care professionals on how to treat this pain. Warms et al. study lends support to the findings of the Mortimer et al. study in the lack of information the person receives regarding phantom pain and its treatment.

In a quantitative analysis of phantom pain, Ehde et al. (2000) looked at a large sample (n = 255) of community dwelling lower limb amputees for frequency, duration, intensity, disability and descriptors. The sample was predominantly male (81%), well educated (87%) and white (86%). The mean time since amputation was 14.2 years. The prevalence of phantom pain in this sample was 72%. The Short Form-McGill Pain Questionnaire was used for descriptive analysis of the pain. The six words that described phantom pain most often in the group were: sharp (78%), tingling (77%), stabbing (72%), shooting (76%), throbbing (67%) and aching (56%). The

authors suggested that future research needed to change from looking at prevalence to other factors affecting pain, such as disability or psychosocial aspects.

Jensen et al. (2001) looked at descriptors of pain through categories.   The authors were testing a previously published classification of pain into the categories of mild, moderate and severe. The authors found that this classification system did not work for phantom limb pain. Richardson et al. (2007) looked at the pain experience of those with phantom pain as multidimensional with various aspects affecting this pain type. The authors conducted a prospective study looking at physical and psychological factors of pain in the lower extremity amputee that had this surgery due to severe peripheral vascular disease. Phantom pain was found in 78.8% of the sample (n=59).   The psychological factor that was found to correlate with phantom pain was catastrophizing. They also found that those that used the word "tender" as a descriptor of pain had a higher level of phantom pain at 6 months. A limitation of this study is the small sample size.

In a recent study by Clark et al. (2013) studying PLP and phantom sensations among a group of diabetes compared to non-diabetics, PLP descriptors were similar to those found by Ehde et al. (2000). Prevalent descriptors of PLP were sharp/stabbing (47%), dull ache (34%), shooting/electric (33%), cramping (22%) and burning (17%) among the total sample of 88 participants. A limitation of the study was self-reporting since this was done by mailed questionnaire.

Residual Limb Pain

The second type of pain experienced after amputation is residual limb pain (RLP). Residual limb pain is any painful sensation that is localized to the remaining part of the limb (Wiffen et al., 2006). RLP occurs with PLP after amputation but should be distinguished from

this type of pain for treatment purposes (Behr et al., 2009; Flor, 2002; Dudgeon et al., 2005; Ephraim et al., 2005; Wiffen et al., 2006). Reports of non-neuropathic or residual limb pain ranged from 32% to 74% (Ehde et al., 2000; Ephraim et al., 2005; Gallagher et al., 2001; Probstner et al., 2010; Smith, Comiskey & Ryall, 2008; Smith et al., 1999). RLP is less often reported in the literature due to its similarity to postoperative pain. A few studies reporting prevalence of RLP in the literature were found (Ephraim et al., 2005; Gallagher et al., 2001; Probstner et al., 2010; Smith et al., 2008). Several studies looked at description of RLP by the amputee (Ehde et al., 2000; Ephraim et al., 2005; Dudgeon et al., 2005; Smith et al., 1999).

Prevalence. Probstner et al. (2010) focused on the prevalence of pain in the amputee who had lost their limb due to cancer. In this study, they found that RLP was 32%, which was a lower prevalence than other studies. Limitations of this study were a small sample (n= 75) and lack of generalizability due to the study only taking place with cancer patients in Brazil. Another study by Smith et al. (2008) measured RLP in lower extremity amputees in Ireland with various causes for the amputation (trauma, peripheral arterial disease and diabetes). Prevalence of RLP in the sample (n= 107) was 56.1%. The primary cause for the residual limb pain was prosthetic wear. A correlation was made between RLP intensity and those that sustained the amputation due to a dysvascular cause. A limitation of this study is generalizability of the sample.

The remaining four studies found a high rate of prevalence of RLP (Ehde et al., 2000; Ephraim et al., 2005; Gallagher et al., 2001; Smith et al., 1999). Smith et al. (1999) found a high rate (76.1%) of RLP among a sample (n = 92) of primarily Caucasian, well-educated men. In the study the authors found that RLP was as common as phantom pain and in some cases was worse than PLP. Ehde et al. (2000) found a RLP prevalence rate of 74% in a sample (n = 188) that had similar characteristics of being primarily Caucasian, well-educated men. Ehde et al. came to the

same conclusion as Smith et al., that RLP and PLP were equally prevalent. A limitation of the Ehde et al. study is that it took place in the same geographic area as the Smith et al. study, which could have a sampling overlap between studies.

Gallagher et al. (2001) found a much lower rate of RLP (48.1%) in her sample (n=104). The study took place in Ireland and consisted of primarily males (75%). The study did not include other demographics, such as education or ethnicity. Forty-one percent of those experiencing residual pain reported that they experienced the pain two to five times per week. Another 22% experienced it 5 to 10 times per week and 13% had constant RLP.

Ephraim et al. (2005) completed a national cross sectional survey of prevalence of amputation pain. The authors found that 67.7% of the sample experienced RLP. The sample was primarily white (85.8%), male (60.4%) and educated above high school level (93.8%). Thirty-eight percent of the sample had an amputation due to dysvascular causes. After controlling for confounding variables, trauma patients were found to be 1.7 times more likely to have RLP than those that received an amputation for a dysvascular cause or due to cancer.

Descriptors. The description of RLP is particularly important when trying to treat pain in the acute postoperative phase. Two studies reported on the bothersomeness of RLP. Smith et al. (1999) reported that RLP was more bothersome than phantom pain, but the intensity of both types of pain were the same. Ephraim et al. (2005) also reported on bothersomeness of pain. More than half the sample (59.7%) reported RLP as somewhat bothersome and another 26.5% reported that it was extremely bothersome. No other descriptive terms were used for RLP in these studies.

Dudgeon et al. (2005) in their mixed methods study used the McGill Pain Questionnaire (MPQ) to provide descriptors of RLP in a sample (n=1053) of disabled individuals. The

objective of the study was to identify common pain descriptors and determine if the MPQ needed modification. Of those in the sample, 459 were amputees. The authors used a cluster analysis to list the frequency of descriptive words for each disability and to differentiate between musculoskeletal and neurogenic pain. The three words most commonly clustered for amputees in describing neurogenic pain were shooting, sharp and stabbing. The authors reported that the three words that were used in amputees for musculoskeletal description were aching, tight and tiring-exhausting. The authors found that the MPQ needed modification to capture different types of pain and suggested a short form of the original instrument.

Ehde et al. (2000) in their cross-sectional survey of community-based lower limb amputees reported descriptors of amputation pain. RLP was described by the sample as intermittent occurring one to six times a week. The pain was reported as lasting from minutes to hours with a mean score of 5.4 (on 1-10 rating scale). Thirty-eight percent of the sample reported severe intensity (7 to 10) during episodes of RLP. RLP descriptors in the sample (n = 255) included; aching, sharp, throbbing, hot-burning, tingling and shocking.

<div align="center">

Contextual Input Variables

</div>

Patient Characteristics

Age. Only three studies examined age in relation to amputation pain. (Ephraim et al., 2005; Gallagher et al., 2001; Hanley et al., 2007). Ephraim et al. (2005) reported the prevalence of pain type per demographic characteristics for her sample (n = 914). Prevalence for each age group was similar for PLP in the 18-44, 45-54, 55-64 and 65 plus groups, with percentages of 78.3, 79.5, 83.9 and 79.0 respectively. RLP was also reported for the same age groups at 73.3% (18-44 years), 75.3% (45-54 years), 58.9% (55-64 years) and 54.1% (65 plus years). RLP was the only one that showed a decrease with the two older age groups. Gallagher

et al. (2001) found conflicting results with age and PLP. The authors found that participants

reporting phantom pain were older than their younger counter part.   The sample for this study

was much smaller than the Ephraim et al. study, which could cause a smaller effect size.

In the study by Hanley et al. (2006a) a reanalysis of two randomized control trials was

completed to study the changes in chronic pain levels of two disabled groups, lower limb

amputees and spinal cord injury patients. The groups were randomly assigned to treatment

groups of amitriptyline or an active placebo that were administered for six weeks. They found a

relationship between percent of meaningful change in pain scores and age. Age had a significant

positive correlation with change in pain scores with treatment. Older individuals (42 years or

greater) reported a better pain score with treatment than those that were younger. A limitation of

this study was the small sample size of amputees (n = 34). Even though the study did find an

association of pain and age for the overall group, the association of pain and age was not broken

down into spinal cord injury patients and amputees.

Gender. Four studies examined the relationship between phantom limb pain and gender

(Bosmans et al., 2010; Ephraim et al., 2005; Gallagher et al., 2001; Hirsch, Dillworth, Ehde &

Jensen, 2010). Bosmans et al. (2010) and Gallagher et al. (2001) both found that women

experience PLP more often than men. Gallagher et al. reported that the prevalence of phantom

pain in their sample (n = 104) was 87% for females (n = 26) and 67.1% for males (n = 78).

Bosmans et al. did a regression analysis and reported that the odds for females (n=33) having

phantom pain were 1.24 compared to males (n = 52). In both studies there were more males than

females, which has been consistent throughout most amputation studies.

In comparing the prevalence of PLP and RLP with gender, Ephraim et al. (2005) found

that both types of pain were similar in males and females. PLP for males and females was 80.4%

and 79.2% respectively within their study. RLP for males and females was 70.3% and 63.7% respectively. In this study the sample was also predominantly male (60.4%).

Hirsh et al. (2010) also studied the moderating effects of gender on pain perception. The study sample (n=335) primarily consisted of a large sample of men (72%), which is twice the percentage of women in the study. The findings of this study were contrary to prior studies. The authors found that males had a greater prevalence of phantom pain than females (86% vs. 77% respectively). After controlling for limb loss, they found no statistical difference in reported pain. No differences were found among males and females in RLP , which has been supported by previous studies. The authors did find a significant difference in overall pain and pain interference with females reporting greater pain overall and greater interference with pain in their daily activity level. Limitations of the study were overrepresentation of men and a high percentage of Caucasian participants (92%). In addition, men were more likely to be married than women (68% vs. 42%). This difference was statistically significant. Social support has been linked to pain differences and marital status may be a confounding variable in this study.

Education Level. Two studies were found that examined education level as a variable associated with amputation pain. Hanley et al. (2006b) found that the higher the educational level the less likely the amputee will seek treatment for pain. They also found that a higher education level was not significantly associated with a lower pain level. The authors could not understand why the person would be in pain and not seek treatment.   This occurrence was not explored in their study. Castillo et al. (2006) found that a lower education level was associated with higher pain in their study sample (n = 397). The authors examined the impact of education on those patients experiencing the highest level of chronic pain (Chronic Pain IV). They reported chronic pain IV for those with some college, those with a high school degree and those

with less than a high school degree. Chronic pain was more prevalent (32%) in those with less than a high school degree when compared to those with a high school degree (15%) or some college (4%). Limitations to generalizability in both studies are that the sample consisted of primarily Caucasian males with a higher level of education (high school graduate or above). The Castillo et al. study was longitudinal and had a dropout rate of approximately 29% over the seven years.   Those that were lost to follow up were less educated than the group that completed the study.

Race. In the model presented, race is an included variable. No studies were found examining race with amputation pain. Studies that were found discussed the racial differences related to amputation rate. All studies reported that the rate of amputation is higher among African Americans compared to Caucasians (Collins, Johnson, Henderson, Khuri & Daley, 2002; Dillingham, Pezzin & MacKenzie, 2002; Feinglass, Rucker-Whitaker, Lindquist, McCarthy & Pearce, 2005; Peek, 2011, Resnick, Valsania & Phillips, 1999; Ziegler-Graham et al., 2008). Dillingham et al. (2002) and Feinglass et al. (2005) both found that African Americans were two times more likely to have an amputation. Collins et al. (2002) found that race was a risk factor for lower extremity amputation in people with peripheral vascular disease. African Americans and Hispanics are more likely to receive an amputation than Caucasians. However, most studies that have been discussed thus far had a representative sample of primarily Caucasian males (Ehde et al., 2000; Ephraim et al., 2005; Hanley et al., 2006a; Hanley et al., 2007; Hirsch et al., 2010; Smith et al. 1999). All but one of these studies took place in the Northwest region of the United States.

Clinical Characteristics.

    Surgical Procedure. Four studies examined pain associated with the level of lower limb amputation (Bosmans et al., 2010; Ephraim et al., 2005; Gallagher et al., 2001; Hanley et al., 2007). Bosmans et al. (2010) and Gallagher et al. (2001) found similar results in their studies. The authors of each study reported that those individuals who had an above the knee amputation (AKA) have more PLP than those who have a below the knee amputation (BKA). Ephraim et al. (2005) found conflicting results in their study. After controlling for confounding factors in the study, they reported that there was no statistical difference in prevalence of PLP and level of amputation. Hanley et al. (2007) supported Ephraim's study with results showing that there was no significant association of level of amputation in either PLP or RLP. A limitation of the Bosmans et al., Gallagher et al. and Hanley et al. studies is the small sample size in each. Another limitation in the Hanley et al. study was that the findings were based on reanalysis of a previous study that had been done.

    Cause. There are different causes of amputation: trauma, chronic disease, congenital deformity and cancer. Several studies reported PLP associated with cause or etiology for the amputation (Bosmans et al., 2010; Ephraim et al., 2005; Gallagher et al., 2001; Hanley et al., 2007). Bosmans et al. (2010) and Hanley et al. (2007) found no association between cause and amputation pain. The Ephraim et al. (2005) study included dysvascular, trauma and cancer related causes in their sample (n = 914). They reported prevalence of PLP and RLP for each cause. Phantom pain was highest in dysvascular patients (82.9%) when compared to trauma (81.2%) and cancer patients (73%). RLP was highest in the trauma group (74.8%) followed by the dysvascular group (65.3%) and lowest in the cancer group (59.7%). However, after controlling for other factors, the authors concluded that etiology showed no statistical

relationship with pain. The findings from this study did suggest that RLP was greater for trauma

related amputations with likelihood that it would occur 1.7 times more in the trauma amputee.

Gallagher et al. (2001) found that PLP varied depending on cause. The authors reported that

85.7% of those that sustained an amputation due to a congenital condition did not experience

phantom pain compared to those with cancer (12.5%), trauma (27.1%) and other causes (26.3%).

The authors did not define "other" causes. A limitation of the Gallagher study is that the sample

consisted of a younger male population with the major cause of amputation being trauma. Both

Hanley et al. and Bosmans et al. had small sample sizes.

     Comorbidities. Two studies linked chronic comorbid diseases with amputation pain

(Gallagher et al., 2001; Ephraim et al. 2005). Gallagher et al. (2001) found multiple comorbid

diseases are associated with RLP. They also found those experiencing phantom pain has more

comorbidities than those without phantom pain (36.4% vs. 11%). A limitation of this study is

recall bias. The study was a mailed survey asking patients to recall comorbidities at the time of

surgery. Another limitation is the sample is younger (45, mean age) and may not suffer from as

many chronic diseases as those that are older.

     Ephraim et al. (2005) showed an increase in both PLP and RLP in relation to the number

of comorbid conditions. Comorbidities increased the adjusted odds of phantom pain from a "not

bothersome" state to an "extremely bothersome" state by 2.6 (95% CI, 1.0-6.4) for one comorbid

state and up to 2.8 (95%, CI 1.2-6.7) for those with two or more conditions. The same was found

with RLP. An adjusted odds ratio for residual pain was 2.2 (95%, CI 1.3-3.7) for participants

with two or more comorbidities.

     Anesthesia. There have been limited studies related to the administration of anesthesia

and amputation pain. Three studies were found looking at route of anesthesia administration

(Lambert et al., 2001; Campbell et al., 2000; Ong, Arneja & Ong, 2006). Campbell et al. (2000) completed a retrospective review of 349 charts of patients receiving a lower limb amputation over a seven-year period. Anesthesia for this type of surgery was done by general anesthesia (55%) more often than by spinal (29%) or epidural (14%). There was no statistical significance in mortality rate with types of anesthesia, however, the percentage of those receiving epidural anesthesia was higher (27%) compared to general (17%) or spinal (19%). A limitation of the study was performing a retrospective chart review covering years 1992-1998 and the data only included one anesthesia practice.

Ong et al. (2006) evaluated pain levels of patients receiving epidural (54%), spinal (32%) and general anesthesia (32%) in a sample of 150 lower limb amputees. They found that after one week post-surgery the pain level was lower in those that received epidural and spinal anesthesia but it did not reach statistical significance. During follow up at 14 months, there was no statistical difference in the amount of pain experienced. The authors also found that at follow up phantom pain was frequent and severe regardless of whether the patient was on pharmacologic agents or not for this type of pain. One major limitation of this study was that the data was gathered by recall when the participant returned to clinic.

Campbell et al. (2000) used general anesthesia and a perineural catheter on sixteen participants. The catheter was inserted during surgery and was used to dose bupivacaine during the procedure and then infuse the medicine for up to 72 hours afterwards. RLP scores were statistically higher in the perineural group. Phantom pain was also reported in this group but it did not reach statistical significance. The small sample size limited this study.

Prior Pain Control. Presurgical pain control occurs during pre-hospitalization and is inclusive of the time spent in the hospital prior to surgery. Most of the studies examining the

relationship of preoperative analgesia to postoperative pain were done using epidural administration of pain medication (Bach, Noreng & Tjellden, 1988; Karanikolas et al., 2011; Lambert et al., 2001; Nikolajsen, Ilkjaer, Christensen, Kroner & Jensen, 1997; Nikolajsen, Ilkjaer & Jensen, 1998). Three of the studies used epidural administration of the analgesics bupivacaine and morphine (Bach et al, 1988; Lambert et al., 2001, Nikolajsen et al., 1997). Nikolajsen et al. (1998) used the same medications as the other three studies but used an extradural catheter instead of the typical epidural placement. In all studies the medication was administered the day prior to surgery and then maintained during and after surgery. In the three epidural studies and the one extradural study, the outcomes were all the same. The conclusion of all the studies was that there was no effect on either PLP or RLP.

A study done by Karanikolas et al. (2011) used five analgesic regimens to investigate whether preoperative analgesia has an effect on PLP long term in four groups of randomized patients. Medications used in the study were bupivacaine and fentanyl for the epidural administration and only fentanyl for the patient controlled analgesia (PCA). All regimens used either preoperative epidural analgesia or preoperative PCA administration followed by either epidural anesthesia or general anesthesia in the operating room. The study did find that pain was statistically better at six months if epidural or PCA analgesia was optimized preoperatively and for forty-eight hours postoperatively when compared to a control group that received normal analgesia and general anesthesia. The result of this study varies from the previous studies that found no effects on long-term pain control.

Literature related to pain control pre-hospitalization is limited. Ong et al. (2006) reported that only 58% of their sample (n=150) used an opioid for pain control prior to surgery. Hanley et al. (2007) reported 56% of their sample had constant pain prior to surgery but did not mention

how it was controlled. Hanley et al. (2007) also found in their study that pre-amputation pain correlated with chronic phantom limb pain. A limitation of both Hanley studies was secondary analysis of existing data. Generalizability is also a limitation for Hanley since the studies were done with the same population. The Ong et al. study had a larger sample with adequate measurement of preoperative medication.

Anxiety and Depression

Studies, which measure anxiety and depression, have shown that affective disorders can impact postoperative pain. A number of studies have examined the influence of anxiety and/or depression on amputation pain (Cansever et al., 2003; Castillo et al., 2006; Chini & Boemer, 2007; Darnall et al., 2005; Desmond & MacLachlan, 2006; Ephraim et al., 2005; Hawamdeh et al., 2008; Horgan & MacLachlan, 2004: Jensen et al., 2002; Kazemi et al., 2013; Liu, Williams, Liu & Chien, 2010; Price, 2005; Sherman, Gall & Gormly, 1979; Trame et al., 2008; Whyte & Niven, 2001).

Anxiety

Two studies measured anxiety alone in relation to amputation pain. One study based the research on the pain-anxiety-tension cycle (Sherman et al., 1979). The premise behind the study was that anxiety magnifies phantom pain in amputees by muscle tension in the residual limb. The authors felt that muscle tension feedback would decrease anxiety and subsequently pain. The sample (n=16) was supplied a muscle relaxation tape with exercises to perform when residual limb tension started, as well as, feedback of residual limb muscle tension. Two of the participants were new amputees and the remaining sample was experiencing chronic pain from their amputation. Fourteen patients out of the sample showed complete to significant pain relief. Follow-up of the sample showed sustained pain relief at six months and up to three years. While

this study is dated and has a small sample, the results of this type of complementary therapy that can be self administered and is cost effective shows that these interventions are needed in the amputee experiencing pain in the acute and chronic periods.

Trame et al. (2008) also looked at anxiety in the lower extremity amputee to see if the level of anxiety affected pain level in the sample (n=23). Anxiety levels were measured preoperatively and postoperatively using the Beck Anxiety Inventory. The authors found that there was no correlation between pain levels and anxiety level postoperatively. The study was limited by sample size.

Depression

Multiple studies have focused only on depression in relation to amputation pain (Cansever et al., 2003; Chini & Boemer, 2007; Darnall et al., 2005; Ephraim et al., 2005; Jensen et al., 2002; Liu et al., 2010; Price, 2005; Whyte & Niven, 2001). Two phenomenological studies looked at the lived experience of amputees in Latin America and Taiwan (Chini & Boemer, 2007; Liu et al., 2010). Themes found in both studies related depression to pain. Cansever et al. (2003) found in a group of Turkish military men that depression was higher for those who sustained the amputation because of disease (51.4%) rather than those who had an amputation due to trauma (34.7%).

Three of the studies found that those experiencing PLP were more likely to have depressive symptoms than those who did not have PLP but the depression was linked to factors other than the pain experience (Jensen et al., 2002; Price, 2005; Whyte & Niven, 2001). Jensen et al. (2002) found higher depression was predictive of adjustment to PLP. He also found that psychosocial factors were responsible for the experience of phantom pain and in order to control pain, these factors have to be addressed. Price's (2005) findings were similar to Jensen. He

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found that there is a large common variance between social experiences and depression. He found that phantom pain was non-significant in depression for the amputee. Whyte and Niven (2001) found that the depression was not linked to pain or psychosocial factors but was related to the physical disability experienced by the amputee. All of these studies were limited by small sample size.

Darnall et al. (2005) found that pain was directly related to depression in the amputee. Darnall et al. reported in their cross-sectional study (n=914) that the prevalence of depression was 28.7%. Persons in the study that described PLP as extremely bothersome were 2.92 times more likely to have depression. Those that reported that their RLP was extremely bothersome were 4.78 times more likely to have depression if between the ages of 18-54 years old. The study also found that 32.9% of those with significant depression reported not receiving any treatment. The group concluded that depression is common and often not properly treated. The study by Ephraim et al. (2005) was done on the same sample as the Darnall study. The conclusion about depression and pain for this study was the same in that depression and pain is correlation and that treating the depression may also assist in treating the pain. The limitation is that both published studies are identical in sample and findings. The sample is limited in that it is predominantly made up of Caucasian males that are educated.

Anxiety and Depression

The majority of studies have measured both anxiety and depression simultaneously in the amputee population (Atherton & Robertson, 2006; Castillo et al., 2006; Coffey et al., 2009; Desmond & MacLachlan, 2006; Hawamdeh et al., 2008; Kazemi et al., 2013; Rybarczyk, Edwards & Behel, 2004; Singh et al., 2007; Singh et al., 2009).

Prevalence. Three studies reported anxiety and depression prevalence in the amputation population (Atherton & Robertson, 2006; Singh et al., 2007; Singh et al., 2009). In the cross sectional study by Atherton and Robertson (2006), they reported prevalence rates of anxiety (29.9%) and depression (13.4%) in a sample of 67 amputees.

Singh et al. (2007) measured prevalence of anxiety and depression after amputation and after inpatient rehabilitation in a convenience sample of 105 successive admissions of lower extremity amputees. The authors found that at admission the depression and anxiety rates were 26.7% and 24.8% respectively. At discharge from inpatient rehabilitation the rates dropped to 3.8% and 4.8% respectively for depression and anxiety with a mean stay of 54 days. The authors found that depression and anxiety were linked to a longer length of stay. They found that depression was statistically significant in those with other medical comorbidities. Anxiety was found to be higher in those living alone. Singh did a second study that measured anxiety and depression after two to three years post hospitalization (Singh et al., 2009). In this group (n=68) he measured a baseline anxiety and depression rate for both anxiety and depression on admission to the hospital and found a prevalence rate similar to his previous study (23.5%). Singh et al. also found similar results at discharge from the initial hospital stay with a depression and anxiety rate of 2.9%. The authors completed a follow up of the participants between years two and three. They found that depression and anxiety rates had approached baseline admission rates. A rate of 17.6% for depression and 19.1% for anxiety was found in the participants. Depression, similar to the findings of the first study, was related to comorbid conditions. The authors also found that anxiety was higher among those participants that were younger. The authors could not explain why there had been an increase in prevalence after discharge.

Anxiety, Depression and Pain

Hawamdeh et al. (2008), Coffey et al. (2009) and Kazemi et al. (2013) did not find an association among depression, anxiety and pain. Hawamdeh et al. in their study on Jordanian amputees (n – 56) found 37% prevalence for anxiety and 20% prevalence for depression. In this study, there was no difference in prevalence rates of anxiety and depression compared to similar groups in the United States (20% Jordanian vs. 28% in U.S studies). Factors the authors found that correlated with depression and anxiety were being female, no social support, unemployment, traumatic cause, shorter time since amputation and having a below the knee amputation as compared to someone with an above the knee amputation.

Coffey et al. (2009) measured anxiety and depression in a group (n=38) of diabetic amputees. The authors found a prevalence of over 18% for anxiety and depression in this group. Anxiety was correlated with depression and body image in this study. Depression was correlated with body image only. The authors found no correlation of these affective disorders and pain experienced by the sample.

Kazemi et al. (2013) likewise found no association between depression and anxiety in the PLP patient compared to non-phantom chronic pain patients. The authors used the Hospital Anxiety and Depression Scale (HADS) to measure anxiety and depression in 16 PLP patients and 24 non-phantom patients in an all male sample in Iran. The sample consisted of upper and lower amputations that had sustained limb loss due to trauma. Prevalence of anxiety and depression were found to be lower in the PLP group as compared to the chronic pain group. Limitations of this study included an all male sample, small sample size and generalizability.

Two studies have shown an association between the pain experienced after amputation and affective distress. Castillo et al. (2006) evaluated secondary data from a larger multi-center

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study comparing limb salvage patients to those sustaining an amputation. The authors did find that elevated levels of anxiety and depression at three months after discharge from having an amputation is a strong predictor for chronic phantom pain seven years later. Desmond and MacLachlan's (2006) study supports Castillo et al. They found in a sample of older men (n = 582) a prevalence rate of 32% and 34% respectively for depression and anxiety. Phantom and residual limb pain was reported by approximately 88% of the sample. Of significance in the study was that depression was associated with elevated residual limb pain. Limitations of the study included generalizability since the sample was all males. The sample consisted of traumatic limb amputees suffering from posttraumatic stress disorder sustained in the war.

Coping Strategies: Adaptation to Pain

Research on coping strategies or adaptation to amputation pain is limited. Halbert, Crotty and Cameron (2002) performed a systematic review of the literature to examine the studies done on optimal management of acute and chronic phantom pain. The researchers used Medline for the search, which included years of 1966-1996. Studies that included a control group and distinguished phantom and residual limb pain as separate were included in this review. Twelve studies met the criteria. They found 8 studies focusing on acute pain and 4 on chronic pain. The eight trials on acute pain used treatments of epidural medication administration (3), nerve blocks (3), treatment with calcitonin (1) and transcutaneous electrical nerve stimulation (TENS)(1). The four trials reported on chronic amputation pain used TENS (2), electromagnetic stocking (1) and ketamine (1). No significance was found in any of the trials. The authors felt that the studies were contradictory and poorly randomized without supporting evidence for treatment in phantom limb pain whether acute or chronic.

Pharmacologic Therapy

Opioid medication has long been the standard for pain relief after amputation surgery (Ehde & Smith, 2004; Huang & Kuiken, 2004). Narcotic administration in the immediate postoperative period is suggested by amputation guidelines (Veterans Administration/Department of Defense [VA/DoD], 2007). Opioids fail to work at the site of pain but work within the brain to numb the sensation (Ehde & Smith, 2004). Despite the number of amputations that have been performed over a multitude of years, few interventional studies can be found that look at the effects of opioids on residual and phantom limb pain. Interventional studies found in the literature researched drug use of systemic anesthetics, local anesthetics, opioids, anticonvulsants and tricyclic antidepressants in the amputation population.

Systemic Anesthetics. Three randomized control trials examined the use of ketamine during and after surgery for residual and phantom pain (Eichenberger et al. 2008; Hayes, Armstong-Brown & Burstal, 2004; Wilson, Nimmo, Fleetwood-Walker & Colvin, 2008). Ketamine, which is classified as a systemic anesthetic, was used for its effects on the opioid receptor sites. Wilson et al. (2008) delivered the medicine through an epidural, while Hayes et al. (2004) delivered it intravenous. The results of both of these studies showed no statistical difference between groups treated with the drug and a control group immediately after surgery, at 6 months and then again at 12 months. Limitations of both studies were the small ample size.

Eichenberger et al. (2008) compared ketamine to placebo, calcitonin and a combination of ketamine and calcitonin in a double blind crossover study of chronic phantom pain (n=20). Medications were delivered intravenous on four separate occasions with intensity of pain recorded by a visual analog scale before, during, immediately after and after forty-eight hours. The main outcome of the study was a significant difference in pain intensity with ketamine alone

and ketamine in combination with calcitonin. No difference in pain was seen in the calcitonin alone administration as compared to placebo. A major limitation of the study was the small sample size.

Local Anesthetics. Madabhushi, Reuben, Steinberg and Adesioye (2007) used the local anesthetic, bupivacaine in a case study to describe the effects on phantom limb and residual limb pain. In the case presented the patient underwent general anesthesia. Prior to transection of the tissues the authors infused bupivacaine and clonidine into the sciatic nerve. After nerve transection, the nerve was rotated at an angle and exposed through the skin. The nerve was injected with a bolus of the bupivacaine and clonidine. A continuous infusion of the mixture was started in the nerve and maintained for 96 hours postoperatively. The mean pain score after surgery was 1.2 on a 1-10 scale. The only required pain medication after surgery was 10 milligrams of oxycodone. The patient was followed for one year postoperative with reports of no residual or phantom pain.

Borghi et al. (2010) used a convenience sample of 71 patients undergoing lower limb amputation to infuse ropivacaine into a perineural catheter.   Participants were evaluated the first postoperative day and then weekly for four weeks and again at three, six, nine and twelve months. The catheter infusion was turned off prior to survey administration, at which point the pain was rated on a pain scale of 0-4. If the score was greater than 1 then the infusion was restarted. Some infusions lasted long term (up to 83 days).   Mean infusion time was 30 days with 73% of the participants reporting intolerable pain on the first postoperative day. Pain scores after 12 months had fallen into the 0 to 1 category for overall pain. However, at the one-year period 39% of the patients were still experiencing phantom limb pain. A limitation of this study was lack of randomization and a control group.

Opioids. Four studies tested the effects of opioids on phantom limb pain in the amputee patient (Huse, Larbig, Flor & Birbaumer, 2001;Wilder-Smith, Hill & Laurent, 2005; Wu et al., 2002; Wu et al., 2008)

Huse et al. (2001) tested the efficacy of oral morphine against a placebo in a double blind crossover study with a four-week washout period on 12 patients. Measurement of pain included intensity, sensory level and affective descriptive level. Patients receiving morphine had significantly lower pain, intensity, sensory and affective perception related to pain when compared to the placebo group. A secondary aim of the study was to look at cortical reorganization using neuromagnetic imaging. Only three participants could participate in the imaging. Two of the three with high pain intensity did show cortical reorganization, while the third, which had less pain intensity, showed no reorganization. The limitations of the study were a small sample size and lack of power of the study.

Wu et al. (2002) used a randomized double blind active placebo controlled cross over trial to study the effects of morphine and lidocaine on amputation pain. A combination of lidocaine, morphine and diphenhydramine was used to formulate six variations of intravenous treatment. The purpose of the study was to see if opioids are better than anesthetics for postoperative pain control after amputation. The study found that morphine and lidocaine provided better relief for residual limb pain after surgery. They also found that morphine was the better drug for relieving phantom limb pain. The authors completed a power analysis prior to the study based on pilot data and found that 32 participants were needed to obtain power in order to obtain a 20% change in pain from baseline. Participants in the study were only 31, which failed to obtain power for the study. Another limitation of the study was that this was done with chronic pain patients. The median time since amputation was five years. The participants were

brought back to the hospital to implement this study. Wu et al. (2008) conducted a second study using a double blind placebo controlled crossover design to study morphine versus mexiletine for chronic postamputation pain. Participants treated with morphine had better pain control when compared to those treated with mexiletine or a placebo.   Although, the authors did report that morphine caused higher rates of side effects.

Wilder-Smith et al. (2005) randomized 94 participants into three arms of a randomized clinical trial. The participants received tramadol, amitriptyline or a placebo. If they were found to be nonresponders to tramadol (pain decreased by less than 10 on a visual analog scale), a wash out period was performed and they were placed in the amitriptyline group and vice versa. The study showed no statistical difference in baseline intensity of phantom or residual pain, but did show an overall decrease in mean pain scores after one month of treatment for both the tramadol and amitriptyline group. A limitation of this study is that the sample is not generalizable due to the majority of the population being male (n=84). The study did meet power calculations for sample size.

Anticonvulsants. Several studies were found that examined the effects of the anticonvulsant drug Gabapentin on postamputation pain (Bone, Critchley & Buggy, 2002; Nikolajsen et al., 2006; Smith et al., 2005). Nikolajsen et al. (2006) performed a randomized control trial (n = 41) starting the Gabapentin on postoperative day one and continuing for 30 days. The max dose received by the participants was 2400 mg daily. The control group received a placebo. The study showed no statistical relationship between the drug and pain level at 30 days and up to 6 months after surgery. Limitations of this study were a small sample size, a slow titration schedule and pain intensity lower than normal. Bone et al. and Smith et al. completed double blind cross over studies with wash out periods comparing Gabapentin to a placebo. The

period of washout was different for each study with Smith et al. having a five-week washout and

Bone et al. having a one-week washout. The amount of drug was also different in each study.

Smith et al. titrated up to 3600 milligrams a day while Bone et al. titrated only to 2400

milligrams per day. Smith et al. found that there was no statistical difference in pain between

Gabapentin and placebo groups on a pain numerical rating scale. Bone's findings were different.

Bone et al. found that after six weeks Gabapentin controlled phantom pain better than placebo as

measured by a visual analog scale. The difference in the results could be in the amount of time

for washout, amount of maximum drug used or difference between scales. Limitation of both

studies was a small sample size.

   Tricyclic Antidepressants. Two studies were found using the tricyclic antidepressant,

amitriptyline to treat amputation pain. Robinson et al. (2004) studied the effects of amitriptyline

versus an active placebo after a six-week administration. They found no significant difference in

pain levels between groups. Depression was a secondary outcome of the study with no reported

difference. Wilder-Smith et al. (2005) studied pain response as part of a placebo-controlled

randomized three-arm trial. The three groups were randomized to either a group receiving

tramadol, amitriptyline or placebo. The participants (n = 94) were considered treatment naïve

since they had not received analgesics prior to the study. Both tramadol and amitriptyline did

not reach significance for control of both phantom and residual limb pain when compared to the

placebo group, but did show an overall decrease in pain mean scores after one month of therapy.

Non-Pharmacologic Therapy

   Coping with pain has primarily been viewed as a one-treatment approach with medication

as the primary therapy. Another treatment choice for pain control is non-pharmacologic therapy

as a primary therapy or as a complementary therapy. Although it is not widely recognized

within the medical community, literature does support the use of these therapies for pain relief (Ellis, 2002; Flor, 2002, Gatlin & Shulmeister, 2007; Nikolajsen & Jensen, 2001). Nonpharmacologic therapy works differently from pharmacologic therapy in that the goal is to decrease the perception of pain by increasing tolerance, decreasing intensity and increasing adaptive behavior (Gaitlin & Shulmeister, 2007). With amputation pain, adaptation is important due to the projected chronic nature of this pain. Nonpharmacologic therapy may help to reduce the intensity of the pain and increase tolerance by using this as a complementary therapy with the traditional pain control methods after amputation. Richardson (2008) and Ketz (2008) discuss the need for nursing to use complementary therapy for pain control for amputees. Several forms of non-pharmacologic therapies were found in the literature being used with amputees for pain control. None of these studies were randomized trials. Therapies reported in the literature included acupuncture, reflexology, transcutaneous electrical nerve stimulation (TENS), mirror therapy and desensitization.

Acupuncture. Bradbrook (2004) describes three case studies using acupuncture for relief of phantom limb pain and phantom sensation. The intact limb was used for the acupuncture treatment. A visual analog scale measured outcome. Two of the three cases noted a lower pain level immediately after treatment. One case required three further treatments for relieve of pain and then remained pain free for two months during rehabilitation. The second case had immediate relief of pain with the first treatment and required no further sessions during rehabilitation.

In a current case study, reported by Davies (2013), the author describes a case of a 45 year-old man with PLP and phantom sensations 3 months after amputation of the right arm. He

underwent acupuncture sessions on the contralateral arm with complete relief of PLP after seven sessions. The subject was three months post surgery.

Reflexology. Brown and Lido's (2008) pilot study (n=10) measured the effects of reflexology on phantom pain. Reflexology was performed on the intact leg and the ipsilateral (same side as amputation) hand. The treatment was taught to the patient for self-administration. Pain level and pain duration was significantly lower during the treatment phases compared to phases when the therapy was not performed. Follow up was done at 12 months. All participants continued to have a reduction of phantom pain with 67% of the participants continuing to self-administer. A limitation of the study was the small sample size.

Transcutaneous Electrical Nerve Stimulation (TENS). TENS is often used as treatment for pain that is associated with a nerve conduction disorder. Mulvey, Bagnall, Johnson and Marchant (2010) performed a systematic review of the use of TENS for phantom and residual limb pain after surgery in adults. The authors found no randomized control trials among fourteen studies meeting criteria. The fourteen studies consisted of primarily case studies with two studies that were nonrandomized. In these cases there was no consistent outcome. The authors concluded that there was an inability to claim effectiveness in amputation pain with TENS.

Since publishing the above systematic review, the authors have completed a pilot study using TENS to study the effect on phantom pain and residual limb pain at rest and with movement on a sample of ten lower extremity amputees (Mulvey, et al., 2013). TENS therapy was applied for one hour. Mean pain scores were reduced at rest and during movement. The study was only a pilot and the authors suggested a follow-up feasibility study.

Mirror Therapy. Mirror therapy is a relatively new therapy used as an intervention to help with pain in persons who are unable to move one extremity or having an absence of that

extremity with associated pain. The therapy is based on sensory feedback of seeing two

functional limbs with the help of a mirror. A systematic review by Rothgangel, Braun,

Beurskens, Seitz and Wade (2011) included ten randomized trials, seven series reports and four

case studies. Patients who suffered strokes, amputation and complex regional pain syndrome

were included. Two of the ten randomized trial studies pertained to phantom limb pain

experienced by amputees. The authors found that most studies were small and had limited

evidence for conclusive findings. Another concern was the lack of details related to treatment

and side effects.

A study done by Darnall and Li (2012) related to mirror therapy used a prospective

design for a pilot study on forty community dwelling amputees with phantom pain to test pain

intensity using mirror therapy. The therapy was self administered at home. Pain intensity was

significantly reduced one month and again at two months. The authors also found that higher

educated participants had a greater pain intensity reduction.   Casale, Damiani and Rosati (2009)

questioned the ethics in using this therapy. They retrospectively reviewed side effects and

adverse outcomes of thirty-three patients who received mirror therapy and found twenty-five

with side effects which included confusion, dizziness and irritation. Four refused to continue the

treatment. Only four participants had no complaints. The conclusion was that patient selection

should be more structured for studies with this therapy.

Desensitization. Desensitization is a form of non-pharmacologic therapy.

Conceptually, desensitization is defined as a technique of massage and tapping of the residual

limb beginning the first day after surgery to help reduce and control pain through self

management (Huang & Kuiken, 2004; VA/DoD, 2007). Although no formal research literature

was found using desensitization to control amputation pain, Atkins (2004) describes the

technique as a needed skill for two reasons. First, the patient knows their tolerance to the therapy and can easily administer it based on their own comfort level. Second, the patient becomes accustomed to their body after surgery. Huang and Kuiken (2004) describe the technique as assisting with pain by affecting the gate control mechanism. The benefits of using this technique are pain control, establishment of body image and psychological adjustment (Huang & Kuiken, 2004). Clinical practice guidelines for the care of the amputation patient have been established through the Agency of HealthCare Quality Research (VA/DoD, 2007). These guidelines recommend narcotics immediately after surgery with the addition of other nonpharmacologic measures, including desensitization. The guidelines not only refer to the technique as a pain modulator but also discuss using the technique to help with body image adjustment. No protocol or randomized trials were found in the literature using this as a complementary therapy in acute or chronic amputation pain.

Application of Models

Roy's Adaptation Model

Roy's' Adaptation Model supports the premise of this study by providing a complementary therapy in the adaptation to amputation pain in order to establish a holistic environment after surgery. The model is based on the sensory aspect of the pain experience. Roy's Adaptation Model has been used in a number of various settings, including practice, education and research. The model has also been used to develop research instruments, as well as, middle range theories (Ducharme, Ricard, Duquette, Levesque & Lachance, 1998; Dunn, 2004; Levesque, Ricard, Ducharme, Duquette, & Bonin, 1998; Newman, 1997; Tsai, Tak, Moore & Palencia, 2003). The extensive use of the model shows its adaptability to assist in helping the patient adapt with nursing practice.

However, only one study was found in the literature that used the Roy Adaptation Model with amputation patients. Santarlasci (2009) used the model to measure the relationships of pain, functional ability, depression and social support with coping and returning to work for lower extremity amputees in her dissertation. A secondary purpose of the study was to measure interrelatedness of the concepts for congruency with Roy's model. The author was unable to perform a path analysis to measure interrelatedness. She did find relationships with pain and depression and pain and functional ability during the process of coping or trying to adapt to their situation.

Neuromatrix Theory

The Neuromatrix theory is described by Melzack (1999) as going beyond the pain gate theory to explain how an individual perceives pain in the brain when there is no apparent sensory input, such as from a phantom limb. One study was found that used Melzack's Neuromatrix theory to study phantom limb pain. Pucher, Kickinger and Frischenschlager (1999) performed an empirical-diagnostic study looking at coping with limb loss, body image and phantom pain based on Melzack's Neuromatrix theory. The authors interviewed a sample of 43 amputees that were divided into two groups, those with phantom pain and those without pain for coping strategies. Body image was evaluated by drawing pictures of their body after the amputation. The authors found that coping with loss and lack of complaints was positively correlated. The cognitive image portrayed by drawing correlated with suffering from phantom pain. If the person drew himself or herself intact then they suffered more than those that did not. The correlation between coping by psychological adjustment of the patient and neuronal adjustment of the cognitive process supports the neuromatrix principal of modification of the pathway.

In this study, the Roy Adaptation Model fits well within the adaptation of the amputee in the acute setting following surgery. The patient is attempting to adapt to a number of unfamiliar experiences after surgery. However, the first stimulus the amputee must cope with is the pain experienced after the surgery. The only way for adaptation to continue within this population is to alleviate the focal stimulus. The process of adaptation to amputation pain is both a physiological and psychological process. Understanding how to interrupt the physiological process of the pain pathway is needed in order to cope. Without relief from pain, rehabilitation and adaptation cannot proceed. The patient will then enter a compromised state without adequate pain measures.

Summary

Pertinent literature related to the variables in this study was presented in this chapter. Pain is the focal stimulus of the person recovering from an amputation. The literature has given prevalence rates of residual limb pain and phantom limb pain.   Phantom limb pain has been reported occurring in between 63% to 84% of those with an amputation years after the surgery. Residual limb pain is reported at prevalence rates of 32% to 74% after surgery. Residual limb pain can be chronic but is less likely than phantom limb pain to continue in a chronic state. Literature has also reported descriptors of the two types of pain to help distinguish between them. This is important when attempting to treat the pain. Descriptors for phantom pain included sharp, tingling, stabbing, shooting, burning and stinging. Descriptors used in residual limb pain were aching, tight, throbbing and bothersome.

The focal stimulus of pain is often heightened by contextual factors, which can be related to demographics, clinical characteristics or affective distress.   Demographics (age and gender) showed mixed results related to their effect on pain. Although two out of the three studies

reported that women had a higher rate of pain, it is uncertain if this is because women seek treatment and are more open than men about their pain. Education level was seen as a factor in chronic pain. Those with lower educational levels tend to report chronic pain after amputation years after the initial surgery. A gap in demographics was found in race and amputation pain. Although, no studies reported a correlation between the two variables, it was found that African Americans are twice as likely of having an amputation related to diabetes or peripheral arterial disease. This is an important aspect in research related to amputation pain since a majority of the reviewed studies had predominately Caucasian participants.

Clinical characteristics that have been studied in association with amputation pain are surgical procedure type, cause of amputation, comorbidities and anesthesia used. The type of surgical procedure type made no difference in the amount of pain experienced by the amputee. Cause did seem to be a contributing factor. Those that lost a limb due to a congenital factor had less pain when compared to those who had an amputation due to a dysvascular condition or trauma. Comorbidities significantly affected the amount of pain the amputation patient experienced. A correlation was found between comorbid conditions and reported pain. Type of anesthesia used during the surgical procedure had no effect on pain experienced after surgery.

Pre-surgical pain control, anxiety and depression have been identified as possible contributing factors to the experience of pain after amputation. Pre-surgical pain control interventions that have been studied have been centered on the use of epidural administration for pain control. The majority of the studies found no significance difference in pain control using an epidural. The literature did not report pain control pre-hospitalization but did find a lack of overall optimization of pain control in the amputee. Depression and anxiety have been found to have a higher prevalence rate in the amputation population when compared to the general

population. Studies have found mixed results on whether anxiety and depression are related to amputation pain experienced after surgery.

Coping strategies for amputation pain have centered on the use of pharmacologic agents with minimal studies done using non-pharmacologic methods. A limited number of studies were found that used complementary therapy in treating this type of pain. Pharmacologic studies have focused on several classes of drugs: systemic anesthetics, local anesthetics, opioids, tricyclic antidepressants and anticonvulsants. Most of the studies have had mixed results.   The use of morphine has shown the best effect for the relief of amputation pain. The studies using morphine were done on samples that were experiencing chronic pain.   The anticonvulsant, Gabapentin has been used in the relief of phantom pain. The studies completed thus far have shown no significance with amputation pain and its use.

Non-pharmacologic therapy has been reported as case studies or has been nonrandomized studies.   Desensitization is a non-pharmacologic therapy that has been extensively taught in nursing and allied health as a pain relief measure for this population. The technique is also described in clinical practice guidelines on the care of the amputation patient. No research could be found that supported the use of the technique in pain control.

Most studies were methodologically limited and provided information into the complexity of amputation pain. However, two areas in the literature are void of information. One of the gaps in the literature relates to the patient characteristic of race and amputation pain. Most studies reported a representative sample of Caucasian males. These studies have primarily been done in the Northwest United States.   It is important to understand the differences in pain experience among races for efficacious treatment. A gap is also found in the use of nonpharmacologic therapies as a technique to control pain in the postoperative setting either as a

stand alone or complementary therapy. Desensitization is theoretically supported in the literature as a pain relief complementary measure, although, there is no supporting research evidence found for this technique.

Due to limited complementary therapy studies and seeing the complexity of amputation pain, this pilot study on the use of desensitization as a complementary measure in controlling amputation pain in the acute care setting was designed to explore this topic.

CHAPTER 3: RESEARCH METHOD AND DESIGN

This pilot study tested the feasibility and efficacy of a desensitization protocol in hospitalized amputees in the immediate postoperative period. This chapter will discuss sample, setting, instruments, measurement, data collection and the data analysis procedure.

Research Design

The study used a prospective repeated measure design to test the feasibility of using desensitization in the person who had received a major lower limb amputation. The participants were taught a desensitization protocol after surgery. The normal pharmacological pain regimen was administered as ordered by the physician and when requested by the participants during the study.

Setting and Sample

The facility where the study took place is comprised of an 850-bed academic tertiary care facility in the Eastern United States with non-acute, intermediate and acute beds. It is part of a larger multihospital system and receives patients from twenty-nine counties surrounding the immediate area. Referrals for amputation surgery are received from all twenty-nine counties. The facility has an associated acute rehabilitation center attached to the main hospital. The rehabilitation center is a 75-bed inpatient facility. The rehabilitation center admits spinal cord injury, traumatic brain injury, stroke and general rehabilitation patients. A majority of new amputees are admitted to the general rehabilitation population after spending approximately six days in the acute setting. Approximately 55% of patients that have amputation surgery transfer to the rehabilitation facility. Of the remaining amputee patients, 10% are discharged to home with home health and outpatient referral for rehabilitation, 20% return to a skilled facility where

they previously resided, 10% require new skilled facility placement after surgery and 5% are moved to a rehabilitation facility nearer to their place of residence.

One academic surgical practice specializing in vascular surgery receives 95% of patients referred for an amputation with a diagnosis of a dysvascular condition. The surgical practice is comprised of four attending surgeons, four residents and two physician assistants. The practice holds clinic four days per week with one attending in clinic each of those days.

The surgical group admits amputation patients primarily to one intermediate unit after surgery. The intermediate unit is a 32-bed unit that specializes in the postoperative care of the vascular surgery and cardiac surgery patient. The unit is staffed with a 4 (patients) to 1 (nurse) ratio. Physical therapists and occupational therapists are available by a consult on the unit. A physical therapy, occupational therapy and rehabilitation consult are usually completed on patients that have the potential to go through a full rehabilitation and that are not from a skilled nursing facility. An electronic medical record is used for patient charting. The unit does allow two family members to stay with the patient at all times. Visitation by other family and friends can occur any time during the day until evening.

The study sample consisted of participants that had an amputation by the vascular surgery group with a primary cause of peripheral vascular disease, diabetes and/or end stage renal disease (ESRD). A convenience sample was used that met inclusion criteria. Inclusion criteria for the study were: 1) 18 years of age or older 2) participants must be able to understand and speak English 3) mental capacity to participate in using the protocol 4) receiving a lower extremity amputation due to a dysvascular cause. Exclusion criteria were: 1) amputations caused by trauma 2) partial foot, toe or arm amputations 3) non-English speaking 4) diagnosed mental illness or drug addiction. Trauma patients that have an amputation were excluded due to

variation in pain protocols with this population. A sample size of 30 participants was projected for the study, but due to exclusion criteria and research recruitment difficulties this sample size was not reached in this pilot study.

Study Approval

The principal investigator received support from the Director of Nursing Research at the facility where the research was conducted. Once support was obtained, submission to the University and Medical Center Institutional Review Board (UMCIRB) was submitted and approved. See Appendix A.

Data Collection and Instrumentation

Data collection consisted of a general demographic and clinical questionnaire, Short Form McGill Pain Questionnaire-2 (SF-MPQ-2), Hospital Anxiety and Depression scale (HADS), intervention journal card for recording times desensitization used, intervention questionnaire and feasibility questionnaire.

The general demographic questionnaire consisted of information related to age, gender, race and educational level. Chart reviews were completed to determine clinical characteristics related to the surgery including type of procedure, comorbidities, cause of amputation and anesthesia type. Type of procedure was classified as above the knee amputation, below the knee amputation or knee disarticulation. Comorbid conditions included cardiac disease, peripheral vascular disease including aneurysm and carotid disease, chronic lung problems, hypertension, diabetes and history of amputation with notation of underlying disease state of present amputation. The chart review included information on operative induction. Induction was classified as general, spinal or epidural. Pain medication taken in the preoperative setting was collected, as well as, any interventions the patient used to relieve pain. Pain medication in the

postoperative setting included drug, route and amount in milligrams each day after surgery until

discharge or postoperative day six. Pain medication was converted using equianalgesic

conversion in order to have a comparative analysis of amount. The majority of participants

received intravenous (IV) pain medication immediately after surgery for approximately two

days. The participants were usually switched to an oral opioid form after the initial two days.

For some participants, administration of an IV pain medication for break through pain was

ordered during the remainder of the hospitalization, if needed, after switching to the oral opioid.

Conversion of the initial IV pain medication, as well as, any IV pain medication used for

breakthrough pain was done by converting the IV milligrams of the opioid to oral milligrams of

the primary opioid the participant was converted to after surgery.

Feasibility was recorded with several measures. Intervention journal cards were left with

the patient to record the number of times the patient used desensitization each day, pain level

before and after and who performed the desensitization. Verification that the protocol was being

done correctly by the patient was measured using an intervention questionnaire that confirmed

steps of the protocol. A feasibility survey was given to the patient for completion at the end of

the acute care period, which measured ease of use, satisfaction with the procedure and perceived

benefits.

Revised Version of the Short-form McGill Pain Questionnaire (SF-MQP-2)

The SF-MPQ-2, developed and validated by Dworkin et al. (2009), was used to measure

the quality of pain in the study subjects and consists of 22 pain descriptors with responses scaled

from 0 (no pain) to 10 (worst possible pain). On the basis of exploratory factor analyses,

confirmatory factor analyses, and prior research on human pain, four SF-MQP-2 subscales were

defined. The subscales and their sensory descriptors include the following: (1) *continuous pain*

descriptors (6 items): 'throbbing pain", "cramping pain", "gnawing pain", "aching pain", "heavy pain", and "tender"; (2) *intermittent pain descriptors* (6 items): "shooting pain", "stabbing pain", "sharp pain", "splitting pain", "electric-shock pain", and "piercing"; (3) *predominately neuropathic pain descriptors* (6 items): "hot-burning pain", "cold-freezing pain", "pain caused by light touch", "itching", "tingling or pins and needles", and "numbness"; and (4) *affective descriptors* (4 items): "tiring-exhausting", "sickening", "fearful", and "punishing-cruel". The validation sample for the SF-MQP-2 consisted of 882 subjects who had experienced chronic pain for an average of over 8 years. Internal reliability assessed with Cronbach's alpha for the total score and four subscales are as follows: total score ($\alpha = 0.91$); continuous pain ($\alpha = 0.73$); intermittent pain ($\alpha = 0.85$); neuropathic pain ($\alpha = 0.78$); and affective descriptors ($\alpha = 0.77$).

Other Pain Measures

In addition to the SF-MPQ-2, a visual analog scale was used to measure the intensity of the patient's current pain with scale endpoints of 0 = no pain and 10 = worst possible pain. A 6-point ordinal scale asked the patient to describe their current pain using the following response categories: 0 = no pain; 1 = discomforting; 3 = distressing; 4 = horrible; and 5 = excruciating. A 3-point ordinal scale asked the patient to describe the frequency of their current pain by selecting either the word brief, intermittent, or continuous.

Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS) is a patient-completed, 14-item scale, with seven items measuring anxiety and seven measuring depression on a 4-point (0 – 3) response scale. Scores range from 0 to 21 for each scale with higher scores representing more distress. Various cut off points have been proposed for indicating severity and consensus suggests a score of eight to ten (on each scale) to represent possible cases, 11 or more for definite

cases, and 14/15 to represent severe disorder (Bjelland, Dahl, Haung & Neckelman, 2002).

Evidence of validity comes from correlating the HADS with other anxiety or depression

instruments. The Beck Depression Inventory and HADS depression had a correlation of .73, and

HADS anxiety had a correlation of .71 with the State Trait Anxiety Inventory (Bjelland et al.,

2002). Five studies used the HADS for research with lower extremity amputations (Coffey et al.,

2009; Desmond & MacLachlan, 2006; Hawamdeh et al., 2008; Singh et al., 2007; Singh et al.,

2009). None of these studies reported internal consistency reliability for the scales.

Intervention Journal Card

The participant recorded the time on each post-operative day that desensitization

was self-administered along with pre-intervention and post-intervention pain level on a 11-point

numerical scale (0-10) on the card. One card was designated for each postoperative day. See

Appendix C.

Intervention Questionnaire

The purpose of completing an intervention log questionnaire was to confirm that the

participant knew how to administer the steps of the intervention and if it could be followed

easily. The principal investigator completed the log on repeated measure days after the

intervention was taught. The log was based on the protocol for administering desensitization that

was created by the principal investigator. The protocol was developed based on a review of the

literature and in consultation with physical therapists. Information was gathered from material

related to desensitization, therapeutic clinical massage and dermatomes. The participant was

asked if the knee immobilizer was removed, where the massage took place, if a circular massage

pattern was used, the number of times massaged, if tapping was used and if there were any

special areas that needed attention. A picture of a limb was also available for the participant to

point to areas that were particularly painful and had to be massaged and tapped more often. See Appendix D for the Desensitization Protocol and Appendix E for the Intervention Questionnaire.

Feasibility Questionnaire

Feasibility was measured with a five-item questionnaire that also had an open comment at the end of the questionnaire for feedback about the intervention (See Appendix F). The feasibility survey was given to the participant during postoperative day six or when the participant was discharged, if the participant was still available.

Procedure

After IRB approval, the principal investigator (PI) met with staff and designated contacts in the clinic and hospital. The PI discussed enrollment procedures, inclusion/exclusion criteria and the study protocol. Advertisement flyers giving a brief description of the study were placed in a designated location within the hospital for staff to see. After three months of difficulty in recruitment, the PI met with the vascular surgery group in order to explain the study again and answer any questions. During the discussion, a conflict was noted in consenting potential participants for this study prior to surgery due to another pain study currently enrolling amputation participants at the same time. The group felt this was confusing to potential participants of this study. After discussion of a feasible change in protocol, it was decided to change the day of consenting potential participants for this study to postoperative day two. It was felt that the participant could consent without any untoward effects of the anesthesia. No participants had been enrolled prior to this meeting, so a revision was made and submitted to the UMCIRB with approval. Enrollment began after the revised protocol. Notification of potential participants by the designated contacts within the hospital was done once the person had agreed to discuss the research.

After notification, the PI met the patient on the second postoperative day to consent the participant, do baseline collection of the SF-MPQ-2 and HADS questionnaires, teach the desensitization technique and answer any questions. After consent and baseline data was collected, the PI taught the desensitization protocol to the patient and any family that may be interested. After instruction and a return demonstration by the patient, the PI left a patient teaching booklet on desensitization for the patient's reference (See Appendix G). The participant was supplied with the journal cards with instructions on recording times the desensitization was used, for how long, pain scores before and after use and who performed the intervention.

The PI returned on postoperative day 4 and 6 to gather data on the SFMP-Q, the HADS, the intervention questionnaire and pick up any completed journal cards. The participant was then re-instructed on the use and completion of the journal cards if the participants were not completing them. The PI also answered any questions and reinforced the desensitization technique. On postoperative day 6, the Feasibility Questionnaire was completed with the participant. The participant also was asked to share any comments about their experience using desensitization or the technique in general. Due to early discharges and one withdrawal, not all participants completed the Feasibility Questionnaire. Retrieval of data on demographics, clinical characteristics and pain medication was collected by chart review during each visit.

Data Analysis

All statistical analyses were completed with IBM SPSS version 20 after coding and entering into the system. Descriptive statistics including frequency, percentile, mean and standard deviation was used to describe the variables of the study. Psychometric properties of the SF-MPQ-2 and HADS were analyzed for reliability by Cronbach's coefficient alpha. Correlation analysis was used to determine the strength and direction of variables including medication

dosages, continuous pain, intermittent pain, neuropathic pain, affective descriptors, anxiety and depression were completed using Spearman rho coefficient. Paired sample t-test was used to compare mean scores of the group on minutes intervention completed and pain difference before and after the intervention during repeated measure time frames. Statistical significance level was set at a p value of <.05.

Summary

This chapter has described the research design, sample, setting, instruments, data collection, human protection measures and data analysis plan completed in this study. In this prospective repeated measure design, a convenience sample was used. A newly constructed desensitization protocol was taught to participants in order to see if the technique met feasible and efficacious use and to explore any correlations among variables including pain, anxiety and depression while using the protocol.

Chapter 4: FINDINGS

In this chapter the findings of the study will be presented. Before the findings related to each research question are presented, the internal consistency reliability of the SF-MPQ-1 and HADS are presented for the three measurement times.

Instrument Characteristics

The internal consistency reliabilities (Cronbach's alpha) for the SF-MPQ-2 total scores are all above .80. As expected some of the subscales have reliabilities lower than the .70 criterion because of the small number of pain descriptors associated with the subscale and not all the patients are expected to have experienced the same sensory, affective, and evaluative qualities of pain which result in low inter-item correlations. The HADS anxiety and depression scales administered before postoperative day 6 also had lower reliabilities than expected. This could be related to several items that were inappropriate to these patients in the immediate post-operative period. For example, three of the anxiety statements asked if they were able to sit at ease and feel relaxed, looking forward with enjoyment to things, and being able to enjoy a good book, radio or television program. Statements related to the depression subscale seen as problematic for this population were being able to laugh and see the funny side of things and losing interest in their appearance. All of the skewness values showed there was not any marked skewness in any of the measures. See Table 1.

Table 1

Psychometric Properties of the Study Instruments

Instrument	POD	Cronbach's Alpha	Skewness
SF-MPQ-2	1		
Continuous pain		.74	.85
Intermediate pain		.64	1.07
Neuropathic pain		.78	.39
Affective description		.55	.94
Total score		.90	1.18
SF-MPQ-2	2		
Continuous pain		.45	.53
Intermediate pain		.88	1.00
Neuropathic pain		.75	1.11
Affective description		.61	1.09
Total score		.88	.66
SF-MPQ-2	3		
Continuous pain		.67	1.05
Intermediate pain		.73	.41
Neuropathic pain		.38	-.49
Affective description		.84	1.52
Total score		.81	.16
HADS	1		
Anxiety		.63	.19
Depression		.42	-.04
HADS	2		
Anxiety		.62	.65
Depression		.79	1.25
HADS	3		
Anxiety		.85	1.34
Depression		.87	1.46

Note. POD = post-operative day. SF-MPQ-2 = Short Form McGill Pain Questionnaire 2.
HADS = Hospital Anxiety and Depression Scale.

Research Questions

Research Question 1

(1) What are the demographic (age, gender, ethnicity, education level) and clinical characteristics (type of amputation, reason for amputation, pre-amputation pain management) of the lower limb amputee patients in the study?

Participants were considered for enrollment over eleven months. Eleven of the patients refused enrollment with the primary reason being fatigue. Of those that refused, most were men (82%) and African American (82%). Another nineteen patients were excluded due to dementia, change in neurological status, medical emergency, another procedure being performed, system issues or healthcare power of attorney not present. The final sample consisted of twelve enrolled participants. One participant withdrew from the study on postoperative day four, before administering the surveys. Two participants were discharged on postoperative day four and one on postoperative day five.

The final sample ($N = 12$) consisted of predominantly African American (66.7%) females (58.3%) with less than a high school education (41.7%). The ages of the participants ranged from 52 to 73 years ($M = 60$, $SD = 7.47$). The final sample included 7 females and 5 males. Two had some college, 1 was a college graduate, 4 were high school graduates, and 5 had less than a high school education.

Table 2 presents the clinical characteristics of the study sample. Amputation rates were similar above or below the knee, with most amputations involving the right leg. The reason for the amputations was primarily related to peripheral vascular disease (PVD) caused by diabetes. The most common comorbidities were hypertension, diabetes, and peripheral vascular disease.

Pain prior to surgery was controlled by oral opioids. Almost all of the patients had general

anesthesia.

Table 2

Clinical Characteristics (N = 12)

Variable	*n*	*%*
Amputation Level		
Above Knee Amputation	5	41.7
Below Knee Amputation	6	50.0
Knee Disarticulation	1	8.3
Side Amputated		
Right	8	66.7
Left	4	33.3
Cause of Amputation		
PVD with Diabetes	8	66.7
Diabetes with ESRD	2	16.7
PVD only	1	8.3
PVD with ESRD	1	8.3
Comorbidities		
Hypertension	12	100
Diabetes	10	83.3
PVD	10	83.3
Coronary Artery Disease	4	33.3
COPD	3	25.0
ESRD	3	25.0
History of previous amputation	3	25.0
Pain Control Before Surgery		
Oxycodone 5- 325	8	66.7
Gabapentin	6	50.0
Tramadol	2	16.7
Flexeril	2	16.7
Roxicodone IR	1	8.3
Duragesic patch	1	8.3
Voltaren	1	8.3
Hydrocodone 5 -325	1	8.3
Anesthesia		
General	11	91.7
Spinal	1	8.3

Note. PVD = Peripheral Vascular Disease. ESRD = End Stage Renal Disease. COPD =
Chronic Obstructive Pulmonary Disease

Research Question 2

2a. What are the patterns of pain quality, total pain, type of pain, pain management (opioid use), anxiety and depression in the immediate post-operative period (POD 2, POD 4, POD 6)?

Descriptive statistics for the SF-MPQ-2 total score, subscale scores, and pain and affective descriptors are summarized in Table 3 for the three measurement days. At POD 2 the subscales of intermittent pain and affective description had the highest mean, with neuropathic and continuous pain having the lowest means. The POD 2 pain descriptors with the highest intensity included sharp pain (M = 7.2), tiring-exhausting (M = 6.6), tender (M = 5.25), pain caused by light touch (M = 5.25), and piercing (M = 4.8). By POD 6, all the pain measures had decreased with continuous pain showing the largest mean (M = 2.4). At POD 6 the pain descriptors with the highest intensity included tender (M = 4.9), pain caused by light touch (M = 4.25) and throbbing pain (M = 3.6).

Table 3

Pattern of SF-MPQ-2 Pain Types and Associated Sensory and Affective Descriptors at Post-Operative Day 2, 4 and 6

Pain type and descriptors	POD 2 (*n*=12) *M* (*SD*)	POD 4 (*n*=10) *M* (*SD*)	POD 6 (*n*=8) *M* (*SD*)
Continuous pain	3.39 (2.51)	3.17 (1.85)	2.40 (1.91)
Throbbing pain	4.92 (4.56)	5.20 (3.94)	3.63 (3.93)
Cramping pain	0.42 (1.44)	1.00 (3.16)	1.00 (2.83)
Gnawing pain	1.92 (3.50)	3.10 (4.18)	1.75 (3.28)
Aching pain	4.42 (4.38)	2.40 (3.27)	1.88 (2.64)
Heavy pain	3.42 (4.30)	2.20 (2.94)	1.25 (2.38)
Tender	5.25 (3.82)	5.10 (3.84)	4.88 (3.27)
Intermittent pain	4.03 (2.36)	3.90 (3.27)	1.58 (1.68)
Shooting pain	3.75 (4.20)	4.90 (4.56)	1.38 (2.67)
Stabbing pain	4.50 (4.74)	3.50 (4.04)	2.75 (3.15)
Sharp pain	7.17 (2.86)	5.90 (3.54)	2.88 (3.31)
Splitting pain	3.08 (4.17)	3.10 (4.28)	0.50 (1.41)
Electric-shock pain	0.83 (2.89)	3.10 (4.28)	1.50 (2.83)
Piercing	4.83 (4.51)	2.90 (4.01)	0.50 (1.41)
Neuropathic pain	3.46 (2.80)	2.50 (2.36)	1.77 (1.29)
Hot-burning pain	4.08 (4.36)	2.20 (3.74)	2.13 (3.48)
Cold-freezing pain	1.67 (3.28)	0.70 (2.21)	0.0
Pain caused by light touch	5.25 (4.18)	4.90 (4.33)	4.25 (3.45)
Itching	4.17 (4.13)	3.60 (3.53)	2.25 (2.87)
Tingling / pins and needles	2.75 (4.14)	1.90 (4.01)	0.63 (1.77)
Numbness	2.83 (4.24)	1.70 (2.95)	1.38 (2.56)
Affective description	3.94 (2.72)	1.90 (2.21)	1.06 (1.71)
Tiring-exhausting	6.58 (3.58)	3.50 (3.95)	2.00 (2.78)
Sickening	3.67 (4.60)	0.0	0.0
Fearful	2.08 (3.96)	1.80 (3.82)	0.87 (2.48)
Punishing-cruel	3.42 (4.48)	2.30 (4.00)	1.38 (2.56)
Total score	3.68 (2.27)	2.95 (1.95)	1.76 (1.21)

Table 4 shows the descriptive statistics for present pain, HADS anxiety and depression, medication dose, pain description and pain frequency at the three measurement periods. Present pain, anxiety, depression and medication dose show decreases from POD 2 to POD 6. Similarly, the proportion of patients reporting pain descriptions of distressing, horrible, or excruciating decreased over the measurement days.

Table 4

Descriptive Statistics of Present Pain, HADS Anxiety and Depression, Medication Dose, Pain Description and Frequency of Pain at POD 2, 4 and 6

	POD 2 (n=12)	POD 4 (n=10)	POD 6 (n=8)
Measure	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)
Present pain	5.15 (3.23)	4.64 (2.86)	3.83 (2.87)
HADS			
Anxiety	6.92 (4.19)	6.40 (3.89)	5.43 (5.80)
Depression	7.08 (3.37)	6.60 (4.99)	5.43 (4.96)
Medication dose (mg)	54.31 (37.31)	27.88 (19.75)	23.50 (24.07)
Pain description *n (%)*			
No pain	2 (16.7)	1 (8.3)	2 (16.7)
Mild	2 (16.7)	5 (41.7)	2 (16.7)
Discomforting	2 (16.7)	1 (8.3)	3 (25.0)
Distressing	3 (25.0)	2 (16.7)	1 (8.3)
Horrible	1 (8.3)	1 (8.3)	
Excruciating	2 (16.7)		
Pain frequency *n (%)*			
Brief	2 (16.7)	4 (40.0)	2 (25.0)
Intermittent	2 (16.7)	3 (30.0)	3 (37.5)
Continuous	8 (66.7)	3 (30.0)	3 (37.5)

2b. What are the relationships among pain quality, total pain, type of pain, pain management, anxiety, and depression in the immediate post-operative period (POD 2, POD 4, POD 6)?

Tables 5 (POD 2), 6 (POD 4) and 7 (POD 6) display the intercorrelations among medication dosage, HADS anxiety and depression, present pain, and the SF-MPQ-2 pain measures. Using Cohen's suggestion that correlations of .50 or greater represent a large effect size, there were no large correlations between medication dosage and any of the other measures at POD 2. At POD 4 dosage was related to neuropathic pain intensity (r = .50), and by POD 6 dosage was strongly related to present pain (r =.58), total SF-MPQ-2 score (r = .76), continuous pain intensity (r = .68), intermittent pain (r = .53) and neuropathic pain intensity (r = .66).

At POD 2, HADS anxiety showed a statistically significant correlation with the affective descriptors of the SF-MPQ-2 (r = .70). Depression also showed an inverse correlation with pain during this time (r = -.56) but was not statistically significant. There were no other large correlations between HADS and other measures at POD 4 (Table 6). At POD 6 anxiety was correlated with present pain (r = .51), intermittent pain (r = .65) and affective descriptors (r = .81), while depression had no strong correlations with the pain measures.

On POD 6 (Table 7), present pain showed significant correlations to SF-MPQ-2 (r = .84), continuous pain (r =.92), intermittent pain (r = .78) and affective descriptors (r = .80). As mentioned above, medication dosing had strong correlations with SF-MPQ-2, continuous, intermittent and neuropathic pain during this same measurement period.

Table 5

Intercorrelations for Medication Dosage, HADS Anxiety and Depression, Present Pain, and SF-MPQ-2 Pain Dimensions at POD 2

Measure	1	2	3	4	5	6	7	8	9
1. Medication dosage	-								
2. Anxiety	.34	-							
3. Depression	-.23	.55	-						
4. Present pain	.43	-.07	-.56	-					
5. SF-MPQ-2 total	.45	.51	.36	.22	-				
6. Continuous pain	.35	.32	.31	-.07	.82**	-			
7. Intermittent pain	.44	.28	.31	.01	.78**	.60*	-		
8. Neuropathic pain	.17	.42	.46	.17	.87**	.54	.71**	-	
9. Affective description	.19	.70*	.34	-.09	.50	.36	.42	.34	-

Note. *p < .05. **p < .01.

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Table 6

Intercorrelations for Medication Dosage, HADS Anxiety and Depression, Present Pain, and SF-MPQ-2 Pain Dimensions at POD 4

Measure	1	2	3	4	5	6	7	8	9
1. Medication dosage	-								
2. Anxiety	.09	-							
3. Depression	.05	.87**	-						
4. Present pain	.44	.23	.12	-					
5. SF-MPQ-2 total	.37	.45	.31	.31	-				
6. Continuous pain	.27	.39	.22	.41	.87**	-			
7. Intermittent pain	.25	.19	.20	.34	.86**	.66*	-		
8. Neuropathic pain	.50	.43	.28	-.02	.69*	.39	.47	-	
9. Affective description	.46	.49	.31	.30	.65*	.50	.34	.58	-

Note. *$p < .05$. **$p < .01$.

Table 7

Intercorrelations for Medication Dosage, HADS Anxiety and Depression, Present Pain, and SF-MPQ-2 Pain Dimensions at POD 6

Measure	1	2	3	4	5	6	7	8	9
1. Medication dosage	-								
2. Anxiety	.02	-							
3. Depression	- .36	.71	-						
4. Present pain	.58	.51	-.02	-					
5. SF-MPQ-2 total	.76*	.40	-.02	.84**	-				
6. Continuous pain	.68	.13	-.41	.92**	.83*	-			
7. Intermittent pain	.53	.65	.19	.78*	.87**	.72*	-		
8. Neuropathic pain	.66	-.04	-.08	-.05	.39	.05	.06	-	
9. Affective description	.41	.81*	.29	.80*	.87**	.66	.89**	.11	-

Note. *p < .05. **p < .01.

Research Question 3

3a. What is the acceptability and feasibility of a desensitization intervention (recruitment, retention, patient acceptance, ease of use) for lower limb amputees in the post-operative period?

Issues related to recruitment and retention was discussed previously. Participants that enrolled in the study were administered a feasibility questionnaire on POD 6 or during the last visit. Two patients were discharged before POD 6 without administering the questionnaire. One patient withdrew from the study prior to administering the questionnaire. Nine patients completed the feasibility questionnaire. All of patients that completed the feasibility questionnaire agreed or strongly agreed that the technique was easy to use. When asked if desensitization helped the pain, 87.5% agreed or strongly agreed that it was helpful with 12.5% undecided if it helped or not. All those responding felt that they would continue to use the

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technique, even after the study was completed. When asked if they would recommend this

technique to others that had the same type of surgery, 77.8% strongly agreed and 22.2% agreed.

The majority of patients felt that they could do it by themselves without any help (89.9%). Open

comments about the use of desensitization were also elicited during the study; Table 6 has

comments provided by the participants. Overall, the comments received were positive.

Table 8
Feasibility Questionnaire Comments (n =5)

Participants comments

Rubbed a lot longer. I felt I had to, to help the pain. (P 1)

A couple of days ago I would not have believed it to work, but it did. Stay an inch and a half
back, if not it will hurt. (P 2)

Eased the pain very much. (P 7)

I understand the importance. When I used it, it helped to knock the pain down during the
first few days. These last two days when I have had a pain, I used it and I did not have to
get any pain medicine. (P 8)

It helps. I didn't think it would. I think everyone should know how to use this therapy. (P 9)
Note. P = participant

The intervention questionnaire was administered during POD 4 and POD 6 to confirm

that the participant was complying with the intervention according to protocol. Questions asked

were: if they removed the knee immobilizer, massaged over the dressing, used a circular pattern

to massage, massaged across the limb at least three times, massaged any painful areas, tapped

across the limb and tapped any painful areas. See Table 8. The participants had no difficulty

with the intervention during either time period. The majority of participants did not identify any

one area that was more painful.

Table 9

Compliance with the Intervention Protocol

| | POD 4 (*n*=10) | | POD 6 (*n*=7) | |
Protocol	*n*	*%*	*n*	*%*
Removed immobilizer	8	80	5	71
Massaged over dressing	10	100	7	100
Used circular pattern	10	100	7	100
Massaged across 3 times	10	100	7	100
Massaged painful area	4	40	3	43
Tapped across 3 times	9	90	7	100
Tapped painful area	3	30	3	43

 3b. How does the desensitization intervention affect self-reported short-term pain in lower limb amputees during the immediate post-operative period?

Each time the patient performed an intervention they recorded the amount of time they applied the intervention in minutes, their pain level just before the intervention and their pain level immediately after the intervention. Table 10 shows the average pre and post intervention pain levels for the daily and total interventions. For the 50 total intervention events, and the events at each postoperative day there was a statistically significant decrease in pain from pre-intervention to post intervention and all the statistical comparisons had a large effect size. The average time spent on the 50 interventions was 4.2 minutes per intervention, with the daily times ranging from 3.5 to 5.8 minutes per intervention.

Table 10

Effect of Desensitization Intervention on Pain at POD 2, 3, 4 and 5

POD	*n*	Pre intervention *M* (*SD*)	Post intervention *M* (*SD*)	Difference *M* (*SD*)	*Eta²*
2	8	8.38 (1.60)	5.75 (1.58)	2.63 (1.41)	.80
3	11	9.09 (1.22)	5.18 (2.14)	3.91 (2.34)	.75
4	15	7.87 (1.61)	5.17 (1.55)	2.70 (1.44)	.79
5	16	6.69 (1.25)	4.25 (1.77)	2.44 (1.03)	.86
Total	50	7.84 (1.65)	4.97 (1.80)	2.87 (1.63)	.76

Note. *n* = the number of events preformed by the sample during that postoperative day. All paired comparisons p < .001; All effect sizes indicate a large effect

Summary

Although, the SF-MPQ-2 had never been used in the amputation population, it did show adequate total score internal consistency reliability when used during the acute period. The HADS anxiety scores did not achieve adequate internal consistency reliability until POD 6, and HADS depression reached adequate reliability by POD 4. This instrument has previously been used with amputees but not in an acute care setting. It is possible the wording on several of the HADS questions contributed to the lack of response consistency with persons that have just lost their leg.

The study sample was primarily female, African American, with either a high school degree or less, and an average age of 60 years. The most common co-morbidities included hypertension, diabetes and PVD. The majority of the group controlled preoperative pain by use of the oral opioid Oxycodone 5 -325. General anesthesia was primarily used for the surgical procedure. The majority of the group had the right leg amputated with a primary cause of PVD

related to diabetes. Refusal rate of the sample was 48% with the primary reason for refusal being fatigue. Those refusing were primarily African American men.

The total pain intensity mean scores decreased over the three measurement days. Intermittent pain and affective descriptors with the highest intensity at POD 2 included sharp pain, tiring-exhausting, tender, pain caused by light touch, and piercing. All of the neuropathic pain descriptors and affective descriptors decreased from POD 2 to POD 6. Three continuous pain descriptors (throbbing, cramping and gnawing) and one intermittent pain descriptor (shooting pain) increased from POD 2 to POD 4 before decreasing on POD 6. All of the other continuous and intermittent pain descriptors decreased over the three measurement days. By POD 6, continuous pain followed by neuropathic pain had higher mean scores. Descriptors during this period included, "tender", "throbbing" and "pain caused by light touch". Pain on a numerical rating scale, anxiety, depression and medication dosages also showed decreases over the measurement time periods. Pain was noted to be less excruciating or horrible for the participant as the study progressed.

Intercorrelations among pain measures, anxiety, depression and medication dosage were analyzed for the three time intervals. Large correlation effects ($r \geq .50$) were noted starting on POD 4 with neuropathic pain strongly related to medication dosage. On POD 6, medication dosage was strongly correlated to present pain, SF-MPQ-2 total score, continuous pain, and neuropathic pain. At POD 6, anxiety was strongly correlated with present pain, intermittent pain and affective descriptors, while depression had no strong correlations with any of the pain measures.

Acceptability and feasibility were measured by compliance with the protocol, a feasibility questionnaire administered on the last day and patient records of times intervention

was used with pain scores. Compliance with the protocol was high on POD 4 and 6. Participants

felt that the intervention was easy to use and helped the pain. They said that they would continue

to use it and they would recommend to others. Comments were positive about the intervention.

The effect of desensitization on pain was recorded each time the participant self-administer the

protocol. The participants administer a total of 50 interventions with an average administration

time of 4.2 minutes per each intervention. Scores showed a decrease in pain scale from pre-

intervention to post intervention with statistically significant paired comparisons and a large

effect size for POD 2, 3, 4 and 5.

Chapter 5: DISCUSSION

Pain from amputation is not well understood due to the multidimensional nature of pain and the unexplained pathophysiological pathway of phantom pain. Unidimensional treatment may not help alleviate post surgical pain in the amputee. The primary goal of this study was to evaluate the feasibility and efficacy of using desensitization with a regular pain regimen of medications in those sustaining a lower extremity amputation during acute hospitalization. A secondary purpose of the study was to explore relationships of variables that contribute to neuropathic and non-neuropathic pain, as well as, affective descriptors and to explore patterns and types of pain in this population. This chapter presents major findings of the study, limitations of the study, recommendations for future research and implications for nursing practice.

Characteristics of the Study Sample

The study sample primarily consisted of women (58.3%), African Americans (66.7%) and people educated below the high school level (41.7%) with a mean age of 60. This sample was different than samples from previous studies that reported on post-operative pain in amputees. The current sample included a higher percentage of women when compared to prior studies. Previous studies were predominantly populated by a large percentage of men (60 -91%) (Bosmans et al., 2010; Castillo et al., 2006; Ehde et al., 2000; Ephraim et al., 2005; Gallagher et al., 2001; Hanley et al., 2006b; Hanley et al., 2007; Hirsch et al., 2010; Richardson et al., 2007; Ziegler-Graham et al., 2008).

Another difference in the current sample compared to previous studies was mean age. The sample for this study tended to be older than most other studies. (Bosmans et al., 2010; Castillo et al., 2006; Ehde et al., 2000; Ephraim et al., 2005; Gallagher et al., 2001; Hanley et al.,

2006a; Hanley et al., 2007; Hirsch et al., 2010). In previous studies traumatic amputations were part of the sample, which would lower the age of the sample. Since vascular disease does affect primarily adults that are older, the current sample was older. When looking at ethnicity of previous samples there is a large divergence between this study and other studies. Prior studies included mainly Caucasian individuals (81%-92%) compared to the high percentage of African Americans (66.7%) in this study (Ehde et al., 2000; Ephraim et al., 2005; Hanley et al., 2006b; Hanley et al., 2007; Hirsch et al., 2010; Ziegler-Graham et al., 2008). No studies were found in the literature specific to ethnicity and difference in amputation pain type and description. This is an area that needs to be researched further, in order to provide culturally sensitive and appropriate treatment measures.

A final demographic characteristic that was unlike other studies was education level. In this study, almost half of the participants had an education level below high school, while other studies have reported participants having primarily a high school or greater than high school education (Castillo et al., 2006; Ephraim et al., 2005; Hanley et al., 2006b; Hirsch et al., 2010). Demographic characteristics may be different due to the geographic location of the studies. Very few studies have been completed with amputees in the southeastern part of the United States. A majority of the studies were either international or conducted in the northwestern or northeastern United States (Bosmans, et al., 2010; Castillo et al., 2006; Ehde et al., 2000; Gallagher et al., 2001; Hanley et al., 2006b; Hanley et al., 2007; Hirsch et al., 2010; Richardson et al., 2007). Only one national study included subjects from the south (Ephraim et al., 2005). Using this population provides insight to amputation pain and treatment in this geographic area.

Clinical characteristics of this study included level of amputation, side amputated, cause of amputation, measures for pain control prior to surgery and anesthesia type. In this study the

right leg (66%) was amputated more often and occurred primarily as a BKA (50%). Level of amputation of this study is consistent with most studies (Bosmans et al., 2010; Ehde et al., 2000; Ephraim et al., 2005; Gallagher et al., 2001; Hanley et al., 2006b; Ziegler-Graham et al., 2008). Previous studies have not reported on which side was amputated. The primary cause of amputation in this study was peripheral vascular disease caused by diabetes. Only one other study had similar rates of peripheral vascular disease, but did not specify if it was related to other comorbid disease states (Bosmans et al., 2010). Comorbidities of the sample were similar to other studies. In this study all participants had a medical history of hypertension. Peripheral vascular disease and diabetes were the next two most cited comorbid conditions.

Pre-operative pain control of the sample was achieved by pharmacologic management with oral medication. The two primary drugs given for pain control were Oxycodone 5-325 milligrams and Gabapentin. This study supported what other studies have found for pain control measures both before and after surgery (Huse et al., 2001, Wu et al., 2002, Wilder-Smith et al., 2005). A question asked during the study was to list all types of pain control methods, other than pharmacologic, used to alleviate the pain prior to surgery. None of the participants used any other type of complimentary or alternative pain relief methods. This finding is significant in that it suggests that patients are not familiar with complementary therapies that may be useful in controlling pain. Studies have shown that health care providers do not supply the amputee with a means of adequately controlling their pain either by pharmacologic or non-pharmacologic measures and that there is a general lack of knowledge on the types of pain experienced (Dudgeon et al., 2002; Hanley et al., 2006b; Mortimer et al., 2002; Smith et al., 1999; Warms et al., 2005). Research on how providers inform the amputee about both pre- and post-operative management of pain needs further exploration.

Patterns and Relationships of Pain, Anxiety and Depression

The current study showed that overall mean pain scores during the intervention period decreased. Using the SF-MPQ-2 provides the researcher with information on neuropathic, non-neuropathic pain and affective descriptors. A new finding of the study was that the SF-MPQ-2 measure of pain types, pain description and pain intensity found variability in those measures among participants and between postoperative days in this population. Due to the multidimensional nature of amputation pain, this instrument provides insight to these types of pain and mediators of pain. Descriptors noted in the study population during all measurement time periods included words related to continuous, intermittent and neuropathic pain. Most studies have measured amputation pain after it has been a number of years since surgery and found that the primary type of pain experienced by amputees was neuropathic (Flor, 2002; Nikolajsen & Jensen, 2001; Wiffen et al., 2006). This study found that neuropathic and non-neuropathic pain occurs immediately after surgery. At POD 2, pain descriptors with the largest intensity scores included "sharp pain" (intermittent), "tiring-exhausting" (affective), "tender" (continuous) and "pain caused by light touch" (neuropathic). At POD 4 the same POD 2 descriptors were still reported with large intensity scores along with two new descriptors, "throbbing" (continuous) and "shooting pain" (intermittent).   On POD 6 most of the pain measures were much lower compared to POD 2 and POD 4. Only the pain descriptors of "tender" (continuous) and "pain caused by light touch" (neuropathic) remained high. The descriptor indicating neuropathic pain (phantom limb pain) in this population was "pain caused by light touch", which occurred during all measurement times. The descriptor for neuropathic pain in this study is different from other studies (Dudgeon et al., 2005; Ehde et al., 2000; Mortimer et al., 2002). Descriptors related to non-neuropathic pain (residual limb pain) in this

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study consisted of "sharp pain", "shooting", "tender" and "throbbing". The descriptors in this study were similar to results found by Ehde et al. (2000) for non-neuropathic pain. Differences in pain description may be related to instrument use among the various studies. Dudgeon et al. and Mortimer et al. used instruments that were individualized for their studies. Ehde et al. used an earlier version of the MPQ. All prior studies were done on samples that were in a chronic pain state. The sample of this study all used the intervention so variability and reduction in SF-MPQ-2 cannot be attributed to the intervention. More studies need to be done on pain description and patterns within various populations using a comparative sample.

In this study, there was also a noted decrease in pain frequency over time. Pain became less continuous and more intermittent and brief. At the same time, the participant's classification of the quality of the pain changed from excruciating/horrible to mild/discomforting during the post-operative period. As pain decreased there was also a decrease in medication dosages. Although, the typical surgical patient should use less medication as time continues after surgery, the multidimensional nature of the amputee's pain is different. Some researchers suggest that neuropathic pain does not usually decrease with time after amputation surgery, but becomes chronic with increasing intensity (Castillo et al., 2006; Ephraim et al., 2005, Hanley et al., 2006b; Kern et al., 2012). This study was not designed to examine the nature of chronic pain.

There were no significant relationships among medication dosing, continuous pain, intermittent pain or neuropathic pain during POD 2. By POD 4, medication dosage was strongly related to neuropathic pain with increased neuropathic pain intensity associated with higher pain medication dosage. On POD 6 medication dosage was strongly related to continuous pain, intermittent pain, neuropathic pain and present pain scores. Present pain during this time showed a statistically strong correlation with affective descriptors, SF-MPQ-2, continuous and

intermittent pain. The strong correlations during POD 6 between pain types, affective descriptors, medication dosing and present pain could indicate improvement in pain management with the participant's current regimen of pain control measures. All of these correlations represent new findings.

Depression had an inverse strong correlation with present pain during POD 2. Since the HADS did not show internal consistency during this time period, the correlation cannot be substantiated. Depression showed no other strong correlations during the study. This could be due to the use of the HADS instrument to measure this variable. Other studies have found that depression does exist in persons with limb loss but not all depression was found related to the pain experience (Jensen et al., 2002; Price, 2005; Whyte & Niven, 2001). Anxiety did show strong relationships with affective descriptors, intermittent pain and present pain. Anxiety is an affective disorder, so this correlation is expected. The correlation between anxiety, present pain and intermittent pain, indicates that when pain increases so does the patient's anxiety level. It is unknown why this occurs but could be due to anxiousness of the participant in receiving adequate pain control in a timely manner. Only one previous study gave an explanation of the correlation between pain and anxiety in the amputee. Sherman et al. (1979) describes the pain-anxiety-tension cycle. In this cycle, when muscle tension occurs in the residual limb, anxiety and pain level increase. Relaxation used by Sherman et al. showed a decrease in tension with subsequent decrease in anxiety and pain. No further studies were found discussing the pain-anxiety-tension cycle in the amputee population. Even though this is an older study, further research should explore this cycle, as well as, correlation of pain and anxiety after amputation. Overall, mean anxiety and depression scores did decrease from POD 2 to POD 6. The findings related to anxiety and depression must be interpreted with caution due to the lack of internal

consistency with a low Cronbach alpha for this instrument up to POD 4. In further studies completed in the acute setting with amputation patients, other anxiety and depression scales may need to be considered.

Feasibility and Efficacy of Desensitization

There are currently no studies that report the use of desensitization with the amputation population. Any complementary therapy that will assist in pain control needs to be efficacious and feasible for the patient to use. This study is the only one that has measured efficacy and feasibility with the technique of self-administered desensitization. This study points to promising results for using desensitization, although the results are not definitive.

All participants of the study used the intervention. Participants reported that the technique was easy to use, they would recommend it to others and would continue to use it. The participants were able to perform the technique by themselves with little to no help. Most importantly, the majority of participants reported that desensitization did help reduce their pain. Comments provided by participants supported the use of desensitization, even though some participants were initially skeptical that the technique would have any benefit. All participants reported using the protocol correctly. It is important to note that the technique could be performed by a sample that had an educational level that was less than high school, making this an easy to follow and simple way to add to their therapeutic pain management plan.

Reduction in pain was statistically significant from pre to post intervention with each event performed by the participant. This, along with the positive feasibility results and positive comments supports the use of this desensitization protocol. The difference in pain levels is both statistically and clinically significant. The actual reduction in pain varied from two to five points on a numerical rating scale suggesting that patients did feel substantial relief after administering

the intervention. Clinically, nursing can provide a way for the amputee to have control over their pain without any added cost.

Theoretical Frameworks

In order to understand the multidimensional aspect of amputation pain, two frameworks guided this study. Adaptation by anyone having an amputation has to occur on multiple levels. Roy's Adaptation Model describes the focal stimulus as the start of adaptation. Roy suggests that adaptation to a focal stimulus like pain requires interventions by the individual and nursing within the context of the situation. In this study, the context is the immediate post-operative period where the individual is experiencing both non-neuropathic and neuropathic pain. The usual response in dealing with any type of pain is by using opioids. This study suggests that this type of intervention is somewhat effective. However, the study also suggests that using the desensitization protocol within this context augments adaptation at least temporarily while the patient is recovering.

Melzack's Neuromatrix Theory (1999) was also used to look specifically at neuropathic or phantom limb pain in this study. Melzack's theory describes how pain is perceived when there is no stimulus, such as with a phantom limb. In this study, an attempt to restructure the neurosignature was done through desensitization. Using stimuli at the site to restructure the innate pathway through massage and tapping guided by dermatome mapping was reported by participants as helping the overall pain experienced after surgery.

In order to conceptualize a model for amputation pain there needs to be a melding of theories to explain the multidimensional nature of the various types of pain experienced. Overall, Roy's Adaptation model and Melzack's Neuromatrix theory were supported and useful in guiding this study.

Strengths and Limitations

A major strength of this study is the diverse population represented. This study had a high representation of African Americans and females. In most amputation studies these two groups are underrepresented. There are no studies in the literature that examine race with neuropathic and non-neuropathic pain after amputation.

Another strength of the study was exploration of the SF-MPQ-2 and HADS with an amputee population during acute hospitalization. This study confirmed that the SF-MPQ-2 was a reliable instrument to use immediately after surgery in this population. On the other hand, the HADS was not reliable immediately after this type of surgery, even though the instrument is conceptualized for use in the hospitalized patient.

Although this was a small pilot study, it is the first time desensitization has been studied as a feasible and efficacious technique in the amputation population immediately after surgery. The positive result of feasibility along with the effects of decreased pain levels after intervention supports the need to find out more about the technique and its effect on amputation pain as a complementary measure.

The major limitation of this study was sample size. An initial projection of thirty participants was planned. Due to a large number of refusals and excluded patients, sampling was limited to twelve patients. Since this study was done in the immediate period following amputation surgery, a majority of potential participants were fatigued due to surgery and postoperative therapy. Sample size was also limited due to an overall decrease in the number of amputations performed by the surgical group and limitations within the medical staff. One way to address this is by studying pain management therapies in this population with a multisite study

or consenting participants before surgery. Using an interdisciplinary research team who are familiar with this population could also increase recruitment.

Another limitation of the study was sample method. A convenience sample was used for this study without a comparison group. Since it was an exploratory study, this type of sampling was appropriate. However, a study using random assignment would provide a more rigorous evaluation of the effect desensitization might have on pain. Patients who sustained a traumatic amputation were excluded from this study, but could add to the overall sample in future studies. Future research studies need to examine traumatic amputation patients using this type of desensitization protocol.

Due to the study sample consisting of primarily older patients with vascular problems and small sample size, generalizability of this study is limited. Patients who sustain traumatic amputations are younger and may react differently to pain. Future studies need to consider including traumatic amputation patients in examining complementary measures for pain control.

This study measured only the short-term effects of the intervention on post acute amputation pain. A limitation of the study and what is not known is the cumulative effect on pain types in this population. Research design prevented examining desensitization longitudinally, but is an important aspect for future studies.

Recommendations for Research

Future research needs to be conducted with a larger representative sample of amputation patients. Ideally, desensitization needs to be evaluated using a randomized control trial design that includes patients from different socioeconomic and ethnic backgrounds who are receiving an amputation for various conditions. Longitudinal studies also need to be conducted in order to explore how desensitization over time with chronic pain. Repeating this study during the

rehabilitation phase of recovery or in the home setting would help determine if there is a cumulative effect and if pain restructuring does occur.

This is the first study that examined the use of a set protocol of desensitization with the amputation population. The findings of this study need to be validated in a larger cohort to better understand pain control of the amputee in the post-operative period. Further studies need to continue exploring complementary therapies for pain management in the amputee. Most research has examined pain interventions using only one therapy at a time. There are mixed reviews of these studies (Clarke, Lindsay, Pyati & Buchheit, 2013). Since amputation pain is multidimensional and complex, studies should measure multimodal therapies simultaneously. Lastly, randomized control studies need to take place during acute hospitalization and acute rehabilitative phases.

Implications for Nursing

Pain among amputation patients consists of various types of pain; continuous, intermittent and neuropathic. Along with the pain, affective disorders are also present. Nursing needs to understand how to distinguish among the various types of pain in the post-surgical amputation patient. The nurse should be knowledgeable about appropriate treatment measures that alleviate these types of pain.   In practice, the clinician needs to recognize high levels of anxiety and depression as modulators of pain and be able to implement measures to also resolve affective disorders at the same time.

This study provides support in using the technique of desensitization in the acute hospitalization phase for amputation patients. Participants in this study found it easy to use, as well as, helpful in alleviating their pain. Imparting knowledge to patients that aids in outcome and recovery is crucial. Adding this type of therapy to routine care provided by nursing and

allied health may improve patient outcomes without added cost to the patient and organization. The intervention also gives some control to the patient in managing their pain.

One of the largest implications of the study is the need for more research on pain interventions provided by nurses for amputation pain during acute post-surgical care. The focal point of care during this period should center on pain relief. Without adequate pain control, the patient is unable to continue with activities of daily living and rehabilitation. At present, only one means of pain relief, pharmacological therapy, is used for multidimensional pain.

In summary, this pilot study provides beginning information on using one type of complementary therapy with amputation patients during acute hospitalization. Although, the sample was small in this repeated measure study, it did give insight to the need for more amputation research with a diverse population. Desensitization was reported by most participants as being beneficial. Nursing is responsible for managing pain in the patient after surgery in the acute setting. It is important to build evidence through nursing research on the best strategies for controlling pain caused by limb loss.

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APPENDIX A: INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board Office
4N-70 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914** · Fax **252-744-2284** · www.ecu.edu/irb

Notification of Initial Approval: Expedited

From: Biomedical IRB
To: Carolyn Horne
CC:
         Martha Engelke
Date: 2/8/2013
Re: UMCIRB 12-001221
         Complementary Therapy for Amputation Pain

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) is for the period of 2/7/2013 to 2/6/2014. The research study is eligible for review under expedited category #4,5,7. The Chairperson (or designee) deemed this study no more than minimal risk.

Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The Investigator must adhere to all reporting requirements for this study.

The approval includes the following items:

Name	Description
AKA Patient Educational Booklet	History	Additional Items
BKA Patient Educational Booklet	History	Additional Items
Consent Form-Horne-2	History	Consent Forms
Daily Intervention Card	History	Surveys and Questionnaires
Demographic and Clinical Questionnaire	History	Surveys and Questionnaires
Demographic and Clinical Questionnaire	History	Data Collection Sheet
Desensitization Protocol	History	Study Protocol or Grant Application
Feasibility Questionnaire	History	Surveys and Questionnaires
Hospital Anxiety and Depression Scale	History	Surveys and Questionnaires
Periodic Intervention Log	History	Surveys and Questionnaires
Proposal	History	Study Protocol or Grant Application
Short Form McGill Pain Questionnaire-2	History	Surveys and Questionnaires

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418 IRB00004973

APPENDIX B: DEMOGRAPHIC AND CLINICAL QUESTIONNAIRE

Demographic and Clinical Questionnaire for Study on Complementary Therapy for Amputation Pain

1. Gender

   Male   ☐

   Female

2. Age   _____

3. Highest level of education

   Less than high school
   High School/GED
   Some college
   2-year college degree
   4-year college degree
   Graduate degree

4. Race/Ethnicity

   African American (non-Hispanic)
   Hispanic
   Caucasian (non-Hispanic)
   Asian
   Pacific Islander
   Native American
   Other (specify)_____

5. Pain medication used at time of admission to the hospital (List all that apply with dose, frequency and route. Include any medication used for any chronic pain syndromes.)

   _____

   _____

   _____

_____

6. Other interventions used by the patient for pain relief before coming in the hospital (List all that apply. Examples: Rubbing, Cold packs, Heating pads, acupuncture)

_____

_____

_____

Review the chart for the following information.

7. What is the level of amputation?

>   Above the knee

>   Below the knee

>   Knee Disarticulation

8. What side was amputated this admission? Check both if both legs were amputated during this admission.

>   Right
>   Left

9. What history of health problems does the patient have?

>   Coronary Artery Disease/Heart problems
>   Chronic Obstructive Pulmonary Disease
>   Peripheral Vascular Disease/Carotid/Aneurysmal
>   High blood pressure
>   Diabetes
>   History of previous amputation
>   Other(s)_____

10. What type of anesthesia was used (include medication used)?

General

Spinal

Epidural

Anesthetic Medication Used	Route	Dose in mg.	Used during Procdure (P) or Used during Induction (I)

11. What pain medication was the patient placed on in the postoperative period? (Postoperative Day 0 = POD 0; Postoperative Day 1 = POD 1). Please list medication name, route and cumulative dosage for each day (24 hour period beginning at midnight to midnight). If patient has an epidural, list all medications that the solution has mixed in the bag if it is a mixture.

	Medication	Route	Dose in mg./6 hr intervals
POD 0			
00:00-06:00			
06:01-12:00			
12:01-18:00			
18:01-24:00			
POD 1			
00:00-06:00			
06:01-12:00			
12:01-18:00			
18:01-24:00			

POD 2			
00:00-06:00			
06:01-12:00			
12:01-18:00			
18:01-24:00			
POD 3			
00:00-06:00			
06:01-12:00			
12:01-18:00			
18:01-24:00			
POD 4			
00:00-06:00			
06:01-12:00			
12:01-18:00			
18:01-24:00			
POD 5			
00:00-06:00			
06:01-12:00			
12:01-18:00			
18:01-24:00			
POD 6			
00:00-06:00			

06:01-12:00			
12:01-18:00			
18:01-24:00			

APPENDIX C: JOURNAL CARD

Time of Day	How long did you rub/tap (minutes)	What was your pain before you started on a scale of 1 (no pain) to 10 (worst pain)	What was your pain after you finished on a scale of 1 (no pain) to 10 (worst pain)	Who did the rubbing and tapping

APPENDIX D: DESENSITIZATION PROTOCOL

Desensitization Protocol Guideline for Practitioner

1. Provide a quiet environment for the patient.

2. Explain to patient and family member that this is a training session. At the end you would like the patient and/or family member to show you how to perform the desensitization technique.

3. Describe the technique of desensitization (It is a technique to help with your pain. It can be used for both types of pain you are experiencing. Desensitization is a gentle tapping on the dressing above the incision line and then a gentle rubbing of the residual limb.)

4. Wash hands.

5. Apply gloves.

6. Tell the patient when you are going to begin.

7. Remove the knee immobilizer (if one is present) leaving the compression dressing intact. The compression dressing may be an ace wrap or a shrinker.

8. Inspect the bandage. If a large amount of active bleeding is noted (bright red) then defer the treatment and report this to the nurse so the physician can be notified. If dried blood present, desensitization can proceed.

9.. Putting your index and middle finger together, position these 1 inch above the end of the residual limb. Use a centripetal direction by gently tapping from the lateral edge of the incision inward to the proximal edge in a rhythmic motion. The nail beds of the practitioner should remain pink and without blanching of the nail bed (level 1 pressure) . If blanching occurs, then the pressure is too great.

10. Repeat this three times without change in pressure.

11. Inform the patient that you will now be gently massaging the limb in the same pattern that you used for the tapping.

12. Ask if there is a certain part of the patient's phantom leg or foot that is hurting.

13. Use the index, middle and ring finger together for massaging. Press down using a pressure where the fingertips blanch but the nail beds do not change color (level 2 pressure). Starting at the lateral side of the limb, massage in a circular pattern using a centripetal pattern. Do not lift fingers, but continue motion back across the limb to the

lateral aspect of the limb or centrifugal pattern. Continue this massage for three repeated patterns.

14. If the patient has an area on the phantom limb that is painful or hurts, locate the area by using the charts provided that corresponds to areas on the residual limb. Use the same massage technique in this area only. Massage the area for 1 minute. Reassess the pain in the phantom limb using the numerical rating scale.   Repeat for another minute. Reassess pain by using the numerical scale. Repeat a third and final time. Reassess pain after completion. Repeat for any other areas noted by patient.

15. Allow the patient to rest for five minutes.

16. Ask the patient and or family member to repeat the desensitization technique. Guide the patient or family member as needed.

17. Instruct the patient or family member to repeat this technique every three hours while awake or when the patient first begins hurting.

# APPENDIX E: INTERVENTION QUESTIONNAIRE

Intervention Log

(completed by Investigators on repeated measure days)

Date_____   POD_____   AKA   BKA   Bilateral   (Circle one)

Which of the following did you do or not do. Please share any comments or that might help us to understand what you found helpful or not helpful. For example, if you tapped or rubbed a special spot, tell us where. If you didn't do something (like tapping) please tell us why.

	Yes	no	Comments
Removed the knee mobilzer			
Massaged over the bandages			
Used a circular pattern			
Massaged across the limb 3 times			
Massaged a special spot (please put an M on the picture below)			
Tapped across the limb			
Tapped a special spot (please put a T on the picture below)			

Picture of the limb and have them put an x on the spots.
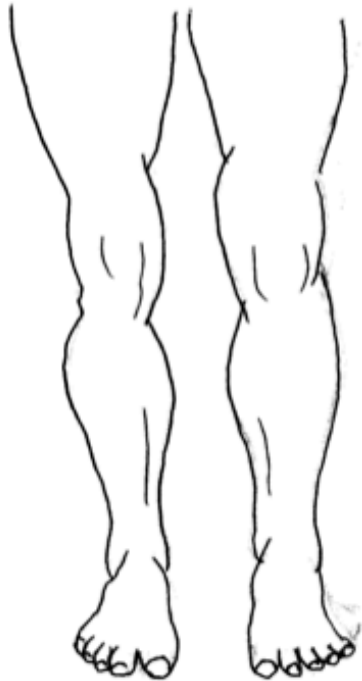
APPENDIX F: FEASIBILITY QUESTIONNAIRE

Desensitization Feasibility Questionnaire for Study on Complementary Therapy for Amputation Pain

1. The technique was easy to use.

   - o   Strongly Agree
   - o   Agree
   - o   Undecided
   - o   Disagree
   - o   Strongly Disagree

2. The rubbing and tapping helped my pain.

   - o   Strongly Agree
   - o   Agree
   - o   Undecided
   - o   Disagree
   - o   Strongly Disagree

3. I will continue to use it.

   - o   Strongly Agree
   - o   Agree
   - o   Undecided
   - o   Disagree
   - o   Strongly Disagree

4. I would recommend this therapy to others that have had this type of surgery.

   - o   Strongly Agree
   - o   Agree
   - o   Undecided
   - o   Disagree
   - o   Strongly Disagree

5. I needed help using it this therapy.

   - o   Always
   - o   Very Often
   - o   Sometimes
   - o   Rarely
   - o   Never

Any thing you would like to add:

Added Therapy for Amputation Pain©

(A-TAP)

Pain after Surgery

It is normal to have pain after amputation surgery. You may experience different types of pain. One type of pain is the pain that everyone experiences after surgery. It is usually located at or near the incision. Another type of pain you may experience is called "phantom limb pain". This type of pain is felt in the leg that was removed. The leg is not there but you still feel pain in the leg. This is normal. Most amputees experience phantom limb pain.

Your health care team should or already has ordered you medicine for your pain. Your nurse should provide you with pain medicine when you need it. Sometimes the pain may not go away even with the medicine. It may take other types of therapy to help you get relief from the pain.

One therapy to help with pain is called desensitization [dee-sen-si-tuh-zey-shuh n]. This may help to ease the pain when done routinely or when you are experiencing pain. Desensitization is done by tapping the amputated leg above the incision and following this by rubbing the same area. Doing this may or may not help the pain to ease. Using pain medicine and desensitization together could help with your relief of pain.

Pain in the Phantom Limb

The experience of pain in the missing limb is very real. The pain may be experienced in the entire missing limb or it may be in just one area of the limb, such as the right side of the foot or a toe. Being able to ease the pain in a certain area of the missing leg or foot can be difficult and frustrating. In order to do this, you can use the same tapping and rubbing technique used for desensitization. The area of the foot or leg that is hurting corresponds to the same side or location on the leg that remains. You can rub or tap the area of the limb on the same side of the painful area.

Guide to Performing Pain Control Therapy

1. Make sure that you are in a relaxed place.

2. Your dressing and/or shrinker should remain on.

3. Take your index finger and middle finger and put them together like in Figure 1. Place your fingers 1 to 2 inches above your surgery line (Figure 2.). Begin tapping along this line gently. It is like tapping on the desk with two fingers. Tap from the outside of your leg toward the inside of the leg (Figure 3). You should do this with a quick tap. Do not use pressure or force to tap. It should feel like light pressure but should not be painful. If it is painful then you may stop.

Figure 1: Use two fingers
For tapping.

Figure 2: The fingers should be placed one inch
From end of leg.

Figure 3: Tap from outside of leg to inside with two fingers

4. Repeat the tapping pattern three times.

5. The next step is to take your three fingers, like used in a boy scout salute (Figure 4.).   Place them 1 inch above the incision area, like in Figure 2 above. Begin rubbing above the incision in a circular pattern (Figure 5), starting from the outside of your leg and working to the inside. This should be slower than the tapping. When you get to the inside of the leg, do not lift your fingers but continue to rub back to the outside of the leg. Do this three times (one time is considered going across and back).
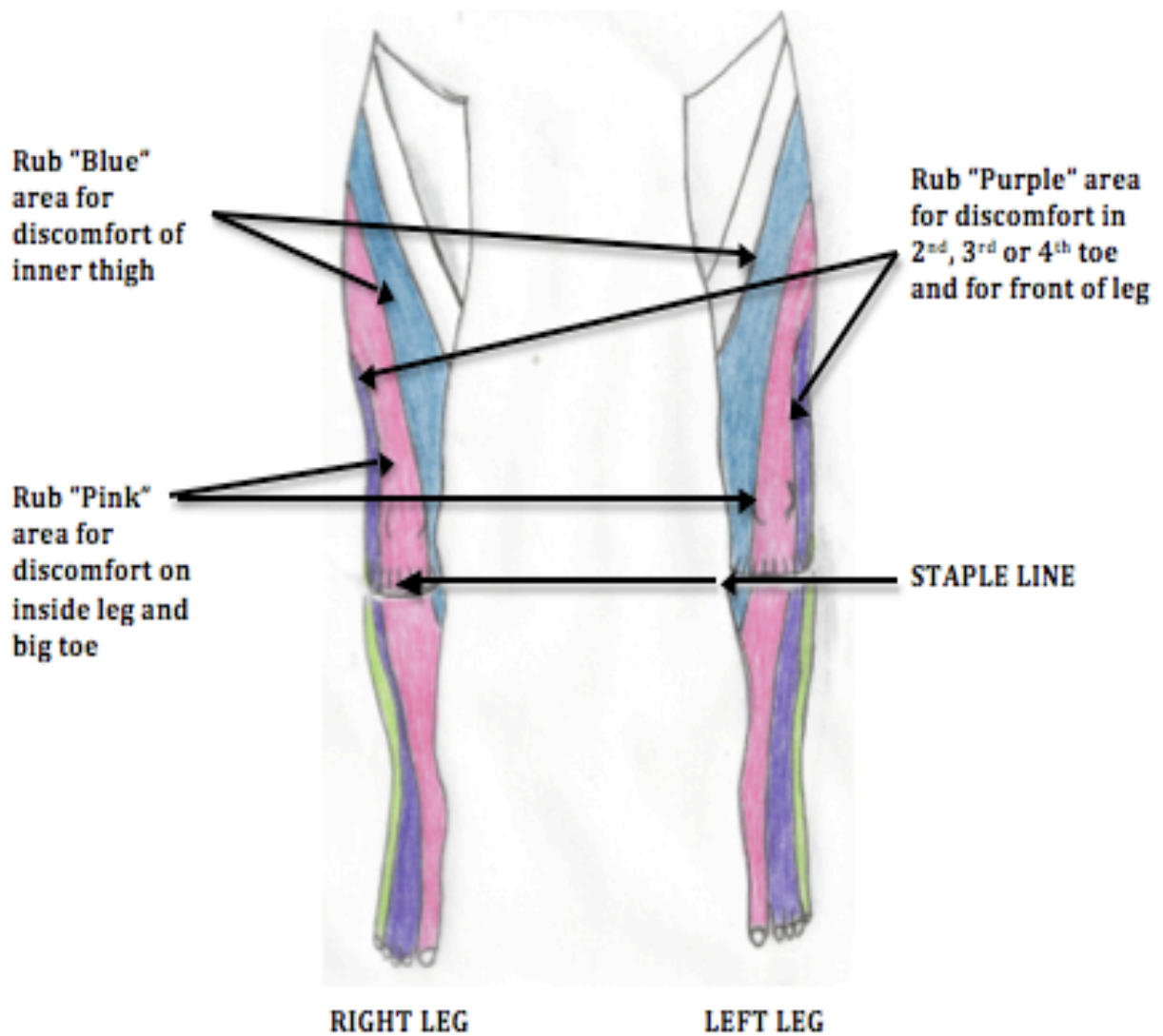
Figure 4. Use three fingers

Figure 5: Start from outside and rub in circular motion across leg and back

6. If you have a spot on your missing or phantom leg that is painful or itching, try to locate the pain or itch on the leg that remains. Use the color-coded map below to locate the point on your remaining leg that you can tap and rub to relieve the spot on your missing leg that is giving you the problem. See Figure 8. for the areas that relate to the missing part of the leg.

FRONT OF LEGS
Below Knee Amputation (BKA)

Rub "Blue" area for discomfort of inner thigh

Rub "Purple" area for discomfort in 2nd, 3rd or 4th toe and for front of leg

Rub "Pink" area for discomfort on inside leg and big toe

STAPLE LINE

RIGHT LEG   LEFT LEG

BACK OF LEGS
Below Knee Amputation (BKA)

Rub "Yellow" area (on back of leg) for discomfort in middle part of lower leg or for discomfort in your heel
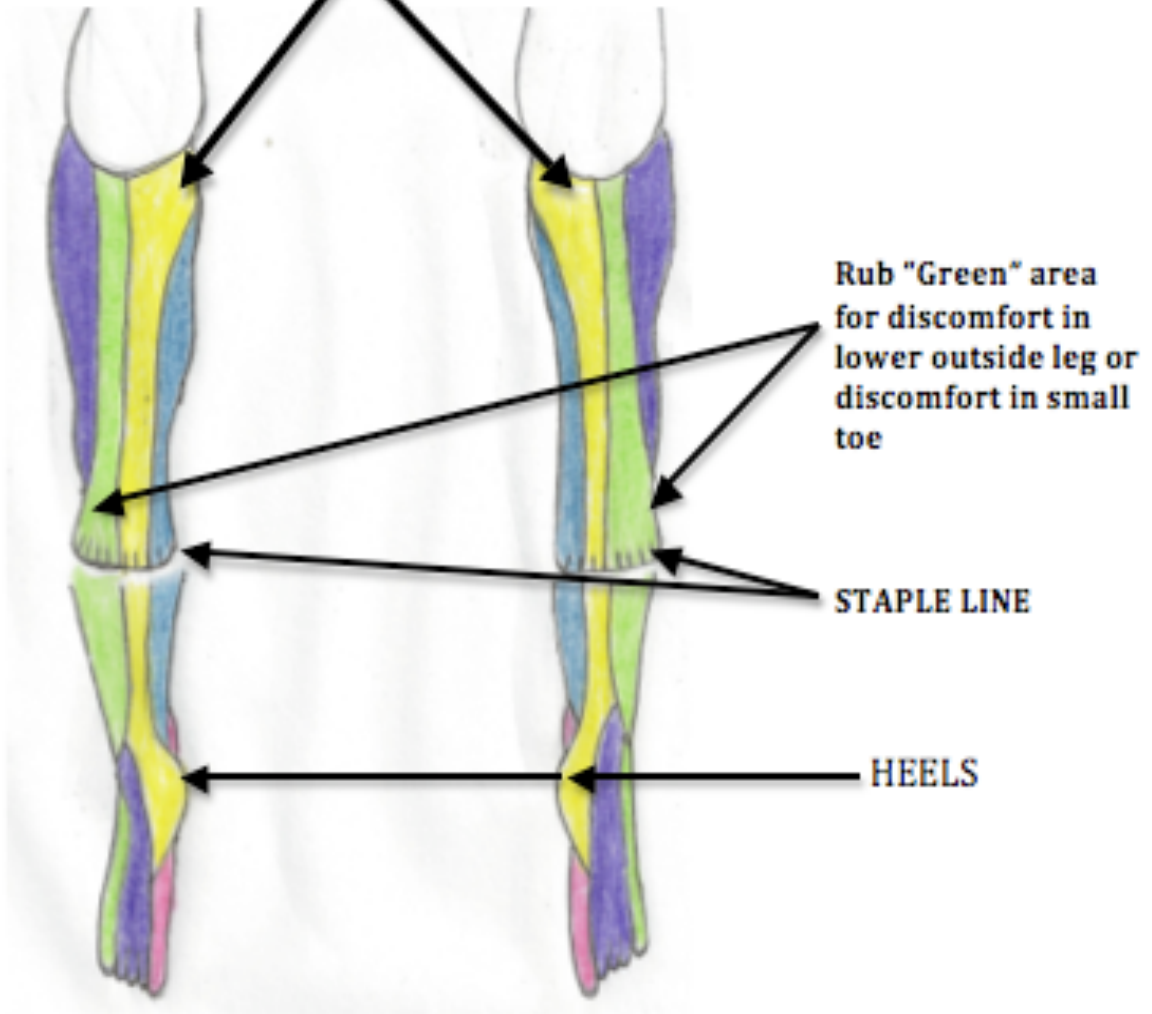
Rub "Green" area for discomfort in lower outside leg or discomfort in small toe

STAPLE LINE

HEELS

LEFT LEG   **RIGHT LEG**

7. Rub and tap like described above on the spot you located. Use the same pattern until you feel that the spot that is painful or itching is getting better.

8. In order for you to get pain relief from your phantom limb, you need to repeat this every three hours while you are awake. Doing this regularly will help the skin and nerves to heal.