THE EFFECT OF LOW LEVEL LASER THERAPYAND EXERCISE ON PERCEIVED PAIN AND ACTIVITIES OF DAILY LIVING IN LOW BACK PAIN PATIENTS

by

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The purpose of this study was to investigate the effect of LLLT on pain reduction and daily living activities among low back pain patients when compared to traditional treatment lumbar anaerobic mat exercises. A secondary focus was to establish the extent to which pain and daily living activities change when receiving LLLT and traditional lumbar anaerobic mat exercises as compared to laser alone. The sample included 43 patients with varied low back pathology, 34 females and 10 males. A 3 X 2 repeated measures MANOVA showed that participants did not differ across treatment groups (laser, laser and exercise, and laser only) on the factors of pain and function as measured by the McGill Pain Questionnaire and the Oswestry Low Back Pain Disability Questionnaire $F(4, 78) = 2.18, p > .05$. However, all groups improved significantly from pretest to posttest score on both outcome measures of pain and function $F(2, 39) = 33.82$, $p < .001$. These data support the findings that when patients are unable to exercise, LLLT is an appropriate alternative for pain reduction and increased daily function for individuals suffering from low back pain.

DEDICATION

I dedicate this dissertation to my father who died during the time in which I was writing this document. Ken Newman was a wonderful loving father, who taught me how to reach for the sky. He always supported me in my endeavors and I know he would be extremely proud of my accomplishment.

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CHAPTER 1

Introduction

Back pain is prevalent in the U.S. due to various causes such as muscular strain, postural stress, ligament sprains and disc overload. Causes of low back pain (LBP) may be progressive or traumatic. Progressive injuries to the disc or joint caused by microtrauma may predispose individuals to degenerative disc disease (DDD), spinal stenosis, spondylolysis, spondylolithesis, vertebral stress fractures, sacroiliac dysfunction, and facet arthrosis. Other predispositions to these diseases are related to scoliosis, kyphosis, lordosis, and/or chronic improper posture, not to mention genetic conditions like spina bifida and rheumatoid arthritis. Additional strain to the low back may also be related to obesity, chronic hamstring tightness, and improper muscle activation. Other causes for low back pain include traumatic injuries due to accidents or as a result of improper lifting techniques, weight training, motor vehicle accidents (MVA), and an unexpected fall or forceful collision, which is prevalent in sports (Starkey & Ryan, 2002).

There is currently little consensus among medical professionals on the proper treatment of low back pain. As Smith, McMurray, and Disler (2002) state, "this is a problem of enormous clinical and economic import, and hopefully, with the push for continued research characterized by scientific rigour, clearer recommendations will soon be available" (p. 9). Chibnall, Dabney, and Tait (2000) claim that management of low back pain may be idiosyncratic, resulting in poor patient care. The lack of a systematic

treatment plans hinders a clinician's ability to choose the most appropriate care for patients.

The effectiveness of various back pain treatments for patients remains unclear. Maluf, Sahrmann, and Van Dillen (2000), for instance, support the use of moderate physical activity that emphasizes restriction of specific motions to manage pain. Others, such as Cohen and Rainville (2002) and Alaranta, Rytokodki, and Rissanen (1994) advocate more aggressive forms of exercise, such as aerobic training, to overcome chronic low back pain. Moseley (2004) advocates a multidimensional approach which includes changing pain cognitions for those patients who have an unhealthy fear of pain related to activity. Another viable option for back pain patients is consistent aerobic activity which also reduces back pain (Mannion, 2000). Current conservative treatments, defined as those treatments not including surgery, consist of medication, chiropractic manipulations, joint mobilizations, pain-free walking, massage, traction, ultrasound, moist heat, and/or mat exercises. Nonconservative treatment consists of numerous surgical options.

In their review of literature, Smith et al. (2002) reviewed treatment options which included bed rest, nonsteroidal anti-inflammatory drugs (NSAIDS), traction, spinal manipulation, exercise, and education related to lifting and corrective posture. They concluded that bed rest as a treatment for acute LBP was ineffective and may actually promote increased back pain. NSAIDs appeared to have positive short-term benefits for relieving LBP, however, these results varied when different statistical models were used. The integrity of these results, therefore, may be questionable. Traction as a treatment for low back pain has not been recommended for many years and continues to lack efficacy.

Spinal manipulation is also not recommended as a treatment for low back pain, however, Smith et al. acknowledged more research is needed in this area. Exercise is less effective for relief of acute back pain than for treatment of chronic back pain. Additionally, the concept known as "back school," or educating patients about proper back lifting technique, and proper back postural for daily activities, showed contradictory results. Smith et al. could not recommend any of the LBP treatments based on their review of this literature due to inconclusive evidence on most treatment types. The authors concluded that more vigorous research is needed in the area of LBP treatment.

Management of low back pain by health care providers has not been established in evidence-based research. The difficulty of measuring the effectiveness of treatments and the lack of studies have forced clinicians to provide treatment based on their own personal experiences that provided positive outcomes. Due to the lack of double blind, randomized control studies on low back pain management many current treatments are based on the physician's own health care philosophy. It is surprising that more research has not been conducted in this area. Two reasons for limited research might be the complexity of low back pain and the paucity of funding opportunities for clinical trials. Low back pain is complex due to the variety of diseases and injuries that may cause similar signs and symptoms.

Alternatives to expensive and time consuming double blind, randomized control studies include research that addresses the need for better clarification of injury type. For example, Alderink (2000) advocates that a treatment regimen for back pain should consist of a diagnostic classification system which would provide more effective treatments based on patients' signs and symptoms. Currently, classification for non-

specific low back pain (NSLBP) is apparently non-existent by primary care physicians (Kent & Keating, 2005). Aligning the cause and diagnosis to dictate the treatment is difficult because diagnosing the factors that cause an individuals' low back pain is multidimensional. Physicians currently use diagnostic techniques, such as plain radiography (x-rays), magnetic resonance imaging (MRI), single-photon emission computerized tomography (SPECT), diagnostic blocks, and discography (Saal, 2002) to determine the extent and diagnosis of different injury types. The generic diagnosis of "non-specific low back pain" will probably continue to hinder the success of low back pain management.

One modality in the U.S. that has received increased attention in recent years for treatment of musculoskeletal conditions is low level laser therapy (LLLT). Theories that help explain the effectiveness of this modality include increased Adenosine Triphospate (ATP) production (Passarella, 1989), muscle cell proliferation (Medrado, Pugliese, Reis, & Andrade, 2003; Shefer, Orion, Irintchev, Wernig, & Halevy, 2001), oxygen consumption at the cellular level (Yu, Naim, McGowan, Ippolito, & Lanzafame, 1997), increase endorphins (Yamamoto, Ozaki, Iguchi, & Kinoshita, 1988), changes in serotonin (Mizokami et al., 1993), nerve repair (Assia, Rosner, Belkin, Solomon, & Schwartz, 1989), and bone cell resorption and formation around an injury site without changing the bone structure (Nicolau et al., 2003). Additionally, attenuation of reactive oxygen species production by neutrophils (Fujimaki et al., 2003) may play a role in reduction of inflammation (see Chapter II for more details).

Three conditions with similar nervous tissue pathology as low back pain that have shown promising results from low level laser therapy are carpal tunnel syndrome

(Naeser, Hanhn, Lieberman, & Branco, 2002), peripheral nerve regeneration (Geuna, 2005) and diabetic neuropathy (Fiszerman, 2005). In addition to nervous tissue, studies (Fukuuchi, Suzuki, & Inoue, 1998; Mizokami, et al., 1993; Shiroto, Ono, & Ohshiro, 1989) that have used LLLT for pain reduction also have a theoretical basis for alleviation of LBP. Positive nerve studies and pain studies provide evidence to support the theoretical application of LLLT on LBP patients.

The effect of LLLT on low back pain patients has been equivocal in previous research. Researchers have found that LLLT reduced pain for patients with low back pain (Basford, Sheffield, & Harmsen, 1999; Mehdrad, Djavid, Hasanzadeh, Sotoodehmanesh, & Ghasemi, 2005; Soriano & Rios; 1998). However, Klein and Eek, (1990) and Gur et al. (2003) found that LLLT was no better than an exercise treatment for those patients experiencing low back pain. More research is needed to establish LLLT efficacy on LBP patients.

Statement of the Problem

The equivocal results of past studies on the effectiveness of treating low back pain patients have resulted in more extensive use of complementary and alternative medicine (CAM). A recent analysis of 100,000 health insurance claims indicated that 15% of all outpatient visits were due to low back pain, with 43% of payments delegated to CAM (Lind et al., 2005). CAM treatments include chiropractic, acupunture, and massage therapy. Although not considered a CAM treatment, pain management is another treatment approach in response to chronic LBP. A pain management study (Rome et al., 2004) investigated the effects of using a cognitive-behavioral model on pain medication usage. More than one-third (i.e., 135 of 356) of the patients were taking opioids daily

during admission at the Mayo Comprehensive Pain Rehabilitation Center. All but three patients discontinued opioid treatment during the 12-month intervention. The researchers concluded that the cognitive-behavioral model that incorporated an opioid withdrawal allowed patients with severe pain to improve their physical and emotional health. While this study demonstrated that overall health could be improved for chronic pain patients, the results neglected to provide further insight into LBP treatment. Therefore, it appears when conventional, nonconventional, CAM, and pain management do not alleviate low back pain many patients choose lumbar fusion.

For patients who pursue a lumbar fusion to alleviate LBP, success, defined as less pain, is limited (Turner, Ersek, & Herron, 1992; DeBerard, Masters, Colledge, Schleusener, & Schlegel 2001). However, the lack of success in decreasing pain for patients who chose lumbar fusions has not hindered the rate of surgeries because the fusion incidence have doubled, a relative increase of 220% from 1990 to 2001 (Deyo, Gray, Kreuter, Mirza, & Martin, 2005). It may be speculated that the need for lumbar fusions has increased as a function of increased severity of low back injuries. A review of literature of 47 published studies examining spinal fusion between 1966 and 1991 indicated that the percentage of patients with "satisfactory" results varied from 16% to 95% (Turner et al., 1992). More recently DeBerard, et al. (2001) conducted a telephone outcomes survey among 185 Utah's Workers' Compensation patients who received lumbar fusions indicated that while radiographically the fusion was considered successful (74%), the measurement of pain relief success was limited. Within this radiographically successful group, 24% of the population required a reoperation. Numerous patients (25%) that elected lumbar fusion were ultimately considered disabled. Many of the patients

(41%) reported no change in pain or a worsened quality of life, even after the second operation. These results are difficult to interpret because the injury classification was not provided. However, other researchers have investigated injury type in relation to spinal fusion. In one study, Deyo and Nachemson (2004) concluded that the efficacy of spinal fusion is limited when performed on degenerative disc disease patients. Therefore more research is needed to support lumbar fusion efficacy.

As reported by the American Pain Foundation (2007), the United States annual expense for chronic pain, including healthcare costs, lost income, and lost productivity is approximately $100 billion. More specifically, a spinal fusion is expensive (approximately $34,000 hospital bill, excluding professional fees) with limited success (Deyo, Nachemson, & Mirza, 2004). Brox et al. (2004) recently questioned the use of lumbar surgery when they compared cognitive intervention and exercising groups whom had chronic LBP or DDD to a lumbar fusion group and found non-significant differences on numerous outcome measures (e.g. back pain, use of analgesics, emotional distress, life satisfaction, and return to work) between groups. The cost of surgery as compared to exercise was considerably more without added benefits. The lack of surgical success, surgical complications, and the extent of repeat operations has made the consumers apprehensive to choose surgery, partly related to the costs associated with lumbar fusion. For example, the Lind et al (2005) study indicated that 100,000 claims for LBP cost $52 million. The additional cost associated with pain management clinics exacerbate overall rehabilitation health care costs. An alternative treatment for low back pain is needed.

The debilitating effects of low back pain can be devastating with consequences spreading throughout the entire society. Some adults will retire early from work because

of chronic LBP (Pranskey, Benjamin & Savageau, 2005). The Nonfatal Injury Report by the National Institute of Safety and Health (NIOSH) in 1999 concluded that of the approximately 800,000 sprain, strain, and tears in musculoskeletal injuries in American workers over half of the cases missed six or more days of work. Some chronic LBP patients will experience fear of movement, depression, anxiety, and grief, therefore researchers have analyzed the relationship between cognitive-bias and utilization of health care services (Pincus, 2001). Other researchers have investigated interventions to address some of these cognitive-behavioral treatments (Smeets, Vlaeyen, Kester, & Knottnerus, 2006).

Improving the management of LBP could elevate the quality of life, possibly decrease the current health care economic burden, and decrease rate of disability attributed to chronic low back pain. Laser treatment may provide this alternative treatment. The current study has examined the efficacy of laser treatment for low back pain.

It is plausible to surmise that LLLT has gained popularity in recent years. Newspapers and magazine articles (e.g. Wall Street Journal, 2006 & NATA News, 2003) have been published to define the role of LLLT as a rehabilitative device. New "Laser" centers sponsored by Chiropractors are beginning to open in response to the increased use of LLLT (Fahmy, 2004). Laser therapy is currently popular among chiropractors and athletic trainers (e.g. NATA news, March 2003 featured an ATC using light therapy on a patient for its magazine cover). These two professions (athletic training and chiropractic) may be more receptive to using the modality because insurance reimbursement doesn't have as big of an impact on these professions as it does for formal physical therapy. One

of the primary uses for LLLT in the chiropractic profession is on the LBP patient. Although laser popularity is advancing, the research available to support laser efficacy in LBP is limited.

Purpose of the Study

The primary purpose of this study was to investigate the effects of LLLT on reduction of perceived pain in the low back and increased function related to daily living among patients, as compared to a placebo LLLT and traditional lumbar mat exercises. A secondary focus of this study was to determine the effect of receiving LLLT and traditional lumbar mat exercises, as compared to laser therapy alone on perceived pain and increased function related to daily living.

Significance of the Problem

Low back pain (LBP) is a common occurrence in adults in the U.S. with an incidence rate of 80% (Anderson, 1999). Common low back pain conditions include degenerative disc disease, sciatica, postural dysfunction, and disc prolapsed. Traditional approaches for treating low back pain include McKenzie lumbar exercises, manipulation, mobilization, and Swiss ball stabilization exercises. Common electrophysical modalities used to treat LBP include interferential electrical stimulation, ultrasound, pulsed shortwave diathermy, and transcutaneous electrical nerve stimulation. According to Gray (2000), however, "many of the approaches used by physiotherapists are supported only by fragmentary and unconvincing evidence" (p. 199). Subsequently, the need for high controlled clinical trials on treatment for LBP is a current problem in health care.

One technique that has been successful in treating pain associated with trigger points (Simunovic, 1996), carpal tunnel syndrome (Naser et al., 2002), elbow tendonitis

(Simunovic, Trobonjaca, & Trobonjaca, 1998) and chronic low back pain (Soriano & Rios, 1998) is LLLT. LLLT may provide an additional treatment option for physical therapists and athletic trainers treating LBP.

Although selected countries are currently using LLLT for many health conditions (Basford, 1995), the U.S. has neglected to acknowledge laser efficacy. Before the U.S. Federal Drug and Administration (FDA) will allow the private sector to market their product as an effective treatment for low back pain, more research is needed to establish the efficacy of LLLT. The FDA's specific equipment endorsement is the first step in product efficacy, which should eventually influence payment approval for LLLT by insurance companies. FDA has approved some laser units as effective modalities for treating carpal tunnel syndrome. These companies received an FDA approval, which corresponded to the coding of "NHN". The NHN code represents a nonheating laser that has demonstrated positive physiological change in human tissues. However, only 23 laser devices are listed as NHN while 110 other manufacturers are listed under a product code as "ILY" or infrared lamp as indicated on FDA device verification website on December, 30, 2006 (http://www.fda.gov/cdrh/). The ILY product code is defined by its intended uses, which include:

> "... intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle."

To date, the insurance industry has a low reimbursement rate for the laser modality, regardless of FDA product code assignment, as described by clinicians in the field of rehabilitation (Nevil & Coulter, 2006). Consequently, many rehabilitation facilities do not provide laser equipment as standard treatment. Based on these issues, more research is needed to examine the efficacy of LLLT to treat low back pain.

Delimitations of the Study

The following delimitations are acknowledged in this study.

1. The participants consisted of 42 patients from the southeast U.S. with selected types of back injuries. Therefore, generalizations of the results are limited to these low back pain patients and their respective conditions. In addition, external validity could be diminished due to the relatively low number of participants, type of back pain treated, and regional location of this study.

2. Participants completed an orthopedist diagnosis in the lumbar area of one of the following: strain/sprain/pain, degenerative disc disease, disc herniation/prolapse, sciatica, or trigger points. Additional conditions such as cancer, stress fractures, or spondylolithesis are beyond the scope of this research.

3. Only participants without discectomy, laminectomy, and lumbar fusion history were permitted to participate in the study to decrease the number of control variables.

4. Because severe chronic pain patients may have altered pain receptors and suffer from psychological factors associated with this condition, individuals on morphine pumps and/or currently being treated by a pain management physician were excluded from this study to eliminate mediating factors that may compromise the integrity of these data.

5. The data were collected in two facilities that were conveniently located close to participants' physician offices or homes. Allowing the participants to pick the closest location to their homes or work allowed participants decreased travel time. The dual location design was used to promote patient compliance. Data collectors at each facility were blind to the treatment to decrease experimenter bias.

Limitations of the Study

The following limitations are acknowledged in this study:

1. Research has been limited that lends support to the efficacy of the Nd:YAG (neodymium doped, yittrium-aluminum-garnet) produced by Therapeutic Laser, Inc. to reduce low back pain. The FDA currently has approved use of this laser treatment for temporary relief of "minor" muscle and joint pain and stiffness, muscle spasm, the temporary increase in local blood circulation, and promoting muscle relaxation, each of which could reduce low back pain. This equipment has an ILY FDA classification.

2. One certified athletic trainer and one physical therapist administered all treatments. This may have affected results by allowing potential experimenter effects. Uncontrolled experimenter bias may be related to patient-clinician demeanor as the patient-clinician relationship grows during the duration of the treatment. Experimenter differences in administering the exercise protocols may also affect the results. However, statistical analysis was performed on this extraneous variable and no experimenter effects were detected (see Results section).

3. The exercise protocol was specific for each patient's physical ability and pain level, therefore, some variability in treatment was related to the clinician's decision based on the patient's symptoms. The clinicians decided when to increase or decrease exercise

regiment based on patients reporting their sleep comfort, daily pain levels, previous pain levels the day after treatment, medication usage, and daily function.

4. Participants may have responded differently to each treatment due to variation in their attitude concerning laser and exercise efficacy. Some patients have a preconceived notion that the laser is effective, which may have lead to an expectancy effect. This expectancy effect can cause patients to get better regardless of intervention type. Patients varied in the duration of back pain which may have hindered the belief that their pain would respond to any treatment.

4. Gender differences in perceived pain, not controlled in this study due to low sample size, may have existed among participants. Men may have been less prone than women to acknowledge the extent of their pain. This may have resulted in a decreased change in perceived pain scores.

5. Physician diagnosis and severity of the condition may not have been identical among the referring physicians. The severity of conditions was ranked as mild, moderate, or severe. It is likely that individuals differ in their understanding of these classifications. In addition, some injuries are not always apparent in the first evaluation, and physicians differ on their tendency to use diagnostic tests to confirm different types of low back pain. Therefore, the use of stratified randomization assignments of patients to each group may have been compromised in this study.

6. Because of the limited regional participant selection, results may not be generalized beyond the data collection region of eastern Tennessee.

Assumptions

The following assumptions were acknowledged in this study:

1. Patients responses to items on the McGill's Pain Questionnaire MPQ (SF-MPQ, Melzak 1975) and Oswestry Low Back Pain Disability Questionnaire (Roland & Fairbank, 2000) were honest.

2. The Nd:YAG (neodymium doped, yittrium-aluminum-garnet) produced by Therapeutic Laser emitted infrared light at 1,064 nanometers, as required.

3. The diode driven solid state laser was assumed to be a valid means of effectively producing the desired output of laser irradiation. Calibration was performed prior to each use of the equipment.

4. Physicians accurately diagnosed low back conditions of their respective patients who engaged in the study.

5. Participants were blinded to their treatment. Each participant was informed that not all groups would receive the actual laser treatment. The consent form indicated that the purpose of the study was to examine if exercise, laser treatment, or the combination of laser treatment and exercise would have a positive impact on patients. In order to examine this hypothesis, however, some of the lasers were inactive to determine if the placebo effect would influence the patients' outcomes. Participant interaction during the research data collection procedure was minimized. Thus, it is assumed that participants were not aware of the condition to which they are exposed. A manipulation check was established at the end of the study to validate this assumption. Each patient was asked if they thought they received a "real" laser treatment (see Discussion section).

6. Patients experienced sufficient pain to receive noticeable pain relief due to the laser treatment.

Research Hypotheses

Within the limitations of this study, the following research hypotheses were tested using an alpha equal to .05 level of significance:

1. When controlling for gender, age, amount of medication, type of condition, amount of physical activity, duration of pain, and time of last epidural, patients who received low level laser therapy would score lower on the McGill Pain Survey at posttest than patients who received traditional (mat) exercises.

2. When controlling for gender, age, amount of medication, type of condition, amount of physical activity, duration of pain, and time of last epidural, patients who received low level laser therapy and traditional (mat) exercises would score lower on the McGill Pain Survey at posttest than patients who received the laser treatment only.

3. When controlling for gender, age, amount of medication, type of condition, amount of physical activity, duration of pain, and time of last epidural, patients who received low level laser therapy would score lower on the Oswestry Low Back Pain Disability Questionnaire at posttest than patients who received the traditional (mat) exercises.

4. When controlling for gender, age, amount of medication, type of condition, amount of physical activity, duration of pain, and time of last epidural, patients who received low level laser therapy and traditional (mat) exercises would score lower on the Oswestry Low Back Pain Disability Questionnaire at posttest than patients who received the laser treatment only.

Operational Definitions

The following operational definitions were used in this study:

Perceived Pain: The degree of discomfort was represented by the McGill Pain Questionnaire Score. The scores ranged from 0% – 100%, with zero representing no pain and 100% representing maximal pain.

Activities of Daily Living (ADL): Tasks performed in a typical day that enabled participants to have independent living was measured by obtaining a score from the Oswestry Low Back Pain Disability Questionnaire. The key concepts related to low back ADL's are personal care, lifting, walking, sitting, standing, sleeping, and traveling. The scores range from 0 to 100%, with zero representing no disability and 100% representing total disability (crippled or bed bound).

Mat Exercises is defined as traditional exercises performed on an exam table or a large exercise table. Exercise repetitions were dependent on patient tolerance. The exercises were used to improve muscle guarding, tautness, dominance, and imbalances through flexibility, strength, endurance, and coordination training of the abdominal, low back, and hip muscles which contribute to low back pain.

Low Level Laser Treatment (LLLT) is defined as a medical treatment with coherent light applied to various points on the body (acupuncture points, muscle trigger points, areas of inflammation). All light-induced biological effects depend on the parameters including wavelength, dose, intensity, irradiation time, and continuous or pulsed waves.

Duration of Pain is a term that consists of subjective information about the length of time (months) each participant has experienced low back pain.

Severity of Condition was defined by physicians who ranked their diagnoses from 1 to 3, in which 1 represented "mild severity", 2 represented "moderate severity" and 3 represented "highly severe" low back pain relative to their diagnosis.

Type of Condition was defined by physicians who diagnosed patients with a sprain, strain, mechanical pain, or sciatic pain not associated with a disc injury were lumped together as similar soft tissue conditions. The second condition was degenerative disc disease (e.g., disc collapse), which physicians primarily diagnosed through use of a magnetic imaging resonance. The third condition included diagnoses of disc bulge or herniation, which includes protrusion of the disc onto the nerve root.

Amount of medication is any ingested substances classified as an over the counter or prescription medication to alleviate pain and inflammation. This information was gathered at the beginning and, again, at the end of the study. Before the study, each patient was interviewed by the principle investigator and answered questions concerning the type and amount of medications, which they were currently consuming for their low back pain. The drug name, dosage, and daily intake were documented on the approved enrollment forms. At the end of the study as part of the final questionnaire, the participants were asked to describe any change in prescription medication.

CHAPTER II

REVIEW OF RELATED LITERATURE

Introduction

In recent years, there has been controversy about the most appropriate treatment for low back pain (Gray, 2000). Low back pain (LBP) is treated with numerous modalities such as moist heat packs, ultrasound, diathermy, biofeedback, traction, and transcutaneous electrical nerve stimulation (TENS) (Starkey, 2004). Additionally, treatments include exercise, massage, manipulation (Smith et al., 2002), acupuncture, and various types of oral and injectible medications. For example, Mannion's research (2000) found that aerobic training markedly reduces low back pain. However, one treatment for LBP has not been irrevocably more effective than another. Few clinical guidelines are available because of limited research needed to assess LBP treatments (Arnau et al., 2006; Smith et al., 2002).

The research question consists of determining the effectiveness of low level laser treatment for low back pain. The focus of this review is two-fold. This review of literature examines previous research related to low back pain treatment, as well as the effectiveness of low lever laser treatment on changes in various pathological conditions.

This review of literature is divided into the following sections: (1) the prevalence of LBP, (2) the debilitating effects of LBP, (3) the treatment for LBP, (4) theoretical foundation of LLLT, (5) LLL technology and (6) LLLT efficacy.

Low Back Pain

Prevalence of Low Back Pain

The prevalence of LBP represents of how often a symptom occurs in a given populace. LBP transcends ethnicity, socioeconomic class, and educational demographics. In an epidemiological study, Anderson (1999) concluded that 70-85% of individuals will experience back pain at some point in the course of their lives. The prevalence of chronic LBP is considerably less than acute LBP, with approximately 10% of the population plagued with chronic LBP. Jette, Smith, Haley, and Davis (1994) contend that "low back pain is one of the most common challenges faced by physical therapists in these outpatient hospital-based and private practices" (p. 105). These researchers performed a survey of 2,328 discharged patients from hospital-based and private practice rehabilitation agencies from 1989 to 1990; over 25% of the patients were experiencing back pain. The second ranked injury treated was knee and hip pain (12%).

An occupational injury assessment by National Institute of Safety and Health from 1992-1997 established that of the 799,000 cases of sprains, strains, and tears, the prevalence of back injuries accounted for nearly half (385,000) of those cases (NIOSH, Nonfatal Report; 1999). It is apparent that back pain is a serious and prevalent condition affecting many American workers.

The American Pain Foundation (2006) estimates that over 76.2 million Americans are afflicted with pain as compared to 20.8 million with diabetes, 18.7 million with coronary heart disease or strokes, and 1.4 million people with cancer. Respondents of the National Institute of Health Statistics survey reported that the four common causes of pain were LBP (27%) followed by headache (15%), neck pain (15%) and facial pain

(4%). The emotional toll of LBP on patients and their caregivers is immense. Individuals suffering with chronic pain have a decrease in quality of life, due to the emotional and physical demands of dealing with chronic pain.

According to the National Collegiate Athletic Associate (NCAA Statistical Injury Report, 2003), low back injuries are ranked between the sixth and ninth body part (out of 42 other injured body parts) injured in competitive sports. Whether participating in NCAA or playing recreational sports, the prevalence of low back pain can cause extensive pain and discomfort. Incidence rates for LBP may not be well documented in the general athletic population due to the insidious nature of low back pain. Much back pain in athletics does not interrupt playing status during competition, therefore the incidence rate may not be well documented. It seems, however, as athletes' age the back pain of unknown origin continues to present problems. It is unspecificed how many cases of LBP are muscle strains or due to the early onset of lumbar disc disease (LDD). The need for early and effective low back pain treatment is needed in competitive sport.

One reason for low back pain is the occurrence of LDD. LDD is one of the most common musculoskeletal diseases with a prevalence rate of 5% (Paassilta et al., 2001). Because degenerative disc disease (DDD) is a progressive condition, projecting its exact onset is difficult. Perhaps even more difficult is establishing treatment protocols. DDD is often misdiagnosed as a lumbar strain or sprain in both the normal working population as well as the athletic population. Perhaps understandably, the treatment and diagnosis of LBP varies. LBP is common, however, the numerous pathologies causing back pain makes diagnosis of LBP difficult.

Inaccuracies of magnetic resonance imaging (MRI) limit accuracy of diagnosing lumbar pain. MRI films may show DDD or disc protrusions, yet the patient has no apparent symptoms. The patient may not have any back pain, leg pain, or leg numbness that attributes a current condition to the MRI findings. This evidence is very perplexing for the clinicians trying to diagnose pathology. Although MRIs may not be an excellent tool for diagnosing LBP, it is an excellent tool for evaluating neoplastic conditions, infectious disorders, or neurological impairment (Beattie & Meyers, 1998). MRI use is controversial for low back pain because of these unexplained abnormal MRIs which do not generate pathological symptoms. Patel and Lauerman (1997) advocate using MRI diagnosis among back pain patients who exhibit neurological abnormality and a positive straight leg raise with history of failed rehabilitative services after 4 to 6 weeks of nonoperative treatment.

In summary, the prevalence of a low back injury is very high for virtually all populations. A significant number of patients are treated each year in outpatient physical therapy for low back injuries. Low back injuries include degenerative disc disease, currently one of the most untreatable low back pain disorders. Prevalence and type of low back pain may not be reported accurately due to the difficulties associated with diagnosing low back pain into low back pathology. Different low back pathologies can have varied degrees of debilitation.

Debilitating Effects of Low Back Pain

Physical disability is anything that physically hinders or prevents individuals from performing their normal expected daily activities at home, work, or play. Waddell and Main (1984) found that physical disability was related to nine activities, including heavy

lifting, sitting at least one-half hour, traveling one-half hour, standing one-half hour, sleep disturbance, social life restriction, sex life restriction, and help with putting on shoes. The researchers also found common physical characteristics that accounted for 45.5% of the influence of disability. The highest rating (12.2 %) was a decrease in lumbar flexion. Additionally, physical impairment injuries included compression fractures (8.1%), spondylolisthesis (17.1%), and paraplegia (18.6%). Back pain is the leading cause of disability in Americans under 45 years (American Pain Foundation, 2007). Two outcomes of LBP are work absenteeism and early retirement (Pransky et al., 2005).

Work loss and sick leave have been directly related to low back disability in the Western countries (Niemisto et al., 2005). In the Nonfatal Injury Report by the NIOSH (1999), of the approximately 800,000 sprain, strain, and tears in musculoskeletal injuries in American workers, over half of the cases missed six or more days away from work. Missed days of work due to LBP can place financial strain on the individuals. Businesses and worker's compensation plans have a great economic burden related to workers who experience low back pain during employment. Ultimately, low back pain places an economic burden on societies (Gandjour, Telzerow, & Lauterback, 2005). Each injury generates costs associated with doctor's fees, prescription drugs, physical therapy fees, travel to and from health care provider offices, and the over-arching costs related to loss of productivity.

In summary, LBP is a common reason for disability, work loss, and early retirement. Jermyn (2001) concluded that "low back pain, a leading cause of disability, in the United States, has a significant economic impact not only on lost productivity but also on healthcare expenditures" (p.S6).

Treatment for Low Back Pain

Traditional LBP Treatment

Traditional LBP treatment consists of medication, joint mobilizations, pain-free walking, massage, traction, ultrasound, moist heat, and/or mat exercises (Smith et al., 2002). Despite low back pain being the most commonly treated disorder in outpatient physical therapy, the ways of managing low back pain differ among clinicians (Jette et al.,1994). Morlock, Adler, Thomas, and Hartway (2000) advocate a comprehensive treatment plan that includes directed exercises based on specific components related to evaluation findings. This plan supported using treatments based on clinical pretest scores on function and pain. Each treatment implement was supported by an intense review of literature. The Oswestry instrument was used on the 24 patients, with 10% improvement on functional activities from baseline to discharge and 20% better improvement in the comprehensive plan, as compared to the standard of care group. The results of Morlock et al.'s study advocated that less treatment variation is needed to produce improved patient outcomes and satisfaction.

In summary, numerous studies (e.g. Jette et al.,1994; Morlock et al., 2000; Smith et al., 2002) suggest that a high rate of variation in treatment for low back pain results in poor clinical outcomes. The lack of effective low back treatment has encouraged greater use of complementary and alternative forms of low back pain treatment.

Complementary and Alternative Medicine

Researchers have advocated using low impact aerobic dance as an alternative for costly physical therapy to relieve low back pain (Mannion, 2000). Although low impact aerobic dance was not significantly different than a traditional physical therapy results,

the individual financial difference was excessively less expensive for the aerobic dance. Other researchers (Hoffman, Shepanski, MacKenzie, & Clifford, 2005) concluded that exercising for 25 minutes could reduce experimentally induced pain in patients with chronic low back pain. Although not very applicable to everyday LBP because the patient's pain was induced by a pain stimulus to the nondominant index finger, this study did demonstrate that exercising may provide a more systematic effect in dealing with pain than a direct neuromuscular effect on the tissue in the low back region. Aerobic training promotes the release of pain endorphins, increases circulation, and increases oxygen uptake which appears to by advantageous for the LBP population.

Cohen and Rainville (2002) advocated additional support for cardiovascular endurance as part of a low back pain clinical plan. They contend that by eliminating impairment in back function and altering beliefs and fears about patient's pain, disability was reduced. Cohen and Rainville support an aggressive exercise and psychological mentoring program as a way to improve quality of life in LBP patients. Additional components of their intervention included flexibility, trunk strength, and lifting capacity which would not be considered complementary and alternative treatments. Hence their research on cardiovascular endurance was an adjunctive treatment to traditional types of LBP treatments. The second phase of their rehabilitation protocol was to educate the patient regarding their spine anatomy, pathology, physiology which is also traditional to LBP management. However, the inclusion of the deleterious effects of lack of personal physical conditioning and the extent of aggressive exercise is not considered a traditional approach to low back pain. The initial increase in patient pain was expected and patients were aware of this. Rehabilitation goals were set and monitored for 2 and 4 week

treatments. The patients would exercise for 1 to 2.5 hours each session for 2 to 3 times per week. The results were significantly better in the group that received adjunctive aerobics, aggressive exercise, and educational training as compared to the group of patients that received educational training.

Another approach to managing LBP that is complementary and alternative medicine includes yoga therapy. An estimated 14.9 million American practice yoga, with a small portion (21%) using it for neck and low back pain treatment as reported by Saper et al. (2002) in a poster presentation at the International scientific conference on complementary alternative and integrative medicine research (Williams et al., 2005). Although it appears many people are using this intervention, the research is limited. One of the first scientific research studies to assess benefits of yoga for the chronic LBP patient was performed by Williams et al. (2005). This study was implemented to assess pain-related outcomes in 42 persons with chronic LBP by using the interventions of Iyenagr yoga, as compared to a control group. Both the control group and the yoga group were given educational information and two, one hour lectures on occupational/physical therapy education regarding chronic LBP. Both groups received weekly (for 12 weeks) newsletters on proper back care. The yoga group attended one 1.5 hour class each week. The functional disability score was the primary outcome as measured by the Pain Disability Index. Secondary outcomes included clinical which was measured by numerous scales (e.g. MPQ, VAS, and PPI). Pain associated with fear of movement was quantified by the Tampa Scale of Kinesiophobia (TSK). Numerous other outcomes (e.g. pain attitudes, coping strategies, self-efficacy, range of motion, pain medication usage) were assessed. The results demonstrated that the yoga group experienced significantly

better function and less pain than the control group. This significance was sustained when measured again 3-months after the baseline scores were taken. At this 3-month follow up, the Yoga group reported 70% decrease in pain compared to the 38% decrease in pain as reported by the control group.

Besides the aerobic conditioning, aggressive exercises, and yoga, other complementary and alterative approaches to low back pain are spinal manipulation and massage. Khalsa, Eberhart, Cotler, and Nahin (2006) report that the NIH and Canadian Institutes of Health Research have jointly provided funding considerations for high-quality studies of basic science due to the lack of research in this area. Research is needed to support the use of manual therapy by understanding the mechanisms of action incorporated in the pathophysiology of numerous body systems. These manual therapies include spinal manipulation, mobilization, and massage therapy. These types of treatment for pain relief are well known, however, research in these areas is limited. The need for highly controlled studies to substantiate clinical findings in the field of Chiropractic medicine has been an issue of medical concern for some time. Numerous insurance companies do not reimburse for these alternative types of care based on the lack of medical research to substantiate their validity. The phone survey by Barnes, Powell-Griner, McFann, and Nahin (2002) reported that 7.5% of the Americans had chiropractic visits in 2002. Common injuries that are treated by chiropractors include musculoskeletal neck and back pain.

In areas like Washington State, where insurance companies are required to cover licensed CAM providers, the chiropractic claim rate (43%) was almost equivalent to traditional providers (45%) with a low percentage that used both providers (12%) as

documented by Lind et al. (2005). A cost comparison was provided in this study of CAM treatments and results revealed that 15% of all outpatient claims were on LBP which accounted for $52 million on 652,593 claims. The CAM treatments mean cost was $58 and the mean traditional treatment cost was $128. An important covariate of this study included extent of injury. The more extreme conditions were not as commonly treated by the CAM treatments, thus the mean cost would most likely be higher in the group with the more severe injuries. Lind et al. concluded that more cost effectiveness studies were needed to address the issue of CAM treatments for LBP.

In summary, CAM treatments such as manipulation and massage are common for low back treatment, however, aggressive exercise and aerobic training have more recently been investigated as a treatment option to reduce LBP. One alternative treatment for low back pain includes low level laser treatment. LLLT is often performed by chiropractors after a spinal manipulation (Fahmy, 2004). Evidence relating to the efficacy of LLLT is provided in the next section.

Low Level Laser Treatment Theoretical Foundations, Technology, and Treatment Efficacy

Theoretical Foundation of Low Level Laser Treatment

Pain Reduction

Numerous studies advocate that laser treatments can reduce pain (Basford, Sheffield, & Harmsen, 1999; Bjordal, Couppe, Chow, Tuner, & Ljunggren, 2003; Cecherelli et al., 1989; Chow, Heller, & Barnsley, 2006; Enwemeka et al., 2004; Ferreira et al, 2005; Kemmotsu et al., 1991; Shiroto, Ono, & Ohshiro, 1989; Simunovic, 1996), although the exact mechanism of analgesia is unclear. Kemmotsu et al. (1991) conducted

numerous research studies on chronic pain and they concluded that the contributing factors of LLLT efficacy were blood flow improvement, acupuncture-like effect, and normalization of nerve cell function. Pain attenuation through an increase in serotonin is another likely mechanism that explains LLLT efficacy (Mizokami et al.,1993). Both the gate control theory and the opiate pain control theory may be activated as a method of pain reduction when laser biostimulation occurs. It is apparent that research is needed in this area.

A study by Ferreira et al. (2005) examined the effects of LLLT on acute pain. Because different theories exist to explain why people experience pain, the pathway by which LLLT affects the body was under investigation. The researchers imposed an environmentally induced state of inflammation on two groups of rats. The first group was injected with carrageenin and naloxone (inflammatory mediators) and then evaluated for the effects of LLLT on opioid receptors. The second group was injected with prostaglandin E_2 and evaluated for the effect of LLLT on sensitization increase of nocioceptors. The results showed that the reduction in pain is more attributed to the change in hyperalgesic mediators (95% increase in pain threshold) than to the opioid receptors (68% increase in pain threshold). It appears LLLT is effective for decreasing acute pain via more of the peripheral pain modulation theory than the opioid receptor pain theory.

Inflammation Reduction

A second theory, other than the pain reduction theory, that supports the use of LLLT is for its inflammation reducing properties. Active inflammation is well known for its production of neutrophils, a white-blood cell that invades the area in an attempt to rid

the area of pathogens. Neutrophil cause reactive oxygen species (ROS) which promote inflammation in the area. Results of a study by Fujimaki et al. (2003) suggests that the modulation of neutrophil functions, particularly the ROS production, is involved in the positive effects of biostimulation related to laser irradiation. Other viable mediators during inflammation are known as the prostaglandins which play a significant role in pain production. Bjordal, Martin-Lopez, and Iversen, (2006) found that LLLT can suppress inflammation as measured by a reduction in the inflammatory mediator known as prostaglandin E_2. Thus, it appears that LLLT can reduce inflammation by affecting the cellular cascades which cause inflammation, specifically by modulating neutrophil and prostaglandin E_2 production.

Healing Enhancement

Another theoretical foundation for LLLT efficacy is the ability to enhance the healing of biological tissue. The research on wound care is more prolific than on any other area of laser treatment (e.g. Hawkins, Houreld, & Abrahamse; 2005; Horwitz, Burke, & Carnegie, 1999; Lucas, Criens-Poublon, Cockrell, & Haan, 2002; Simunovic, Ivankovich, & Depolo, 2000). It is well documented that the biomedical effects of laser application include increased collagen formation, tensile strength, ATP synthesis, and in the number and rate of degranulation of mast cells (Enwemeka et al., 2004; Mester et al., 1985; Woodruff et al., 2004). The growth of new capillaries also influences wound healing and therefore is another way in which laser irradiation can enhance the healing cycle (Mester et al., 1985). LLLT can also hinder the growth of Staphylococcus aureus bacteria that commonly cause skin infections (Dadras, Mohajerani, Eftekhar, & Hosseini,

2006). The effects of laser irradiation on wound healing are probably two-fold. Thus, laser irradiation enhances healing and hinders the factors that slow the healing process.

The most commonly studied tissue is the integumentary system (as cited previously), however, research on other tissue types have also supported LLLT efficacy. Researchers have found that LLLT of articular cartilage (Calatrava, et al., 1997), ligament (Fung, Ng, Leung, & Tay; 2002), muscle (Shefer, Oron, Irintchev, Wernig, & Halevy; 2001), and bone (Silva, et al.; 2002) provides an increase in cell proliferation and tensile tissue strength, which both play a role in tissue healing. In highly controlled research labs, articular cartilage, ligaments, muscles, and bone cells have all demonstrated better healing capacity when compared to a control group (non-laser irradiated group).

The summary of theoretical foundations which support LLLT efficacy are based on pain reduction, inflammation reduction, and healing enhancement. Pain reduction is supported by laser irradiation through the opiate pain theory and gate control theory. Inflammation reduction is supported by laser irradiation through its influence on the ROS and the prostaglandin E_2. LLLT can enhance healing by encouraging cell growth of the collagen matrix and blood vessel repair, which enhances tissue rebuilding and tensile strength. It should be noted that most of the research in theory-based application is conducted in a highly controlled environment and provides astonishing, overall positive results.

Low Level Laser Technology

Definition of a Laser

The term *L.A.S.E.R.* is an acronym for Light Amplification by Stimulated Emission Radiation. Stimulation emission is the reaction that photons have when the light source produces energy which excites atoms (Tuner & Hode, 2002). These identical photons are released when other excited atoms are present. Together these photons will produce radiating energy which is transmitted by varied means. This mode of transmission is why there are so many different types of lasers (e.g. crystal, gas, semiconductor, liquid, chemical). Various types of lasers have different wavelengths.

Common lasers are typically categorized according to a specific wavelength. For example, the neodymium doped, yittrium-aluminum-garnet (Nd:YAG) laser has a wavelength of 1,064 nm (invisible, near infrared), which penetrates deep tissue, while argon has a wavelength of 488 nm (visible blue) and 514.5 nm (visible green), penetrating less deeply. The Nd: YAG was selected for this research because the intended area in the low back was approximately 5 to 7 cm deep. Some instrument types with power sources and wavelengths are listed below:

HeNe, wavelength 632.8 nm, 25 mW

Diode system, wavelength 830 nm, 15mW

Co2, wavelength 10,6000 nm, .5W

Krypton, wavelength 521, 530 ,568 ,647 nm

Ruby, wavelength 694 nm

Nd:YAG, wavelength 1064 nm, 5W (used in this research).

The difference in wavelength will have a direct effect on laser penetration. The longer the wavelength the deeper the laser irradiation penetrates. The higher the power output availability the greater the FDA classification regulations. For example, the Nd:

YAG laser used in the current study in categorized as a Class IIIb or medium power laser, while the HeNe lasers is classified as a Class II or low power laser. This technology can be dangerous to tissue if the dosage is too high or if direct eye contact is maintained with laser irradiation. HeNe lasers may be preferred for wound healing if the depth of penetration is less than 2 cm, while a Nd:YAG would be preferred for deep muscle contusions or deep low back muscle injuries (Starkey, 2004).

An important element of lasers is the property of *coherence*, which is a physical element distinctive from the wavelength and power output. The factors associated with coherence include identical photons, monochromatic beam, parallel rays moving in a sequence or in the same phase, which allow the beams to be a concentrated light source. Another property of lasers includes collimation or the projection of photons in a straight line. This property allows the laser to irradiate in a focused area. This high concentration of photons in a straight line allows less divergence of the energy as it enters tissue (Tuner & Hode, 2002).

Not a laser but commonly referred to as a laser is the light emitted diodes. The difference in light emitted diode (LED) treatment and laser treatment is that laser light is coherent and collimated and the LED treatment is divergent (Tuner & Hode, 2002). The divergent form of light energy can produce the same biological stimulation, however, the depth of penetration is severely hampered when the light source is not coherent or collimated. Mester et al. (1985) described a 20% decrease in efficacy when they compared a non-coherent light source to a coherent light source with the same wavelength in a wound healing study.

(50 J/cm2) causes inhibiting effects, while, low-power intensity (.05 to 5 J/cm2) causes positive effects. Since 1985 a larger dose has been prescribed as effective for specific injury sites (e.g. 48-480 Joules for chronic back pain, Bjordal et al.; 2003). The current study used a dose of 360 Joules and a power density of 300mw/cm2 with an energy density of 36 J/cm2. Power density of a laser can generate a very low power light dissipation into the tissue that promotes physiological responses due to its photobiological effects on tissue. These physiological responses of pain reduction, decreased inflammation, and healing enhancement were discussed previously under theoretical foundations of low level laser treatment.

The approaches to delivering the recommended dosage include spotting, gridding, wanding, and scanning. The spotting technique is performed by holding the laser wand directly against the skin for certain duration at a specific intensity. In order to document exact dosage for selected area the spotting technique is best, therefore this was the technique used in the current study. The wanding and scanning technique may be applicable with an open wound in which direct contact may be too painful. The gridding technique is applied when a higher dosage is warranted for a large tissue area.

The final parameter related to effective tissue irradiation is the amount of continuous or pulsed rate of irradiation. A continuous laser will produce more irradiation in a given area over a specific time than a pulsed laser. The pulsed lasers irradiate the cells only a fraction of the time that continuous laser irradiate cells. Pulsed lasers are known to have an average power. Pulsed laser treatment times may be exceedingly long to deliver the same energy density as a continuous laser. Thus, a continuous laser was used during this research study.

In summary, lasers are similar to sunlight, light bulbs, and LEDs because they all emit electromagnetic radiation. Light bulbs, lasers and LEDs are man-made fabricated sources that emit electromagnetic radiation. The monochromaticity is a shared property of these light sources. The laser light properties of coherence and collimation allow the emitted photons to affect a small isolated area which enhances depth of absorption. Although wavelength is also a predictor of depth of penetration, the divergence of LEDs may negate that effect of depth of penetration based on the wavelength choice. More research is needed to define the effects of LEDs as compared to lasers, however, that area is beyond the focus of this study.

Low Level Laser Parameters

Additional elements of lasers other than wavelength, coherence, and power output are the parameter of each device. After selection of an appropriate laser type each clinician needs to be well-versed in parameter selections. These parameters include a continuous or pulsing setting, treatment technique, and laser dosage. These parameters have a direct impact on laser effectiveness. If the dosage of energy delivered is minimal then tissue affects may lack clinical significance.

Laser dosage (Joules) is expressed as laser output in relationship to the time duration of treatment. Power density (Milliwatts or Watts/cm2) is an expression of output in relationship to target area (or watts divided by target area). And energy density is considered Watts multiplied by time and divided by target area. The energy density is the most important measure for clinicians because this represents all three important factors for patient treatments. Mester et al. (1985) began the process of defining appropriate power intensity. One conclusion of the author's research was that high-power intensity

In summary, the parameters of wavelength, coherence, power output, continuous or pulsing, treatment technique, and laser energy density all influence the effectiveness of LLLT. Examining each parameter can lead clinicians and researchers to improve applications of the laser irradiation. Recognizing that LEDs and LASERs have different physical properties which affect depth of tissue irradiation helps explain why the LED research should not be used interchangeably with LASER research.

Low Level Laser Treatment Efficacy

The results of numerous laser studies have indicated that LLLT is effective which might account for the 1.5 million patients treated annually in recent years (Moshkovska, 2005). A review of these studies is difficult because the variety of pathologies under investigation leads to limited research on a specific topic. In a review of literature, Basford (1995) examined 17 pathologies, such as arthritis, tendonitis, neuropathic pain, oro-facial, patellafemoral pain, soft tissue wounds, sports injuries, Buerger's disease, headaches, pruritus, nerve repair, sympathetic nervous system dysfunction, Leukemia, tinnitus, immune modulation, bactericidal effects, and Pyronie's disease. Basford concluded that while laboratory studies support the use of LLLT, evidence was insufficient to support LLLT efficacy, other than marginal effectiveness in the area of neurological applications.

Positive Nerve Studies on Low Level Laser Treatment

A common neurological condition under investigation for laser efficacy is carpal tunnel. Naeser, Hahn, Lieberman, and Branco (2002) evaluated the effectiveness of LLLT on treating carpal tunnel syndrome in a double-blind, randomized, placebo-control study. The researchers found that the experimental group had better sensory latencies,

less pain, and significantly better objective nerve field tests (e.g., Tinel's Sign and Phalen's Sign) than the control group (non-laser irradiated group). The researchers concluded that LLLT should be applied early in carpal tunnel syndrome which would perhaps eliminate the need for surgery. This study provided supporting information for FDA approval of laser use in carpal tunnel syndrome.

In combination with Naeser et al.'s (2002) clinical research on nerve pathology, other laboratory studies have also indicated that LLLT is effective for treating nerve injuries. For example, Assia, Rosner, Belkin, Solomon, and Schwarts (1989) performed an animal experiment where the researchers severed the optic nerve and applied irradiation to one group of two groups. The group of rats that received the irradiation had delayed degeneration of the optic nerve unlike the control group which had early degeneration of the optic nerve. In another study, Snynder-Mackler and Bork (1988) asked healthy subjects to perform one session of laser irradiation on the radial nerve. They concluded that the radial nerve had significantly better electrophysiological parameters (e.g. nerve latency, motor latency, sensory latency) than the non-irradiated radial nerve group. Hence, this highly controlled research demonstrated that LLLT can provide positive results in noninjured nervous tissue. Additionally, Naeser et al.'s and Assia et al.'s laboratory studies concluded LLLT is an effective method for treating injured nervous tissue.

Positive Musculotendinous Studies on Low Level Laser Treatment

The effect of LLLT on tendon and muscle tissue has some supporting evidence, but not to the extent of nervous tissue. Results are varied when you review the available literature on the musculotendinous injuries. The collagen fibers in these structures are

much denser and they have higher water content, so it is not surprising that results may vary in different tissue types. Common types of musculotendinous injuries include tendonitis, muscle strains, and tendon strains.

Tendonitis is a common musculotendinous disorder among people with some cases causing days of missed work and painful areas lasting for years. A multicenter, double-blind placebo controlled clinical study on elbow tendonitis was performed on 324 patients by Simunovic, Trobonjaca, and Trobonjaca (1998). The researchers divided the patients into three groups: (1) patients who used a scanner application technique with the maximum dosage of 12 J/cm2 , (2) patients who used spotting technique above each trigger points with a maximum dosage of 10 J/cm2, and (3) those who used a scanner and trigger point applications; there was no report of dosage for this group. Measurements included the McGill Pain Questionnaire, Visual Analogue Scales, Verbal Rating Scales, and the patients' pain diaries. The final group or combination group produced the most favorable outcomes; however, this was not statistically more beneficial than the spotting technique alone. Although the techniques used were not different the overall results demonstrated that LLLT had efficacy in tendonitis patients.

Other clinical trials have also found LLLT to be an effective tool for treating tendonitis (e.g., England, Farrell, Coppock, Struthers, & Bacon., 1989; Saunders, 1995). For example, Saunders (1995) research investigated laser efficacy for supraspinatus tendonitis patients. The purpose of this study was to assess the improvements in pain and strength of the supraspinatus tendon after receiving nine laser treatments. The laser irradiated group had significantly better pain scores and more strength than the non-irradiated group. These results are similar to the research conducted by; England et al.,

(1989). The studies differed in treatment duration and control group, England et al's study only lasted two weeks (or six treatment sessions) and the control group was actively taking Naproxen sodium. The laser irradiated group had significant improvement compared to those patients taking Naproxen sodium (control group) on subjective pain measures, objective motions, and functional assessments. This collection of literature on tendonitis efficacy is important because it directly measured patient outcomes.

Other research that supports the use of LLLT for tendonitis is a laboratory study conducted by Bjordal et al. (2006). They induced Achilles tendonitis in 14 participants and then irradiated the tendons at 5.4 Joules and then compared the irradiated tendons to the non-irradiated tendons (control group). The factors the researchers compared were Prostaglandin E2 (PGE2) concentrations, single leg hop test, and pressure pain thresholds. The researchers concluded that the irradiated tendons had a significantly lower PGE2 concentration. While the laser irradiated group had better scores on the single leg hop test and the pressure pain threshold tests, these were not significantly better than the placebo group. This study addressed the exact mechanism of efficacy which is much needed in the LLLT research.

Another laboratory study dealing with the musculotendinous category of LLLT efficacy was performed by Shefer et al. (2001). This microscopic study viewed the pathway by which muscles rebuild, and they found the laser irradiated cells when compared to pretreatment cells had significantly more rebuilding muscle cells as compared to posttreatment cell growth. The laser group had a significantly higher rate of myogenesis than the nonirradiated cells directly related to the MAPK and ERK pathways.

This study much like the Bjordal et al. study focused on the exact mechanism of laser efficacy as it relates to healing muscle tissue.

In summary, when patients with varied types of tendonitis (e.g. elbow, bicipital, supraspinatus, achilles) are compared to a control group receiving no treatment or a treatment consisting of NSAIDS then the LLLT is a superior treatment. Additionally, when researchers induce pathology in a highly controlled environment and then irradiate the tissue with a laser the cellular response is to decrease the pain causing factors (PGE2) during inflammation. And finally, the increased growth of new muscle cells after LLLT in a laboratory study leads the reader to the conclusion that LLLT is an advantageous treatment for musculotendinous pathologies.

Positve Pain Studies on Low Level Laser Treatment

Two earlier mentioned studies, Kemmotsu et al. (1991) and Mizokami et al. (1993), have established some of the theoretical foundations for laser efficacy of pain control. Still other clinical studies add additional evidence that supports LLLT for trigger point pain reductions, as well as, overall pain reduction for numerous pathologies. Simunovic (1996) conducted a single-blinded study of 243 patients with various injuries to investigate the efficacy of LLLT on acute and chronic pain with a placebo comparison group (sometime the placebo treatment occurred on the other side of the patient, when they had bilateral pain). Dosage progressively increased as the patient's pain persisted (acute pain patients started at 20 Joules and chronic pain patients started at 25 Joules but no cases exceeded 60 Joules per unilateral treatment). All participants were treated from 3 to 5 times per week with total number of treatments ranging from 6 to 24. The researcher concluded the effectiveness of LLLT on trigger points was 70% improvement

for acute pain and 60% improvement for chronic pain. This study supports the use of LLLT as a monotherapy, as well as a supplementary treatment. Simunovic concluded that ineffective laser treatment is a product of incorrect parameter selection. He believes the controversy surrounding LLLT is related to negative studies not having adequate dosage delivered on a gradual and regular basis. He further explains that the dosage is more important than the wavelength of the laser device.

Research on varied pathology with pain as the subjective measure can be investigated further because numerous studies incorporated different laser parameters to completely justify LLLT efficacy. Fukuuchi et al. (1998) conducted a double-blind clinical trial on 82 patients with chronic pain. The researchers evaluated pain on a 5-point scale and determined the laser treatment was effective if the patient experience either a 2 or 3-point change in the way they rated their pain. The percentage of effective laser treatments was 74.5 % with the laser treatment and 12.9% pain reduction in the control group. This improvement in chronic pain was significant. A high dosage of 570 J/cm^2 per spot was delivered. However, only a maximum of four spots were treated each session. Each patient had to receive at least one session per week to meet inclusion criteria. This research supports the theory that LLLT can decrease patient's pain levels with a high dose of laser irradiation.

Another study that supports the use of LLLT for pain attenuation was conducted by Shiroto et al. (1989). This study was conducted over a 46-month term and included 3635 patients. This retrospective design did not control for the placebo effect but the large numbers of patients treated increases the external validity. The range of power density delivered was 1.2 W/cm2 up to 3 W/cm2 with an average treatment time of 6.34

minutes. The pain efficacy rate was 76%. The mean number of treatment session was 12.9 for this population. The researchers felt that the amount of pressure applied during the treatment was important (substantial pressure was used and patients requested increase pressure to be applied). Additional suggestions by the researchers were to increase time of irradiation for future studies.

In summary, numerous pain attenuation clinical trials have demonstrated efficacy of LLLT. Each author added to the body of knowledge of LLLT by emphasizing a particular parameter they felt was important. Simunovic (1996) reported dosage was very important and he felt a high dose of 60 Joules was appropriate for the more chronic type of injuries. Similarily, Fukuuchi et al. (1998) felt an energy density of 570 J/cm2 per spot was adequate for chronic pain and finally Shiroto et al. (1989) emphasized the pressure applied at each spot was important. Shiroto et al. also agreed with the previous two studies that dosage was very important because when these researchers stated they would increase the treatment duration in future studies, they in essence, stated they would increase the energy density, because the energy density is the by product of dose (J) divided by area and multiplied by time.

Effective LB Low Level Laser Treatment

Building on the positive results of LLLT for pain reduction, other researchers have analyzed specific pathology related to pain, such as low back pain. Currently, two studies have demonstrated that LLLT is effective on low back pain (Soriano & Rios, 1998; Basford, 1999). Research in chronic low back pain by Soriano and Rios (1998) included 85 participants, 60 years or older, not taking non-steroidal anti-inflammatory drugs (NSAIDS) and experiencing chronic back pain for more than 3 months. Therapy

consisted of five sessions a week for two weeks. Parameters included pulsed GaAs diode laser, wavelength 904 nm, with a spot technique, and a dosage of 4 J/cm2 per point. Pain relief was measured by a pretest and posttest research design. The researchers found LLLT to be effective for pain relief above 60%, for a significant number of patients as compared to the placebo group. Basford et al.'s study on low back pain included 63 patients with back pain for more than 30 days. The power density was 542 mW/cm2 and each site was irradiated for 90 seconds at eight symmetric sites along the lumbosacral spine for at least 11 treatments in 4 weeks. These researchers used a continuous Nd Yag laser with a 1064 nm wavelength. Basford et al.'s research concluded that lumbar mobility did not change among the two groups but perceived pain reduction, as measured by the Oswestry Disability Questionnaire, was significantly better in the LLLT group as compared to the placebo group. In regard to the finding of these two studies, LLLT is considered a possible treatment option for people with low back pain; however, the methodology was considerably different (e.g. covariates, number of treatment sessions, laser types, and power densities).

Ineffective Low Level Laser Treatment

Some researchers have not supported LLLT effectiveness on epicondylitis (Basford, Sheffield, & Cieslak, 2000), ankle sprains (Bie et al., 1998), neck pain (Thorsen et al., 1992), carpal tunnel syndrome (Bakhtiary et al., 2004) or wound healing (Lucas et al., 2002). LLLT may not enhance certain pathological conditions. Bie et al. examined the different levels of irradiation (placebo- 0 J/cm2, 5 J/cm2 and .5 J/cm2) on lateral ankle sprains for outcome measures of pain and function. The laser used was a pulsed 904nm, GA-As, with an irradiation area of 1 cm2. The results indicated that the laser

group had lower pain scores in the first five days but by the end of the trail the placebo group had lower pain scores than both the 5 J/cm2 dose group and the .5 J/cm2 dose group. Additionally, the researchers found that the placebo group was able to return to work earlier than the laser groups. There is too little research on ankle pathology and LLLT to speculate why these results were different from other studies. More research on injured ankles and LLLT would be appropriate for this particular area.

However, the area of wound healing has been substantially studied, and both Basford (1995) and Lucas et al. (2002) agreed after an in-depth review of articles that LLLT is ineffective in wound healing. Basford stated that the early studies on wound healing (e.g. Mester et al., 1985) were poorly controlled, which caused great skepticism on LLLT efficacy. Basford discussed the animal studies and found conflicting results between with the pig studies (negative results) and rat studies (positive results), so he concluded since pig skin more closely resembles human skin, he would have to agree with the pig studies and not advocate the use of LLLT for wound healing. And after a rather limited review of two clinical trials that produced no effect on wound healing after laser application, Basford concluded he did not support LLLT in wound healing. Lucas et al., on the other hand, reviewed 36 studies, with 49 outcome parameters, in which 30 parameters were positive and 19 were not positive. When Lucas et al. tried to pool effect size of the data with the highest methodological quality scores they found a negative effect size. Hence, they concluded the number of quality research studies for wound care was poor and based on the negative effect size for pool data, LLLT is not a valuable (adjuvant) treatment for wound healing.

In addition to the other ineffective laser studies on musculoskeletal injuries, research conducted by Basford et al. (2000) also investigated effectiveness of LLLT. This study was a double-masked, placebo-controlled, randomized clinical trial on lateral epicondylitis. Although the researchers hypothesized that pain, point tenderness and strength would improve with laser irradiation the results did not support their hypothesis. In their summary, the researchers reviewed every parameter and found no reason that chronic elbow tendonitis would not be positively affected unless factors associated with chronic pathology of tendons inhibited tissue healing. If the theoretical foundation of acute healing is the primary reason for the efficacy of LLLT in musculotendinous injuries then the inability to encourage healing in the chronic state of an injury could be a justifiable explanation for this research result. But this explanation does not explain why other research studies (e.g. Bjordal et al., 2006; England et al., 1989; Saunders, 1995) have found positive results for different types of tendonitis.

Another area of ineffective treatment for LLLT is for carpal tunnel. A study by Bakhtiary et al, (2004) with ninety hands of fifty patients with carpal tunnel was randomized into two groups. The interventions for the groups were ultrasound therapy or laser therapy. The ultrasound therapy group had significantly better pain scores as measured by the VAS scale and other electrophysiological parameters. Regardless of the nine measurements used to test effectiveness the ultrasound group far out scored the LLLT group.

In summary, the ineffective results of LLLT include pathologies such as ankle sprains, tendonitis, carpal tunnel, and wound healing. It is still unclear why some studies have contradictory effects of LLLT. Most of the current research have addressed the

issue of low dosage and yet there are still research studies that find no differences between groups. It should be noted that more studies find no difference when the placebo group is receiving treatment equivalent to current standards of care (e.g. exercise, ultrasound) rather than no care.

Ineffective Low Back Low Level Laser Treatment

Similarly to other areas concerning musculotendinous and/or nerve pathology, a few studies do not support the use of LLLT for low back pain. As previously mentioned, low back pain is difficult to diagnosis and even more difficult to treat, especially in the area of chronic low back pain. In a study of 20 patients, Klein and Eek (1990) investigated whether LLLT in combination with exercise would be better than exercise only. The parameters of this research included using a gallium-arsenide pulsed infrared laser with a wavelength of 904 nm. The energy produced at each point was approximately 1.3 J/cm2 for a total treatment time of 20 minutes. Patient treatments lasted three times per week for four weeks. Results from this study concluded that exercise and LLLT had significant improvements in range of motion (e.g. rotation flexion, flexion, side bending) when compared from pretest to posttest, however, groups did not differ. The subjective pain scale and disability ratings were significant for both groups when comparing pretest to posttest but no difference was found between groups. The combination of LLLT and exercise when compared to exercise only does not appear to be a superior treatment. Hence, LLLT may not be an effective tool for low back pain treatment at the specific parameter setting established in this research design.

Other research in the area of LBP by Gur et al. (2003) found very similar results as Klein and Eek (1990). The single blind study of Gur et al. used the same laser

(Gallium Arsenide) as Klein and Eek but treatment sessions differed and dosage differed. Klein and Eek did eight sessions over two weeks and Gur et al performed 20 sessions over four weeks. The energy dose used in the Klein and Eek's study [as described by Bjordal et al. (2003)] was .4 mW/cm2 and 1 J/cm2 in Gur et al.'s research. The difference of dose was important because Klein and Eek's dose was not very high for chronic pain. The design differed because Gur et al. added a laser only group and they concluded that laser was effective because all three groups (laser only, laser and exercise, and exercise only) improved significantly from a pretest to posttest measurements on pain and function as measured by five (Visual analogue scale, Roland disability questionnaire, Modified Oswestry disability questionnaire, Schober test, Antero-posterior flexion) outcome measurements. Lateral bending showed no difference in pretest to posttest scores in any group. It is interesting the Klein and Eek concluded that LLLT was ineffective because groups did not differ; although the pretest to posttest scores were both significantly better after either exercise or laser irradiation but when Gur et al. reported the same effect they reported the laser as an effective tool for LBP.

In summary, Klein and Eek (1990) as well as Gur et al. (2003) found exercise and laser treatment was not better than exercise only for people suffering with varied degrees of chronic low back pain. Interestingly, the effect of treating low back pain with a laser only was similar to treating with a laser and exercise in the Gur et al. study. Most clinicians would not choose a passive modality (LLLT only) over exercise because the theory of motor control and correct biomechanics is the foundation for most therapy programs. However, the theoretical foundations of how the laser is able to assist in the healing process make it a very attractive device to implement as an adjunctive

rehabilitation tool. The complexity of chronic low back pain makes analysis of clinical laser efficacy elusive, or difficult to determine, however the need to treat low back pain more effectively has already been established and therefore this area is in need of more research. The laser parameter selection for acute or chronic low back pain is also in need of research due to limited research in the area of low back pain. These studies have limited application because both studies did not allow patients with radiating leg pain which is very prevalent in patients experiencing low back pain. Further research is needed in the area of parameter selection for LLLT and expanded patient populations with regard to acute low back pain and possibly patients with leg pain as a result of low back pathology.

Summary

The prevalence of LBP coupled with the debilitating effects of LBP and the limited efficacy in treatment selections for LBP, whether traditional or alternative approaches to treatment, provides a foundational need for more research in this area. Low back pain causes days of missed work and early retirement. Research is available that supports aerobic, anaerobic, and manual therapies for treatment of low back pain. However, of the numerous avenues to treat low back pain the most productive and economical method is yet to be determined. The multifaceted pathology of low back pain has limited success in treatments, therefore additional clinical trials are needed to provide guidelines for patient care.

The theoretical foundation of LLLTs are based on laboratory studies that attempt to explain how the laser irradiated cells react differently than the non irradiated cells or how pathological cells respond differently when irradiated. Three main themes were

developed which attempted to explain why laser irradiation is beneficial. These theoretical themes included pain reduction, inflammation reduction, and healing enhancement. Research in theory-based applications provided astounding, positive results which explained why numerous clinical trials have provided patients with pain relief, increased healing, and more functional abilities. These positive results are directly linked to the physical properties of lasers and their ability to emit electromagnetic radiation based on monochromaticity, collimation, and coherence. Research in the area of LLLT has provided insight that dosage is very important and a spot technique is preferred for documenting dosage delivered.

Efficacy of LLLT is currently equivocal and the areas of pathological debate are vast. This review was delineated to those studies which might affect low back pain (e.g. pain attenuation, musculotendinous, neurological). Numerous pain attenuation clinical trials have demonstrated the efficacy of LLLT. Early research on pain began with the investigation for appropriate LLLT parameters (e.g. wavelength, technique, and dosage). From these studies, researchers have been more specific about reporting exact methodology in order to better review clinical trails for similarities. Although numerous questions still exist concerning parameter selection, one improvement has been the inclusion of dosage delivered per area. Shorter wavelengths like 600-700nm provide better healing potential for wounds and increased dosage (5-100 Joules) is necessary for chronic pain pathology to respond (Tuner & Hode, 2002). This range of dosage is still quite large but at least the early studies of .001 Joules can be eliminated as probably not enough laser irradiation to produce clinical effects. Some studies support the use of LLLT for tendonitis pathology when compared to a placebo group and one laboratory

study reviewed demonstrated the exact pathway of muscle cell myogenesis. Finally, many neurological studies have provided supportive evidence for nervous tissue enhancement. Some of these finding included nerve cell latency (which decreases the amount of impulse sent to the pain receptors on certain nerves), as well as better motor response which would indicate some nervous tissue healing. Since nerve root irritation is one of the most common causes for low back pain these findings are supportive evidence for why LLLT could be beneficial in LBP patients.

In summary, it is apparent that the effectiveness of LLLT on chronic low back pain has yielded equivocal results. Two studied demonstrated that there was a benefit of LLLT on pain and function, while two other studies when comparing LLLT with exercise and LLLT found no differences between groups. However, one of the LBP study included a low dosage that indicated low efficacy. The focus of this study, therefore, was to examine the effect of LLLT alone or in combination with anaerobic exercise among patients who experience acute and chronic low back pain. Additionally, this study will determined the effect of receiving LLLT and traditional lumbar mat exercises as compared to laser alone on perceived pain and daily living activities.

CHAPTER III

METHODS

Participants

A convenience sample of 43 patients with previously diagnosed low back pain living in the southeast region of the U.S. was recruited to participate in this investigation. Licensed orthopedic surgeons diagnosed patients for similar back pain symptoms. The participants were informed about the investigation while in their doctor's office seeking medical attention for back pain.

Demographics of this sample included an average age of 50 years, 29.70% body fat, 68.52 months of back pain before the study, 9% had acute pain, 44% were diagnosed with some type of disc herniation, 28% were diagnosed with degenerative disc disease, 28% were diagnosed with muscle sprain, and strain or sciatica without disc involvement. Of this sample, 65% were females, 61% were not taking OTC medication or using it infrequently, 65% were not taking prescription pain medication or using it infrequently, and 84% were not taking NSAID or using it infrequently. Within this group of patients, 64% of patients had never had an epidural, 56% had never been in a formal physical therapy program, 84% were not doing any type of prescribed home exercise program, 24% were extremely inactive at work and in leisure, and 39% performed frequent physical activity or exercise during employment or leisure. Most of the participants (83%) had received an MRI prior to being enrolled in the study. Similar demographics according to group assignment are provided in Table 1.

Table 1

Baseline Characteristics of all Participants with LBP by Group Assignment (N = 43)

Variables	Exercise	Exercise & Laser	Laser
	M (SD)	*M (SD)*	*M (SD)*
Mean age, years	51 (14.52)	51 (10.04)	48 (16.66)
Duration of LBP, months	82.64 (138.82)	64.60 (84.93)	58.61 (86.02)
Medication Index	4.79 (2.61)	5.73 (3.75)	3.64 (2.82)
Female %	78	67	50
Amount of Physical Activity (PA) %			
None	21	26	21
Infrequent PA	36	27	50
Frequent PA	21	20	21
Combinations of PA	21	27	7
Injury type %			
Non-disc	22	27	36
DDD	28	27	28
HNP	50	46	36
Body Fat Groups %			
Lean to Normal	0	13	31
Above Average	14	13	15
Overfat	43	13	23
Obese	43	60	31

Table 1 (continued)

Variables	Exercise	Exercise & Laser	Laser
	M (SD)	*M (SD)*	*M (SD)*
Epidural for LBP %			
No Epidural	57	71	64
Recent Epidural	21	21	7
Non-recent Epidural	21	7	29

Note: Figures represent mean (and standard deviations), unless stated to be a percentage of the group.

To ensure adequate sample size a power analysis was performed prior to the investigation. To detect a medium effect with a correlation of .50 between pretest and posttest scores, and an alpha $p < .05$, a sample size of 42 people to have power equal to 80% (Maxwell & Delaney, 2004). Thus, after approximately two years of data collection, an appropriate sample size of 43 participants was included in the study. The drop out rate of those participants which started their first treatment was 28%. There were similar numbers of drop outs in each group assignment (5 exercise, 4 exercise & laser, and 4 laser).

Apparatus

The instrument used to deliver LLLT was an Nd:YAG (Therapeutics, Inc). This device operates under a1069nm wavelength. This instrument has been FDA approved for topical heating for temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or

promoting relaxation of muscle (FDA approval letter: Appendix A). The power of 3 watts is conveyed by a 22 degree divergent beam to a treatment area of 10 cm^2 at the skin surface for each treatment site. Hence the power density delivered was a 300 mW/cm^2 and the dosage 36 Joules / cm^2. The beam is a continuous wave not pulsed. It is a diode pumped Nd:YAG with the energy delivered by appropriate fiber optic cable and the output is calibrated at the delivery point prior to each treatment as required by the software. The calibration is done by fastening the handpiece into the mount on the Ophir Model L40 Thermopile and the output power is read on the screen via the Ophir software. The infrared light is polarized from the laser, but loses this characteristic by the delivery point owing to the length and properties of the fiber optic cable.

The Omron body fat analysis device (model HBF-306BL) from Country Technology, Inc. (Gays Mills, WI) used during participant inclusion. Similar types of bioelectrical impedance body fat analysis have been compared to the gold standard of dual-energy X-ray absoprtiometry (DEXA) with similar degrees of accuracy (r = .89) in a study by Lintsi, Kaarma, and Kull (2004). Good correlations (r = similar to .9) between alternative methods of body fat percentages were also found in a study by Bhat et al. (2005). In this study, these researchers compared anthropometry (height, weight, and multiple skinfold measurements) using the standardized technique by Durnin and Womersley's equation, bioelectrical impedance analysis (BIA), and deuterium oxide dilution (D2O). In their conclusions, they found that the BIA overestimated body fat by 1.2 kg and the anthropometric equation underestimated body fat by 1.0 kg as compared to the D20 method. Research pertaining to cardiovascular disease and dietary habits has also used the BIA method of body fat analysis. BIA method has been used to assess the

extent of increased risk that higher body fat percentages impose on myocardial infarctions (Wallstrom, Mattisson, Tyden, Berglund, & Janzon, 2005).

Materials

The McGill Pain Questionnaire (MPQ; Melzack, 1975) was administered to all groups during the pretest and posttest to determine the amount of perceived pain before and after treatment. The MPQ has four categories for describing pain: sensory, affective, evaluative, and miscellaneous. These categories comprise 20 separate word sets. The words are ranked by the most painful word or most intense word being at the top of the list and the least painful word found at the bottom on each word set. Scoring of the MPQ was done by giving the higher word choice a larger score and the lower word chose a small numerical score. Scores ranged from zero to 78. This common inventory has been used in many similar research studies (e.g., Chow, Barnsley, Keller, & Didall, 2004; Chow, Hettler, & Barnsley, 2006; Simunonic et al., 1998).

The Oswestry Low Back Pain Disability Questionnaire was also administered during the pretest and posttest to determine the extent of the patient's ability to perform normal activity. It assesses degree of disability by word sets with assigned numerical value. For example, there are 10 word sets including pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, traveling, and changing degree of pain. Correlation coefficient of test-retest reliability is $r = .99$ (Fairbank, Couper, Davies, & O'Brien, 1980) and Cronbach alpha's of .76 by Fisher and Johnson and .87 by Kopec for internal consistency (Roland & Fairbank, 2000). Score interpretations include minimally disablility (0-20%), moderate disability (20-40%), severe disability (40-60%), crippled (60-80%), and most likely bed bound (80-100%). Numerous studies have used this

inventory to predict change in daily function as perceived by patients with low back pain (Albert, Pinto, & Denis, 2000; Maluf, Sabrmann, Dillen, 2000; Niemisto et al., 2005)

Procedures

Three groups of back pain patients were included in this study: (1) individuals who received LLLT in the lumbar area, (2) a placebo group or control group who believed they were receiving LLLT treatment (in addition to traditional mat exercises) but, in fact, did not receive LLLT, and (3) the experimental group that received standardized therapeutic mat exercises in addition to LLLT. All groups performed a pretest and posttest that assessed perceived pain level and activities of daily living based on two questionnaires. The participants were interviewed by the primary researcher, who explained the questionnaires. The participants were asked to complete the questionnaires the night preceding their first laser treatment. The participants were given a contact phone number if questions arose during completing the questionnaires. If participants neglected to bring the forms, they received personal attention while completing the form immediately preceding their first laser treatment. Two medical facilities were used for data collection for patient convenience.

A stratified random assignment technique was used to place participants into groups. Group assignment was based on the number of participants already in the group with similar severity of condition, as well as diversifying the type of condition and duration of pain. The placebo group was evenly distributed within both facilities. All participants were excluded if they had experienced previous back surgeries related to the lumbar area, suspicion of cancer, osteomyelitis, stress fractures, spondylothesis, sacroiliac dysfunction, or other health related illness that could affect overall healing

ability. Current medication and physical activity were monitored as covariates that could interfere with expected results. Patients who exhibited characteristics like cigarette smoking or body fat percentage of 30% for men and 40% for women as measured by handheld electrical impedance equipment were excluded from participation in the study. In addition, individuals using a morphine pump or receiving current treatment at a pain management facility were excluded from this research. Appendix B includes the application approval forms provided by Institutional Review Board for the Protection of Human Subjects from the Middle Tennessee University.

Participants were informed about the research study from one of three sources, their evaluating physician, an information poster at the physician's office, or a phone call from a research assistant. Participants were provided information about the light therapy and the associated risks. If the patients preferred to learn more about the study the physician referred them to the primary investigator. The primary investigator asked the patient to read and sign the consent form (Appendix C). The inclusion, exclusion, and covariates (Appendix D) were assessed for each patient, and if appropriate, the questionnaires were distributed. Each patient was instructed to complete the questionnaire the night prior their first laser treatment, or if questionnaires were completed too early, the participant filled out new forms preceding the first laser treatment.

Data Collection Process

The data collectors were a certified athletic trainer (ATC) and a physical therapist (PT) that had been trained in LLLT, as mandated by the equipment manufactures. The ATC and PT each had current state licenses and IRB training prior to administering the

treatments. The clinical setting in which the data collectors treated participants consisted of established physical therapy clinics. Bradley Memorial Rehabilitation (located in Cleveland, Tennessee) and Center for Sports Medicine Physical Therapy Centers (located in Chattanooga, Tennessee) were facilities where data collection occurred simultaneously with explicit instruction on procedural therapy. Each laboratory had a standard treatment table in which the participants were positioned either prone or side lying with a pillow to support the low back, when needed. The hour of day for data collection was determined by the patient's schedule.

During the first evaluation each participant underwent an examination to determine underlying issues that might address back pain (Appendix E). The clinicians examined the patients for muscle weakness, imbalance, or tightness. Dynamic and core stabilizers for the low back include the hip flexors, hip extensors, hip rotators, abdominals, latissimus dorsi, multifidus, piriformis, tensor fasciae latae, and gluteus muscles. After the first evaluation procedure the patients rescheduled for 12 treatments of either laser "only" or laser and exercise.

Duration for administering 12 treatments varied considerably based on patient convenience (4-10 weeks). After the final treatment the patients filled out the MPQ and Oswestry questionnaires and returned it to the data collectors, which were also their clinicians. Shortly after the last participant received her final treatment all participants were mailed a follow up letter to explain which group they were assigned and whether the results of the study demonstrated laser efficacy for decreasing pain and increasing daily activity.

Treatments

Low Level Laser Treatment

The treatment consisted of irradiation with a Nd: YAG diode laser at 1069 nm. A spot technique with a 10 cm^2 transducer head was used with a contact irradiation with the dose of approximately 36 J/cm^2 per point. These points included seven spots in the lumbar area. The total amount of energy delivered to the LB was 360 Joules. The treated areas included were medial to the posterior superior iliac spine (PSIS), over the spinous process of involved disc spaces, and bilateral erectae spinae muscles of the involved disc space. Patients with leg pain and palpable pain in the sciatic notch were treated in that area. These exact point application per participants varied slightly based on where the patient's pain was located.

The treatment irradiation technique is similar to a study conducted by Soriano and Rios (1998). The researchers, however, used a much lower dose of 4 J/cm2 and found significant effectiveness of LLLT in an older population with chronic back pain. Therapeutic lasers, Inc., the laser manufacturer involved in this study, recommended an increase in dosage based on their current research of efficacy.

The placebo group received a replication treatment of the experimental groups, however, the laser was a deactivated laser. Neither the ATC/PT's nor the patients knew when the laser was activated, hence this study consisted of a double-blind approach with a placebo group. This process was accomplished by having a physical therapy technician turn the machine to the desired intensity of 3 watts or zero watts for each treatment based on group assignment. All groups received a detailed explanation about the proper use of the laser prior to the initial exposure to LLLT.

Exercise Treatment

Participants assigned to the exercise groups performed a variety of exercises prior to receiving the LLLT. The exercises were outlined in a protocol handout (Appendix F) in which each data collector chose any exercise deemed necessary to meet the unique needs of each patient's low back pain. Exercises include double knee to chest, single knee to chest, prone extension, side rotation stretch, abdominal strengthening with and without upper, and lower extremity movement. Stretches based on initial evaluation could have included piriformis, adductors, hamstrings, quadriceps, gluteus maximum, and tensor fascia latae. Prior to laser treatment, the participants were given an exercise and stretching program that was unique for their condition and needs. Exercise progression was dependent on the patient's pain level and response to exercise. If isometric exercises did not increase the patients' pain then more aggressive isotonic exercises were used. No patients progressed to a level in which weights were added. Those patients who continued to improve were given more exercises and increased their number of repetitions, while other patients had to reduce their exercise if their symptoms worsened. Each patient had an individualized program designed to meet their unique needs with varying rates of progression.

CHAPTER IV

RESULTS

Introduction

The primary research question addressed in this study investigated the effects of LLLT on reduction of perceived pain in the low back and increased function related to daily living among patients, as compared to a placebo LLLT and traditional lumbar mat exercises. The second research question addressed in this study was to determine the effect of receiving LLLT and traditional lumbar mat exercises, as compared to laser therapy alone on perceived pain and increased function related to daily living.

Prior to answering the above research questions, descriptive statements of participants were computed with frequencies, means, and standard deviations established and reported in Chapter 3. To address the research hypotheses as given in chapter one groups were compared at pretest by gender, age, amount of medication (described as medication index), type of condition, amount of physical activity, duration of pain, and time of last epidural. These factors were grouped as follows according to five criteria, medication index, type of condition, amount of physical activity, duration of pain, and time of last epidural.

After recording the type of medication taken and the frequency an index was developed to quantify medication as one variable. Medication was categorized by over the counter (OTC), prescription NSAIDS or muscle relaxants, and narcotics. The categories were multiplied by 1, 2, or 3 for OTC, NSAIDS or relaxants, and narcotics,

respectively. The total scale ranged from 0 (no medication) to 12 (varied types and frequencies). Frequency of each medications was categorized by amount taken, which included 0 (none), 1 (infrequently), and 2 (frequently). Once each drug was multiplied by its numerical value then the data was added together for a total score per patient. Because narcotics have the potential to be addictive they were considered of higher value (multiplied by 3) than the prescription NSAIDs and muscle relaxants (multiplied by 2). The OTC medications would be the least potent of all three types and therefore they were multiplied by one.

To determine type of condition patients diagnosed with a sprain, strain, or mechanical pain, or sciatic pain not associated with a disc injury were combined as similar soft tissue conditions as group one. The second group was degenerative disc disease (e.g., disc collapse), which physicians primarily diagnosed with a magnetic imaging resonance. The third group included diagnoses of disc bulge or herniation of all degrees, which includes protrusion of the disc onto the nerve root.

Patients were grouped into one of three groups to determine their level of physical activity. Group one consisted of those patients that were inactive either at work or at home. Group two consisted of those patients who were very active at home or at work. The final group was comprised of those individuals who had a combination of activities (e.g. combinations could include individuals who might be active at home or work and also have an established consistent exercise routine, other combinations were also available).

With respect to duration of pain, patients reported the number of months in which a person had been experiencing low back pain. Acute pain patients reported exact

duration of pain, while chronic back pain patients reported months of pain as approximations.

Finally, time that patients received their last epidural (over the past 4-8 weeks) were in group one, while the patients that received an epidural longer than eight weeks but less than two years comprised group two. The third group consisted of any individuals who had an epidural two years or more prior to engaging in this study.

Data Analysis

A repeated measures doubly multivariate analysis of variance (MANOVA) was used to determine differences on perceived pain and daily function. The 14th version of the Statistical Package for Social Sciences (SPSS 14) was used to compute descriptive statistics, Chi-Square analyses, univariate ANOVAs, and multivariate ANOVAs. The dependent variables were scores from the McGill Pain Questionnaire and the Oswestry Low Back Questionnaire. The independent variables were the covariates of medication used, type of condition, amount of physical activity, duration of pain, and time of last epidural, as well as the treatment groups (exercise, laser and exercise, and laser) in addition to the time (pretest and posttest). A 3 (treatment groups) X 2 (time) repeated measures MANOVA was performed to examine the research questions.

Covariate Analyses

Because groups were divided by stratified randomization, the chance of the dependant variables being influenced by the differences within each group is very low. However the sample size was low, therefore, each covariate was individually analyzed. Categorical covariates included gender, amount of physical activity, injury type, and recently experienced epidurals, and were examined with Pearson's Chi-Square analyses.

The percentage of participants that were females did not differ across treatment groups, $X^2(2, N = 43) = 2.54, p > .05$. The exercise group, laser and exercise, and laser only group included 11 (78%), 10 (67%), and 8 (50%) females, respectively.

A Pearson's Chi-Square analysis revealed that the percentage of participants that exercised none, infrequently, frequently, or in combination of these frequencies in daily living, either during leisure or at work, were not statistically different among treatment groups, $X^2(6, N = 43) = 2.77, p > .05$. The percentages of participants in each treatment group were provided in Table 1 of Participant Characteristics (refer to Chapter 3).

The percentage of participants that had injuries similar to a muscle strain or sciatica without disc involvement, degenerative disc disease, and herniated discs were not significantly different across treatment groups , $X^2(6, N = 43) = 1.60, p > .05$. The percentages of each group were provided in Table 1 of Participant Characteristics (refer to Chapter 3).

The final categorical covariate analysis was the extent to which not having an epidural, recently having an epidural, or having an epidural at some point in the patient's history would affect the pain scores or function scores. Extent of epidural usage was not significantly different across treatment groups. The percentage of participants' use of epidurals was similar across treatment groups, $X^2(4, N = 43) = 3.11, p > .05$. Over half the sample (64%) had never chosen to get an epidural for pain relief, and these individuals were similarly distributed among the treatment groups. The percentage of participants never electing an epidural across groups were 9 (57%), 11 (71%), and 10 (64%) for the exercise, exercise and laser and laser only, respectively. Further percentage comparisons of epidural usage across groups can be found in Table 1.

A Welch's analysis of variance (ANOVA) was conducted on the continuous covariates of age, duration of back pain, and medication index. The participant's age was not statistically different across treatment groups, $F(2, 40) = 0.22, p > .05$. The exercise group had a mean age of 51.29 years. The exercise and laser group had a mean age of 50.87, and the laser only group had a mean age of 50.09 years old.

Welch's ANOVA indicated that participants did not significantly differ on duration of back pain across treatment groups prior to enrolling in the study, $F(2, 40) = 0.20, p > .05$. Comparison of group means indicated that the exercise group had the longest duration of back pain ($M = 82.64$ months), and the exercise and laser group had a similar duration of back pain ($M = 64.60$ months). The laser only group experienced the shortest duration of back pain prior to enrolling in the study than the other two groups ($M = 58.61$ months).

The medication index was designed to take into account the extent of medication being consumed by each participant prior to enrolling in the study. Welch's ANOVA indicated no significant difference in the consumption of medication of the participants across the three treatment groups, $F(2, 40) = 0.24, p > .05$. The laser only group consumed the lowest amount of medication with a medication index scores of 3.64, 4.79 and 5.73 for laser, exercise, and laser and exercise, respectively.

No significant differences were found between treatment groups based on the Pearson's Chi-Square analyses or the Welch's ANOVA analyses, therefore, the covariates (gender, age, amount of medication, type of condition, amount of physical activity, duration of pain, and time of last epidural), did not likely influence treatment

group outcomes. Thus, the final analysis was conducted without controlling for the covariates due to the limited sample size.

Descriptive Statistics

Differences between pretest and posttest scores on the McGill Pain Questionnaire and Oswestry Low Back Pain Disability Questionnaire were measured. The means and standard deviations are listed in Table 2. The decrease in the posttest scores as compared to the pretest scores among all groups demonstrates that on the average participants' experienced less pain and more function after participating in this study.

Inferential Statistics

A repeated measures doubly MANOVA was used to assess the differences in perceived pain and function between the main effects of treatment type (exercise, exercise and laser, or laser). The first dependent variable was perceived pain. It was measured by the MPQ. The second dependent variable was activities of daily living or function. It was measured by the Oswestry Low Back Pain Disability Questionnaire. This same analysis was used to investigate the within participant's main effects by measuring the differences in pain and function at the pretest as compared to the posttest. In addition, an analysis was performed to determine if an interaction between treatment type and time had affected the patients' pain and function. A 3 X 2 repeated measures MANOVA revealed that treatment type did not significantly affect the outcome scores of pain and function, $F(4, 78) = 2.18, p > .05$). The Wilks's lambda score was .809. However, the main effect of time was statistically significant, the participant's improved on pain and function from pretest to posttest, $F(2, 39) = 33.82, p < .001$. All patients improved on pain and function scores from the pretest to the posttest. On a 100% scale,

Table 2

Means and Standard Deviations of Pain and Function Scores of Participants by Treatment Groups at Pretest and Posttest with Difference Scores

Outcomes	Pretest	Posttest	(Pretest-Posttest)
McGill Pain Questionnaire Groups			
	M (SD)	*M (SD)*	Difference Scores
Exercise	48.16 (18.86)	26.78 (23.90)	21.38
Laser & Exercise	54.98 (14.11)	27.92 (19.53)	27.07
Laser	50.71 (13.04)	30.70 (18.84)	20.01
Oswestry Low Back Disability Groups			
Exercise	51.23 (11.47)	28.44 (19.10)	22.84
Laser & Exercise	44.80 (12.04)	25.60 (15.17)	19.20
Laser	37.98 (12.70)	23.30 (17.27)	14.68

with 100 representing a large degree of pain, the mean drop in percentage of pain was 22.82, which was significant. The omega-squared was .276, meaning that 28% of the improvement in low back pain was attributed to the interventions. On a 100% function scale, with 100% being extremely dysfunctional, a mean drop in function score of 18.81 was also significant. The omega squared was .276, meaning that 28% of the improvement in low back function was attributed to the interventions.

However, the interaction between time and treatment type was not statistically significant, $F(4, 78) = 1.10$ $p > .05$. When controlling for treatment type, the difference between pretest scores and posttest scores on pain and function did not differ in relationship to type of treatment. Exercise, laser and exercise, and laser only treatment

did not differ on pain and function scores from pretest to posttest. The results are summarized in Table 3. An omega square for the significant interaction between treatment type and time was of .001, indicating 0% of the variance in pain and function scores were accounted for by treatment type.

The univariate ANOVA procedure was conducted on individual comparisons of treatment type, time and their interactions on each dependent variable (pain scores and functions scores). The main effects for treatment group as related to pain scores indicated that treatment groups were not statistically significant, $F(2, 40) = 0.28$ $p > .05$.

The main effects for treatment group as related to function scores indicated that treatment groups were not statistically significant, $F(2, 40) = 1.85$ $p > .05$. An omega square for the treatment type was of .052, indicating 5% of the variance in pain and function scores were accounted for by treatment type. Unlike the treatment groups, the univariate ANOVA indicated that the main effect of time on pain scores was statistically significant, $F(1, 40) = 50.37$ $p < .001$. In addition, the univariate ANOVA approach indicated that the main effect of time on function scores was statistically significant $F(1, 40) = 64.34$ $p < .001$. Results from the univariate ANOVA has similar finding as the previously mentioned MANOVA.

The interaction between time (pretest-posttest) and treatment conditions was not significant for the pain scores, as measured by the MPQ, $F(2, 40) = 0.46$, $p > .05$. The univariate ANOVA revealed that the interaction between time and treatment type was not significant for the function scores, as measured by the Oswestry Low Back Questionnaire, $F(2, 40) = 0.98$, $p > .05$. Results are summarized in Table 3.

Table 3

Multivariate Analysis of Variance Results for Treatment Groups and Time Variables

Effect	Measure	F	Hypothesis df	Error df	significance
Multivariate					
Groups		2.177	4	78	.079
Time		33.824	2	39	.000*
Time X Groups		1.095	4	78	.365
Univariate					
Group	McGill	0.282	2	40	.756
	Oswestry	1.845	2	40	.171
Time	McGill	50.365	1	40	.000*
	Oswestry	64.342	1	40	.000*
Time X Groups	McGill	0.461	2	40	.634
	Oswestry	0.980	2	40	.384

$p < .001$

A manipulation check was performed to determine if different clinicians affected the positive outcomes of less pain and increased function. A two-way repeated measures was performed on the outcome of pain which demonstrated no significant difference between clinician, $F(1, 41) = 2.90$, MSE = 418, $p = .10$. Similar results were found for the outcome function. When the same analysis was performed on function, there was no significant difference between clinicians and patients function scores, $F(1, 41) = 0.17$,

MSE = 342.41, p = .68. The two clinicians design of this experiment did not interfere with the outomes, thus the effect on the pain and function scores were not influenced based on which clinician was working with them.

In conclusion, the repeated measures MANOVA approach was clearly supported by each univariate ANOVA. The results of this study indicated that patients who received low level laser therapy did not score lower on the McGill Pain Survey or the Oswestry Low Back Questionnaire at posttest than patients who received traditional (mat) exercises. Thus, the laser group had similar difference scores for pain and function as the exercising group.

In reference to the second research question, the laser only treatment was not superior to the exercise and laser treatment in relationship to pain and function scores. Similar difference scores across treatment groups support this finding. Although all groups reached statistical improvement of scores related to reduction of pain and increased daily function, the effectiveness of treatments delivered were similar. It was concluded that exercise, laser and exercise, and laser are all effective treatments for improving back pain among patients. It was also concluded that exercise, combined laser and exercise, and laser only are each effective treatments for improving daily function among low back patients.

CHAPTER V

DISCUSSION

Summary

The purpose of this study was to investigate the effects of LLLT on perceived low back pain and daily living activities when compared to a placebo LLLT condition and traditional lumbar mat exercises. Additionally, this study examined the effect of receiving LLLT and traditional lumbar mat exercises, as compared to laser alone on perceived pain and daily living activities. Four hypotheses were tested. First, patients who received low level laser therapy will score lower on the McGill Pain Survey at posttest than patients who received traditional (mat) exercises. Second, patients who received low level laser therapy and traditional (mat) exercises will score lower on the McGill Pain Survey at posttest than patients who received the laser treatment only. Third, patients who received low level laser therapy will score lower on the Oswestry Low Back Pain Disability Questionnaire at posttest than patients who received the traditional (mat) exercises. Finally, patients who received low level laser therapy and traditional (mat) exercises will score lower on the Oswestry Low Back Pain Disability Questionnaire at posttest than patients who received the laser treatment only. Covariates were controlled for by analyzing each treatment group for differences in gender, age, amount of medication, type of condition, amount of physical activity, duration of pain, and time of last epidural.

The results indicated mixed support for these hypotheses, in particular the results did not support the hypothesis that patients who received low level laser therapy would

score lower on the McGill Pain Survey at posttest than patients who received traditional (mat) exercises. These results suggest that the laser treatment was similarly effective as the exercise treatment for pain reduction for patients suffering from low back pain.

The patients who received low level laser therapy and traditional (mat) exercises did not score lower on the McGill Pain Survey at posttest than patients who received the laser treatment only, which did not support hypothesis two. It appears that the combination of laser and exercise is no more effective than administering a laser treatment for pain reduction in patients with LBP.

The patients who received low level laser therapy did not score significantly lower on the Oswestry Low Back Pain Disability Questionnaire at posttest than patients who received the traditional (mat) exercises, therefore hypothesis three was not supported by the data. Additionally, the patients who received low level laser therapy and traditional (mat) exercises did not score lower on the Oswestry Low Back Pain Disability Questionnaire at posttest than patients who received the laser treatment only, which did not support hypothesis four. Although treatment groups did not differ statistically, several patients improved from the pretest to posttest on function. Regardless of treatment choice, patient's daily function improved with organized formal rehabilitation. When function scores where analyzed from pretest to posttest all groups improved, therefore patients were able to perform move daily activities without as much pain.

The reason it was hypothesized that patients receiving a laser treatment would perform better than those individuals exercising on both measures of pain (hypothesis 1) and function (hypothesis 3) was because many acute HNP injuries cannot endure too much exercise without having negative implications from an exercise program. The lack

of acute HNP injured patients enrolling in the study might explain why the hypotheses were not supported. The majority of patients treated were chronic pain patients. Researchers support the use of exercise as a treatment to reduce chronic LBP (Basford et al., 1999; Gur et al., 2003; Soriano & Rios, 1998). The current study further supports the use of exercise for reduction in chronic LBP.

Hypotheses #2 and hypotheses #4 predicted that laser and exercise would be better than laser only. These hypotheses were written based on the previous research that if laser treatments are more effective than a placebo for improving pain and function (Basford et al., 1999; Soriano and Rois,1998) and that exercise is superior to other interventions (Clare, Adams, & Maher, 2004; Cohen & Rainville; 2002). Ostensibly, then the combination of exercise and laser treatments should be better than each individual treatment for reducing pain and improving function. Klein and Eek (1990) found LLLT and exercise not to be significantly better than exercise only for improving disability, reducing pain, or improving objective scores related to range of motion, isometric torque, and isodynamic velocity. Their research however, has been criticized by Bjordal et al. (2003) for providing a low treatment dosage and, therefore these results were not highly regarded during the hypotheses writing of the current study. Incidentally, a higher dosage of laser irradiation (360 Joules) was utilized in this study. Bjordal et al. (2003) estimated that Klein and Eek delivered a low energy dose of .1 Joules, while the energy dose was not provided in the literature by Klein and Eek.

The most similar research design to the current study exists with the Gur et al. (2003) study. Both studies had three treatment groups (laser, exercise, and laser and exercise) and they both measured function and pain to determine laser efficacy. Both

studies concluded that pain decreased and function increased in low back pain patients regardless of treatment group. While the findings were similar, many differences exit between the Gur et al. study and current study. Differences included, dosage, number of areas irradiated, location of irradiation, laser type, and injury type. The researchers in the Gur et al. study used an estimated 10 J/cm2 as compared to 36 J/cm2 in the current study. Gur et al. chose a pulsing laser while a continuous laser was used the current study, which explains why the power densities were so different (e.g. 2 minutes/7 spots vs. 4 minutes/10 spots). There were approximately 10 locations irradiated in the Gur et al. study, whereas the current study selected 7 locations. Areas of location for treatment sites were also different. The current study irradiated the LB and sciatic notch areas, while the Gur et al. study irradiated the LB, gluteal fold, hamstrings, and gastro-soleus complex. By expanding the locations to include the leg and calf the Gur et al. study was focusing on peripheral nerves instead of central nerve roots. Determining which target tissue to irradiate may be as important as energy density selection. Both factors may affect whether or not laser treatment is effective. In addition, Gur et al. study excluded patients experiencing neurological deficits which is common among HNP patients, while the current study included many HNP patients with neurological signs and symptoms (e.g. weak foot dorsiflexors, numbness and tingling, as well as diffuse unilateral and bilateral leg pain). Finally the device selection differed between the studies. The current study used a Nd: YAG with 1064 nm as compared to the Gallium-Arsenide with no wavelength presented in the Gur et al study. The Gallium-Arsenide used by Soriano and Rios (1998) was a 904 nm, therefore, the Gur et al. laser was probably 904 nm as well. Although the type of laser used was different between studies, the probable wavelength

choices of 904 nm, as compared to 1064 nm, results in similar depth of penetration in order to reach deep lumbar muscles and nerves. Therefore, the difference in laser selection between studies is probably insignificant.

In summary, although research is limited in the area of LB pain and LLLT, it appears that the use of LLLT is no more effective than using exercise alone when trying to alleviate pain or increase function. The results of this study indicated that the combination of exercise and LLLT markedly reduced pain than the other groups; however, this change did not reach statistical significance. Based on this exercise regimen and population it seems unclear why groups did not differ. One explanation could be that within this population group there were a high percentage of patients with chronic herniated disc injuries across the three groups (i.e., 50%, 46%, 36%) respectively. However, based on these conclusions and the assumption that patients with HNP injuries can easily exasperate their pain with exercise, a treatment such as LLLT which has direct effects on the pain cycles could continue to positively affect patients. Thus, it may be concluded that when exercise is not an option for patients with extreme pain, it appears that laser treatment could be an appropriate option.

The conclusion that the laser treatments would be more beneficial for pain because it is a passive treatment which affects nerve function would explain why more improvement was noted on the pain scale than the function scale, across all laser groups (laser and exercise, and laser). The ability to increase daily function would logically be linked to an increase in muscular endurance which would be related to exercising groups. However, when patients are in extreme pain, the ability to exercise is hindered therefore, pain is usually a priority in a rehabilitation plan of progression in order to assist patients

in recovering. Exercise alone can also provide pain relief when it is appropriately administered. This may be an explanation for why the exercise group had similar scores for improvements in pain and function.

Perhaps, one implication of this study on practical skills of certified athletic trainers or physical therapists is to continue to use the LLLT among individuals experiencing low back pain, especially patients suffering from chronic mechanical LBP and myofascial pain syndrome. Based on the current results, it appears that numerous types of LBP patients can benefit from exercise, laser, or a combination. The more superficial the injury (e.g. non-disc pathology) the more probable the success in reducing pain. As seen in other research (Basford et al., 1999; Gur et al., 2003; Gur et al., 2004; Soriano & Rois, 1998), the more efficiently the laser light can penetrate the target tissue (e.g. muscles, ligaments, nervous tissue) the more likely the patient will experience less pain and more function as a result of laser irradiation. Due to limited research in this area, however, it is not advisable to use this device on LBP patients who are experiencing disc pathology until additional evidence is provided by researchers to support LLLT efficacy for this type of injury.

Recognition of location-specific dosage of LLLT for patients will continue to be a focus point for the future (Bjordal et al., 2003). The total energy delivered to the LB was 360 Joules in the current study which is considerable higher than the recommended treatment dosage for chronic muscle strains (35-45 J), as presented by McLeod (2004). However, the current delivered dose was similar to the dose for neck (11-360 J) and back (48-480 J) pain patients recommended by Bjordal et al. The dosage recommendation by Bjordal et al. has a varied range of intensity and may add to the lack of standardizing

protocols. Based on patient comments during the study, it is also recommended to use a lower dosage of laser irradiation for patients suffering with acute LB injuries.

Two patients in the current study categorized as acute conditions (i.e. pain for less than 4 weeks) had immediate increased pain that endured for two to three days, however, after the initial elevation in pain, both patients recovered remarkably. One patient was diagnosed with a lumbar strain (no MRI was performed on this patient); however, she had remarkable leg pain which completely resolved after receiving the laser only treatments for four weeks. The other patient was diagnosed with an HNP and his verbal pain analogue scale decreased 35 points (on a 100 point scale). In addition to a decrease in daily pain, this patient no longer needed to take pain medication to control his pain. He was treated with laser and exercise and was almost pain free after his four weeks of treatment.

LLLT parameter selection is very important to patient outcome. This study reiterates the emphasis on parameter selection as supported by Tuner and Hode (1998) in their article entitled, "it's all in the parameters." Tuner and Hode claim that laser research has not been sufficiently scrutinized based on parameters selected. They state that studies with low intensities should not be used as evidence to conclude that lasers are ineffective. Basford et al. (1999) stated that treatment parameters are not trivial and future research is needed to provide more direction in parameter selection. In addition, clinicians should make "educated" decisions on what type of laser to use based on target tissue. For example Bjordal et al. (2003) suggested lasers with a wavelength of 632 nm are not applicable for low back treatment because the depth of penetration would not be adequate. The lasers with longer wavelengths have deeper penetration, therefore, the

830 nm, 904 nm, and 1060 nm lasers are recommended for low back pain patients. The pulsed lasers will require longer treatment times to produce valid dosage appropriate treatments as previously demonstrated in the comparison on power density of the current study and the study by Gur et al. (2003).

Limitations

There were several limitations in this study. For example, the assumption that the effect size would be medium could have varied the results based on the number of participants needed. The current sample size was based on an interaction between time and treatment group, if the effect size was a medium then the indicated sample size was 42 people with the correlation of .50 between dependent variables, which would have resulted in 80% power (Maxwell & Delaney, 2004). Based on the current research findings, future researchers should estimate sample size based on a small effect size. The current study indicated an effect size for all treatments from pretest to posttest was .27 which is closer to the small effect size (.25) than the medium effect size (.50). If a similar design (repeated measures doubly MANOVA) was developed, a small effect size would warrant 158 participants needed to reach the 80% power. Therefore, a weakness of the current study is the limited statistical power. However, in field studies, similar to the current study, clinicians support outcomes which represent clinical effectiveness, sometimes measured as a 20% change in patient's pain ratings, as measured by the McGill Questionnaire in the study by Ceccherelli et al., (1989). For the current study pain and functions scores were computed in percentages, therefore, all differences above 20% represented clinical effectiveness. It should be noted that all treatment groups had a 20% change in pain scores from pretest to posttest, however, the exercise group was the

only group with a change in function score of more than 20%. Although not statistically significant, the laser treatments provided more reduced pain than it provided increased function, based on the two scales used (MPQ and Oswestry Disability Questionnaire).

To increase the vigor of clinical effectiveness, Basford et al. estimated a reduction of symptoms from 35% to 40% as clinically significant. They found that laser treatment for low back pain was better than a placebo treatment for patients with low back pain. They also concluded that pain reduction was not sustained when assessed one month after laser treatment. Conceivably, true clinical success is found in long-term sustainable changes, a concept not addressed in this study. Therefore, the lack of long-term effects is considered a weakness of the current study. Unlike Basford et al., Soriano and Rios (1998) found that LLLT reduced back pain for a period of four to six months. The efficacy of LLLT should be evaluated on acute pain relief as well as sustainable pain relief over time, the more sustainable the changes the more valuable the laser tool will become in the rehabilitative realm.

The longer a person has experienced low back pain, the less likely the person will respond to varied treatments (although not research based, this seems to be a logical deduction). Therefore, duration of low back pain may affect the patient's ability to sense a reduction of pain. Although, the average duration of low back pain (1 month – 40 years) in the current study was not significantly different across treatment groups, the drastic range of duration of low back pain is different than other studies and could be considered a limitation of the current study. Basford et al. (1999) evaluated patients from approximately 7 to 18 months of LBP. Gur et al. (2003) evaluated patients from 7 to 31 months of LBP. Additionally, Klein and Eek (1990) studied participants with

approximately 2 to 17 years of LBP. Duration of LBP may have been an extraneous variable in the Klein and Eek study that attributed to their finding that range of motion, pain, and disability rates were no better in the LLLT and exercise group as compared to the exercise group only. Similar extraneous effects may have occurred in the current study because 26% of the population sampled had been dealing with low back pain for more than six years (72 months). Thus, the chance of providing less pain and more daily function may have been limited by duration of low back pain. Future researchers may need to consider a more restrictive inclusion criterion for months of low back pain.

The sampling population in this study was not limited to one type of low back injury. Therefore, it is unknown if results would have been different for a more homogenous group. This limitation hinders appropriate comparisons to previous research. For example, Gur et al. (2003) excluded patients with neurological deficits, however, the current study included more complicated types of injuries. Klein and Eek (1990) and Soriano and Rios (1998) excluded all radicular pain patients unlike the current study. By allowing the patients with radicular pain and neurological deficits, this study is original and adds more depth to the current literature on LBP laser efficacy.

In conclusion, the limitations of the current study include low statistical power, limited number of patients, and lack of investigational long term clinical effects. The lack of homogeneity (e.g. months of low back, injury types) of the population sample limits the comparison of the current study to other studies. In general, clinical research has its own limitations related to controlling extraneous variables, therefore it is speculated that any combination of extraneous variables such as lifestyle activities,

nutritional consideration, financial security, work status, and etc., may have affected the patients during their enrollment and these variables were not taken into consideration.

Recommendations for Future Research

Support for continued research of LLLT and LBP patients is found in the theoretical foundations for which LLLT is thought to be effective. The theoretical basis that LLLT can decrease inflammation related to chemical inflammatory responses by increasing neutrophil production and decreasing prostaglandin production supports this type of research (Bjordal et al., 2006; Fujimaki et al., 2003). The intensity of pain experienced by LBP patients with a HNP can inhibit a patient's ability to exercise, therefore, this area of research could have significant impact on the current treatment protocols for this injury group. Additional studies should compare between LLLT treatment and traditional HNP treatments (e.g. NSAIDS, discectomy, activity modification, or walking).

Based on a review of previous related studies, this study is the first attempt of a double-blind clinical design to examine the effects of LLLT on LBP patients with a clinical diagnosis of herniated disc injuries. Almost half (44%) of the current sample was suffering from a HNP injury. Three-fourths of the HNP patients of this sample had been suffering from pain for more than one year. Intense pain and poor daily function of many patients may be not only related to the herniation of the nucleus pulpous but it may also be linked to the inflammation of the surrounding tissues. More research is needed on the efficacy of LLLT on pain and function levels of HNP patients based on the foundation of treating the inflammation around the herniated nucleus pulpous. The current use of epidural and oral medications for disc space tissue inflammation would continue to

provide anti-inflammatory affects for area in which the laser depth can probably not reach (e.g. disc space). For this reason, it is not recommended to use the laser irradiation as a monotherapy but rather an adjunctive therapy to current successful HNP patient treatments.

Based on the theoretical foundation that LLLT can enhance healing by increasing collagen synthesis, tensile strength, ATP synthesis, and the number of degranulation mast cells (e.g. Enwemeka et al., 2004; Woodruff et al., 2004) future studies are needed to investigate the effect of LLLT on patients with more acute LB pain. Other outcomes of interest in future studies should include return to work status and reoccurrence of LB pain in both acute and chronic LBP patients. Examining these different outcomes may provide more insight into the effectiveness of LLLT on LBP patients.

Future studies should provide different laser irradiation intensities for acute LBP patients as compared to chronic LBP. The acute pain patients should be below the current dosage of 36 J/cm2 based on patient's perceived pain the day after laser irradiation. An intensity with too much laser irradiation on acutely injured tissue may increase inflammation and have negative affects on patient care (e.g. increase pain and delayed healing). Numerous other studies have supported the need for more research on parameter selection (Basford et al., 1999; Ceccherelli et al., 1989; Tuner & Hode; 1998). Tuner and Hode (1998) recommended eliminating those studies with low dosages as part of a systematic review for LLLT efficacy. It is obviously unjustified to say LLLT is ineffective if the adequate dosage is not delivered. In numerous conclusion statements of previous research, the intended dosages were arbitrarily selected due to limited research in the area of LBP.

More research is needed on a larger scale with greater control of covariates. The current research, in addition to many other research studies, have evaluated varied covariates for equality across groups but not the impact that each covariate would have on overall results. A large regression analysis on covariate affects is needed to help explain how obesity, smoking, and chronic pain affect patients with LBP.

More research is needed on ranking injury types and planning appropriate exercise programs, which are more controlled than the current study for better cross comparisons to other studies. Each exercise program of the current study was specifically designed to meet each persons varied needs based on their pain tolerance and muscular conditioning level. Much variation existed across patients, therefore the type of exercise performed would be difficult to repeat in future studies.

Future studies on patients with HNP injuries should include an in-depth discussion of varied types of HNP injures. While most patients in the current study had an MRI which showed disc injuries the extent of the injuries were not reviewed, other than to place them in the degenerative disc disease group or the herniated disc injury group. It should be noted, numerous patients had some overlap and the enrolling physician would determine which pathology appeared more dominate based on MRI results and clinical signs and symptoms. As the medical field advances, it is hoped that enhanced understanding of differing HNP injuries will assist the development of injury-specific treatment research which will improve health care for patients experiencing low back pain.

Future studies that addressed length of laser treatment may add to the body of knowledge in such a way that insurance companies may elect to pay for services if the

laser services are found to provide cost savings. If patients are able to recover quicker and cost the economy less money via way of less surgeries than the LLLT industry may be able to provide a more valuable tool for healthcare providers.

In summary, more comprehensive research that accounts for extraneous variables is needed in order to accurately determine effective LBP and LLLT management. The combination of complex parameters for LLLT and the multidimensional treatment plan needed for LBP provides researchers with numerous avenues in which to continue researching.

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APPENDIXES

APPENDIX A

U.S. Food and Drug Administration Letter

APPENDIX C

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): ~~Pending~~ K033986

Device Name:

MLT - 1000 IR Laser System

Indications for Use:

The MLT - 1000 IR Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ **OR** **Over the Counter Use:**
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

(Division Sign-Off) Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033986

K033986

MAR 2 9 2004

APPENDIX B

510(k) PREMARKET NOTIFICATION SUMMARY
(per 21 CFR 807.92)

MLT – 1000 IR Laser System

I. Applicant:

Medical Laser Therapeutics LP
1019 Dragon Street
Dallas, Texas 75207
1 214 748 - 1088

Contact Person: James Nairne

Date Prepared: December 22, 2003

II. Device Name

Proprietary Name:	MLT – 1000 IR Laser System
Common / Usual Name:	Infrared Lamp
Classification Name:	Infrared Lamp (21 CFR 890.5500)
Product Code:	ILY

III. Intended Use of the Device

The MLT - 1000 IR Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

IV. Predicate Devices

The MLT-1000 IR Laser System is substantially equivalent to other infrared therapeutic lamps that are currently in commercial distribution. These predicate devices include, but are not limited to, the Bales Scientific, Inc. Photonic Stimulator (K974468), Light Force Therapy, Inc. Super Nova and Acubeam Systems (K001179), the Meditech International Inc BioFlex Professional Therapy System (K023621) and the Spectrum Laser & Technologies, Inc. Neurolase Series (K032787).

V. Description of the Device

The MLT - 1000 IR Laser System is an innovative, safe, easy to use, hand-held, non-invasive therapeutic device that provides continuous heat therapy. The System consists of a Control Unit that houses the electronics and controls and a treatment probe hand piece that delivers the infrared energy.

VI. Summary of the technical characteristics of the MLT - 1000 IR Laser System to the referenced predicate devices

The MLT - 1000 IR Laser System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared and visible laser diodes to generate topical heating for the purpose of elevating tissue temperatures for temporary relief of muscle and joint pain.

VII. Testing

Testing of the MLT – 1000 IR Laser System will include functional performance testing and electrical safety testing in accordance with all applicable standards for this type medical device.

VIII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the MLT-1000 has the same intended uses, with similar functional and performance characteristics. The System is designed to comply with the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in literature and accepted by the Federal Food and Drug Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2004

Medical Laser Therapeutics LP
c/o Ms. M. Joyce Heinrich
Texas Applied Biomedical Services
12101-A Cullen Boulevard
Houston, Texas 77047

Re: K033986
Trade/Device Name: MLT – 1000 IR Laser System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: II
Product Code: ILY
Dated: December 22, 2003
Received: December 30, 2003

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

APPENDIX C

Consent

Consent Form for Study Participants

THE EFFECT OF LOW-LEVEL LASER THERAPY ON LOW BACK PAIN PATIENTS

What is the research design?

Thank you for your participation in this study. You will be randomly assigned a treatment group. Randomization into groups will depend on your physician diagnosis and the amount of exercise you do on a regular basis related to your back pain. You will need to fill out two questionnaires relating to your pain and activity level at the beginning and again at the end of the treatment. You may be assigned to an exercise group or a laser group, or an exercise and laser group. Some of the lasers are inactive to allow the researcher to determine if this laser treatment is truly effective in treating low back pain. The clinicians who administer the treatment will no know which laser is active or inactive. Research supports this type of treatment for decreasing pain and encourage healing. When the laser is on, this treatment is painless. The laser treatment will last for one minute at seven soft tissue sites located on your lower back. The exercising groups will perform mat-style strengthening exercises with flexibility training when needed.

What criteria must be met to be in the study?

You must be 18 years or older to participate in this study. You will be excluded from participation if you body fat composition is greater than 40% for women and 30% for men as measured by a hand held electrical impedance unit. You will also be excluded if you have x-rays demonstrating spondylothesis, scoliosis, or severe osteoarthritis. Additional exclusions include morphine pump utilization, pregnancy, smoking, and significant past medical history (lumbar fusion, diabetes, photo-sensitivities, cancer, etc.). If you have a chance of being pregnant the risks out weigh the benefits and it is not advised that you participate in this study.

What risks are involved in being in the study?

Your potential soft tissue injury risk is non-existent when equipment is used appropriately. Only trained professionals who are currently practicing as an athletic trainer or physical therapist will be allowed to administer treatment. There are no foreseeable injuries that you will encounter. Of course we will take every precaution to watch for and prevent any side effects, no current side effects are known. Clinicians administering the treatment are required to attend a manufacturer seminar in appropriate utilization training in order to operate the laser. The manufacturer protocols are available for review upon participant request. In the case of an injury you can be assured proper care and treatment will be given. It should also be noted that similar treatments are provided in many rehabilitative centers around the United States.

How do I know this equipment is safe?

In 1996, the FDA allowed clearance for similar light therapy treatment based on clinical trials. FDA approved additional manufacturers for marketing and utilization of laser units for carpal tunnel syndrome in 2001 with numerous current studies applying it to additional injury sites (low back, cervical, and osteoarthritis joints). This equipment if very safe and FDA considers it to

be a very minimal risk device. Although retina damage is very rare, you and the clinician will be required to wear safety goggles to ensure your eyes are protected from the light therapy.

Why should I participate in this study?

If you participate in this study, you may gain some pain relief and increased functional ability short and/or long term, which may be beneficial to your quality of life. The information gained from this study may help others receive similar treatment if it is deemed effective. No compensation will be awarded to the participants.

Are my records kept private?

Any information that we learn about you that can be traced to you will be used responsibly and will be protected against release to unauthorized persons. The primary researcher, Kelly Lumpkin, will be the primary person to view and analyze the results from the questionnaires. Your assigned physical therapist or the primary researcher will have access to your medical records for treatment determination (which is common in rehabilitation services). Once the data reaches faculty members associated with this study, no names will be attached to results. This study will uphold all HIPAA regulations and all past medical history will be kept in a secure location with limited access to only those in the professional health care arena that are directly related to the research study (your physician, nurse and physical therapist or certified athletic trainer). The results of this study may be published in the professional research literature, but no publication will contain information that will identify you.

What does it mean to sign this consent?

Your decision to participate in this study is voluntary. Even if you decide to participate, you may withdraw at any time. Of course we will tell you anything we learn during the study that may help you decide whether to continue participation. You are making a decision whether or not you will participate in this study. If you sign this form, you agree to participate based on reading and understanding this form. If you have any questions, please ask Kelly Lumpkin 423-780-9251.

If you have any questions about this study please contact Dr. Mark Anshel, Faculty Advisor, Health, Physical Education and Recreation Department, Middle Tennessee State University, 615-898-2812 or 898-2811. You will receive a copy of this form.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____
Witness Date

APPENDIX D

Letters of Approval and Changes from

Middle Tennessee State University

Institutional Review Board

Institutional Review Board
P.O. Box 124
Middle Tennessee State University
Murfreesboro, Tennessee 37132
Office: (615) 898-5005

MIDDLE TENNESSEE STATE UNIVERSITY

March 21, 2005

Protocol Title: Effect of low level laser therapy and exercise on low back pain
Protocol Number: 05-162
klumpkin@leeuniversity.edu

Dear Kelly Lumpkin,

The MTSU Institutional Review Board has reviewed your research proposal identified above. The project was approved and you may begin data collection.

Please note that any unanticipated harms to subjects or adverse events must be reported to the Graduate Office at (615) 898-2840.

Approval is granted for one (1) year from the date of this letter for 75 participants.

You will need to submit an end-of-project report to the Graduate Office upon completion of your research.

Please note that any change to the protocol must be submitted to the IRB before implementing this change.

Sincerely,

William Langston
Chair, MTSU Institutional Review Board

Institutional Review Board
P.O. Box 124
Middle Tennessee State University
Murfreesboro, Tennessee 37132
Office: (615) 898-5005

MIDDLE TENNESSEE STATE UNIVERSITY

Notice of approval of Changes and Continuation of Protocol (Expedited Review)

June 13, 2005
Effect of Low Level Laser Therapy and Exercise on Low Back Pain
Protocol Number: 05-162
Ms. Kelly Lumpkin
273 Wilson Lane
Cleveland, TN 37312
Klumpkin@leeuniversity.edu

Dear Ms. Lumpkin:

The MTSU Institutional Review Board, or representative of the IRB, has reviewed your research proposal identified above. It has determined that the study poses minimal risk to subjects and qualifies for an expedited review under 45 CFR 46.110 and 21 CFR 56.110.

Please note that any unanticipated harms to subjects or adverse events must be reported to the Office of Sponsored Programs at (615) 898-5005.

The proposed changes to your protocol are approved. Approval is granted for one (1) year from the date of the original approval for the same number of participants.

Please note that any change to the protocol must be submitted to the IRB before implementing this change.

Sincerely,

Dr Robert Kalwinsky Reg. Dean Collins ORSP

Dr. Robert Kalwinsky
Chair, Institutional Review Board
PO Box 58
Middle Tennessee State University
615/904-8366
rkalwins@mtsu.edu

cc: Dr. Mark Anshel

APPENDIX D

Interview Guide for

Inclusion, Exclusion, and Covariates

Subject Initials: ___ ___ ___ Subject No: ___ ___ ___ Group A B C
Site A B C

Standard of Care vs. LLLT
Screening
Page 1 of 3

Screening must occur prior to scheduling an intervention.
Please note that if a subject is randomized into the physical activity group he/she may not initiate extra physical activities (eg recreational leagues, a "new" consistent aerobic workout). Pain medication needs to remain constant or decrease during the duration of the research for all groups. An unexpected pregnancy would result in termination of subject enrollment.

Date consent obtained _____/_____/_____ (subject given copy)

INCLUSION CRITERIA

All responses must be YES or N/A for the patients to be enrolled in the study.

1. The subject must have signed a release of medical information for the primary research to ensure physician diagnosis and verify health history. ☐ Yes ☐ NO
2. Physician approval of patient enrollment. ☐ Yes ☐ NO
3. Patient has seen a physician within 6 months. ☐ Yes ☐ NO
4. The subject is 18 years or older. ☐ Yes ☐ NO
5. Male or female. If subject is female, she must be post-menopausal for at least one year, surgically incapable of childbearing (hysterectomy or tubal ligation), or practicing an acceptable method of birth control (e.g., hormonal contraceptives, intrauterine devices, or barrier and spermicidal). The female subject will continue with the same method of contraception for the duration of the study. If the female subject is practicing an acceptable method of birth control, she must have maintained her normal menstrual pattern within three months prior to study entry. ☐Yes ☐No ☐N/A
6. The subject must read and sign informed consent form. ☐ Yes ☐ NO
7. Subject is willing to have body fat percentage analysis by a hand held electrical impedance equipment. ☐ Yes ☐ NO

Signature: _____ Date: ___/___/___
(signature of person collecting data)

Subject Initials: ___ ___ ___ Subject No: ___ ___ ___ Group A B C
Site A B C

Standard of Care vs. LLLT
Screening
Page 2 of 3

EXCLUSION CRITERIA

All responses must be no or N/A for the patient to be enrolled in the study.

8. The subject is hypersensitive to phototherapy. ☐ Yes ☐ NO
9. The subject has a high chance of low back pain being related to cancer. ☐ Yes ☐ NO
10. The subject has frequent pain management treatments and/or utilizes a morphine pump for pain control. ☐ Yes ☐ NO
11. The subject has positive x-rays for spondylothesis, stress fracture, osteomylitis, or Rheumatoid arthritis. ☐ Yes ☐ NO
12. The subject has had previous lumbar surgery (e.g.fusion, lamenectomy). ☐ Yes ☐ NO
13. The subject is involved in litigation and/or worker's compensation. ☐ Yes ☐ NO
14. The subject smokes cigarettes or chews tobacco. ☐ Yes ☐ NO
15. The subject has a body fat percentage greater than 40% for women and 30% for men. ☐ Yes ☐ NO
16. The subject has a severe infectious, inflammatory or neoplastic disease which may compromise response to light therapy. ☐ Yes ☐ NO

Signature: _____ Date: ___/___/___
(signature of person collecting data)

Subject Initials: ___ ___ ___ Subject No: ___ ___ ___ Group A B C
Site A B C

Standard of Care vs. LLLT
Health History
Page 3 of 3

Date of Birth _____

Diagnosis_____

Describe how long you have had Low Back Pain (months)_____

Have you had any epidural injections? If so when was the last one. _____

Prescription medication taken on regular basis (name, daily dosage)_____

_____

Over the counter medication taken on a regular basis (name, daily dosage)

_____

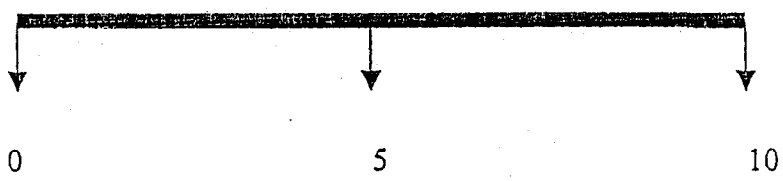
Describe regular physical activity (times per week, type of activity, time duration)

_____

_____

What precautions have you taken to ensure you are not pregnant? _____

Visual Analogue Pain Scale (put a line on this scale to represent your degree of pain on an average day)
0=no pain 10=extremely painful.



Signature: _____ Date: ___/___/____
(signature of person collecting data).

APPENDIX E

Evaluation Form and Treatment Record

LUMBAR SPINE EVALUATION- LLLT Research Study (Lumpkin et al)

Name_____ Date _____ __, 2005
DX_____ Physician SDH, SCH, JEJ _____
PMH_____
HX_____
_____
_____

SYMPTOMS LBP -- SI/Buttock -- Hip/Groin – Leg Sciatica --
Spasms -- Numbness/Tingling -- Pins/neeedles
AGGREVATING Position/activity
Bending – Sitting -- Rising -- Standing –Walking – Lying (supin,pron side)
AM – PM – Cough – Sneeze _____
RELIEVING Position/activity
Bending – Sitting – Rising – Standing – Walking – Lying (supin,pron,side)
AM – PM – Moving – Meds _____
OBJECTIVE
Lumbar Mobility:
Flexion = _____cm (3rd MCP) PN = Extension _____ PN =
Sidebending L = _____cm PN = Sidebneding R ____cm PN =
Rotation L _____%↓ PN= Rotation R _____%↓ PN =
Gait : Normal Antalgic
DTR:
PTR L= ____+ R =_____ + ATR L=_____+ R=_____+

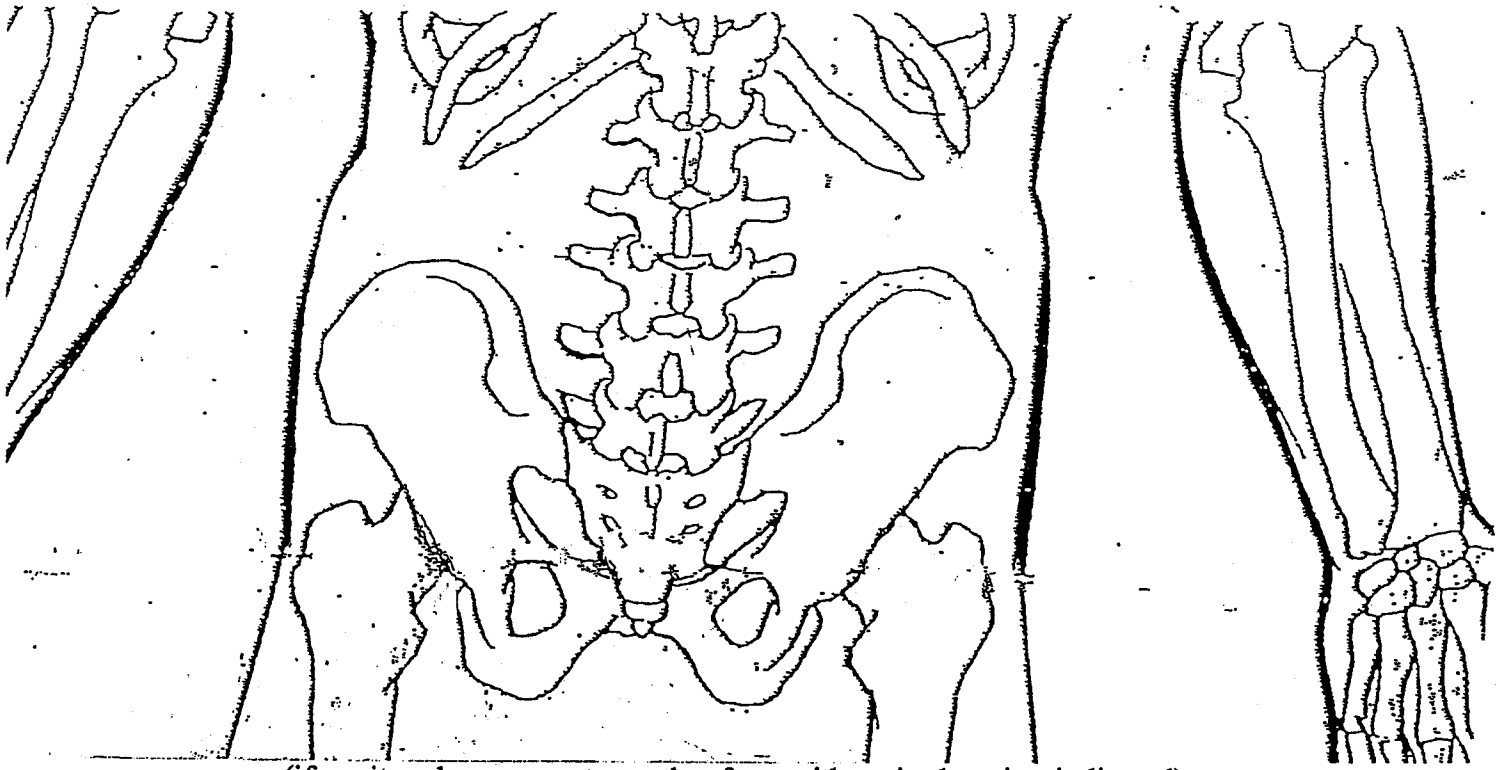
MMT:	Left	Right	SENSATION	Left	Right
Knee ext	/5	/5	Med anterior thigh		
Knee flx	/5	/5	Med Leg & foot		
Ankle Doriflx	/5	/5	Dorsum Foot		
Ankle Evers	/5	/5	Lateral Foot		
EXT Hall Lng	/5	/5	Postrio Thigh		

*Trunk Extsion*_____/5
Trunk Flx _____/5

SPECAILIZED TESTS:
Scaral Spring test
Squish Test
SLR L = _____° PN = _____ & __/10 R = _____° PN =_____ & ___/10
L w dorsflx PN= _____& __/10 R w dorsflx PN= _____ &___/10
Thomas L = - or ____+ R = - or ____+
Ober L = - or ____+ R = - or ____+
FABERE L = - or _____+ R= - or _____+

PALPATION	Tenderness – Spsm/Gurd		Tenderness- Spsm/Gurd
Papsinal	*L/R//B*	*G Medius*	*L/R/B*
Pirifomis	*L/R/B*	*ITB*	*L/R/B*
Q Lumborum	L/R/B	SIJ	L/R/B

LUMBAR SPINE TREATMENT RECORD – LLLT Research Study (Lumpkin et al)
PARTICPANTS NAME _____



(if rx sites change, create another form with revised rx sites indicated)

						INITIALS
1.	Date_____	# sites =	_____	X	_____secs per site	_____
2.	___/10 Date_____	# sites =	_____	X	_____secs per site	_____
3.	___/10 Date_____	# sites =	_____	X	_____secs per site	_____
4.	___/10 Date_____	# sites =	_____	X	_____ secs per site	_____
5.	___/10 Date_____	# sites =	_____	X	_____secs per site	_____
6.	___/10 Date_____	# sites =	_____	X	_____secs per site	_____
7.	___/10 Date_____	# sites =	_____	X	_____secs per site	_____
8.	___/10 Date_____	# sites =	_____	X	_____secs per site	_____
9.	___/10 Date_____	# sites =	_____	X	_____secs per site	_____
10.	___/10 Date_____	# sites =	_____	X	_____secs per site	_____
11.	___/10 Date_____	# sites =	_____	X	_____secs per site	_____
12.	___/10 Date_____	# sites =	_____	X	_____secs per site	_____

12 . FINAL RX MEASUREMENTS

ROM

Flexion = _____cm (3rd MCP) PN = ___

Sidebending L = _____cm PN = __/10 Sidebending R= _____cm PN = __/10

SLR L = _____° PN = _____ & ___/10 R = _____° PN = _____ & ___/10

L w dorsflx PN = _____& ___/10 R w dorsflx PN = _____ & ___/10

APPENDIX F

"Exercise Protocol"

Back Rehabilitation Program

Lumbar Stabilization Exercises

LUMBAR STABILIZATION EXERCISES

by Todd Gross, P.T.

MOST MEMORIAL Orthopaedic & Sports Therapy

The following exercises are recommended by the staff of Memorial Orthopaedic and Sports Therapy to improve stability of the lumbar spine. These exercises must be correctly performed as instructed by your physical therapist or athletic trainer. The basic principles of stabilization exercises are:

1. *No increase in pain or any other symptom should be experienced.*
2. *Each contraction should be held with maximal strength for 5 seconds.*
3. *Order of contraction should be reversed with relaxation.*
4. *Each exercise should be performed slowly without holding breath.*

Do each prescribed exercise _____ repetitions.
Perform prescribed exercises _____ times per day.

1) Supine #1

Position-Lie on back with knees bent and arms at sides with palms toward ceiling. Low back should be flat on floor.

Action-Pull toes toward nose, push heels against floor, squeeze buttocks together, push hands and shoulders into floor, and tuck chin toward throat. Slowly relax in reverse order.

Variation: Knees are straight.

2) Supine #2

Position- Same as Supine #1.

Action- Same as Supine #1 plus curl chin to chest and bring hands up together in front of chest. Slowly relax in reverse order.

3) Supine #3

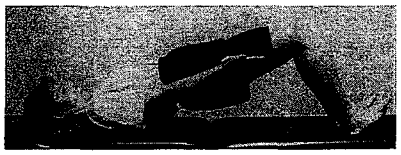
Position- Same as Supine #1.

Action- Same as Supine #1 plus slowly lifting buttocks up until hips are extended. Slowly return to starting position.

4) Supine #4

Position- Same as Supine #1.

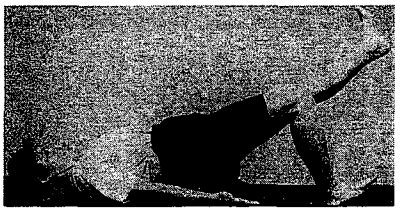
Action-Same as Supine #3 plus simultaneously lifting arms up so that hands remain level with hips. Slowly relax in reverse order.



5) Supine #5

Position- Same as Supine #1.

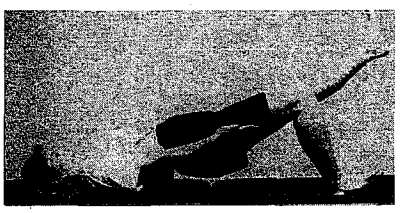
Action- Same as Supine #3 plus slowly straightening one leg up toward ceiling. Lower this leg to bent knee position, and repeat with opposite leg. Lower second leg and return to starting position. Slowly relax in reverse order.



6) Supine #6

Position- Same as Supine #1.

Action- Same as Supine #4 wth arms up, plus straightening and lowering legs as in Suprine #5. Slowly relax in reverse order.



7) Prone #1

Position-Lie on stomach with forehead resting on floor and arms at sides with palms against floor. Tips of toes rest on floor.

Action-Push tips of toes against floor while keeping knees on floor, squeeze buttocks together, push hands against floor while keeping shoulders back, tuck chin into throat, and lift head from floor while maintaining chin tuck position. Slowly relax in reverse order.

8) Prone #2

Position - Same Prone #1

Action-Same as Prone#1 plus adding tightening and lifting arms to shoulder level before tucking chin and lifting head. Slowly relax in reverse order.

9) Prone #3

Position - Same as Prone #1

Action-Same as Prone #1 plus slowly lifting one leg off floor. Lower leg and lift opposite leg. Slowly relax in reverse order.

10) Prone #4

Position - Same as Prone #1

Action-Same as Prone #1 plus simultaneously and slowly lifting one arm and opposite leg. Slowly lower arm and leg, and repeat with opposite arm and leg. Slowly relax in reverse order.

11) Sidelying #1

Position-Lie on side with knees pulled up toward chest without arching or flattening low back. Cup head in lower arm with hand on head, and place upper hand on floor in front of chest.

Action-Tuck chin in toward throat while pushing back of head into hand, push upper hand into floor while keeping elbow to chest, flex ankles toward head, and slowly lift upper leg to level of hip while keeping knee and ankle level. Slowly relax in reverse order. Repeat exercise on other side.

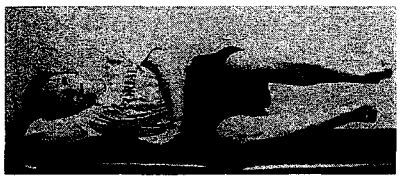
Progression: Knees are straight.

12) Sidelying #2

Position-Same as Sidelying #1

Action-Same as Sidelying #1 plus lifting lower leg toward upper leg, leaving space between legs. Slowly relax in reverse order. Repeat exercise on other side.

Progression: Knees are straight.

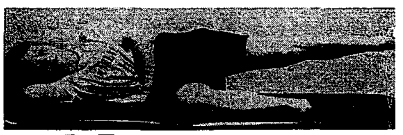


13) Sidelying #3

Position-Same as Sidelying #1 except upper leg is straight and upper hand is resting on midthigh of bottom leg.

Action- Same as Sidelying #1 plus lifting upper leg to hip level. Slowly lift lower elbow from floor. Slowing relax in reverse order.

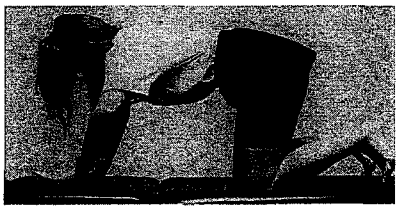
Progression: Lift lower leg.



14) Hands and Knees #1

Position-In hands and knees position with hands under shoulders and knees under hips, place feet hip width apart with tips of toes resting against floor. Place fingers straight ahead with elbows slightly bent so that shoulders and hips are level and back is straight.

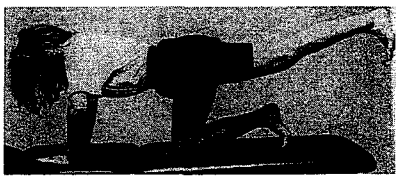
Action-Push toes and knees into floor, push hands into floor while keeping elbows bent, tuck chin toward throat, lift head up, and lift one hand slightly off floor while maintaining rigid trunk. Switch hands holding this contraction. Slowly relax in reverse order.



15) Hands and Knees #2

Position-Same as Hands and Knees #1

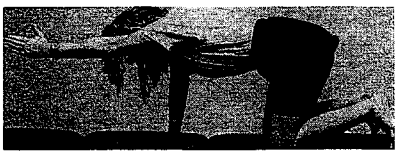
Action-Tighten feet, knees, arms and neck as in Hands and Knees #1 plus lifting one leg to hip level while keeping back level and ankle flexed. Return to starting position, and repeat with other leg. Slowly reverse order.



16) Hands and Knees #3

Position-Same as Hands and Knees #1

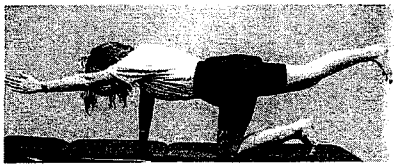
Action-Tighten feet, knees, arms and neck as in Hands and Knees #1 plus lifting one arm next to head with elbow straight and thumb pointing up. Return to starting position, and repeat with other arm. Slowly relax in reverse order.



17) Hands and Knees #4

Position-Same as Hands and Knees #1

Action-Tighten feet, knees, arms and neck as in Hands and Knees #1 plus simultaneously lifting arm and opposite leg to head and hip level, respectively. Return to starting position without relaxing and alternate sides. Slowly relax in reverse order.



18) Kneel Standing #1

Position-Kneel with body upright and head straight. Push toes against floor and lift arms in front of body. Tighten buttocks.

Action-Move arms up and down in an alternating chopping motion. Increase speed of motion gradually. Decrease arm motion and slowly relax in reverse order.

19) Kneel Standing #2

Position-Kneel on one knee and place other leg up in front of body with foot flat on floor, directly under the knee with toes pointed forward.

Action-Raise arms to shoulder height with palms turned away from body and elbows slightly bent. Push both feet into floor. Tighten both arms. Slowly lift back knee approximately one inch off floor. Slow relax in reverse order. Repeat ____ times and switch sides.

20) Standing #1

Position-Stand with feet hip width apart slightly more than arms length away from wall with back and knees straight. Raise arms to shoulder height with palms flat against wall and slightly bend elbows.

Action-Push heels into floor while tightening arms and pushing against wall as possible. Slowly relax in reverse order.

21) Standing #2

Position-Stand with one foot ahead of the other with toes pointed straight toward wall, keeping back and back leg straight. Raise arms to shoulder height with palms flat against wall and slightly bend elbows.

Action-Push heels into floor while tightening arms and pushing against wall as firmly as possible. Slowly relax in reverse order.

BACK REHABILITATION PROGRAM

C E N T E R
For Sports Medicine & Orthopaedics

BACK ANATOMY

The spine of the low back consists of five lumbar vertebrae, the sacrum and the coccyx. The vertebrae are connected to each other by facet joints and separated from each other by an intervertebral disc (Fig. 1). The facet joints control the amount and direction of movement in the spine. The intervertebral disc consists of a gel-like center, called the nucleus pulposus, and tough outer fibrous rings, called the annulus fibrosis. The intervertebral discs provide flexibility to the spine and act as shock absorbers. The muscles of the back are divided into two layers - the surface layer and the deep layer (Fig. 2). The muscles of the surface layer are the trapezius and latissimus dorsi. The deep muscles are called the erector spinae. These surface and deep muscles of the back, along with the abdominal and gluteal (buttock) muscles, provide movement and stability to the spine.

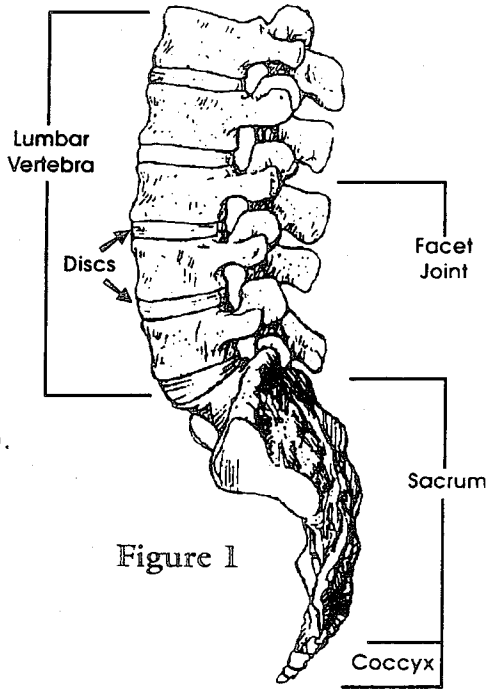


Figure 1

BACK CARE INFORMATION AND INSTRUCTIONS

To properly rehabilitate the back, it is necessary to know the cause, or causes, of back disorders or injuries so that the rehabilitation program can address these causative factors. Most back disorders or injuries are caused by the accumulation of months, or even years, of poor posture, faulty body mechanics, loss of flexibility and strength, and a general lack of decline of physical fitness.

The purpose of the back rehabilitation program is to provide safe and effective exercises designed to improve back and lower extremity flexibility, trunk strength, general physical fitness and trunk stability.

The exercises shown in the back rehabilitation program are recommended by the staff of The Center For Sports Medicine and Orthopaedics to achieve the purpose of the rehabilitation program. Perform only those exercises prescribed by your physical therapist or athletic trainer. These exercises should be performed slowly, smoothly, and gently, and as instructed by our physical therapist or athletic trainer.

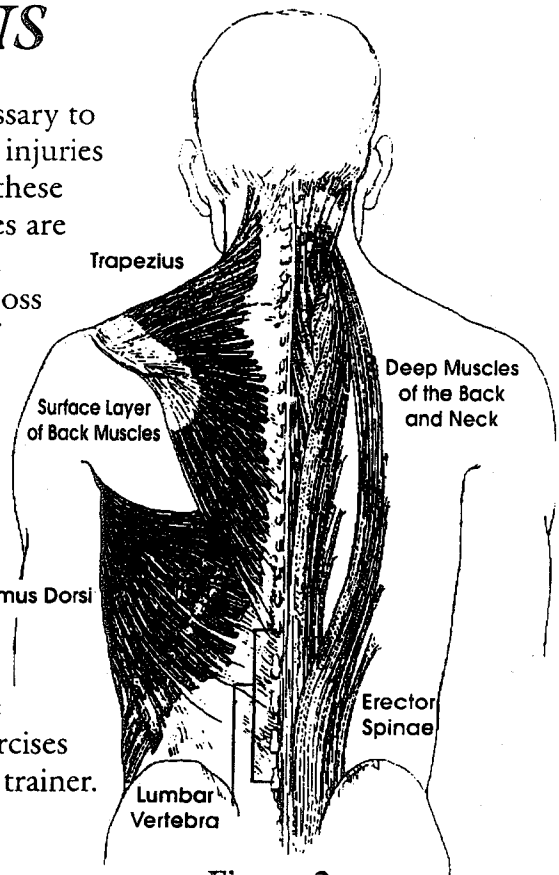


Figure 2

BACK AND LOWER EXTREMITY FLEXIBILITY EXERCISES

By Todd Gross, PT

Please inform your physical therapist or athletic trainer should any unusual pain or soreness occur with prescribed exercises.

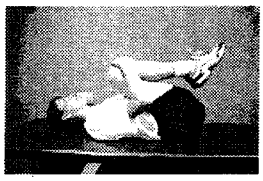
Perform prescribed exercises _____ times per day.

1) Single Knee to Chest

Lying on back, pull one knee toward chest until a stretch is felt in lower back and buttock. Repeat with opposite leg.

Hold _____ seconds. _____ Reps.

2) Double Knee to Chest



Lying on back, pull both knees toward chest until a stretch is felt in lower back and buttock.

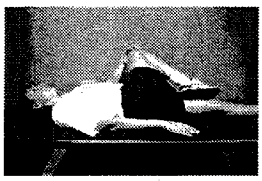
Hold _____ seconds. _____ Reps.

3) Lower Trunk Rotation

Lying on back with feet together, rotate knees to one side and hold. Repeat to other side.

Hold _____ seconds. _____ Reps.

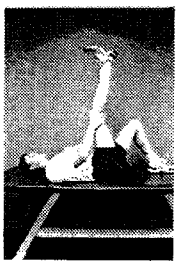
4) Piriformis Stretch



Lying on back with _____ leg straight, grasp outside of knee and pull toward shoulder. A stretch should be felt on outside of hip.

Hold _____ seconds. _____ Reps.

5) Hamstring Stretch 1



Lying on back with knees bent, grasp underside of knee and pull toward chest. Straighten knee until a stretch is felt in the back of thigh.

Hold _____ seconds.

_____ Reps.

6) Hip Adductor

Sitting with soles of feet together, gently pull body forward with arms, bending at hips, until stretch is felt in the inner thighs.

Hold _____ seconds.

_____ Reps.

7) Back Stretch

Sitting with buttocks on ankles, lean body forward while reaching arms out in front of you as far as you can.

Hold _____ seconds. _____ Reps.

8) Prone on Elbows

Lying on stomach with elbows under shoulders, prop up on elbows while keeping hips on floor.

Hold _____ seconds.

_____ Reps.

9) Press-Ups

Lying on stomach with hands under shoulders, press upper body up with arms while keeping hips in contact with floor and relaxing low back and buttocks.

Hold _____ seconds. _____ Reps.

10) Slide Glides

Standing with feet shoulder width apart and placing one hand on side of shifted rib cage and placing other hand over opposite pelvis, gradually push with hands toward center of body until spine is straight

Hold _____ seconds. _____ Reps.

11) Backward Bending

Standing with feet shoulder width apart and placing palms of hands on low back, slowly and carefully bend backwards over your hands.

Hold _____ seconds.

_____ Reps.

12) Hamstring Stretch II

Standing with foot of one leg propped on box or chair of appropriate height, slowly lean forward at hips until a stretch is felt in back of thigh.

Hold _____ seconds.

_____ Reps.

13) Hip Flexor Stretch

Standing with _____ foot of one leg propped on box or chair of appropriate height, slowly lean forward at hips until a stretch is felt in front of thigh.

Hold _____ seconds.

_____ Reps.

14) Quadriceps Stretch

Standing with feet hip width apart and bending one knee up until ankle can be grasped by opposite hand, gently pull your heel toward your buttocks until a stretch is felt in front of the thigh.

Hold _____ seconds. _____ Reps.

15) Calf Stretch

Standing with hands placed on wall for support, place one leg approximately 12-18" behind the other leg. Slowly lean forward until a stretch is felt in the calf of the leg.

Hold _____ seconds. _____ Reps.

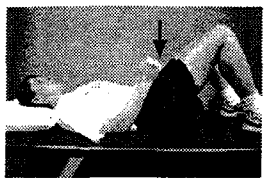
TRUNK STRENGTHENING EXERCISES

By Todd Gross, PT

Please inform your physical therapist or athletic trainer should any unusual pain or soreness occur with prescribed exercises.

Perform prescribed exercises _____ times per day.

16) Isometric Abdominal

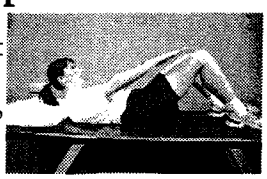


Lying on back with knees bent, press elbows into floor while tightening stomach muscles to draw navel toward spine. Do not hold breath. Hold____ seconds ____ reps. Goal: ____ Reps @ ____seconds each rep.

17) Pelvic Tilt

Lying on back with knees bent, tightening stomach muscles and buttock muscles to flatten low back toward floor. Hold ____ seconds ____ reps. Goal: ____ Reps @ ____seconds each rep.

18) Curl-Up

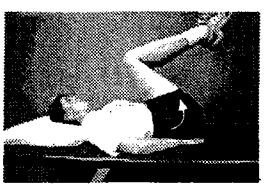


Lying on back with knees bent and hands resting on thighs, tilt pelvis to flatten low back. Raise head and shoulders from floor and reach for knees with hands. Hold ____ seconds ____ reps. Goal: ____ Reps @ ____seconds each rep.

19) Diagonal Curl-Up

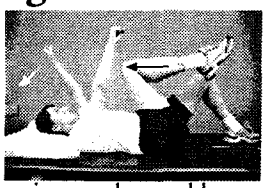
Lying on back with knees bent, tilt pelvis to flatten low back. Raise head and shoulders, reaching with hands to right knee until left shoulder blade clears floor. Repeat to left side. Hold ____ seconds ____ reps. Goal: ____ Reps @ ____seconds each rep.

20) Reverse Curl-Up



Lying on back with knees under buttocks and legs lifted with knees bent, tighten stomach muscles to pull knees towards chest. Hold ____ seconds ____ reps. Goal: ____ Reps @ ____seconds each rep.

21) Dead Bug



Lying on back with knees bent and arms lifted toward ceiling, tighten stomach muscles to keep trunk rigid. Slowly raise one leg and lower the opposite arm over head without arching back. Slowly return to starting position and repeat with opposite arm and leg. Hold ____ seconds ____ reps. Goal: ____ Reps @ ____seconds each rep.

22) Bridging

Lying on back with knees bent, tighten stomach muscles to flatten low back toward floor. Slowly lift buttocks from floor. Hold____ seconds ____ reps. Goal: ____ Reps @ ____seconds each rep.

23) Gluteal Sets

Lying on stomach, squeeze buttock muscles together while keeping pelvis on floor. Hold ____ seconds ____ reps. Goal: ____ Reps @ ____seconds each rep.

24) Isometric Extension

Lying with pillow under stomach and hands clasped behind back, lift head and upper body off floor until a C-curve begins to develop in low back. Hold this position. Hold____ seconds ____ reps. Goal: ____ Reps @ ____seconds

25) Prone Leg Lift

Lying with pillow under stomach and keeping knee straight, lift leg from floor without arching back. Repeat with other leg. Variation: Knee bent from leg lift. Hold____ seconds ____ reps. Goal: ____ Reps @ ____seconds each rep.

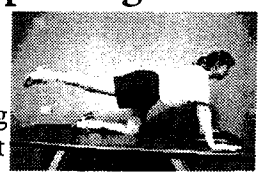
26) Prone Opposite Arm & Leg Lift

Lying with pillow under stomach and towel roll under forehead, lift leg and opposite arm off floor. Repeat with other leg and arm. Hold ____ seconds ____ reps. Goal: ____ Reps @ ____seconds each rep.

27) Quadruped Arm Lift

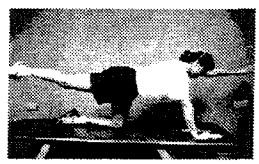
In hands and knees position, raise arm without arching back or neck. Repeat with opposite leg. Hold____ seconds ____ reps. Goal: ____ Rep @ ____seconds each rep.

28) Quadruped Leg Lift



In hands and knees position, lift one leg to hip level without arching back or neck. Repeat with opposite leg. Hold____ seconds ____ reps. Goal: ____ Rep @ ____seconds each rep.

29) Quadruped Opposite Arm & Leg Lift



In hands and knees position, lift leg and opposite arm together without arching back or neck. Repeat with opposite arm and leg. Hold____ seconds ____ reps. Goal: ____ Rep @ ____seconds each rep.

30) Wall Slide

Standing with feet shoulder width apart in front of body, press head, shoulders and back against wall, Slowly slide buttocks down wall until thighs are parallel to floor. Keep back flat against wall by tightening stomach muscles. Hold____ seconds ____ reps. Goal: ____ Rep @ ____seconds each rep.