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Effect of Deep Oscillation Therapy on the Reduction of Swelling and Pain following

Acute Ankle Sprain

Lisa Marie Friesen

A thesis submitted to the Graduate Faculty of

JAMES MADISON UNIVERSITY

In

Partial Fulfillment of the Requirements

For the degree of

Masters of Science

Kinesiology

May 2010

Dedication

This project is dedicated to my Dad and Mom, Drs. Paul and Virginia Friesen.

Thank you for always teaching me to do my best in all things and to persevere especially
when it gets tough.

I love you both so much and pray that I will honor God as much with my life as you do
with yours.

Acknowledgements

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Table 1

Change in Pain Scores

Change in pre to post scores on treatment 1

Verbal Pain scale of 0-10

Table 2

Change in Girth Measurements

Change in pre to post scores on treatment 1

Centimeters

Abstract

Context: Deep oscillation therapy is a novel form of therapy that claims to reduce the amount of pain and swelling in acute orthopedic injuries. However, these claims are based on anecdotal evidence and there have not been any published studies on the efficacy of deep oscillation therapy in reduction of pain and swelling. Due to the prevalence of ankle sprains in physically active individuals, this study compared the effect of deep oscillation therapy in reduction of pain and swelling to conventional treatment.

Objective: To compare the effect of deep oscillation therapy on pain and swelling resulting from acute ankle sprains to conventional therapy consisting of cryotherapy and compression.

Methodology: Volunteers were healthy, physically active, college students with acute ankle sprains, ranging in age from 18-25. Volunteers were randomly assigned to a control group (11 volunteers) or a treatment group (10 volunteers). The control group was treated with conventional cryotherapy and compression therapy and a placebo deep oscillation therapy treatment. The treatment group was treated with conventional treatment and deep oscillation therapy. Each group was treated two times a day for a five-day treatment period.

Measurements: Objective data for swelling measurements was obtained through the use of the figure-of-eight girth measurement reported in centimeters. Subjective data for pain measurements was obtained utilizing a verbal numeric pain scale (0-10). Measurements were taken before and after every treatment administered.

Findings: There was not a significant difference in girth measurements or perceived pain between the two groups over the five-day treatment period.

Future Recommendations: 1) Utilize a more sensitive measurement tool for swelling.
2) Investigate injuries that have more measurable swelling.

Chapter 1

Introduction

Ankle sprains are one of the most common injuries in America resulting in 25% of time lost in many sports¹⁻³. It is estimated that 23,000 ankle sprains occur per day in the United States representing 4.7-24.4 percent of all musculoskeletal injuries^{4,5}. Ankle sprains can vary in healing time and treatment is often used to reduce injury time and promote tissue healing.

Traditional treatment of ankle sprains consists of cryotherapy, compression, and elevation. Therapeutic modalities have been used to control swelling, increase tissue mobility, and decrease pain. Research has shown that cryotherapy reduces healing time significantly by lowering cellular metabolism that in turn decreases secondary ischemic injury^{6,7}. Secondary ischemic injury is the result of diminished oxygen supply, decreased fuel, and an inability to remove waste from the site of injury⁸. The more the swelling is controlled, the less secondary ischemic injury occurs and the faster the injury can progress and heal. Compression and elevation help reduce excess fluids at the site of injury by aiding the vascular and lymphatic systems⁹.

Clinically, swelling can be measured by volumetric measurements or girth measurements. Both methods have been found to be valid and reliable¹⁰⁻¹². Girth measurements are commonly used in clinical settings to measure swelling, and are often preferable over volumetric measurements due to lower cost and ease of use. The figure-of-eight method, the most common way to measure girth at the ankle joint, was first

published by Esterson in 1979¹³.

Nociceptors feedback to the central nervous system appears to be associated with the degree of soft tissue damage¹⁴, thus pain level assessments can indicate soft tissue healing and are often used clinically. Although there are varying ways to measure pain, the numeric pain scale is preferable to other pain assessments due to the ease of use¹⁵. The numeric pain scale ranges from 0-10 and allows the individual to assign a number to the amount of pain they are experiencing¹.

While traditional therapy, including rest and protection, ice, compression, and elevation continue to be a gold standard of ankle therapy treatment; new therapies are often utilized to help improve the healing environment of the injured tissue. The HIVAMAT, a relatively new modality created in Germany, claims to reduce swelling through the utilization of a pulsed electrostatic field. The pulsed electrostatic field causes vibrations in the tissue referred to as deep oscillations. These oscillations increase the micro-circulation in the affected connective tissue, helping to reduce swelling, and thus minimize secondary ischemic injury. It also aids the affected tissue by helping to flush out waste products and increase lymphatic flow. Two studies have shown that deep oscillation therapy can reduce swelling and pain as well as improve wound healing^{17,18}. Anecdotal evidence and some published literature supports that deep oscillation therapy aides in the reduction of pain and swelling, but to date no clinical studies have been performed documenting reduced swelling and pain in acute orthopedic injuries.

The purpose of this study is to compare the effectiveness of deep oscillation therapy on the reduction of pain and swelling in patients following acute ankle sprains. It

is hypothesized that there will be a greater reduction in swelling and a decrease in pain in the ankle with the deep oscillation group when compared to the control group.

Statement of Problem

The purpose of this study is to study the efficacy of deep oscillation therapy to reduce swelling and pain in acute ankle sprains. To date there has not been any published research to support the claims made regarding the effectiveness of deep oscillation therapy in acute orthopedic injuries. This study will compare conventional treatment of ankle sprains to conventional treatment with the deep oscillation treatment in the reduction of measured swelling and reported pain. A group of twenty subjects will randomly be assigned to either a control group or the treatment group. It is hypothesized that there will be greater reduction in swelling and a decrease in pain in the ankle with the deep oscillation group compared to the control group. The findings of this study could greatly affect the future treatments of one of the most common injuries in athletics.

This study will address the following questions:

- 1) Does the deep oscillation therapy in conjunction with conventional treatment allow greater reduction in swelling in acute ankle sprains?
- 2) Does the deep oscillation therapy in conjunction with conventional treatment allow greater reduction in pain following acute ankle sprains?

Significance of Study

Ankle sprains are the most common injuries reported in athletics. Lingering swelling often slows healing time and therefore increases time loss due to injury. If this study shows significance in the reduction of swelling and pain with the therapeutic affect of deep oscillations, treatment of ankle sprains could be improved by allowing symptoms to decrease more rapidly. The benefit to the patients would be appreciable in reducing injury time and helping to return to play more expediently.

Clinically speaking, athletic trainers and other allied health professionals are continually faced with new products on the market. This study will help to assess the efficacy of a modality that currently has no research to support its claims on orthopedic injuries. This study will help clinicians assess whether this therapeutic modality is worth buying and utilizing in their clinics.

Assumptions of the Study

The study assumes that the volunteers will comply with the guidelines set forth in the study. The volunteers are asked to ice three times a day for twenty minutes in addition to the treatments applied by the examiner. Volunteers are also expected to keep the injured extremity wrapped continuously in a compression wrap and horseshoe pad and to have it elevated above their heart as much as possible. In addition, they will be expected to follow a home exercise program that will be given to them each day.

Delimitations of the Study

Application of our findings are limited to patients with lateral ankle sprains who are experiencing pain and swelling. We will not know the effect of deep oscillation therapy on other orthopedic injuries.

Limitations of the Study

There are no known limitations to the study at this point.

Operational Definitions

Lateral ankle sprain- injury to the lateral ligamentous complex of the ankle. The injury can be classified in three grades (I-III).

Grade I lateral ankle sprain- minimal stretching or tearing of the lateral ligamentous complex. Classified by minimal swelling, minimal pain, and minimal/no loss of function.

Grade II lateral ankle sprain- moderate stretching or tearing of the lateral ligamentous complex as noted by a positive anterior drawer test, moderate swelling, point tenderness over the lateral ligaments.

Grade III lateral ankle sprain- complete tear of the lateral ligament complex resulting in instability. Classified by extreme swelling and point tenderness on the lateral aspect of the ankle.

Secondary Ischemic Injury- After the primary injury, the chemical and vascular response

can cause further cell death because of a decreased amount of oxygen and fuel to the site of injury.

(P.) R.I.C.E.- (**P**rotection), **R**est, **I**ce, **C**ompression, and **E**levation- the acronym for conventional treatment of lateral ankle sprains.

Rehabilitation- Exercises and stretches done to regain strength and full range of motion following an injury.

Electrostatic Field- The charge that is created between two different electric charges.

Johnsen-Rahbek Effect-The force created by passing voltage between two metal plates and a semiconductive material such as a porous stone. The voltage is passed through the metal plate and the semiconductive material and creates an electric attraction between the two materials.

Deep Oscillation- The repeated lifting and dropping of tissue due to the electrostatic field.

Figure-of-Eight Girth Measurement- A method to measure swelling of the ankle by measuring the distance around the ankle using a figure eight pattern.

Numeric Pain Scale - A pain assessment system in which patients are asked to rate their pain on a scale from 0 to 10, with 0 representing no pain and 10 representing the worst pain they have experienced or could imagine.

GameReady® System - An advanced cold and intermittent compression regimen that can

help reduce pain, swelling, tissue damage and muscle spasms.

Histamine- A hormone which aides in healing by increasing the vascular permeability allowing other necessary healing agents to enter site of injury.

Leukocytes- White blood cells which aide in the removal of waste from the site of injury.

Macrophages- aid in regulation during injury repair by removal of waste from the site of injury. Also aides in healing by keeping inflammation localized.

Prostaglandin- Necessary to maintain vascular permeability, regulates the levels of serotonin and histamine.

Neutrophil- Type of white blood cell which aides in the healing process by attracting other needed chemical to the site of injury and by increasing phagocytosis at the site of injury.

Summary

Ankle sprains are the most common orthopedic injury in America. To date there has not been any research on the effectiveness of deep oscillation therapy in the reduction of pain and swelling during the healing process following a lateral ankle sprain. This study will look at the efficacy of deep oscillation therapy in reducing pain and swelling in acute ankle sprain management.

Chapter Two

Review of Literature

The purpose of this literature review is to discuss: ankle sprains, soft tissue healing progression, traditional therapeutic treatment (including rest, ice, compression, and elevation), deep oscillation therapy, and swelling measurements.

Ankle Sprains

Ankle sprains are the most common injury in sports ^{1,2,19}. Sprains represent 4.7-24.4 percent of all musculoskeletal injuries ⁵ and are responsible for 25% of time lost in basketball, cross country, and football ²⁰. There are an estimated 23,000 ankle sprains per day in the United States of America ⁴. One definition of a lateral ankle sprain is a lesion resulting from an inversion injury, with effusion and pain at the lateral ankle joint with no fractures ¹. Sprains can also be defined as an injury that stretches the fibers of a ligament; with the more severe the injury the more damage of the fibers ¹⁹. The most often reported mechanism of injury is inversion and plantar flexion of the ankle joint ¹.

Anatomically, there are three ligaments that compose the lateral ligamentous complex; the anterior talofibular ligament (ATFL), the calcaneofibular ligament (CFL), and the posterior talofibular ligament (PTFL). The ATFL is the most often injured ligament in the lateral ligamentous complex due to its anatomical position ^{19,22}. Injury to the ATFL

is an isolated injury 66% of the time²³. These three ligaments provide three major functions for the ankle. First, they aid in proprioception. Secondly, the ligaments provide static stability to the ankle joint³. Lastly, the ligaments act as a guide for ankle motion: inversion, eversion, plantar flexion, and dorsiflexion¹⁹.

Sprains can be classified by degree of injury to the soft tissue. Three grades of sprains are commonly used to distinguish the severity of the sprain. One system of classification defines grade one ankle sprains as a partial tear of the lateral ligaments²⁴. Grade one sprains or mild sprains can also be classified as mild stretching of the ligaments resulting in no loss of function or loss of strength²⁵. Grade one sprains have been defined by minimal tenderness and swelling, minimal impairment, and microscopic tearing of collagen fibers²⁶.

Grade two, or moderate sprains, include decreased range of motion and loss of strength. Moderate swelling is seen as well as moderate tenderness with palpation. An injury that presents with a positive anterior drawer test signifying instability and complete tears of some but not all of the collagen fibers in the ligament are classified as grade two sprains^{3,24,26}.

Grade three sprains present with complete loss of function, swelling, and extreme point tenderness. Ligamentous instability indicates capsular disruption and complete tears or rupture of the lateral ligamentous complex. Special tests that indicate a grade three injury include a positive talar tilt and positive anterior drawer test^{26,27}.

Phases of Healing

Regardless of the severity of the injury, all tissue healing will progress through the same stages of healing¹⁹. The more damaged the soft tissue, the longer each phase will take. Traditionally the phases of healing are; 1) inflammation, 2) proliferation, 3) and maturation or remodeling⁹. While each of these phases are defined by distinct roles in healing, they occur on a continuum and overlap. The following section will describe the general time frame and the events that occur in each phase.

Acute Inflammatory Response -Phase I

Phase one in healing is the inflammatory response phase that occurs from the onset of injury to as many as four^{28,29} to five days⁹ depending on the extent of injury. This phase is characterized by pain, active effusion, and increased temperature at the sight of the injury³.

Physiologically, as injury occurs, there is degeneration of the sarcolemma (the outer membrane of the muscle fiber). The disruption of the sarcolemma causes a change in membrane permeability that allows larger amounts of calcium to enter into the myofiber at a greater rate. The influx of calcium starts a cascade of chemical reactions resulting in myofiber death and creating a gap in the myofibers³⁰. In addition, the influx of calcium is linked with the change in mitochondrial membrane depolarization and osmotic swelling which leads to outer membrane rupture. This chain of events is linked to cell death associated with what is known as secondary hypoxic injury⁸. The disruption of the myofiber causes ruptures of capillaries in the muscle. The increased

blood from the disrupted capillaries settles in the gap of the myofiber and a hematoma is formed.

Two main categories of response exist in the inflammatory response phase: the vascular response phase and the chemical response. They occur simultaneously and are interlinked on a number of levels²⁹.

Vascular Response:

The vascular response begins as soon as an injury occurs. First, immediate vasoconstriction occurs in the first five to ten minutes following injury^{9,28}. The purpose of the vasoconstriction is to create a local anemia²⁸. The local anemia is followed by vasodilation that allows increased blood flow to the site of injury⁹. The vasodilation is important for increasing the blood flow to the area allowing for the chemical response. In addition to vasodilation, there is a corresponding vascular permeability that is essential for the healing process to occur. The increased vascular permeability allows for plasma proteins and white blood cells to enter into the area of injury²⁹.

Chemical Response:

The primary function of the chemical response is to aide in debris removal and to prepare the site for repair²⁹. Histamine is one of the most important chemicals released at the site of injury by platelets and mast cells⁹, and is crucial for the initiation of inflammation. Histamine has a short half-life and is followed by prostaglandins, which promote attraction of leukocytes, and perpetuates vascular permeability^{9,31}.

The chemical response causes the influx of certain elements that aide in healing. Neutrophils are the first cell to enter the site of injury and peak at 24 hours post injury. Macrophages, which aide in the removal of dead cells and help stimulate repair, are attracted to the cytokines and enter into the site of injury³⁰. Platelets, which enter due to the vascular permeability, begin binding to collagen and release phospholipids to aide in clotting. Fibrin and fibronectin begin constructing a “fibrin lattice” which gives minimum structural support⁹. Neovascularization begins within 24 hours of injury and continues for the next 72 hours³⁰. Lastly, fibroblasts enter the area and begin to lay down collagen that will later form the scar tissue^{9,29}.

Secondary Ischemic Injury

Although inflammation is necessary for healing, controlling the edema is vital for the injured person to heal expediently. Controlling edema decreases the effects of secondary hypoxic injury, defined as cell death that occurs due to local ischemia⁸. Secondary ischemic injury explains the two levels of cellular injury. The primary injury is the cell death that occurs because of a mechanical, chemical, thermal, metabolic, or biological mechanism⁸. The chemical and vascular reaction to the primary injury can lead to further cell death due to decreased oxygen, decreased fuel, and an inability to remove waste from the site of injury⁸. The more the edema is controlled, the less secondary ischemic injury occurs and the faster the injury can progress and heal.

Proliferation Phase-Phase II

The proliferation phase begins during the inflammatory response phase as early as 24-

48 hours post injury²⁹. The proliferation phase is needed for the repair and production of collagen^{9,29}. The beginning of this phase is marked by the increase of fibroblast, myofibroblasts, and endothelial cells^{9,29}. Fibroblasts from the inflammatory stage are responsible for producing collagen during the proliferation phase^{9,29}. At the same time the angiogenic response is responsible for the formation of new blood vessels that are needed to provide oxygen in environments where fibroblasts are limited by the availability of oxygen²⁹. These two systems together create granulation tissue, which replaces the fibrin clot from the inflammatory stage. The granulation tissue has more strength compared to the fibrin clot⁹. Tissue at this stage is continually being replaced and strengthened. By day seven the granulation tissue, replaced by type III collagen, is considerably stronger and by day twelve the collagen is replaced by type one collagen, a more mature and stronger tissue⁹. At this point the maturation phase and the proliferation phase are difficult to differentiate due to the cross over of these two phases in healing.

Maturation-Remodeling Phase-Phase III

The remodeling phase is believed to begin as early as a week after the original injury³⁰ and can last for months to over a year^{29,32}. During the maturation phase the collagen continues to get stronger as more fibers switch from type three (immature) to type one (mature) collagen⁹. According to the SAID principle (specific adaptations to imposed demands) and Wolffs Law, the collagen fibers align based on the stresses that are applied to it during this phase^{9,33}.

Common Treatment of Acute Ankle Sprains

Treatment for ankle sprains has been studied extensively. Treatment often includes some combination of ice, compression, non-steroidal anti-inflammatory drugs (NSAIDs), elevation, taping and bracing². The acronym PRICE (protection, rest, ice, compression, elevation) or RICE (rest, ice, compression, and elevation) are used to help injured athletes remember how to properly treat sprains.

Treatment of acute sprains (0-72 hrs following injury) during the first hours of injury often will apply the principles of PRICE: **P**rotection, **R**est, **I**ce, **C**ompression, and **E**levation^{19,34}. The goal of this stage is to control edema and inflammation, which can be controlled in a number of ways^{3,35}.

Protection and Rest

Protection and rest are usually the first treatments applied to ankle sprains. It is important to protect the injured ligaments from further damage. This can be done with the use of a cast, air cast, or a walking boot. There is controversy as to the helpfulness of immobilizing the injured limb during the early stages of injury. Lamb et al proposed that casting below the knee for ten days as the best care to reduce further injury and complication for an acute ankle sprain³⁶. Yet, classification for conventional treatment according to van Rijn et al included early mobilization with support of some type of support (brace, tape or compression bandage)³⁷. **Rest** is the key in this stage. It is vital for the injured person to be non-weight bearing as long as there is pain and altered gait with ambulation. This protects the ankle structures from further damage and injury.

Stress placed upon injured structures can lead to a delay in the healing process and a longer recovery ⁹.

Cryotherapy

Ice is one of the most commonly used modalities in controlling inflammation and reducing pain. Ice has been cited for decreasing pain, slowing metabolic rates and muscle spasm, and controlling inflammation ^{38,39}. The use of ice is most important for the reduction of cellular metabolic activity in the area of injury immediately after the injury occurs ³⁸. The decrease in cellular metabolic activity reduces the oxidative requirements and the inflammatory chemicals released at the sight of injury ⁹. Ice is used in acute situations to decrease secondary ischemic injury by reducing metabolism and further soft tissue injury ^{38,39}.

The sooner ice is initiated, the more effective it is in controlling inflammation ⁴⁰.

Standard ice application includes placing ice on the site of injury for twenty minutes and repeating every one to two hours ³⁸.

Compression

Compression wraps, such as ACE wraps, have been shown to be very effective in limiting and controlling edema ^{27,39}. Compression helps reduce hydrostatic pressure at the site of injury by aiding the vascular and lymphatic systems ⁹. Research comparing the time of return to pain-free walking between the common ace wrap, the Aircast ankle brace, and the combination of the two found that for mild to moderate ankle sprains, the combination of the ace wrap and the Aircast created the best environment for the return

to functional activity²⁷. Though a reduction in healing time was noted, the reduction was not statistically significant between the three groups. Similarly, a comparative study between the traditional ace wrap compression and the Aircast ankle brace in controlling moderate to severe ankle injury found no statistical difference between the two treatments. They did not, however, test a third group with both the compression wrap and the Aircast⁴¹. Compression is vital in controlling edema and allowing for faster recovery.

Another study looked at the effects of an elastic bandage alone to the effects of an elastic bandage combined with intermittent compression in subjects with ankle sprains. The study compared two groups of 22 subjects who had sustained ankle sprains. The control group was treated with a compression wrap. The treatment group was treated with one treatment a day of intermittent compression for thirty minutes. After the treatment was performed the subject was then wrapped in an elastic wrap until the next treatment. Pain was recorded as less for the treatment group compared to the control group. Edema was measured by water plethysmography. A statistically significant decrease in edema was observed in the treatment group. It can be concluded from this study that intermittent compression is more effective in reducing edema and pain in patients with ankle sprains compared to compression wraps alone¹.

Elevation

Elevation is essential to assist in reducing and controlling swelling. Elevation reduces the amount of blood pooling in the injured extremity by using gravity to bring the blood back to central circulation²⁸. Elevation helps aide the vascular and lymphatic systems

to reduce fluids in the area of injury⁹. The injured site should be elevated above the heart to maximize effects. The longer the injury is elevated the more effective the elevation is in reducing swelling²⁸.

Rehabilitation

Rehabilitation goals include controlling inflammation, gaining full range of motion (ROM), and increasing strength through exercises^{28,42}. During Phase I, rehabilitation is focused on controlling the swelling and resting the injury. Swelling is controlled with the above-mentioned PRICE principle. Gentle ROM may be initiated at this time within a pain free range of motion. During phase II of the healing process, it is important to restore full ROM, begin to regain strength and regain neuromuscular strength. Lastly, phase III rehabilitation is focused on returning to full sports activity.

For the purposes of this paper, rehabilitation will focus on exercises that increase range of motion. Exercises to increase ROM can include, but are not limited to, alphabet exercises, ankle circles, plantar flexion, dorsiflexion, inversion, and eversion^{27,35}.

Deep Oscillation Therapy

The HIVAMAT is a relatively new therapeutic modality that uses an intermittent electrostatic field to provide deep oscillations to the treated area. In order to understand the theory, it is important to understand the fundamentals of electricity.

Electricity is the force created by an imbalance in the number of electrons at two points. The force created is known as an electromagnetic force. An electrical current is created

when the electromagnetic force causes the electrons to flow in an attempt to equalize charges. Electromagnetic fields are produced by an electric current passing through a wire and can be manipulated by changing the current ⁴³. An electrostatic field is defined as the charge that is created between two different electric charges. Deep oscillation therapy utilizes the Johnsen-Rahbeck effect to produce and deliver energy to the tissues. The Johnsen-Rahbeck effect is developed when two electrodes are separated by a barrier layer (porous stone) creates a high magnetic force between the two electrodes (manual). More specifically, the Johnsen-Rahbek Effect is the force created by passing voltage between two metal plates and a semi conductive material such as a porous stone ^{44,45}. The voltage is passed through the metal plate and the semi conductive material and creates an electric attraction between the two materials. The HIVAMAT uses the Johnsen-Rahbek effect to create an electrostatic charge that is delivered to the body. The force of the electrostatic field is delivered intermittently providing deep oscillations to the tissues through the lifting and dropping of the tissue being treated. The lifting and dropping of the tissue increases mobility and flexibility of the tissue being treated (Manual).

While much anecdotal evidence supports the claims of deep oscillation therapy, little empirical research has been done to document its effects. One study found that deep oscillation therapy was effective in improving wound healing, reducing inflammation, and increasing antioxidants in rat tissue ¹⁸. In a separate study, deep oscillation therapy also reduced pain and swelling in women experiencing lymphoedema after surgery. Twenty-one subjects had all undergone breast sparing surgery and radiation and were all experiencing reduced motion and increased pain due to swelling before deep oscillation

treatments¹⁷. Therefore, while there is limited research on deep oscillation therapy, these limited studies have documented positive effects on tissue healing.

Girth Measurements

Common ways of measuring change in effusion are circumferential girth measurement and volumetric measurements. Volumetric measurements are based on Archimedes Principle, which states that the water volume displaced is equal to the volume of the object immersed in the water⁴⁶.

A study of water displacement found that volumetrics have a standard error of less than 1% in measuring hands and upper extremities in subjects without edema⁴⁶.

Volumetric measurements are considered the gold standard for measuring limb volume, yet these measurements are often too difficult to perform in the clinical setting due to their complexity¹⁰.

Girth measurements are easier to use in a clinical setting and have been validated by numerous studies to be comparable to the volumetric measurements^{11,47}. Girth measurements are used to obtain data regarding the change in size of a limb. These measurements are taken by identifying fixed points of the injured limb and recording the distance around that limb.

The validity of both of these techniques was studied by conducting a literature search of all the studies comparing the two techniques¹⁰. Comparisons of measurements of the leg using both girth measurements and volumetric measurements have also been studied and shown strong correlation ($r=0.80$). An even higher correlation coefficient

has been found between girth measurements and volumetric measurements of the leg minus the foot ($r=0.98$ and 0.99)^{48,49}.

Differences in measured volume between the girth measurements and the volumetric measurements for the upper extremity have also yielded strong correlation¹⁰. A correlation between the calculated volume (girth measurement) and the upper extremity water displacement volume had an r -value of 0.99 .

The figure-of-eight method of girth measurement was published by Esterson in 1979¹³. This method was developed so that the measurement would include many of the common sites of swelling during acute ankle sprains. The technique measures ankle swelling using a tape measure beginning between the tibialis anterior and the lateral malleolus and wrapping in a figure eight pattern around the foot. The foot is in a neutral position while the tape measure is wrapped around. This measurement is easier to obtain in a clinical setting and significantly less expensive than volumetric measurements. A study performed by Tato-Adams et al⁵⁰ showed significant interrater and intrarater reliability ($ICC=0.99$) when testing 50 non-injured participants.

The interrater and intrarater reliability of water volumetry and the figure-of-eight method has also been studied in subjects with ankle swelling⁴⁷. Twenty-nine subjects with ankle swelling volunteered to have their ankles measured both by volumetry and by the figure-of-eight method. Each tester performed three measurements using both types of volume measures. The interrater reliability for water volumetry was 0.99 and the interrater reliability for the figure-of-eight method was 0.98 . There was a positive correlation between the two types of measurements with a Pearson coefficient $r=0.95$

and the coefficient of determination $r^2=0.91$.

Another study examined the validity of the figure-of-eight method compared to the volumetric measurement ¹¹. Fifteen subjects with ankle swelling due to ankle sprains or another musculoskeletal injury were included in the study. The participants were measured three times using the figure-of-eight method and then by water volumetry measurement. Out of the three measurements the third figure-of-eight measure and the volumetry measurement had the highest Pearson Product moment correlation coefficient ($r=0.92$).

Similarly, the correlation between the figure-of-eight method and volumetry was studied in males with no injury ⁵¹. Twenty males with no previous trauma between the age of 15 and 30 volunteered for the study. Each measurement was taken three times and recorded. The statistical analysis showed no significant difference between the figure-of-eight method and the volumetry measurements and a high Pearson product-moment correlation coefficient of $r= 0.91, 0.95$ and 0.96 (variation between examiners).

Based on these past studies, either method for measuring volume of the ankle is valid and reliable ^{10,46,51-53}. The protocol for the figure-of-eight girth measurement based on the original protocol by Esterson was used by both Mawdsley and Rios is as follows.

Protocol:

1) *Place ankle in a neutral position.*

2) *Place the zero point of the tape between the tibialis anterior tendon and*

the lateral malleolus.

3) Draw tape measure was medially across the instep and distal to the navicular tuberosity.

4) Pull tape measure across the Achilles tendon, continue to the distal edge of the lateral malleolus.

5) End the figure eight at the zero point of the tape measure.

6) Pull the tape measure snugly and release slightly to prevent compression of soft tissue (Mawdsley; Rios).

Pain Measurement

Pain is a difficult aspect of injury to measure based on the subjective nature of reporting. Many different scales can be used to assess pain including but not limited to: Visual analog scale (VAS), McGill Pain Questionnaire (MPQ), Faces Pain Scale (FPS-11), and Numeric rating scale. Finding an effective way to rate pain is essential in many health care practices. A study was conducted to find which pain scale was the most sensitive and easy to use for older adults and younger adults¹⁵. The results of this study showed that younger adults preferred to use the numeric rating scale to assess and express pain. Similar findings were reported after an extensive Medline review comparing three popular pain rating scales; verbal rating scale, numeric rating scale, and the visual analogue scale. All three scales were found to be valid and reliable. For

sensitivity and ease of use the numeric rating scale was recommended^{15,16}. The numeric rating scale ranges from 0-10 and allows the individual to assign a number to the amount of pain they are experiencing¹⁶. For the purposes of this study the numeric rating scale was chosen based on the validity, accuracy, and ease of use.

Chapter Three

Methodology

Experimental Design

A repeated measures design was used for this study. The independent variable was treatment group (control and deep oscillation group). The dependent variables were girth and pain measurements.

Subjects

Volunteers with inversion ankle injuries resulting in swelling and point tenderness were used in this study. Volunteers were randomly assigned to each of the two groups. The control group had 11 subjects (Height = 175.67 ± 10.81 cm, Weight = 75.83 ± 13.03 kg, Age = 20.08 ± 1.56 years) and the treatment group had 10 (Height = 173.97 ± 13.78 cm, Weight = 80.67 ± 26.92 kg, Age = 19.86 ± 1.79 years) subjects. All groups received treatment for 5 days.

Subjects were excluded for any of the following contraindications: acute infection, active tuberculosis, infectious skin disease, untreated malignant disease, untreated thromboses or vascular disorders, erysipelas, heart complaints, heart disease, pregnancy, cardiac pacemakers, implanted stimulators, or sensitivities to electrical fields. If the volunteer

answered positively to any of these contraindications for deep oscillation therapy, they were not allowed to participate in the study. Contraindications were applied to both the volunteer and person delivering the treatment.

Instrumentation

The deep oscillation therapy was performed using a HIVAMAT 200 Deep Oscillation Therapy Unit (Physiomed North America, Farmerville, LA). Intermittent compression and cryotherapy was administered using the GameReady® (CoolSystems Alameda, CA). Measurements were taken using unmarked white, ¼ inch athletic tape. The tape was then measured using a generic tape measure. The pain scale was assessed using a verbal numerical rating scale of 0-10. The injured extremity was elevated using a standard foam elevation bolster with a height of 20.32cm.

Study Entrance

Volunteers were informed about the study and were given an opportunity to ask questions. Once all questions were answered, the volunteer signed an informed consent document. Baseline measurements, including height, weight, bilateral figure-of-eight girth measurement, and pain level (taken by a verbal numerical rating scale), were taken before beginning the study.

Volunteers were randomly assigned to one of two treatment groups. One group was assigned as the control group and the second group was assigned as the deep oscillation therapy group.

Group 1 = Control Group

Individuals in each group received conventional treatment for a sprained ankle. They first received a 20 minute cold/intermittent compression treatment with a Game Ready® cold/compression unit. The Game Ready® was filled with cold water to 50-55°C. The injured extremity was elevated 20.32 cm during conventional treatment.

The subject was instructed to lay supine on a treatment table with their affected leg elevated using a standard elevation bolster with a height of 20.32cm. An ankle compression sleeve was placed on their lower limb. The parameters on the unit were set to place moderate intermittent compression (5 mm Hg- lowest pressure to 50 mm Hg- highest pressure) approximately 2 to 3 minutes of inflation to one minute of deflation, on their limb for 20 minutes. The pressure was first set to medium and then adjusted as necessary to maintain patient comfort. This treatment resulted in comfortable pressure aimed to decrease swelling.

Following the cold/compression treatment, volunteers in Group 1 received a placebo deep oscillation treatment. The volunteer remained supine on the table but bolster was removed. The volunteer was given a bar electrode to hold in their hand. The second electrode was placed on the therapists arm. (This completes the circuit between the volunteer and therapist.) The therapist applied the placebo deep oscillation treatment through their hands. The therapist wore non-latex gloves covered in baby powder (to maintain a dry surface) to apply the treatment. The machine was not turned on for group 1, thus no therapeutic treatment was administered.

Lymph Node Progression Treatment:

The placebo deep oscillation treatment was given according to the treatment guidelines of the owner's manual. Deep oscillation treatment begins by treating major lymph nodes within the lymph system to increase circulatory abilities of the system. This progression began all placebo deep oscillation treatments.

The researcher set the HIVAMAT frequency to 150 Hz but did not turn on the machine, thus no therapeutic treatment was administered, and began with 12 revolutions of their index and middle fingers over the patient's cervical lymph nodes. This was followed by 12 revolutions over the subclavian trunk lymph node. Twelve revolutions were then done over the mediastinal lymph node, located in the center of the sternum. The examiner then did approximately 30 seconds of clockwise circular revolutions over the cisterna chyli lymph node, which is halfway between the xyphoid process and the navel. This was followed by 12 revolutions over the inguinal lymph node. The therapist continued the progression into the lower extremity; the examiner spent about 1 minute of circular revolutions on the popliteal lymph node. All of the above revolutions were done with the machine turned off and in a circular motion, with the cisterna chyli lymph node being only done in a clockwise direction. This was all done with the athlete lying supine, without their ankle elevated.

Acute Deep Oscillation protocol (Days 1 and 2):

Following the Lymph Node Progression, the volunteer was instructed to lay prone with a small bolster under their lower leg, with the knee was flexed and the ankle elevated. The

HIVAMAT remained off. The placebo deep oscillation was then applied for 10 minutes. This treatment was administered with a circular pattern moving distal to proximal and vice versa. This was followed by 5 minutes of a specific distal to proximal motion. The examiner applied movement only distal to proximal during this last 5 minutes. This treatment was performed for a total of 15 minutes.

Outcome Measurements:

Pain Measurement: A numeric pain scale was used to assess the subject's pain before and after each treatment. The subject described their pain on a scale of 0 to 10 (0 being no pain at all, 10 being excruciating pain).

Swelling Measurements: Assessment of the subject's swelling was taken by the figure-of-eight girth measurement. The girth measurement involved wrapping $\frac{1}{4}$ inch athletic tape around the ankle and measuring the ankle girth. This was done three times. Each measurement was recorded and the average was recorded. The figure-of-eight girth measurement began on the anterior tibial tendon then passed over the navicular bone and under the medial arch. The tape then came over at the base of the fifth metatarsal and on to the dorsal aspect of the foot. The tape was pulled over the medial malleolus and around the calcaneus. Lastly, the tape was pulled over the lateral malleolus to the zero point of the tape. Minimal tension was applied to the tape.

Rehabilitation Exercises

On day 1, the subject was given basic exercises following their treatment and girth measurements to help increase their range of motion. Subjects were instructed to do the

following exercises:

Alphabet: The subject moved the injured foot at the ankle joint through the air as if he/she was writing the lower case alphabet. The subject went through the alphabet two times.

Circles: The subject moved their injured foot through the air in a circular fashion. The subject was instructed to do 15 clockwise circles and 15 counterclockwise circles.

The examiner used their discretion to limit number of exercises based on the subject's pain feedback.

On day 2 of the treatment, the subjects received the same modality treatments and continued with the exercises listed above. They were also given active range of motion exercises. These exercises continued to be performed post treatment and measurements.

Subjects were instructed to do the following exercises:

1. 4-way ankle range of motion exercises: The subject was seated with the knee extended and a rolled towel was placed under their injured ankle. The subject was instructed to move their ankle in four directions. He/she was instructed to pull the foot up towards the body, down towards the table, towards the midline of their body, and away from the midline of their body. The subject performed this exercise 30 times, with a rest after each repetition of 10.

The examiner used their discretion to limit number of exercises based off of the

subject's pain feedback. Resistance was added on days 3 -5 if these exercises became easy for the subject and the examiner felt it was advisable.

Following all treatment sessions, the subjects injured ankle was placed in a compression wrap from the base of their toes to the bottom third of their lower leg. A horseshoe felt pad was placed around the lateral malleolus before the compression wrap was put in place. The volunteer was taught how to remove and re-wrap his/her ankle for when they were at home.

Instructions for the rest of the day:

Volunteers were instructed to elevate their ankle above their heart throughout the day whenever possible and keep their ankle wrapped in a compression wrap at all times (unless bathing). In the event the volunteer felt their ankle, foot, or leg throbbing, they were instructed to remove the compression wrap for approximately 20 minutes and then re-apply the wrap. The volunteer was instructed to sleep with their compression wrap on unless it became uncomfortable or was throbbing. In that case, the volunteer was instructed to remove the wrap for the remainder of the night. Throughout the day, the volunteer was instructed to ice their ankle for 20 minutes at 3 different times while at home. The volunteer was instructed to leave ice off for at least an hour in between icing sessions.

Subacute Placebo Deep Oscillation Protocol (Days 3-5):

As stated above, all deep oscillation treatments and placebo deep oscillation treatments began with the same lymph node progression.

Following the Lymph Node Progression, the volunteer was instructed to lay prone with a small bolster under their lower leg, with the knee was flexed and the ankle elevated. The HIVAMAT again was not turned on. The placebo deep oscillation therapy was applied for 20 minutes in a circular pattern moving distal to proximal and vice versa. This was followed by 5 minutes in a specific distal to proximal motion. The examiner applied only distal to proximal treatment during the last 5 minutes of all treatments. These parameters were chosen due to manufacturer recommendation and lasted a total of 25 minutes.

Outcome measures were taken and recorded in the same fashion described above.

Instructions for the rest of the day follow the same guidelines as described above.

Group 2: Deep Oscillation Group

Following the 20 minute cold/compression treatment with the GameReady®, volunteers in Group 2 received a deep oscillation treatment.

The volunteer remained in supine position that they were in during their cold/compression treatment with the bolster removed. The volunteer was given a bar electrode to hold in their hand. The second electrode was placed on the therapists arm. (This completed the circuit between the volunteer and therapist.) The therapist applied the therapeutic vibrations through their hands. The therapist wore non-latex gloves covered in baby powder (to maintain a dry surface) to apply the treatment.

Lymph Node Progression Treatment:

The deep oscillation treatment was given according to the treatment guidelines of the

owner's manual. Deep oscillation treatments began by treating major lymph nodes within the lymph system to increase the circulatory abilities of the system. This progression was administered at the start of all deep oscillation treatments. Lymph node progression was performed in an identical fashion to the control group with the HIVAMAT turned on.

Acute Deep Oscillation protocol (Days 1 and 2):

As stated above, all deep oscillation treatments began with the same lymph node progression.

Following the Lymph Node Progression, the volunteer was placed prone with a small bolster under their lower leg, with the knee flexed and the ankle elevated. The HIVAMAT mode setting was 1:1 and at 85% intensity. The deep oscillation was applied for 10 minutes at 150 Hz. Treatment was administered in a circular pattern moving distal to proximal and vice versa. This was followed by 5 minutes at 20 Hz with a specific distal to proximal motion. The examiner applied hand movement only in a distal to proximal during this last 5 minutes. This treatment was performed for a total of 15 minutes.

Outcome measures were obtained in the same fashion for group 2 as for group 1. Volunteers in group 2 performed the same exercises as those in group 1. Volunteers in the group 2 were instructed to elevate their ankle and to use a compression wrap just as group 1. Group 2 was instructed to follow the same exercise protocol as the volunteers in

group 1.

Subacute Deep Oscillation Protocol (Days 3-5):

As stated above, all deep oscillation treatments began with the same lymph node progression.

Following the Lymph Node Progression, the volunteer was instructed to lay prone with a small bolster under their lower leg, with the knee was flexed and the ankle elevated. The HIVAMAT mode setting was set at 1:1 and at 85% intensity. The deep oscillation therapy was applied for 20 minutes at 150 Hz with a circular pattern moving distal to proximal and vice versa. This was followed by 5 minutes at 20 Hz with a specific distal to proximal motion. The examiner administered only distal to proximal during this last 5 minutes. These parameters were chosen due to manufacturer recommendation and were applied for a total of 25 minutes.

Outcome measures were taken and recorded in the same fashion as group 1. Instructions for the rest of the day followed the same guidelines as group 1.

Post-treatment Protocol:

Following treatment, the volunteers were instructed to drink $\frac{1}{2}$ of their body weight in fluid ounces through out the day. This is encouraged by the HIVAMAT manufacturer to aid in flushing the system and removing toxins that were introduced back into their bloodstream due to the treatment.

Independent Variables:

1. Control group receiving conventional treatment and the placebo deep oscillation treatment.
2. Deep Oscillation group (receiving conventional treatment + Deep Oscillation treatment)

Dependent Variables:

1. Ankle girth measurement
2. Pain measurement

Statistical Analysis

Independent T-tests were used to analyze the change score between injured and uninjured extremities.

A 2 x 5 repeated measures ANOVA (group and day) was used to determine statistical significance on the change score of the first treatment of the day (pre-measurement – post-measurement) over the five days for both in girth measurements and pain measurements.

Chapter 4

Results

Ten subjects completed the full five-day trial in the treatment group and eleven subjects in the control group. There were five subjects who participated in the study but for various reasons did not finish the entire five day treatment.

Table 1 displays means and standard deviations of perceived pain in both the control and treatment groups. A significant difference between groups was found on day one of the treatment for pain reduction ($F(1,24) = 4.477, p=0.045$), although no significant differences were found for on days 2 through 5. Mean pain measurements for the control group were 1.58 ± 1.38 . Mean pain measurements for the HIVAMAT group were 1.06 ± 1.25 .

Table 2 displays means and standard deviations of girth measurements in both the control and treatment groups. A significant difference between groups was found on day four of the treatment for girth reduction ($F(1,20) = 4.951, p = 0.038$). Mean girth measurements for the control group were -0.11 ± 0.46 . Mean girth measurements for the HIVAMAT group were 0.11 ± 0.46 .

Table 1
 Change in Pain Scores
 Change in pre to post scores on treatment 1
 Verbal Pain scale of 0-10

Treatment	Day 1*	Day 2	Day 3	Day 4	Day 5
Deep Oscillation Therapy	0.6071 ± 0.964	0.392 ± 0.487	0.136 ± 0.762	0.136 ± 0.762	0.107 ± 0.289
Conventional Treatment	1.5 ± 1.389	1.08 ± 1.56	0.136 ± 0.762	0.136 ± 0.762	0.25 ± 0.622

*=P<0.05

Table 2
 Girth Measurements
 Change in pre to post scores on treatment 1
 Centimeters

Treatment	Day 1	Day 2	Day 3	Day 4*	Day 5
Deep Oscillation Therapy	0.089 ± 0.47	-0.0236 ± 0.401	0.16 ± 0.443	0.292 ± 0.375	0.013 ± 0.33
Conventional Treatment	-0.148 ± 0.473	-0.132 ± 0.319	0.095 ± 0.447	-0.107 ± 0.466	0.084 ± 0.369

*=P<0.05

Chapter 5
SUMMARY, CONCLUSIONS, DISCUSSION, AND
RECOMMENDATIONS FOR FUTURE STUDY

Summary

Only two studies to date have evaluated the effectiveness of deep oscillation therapy on wound healing and the reduction of pain and swelling. Unfortunately, these studies did not involve musculoskeletal injuries. One study measured the reduction of swelling in lymphodema patients to see if deep oscillation therapy reduced girth measurements more than manual therapy¹⁷. This study showed a reduction in swelling with the use of deep oscillation therapy compared to manual therapy treatments. Swelling was measured using a three-dimensional measuring system. There was no difference in pain recorded between the two groups. There was, however, a statistical decrease in swelling post deep oscillation therapy treatment¹⁷.

The second study researched deep oscillation therapy and wound healing in rats¹⁸. The wounds were full thickness excision wounds inflicted by the researcher. This study found a significant improvement in wound size reduction with deep oscillation therapy¹⁸. Additionally, deep oscillation therapy reduced myeloperoxidase, a highly reactive oxidizing enzyme released by neutrophils at the site of initial injury^{54,55}. A decrease in this enzyme demonstrates the anti-inflammatory affect of deep oscillation therapy in wounds¹⁸.

The present study was conducted to assess the efficacy of deep oscillation

therapy to reduce swelling and pain in acute ankle sprains in addition to cryotherapy and compression treatments. Numerous studies have shown the effectiveness of reducing both swelling and pain through the combination of cryotherapy and compression^{7,38-40,56,57} although limited research exists on the effects of deep oscillation therapy on acute orthopedic injuries. While the manufacturers of deep oscillation therapy make multiple claims on its uses, this study focused on the possible ability to reduce swelling and pain.

Our primary goal was to assess the effectiveness of deep oscillation therapy to decrease swelling following ankle sprains. Our data did not demonstrate that deep oscillation therapy decreased swelling, as measured by a standard figure-of-eight girth measurement, more than standard cryotherapy/compression treatment. Therefore, swelling went down at the same rate for both the control and deep oscillation therapy groups. It should be noted that the study did not include a true control group (i.e. a group that received no treatment). Ethically, it was determined to be wrong to not provide treatment that has been shown to decrease pain and swelling in acute orthopedic injuries.

Injured volunteers were randomly assigned to the control and treatment group in an attempt to attain two similar groups to compare. The control group had seven grade I, four grade II, and no grade III sprains. The treatment group reported five grade I, four grade II, and one grade III sprains. When evaluating the means of the girth measurements for each group, it was noted that the means for the control group were slightly higher than our treatment group (Control, mean \pm SD, 6.8 mm \pm 7.7 mm; Treatment, mean \pm SD, 5.8 mm \pm 8.1 mm). Differences in girth between groups may be

due to the amount of injury swelling and the body type of the individuals. During the initial evaluation baseline figure-of-eight measurements were taken of the injured ankle and the uninjured ankle. To determine if the groups differed in the amount of initial swelling, we ran an independent t-test on the changes in girth (calculated as: injured initial girth measurement – uninjured girth measurement). No significant differences ($F(1,23) = 0.449$, $p = 0.509$) were observed between the control group (mean \pm SD, 6.8 mm \pm 7.7 mm) and the treatment group (mean \pm SD, 5.8 mm \pm 8.1 mm). Therefore, the two groups tested were statistically similar at the start of treatment. These measurements support the findings of the study, similar groups of ankle sprains responded in similar ways to two different treatments. Therefore, the deep oscillation therapy does not reduce swelling faster than cryotherapy and compression over a five-day treatment period.

There is little published data reporting the difference of girth between injured ankles and uninjured ankles, thus it is difficult to determine if the measured swelling in subjects in the current study are representative of normal Grade I and II ankle sprains. The severity of ankle sprains reported in our study appear to be consistent with the severity of sprains found in other studies. The majority of sprains included in other studies were also classified as either grade I or grade II⁵⁸, or with mild to moderate swelling⁴⁷. The variation of severity of injury in our subject pool is consistent with other studies.

Future studies should be performed on injuries that cause a greater amount of swelling when compared to the uninjured extremity. Greater girth differences between injured and uninjured subjects have been reported when studying ankle swelling in

malleolar fracture post-operative patients⁵⁹. Differences between injured and uninjured ankles ranged from 27.4 ± 11.3 mm for mild edema and 41.7 ± 10.2 mm for severe edema⁵⁹. These differences are much larger than the differences reported in our study. The reported differences in the control group ($6.8 \text{ mm} \pm 7.7 \text{ mm}$) and the treatment group ($5.8 \text{ mm} \pm 8.1 \text{ mm}$) are comparatively smaller than the swelling associated with post-operative swelling. Future studies should therefore consider including injuries that produce more severe swelling than ankle sprains.

In order to measure swelling, we choose to utilize a figure-of-eight measurement, as it is a common clinical tool used to assess swelling clinically. While it has been shown to be a reliable tool, it may not be sensitive enough to assess small differences in girth. Current literature has shown the reliability and validity of the figure-of-eight method^{11,47,51,59} but to our knowledge there has not been an investigation conducted to validate its sensitivity in measuring swelling. One reliability study which examined the reliability of the “figure-of-eight -20” method (a modification to the figure of eight method where the foot is braced in 20 degrees of plantar flexion) limited the inclusion of the study to malleolar fracture post-operative patients⁵⁹. The study supported other research regarding the reliability of the figure-of-eight-20 method but concluded that the figure-of-eight-20 method was most reliable in measuring localized ankle edema in patients with severe ankle trauma and thus severe swelling⁵⁹. It can be hypothesized that if the current study had obtained data on more significant swelling the effect of the therapy may have been more conclusive. Further investigation using either a more sensitive measuring device for swelling or injuries with greater swelling should be considered. After the conclusion of the study the statistical power was calculated

(0.12). This indicates that 144 subjects would be needed to sufficiently power this study. These findings support the inclusion of more sensitive measures to strengthen the study.

Upon working with the subjects, it was noted that some subjects retained swelling in their ankle while some retained swelling in their foot during the course of the study. While girth measurements are a reliable and quick tool for clinicians to use, volumetric measurements may be a better tool to measure girth following acute ankle sprains as means to encompass swelling found throughout the low leg, ankle, and foot. This consideration was addressed by Man,⁶⁰ noting that the figure-of-eight girth measurement does not take into account swelling in the toes and forefoot. Peterson et al⁵² made a similar point, noting that though the coefficient of determination between the figure-of-eight and the volumetric measurement was high ($r^2=0.91$), 9% of variance could be attributed to the swelling above the malleoli and in the foot⁵². This would most likely not change the findings between the two groups, but could add statistical power to the study. Thus, attempting to capture swelling in the foot, ankle, and low leg may be a better choice for future studies.

Our secondary goal was to assess the effectiveness of deep oscillation therapy to decrease pain following ankle sprains. The present study utilized a numeric pain scale to objectively assess pain during the five-day treatment period both before and after each treatment. A significant decrease in pain both pre and post treatment and over the five-day period was observed in both the control and deep oscillation groups. This finding is consistent with prior tissue healing literature⁹. However, no differences were found between groups over the five-day period. Swelling is caused by the cellular and

vascular response to injury. After the acute inflammatory phase there is a reduction of chemical responses that increase edema and pain at the site of the injury. The pain and swelling should both decrease as the inflammatory phase transitions to the proliferation phase. This is estimated to occur approximately between the third and fifth day post injury⁹. Chemical mediators such as histamine, prostoglandins, and bradykinin are directly related to pain⁹.

Previous studies have documented the analgesic effects of cryotherapy^{6,7,40,57}. Cryotherapy has shown to decrease nerve conduction velocity, cellular metabolism, and blood flow to the site of injury⁶¹. It is likely that some, and possibly all of the decrease in pain could be attributed to the analgesic effect of the cryotherapy treatment. Again, this brings up the issue of not having a true control group receiving no treatment. Conventional treatment including the GameReady® (cryotherapy and intermittent compression), has already been shown to decrease pain and swelling in acute orthopedic injuries, thus it is difficult to assess if the deep oscillation therapy would have reduced pain and swelling to a greater extent if the comparison had been to no treatment at all.

Delimitations

The protocol requested two treatments per day but allowed for flexibility of when those treatments occurred to accommodate the volunteers' schedule. Activity performed during the day can either increase or decrease the volunteers' swelling measurement, thus it may be advisable to regulate treatments times to standardized to similar times during each 24-hour period. However, it is unlikely in a clinical setting to treat all of your patients at the same time of day. Therefore, we do not believe

variations in treatment times should influence the results of the study.

Subjects were accepted into the study with varying levels of ankle sprains. Therefore, some volunteers participating in the study who suffered mild ankle sprains who were able to return to functional activity while still receiving their 5-day treatment. Six volunteers in the deep oscillation group and seven in the control group returned to activity before the treatment was over. This could indicate that the injury was not severe enough to warrant extensive treatment.

Future studies should consider if swelling and pain are the most accurate measures of comparison or if a more functional comparison should be made to assess greater changes. Other studies have included criteria such as range of motion, motor activity score, and self-reported athletic ability⁵⁸. This multifaceted approach may be more of a functional and clinically helpful determinant to the efficacy of deep oscillation therapy rather than limiting change scores to pain and swelling.

Conclusion

Based on the findings of the current study, it can be concluded that the addition of deep oscillation therapy to cryotherapy and compression is not more effective at reducing pain and swelling over a five-day period in acute ankle sprains.

After evaluating the study, we believe future research should utilize more precise measurements of swelling and assessing more severe injuries that cause larger amounts of swelling. This may mean including a different type of injury such as swelling in post-operative cases or soft tissue injuries involving larger surface area such as injuries to the knee.

The measurement of swelling should be more precise and be sure to encompass

all areas of swelling. It would also be beneficial to consider other means of swelling measurements such as three-dimensional measurements or a specific measure of one of the chemical mediators such as myeloperoxidase to measure the anti-inflammatory affect of deep oscillation therapy.

Appendix A

IRB

<i>Full Board or</i>	<i>James Madison University</i> HUMAN RESEARCH REVIEW REQUEST	<i>Expedited</i>
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<p>Investigators: This form is required for Full Board or Expedited review for all JMU research involving human subjects. If you are eligible for an exemption request, please use the alternate form at: http://www.jmu.edu/sponsprog/irb/irbExemptRequest.doc</p> <p>Reviewer: _____</p> <p>Reviewer: _____</p>	<p>FOR IRB USE ONLY: Protocol Number: IRB- _____</p> <p>Received: _____ 1st Review: _____ 2nd Review: _____ 3rd Review: _____</p> <p><input type="checkbox"/> Approved _____ Date: _____</p> <p><input type="checkbox"/> Disapproved _____ Date: _____</p> <p><input type="checkbox"/> Exempt _____ Date: _____</p>
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External Funding:	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO	If YES, Sponsor(s): _____
Project Title:	Effect of Deep Oscillation Therapy on the Reduction of Swelling and Pain Following Acute Ankle Sprains		
Project Dates:	From:	To:	Minimum Number of Participants
Dates cannot exceed 1 yr.	7/01/09	06/30/10	16
	MM/DD/YY	MM/DD/YY	Maximum Number of Participants
			20
Responsible Researcher(s):	Lisa Friesen		Department: Kinesiology
E-mail:	frieselm@jmu.edu		Address 293 Old S. High St
Telephone:	(781)572-9757		and/or (MSC): Harrisonburg, VA 22802
Please select:	Visiting	Adjunct	Research
<input type="checkbox"/> Faculty	<input type="checkbox"/> Faculty	<input type="checkbox"/> Faculty	<input type="checkbox"/> Associate
	Administrator/	Undergrad	Graduate
	<input type="checkbox"/> Staff Member	<input type="checkbox"/> Student	<input checked="" type="checkbox"/> Student
(if Applicable):			
Research Advisor:	Jamie L. Frye		Department: Health Sciences
E-mail:	fryejl@jmu.edu		Address 4301

Telephone: (419) 902-3760 (cell) 8- and/or (MSC): _____
8836 (office)

Investigator: Please respond to the questions below. The IRB will utilize your responses to evaluate your protocol submission.

1. YES NO Does the James Madison University Institutional Review Board define the project as *research*?

The James Madison University IRB defines "research" as a "systematic investigation designed to develop or contribute to generalizable knowledge."

All research involving human participants conducted by James Madison University faculty, staff, and students is subject to IRB review.

Some, but not all, studies that involve human participants are considered research and are subject to full or expedited IRB review, including those:

- **intended to satisfy the academic requirements for Independent Study, Bachelor's Essay, Honors/Senior Thesis, or the Master's Thesis;**
- **intended or expected to result in publication, presentation outside the classroom, or public dissemination in some other form;**
- **conducted outside the classroom and/or departmental research participant pool if they involve**
 - external funding
 - minors (*i.e.*, persons under the age of 18),
 - a targeted population of adults whose ability to freely give informed consent may be compromised (*i.e.*, persons who are socio-economically, educationally, or linguistically disadvantaged, cognitively impaired, elderly, terminally ill, or incarcerated),
 - pregnant women and/or fetuses who may be put at risk of physical harm,
 - a topic of a sensitive or personal nature, the examination or reporting of which may place the research participant at more than minimal risk, or
 - any type of activity that places research participants at more than minimal risk.

Other studies are eligible to *request* exemption from IRB review, including those

- conducted solely within the confines of the classroom or within a departmental research participant pool if they
 - are a general requirement of a course,
 - have the sole purpose of developing the student's research skills, and
 - will be overseen by a faculty member;
- conducted outside the classroom and outside departmental research participant pools, provided they do not involve minors, do not target special adult populations, do not pose a risk of physical harm to pregnant women and fetuses, do not deal with a topic of sensitive or personal nature, or do not involve any type of activity that places the participants at more than minimal risk (see details above); and provided the investigator does not intend to publish the results or share them with others in a public forum (*i.e.* conference presentations, senior theses).
- that are part of a larger research project that has current James Madison University IRB approval; or
- that are part of a larger research project that has current approval of a registered IRB at another institution, provided that, if research participants are to be recruited at James Madison University, the University's IRB has given permission for such on-campus recruitment.

2. YES NO Are the human participants in your study *living* individuals?

3. YES NO Will you obtain data through *intervention* or *interaction* with these individuals?

"Intervention" includes both physical procedures by which data are gathered (*e.g.*, measurement of heart rate or venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between the investigator and participant (*e.g.*, surveying or interviewing).

4. YES NO Will you obtain *identifiable private information* about these individuals?

"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect

that no observation or recording is taking place, or information provided for specific purposes which the individual can reasonably expect will not be made public (e.g., a medical record or student record). "Identifiable" means that the identity of the participant may be ascertained by the investigator or associated with the information (e.g., by name, code number, pattern of answers, etc.).

5. YES NO Does the study present *more than minimal risk* to the participants?

"Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Note that the concept of risk goes beyond physical risk and includes psychological, emotional, or behavioral risk as well as risks to employability, economic well being, social standing, and risks of civil and criminal liability.

CERTIFICATIONS:

For James Madison University to obtain a Federal Wide Assurance (FWA) with the Office of Human Research Protection (OHRP), U.S. Department of Health & Human Services, **all** research staff working with human participants must sign this form and receive training in ethical guidelines and regulations. "Research staff" is defined as persons who have direct and substantive involvement in proposing, performing, reviewing, or reporting research and includes students fulfilling these roles as well as their faculty advisors. The Office of Sponsored Programs maintains a roster of all researchers who have completed training within the past three years.

By signing below, the Responsible Researcher(s), and the Faculty Advisor (if applicable), certifies that he/she is familiar with the ethical guidelines and regulations regarding the protection of human research participants from research risks. In addition, he/she agrees to abide by all sponsor and university policies and procedures in conducting the research. He/she further certifies that he/she has completed training regarding human participant research ethics within the last three years.

Test module at OSP website <http://www.jmu.edu/sponsprog/irb/irbtraining.html>

Name of Researcher(s)	Signature of Researcher(s) and Faculty Advisor (if applicable)	Date	Training Completed
Lisa Friesen		6/24/09	<input checked="" type="checkbox"/>
Grace Weniger		6/24/09	<input checked="" type="checkbox"/>
Dr. Christopher Womack		6/24/09	<input checked="" type="checkbox"/>
Dr. Michael Saunders		6/24/09	<input checked="" type="checkbox"/>
Signature of Faculty Advisor also required (if Student protocol) ⇨	Jamie Frye	6/24/09	<input checked="" type="checkbox"/>

For additional training interests visit the National Institutes of Health Web Tutorial at:
<http://cme.nci.nih.gov/>

To Submit a Complete protocol, this document should include the following:

- Human Research Review Request form (i.e. *the questions above*)
- IRB Checklist (included on this form)
- Research Narrative (use the categories indicated below. 10 pages maximum, do *not* include your literature review)
- Additional relevant research materials (i.e. letter of consent, questionnaire, survey, where used)

PLEASE SUBMIT AN ELECTRONIC VERSION OF YOUR **ENTIRE** PROTOCOL TO JMU_GRANTS@JMU.EDU

PLEASE PROVIDE A **SIGNED** HARD COPY OF THE RESEARCH REVIEW REQUEST FORM TO:

OFFICE OF SPONSORED PROGRAMS, MSC 5728, JAMES MADISON ADMINISTRATIVE COMPLEX, BLDG #6,
SUITE 26

Research Proposal Checklist
for Submission to the Institutional Review Board on the Use of Human Subjects in Research

Title of Study:	Effect of Deep Oscillation Therapy on the Reduction of Swelling and Pain Following Acute Ankle Sprains		
Name of Investigator(s):	Lisa Friesen	Phone :	(781)572-9757
Campus Address:	Godwin 128	MSC:	2301
Email Address:	frieselm@jmu.edu		
Research Advisor (if applicable):	Dr. Jamie Frye	Phone:	419-902-3760 (cell) or 8-8836
Email Address:	fryejl@jmu.edu	MSC:	4301

(Investigator - Please Organize Material on the following page using the Topics Below)

PURPOSE OR OBJECTIVE(S)

- Limited to one page

PROCEDURES (Included are:)

- Research design and sampling
 Method of collecting data (emphasize possible risks, and protection of subjects)
 Time frame of study

DATA ANALYSIS

- Discussed how confidentiality of subjects and their responses will be maintained
 Discussed how data will be stored to ensure confidentiality of subjects

REPORTING PROCEDURES

- Identified audience to be reached in the report of the study
 Identified the presentation method(s) to be used
 Discussed how feedback will be provided to subjects

EXPERIENCE OF THE RESEARCHER

- Prior relevant experience of the researcher, supervisor, and/or consultants

ADDITIONAL ATTACHMENTS (if applicable:)

- Consent forms
 Letters of permission
 Cover letter(s)

- Questionnaire
- Tests
- Additional attachments relevant to the study

NOTIFY OSP OF INTENT TO SUBMIT FOR EXTERNAL FUNDING

- Project will be submitted for External Funding
If yes, submit proposal to Sponsored Programs: MSC 5728

Funding
Agency

Program

- *SUBMIT PROPOSAL AND CHECKLIST ELECTRONICALLY TO: JMU_grants@jmu.edu

TRAINING, TESTING AND FORM COMPLETION REQUIREMENTS

- Completed IRB training on (5/24/2009) at <http://www.jmu.edu/sponsprog/irb.html>

Purpose and Objectives:

The purpose of this study is to assess the effectiveness of deep oscillation therapy provided by the Physiomed Hivamat System® (Hivamat®) on decreasing acute swelling and pain following ankle sprain injuries.

Deep oscillation therapy is a therapeutic modality that uses a magnetic force to create a minimal electrostatic field. It was developed in Germany and was patented in 1987 and since has been used by numerous clinicians, including clinicians in the Athletic Training Facility at James Madison University. When applied to human tissue the electrostatic field is designed to create deep oscillations that produce tiny vibrations in the treated tissue. This type of therapy makes numerous claims regarding its therapeutic benefits including the ability to reduce edema (i.e. swelling) following injury. It is also marketed to relieve pain once edema is reduced. While this modality is marketed to decrease edema and pain and has gotten promising testimonial results, there has been no orthopedic research done on this modality.

Deep oscillation therapy has been used in the Athletic Training Facility at James Madison University for the past year with no adverse events on their patients. Their own anecdotal benefits of the therapy have supported the use of the device enough to warrant purchasing a second Hivamat® Device for the department.

Procedures/Research Design/Methodology/Timeframe:

The data in this study will be collected over the next two years.

Volunteers will be recruited from James Madison University athletics, university recreational center athletes, and the student population. Individuals entered into the study will have sustained an ankle sprain resulting in moderate swelling and pain. The advantage to all participants enrolled in the study is to receive free treatment for their ankle sprain for 5 days.

Twenty volunteers will be recruited and will be randomly assigned to one of two groups. Participants in both groups will receive standard therapeutic care for ankle sprains (rest, cold therapy, compression, elevation, and light exercises). All groups will receive treatment 2 times per day for 5 days.

The independent variables will be group (control vs. treatment) and time (days 1-5). The dependent variables will be swelling and pain. A separate 2 x 5 repeated measures ANOVA will be used to analyze the data on swelling and pain.

Volunteers will be asked if any of the following contraindications can be applied to their current physical state: acute infection, active tuberculosis, infectious skin disease, untreated malignant disease, untreated thromboses or vascular disorders, erysipelas (a skin infection), heart complaints, heart disease, pregnancy, cardiac pacemakers, implanted stimulators, or sensitivities to electrical fields. These conditions are considered to be contraindications for deep oscillation therapy by the manufacturer of the Physiomed Hivamat System®. If the volunteer has any of the above contraindications they will not be allowed to participate in the study.

Volunteers will be informed about the study and will be given an opportunity to ask questions. Once all questions have been answered to the volunteer's satisfaction, they will sign an informed consent document. Baseline measurements including height, weight, bilateral figure-8 girth measurement (taken with a measuring tape), and pain level (taken by a numeric pain scale) will be taken before they begin the study.

Control: Group 1

Ten volunteers will randomly be placed into the control group. This group will receive traditional treatment for a sprained ankle. This will include 2 treatments per day of 20 minutes of cold/compression, followed by light range of motion exercises, and having a compression wrap applied to their ankle. Additionally, they will receive a sham deep oscillation therapy. During this treatment, no therapeutic energy will be emitted into their tissues. This group will be used to evaluate the effectiveness of traditional ankle therapy plus a sham treatment to decrease pain and swelling when compared to the treatment group.

Experimental Treatment: Group 2

Ten volunteers will receive traditional treatment (20 minutes cold/compression and compression wrap application) plus deep oscillation treatment. The deep oscillation treatment will be 15 minutes for the first 2 days following injury and 25 minutes for days 3-5. The deep oscillation treatment will be followed by light range of motion exercises and having a compression wrap applied to their ankle.

Treatment: Group 1 and 2

All volunteers will have their ankle girth taken to measure their ankle size. A measuring tape will be placed around their ankle in a figure 8 pattern. Three measurements will be taken and the three measurements will be averaged. This will serve as a reference for the amount of ankle swelling in their injured ankle. This measurement will be repeated on their unaffected ankle so we can individually compare the amount of swelling found in the volunteer's affected and unaffected ankles.

The volunteer's pain level will be assessed using the Numeric Pain Scale. The patient will be asked to move their ankle and stand on it as they are able. They will then be asked to assess their pain on a scale of 1-10. Ten will be the worst pain they could imagine; one will be little to no pain. This measurement will serve as a reference of the volunteer's pain prior to treatment.

All volunteers in each group will receive traditional treatment for a sprained ankle. The subject will lie on their back on a treatment table and will have their affected ankle elevated with an elevation foam pad. A lower leg compression sleeve will be placed on their lower limb. First, they will receive a 20 minute cold/compression treatment with a Game Ready® cold/compression unit. In this therapy, a compression sleeve is placed over the ankle. When turned on, the sleeve fills with cold water (50-55 degrees) thus applying both cold and compressive therapy designed to decrease swelling. The parameters on the unit will be set to place moderate compression (beginning at 5 mmHg and increasing to 50 mm Hg) on their limb for 20 minutes. The pressure will first be set so that the volunteer feels comfortable compression and will be adjusted as necessary to maintain patient comfort. When the treatment begins, the sleeve will provide intermittent compression by inflating and deflating to encourage swelling to be pressed out of the swollen ankle.

Volunteers in Group 1 will now receive their sham deep oscillation treatment. The machine will be turned on so that volunteers believe they are getting a treatment but the treatment will not be started. A towel will be used to cover the face of the machine anytime the Hivamat® unit is used. The researcher will go through the motions of the lymph node progression and the treatment (described below in the Group 2 treatment). The patient will feel the clinician's hands on their skin and the light massage that accompanies the normal deep oscillation treatment.

Following all volunteers therapeutic treatment (following the sham and deep oscillation therapy), the volunteers will perform light ankle exercises to help the patients regain their ankle range of motion. Their ankle exercises will be followed by placing a compression wrap similar to an ACE bandage on their ankle to decrease swelling.

On day 1, the subject will be given basic exercises following their treatment to help increase their ankle range of motion. Volunteers will be instructed to do the following exercises within their comfort level:

- **Alphabet: The subject will move the injured foot at the ankle through the air as if he/she is writing the lower case alphabet. The subject will go through the alphabet two times.**
- **Circles: The subject will move their injured foot through the air in a circular fashion. The subject will do 15 clockwise circles and 15 counterclockwise circles.**

The examiner will use their discretion to limit number of exercises based on the subject's pain feedback.

On day 2 of the treatment, the volunteers will receive the same modality treatments and will continue with the exercises listed above and will also be given the following active range of motion exercises. These exercises will continue to be performed post conventional treatment and measurements for the rest of the volunteers' time in the study. Volunteers will be instructed to do the following exercises within their comfort level:

- **4-way ankle range of motion exercises: The subject will be seated with the knee extended and a foam roll placed under their injured ankle. The subject will move their ankle four directions. He/she will pull the foot up towards the body, down towards the table, in towards the midline, and out away from the midline. The subject will perform this exercise 30 times, with a rest after each repetition of 10.**

Treatment: Group 2

Following the traditional treatment described above, the treatment group (Group 2) will receive deep oscillation therapy as recommended by the manufacturer. When applying the deep oscillation therapy, the patient feels a mild vibration sensation similar to the vibrations felt from an inexpensive back massager. These vibrations are supposed to help get the excess fluid in a joint (or other swollen body part) moving back into the lymph system so that it may return to the circulatory system and be removed.

The treatment is not painful and is relatively pleasant for the patient. The treatment begins with therapy over the lymph nodes to stimulate their ability to help drain the fluid from the swollen body part (manufacturer's claim). The lymph node treatment is followed by treatment over the injured ankle.

Lymph Node Progression Treatment:

The deep oscillation treatment will be given according to the treatment guidelines of the owner's manual. The therapy will begin by treating major lymph nodes within the lymph system to increase their circulatory abilities of the system. This progression will begin both the acute and subacute deep oscillation treatments and takes approximately 1.5-2 minutes to complete.

The researcher will set the HIVAMAT® frequency to 150 Hz and will provide treatment to the following lymph nodes:

- 1. Twelve revolutions over the patients cervical lymph nodes (found in their neck)**
- 2. Twelve revolutions over the subclavian trunk lymph node (found near their collar bone)**
- 3. Twelve revolutions over the mediastinal lymph node (found in the center of the sternum)**
- 4. 30 seconds of revolutions over the cysternia chyle lymph node (found halfway between the base of the sternum and the navel)**
- 5. Twelve revolutions over the inguinal lymph node (found where the thigh bends at the hip)**
- 6. The therapist's revolutions will continue by working down into the lower extremity. The examiner will do about 1 minute of circular revolutions on the popliteal lymph node (the back of the knee).**

All of the above revolutions will be done at a frequency of 150 Hz and in a circular motion, with the cysternia chyle lymph node being only done in a clockwise direction. This should all be done with the athlete lying supine, without their ankle elevated.

Acute deep oscillation protocol (Days 1 and 2):

The deep oscillation treatment will be applied for 10 minutes using a high frequency (150 Hz) followed by 5 minutes of a low frequency (20 Hz; total of 15 minutes) based on the manufacturer recommendations. The volunteer will be placed prone with a small bolster under their lower leg, so the knee is flexed but the ankle is elevated. The HIVAMAT® will be applied for 10 minutes at 150 Hz treatment with a circular pattern moving from the toes toward the shin and back down toward the toes. This will be followed by 5 minutes at 20 Hz moving specifically from the toes toward the shin. This

treatment will be performed for a total of 15 minutes.

Subacute deep oscillation Protocol (Days 3-5):

The deep oscillation therapy will be applied for 20 minutes using a high frequency (150 Hz) and 5 minutes using a low frequency (20 Hz; total of 25 minutes).

While reactions to the treatment are rare, a few possible reactions may occur. Volunteers will be advised of these possible reactions to treatment in the informed consent document. Patients will be reminded of these possible reactions upon completing each treatment. If the volunteer does have a reaction, they will be instructed to contact the researchers.

The following are possible reactions to the treatment as described by the manufacturer:

- Pain sensations in the area undergoing treatment that develop approximately 3-4 hours following treatment. These sensations may go away following urination.
- Color and smell of urination may be altered from increased lymph drainage.
- Increased sensitivity of the skin treated. This reaction is most likely redness that may last for 1-2 days.
- Tiredness following treatment.
- Rise in local temperature (rare).
- Reduction in blood pressure.

Following Group 1 and Group 2's treatment, their ankle girth will be taken as a measurement of their ankle size. A measuring tape will be placed around their ankle in a figure 8 pattern. Three measurements will be taken and the three measurements will be averaged. This measurement will serve as a reference to see if the treatments decreased ankle swelling. Pain will again be assessed using the Numeric Rating Scale (scale from 1-10) to determine if the volunteer's pain level decreased as a result of the treatment.

The same therapeutic exercises described above will be done now for group 2.

Data Analysis:

Data gathered from our volunteers will never be referred to by name. Each volunteer will be randomly assigned to a number that will be the same throughout the study. Findings will be stored in a locked office on the campus of JMU. No names will be used in future presentations or publications of this data.

Reporting Procedures:

The findings of this study will be used as material for the thesis of Lisa M. Friesen. Following completion, it will be submitted for publication in a relevant athletic training journal.

The volunteers in the study will be given an option to know the results at the end of the study. Once the data is completed, the results will be e-mailed to the volunteer.

Experience of the researcher (and advisor, if student):

Lisa Friesen is a master's student at JMU working to complete her thesis. This is her first research experiment; however, she has completed basic research classes in her Kinesiology Masters Program. The primary advisors for the conduct of this study will be by Jamie L. Frye, PhD, ATC and Grace T. Weniger, ATC. Jamie L. Frye is professor in Health Sciences who has been involved with a number of studies involving human volunteers while a master's student at Indiana State University, a doctoral student at the University of Virginia, a faculty member at the University of Toledo, and a faculty member at James Madison University. Additionally, Dr. Frye is a certified athletic trainer. Grace T. Weniger is a certified athletic trainer employed by athletics at James Madison University. She is experienced in the use of deep oscillation therapy as it has been used in the sports medicine department at JMU for the past year. During this time, there have been no documented side effects from the therapy.

Dr. Chris J. Womack and Dr. Michael J. Saunders, from the Kinesiology Department at JMU, will primarily be providing research design input. Each has conducted numerous studies at JMU with human volunteers.

Additional Attachments as applicable: Volunteer Advertisement

Research Volunteers Needed

Clinical Investigator: Lisa Friesen, ATC

Purpose:

This research project will study the effect of deep oscillation treatment on ankle pain and swelling in new ankle sprains. Deep oscillation treatment causes deep massage and a pumping effect at the site of an injury to remove swelling.

Eligibility:

- All participants must be between 18 and 60 years of age
- All subjects must have a new ankle sprain with noticeable swelling

You may NOT participate if:

- You currently have a broken bone in your ankle
- You have an acute infection
- active tuberculosis
- infectious skin disease
- untreated malignant disease
- untreated thromboses or vascular disorders
- erysipelas
- heart complaints
- heart disease
- pregnancy
- cardiac pacemakers
- implanted stimulators
- sensitivities to electrical fields

Benefits:

- Initial evaluation of an ankle sprain by a certified athletic trainer.
- Treatment for an ankle sprain by a certified athletic trainer.
- Free compression wrap, exercise band, and home exercise program.

Time:

- 2 visits a day for 5 days each lasting approximately 1 hour.

Study Location:

Godwin Athletic Training Room

If interested in participating, please contact:

Lisa Friesen FrieseLM@jmu.edu 781-572-9757

Consent to Participate in Research

Identification of Investigators & Purpose of Study

You are being asked to participate in a research study conducted by Lisa Friesen, a master's student at James Madison University. Her research will be supported by her research committee Jamie Frye, Chris Womack, Michael Saunders, and Grace Weniger. This study will contribute to the student's completion of her master's thesis.

The purpose of this study is to test treatments used to reduce pain and swelling following ankle sprains. In addition to ice and compression, a piece of equipment called the Hivamat® unit will be used to treat your ankle sprain. The Hivamat® is a machine that will use electrostatic principles to help decrease the swelling and pain caused by your ankle sprain. It will use the machine to help "push and pull" the swelling from your ankle. This is a massage type of treatment in which the examiner will lightly rub their hands over your ankle joint.

Research Procedures

Should you decide to participate in this research study, you will be asked to sign this consent form once all your questions have been answered to your satisfaction. This study consists of receiving treatments for your ankle sprain two times a day for five days. Treatments will be administered on the JMU campus in the Godwin Hall Athletic Training Room. When you arrive, you will first receive a basic evaluation of your ankle injury. We will evaluate how much pain you have when certain parts of your ankle are touched, how much you can move your ankle, and how much strength you have in your ankle. We will also perform some special examination tests to see how bad you have injured your ankle and what structures may be injured.

Once we have determined that we agree you have an ankle sprain, you will be asked to rate your pain on a scale of one to ten based on the amount of pain you are feeling when moving your ankle and placing weight on your ankle. On this scale, one will be no pain at all and ten will be excruciating pain. After your answers are recorded, measurements of the swelling around your ankle will also be taken. We will gently wrap a tape measure around your ankle joint to measure how big it is. We will also do this on your non-injured ankle so we can compare the sizes of your ankles. Lastly, we will take your height and weight. We will record these measurements.

Once these initial measurements have been taken, volunteers will be randomly assigned to one of two groups. These groups will be called the control group and the treatment group.

Group A

If you are placed in Group A, you will be asked to report to the Athletic Training Room two times a day. You will lie down on your back on a treatment table with your shoe and sock off. Your injury leg will be elevated with a foam cushion. Your ankle will be wrapped with a sleeve that is attached to an electric unit called the Game Ready™. This unit will provide cold therapy and comfortable compression to the ankle joint. This is applied to help reduce swelling and pain. You will feel a cold sensation and mild pressure while you are attached to the Game Ready. The sleeve will fill and deflate to create a pumping motion to help remove swelling. If you feel uncomfortable at any point, please tell the clinician so they can change the settings in order to make you more comfortable. You will receive this treatment for 20 minutes.

Following the Game Ready™ treatment, you will receive a treatment with the Hivamat® unit. The

Hivamat® is a machine that will use basic electrostatic principles to help decrease the swelling and pain caused by your ankle sprain. It will use the machine to help “push and pull” the swelling from your ankle. This is a massage type of treatment in which the examiner will lightly rub their hands over your ankle joint. You will lie on your stomach with your knee slightly bent. You will be given a metal bar electrode to hold in your hand, which will help complete the electric circuit needed for the Hivamat® to properly work. During this treatment you will feel the clinician’s hands as they move over your skin but should not expect to feel anything else during the treatment. This treatment includes a series of circular movements around the body.

The Hivamat® treatment will start with a treatment to the major lymph nodes of the body. This will help to move the swelling into the lymphatic system and help it drain. This part will take approximately 1.5-2 minutes to complete. Once this is completed the following treatment will be performed:

With two fingers, they will move clockwise over the front portion of your neck,. The will do 12 revolutions.

They will move over the middle of the collar bone and with two fingers they will move clockwise 12 times.

The will continue to move down to the center of your chest bone where they will move clockwise 12 times.

They will then move halfway between the base of the chest bone and belly button (top of the stomach) and will perform a clockwise motion for 30 seconds.

The examiner will move to the front area where your thigh bends at your hip. 12 revolutions will be done in a clockwise motion.

The examiner will move to the back of the knee and will do about 1 minute of clockwise revolutions at this location.

This progression will be performed every time before receiving treatment with the Hivamat®.

On Days 1 and 2, the Hivamat® will be applied for 10 minutes with a circular pattern moving from the toes toward the shin and back down toward the toes. This will be followed by 5 minutes moving specifically from the toes toward the shin. This treatment will be performed for a total of 15 minutes.

On Days 3-5, the Hivamat® will be applied for 20 minutes with a circular pattern moving from the toes toward the shin and back down toward the toes. This will be followed by 5 minutes moving specifically from the toes toward the shin. This treatment will be performed for a total of 15 minutes.

Following the Hivamat® treatment, you will once again be asked to rate your pain on a scale of one to ten based on the amount of pain you are feeling due to your ankle sprain. After your answers are recorded, measurements of the swelling around your ankle will be taken with the tape measure again. We will take this measurement and compare it to your non-injured ankle to see how much swelling you still have in your injured ankle.

You will complete your therapy by performing light ankle exercises that will help increase your ankle movement and increase your ankle strength. These exercises should be mostly pain-free. You may feel slight discomfort, but should report anything that is painful to the clinician so they can modify or discontinue the exercise.

On Day One, these exercises will include:

- **Writing the alphabet with your ankle: You will move your injured foot at the ankle joint through the air as if you are writing the lower case alphabet. You will go through the alphabet two times if not too painful.**
- **Making circles with your ankle: You will move your injured foot through the air in a circular fashion. You will do 15 clockwise circles and 15 counterclockwise circles if not too painful.**

The clinician will use their discretion to limit the number of exercises based on how much pain you are experiencing. Therefore, it is important that you tell the clinician if you are experiencing pain with the exercises.

On day 2 -5 of the treatment, you will continue with the exercises listed above and will also be given the following exercises. These exercises will continue to be performed after you have received treatment and measurements have been taken. You will add the following exercise to the ones listed above:

- **4-way ankle movement exercises: You will be seated with your knee straight and a foam roll placed under your injured ankle. You will move your ankle in four directions. You will pull the foot up towards the body, down towards the table, in towards the midline, and out away from the midline. You will perform this exercise 30 times, with a rest after each repetition of 10.**

Once the measurements have been performed, you will have a foam pad in the shape of a horseshoe placed around the outside of your ankle bone. The ankle will be wrapped with a compression wrap, similar to an ACE bandage. The examiner will start the wrap at the toes and end at the mid calf. The horseshoe pad and compression wrap will help push swelling out of the ankle. The examiner will teach you how to place the wrap on your ankle in case you need to remove it and replace it later.

You will be instructed to wear the wrap for the remainder of the day. You may take the wrap off to take a shower or bath or if it becomes uncomfortable. If you take it off, please put the wrap back on after about 20 minutes. You will be given ice bags and will be instructed to ice three more times during the day while at home. Please keep the ice on for 20 minutes. You will also be given the exercises above to perform at home. These exercises are very basic and should not take more than 15 minutes. The purpose of the exercises is to increase the range of motion in your ankle.

Group B

If you are assigned to Group B, you will be asked to report to the Athletic Training Room two times a day. You will lie down on your back on a treatment table with your shoe and sock off. Your injury leg will be elevated with a foam cushion. Your ankle will be wrapped with a sleeve that is attached to an electric unit called the Game Ready™. This unit will provide cold therapy and comfortable compression to the ankle joint. This is applied to help reduce swelling and pain. You will feel a cold sensation and mild pressure while you are attached to the Game Ready™. The sleeve will fill and deflate to create a pumping motion to help remove swelling. If you feel uncomfortable at any point, please tell the clinician so they can change the settings in order to make you more comfortable. You will receive this treatment for 20 minutes.

Once the Game Ready™ treatment is completed, you will receive the Hivamat® treatment. You will lie on your stomach with your knee slightly bent. You will be given a metal bar electrode to hold in your hand, which will help complete the electric circuit needed for the Hivamat® to properly work. The treatment should not be painful. You will feel the examiner's hands as they are rubbing over the injured ankle. You may feel a light tapping or vibrating sensation caused by the Hivamat® treatment. This sensation should not be painful.

The Hivamat® Treatment will start with a treatment to the major lymph nodes of the body. This will help to move the swelling into the lymphatic system and help it drain. This part will take approximately 1.5-2 minutes to complete. After setting the machine to a frequency of 150 Hz, the following progression will be performed with the examiner's index and middle finger:

1. With two fingers, they will move clockwise over the front portion of your neck,. The will do 12 revolutions.
2. They will move over the middle of the collar bone and with two fingers they will move clockwise 12 times.
3. The will continue to move down to the center of your chest bone where they will move clockwise 12 times.
4. They will then move halfway between the base of the chest bone and belly button (top of the stomach) and will perform a clockwise motion for 30 seconds.
5. The examiner will move to the front area where your thigh bends at your hip. 12 revolutions will be done in a clockwise motion.
6. The examiner will move to the back of the knee and will do about 1 minute of clockwise revolutions at this location.

This progression will be performed every time before receiving treatment with the Hivamat®.

On Days 1 and 2, the Hivamat® will be applied for 10 minutes at a high frequency (150 Hz) with a circular pattern moving from the toes toward the shin and back down toward the toes. This will be followed by 5 minutes at a low frequency (20 Hz) moving specifically from the toes toward the shin. This treatment will be performed for a total of 15 minutes.

On Days 3-5, the Hivamat® will be applied for 20 minutes at a high frequency (150 Hz) with a circular pattern moving from the toes toward the shin and back down toward the toes. This will be followed by 5 minutes at a low frequency (20 Hz) moving specifically from the toes toward the shin. This treatment will be performed for a total of 15 minutes.

Following the Hivamat® treatment, you will once again be asked to rate your pain on a scale of one to ten based on the amount of pain you are feeling due to your ankle sprain. After your answers are recorded, measurements of the swelling around your ankle will be taken with the tape measure again. We will take this measurement and compare it to your non-injured ankle to see how much swelling you still have in your injured ankle.

You will complete your therapy by performing light ankle exercises that will help increase your ankle movement and increase your ankle strength. These exercises should be mostly pain-free. You may feel slight discomfort, but should report anything that is painful to the clinician so they can modify or discontinue the exercise.

On Day One, these exercises will include:

- **Writing the alphabet with your ankle: You will move your injured foot at the ankle joint through the air as if you are writing the lower case alphabet. You will go through the alphabet two times if not too painful.**
- **Making circles with your ankle: You will move your injured foot through the air in a circular fashion. You will do 15 clockwise circles and 15 counterclockwise circles if not too painful.**

The clinician will use their discretion to limit the number of exercises based on how much pain you are experiencing. Therefore, it is important that you tell the clinician if you are experiencing pain with the exercises.

On day 2 -5 of the treatment, you will continue with the exercises listed above and will also be given the following exercises. These exercises will continue to be performed after you have received treatment and measurements have been taken. You will add the following exercise to the ones listed above:

- **4-way ankle movement exercises: You will be seated with your knee straight and a foam roll placed under your injured ankle. You will move your ankle in four directions. You will pull the foot up towards the body, down towards the table, in towards the midline, and out away from the midline. You will perform this exercise 30 times, with a rest after each repetition of 10.**

Once the measurements have been performed, you will have a foam pad in the shape of a horseshoe placed around the outside of your ankle bone. The ankle will be wrapped with a compression wrap, similar to an ACE bandage. The examiner will start the wrap at the toes and end at the mid calf. The horseshoe pad and compression wrap will help push swelling out of the ankle. The examiner will teach you how to place the wrap on your ankle in case you need to remove it and replace it later.

You will be instructed to wear the wrap for the remainder of the day. You may take the wrap off to take a shower or bath or if it becomes uncomfortable. If you take it off, please put the wrap back on after about 20 minutes. You will be given ice bags and will be instructed to ice three more times during the day while at home. Please keep the ice on for 20 minutes. You will also be given the exercises above to perform at home. These exercises are very basic and should not take more than 15 minutes. The purpose of the exercises is to increase the range of motion in your ankle.

Time Required

Participation in this study will require approximately two hours a day of your time. Each treatment will last approximately one hour and you will be asked to receive treatment two times a day for five days.

Exclusions

If you have any of the following conditions, you will be asked to not participate in the study: acute infection, active tuberculosis, infectious skin disease, untreated malignant disease, untreated thromboses

or vascular disorders, erysipelas, heart complaints, heart disease, pregnancy, cardiac pacemakers, implanted stimulators, or sensitivities to electrical fields. Please let the clinician know if any of these contraindications apply to you.

Risks

The investigator does not perceive more than minimal risks from your involvement in this study. Following the ice treatment, your skin may appear red. Occasionally people may have a cold reaction where the iced area is itchy and the area becomes raised. This usually goes away within 24 hours. If this occurs, you will be dismissed from the study because you may have a cold allergy.

Following the Hivamat® treatment, we do not expect more than minimal risks. The makers of the Hivamat® report that you could possibly have the following reactions to the treatment:

- You could experience pain sensations in the area undergoing treatment that develop approximately 3-4 hours following treatment. These sensations may go away following urination. (described by manufacturer)
- *You could experience an increased desire to urinate. The color and smell of urination may be altered from normal due to the removal of the swelling in your ankle. This is not dangerous but a product of your body trying to remove the increased fluid in your system from the swelling.*
- Your skin in the area treated could be more sensitive following treatment. This reaction will most likely be redness that may last for 1-2 days.
- You could feel tiredness following treatment.
- You could have a rise in local skin temperature (rare).
- You could have a reduction in blood pressure.

Benefits

Potential benefits from participation in this study include treatment of your ankle sprain by a certified athletic trainer. This will aide in the reduction of swelling and healing of your injury.

Would like to have the results of the study sent to you by e-mail when the study is completed? Yes

No

E-mail Address: _____

Confidentiality

Your name and identity will not be disclosed at any point during or after this study. You will be identified by a number to keep records separate and to maintain your privacy.

The results of this research will be presented at James Madison University to Lisa Friesen's Thesis committee. The results of this project will be coded in such a way that the respondent's identity will not be attached to the final form of this study. The researcher retains the right to use and publish non-identifiable data. While individual responses are confidential, aggregate data

will be presented representing averages or generalizations about the responses as a whole. All data will be stored in a secure location accessible only to the researcher.

Participation & Withdrawal

Your participation is entirely voluntary. You are free to choose not to participate. Should you choose to participate, you can withdraw at any time without consequences of any kind.

Questions about the Study

If you have questions or concerns during the time of your participation in this study, or after its completion or you would like to receive a copy of the final aggregate results of this study, please contact:

Lisa Friesen	Dr. Jamie L. Frye	Dr. Christopher J. Womack
Kinesiology	Health Sciences Advisor	Kinesiology Advisor
James Madison University University	James Madison University	James Madison
(781) 572-9757	(540) 568-8836	(540) 568-6145
FrieselM@jmu.edu	fryejl@jmu.edu	womackcx@jmu.edu

Questions about Your Rights as a Research Subject

Dr. David Cockley
Chair, Institutional Review Board
James Madison University
(540) 568-2834
cocklede@jmu.edu

Giving of Consent

I have read this consent form and I understand what is being requested of me as a participant in this study. I have been given satisfactory answers to my questions. I freely consent to participate and understand that I can withdraw from the study at any time without consequence. The investigator has provided me with a copy of this form. I certify that I am at least 18 years of age.

Name of Participant (Printed)

Name of Participant (Signed)

Date

Name of Researcher (Signed)

Date

Appendix B

Informed Consent

Consent to Participate in Research

Identification of Investigators & Purpose of Study

You are being asked to participate in a research study conducted by Lisa Friesen, a master's student at James Madison University. Her research will be supported by her research committee Jamie Frye, Chris Womack, Michael Saunders, and Grace Weniger. This study will contribute to the student's completion of her master's thesis.

The purpose of this study is to test treatments used to reduce pain and swelling following ankle sprains. In addition to ice and compression, a piece of equipment called the Hivamat® unit will be used to treat your ankle sprain. The Hivamat® is a machine that will use electrostatic principles to help decrease the swelling and pain caused by your ankle sprain. It will use the machine to help “push and pull” the swelling from your ankle. This is a massage type of treatment in which the examiner will lightly rub their hands over your ankle joint.

Research Procedures

Should you decide to participate in this research study, you will be asked to sign this consent form once all your questions have been answered to your satisfaction. This study consists of receiving treatments for your ankle sprain two times a day for five days. Treatments will be administered on the JMU campus in the Godwin Hall Athletic Training Room. When you arrive, you will first receive a basic evaluation of your ankle injury. We will evaluate how much pain you have when certain parts of your ankle are touched, how much you can move your ankle, and how much strength you have in your ankle. We will also perform some special examination tests to see how bad you have injured your ankle and what structures may be injured.

Once we have determined that we agree you have an ankle sprain, you will be asked to rate your pain on a scale of one to ten based on the amount of pain you are feeling when moving your ankle and placing weight on your ankle. On this scale, one will be no pain at all and ten will be excruciating pain. After your answers are recorded, measurements of the swelling around your ankle will also be taken. We will gently wrap a tape measure around your ankle joint to measure how big it is. We will also do this on your non-injured ankle so we can compare the sizes of your ankles. Lastly, we will take

your height and weight. We will record these measurements.

Once these initial measurements have been taken, volunteers will be randomly assigned to one of two groups. These groups will be called the control group and the treatment group.

Group A

If you are placed in Group A, you will be asked to report to the Athletic Training Room two times a day. You will lie down on your back on a treatment table with your shoe and sock off. Your injury leg will be elevated with a foam cushion. Your ankle will be wrapped with a sleeve that is attached to an electric unit called the GameReady™. This unit will provide cold therapy and comfortable compression to the ankle joint. This is applied to help reduce swelling and pain. You will feel a cold sensation and mild pressure while you are attached to the Game Ready. The sleeve will fill and deflate to create a pumping motion to help remove swelling. If you feel uncomfortable at any point, please tell the clinician so they can change the settings in order to make you more comfortable. You will receive this treatment for 20 minutes.

Following the GameReady™ treatment, you will receive a treatment with the Hivamat® unit. The Hivamat® is a machine that will use basic electrostatic principles to help decrease the swelling and pain caused by your ankle sprain. It will use the machine to help “push and pull” the swelling from your ankle. This is a massage type of treatment in which the examiner will lightly rub their hands over your ankle joint. You will lie on your stomach with your knee slightly bent. You will be given a metal bar electrode to hold in your hand, which will help complete the electric circuit needed for the Hivamat® to properly work. During this treatment you will feel the clinician’s hands as they move over your skin but should not expect to feel anything else during the treatment. This treatment includes a series of circular movements around the body.

The Hivamat® treatment will start with a treatment to the major lymph nodes of the body. This will help to move the swelling into the lymphatic system and help it drain. This part will take approximately 1.5-2 minutes to complete. Once this is completed the following treatment will be performed:

- 1) With two fingers, they will move clockwise over the lower front portion of your neck. They will do 12 revolutions.
- 2) They will move about 4 inches down and with two fingers to the middle part of your collar bone, they will move clockwise 12 times..
- 3) They will continue to move down to the center of your chest bone where they will move clockwise 12 times.
- 4) They will then move to the next lymph node, found halfway between the base of the chest bone and belly button (at the top of your stomach). They will do a clockwise motion for 30 seconds.

- 5) The examiner will move to the area where your thigh bends at your hip. 12 revolutions will be done in a clockwise motion.
- 6) The examiner will move to the back of the knee and will do about 1 minute of revolutions at this location.

This progression will be performed every time before receiving treatment with the Hivamat®.

On Days 1 and 2, the Hivamat® will be applied for 10 minutes with a circular pattern moving from the toes toward the shin and back down toward the toes. This will be followed by 5 minutes moving specifically from the toes toward the shin. This treatment will be performed for a total of 15 minutes.

On Days 3-5, the Hivamat® will be applied for 20 minutes with a circular pattern moving from the toes toward the shin and back down toward the toes. This will be followed by 5 minutes moving specifically from the toes toward the shin. This treatment will be performed for a total of 15 minutes.

Following the Hivamat® treatment, you will once again be asked to rate your pain on a scale of one to ten based on the amount of pain you are feeling due to your ankle sprain. After your answers are recorded, measurements of the swelling around your ankle will be taken with the tape measure again. We will take this measurement and compare it to your non-injured ankle to see how much swelling you still have in your injured ankle.

You will complete your therapy by performing light ankle exercises that will help increase your ankle movement and increase your ankle strength. These exercises should be mostly pain-free. You may feel slight discomfort, but should report anything that is painful to the clinician so they can modify or discontinue the exercise.

On Day One, these exercises will include:

- *Writing the alphabet with your ankle: You will move your injured foot at the ankle joint through the air as if you are writing the lower case alphabet. You will go through the alphabet two times if not too painful.*
- *Making circles with your ankle: You will move your injured foot through the air in a circular fashion. You will do 15 clockwise circles and 15 counterclockwise circles if not too painful.*

The clinician will use their discretion to limit the number of exercises based on how much pain you are experiencing. Therefore, it is important that you tell the clinician if you are experiencing pain with the exercises.

On day 2 -5 of the treatment, you will continue with the exercises listed above and will also be given the following exercises. These exercises will continue to be performed after you have received treatment and measurements have been taken. You will add the following exercise to the ones listed above:

- *4-way ankle movement exercises: You will be seated with your knee straight and a foam roll placed under your injured ankle. You will move your ankle in four directions. You will pull the foot up towards the body, down towards the table, in towards the midline, and out away from the midline. You will perform this exercise 30 times, with a rest after each repetition of 10.*

Once the measurements have been performed, you will have a foam pad in the shape of a horseshoe placed around the outside of your ankle bone. The ankle will be wrapped with a compression wrap, similar to an ACE bandage. The examiner will start the wrap at the toes and end at the mid calf. The horseshoe pad and compression wrap will help push swelling out of the ankle. The examiner will teach you how to place the wrap on your ankle in case you need to remove it and replace it later.

You will be instructed to wear the wrap for the remainder of the day. You may take the wrap off to take a shower or bath or if it becomes uncomfortable. If you take it off, please put the wrap back on after about 20 minutes. You will be given ice bags and will be instructed to ice three more times during the day while at home. Please keep the ice on for 20 minutes. You will also be given the exercises above to perform at home. These exercises are very basic and should not take more than 15 minutes. The purpose of the exercises is to increase the range of motion in your ankle.

Group B

If you are assigned to Group B, you will be asked to report to the Athletic Training Room two times a day. You will lie down on your back on a treatment table with your shoe and sock off. Your injury leg will be elevated with a foam cushion. Your ankle will be wrapped with a sleeve that is attached to an electric unit called the GameReady™. This unit will provide cold therapy and comfortable compression to the ankle joint. This is applied to help reduce swelling and pain. You will feel a cold sensation and mild pressure while you are attached to the GameReady™. The sleeve will fill and deflate to create a pumping motion to help remove swelling. If you feel uncomfortable at any point, please tell the clinician so they can change the settings in order to make you more comfortable. You will receive this treatment for 20 minutes.

Once the GameReady™ treatment is completed, you will receive the Hivamat® treatment. You will lie on your stomach with your knee slightly bent. You will be given a metal bar electrode to hold in your hand, which will help complete the electric circuit needed for the Hivamat® to properly work. The treatment should not be painful. You will feel the examiner's hands as they are rubbing over the injured ankle. You may feel a light tapping or vibrating sensation caused by the Hivamat® treatment. This

sensation should not be painful.

The Hivamat® Treatment will start with a treatment to the major lymph nodes of the body. This will help to move the swelling into the lymphatic system and help it drain. This part will take approximately 1.5-2 minutes to complete. After setting the machine to a frequency of 150 Hz, the following progression will be performed with the examiner's index and middle finger:

With two fingers, they will move clockwise over the mid front portion of your neck. They will do 12 revolutions.

They will move about 4 inches down and with two fingers over the middle of the collar bone, they will move clockwise 12 times.

They will continue to move down to the center of your chest bone where they will move clockwise 12 times.

They will then move to the next lymph node, found halfway between the base of the chest bone and belly button (top of the stomach). They will do a clockwise motion for 30 seconds.

The examiner will move to the inguinal lymph node, which is located where your thigh bends at your hip. 12 revolutions will be done in a clockwise motion.

The examiner will move to the back of the knee and will do about 1 minute of revolutions at this location.

This progression will be performed every time before receiving treatment with the Hivamat®.

On Days 1 and 2, the Hivamat® will be applied for 10 minutes at a high frequency (150 Hz) with a circular pattern moving from the toes toward the shin and back down toward the toes. This will be followed by 5 minutes at a low frequency (20 Hz) moving specifically from the toes toward the shin. This treatment will be performed for a total of 15 minutes.

On Days 3-5, the Hivamat® will be applied for 20 minutes at a high frequency (150 Hz) with a circular pattern moving from the toes toward the shin and back down toward the toes. This will be followed by 5 minutes at a low frequency (20 Hz) moving specifically from the toes toward the shin. This treatment will be performed for a total of 15 minutes.

Following the Hivamat® treatment, you will once again be asked to rate your pain on a scale of one to ten based on the amount of pain you are feeling due to your ankle sprain. After your answers are recorded, measurements of the swelling around your ankle will be taken with the tape measure again. We will take this measurement and compare it to your non-injured ankle to see how much swelling you still have in your injured ankle.

You will complete your therapy by performing light ankle exercises that will help

increase your ankle movement and increase your ankle strength. These exercises should be mostly pain-free. You may feel slight discomfort, but should report anything that is painful to the clinician so they can modify or discontinue the exercise.

On Day One, these exercises will include:

- *Writing the alphabet with your ankle: You will move your injured foot at the ankle joint through the air as if you are writing the lower case alphabet. You will go through the alphabet two times if not too painful.*
- *Making circles with your ankle: You will move your injured foot through the air in a circular fashion. You will do 15 clockwise circles and 15 counterclockwise circles if not too painful.*

The clinician will use their discretion to limit the number of exercises based on how much pain you are experiencing. Therefore, it is important that you tell the clinician if you are experiencing pain with the exercises.

On day 2 -5 of the treatment, you will continue with the exercises listed above and will also be given the following exercises. These exercises will continue to be performed after you have received treatment and measurements have been taken. You will add the following exercise to the ones listed above:

- *4-way ankle movement exercises: You will be seated with your knee straight and a foam roll placed under your injured ankle. You will move your ankle in four directions. You will pull the foot up towards the body, down towards the table, in towards the midline, and out away from the midline. You will perform this exercise 30 times, with a rest after each repetition of 10.*

Once the measurements have been performed, you will have a foam pad in the shape of a horseshoe placed around the outside of your ankle bone. The ankle will be wrapped with a compression wrap, similar to an ACE bandage. The examiner will start the wrap at the toes and end at the mid calf. The horseshoe pad and compression wrap will help push swelling out of the ankle. The examiner will teach you how to place the wrap on your ankle in case you need to remove it and replace it later.

You will be instructed to wear the wrap for the remainder of the day. You may take the wrap off to take a shower or bath or if it becomes uncomfortable. If you take it off, please put the wrap back on after about 20 minutes. You will be given ice bags and will be instructed to ice three more times during the day while at home. Please keep the ice on for 20 minutes. You will also be given the exercises above to perform at home. These exercises are very basic and should not take more than 15 minutes. The purpose of the exercises is to increase the range of motion in your ankle.

Time Required

Participation in this study will require approximately two hours a day of your time. Each treatment will last approximately one hour and you will be asked to receive treatment two times a day for five days.

Exclusions

If you have any of the following conditions, you will be asked to not participate in the study: acute infection, active tuberculosis, infectious skin disease, untreated malignant disease, untreated thromboses or vascular disorders, erysipelas, heart complaints, heart disease, pregnancy, cardiac pacemakers, implanted stimulators, or sensitivities to electrical fields. Please let the clinician know if any of these contraindications apply to you.

Risks

The investigator does not perceive more than minimal risks from your involvement in this study. Following the ice treatment, your skin may appear red. Occasionally people may have a cold reaction where the iced area is itchy and the area becomes raised. This usually goes away within 24 hours. If this occurs, you will be dismissed from the study because you may have a cold allergy.

Following the Hivamat® treatment, we do not expect more than minimal risks. The makers of the Hivamat® report that you could possibly have the following reactions to the treatment:

- You could experience pain sensations in the area undergoing treatment that develop approximately 3-4 hours following treatment. These sensations may go away following urination. (described by manufacturer)
- You could experience an increased desire to urinate. The color and smell of urination may be altered from normal due to the removal of the swelling in your ankle. This is not dangerous but a product of your body trying to remove the increased fluid in your system from the swelling.
- Your skin in the area treated could be more sensitive following treatment. This reaction will most likely be redness that may last for 1-2 days.
- You could feel tiredness following treatment.
- You could have a rise in local skin temperature (rare).
- You could have a reduction in blood pressure.

Benefits

Potential benefits from participation in this study include treatment of your ankle sprain by a certified athletic trainer. This will aide in the reduction of swelling and healing of your injury.

Confidentiality

Your name and identity will not be disclosed at any point during or after this study. You will be identified by a number to keep records separate and to maintain your privacy.

The results of this research will be presented at James Madison University to Lisa Friesen's Thesis committee. The results of this project will be coded in such a way that the respondent's identity will not be attached to the final form of this study. The researcher retains the right to use and publish non-identifiable data. While individual responses are confidential, aggregate data will be presented representing averages or generalizations about the responses as a whole. All data will be stored in a secure location accessible only to the researcher.

Participation & Withdrawal

Your participation is entirely voluntary. You are free to choose not to participate. Should you choose to participate, you can withdraw at any time without consequences of any kind.

Questions about the Study

If you have questions or concerns during the time of your participation in this study, or after its completion or you would like to receive a copy of the final aggregate results of this study, please contact:

Lisa Friesen Womack	Dr. Jamie L. Frye	Dr. Christopher J.
Kinesiology	Health Sciences Advisor	Kinesiology Advisor
James Madison University University	James Madison University	James Madison
(781) 572-9757	(540) 568-8836	(540) 568-6145
FrieseLM@jmu.edu	fryejl@jmu.edu	womackcx@jmu.edu

Questions about Your Rights as a Research Subject

Dr. David Cockley
Chair, Institutional Review Board
James Madison University
(540) 568-2834
cocklede@jmu.edu

Giving of Consent

I have read this consent form and I understand what is being requested of me as a participant in this study. I have been given satisfactory answers to my questions. I freely consent to participate and understand that I can withdraw from the study at any time without consequence. The investigator has provided me with a copy of this form. I certify that I am at least 18 years of age.

Name of Participant (Printed)

Name of Participant (Signed)

Date

Name of Researcher (Signed)

Date

Appendix C

Data Collection Sheets

Initial Evaluation

Screen for the following contraindications: acute infection, active tuberculosis, infectious skin disease, untreated malignant disease, untreated thromboses or vascular disorders, erysipelas, heart complaints, heart disease, pregnancy, cardiac pacemakers, implanted stimulators, allergy to ice, or sensitivities to electrical fields. Any contraindications are cause for removal from study.

Date: _____

Treatment Group: A/B

Researcher: _____

Subject Identification Number: _____ M/F

Ht (cm): _____ **Wt (kg):** _____ **Pain Scale:** 0 1 2 3 4 5 6 7 8 9 10

Girth Measurement:

Pre-treatment

Right Injured/Uninjured

1) _____ +2) _____ +3) _____ = _____ /3= _____ (cm)

Left Injured/Uninjured

1) _____ +2) _____ +3) _____ = _____ /3= _____ (cm)

History:

Mechanism:

Observation:

Previous Treatment to current injury:

Special Tests:**Anterior Drawer: +/-****Talar Tilt: +/-****Tap Test: +/-****Point Tender at: ATF CFL PTF****Grade:****I +/-****II +/-****III +/-****Post Treatment Measurements:****Pain Scale: 0 1 2 3 4 5 6 7 8 9 10****Girth Measurement of Injured Ankle:****1) _____ +2) _____ +3) _____ = _____ /3= _____ (cm)**

Researcher Log

Make sure pain is assessed before the treatment is given

Name of Researcher: _____

Subject Identification Number: _____

Date: _____ **Time:** _____

Treatment: A B

Day of Treatment: 1 2 3 4 5

Subject Notes: (Please take note of any changes from the day before, reported increased pain, activities that increased pain, amount of time off feet)

Observation: (ecchymosis) Y/ N? If yes, where ? _____

Pre treatment:

Pain Scale 0 1 2 3 4 5 6 7 8 9 10

Girth Measurement: 1) _____ 2) _____ 3) _____

Post Treatment:

Pain Scale 0 1 2 3 4 5 6 7 8 9 10

Girth Measurement: 1) _____ 2) _____ 3) _____

Name of Researcher: _____

Subject Identification Number: _____

Date: _____ **Time:** _____

Treatment: A B

Day of Treatment: 1 2 3 4 5

Subject Notes: (Please take note of any changes from the day before, reported increased pain, activities that increased pain, amount of time off feet)

Observation: (ecchymosis) Y/ N? If yes, where ? _____

Pre treatment:*Pain Scale* 0 1 2 3 4 5 6 7 8 9 10*Girth Measurement:* 1) _____ 2) _____ 3) _____**Post Treatment:***Pain Scale* 0 1 2 3 4 5 6 7 8 9 10*Girth Measurement:* 1) _____ 2) _____ 3) _____

Subject Log

**Please elevate your ankle on your own throughout the day when possible.*

**Please keep your compression wrap on at all times unless you are showering or if it is increasing your pain. If your pain is increased with the compression wrap on please unwrap your ankle for 20 minutes before rewrapping.*

**Please ice your injured ankle three additional times to the treatments you are receiving. Please allow at least an hour between icing sessions.*

** Please bring this log with you to each treatment session.*

Day 1

Date: _____

Subject Identification Number: _____ **Treatment Group:** A/B

Time of Icing 1) _____ **2)** _____ **3)** _____

Time of Exercises: 1) _____ **2)** _____ **3)** _____

Notes: *(In this section please take note of increased pain, your activity level, amount of time wearing the compression wrap, amount of time without the compression wrap, if you have taken any medication to reduce pain or swelling, did any of the exercises increase your pain?, are you experiencing any adverse effects to the treatment?)*

Day 2

Date: _____

Time of Icing 1) _____ **2)** _____ **3)** _____

Time of Exercises: 1) _____ **2)** _____ **3)** _____

Notes:

Day 3

Date: _____

Time of Icing 1) _____ 2) _____ 3) _____

Time of Exercises: 1) _____ 2) _____ 3) _____

Did you add resistance to the four way ankle exercises? Y/N

Notes:

Day 4

Date: _____

Time of Icing 1) _____ 2) _____ 3) _____

Time of Exercises: 1) _____ 2) _____ 3) _____

Notes:

Day 5

Date: _____

Time of Icing 1) _____ 2) _____ 3) _____

Time of Exercises: 1) _____ 2) _____ 3) _____

Notes:

Appendix D

Take Home Instructions

Volunteer Take Home Instructions

Rest: Stay off your feet as much as possible. Reduce activity to a minimal level (i.e. getting around to class etc.) and avoid activities that increase the pain in your ankle.

Ice: Ice three times a day for 20 minutes. While icing keep your lower leg elevated above your heart.

Compression: Keep a compression wrap with a horseshoe pad on continually. When applying the wrap begin at the base of your toes and wrap up toward your leg. The horseshoe pad should be placed around the outside of the ankle bone, with the opened end closest to the knee. Wrap should be tight but not cutting off circulation. You should not feel numbness or tingling in your foot, your toes should not turn blue. If you notice any numbness, decreased blood flow, or throbbing in your foot remove wrap for 20 minutes and re-wrap.

Elevate: Whenever possible keep foot elevated above the heart. If possible sleep with foot elevated on pillows.

Exercises:

Please perform these exercises **three** times a day. Please concentrate on moving your ankle at the joint and place a rolled up towel under your ankle while performing the exercises.

Day 1: Circles- 15 times counterclockwise, 15 times clockwise. Alphabet-2 times through. (This set of exercises is to be done at three different times during the day.)

Day 2: Circles- 15 times counterclockwise, 15 times clockwise. Alphabet-2 times through. Four way ankle, 3 sets of 10 repetitions. (This set of exercises is to be done at three different times during the day.)

Day 3-5: Circles- 15 times counterclockwise, 15 times clockwise. Alphabet-2 times through. Four way ankle, 3 sets of 10 repetitions. **Resistance may be added if directed by your therapist.* (This set of exercises is to be done at three different times during the day.)

Explanation of Exercises

Please perform all exercises seated with leg straight and towel rolled under the ankle joint.

Circles: move ankle joint in a circular motion gently both clockwise and counterclockwise.

Alphabet:

With ankle supported on a rolled up towel move foot as if writing the alphabet in the air.



Four Way Ankles:

With ankle supported on a rolled up towel:

Dorsiflexion and plantarflexion- point toes toward the floor and then pull toes up toward the body.

Inversion: pull toes in toward the midline of the body; **try to move just the foot and not the leg.**

Eversion: pull toes away from the midline of the body. **Again try to keep movement at ankle joint.**

Appendix E

Additional Methods

Swelling and Pain Measurements:

Swelling: Assessment of the subject's edema will be taken a girth measurement. The girth measurement involves wrapping ½ inch generic athletic tape around the ankle.

- 1) Begin by asking volunteer to sit down with leg extended on a table. The ankle should extend off the table from mid calf.
- 2) Have volunteer keep ankle in a neutral position.
- 3) Begin measurement on the anterior tibial tendon.
- 4) Pass over the navicular bone and under the medial arch.
- 5) Come over at the base of the fifth metatarsal and onto the dorsal aspect of the foot.
- 6) Pull tape over the medial malleolus and around over the calcaneus.
- 7) Pull the tape measure over the lateral malleolus to the zero point of the tape measure.
- 8) This measure should be taken three times.
- 9) Measure tape with a generic tape measure.
- 10) Record measurements and average the three measurements.

Pain Measurement:

- 1) Verbally ask the volunteer to rate their pain on a scale of 0 (no pain at all) to 10 (the most excruciating pain they have ever experienced before).
- 2) Record pain on researcher log.

GameReady® Set up:

- 1) Fill bladder of GameReady® with ice and then water.
- 2) Bring GameReady® to treatment table.
- 3) Plug GameReady® into power source.
- 4) Wrap GameReady® ankle boot comfortably around injured ankle.
- 5) Make sure ankle boot is secure.
- 6) Turn GameReady® on
- 7) Increase pressure to medium for 20 minutes.
- 8) Place foam bolster under injured ankle to keep elevated for entire 20 minute treatment.

Lymph Node Progression

This progression should be done before all HIVAMAT treatments (both placebo and real) are performed.

- 1) Start with athlete lying supine, without their ankle elevated.
- 2) Set HIVAMAT to 150 Hz, 85% dosis (intensity) for desired time (day 1 and 2 for 18 minutes, days 3-5 28 minutes).
- 3) Set mode at 1:1.
- 4) Give volunteer bar electrode and ask them to hold it in their hand.
- 5) Stick the circular electrode on the therapists arm. If electrode has lost some of its adhesiveness it is recommended to secure it to arm with an elastic wrap.
- 6) Put on non-latex gloves and pour a small amount of baby powder in hand to help keep surface dry.
- 7) With the HIVAMAT frequency set to 150 Hz and begin with 12 revolutions of their fingers over the patient's cervical lymph nodes. Use the index and middle finger for the revolutions.
- 8) Progress to 12 revolutions over the subclavian trunk lymph node.
- 9) Then do 12 revolutions over the mediastinal lymph node, located in the center of the sternum.

10) The sternal revolutions will be followed by 30 seconds of clockwise circular revolutions over the cisterna chyli lymph node, which is halfway between the xyphoid process and the navel.

11) Move to the inguinal lymph node and do 12 more revolutions.

12) Lastly, do 1 minute of circular revolutions on the popliteal lymph node.

13) All of the above revolutions will be done at a frequency of 150 Hz and in a circular motion, with the cisterna chyli lymph node being only done in a clockwise direction.

*All lymph node revolutions should be done on skin when possible to maximize treatment.

Deep Oscillation Therapy Treatment

After the lymph node progression have volunteer lay in a prone position and place a bolster under the injured ankle, with knee in slight flexion and injured ankle elevated.

For days 1 and 2:

- 1) the deep oscillation will be applied for 10 minutes at 150 Hz Treatment with a circular pattern moving distal to proximal and vice versa.
- 2) Apply light pressure and move hands in an effleurage pattern.
- 3) This will be followed by 5 minutes at 20 Hz with a specific distal to proximal motion. The examiner will move only distal to proximal during this last 5 minutes.
- 4) This treatment will be performed for a total of 15 minutes.

For days 3-5:

- 1) Begin with same lymphatic progression as above.
- 2) After lymphatic progression ask volunteer to lay on stomach (prone) with a small bolster under their lower leg, so the knee is flexed and the ankle is elevated.
- 3) The HIVAMAT mode setting will be 1:1 (this may be adjusted for the patients comfort) and at 85% intensity.
- 4) Set time for 28 minutes.
- 5) The deep oscillation therapy will be applied for 20 minutes at 150 Hz with a circular pattern moving distal to proximal and vice versa.

- 6) This will be followed by 5 minutes at 20 Hz with a specific distal to proximal motion. The examiner will move only distal to proximal during this last 5 minutes. These parameters were chosen due to manufacturer recommendation and will be for a total of 25 minutes.

After all deep oscillation treatments advise volunteer to drink plenty of water throughout the day. They will be instructed to drink $\frac{1}{2}$ of their body weight in fluid ounces. *This is encouraged by the HIVAMAT manufacturer to aid in flushing their system and removing toxins that were introduced back into their bloodstream due to the treatment.*

At the end of each treatment take three girth measurements. Average these three girth measurements and record. Record verbal pain quotient.

Range of Motion Exercises

Please concentrate on volunteer moving ankle at the joint.

Place a rolled up towel under the volunteers' ankle while performing the exercises.

Day 1: Circles- 15 times counterclockwise, 15 times clockwise. Alphabet-2 times through. (This set of exercises is to be done at three different times during the day.)

Day 2: Circles- 15 times counterclockwise, 15 times clockwise. Alphabet-2 times through. Four way ankle, 3 sets of 10 repetitions. (This set of exercises is to be done at three different times during the day.)

Day 3-5: Circles- 15 times counterclockwise, 15 times clockwise. Alphabet-2 times through. Four way ankle, 3 sets of 10 repetitions. **Resistance may be added if directed by your therapist.* (This set of exercises is to be done at three different times during the day.)

Explanation of Exercises

Please perform all exercises seated with leg straight and towel rolled under the ankle joint.

Circles: move ankle joint in a circular motion gently both clockwise and counterclockwise.

Alphabet:

With ankle supported on a rolled up towel move foot as if writing the alphabet in the air.

Four Way Ankles:

With ankle supported on a rolled up towel:

Dorsiflexion and plantarflexion- point toes toward the floor and then pull toes up toward the body.

Inversion: pull toes in toward the midline of the body; **try to move just the foot and not the leg.**

Eversion: pull toes away from the midline of the body. **Again try to keep movement at ankle joint.**

After exercises re-wrap volunteers ankle with the compression wrap and horseshoe pad.

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