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UNIVERSITY OF ALBERTA

ACUPUNCTURE FOR THE TREATMENT OF PAIN OF OSTEOARTHRITIC KNEES

BY

WENDY TAEKO TAKEDA

A THESIS

SUBMITTED TO THE FACULTY OF

GRADUATE STUDIES AND RESEARCH

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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, "ACUPUNCTURE FOR THE TREATMENT OF PAIN OF OSTEOARTHRITIC KNEES", submitted by Wendy Taeko Takeda in partial fulfillment of the requirements for the degree of Master of Science in Physical Therapy.

Jean Wessel

Jean Wessel (Supervisor)

Brian Fisher (Committee Member)

Anthony Russell (Committee Member)

Date: July 29 1992

DEDICATION

This body of work is dedicated to both family and friends who have been so important in my life. To my mother Katie, who provided me with the strength to meet my goals and taught me to believe in myself. To my father Minoru, who taught me the importance of learning and living life to its fullest. To my husband Blaine, for his never-ending patience, love and support that was so vital for making my dreams become reality and making life so complete.

ABSTRACT

The purpose of this study was to determine whether true acupuncture treatments would be more effective than sham/placebo acupuncture, in reducing pain in persons with OA of the knee. The study was a double-blind, randomized, controlled clinical trial with one experimental group that received real acupuncture and one control group that received sham/placebo acupuncture. The subjects were 40 men and women (between 40 and 77 years) with radiographic evidence of OA of the knee. All subjects were treated 3 times per week for 3 weeks. They were assessed at 3 test sessions: Pretest (before treatment), Midtest (within the week following the last treatment), and Posttest (4 weeks following the Midtest). Outcome measures were: 1) the PRI of the McGill Pain Questionnaire (MPQ), 2) the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and 3) pain threshold at 4 sites at the knee. The analysis involved 4 separate 2-way ANOVAs with repeated measures (group vs. time) on the PRI and on the pain, stiffness, and physical function components of the WOMAC, and a 3-way ANOVA with repeated measures on 2 factors (group vs. treatment vs. site) for the pain threshold.

There was a decrease in pain and stiffness and an improvement in function in both groups over time, but no significant difference between groups. Acupuncture and placebo acupuncture were equally effective in reducing pain

in the osteoarthritic knee. Other findings were that men responded better to treatment than women and that subjects who regularily experienced 'Te chi' with the treatment responded better than those who did not experience this sensation.

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I would like to thank first and foremost my advisor Jean Wessel, for her advice, assistance, and support in this project which would not have been done half as well without her. She truly was a driving force behind my work and myself. Thank you to my committee member Brian Fisher, for always making me question 'why' and bringing a strong physiological background to this project. Thank you to my committee member Anthony Russell, for bringing a fresh perspective to my work and providing the expertise in the field of rheumatology.

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CHAPTER ONE

THE PROBLEM

Introduction

Osteoarthritis (OA) is a very common disease afflicting man. The knee is the large joint most often affected by OA and is the most frequent source of major problems related to disability and pain (Sissons, 1983). However, there seems to be a lack of effective treatments for OA pain. In recent years, acupuncture has been proposed as a physical treatment that could be an effective adjunct to medication for OA pain, but limited documentation on the physiological effects of acupuncture has prevented its widespread use (Bannerman, 1980).

Persons with OA have many symptoms, but the most significant and debilitating one is pain (Bombardier et al, 1982; Kantor, 1989). Bombardier et al (1982) surveyed a group of rheumatologists who unanimously agreed that pain was the single most important factor to their arthritic patients. Even though OA is not considered a severe form of arthritis, statistics have shown that persons with OA take a higher number of analgesic prescriptions than those having any other type of arthritis (Ruoff, 1986). The necessity for analgesic medications indicates that pain plays a primary role in the patient's perception of the severity of the disease.

OA (Lawrence et al, 1966; Altman, 1987). As a result, the disabilities caused by OA will continue to be a large socioeconomic burden on society. According to British studies in 1974, 2.3 percent of men and 1.3 percent of women retired from employment because of OA or related conditions (Peyron, 1984). In the United States, OA afflicts approximately 20 percent of the population and is considered the 2nd ranking cause of permanent incapacity in people over 50 years of age (Edstrom, 1977 cited in Peyron, 1984).

The initial treatment for pain in OA is generally antiinflammatory/analgesic medications. However, the success of these treatments for pain relief has been limited (Kantor, 1989). Although these medications alleviate pain temporarily, they do not necessarily affect the processes responsible for pain in arthritis (Ehrlich, 1981). As the disease progresses, the medications are less likely to reduce the symptoms, and surgery may be the only means of significantly reducing the pain (Ehrlich, 1981). Physical therapy is often prescribed at all stages of the disease, but there are few studies that have evaluated the effects of modalities and other therapies on pain and disability (Ehrlich, 1989).

Acupuncture is an ancient physical treatment involving the insertion of needles for healing purposes (Baldry, 1989). Since 1976, growing physiological evidence has suggested that acupuncture may be effective in pain

reduction. Pomeranz and Chiu (1976) first demonstrated that acupuncture could relieve pain by increasing production of endorphins and enkephalins. According to Han and Terenius (1982), acupuncture stimulates the afferent pathways which eventually impact on the endogenous antinociceptive system. In support of this theory, Rapson (1984) points out that most acupuncture points correspond to the location of motor points, peripheral nerves or musculotendinous junctions.

Acupuncture might also reduce pain in OA, by reducing inflammation (Sin et al, 1983). Sin et al (1983) suggested that acupuncture may reduce the number of chemotactic agents and possibly decrease vascular permeability of damaged cells. In other studies, acupuncture reduced the number of leukocytes in experimentally-induced inflammation in rats (Sin et al, 1983) and increased phagocytic activity in these animals (Min, 1983).

There are many testimonials to support acupuncture as an effective treatment for OA pain (Zhang, 1982; Arichi et al, 1983). Researchers (Zhang, 1982; Lee et al, 1975; Junnila, 1982) have reported that acupuncture reduced pain symptoms in those with osteoarthritis, but they were unable to demonstrate this in randomized controlled trials.

Gaw et al (1975) examined the efficacy of acupuncture for OA in a randomized controlled study. They reported no significant difference between the placebo acupuncture and true acupuncture groups. However, there were several

problems with their study. The subjects were treated only once a week, a frequency that may not have been sufficient to produce analgesia. All 40 subjects had OA, but the joint that was affected by OA varied: hip, knee, lumbar spine, thoracic spine, cervical spine, and fingers. Because the subjects were not stratified according to gender, the researchers may not have accounted for possible gender differences in response to treatment (Bhatt-Sanders, 1985). Subjects were to stop taking medications 7 days prior to the start of study, but those that were unable to stop medications over this time period were still included in the study.

The present study has dealt with some problems found in the previous study. For example, subjects were treated 3 times per week, all subjects had OA in their knee(s), subjects were stratified by gender, and all subjects remained on their present medications (no change in dosage) throughout the study.

Purpose of the Study

The purpose of this study was to determine whether manual acupuncture treatments would be more effective than sham/placebo acupuncture, in reducing pain in persons with OA of the knee.

The specific aims of this study were as follows:

1. To determine whether acupuncture (used as an adjunct to

treatment with medication) increased the local pain threshold of the knee.

2. To determine whether acupuncture decreased pain during activity, stiffness and physical disability in persons with OA of the knee.
3. To describe changes in pain quality that occurred with acupuncture treatment.

Definitions

Acupuncture is an ancient Chinese medical treatment involving the deep insertion of fine needles into specific body points (acupoints) accompanied by twirling or stimulation of the needle to elicit Te chi (Bhatt-Sanders, 1985).

Placebo/Sham Acupuncture is the superficial insertion of needles into non-traditional acupuncture points. There is no stimulation and Te chi is not elicited (Bhatt-Sanders, 1985).

Te chi is a local sensation of heaviness, soreness, numbness or paraesthesia that accompanies deep insertion of the needles during "real" acupuncture (Bhatt-Sanders, 1985).

Acupoint is a traditional Chinese body point that is thought to have an effect on a particular organ or organ system (Rapson, 1984). There are approximately 311 traditional body points and virtually all are located where peripheral nerves and/or their branches terminate

(Macdonald, 1989; Rapson, 1984).

Pain Threshold is the lowest stimulus value at which the subject reports that a pressure changes to a discomfort or a pain (Melzack and Wall, 1988; Fischer, 1987).

Algometer/Dolorimeter is a device used to measure the quantity of a stimulus required to evoke pain (Simmonds, 1990).

Delimitations

This study was delimited to:

1. The testing of subjects, 40-77 years old, with painful osteoarthritis in the knee.
2. The measurement of pain threshold with a pressure dolorimeter.
3. Assessment of pain, stiffness and functional disability as measured by the WOMAC OA Index.
4. Assessment of pain quality as measured by the MPQ.
5. The application of acupuncture or placebo/sham acupuncture.

Limitations

The study was limited by:

1. The reliability of the pressure dolorimeter r=0.9 (Scudds and Fischer, 1988; Wessel, 1991).
2. The reliability of the WOMAC OA Index r=0.61-0.91 (Bellamy et al, 1988).

3. The ability of the subjects to fully comprehend and complete the MPQ.
4. The ability of the therapist to apply acupuncture needles in a similar manner with all subjects.

Research Hypothesis

Acupuncture and medication is more effective than medication alone, in reducing pain in osteoarthritic knees.

The null hypothesis was: the mean change in pain with acupuncture treatment = the mean change in pain with placebo/sham acupuncture.

CHAPTER TWO

REVIEW OF THE LITERATURE

Overview

This chapter is comprised of four sections. The literature has been reviewed in the areas of osteoarthritis, acupuncture, osteoarthritis and acupuncture, and measurements for pain and function.

First, the pathology, etiology and pain in osteoarthritis are summarized. Then, the history and physiological basis for acupuncture are introduced to the reader. To tie acupuncture and OA together, the efficacy of acupuncture in OA and the potential problems with acupuncture studies are addressed. Measures that can be used for different dimensions of pain and different aspects of function are also discussed in this chapter.

Osteoarthritis

a. Pathology

Osteoarthritis (also known as degenerative joint disease or osteoarthrosis) has been described as a slow progressive disease of unknown etiology and ambiguous pathogenesis affecting primarily the hands and the large weight-bearing joints of the body (Mankin, 1989). There are many gross joint changes that occur in OA: capsule thickening, subchondral bone sclerosis, synovial inflammation, osteophyte formation, and subchondral cysts.

However, the primary change is a progressive loss of articular cartilage (Moskowitz and Goldberg, 1988). The articular cartilage may not be the first site of abnormality in OA, but is the structure most severely affected by this disease (Altman, 1987; Mankin and Brandt, 1989). The cartilage, once firm, white and gleaming; becomes soft, yellowish and dull in OA (Mankin, 1989; Rodnan and Schumacher, 1988).

Normal articular cartilage is composed primarily of type II collagen, water and fibronectin (Mankin and Brandt, 1989). In addition, proteoglycans (95% carbohydrates and 5% proteins) although small in quantity, have an important role in the normal functioning of the cartilage (Fisher, 1991). Proteoglycans combine with hyaluronic acid in the normal cartilage to form larger molecules called proteoglycan aggregates. Researchers (Maroudas et al, 1986; Mankin and Thrasher, 1975) have observed that these aggregates are important for absorbing water, providing nutrition to the joint and giving resilience to the cartilage when stresses are applied to it.

In the OA joint, the normal articular cartilage has undergone many changes to become pathological. Mankin and Brandt (1989), in their review article, reported that the water content of the cartilage increases according to the severity of OA. The excess water weakens the collagen fibers of the cartilage. Also, the concentration of

proteoglycan aggregates decreases as a result of: 1) an increase in lysosomal enzymes which attack the core proteins and 2) a change in proportion of the carbohydrate units or glycosaminoglycans (Mankin and Brandt, 1989). An unknown insult releases these lysosomal enzymes and collagenase from chondrocytes (Ehrlich et al, 1977 and 1978), disrupts the stability and function of the articular cartilage and results in destruction and degradation of the cartilage's matrix, proteoglycans and collagen (Moskowitz et al, 1979). Immune responses may be generated in OA, accelerating destruction of cartilage and additional tissues (Moskowitz and Goldberg, 1988).

Pathological changes in bone also occur in OA (Mankin and Brandt, 1989). The actual mechanism producing osteophytes has not yet been determined, but these bony masses that form at the margins of the joint have been attributed to a variety of causes: blood vessels penetrating the cartilage layers, abnormal healing of stress fractures, or venous congestion (Trueta, 1968 cited in Mankin and Brandt, 1989; Swanson and Freeman, 1970 cited in Mankin and Brandt, 1989). OA may also give rise to subchondral cysts caused by synovial fluid under pressure. In the later stages of OA, subchondral bone sclerosis and degeneration occur (Landells, 1953 cited in Mankin and Brandt, 1989). The subchondral bed thickens when the underlying trabeculae decrease in size and number (Radin et

al, 1991).

b. Etiology

Epidemiological studies (Lawrence et al, 1966; Altman, 1987) have indicated that the prevalence of OA increases with age. Increasing age does not necessarily lead to OA, but changes that occur with age, in the soft tissues and bone, may help facilitate the development of the disease (Mankin and Brandt, 1989). These changes could include an alteration in the peripheral nervous system or an imbalance of proteoglycan chains (increased chondroitin-4-sulfate, decreased keratin-sulfate), as was described earlier in the pathology section (Mankin and Brandt, 1989).

The role that trauma plays in the development of OA could be quite extensive, but is still under investigation. It is universally recognized that fractures that have not been properly reduced or that allow for hypermobility of the joint will lead to OA (Mankin, 1989). Donohue et al (1983) observed that mal-aligned bone produced loads that could break cross-links in the cartilage matrix (Freeman, 1975 cited in Radin et al, 1991). These cross-links are important for prevention of swelling of the hydrated proteoglycans. Ligament injuries have also been associated with post-traumatic OA in the knee. Ruptured ligaments that were not adequately stabilized with surgery resulted in severe radiographic changes in the knee (Kannus and

Jarvinen, 1987; Kannus, 1988).

Other possible mechanical causes for OA were noted by Reilly and Mertens (1972) and Radin et al (1991) who reported progressive cartilage deterioration in animal models from repetitive impulsive loading on the joint. Impulsive loads include acute dislocation of the patella or a rapidly applied load that induces microscopic damage to the bone and cartilage (Radin et al, 1991).

Increased body weight is considered a risk factor for OA and is primarily associated with OA of the knee (Hartz et al, 1986). A decrease in the body mass index (2 units or more) has been reported to significantly reduce the progression of OA in the knee (Felson et al, 1992). Obesity (body mass index greater than 30) has only been reported as a risk factor for OA in women (Hartz et al, 1986; Davis et al, 1989). Mankin and Brandt (1989) have considered that the impact of obesity on OA may not be limited to increased load on the joints. They (Mankin and Brandt (1989) suggest obesity may also affect the metabolic, genetic and neural factors in OA.

Race affects the prevalence and distribution of affected joints probably due to differences in occupation, lifestyle, and genetic predisposition (Moskowitz and Goldberg, 1988). For example, OA of the knee is more common in black African women than in caucasian women (Ebong, 1985). However, further studies are still required to

estimate the incidence of OA in a particular race or culture.

c. Pain

Rheumatologists agree that pain is the most important symptom in OA, and is why patients seek medical help (Bombardier et al, 1992). Pain in OA can be caused by a variety of physiological and psychological mechanisms.

There is evidence to suggest that inflammation decreases nociceptive thresholds and produces an afterdischarge of the nociceptors that may result in persistent pain (Campbell et al, 1989). Cooke (1983) has suggested that inflammation could be the initial insult that changes nonpainful OA to painful OA. Also, chronic inflammation has been reported (Dieppe et al, 1984; Levine, Coderre and Basbaum, 1988) to release various noxious chemical substances that could contribute to the pain cycle: bradykinins, histamines, prostaglandins, leukotrienes and interleukins. These chemical substances are detected by muscle, joint and skin receptors (nociceptors) that send the information to the CNS and activate neurones within the somatosensory cortex. This information may be interpreted as pain (Guilbaud, 1988). There is evidence to suggest that other pain-enhancing neuropeptides in the CNS are also activated in diseases such as OA. These substances include: substance P, neurokinin A, neurokinin B, and calcitonin

gene-related peptide (CGRP) (Levine et al, 1988).

Soft tissue and bone are also involved (Levine et al, 1988; Guilband, 1988) in the production of pain. In OA, overstretching of the capsule and ligaments surrounding the joint can lead to muscle spasm and pain (Dieppe et al, 1984). Galletti et al (1990) observed that subjects with OA of the knee experienced lower pain thresholds and lower muscle density than normal subjects. They and others (Brucini et al, 1981) speculated that low pain thresholds caused reflex inhibition and pain with activity (Brucini et al, 1991; Galletti et al, 1990). Remodelling of the subchondral bone may be another cause of pain in OA by: 1) nerve impingement from osteophytes and 2) periosteal irritation, as eburnation elevates the periosteum to the surface (Dieppe et al, 1984).

Psychological factors were reported to be important in OA (Summers et al, 1988). Summers et al (1988) determined that emotions such as anxiety and depression were important in the expression of pain and functional impairment in persons with OA. For example, Summers et al (1988) reported that OA patients labelled as depressed had elevated degrees of affective pain, present pain intensity and functional disability. However, it is not known whether the depression preceded or followed the painful condition. Also, it is well-documented that emotional stress can increase pain according to the "pain-anxiety-tension cycle" (Craig, 1989);

pain produces anxiety, causing muscle tension/release of chemical substances resulting in more pain and anxiety and the cycle continues.

Other authors (Dubuisson and Melzack, 1976) have found that people perceive pain differently, but there are key words that persons with OA have used to describe their pain. Some words that describe the sensory qualities (spatial, pressure, thermal) of pain included: tingling, aching, and tender (Nolli et al, 1988). However, some words that described the affective (tension, fear - tiring, sickening) and evaluative (overall pain experience - annoying, agonizing) components of pain were also chosen.

The pain experience is often different for men and women. Generally, women with OA in their knees express pain and dissatisfaction more frequently than men (Hochberg et al, 1989; Crook et al, 1984). Buckelew et al (1990) found that older men were more likely to rely on external coping strategies or passive loci of control to decrease the pain and women were more likely to utilize active coping strategies. Crisson and Keefe (1988) defined persons with an internal locus of control, as individuals who believe there is a causal relationship between their actions and the pain outcome they experience. Individuals with an external locus of control feel their pain is controlled by outside influences such as chance, powerful others or fate. However, when geriatric patients with chronic pain were

treated on a rehabilitation program, there was no significant difference between men and women in their response to treatment (Middaugh et al, 1989).

d. Osteoarthritis of the Knee

The knee is the large joint most often afflicted by OA (Sissons, 1983). The highest prevalence of OA knees was found in those over the age of 60 (Massardo et al, 1989). One major survey (Davis et al, 1989) reported that bilateral OA was more common than unilateral OA and twice as prevalent in women than in men (Davis et al, 1989). The severity of the disease has been reported to be greater in women than in men (Kaplan, 1983). Felson et al (1987) reported that 31% of the women with radiological evidence of OA of the knee had clinical symptoms, as compared to only 21% of the men. Davis et al (1989) also found that a large majority of men had knee injury prior to the onset of OA.

Researchers undertaking radiographic studies observed that the medial compartment of the knee was subject to the greatest degree of change in those with OA (Massardo, Watt, Chushnaghan, Dieppe, 1989). However, the radiographic changes seem to occur slowly over time. Some researchers reported no change in their subjects over an eight year time period (Massardo et al, 1989). Also, the amount of pain experienced has not been found to correspond to the radiographic disease severity (Schaible, Neugebauer,

Schmidt, 1989).

Acupuncture

a. History

Acupuncture was developed thousands of years ago in China. The earliest record of its use was in 2696 B.C. (Man and Chen, 1972). Acupuncture derived its name from the Latin words "acus" which means sharp or needle, and "punctura" which comes from the verb to pierce or to puncture (Macdonald, 1989; Bannerman, 1980). In the traditional practice of acupuncture, acupuncture is described as the insertion of needles for the relief of pain and the treatment of disease (Rapson, 1984).

Credibility for acupuncture as a science did not develop smoothly for several reasons. For example, acupuncture's popularity fell with the introduction of Western medicine. Any form of Traditional Chinese Medicine was considered ineffective (Man and Chen, 1972). Also, the Western researcher remained skeptical, because of a lack of communication with Eastern (often Communist) countries and a lack of knowledge of the physiological rationale behind acupuncture (Stux and Pomeranz, 1989; Man and Chen, 1972).

In the early 1970's, acupuncture came to the forefront in the West (Rapson, 1984). The media coverage of Nixon's 1971 trip to China was the catalyst that motivated western researchers to take a second look at acupuncture (Rapson,

1984; Stux and Pomeranz, 1989). With the renewed interest in the subject and the increase in basic studies, researchers were able to claim that acupuncture did have a physiological basis (Mayer et al, 1977; Pomeranz and Chiu, 1976).

b. Physiological Basis

Researchers initially hypothesized that acupuncture was a placebo or a form of hypnosis (Moret et al, 1991). However, numerous authors (Man and Chen, 1972; Melzack, 1989; Rapson, 1984) have reviewed the literature and found that acupuncture produces a much greater analgesic effect than can be accounted for by placebo alone. Moret et al (1991) examined the relationship between hypnosis and acupuncture and observed that subjects who were responsive to acupuncture, often did not respond to hypnosis. In addition, Barber and Mayer (1977) reported that hypnotic analgesia was not naloxone (a strong opioid antagonist) reversible. However, there is sufficient evidence to indicate that acupuncture analgesia is naloxone reversible (Mayer et al, 1977; Pomeranz and Chiu, 1976).

Peripheral nerve transmission has been very important for a successful acupuncture response (Melzack, 1989). Han et al (1986 cited in Melzack, 1989) found that local injections of procaine (a local anaesthetic) into acupuncture points blocked acupuncture analgesia in the

painful area. Also, morphologically, the acupuncture points have been reported to be closely adjacent to termination points of peripheral nerves or their branches (Macdonald, 1989). Chen et al (1986 cited in Macdonald, 1989) found that in rabbits, acupuncture analgesia was the greatest when Type III and IV afferent fibers in the muscle and the A-delta and C-fibers in the cutaneous tissue were stimulated.

Acupuncture does not elicit a purely peripheral response. Han (1989) blocked C-fibers in rats and still found the abolishment of the withdrawal response of the rats' hind limbs to noxious heat with acupuncture. C-fibers were not essential for effective acupuncture analgesia in rats. The Research Group of Acupuncture Anaesthesia (1986 cited in Macdonald, 1989) found that acupuncture analgesia often transversed many peripheral nerves and segmental boundaries. Xue (1986 cited in Macdonald, 1989) also observed that acupuncture given to the stump of a subject with a below-knee amputation resulted in sensations radiating downwards into the phantom limb as far as the absent foot. These findings illustrated that the central nervous system was also involved in the acupuncture process (Melzack, 1989). For example, in paraplegics and hemiplegics, acupuncture analgesia was not achieved in the affected soft tissues (Chang, 1978). In rat studies, Pomeranz and Chiu (1974) found that spinal cord transection resulted in almost total abolishment of the analgesic effect

of acupuncture.

Melzack (1989) has summarized the possible mechanisms of acupuncture. He stated that intense inputs activate the peripheral system projecting information to the spinal cord and on to the brainstem. In the CNS, the information is processed and the serotonergic and endorphin systems are activated, resulting in direct and indirect inhibition of nociceptive activity. See Figure 2.1.

In 1975, Mayer et al (1977) isolated the first endogenous opioid peptides and their receptors. Opioid peptides or endorphins are naturally-occurring polypeptides that mimic narcotic analgesics. The opioid peptides are found in large quantities in the pituitary gland, the periaqueductal gray matter of the midbrain, the medulla and the spinal cord. These substances provided a centrally-mediated humoral basis for explaining the acupuncture phenomena (Watkins and Mayer, 1982). Stux and Pomeranz (1985) reported a high correlation between acupuncture analgesia and morphine analgesia; rats that responded well to morphine, also responded well to acupuncture. Watkins and Mayer (1982) suggested that the type of stimulus (intensity, frequency, duration) could determine whether there is an opiate or a non-opiate (serotonergic) pain control system involved. For example, in monkey studies, Huang (1986) discovered that electroacupuncture given at 2 Hz was naloxone reversible, but at 80 Hz was not.

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Figure 2.1: The 'Central Biasing Mechanism' (Melzack, 1989) is involved in the relief of pain by intense stimulation at a distant site (acupuncture). Large (L) and small (S) afferent fibers activate neurons in the spinal cord that increase the neuronal activity at higher centres. The central biasing mechanism originates in the brainstem. It acts as an inhibitory feedback system (modulates activity) where increased input to the system increases the inhibition

Mayer et al (1977) and Pomeranz and Chiu (1976) were the first researchers to discover that naloxone reversed the effects of acupuncture. However, Moret et al (1991) were unable to replicate this finding. As a result, the opiate receptors rather than the opioid substances were examined (Peets and Pomeranz, 1978). Peets and Pomeranz (1978) observed that mice deficient in opiate receptors had markedly less analgesia with acupuncture than those with normal opiate receptors. Stux and Pomeranz (1989) have reported that 15-20% of rats do not respond to acupuncture. Similar findings in the clinical setting, suggest that some people may inherently have a lower number of opioid receptors.

Osteoarthritis and Acupuncture

a. Acupuncture Studies for OA

There are few solid clinical studies that have adequately addressed the efficacy of acupuncture in OA (Gaw, Chang and Shaw, 1975). Bhatt-Sanders (1985) has indicated that research in the areas of acupuncture and the rheumatic diseases has been primarily focused on rheumatoid arthritis. However, the National Institutes of Health concluded that in the rheumatic diseases, acupuncture would be best studied in non-inflammatory arthritis such as OA (Plotz et al, 1974).

There have been some clinical studies that did examine acupuncture in the treatment of OA. Junnila (1986) compared

acupuncture with the drug piroxicam in persons with OA in their knees. She concluded that acupuncture reduced pain better than piroxicam. However, this study was not without its problems: 1) only sixteen subjects were non-randomly allocated to each group, 2) the number of treatments given to subjects varied (ranged from 1-9) and 3) the outcome measures reflected crude changes in the quantity of pain, but not changes in the quality of pain nor changes in function (Junnila, 1982). Gaw et al (1975) randomly allocated 40 OA subjects to a placebo acupuncture group or a true acupuncture group. Subjects and assessor were blinded to group assignment. Subjects had a variety of joints affected: knee, hip, lumbar spine, thoracic spine, cervical spine and finger joints (Gaw et al, 1975). No significant differences in joint tenderness, sensation of pain and joint range of motion were found between the two groups. No gender differences were addressed in this study (Gaw et al, 1975).

Most researchers agree that acupuncture is primarily for the reduction of pain in the rheumatic diseases (Plotz et al, 1974). However, there has been some evidence to suggest that acupuncture also has an anti-inflammatory or an immune response (Plotz et al, 1974; Ionescu-Tirgoviste et al, 1991). Min (1983) demonstrated in rats that acupuncture was able to enhance the phagocytic activity of the reticulo-endothelial system. This was an important finding, because

the arthritic condition often impedes phagocytic activity. Sin et al (1983) observed that acupuncture treatments would also decrease the number of leukocytes within the endothelial cells in carageenan-injected rats. Sin et al (1983) concluded that acupuncture could be used as a treatment in the rheumatic diseases, and that this treatment did not have the serious side effects associated with antiinflammatory drugs.

Lundeberg et al (1991) suggested that acupuncture could also have compromising effects on the immune response. Opiate substances have been shown to modulate the immune response by activating the autonomic nervous system. In mice studies, Lundeberg et al (1991) observed an increase in IgM plaque-forming cells (PFC) in vivo with acupuncture treatments. These results appeared to indicate that enhancement of PFC levels by acupuncture was due to stimulation of the sympathetic nervous system (Lundeberg et al, 1991). In this study, the increases in immunoglobulins were attributed to increased activity of non-specific T-lymphocytes. In idiopathic OA, immunoglobulins were found in higher concentrations than normals (Cooke, Bennett and Ohno, 1980 cited in Moskowitz and Goldberg, 1988). This study suggests that although acupuncture may reduce pain, it may also accelerate the immune response in an inflammatory disease.

b. Limitations of Acupuncture Studies

In general, acupuncture studies have been difficult to administer, because of several factors (Bhatt-Sanders, 1985; Plotz et al, 1974; Lee and Yang, 1985). First, there is no accepted standard method of applying acupuncture. Second, there are different forms of acupuncture stimulation and application. Third, 'placebo' acupuncture is difficult to define. Finally, there were problems with the measurements and designs in previous studies (Riscalla, 1979).

In Traditional Chinese acupuncture, not only have different methods been used, but often different acupuncture points were used for the same condition (Vincent and Richardson, 1986). The acupuncturist has not been guided in terms of the number of treatments, the depth of penetration of needle, the angle of penetration, the width of needles nor the exact duration of each treatment (Bhatt-Sanders, 1985; Vincent and Richardson, 1986).

In addition there are many forms of acupuncture. For example, acupuncture can be performed with needles alone, needles and electrical stimulation, electrical stimulation alone (TENS), laser or burning herbs (moxibustion). Takeshige (1989) stated that activation of the specific pain inhibitory system is dependent upon the stimulus given. For example, TENS over acupuncture points can be high frequency or low frequency. Although both methods have been reported to relieve pain (Huang, 1986), only the low frequency TENS

was naloxone-reversible. Also, there were reports that manual stimulation with the needles was more effective than electrostimulation (Stux and Pomeranz, 1989). The physiological mechanisms involved in producing analgesia may be different according to the type of acupuncture treatment given, even if the result is similar (Stux and Pomeranz, 1989; Macdonald, 1989).

There is no perfect placebo for needle acupuncture (Vincent and Richardson, 1986). A true placebo requires a psychological effect without a physiological effect. Needles not inserted, but taped to the skin, did not appear to elicit a true placebo response (Lee and Yang, 1985). Non-acupuncture placebo produces no physiological effect, but it may not produce the desired psychological effects either (Vincent and Richardson, 1986). Instead, most researchers (Bhatt-Sanders, 1985; Lee and Yang, 1985) recommend a superficial placement of needles into incorrect sites (non-acupuncture points) without added stimulation. However, Lewith and Machin (1983) reported that even with this technique, reductions in pain occurred in 50% of subjects, a higher rate than expected with placebo.

The last problem in designing acupuncture studies, especially in the rheumatic diseases, has been that the measurement tools were generally very limited (Bhatt-Sanders, 1985). In reviewing the literature, Bhatt-Sanders (1985) has commented that the use of unidimensional pain

indices was very common. Few tried to incorporate the use of more complex measurements, such as the McGill Pain Questionnaire (MPQ). The author (Bhatt-Sanders, 1985) has also suggested a need for studies to have a double-blinded design. Although the acupuncturist cannot be blinded, some bias can be eliminated by a third-party tester who is blinded to group allocation.

Measurement of Pain and Function

Bellamy and Buchanan (1986) reported that the most common problems expressed by persons with OA of the knee or hip were pain, stiffness and limitation in functional activities. The following sections describe various measurement tools used for the evaluation of different aspects of pain and function. These measurements include: the visual analogue scale (VAS), the MPQ, the pressure dolorimeter, and the functional index.

a. Visual Analogue Scale (VAS)

The visual analogue scale (VAS) is a 10 cm line (vertical or horizontal) with verbal descriptor endpoints that represent each extreme of pain (Langley and Sheppeard, 1984). In most studies (Langley and Sheppeard, 1984; Badley and Papageorgiou, 1989), 'no pain' has been used at the lower end of the scale and verbal descriptors such as 'extreme pain', unbearable pain' or 'worst pain ever' at the

upper end.

The VAS is a valid, sensitive and reproducible instrument that is easy to administer and understand (Huskisson, 1983). Badley and Papageorgiou (1989) reported that the VAS was used extensively in studies of people with rheumatic diseases to measure the quantity of overall pain at rest. However, they found that subjects often reported no overall pain at rest on the VAS, when they would record pain on movement on the VAS (Badley and Papergeorgiou, 1989). Therefore, more than one VAS may be required.

b. McGill Pain Questionnaire (MPQ)

The McGill Pain Questionnaire (MPQ) is a multidimensional instrument that uses word descriptors to delineate the sensory, affective and evaluative components of pain (Melzack, 1975). Melzack and Torgerson (1971) were the first to classify 78 adjectives into three classes and 20 subclasses describing the pain experience. The three classes were: 1) sensory (subcategories 1-10) - temporal spatial, pressure and thermal qualities 2) affective (subcategories 11-15) - feelings that the pain experience brings out and 3) evaluative (subcategory 16) - describing the overall pain experience. The subcategories 17-20 were added at a later date and classed as miscellaneous qualities (sensory, affective, and evaluative) (Reading, 1989). The MPQ was the first pain measurement tool that deviated from

the typical unidimensional pain rating scales (Reading, 1989). See Appendix A.

The MPQ is a valid and reliable instrument (Melzack, 1975). Kremer and Atkinson (1981) claimed the MPQ had construct validity, because chronic pain patients who had higher scores in the affective components of the MPQ also had higher scores on depression and anxiety scales. Reading (1982) observed that subjects with acute pain limited their descriptions to only the sensory words in the MPQ. However, those with chronic pain exhibited a greater need for the affective or evaluative word descriptors.

The MPQ has been used to describe the pain experience for different conditions: arthritis, cancer, labour pain, post-herpetic pain, and toothache (Dubuisson and Melzack, 1976). A few indices have been developed to try to quantify pain using the MPQ, but there is still some difficulty in encapsulating the pain experience into one value (Reading, 1989). One method is to compute the Pain Rating Index (PRI), which gives each word a rank value (Reading, 1989). The PRI is the total of the values of the words chosen. This method is limited because affective words have higher scaled or weighted values than sensory words, even though the rank of the words may be the same (Melzack et al, 1985). As a result, Melzack et al (1985) developed a new system of weighted rank values that would give more meaning than the simple rank values. For example, 'throbbing' and 'vicious'

both have a ranking of 4, but on this new weighting scale have values of 2.68 and 4.26 respectively.

c. Pressure Dolorimeter/Algometer

As early as the Victorian days, a crude force gauge instrument was used for the assessment of analgesia (Keele, 1954). Today, the instrument has been modified, but is still used for the evaluation of pain. This gauge is called the pressure algometer or the dolorimeter. The most recent versions of these instruments were developed by Fischer (1987). The instrument is a pressure (force) gauge with attachments of various sizes that interface with the part being evaluated for pain (Fischer, 1987). The dolorimeter has been used for evaluating hypersensitive spots, fibrositis, trigger points, arthritis activity and visceral pain-pressure sensitivity (Fischer, 1987).

The pressure dolorimeter can be used both to measure pain threshold and pain tolerance, but most research studies rely on the dolorimeter as a measure of pain threshold (Tunks et al, 1988; Ohrbach and Gale, 1989). Pain threshold can be defined as 'the minimum pressure which induces pain or discomfort'(Fischer, 1987). The instrument has a range of 11 kg and was both valid (Scudds and Fischer, 1988) and reliable r=0.85-0.96 (Wessel, 1990) for subjects with OA in their knees.

Gerecz-Simon et al (1989) examined pain thresholds in

arthritic diseases. They found that overall, women had much lower pain thresholds than men. This is consistent with other findings in myofascial pain syndrome patients (Schiffman et al, 1988). Also, they (Gerecz-Simon et al, 1989) observed that those with osteoarthritis had higher pain thresholds than healthy subjects and those with rheumatoid arthritis. Neutral points on both sides of the body were used to evaluate the subjects' overall pain sensitivity. However, O'Driscoll and Jayson (1974) found that although persons with OA hips not awaiting surgery did have higher pain thresholds than normals, those awaiting surgery had significantly lower pain thresholds than normals. The difference between this study and Gerecz-Simon et al (1989)'s study was that Gerecz-Simon et al (1989) did not include OA subjects who were awaiting surgery.

d. Functional Indices

Functional indices measure how well a person is functioning within his/her environment and describe the impact of disease on a person's life. In the past, many functional indices were introduced to evaluate health status in various arthritic and chronic pain conditions (Liang et al, 1985). The most commonly used functional indices for arthritis include: 1) the Arthritis Impact Measurement Scales (AIMS), 2) the Functional Status Index (FSI), and 3)

In the past, the modified Doyle and Lequesne were the only functional indices specific to OA populations (Bellamy and Buchanan, 1986). Indices developed for rheumatic diseases were primarily designed for rheumatoid arthritis (RA) patients (Bellamy and Buchanan, 1986). However, the clinical manifestations and disabilities that develop in OA are different than those in RA and other rheumatic diseases (Bombardier and Tugwell, 1987). The Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index was developed in response to this need for an OA-specific, multidimensional, functional index (Bellamy et al, 1988).

The WOMAC OA Index is a functional index designed specifically for persons with OA of the knee and/or hip (Bellamy et al, 1988). The WOMAC is divided into 3 dimensional components: stiffness, pain, and physical function (Bellamy et al, 1988). Aggregate scores are calculated for each dimension by summing component item scores. Each dimension is composed of various questions that require responses on a horizontal VAS. The complete questionnaire is in Appendix B. Each question is answered according to the subjects' experiences within the last 48 hours.

Each dimensional component of the instrument had construct validity; the index was able to represent a change between the control and experimental groups (Bellamy et al,

validity by correlating the components to the Doyle and Lequesne Indices: stiffness r=0.27-0.47, pain r=0.57-0.62, physical function r=0.56-0.59). Finally, the instrument was found to be reliable: stiffness (r=0.61), pain (r=0.81), and physical function (r=0.91) (Bellamy et al, 1988).

CHAPTER THREE

MATERIALS AND METHOD

Research Design

This was a double-blind, randomized, controlled clinical trial with one experimental group that received real acupuncture treatment and one control group that received placebo/sham acupuncture. Subjects were stratified by sex, because of the possible gender differences in response to treatment, and randomly allocated to groups in blocks of four. Measurements of pain threshold, pain intensity and pain quality were taken before and after 3 weeks of treatment (or placebo treatment), and at follow-up 4 weeks later (refer to Figure 3.1).

Subjects

Subjects were 40 volunteers (20 men, 20 women) with grade I-IV OA (Kellgren et al, 1963) of the affected knee. Subjects had an x-ray of the affected knee(s) within the last 5 years. Prior to the subject's participation in the study, physicians were contacted to verify the radiological grade of OA.

Inclusion criteria consisted of the following:

1. Pain in one or both knees
2. Joint space narrowing of medial compartment (on

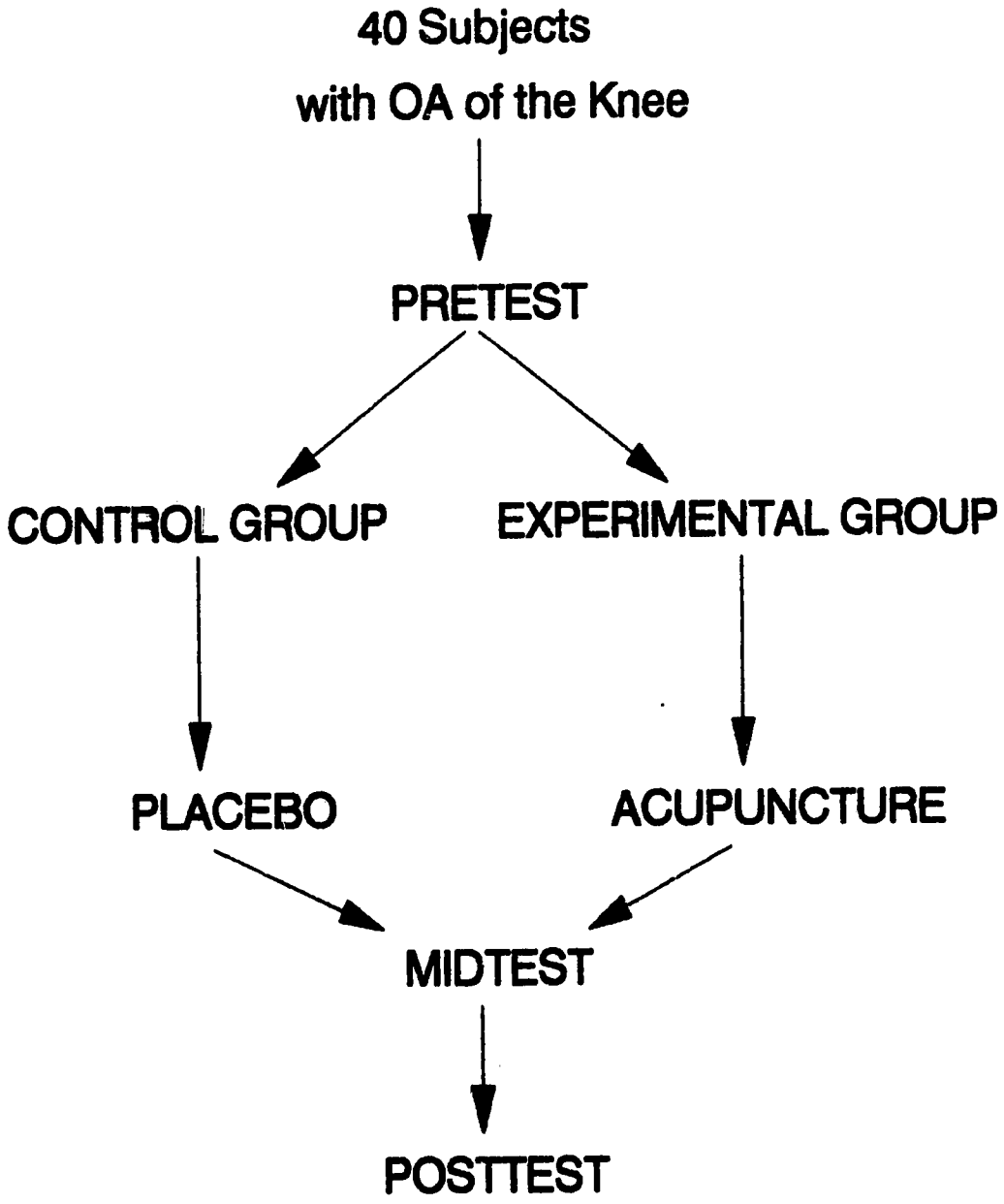


Figure 3.1: Flow chart of study protocol

3. Stable on present arthritis medications for the last 3 weeks
4. Stable on medications for other conditions (for example, cardiovascular disease)
5. No previous experience with acupuncture of the knee

Exclusion criteria were:

1. Serious systemic conditions (such as diabetes)
2. Neurological or musculoskeletal conditions (such as stroke or rheumatoid arthritis)
3. Inability to understand instructions or give consent
4. Hemophilia
5. Intra-articular steroid injections in the previous 2 months
6. Receiving any treatment (for example, physical therapy) other than medication for their arthritis
7. Strong aversion to needles
8. Pregnancy
9. Reconstructive surgery on the affected knee (for example, total knee replacement)

Subject characteristics for each group are shown in Table 3.1. There were two subjects who dropped out of the study, but for reasons not related to the treatment. These subjects were replaced by new recruits.

Table 3.1

Subject Characteristics for Control and Experimental Groups

Factors	Control Group n=10 F, 10 M	Experimental Group n=10 F, 10 M	Female Group n=20	Male Group n=20
Age (yrs)	60.20 (9.75)	63.00 (8.78)	61.55 (9.68)	61.65 (9.09)
Height (cm)	163.70 (10.44)	166.25 (9.08)	157.95 (6.44)	172.00 (7.03)
Weight (kg)	88.22 (15.50)	92.12 (21.62)	86.53 (15.64)	93.81 (21.04)
BMI (kg/m^2)	33.06 (6.26)	33.19 (6.19)	34.66 (6.09)	31.60 (5.98)
Grade I OA	n=4	n=1	n=2	n=3
Grade II OA	n=8	n=6	n=8	n=6
Grade III OA	n=4	n=8	n=6	n=6
Grade IV OA	n=4	n=5	n=4	n=5

() = standard deviation

F = female

M = male

Subjects were also requested to stay on their medications during the 3 week treatment period. During the follow-up period, the subjects were able to alter their medication dose if they wished, but they were to record any changes that they made. Subjects were told that they would be assigned to one of two acupuncture groups and that one could be more effective than the other. All subjects signed a consent form prior to participation (Appendix C).

Testing

All measurements were performed by a professional assistant who was blind to group assignment of the subjects. Measurements were taken at approximately the same time of day and subjects were asked to keep their activity level, and caffeine and alcohol intake constant during the study period.

There were three testing sessions: the Pretest (during the week prior to the acupuncture trials), the Midtest (within one week of the last treatment), and the Posttest (4 weeks following the Midtest). Each session took approximately 30 minutes of the subject's time and included measurements with the dolorimeter, the MPQ, and the WOMAC OA Index. The Pretest also included signing of the consent form and determining the eligibility of the subject for the study using the Participant Questionnaire (Appendix D).

The MPQ (Appendix A) was used to describe the quality of pain. Subjects were asked to choose only 1 word out of each category to describe the pain in their knee in the preceding 24 hours. If none of the words fit their description of the pain, then none of the words in the category were circled. The assistant explained the meaning of some words if the subject requested. The PRI, using the rank values of words, was calculated and the most commonly used words were noted.

Function was measured with the WOMAC OA Index (Appendix B). Subjects were instructed to rate on a 10 cm VAS, their pain, stiffness, and physical function over the last 48 hours.

The Pain Threshold Meter (Figure 3.2), distributed by Pain Diagnostics and Thermography, was used to measure pain threshold at the knee joint. This particular threshold meter had a rubber plunger tip with a 1-cm squared surface (diameter = 1.12 cm). The dolorimeter was applied over 4 points surrounding the knee joint. The four points were: the medial joint line, the lateral joint line, the distal musculotendinous junction of vastus medialis, and the distal musculotendinous junction of vastus lateralis. The subject was supine, with the knee over a rolled towel. At each point, the assistant applied slow even force (approximately 1 kg per second) with the dolorimeter perpendicular to the

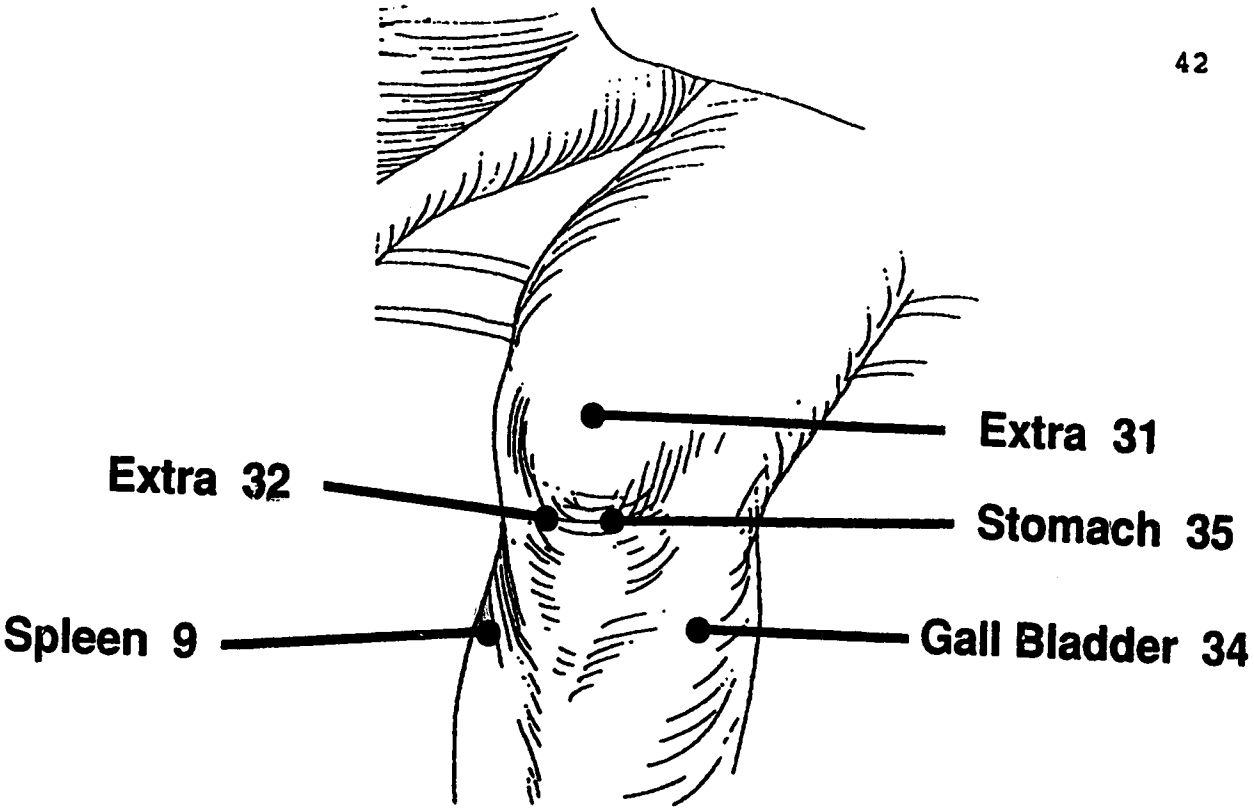
this point, the assessor removed the dolorimeter and recorded the force reading on its gauge. The values were recorded as pressure (kg/cm^2).

Subjects also recorded their knee pain immediately before and after each treatment session on the VAS (Appendix E). Patients were asked to report the amount of pain presently in their knee.

Treatment

Subjects in both the experimental and control groups received treatment 3 times per week for 3 weeks from a physical therapist trained in acupuncture. Subjects were supine with a pillow under the knees during the treatment session. For the experimental treatment, the therapist inserted disposable, 30 mm needles with 0.23 mm diameter into the 5 acupuncture points (see Figure 3.3), specifically for knee and osteoarthritic pain (The Academy of Traditional Chinese Medicine, 1975). The skin area was prepared with alcohol prior to insertion of needles. The needles were inserted to a depth (approximately 1-2 cm) at which the subject experienced Te chi (deep, full sensation), and rotated back and forth manually for 5 minutes. The needles were left in the subject for 30 minutes and inserted in the same order each time.

For the placebo treatment, the same type of needles



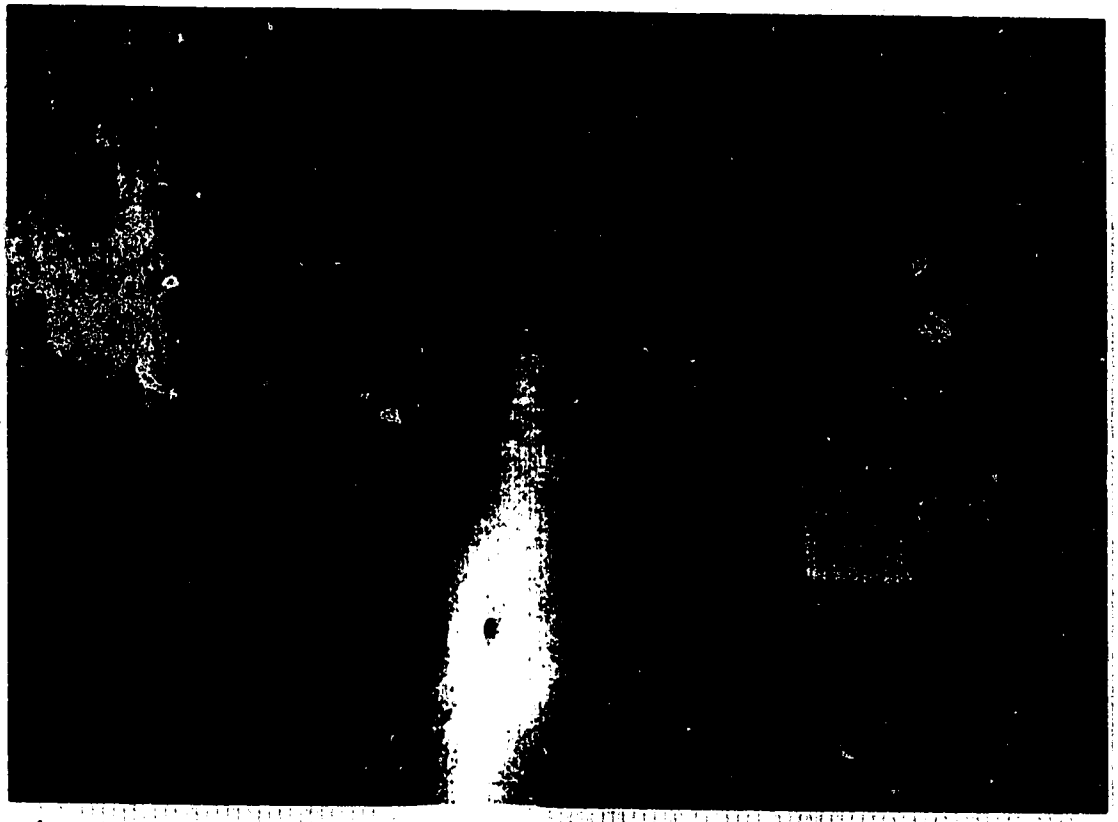


Figure 3.3: Acupuncture Points For Experimental Treatment

approximately 1 inch from the acupuncture points. Care was taken not to impinge on another acupuncture meridian. The needles were touched periodically to give the impression that movement of the needles was taking place. The location of the points was the same for all subjects. Needles were not rotated to elicit 'Te chi' during the 30 minute session.

Data Analysis

There were 5 outcome measures: pain, stiffness and physical function from the WOMAC; pain threshold; and the PRI from the MPQ. Four separate 2-way ANOVAs with repeated measures (group vs. time) were used to examine group differences and treatment effects on the pain, stiffness and physical function components of the WOMAC and the PRI of the MPQ. A 3-way ANOVA with repeated measures on 2 factors was used to examine the differences between groups, treatments and locations for the pain threshold. When the ANOVA revealed significant differences ($p<.05$), Newman Keul post hoc analyses were performed. The categories of the MPQ used before and after treatment were described for each group.

Linear trend analysis was performed to compare pain immediately before and after each treatment session for the two groups over the study period. This technique attempts to fit a line (usually linear) to a series of data points (Norman and Streiner, 1986). If the line changes in one direction over time, this indicates a change in trend.

Ethical Considerations

The study was approved by the department ethics committee. All subjects were informed of the potential risks and benefits of the study, and informed consent was obtained. Subjects were free to withdraw from the study at any time without prejudice.

Potential risks were minimal and the subjects were informed of this. However, subjects were aware that the treatments might cause slight bleeding, pain, infection or temporary increase in symptoms after the initial treatment. Infection was avoided as all the needles were disposable and sterilized by the manufacturer. Because the needles were very small in diameter, there was generally little problem with bleeding. It was recognized that persons on antiinflammatory medication could bleed more easily; and therefore pressure gauze bandages were used if necessary.

The therapist also followed the guidelines outlined by the Biosafety Committee in "Working With Biohazardous Materials" (see Appendix F) for administration and disposal of acupuncture needles, including Hepatitis B innoculations. During each treatment session, new sterilized needles were used and disposed of in a clearly marked and labelled, puncture-proof container.

To ensure the internal validity of the study, subjects were told they would be randomly allocated to one of two acupuncture groups. They did not know that one group was a

placebo, because subjects could have compared treatments. However, subjects were told that if a significant difference was found between the two groups, those assigned to the less effective group would be offered a trial of the more effective acupuncture treatment.

The therapist was certified by the College of Physical Therapists of Alberta to use acupuncture in physical therapy. To obtain this certification, she had to successfully complete an examination for certification by the Acupuncture Foundation of Canada. She also held a valid Emergency First Aid Certificate.

CHAPTER FOUR

RESULTS

McGill Pain Questionnaire (MPQ)

The results of the PRI are shown in Tables 4.1 and 4.2. There was no significant difference between the groups. Both groups had a decrease in PRI over time. Post hoc results showed that the Pretest > Midtest = Posttest. No interactions were demonstrated.

The frequency of words chosen by the control (20) and experimental (20) subjects are depicted in Figures 4.1 and 4.2. Table 4.3 outlines the type and the quality of pain each MPQ category describes.

The categories most commonly chosen from the MPQ were similar in both control and experimental groups. Categories 9 and 16 were the most popular. Both groups chose fewer words and fewer categories after treatment. In the experimental group, the frequency of response decreased in every category (20) post-treatment compared to 11 categories in the control group. The experimental group showed a greater drop in the affective (11-15) and evaluative (16) components of pain post-treatment than the control group. Also, no experimental subjects chose words from categories 12-15 and 19 after treatment.

Figures 4.3 and 4.4 demonstrate the gender differences in the use of the MPQ. To describe their pain, male

Table 4.1

Pain Rating Index (PRI) of the Control and Experimental Groups at 3 Test Sessions

Time	Control Mean (SD)	Experimental Mean (SD)
Pretest	19.65 (13.01)	17.55 (13.16)
Midtest *	14.30 (12.15)	6.50 (5.39)
Posttest *	15.00 (17.51)	10.20 (7.43)

* significant difference ($p < 0.05$) from Pretest

Table 4.2

ANOVA Summary Table for PRI

	SS	MS	F-Ratio	DF	Prob
Group	594.07	594.07	2.13	1.0	0.1523
- Error	10583.52	278.51		38.0	
Time	1521.62	760.81	11.88	2.0	0.0002@*
- Error	4868.93	64.06		76.0	
GrpxTime	177.45	88.72	1.38	2.0	0.2554@
- Error	4868.93	64.06		76.0	

@ Greenhouse-Geiser Adjustment

* significant difference ($p < 0.05$)

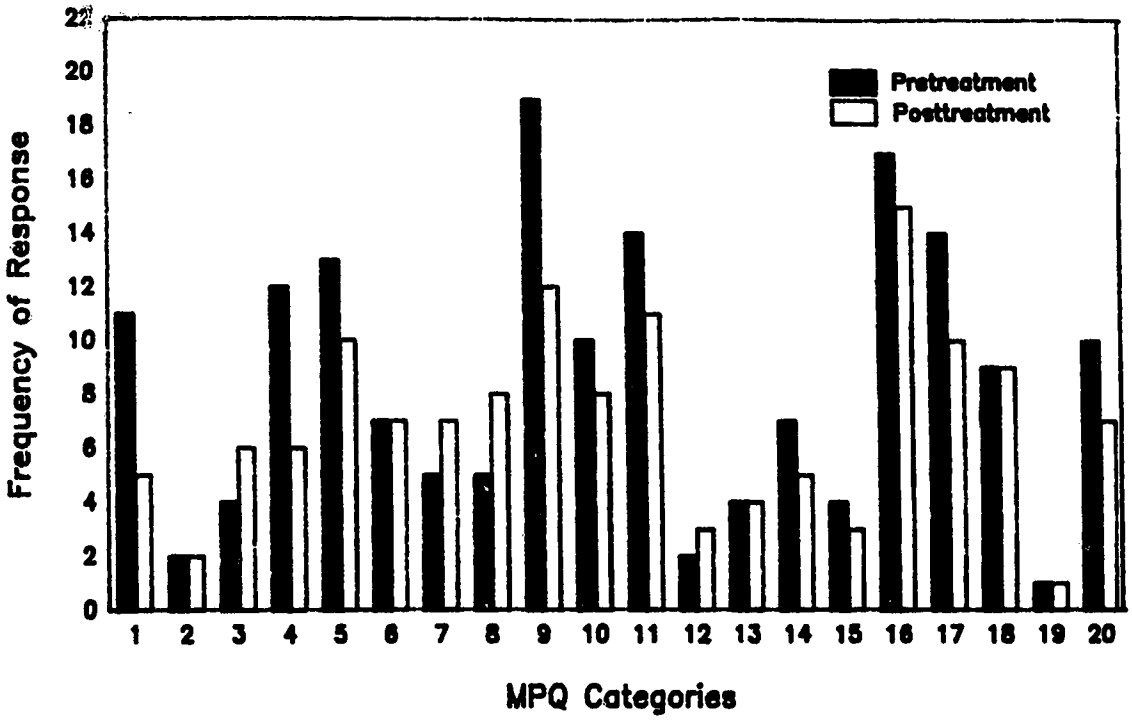


Figure 4.1: Number of Control Subjects Choosing a Word in Each MPQ Category

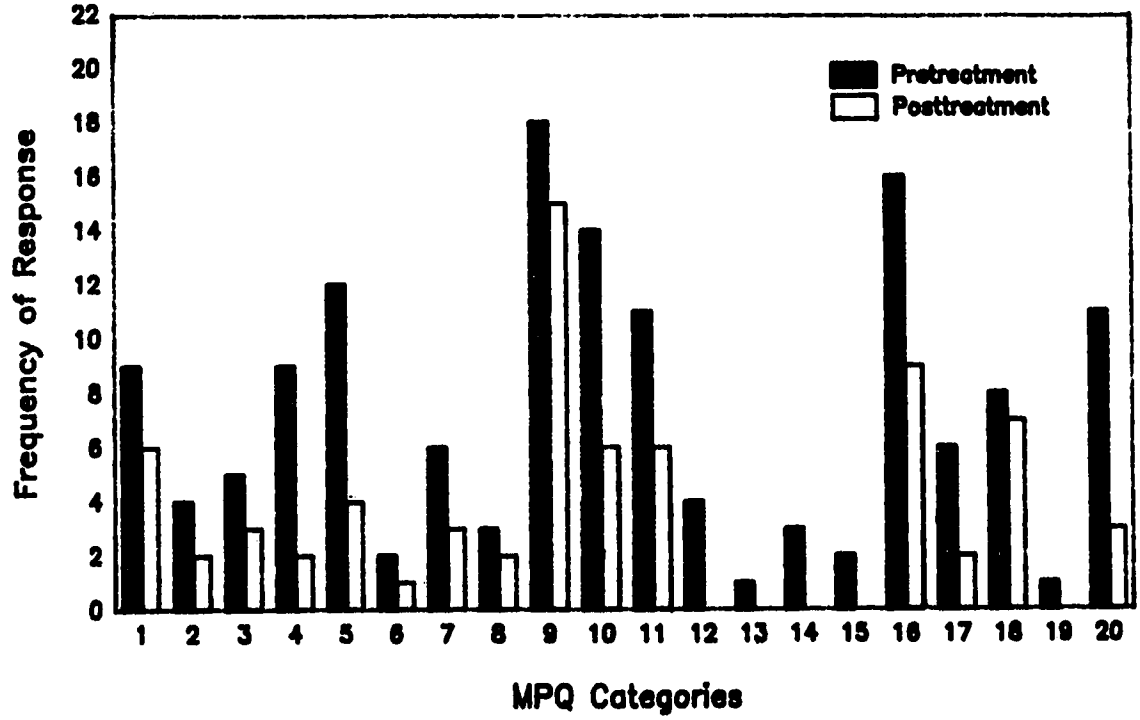


Figure 4.2: Number of Experimental Subjects Choosing a Word in Each MPQ Category

Table 4.3

Qualities of Pain for MPQ Categories (Nolli et al, 1987)

Subclasses	Quality of Pain	Word Descriptors (Examples)
1 (S)	Temporal	flickering/pounding
2 (S)	Spatial	jumping/shooting
3 (S)	Punctate Pressure	pricking/lancinating
4 (S)	Incisive Pressure	sharp/lacerating
5 (S)	Constrictive Pressure	pinching/crushing
6 (S)	Traction Pressure	tugging/wrenching
7 (S)	Thermal	hot/searing
8 (S)	Brightness	tingling/stinging
9 (S)	Dullness	dull/heavy
10 (S)	Miscellaneous	tender/splitting
11 (A)	Tension	tiring/ exhausting
12 (A)	Autonomic	sickening/suffocating
13 (A)	Fear	fearful/terrifying
14 (A)	Punishment	punishing/killing
15 (A)	Miscellaneous	wretched/blinding
16 (E)	Evaluative	annoying/unbearable
17 (M)	Evaluative	spreading/piercing
18 (M)	Sensory	tight/tearing
19 (M)	Thermal Sensory	cool/freezing
20 (M)	Affective Evaluative	nagging/torturing

S = Sensory

A = Affective

E = Evaluative

M = Miscellaneous

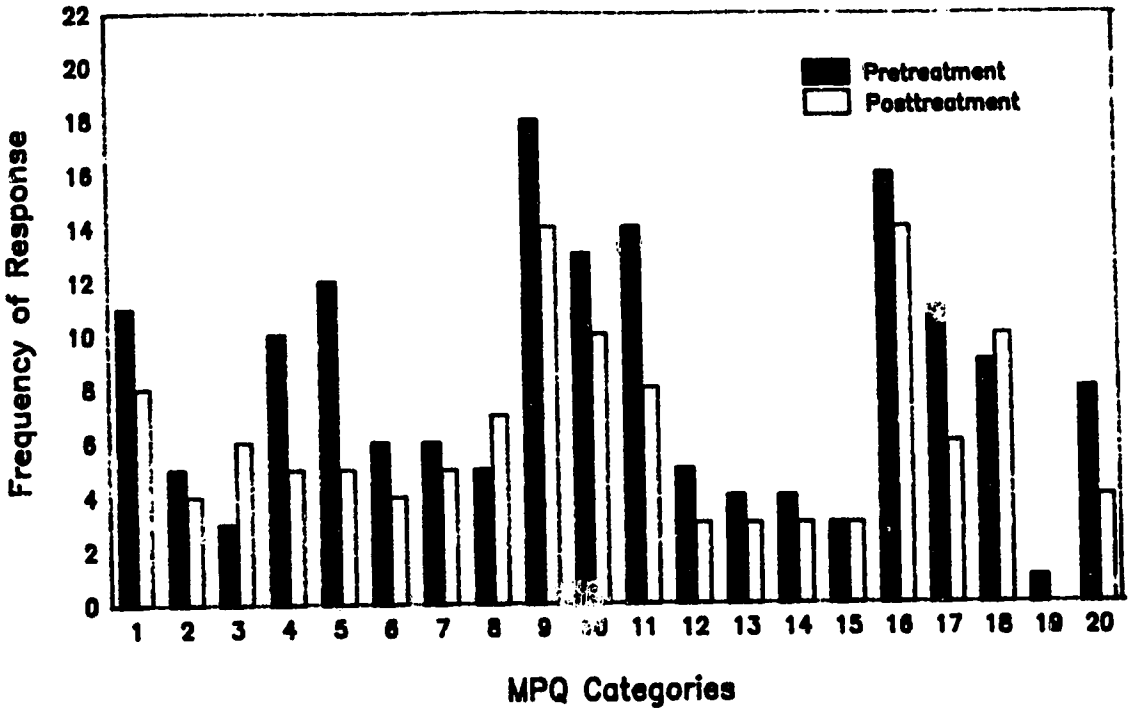


Figure 4.3: Number of Female Subjects Choosing a Word in Each MPQ Category

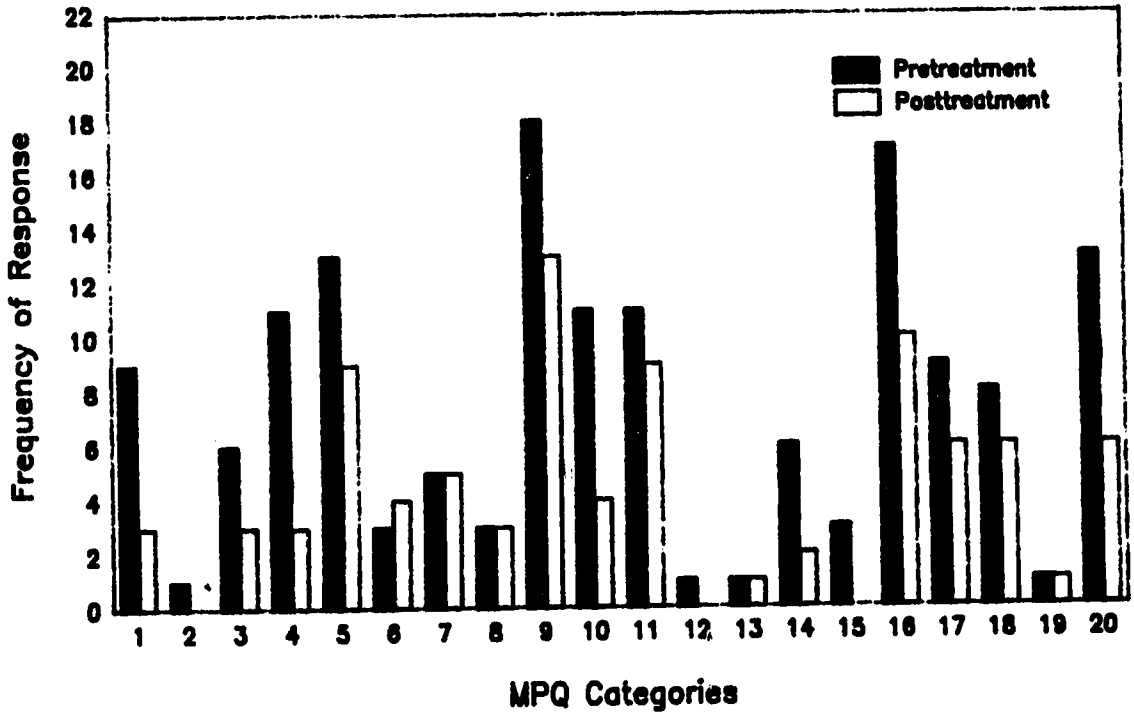


Figure 4.4: Number of Male Subjects Choosing a Word in Each MPQ Category

subjects primarily chose sensory words i.e.- tiring, tight, but the female subjects also chose affective words such as annoying and troublesome. Overall, the men selected fewer words than the women.

WOMAC OA Index

Results for the WOMAC OA Index are shown in Tables 4.4-4.9. Subjects in both groups showed a significant improvement in all 3 dimensions of the WOMAC over time, but there were no significant differences between groups.

Pressure Dolorimeter

Table 4.10 illustrates the means and standard deviations for pain threshold using the pressure dolorimeter over the medial joint line, the lateral joint line, and the musculotendinous junctions of the vastus medialis (VM) and the vastus lateralis (VL). The only site that showed greater than 1 kg/cm^2 of change was the lateral joint line in the experimental group. Both groups showed differences in pain threshold values over time and between sites. There were no significant group effects (See Table 4.11). Post hoc analysis for site did show significant differences between the bony points (medial joint line, lateral joint line) and the muscular points (VM, VL). The midtest results were also significantly different than the pretest results.

Table 4.4

WOMAC Pain Index of the Control and Experimental Groups at 3 Test Sessions

Time	Control Mean (SD)	Experimental Mean (SD)
Pretest	21.93 (8.71)	19.44 (13.53)
Midtest *	14.84 (14.14)	11.15 (11.27)
Posttest *	19.44 (18.91)	14.01 (12.29)

* significant difference ($p < 0.05$) from Pretest

Table 4.5

ANOVA Summary Table for the WOMAC Pain Index

	SS	MS	F-Ratio	DF	Prob
Group	345.10	345.10	0.92	1.0	0.3438
- Error	14274.66	375.65		38.0	
Time	1226.60	613.30	8.06	2.0	0.0007@*
- Error	5785.97	76.13		76.0	
GrpxTime	12.66	6.33	0.08	2.0	0.9181@
- Error	5785.97	76.13		76.0	

@ Greenhouse-Geiser Adjustment

* significant difference ($p < 0.05$)

Table 4.6

WOMAC Stiffness Index of the Control and Experimental Groups at 3 Test Sessions

Time	Control Mean (SD)	Experimental Mean (SD)
Pretest	11.40 (6.12)	8.45 (5.53)
Midtest *	7.07 (5.96)	5.29 (4.52)
Posttest *	8.03 (6.22)	5.57 (5.68)

* significant difference ($p < 0.05$) from Pretest

Table 4.7

ANOVA Summary Table for the WOMAC Stiffness Index

	SS	MS	F-Ratio	DF	Prob
Group	141.05	141.05	1.67	1.0	0.2039
- Error	3208.42	84.43		38.0	
Time	355.58	177.79	26.32	2.0	0.0000@*
- Error	513.39	6.76		76.0	
GrpxTime	9.28	4.64	0.69	2.0	0.5059@
- Error	513.39	6.76		76.0	

@ Greenhouse-Geiser Adjustment

* significant difference ($p < 0.05$)

Table 4.8

WOMAC Function Index of the Control and Experimental Groups at 3 Test Sessions

Time	Control Mean (SD)	Experimental Mean (SD)
Pretest	77.80 (36.55)	61.44 (43.15)
Midtest *	50.49 (42.49)	40.16 (34.72)
Posttest *	60.02 (45.85)	48.03 (43.58)

* significant difference ($p < 0.05$) from Pretest

Table 4.9

ANOVA Summary Table for the WOMAC Function Index

	SS	MS	F-Ratio	DF	Prob
Group	3579.58	3579.58	0.82	1.0	0.3706
- Error	165712.65	4360.86		38.0	
Time	12535.74	6267.87	15.38	2.0	0.0000@*
- Error	30970.46	407.51		76.0	
GrpxTime	535.55	267.78	0.66	2.0	0.5051*
- Error	30970.46	407.51		76.0	

@ Greenhouse-Geiser Adjustment

* significant difference ($p < 0.05$)

Table 4.10

Pain Threshold Scores (kg/cm^2) of the Control and Experimental Groups at 3 Test Sessions

Site	Control Mean (SD)			Experimental Mean (SD)		
	Pre	Mid +	Post	Pre	Mid +	Post
Med Jt Line *	3.64 (1.61)	4.19 (2.61)	3.69 (2.59)	4.06 (2.31)	4.69 (2.71)	4.38 (2.36)
Lat Jt Line *	3.87 (1.59)	4.46 (2.34)	4.05 (2.42)	4.15 (2.02)	5.47 (2.40)	4.10 (1.73)
Vastus Med	3.18 (1.43)	3.74 (2.14)	3.25 (2.48)	3.63 (1.78)	4.04 (2.09)	3.51 (1.87)
Vastus Lat	3.32 (1.61)	3.79 (2.17)	3.57 (2.22)	3.87 (2.21)	4.34 (1.88)	4.04 (2.28)

* significant difference ($p < 0.05$) from VM and VL

+ significant difference ($p < 0.05$) from Pretest

Table 4.11

ANOVA Summary Table of Pain Threshold Scores

	SS	MS	F Ratio	DF	Prob
Group	26.98	26.98	0.65	1.0	0.4244
- Error	1572.56	41.38		38.0	
Time	31.97	15.98	4.77	2.0	0.0138@*
- Error	254.89	3.35		76.0	
Site	45.50	15.17	11.41	3.0	0.0000@*
- Error	151.55	1.33		114.0	
Grp x Time	0.79	0.40	0.12	2.0	0.8706@
- Error	254.89	3.35		76.0	
Site x Time	4.67	0.78	1.49	6.0	0.1965@
- Error	118.96	0.52		228.0	
Grp x Site	0.37	0.12	0.09	3.0	0.9421@
- Error	151.55	1.33		114.0	
GrpxTime xSite	3.45	0.57	1.10	6.0	0.3604@
- Error	118.96	0.52		228.0	

@ Greenhouse-Geiser Adjustment

* significant difference ($p < 0.05$)

Visual Analogue Scale (VAS)

The changes in pain within and between treatment sessions are illustrated in Figures 4.5 and 4.6. Using trend (modified time series) analysis, it was determined that the experimental group had a significantly better treatment effect from session to session. There was a significant difference in the overall linear trends between the two groups. This means that the trend over sessions of the pre/post difference was significantly different between groups. In the control group, the subjects improved after every treatment, but each pre-session value was close to the same level of pain as the day before. In contrast, the experimental group's pre-session values gradually decreased over time, i.e. - the pain experienced was gradually decreasing over time. The pre and post values in the experimental group came closer together.

Additional Observations

Because there were no significant differences between groups for any of the main outcome variables, further analysis was done to try to discover why these results occurred. Four 3-way ANOVAs with repeated measures (group vs. time vs. gender) for the PRI and the 3 components of the WOMAC OA Index, and one 4-way ANOVA with repeated measures (group vs. time vs. site vs. gender) for the pressure dolorimeter were performed. The probability values for the

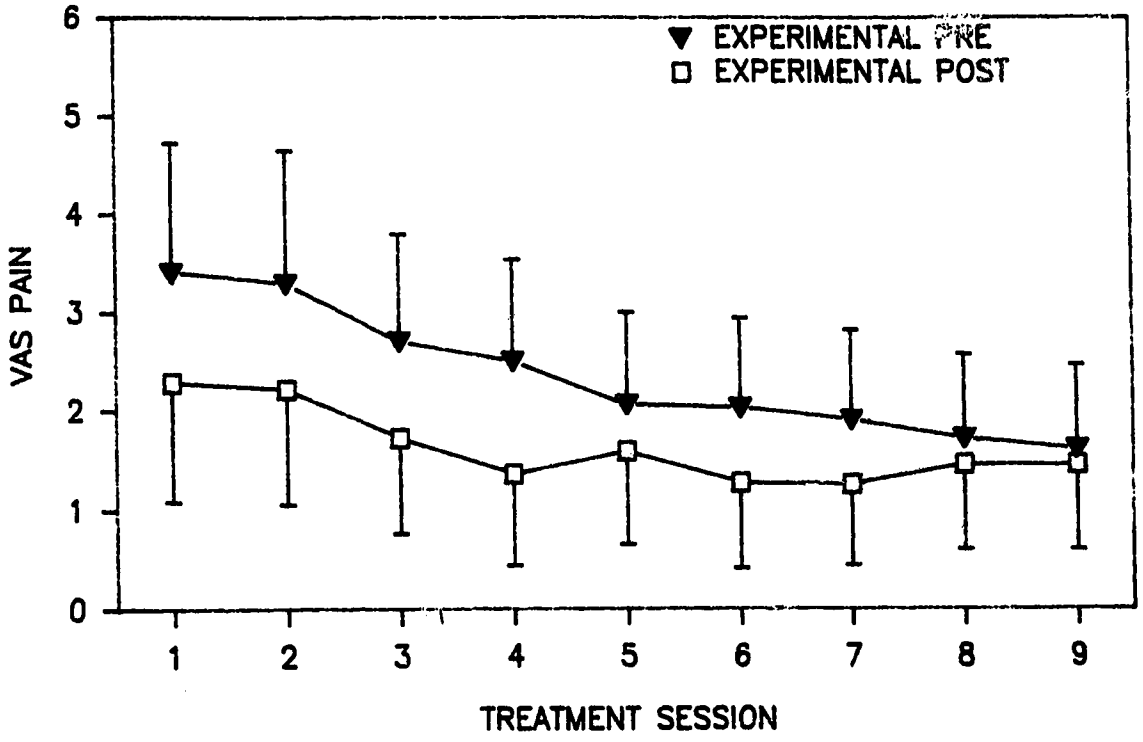


Figure 4.5: VAS pre and post treatment values for Experimental Subjects

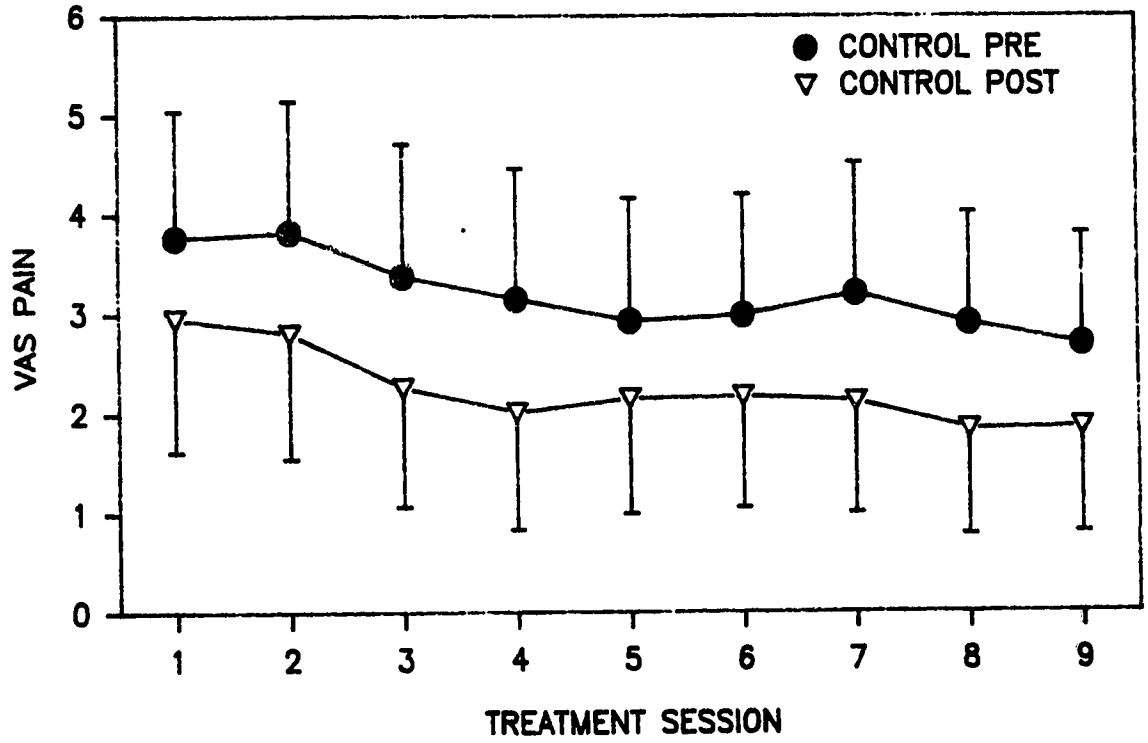


Figure 4.6: VAS pre and post treatment values for Control Subjects

analyses are shown in Table 4.12. Even with only 10 subjects per cell, there were significant gender*time interactions in the WOMAC Pain Index and the pressure dolorimeter scores.

Subjects in both groups had similar levels of pain, stiffness and physical dysfunction prior to the start of the treatment. However, the values for subjects in the control group were slightly higher on all measures. All subjects demonstrated an improvement on at least one measure following the acupuncture treatments. No subjects dropped-out as a result of the treatment.

Subjects were asked to record their changes in medications throughout the study. We found that only 5 subjects (1 experimental, 4 controls) changed their antiinflammatory medications between Pretest and Midtest. The 4 control subjects changed their antiinflammatory medications by increasing their medications (1 tablet) not more than 2 days near the start of the study. The experimental subject was on prn medications. Although she was told to keep her medications constant, she did vary her intake of medications occasionally. Two control subjects took antibiotics during the study because of flu symptoms. Between Midtest and Posttest, only 2 subjects (control) increased their medications.

'Te chi' was experienced regularly during treatment by 25 subjects (14 experimentals, 11 controls). The remaining

Table 4.12

Probability Values for ANOVAs with Gender as a Factor

	DEPENDENT VARIABLES				
	PRI	WOMAC PAIN	WOMAC STIFF	WOMAC FUNCTION	DOLORI-METER
GENDER	0.5005	0.0382*	0.0085*	0.0091*	0.0000*
GENDER x GRP	0.9702	0.8152	0.3692	0.6842	0.4064
GENDER x TIME	0.8228@	0.0436@*	0.2132@	0.7729@	0.0218@*
GENDER x SITE	-	-	-	-	0.0749@
GENDER x GRP x TIME	0.4546@	0.7488@	0.3188@	0.4834@	0.6208@
GENDER x SITE x TIME	-	-	-	-	0.3721@
GENDER x GRP x SITE x TIME	-	-	-	-	0.8452@

@ Greenhouse-Geiser Adjustment

* significant difference ($p < 0.05$)

15 subjects (6 experimentals, 9 controls) did not experience this sensation. The analyses were repeated using 'Te chi', as the group factor. Significant differences between the Te chi and Non-Te chi groups were found in the WOMAC Pain Index and the pressure dolorimeter scores. The Te chi group had significant reductions in pain over time, but the Non-Te chi group did not. See Table 4.13-4.15 for results.

Table 4.13

Group*Time Interactions from ANOVAs Using Te chi and Non-Te chi as the Groups

	SS	MS	F-Ratio	DF	Prob
PRI	412.21	206.11	3.38	2.0	0.0507@
- Error	4634.17	60.98		76.0	
WOMAC PAIN	672.97	336.48	4.99	2.0	0.0097@*
- Error	5125.66	67.44		76.0	
WOMAC STIFF	0.22	0.11	0.02	2.0	0.9840@
- Error	522.45	6.78		76.0	
WOMAC FUNCTION	1036.57	518.29	1.29	2.0	0.2792@
- Error	30469.44	400.91		76.0	
DOLORI-METER	31.87	15.93	5.41	2.0	0.0074@*
- Error	223.81	2.94		76.0	

@ Greenhouse-Geiser Adjustment

* significant difference ($p < 0.05$)

Table 4.14

WOMAC Pain Index of Te chi and Non-Te chi Groups at 3 Test Sessions

Time	Te chi (n=25) Mean (SD)	Non-Te chi (n=15) Mean (SD)
Pretest	19.24 (12.91)	23.08 (7.75)
Midtest	7.98* (8.80)	21.33 (14.19)
Posttest	9.99* (10.64)	2[illegible].88 (17.51)

* significant difference ($p < 0.05$) from Pretest

Table 4.15

Pain Threshold Scores (kg/cm^2) of the Te chi and Non-Te chi Groups at 3 Test Sessions

Site	Te chi Mean (SD)			Non-Te chi Mean (SD)		
	Pre	Mid *	Post *	Pre	Mid	Post
Med Jt Line	4.30 (2.14)	5.54 (2.68)	5.15 (2.66)	3.09 (1.44)	2.58 (1.10)	2.62 (1.29)
Lat Jt Line	4.28 (1.92)	5.84 (2.38)	4.97 (2.23)	3.56 (1.54)	3.48 (1.59)	2.96 (1.02)
Vastus Med	4.01 (1.55)	4.88 (1.93)	4.30 (2.37)	2.39 (1.16)	2.27 (1.03)	2.14 (0.85)
Vastus Lat	4.14 (2.09)	4.81 (2.03)	4.64 (2.14)	2.66 (1.20)	2.81 (1.28)	2.42 (0.84)

* significant difference ($p < 0.05$) from Pretest

CHAPTER 5

DISCUSSION

The results of the study indicated that both groups had a positive response (on all variables) to acupuncture and there was no difference between groups. These findings suggest that either both groups had a placebo effect or both responded physiologically to their respective treatments. The following discussion will address these two possibilities.

McGill Pain Questionnaire (MPQ)

There was a decrease in the PRI over time, but no difference between groups. When one observes the mean scores, there was a greater reduction in pain in the experimental group than the control group. Although not significant. The degree of change after treatment was large enough to suggest that both groups experienced a physiological effect, but the experimental group had a greater response. Watkins and Mayer (1982) suggest that there are both opioid and non-opioid systems involved with pain relief. In TENS studies, the opioid systems are reportedly activated by low-frequency-high-intensity stimulation and the non-opiate (serotonergic) systems by high-frequency-low-intensity stimulation (Melzack, 1989; Sjolund and Eriksson, 1979). In this study, the

investigator hypothesizes that rotation of the needles may have been a high intensity stimulation, and touching the needles a low intensity stimulation. If so, the experimental group would be more likely to receive an opioid response and the control group a non-opioid response. If the real acupuncture is responsible for stimulation of the opiate system, then this system may have a greater effect on the psychological components of pain. The changes in pain quality seen in this study supported the theory that only the real acupuncture changes the affective and evaluative aspects of pain. Following the acupuncture treatments, the experimental group showed greater reductions in all three aspects of pain in the MPQ: the sensory, the affective and the evaluative components. In contrast, the control group showed the greatest reductions in the sensory components and less so in the affective and evaluative components.

WOMAC Pain Index and Pressure Dolorimeter

One could conclude that the real acupuncture had a greater effect on the quality of pain, but the two treatments did not differ in terms of the quantity of pain. The WOMAC Pain Index and the pain thresholds showed that both groups had decreases in pain in a similar manner. The results in this part of the study are similar to Gaw et al (1977)'s study. Gaw et al (1977) observed reductions in pain tenderness in both treatment groups, but no significant

difference between groups. One explanation for the lack of significant difference between the two groups in our study, could be that the 'needle effect' alone was responsible for the physiological effect and alterations in pain conduction to the CNS (Gaw et al, 1977; Lewit, 1979). The mechanism would be similar to the non-opiate systems described earlier. Future studies including a third non-treatment group would help in determining these answers.

The pressure dolorimeter scores demonstrated a difference between muscle and bony points. This difference is supported by Fischer (1987) who reported that trigger points (VM, VL) exhibit lower thresholds than other points on the body. In a preliminary pilot of OA subjects, the dolorimeter scores were higher for the bony points than the muscular points (Wessel, 1991). In this study, women had lower thresholds than men. These findings are again consistent with Fischer's (1987) results on normal subjects.

Two male subjects, in the experimental group, ceilinged (11 kg/cm^2) at Midtest with the pressure dolorimeter. Because the Midtest values were 2 times the Pretest values in both cases, this large increase in pain threshold indicates that acupuncture is probably more than a placebo. These 2 subjects may have had thresholds much higher than 11 kg, but there was no way of measuring anything above the ceiling. As a result, the analysis might have been affected if the dolorimeter means recorded for the experimental group

did not accurately represent the subjects with the group.

Visual Analogue Scale (VAS)

The VAS demonstrated that the experimental group was gradually improving with every treatment; a positive trend was seen. However, subjects in the control group improved after every treatment, but tended to return to about the same level of pain prior to each session. It may be that control subjects believed that they should improve with treatment. As a result they did. This 'Hawthorne effect' also a consideration in Gaw et al (1977)'s study.

The positive response to treatment could have also been accentuated by a good therapist-patient relationship (Dimatteo and DiNicola, 1982 cited in Cousins, 1989). During, the VAS measurements, the therapist was always present. This presence may have influenced the control subjects to record decreases in pain after every treatment. However, it appeared that the experimental group experienced an actual decrease in pain. The difference between pre and post values in each session steadily decreased in the experimental group. These results indicate that changes occurred immediately after treatment, but that there was also a carry-over effect to the next treatment session.

Overall Changes in Pain

There were no significant differences in the pain

measures between the experimental and control groups. If there was no true difference between the groups, one would assume acupuncture was a placebo. A placebo effect is the relief of pain based on the expectation that treatment will make the pain go away (Melzack and Wall, 1988). The subjects were able to see the needles inserted. The needles possibly gave them the impression that they were receiving an effective treatment (Bhatt-Sanders, 1985). The placebo has produced powerful and long-term success in other studies (Weisenberg, 1977 cited in Weisenberg, 1989). Evidence presented in this study suggests that acupuncture was more than a placebo. For example, in a normal placebo 30-35% of control subjects respond to treatment (Beecher, 1955 cited in Richardson and Vincent, 1986). However, in this study, 70% of controls showed decreased PRI values and 80% of controls showed a decrease in pain, stiffness and physical difficulty in the WOMAC OA Index. These findings do not reflect the normal placebo rate (Beecher, 1955 cited in Richardson and Vincent, 1986).

There were 15 subjects who did not experience 'Te chi'. An explanation for lack of response to acupuncture could be that some subjects (approximately 15-20%) may not have sufficient opiate receptors to elicit the analgesic response. These findings were demonstrated in rat and human studies (Stux and Pomeranz, 1989). Other explanations for the presence or lack of the 'Te chi' response are discussed

under gender differences. It was important in this study that a significant difference was found between the Te chi and Non-Te chi groups. Although there were problems with this analysis: 1) uneven numbers within groups 2) non-random allocation, the findings supported the idea that 'Te chi' is the key to the physiological pain-relieving response.

Stiffness and Function

In both groups, there was an improvement of stiffness and function over time. Gaw et al (1977) and Godfrey and Morgan (1978) found the same results using different measures. If one hypothesizes that both treatments affect the sensory components of pain, then it is reasonable to assume that there would be no significant difference between groups. Since the WOMAC Stiffness and Function Indices are not influenced by the affective and evaluative components of pain, these results were not unexpected.

The lack of homogeneity between subjects may have affected the results. In studies where researchers have found significant changes in the WOMAC with these measures (Bellamy et al, 1988; Gerecz Simon et al, 1989), the subjects had a similar severity of OA and came from the same populations. In this study, the subjects came from various sources. This could explain why there were no significant differences between groups in all three dimensions: pain,

stiffness, and function.

Gender Differences

In all the pain measures, the men had greater changes than the women. Because women tend to report their pain more frequently than men (Hochberg, 1989), it is possible that they are more accurate in their description and analysis of their pain. There are other findings that suggest women rely on internal loci of control or active coping strategies (Crisson and Keefe, 1988) rather than outside forces to cope with pain. In this study, the women may have felt they were not playing an active role with the acupuncture treatments.

Placebo and expectation seemed to play a greater role in the male subjects. An explanation for this role may be that men are more likely to utilize passive coping strategies for chronic pain (Crisson and Keefe, 1988). Acupuncture may have been an easier treatment for the men to accept because it was an external force controlling the pain. The other possible reason that men did better than women in response to treatment may be partly due to a female therapist administering the treatment. The men appeared more receptive to the treatments and commented more often than the women that they felt they were benefitting from treatment.

The amount of adipose tissue surrounding the knee may

have influenced how well the subjects would respond to treatment and could have been the main reason that: 1) men did better than women and 2) control and experimental groups were not significantly different. Usually, the Body Mass Index (BMI) is a measure used in epidemiological studies to determine high-risk groups (Health and Welfare Canada, 1988). Sharp increases in morbidity were reported in both males and females with BMI (weight (kg) divided by height (metres) squared)'s greater than 27 kg/m^2 (Health and Welfare Canada, 1988).

In this study, women with the high BMI's (32.0-49.4 kg/m^2) had large amounts of adipose tissue around the knee and tended to do the poorest in terms of results, regardless of group allocation. In 13 of the 20 women who participated in the study, 'Te chi' was not achieved. Part of the problem could have been that the needles were not of sufficient length or width to stimulate the nerves in the deeper tissues (muscle for example). The 2 women who showed improvement in every pain measure were in the control group, but their BMI's were very low (24.5 and 28.1 kg/m^2) in comparison to the other women.

In this study, 18 of the 20 male subjects experienced the 'Te chi' sensation. A large majority of the older men (50-70) who showed improvement with acupuncture had very little adipose tissue around the knee, but high BMI's (36.8-47.8 kg/m^2). Schwartz et al (1990) confirmed that in the

'older men' (60-82 years) tested, there was a redistribution of the adipose mass from the periphery to the central areas of the body, such as the abdomen. Therefore, it appears as though the BMI in the men did not reflect the success of the treatment. There were 9 male subjects in the control group with BMI's ranging from 27.3-49.4 kg/cm^2 who experienced 'Te chi'. These subjects recorded large reductions in pain. All of these subjects had small knees with little adipose tissue. As a result, men were more likely to experience the analgesic response and beneficial effects just by the insertion of the needles alone.

If only males or only females were used in the study, the outcomes may have been altered. To expand on this study, one could increase the sample size (for sufficient power) and then reanalyze the results using gender as a factor. If we had used only one gender, Te chi may have been easier to control and a significant difference between groups might have become evident. Also, to eliminate any control subjects that experienced 'Te chi' could have made a large difference to the results.

Standardized Treatment

One difficulty in studying acupuncture is that the optimal parameters for acupuncture analgesia are not yet known. Therefore, any changes to the procedures could have affected the outcomes. There are many parts of the

treatment that could have changed: the size of the needles, the number of treatment sessions, the frequency of treatments per week, the type of stimulation, or the acupuncture points chosen. In addition, results could be affected by study design parameters such as: length of follow-up period, level of medication, or choice of control treatment. Richardson and Vincent (1986) have reviewed acupuncture studies and found great variation in terms of: the number of treatments (1-18), the type of control treatment (sham acupuncture, TENS, mock TENS, no treatment), the type of experimental treatment (manual, ear, electroacupuncture) and the follow-up periods (none to 1 year). However, the results also ranged from no significant difference to significant difference between groups. There were no obvious patterns. Since the present study did not show a significant difference, possible changes that may have increased the likelihood of a difference are discussed here.

Inclusion of a third group that had mock TENS would have eliminated the possibility of a physiological response in this group (Richardson and Vincent, 1986). The length of the study may have needed to be longer in order for the subjects to reach maximum benefits. The VAS scores at the last session were getting closer together, but there was no evidence that subjects had plateaued. A greater number of sessions may have been necessary to see the differences

between the groups. There is also the possibility that each treatment was not of sufficient length or that greater stimulation of each needle was required for maximum benefits. Electrical stimulation of the needles would have been an easier way to maintain constant stimulation on each needle for a longer period of time.

The medications that the subjects took could have also affected the outcomes. However, only a small number of subjects (mainly controls) changed their medications. Because the changes in medications occurred early in the study, it is unlikely that these changes would affect the results. A greater change may have been detected if the subjects were not on any antiinflammatory medications. However, a wash-out period would have been required. For most drugs this is a 48-72 hour period depending on the half-life of the drug (Gaw et al, 1975). Subjects might have difficulty refraining from taking medications if their pain was severe.

The points used for acupuncture may have also been a factor influencing the outcomes. Acupuncture is considered to be most effective when suited specifically for each subject (Guillaume, 1991). Guillaume (1991) suggests that Western protocols are not adequate for evaluating the effects of acupuncture. He emphasizes that the acupoints used in Traditional Chinese acupuncture are based not only on the diagnosis of the subject, but also on other symptoms

the subject exhibits. It is possible that the experimental subjects would have had an even greater response to treatment if the acupuncture points were individually chosen for each subject. However, it would be difficult to generalize the results of a study involving a non-standardized treatment method (Bhatt-Sanders, 1985).

CHAPTER 6

SUMMARY AND CONCLUSIONS

The purpose of this study was to determine whether acupuncture was more effective than placebo in the reduction of pain in persons with OA of the knee. The study was a double-blind, randomized, controlled clinical trial with one experimental group that received real acupuncture and one control group that received sham/placebo acupuncture.

40 subjects (20 males, 20 females) with radiographic evidence of OA of the knee participated in the study. Subjects were stratified by gender and randomly assigned to either the experimental or control groups. Subjects were treated 3 times per week for 3 weeks and evaluated at 3 test sessions: Pretest (prior to treatment), Midtest (within one week of the last treatment), and Posttest (4 weeks following the Midtest). Outcome measures were: 1) the PRI of the McGill Pain Questionnaire (MPQ), 2) the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and 3) pain threshold at 4 sites at the knee.

The data was analyzed using 4 separate 2-way ANOVAs with repeated measures (group vs.time) on the PRI and on the pain, stiffness, and physical function components of the WOMAC, and a 3-way ANOVA with repeated measures on 2 factors (group vs. time vs. site) for the pain threshold. Neuman Keul tests were used for post hoc analysis.

The following conclusions were drawn based on the results of this study:

1. Both the true acupuncture and sham acupuncture significantly reduced pain in the osteoarthritic knee.
2. There was no significant difference between the real acupuncture and the sham/placebo acupuncture.
3. Men responded better than women to acupuncture treatment.
4. Subjects experiencing 'Te chi' regularily during treatment responded better than those who did not experience this sensation.
5. Further study on acupuncture is warranted with better control of Te chi and a more homogeneous group.

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APPENDIX A: THE MCGILL PAIN QUESTIONNAIRE (MPQ) BY MELZACK (1977)

Some of the words below describe your pain over the last 24 hours. Circle ONLY those words that best describe it. Leave out any category that does not apply to your pain. Use only a SINGLE WORD in each appropriate category - the one that applies best.

1	2	3	4
Flickering	Jumping	Pricking	Sharp
Quivering	Flashing	Boring	Cutting
Pulsing	Shooting	Drilling	Lacerating
Throbbing		Stabbing	
Beating		Lancinating	
Pounding			
5	**6**	**7**	**8**
Pinching	Tugging	Hot	Tingling
Pressing	Pulling	Burning	Itchy
Gnawing	Wrenching	Scalding	Smarting
Cramping		Searing	Stinging
Crushing			
9	**10**	**11**	**12**
Dull	Tender	Tiring	Sickening
Sore	Taut	Exhausting	Suffocating
Hurting	Rasping		
Aching	Splitting		
Heavy			
13	**14**	**15**	**16**
Fearful	Punishing	Wretched	Annoying
Frightful	Gruelling	Blinding	Troublesome
Terrifying	Cruel		Miserable
	Vicious		Intense
	Killing		Unbearable
17	**18**	**19**	**20**
Spreading	Tight	Cool	Nagging
Radiating	Numb	Cold	Nauseating
Penetrating	Drawing	Freezing	Agonizing
Piercing	Squeezing		Dreadful
	Tearing		Torturing

APPENDIX B: WOMAC OSTEOARTHRITIS INDEX

The following questions concern the amount of pain you are currently experiencing due to arthritis in the most severely affected knee. For each situation please enter the amount of pain experienced in the last 48 hours. (Please mark your answers with an "X").

QUESTION: HOW MUCH PAIN DO YOU HAVE?

1. Walking on flat surfaces.

No Pain ├──────────────────────────────────────┤ Extreme Pain

2. Going up or down stairs.

No Pain ├──────────────────────────────────────┤ Extreme Pain

3. At night while in bed.

No Pain ├──────────────────────────────────────┤ Extreme Pain

4. Sitting or lying.

No Pain ├──────────────────────────────────────┤ Extreme Pain

5. Standing upright.

No Pain ├──────────────────────────────────────┤ Extreme Pain

The following questions concern the amount of joint stiffness (not pain) you have experienced in the last 48 hours in your most severely affected knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

1. How severe is your stiffness after first awakening in the morning?

No Stiffness ├──────────────────────────────────────┤ Extreme Stiffness

2. How severe is your stiffness after sitting, lying or resting later in the day?

No Stiffness ├──────────────────────────────────────┤ Extreme Stiffness

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours due to arthritis in your most severely affected knee. (Please mark your answers with an "X").

1. Descending stairs.

No Difficulty ├──────────────────────────────────────┤ Extreme Difficulty

2. Ascending stairs.

No Difficulty ├──────────────────────────────────────┤ Extreme Difficulty

3. Rising from sitting.

No Difficulty ├──────────────────────────────────────┤ Extreme Difficulty

4. Standing.

No Difficulty ├──────────────────────────────────────┤ Extreme Difficulty

5. Bending to floor.

No Difficulty ├──────────────────────────────────────┤ Extreme Difficulty

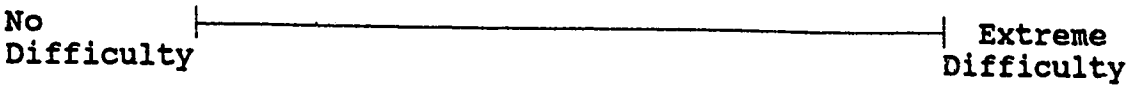
6. Walking on flat.

No Difficulty ├──────────────────────────────────────┤ Extreme Difficulty

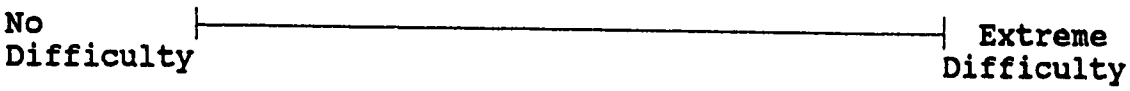
7. Getting in/out of car.

No Difficulty ├──────────────────────────────────────┤ Extreme Difficulty

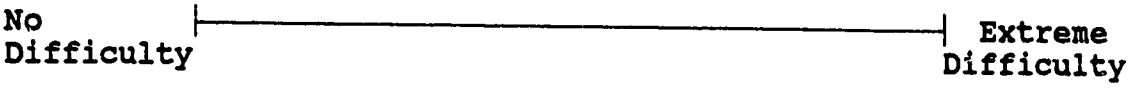
8. Going shopping.



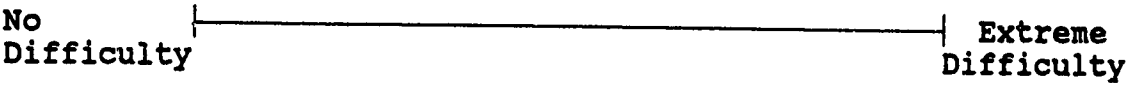
9. Putting on socks/stockings.



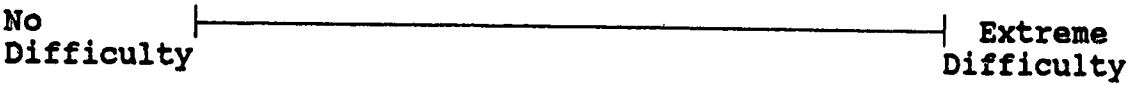
10. Rising from bed.



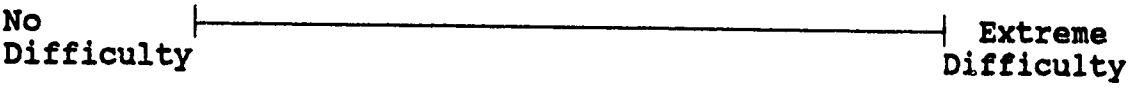
11. Taking off socks/stockings.



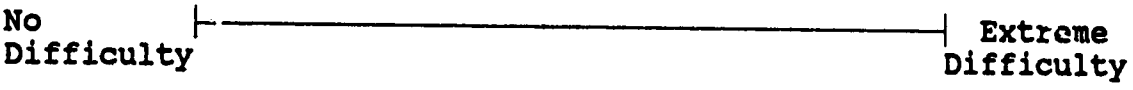
12. Lying in bed.



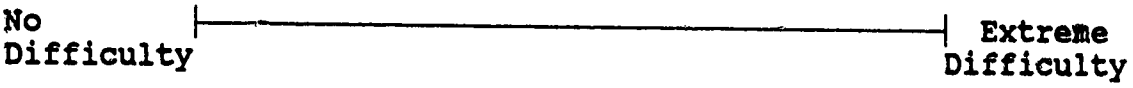
13. Getting in/out of bath.



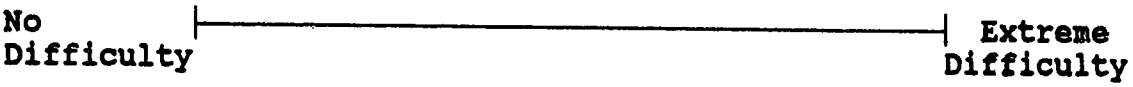
14. Sitting.



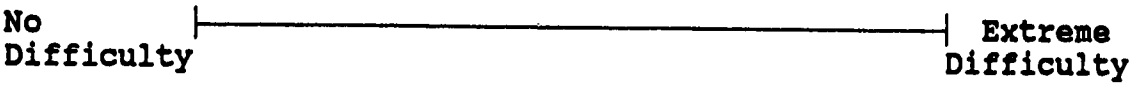
15. Getting on/off toilet.



16. Heavy domestic duties.



17. Light domestic duties.



An Explanation of The Meaning of Questions in the WOMAC Osteoarthritis Index Inventory

PAIN

Question 1:

Refers to pain experienced while walking on even rather than uneven ground (i.e. - walking in a shopping mall or on the sidewalk, or some other surface where there is a fair degree of regularity). This question does not refer to walking on uneven (i.e. - rough) ground.

Question 2:

"Going up or down stairs" is self explanatory. If the pain is different going in one direction than the other, patients should rate according to the direction which produces the greatest pain.

Question 3:

Refers to the kind of pain that disturbs sleep rather than that which occurs while lying in bed between going to bed and finally falling to sleep, or between waking up and finally getting out of bed.

Question 4:

Refers to pain experienced either while in a position of sitting (i.e. - in a chair) or while lying awake in bed.

Question 5:

Refers to pain occurring while in the standing position but not moving.

STIFFNESS

Question 1:

Refers to the severity (rather than the duration) of stiffness which occurs after first awakening in the morning. In OA this is usually, but not always, of short duration and often improves or disappears shortly after arising.

Question 2:

Refers to the severity (rather than the duration) of stiffness which occurs after periods of inactivity later in the day. This is termed "gelling" in the literature.

These two questions have been phrased in this way because some patients seem to have a lot of morning stiffness but no gelling, and others have gelling with very little morning stiffness. Still other patients have some of both or neither.

PHYSICAL FUNCTION

Question 1:

Refers to the degree of difficulty descending stairs (irrespective of length, height or number).

Question 2:

Refers to the degree of difficulty ascending stairs (irrespective of length, height or number).

Question 3:

Refers to the degree of difficulty getting out of a chair (i.e. - rising from the sitting position).

Question 4:

Refers to the degree of difficulty of remaining in a standing position and should not be confused with question 6, which includes a dynamic component. It should also not be confused with question 3 (i.e. - it is the act of being in the standing position not the act of getting from another position to the standing position).

Question 5:

Refers to the degree of difficulty bending to pick something up off the floor. This usually involves some ankle movement, flexion of the knee and hip and also some lumbar spinal flexion. Female patients seem to use more lumbar flexion and relatively little knee flexion, others appear to squat to pick up objects from the floor.

Question 6:

Refers to the degree of difficulty walking on a flat surface, that is an even surface such as a sidewalk or the inside of a shopping mall. It does not refer to walking on uneven (i.e. - rough) ground.

Question 7:

Refers to the degree of difficulty getting in and out of a car, irrespective of whether this is into the driver's seat or a passenger seat. If the degree of difficulty differs between getting in versus getting out of a car, then the patient should rate the direction which produces the greatest difficulty.

Question 8:

Refers to a composite activity which involves leaving a place of residence and negotiating the various obstacles and musculoskeletal challenges in the act of going shopping. This may include such simple impediments as getting on or off a curb, going up a slight rise, walking and standing for prolonged

periods, and, in addition, is probably modulated by various social and emotional factors.

Question 9:
Refers to the degree of difficulty experienced while putting on socks or stockings. This question has been phrased to allow both male and female patients to respond.

Question 10:
Refers to the degree of difficulty in getting out of bed (i.e. - the act of swinging ones legs over the side and then getting into the standing position). This question differs from Question 3, in that the movement is made from a bed rather than a chair.

Question 11:
Refers to the degree of difficulty experienced while taking off socks and/or stockings and again has been modified so that male and female patients can both respond to the question.

Question 12:
Refers to the degree of difficulty lying in bed (i.e. - turning from side to side, or maintaining one particular position in the lying posture).

Question 13:
Refers to the degree of difficulty in getting in and out of the bath tub. For patients who take a shower, this question could refer to the shower rather than the bath. If the difficulty differs between getting in and out of the bath, then the patient should rate the activity that produces the greatest difficulty.

Question 14:
Refers to the degree of difficulty being in a sitting position (i.e. - static positioning).

Question 15:
Refers to getting on or off the toilet. If the degree of difficulty is different for the two actions, then the patient should rate that action which produces the most difficulty.

Question 16:
Refers to heavy domestic duties. It has been phrased in these terms to allow both male and female patients to respond. Heavy domestic duties might include mowing the lawn, raking leaves, shovelling snow, moving heavy boxes, vacuuming, scrubbing floors, lifting heavy grocery bags, etc. There are, of course, various other

examples.

Question 17:

Refers to light domestic duties. Again this has been phrased to allow both males and females to respond. Light domestic duties might include tidying up a room, indulging in crafts or hobbies, laying or clearing a table, cooking a meal, etc. There are, of course, various other examples.

APPENDIX C: CONSENT FORM

Investigator: Wendy Takeda 439-5177/492-7336
Supervisor: Dr. Jean Wessel 492-2988/492-7336

I, _____, agree to participate in a study conducted by Wendy Takeda, Physical therapist and Master's student, Department of Physical Therapy, University of Alberta. The purpose of the study is to determine whether acupuncture (used as an adjunct to treatment with medication) decreases the pain in persons with osteoarthritic knee(s). I am willing to participate in one of two different acupuncture groups, and to participate in 3 test sessions: 1) one week prior to acupuncture treatments, 2) one week after acupuncture treatments and 3) 4 weeks following the last test session. I understand I will be randomly allocated to one group or the other.

In all test sessions, the pain in my knees will be assessed using various rating scales. I will be asked to rate my pain after walking and stair climbing activities and to answer questions concerning my pain. I will also be asked to indicate when pain is first felt as a pressure instrument is applied to several points on my knee.

I will attend Ms. Takeda's laboratory 3 times per week for 3 weeks. Each session will take no longer than 30 minutes. Skin preparations will involve alcohol swabs over the treated areas and new sterilized needles will be used each time.

I may feel an aching sensation during the treatments and a temporary increase in symptoms after the initial treatment. Some potential risks 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. I may find during the study, that my pain will decrease. However, it has been requested that I do not alter my present medications during the first 5 weeks of the study.

The information that has been obtained in this study and that bears my name will be seen only by the investigator and those persons involved in the treatment of my arthritis. Any information that is published or presented at conferences will not refer to me by name, but only by number and only when necessary.

I understand that the investigators will be pleased to answer any questions during the study and I may decline to enter the study or I may withdraw from the study at any time without any effect on my medical treatment.

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 Subject's Signature

_____ _____
Witness's Signature Date

APPENDIX D: PARTICIPANT QUESTIONNAIRE FORM

PARTICIPANT

QUESTIONNAIRE

1. Has your doctor recently prescribed blood thinners or said that you bleed easily?

   Yes _____ No _____

2. Has your doctor ever said you have heart trouble?

   Yes _____ No _____

3. Do you often feel faint or have spells of severe dizziness?

   Yes _____ No _____

4. Do needles make you feel faint or nauseous?

   Yes _____ No _____

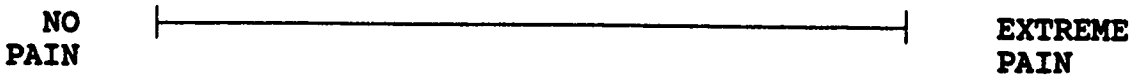
5. Is there a good physical reason not mentioned here why you should not receive acupuncture treatments even if you wanted to?

   Yes _____ No _____

Signature of Subject _____

Date _____

APPENDIX E: VISUAL ANALOGUE SCALE (VAS)



APPENDIX F: GUIDELINES FROM OCCUPATIONAL HEALTH AND SAFETY

The candidate and her advisor have registered with the department of Occupational Health and Safety and will be licensed to work with biohazard materials prior to the start of the data collection.

Needle Disposal:

Needles will be disposed of in a bleach bottle (with lid). The bottle will display a biohazard label and be clearly marked as dirty needles. The bottle will be kept in the lab, under the sink area. Any dirty gauze will be put a in bleach bottle and doused with bleach after disposal. Once the bottle is 3/4 full, the candidate will phone Tony at the Biosafety office for pick-up and incineration of needles.

Decontamination procedure (from "Working with Biohazardous Materials" issued by the Biosafety Committee):

Bleach will be used to decontaminate any areas touched by dirty needles. The bleach will be left on the contaminated surface for a minimum of 30 minutes.

Safety Procedures:

Biohazard signs will be on all entrances to the lab. There will be limited access to the lab. All persons working in the lab will be educated on Workplace Hazardous Material Information System (WHMIS) and have access to Material Safety Data Sheets (MSDS). These data sheets outline precautions for working with human blood. During treatment sessions, the candidate will wear a lab coat and gloves when applying needles.