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UNIVERSITY OF ALBERTA

THE EFFECTS OF ACUPUNCTURE ON ACUTE SECOND DEGREE LATERAL ANKLE SPRAINS

BY

CINDY CINATS ©

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of **MASTER OF SCIENCE.**

DEPARTMENT OF PHYSICAL THERAPY

EDMONTON, ALBERTA

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled **THE EFFECTS OF ACUPUNCTURE ON ACUTE SECOND DEGREE LATERAL ANKLE SPRAINS** submitted by **CINDY CINATS** in partial fulfillment of the requirements for the degree of **MASTER OF SCIENCE.**

Dr. David Magee - Supervisor

Mr. Sandy Rennie

Dr. Jim Vargo

Dated: July 29 1998

ABSTRACT

The purpose of this study was to determine if a combination of acupuncture and ice and compression were more effective than acupuncture alone or ice and compression together in reducing pain and swelling and improving ROM and function in subjects with acute second degree lateral ankle sprains.

Thirty subjects in total were recruited, ten in each of the three treatment groups. The treatment groups were acupuncture, ice and compression, and a combination of acupuncture and ice and compression. The outcome measures that were used were pain (VAS), swelling (figure of eight method of measuring ankle circumference), ROM, and function.

The results of this study demonstrated a consistent trend and the direction of the data with a small sample size suggests that subjects who did receive a combination of acupuncture and ice and compression did better on all measures. The results of this study suggest that the physiological effects of the combination treatment (acupuncture and ice and compression) were more effective in reducing pain and swelling and improving ROM and function in subjects with second degree ankle sprains suggesting the use of acupuncture as a modality for treating acute soft tissue injuries.

DEDICATION

I would like to dedicate this work to several but not all the important people who have helped shaped my life.

To my parents who within themselves are truly inspirational. Thank you for your continuing love and support in whatever I do. Thank you for teaching me the value of hard work and perserverance and most of all thank you for always being just a phone call away.

To my siblings, Doug, Debbie and Trudi who know the true meaning of family, love, support and encouragement. We have been there for all of us whenever we needed to be - thank you for being there and supporting and understanding me throughout my life.

To my husband and best friend, John. Thank you for teaching me to believe in myself and constantly reminding me that I can accomplish anything I set out to do. You are a very important part of my life and words can not thank you enough for always being there.

And finally, to my children, David and Emily. Thank you for being so unselfish and helping me to count down subjects! You will always be the greatest and most important accomplishments in my life - you are my heroes.

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CHAPTER ONE

INTRODUCTION:

Ankle injuries are the most common sports related injury (49). Recent studies have recommended different types of conventional treatment but there is no consensus in the literature as to the best treatment in the early phase (21,53,69). Recently, in clinical practice, acupuncture has been used in the early phase of musculoskeletal treatment but there is no documented evidence to support its use (1).

The lateral ligaments of the ankle are most commonly sprained when the ankle joint is in the unstable position of plantar flexion and inversion. The lateral ligaments are sprained in a progressive manner depending on the force applied. The anterior talofibular ligament (ATFL), is usually the first ligament to stretch and/or tear followed by the calcaneofibular ligament (CFL). If the injury is more severe, the posterior talofibular ligament (PTFL) is involved (29).

The degree of sprain is classified according to the amount of damage. A grade one ligament injury is classified as a first degree sprain with the symptoms of pain and mild swelling with little or no hemorrhage. There may be some point tenderness with mildly decreased range of motion (ROM) and some difficulty with full weight-bearing at least for a short period of time but the joint is stable. This injury involves stretching of the ligament without a macroscopic tear. A grade two injury, which was the injury studied in this research project, is a moderate injury with pain and disability. There is a functional loss and the injured individual has difficulty with rising on toes or

hopping on the injured extremity. There is moderate point tenderness over the injured ligament, decreased ROM, swelling and localized hemorrhage. This injury often involves a complete tear of the ATFL and a partial tear of the CFL. A grade 3 sprain is a more serious injury with direct or indirect trauma to the joint with pain and severe disability. There may be diffuse swelling, ecchymosis, instability and loss of function. This injury usually involves a complete disruption of the ATFL and the CFL with a capsular tear. It may also involve tearing of the PTFL (29,64).

Treatment and rehabilitation of ankle sprains vary according to the severity of the problem and range from no treatment to surgical repair. Treatment selection has been based on past clinical experience and patient preference rather than clinical research. Standard initial treatment of acute lateral ankle sprains usually consists of ice, compression and elevation and weight bearing to tolerance and early protected ROM exercises (23,41,53,63,69). The treatment principle in this initial phase is to decrease the intensity of the inflammatory response and decrease pain in order to achieve early weight-bearing activity and early ROM (21,32,53,66,69).

Ice produces a local vasoconstriction which reduces the intensity of the inflammatory response and the amount of swelling (32,59). The less the initial swelling, the less pain, muscle spasm and loss of movement experienced by the patient allowing less time being needed for rehabilitation and a quicker return to activity (32,53). This treatment allows for early motion and activity which is beneficial to the healing process. It has been shown that early cyclic motion promotes scar proliferation and remodeling thereby making the ligament stronger than if no motion had been done (9,72). Pain is decreased when ice is applied. The mechanical and chemical responses to ice application are fairly well understood and documented

(44,53,59,63,68,69). Ice decreases pain by decreasing inflammation, causing local vasoconstriction, and thereby decreasing blood flow and decreasing cell metabolism (20,32,59,66).

The neurophysiological mechanisms are less well understood and there are differing statements in the literature as to the exact mechanisms involved (14,33,40,47). Ice elevates the pain threshold by decreasing the excitability of the nerve endings (32). Ice may stimulate sensory cutaneous nerves that via the gating mechanism block or decrease pain (large, fast conducting nerve fibers block the pain transmission of small, slow conducting fibers in the spinal cord) (30,40). In an acute injury, there is swelling, pressure and a release of chemicals (vasoactive amines) from the cells. Ice decreases this swelling, pressure and chemical activity which may result in fewer pain signals, less mechanical and chemical input and therefore less pain. Ice not only decreases the speed of the nerve impulse but also the intensity. The decreased sensitivity of the nerves, due to the resulting higher stimulation threshold, will result in a decrease in the frequency of nerve impulses to the brain. With ice application, the pain threshold rises due to a decrease in the excitability of the free nerve endings and peripheral nerve fibers (32). There is a close relationship between velocity and frequency of nerve conduction. There is a decrease in frequency and intensity (decreased velocity), which in all probability results in a decrease in perception of pain. The decrease in pain therefore may arise from a combination of several related activities.

Compression decreases pain by promoting reabsorption, and mechanically reducing the amount of space available for swelling by applying pressure around an injured area (69). Elevation decreases pain by facilitating reabsorption through the effect of gravity. Elevation has been shown to decrease edema in acute ankle injuries and has been shown to be superior to

compression in reducing ankle edema (45). Cold causes vasoconstriction resulting in less fluid leakage into the tissues and therefore because of the decreased swelling, there will be less triggering of sensory nerve endings. The decrease in chemical irritation (due to a reduction in the release of vasoactive amines) also causes less stimulation of the sensory nerve endings. The combined effects of ice, compression, and perhaps elevation, leads to a decrease in the nerves ability to conduct a signal. The cutaneous analgesia that is produced is probably due to a decreased peripheral sensory discharge, and the effects of cold on the metabolism of the damaged cells and nerves resulting in decreased oxygen consumption of the nerve (30). This change may account for the perceived decrease in pain similar to that of the numbness that occurs with freezing from the dentist's needle (30,33,40). It has also been mentioned that ice may decrease pain by stimulating the body's production of endorphins (47).

It is the clinical impression of therapists who use acupuncture for acute injuries, including acute ankle sprains, that acupuncture facilitates the reduction of inflammation and pain. Whether it reduces inflammation and pain more quickly than conventional modalities has not been studied. Acupuncture is also used in the initial stages of an acute injury to decrease the intensity of the inflammatory reaction and reduce pain. Pomerantz and Stux (60) demonstrated the analgesic effect of acupuncture. They related this analgesic effect to the action of neurotransmitters at different levels of the nervous system. The neurotransmitters that are released include endorphins, monoamines (serotonin and norepinephrine) and cortisol. Pomerantz and Stux (60) also demonstrated that naloxone, an endorphin antagonist, completely blocked acupuncture analgesia but had no effect on sham acupuncture suggesting that acupuncture analgesia is produced by stimulation

of the body's endogenous opiates (48). Acupuncture research has shown that acupuncture reduced inflammation by reducing the number of leukocytes and possibly decreasing vascular permeability of damaged cells (57). Sin (57) and Min (35) also showed that acupuncture reduced the number of leukocytes in experimentally induced inflammation in rats and increased phagocytic activities in these animals. Rapson (48) discussed the equimolar release of ACTH with endorphins when acupuncture was applied and also discussed other studies that have shown that electroacupuncture has increased blood cortisol levels in horses and human beings and may explain the anti-inflammatory role of acupuncture. Pomerantz (43) has performed years of laboratory studies on the effects of acupuncture stimulation and discussed the correlate release of pituitary B-endorphins and ACTH. He explained that ACTH travels to the adrenal cortex and stimulates a release of cortisol which may explain the anti-inflammatory role of acupuncture.

STATEMENT OF THE PROBLEM:

Lateral ankle sprains are the most frequently occurring injury of the musculoskeletal system and are the second greatest cause of days lost from work (7,12,15,23,51,63,68). In sports, ankle sprains occur at a frequency of one ankle injury per 17 participants and are most common in those activities which involve running and jumping. This injury comprises more than 50% of all basketball injuries and 25% of all soccer and volleyball injuries. The lateral ankle ligaments account for approximately 95% of all ankle sprains (15,49).

Ice and compression are advocated in the early phases of the injury to control swelling and pain and have become the treatment of choice for most

therapists (44,53,63,69). Many physical therapists are now trained in acupuncture and are using acupuncture as a treatment modality for acute injuries. Clinically, it is intuitively known that acupuncture works but there is lack of scientific studies supporting the use of acupuncture in acute injuries. It has been the author's clinical impression that if acupuncture is effective in controlling pain and swelling, then a combination of acupuncture, ice and compression should be the most effective form of treatment for acute second degree lateral ankle sprains.

The purpose of this research project was to determine if a combination of acupuncture, ice and compression would be effective in the treatment of acute lateral ankle sprains.

OBJECTIVES:

The purposes of this study were:

1. To determine if a combination of acupuncture, ice and compression were more effective than ice and compression, or acupuncture alone, in decreasing pain in acute second degree ankle sprains
2. To determine if a combination of acupuncture, ice and compression were more effective than ice and compression, or acupuncture alone, in improving ROM in acute second degree ankle sprains.
3. To determine if a combination of acupuncture, ice and compression were more effective than ice and compression, or acupuncture alone, in reducing swelling in acute second degree ankle sprains.
4. To determine if a combination of acupuncture, ice and compression were more effective than ice and compression, or acupuncture alone, in improving function in acute second degree ankle sprains.

5. To determine the effectiveness of the hop test and the timed hop test as measures of function at time of discharge.

HYPOTHESIS:

The research hypotheses of this study were based on a review of the literature and clinical impression that: a combination of acupuncture, ice and compression would be more effective than ice and compression alone, or acupuncture in a) reducing pain b) reducing swelling c) improving ROM and d) improving function in acute second degree lateral ankle sprains.

DEFINITIONS:

1. Acupuncture: This is an ancient Chinese medical treatment, which involves the insertion of very fine needles into specific points on the body to treat disease or control pain (48).
2. De Qi: This is the sensation of aching, numbness or soreness that the patient feels with stimulation of acupuncture points with needles.
3. Second degree ankle sprain: This is a moderate sprain or partial tear of the anterior talofibular and possibly the calcaneofibular ligaments with the symptoms of pain and moderate disability felt by the patient. The present study included only extracapsular sprains which presented with localized swelling as opposed to intracapsular sprains where the swelling was more generalized and would be evident on both sides of the Achilles tendon. Other signs of a second degree sprain were as follows: point tenderness over the anterior talofibular ligament and possibly the calcaneofibular ligament, sudden onset of localized

swelling and ecchymosis, solid endfeel to stress when performing the talar tilt test, solid endfeel when performing the anterior drawer sign, no inversion laxity as detected by performing the talar tilt, decreased ROM, inability to rise on toes, difficulty climbing stairs, pain and difficulty with full weight bearing (2,29,49,69). There is no uniform or widely accepted method of precisely defining ankle sprain severity (69). Consequently there is some variability in the diagnosis of an acute second degree ankle sprain. There will be variability with respect to the amount of soft tissue injury depending on the severity of the traumatic incident. Second degree sprains may vary according to the amount of apparent joint instability, ecchymosis and clinical symptoms.

4. Acute: The state of injury from onset of injury to 72 hours.
5. Functional Ability: The ability to walk full weight-bearing without pain and the ability to perform the single hop test and the timed hop test.

LIMITATIONS:

This study was limited by:

1. The ability of the therapist to apply acupuncture needles in a consistent manner.
2. The ability of the subjects to comprehend, understand and do the visual analog scale and the required functional tests.
3. The reliability of the therapist to measure swelling (ICC=0.97).
4. The reliability of the therapist to measure ROM (plantar flexion ICC=0.88, dorsiflexion ICC=0.92).
5. The lack of matching for age, sex, activity level and severity of injury.

DELIMITATIONS:

This study was delimited by:

1. The testing of subjects with acute extracapsular, second degree lateral ankle sprains.
2. The consistent application of acupuncture, ice and compression.

CHAPTER 2
LITERATURE REVIEW

The literature has been reviewed in five sections: 1) The epidemiology, anatomy and biomechanics of the ankle, 2) The treatment of ankle sprains, 3) The physiological basis of ice and compression, 4) The physiological basis of acupuncture and acupuncture research, 5) Methodological problems associated with acupuncture research.

1. EPIDEMIOLOGY, ANATOMY AND BIOMECHANICS OF THE ANKLE:

A. Epidemiology: Ankle sprains are the most frequently occurring injury in athletic participation (2,3,7,13,15,23,51,63,68) and account for about 35-50% of all sports related injuries that occur (23). A lateral ligament sprain accounts for approximately 85-90% of these injuries (2,13,49). Most of these injuries occur, in order of descending frequency, in basketball, soccer, volleyball, football and falls from heights (2,7,49,63).

B. Functional Anatomy and Biomechanics: The ankle is a hinge joint with dorsiflexion and plantar flexion being the major movements that occur and inversion and eversion occurring at the subtalar joint (7,49,68). There are three major lateral ligaments of the ankle: the ATFL, the CFL and the PTFL (2,5,42). These ligaments serve as stabilizers of the ankle, guide and direct motion, and aid in proprioception. Of the three lateral ligaments, the ATFL is

the most commonly injured (2,7,49). In the weight - bearing position, the ankle assumes its stability from the bony structures (49).

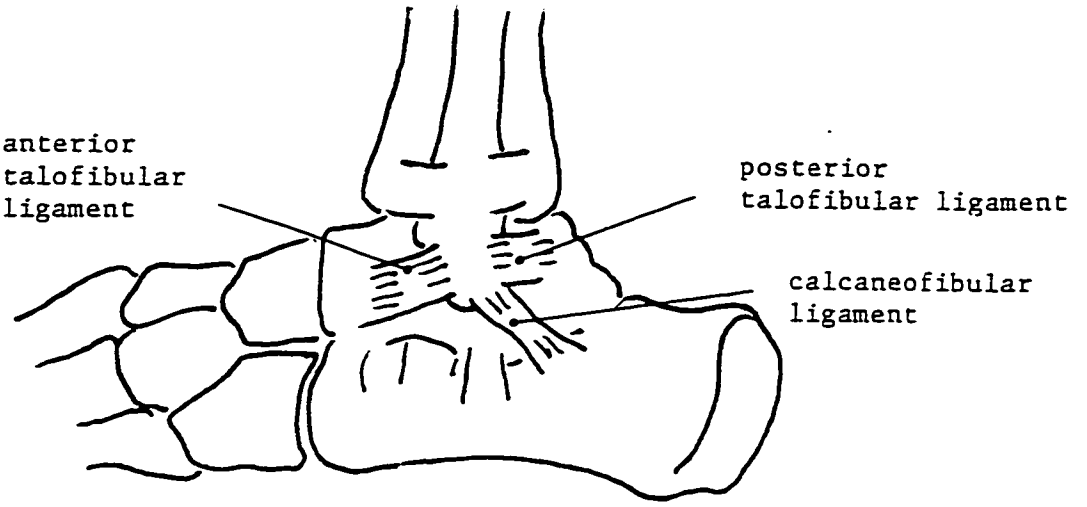

Figure 2-1: Anatomy of the lateral ligament complex

Strain measurements show that the ATFL is the most important ligament in lateral ankle stability (12). The ATFL is considered the key ligament to stability and rupture of this ligament requires the best treatment possible to restore function (49). Due to the bony anatomy, the ankle is most stable in dorsiflexion and less stable in plantar flexion. In the plantar flexed position, the ATFL is taut and most vulnerable in this position. The ATFL is the most anterior structure and is intracapsular and intra-articular (29). It runs from the anterior tip of the fibula to the neck of the talus. The ATFL is the first ligament to be torn in any inversion injury and if ruputured can also tear the joint capsule (7,49). Other studies have also shown that the ATFL and the CFL function together to provide lateral ankle stability in all positions of the ankle (12). It has been shown under biomechanical testing that the ATFL has the weakest tensile strength of the lateral ligament complex (7,12). The CFL is extra-articular and runs from the tip of the fibula to the tubercle of the calcaneus. Under biomechanical testing, this ligament has a higher yield

force and ultimate load than the ATFL. It is also the most elastic of the three ligaments (12,55). The PTFL runs from the lateral border of the lateral malleolus to the lateral tubercle of the talus and is the strongest ligament of the three (2). It has been shown that the ATFL has increased strain placed on it in plantar flexion, inversion and internal rotation of the foot and ankle. The CFL is strained most commonly in dorsiflexion and inversion while the PTFL receives greatest stress in dorsiflexion, the most stable ankle position. Consequently the ATFL is usually the first ligament injured in a plantar flexion/inversion sprain whereas the CFL is usually torn in the position of dorsiflexion and inversion (12). Operative repair of these acute ligament injuries has demonstrated that the ATFL is always torn and the CFL is often torn in association with the ATFL if the inversion trauma is more severe (7,63). Kannus et al (23) report that approximately two-thirds of the sprains of the ankle are isolated ATFL sprains. Isolated CFL tears are rare and the PTFL is usually torn in association with ankle dislocations (23).

This research project focused on acute second degree sprains of the ankle which involves stretching and macroscopic tearing of the ATFL. In accordance with the literature, the CFL may or may not be involved (23).

C. Mechanism of injury and the healing process: A lateral ligamentous injury usually occurs when the body weight lands on a plantar flexed and internally rotated foot (2,3). When ligaments tear, there is immediate localized pain which is due to stimulation of the pain fibers within the ligament, and bleeding due to tearing of the vessels in and around the ligament. In this first or acute phase, platelets in the area promote clotting and a fibrin clot is established. At the same time, vasoactive amines are released

from the damaged cells and promote the inflammatory process. Local blood vessels dilate and acute inflammatory cells (leukocytes) infiltrate and fibroblastic scar cells begin to appear. This acute inflammatory phase starts immediately and can last from hours to days. The hematoma and edema that occur in this period lengthen the recovery time (59).

The second phase starts from forty eight to seventy two hours post injury and lasts to approximately six weeks. In this phase, the tissue repair occurs through three processes. These are: (1) resolution - where normal restoration of tissue occurs; (2) formation of granulation tissue; and (3) regeneration of the same tissue or replacement tissue (production of scar matrix).

The third phase initiation is varied occurring at three to six weeks and can last from three months to one year. The matrix remodeling occurs with improvement in scar quality over this time (3,72). Therefore, the goal of treatment in the acute (first) stage is to decrease the magnitude of the inflammatory response by choosing the best method of treatment. This research project compares three types of treatment for the acute phase to determine which method of treatment is most effective.

2. TREATMENT OF ANKLE SPRAINS:

There is consensus in the literature that "functional treatment" is the treatment of choice and has been shown to return the patient to normal activity quicker than surgical repair (23,63). Functional treatment consists of early controlled movement (63) and early control of the inflammatory process. In the early inflammatory phase, the PRICE protocol has been used

as the treatment of choice. PRICE stands for protection, relative rest, ice, compression and elevation. The use of ice and compression is widely accepted as a means of pain and edema control which has been shown to facilitate early weight bearing (53,69) and earlier complete recovery (32,53,59,69). Early application of ice to an acute ankle sprain controls the hemorrhage and edema and allows for an earlier return to basic activities without pain (21). Physiologically, ice produces vasoconstriction which decreases over all blood flow which, in turn, limits the amount of edema (20,32). Cold decreases tissue metabolism and the chemical action of the cells thereby decreasing oxygen needs. This decrease in pain allows for earlier weight-bearing and an overall decrease in recovery time (69).

It has also been stated in the literature that early functional utilization and early movement, may enhance both the rate and quality of ligament healing (9,21,69,72). Movement increases the strength of the ligament if performed within the available range and without pain (9). Protected motion facilitates proper collagen reorientation which increases the strength of the healing ligaments (44). Active movement is beneficial because it prevents muscle atrophy, and stresses the tissues appropriately, allowing fewer adhesions (1,21).

It has also been stated that the recovery rate for ankle function following an inversion sprain may be related to the effectiveness of edema control at the site (69). Scotece and Guthrie (53) compared three types of treatment approaches for Grade I and II ankle sprains. They compared one single ankle strapping, application of a gel cast and daily strapping each for three days. They found that daily strapping was the most effective form of treatment for acute ankle sprains in reducing days lost from work. Wilkerson (69) compared different modes of compression and cryotherapy and found

that focal compression appeared to be the most beneficial and that increasing the frequency and duration of cryotherapy did not increase the rate of recovery following inversion ankle injuries. Other authors advocate the use of ice and daily taping with progressive weight -bearing to tolerance (13). These authors also discussed the possible use of cast immobilization and concluded that daily ice and taping was preferable because the patient could return to full activity more rapidly, there was less muscle atrophy, and daily ROM exercises could be performed. Trevino et al (63) stated that conservative treatment should always be attempted and that surgical reconstruction was recommended only in chronic instability. Trevino also supported the use of functional treatment and stressed the importance of early control of the inflammatory process using the PRICE protocol.

Hocutt et al (21) advocated the use of cryotherapy and compression for treatment of acute ankle sprains and found that early use of cryotherapy (within the first 36 hours), was significantly more effective than late cryotherapy (after 36 hours) or heat. Patients with severe sprains who were treated early, returned to activity on the average 13.2 days compared to 30.49 (late cryotherapy) and 33.13 (heat). Paris, Baynes and Gucker (41) evaluated the effects of adding a neuroprobe (low frequency point stimulator) to basic physiotherapy treatment on second degree ankle sprains. They evaluated ROM, edema and pain. Their results showed that the patients who received the neuroprobe treatment were discharged on average 3 days sooner. The results showed a significant difference for the release day of patients treated conservatively and those treated with the neuroprobe suggesting that use of a neuroprobe could shorten treatment time. A research study done in 1992 (22), studied the effects of ice and compression and elevation compared to ice and compression, elevation and acupuncture TENS. Fourteen subjects were

treated with seven subjects in each group. This studied treated both groups until they rated their ankle as comparable in painfree activity to the opposite ankle. This study showed a significant difference ($p<0.05$) in return to activity for the acupuncture TENS group. The acupuncture TENS group returned to activity 1.8 days earlier than the ice and compression and elevation group. In 1991, a study evaluated the effects of intermittent compression on edema in postacute ankle sprains (45). The authors used elevation as the control group and intermittent compression and an elastic wrap as the treatment groups. They demonstrated that elevation alone without compression, reduced edema in acute ankle sprains and was superior to compression. They felt that elevation was the the most appropriate treatment to use in reducing edema.

3. PHYSIOLOGICAL BASIS OF ICE AND COMPRESSION:

It has been shown that ice and compression decrease the amount of swelling, and pain (20,63). The mechanisms involved with the application of ice are as follows: cold causes a vasoconstriction which produces a decrease in blood flow, blocking of the release of histamine (which is responsible for vasodilatation and exudate formation) (40), a decrease in the inflammatory response, a decrease in local edema (by decreased flow through damaged vessels) and a decrease in hemorrhage due to this local decrease in blood flow (20,21,33,59). The application of ice also causes a decrease in tissue temperature which decreases metabolism and the chemical actions occurring in the cells which in turn causes a decrease in the oxygen and nutrient needs in the affected area (20,21). The decreased blood flow leads to less edema; less histamine is released from the damaged cells and there is less capillary

breakdown. There is also better lymphatic drainage because of lower pressure on the extra-vascular fluid (21). There is less triggering of sensory nerve endings due to the decrease in metabolism and released chemical irritants, and vasoconstriction. Ice decreases the excitability of free nerve endings and peripheral nerve fibers by increasing the pain threshold. Ice decreases the frequency and velocity (intensity) of nerve conduction resulting in some degree of analgesia.

4. THE PHYSIOLOGICAL BASIS OF ACUPUNCTURE AND ACUPUNCTURE RESEARCH:

A: Physiological Basis: Extensive scientific research on the mechanism of acupuncture analgesia has been done throughout the world with China being a leader in this area (60). A review of the literature indicates that acupuncture does have an analgesic effect and relates this effect to the action of the neurotransmitters at different levels of the nervous system (26, 36,48). Basic scientific research has revealed certain neurophysiological reactions to acupuncture such as an increase in beta-endorphins and increase in 5-hydroxytryptophan levels in the cerebrum, which partly explain the analgesic effect of acupuncture (17,36,31). Acupuncture has also been shown to have an anti-inflammatory action via cortisol, 17-hydroxycortisone, ACTH secretions and the vascular effects of both vasoconstriction and vasodilatation (36,31). Rapson (48) also indicates that cortisol is released on an equimolar basis with endorphins when acupuncture is used.

It is important to understand the effects of endorphins in order to understand the effects of acupuncture. Rapson (48) outlines the effects of

endorphins such as analgesia and anti-inflammatory. Corticosterone is synthesized and along with ACTH is secreted from the pituitary suggesting that both an analgesic and anti-inflammatory effect occur with acupuncture (11,27). Pomerantz and Stux (60) demonstrated that naloxone (an endorphin antagonist) completely blocked acupuncture analgesia and that sham acupuncture was not affected by naloxone. Electrophysiological evidence has shown that acupuncture stimulates the muscle afferent fibers (Types II and III) and produces the De Qi sensation which sends messages to the brain to release neurochemicals at different levels of the spinal system (43,48,60).

The levels of the spinal system that are stimulated are based on Cheng's hypothesis of the analgesic effect of acupuncture (1,43,48,60). At low frequency (4Hz), which is believed to be the frequency of manual needle stimulation (personal communication Dr. J. Wong), the following events occur: sensory receptors are stimulated and a message is sent via high-threshold sensory nerves (type II and II) to the spinal cord. These nerves connect onto an anterolateral tract (ALT) cell, which projects to three levels of the nervous system: the spinal cord, midbrain and pituitary (43). There is a segmental release of endorphins from the spinal cord interneurons which prevents transmission of pain messages from the spinal cord and produces analgesia. Secondly, the ALT cell projects to the midbrain via the ALT which stimulates the periaqueductal gray. Enkephalins are released and indirectly stimulate the raphe nucleus and/or the reticular magnocellular nucleus. This sends descending inhibition via the dorsolateral tract to release serotonin and norepinephrine to the spinal cord pain cells. Thirdly, acupuncture stimulation reaches the pituitary-hypothalmic region via the ALT. Here, the midbrain is activiated and the pituitary releases β-endorphins. The exact mechanisms involved are unclear. However, as

pituitary β-endorphins are released there is a coreleate release of ACTH. ACTH travels to the adrenal cortex and stimulates the release of cortisol.

B. Clinical Acupuncture Research: An extensive review of the literature indicates that there are no studies done on the effects of acupuncture and acute second degree ankle sprains. A review article in 1986 indicated that the effects of acupuncture on acute pain and chronic pain show a clinically significant short-term pain relief of 50-70% and that this effect was more than could be explained by placebo alone where the percentage improvement was usually 30-35% (21). The literature shows that placebo was 30-35%, sham 50% and real acupuncture 65-75% effective in relieving chronic pain (50,65). However a review of the literature demonstrated that there was a lack of good controlled studies with most acupuncture studies being descriptive (5).

Marcus and Gracer (31) treated 16 patients diagnosed with shoulder pain using a combination of Cyriax based diagnosis followed by acupuncture. They found this combination to be superior to the use of traditional Oriental acupuncture alone with minimal assessment. They felt that the Cryiax diagnosis was more accurate and therefore more appropriate acupuncture points could be chosen. Other research studies imply that the Anatomical or Western approach to acupuncture has not been satisfactory in the evaluation of the true results of acupuncture (18). Molsberger and Hille (36) demonstrated that non-segmental acupuncture treatment was more effective than sham acupuncture in the treatment of chronic tennis elbow pain. This study used reliable outcome measures, calculated the sample size and used a non-invasive acupuncture placebo. As the literature has shown that puncturing of the skin raises beta - endorphin levels they wanted to eliminate this effect to truly evaluate the effects of real acupuncture (36). Brattberg (8)

administered acupuncture to subjects with persistent lateral epicondylitis who had previous steroid injections with unsatisfactory results. He found that acupuncture was significantly better than steroid therapy in producing painfree results. Takeda and Wessel (61) used acupuncture to treat 40 patients with osteoarthritis of the knee. In this study, they compared sham acupuncture to real acupuncture and found no difference between the two groups. Sham acupuncture consisted of needling non-acupuncture points. Gaw et al (17) treated 40 patients with chronic pain from osteoarthritis and administered sham acupuncture and real acupuncture to these patients. Gaw found a significant improvement in tenderness and pain in both groups. He discussed several possibilities for this effect. He felt needling of non acupuncture points could still produce an effect greater than that of placebo alone, and the advice given to rest and use heat by some of the physicians to some subjects whereas other subjects may not have received the same advice. A study published in 1994 showed a statistically significant result on the effectiveness of acupuncture in relieving phantom limb pain, lending support to the analgesic effect of acupuncture (28). These authors also concluded that acupuncture was effective in shortening the total suffering period of those with phantom limb pain.

Sin (57) used electro-acupuncture on rats who were injected with carrageenan, which is a commonly used inflammatory irritant. They found that there was a significant reduction in leukocyte accumulation and a decrease in the inflammatory lesions. The study, using a control and three experimental groups, concluded that acupuncture could affect the fundamental mechanisms involved in the inflammatory response. Planas (42) demonstrated the involvement of the endogenous opioid system in the response to local inflammation induced in the paw of a rat. Planas felt that

because acupuncture caused a release of endogenous opioids, it might have a role in inflammation. Min (35) demonstrated on rats that acupuncture increased the phagocytic activity of the reticulo-endothelial system and could play a role in decreasing inflammation and affecting the immune system. The reticulo-endothelial system is a system in the body that is a combination of monocytes, macrophages, bone marrow, spleen and lymph nodes (19).

5. METHODOLOGICAL PROBLEMS ASSOCIATED WITH ACUPUNCTURE RESEARCH:

Clinical research into the effects of acupuncture shows that there are problems that are unique to acupuncture research which make it difficult to provide scientific evidence that indicates that acupuncture is effective in treating acute and chronic conditions.

Problems associated with acupuncture research are as follows: designing appropriate protocols, type of placebo treatment, type of study (randomized control) and using Traditional Chinese Medicine (TCM) diagnosis and treatment versus Western diagnosis and the Anatomical approach to acupuncture. There has also been considerable debate regarding the approach to use, the method of needle stimulation (manual versus electrical), and the point selection. A review article (5) offered recommendations for trials using acupuncture. Lewith (5) stressed that trials that produce non-significant results should not automatically conclude that acupuncture is ineffective. He recommended that specific outcome criteria to determine the success or failure of the treatment, defined objectives, specific description of methodology i.e.: points stimulated be named and the same

for each subject, type and length of stimulation, randomization, proper control groups and single blind trials be used. Acupuncture research is difficult because it involves the application of a scientific method to a system of medicine that traditionally has not been scientifically based (65).

CHAPTER 3
MATERIALS AND METHODS

SUBJECTS:

Subjects were recruited from the emergency department of the Misercordia hospital, Callingwood Physiotherapy Clinic and the Edmonton Soccer Center using verbal contact and followed by a letter and information package (see Appendix A and B). The physician, therapist or coach who first assessed the subject informed the subject of this study and advised them to call Callingwood Physical Therapy Clinic to set up an appointment if he or she wished to participate. Once the subjects agreed to participate in the study and were examined to determine if they qualified, they were given the informed consent to read and sign. Parents of subjects who were under legal age (18 years) were also given a consent form to read and sign. Subjects were given a copy of the informed consent (Appendix C). Subjects who were not seen by a physician initially were referred to a physician who works in conjunction with Callingwood Physical Therapy, prior to participating in the study. This physician examined the subject and ordered x-rays. Subjects then booked an appointment at Callingwood Physiotherapy and were randomly allocated from a prepared list by the receptionist (see Appendix D). Subjects were randomly allocated one of three treatment groups:

1. acupuncture
2. ice and compression
3. acupuncture and ice and compression

Ten subjects were recruited to each of the 3 groups for a total of 30 subjects. (See Appendix E for calculation of sample size). Subjects were continually recruited until there was data collected on 30 subjects for a total of 10 per group.

Once the subject was allocated to the group, the first physiotherapist (the author), who was blind to group allocation, measured ROM, pain, swelling and function. A pilot study has shown this physiotherapist to be reliable for measuring ROM and function (see Appendix F and G).

The treatment was then given to all subjects by a second physiotherapist who was certified to practice acupuncture (see Appendix H) and worked at the sports clinic.

INCLUSION CRITERIA:

The subjects who participated in this study had a diagnosis of an acute second degree extracapsular lateral ankle sprain confirmed by the initial consulting medical personnel. The diagnosis was also confirmed by the physiotherapist administering the treatment. The criteria for diagnosis of an acute second degree ankle sprain was as follows: symptomatic complaints of pain on the lateral aspect of the ankle, immediate localized extracapsular swelling around the lateral malleolus, solid end feel to inversion stress at the ankle, anterior drawer sign with less than 5 mm of movement at the ankle and a solid endfeel, decreased ROM at the ankle, difficulty in weight-bearing and ambulation, and inability to rise on toes. X-ray examination was ordered by the physician. All subjects in the study were given x-rays to exclude fractures. Those subjects with fractures or suspected fractures were not included in the study.

EXCLUSION CRITERIA:

Subjects were excluded from this study if they suffered or had suffered from: fractures of the lower leg or ankle, osteoarthritis of the ankle, previous major ankle problems or more than two previous ankle sprains within the last six months. Subjects were excluded if they were pregnant, on anticoagulants, had a strong aversion to needles, had an inability to understand consent, had a major systemic disease(diabetes or neurological conditions), were hemophiliacs, and/or had a sensitivity to cold or had abnormal sensation.

STUDY DESIGN:

This study was a single blind, randomized controlled clinical trial using a non-probability, convenience sample. The subjects were recruited as stated in the sampling section. When the subjects agreed to participate in the study, they were allocated as specified in the sampling section. The outcome measures were administered by the first physiotherapist (the author), who was blind to the group assignment of the subjects. Measures of pain, swelling, ROM and function were taken by the first physiotherapist before each treatment session. After the outcome measures were taken and recorded, the second physiotherapist administered all the treatments for all the subjects.

The independent variables identified in this study were treatment and time. The treatment groups consisted of acupuncture, ice and compression and a combination of acupuncture, ice and compression. These variables were measured at the nominal level. The dependent variables that were measured were: pain, swelling, ROM, and function. The VAS has been reported in the literature to be used as a ratio scale even though it is an

ordinal scale (45). The figure of eight method for determining swelling, ROM and function are all ratio scales.

Internal validity is the degree to which the relationship between the independent and dependent variables is free from the effects of extraneous variables. In this research project, the inclusion criteria were very strict so that any difference between groups would be due to treatment and therefore eliminating as many intervening variables as possible. This action gave the study good internal validity. Some intervening variables over which there was no control, could have occurred in this study and will be discussed here. It has been mentioned in the literature (1,60) that some people may be naturally low in opiate receptors and may not respond to acupuncture treatment. Some of the subjects may use medication such as anti-inflammatories, that may affect swelling and some subjects may use ice at home while others may not. Some subjects may want one of the treatments to work (ie: acupuncture), and gender may have an influence on the effect of treatment. One study suggested that men responded better to the effects of acupuncture and pain than women (61). The literature also shows that those people who do not experience the De Qi sensation do not respond as well as those who do (43,61). History will not affect internal validity in this particular study due to the short time frame for data collection (five days). People who sprain their ankles do eventually become better but clinical observation and experience shows that on average, without treatment, patients can still be on crutches or ambulating with pain fourteen to twenty days post-injury. Because of the strict inclusion criteria, the degree to which the results of the study could be generalized to other acutely sprained ankles and other joints could be limited by the characteristics of the sample and could be a threat to external validity.

INTERVENTION:

The subjects were booked at their convenience and treated at Callingwood Physiotherapy and Sports Injury Clinic. The treatment was administered by a physiotherapist who is certified to practice acupuncture and was blind to the measures taken by the first physiotherapist (see Appendix H for certificate). All subjects, regardless of the group to which they were allocated, had their ankle elevated on a wedge that had a 30 degree incline. All subjects were allowed weight-bearing to tolerance and a treatment protocol was established prior to the study (see Appendix I) so that all subjects received the same instructions and active exercise program for the first five treatments. All subjects had a three inch tensor applied post-treatment and were instructed to wear this tensor for the five days of treatment except for sleeping. All subjects were advised to purchase an ankle brace to wear for the next three to six months in order to protect the ligament while healing. All subjects purchased an Active Ankle brace. This brace was chosen from clinical experience, recommendation in the literature and from previous courses (16, 58,67). Ankle bracing post injury is strongly recommended in the literature for the first three to six months following an ankle sprain (16,67).

Ice and compression were administered in the following manner: the subjects sensation between hot and cold was tested using test tubes filled with hot and cold water. If their sensation was normal to hot and cold differentiation, crushed ice was placed in a wet towel and was secured around the lateral aspect of the ankle and held in place by a four inch tensor bandage. As fifteen to twenty minutes is the recommended time for ice

application in the literature (14,15,22,31), the ice pack was left on for 15 minutes at which time it was removed.

Acupuncture treatment was administered as follows: The proper needling point was identified and marked with a hollow tube from a previously disposed needle. The area was swabbed with alcohol and the needle was inserted with manual stimulation for 2 minutes or until the patient felt the De Qi sensation. The needle was left in place for 20 minutes after which the needle was withdrawn and disposed of in a proper sharps container. The points stimulated were as follows: UB 60, K3, GB34, Liv3, Sp6, Sp8, St41, and GB40 (see Appendix K). In a review of the literature, there is no scientific evidence to verify that these were the optimal points to use for the treatment of an acutely sprained ankle. These points were recommended from clinical experience and by the Acupuncture Foundation of Canada for the treatment of acute lateral ankle sprains (1). These points are a combination of Traditional Chinese Medicine points and Anatomical points.

The acupuncture was administered in the following order for all acupuncture patients: On the first visit, the subjects received acupuncture to GB34, K3, UB60, and Liv3. The next visit, they received acupuncture to St41, GB40, Sp6, and Sp8. The acupuncture was alternated in this manner to avoid any soreness that could arise from needling consecutive points daily. Because the subjects were treated for five days consecutively and the points were alternated, GB34, Liv3, UB60 and K3 were done on time 1, 3,and 5 and St41, GB40, Sp6 and Sp 8 were done on time 2 and 4.

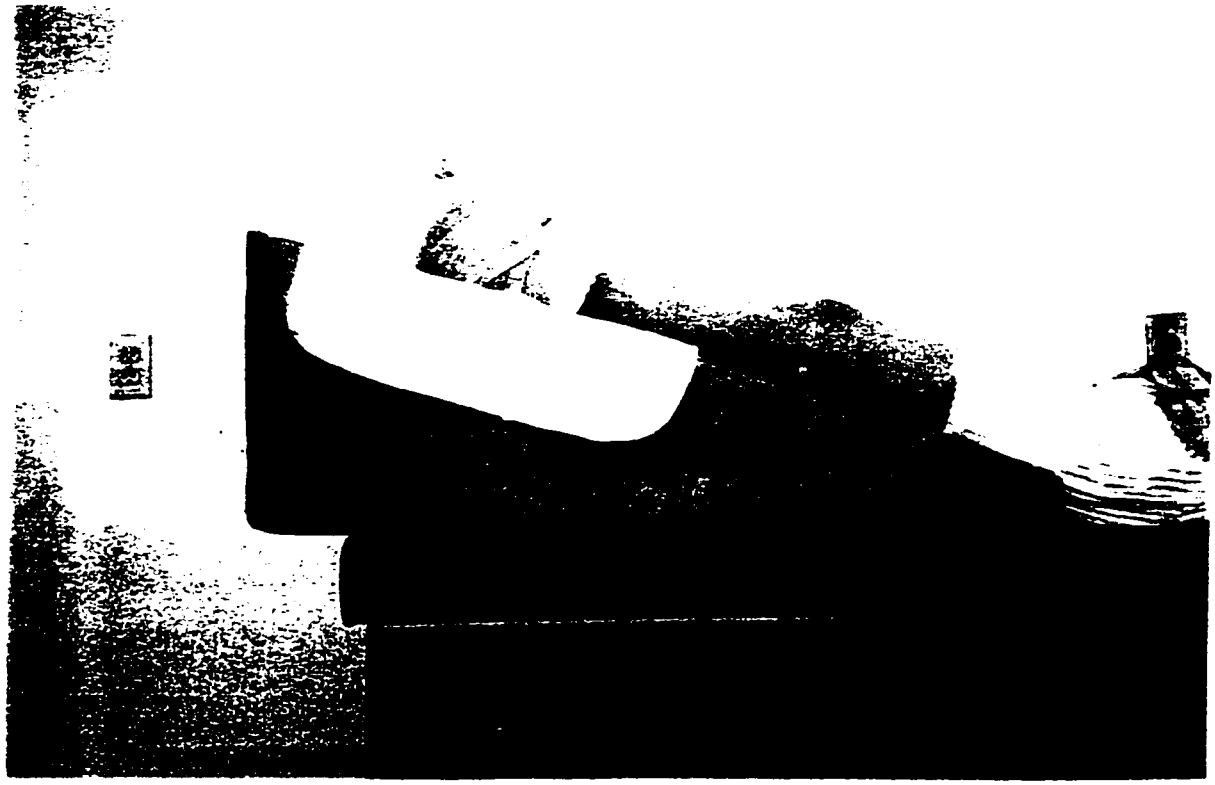

Figure 3-2: Application of ice and compression with elevation to 30 degrees

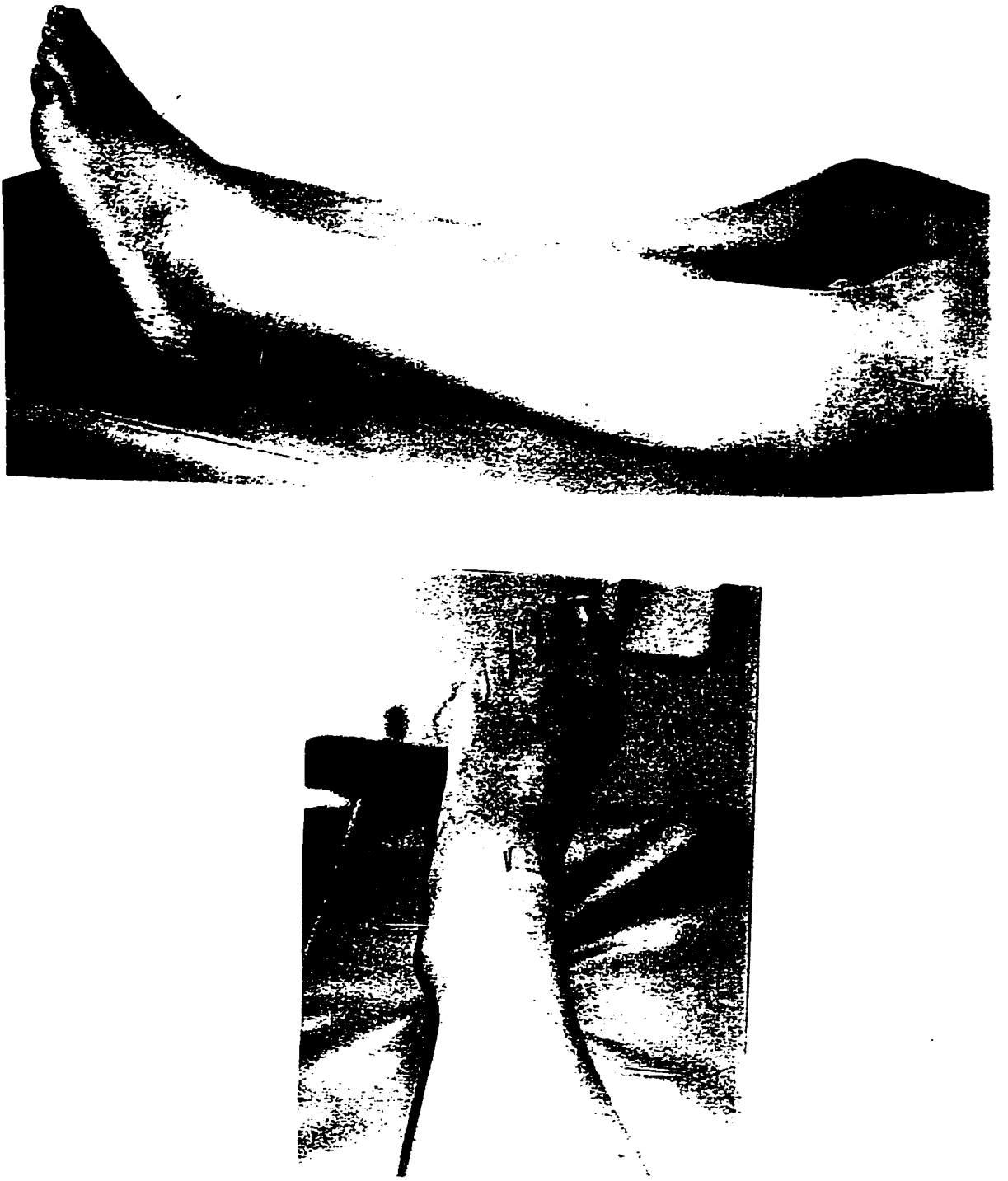

Figure 3-3: Acupuncture treatment with the foot and leg elevated to 30 degrees. The following points are shown: GB34, UB60, Liv3, Sp6 and St41

The third group received acupuncture first, which was administered in the same manner as to the acupuncture group. Acupuncture was followed by the ice and compression, which was administered as described previously. Acupuncture was administered first as it has been shown that pain caused by a pin prick was decreased after ice application (14). There has not been any research in the literature with respect to acupuncture application before or after ice. The subjects in all groups were treated in supine on a treatment table. All subjects were asked to refrain from the use of alcohol and caffeine two hours prior to and after treatment, as it has been found that alcohol and caffeine decrease an individuals response to acupuncture (1).

ETHICAL CONSIDERATIONS:

Acupuncture is a modality that has proven to be relatively risk free. The chance of infection is extremely rare due to the aseptic sterile technique that is used. Occasionally, minor bruising can occur and has been reported to be of no major consequence (48). Acupuncture is used by physical therapists and physicians for treatment of pain in a variety of musculoskeletal conditions. The application of ice is safe, simple and inexpensive with relatively few side effects (65). Ice can cause burns or frostbite to the skin if applied to areas that are insensitive to temperature change, if the ice is left on too long, if the ice is encased in plastic, or if the subject is not given adequate instructions regarding what he/she should feel with each application of ice. None of the concerns were a problem in this study as each subject was given a hot - cold differentiation check, he/she was instructed in what should be felt with each ice application and a standard method of ice application was used. Care was taken to ensure that the compression bandage was not be

applied too tightly or unevenly and at the eight minute interval (which was arbitrarily chosen from clinical experience) the ice was partially unwrapped and the skin was checked. The ice was then rewrapped for the remaining seven minutes .

The subjects were told that three different treatments were being compared in the treatment of acute second degree ankle sprains and they were offered continuance of their therapy until they could ambulate normally without pain and had returned to their normal activities following collection of the data for the study.

Subjects were also told they could withdraw from the study at any time without prejudice. All subjects who agreed to participate in the study completed the study with no complications. All subjects were treated beyond the study period until they were fully rehabilitated at no cost to the subjects.

DATA COLLECTION:

1. Pain measurement: All subjects were asked to mark a Visual Analog Scale (VAS) prior to each treatment to define their subjective experience of pain. The subject was asked to make a mark that described the intensity of their pain within the last 24 hours. The VAS is a 10 cm. horizontal line, the ends of which define the minimum and maximum extremes of pain. A mark on the line was made by the patient to indicate the intensity of the pain and the length of the line from the beginning to the mark is used as a numerical value for future statistical analysis. The VAS has been shown to be a sensitive and valid measure for measuring pain and changes to pain with respect to treatment (39,54). (See Appendix J). Pain was measured prior to

treatment to see if there was a change in pain from one treatment time to the next.

2. Swelling: Swelling was measured before each treatment session using the figure of eight method of ankle measurement. This method of ankle measurement for swelling has been shown to be reliable (ICC 0.99) and has been used in other research studies (53, 62). This method of measurement is reproduced by using bony landmarks about the ankle. A one-quarter inch retractable, cloth measuring tape was used.

The tape was applied in the following manner: The subject was seated in a supine position with the foot extended beyond the edge of the treatment table and the knee was flexed to approximately 30 degrees using towels rolled under the knee. With the leg in this position, the ankle assumed the normal resting or neutral position. The tape was first placed midway between the tibialis anterior tendon and the lateral malleolus and was drawn medially across the instep and placed distal to the navicular tuberosity. The tape was pulled across the arch and proximal to the base of the fifth metatarsal. The tape was pulled across the tibialis anterior tendon and around the ankle joint distal to the tip of the medial malleolus. The tape is then pulled across the achilles tendon and distal to the tip of the lateral malleolus. The tape ended where it started (62). In a pilot study, the measuring therapist's intra-rater reliability was ICC = 0.97 and the SEM = 0.57 cm. (See Appendix G).

3. ROM measurement: ROM was measured using standard bony landmarks (2) and an universal goniometer before each treatment session. Both dorsiflexion and plantar flexion were measured and the two added together to determine the full ROM. The patient was supine with two towels

rolled under the knee so that it flexed to 30 degrees rendering the foot in a neutral position. The axis of the goniometer was placed 1.5 cm inferior to the lateral malleolus and the stationary arm was placed parallel to the longitudinal axis of the fibula. The moveable arm was parallel to the longitudinal axis of the fifth metatarsal. In a pilot study, the measuring therapist's reliability for dorsiflexion was ICC=0.917 and the SEM=1 degree and for plantar flexion ICC = 0.880 and the SEM = 3.04 degrees (See Appendix G).

Figure 3-4: Figure of eight method for measuring ankle swelling

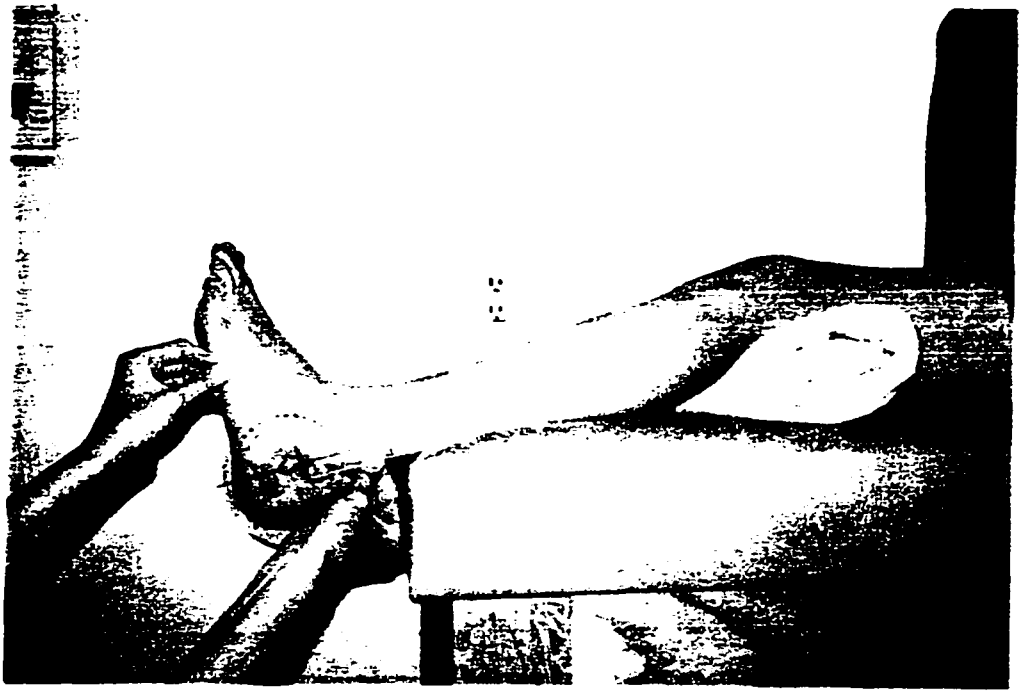

Figure 3-5: ROM measurement for the ankle using a goniometer

4. Functional tests: Different functional tests have been reported in the literature (31,64,66) with different criteria for measurement ranging from the amount of time between injury and return to work to a 50 point scoring system (53). Recovery of function following acute ankle sprains has been defined subjectively in the literature (69). It has also been suggested that function can be assessed by using activities that assess knee function and subsequently lower limb function (72).

In this study, function was assessed by the number of days to painfree full weight-bearing, the timed hop test, and the single hop test. In the literature, treatment effectiveness has been evaluated by the time (in days) that it takes to return to full activity or the number of days until full painfree weight bearing is achieved (21,59,66). Because this research project was interested in evaluating the effects of three different treatments in the acute

phase, the number of days until painfree full weight-bearing was considered the most important criteria for assessing a change in function and a successful treatment.

Full return to activity may be dependent on pain, swelling, subjects previous experience with injuries, desire to return to activity or work, and ROM as well as other factors such as strengthening and proprioceptive exercises. The two hop tests were evaluated to determine if the initial early treatment made a difference with respect to returning to activity or work. After the five inital treatments that the subjects received, they were individually rehabilitated until discharge. The criteria for discharge was as follows: full pain free ROM, muscle strength of at least a grade of 4+, minimal swelling and tenderness around the lateral malleolus, and a return to normal activity at the same level or a slightly modified level. At the time of discharge, the subject performed the two hop tests. The average number of days until discharge from the time of injury was approximately 12.5 days (range from 10-14 days) for most of the subjects.

The timed hop test involved measuring the time required to cover a 6-meter distance in seconds and compared this to the uninjured leg. The single hop test involved measuring the distance hopped in a single hop. Both these tests used a percentage of the injured leg compared to the uninjured leg as the recorded value (44). These two tests have been shown to have a high specificity and low false positive rates when used to determine alterations in lower limb functions in ACL deficient knees (38). No validity or reliability testing of the hop tests has been done for the ankle. These two tests can be performed in a clinical setting, require minimal time, equipment and use the other extremity as a control.

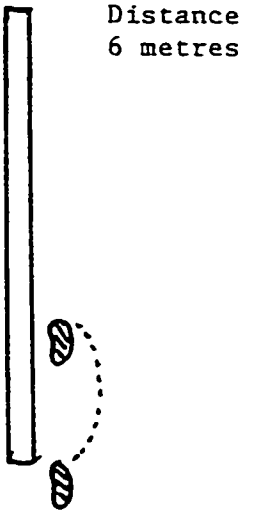

Figure 3-6: Hop test

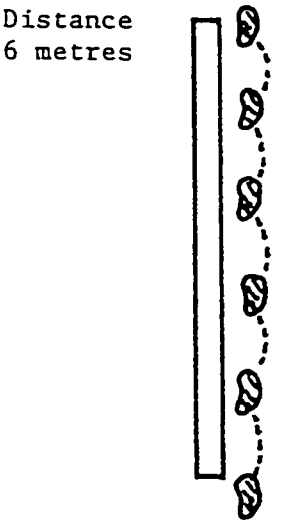

Figure 3-7: Timed Hop test

STATISTICAL ANALYSIS:

This study was a five by three (5 X 3) factorial design. The independent variables were time and treatment. Treatment had three levels. The three levels were: the acupuncture treatment groupd, the ice and compression treatment group, and the acupuncture, ice and compression treatment group. Time was measured for five sessions at the nominal level.

The dependent variables were the measures for pain, swelling, ROM and function (measured by the number of days until full painfree weight bearing). They were measured using the VAS (pain), figure of eight method for ankle swelling, a goniometer (ROM) and function (the number of days until full pain free weight bearing). This study was concerned with treatment in the acute phase and was most interested in the first five days of treatment, therefore function was analyzed using the number of days until full painfree weight bearing. After the initial five treatments of the study, the subjects were treated according to their different objective findings, symptoms and activity requirements. The timed hop test and the hop test (hop test 1 and hop test 2 respectively), were done at the end of the rehabilitation period and were therefore analyzed separately to determine if the initial treatment had any bearing on function when returning to activity. There are four dependent measures, each measured five times (time 1-time 5) for analysis in the acute phase. There are two dependent measures, each measured once, at the completion of the subjects rehabilitation.

Appropriate descriptive and inferential statistics were used to determine the amount of pain relief and improvement in swelling, function and ROM. Descriptive statistics were used to describe the mean or average amount of improvement in ROM and swelling, pain relief and number of days to full pain free weight bearing experienced by the subjects and the

standard deviation of each measure. Post hoc analysis were done to support the data. These tests included t-tests for dependent and independent samples, cross-tabulations and one-way Anovas.

Three, two-way Anovas with one independent factor (group), and one repeated measure or factor (time), were used to examine group and treatment effects on pain, swelling, and ROM. A p value of $p<0.01$ was chosen to reduce the chance of a type 1 error. When one is performing multiple analysis, some of the results could be significant by chance alone. The accepted p value of $p<0.05$ was divided by the four outcome measures. One, one-way Anova was done for the number of days until full pain free walking to determine if there was a difference between the three groups. Two, one-way ANOVAs were performed for hop test 1 and hop test 2 to determine if there was a difference between the groups.

Due to the various difficulties in recruiting subjects for this study, there was no matching done on the variables of gender, age or activity level. If matching would have been possible, the within subject variance would most likely have been less. Matching would have allowed the results to become more significant due to the reduced within subject variance.

CHAPTER 4

RESULTS

Acupuncture has been used for many years to treat chronic pain. There have been research studies done in China and around the world on the effects of acupuncture and chronic pain (6, 43). Recently, acupuncture has gained popularity as a treatment modality in the physiotherapy profession. A review of the literature has found that there have not been any studies to date that evaluate the effects of acupuncture on acute soft tissue injuries. It is possible that, through the neurophysiological mechanisms involved when acupuncture is applied, it may not only affect pain in acute injuries but also swelling, inflammation, healing and function.

The purpose of this study was to determine if a combination of acupuncture and ice and compression were more effective in decreasing pain and swelling and improving range of motion and function than acupuncture alone or ice and compression.

1. SUBJECT CHARACTERISTICS:

Subject recruitment took fourteen months. Subjects were recruited from February 1997 to April 1998. Thirty subjects were utilized in this study; ten in the acupuncture group (group 1), ten in the ice and compression group (group 2), and ten in the acupuncture, ice and compression group (group 3). T - tests for independent samples were done at time 1 for all groups on all outcome measures to see if there were any differences between the groups at the beginning of the study. At time 1, all groups were shown to be similar on all the outcome measures (pain, swelling, ROM and function) and there were no significant differences between groups. The demographics for all subjects are shown in Tables 4 -1 and 4 -2.

TABLE 4-1

SUBJECT DEMOGRAPHICS FOR AGE, SEX, AND ANKLE INJURED

GROUP	AGE		SEX	ANKLE INJURED
	Range	Mean	Female/Male	Right/Left
Group 1	11-44	25	6/4	5/5
Group 2	13-42	21.4	2/8	4/6
Group 3	12-44	28.7	2/8	4/6

Group 2 had an overall younger population than groups 1 and 3 and group 2 had only one subject over the age of 24. Group 3 had subjects who were older than the subjects in groups 1 or 2. Group 1 had a higher percentage of females than group 2 and 3.

TABLE 4-2

PERCENTAGE OF SUBJECTS IN EACH GROUP BY AGE(YRS)

AGE(yrs)	11-19	20-24	25-29	30-34	35-39	40+
GROUP 1(%)	30	30	10	10	10	10
GROUP 2(%)	40	50				10
GROUP 3(%)	20	20	10	20	10	20

The mean age for all subjects was higher in group 3. Ninety percent of the subjects were under 25 in group 2 and group 2 only had one subject over 25. Groups 1 and 3 had a more even distribution of subjects from 11 years of age to over 40. In reviewing the charts on all subjects, those in group 2 were not only younger but had clinically, less severe grade 2 sprains then those in

group 1 and the subjects in group 3 clinically had the "worse" grade 2 sprains. Also the subjects in group 2 were more athletic than the subjects in groups 1 and 3. Because group 2 had a younger population, were more athletic and experienced a less grade 2 ankle sprain, one would expect them to recover faster than subjects in groups 1 and 3. This did not happen, in fact subjects in group 3 did better on all measures except for the two hop tests.

Group 1 one had more females than males compared to groups 2 and 3 who had a similar distribution of two females to eight males. The literature has shown that males respond more positively than females to acupuncture treatment and pain(61). This may have been a factor affecting the outcome of the measures in this study. These combined effects of age, severity of injury and female/male ratio could have affected the outcome in this study.

2. DATA ANALYSIS FOR PAIN, SWELLING, ROM AND FUNCTION:

Descriptive statistics for the average amount of pain relief (VAS), decrease in swelling (figure of eight), improvement in range of motion (total range measured by an universal goniometer), and improvement in function (number of days until painfree weight bearing) were done. Three, one-way Anovas were performed to determine if there was a difference in function between groups. The number of days until full painfree weight bearing was the dependent variable analyzed in the first five days of the study and was considered the marker for function. In the literature (7, 41, 53), the number of days until full painfree weight bearing has been used as an evaluation of function. The hop test and the timed hop test were tested at the end of the study to see if there was a difference between the three groups. Post hoc

analysis included the t-tests for independent and dependent samples, one-way Anova at time 5 and cross-tabulations were performed to support the pattern found in the descriptive statistics. The results are presented in Tables 4 -3 to 4 -19 and Figures 4 - 8 to 4 - 13.

A. PAIN

TABLE 4-3

MEAN CHANGE IN PAIN (VAS) BETWEEN GROUPS FOR FIVE DAILY TREATMENTS

TREATMENT	1	2	3	4	5
GROUP 1	7.58	5.17	3.82	2.37	1.19
GROUP 2	6.20	3.87	2.50	1.63	1.19
GROUP 3	7.48	4.94	2.19	1.43	0.18

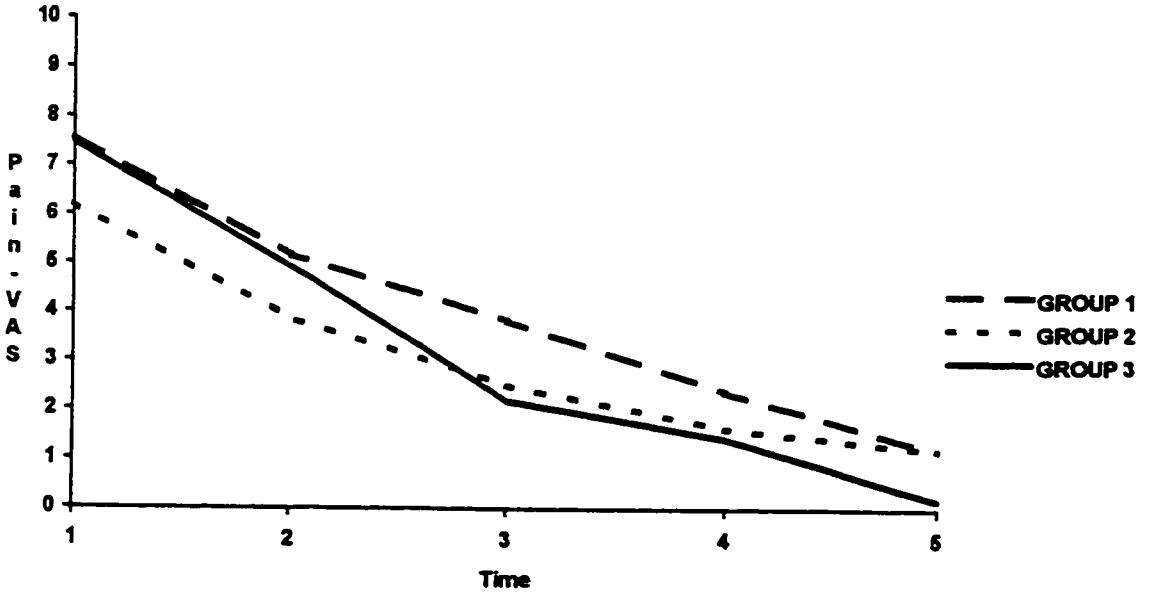

Figure 4-8 : Mean change in pain (VAS) for five daily treatments

At time 1, there were no statistically significant differences between groups. Group 2 changed the least from time 1 to time 5. All subjects in group 3 were painfree at time 5 whereas only half the subjects in groups 2 and 3 were painfree at time 5.

TABLE 4-4

PERCENTAGE OF SUBJECTS IN EACH GROUP- PAIN (VAS) MEASURED AT TIME 5

VAS	0	0.1-0.9	1.0-1.9	2.0-3.9	4.0+
GROUP 1 (%)		60	30		10
GROUP 2 (%)	10	40	20	30	
GROUP 3 (%)	20	80			

Cross-tabulations showed that 20% of the subjects in group 3 were painfree at time 5 and 80% rated their pain to be 0.1-0.9. Sixty percent of those subjects in the acupuncture group (group 2), rated their pain 0.1-0.9 at time 5 and 30% rated their pain at 1.0-1.9 at time 5. Among the subjects in group 2, only 10% were painfree at time 5 and 40% rated their pain from 0.1-0.9. Twenty percent of the subjects in group 2 rated their pain 1.0-1.9 at time 5 and 30% rated their pain 2.0-3.9 at time 5.

TABLE 4-5

T-TESTS FOR INDEPENDENT SAMPLES PAIN (VAS) AT TIME 5

Group	Mean Difference	DF	P - Value
1 & 3	1.01	18	**0.021**
2 & 3	1.01	18	**0.012**

TABLE 4-6
TWO-WAY ANOVA RESULTS FOR PAIN

Source	SS	df	MS	F	Sig
Group	25.63	2	12.81	1.01	0.38
Error	344.02	27	12.71		
Time	734.94	4	183.73	92.92	**0.00**
Error	213.56	108	1.98		
Grp x Time	22.53	4	2.82	1.42	0.195
Error	213.56	108	1.98		

T-tests for independent samples at time 5 for group 1 and group 3 were significant with a p-value of 0.021. The t-test for group 2 and group 3 was significant at 0.012. A one-way Anova at time 5 was significant at $p<0.05$. These consistent findings lend support to the research hypotheses.

The two way Anovas for pain demonstrated that all three groups improved significantly with treatment. Group 3, as expected, demonstrated the greatest change in pain with treatment. All subjects in group 3 were pain free at time 5 compared to 50% in group 2 and 60% in group 1. The greatest difference occurred between groups 2 and 3. The biggest decrease or change in pain occurred in group 3 between the first and last treatment. Subjects in group 3 experienced a continual drop in pain to zero at time 5. Subjects in group 2 started to plateau at time 4 and in reviewing the raw data, this group had smaller decreases in pain from time 1 to time 5. One way Anova at time 5 demonstrated statistical significance at $p<0.05$. T-tests for paired samples

indicated a much larger t-value (double) for groups 1 and 3 than group 2 indicating more change occurring over time for groups 1 and 3 than group 2. This consistent trend supports the research hypotheses.

B.) ROM

TABLE 4-7

MEAN CHANGE IN ROM BETWEEN GROUPS FOR FIVE DAILY TREATMENTS

TREATMENT	1	2	3	4	5
GROUP 1(degrees)	26.20	39.50	48.10	51.10	53.70
GROUP 2(degrees)	28.20	37.90	40.80	47.90	48.90
GROUP 3(degrees)	30.50	44.50	51.50	55.10	57.00

Subjects in group 3 had close to normal range of motion at time 5. Subjects in group 1 had close to normal range of motion at time 5. Subjects in group 2 demonstrated the least improvement in range of motion and at time 5 did not have normal range of motion.

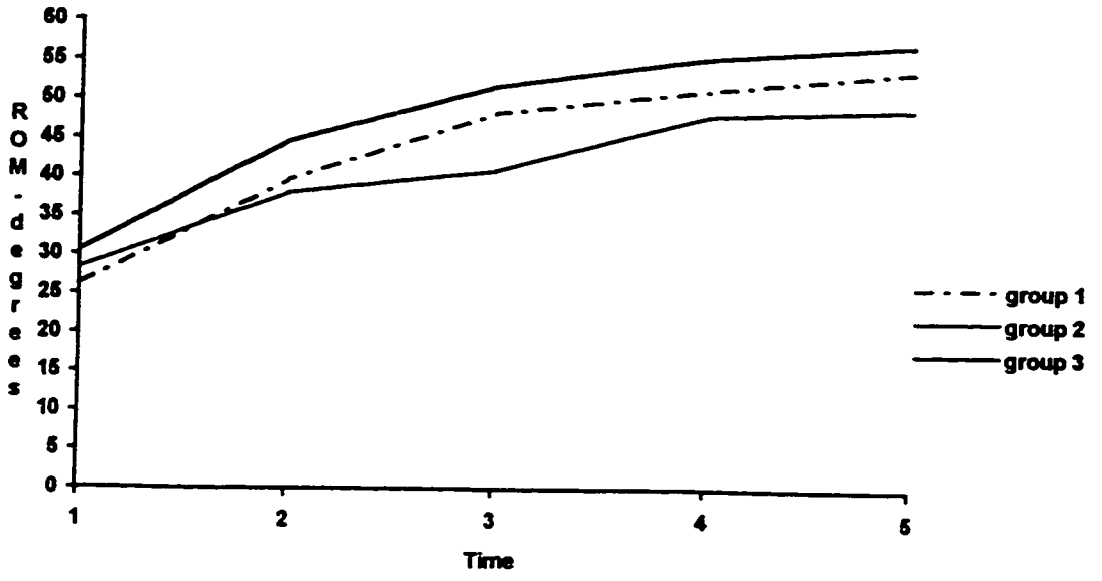

Figure 4-9: Mean change in ROM over five daily treatment times

TABLE 4-8

PERCENTAGE OF SUBJECTS IN EACH GROUP FOR ROM AT TIME 5

ROM(degrees)	30-39	40-49	50-59	60-70
GROUP 1 (%)		50	10	40
GROUP 2 (%)	20	20	50	10
GROUP 3 (%)			90	10

This table shows that all the subjects in group 3 had normal ROM at time 5. Fifty percent of the subjects in group 1 had normal range of motion at time 5 and fifty percent had ROM between 40 - 49 degrees. Sixty percent of the subjects in group 2 had normal ROM by time 5. Twenty percent of the subjects in group 2 had between 30 - 39 degrees of motion by time 5.

TABLE 4-9

T-TESTS FOR INDEPENDENT SAMPLES ROM AT TIME 5

Group	Mean Difference	DF	P-Value
1 & 3	3.3	18	0.366
2 & 3	8.1	18	**0.042**

TABLE 4-10

TWO WAY ANOVA RESULTS FOR ROM

Source	SS	df	MS	F	Sig
Group	1226.68	2	613.34	1.84	0.18
Error	8995.78	27	333.18		
Time	12136.18	4	3034.16	79.60	**0.00**
Error	4116.52	108	38.12		
Grp x Time	292.85	8	36.61	0.96	0.47
Error	4116.52	108	38.12		

Table 10 shows that all groups improved in ROM with time but there was more improvement in group 3.

All the subjects in group 3 demonstrated normal ROM values at time 5. Subjects in group 3 continued to progress from time 1 to time 5 as did subjects in group 1. Subjects in group 2 were the slowest to progress through all five times. The data demonstrates that at time 5, almost all of the subjects in group 3 had normal ROM and only 60% in group 2 and 50% in group 1. T-tests for paired samples demonstrated a larger t-value for group 3 compared to groups 1 and 2 indicating more change for that group. T-tests for independent samples demonstrated significant difference between groups 2

and 3 at $p<0.04$. This consistent trend in the data lends support to the research hypotheses.

C.) SWELLING

TABLE 4-11

MEAN CHANGE IN SWELLING (FIGURE OF EIGHT) BETWEEN GROUPS FOR FIVE DAILY TREATMENT TIMES

TREATMENT	1	2	3	4	5
GROUP 1	55.73	54.89	54.69	54.56	54.30
GROUP 2	55.97	55.28	54.98	54.46	54.33
GROUP 3	56.04	54.72	54.07	53.24	53.21

Measured in centimeters (cm)

All subjects had a reduction in swelling from time 1 to time 5. Subjects in group 3 had almost a 3 cm reduction in swelling with treatment, which was more than groups 1 and 2.

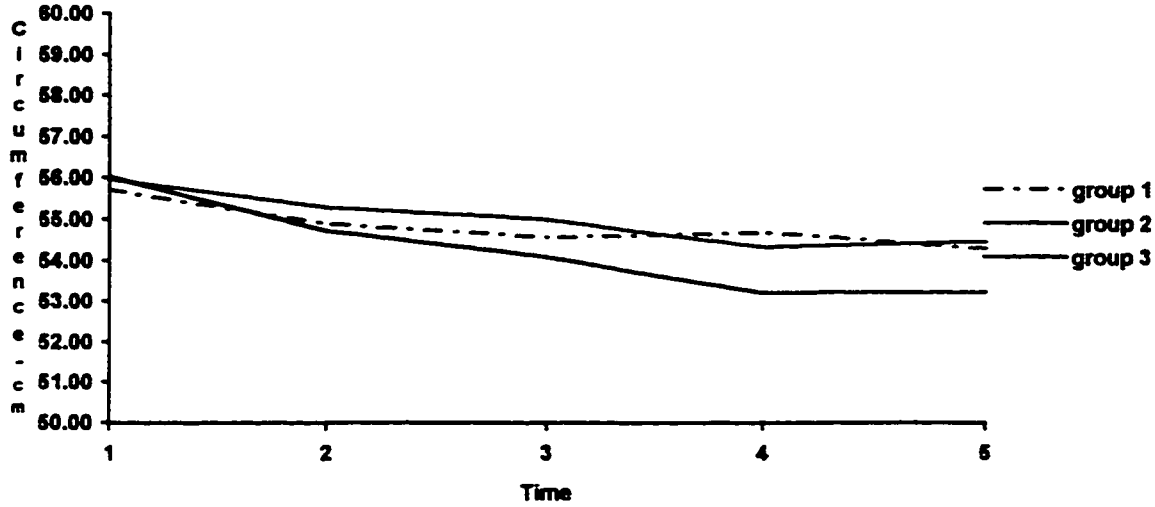

Figure 4-10: Mean change in swelling over five daily treatment times

TABLE 4-12

PERCENTAGE OF SUBJECTS IN EACH GROUP FOR SWELLING AT TIME 5

SWELLING (cm)	45-49.9	50-54.9	55-59.9
GROUP 1 (%)	10	30	60
GROUP 2 (%)	10	50	40
GROUP 3 (%)	20	60	20

Swelling was reduced the most in the subjects in group 3. Subjects in this group had a consistent decrease in swelling from time 1 to time 5 with eighty percent of the subjects having a decrease of almost 3 cm by time 5.

TABLE 4-13

TWO-WAY ANOVA FOR SWELLING

Source	SS	df	MS	F	Sig
Group	15.37	2	7.69	10	0.91
Error	2098.33	27	77.72		
Time	73.40	4	18.35	29.08	**0.00**
Error	68.14	108	.63		
Grp x Time	11.66	8	1.46	2.51	**0.03***
Error	68.14	108	.63		

*** Significant interaction effect at p<0.05.**

Table 13 shows that there was a significant interaction effect between groups with time and demonstrates statistical significance at $p<0.03$.

Subjects in group 3 had almost 3 cm. reduction in swelling with treatment and there was a significant difference between the groups at $p<0.03$. The difference of 3 cm. in swelling is clinically important. As clinicians, if one can reduce swelling significantly in five days, it indicates that the magnitude of the inflammatory response is being decreased and the scenario for healing and rehabilitation is improved. Eighty percent of the subjects in group 3 had approximately 3 cm. change in swelling at time 5 and only 60% in group 2 and 40% in group 1. There was a significant interaction effect between groups over time indicating that the groups did react differently over time to the different treatments. These findings lend support to the research hypotheses.

D.) FUNCTION

TABLE 4-14

MEAN CHANGE IN FUNCTION (NUMBER OF DAYS UNTIL FULL PAINFREE WEIGHT BEARING) BETWEEN GROUPS

GROUP 1	4.70
GROUP 2	5.00
GROUP 3	4.10

Table 14 shows that the subjects in group 3 were full pain-free weight bearing almost one day sooner than subjects in group 2. Subjects in groups 1 and 3 were full pain-free weight bearing sooner than subjects in group 2.

TABLE 4-15

PERCENTAGE OF SUBJECTS IN EACH GROUP FOR FUNCTION AT TIME 5

FUNCTION	PWB	FWB-MIN PAIN	FWB-PAINFREE
GROUP 1 (%)		30	70
GROUP 2 (%)	10	30	60
GROUP 3 (%)			100

PWB - partial weight bearing with crutches or cane
FWB - full weight bearing

All subjects in group 3 were full pain-free weight bearing at time 5. In group 1, seventy percent of the subjects were full pain-free weight bearing at

time 5 and only sixty percent of the subjects in group 2 were full pain-free weight bearing at time 5.

TABLE 4-16

T-TESTS FOR INDEPENDENT SAMPLES FOR NUMBER OF DAYS UNTIL FULL PAINFREE WEIGHT BEARING AT TIME 5

Group	Mean Difference	DF	P-Value
1 & 3	0.3	18	**0.06**
2 & 3	0.5	18	**0.04**

TABLE 4-17

ONE-WAY ANOVA RESULTS FOR FUNCTION (# OF DAYS UNTIL FULL PAIN FREE WEIGHT BEARING)

Source	SS	df	MS	F	Sig
Between Grps	4.2	2	2.1	1.9	0.16
Within Grps	29.0	27	1.07		

The results of the t-tests show that there was a significant difference between groups 1 and 3 at $p<0.06$ and between groups 2 and 3 at $p<0.04$. The one-way Anova doesnot demonstrate a difference between groups.

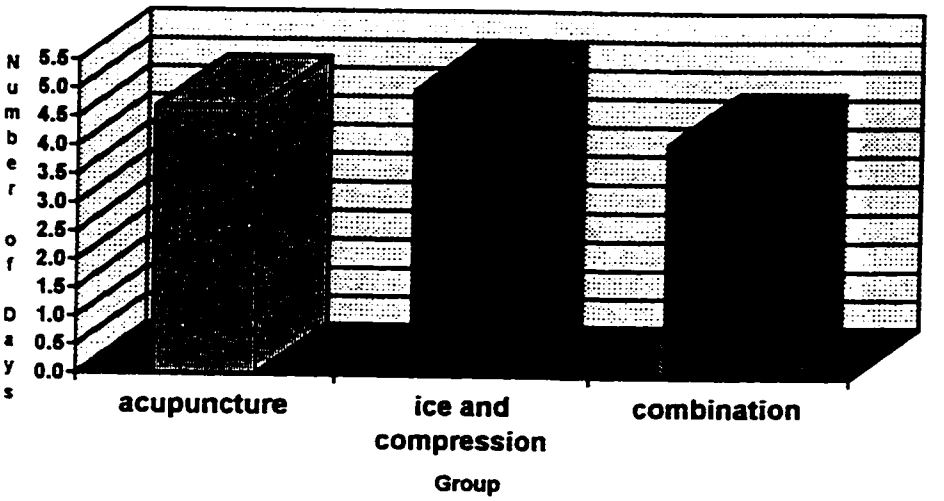

Figure 4-11: Number of Days to Full Pain-Free Weight Bearing

All the subjects in group 3 were full pain free weight bearing at time 5; only 60% in group 2 and 70% in group 3. The biggest difference was between groups 2 and 3. The subjects in group 3 consistently showed more improvement in pain reduction, swelling and ROM, therefore it is not surprising that all the subjects in group 3 were full pain free weight bearing at time 5. These were the expected results in this study; however, it was expected that there would have been a bigger difference in the number of days until full pain free weight bearing between the three groups. Previous studies reported differences between 1.8 and 3 days (22, 41).

T-tests at time 5 indicate a significant difference between groups 1 and 3 at $p<0.06$ and between groups 2 and 3 at $p<0.04$ indicating that group 3 did better with respect to an earlier return to function. These findings lend support to the research hypotheses.

TABLE 4-18

RESULTS OF ONE WAY ANOVA FOR THE HOP TEST

Source	SS	df	MS	F	Sig
Between Grps	867.3	2	433.64	1.35	0.28
Within Grps	8645	27	320.20		

The findings for the hop test indicated that there was no significant difference between the groups when performing this test.

TABLE 4-19

ONE WAY ANOVA RESULTS FOR TIMED HOP TEST

Source	SS	df	MS	F	Sig
Between Grps	2049.4	2	1024.8	2.05	0.15
Within Grps	13499.1	27	499.96		

This table shows that there was no significant difference between groups when performing this test.

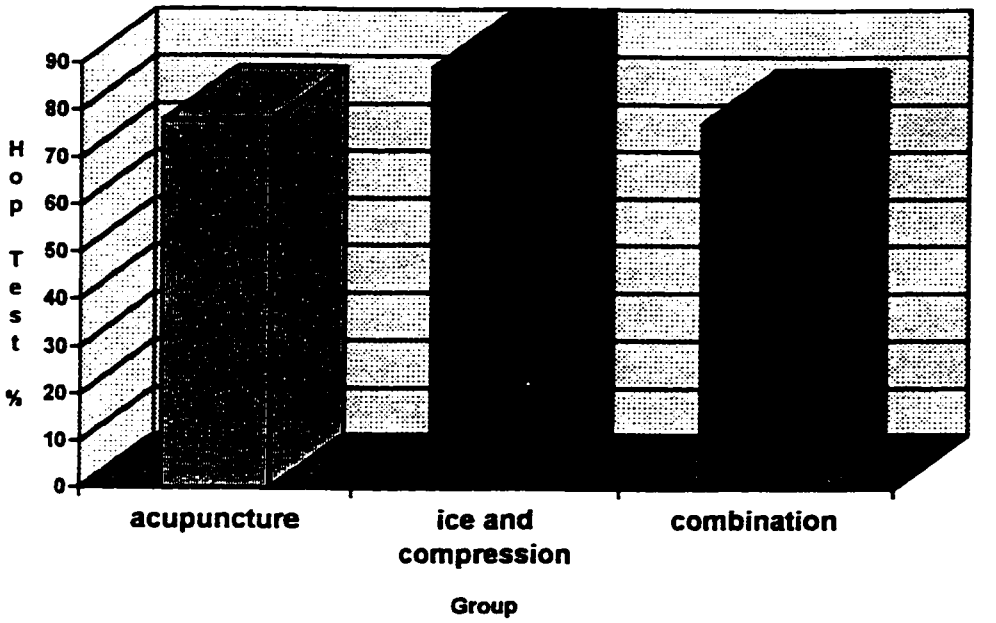

Figure 4-12: Hop Test Percentage

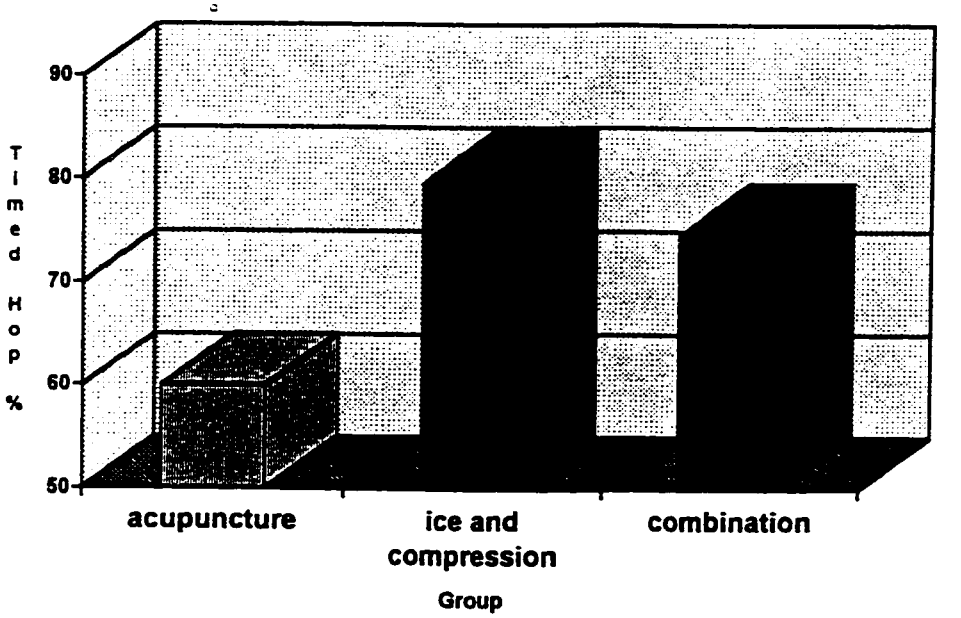

Figure 4-13: Timed Hop Test

The two hop tests did not show any statistical significance between the three groups. Group 2 did better on these two test than groups 1 and 3. This may have been due to subjects characteristics which will be discussed in Chapter 5. The validity and reliability of these two tests and their use in a clinical and experimental situation for acute ankle sprains will be discussed in Chapter 5.

CHAPTER 5

DISCUSSION

The use of acupuncture as a modality in acute injuries is an area that has not been studied or reported in the literature. Acupuncture has been used to treat chronic pain and the effects of acupuncture on chronic pain are well documented from laboratory and clinical studies. The reports of acupuncture on acute orthopaedic and sports injuries have mainly been anecdotal with no clinical research. This is an area that proves to be very promising and exciting in terms of future research and clinical application. In patients with acute injuries, it would appear to be beneficial to use a modality that would expedite their rehabilitation and return them to activity as soon as possible. The consequences of achieving that are far reaching: decreased days missed from work, less cost to health care, less burden on family and friends and a quicker return to activity or sport (professional or recreational) with minimal side effects.

The purpose of this study was to determine if a combination of acupuncture and ice and compression were more beneficial than acupuncture alone or ice and compression together in reducing pain, improving ROM, decreasing swelling and improving function in acute second degree ankle sprains. Pain was measured using the VAS, ROM was measured with a goniometer, and swelling was measured using the figure of eight method for ankle swelling. Function in the first five days was measured using the number of days to full painfree weight bearing. Post study, function was measured using the hop test and the timed hop test.

The results of this study revealed a consistent, directional trend occurring in all three treatment groups. As was expected, there was a

physiological response in all groups as indicated by a decrease in pain and swelling and an improvement in ROM and function. Even though the results were not significant for the two-way Anova's at $p<0.01$, group 3 appeared to have improved more on some measures over time. The most difference occurred between groups 2 and 3.. All groups were expected to improve but it was thought that the third group would improve more quickly due to the combined effects of both treatments. T-tests for independent samples and a one-way Anova done at time 5 demonstrated significance at $p<0.05$ for the outcome measures of pain, ROM and function. A two-way Anova that was done on the variable swelling demonstrated significance at $p<0.03$. Although the results were not statistically significant at $p<0.01$, they did lend support to the research hypotheses and the trends and differences between the groups are clinically important. Because there is a trend toward statistical significance at $p<0.01$ with a small sample, using a larger sample would have demonstrated larger and more likely statistically significant differences. With a small sample size, there is a larger sampling error and less variance among the sample cases. As the sample size increases, the sampling error decreases and less difference is required between groups to show a statistical difference (70). This was an exploratory study using a small sample and it is believed that these differences between the groups would become significant with a larger sample. Statistical significance may not have clinical importance and it is essential to keep in mind the clinical implications which will be discussed in this chapter.

The following discussion will address the important differences between groups, the patterns found and the clinical importance of these findings, the strengths and limitations of this study, the short comings of acupuncture research, and the implications for future of further research.

1. PAIN

A one-way Anova done at time five demonstrated statistical significance at $p<0.05$ among the groups, indicating a strong trend. T-tests for independent samples demonstrated significance between the groups. Groups 1 and 3 demonstrated a difference at $p<0.021$ and groups 2 and 3 demonstrated a difference at $p<0.012$.

At time 5, all the subjects in the third group were pain free whereas only 50% in group 2 and 60% in group 1 were painfree. At time 5, there were still three subjects in group 2 who had rated their pain over 2 and one in group 1 who had rated his or her pain over 4. Group 3 had the overall largest decrease in pain measured by the VAS, over five consecutive days. These findings suggest that the combination of the two treatments - acupuncture and ice and compression, had stronger physiological effects than any one treatment given at a time. This result could be due to several factors. Ice has been shown to decrease the intensity of the inflammatory response by decreasing the amount of swelling, pressure and the irritants that produce pain and inflammation (20, 32, 59). Neurophysiologically, ice temporarily decreases the sensitivity of the nerve by raising the pain threshold (14, 30, 33, 40, 47). There is a decrease in frequency and intensity (velocity), which may decrease pain perception. Once the effect of the cooling has worn off, the nerve resumes its normal function thereby allowing the normal conduction of the nerve impulses and possibly pain impulses. Acupuncture appears to have a more systemic and longer lasting effect due to the action of neurotransmitters at different levels of the nervous system and may therefore decrease pain several hours after application (22, 43). This increased pain threshold may allow for decreased muscle spasm and pain. It has been shown that the analgesic effect of acupuncture in chronic pain occurs due to the

action of endorphins and other neurotransmitters (22, 43, 48, 60). A decrease in pain would cause a decrease in muscle spasm and allow the patient to perform ROM exercises more easily and weight bear with less difficulty. By combining the two treatments, the local and temporary effects of the ice and compression plus the systemic and the anti-inflammatory and longer lasting analgesia of acupuncture may contribute to an overall greater decrease in pain. The results of this study show such a trend.

There have been no known reports published in the literature on the effects of acupuncture and acute pain. One similar study that evaluated the effects of a neuroprobe to acupuncture points for sprained ankles had subjects rate their pain from 1 to 5. The researchers did not find a statistical significance between the two groups but they did find that the group receiving the neuroprobe treatments had relief of pain sooner than subjects who received ice and compression. Similar to the present study, the neuroprobe study had a very small sample size of eight subjects per group and may have demonstrated statistical significance with a larger group. Similarly, both studies showed a consistent trend in that the group which had a combination of acupuncture and conservative treatment demonstrated better pain relief than the other treatment groups.

The acupuncture only treatment group did not have as great a response as did group 3 but did have a better response than group 2. Group 1 may have done better than group 2 due to the longer lasting effect of analgesia produced by the acupuncture. Group 1 may not have done as well as group 3 as they did not receive the benefits of ice and they also had a larger female/male ratio. Males have been shown to respond better to the effects of acupuncture and pain (61). It has been shown in the literature that 15 - 20%

of individuals may be naturally low in opiate receptors and may not be able to elicit the analgesic response associated with acupuncture stimulation (43,61).

Another problem that has been identified in the literature is the lack of a De Qi response in individuals (43,61). The De Qi response is the deep aching or numb sensation that is felt by the patient when acupuncture stimulation occurs. It is felt that the production of this De Qi response is a direct result of the stimulation of high threshold, small diameter nerves that produces the release of neurochemicals (43). Takeda and Wessel (61) felt that subjects who experienced the De Qi did better than those who did not. This finding did not appear to be a problem in this study as almost all subjects achieved this response on all points at all times.

2. SWELLING

The figure of eight measurements for swelling showed that group 3 had a larger decrease in swelling from time 1 to time 5. The two-way Anova demonstrated statistical significance at $p<0.03$ showing that the groups reacted differently to the different treatments over time. It is difficult to achieve statistical significance with a small number of subjects but this consistent directional trend towards significance with a small sample size is very encouraging and reinforces the need to replicate this study with a larger sample size. This directional trend may indicate that the combination treatment is the best for reducing swelling. The effect of acupuncture on swelling in acute injuries in humans has not been widely researched or reported in the literature or in clinical studies. It has been shown in the literature that healing is improved as swelling is decreased (32,53). It has also been stated in the literature that the recovery rate for ankle sprains may

be directly related to the effectiveness of edema control at the site (69). It has been reported that leukocytic activity and vascular permeability is decreased with acupuncture and blood cortisol levels are increased with acupuncture stimulation (27,35). Both of these factors may contribute to a decrease in inflammation in acute injuries which is a desirable effect. Ice decreases swelling and inflammation by vasoconstriction, decreased blood flow and reduced metabolic activity (20,21,33,59). The subjects in group 3 may have done better due to the combination of the physiological effects of acupuncture and ice and compression. Paris, Baynes and Gucker (41) did not show any differences in swelling between the groups. A problem in their study could have been their method of measurement for swelling. The displacement method for evaluating swelling is insensitive to small changes, not portable or easy to use. The figure eight method for measuring swelling, which was used in this study, is easy, inexpensive, portable and has been shown to be valid and reliable for assessing this type of injury (62). In the Paris study, the use of a smaller tank was recommended in order to produce more sensitive readings. If studies were standardized as to what method they used for measuring swelling then perhaps the results would become more consistent.

The clinical implications of these findings for a significant decrease in swelling due to a combination of acupuncture and ice and compression are important. There have been varying results in the literature as to the effectiveness of various modalities for reducing inflammation and swelling (52,69). If acupuncture combined with ice and compression can more effectively reduce swelling and aid recovery, it should become the treatment of choice. If patients in group 3 have better pain control and reduction in swelling then their return to activity should occur sooner.

Acupuncture has fewer side effects than the use of anti-inflammatory drugs (43) and it has been reported in the literature that the use of NSAIDS for inflammation in single impact acute injuries is controversial. The potential benefits of taking NSAIDS may out weigh the risk involved such as prolonged bleeding at the injury site and interference with the strength of the healing tissue (34). Acupuncture may be a better choice for the treatment of acute injuries due to its fewer side effects. Acupuncture needles are inexpensive, portable and easily disposed of making their use on the field or in a clinical setting easy and beneficial to the patient.

The ankles of the subjects in group 3 were elevated for twice the amount of time than groups 1 and 2. They were elevated for the thirty five minutes-twenty minutes for the acupuncture needles and fifteen minutes for the ice and compression. This important fact could have contributed to the large decrease in swelling. The literature reports that elevation alone was significant in reducing swelling compared to other forms of treatment in treating this type of injury (52). Further research evaluating the effects of acupuncture, ice and compression with and without elevation would help to clarify this possible positive effect of elevation. This study does appear to be encouraging with the respect to the use of acupuncture in soft tissue sport injuries and the effect of acupuncture on swelling and inflammation.

3. ROM

All groups showed improvement in ROM irrespective of the treatment they received. All subjects in group 3 had close to normal ROM by treatment 4 compared to 50% in group 2 and 10% in group 1. This trend is not surprising as subjects in group 3 had lower levels of pain and a greater decrease in swelling. Because there is less pain and a greater reduction in

swelling, the exercises would be carried out more frequently and through greater ROM. This finding is also supported by Paris, Baynes and Gucker (41) and Javens (22). Physiologically, this improved movement in a pain free range is very important for ligament healing. The literature states that controlled movement early in the acute phase makes the ligament stronger by promoting scar production (9,71). This desirable effect is very important in the outcome in the treatment of ankle sprains or any ligamentous injury. Subjects in group 2 reported "stiffness" after the ice application and were reluctant to perform the ROM exercises. Subjects in groups 1 and 3 did not report this finding. This finding may explain the better ROM in groups 1 and 3. As clinicians, it is important to discover methods that encourage patients to perform their exercises and progress their mobility. It is the author's clinical observation that patients who feel "stiff" or what they may consider "worse" after treatment are not as compliant as those patients who do not feel stiff or are experiencing less pain.

4. FUNCTION

As expected, all three groups showed improved function over time. It was expected that subjects in group 3 would improve faster in pain free weight bearing and function than groups 1 and 2 based on information from two previous studies (22,41) and clinical experience. All of the subjects in group 3 were weight bearing pain free by time 5 while in group 1, there were seven, and six in group 2. The raw data shows that at time 3, group 3 had four subjects who were full weight bearing pain free compared to one in group 1 and one in group 2. A t-test for independent samples done at time five, demonstrated significance at $p<0.06$ for groups 1 and 3, and $p<0.04$ between groups 2 and 3. These results were in the expected direction as subjects in

group 3 had less pain, and swelling and greater, painfree ROM. These results followed the same pattern that was found in two other studies. In the Paris, Baynes and Gucker study (41), those subjects treated with a neuroprobe on average, were ambulating three days sooner than those treated with ice and compression. Javens (22), showed a difference of 1.8 days in function (statistically significant at $p<0.05$) between subjects treated with acupuncture TENS and those treated with ice and compression. The authors of both studies discussed the clinical importance of full weight bearing and return to activity as quickly as possible. Promoting motion and function allows the joint to be mobilized earlier (within protected range ie: pain free), strength and function are restored more rapidly thereby providing and earlier return to normal activity (43). The quicker range and mobility are restored, the less chance of a recurrent injury and the stronger the ligament (16,34,72). Early functional use enhances the rate and quality of ligament healing (69). By improving efficacy of treatment, cost is reduced and patients can resume their normal activities more quickly thus shortening the rehabilitation process (41,53).

The number of days to full painfree weight bearing was chosen as a marker for function for various reasons. It was the clinical impression of the author and various other experienced therapists that this was an important clinical milestone for the patient. The ability to walk without pain or with aids (such as crutches or a cane), and a shorter recovery time is psychologically and physiologically important. Patient motivation remains high, they return to normal activity sooner, the scenario for healing remains optimal and costs are reduced. It is important to remember that even though the goal is to return to activity quicker and hasten the rehabilitation process, the patient must be educated. In this study, subjects were educated with

respect to the time it takes the ligament to heal (six months to one year) and they must wear protective devices during the first three to six months. All subjects purchased an Active Ankle brace and began to wear this as soon as the first five days of the study had passed. Subjects were always reminded to use pain as their guide and all subjects were instructed in proprioceptive, strengthening and mobility exercises.

In this study, subjects were very anxious to be full weight bearing for many reasons. They would have to depend less on others for rides and care, return to their job sooner without losing pay and be able to carry out their regular duties more quickly.

5. HOP TEST AND TIMED HOP TEST

The two hop tests were performed to determine if the treatment in the initial phase of the injury made any difference on return to activity. These two tests have been shown to have high specificity and low false positive rates in confirming defects in lower limb function in subjects with ACL deficient knees (38). Consequently, these two tests have been assumed to test lower limb function and have been used as markers for return to sport after acute ankle sprains (68, 72). For these two tests, the subjects in group 2 performed better than the subjects in groups 1 and 3. There are several possible explanations for this. One, the subjects in group 2 were younger, they had overall less severe second degree sprains and were a more fit and active group. The subjects in this study were not homogenous in their activity levels. Subjects in group 2 were all athletic or physically fit and none of these subjects had sedentary desk job and were either students or employed in active jobs. In group 3, five subjects had sedentary jobs, three subjects were inactive and did no other regular activity and two were over weight.

Four subjects in group 1 were not physically active. The subjects who were apprehensive about doing this test were those subjects who were inactive or did not perform any regular physical activity. They were concerned they would re-injure their ankle or experience pain. The younger more athletic subjects were not intimidated by these tests and consequently did much better.

These two tests have been reported in the literature as assessing knee function and lower limb function on returning to activity or sport. As mentioned earlier, these two tests have been used to determine if the individual is ready to return to activity after an acute second degree ankle sprain (68). However, there have not been any reliability or validity studies on these two tests when they are used to test ankle function in acute ankle injuries. The single hop test has been used in a previous study (68) as a diagnostic tool for second degree ankle sprains. In this previous study, they confirmed the diagnosis of an acute second degree ankle sprain retrospectively. If the subject was able to perform the single leg hop test within 14 days but not sooner than four days, their diagnosis of a second degree ankle sprain was confirmed. There was no mention of the validity or reliability of using these two tests for acute ankle sprains.

Although these two tests were perhaps not suitable for evaluating function in this present study, due to the inconsistencies found, there are some clinical applications for using these two hop tests when determining if the patient is ready to return to sport, job or activity. These two tests were very informative for the subjects, especially the younger subjects who very anxious to return to hockey, basketball or volleyball. When they performed these tests, the subjects realize that even though they were painfree weight bearing, could run up and down stairs and straight lines, their capacity to

jump and land was not at the potential required for their sport. Therefore, these two tests are good outcome measures for evaluating return to sport and as a marker to objectively let the subjects/patients evaluate their level of readiness. These two tests are very useful in the clinic as they were easy to do, require little equipment and time and use the opposite limb as a control (38).

Future research is required to validate these two tests for use in acute ankle sprains. There is also a need for the development of a functional assessment test for injured ankles. Such tests would be very useful for clinical and research purposes.

CHAPTER 6

CONCLUSION

1. Summary

The purpose of this study was to evaluate the effects of three different treatment interventions: 1) acupuncture 2) ice and compression and 3) a combination of acupuncture and ice and compression in the treatment of acute second degree ankle sprains. The research hypotheses of this study were that a combination of acupuncture and ice and compression would be more effective than either acupuncture or ice and compression alone in a) reducing pain, b) decreasing swelling, c) improving ROM and d) improving function in acute second degree ankle sprains.

This study was a single blind, randomized controlled clinical trial using a non-probability, convenience sample. Thirty subjects were included in this study, ten in each of the three groups. All subjects were given a clinical examination by the attending physician and the two therapists involved in the study to confirm eligibility.

Descriptive statistics, cross-tabulations, t-tests for dependent and independent samples, one and two-way Anovas were done on subject demographics, VAS for pain, ROM, swelling and function to determine if there was significant differences between groups at $p<0.01$. This level of significance was chosen to reduce the chance of making a type 1 error by requiring stronger evidence for a test to demonstrate significant differences.

The data showed very consistent trends in the expected direction. The two-way Anova for swelling showed a strong interaction effect at $p<0.03$ and the t-test at time 5 was significant for swelling between groups 2 and 3. A

one-way Anova and t-tests for independent samples at time 5 for pain, demonstrated significance at $p<0.05$. ROM and function also demonstrated significant differences between the groups. The raw data and means showed that group 3 did better on all measures.

Sample size may have had an affect on the results. If the size of the sample was increased to twenty subjects in each group, statistical significance may have been reached. Sample size can affect the outcome of the research hypotheses (70). With a small sample size, it is difficult to show statistical significance and even though the hypotheses may be true, the large standard error may not be sensitive enough to detect an important effect (70). Moreover, some of the group differences were significant at $p<0.05$ level and one was significant at $p<0.01$. The small sample size may have resulted in a reduced effect of the test and if the size of the sample was increased to 20 or more per group, perhaps higher statistical significance may have been reached. However, the results demonstrate a definite trend that has important clinical implications and implications for further research. This study could be considered exploratory as there have not been any research studies on the effect of acupuncture versus conventional treatment on acute injuries or acute second degree ankle sprains.

This study does suggest the use of acupuncture in combination with elevation and ice and compression appears to be effective in the treatment of acute second degree ankle sprains. It also suggests that there is a place for the use of acupuncture in the treatment of acute single impact sport injuries.

2. STUDY STRENGTHS AND LIMITATIONS

The strengths of this study are as follows: this study had very strict inclusion criteria which gave the study good internal validity. Therefore, it

was assumed that the results of the study were due to treatment effects and not extraneous factors. None of the subjects were taking any medication, prescription or non prescription, that would have influenced the study. Subjects in the acupuncture group did not appear to have a high percentage of subjects deficient in opiate receptors, as has been reported in the literature (61), as they all responded on all measures and did respond better than the ice and compression group. The one factor that was overlooked at the start of the study was the activity level of the subjects. The activity level was thought to have affected the outcome of the ROM and function tests. It would have been very difficult to control this factor and recruit thirty subjects.

The main limitation of this study was sample size and could have affected external valididty and the generalizability of the results. Although the sample size calculation was based on information from the literature, it is very difficult to show statistical significance with a small number of subjects. Every effort was made in this study to recruit even more than the thirty subjects, but this proved to be very difficult. The difficulties lay in many areas and the following difficulties were found with the present research project: inability of major centers to recruit subjects, subjects did not always respond within the 72 hours specified, lack of communication from referral sources, and the inability to meet the criteria.

The results of this study can be generalized to other acute, single impact injuries that react similar to acute ankle sprains. The results could not be generalized to conditions with chronic swelling or repetitive type injuries. Since most joints that suffer acute, single impact trauma behave in a similar way, the generalizability to other joints is possible. Because there was a wide range of ages in the study, the applicability of the results to those age groups of eleven to mid forties is reasonable, but is questionable to older subjects.

The athletic subjects were recreational athletes, therefore the applicability to professional athletes is also questionable due to other factors involved such as monetary gains, subjects physicial condition and psycological factors.

3. ACUPUNCTURE RESEARCH

The area of acupuncture research is difficult because of the inherent problems associated with scientifically testing a form of treatment that is not scientifically based. There is much debate in the literature as to the best method of testing this treatment but there is no consensus(5,10,18). Basic principles of research should be followed so that studies and results can be compared and be reproduced. It has been debated whether to use a set of points that is similar in all subjects versus evaluating each subject individually and using those points suitable for each subject. There are pros and cons and criticism to both of these methods. By standardizing the points that are used, the study can be replicated. In acute injuries, this method may be more practical than in a chronic injury where other factors such as the psycological effect of chronic pain, chronic tissue changes, and secondary gain may be involved. Traditional Chinese Medicine believes that there is no "set" points and that each person is to be treated individually. Clinically, physiotherapists generally practice the individual method of treatment, but for research methods, it is not reproducible and is therefore considered poor research methodology. There is a need to research acupuncture in order to show its clinical efficacy beyond that which is anecdotal.

4. CLINICAL IMPLICATIONS OF THE STUDY

It is evident from the above discussion that proper treatment of acute ankle sprains is very important. Early control of the inflammatory process

and early mobilization (active movement in the painfree range) are all important to the successful rehabilitation of the patient with this type of injury. Proper diagnosis of this injury and patient education are also of upmost importance. Because it is essential to treat this injury with those modalities that reduce the intensity of the inflammatory response and promote early pain relief and movement, it is essential that physiotherapists evaluate the treatment that they give. The consistent trend in the data demonstrates that acupuncture should be used along with conventional treatment in order to facilitate healing and rehabilitation of acute soft tissue injuries. Pain, ROM, function and swelling appeared to be facilitated by the combination of the two treatments with no side effects. Early control of the inflammatory process has been shown to increase ligament strength and provide for a better outcome (7,13,16,22,34,53).

This study suggests that acupuncture, in combination with conventional treatment, may be an effective modality in the treatment of acute second degree ankle sprains.

5. FUTURE RESEARCH CONSIDERATIONS

This study has brought forth several areas for future research and consideration.

1. The effects of acupuncture for other acute injuries and other joints. Consideration should be given not only to the analgesic effect of acupuncture but the anti inflammatory effect of acupuncture therefore the use of outcome measures that properly measure these effects.
2. Evaluation on the effects of elevation on acute injuries versus other treatment.

3. Development of functional outcome measures for the ankle and evaluation of the hop test and the timed hop test for use in evaluation of ankle sprains.
4. Evaluation of the effects of acupuncture versus NSAIDS in reducing pain and inflammation in acute single impact injuries.
5. Repeating the study with a larger number of subjects to see if the apparent trend to improvement might be significant if a larger group of subjects is used.

CONCLUSIONS

The results of this study support what has been shown in the literature for similar studies. Subjects who receive acupuncture-like stimulation have a greater response than those subjects who do not. There is a greater decrease in pain and swelling, a larger increase in ROM and a quicker recovery with respect to full pain free weight bearing and return to activity. The findings of this study suggest that acupuncture should be considered as a treatment modality to be used in soft tissue injuries with few side effects.

Based on the findings of this study the following are recommended:

1. The VAS has been shown to be reliable and valid for acute pain and in changes in pain with respect to treatment. This scale is recommended as subjects found it simple and easy to use and understand. Statistical analyses using this scale is quick and easy. This scale is also clinically useful.

2. The figure of eight method of measuring swelling for acute ankle sprains is easy to use, portable, inexpensive and has been shown to be valid and reliable. It would be useful for evaluation in a clinic setting.
3. The number of days to full painfree weight bearing was shown to be an important marker for determining function when treating or evaluating the effects of treatment in acute second degree ankle sprains. This measure would also be useful in a clinic setting.
4. The two hop tests need to be validated for use in evaluating the tests for use in determining function in acute ankle sprains and their use as evaluative tools in a research setting. These two tests were useful in demonstrating to the clinician and the subject their readiness for returning to activity. These two tests therefore have clinical applicability.
5. The use of acupuncture for chronic pain is widely utilized. The results of this study do lend support for the use of acupuncture in treating acute soft tissue injuries. It is apparent from this study that not only the analgesic effect of acupuncture should be measured, but the effect of acupuncture on other factors such as swelling and inflammation should be measured with reliable and valid outcome measures.
6. There is a need for further clinical research evaluating the effects of the treatment done. Subject recruitment and the time involved are two main obstacles in performing clinical research.

This study evaluated the use of acupuncture in combination with ice and compression. Although the results did not attain statistical significance, the directional trend with a small sample indicated the use of acupuncture in combination with ice and compression in the treatment of acute ankle sprains was warranted. Continuing research is required in this area in order to

validate the treatment used and to continually motivate professionals to evaluate their treatment methods.

REFERENCES

1. Acupuncture Foundation of Canada: Part 1, 2, and 3 course notes. Shoppers World Postal Outlet, P.O. Box 93688, 3003 Danforth Avenue, Toronto Ontario, M4 5R5
2. American Academy of Orthopaedic Surgeons: Athletic Training and Sports Medicine. Second Edition; Chapter 23:414-415, Rosemont IL,1991.
3. Arnheim D, Prentice E: Principles of Athletic Training. Eighth Edition; Chapter 17:487-527, Mosby Yearbook, St. Louis, Missouri, 1993.
4. Aung S.K.H.: Relevant points and the post-traumatic vital alignment procedure. Acupuncture Newsletter Spring 1995;7-10
5. Bensoussan A: Contemporary Acupuncture Research: The difficulties of research across scientific paradigms. American Journal of Acupuncture 1994;19(4):357-365
6. Birch S., Hannerschlag R., Berman B.: Acupuncture in the treatment of pain. The Journal of Alternative and Complementary Medicine 1996;12(1):101-121
7. Boruta P.M., Bishop J.O., Braly W.G., Tullos H.S.: Acute lateral ankle ligament injuries: A literature review. Foot and Ankle 1990;11(2):107-113
8. Brattberg G: Acupuncture therapy for tennis elbow. Pain 1983;16:285-88
9. Burroughs P., Dahners L.: The effect of enforced exercise on the healing of ligament injuries. The American Journal of Sports Medicine 1990;18(4):376-80
10. Carlsson C.P.O., Sjolund B.H.: Acupuncture and Subtypes of Chronic Pain: Assessment of Long-term results. The Clinical Journal of Pain 1994;10: 290-295
11. Cheng R., McKibbon L., Roy B., Pomeranz B: Electroacupuncture elevates blood cortisol levels in naive horses: Sham treatment has no effect. International Journal Of Neuroscience 1980; 10:95-97
12. Colville M.R., Marder R.A., Boyle J.J., Zarins B. : Strain measurement in lateral ankle ligaments. The American Journal of Sports Medicine 1990;18(2):196-200

13. Cox J.S., Brand R.L.: Evaluation and treatment of lateral ankle sprains. The Physician and Sports Medicine 1977; 5:51-55

14. Ernst E., Fialka V.,: Ice Freezes Pain: A review of the clinical effectiveness of analgesic cold therapy. Journal of Pain Symptom Management 1994; 9(1): 56-59

15. Garrick J.G.: The frequency of injury, mechanism of injury and epidemiology of ankle sprains. The American Journal of Sports Medicine 1977;5(6):241-242

16. Garrick J.G.: Managing Ankle Sprains. The Physician and Sports Medicine, March 1997;25(3):56-68

17. Gaw A.C., Lennig W.C., Shaw Lein-Chun : Efficacy of acupuncture on oteoarthritic pain. The New England Journal of Medicine 1973;293(8):375-378

18. Guillame Gerard: Why western protocols are unsuitable for assessing the effects of aupuncture: The need for an evaluation of methodology specific to the investigation of acupuncture. American Journal of Acupuncture1991;19(2):153-56

19. Guyton A.C., Hall J.E.: Textbook of Medical Physiology. Ninth Edition; Chapter 33:438-445, WB Saunders Co., Philadelphia, Pennsylvannia, 1996

20. Ho S. S., Coel M., Kagawa R., Richardson A.: The effects of ice on blood flow and bone metabolism in knees. The American Journal of Sports Medicine 1994;22(4): 537- 540

21. Hocutt J. E.Jr., Jaffe R., Rylander R., Beebe J.K.: Cryotherapy in ankle sprains. The American Journal of Sports Medicine 1982;10(5):316-319

22. Javens Julie: Effect of acupuncture TENS in second degree ankle sprains. Master Thesis, Temple University Microfiche, Eugene 1992.

23. Kannus P., Renstrom P.: Treatment for acute tears of the lateral ligaments of the ankle. Journal of Bone and Joint Surgery 1991; 73A(2):305-311

24. Knight K.L.: Cryotherapy in Sport Injury Management. Chapters 7:85-98,10:127-148, 11:149-169, Human Kinetics Champaign IL. ,1995

25. Lee P.K., Andersen T.W., Modell J.H., Saga S.A.: Treatment of Chronic Pain with Acupuncture. Journal of the American Medical Association 1975;232(11):1133-1135

26. Lewith G. T., Machin D.: On the evaluation of the clinical effects of acupuncture. Pain 1983;16:111-127

27. LiaoY.Y., Seto K., Saito H., Fujita M., Kawa Kamim: Effect of acupuncture on adrenocortical hormone production. (II)Effect of acupuncture on the response of the adrenocortical hormone production to stress: American Journal of Chinese Medicine 1980; 8(2):160-166

28. Liaw M.Y., Wong Alice May-Kuen, Cheng Poa-Tsai: Therapeutic trial of acupuncture in phantom limb pain of amputees. American Journal of Acupuncture 1994;22(3):205-213

29. Lui Stephen, Jason William: Lateral ankle sprains and instability problems. Clinics in Sports Medicine 1994;13(4):793-809

30. Magee D.: Personal Communication

31. Marcus A., Gracer R: A modern approach to shoulder pain using the combined methods of acupuncture and Cryiax based "Orthopaedic Medicine". American Journal of Acupuncture 1994;22(1):5-14

32. McMaster W.C.: A literary review on ice therapy in injuries. The American Journal of Sports Medicine 1977; 5(3):124-126

33. McMaster W.C.: Cryotherapy. The Physician and Sports Medicine 1982; 10(11):112-119

34. Micheli L.J.:Common Painful Sport Injuries: Assessment and Treatment. The Clinical Journal of Pain 1989;5(Suppl2): S51-S60

35. Min S.Y.: Effect of electric acupuncture and moxibustion on phagocytic activity of the reticulo-endothilial system of mice. American Journal of Acupuncture 1983; 11(3):237-241

36. Molsberger A., Helle E.: The analgesic effect of acupuncture in chronic tennis elbow pain. British Journal of Rheumatology 1994;33:1162-1165

37. Nissel H.: Pain treatment by means of acupuncture. Acupuncture and Electro-therapeutics Research, The International Journal 1993;18:1-8

38. Noyes F.R., Barber S., Mangine R.E.: Abnormal lower limb symmetry determined by function hop tests after anterior cruciate ligament rupture. The American Journal of Sports Medicine 1991;19(5):513-518

39. Ogon M., Krismer M., Sollner W., Kantner-Rumplmair W., Lampe A.: Chronic low back pain measurement with visual analog scales in different settings. Pain 1996; 64:425-28

40. Olson J.E., Stravion V.D.: A review of cryotherapy . Physical Therapy 1972;52(8): 840-45

41. Paris D.L., Baynes F., Gucker B.: Effects of the neuroprobe in the treatment of second-degree ankle inversion sprains. Physical Therapy 1983; 63(1):35-40

42. Planas M.E., Rodriguez L., Sanchez S., Pol O., Puig M. M.: Pharmological evidence for the involvement of the endogenous opoid system in the response to local inflammation in the rat paw. Pain 1995;60:67-71

43. Pomerantz B.: Scientific research into acupuncture for the relief of pain. The Journal of Alternative and Complementary Medicine 1996; 2(1):53-60,

44. Prentice W. E. : Rehabilitation Techniques in Sports Medicine. Second Edition; Chapters 1:1-26; 12:181-194 Mosby Year Book, St. Louis, Missouri,1994

45. Price D.D., McGrathe D.A., Rafi A., Buckingham B.: The validation of visual analog scales as ratio scales. Measures for chronic and experimental pain. Pain 1983; 17:45-56

46. Price D., Bush F., Long S., Harkins S.: A comparison of pain measurement characteristics of mechanical visual scale and simple numerical rating scale. Pain 1994;56:217-226

47. Rather P.D.: The Cold Treatment. The Runner 1983: 14

48. Rapson Linda: Acupuncture: A useful treatment modality. Canadian Family Physician 1984; 30:109-115

49. Reid D.C.: Sports Injury Assessment and Rehabilitation. First Edition; Chapter 9:215-268, Churchill Livingstone, 1992

50. Richardson P.H., Vincent C.A.: Acupuncture for the treatment of pain: A review of evaluative research. Pain 1986;24:15-40

51. Rifat S.F., McKeag D.B.: Practical methods of preventing ankle injuries. American Family Physician 1996; 53(8):2491-2498

52. Rucinski T.J., Hooker D.N., Prentice W.E.Jr., Shields E.W., Cote-Murray D.J.: The effects of intermittent compression on edema in post-acute ankle sprains. Journal of Orthopaedic and Sport Physical Therapy 1991;14(2):65-69

53. Scotece G.G., Guthrie M.P.: Comparison of three treatment approaches for grade 1 and 2 ankle sprains in active duty soldiers. Journal of Orthopaedic and Sport Physical Therapy 1992;15(1):19-23

54. Scott J., Huskisson E.C.: Graphic representation of pain. Pain 1976;2:175-184

55. Siegler S., Block J., Schneck C.: The mechanical characteristics of the collateral ligaments of the human ankle joint. Foot and Ankle 1988;8(5):234-241

56. Sim D.: Effects of positioning on ankle edema. Journal of Orthopaedic and Sport Physical Therapy 1986; 8(1):30-33

57. Sin Y. M., Sedgewick A.P. Mackay A; R. Bates M.B., Willoughby D.A. : Effect of electric acupuncture stimulation on acute inflammation. American Journal of Acupuncture 1983;11(4):359-362

58. Sports Medicine Symposium: Ankle and knee bracing: An update. Saskatoon, Saskatchewan, November 1997

59. Starkey J.A.: Treatment of ankle sprains by simultaneous use of intermittent compression and ice packs. Sports Medicine 1976;4(4):142-144

60. Stux G., Pomeranz B.: Basics of Acupuncture. Second Edition, Chapter 2;4-55 Springer Verlag, 1991

61. Takeda W.K., Wessel. J.: Acupuncture for the treatment of pain of osteoarthritic knees. Arthritis Care and Research 1994;293(8):375-378

62. Tatro-Adams D., Forrestor McGann S., Carbone W.: Reliability of the figure of eight method of ankle measurement. Journal of Orthopaedic and Sports Physical Therapy 1995; 22(4):161-163

63. Trevino S.G., Davis P., Hecht P.J.: Management of acute and chronic lateral ligament injuries of the ankle. Orthopaedic Clinics of North America 1994;25(1): 1-15

64. Vegso J.J., Harmon L.E.: Non-operative management of athletic ankle injuries. Clinics in Sports Medicine 1982;1(1):85-98

65. Vincent C.A., Richardson P.H.: The evaluation of the clinical effects of acupuncture. Pain 1983;16:111-127

66. Weston M., Taber C., Casagranda L., Cornwall M.: Changes in local blood volume during cold gel pak application to traumatized ankles. Journal of Orthopaedic and Sports Physical Therapy 1994;19(4):161-163

67. Wiley J.P., Nigg B.M.: The effect of an ankle orthosis on ankle range of motion and performance. Journal of Orthopaedic and Sports Physical Therapy 1996;23(6):362-369

68. Wilkerson L.: Ankle injuries in athletes. Sports Medicine 1992;19(2):377-392

69. Wilkerson G.B., Horn-Kingery H.M.: Treatment of the inversion ankle sprain: comparison of different modes of compression and cryotherapy. Journal of Orthopaedic and Sports Physical Therapy 1993;17(3): 240-247

70. Witte R.S.: Statistics. Chapter 14;243-258, Harcourt Brace College Publishers 1993

71. Wong J, Cheng R.: The science of acupuncture therapy. Kola Mayland Co. Hong Kong, 1987

72. Zachazewski J.E., Magee D.J., Quillen W.S.: Chapters 2:9-23; 13:229-261; 32:729-755 Athletic Injuries and Rehabilitation. WB Saunders Company, 1996

APPENDIX A

INFORMATION SHEET FOR PHYSICIANS/CLINICS

RESEARCH STUDY: The effects of acupuncture and/or ice and compression on acute second degree lateral ankle sprains.

CONTACT: Cindy Cinats, physiotherapist at pager number 480-4463 or home at 487-0923 or Callingwood Physiotherapy Clinic - 481-2293

Subjects required for this study will have sustained an acute (within 72 hours) second degree lateral ankle sprain. All subjects will be treated at Callingwood Physiotherapy and Sports Injury Clinic at #315, 6650 - 177 Street. All subjects will be treated free of charge and will be treated for a minimum of five treatments to a maximum of ten. The following are the inclusion and exclusion criteria:

INCLUSION CRITERIA: History of a lateral ankle injury within the last 72 hours, symptomatic complaints of pain, swelling on the lateral aspect of the ankle (extracapsular), solid endfeel to inversion stress, anterior drawer sign with less than 5 mm of movement compared to the normal side, decreased ROM, difficulty in weight-bearing and ambulation, and the inability to rise on toes. X-ray examination will be done if indicated to rule out a fracture.

EXCLUSION CRITERIA: Subjects will be excluded if they have the following: fractures of the lower leg or ankle, osteoarthritis of the ankle, previous major ankle problems or more than two previous sprains within the last six months, pregnancy, on anticoagulants, have a strong aversion to needles, have an inability to understand consent, have a major systemic disease - diabetes or neurological conditions, are hemophiliacs, have a sensitivity to cold or have abnormal sensation.

APPENDIX B

PATIENT INFORMATION SHEET

CONTACT: Callingwood Physiotherapy and Sports Injury Clinic at 481-2293
between 7:00AM - 9:00 PM Monday through Friday.

Ankle injuries are one of the most common sports related injuries and lateral ankle sprains account for 95% of all ankle injuries. This study will evaluate the effectiveness of 3 treatment programs for acute ankle sprains. If you would like to participate in the study and are eligible to participate, the following will occur:

You will be randomly assigned to one of the 3 treatment groups

1. Acupuncture
2. Acupuncture, ice and compression
3. Ice and compression

The treatment you receive will depend upon the protocol to which you are assigned. In addition, every subject will be instructed in mobility and strengthening exercises. You must be willing to attend daily treatments, including weekends if applicable, for the first 5 days. After that time, you rehabilitation will continue on an as needed basis.

You will be given an informed consent form to read and sign at the clinic, prior to entering the study.

Please call Callingwood Physical Therapy at 481-2293 if you would like to participate in the study. It is very important that you are entered into the study **within 72 hours of your injury**. As participation in the study is voluntary, treatments are being offered without charge.

Thank you for your time.

APPENDIX C

CONSENT FORM

Title: Effects of acupuncture and/or ice and compression on acute second degree lateral ankle sprains

Investigators: Cindy Cinats, Graduate Student, Phone: 487-0923
David Magee, Professor, Faculty of Rehabilitation Medicine, Phone: 492-5765

CONSENT:

I, _____, agree to participate in the above named project conducted by Cindy Cinats, Physical Therapist and Masters Student and David Magee, Professor, Department of Physical Therapy, University of Alberta. Acupuncture is a treatment modality presently used by some physiotherapists to treat acute soft tissue injuries. Acute lateral ankle sprains are a common musculoskeletal injury. Presently, there is no consensus as to the most effective treatment in the early phase of this injury. The purpose of this study is to compare three types of treatment in acute second degree lateral ankle sprains to determine which treatment is most beneficial.

I have read the information sheet and understand its meaning.

I understand that I may withdraw from this study at any time without any consequence and at the conclusion of the study, I will be able to continue therapy until I have returned to my normal activities. If one form of treatment appears to be superior over another, I will have the option to receive that treatment at the end of the study.

With my signature below, I indicate that I understand all that is required of me in this study, and I acknowledge receipt of a copy of the information and consent forms.

_____ _____
Investigator's Signature Participant's Signature

_____ _____
Witness's Signature Date

INFORMATION SHEET

Title: Effects of acupuncture and/or ice and compression on acute second degree lateral ankle sprains

Investigators: Cindy Cinats, Graduate Student, Phone: 487-0923
David Magee, Professor, Faculty of Rehabilitation Medicine, Phone: 492-5765

INFORMATION:

If I agree to participate in this study, I will be randomly allocated to one of three groups: those receiving acupuncture, those receiving ice and compression, and those receiving acupuncture and ice and compression. I will be asked to make a mark on a line to describe my level of pain prior to each treatment. Prior to each treatment, a physiotherapist will use a measuring tape that is applied around my ankle to measure the amount of swelling at my ankle. A physiotherapist will also use a plastic goniometer to measure the amount of movement at my ankle prior to each treatment. During my treatment, my leg will be elevated on a large cushion. I will be asked to demonstrate when I can walk full weight-bearing without pain. Further on in the study, I will be asked to perform further functional tests that will require me to hop on one foot at a time repeatedly. I will receive all of my treatment at Callingwood Physiotherapy & Sports Injury Clinic. I will receive a minimum of five daily treatments to a maximum of ten daily treatments. In addition to the treatment I receive from the group I was allocated to, I will receive common exercises to improve the movement in my ankle and to strengthen my ankle.

If I receive acupuncture, the following will occur: the physiotherapist will mark the acupuncture points with a hollow tube. The area will be swabbed with alcohol and the needle will be inserted and the physiotherapist will twirl the needle between her fingers for two minutes or until I feel an aching, numbness or heavy sensation. The physiotherapist will then insert three more needles, one at a time, in the same manner for a total of four needles. I will receive four needles at each treatment, and two different sets of points will be needled on alternate days to avoid any soreness that could occur. The points where the needles will be inserted are located below the knee on both the outside and inside of the leg, on either side of the ankle, on the front of the ankle and between the first and second toes on the top of the foot. Each needle will be left in for twenty minutes after the last needle was put in, therefore, the first needle inserted will be left in for 26 minutes, the second needle will be left in for 24 minutes, the third needle will be left in for 22 minutes and the last needle will be left in for 20 minutes. The therapist will remove the needles and dispose of them in a container for needles.

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Some potential risks of acupuncture include bleeding or pain from the needles, but the risk of side effects from acupuncture are minimal. The use of disposable, sterilized needles should prevent infection and the small diameter of the needles will minimize bleeding.

If I receive ice and compression, the following will occur: the physiotherapist will test my sensation to hot and cold by using two test tubes, one filled with hot water and one filled with ice chips and cold water. If my sensation is normal, a crushed ice pack (ice chips wrapped in a moist towel) will be applied around the outside and inside of my ankle and held in place by a four inch tensor bandage. The ice will be left on for fifteen minutes and then removed. I will be told that initially with the ice I will feel cold, then a warm sensation, followed by numbness. Some potential risks include frostbite or ice-burns, but this is unlikely to be a problem because I will be tested for normal hot-cold sensation, the ice will be applied carefully and in the proper manner, and I will be given proper instruction in what I should feel.

If I receive acupuncture and ice and compression, the following will occur: I will have my sensation to hot and cold tested by the physiotherapist using two test tubes, one filled with hot water and one filled with ice chips and cold water. When it is established that my sensation is normal, I will receive acupuncture and the following will occur: the physiotherapist will mark the acupuncture point with a hollow tube. The area will be swabbed with alcohol and the needle will be inserted and the physiotherapist will twirl the needle between her fingers for two minutes or until I feel an aching, numbness or heavy sensation. The physiotherapist will then insert three more needles, one at a time, in the same manner for a total of four needles. I will receive four needles at each treatment, and two different sets of points will be needled on alternate days to avoid any soreness that could occur. The points where the needles will be inserted are located below the knee on both the outside and inside of the leg, on either side of the ankle, on the front of the ankle and between the first and second toes on the top of the foot. Each needle will be left in for twenty minutes after the last needle was put in, therefore, the first needle will be left in for 26 minutes, the second needle will be left in for 24 minutes, the third needle will be left in for 22 minutes and the last needle will be left in for 20 minutes. The therapist will remove the needles and dispose of them in a container for needles. Following removal of the needles, a crushed ice pack (ice chips wrapped in a moist towel) will be applied

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around the outside and inside of my ankle and held in place by a four inch tensor bandage. The ice will be left on for fifteen minutes and then removed. I will be told that initially with the ice I will feel cold, then a warm sensation, followed by numbness. Some potential risks of the ice application include frostbite or ice-burns, but this is unlikely to be a problem because I will be tested for normal hot-cold sensation, the ice will be applied carefully and in the proper manner, and I will be given proper instruction in what I should feel. Some potential risks of acupuncture include bleeding or pain from the needles, but the risk of side effects from acupuncture are minimal. The use of disposable, sterilized needles should prevent infection and the small diameter of the needles will minimize bleeding.

All information will be confidential and I will not be identified by name on any reports or published materials.

****

APPENDIX D

RANDOM ALLOCATION OF PATIENTS FOR ANKLE STUDY

When subjects call to book an appointment write their name by the corresponding patient number. Advise all subjects to have a light snack before coming and to wear or bring gym shorts. Cindy can be contacted at 487-0923 or 480-4463 (pager).

For the three treatments: A = acupuncture

B = ice and compression

C = acupuncture and ice and compression

Assign A for digits 0 - 2

B for digits 3 - 5

C for digits 6 - 8

Patient Assignment:

1st pt. = 0 = A

2nd pt. = 5 = B

3rd pt. = 2 = A

4th pt. = 7 = C

5th pt. = 8 = C

6th pt. = 4 = B

7th pt. = 2 = A

8th pt. = 7 = C

9th pt. = 4 = B

10th pt. = 1 = A

11th pt. = 6 = C

12th pt. = 2 = A

13th pt. = 3 = B

14th pt. = 8 = C

15th pt. = 5 = B

16th pt. = 1 = A

17th pt. = 5 = B

18th pt. = 6 = C

19th pt. = 5 = B

20th pt. = 6 = C

21st pt. = 8 = C

22nd pt. = 1 = A

23rd pt. = 8 = C

24th pt. = 0 = A

25th pt. = 4 = B

26th pt. = 1 = A

27th pt. = 8 = C

28th pt. = 2 = A

29th pt. = 3 = B

30th pt. = 4 = B

APPENDIX E

SAMPLE SIZE CALCULATIONS

With this study, according to the literature, we expect a large effect size (ES) of .80 or more (5,10,21,26,47). There is no literature on the effects of acupuncture and acute second degree ankle sprains. One article (47), on the effects of conventional physical therapy treatment (ice and elevation) versus conventional therapy plus the use of a neuroprobe to stimulate acupuncture points, demonstrated an average difference between treatments to be 3 days (in favor of the neuroprobe). Another article (21) reviewed the effects of cryotherapy on acute ankle sprains and showed that the average number of days to full pain-free weight-bearing is 4.2.

The literature on acupuncture research (26) recommends using a power of 0.80 in order to avoid making a type two error. Therefore, using the following table (K-1 = 3-1 = 2) with a power of 0.80 and ES = 0.80, 9 subjects will need to be recruited per group for a total of 27 subjects. This research project will recruit 10 subjects per group for a total of 30 subjects.

With multiple analysis, such as was done in this study, significant differences may occur by chance alone. To avoid making a type one error, the p value will also be adjusted. $P<0.05$ will be divided by four ($\alpha 0.05/4$) (4 outcome measures of a 4 dependent variables) = $p<0.01$, power 0.80, ES = 0.80.

APPENDIX F

PILOT STUDY - CONSENT FORM

TITLE: Determination of intra-rater reliability for the figure eight method of ankle measurement for swelling and range of motion (ROM) of the ankle.

INVESTIGATOR: Cindy Cinats, Graduate Student, Phone: 487-0923

CONSENT:

I, _____, agree to participate in the above named project conducted by Cindy Cinats, Physical Therapist and Graduate Student, Department of Physical Therapy, University of Alberta. The investigator will measure the ROM at my ankle using a goniometer and will measure the distance around my ankle using a metal measuring tape. This project is an information gathering project that will not affect my physical health. There are no risks involved and I can agree to drop out of this project at any time without consequence. My name or identity will not be revealed at any time and I can be assured confidentiality.

With my signature below, I indicate that I understand all that is required of me in this study, and I acknowledge receipt of a copy of this consent form.

_____ _____

Investigator's Signature Participants Signature

_____ _____

Witness's Signature Date

APPENDIX G

PILOT STUDY RELIABILITY CALCULATIONS

$$ICC = \frac{MSB - MSW}{MSB + (K-1)}$$

$$SEM = \sqrt{MSW}$$

1. Figure 8 Method of Measurement for Swelling

$$ICC = \frac{29.6 - 0.3257}{29.6 + 0.6514} = 0.970$$

$$SEM = \sqrt{0.3257} = 0.570$$

2. Dorsiflexion (ROM Measurement)

$$ICC = \frac{34.3 - 1}{34.3 + (2)1} = 0.917$$

$$SEM = \sqrt{1} = 1$$

3. Plantar Flexion (ROM Measurement)

$$ICC = \frac{215 - 9.3}{215 + 18.6} = 0.880$$

$$SEM = \sqrt{9.3} = 3.04$$

APPENDIX H

CERTIFICATE FOR ACUPUNCTURE

The Acupuncture Foundation of Canada

JACQUELINE WILLIS, PT

Having fulfilled the requisite post-graduate study required by
the Education Committee of
The Acupuncture Foundation of Canada
and having successfully completed the
Examination in Acupuncture for Physicians, Dentists and Physiotherapists
is awarded this certificate

In witness whereof
we hereby set our hand and seal
At Toronto this 29 day
of April 1994

Director of Education

Cert. No. 93/94

APPENDIX I

TREATMENT PROTOCOL

Patient will have pre measures for ROM, pain and swelling done by Cindy. Patient will receive the treatment that they have been assigned by random allocation. Jacquie will administer all treatments. For treatments Time 1 to Time 5 the following will occur for all patients:

Time 1 - The subject will be instructed to perform dorsiflexion and plantarflexion within their pain free ROM. They will be instructed to perform this ten times every hour that they are awake. They will be instructed in proper gait and weight-bearing tolerance.

Time 2 - Same as above plus gentle dorsiflexion and plantarflexion exercises will be instructed with the foot on the floor, within the pain free range. They will be instructed to perform this ten times per waking hour.

Time 3 - They will continue with the same.

Time 4 - Active inversion and eversion will be added in addition to the above. They will perform this ten times 2-3 times per day.

Time 5 - Same

Time 6 - 10: The subject will receive individual treatment based on their improvements. The treatment will be as standard as possible to avoid any marked differences. The subjects will perform the hop test and the timed hop at the end of their treatment.

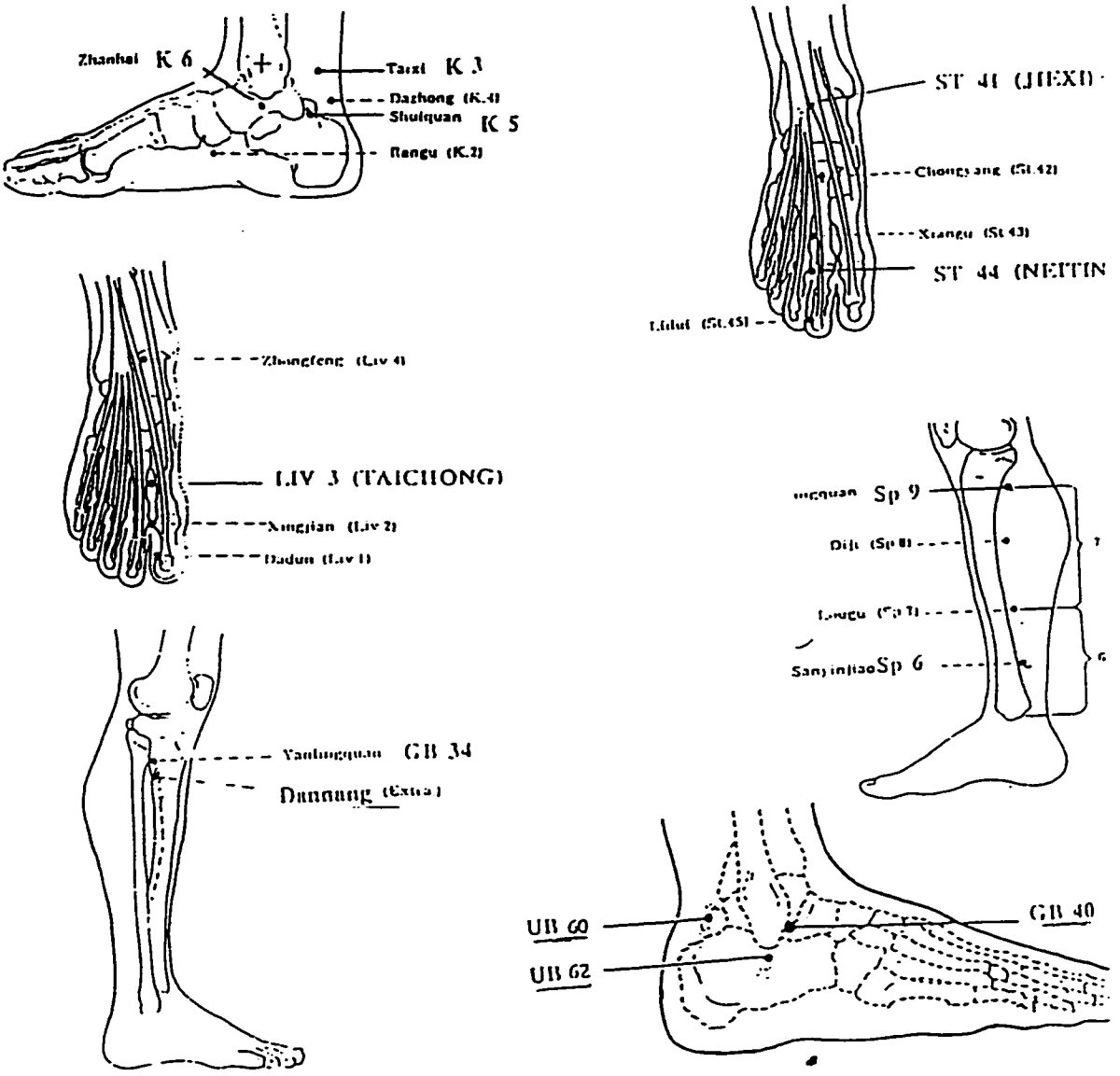
APPENDIX J

VAS

VISUAL ANALOG SCALE FOR PAIN

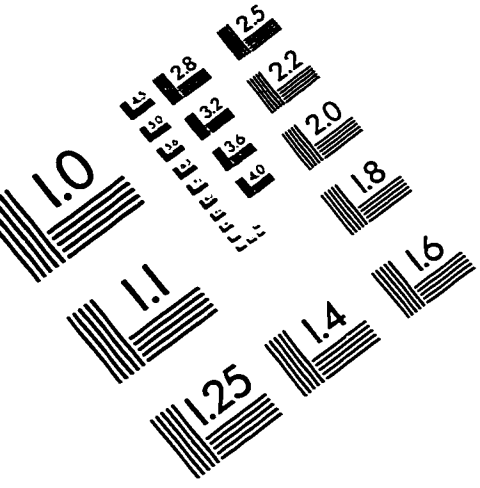
APPENDIX K

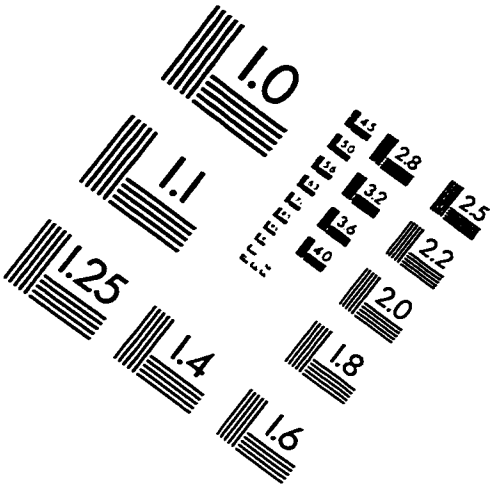
ACUPUNCTURE POINTS

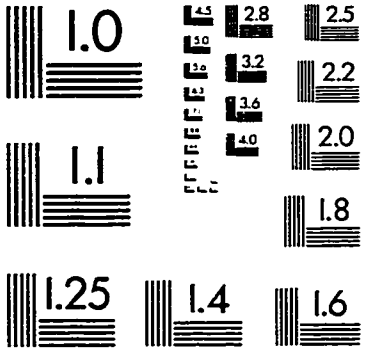


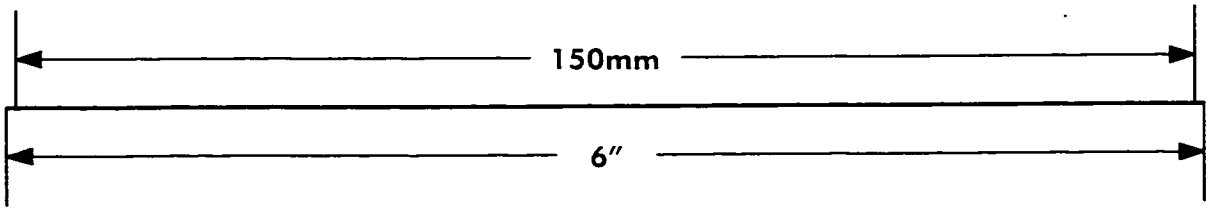
* Copied with permission from the Acupuncture Foundation of Canada Institute (AFCI).

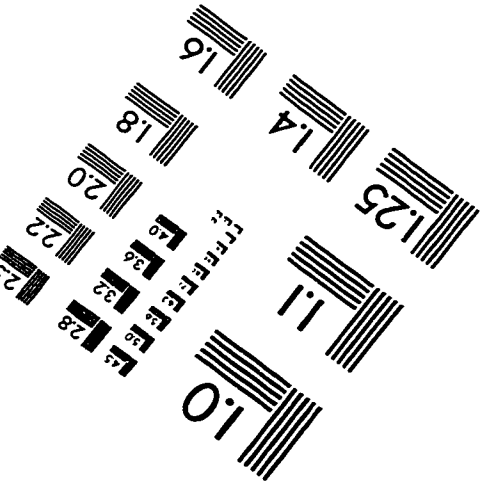
IMAGE EVALUATION
TEST TARGET (QA-3)

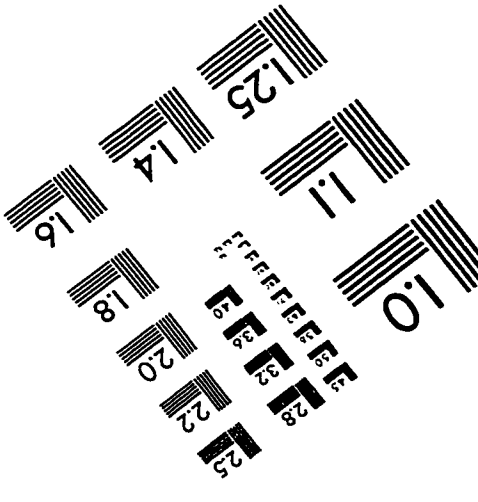












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