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The Effects of Guided Imagery and HRV Biofeedback Training on Psychological Variables and Post-Operative Outcome Measures of Orthopaedic Surgical Patients

Lisa E. (Lisa Estevez) Grossman
THE EFFECTS OF GUIDED IMAGERY AND HRV BIOFEEDBACK TRAINING ON
PSYCHOLOGICAL VARIABLES AND POST-OPERATIVE OUTCOME MEASURES OF
ORTHOPAEDIC SURGICAL PATIENTS

By

LISA E. GROSSMAN

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The members of the supervisory committee were:

Gershon Tenenbaum
Professor Directing Dissertation

Lynn Panton
University Representative

Alysia Roehrig
Committee Member

Jeanine Turner
Committee Member

The Graduate School has verified and approved the above-named committee members, and certifies that the dissertation has been approved in accordance with university requirements.
To my best friend, my mom. Thank you will never be enough. This and so much more would never have happened without you. Thank you for your love, encouragement, and support.
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ABSTRACT

Complementary and Alternative Medicine (CAM) comprises a range of therapeutic modalities and atypical practices that have been found to successfully accompany standard medical care. Interventions such as guided imagery and stress management education, among many others, have been linked to improved health outcomes and recovery in the area of mind-body research (Freeman, 2005; Tusek et al., 1997). The objective of this study was to ascertain the degree of impact biofeedback and guided imagery have on psychological variables and medical measures as individual and combined interventions among orthopedic patients who underwent joint replacement surgery.

Hip and knee arthroplasty patients ($n=60$) were assigned to one of four groups where each received some form of preoperative intervention. Participants in the guided imagery, biofeedback, guided imagery and biofeedback, and standard care control groups all met with the researcher one to two weeks preoperatively where baseline measures were collected, instruction and demonstration on the use of the interventions were provided, and packets were distributed with assessments to be completed during their inpatient stay. Anxiety, stress and coping strategies were all measured at baseline, the day of surgery, and in the hospital on the last day of admission just prior to discharge. In addition, the patients level of reported pain each day following surgery while inpatient was appraised as well as the amount of pain medication needed and length of hospital admission.

Results of the present study support continued use of biofeedback and imagery in medicine and demonstrated the enhanced benefit of combining interventions as proposed. The imagery intervention reduced anxiety and perceived pain among the patients. A reduction in state anxiety scores was observed from baseline measurement to the day of discharge and its patients experienced a significant ($p < .01$) reduction in pain on post-operative day 3 from days 1 and 2. The biofeedback intervention generated positive results on a number of variables evaluated. A steady decline in stress was observed among patients from baseline measurement through discharge from the hospital as well as the continued reduction in medication use from post-operative day 1 through day 3. Furthermore, participants in the biofeedback treatment reported a significant ($p < .05$) reduction in pain from post-operative day 2 to day 3. Combining both imagery and biofeedback to be used simultaneously as its own intervention elicited the most
significant outcomes compared to all other treatment conditions in reducing stress and medication use. Only participants in the combo intervention experienced a significant ($p < .001$) reduction in stress from the day of surgery to the day of discharge and required significantly ($p < .001$) less medication administered through the pain pump than any other treatment condition ($p < .01$). Patients in the general standard of care intervention receiving education experienced a reduction in anxiety from the initial baseline measurement to day of discharge although it was minimal.

Positive outcomes were observed for all interventions provided in the present study. Outcomes reflect those reported across much of the CAM research exploring the benefits of interventions such as guided imagery and biofeedback on health related outcomes (Blanchard et al., 1987; Gervitz, Hubbard, & Harpin, 1996; Scherwitz et al., 2005). While guided imagery and biofeedback yielded benefits for the variables evaluated as sole treatment approaches, current findings reflect the efficacy of a combined approach with greater significance. The benefits of patients in any complementary and alternative medical practice positively influence the overall experience and potential results. Continued development and evaluation of more multifaceted approaches are essential in order to provide an optimal level of care.
CHAPTER 1
INTRODUCTION

Whether elective or medically necessary, patients undergo various procedures and surgery with the expectation of a successful recovery outcome. Despite optimal conditions and excellent medical care, the possibility of complications and poor results can often occur. Pain and post-operative nausea and vomiting (PONV) are common complications following surgery (Laurion & Fetzer, 2003). Although a wide selection of pharmacological treatments and preventative measures exist, they continue to be less than effective (Lee & Done, 1999).

As the number of medical procedures performed rise each year (Dallas, 2014), methods for facilitating successful outcomes include more than the general standard of care historically provided by the medical community. This form of “healthcare” (Complimentary and Alternative Medicine or CAM) encompasses a range of complementary and alternative practices (i.e., acupuncture, biofeedback, imagery, relaxation therapy), which are not under the umbrella of conventional medicine (NCCAM: National Center for Complementary and Alternative Medicine, 2008). Researchers and practitioners have demonstrated the impact of these supplemental therapies as beneficial for helping patients through a spectrum of medical conditions and treatments including cancer (Leon-Pizarro, 2007), sports injuries (Heil, 1993), post-operative physical rehabilitation (Ross & Berger, 1996), and various forms of surgery (Schwab et al., 2007).

Complementary and alternative medical practices have developed and grown in recent years as a result of mind-body medicine research. Mind-body medicine is a growing field encompassing the interaction between the brain and physiological systems. It was demonstrated that changing mental processes (i.e., thoughts, feelings, and emotions) could alter brain functions, and subsequently cause biochemical and physiological bodily changes (Ray, 2004). These changes could potentially enhance or hinder an individual’s health. Research findings support the relationship between negative mental states such, as anxiety, and delayed healing (Padgett & Glaser, 2003), and the negative impact of these states on surgical outcomes such as pain (Wells et al., 1996). As opposed to traditional forms of medical care that target physical symptoms or conditions (i.e. medicine), CAM practices and techniques address the mind-body
interaction by enabling the patient to consciously alter thoughts and emotions, producing biophysiological changes, and thus, improving health conditions.

Many forms of CAM have been found to positively influence recovery outcomes. For instance, Cupal and Brewer (2001) reported a significant increase in knee strength and reduced pain among post-operative anterior cruciate ligament (ACL) reconstruction patients receiving relaxation and guided imagery sessions. Tsai et al. (2007) examined the effects of electromyography biofeedback on cancer patients’ level of pain. The treatment group received six biofeedback-assisted relaxation sessions, and subsequently reported a reduction in pain greater than those receiving conventional care. Tusek et al. (1997) reported a 40-60% reduction in worst and least post-operative pain as well as a 44% reduction in analgesic use among colorectal cancer patients practicing guided imagery.

While continuing scientific effort is directed toward investigating the influence of various complementary and alternative techniques on health and well-being, there remains a lack of investigated dynamic and multi-faceted approaches applied to orthopaedic surgical outcomes. Because the number of orthopaedic surgical cases, such as joint replacement and soft tissue repair continues to rise annually (Dallas, 2014), the risks for complications and permanent disability grow. Surgical failure, infection, and loss of motion are all possible despite top medical care (American Association of Hip and Knee Surgeons, 2009). These and other complications such as pain can have lasting effects on the patient’s physical, emotional, social, and financial health. Thus, the issue remains, what can be done earlier in the course of treatment (i.e. pre-operatively) and carried throughout recovery to prevent or limit the number of complications experienced, and facilitate the healing process immediately following surgery?

Exploration into the effects of pre-operative CAM practices and in particular, the integration of techniques on orthopedic surgical candidates continues to be warranted. The current study compared the effects of pre-operative guided imagery (delivered through a procedure specific CD or MP3 file) and heart rate variability (HRV) biofeedback training as individual treatment techniques and in combination with a standard care control group on psychological variables; specifically, anxiety, perceived stress, and coping strategies, and post-operative outcome measures; specifically, pain, medication use, and length of hospital stay. While the interventions listed have been explored individually and reported on across mind-body interaction literature, the current research further examined these interventions on targeted
measures and explored the combined impact of these practices. It is theorized that the use of these interventions collectively will have a greater impact than when used alone. The literature review that follows highlights the relationship between the mind-body connection and medicine, the benefits of CAM practices (specifically guided imagery and HRV biofeedback training), and the implications for surgical patients as assessed by psychological variables such as stress and anxiety as well as recovery measures such as pain.
CHAPTER 2
LITERATURE REVIEW

Pre-Operative Experience

A patient’s pre-operative psychological well-being can have a significant and direct impact on surgical outcomes (Laufenberg-Feldmann, Kappis, Schuster, & Ferner, 2016). Impending surgery and subsequent hospitalization can generate a range of particularly threatening feelings and emotions. Moreover, it has been suggested that healing may result from factors such as expectation and intention (Scherwitz et al., 2005). The correlation between pre-operative distress and poor outcomes has been supported by a number of studies reporting higher incidences of post-operative complications, lengthier hospital stays, and a more frequent need for re-hospitalization (Contrada, Leventhal, & Anderson, 1994).

Patients anticipating surgical procedures undergo considerable levels of anxiety during the pre-operative stage of treatment (Stoddard, White, Covino, & Strauss, 2005). Maranets and Kain (1999) found 11 to 80% of adult patients experience anxiety preoperatively. The most common reasons are loss of control, fear of the unknown, and fear of anesthesia (Reider, 1991; Tusek et al., 1997). Anxiety varies among patients and has been found to be more prevalent among young people, women, and patients with no prior history of anesthesia (Rosen, Svensson, & Nilsson, 2008). Nevertheless, the patient’s overall psychological state and mental processes may notably influence the length of time for recovery from severe illness or medical procedures (Mumford, Schlesinger, & Glass, 1982). While negative cognitions and emotions have been associated with medical complications, conversely, feelings of hope can be vital for enhanced health (Ray, 2004). This relationship between mental processes and physiological responses was substantiated through medical research and serves as a foundation for mind-body medicine (Stoddard et al., 2005).

Mind-Body Connection and Medicine

Mind-body medicine evolved in the late 20th century and encompasses a range of practices as an approach to healing (Wolsko et al., 2004). These practices and techniques have emerged through the identification of mechanisms by which the mind and body work
collectively (Ray, 2004). With ties to research dating back to the early 1900’s, psychoneuroimmunology (PNI) has provided the most significant support for the mind-body connection (Gouin & Kiecolt-Glaser, 2012). Taking a multifaceted approach, PNI is the interaction between psychology and the nervous, immune, and endocrine systems (Irwin & Vedhara, 2005; Maier, Watkins, & Fleshner, 1994). Findings by Pert et al. (1985) further strengthened the basis of PNI, and revealed that neuropeptide (i.e., molecules used by neurons to communicate with each other) receptors are present on the cell walls of the immune system and brain. Furthermore, these neuropeptides directly impact immune function with a close association to emotional processes. Thus, the interaction of these systems with the mind can greatly influence one’s health or state of well-being (Bosch, Engeland, & Cacioppo, 2007).

To explore the implications of the mind-body connection in medicine, the connection itself must be broken down to its core entities, the mind and body. The mind or psyche, a function of the brain (Andreasen, 1997), involves cognitions, emotions, and feelings. As these are experienced, chemical and neurological activity occurs, thus changing biological states (Ray, 2004). Therefore, the biology which involves the body, responds to various processes in the mind (i.e. cognitions and feelings) whether actual or perceived, or whether they are warranted or not. In that reason, lies the foundation for mind-body medicine and the rationale for introducing CAM practices into the treatment of medical conditions and illness. Optimizing activity in the brain/mind may optimize activity in biology/body enhancing one’s health and medical outcomes. With this rationale, there is strong evidential support for the efficacy of mind-body interventions or CAM practices for coronary heart disease, cancer treatment, chronic pain, and improving surgical results (Astin, Shapiro, Eisenberg, & Forys, 2003). Positive outcomes using therapeutic techniques such as relaxation, stress management, imagery and biofeedback, carry considerable implications for a range of health related illnesses and conditions (Wolsko et al., 2004). The premise to mind-body interventions is to achieve focused concentration on both the mind and body (Brower, 2006). In medicine, the objective is to harness control over both in order to reduce the negative physiological changes found to be detrimental to health and recovery. By introducing various interventions aimed at optimizing control over the mind, patients can learn to self-regulate the negative and perceived cognitions and emotions, inhibiting the adverse changes to their biology necessary for a most favorable recovery. Furthermore, introducing these interventions preceding the treatment of medical conditions can serve to
eliminate or reduce a number of complications found to be associated with an increase or greater occurrence of negative thoughts and beliefs (Kimball, 1969).

The Mind and Recovery

While quality of medical care such as a physician’s skill and rehabilitation protocols can influence recovery outcomes, the patient’s state of mind and preparedness for imminent medical treatment can greatly influence the course of recovery (Mavros, Athanasiou, Gkegkes, Polyzos, Peppas, & Falagas, 2011). Sime (1976) reported that patients experiencing high levels of fear pre-operatively required a greater use of analgesics and recovered slower than less fearful patients. Even more noteworthy, Kimball (1969) found the highest mortality rate among open-heart surgery patients who were identified as “depressed” pre-operatively. Thus, the mind, a function of the brain, can serve as a barrier against illness and supports well-being.

Mind-body medicine and psychoneuroimmunology offer scientific reasoning for the clinically significant relationship between psychological factors or state of mind and health outcomes. This growing body of research and literature has changed the concept of health to one in which the interaction of psychological and socio-cultural factors with bio-physiology determines the course of illness from onset to outcome (Ray, 2004). The mind-body connection has been demonstrated by showing the impact of the mind on immune function (Pert, Ruff, Weber, & Herkenham, 1985), which can significantly impact the recovery process. Glaser, Kiecolt-Glaser, Speicher, and Holliday (1985) examined the relationship between the mind and immune function by studying the influence of loneliness and exam stress on herpes virus latency (viral presence within cells). Blood samples were collected from first year medical students one month before final examinations, the first day of final examinations, and during the first week following the return from summer break. The effect of mood and stress on immune function was measured by the changes in antibody levels of three herpes viruses including Herpes Simplex type 1 (HSV-1), Epstein-Barr (EBV), and cytomegalovirus. Significant changes in antibody titers (concentration of antibodies) were found with the lowest levels among the low stress sample of students and higher EBV antibody levels among high-loneliness students. Findings suggest negative moods, such as loneliness and stress, can reduce the efficacy of the immune system, which carries significant risks for surgical patients and those receiving other forms of medical treatments. Consequently, examining the construct of stress, as it is a response to mental
processes, is necessary whereas many of the related states such as anxiety and pain, both prevalent in medicine, can inadvertently impede immune function and recovery.

**Stress**

Stress, originally defined by Selye (1956) as a result of the failure to respond to an emotional or physical threat whether perceived or actual, continues to be widely misused and misunderstood. Although discrepancies in definitions and models exist, the stress response itself causes a disruption in the body’s homeostasis in order to prepare the body to meet a threatening or challenging event (Chovatiya & Medzhitov, 2014). According to Selye (1982), various situations or events, such as fear and pain, can cause the stress response to occur therefore disrupting homeostasis. These in particular are of concern in mind-body medicine as patients with various medical conditions undergoing treatments commonly experience fear and pain (Robleda, Sillero-Sillero-Puig, Gich, & Banos, 2014). As such, a theoretical framework for stress that allows for the self-management of internal processes (i.e. coping strategies) is of greatest use in CAM.

Lazarus and Folkman (1984) proposed a cognitive theory of stress involving the interactions between the individual’s cognitive processes and the environment whereas the individual’s appraisal of the situation determines whether the stress response will be experienced. According to Lazarus and Folkman, the occurrence and extent of a stress response is a product of a two-step process involving the individual’s appraisal of the situation and the coping strategies he or she may, or may not, have to utilize. The first step of this cognitive process, primary appraisal, involves the evaluation of the situation in which the individual determines the extent of threat. Following primary appraisal is the secondary appraisal, when the individual determines if and how he or she copes with the situation. Consequently, the stress response occurs if the event or situation, is personally significant and there is an imbalance between those demands and the individual’s ability to cope. While many events and situations can be appraised as controllable and managed accordingly, changes in health status, injury and illness are far more challenging (Salleh, 2008). Onset of illness or injury is often uncontrollable and unforeseen. Sudden change in well-being, unpreparedness, uncertainty, and inexperience can easily shift the balance and outweigh coping strategies, causing an immediate disruption in homeostasis when its needed the most (Roberts et al., 1977).
While high levels of stress have been associated with a greater risk for sustaining injury (Ivarsson & Johnson, 2010), stress also plays a vital role in the rehabilitation and recovery from injury (American College of Sports Medicine, 2006). Stress and related negative emotional responses generate a range of behavioral, emotional, and physical symptoms that can all be counterproductive during the healing process (Kiecolt-Glaser et al., 1995). Likewise, stress has been found to considerably impede wound healing, which carries significant implications for surgical patients (Christian et al., 2006). Kiecolt-Glaser et al. (1995) examined the difference in wounded healing between caregivers and their less stressed counterparts. The experimental group was comprised of 13 women (ages 47-81 years) who all cared for relatives suffering from dementia. An additional 13 women were matched according to age and income and served as the control. A ‘punch biopsy’ wound was given to both groups and wounds were dressed and treated by a medical practitioner in the same manner. Immune function was further measured as the level of cytokines (signaling molecules of the immune system). Findings revealed caretakers, who indicated feeling more stressed as reported by the Perceived Stress Scale, experienced significantly longer healing periods, nine days (24% longer), than the non-caretakers in the control group. Furthermore, lower levels of cytokines were found among the caretakers indicating a disruption in immune response.

Wound healing, if impaired, can cause infections, prolonged hospital stay, and increased morbidity (Gould et al., 2015); all of which carry significant risk for surgical patients. Broadbent, Petrie, Alley and Booth (2003) studied the relationship between psychological stress and wound repair following inguinal hernia surgery. Findings revealed greater pre-operative stress significantly predicted lower levels of interleukin-1 (molecules which remove infectious agents and prepare sites for growth of new tissue), and increased worry predicted lower levels of matrix metalloproteinase-9 (enzymes involved in tissue regeneration) as well as a more painful, poorer, and slower recovery.

While stress has been shown to directly impact wound healing, it carries broader risks due to its relationship to infection and illness (Segerstron & Miller, 2004). Cohen, Tyrell, and Smith (1991) studied this relationship by administering various strains of rhinoviruses to quarantined young adults. Participants completed self-report stress measures prior to quarantine assessing negative affect, perceived stress, and stressful life events occurring within twelve months of testing. Results indicated an increase in numbers of participants with replicating
viruses (from approximately 70 to 90%) with an increase in measured stress. Furthermore, the percentage of participants with cold symptoms increased with a rise in their reported levels of stress. The relationship between stress, infection, and illness has noteworthy implications for surgical patients given that immune function can influence the healing process and ultimately, surgical outcomes.

Stress, addressed in mind-body research with regard to health and immune function, remains a broad concept and one that involves a range of feelings and states that occur as a result of and contribute to the stress response. In particular, anxiety, which is closely related to the stress response, is commonly researched due to its prevalence among patients in medical settings (Calvin & Lane, 1999; Pellino et al., 2005). Additionally, scientific data indicate a correlation between pre-operative anxiety and recovery outcomes (Stoddard, White, Covino & Strauss, 2005).

Anxiety

Anxiety, characterized by cognitive, somatic, emotional, and behavioral factors (Seligman, Walker, & Rosenhan, 2001) is a reaction to stress widely studied throughout medical research (Calvin & Lane, 1999; Pellino et al., 2005; Rosen, Svensson, & Nilsson, 2008). The generally stable construct, trait anxiety, relates to the disposition of the individual or part of his or her developed personality (Julian, 2011). This tendency predisposes an individual to perceive a threat, which causes a change in state anxiety. State anxiety refers to the variation and fluctuation of mood over time, and is a function of stress (Julian, 2011). It is characterized by perceived feelings of apprehension or worry and activation of the autonomic nervous system (Spielberger, 1966). Thus, the perceived threat of imminent surgery can produce high anxiety, and if unresolved, can cause changes in vital signs (Vaughn, Wichowski, & Bosworth, 2007), and worsen a patient’s medical condition (Calvin & Lane, 1999).

While unique to each patient, pre-operative anxiety can be provoked by a variety of issues such as impending post-operative pain and the possibility of death (Lederberg & Holland, 1995). Despite the cause, pre-operative anxiety has been found to negatively impact recovery. Poor compliance with treatment recommendations (Caumo et al., 2001), increased levels of pain (Anderson & Masur, 1983), and greater demand for analgesics (Gil et al., 1990) have been associated with heightened pre-operative anxiety, and subsequently increase the risk for
complications. Although patients differ on the source of anxiety and the level of significance its impact has, the prevalence remains for all potential surgical candidates.

Pre-operative anxiety varies among patients, and is experienced across gender and age (Antall & Kresevic, 2004; Brewer et al., 2006). Rosen et al. (2008) surveyed 163 participants scheduled for elective surgery, and assessed their feeling of calmness and their current mood. Results indicated that 57% of the patients did not feel calm; 65% of those respondents being women. Nearly half of the participants who did feel calm before surgery did so due to earlier positive experiences, feelings of caring and security, having positive expectations, and being well-informed.

For patients never experiencing surgery, anxiety may stem from what is unknown about the process involved. Cobley, Dunne, and Sanders (1991) investigated the impact of pre-operative procedures on 124 patients. Questionnaires were provided within the first 36 hours post-operatively and revealed the most common factors contributing to pre-operative distress were waiting to be transferred to the operating room, the inability to take in fluids, and the removal of dentures. Schmitt and Wooldridge (1973) investigated the effects of addressing patients’ fears pre-operatively and its impact post-operatively. Male patients ($n=25$) were provided the opportunity to discuss any concerns, and were provided an explanation of what to expect the day before surgery in a nurse led informative group session. In a comparison against those receiving a standard and routine level of care, participants of the group session experienced far less anxiety the morning of surgery, required less pain medication, and were discharged from hospital care sooner.

A patient’s perception of threat warranted or not, is related to his or her appraisal of the situation (Britton, Lissek, Grillon, Norcross, & Pine, 2011). If fears and uncertainties regarding upcoming medical procedures are addressed and appraised as manageable, anxiety is reduced (Schmitt & Woolridge’s, 1973), therefore allowing the individual’s coping resources to meet the demands of the threat and inhibit the stress response from occurring (Folkman & Lazarus, 1984). Unlike anxiety, where the source and management is solely cognitive, pain is a more challenging experience as a result of both physical and psychological contributing factors. Moreover, pain is commonly experienced with negative psychological states such as anxiety, which has been shown to hinder post-operative recovery (Stoddard, White, Covino & Strauss, 2005).
Pain

Subjective in nature and unpleasant, pain is a natural occurrence that supports the body’s defense mechanism by enabling withdraw from painful stimuli and protects damaged areas during the healing process (Bigliardi, Neumann, Teo, Pant, & Bigliardi-Qi, 2015). Although natural, pain can be disruptive, inhibiting the ability to regain function and intensifying a patient’s suffering (Strong, Unruh, Wright, & Baxter, 2002). Thus, the construct of pain must be explored in order to most effectively manage the experience and minimize possible disruptions.

The Gate Control Theory of pain posited by Melzack and Wall (1965) provides an explanation of how pain is experienced, and has profoundly influenced the way in which pain is treated. The premise of this theory states that two types of neural fibers (C-fibers and A-fibers) influence the “pain gate” located within the spinal cord (Eimer & Freeman, 1998). C-fibers transmit pain signals up the spinal cord and to the brain whereas A-fibers stop the pain signal from moving by closing the gate. Due to the involvement of the brain through the transmission of pain signals, it was hypothesized that the perception of pain is strongly influenced by cognitive processes. Melzack and Wall went on to identify three dimensions of the perception of pain, which include sensory-discriminative, cognitive-evaluative, and motivational-affective. Thus, sensing pain (i.e. intensity, location, etc.), the evaluation and appraisal of pain, and the influence of motivation and affect on the emotional reaction to pain, all converge to produce an individual’s pain experience (Eimer & Freeman, 1998). Therefore, thoughts, self-talk, and beliefs, as well as mood states, can manipulate the perception of pain and severity.

In accordance with the gate control theory, pain is determined not only by a physical stimulus, but also by its psychological interpretation (Pellino et al., 2005). The intensity and severity of pain is influenced by a medley of physical and emotional factors (Hamill & Rowlingson, 1994). Fatigue, isolation, fear, and loss of control have been found to significantly lower a patient’s pain threshold (Hamill & Rowlingson, 1994). Likewise, pain has been found to increase psychological distress including levels of anxiety (Leon-Pizarro et al., 2007). A growing number of studies have demonstrated the correlation between anxiety, pain, and outcomes following medical procedures and surgery. Anxious patients have reported higher levels of post-operative pain (Kain, Sevarino, Alexander, Pincus, & Mayes, 2000) and experienced difficulties complying with treatment protocols or recommendations (Caumo et al., 2001). Gil et al. (1990) found psychological measures such as anxiety and social support to be predictors of pain and
patient-controlled analgesia (PCA) use. In particular, anxious patients rated post-operative pain higher than less anxious patients and those with less social support and greater anxiety required the use of PCA pumps more frequently.

Pain resulting from surgical or medical procedures can activate the sympathetic nervous system and increase muscle tension; both associated with a rise in pain (Heil, 1993). Thus, the cycle of emotions, pain, and sympathetic activity can subsequently inhibit the early stages of healing and hinder the patient’s overall recovery. Kiecolt-Glaser et al. (1998) further supported this relationship finding psychological distress in response to surgery results in delayed wound healing while pain affects endocrine and immune functioning. Due to the complexity of pain and its multidimensional roots, the standard use of pharmacological treatment should be supported with complementary and alternative nonpharmacological techniques to address the physical and psychological components of pain. An approach aimed at enhancing emotions and cognitions through self-regulation is ideal and possible through cognitive-behavioral training.

**Cognitive-Behavioral Based Training in Medicine**

The integration and overlapping of cognitive and behavioral psychology serves as the foundation for cognitive-behavioral therapy (Gelso & Fretz, 1992). Cognitive psychology is based on the premise that internal mental states exist in the form of mental representations, and maladaptive thoughts can be changed, whereas behavioral psychology focuses on observable behaviors that can be modified while keeping the mental basis for those behaviors aside (Encyclopedia of Medicine, 2002; Milkman & Wanberg, 2007). Cognitive-behavioral therapy, while encompassing a range of techniques with varying approaches, is based on a central theme (Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012). Principally, individuals gain an understanding for the relationship between affect, cognition, and behavior and the role of thoughts and images on behavior (Turk, Meichenbaum, & Genest, 1987). Although specific interventions can target each underlying event, therapeutic techniques combine behavioral learning and cognitive psychology while focusing on the here and now (Grazebrook & Garland, 2005). Thus, intervention strategies can be directed toward cognitive processes such as coping skills and images, cognitive structures such as beliefs, behaviors, and environmental consequences (Turk et al., 1987).
The purpose, or objective, of cognitive-behavioral therapy is empowering individuals through enabling them to utilize their own resources (Grazebrook & Garland, 2005). In the case of cognitive-behavioral therapy as a supplement to medical treatment, the patient must be actively involved in the treatment process for this to occur (Strong et al., 2002). The various intervention strategies, or techniques, that are under this therapeutic approach enable the patient to actively cope with the psychological distress that accompanies medical procedures (Heil, 1993; Wells, Howard, Nowlin, & Vargas, 1986). The ability to cope and feel a sense of control is a process that needs to be learned and requires active effort (Ray, 2004). However, once learned and mastered, the ability to voluntarily control internal processes during a time a patient may feel a loss of control (i.e. medical treatments) can be of great influence on his or her recovery (Doering, Chen, Cross, Magsarili, Nyamathi, & Irwin, 2013). Laubach et al. (1996) suggested that successful outcomes following interventions might be a result of the patients’ belief that recovery was within their control. Frishman (1996) supported this notion reporting those patients with a sense of control experienced improved health and felt better.

Self-regulation is a self-directed practice that combines behavioral approaches and cognitive factors in order to voluntarily control psychological, physiological, and behavioral processes (Dobson, 2002). Moreover, self-regulation involves the ability to recognize and interpret one’s physiological and emotional state, use cognitive strategies to cope with adverse events, and use behavioral strategies to regulate experiences (Gaus, 2007). The adoption of self-regulating cognitive-behavioral techniques such as relaxation, imagery, and stress inoculation training has proven to be significantly beneficial in the clinical setting (Leon-Pizarro et al., 2007; Ross & Berger, 1996; Scherwitz, McHenry, & Herrero, 2005). Ross and Berger investigated the efficacy of stress inoculation training on post-surgical anxiety, pain, and physical functioning among 60 male athletes prescribed arthroscopic surgery. Participants in the treatment group received physical therapy and stress inoculation training comprised of conceptualization, skills acquisition, and application. As part of conceptualization, education and information was provided to help participants understand their psychological responses to surgery based on pain and emotion. In addition, they expected anxiety and pain throughout the rehabilitation process, but understood that cognitive-behavioral interventions were effective in alleviating these experiences. Skills acquisition involved self-monitoring and control strategies, such as deep breathing, imagery, and positive statements. Lastly, participants were instructed to practice these
strategies daily and utilize them in response to pain. Results demonstrated considerable differences supporting the use of interventions with general medical practice. Particularly, a significant reduction in pain and anxiety during post-operative rehabilitation can be experienced as well as the amount of time to return to a previous level of physical functioning.

Self-reinforcement, a significant feature of cognitive-behavioral training, results in self-regulation by way of cognitive and behavioral changes reinforcing one another (Kornblith, Rehm, O’Hara & Lamparski, 1983). When cognitive change leads to behavioral change a sense of well-being occurs that strengthens the change in thought, further strengthening changes in behavior (Milkman & Wanberg, 2007). As such, cognitive-behavioral techniques, such as imagery and biofeedback, can be advantageous in the management of medical conditions that may be influenced by physical and psychological variables (Strong et al., 2002) through enabling patients to self-regulate internal processes.

Guided Imagery

Guided imagery is a form of concentration that generates feelings of relaxation and empowerment (Deisch et al., 2000). This form of imagery typically delivered by a practitioner or recording, provides a narrative to encourage and guide the minds creation of images (Hart, 2008). Referring to the intentional use of imagery for a therapeutic effect (Kingdom, Stanley, & Kizior, 1998), guided imagery is more effective when multiple senses (i.e. smell, touch) are used (McCaffery, 1979; Weinberg & Gould, 2003). As a cognitive-behavioral technique, imagery serves as a means for modifying and restructuring cognitions and events (Freeman et al., 2005).

Applied sport psychology literature suggests imagery to be one of the most widely used mental skills techniques in athletic performance, and acknowledges imagery as a beneficial tool in learning and subsequent performance (Curry & Maniar, 2004; Mahoney et al., 1987; Ungerleider et al., 1990; Ungerleider & Golding, 1991). In addition to its wide use in performance enhancement training, this cognitive-behavioral therapeutic technique has been used for a range of physical and psychological conditions (Eller, 1999; Scherwitz, McHenry, & Herrero, 2005). In particular, imagery has successfully been used as supplemental intervention for a range of medical procedures and treatments including cardiac surgery (Halpin, Speir, CapoBianco, & Barnett, 2002; Tusek, Cwynar, & Cosgrove, 1999), brachytherapy (Leon-Pizarro et al., 2007) and orthopedic surgery (Antall & Kresevic, 2004).
During medical procedures and treatments, patients experience a great deal of helplessness (Anderson, 1987). Guided imagery allows patients to take control of an often helpless situation by mentally preparing for the process and focus on optimal outcomes. Moreover, improved self-efficacy or belief in one’s capabilities has been found to be associated with the use of imagery during physical rehabilitation (Ievleva & Orlick, 1991). Scherwitz et al. (2005) supported the use of guided imagery in the medical field reporting a range of benefits experienced by patients. Over a two-month period, 323 patients receiving care at a medical center agreed to participate in six guided imagery sessions. Patients had varying primary and secondary diagnoses including cancer, cardiovascular disease and physical trauma. The imagery was provided to the patients by practitioners following an Interactive Guided Imagery treatment protocol. This form of imagery allows the participant to simultaneously interact with the imagery and practitioner. At the conclusion of the sixth imagery session, 71 participants reported multiple benefits including relaxation and stress reduction \( (n=45) \), spiritual connectedness \( (n=28) \), increases in positive outlook \( (n=24) \), learning of new techniques \( (n=13) \), and decreases in physical symptoms \( (n=9) \).

While beneficial to a patient’s psychological and general health, guided imagery has been found to positively influence rehabilitation following orthopedic surgery (Cupal & Brewer, 2001), reduce post-operative pain and length of hospital stay (Deisch et al., 2000; Tusek et al., 1997) and enhance and increase the rate of healing (Laurion & Fetzer, 2003; Scherwitz et al., 2005). Hart (2008) posits that the practice of positive and calming imagery can counteract negative images that produce pain or anxiety, thus training the mind to focus on healing imagery more often. Healing imagery is a technique, which entails imagining the physiological processes of recovery (i.e. bone regeneration) (Milne, Hall, & Forwell, 2005). Likewise, those practicing imagery have experienced an accelerated rate of healing and greater feelings of self-control (Ievleva & Orlick, 1991).

The use of guided imagery has been supported through a wealth of medical research (Gonzales, Ledesma, McAllister, Perry, Dyer, & Maye, 2010; Laurion & Fetzer, 2003). Cupal and Brewer (2001) reported findings consistent with previous research in which imagery coupled with relaxation was significantly effective in facilitating recovery from ACL reconstruction. Particularly, those assigned to the treatment group receiving relaxation and guided imagery, experienced lower levels of pain and re-injury anxiety and greater knee strength in comparison to
those in the control and placebo groups. Tusek et al. (1997) investigated the effects of guided imagery on patients undergoing colorectal surgery. Participants in the experimental group listened to the imagery recordings three days pre-operatively, music only during the surgical procedure and in recovery, and imagery for six days post-operatively. Results indicated a significant reduction in reported pain and nearly a 50% decrease in the use of narcotics for those patients in the guided imagery group in comparison to those in the control group.

As the use of imagery continues to prove successful, medical personnel and healthcare organizations have begun to adopt the use of imagery in conjunction to traditional treatments and methods (Driediger, Hall, & Callow, 2006). In 2000, Blue Shield of California initiated the Pre-surgical Imagery Program investigating the effects of guided imagery on surgical outcomes, patient satisfaction and overall costs (Schwab et al., 2007). Participation was offered to patients scheduled for cardiac procedures and common orthopedic, gynecological and genitourinary surgeries, all with a projected hospital stay of two or more days. The use of guided imagery pre-operatively resulted in a significant reduction of anxiety experienced by patients. Approximately 47% of patients reported “high” or “very high” levels of anxiety prior to listening to the imagery recording pre-operatively. However, a significant drop to 1.6% reported “high” or “very high” levels of anxiety pre-operatively after listening to the recordings. In addition to the benefits for anxiety, the use of imagery positively influenced the levels of pain experienced by patients; 57% of those reporting a greater use of imagery experienced less pain than anticipated.

**Biofeedback**

Biofeedback is a therapeutic technique that provides individuals real time information about various physiological processes so they can learn to voluntarily control those functions in order to achieve a desired state such as relaxation. This process of self-regulation depends on active involvement on behalf of the participant in order to produce and realize the desired outcome (Kingdom, Stanley, & Kizior, 1998). The objective for using biofeedback as an adjunct to medical care in a clinical setting is for improved health outcomes (Freeman, 2005) through understanding the mind-body interaction.

A form of cognitive-behavioral therapy, biofeedback is a noninvasive tool used to monitor, quantify, and feedback physiological signals produced by the body (Kingdom, Stanley, & Kizior, 1998; Pepper et al., 2008). The information processing and feedback loop utilizes at
least one sensor attached to the patient and most often a computer or hand-held device (Freeman, 2005). The information is processed through software, and is then fed back via graphic or auditory signals and displays. It is the visual or auditory feedback that allows individuals to gain insight and control over their cognitions, emotions, and behaviors (Pepper et al., 2008) thus enabling change.

Becoming aware of and exerting control over one’s physiology is the premise for biofeedback, and encompasses any physiological process that can be measured. This is most commonly achieved through monitoring muscle tension (surface electromyogram or SEMG), skin temperature as it relates to peripheral blood flow, brain wave activity (electroencephalography or EEG), skin resistance (electrodermal activity or galvanic skin response), and heart rate (Kingdom, Stanley, & Kizior, 1998). Research examining these biofeedback modalities as a form of complementary medicine has revealed that the use of biofeedback in isolation, and in conjunction with other therapeutic techniques, is highly efficacious in the management of various illnesses and medical conditions. Biofeedback has been found to be advantageous for tension and migraine headaches (Blanchard et al., 1987), low back (Gervitz, Hubbard, & Harpin, 1996), and other myofascial pain (Dohrmann & Laskin, 1978). Moreover, the use of biofeedback has been found to positively influence surgical outcomes. Lobb, Shannon, Recer, and Allen (1984) utilized biofeedback and relaxation training in the reduction of pre-operative anxiety and found improvements in recovery among patients undergoing hysterectomy.

Complementary and alternative medicine provides considerable support for the use of interventions such as biofeedback, which links psychological and physiological factors found to be highly correlated with health outcomes (Frank, Khorshid, Kiffer, Moravec, & McKee, 2010). Achieving a state of relaxation can be greatly influential in medicine as it decreases blood pressure, heart rate, and muscle tone, therefore making pain and other related states more manageable (Kingdom, Stanley, & Kizior, 1998). Biofeedback training involves a shifting of focus inward that facilitates a state of relaxation (Scherwitz, McHenry, & Herrero, 2005), and allows for a balance within the autonomic nervous system.

A state of internal homeostasis, or autonomic balance is optimal as it relates to health and well-being following medical procedures and surgery (Ferri et al., 2013). Physiological coherence characterized by heart/brain synchrony, entrainment between physiological systems,
and sine wave heart rhythms, is reported to facilitate the body’s ability to regenerate (McCraty, 2001). Physiological coherence, although a natural occurring state, can be voluntarily achieved by evoking positive emotions. When physiological coherence is realized by engaging a positive psychological state, psychophysiological coherence is reached. Biofeedback can be used to monitor the level of psychophysiological coherence by measuring HRV (McCraty, Tiller, & Atkinson, 1996).

Heart rate variability or HRV is obtained by the variability between heart beat peaks resulting from a blood volume pulse (BVP) signal and measured as the standard deviation of the interbeat interval (IBI) (Pepper et al., 2008). A strong variability is indicative of a balance within the autonomic nervous system whereas a lack of variability is indicative of an imbalance, and more commonly a lack of parasympathetic activity (Yucha & Gilbert, 2004). HRV can be monitored by placing a plethysmographic sensor on the finger or ear and can be fed back through the display of heart rhythm patterns. The use of HRV feedback is used in conjunction with regulating breathing patterns and emotional states causing a synchronized interaction between brain waves and heart rate. Synchronized activity between the heart and brain is indicative of psychophysiological coherence (McCraty, 1996). Feeling calm and a sense of clarity are characteristics of coherence (Childre & Cryer, 2004), and with those feelings, changes in physiology occur such as improved cardiac function and improved hormonal activity (McCraty et al., 1998).

While achieving a state of coherence can be accomplished through exercising particular breathing patterns, the use of positive emotions can make it easier to sustain a state of coherence for longer periods (McCraty, Tiller, & Atkinson, 1996). The use of HRV biofeedback enables an individual to achieve coherence and identify the physical, mental and emotional feelings associated with that state. Thus, HRV training allows reaching coherence at a later time under various conditions without the assistance of equipment. A number of positive benefits have been observed with the use of coherence training including reduced physical and psychological stress, improved psychosocial functioning, decreased anxiety and increased immunity (McCraty, 2001); all of which significantly influence general health and surgical outcomes (Calvin & Lane, 1999; Christian et al., 2006; Kain et al., 2000). Anxiety for example, commonly experienced by patients pre-operatively (Roden et al., 2008), has been found to activate autonomic function (Spielberger, 1996), and engage the sympathetic nervous system which has been found to
negatively influence medical conditions (Calvin & Lane, 1999). Therefore, the use of HRV training may be instrumental in recovery by providing the patient voluntary control over reaching coherence, thereby achieving a balance in autonomic function.

**Purpose of the Study and Hypotheses**

The current review offers a strong foundation for the use of cognitive-behavioral interventions in medicine. Although the success of applied interventions has been reported for a range of medical conditions and illnesses (Leon-Pizarro et al., 2007; Ross & Berger, 1996), there is much to be explored in identifying the outcomes following combined treatment approaches. While the use of techniques such as imagery (Scherwitz et al., 2005) and biofeedback (Yucha & Gilbert, 2004) have been associated with positive health outcomes, further inquiry is necessary to assess the potential benefits from the use of both imagery and biofeedback within the clinical domain. The merging of two interventions, both producing states of relaxation and improved physical and psychological functioning (Antell & Kresevic, 2004; Holden-Lund, 1997; McCraty, 2001), may subsequently produce considerable improvements in medicine and in particular, post-operative outcomes. In all, much of the research to date is limited to a general set of intervention practices (Haase, Schwenk, Hermann, & Muller, 2005; Laurion & Fetzer, 2003; Ross & Berger, 1996). The effects of education, guided imagery, music therapy, and stress inoculation training are just a few of the interventions studied among patients receiving standard medical treatments. Although this research has generated positive results (Heikkinen, Helena, Taina, Anne, & Sanna, 2008; Schwab et al., 2007), there remains a lack of new approaches offered. Furthermore, much of the research exploring the use of techniques such as guided imagery, has been limited to out-patient or same day surgical procedures (Gonzales et al., 2010; Laurion & Fetzer, 2003). This narrowing of the research field serves as the rationale for the present study.

In an effort to further explore the impact of interventions on specific elements of medicine such as the surgical experience, the purpose of this study was to compare the effects of pre-operative case specific guided imagery and HRV biofeedback training as individual treatment techniques and in combination with a general standard of care group on psychological variables (specifically anxiety, perceived stress, and coping strategies), and post-operative outcome measures (specifically pain, medication use, and length of hospital stay). It was
hypothesized that guided imagery and biofeedback as sole interventions and in combination would positively influence the psychological well-being of all participants and more so, those who received the combined treatment of guided imagery and biofeedback training. Furthermore, it was anticipated that the same positive influences of all interventions would apply to pain levels and the amount of medication needed as well as the length of hospital admission following joint replacement surgery.

The following hypotheses were tested:

1. All interventions would result in reduced state anxiety and stress, and improved coping strategies as assessed by the state version of the State Trait Anxiety Inventory, Perceived Stress Scale and Coping Strategies Questionnaire compared to a standard care control group over the course of the intervention through time of hospital discharge. Participants receiving the combined HRV biofeedback training and guided imagery intervention would experience the greatest reduction of state anxiety and stress as well as most improved coping strategies.

2. All interventions would result in lower levels of reported post-operative pain measured with a Visual Analogue Scale during in-patient status through the time of discharge from the hospital.

3. All interventions would result in reduced levels of medication required and length of hospital admission time compared to the controls.
CHAPTER 3

METHODS

Participants

Participants were patients scheduled for voluntary orthopedic surgeries requiring a length of hospital stay of more than one day (i.e. no out-patient procedures). Orthopedic surgeries requiring a hospital stay of more than one day are generally for total joint arthroplasty and were used for the present study. A power analysis was performed with a moderate effect size, $f = 0.35$, power $(1-\beta)$ value of .80, and $\alpha = .05$, to determine the sample size required ($n = 60$) when considering the repeated measures analysis of variance (RM ANOVA) treatment by time interaction. Placement into a treatment or control group was carried out by first clustering according to the type of surgical procedure, Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA), followed by randomly assigning participants to each intervention/control groups as surgeries were scheduled. Because participants were scheduled for different surgical procedures, random assignment within each cluster was used to avoid one intervention group being overloaded with a particular surgical procedure. Accordingly, the number of THA and TKA meeting the criteria was approximately the same for each of the four groups. All participants were recruited from the same orthopedic office in order to control for differences in general treatment protocols and standards. Consent and approval by the Human Subjects Committee and from participants was obtained, and confidentiality of participants was maintained in accordance with the orthopedic facility’s patient privacy rules (Appendix A, B, C).

Over the course of five months, a sample of 60 knee and hip arthroplasty patients participated in the present study with equal distribution across all four intervention groups ($n = 15$): imagery, biofeedback, combo, and standard care control. Patient demographic information is presented by group in Table 1. The mean age of participants was 66.1 years ($SD = 7.42$, range = 49-81 years). The imagery group with a mean age of 63.3 years consisted of 4 hip arthroplasties, 11 knee arthroplasties and was 86.6% female and 13.3% male. The biofeedback group with a mean age of 67.6 years had 3 hip arthroplasties, 12 knee arthroplasties and was 60% female and 40% male. The combined group with a mean age of 65.5 years had 4 hip arthroplasties, 11 knee arthroplasties and was 80% female and 20% male. The standard care control or education group
with a mean age of 68.2 years consisted of 5 hip arthroplasties, 10 knee arthroplasties and had the most even distribution by gender (46.6% female and 53.3% male). In total, 45% of participants were married, 22% were widowed, 18% were single and 15% were divorced.

Table 1

*Description (demographics) of study sample (%, n)*

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Total % (n)</th>
<th>Imagery % (n)</th>
<th>BFB % (n)</th>
<th>BFB + Imagery % (n)</th>
<th>Ed % (n)</th>
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<td>86.6 (13)</td>
<td>60 (9)</td>
<td>80 (12)</td>
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<td>63.3 (7.16)</td>
<td>67.6 (6.69)</td>
<td>65.5 (8.84)</td>
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*Note. Coll Grad = College Graduate, Prev Surgery = Previous Surgery*

**Instrumentation**

Seven questionnaires were administered to the participants. Participants were asked to complete a general medical history and demographic questionnaire, the State-Trait Anxiety Inventory, the Perceived Stress Scale, the Coping Strategy Questionnaire, the Visual Analogue Pain Scale, a Training Survey, and manipulation check.
Medical History and Demographic Questionnaire (Appendix D)

The medical history form asked participants to indicate any significant health conditions, prior surgical history, and individual expectations about their pending surgical procedure including anticipated length of hospital stay and anticipated level of pain following surgery. Demographic information included gender, age, ethnicity, marital status, and educational level.

State-Trait Anxiety Inventory (STAI; Spielberger, Gorsuch, & Lushene, 1970; Appendix E)

The STAI for adults is a 40-item inventory (20-items for each trait and state) administered to assess how much anxiety a person generally feels (trait-T) and how much anxiety a person feels at the particular time of assessment (state-S). The STAI is a commonly used measure to assess anxiety and is frequently used in medical settings (Gil et al., 1990; Stoddard et al., 2005). For the purposes of the current study, only the STAI-S was used and administered both pre- and post-operatively. The STAI-S includes positive items such as “I feel at ease,” and “I feel joyful,” as well as negative responses such as “I feel upset,” and “I am jittery.” Participants were asked to rate these items related to how they felt at the time of completion on a continuum ranging from 1 (Not at All) to 4 (Very Much So). For 10 of the items on the STAI-S, scoring ranges from 1 to 4 depending on the response and the other 10 are scored in reverse, with higher scores reflecting greater levels of anxiety.

The STAI has demonstrated good psychometric properties and continues to be a reliable and valid tool to assess anxiety. Internal consistency for both STAI measures (trait and state) is good, with Cronbach-alpha coefficients ranging from 0.83 to 0.92 for diverse normative samples with no significant difference in reliability between the state and trait components (Spielberger et al., 1970). The test-retest reliability of the STAI-S ranges from 0.16 to 0.54 (Spielberger et al., 1970). Concurrent validity has been established through correlations ranging from 0.75 to 0.80 between the STAI and other related measures including Zuckerman’s Affect Adjective Checklist, IPAT Anxiety Scale, and Taylor’s Manifest Anxiety Scale, for both college students and neuropsychiatric patients (Spielberger et al., 1970).

Perceived Stress Scale (PSS; Cohen, Kamarck, & Mermelstein, 1983; Appendix F)

The PSS is a 10-item inventory used to assess the degree to which subjects appraise their life as stressful within the past month. Participants specify how uncontrollable and congested their lives are as well as their perceived level of stress at the time of completion. The PSS is a
widely used tool for measuring stress and is widely used in health-related research (Broadbent et al., 2003). For the purposes of the current study, the PSS was utilized as a pre- and post-operative measure. Instructions were altered to assess the level of perceived stress at the time of completion as opposed to how the participant felt within the past month. Participants were asked to rate responses such as “In the last 24 hours, how often have you felt nervous and stressed?” on a response format ranging from 0 (Never) to 4 (Very Often). The PSS scores are produced by reversing responses to the four positively stated items and then summing across all scale items. A low score (range from 0-40) indicates a lower level of perceived stress.

The PSS is a brief and practical tool for medical purposes and has proven to be valid and reliable with Cronbach’s alpha > .70. Reliability was assessed in samples of college students and community research participants with internal consistency of items ranging from 0.84 to 0.86 (Cohen, 1983). The test-retest reliability of the PSS was 0.85 after two days in the sample of college students and 0.55 after six weeks in those of the community research sample (Cohen, 1983). Among the sample of college students, concurrent validity was determined through correlations ranging from 0.17 to 0.35 with Life-Event scores. In addition, the PSS as opposed to Life-Events scores has been found to be a better predictor of both physical and depressive symptomology.

**Coping Strategy Questionnaire (CSQ: Rosenstiel & Keefe, 1983; Appendix G)**

The CSQ is a 42-item measure that assesses the use of cognitive and behavioral coping strategies in controlling and decreasing pain. Strategies are arranged across six subscales and include catastrophizing, divert attention, coping self-statements, ignoring the pain, reinterpreting the pain, and praying and hoping. The CSQ includes a range of statements for each of the dimensions such as “I don’t think about the pain” for cognitive coping and suppression, “I feel my life isn’t worth living” for helplessness, “I try to think of something pleasant” for diverting attention and praying, and “I tell myself that I can overcome the pain” for coping strategies. Each coping strategy is rated on a scale ranging from 0 (Never Do That) to 6 (Always Do That) with higher ratings indicating more use of the strategy. In addition to the strategies, the questionnaire also contains 2-items that assess the respondents’ perception of their ability or effectiveness to control and decrease pain. The CSQ is the most widely used measure of pain coping strategies (Swartzman, 1994). For the purposes of the current study, the CSQ was
administered both pre- and post-operatively. The internal consistency of the CSQ ranges with alpha coefficients from 0.71 to 0.85 (Kreitler, Beltrutti, Lamberto, & Niv, 2007), and research supports the consistency and validity of the measure (Keef, Brown, Wallstone, & Caldwell, 1989). Test-retest reliability of the subscales has been found to range from 0.68 to 0.91 following a one-day interval (Main & Waddell, 1991). The CSQ has also demonstrated good predictive value for measures of state anxiety, pain, and overall distress with individual scores having been found to significantly predict psychological distress.

**Visual Analogue Scale Pain (VAS; Appendix H)**

The VAS is the most common instrument used to assess pain in medicine (Hamill & Rowlingson, 1994) and has been used with a variety of pain populations. The measure has demonstrated to be efficient in the delivery and sensitive to differences in perceived pain intensity (Herr & Mobily, 1993; Rosier, Iadarola, & Coghill, 2002). It consists of a 10-cm horizontal line with end-points of “No Pain” and “Worst Pain Imaginable” at either side. The scale is beneficial in that it is sensitive to changes in the intensity of pain and provides a greater range of possible responses. Scores can be obtained by measuring the scale in relation to where participants marked their level of pain. Higher scores reflect greater levels of pain intensity and vice-versa. The VAS demonstrates good reliability and validity in patients experiencing pain (Maxwell, 1978). Internal consistency has been found to range between 0.71 and 0.73 and inter-rater coefficients between 0.89 and 0.96 (Miller & Ferris, 1993). Correlation coefficients were 0.94, 0.91, and 0.95 for VAS scores and an 11-point verbal pain scale (DeLoach, Higgins, Caplan, & Stiff, 1998). For the purposes of the current study, the VAS was utilized post-operatively and completed during in-patient status through the time of discharge.

In addition to the pain scale on the VAS, patients undergoing TKA were asked to indicate what number their pain pump catheter was set to at the time they assessed their level of pain on each post-operative day during in-patient status. The pain pump setting was used as an indicator of the amount of pain medication needed following surgery while participants were in the hospital. The pump is set pre-operatively, inserted with a catheter under the skin and placed in close proximity to the femoral nerve which controls the anterior portion of the knee. The pump is patient adjusted with a setting of 0-14 with higher numbers indicating a greater level of medication being released by the pump. The medication placed in the pump is a local anesthetic.
The pain pump is utilized immediately following surgery and remains until the patient is discharged from the hospital. The pump is solely used for pain control among the TKA patients and is not an option for THA patients therefore, the amount of medication used by participants in the study was only gathered for those who underwent a knee arthroplasty.

**Training Survey** (Appendix I)

The patient’s training survey was developed for the present study to examine the participant’s use of and experience with the different treatment interventions. The survey includes a set of items for the sole use of guided imagery, a set for the sole use of biofeedback, and a set of items to include the use of both guided imagery and biofeedback collectively. An additional question on the surveys of the treatment interventions was included to ascertain the degree of compliance participants had with the prescribed training protocol. Participants were asked to notate the number of times per day the intervention was practiced pre-operatively. The guided imagery training survey items include questions assessing the participant’s usage of the prescribed intervention, the ease of control over the images, and the vividness of the images. Statements regarding the use of imagery as it relates to the surgical experience are rated on a scale ranging from 1 (Negatively) to 5 (Positively) and include options such as, “my experience with guided imagery influenced my surgical experience…” and “the amount of time listening to guided imagery ______ impacted my experience.” The biofeedback training survey items include questions assessing the participant’s usage of the prescribed intervention and ability to reach coherence as indicated by the software. Additional items measuring the use of the biofeedback on the surgical experience are provided and included statements such as, “practicing biofeedback influenced my ability to reach coherence,” and “using the coherence technique after surgery ______ impacted my ability to control my pain.” Each statement is rated on a scale ranging from 1 (Positively) to 5 (Negatively). The combined intervention survey included items from both individual assessments. An additional survey was developed for the present study to assess the experience of participants in the control group, solely receiving a general standard of care including education regarding the surgical procedure and recovery process. Items included questions exploring the participant’s use of alternative practices (i.e. yoga, meditation) throughout the surgery and recovery period as well as the impact of education on the preparation for and recovery from surgery.
Manipulation Check Questionnaire (Appendix J)

The manipulation check is a procedure used to identify whether the independent variable is in fact being manipulated and the degree to which the intervention was implemented. The manipulation check questionnaire developed included a set of questions for the use of guided imagery and HRV biofeedback. Participants in the intervention groups were asked to rate their experience with imagery and biofeedback on a scale ranging from 0 (not at all) to 10 (very much). Items included questions such as, “how clear or vivid is the image you produced while listening to the guided imagery CD?,” and “how much control did you feel you had over the image you created?” Items for the biofeedback intervention included questions such as, “are you able to reach psychophysiological coherence on command as indicated on the hand-held portable biofeedback device?” and “how effective was achieving psychophysiological coherence?” The combined intervention check included items from both sets of treatments.

Treatment

Three intervention groups were utilized in the current study: guided imagery, biofeedback, and guided imagery and biofeedback. The three groups were evaluated against a control, which consisted of the general standard of care provided to patients. Patients in this group received no additional education or training greater than the routine information provided by the surgeon’s office and treating hospital.

Guided Imagery (Appendix K)

The use of guided imagery is due to its relevance in medicine and benefit as a complementary and alternative method (Herman, Craig, & Caspi, 2005). Imagery has been demonstrated to reduce post-operative pain, decrease levels of anxiety, and increase the rate of healing when utilized in medical treatments (Antall & Kresevic, 2004; Tusek et al., 1997; Laurion & Fetzer, 2003). To achieve these and other benefits, the guided imagery script led the patient through the surgical experience to help prepare them for what was to come.

Participants received a guided imagery CD or MP3 player with the recording for use pre-operatively consisting of a surgery specific script developed by the researcher with the assistance of medical personnel and lasting approximately 6 minutes. The scripts began with the same
introduction for the arrival to the hospital and pre-operative surgical suite, followed by the preparation of the surgical site, elements of the surgery, and post-operative state.

Participants were first guided through an initial breathing exercise allowing them to begin achieving a relaxed state. Following the brief introduction, the script takes the listener to the morning of surgery and directs them through maintaining a calm, relaxed, and prepared state of mind. Details were provided regarding the patients preoperative time with features including the change into a hospital gown, receiving an I.V. and initial fluids, sounds of monitors, and interactions with various hospital personnel. The imagery script then guided the listener into the operating room noting the move to the operating table, sounds of equipment, smells, and sights of the room including the placement of machines and medical staff. These key characteristics of the experience were provided in order to allow the participant to prepare for surgery, and alleviate potential anxiety that could arise during the actual transfer to the operating room. Points included various senses in order to enhance the participant’s image and to make a greater impact.

Following the same basic introduction into surgery, the scripts varied slightly depending on the procedure being performed. Listeners were then led through a brief description of the post-operative experience, which included feeling pain and managing pain through breathing and imagery. Lastly, the imagery script prepared the participant for the days following surgery and initial ambulation.

**Biofeedback**

Biofeedback and more specifically, HRV training, was selected as an intervention for the current study as a result of its relationship to improved health outcomes (Freeman, 2005). Coherence measured through HRV, is a state of homeostasis where brain waves and heart rate are in synchrony. This synchronized activity has been demonstrated to enhance the body’s ability to regenerate (McCraty, 2001) thus proving beneficial to surgical patients.

Participants in the biofeedback intervention group received training in the use of HeartMath’s emWave PC Stress Relief System at the pre-operative visit. The emWave measures HRV through a plethysmographic ear clip sensor and designates psychophysiological coherence as low, medium, or high during the period of recording. There are four challenge levels set in the software increasing in difficulty. During the training session, participants were connected to the emWave starting at challenge level two for a baseline reading and elements of the software as
well as psychophysiological coherence were explained in relation to the display. Participants were then instructed on HeartMath’s three-step Quick Coherence Technique which included “heart focus”, “heart breathing”, and “heart feeling.” Heart focus, involved shifting attention internally to the area around the heart. Following an internal shift of attention, heart breathing entailed deep and controlled breathing allowing a rhythm to occur. During inhalation, attention was directed to “feeling” the breath flow around the heart followed by slowly moving away from the heart upon exhalation. Lastly, heart feeling involved recalling and re-living a positive experience while maintaining heart focus and rhythmic breathing.

Following the introduction and baseline recording, participants were instructed to begin practicing the three-step technique and monitor changes in coherence as displayed on the screen. The objective of the preoperative training session was for each participant to be able to achieve medium to high coherence when attempted, be self-aware and identify the psychological and physiological feelings associated with that state, and maintain it for a desired period of time. In addition to training on the emWave PC software, participants were provided a portable hand held emWave unit and instructed on how to use the device at home in the weeks leading up to surgery. The portable biofeedback also measured HRV through a plethysmographic ear clip sensor and displayed coherence as low, medium, or high by a red, blue, or green light respectively. Participants were able to increase the challenge level if desired on the portable device and were made aware of changes via auditory tone signals.

**Guided Imagery and Biofeedback**

The integration of guided imagery and biofeedback used together as an intervention was selected as a result of their individual benefits in medicine with the premise of being even more influential when used together. Participants in the integrated intervention group received the same guided imagery and biofeedback training as their counterparts in the individual intervention groups during a pre-operative visit. As in the individual treatment group of guided imagery, participants received the same surgery specific script on CD or MP3 player depending on the scheduled procedure, lasting 6 minutes following the same progression. Listeners were first lead through an initial breathing exercise followed by the arrival to the day of surgery. Details were provided regarding the pre-operative time including the preparation for surgery followed by the arrival into the operating room. Following the same basic introduction, the scripts varied.
depending on the procedure being performed and led the participant through the major elements of surgery and immediate recovery from the procedure. The script addressed feeling pain and provided the listener with breathing and imagery points to manage the pain.

In addition to the guided imagery training, participants in the combined treatment group also received the same training in the use of HeartMath’s emWave software as did those in the biofeedback treatment group. During the same pre-operative visit they received imagery training; participants were instructed on HeartMath’s emWave PC Stress Relief System and learned how to identify changes in psychophysiological coherence. Again, HRV was measured using a plethysmographic ear clip sensor and participants started at challenge level two for a baseline reading and introduction to coherence in relation to the display. Participants were then instructed on HeartMath’s three-step Quick Coherence Technique and allowed to practice while monitoring changes as displayed on the screen. The objective for the preoperative training session remained the same and was for each participant to achieve medium to high coherence when attempted, be self-aware and identify the psychological and physiological feelings associated with that state, and maintain it for a desired period of time. Participants were also provided a portable hand held emWave unit and instructed on how to use the device at home along with the guided imagery script in the weeks leading up to surgery.

**Standard Care**

The standard care group served as the control for the present study. Participants were provided the same information and education regarding their scheduled surgical procedure as all patients were given when surgery was prescribed during a pre-operative education session. A brief overview of the information patients learned at the hospital’s Joint Camp was provided, followed by an outline of expectations for the surgical experience, ending with an explanation of the mind-body connection and the rehabilitation process.

**Procedure**

The medical practice participating in the present study comprised of five Orthopaedic Surgeons and patients were referred by all physicians. Participants were recruited when surgery was deemed necessary by his or her surgeon and asked to read the explanation of the proposed study (Appendix L) provided to them by the physician or office staff member. A revision
procedure, replacement of any components from a previous arthroplasty, was the only exclusion criteria in the present study. Additional recruitment of participants took place at the hospital’s pre-operative Joint Camp session where consent was obtained by the researcher following the session. Participants were assigned to one of four groups and met with the researcher for their training session during which, all information, related materials, and instruction were given. The researcher provided the instruction and training in guided imagery and biofeedback. In addition, the researcher reviewed the information provided at Joint Camp regarding surgery, which is a standard pre-operative education appointment provided to all patients in accordance with the physician’s office and the hospital. All participants received this educational review regardless of intervention group assignment. This process controlled for the variable of researcher interaction. To accommodate patients’ schedules and provide training in a conducive environment for injured or physically limited participants, all education, instruction, and training for each treatment and control group was provided in a conference room at the treating hospital.

Patients assigned to the standard care control group, were provided an overview of the surgical procedure they were scheduled for and the effects of the mind-body connection on healing, as well as expectations for the recovery and rehabilitation process following a scheduled pre-operative visit lasting approximately 30 to 60 minutes. Education included the standard information shared with all patients and was provided by the researcher in a similar manner to the three treatment groups. During the session, the researcher offered the opportunity to meet for an additional 30 to 60 minute pre-operative session if necessary to review any questions or concerns.

Participants in the imagery intervention received the same education and overview provided to those in the control group as well as instruction on the use of imagery. The guided imagery CD or MP3 player with the procedure specific script was provided to participants during a scheduled one to two hour pre-operative session. Participants were asked to listen to the script at least twice per day for a minimum of 1 to 2 weeks prior to surgery, and at least once in the pre-operative surgical suite the day of surgery. In addition, participants were encouraged to listen to the imagery script as much as possible prior to their transport to the operating room and in recovery following surgery when possible. During the education and training session, the researcher provided a procedural outline covering the anticipated steps in the surgical process and reviewed the general course of the recovery and rehabilitation process. Participants were also
provided the opportunity to meet with the researcher for an additional 30-minute pre-operative session to review any additional instructions or concerns on behalf of the participant. Participants were asked to return the MP3 player if they received one during training by leaving it in their surgical packets at the hospital on the day of discharge to be collected by the researcher.

For participants assigned to the biofeedback intervention treatment, instruction and training was provided at the pre-operative visit during a scheduled one to two hour session. During which time, the same procedural outline covering the surgical process as well as the recovery and rehabilitation process that was given to participants in the control and imagery group was provided and reviewed by the researcher. Furthermore, participants were introduced to psychophysiological coherence using HeartMath’s emWave PC software and provided a handheld device for home use. During the session, participants trained on the emWave software until they were able to reach medium or high coherence using HeartMath’s three-step Quick Coherence Technique when attempted at level two. If necessary, the challenge level was increased to coincide with ability. Following training and practice on the PC software, participants were instructed on the use of the portable emWave device and had the opportunity to practice achieving coherence during the session. Participants were asked to practice on the handheld biofeedback unit at home for up to 10 minutes as recommended by HeartMath at least twice per day for a minimum of 1 to 2 weeks prior to surgery, and at least once the day of surgery. Participants were also provided the opportunity to meet with the researcher for an additional 30-minute pre-operative session to ensure psychophysiological coherence was achieved on command with minimal to no difficulties. It was encouraged that participants bring the portable unit to the hospital and practice achieving medium to high coherence prior to their transport to the operating room as well as during their recovery through the time of discharge. Participants were asked to return the handheld biofeedback device by leaving it in their surgical packets at the hospital on the day of discharge to be collected by the researcher.

The treatment intervention group receiving the integration of both guided imagery and biofeedback was provided instruction and training for each, following the same procedures individually outlined above. The session lasted up to two hours and started with the same review of the surgical procedure and the recovery and rehabilitation process that was given to participants in the control and individual treatment groups. Participants were then instructed on imagery and provided a CD or MP3 player containing the surgery specific script. Following
imagery training, participants were introduced to biofeedback and psychophysiological coherence using HeartMath’s PC software. As with the biofeedback intervention group, participants were trained on the software using the three-step Quick Coherence Technique until they were able to achieve medium or high coherence when attempted at level two. The portable handheld device and instruction on its use was then provided and participants had an adequate amount of time to practice achieving coherence during the session. Participants were asked to listen to the guided imagery script while monitoring coherence on the portable emWave unit at home. It was encouraged that participants reach medium or high coherence before listening to the script to optimize the experience. Participants were asked to use both tools together for approximately 10 minutes at least twice per day for a minimum of 1 to 2 weeks prior to surgery, and at least once the day of surgery. Participants were encouraged to listen to the imagery script while connected to the biofeedback at the hospital prior to transport to the operating room and through the time of discharge. Participants were asked to return the handheld biofeedback device and mp3 players if they received one by leaving them in their surgical packets at the hospital on the day of discharge to be collected by the researcher.

Across each of the four groups, contact time between the researcher and participant was approximately equal. The control group had a scheduled session lasting up to 60 minutes with an additional session offered lasting the same. The combined contact time between participants and the researcher was up to two hours for the control treatment. The individual imagery and biofeedback treatment groups had a scheduled session lasting up to two hours with an additional session offered if necessary. This training time took place if the original session was completed in less than two hours and was conducted until the two hours maximum contact time was reached. Lastly, participants in the combined treatment group had a scheduled session with the researcher for approximately two hours.

Data collection began prior to the delivery of the interventions. Once patients consented to participation and were assigned to one of the four groups, a packet was provided to them containing the medical history and demographics questionnaire and pretest measures including the STAI-S, PSS, and CSQ. Participants were asked to read the instructions, complete the forms and measures included, and give them back to the researcher prior to the start of the education and training session. Following the delivery of the interventions at the pre-operative training session, all participants were provided with an envelope and questionnaire packet consisting of
all relevant measures (STAI-S, PSS, CSQ, and VAS) to be completed during hospital admission. Participants were asked to read the instructions and complete the first set of measures (STAI-S, PSS, and CSQ) marked for the day of surgery in the pre-operative suite following registration and surgical preparation. Participants were asked to complete the same measures on the last day of hospital admission just prior to being discharged. The VAS with a space for the pain pump setting for TKA participants was also provided in the packet and was marked to be completed on post-operative days one, two, and three at approximately the same time each day. Space for three days was provided due to the standard protocol provided by the orthopaedic group. If participants were discharged early from the hospital on day two, that rating was used as their discharge day indicator of pain. Participants were asked to place the packet of assessments in the envelope provided, and leave it sealed with the nurses’ station before leaving the hospital to be collected by the researcher. Additional information was gathered the day of the patient’s first follow-up physician appointment following surgery. Participants were asked to complete the Training Survey to assess their compliance with the various treatment interventions by indicating how many times per day they practiced the technique instructed and return it to the researcher in the addressed stamped envelope provided. The survey, envelope, and instructions were provided to the participants at the pre-operative education and training session.

In addition to following a strict training protocol outlined in the procedures, a manipulation check was conducted at three times of data collection to assess the degree of engagement with the elements of the intervention employed. Participants were asked to complete the manipulation check the day of surgery, upon discharge from the hospital, and the day of the follow-up visit. The manipulation check was included in the questionnaire packet provided to participants for completion during hospital admission with the Training Survey. The research design is provided in Table 2.

Data Analysis

Data were collected and analyzed using SPSS 22 (SPSS Inc., Armonk, NY). Means and standard deviations (SDs) were calculated to estimate patients’ compliance with the treatments. To test the first and second hypotheses, a one-way analysis of variance (ANOVA) was performed for baseline measures to determine if significant differences among intervention groups existed. A repeated measures (RM) ANOVA was used when no significant difference
was found at baseline among groups and a RM analysis of covariance (ANCOVA) was used when a significant difference was observed with baseline assessment as the covariate. For the RM ANOVA and RM ANCOVA, each dependent variable included anxiety, perceived stress, coping strategies, and pain level and the three intervention groups and control were the between subject’s factor. The repeated factor was time. The use of medication and length of hospital admission (hypothesis three) was compared among the four conditions using a one-way ANOVA, followed by Tukey’s post-hoc test for paired mean comparisons if $p < .05$.

Table 2

*Research design and treatment assignment*

<table>
<thead>
<tr>
<th>Assignment</th>
<th>Group</th>
<th>Pretest</th>
<th>Treatment</th>
<th>Day of Surgery</th>
<th>Post-Op 1</th>
<th>Post-Op 2</th>
<th>Day of Discharge</th>
<th>MD Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>$M_1$</td>
<td>1</td>
<td>STAI, PSS, CSQ</td>
<td>Imagery</td>
<td>STAI, PSS, CSQ, Manipulation Check</td>
<td>VAS, Pain Pump (TKA)</td>
<td>VAS, Pain Pump (TKA)</td>
<td>STAI, PSS, CSQ, VAS, Pain Pump (TKA), Manipulation Check</td>
<td>Training Survey, Manipulation Check</td>
</tr>
<tr>
<td>$M_2$</td>
<td>2</td>
<td>STAI, PSS, CSQ</td>
<td>HRV-BFB</td>
<td>STAI, PSS, CSQ, Manipulation Check</td>
<td>VAS, Pain Pump (TKA)</td>
<td>VAS, Pain Pump (TKA)</td>
<td>STAI, PSS, CSQ, VAS, Pain Pump (TKA), Manipulation Check</td>
<td>Training Survey, Manipulation Check</td>
</tr>
<tr>
<td>$M_3$</td>
<td>3</td>
<td>STAI, PSS, CSQ</td>
<td>HRV-BFB + Imagery</td>
<td>STAI, PSS, CSQ, Manipulation Check</td>
<td>VAS, Pain Pump (TKA)</td>
<td>VAS, Pain Pump (TKA)</td>
<td>STAI, PSS, CSQ, VAS, Pain Pump (TKA), Manipulation Check</td>
<td>Training Survey, Manipulation Check</td>
</tr>
<tr>
<td>$M_4$</td>
<td>4</td>
<td>STAI, PSS, CSQ</td>
<td>Control (ed)</td>
<td>STAI, PSS, CSQ, Manipulation Check</td>
<td>VAS, Pain Pump (TKA)</td>
<td>VAS, Pain Pump (TKA)</td>
<td>STAI, PSS, CSQ, VAS, Pain Pump (TKA), Manipulation Check</td>
<td>Training Survey, Manipulation Check</td>
</tr>
</tbody>
</table>
CHAPTER 4

RESULTS

Manipulation Check

Manipulation checks were used to ensure the treatment was accepted for each of the three intervention groups. The concentration of treatment exposure was measured by asking participants in each of the three intervention groups how well they were able to engage with the elements of the training protocol instructed. For each manipulation check, participants were asked to rate items based on their experience on a continuum ranging from 0 (not at all) to 10 (very much). A summary of means and standard deviations for the assessment’s items are presented by intervention in Tables 3, 4, and 5.

Table 3

*Means and SDs for adherence to and efficacy of imagery intervention*

<table>
<thead>
<tr>
<th></th>
<th>Day of Surgery</th>
<th>Day of Discharge</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vividness of image</td>
<td>6.80 (1.32)</td>
<td>6.26 (1.38)</td>
<td>6.06 (1.16)</td>
</tr>
<tr>
<td>Control over image</td>
<td>6.06 (1.38)</td>
<td>5.80 (1.65)</td>
<td>5.93 (1.44)</td>
</tr>
<tr>
<td>Engagement with image</td>
<td>5.67 (.816)</td>
<td>5.80 (1.37)</td>
<td>5.67 (1.49)</td>
</tr>
<tr>
<td>Degree you followed instruction</td>
<td>4.73 (1.33)</td>
<td>4.86 (1.24)</td>
<td>5.53 (1.40)</td>
</tr>
</tbody>
</table>

Note. n = 15

Table 4

*Means and SDs for adherence to and efficacy of biofeedback intervention*

<table>
<thead>
<tr>
<th></th>
<th>Day of Surgery</th>
<th>Day of Discharge</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach green</td>
<td>4.86 (2.13)</td>
<td>4.73 (2.05)</td>
<td>5.40 (1.68)</td>
</tr>
<tr>
<td>Control felt in green</td>
<td>4.60 (1.45)</td>
<td>3.73 (1.90)</td>
<td>5.26 (1.33)</td>
</tr>
<tr>
<td>Effectiveness reaching green pre-op</td>
<td>4.53 (2.13)</td>
<td>5.13 (1.64)</td>
<td>5.20 (1.65)</td>
</tr>
<tr>
<td>Degree you followed instruction</td>
<td>4.46 (1.06)</td>
<td>3.80 (1.42)</td>
<td>5.00 (1.51)</td>
</tr>
</tbody>
</table>

Note. n = 15
Table 5
Means and SDs for adherence to and efficacy of biofeedback + imagery intervention

<table>
<thead>
<tr>
<th></th>
<th>Day of Surgery</th>
<th>Day of Discharge</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vividness of image</td>
<td>6.24 (1.69)</td>
<td>6.62 (1.24)</td>
<td>5.13 (1.50)</td>
</tr>
<tr>
<td>Control over image</td>
<td>5.26 (2.52)</td>
<td>5.64 (2.47)</td>
<td>5.13 (2.03)</td>
</tr>
<tr>
<td>Engagement with image</td>
<td>6.67 (1.11)</td>
<td>6.26 (1.33)</td>
<td>5.06 (.961)</td>
</tr>
<tr>
<td>Degree you followed instruction</td>
<td>6.44 (1.29)</td>
<td>6.46 (1.32)</td>
<td>6.06 (1.16)</td>
</tr>
<tr>
<td>Reach green</td>
<td>6.12 (2.69)</td>
<td>6.20 (2.27)</td>
<td>6.13 (2.16)</td>
</tr>
<tr>
<td>Control felt in green</td>
<td>5.45 (2.92)</td>
<td>5.40 (2.77)</td>
<td>6.00 (2.53)</td>
</tr>
<tr>
<td>Effectiveness reaching green with script</td>
<td>6.66 (1.84)</td>
<td>6.33 (2.46)</td>
<td>6.06 (1.58)</td>
</tr>
</tbody>
</table>

Note. n = 15

Compliance Analysis

In addition to the measures used to determine the potential efficacy of the interventions administered, a training survey was provided to all participants to be completed at the time of their first follow-up appointment with the surgeon. The training survey assessed the participant’s compliance with the intervention asking participants to specifically notate the number of times per day they practiced using the tool(s) provided. Participants in the three intervention groups were asked to practice their respective activity twice per day for 1-2 weeks leading up to the day of surgery. The prescribed training protocol used is equivalent to HeartMath’s suggested practice for the emWave biofeedback system of twice per day for 1-2 weeks as two of the interventions use the HRV monitoring system. Means and SDs are reported in Table 6 and a one-way ANOVA revealed non-significant difference among groups on the number of times per day participants used their intervention pre-operatively, $F (2, 40) = 1.82, p = .176$.

Table 6
Means and SDs of the number of times per day participants used their intervention tool pre-operatively among treatment conditions

<table>
<thead>
<tr>
<th></th>
<th>Imagery ($n = 13$)</th>
<th>BFB ($n = 14$)</th>
<th>BFB+Imagery ($n = 13$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Times/day used prescribed intervention pre-operatively</td>
<td>1.07 (.73)</td>
<td>1.57 (.87)</td>
<td>1.46 (.52)</td>
</tr>
</tbody>
</table>
Outcome Measures

Anxiety

Means and SDs for each treatment group and control at the three times are presented in Table 7, and mean scores for treatment groups and control at each of the three data points are illustrated in Figure 1.

Table 7

<table>
<thead>
<tr>
<th></th>
<th>Imagery (n = 15)</th>
<th>BFB (n = 15)</th>
<th>BFB+Imagery (n = 15)</th>
<th>Ed (n = 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>37.40 (7.88)</td>
<td>30.86 (6.95)</td>
<td>37.73 (8.77)</td>
<td>32.73 (11.39)</td>
</tr>
<tr>
<td>Day of Surgery</td>
<td>40.40 (9.67)</td>
<td>39.12 (5.42)</td>
<td>41.00 (7.13)</td>
<td>33.22 (7.75)</td>
</tr>
<tr>
<td>Day of Discharge</td>
<td>34.70 (7.22)</td>
<td>35.22 (7.29)</td>
<td>36.42 (5.04)</td>
<td>32.21 (9.18)</td>
</tr>
</tbody>
</table>

Figure 1. State anxiety scores (STAI-S) for each group (imagery, biofeedback, combo, education) at three times of assessment (baseline, day of surgery, day of discharge)

A one-way ANOVA was performed at baseline indicating non-significant difference among groups, $F (3,56) = 2.21, p = .097$. A RM ANOVA was performed using the intervention groups and control as the between subject factor and the three time points as repeated measures. Results are presented in Table 8. Mauchly’s test of sphericity revealed that the normality assumption was violated, $\chi^2 (2) = 11.04, p < .05$, therefore degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity ($\epsilon = .846$).
The analysis revealed a significant main effect on anxiety for time, $F(1.69, 94.76) = 7.44, p < 0.05, \eta^2 = 0.117$. Post hoc analyses revealed anxiety scores on the day of surgery ($M = 38.40, SD = 8.07$) were significantly ($p < .05$) higher than the other two assessment times (pre: $M = 34.68, SD = 9.17, d = 0.43$ and day of discharge: $M = 34.53, SD = 7.28, d = 0.50$). The main effect of treatment was non-significant, $F(3, 56) = 2.5, p = 0.69, \eta^2 = 0.118$, nor was the time by treatment interaction, $F(5.08, 94.76) = 1.56, p = 0.177, \eta^2 = 0.077$.

**Perceived Stress**

Means and SDs measured for each of the between subject factors (groups) at the three times are presented in Table 9 and mean scores for groups at each of the three data points are illustrated in Figure 2.

<table>
<thead>
<tr>
<th></th>
<th>Imagery ($n = 15$)</th>
<th>BFB ($n = 15$)</th>
<th>BFB+Imagery ($n = 15$)</th>
<th>Ed ($n = 15$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>15.30 (5.34)</td>
<td>15.82 (4.12)</td>
<td>17.13 (5.95)</td>
<td>11.32 (3.44)</td>
</tr>
<tr>
<td>Day of Surgery</td>
<td>18.54 (3.66)</td>
<td>14.83 (3.96)</td>
<td>19.13 (4.34)</td>
<td>11.33 (2.77)</td>
</tr>
<tr>
<td>Day of Discharge</td>
<td>18.43 (1.96)</td>
<td>14.34 (3.62)</td>
<td>16.76 (4.59)</td>
<td>12.46 (3.85)</td>
</tr>
</tbody>
</table>

A one-way ANOVA was performed at baseline and yielded a significant difference among groups, $F(3.59) = 4.56, p < 0.01$. A post hoc Tukey test revealed significant differences between the biofeedback and education groups ($p < 0.05$) with the biofeedback group recording significantly higher scores ($M = 15.82, SD = 4.12, d = 1.27$) and between the combined and education groups ($p < 0.01$) with the combined group recording significantly higher scores ($M = 17.13, SD = 5.95, d = 1.26$); the education group had a significantly lower baseline stress score.
A RM ANCOVA was performed using the intervention groups and control as the between subject factor, the times of assessment as repeated measures and baseline assessment as the covariate. Results are presented in Table 10.

![Perceived stress scores (PSS) for each group (imagery, biofeedback, combo, education) at three times of assessment (baseline, day of surgery, day of discharge).](image)

**Figure 2.** Perceived stress scores (PSS) for each group (imagery, biofeedback, combo, education) at three times of assessment (baseline, day of surgery, day of discharge)

**Table 10**

**RM ANCOVA results for stress**

<table>
<thead>
<tr>
<th></th>
<th>Wilk’s λ</th>
<th>F</th>
<th>df</th>
<th>p</th>
<th>η²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>.996</td>
<td>0.23</td>
<td>1.55</td>
<td>.637</td>
<td>.004</td>
</tr>
<tr>
<td>Time * Tx</td>
<td>.793</td>
<td>4.79</td>
<td>3.55</td>
<td>.005</td>
<td>.207</td>
</tr>
<tr>
<td>Tx</td>
<td></td>
<td>8.22</td>
<td>3.55</td>
<td>&lt;.001</td>
<td>.310</td>
</tr>
</tbody>
</table>

The analysis resulted in a significant treatment effect, $F(3,55) = 8.22, p < .001, \eta^2 = .310$. A post hoc analysis revealed that across assessment times, the imagery group ($M = 17.54, SD = 2.58$) was significantly higher on stress than both the biofeedback ($M = 13.93, SD = 2.59, d = 1.40$) and control ($M = 13.72, SD = 2.78, d = 1.42$). The main effect for time on stress revealed that although participants had descriptively higher scores on the day of surgery in comparison to the day of discharge, this difference was not significant $F(1,55) = .225, p = .637, \eta^2 = .070$. Descriptive data on perceived stress are provided in Table 11.
Table 11

*Mean and SDs of perceived stress for four treatment conditions by assessment time*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Day of Surgery</th>
<th>Day of Discharge</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imagery</td>
<td>17.73 (2.80)</td>
<td>17.77 (3.01)</td>
<td>17.54 (2.58)</td>
</tr>
<tr>
<td>BFB</td>
<td>14.29 (2.81)</td>
<td>13.57 (3.02)</td>
<td>13.93 (2.59)</td>
</tr>
<tr>
<td>BFB + Imagery</td>
<td>17.93 (2.88)</td>
<td>14.99 (3.09)</td>
<td>16.47 (2.66)</td>
</tr>
<tr>
<td>Ed</td>
<td>13.31 (3.02)</td>
<td>14.12 (3.25)</td>
<td>13.72 (2.78)</td>
</tr>
<tr>
<td>Total</td>
<td>15.82 (2.79)</td>
<td>15.12 (3.01)</td>
<td></td>
</tr>
</tbody>
</table>

The treatment by time interaction resulted in significant effect, $F(3,55) = 4.79, p < .001, \eta^2 = .207$. A post hoc analysis revealed that the only treatment that significantly reduced stress scores between the day of surgery and day of discharge was the combo group as illustrated in Figure 3 and reflected in Cohen’s $d = 0.98$. The combo intervention was the only one with a gradual decline in perceived stress whereas the control group had a gradual increase in scores. Participants in the imagery group experienced an increase in reported stress while those in the biofeedback groups, although not significant, reported a decrease in scores.

![Figure 3. Impact of treatments on perceived stress by assessment time (*** p < .05)](image-url)

Coping Strategies

Means and SDs of coping strategies for each of the groups in three assessment times are presented in Table 12 and mean scores for groups at each of the three data points are illustrated in Figure 4.
Table 12

Means and SDs for coping strategy scores by treatment condition

<table>
<thead>
<tr>
<th></th>
<th>Imagery (n = 15)</th>
<th>BFB (n = 15)</th>
<th>BFB+Imagery (n = 15)</th>
<th>Ed (n = 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>112.93 (19.23)</td>
<td>126.13 (24.47)</td>
<td>101.30 (34.11)</td>
<td>89.22 (36.49)</td>
</tr>
<tr>
<td>Day of Surgery</td>
<td>109.87 (10.54)</td>
<td>105.53 (28.67)</td>
<td>102.20 (28.96)</td>
<td>89.54 (37.10)</td>
</tr>
<tr>
<td>Day of Discharge</td>
<td>100.82 (17.78)</td>
<td>99.42 (25.68)</td>
<td>96.43 (24.02)</td>
<td>83.63 (32.85)</td>
</tr>
</tbody>
</table>

Figure 4. Coping strategies total scores (CSQ) for each group (imagery, biofeedback, combo, education) at three times of assessment (baseline, day of surgery, day of discharge)

A one-way ANOVA performed at baseline revealed significant effects among treatments, $F (3, 59) = 4.33, p < 0.01$. A post hoc Tukey test yielded a significantly lower degree of coping strategies between participants in the education group ($M = 89.2, SD = 36.49$) than those in the biofeedback intervention ($M = 126.13, SD = 24.47, d = 1.19$). A RM ANCOVA was performed using the intervention groups and control as the between subject factor, assessment times as the repeated measures within subject factor, and baseline as the covariate. Neither the time effect nor the treatment by time interaction was significant. Although the treatment effect was not statistically significant, it did trend strongly that way, $F (3, 55) = 2.49, p = .07, \eta^2 = .12$. A post hoc analysis revealed that across times, the combined group ($M = 103.55, SD = 15.26$) was higher on coping scores than the biofeedback group ($M = 88.73, SD = 15.99, d = 0.95$). Results are presented in Table 13.
Table 13

**RM ANCOVA results for coping strategies by treatment and time**

<table>
<thead>
<tr>
<th></th>
<th>Wilk’s λ</th>
<th>F</th>
<th>df</th>
<th>p</th>
<th>$\eta^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>.985</td>
<td>0.83</td>
<td>1, 55</td>
<td>.366</td>
<td>.015</td>
</tr>
<tr>
<td>Time * Tx</td>
<td>.984</td>
<td>0.31</td>
<td>3, 55</td>
<td>.822</td>
<td>.081</td>
</tr>
<tr>
<td>Tx</td>
<td>2.49</td>
<td></td>
<td>3, 55</td>
<td>.070</td>
<td>.120</td>
</tr>
</tbody>
</table>

Pain

Reported pain was assessed on post-operative days 1, 2, and day of discharge (post-op day 3). Means and SDs for the treatment groups at the three times are presented in Table 14, and mean scores for treatment groups at each of the three data points are illustrated in Figure 5. Both the biofeedback and imagery group participants reported a continual descriptive decline in reported pain from post-op day 1 through post-op day 3.

Table 14

**Means and SDs for VAS pain scores by treatment condition**

<table>
<thead>
<tr>
<th></th>
<th>Imagery ($n = 15$)</th>
<th>BFB ($n = 15$)</th>
<th>BFB+Imagery ($n = 15$)</th>
<th>Ed ($n = 15$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post – Op Day 1</td>
<td>5.92 (1.69)</td>
<td>4.82 (2.34)</td>
<td>4.63 (2.24)</td>
<td>4.63 (2.93)</td>
</tr>
<tr>
<td>Post – Op Day 2</td>
<td>5.26 (1.37)</td>
<td>4.73 (1.99)</td>
<td>5.23 (1.64)</td>
<td>3.33 (1.99)</td>
</tr>
<tr>
<td>Post – Op Day 3</td>
<td>3.84 (1.14)</td>
<td>3.67 (1.77)</td>
<td>4.32 (1.56)</td>
<td>4.62 (2.63)</td>
</tr>
</tbody>
</table>

Post-Op Day 3 lower due to discharge at Day 2

*Figure 5.* Reported pain score (VAS) for each treatment group (imagery, biofeedback, combo, education) at three times of assessment (Post-op day 1, Post-op day 2, Post-op day 3)
A one-way ANOVA performed for post-operative day 1 indicated non-significant difference among groups, $F(3,59) = 1.02, p = .391$. A RM ANOVA was then performed using the intervention groups as the between subject factor and the three times of assessment as repeated measures. Mauchly’s test of sphericity revealed that the normality assumption was violated, $\chi^2(2) = 12.03, p < 0.05$, therefore degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity ($\epsilon = .819$). Results are reported in Table 15.

Table 15

<table>
<thead>
<tr>
<th></th>
<th>MS</th>
<th>$F$</th>
<th>df</th>
<th>$p$</th>
<th>$\eta^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>13.24</td>
<td>4.67</td>
<td>1.64, 80.22</td>
<td>.014</td>
<td>.092</td>
</tr>
<tr>
<td>Time * Tx</td>
<td>8.15</td>
<td>3.06</td>
<td>4.91, 80.22</td>
<td>.015</td>
<td>.158</td>
</tr>
<tr>
<td>Tx</td>
<td>4.29</td>
<td>0.50</td>
<td>3, 49</td>
<td>.682</td>
<td>.030</td>
</tr>
</tbody>
</table>

The analysis revealed a significant main effect on pain for time, $F(1.63, 80.21) = 4.97, p < 0.05, \eta^2 = 0.09$. A post hoc comparison revealed a significant decrease in reported pain between post-operative day 1 ($M = 4.99, SD = 2.34$) and day 3 ($M = 4.11, SD = 1.8, d = 0.42$). The treatment by time interaction was significant, $F(4.9, 80) = 3.06, p < 0.05, \eta^2 = .158$. A post-hoc analysis revealed a significant decrease in reported pain among participants in the imagery intervention on post-operative day 3 ($M = 3.85, SD = 1.14$) from both post-operative days 1 and 2 ($M = 5.93, SD = 1.69, d = 1.44$ and $M = 5.27, SD = 1.37, d = 1.13$). Participants in the imagery intervention reported a significantly ($p < .05$) higher level of pain on post-operative day 2 ($M = 5.27, SD = 1.37$) than those in the education group ($M = 3.3, SD = 1.99, d = 1.15$). Participants in the biofeedback intervention experienced a significant reduction in reported pain from post-operative day 2 ($M = 4.73, SD = 1.99$) to day 3 ($M = 3.68, SD = 1.77, d = 0.56$). In contrast, while a significant reduction in pain from post-operative day 1 ($M = 4.63, SD = 2.93$) to day 2 ($M = 3.3, SD = 1.99, d = 0.54$) was revealed for the educational group, there was a significant increase in reported pain from post-operative day 2 to day 3 ($M = 4.65, SD = 2.53, d = 0.59$). All treatment groups resulted in a reduction of perceived pain except the participants in the educational control group, which gradually increased. The main analysis for treatment effect was non-significant, $F(3, 49) = .50, p = .68, \eta^2 = 0.03$. 
Pain Pump Setting

The amount of medication utilized by participants was assessed for those undergoing total knee arthroplasty (n = 44) as only that surgical procedure used the pain pump. Patients noted the setting of the pump (0 – 14) with each daily pain rating made on the VAS pain scale during in-patient status. A lower setting is optimal due to the impact the medication has on the patient’s ability to control movement in his or her leg. The higher the setting, the more numbing medication is released, potentially making ambulation and active range of motion more challenging. Means and SDs for each group at the three times are presented in Table 16.

Table 16

*Means and SDs for pain pump settings by treatment conditions and assessment time*

<table>
<thead>
<tr>
<th></th>
<th>Imagery (n = 11)</th>
<th>BFB (n = 12)</th>
<th>BFB+Imagery (n = 11)</th>
<th>Ed (n = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post – Op Day 1</td>
<td>8.63 (0.92)</td>
<td>8.41 (1.62)</td>
<td>6.45 (1.12)</td>
<td>7.10 (1.45)</td>
</tr>
<tr>
<td>(n = 10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post – Op Day 2</td>
<td>7.54 (1.29)</td>
<td>7.66 (1.72)</td>
<td>6.09 (0.30)</td>
<td>7.70 (2.05)</td>
</tr>
<tr>
<td>(n = 12)</td>
<td></td>
<td></td>
<td>(n = 11)</td>
<td></td>
</tr>
<tr>
<td>Post – Op Day 3</td>
<td>5.54 (1.35)</td>
<td>6.00 (0.43)</td>
<td>5.18 (0.98)</td>
<td>7.66 (1.73)</td>
</tr>
<tr>
<td>(n = 10)</td>
<td></td>
<td></td>
<td>(n = 10)</td>
<td></td>
</tr>
<tr>
<td>Average Setting</td>
<td>7.32 (1.77)</td>
<td>7.36 (1.45)</td>
<td>5.91 (0.87)</td>
<td>7.43 (1.07)</td>
</tr>
</tbody>
</table>

A one-way ANOVA was performed on the average pain pump setting of total time in the hospital revealing a significant main effect for treatment condition, $F(3, 43) = 5.78, p < 0.01$. A post hoc analysis revealed that the combo intervention ($M = 5.91, SD = .873$) required significantly less medication delivered through the pain pump than the three other groups (imagery: $M = 7.32, SD = 1.77, d = 1.01$; biofeedback: $M = 7.36, SD = 1.45, d = 1.21$; education: $M = 7.43, SD = 1.07, d = 1.56$) as illustrated in Figure 6.

*Figure 6. Effect of treatments on average pain pump settings (***p < .05)*
Days In-Patient

Length of hospital admission was assessed to identify whether any of the interventions resulted in early discharge. A one-way ANOVA was performed to compare length of in-patient status among the four treatment conditions. Non-significant differences were revealed, $F (3, 56) = .152, p = .928$. Approximately 88% of all participants remained in the hospital for three days following surgery. Percentage of participants in either the two or three-day discharge category is presented by treatment conditions in Table 17.

Table 17

*Length of hospital admission by treatment conditions*

<table>
<thead>
<tr>
<th></th>
<th>Total % (n)</th>
<th>Imagery % (n)</th>
<th>BFB % (n)</th>
<th>BFB+Imagery % (n)</th>
<th>Ed % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge Post-op Day 2</td>
<td>12 (7)</td>
<td>13 (2)</td>
<td>7 (1)</td>
<td>13 (2)</td>
<td>13 (2)</td>
</tr>
<tr>
<td>Discharge Post-op Day 3</td>
<td>88 (53)</td>
<td>87 (13)</td>
<td>93 (14)</td>
<td>87 (13)</td>
<td>87 (13)</td>
</tr>
</tbody>
</table>
CHAPTER 5
DISCUSSION

The purpose of the present study was to delineate the effects of two CAM practices on a range of variables associated with the surgical experience. More specifically, the impact of biofeedback and guided imagery practices on stress, anxiety, coping, pain, pharmacological use and the length of hospital admission was explored as sole treatments and in combination. Although substantial research exists investigating the effects of these supplemental therapies in medicine (Leon-Pizarro, 2007; Scherwitz et al., 2005; Yucha & Gilbert, 2004), less has been done to explore the use of interventions concurrently. Furthermore, the evaluation of dynamic approaches toward facilitating the recovery process from major orthopaedic procedures has not been prevalent. To assess the influence of combined treatment approaches in orthopaedic medicine, biofeedback and guided imagery were utilized as individual treatments and in combination by patients undergoing total joint arthroplasty. Although evidence did not reflect all outcomes postulated, there were significant benefits observed supporting the use of these interventions in medical practice.

Mind-body research has grown significantly over the years, generating recurrent positive outcomes (Wolsko, Eisenberg, Davis, & Phillips, 2004). The use of guided imagery and biofeedback in medicine has been explored with benefits experienced by patients ranging from reduced stress (Scherwitz et al., 2005), increased self-efficacy (Ievleva & Orlick, 1991), and decreased anxiety related to the surgical experience (Schwab et al., 2007). Hence, the first hypothesis in the present study stated that while both the imagery and biofeedback interventions would result in reduced anxiety and stress, and improved coping strategies, participants utilizing both interventions collectively would experience more substantial gains. The hypothesis was supported for reducing stress whereas a reduction in anxiety and increase in coping were not observed, thus, failing to reject the null hypothesis.

With respect to stress, the use of the combined intervention (imagery and biofeedback) pre-operatively generated a significant reduction in stress \((p < .001)\), supporting its use in medicine. The combo intervention was the only intervention to reduce stress between the day of surgery and the day patients were discharged from the hospital as reflected in Cohen’s \(d = 0.98\).
These findings are substantial due to the negative effects on the body generated by stress (Segestrom & Miller, 2004). Impeded wound healing (Kiecolt-Glaser et al., 1995) is just one of the countless effects of stress that can be extremely detrimental to patients experiencing health problems or undergoing surgery. While not significant, positive results were observed in the biofeedback intervention. Only patients in the biofeedback treatment condition recorded a steady decline in reported stress from baseline measurements through discharge from the hospital following surgery. Conversely, the patients in the education treatment experienced a gradual rise in stress from baseline measurement through day of discharge. Although the combo intervention had a significantly positive effect reducing stress, scores for the day of surgery increased among the combined intervention patients, as did those in the imagery and general education groups.

Findings for treatment effects on patients’ anxiety and coping strategies, although not significant in demonstrating efficacy, are noted for future implications in research. The analysis revealed that across all treatments, anxiety significantly increased on the day of surgery compared to baseline assessment and those obtained on the day of discharge. While a higher level of anxiety on the day of any surgery is to be expected, it would be advantageous to further explore the specific dimensions, which increase anxiety in patients. Factors such as waiting to go into surgery and not being allowed to eat or drink before surgery have been found to cause feelings of distress among surgical patients (Cobley, Dunne & Sanders, 1991). Identifying concerns and addressing them with patients prior to transfer to the operating room can enhance patients’ emotional states which have been associated with positive health outcomes (Schmitt & Woolridge, 1973). The patients in the imagery and combo treatments had lower anxiety on the day of discharge than at baseline as did those in the education treatment, although the reduction was low. A lower level of anxiety upon discharge from the hospital is noteworthy as the healing and recovery process continues long after patients leave the hospital following surgery (den Hertog, Gliesche, Timm, Muhlbauer, & Zebrowski, 2012).

The use of coping strategies employed by patients was evaluated in the present study on account of the ability to inhibit the occurrence of the stress response when coping resources meet the demands of a threat (Folkman & Lazarus, 1984). There is substantial evidence indicating a significant relationship between stress and recovery (Broadbent et al., 2003; Christian et al., 2006); therefore, developing and strengthening coping skills carries importance in medicine. While no differences were observed in the use of coping strategies as assessed with the Coping
Strategies Questionnaire, there was a notable trend toward significance reflected in a large effect size \((d = 0.95)\) among patients in the combo treatment condition recording higher coping scores compared to those in the biofeedback condition. However, a steady decline in coping for patients in all treatment interventions and the education group was observed, although the decline was non-significant. Thus, I recommend that future research may consider targeting particular strategies geared toward empowering patients and strengthening their ability to cope with physical symptoms such as pain.

Pain was included in this study due to its strong correlation to stress, and subsequent negative health outcomes. When pain is perceived, it instantaneously triggers the activation of the sympathetic nervous system (stress response), thus producing increased muscle tension (Heil, 1993). While effects can be harmful to anyone, muscle tension increases the likelihood of decreased mobility and flexibility, which greatly jeopardizes the success of orthopaedic surgeries such as total joint arthroplasty. In line with the first hypothesis, the second hypothesis in the present study asserted that all interventions would reduce reported pain levels from post-operative day 1 through day 3. The hypothesis was supported for a reduction in pain among participants receiving the imagery and biofeedback intervention whereas the combined group did not have a significant reduction, thus, failing to reject the null hypothesis. Patients in the biofeedback treatment experienced a significant decrease in pain from post-operative day 2 to day 3, although the effect was moderate \((d = 0.56)\). More noteworthy, those in the imagery intervention reported a significant reduction in pain on post-operative day 3 from day 1 and 2 as reflected in a large effect size with \(d = 1.44\) and 1.13 respectively. In contrast, participants in the education group reported a significant \((p < .05)\) increase in pain from post-operative day 2 to day 3. While positive results were realized in the present study, further inquiry into methods of pain modification is of great importance. The implications of uncontrolled pain are vast and can range from minimally significant to life threatening; all strongly dependent upon the individual’s ability to cope and self-regulate (Frederiksen, Karsten, Indahl, & Bendix, 2015).

The final hypothesis proposed in the present study stated that all interventions would result in reduced levels of medication required and length of hospital admission compared to the standard educational intervention. Investigating the effects of biofeedback, imagery, and the combination of both on the amount of medication used in this study was completed by recording the setting of a pain pump inserted by catheter only available to TKA patients. The pump is a
patient controlled device, which is placed in close proximity to the femoral nerve and releases numbing medication at a rate according to the number it is set to. The pain pump can be adjusted from 0 to 14 with a higher number releasing a larger dose of medication indicating a greater need as a result of pain. While pain control is important following joint arthroplasty, a higher setting causes the pump to release more numbing medication therefore potentially limiting the individual’s muscle control. Findings provide support for the combo intervention where patients required less medication delivered through the pump than those in the two other treatment interventions and educational control group. Although non-significant, the pain pump setting for participants in the imagery and biofeedback interventions continually decreased from post-operative day 1 through day 3, whereas those in the education treatment increased the use of medication on day 2. Length of hospital admission, while often influenced by a number of factors such as pain and severity of one’s condition, had a small degree of variation between 2 and 3 days with the majority of patients remaining in the hospital for 3 days following total joint arthroplasty. In this particular study, standard protocol of the surgeons and hospital is 3 days. If the patient is medically cleared for discharge and feeling well enough to leave, there are instances of early discharge. In total, 88% of the participants in this study remained in the hospital for 3 days. While the hypothesis was supported for a reduction in medication used for the combined treatment condition, no significant findings for the other interventions nor on the number of days patients remained in the hospital following surgery were observed, thus, failing to reject the null hypothesis.

The premise of using guided imagery in the present study for the preparation of total joint arthroplasty corresponds to its use in the athletic arena. Mental rehearsal is often employed for upcoming competition to aid in preparedness (Mahoney et al., 1987; Ungerleider et al., 1990) and can alleviate anxiety that is often triggered on the day of competition. As in sports, using guided imagery to prepare for an upcoming surgical procedure can generate significant benefits contributing to positive outcomes. This is even more substantial for patients with little to no previous surgical history. Mentally rehearsing events leading up to surgery such as the pre-operative experience and transport into the operating room can aid in alleviating possible fears with those experiences (Schwab et al., 2007). Fear, while not necessarily experienced by all patients, can be debilitating. Feelings of anxiety from those fears can trigger the activation of the sympathetic nervous system, which is negatively correlated with pain and recovery following
surgical procedures (Stoddard et al., 2005). By mentally preparing oneself for what they may encounter, patients can work through fears prior to surgery and help reduce the negative effects often experienced by many.

While it is known that achieving a relaxed state is optimal in the treatment of health conditions (Leon-Pizzaro et al., 2007), using a tool such as biofeedback to measure one’s ability to reach a relaxed state could be more advantageous. Biofeedback was used in the present study to provide patients a way to identify when they reach a relaxed state, giving them an opportunity to learn to reach a preferred mental state. A potential disconnect between the mind and body can be overcome by using biofeedback to bridge the two together, allowing individuals to see how their bodies are physiologically responding in relation to thoughts and feelings. It allows users to develop a greater sense of self-awareness and teaches self-regulation (Kingdom, Stanley, & Kizior, 1998); becoming more aware of one’s mind and body at any given moment and knowing how to alter both to achieve an optimal state by way of breathing and shifting focus internally. This optimal state produces homeostasis within the body which is ideal when undergoing medical procedures such as surgery, allowing the body to halt the stress response, and therefore aiding in the healing and recovery process (Chovatiya & Medzhitov, 2014). Once self-awareness and self-regulation have been developed and mastered, the technique can be employed without the use of biofeedback in any setting.

Guided imagery and biofeedback were selected for the present study because of their ease of use and their successful application in medicine (Cupal & brewer, 2001; Tsai et al., 2007). The combination of both was investigated due to the lack of research exploring the use of multiple techniques concurrently. Additionally, one can deduce that achieving a self-regulated balance in the autonomic nervous system by way of using biofeedback while listening to a guided imagery script can in fact, enhance the experience and potentially make the benefits of using imagery that much greater than listening to the script alone. The findings of the present study reflected positive outcomes observed in previous research exploring CAM interventions on health outcomes (Blanchard et al., 1987; Gervitz, Hubbard, & Harpin, 1996; Scherwitz et al., 2005) and encourages the merging of techniques. Combining the use of both imagery and biofeedback as one treatment intervention did elicit the best results compared to the other interventions with a reduction in stress and medication use. However, the use of both techniques simultaneously needs to be further explored across a range of patients undergoing various
procedures. Results suggest continued use of interventions such as biofeedback and imagery as part of a treatment plan for all medical patients with general education at the foundation. Additionally, variations in the way in which interventions are implemented warrant further investigation.

**Limitations and Future Research**

Continued research in the field of CAM practices must be encouraged and consideration should be made of the limitations noted from research designs such as those in the present study. A number of limitations in the present study exist, potentially influencing observations made. The first being the degree of compliance patients had with following the prescribed training protocol. Although instructions were given to practice twice per day for 1-2 weeks pre-operatively, participants did not fully adhere to the protocols as directed although no significant difference in the number of days practiced were revealed among the treatment conditions. Participants were asked to notate the number of times per day they utilized the tools provided pre-operatively on the Training Survey; however, the question did not inquire as to the number of weeks participants practiced. Future research exploring the impact of interventions should include specific training logs for participants to indicate the day, time, and length of practice. Researchers should also consider having multiple training or follow-up sessions after the initial instruction is provided. Follow-up helps to ensure that participants fully understand what is being asked of them and gives them the opportunity to inquire about any difficulties they may be experiencing. Not fully grasping the techniques provided or encountering any difficulties may be a large source of non-compliance.

Age and gender are limitations of the present study. This research aimed to delineate the effects of these interventions on joint replacement patients who averaged 66.1 years of age. A limitation of the current study’s design was the technology provided as part of the interventions and potential challenges of the population to fully grasp the use of tools provided such as the MP3 players. While patients were instructed on the proper use of the portable biofeedback handheld unit and the MP3 players when applicable, age and lack of experience may have influenced the participant’s ability to fully comply with the instructed protocol. In addition to age, gender may have played a role in outcomes observed. Although the number of female participants \((n = 41)\) was greater than male \((n = 19)\), focus for assignment to treatment conditions
was on the type of joint arthroplasty to ensure equal distribution and not on gender. It can be advantageous to consider gender as a factor when studying the effects of various interventions to identify additional factors influencing outcomes.

Another significant limitation of the present study is the access to patients due to privacy laws and hospital policy. While an incredible amount of access was granted in order to conduct the current study, future researchers may consider including additional personnel into the study, whenever possible, who have full access to patients and records. The benefits of having a co-investigator who has full access to patients offers the ability to reinforce intervention practices each day with patients while they are in the hospital, which may prove extremely advantageous.

The current study provided instruction to use the interventions pre-operatively and only suggested continued use during in-patient status following surgery. Reinforcement of procedures and additional training for patients while in the hospital may have yielded more positive outcomes such as reduced pain. In addition to continued training benefits, including personnel from the hospital with more patient access offers greater analysis of the interventions’ impact on the amount of medication consumed by patients. A major challenge in the current study is the inability to fully assess the relationship between interventions and medication use. As a result, modifications were made and data from the pain pump for TKA patients was gathered. It is important to note that while patients in the combined intervention used significantly less medication administered through the pain pump, there was no significant impact on their reported pain levels as recorded on the VAS. Conversely, patients in the sole imagery and biofeedback treatment conditions did report a significant reduction in pain on post-operative day 3 but did not have any notable change in pain pump settings. Due to the inability to fully assess the amount of narcotics used while patients were in the hospital, drawing a conclusion as to the impact of the combined intervention on medication use is very limited.

To provide the best standard of care to all medical patients, researchers and practitioners are recommended to consider tailoring programs to meet the specific needs of patients and address issues that may significantly influence outcomes. One way to approach this idea is to identify particular stressors or sources of anxiety for patients prior to any medical procedures. Proper education can potentially limit or alleviate these concerns. Moreover, variations in the practice of CAM interventions can be made for optimal results. In addition to inquiring pre-operatively as to potential stressors or causes of heightened anxiety, it may prove beneficial to
explore these factors while patients are in the hospital as well. Results from the present study reflect a possible increase in stress the day of discharge for some patients. Although the reason can be one of many, it should be considered that patients may be more apprehensive about leaving the hospital and feeling vulnerable if they are unable to fully care for themselves at that point. While tailoring programs based on specific patient needs is ideal, individualizing interventions would likely require lengthening the amount of time spent with patients, which could positively influence outcomes alone. The current study involved meeting with patients only once, and although that time was generally equal across treatment conditions, it may be beneficial to increase patient-researcher contact time. Further exploring the effects of individualized personal contact may prove extremely influential for future development of treatment interventions and CAM practices. Lastly, future researchers must consider assessing psychological readiness and cognitive functional levels of patients (specifically, in elderly patients) as these factors can greatly influence the recovery process.

While the study’s findings offer limited statistical significance in full support of the hypotheses investigated, results are positive on a number of psychological variables and post-operative outcome measures that are not only beneficial for orthopaedic surgical patients, but all patients requiring any surgical procedure. As with previous CAM research, the use of biofeedback and imagery reduced pain but the use of these practices mutually as explored in the present study had a significant impact on stress with lower levels reported by participants compared to those receiving the interventions exclusively. Furthermore, participants practicing imagery and biofeedback training collectively utilized significantly less medication than those using the interventions exclusively. The benefits of participation in CAM practices positively influence the overall experience and potential results of medical procedures but it is essential to push those practices out of the conventional box and utilize them in atypical ways. Continued development and manipulation of practices are essential in order to continually provide an optimal level of medical care.
APPENDIX A

FSU IRB APPROVAL

Office of the Vice President for Research
Human Subjects Committee
P. O. Box 3062742
Tallahassee, Florida 32306-2742
(850) 644-8673 · FAX (850) 644-4392

RE-APPROVAL MEMORANDUM

Date: 12/11/2015

To: Lisa Grossman

Address:

Dept.: EDUCATIONAL PSYCHOLOGY AND LEARNING SYSTEMS

From: Thomas L. Jacobson, Chair

Re: Re-approval of Use of Human subjects in Research:
The Effects of Guided Imagery and HRV Biofeedback Training on Psychological Variables and Post-Operative Outcome Measures of Orthopedic Surgical Patients

Your request to continue the research project listed above involving human subjects has been approved by the Human Subjects Committee. If your project has not been completed by 12/7/2016, you must request a renewal of approval for continuation of the project. As a courtesy, a renewal notice will be sent to you prior to your expiration date; however, it is your responsibility as the Principal Investigator to timely request renewal of your approval from the committee.

If you submitted a proposed consent form with your renewal request, the approved stamped consent form is attached to this re-approval notice. Only the stamped version of the consent form may be used in recruiting of research subjects. You are reminded that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report in writing, any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chairman of your department and/or your major professor are reminded of their responsibility for being informed concerning research projects involving human subjects in their department. They are advised to review the protocols as often as necessary to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

Cc: HSC No. 2015.17033
RE-APPROVAL MEMORANDUM

Date: 11/12/2015

To: Lisa Grossman

Address:

Dept.: EDUCATIONAL PSYCHOLOGY AND LEARNING SYSTEMS

From: Thomas L. Jacobson, Chair

Re: Re-approval of Use of Human subjects in Research:
The Effects of Guided Imagery and HRV Biofeedback Training on Psychological Variables and Post-Operative Outcome Measures of Orthopedic Surgical Patients

Your request to continue the research project listed above involving human subjects has been approved by the Human Subjects Committee. If your project has not been completed by 11/11/2015 you must request renewed approval by the Committee.

If you submitted a proposed consent form with your renewal request, the approved stamped consent form is attached to this re-approval notice. Only the stamped version of the consent form may be used in recruiting of research subjects. You are reminded that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report in writing, any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chairman of your department and/or your major professor are reminded of their responsibility for being informed concerning research projects involving human subjects in their department. They are advised to review the protocols as often as necessary to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

Cc: HSC No. 2014.13850
RE-APPROVAL MEMORANDUM

Date:   10/09/2014

To: Lisa Grossman

Address:

Dept.: EDUCATIONAL PSYCHOLOGY AND LEARNING SYSTEMS

From: Thomas L. Jacobson, Chair

Re: Re-approval of Use of Human subjects in Research:
The Effects of Guided Imagery and HRV Biofeedback Training on Psychological Variables and Post-Operative Outcome Measures of Orthopedic Surgical Patients

Your request to continue the research project listed above involving human subjects has been approved by the Human Subjects Committee. If your project has not been completed by 10/08/2014 you must request renewed approval by the Committee.

If you submitted a proposed consent form with your renewal request, the approved stamped consent form is attached to this re-approval notice. Only the stamped version of the consent form may be used in recruiting of research subjects. You are reminded that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report in writing, any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chairman of your department and/or your major professor are reminded of their responsibility for being informed concerning research projects involving human subjects in their department. They are advised to review the protocols as often as necessary to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

Cc: HSC No. 2013.11266
RE-APPROVAL MEMORANDUM

Date:   09/12/2013

To: Lisa Grossman

Address:

Dept.: EDUCA TIONAL PSYCHOLOGY AND LEARNING SYSTEMS

From: Thomas L. Jacobson, Chair

Re: Re-approval of Use of Human subjects in Research:
The Effects of Guided Imagery and HRV Biofeedback Training on Psychological Variables and Post-Operative Outcome Measures of Orthopedic Surgical Patients

Your request to continue the research project listed above involving human subjects has been approved by the Human Subjects Committee. If your project has not been completed by 9/11/2013 you must request renewed approval by the Committee.

If you submitted a proposed consent form with your renewal request, the approved stamped consent form is attached to this re-approval notice. Only the stamped version of the consent form may be used in recruiting of research subjects. You are reminded that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report in writing, any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chairman of your department and/or your major professor are reminded of their responsibility for being informed concerning research projects involving human subjects in their department. They are advised to review the protocols as often as necessary to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

Cc: HSC No. 2012.8856
RE-APPROVAL MEMORANDUM

Date: 09/13/2012

To: Lisa Grossman

Address:

Dept.: EDUCATIONAL PSYCHOLOGY AND LEARNING SYSTEMS

From: Thomas L. Jacobson, Chair

Re: Re-approval of Use of Human subjects in Research:
The Effects of Guided Imagery and HRV Biofeedback Training on Psychological Variables and Post-Operative Outcome Measures of Orthopedic Surgical Patients

Your request to continue the research project listed above involving human subjects has been approved by the Human Subjects Committee. If your project has not been completed by 9/12/2012 you must request renewed approval by the Committee.

If you submitted a proposed consent form with your renewal request, the approved stamped consent form is attached to this re-approval notice. Only the stamped version of the consent form may be used in recruiting of research subjects. You are reminded that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report in writing, any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chairman of your department and/or your major professor are reminded of their responsibility for being informed concerning research projects involving human subjects in their department. They are advised to review the protocols as often as necessary to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

Cc: HSC No. 2011.6839
Office of the Vice President for Research  
Human Subjects Committee  
Tallahassee, Florida 32306-2742  
(850) 644-8673 · FAX (850) 644-4392

APPROVAL MEMORANDUM

Date: 07/09/2011

To: Lisa Grossman

Address:

Dept.: EDUCATIONAL PSYCHOLOGY AND LEARNING SYSTEMS

From: Thomas L. Jacobson, Chair

Re: Use of Human Subjects in Research  
The Effects of Guided Imagery and HRV Biofeedback Training on Psychological Variables and Post-Operative Outcome Measures of Orthopedic Surgical Patients

The application that you submitted to this office in regard to the use of human subjects in the research proposal referenced above has been reviewed by the Human Subjects Committee at its meeting on 9/8/2010. Your project was approved by the Committee.

The Human Subjects Committee has not evaluated your proposal for scientific merit, except to weigh the risk to the human participants and the aspects of the proposal related to potential risk and benefit. This approval does not replace any departmental or other approvals which may be required.

If you submitted a proposed consent form with your application, the approved stamped consent form is attached to this approval notice. Only the stamped version of the consent form may be used in recruiting research subjects.

If the project has not been completed by 9/7/2011 you must request a renewal of approval for continuation of the project. As a courtesy, a renewal notice will be sent to you prior to your expiration date; however, it is your responsibility as the Principal Investigator to timely request renewal of your approval from the Committee.

You are advised that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report, in writing, any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the chairman of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

By copy of this memorandum, the chairman of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.
This institution has an Assurance on file with the Office for Human Research Protection. The Assurance Number is IRB00000446.

Cc: Gershon Tenenbaum <gtenenbaum@fsu.edu>, Advisor
HSC No. 2010.4873
APPENDIX B

HOSPITAL IRB APPROVAL

MEMORANDUM

TO: Steven Lancaster, MD
FROM: Michael Joyce, MD, PhD
Chairman, Institutional Review Board
DATE: October 27, 2015
RE: Expedited Review – Initial Approval

The Institutional Review Board (IRB) of Baptist Medical Center (BMC) met on October 27, 2015, and the following new protocol was reviewed and approved via expedited review for a period of one year:

#15-68, JOI, "The Effects of Guided Imagery and HRV Biofeedback Training on Psychological Variables and Post-Operative Outcome Measures of Orthopedic Patients"

Enclosed is the stamped consent with the approval and expiration dates needed to enroll patients. The anniversary date for this study is October 26, 2016. At that time, please submit a report of your experiences with this protocol.

Should you have any questions, please contact the IRB office. The BMC IRB meets the requirements in 21 CFR 56 (Rev.), 45 CFR 46 (Rev.) and ICH (E6) GCP guidelines. Good luck with this endeavor.
APPENDIX C

INFORMED CONSENT

Informed Consent to Participate in Research
and Authorization for Collection, Use, and Disclosure of Protected Health Information

You are being asked to take part in a research study. This form provides you with information about the study and seeks your authorization for the collection, use and disclosure of your protected health information necessary for the study. The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will also describe this study to you and answer all of your questions. Before you decide whether or not to take part, read the information below and ask questions about anything you do not understand. Your participation is entirely voluntary. If you choose not to take part in this study, you will not be penalized or lose any benefits to which you would otherwise be entitled.

1. Name of Study Participant
________________________________________________________________________

2. Title of Research Study

The Effects of Guided Imagery and HRV Biofeedback Training on Psychological Variables and Post-Operative Outcome Measures of Orthopedic Surgical Patients

3. Principal Investigator Name, Address, and Telephone Number(s)

Dr. Steven Lancaster; Co Investigator- Lisa Grossman;

4. Source of Funding or Other Material Support

No funding or sponsorship used

5. What is the purpose of this research study?

The purpose of this research is to compare the effects of pre-operative procedure specific guided imagery and HRV biofeedback training as individual treatment techniques, and in combination on psychological variables (specifically anxiety, perceived stress, and coping strategies), and post-operative outcome measures (specifically pain, analgesic use, and length of hospital stay). It is postulated that while HRV biofeedback training and guided imagery will produce positive outcomes on both the pre-operative and post-operative measures as sole treatments, the combined treatment effects of the HRV biofeedback training and guided imagery used jointly, will result in the greatest benefits across all variables and measures.
6. What will be done if you take part in this research study?

Participation in the present study will involve possible assignment to one of four groups including guided imagery, HRV biofeedback training, combined guided imagery and HRV biofeedback training, and an educational informative group. This form of biofeedback monitors the level of coherence (balance within the autonomic nervous system) by measuring heart rate variability (HRV). HRV is monitored through an ear clip or finger sensor and is obtained by the variability between heart beat peaks. I understand that if I participate in the study, I may receive training in guided imagery, biofeedback, or both, and education and information regarding the surgical process and anticipated recovery during a scheduled pre-operative session which will take place in conjunction with the Joint Camp conducted through Jacksonville Orthopaedic Institute. I understand that if I chose to participate in the study, I will receive general information and education regarding the surgical process and anticipated recovery regardless of the group I am assigned. I understand I will have the opportunity to meet with the co investigator for an additional pre-operative session if necessary to review any questions or concerns I may have regardless of group assignment. I understand the co investigator will answer my questions or will refer me to the operating surgeon if necessary.

If assigned to a group receiving guided imagery, I understand I will be given a CD or mp3 file and asked to listen to the imagery track at least twice per day for a minimum of 1-2 weeks prior to surgery and at least once in the pre-operative surgical suite the day of surgery. I understand the imagery track consists of a surgery specific script which guides me through initial breathing exercises, the experience of being in the pre-operative suite while in the hospital the day of surgery, arrival to the operating room, and a brief time at the conclusion of surgery. I understand receipt of the CD/mp3 file is part of the study and does not need to be returned.

If assigned to a group receiving HRV biofeedback training, I understand I will be given a portable hand-held device for home use and asked to practice on the device for 10 minutes at least twice per day for a minimum of 1-2 weeks prior to surgery and at least once the day of surgery. I understand that I will be trained on the use of the emWave during my training session with the co investigator. During this time I will be connected to the equipment and an explanation of the software and it’s measurement of coherence will be explained to me. I understand that I will get a baseline reading of my level of coherence (balance within the autonomic nervous system) and instructed on the software developer’s (Heart Math) three point technique for reaching coherence (including heart focus, breathing, and feeling). I understand I will have the opportunity to practice on the software in order to reach a medium or high level of coherence upon attempt and maintain it for a desired length of time. I understand that the portable device I will be given for home use will provide me the same feedback (level of coherence achieved) by a red, blue or green light coinciding with a low, medium or high level of coherence. I understand if I receive a portable hand-held device I must return it to the researcher upon completion of participation in the study by way of the addressed stamp envelope provided to me.
7. **If you choose to take part in this study, how long will you be expected to take part in the Research?**

I understand I will be asked to complete a series of brief questionnaires and measures at the onset of participation (at Joint Camp), on the day of surgery in the pre-operative suite, on post-operative days 1-3, upon discharge from the hospital, and at the first follow-up physician appointment following suture removal. I understand I will be provided a questionnaire packet and asked to complete the necessary measures at approximately the same time during my in-patient stay in the hospital. I understand completion of questionnaires and related materials will take approximately 20-30 minutes for each occasion.

8. **How many people are expected to take part in this research?**

Approximately 80 research subjects are expected to participate in this study. Participants will all be patients of Jacksonville Orthopaedic Institute.

9. **What are the possible discomforts and risks?**

Great effort will be made to minimize the potential of any risk or harm to you, though none are foreseen. You will receive the education and training of the different treatment groups at Joint Camp to ensure comfort as you will be awaiting surgery to correct or repair some orthopedic ailment. There are no assurances made that participation in this study will impact recovery from surgery. All education materials regarding the procedure and recovery process provided to you have been reviewed by the operating surgeon to ensure no false information is provided. All treatments provided (i.e. guided imagery, HRV biofeedback, and education) have all been shown to benefit medical outcomes. Delivery of these various methods will be in line with previous research that has proven to be successful in order to have the greatest chance of success. There have been no negative outcomes from the use of guided imagery or HRV biofeedback in previous studies that the researchers are aware of.

This study may include risks that are unknown at this time.

Taking part in more than one research study or project may further increase the risks to you. If you are currently enrolled or have recently taken part in another research study, you must tell the person reviewing this consent form with you.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, you may ask questions now or call the Principal Investigator or contact person listed on the front page of this form.
10. What are the possible benefits to you?

You may or may not personally benefit from taking part in this study.

I understand benefits of participation can be expected for all groups. Pre-operative education, guided imagery and biofeedback training have all been found to enhance psychological well-being of patients. Previous research demonstrates that although biofeedback and guided imagery have been found to reduce pain, stress and anxiety, enhance coping, and facilitate recovery from medical procedures, additional education and information regarding the procedure provided prior to the procedure have also been found to decrease stress, anxiety, and improve coping skills. Improved psychological well-being has been linked to improved recovery and enhanced immune function in mind-body medical research, therefore; both are expected for all participants across all four groups.

11. What are the possible benefits to others?

While research has demonstrated the benefits noted above, the purpose of this proposed study is to demonstrate a greater effect when Complimentary and Alternative Medicine practices are used together. Further research in this field such as the proposed study can show greater ease of use of various methods supporting their use and implementation when any individual is required to undergo a medical procedure. The use of these practices has been found to enhance recovery with fewer complications and setbacks. The purpose of this study is to further support this field and contribute to a broader understanding of the benefits with hopes that more practitioners will employ these techniques and others like them into their medical practices.

There is a possibility of no change with regard to the participants’ level of stress, anxiety, and coping ability as well as the possibility of no difference in the normal course of recovery. However, if there is a change, there is a high probability it will be positive due to mind-body medicine research supporting this complimentary "treatment."

12. If you choose to take part in this research study, will it cost you anything?

I understand there will be no costs to me for participation in this research study.

13. Will you receive compensation for taking part in this research study?

As with no cost to me for participation, I understand that I will not receive any compensation for participation in this study.

14. What if you are injured because of the study?

I understand there is minimal risk with participation in this study and there is no anticipated risk of injury.
15. **What other options or treatments are available if you do not want to be in this study?**

Participation in this study is voluntary with the option to withdraw from the study at any time. If you wish to not participate or withdraw, you will continue to receive the high standard of care provided by the surgeon and staff to all patients receiving treatment from the medical office.

16. **Can you withdraw from this research study?**

You are free to stop taking part in this research study at any time without penalty and without losing any benefits to which you are entitled.

If you decide to stop taking part in this research study for any reason, you should contact the co-investigator, Lisa Grossman.

If you have any questions regarding your rights as a research participant, you may call the Baptist Health Institutional Review Board (IRB) office.

17. **If you withdraw from this study, can information about you still be used and/or collected?**

If you stop taking part in this study, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete and protect the validity of the research.

If you decide to stop taking part in the research, you will be asked to return the biofeedback equipment if it was provided to you and/or answer some final questions over the phone if possible.

18. **Can the Principal Investigator withdraw you from this research study?**

You may be withdrawn from the study without your consent for the following reasons:

- You do not qualify to be in the study, because you do not meet the study requirements.
- You need a medical treatment not allowed in this study.
- The investigator decides that continuing in the study would be harmful to you.
- Study treatments have a bad effect on you.
- You are unable to practice the study treatment as directed.
- Some surgical complication that would interfere with continued participation may occur.
- The study is cancelled and/or other administrative reasons.

19. **If you agree to take part in this research study, the Principal Investigator will create, collect, and use private information about you and your health. Once this information is collected, how will it be kept secret (confidential) in order to protect your privacy?**

Only certain people have the legal right to review these research records, and they will protect
the secrecy (confidentiality) of these records as much as the law allows. These people include researchers for this study, certain Baptist Health System officials, the hospital or clinic involved in this research, and the Institutional Review Board(s)/Institutional Review Committee(s) (IRB(s) and IRC(s); an IRB or IRC is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise, your research records will not be released without your permission unless required by law or a court order.

I understand if I choose to participate, all my answers and responses will be kept confidential, identified by subject code and my name will not be used or appear on any of the results. Research records will be stored securely and only the researchers will have access to the records.

I understand that the collection of additional information regarding my surgery (i.e. amount and type of analgesics used and length of time admitted) will be done so by means of the physician’s office staff and the co investigator will not be reviewing or collecting any data from my medical records. I understand that a member of the physician’s office staff will be asked to complete a short form gathering information on specific elements of my surgical procedure (i.e. amount and type of analgesics used and length of time admitted) and nothing else related to my medical history. The form will not include my name and will be coded in the same manner as the questionnaire packet I complete. I understand that none of the data collected for this study will be used or disclosed as part of my health/medical information. Any data generated from participation in this study will solely be used for research purposes.

20. If you agree to take part in this research study, what protected health information about you may be collected, used, and shared with others?

No protected health information will be gathered for participation in this study. Very few specific elements of the surgical procedure regarding the amount of analgesics required, length of hospital stay, and some minimal post-operative subjecting reporting on progress completed by the physician’s office staff will take place and kept in line with coding applied to the participants file.

21. For what study-related purposes will your protected health information be collected, used, and shared with others?

The purpose of this research is to compare the effects of various pre-operative specific guided imagery and HRV biofeedback training as individual treatment techniques, and in combination on psychological variables (specifically anxiety, perceived stress, and coping strategies), and post-operative outcome measures (specifically pain, analgesic use, and length of hospital stay). Data collected about these variables will be gathered through self-reporting questionnaires that will need to be completed at specific times. When you receive your initial research packet, a code will already be assigned to you and be included on all questionnaires/assessments completed through the course of the study.
The only information obtained will be limited to factors associated with immediate care following surgery such as the amount of analgesics required and the number of days you remained inpatient. Any information collected, used, and shared with others to ensure eligibility to take part, to carry out, and to evaluate the results of the research study will be done using the patient code assigned to the file and will only include the surgeon, medical staff affiliated with the physician’s office, those with the Joint Camp and lastly, with the co investigator. Once this information is collected, it becomes part of the research record for this study.

22. Who will be allowed to collect, use, and share with others your protected health information?

Your protected health information may be collected, used, and shared with others as part of your surgical treatment by:

- the study Principal Investigator, Dr. Lancaster and the medical staff associated with Jacksonville Orthopaedic Institute
- other professionals in the Baptist Health System that provide study-related treatment or procedures
- the Baptist Health Institutional Review Board (IRB); an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research

23. Once collected or used, with whom may your protected health information be shared?

No protected health information will be gathered or shared for purposes of this study.

24. If you agree to participate in this research, how long will your protected health information be collected, used, and shared with others?

Information and data collected for the purposes of this study will only be used for the duration of the study which is expected to conclude by Summer 2016. All files made will be destroyed once data is analyzed and results are obtained. Results and data will be published as part of the dissertation process.

25. Why are you being asked to authorize the collection, use and sharing of your protected health information?

Under a new Federal Law, researchers cannot collect, use, or share any of your protected health information for research unless you allow them to by signing this consent and authorization.
26. Are you required to sign this consent and authorization and allow the researchers to collect, use and disclose (give) to others of your protected health information?

No, and your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use, and sharing of your protected health information by signing this consent/authorization.

27. Can you review or copy your protected health information collected, used, or shared with others under this authorization?

You have the right to review and copy your protected health information. However, you may not be allowed to do so until after the study is finished.

28. Is there a risk that your protected health information could be given to others beyond your authorization?

Yes. There is a risk that information received by authorized persons could be shared with others beyond your authorization and not covered by the law.

29. Can you revoke (cancel) your authorization for collection, use, and sharing of your protected health information?

Yes. You can revoke your authorization at any time before, during, or after your participation in the research. If you revoke, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete and protect the validity of the research. You can revoke this authorization by giving a written request with your signature on it to the Principal Investigator.

30. How will the researcher(s) benefit from your being in this study?

In general, presenting research results helps the career of a scientist. Therefore, the researchers may benefit if the results of this study are presented at scientific meetings or published in scientific journals. In addition, the co investigator will be meeting requirements for the completion of a doctoral dissertation and therefore; a PhD.

31. How are the financial interests of the investigator(s) and the other participants in this study associated with this research?

The investigator(s), their family (spouse, dependent, sibling, parent or in-law) and their staff will not profit financially from this study.
32. Signatures

As a representative of this study, I have explained to the participant or the participant's legally authorized representative the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how the participant’s protected health information will be collected, used, and shared with others.

_________________________________________  _____________________
Signature of Person Obtaining Consent and Authorization         Date

You have been informed about this study’s purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used, and shared with others. You will receive a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use, and sharing of your protected health information as described in sections 19 – 29 above. By signing this form, you are not waiving any of your legal rights.

_________________________________________  _____________________
Signature of Person Consenting and Authorizing         Date
APPENDIX D

MEDICAL HISTORY AND DEMOGRAPHICS

PATIENT I.D. ________________________

Instructions: Please complete the following questionnaire.

I. Demographic Information

Gender (circle one):    Male      Female         Age: __________

Marital Status (circle one):  Single     Married     Divorced     Separated     Other

Ethnicity:

____ African American/Black
____ Asian American or Pacific Islander
____ Biracial
____ Caucasian
____ Hispanic/Latino
____ Native American
____ Other (Please Specify): _______________________

Highest level of education:

____ High School or GED
____ Some College
____ AA Degree
____ College Graduate (i.e. B.S., B.A.)
____ Graduate Degree (i.e. M.S., Ph.D., M.D.)
____ Vocational School
____ Other (Please Specify): _______________________

II. Medical and Related Information

Diagnosis and Projected Surgical Procedure:

______________________________________________________________________________

How many days do you anticipate being in the hospital?: ______________________________

What is your anticipated level of pain in the days following your surgery (on a scale of 0 “no pain” to 10 “worst pain imaginable”)?: ______________________________________________

Have you had surgery in the past (circle one):    Yes     No

If you answered yes, please explain (Procedure?, Was it successful?, Were there unanticipated complications?): ________________________________________________________________

_____________________________________________________________________________________

_____________________________________________________________________________________

Do you have a family member or someone close to you that has undergone the same procedure you are scheduled for?    Yes     No
APPENDIX E

STATE-TRAIT ANXIETY INVENTORY (STAI-S)

PATIENT I.D. ________________________
Date: __________________ Time: ________________

Instructions: A number of statements which people have used to describe themselves are given below. Read each statement and circle the number that best indicates how you feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Not at All</th>
<th>Somewhat</th>
<th>Moderately So</th>
<th>Very Much So</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel calm</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. I feel secure</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. I am tense</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. I am regretful</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. I feel at ease</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. I feel upset</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. I am presently worrying over possible misfortunes</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. I feel rested</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. I feel anxious</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10. I feel comfortable</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11. I feel self-confident</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12. I feel nervous</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13. I am jittery</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14. I feel “high strung”</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>15. I am relaxed</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>16. I feel content</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>17. I am worried</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>18. I feel over excited and “rattled”</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>19. I feel joyful</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. I feel pleasant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX F

PERCEIVED STRESS SCALE (PSS)

PATIENT I.D. ________________________
Date: __________________ Time: ________________

Instructions: The questions in this scale ask you about your feelings and thoughts you are experiencing. In each case, you will be asked to indicate by circling how often you felt or thought a certain way in the last day or so.

<table>
<thead>
<tr>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

1. How often have you been upset because of something that happened unexpectedly? ……………………….. 0 1 2 3 4

2. How often have you felt that you were unable to control the important things in your life? ……………. 0 1 2 3 4

3. How often have you felt nervous and “stressed?” …………………………………………………… 0 1 2 3 4

4. How often have you felt confident about your ability to handle your personal problems? …………. 0 1 2 3 4

5. How often have you felt that things were going your way? …………………………………………... 0 1 2 3 4

6. How often have you found that you could not cope with all the things that you had to do? …………… 0 1 2 3 4

7. How often have you been able to control irritations in your life? …………………………………… 0 1 2 3 4

8. How often have you felt that you were on top of things? ……………………………………………… 0 1 2 3 4

9. How often have you been angered because of things that were outside of your control? …………. 0 1 2 3 4

10. How often have you felt difficulties were piling up so high that you could not overcome them? ……….. 0 1 2 3 4
APPENDIX G

COPING STRATEGIES QUESTIONNAIRE (CSQ)

PATIENT I.D. ________________________
Date: __________________ Time: ________________

Instructions: Below is a list of things that patients have reported doing when they feel pain. For each activity, please indicate, using the scale below, how much you engage in that activity when you are experiencing pain. Remember, you can use any point along the scale.

Never
Do That

Sometimes
Do That

Always
Do That

0                1                2                3                4                5                6

When I feel pain…

____ 1. I try to feel distant from the pain, almost as if the pain was in somebody else’s body.
____ 2. I leave the house and do something, such as going to the movies or shopping.
____ 3. I try to think of something pleasant.
____ 4. I don’t think of it as pain but rather as a dull or warm feeling.
____ 5. It is terrible and I feel it is never going to get any better.
____ 6. I tell myself to be brave and carry on despite the pain.
____ 7. I read.
____ 8. I tell myself that I can overcome the pain.
____ 9. I count numbers in my head or run a song through my mind.
____ 10. I just think of it as some other sensation, such as numbness.
____ 11. It is awful and I feel that it overwhelms me.
____ 12. I play mental games with myself to keep my mind off the pain.
____ 13. I feel my life isn’t worth living.
____ 14. I know someday someone will be here to help me and it will go away for awhile.
____ 15. I pray to God it won’t last long.
____ 16. I try not to think of it as my body, but rather as something separate from me.
____ 17. I don’t think about the pain.
____ 18. I try to think about years ahead, what everything will be like after I’ve gotten rid of the pain.
____ 19. I tell myself it doesn’t hurt
____ 20. I tell myself I can’t let the pain stand in the way of what I have to do.
____ 21. I don’t pay any attention to it.
____ 22. I have faith in doctors that someday there will be a cure for my pain.
23. No matter how bad it gets, I know I can handle it.
24. I pretend it is not there.
25. I worry all the time about whether it will end.
26. I replay in my mind the pleasant experiences in the past.
27. I think of people I enjoy doing things with.
28. I pray for the pain to stop.
29. I imagine that the pain is outside of my body.
30. I just go on as if nothing happened.
31. I see it as a challenge and don’t let it bother me.
32. Although it hurts, I just keep on going.
33. I feel I can’t stand it anymore.
34. I try to be around other people.
35. I ignore it.
36. I rely on my faith in God.
37. I feel like I can’t go on.
38. I think of things that I enjoy doing.
39. I do anything to get my mind off the pain.
40. I do something I enjoy, such as watching TV or listening to music.
41. I pretend it is not a part of me.
42. I do something active, like household chores or projects.

Based on all the things you do to cope, or deal with, your pain, on an average day, how much control do you feel you have over it? Please circle the appropriate number. Remember, you can circle any number along the scale.

<table>
<thead>
<tr>
<th>No Control</th>
<th>Some Control</th>
<th>Complete Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Based on all of the things you do to cope, or deal with, your pain, on an average day, how much are you able to decrease it? Please circle the appropriate number. Remember, you can circle any number along the scale.

<table>
<thead>
<tr>
<th>Can’t</th>
<th>Can Somewhat</th>
<th>Can Completely</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX H

VISUAL ANALOGUE SCALE (VAS)

PATIENT I.D. ________________________

Please indicate on the line where your level of pain is at this moment.

Level of pain at Postoperative Day 1 Time: ______________

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
</table>

"No Pain"

If you have a Pain Pump, what number is it set to? ______________

Level of pain at Postoperative Day 2 Time: ______________

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
</table>

"No Pain"

If you have a Pain Pump, what number is it set to? ______________

Level of pain at Postoperative Day 3 (discharge day) Time: ______________

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
</table>

"No Pain"

If you have a Pain Pump, what number is it set to? ______________
APPENDIX I

TRAINING SURVEYS

GUIDED IMAGERY

PATIENT I.D. ________________________

Instructions: Please complete the following survey.

Date: __________________

How many times per day did you listen to the guided imagery recording prior to your surgery date?

_________________________________________________________________________

Did you listen to the guided imagery recording the day of surgery?
Yes  No

Did you listen to the guided imagery recording after surgery?
Yes  No

Did you find it easy to follow along with the guided imagery recording?
Yes  No

Was the image you produced while listening to the recording easy for you to control?
Yes  No

Was the image you produced while listening to the recording vivid in your mind?
Yes  No

Instructions: Please answer the following by circling the number that best describes your response.

My experience with guided imagery influenced my surgical experience:

Negatively      Somewhat Neg.       No Influence   Somewhat Pos.      Positively
1      2           3        4                5

The use of guided imagery influenced the impact of anxiety or negative emotions about my surgery:

Negatively      Somewhat Neg.       No Influence   Somewhat Pos.      Positively
1      2           3        4                5

The amount of time listening to the guided imagery _________ impacted my experience.

Negatively      Somewhat Neg.       No Influence   Somewhat Pos.      Positively
1      2           3        4                5

Using the guided imagery helped me feel __________ empowered and more in control.

Negatively      Somewhat Neg.       No Influence   Somewhat Pos.      Positively
1      2           3        4                5

Was your surgical experience:
Worse than Anticipated  What you Anticipated  Better than Anticipated

Do you believe the use of guided imagery has benefited your overall surgical experience?
Yes  No

Please explain:
_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

Did you do any alternative forms of ‘exercise’ (i.e. yoga, meditation) to help you through the surgical and recovery process?   Yes  No
Please explain:

_____________________________________________________________________________________
_____________________________________________________________________________________

Please indicate on the line where your average level of pain has been since leaving the hospital.

```
0  10
“No Pain” “Worst Pain Imaginable”
```

Please indicate on the line where your level of pain is right now.

```
0  10
“No Pain” “Worst Pain Imaginable”
```

Are you currently taking prescribed medication to control pain?  Yes  No
If yes, please indicate what type of medication it is, how much and how often you have been taking it.

_____________________________________________________________________________________
_____________________________________________________________________________________

What has been the most useful in helping you control pain? (circle those that apply)
Over the counter medication
Prescription pain medication
Ice (cryo-therapy)
Imagery technique
BIOFEEDBACK

PATIENT I.D. ________________________

Instructions: Please complete the following survey.

Date: __________________

How many times per day did you use the portable biofeedback device prior to your surgery date? _______________________________________________________________

How many times per day did you practice the coherence technique you were taught without the use of feedback? ________________________________________________________________

Did you find it easy to achieve medium or high coherence after practice?

Yes  No

Were you motivated to use the biofeedback more than what was prescribed?

Yes  No

Did you use the coherence technique after surgery?

Yes  No

Instructions: Please answer the following by circling the number that best describes your response.

Using the biofeedback and coherence technique _________ influenced my feelings of being empowered and more in control.

Positively  Somewhat Pos.  No Influence  Somewhat Neg.  Negatively

1  2  3  4  5

Practicing on biofeedback influenced my ability to reach coherence:

Positively  Somewhat Pos.  No Influence  Somewhat Neg.  Negatively

1  2  3  4  5

Using the coherence technique after surgery _________ impacted my ability to control my pain.

Positively  Somewhat Pos.  No Influence  Somewhat Neg.  Negatively

1  2  3  4  5

Was your surgical experience:

Worse than Anticipated  What you Anticipated  Better than Anticipated

Do you believe the use of biofeedback has benefited your overall surgical experience?

Yes  No

Please explain:

_____________________________________________________________________________________

_____________________________________________________________________________________ 

Did you do any alternative forms of ‘exercise’ (i.e. yoga, meditation) to help you through the surgical and recovery process?  Yes  No

Please explain:

_____________________________________________________________________________________ 

_____________________________________________________________________________________ 

_____________________________________________________________________________________ 

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________________________________________________________________________________ _____
Please indicate on the line where your average level of pain has been since leaving the hospital.

| | | | | | | | | | | 0 10

“No Pain” “Worst Pain Imaginable”

Please indicate on the line where your level of pain is right now.

| | | | | | | | | | | 0 10

“No Pain” “Worst Pain Imaginable”

Are you currently taking prescribed medication to control pain? Yes No
If yes, please indicate what type of medication it is, how much and how often you have been taking it.

______________________________________________________________________________
______________________________________________________________________________
____________________________________________________________

What has been the most useful in helping you control pain? (circle those that apply)
Over the counter medication
Prescription pain medication
Ice (cryo-therapy)
Biofeedback Technique
GUIDED IMAGERY AND BIOFEEDBACK

PATIENT I.D. ________________________

Instructions: Please complete the following survey.
Date: __________________

How many times per day did you listen to the guided imagery recording prior to your surgery date?
_________________________________________________________________________

Did you listen to the guided imagery recording after surgery?
Yes  No

How many times per day did you use the portable biofeedback device prior to your surgery date?
_________________________________________________________________________

How many times per day did you practice the coherence technique you were taught without the use of feedback?
_________________________________________________________________________

How often did you listen to the guided imagery recording while practicing with the biofeedback?
_________________________________________________________________________

Did you listen to the guided imagery recording the day of surgery?
Yes  No

Did you use the coherence technique after surgery?
Yes  No

Did you find it easy to follow along with the guided imagery recording?
Yes  No

Was the image you produced while listening to the recording easy for you to control?
Yes  No

Was the image you produced while listening to the recording vivid in your mind?
Yes  No

Was the image you produced while listening to the recording more vivid if you were in a medium or high level of coherence?
Yes  No

Did you find it easy to achieve medium or high coherence after practice?
Yes  No

Were you motivated to use the biofeedback more than what was prescribed?
Yes  No

Instructions: Please answer the following by circling the number that best describes your response.

My practice on the biofeedback ________ influenced how well I was able to image.
  Positively       Somewhat Pos.      No Influence       Somewhat Neg.      Negatively
  1               2                 3                          4                           5

The use of guided imagery while in medium or high coherence ________ decreased any anxiety or negative emotions about my surgery.
  Positively       Somewhat Pos.      No Influence       Somewhat Neg.      Negatively
  1               2                 3                          4                           5
Getting into coherence before surgery impacted my anxiety and negative emotions:

<table>
<thead>
<tr>
<th>Positively</th>
<th>Somewhat Pos.</th>
<th>No Influence</th>
<th>Somewhat Neg.</th>
<th>Negatively</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

The combined use of coherence training and the imagery________ influenced my ability to relax.

<table>
<thead>
<tr>
<th>Positively</th>
<th>Somewhat Pos.</th>
<th>No Influence</th>
<th>Somewhat Neg.</th>
<th>Negatively</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Using the coherence technique after surgery _________ impacted my ability to control my pain.

<table>
<thead>
<tr>
<th>Positively</th>
<th>Somewhat Pos.</th>
<th>No Influence</th>
<th>Somewhat Neg.</th>
<th>Negatively</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Was your surgical experience:

Worse than Anticipated  What you Anticipated  Better than Anticipated

Do you believe the use of guided imagery and biofeedback has benefited your overall surgical experience?  Yes  No

Please explain:
_____________________________________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________

Which did you prefer more and/or have the greatest impact?

Guided Imagery  Biofeedback  Combination

Please explain:
_____________________________________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________

Did you do any alternative forms of ‘exercise’ (i.e. yoga, meditation) to help you through the surgical and recovery process?  Yes  No

Please explain:
_____________________________________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________

Please indicate on the line where your average level of pain has been since leaving the hospital.

0  10
“No Pain”  “Worst Pain Imaginable”

Please indicate on the line where your level of pain is right now.

0  10
“No Pain”  “Worst Pain Imaginable”
Are you currently taking prescribed medication to control pain?  Yes  No
If yes, please indicate what type of medication it is, how much and how often you have been taking it.
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
What has been the most useful in helping you control pain? (circle those that apply)
Over the counter medication
Prescription pain medication
Ice (cryo-therapy)
Imagery Technique
Biofeedback Technique
PATIENT I.D. ________________________

Instructions: Please complete the following survey.
Date: __________________

Do you feel the education and overview you received helped you to prepare for your surgery?
Yes  No

Did the information you received make you feel more at ease going into this treatment process?
Yes  No

Did the information you learned help you handle the pain you experienced after surgery?
Yes  No

Was your surgical experience:
Worse than Anticipated  What you Anticipated  Better than Anticipated

Do you believe the education you received pre-operatively has benefited your overall surgical experience?
Yes  No

Please explain:
_____________________________________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________

Did you do any alternative forms of ‘exercise’ (i.e. yoga, meditation) to help you through the surgical and recovery process?
Yes  No

Please explain:
_____________________________________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________

Please indicate on the line where your average level of pain has been since leaving the hospital.

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

“No Pain”  “Worst Pain Imaginable”

Please indicate on the line where your level of pain is right now.

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

“No Pain”  “Worst Pain Imaginable”
Are you currently taking prescribed medication to control pain?  Yes  No
If yes, please indicate what type of medication it is, how much and how often you have been taking it.
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
What has been the most useful in helping you control pain? (circle those that apply)
Over the counter medication
Prescription pain medication
Ice (cryo-therapy)
APPENDIX J

MANIPULATION CHECKS

GUIDED IMAGERY

PATIENT I.D. ________________________
Date: __________________ Time: ________________

Instructions: Please rate your experience and use of the guided imagery by circling the number that best corresponds.

How clear or vivid is the image you produced while listening to the guided imagery CD?

Not at all             Somewhat         Very much
0  1  2  3  4  5  6  7  8  9  10

How much control did you feel you had over the image you created?

Not at all             Somewhat         Very much
0  1  2  3  4  5  6  7  8  9  10

How engaged did you feel within the image while listening to the CD?

Not at all             Somewhat         Very much
0  1  2  3  4  5  6  7  8  9  10

To what degree do you feel you were able to follow the training protocol and listen to the guided imagery CD for the recommended duration preoperatively? (10 minutes, 2x/day, 1-2 weeks before surgery)

Not at all             Somewhat         Very much
0  1  2  3  4  5  6  7  8  9  10
BIOFEEDBACK

PATIENT I.D. _________________________
Date: __________________ Time: ________________

Instructions: Please rate your experience and use of the biofeedback by circling the number that best corresponds.

Are you able to reach coherence (green) on command as indicated on the hand-held portable biofeedback device?

Not at all 0 1 2 3 4 5 6 7 8 9 10
Somewhat
Very much

How much control did you feel you had while in coherence?

Not at all 0 1 2 3 4 5 6 7 8 9 10
Somewhat
Very much

How effective was achieving coherence in preparing for your surgery?

Not at all 0 1 2 3 4 5 6 7 8 9 10
Somewhat
Very much

To what degree do you feel you were able to follow the training protocol and practice with the portable biofeedback unit for the recommended duration preoperatively? (10 minutes, 2x/day, 1-2 weeks before surgery)

Not at all 0 1 2 3 4 5 6 7 8 9 10
Somewhat
Very much
GUIDED IMAGERY AND BIOFEEDBACK

PATIENT I.D. ________________________
Date: __________________ Time: ________________

Instructions: Please rate your experience and use of the guided imagery and biofeedback by circling the number that best corresponds.

How clear or vivid is the image you produced while listening to the guided imagery CD?

Not at all     Somewhat     Very much
0    1    2    3    4    5    6    7    8    9    10

How much control did you feel you had over the image you created?

Not at all     Somewhat     Very much
0    1    2    3    4    5    6    7    8    9    10

How engaged did you feel within the image while listening to the CD?

Not at all     Somewhat     Very much
0    1    2    3    4    5    6    7    8    9    10

To what degree do you feel you were able to follow the training protocol and listen to the guided imagery CD while on the portable biofeedback device for the recommended duration preoperatively? (10 minutes, 2x/day, 1-2 weeks before surgery)

Not at all     Somewhat     Very much
0    1    2    3    4    5    6    7    8    9    10

Are you able to reach coherence (green) on command as indicated on the hand-held portable biofeedback device?

Not at all     Somewhat     Very much
0    1    2    3    4    5    6    7    8    9    10

How much control did you feel you had while in coherence?

Not at all     Somewhat     Very much
0    1    2    3    4    5    6    7    8    9    10

How effective was achieving coherence while listening to the guided imagery CD in preparing for your surgery?

Not at all     Somewhat     Very much
0    1    2    3    4    5    6    7    8    9    10
APPENDIX K

GUIDED IMAGERY SCRIPT

Day of Surgery:
Sit back in a relaxed position and close your eyes. Begin to inhale slowly through your nose and gently exhale through your mouth. As you continue to breathe slowly and controlled, allow your body to lie where it is. Focus inward as your lungs slowly fill with air and slowly exhale. Now connect to your heart, become aware of it, feel it beating in synchrony with your breathing. Continue to stay focused inward, feeling a clear mind and relaxed body.

Now, take yourself to the morning of your surgery…. you wake up feeling rested and prepared for the day ahead. You have been waiting for this day and now that it is here, you have a sense of calm come over you. Today you will undergo surgery to help you feel better and make your body stronger. To rebuild your __________ joint with better parts, free from arthritis. As you make your way to the hospital, you maintain a sense of calm and feel positive about the days ahead. You have prepared yourself mentally and emotionally for this surgery, making you stronger and resilient and positive. Now… take yourself there, you are in the hospital in the pre-operative suite waiting to go into the operating room. You are lying on the gurney with a few blankets draped across you to keep you comfortable and warm, there is an IV in your arm, and there are some machines around you monitoring your vitals. You hear the sounds of machines and people around, nurses, doctors and other patients waiting to go into surgery. You take in the distinct hospital smells, and feel the cotton gown on your body. As you lye waiting to go into the operating room, you close your eyes and begin to take slow and controlled deep breaths in and slow and controlled exhalations out. You feel calm and in control of you, the way you feel inside. With every breath, comes more and more confidence….confidence in the surgery, confidence in the doctors and nurses, confidence in you. You know you can make your mind, body, and spirit stronger, helping you to heal faster and stronger. As surgery time comes you are getting wheeled into the operating room. As you arrive and get moved onto the operating table, you continue to breathe nice and easy. You see people around wearing surgical masks, hear the sounds of the machines, smell the sterile environment. While the surgical team preps you for surgery, attaching monitors to you, you lie on the table, staying calm and confident. Once they are ready, you begin getting the anesthesia. While the mask is on your face you slowly breathe in, breathe in strength, positivity, control, and confidence. Take it nice and easy.

Continue to breathe and keep a calm mind, relaxed body…..

After Surgery:
Now, you have made it through surgery. Your __________ joint has been repaired ….. new hardware has been put into your joint to give it support, make you sturdy and help you become stronger. Slowly and deeply breathe in and exhale out. As you exhale, breathe out any discomfort or pain you feel and as you breathe in, image the warm air filling your lungs. As you begin to focus inward, you send that warmth down your body from your lungs. You feel the warmth travel down slowly as you continue to breathe deeply. Feel the warmth travel through your
stomach….and down, down. The warmth brings power and nutrients to heal your surgical wounds. The tissue that has been operated on is already healing; you are able to bring strength and energy to your ____________ joint and surrounding tissues to make it better. With every exhale, you breathe out any pain or discomfort. As you continue to breathe out, any pain and discomfort you may have felt gets less, and less, and less….it continue to fade until you are unaware of it. As you lie there, you feel the warmth throughout your body. This warmth helps rebuild tissues and strengthens your muscles. As you lie there, you feel a sense of calm and control, knowing you are in control, making your body heal. Your mind is stronger than ever and you are stronger than your injuries. You have powered the healing process. Continue to breathe in slowly and controlled….exhale any stress, anxiety or pain. Feel only positivity and strength and rid yourself of anything negative. You can make that happen and you do. You are stronger than your injuries…..
APPENDIX L

PATIENT PARTICIPATION NOTICE

RESEARCH STUDY PARTICIPATION OPPORTUNITY

Dear Patient:

There is currently an opportunity for patients requiring orthopaedic surgery to participate in a research study. The purpose of this study is to investigate the effects of pre-operative guided imagery (mental rehearsal) and biofeedback training (breathing and relaxation techniques) on psychological variables (i.e. stress) and post-operative measures such as the level of pain reported by patients. Participation is open to those requiring joint replacement surgery.

Participation in the study is completely voluntary and involves no extra medical care or compensation. If interested, participation involves meeting with the researcher prior to surgery (at joint camp or individually) during which time, the researcher will provide one of four possible interventions. Interventions include: guided imagery, biofeedback training, guided imagery and biofeedback training and lastly, education and review of your upcoming procedure and the anticipated recovery process. All interventions carry possible benefits and aid in preparedness for your upcoming surgery. In addition to meeting with the researcher prior to your scheduled surgery date, you may be asked to exercise the various techniques instructed in the weeks leading up to the surgery date. Furthermore, all participants will be asked to complete a few questionnaires and measures, some of which will require completion while admitted in the hospital.

You may be contacted by the researcher once surgery is scheduled to see if you would like to participate. If you would like further information regarding the study or would like to participate, you may contact the primary investigator, Lisa Grossman at.

The doctors at JOI including your orthopaedic surgeon recommend your participation in the study for the added benefits you will receive at NO expense to you or your insurance company.

Thank you for your time and consideration.

Lisa Grossman, M.Ed., ATC, BCB
Doctoral Candidate, Sport Psychology
Florida State University
REFERENCES


Lisa Grossman was born in Miami, FL on August 7, 1978. She grew up with her two brothers and attended Miami Palmetto Senior High School where she spent 3 years as a student athletic trainer. She graduated with her Bachelor of Science degree in Exercise and Sports Science from Florida International University in 2001. Following graduation, Lisa became a Certified Athletic Trainer by completing the National Athletic Trainers Association Board of Certification (NATABOC) exam. Her interest in the psychological aspects of injury and recovery led her to Temple University where she earned her Master of Education degree in Kinesiology with a specialization in Sports Psychology in 2003. While in school, Lisa served as a graduate assistant for Temple University Hospital’s Department of Orthopaedics where she assisted patients in physical therapy and provided sports medicine coverage for local teams. She began her doctoral degree at FSU in 2003 during which, she served as a Volunteer Assistant Coach with FSU’s Track and Field Team providing sport psychology services, instructed a section of the undergraduate Sport Psychology class, served as a graduate assistant for FSU’s Athletic Department in the Office of Student Services, and was the Head Athletic Trainer at John Paul II Catholic High School while also teaching the Care and Prevention of Injuries class. While still pursuing her degree, Lisa left FSU in 2007 when she had the opportunity to work for APEX Performance as a Program Director. She spent 5 years in Charlotte providing peak performance training to a range of clients including government agencies, military personnel, athletes, and corporate executives. While working with APEX, Lisa became Board Certified in Biofeedback by the Biofeedback Certification International Alliance (BCIA). In 2007, she moved to Jacksonville, FL to serve as Director of the APEX Peak Performance Center for the Wounded Warrior Project’s TRACK Program where she continues to provide Wounded Warriors a comprehensive and integrated approach toward helping them realize their goals in work, school, and life.