The Efficacy of Acupuncture Versus Non-Penetrating Sham Acupuncture in Relieving Delayed Onset Muscle Soreness (DOMS) in Healthy Human Adults

By

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Abstract

A single-blinded, randomized controlled study was conducted, enrolling thirty-six healthy adults who had not recently participated in forearm strengthening or occupations/hobbies involving repeated forceful wrist motion. A fatiguing wrist extension exercise protocol was completed to induce delayed onset muscle soreness (DOMS). Group one received no treatment. Group two received acupuncture (ACU). Group three received sham acupuncture (S-ACU) with non-penetrating needles. Outcomes included grip strength, visual analogue scale for pain (VAS) and pain pressure threshold (PPT). Skin conductance (SC), skin temperature (ST) and perfusion (BF) were recorded to quantify the sympathetic nervous system response to treatment. The ACU group showed a significant increase in ipsilateral BF and in bilateral SC. The ACU group showed a significant decrease in distal ST bilaterally. The ACU and S-ACU groups showed decreased ipsilateral proximal ST. The exercise protocol did not consistently produce DOMS. The sample size of 36 may not have yielded sufficient statistical power.

Glossary of Terms

ACU	Acupuncture
Acupoint	Acupuncture Point
ANS	Autonomic Nervous System
CMBC	Concentration of Moving Blood Cells
CNS	Central Nervous System
DOMS	Delayed Onset Muscle Soreness
LDPM	Laser Doppler Perfusion Meter
NIH	National Institutes of Health
PAP	Pain at Pressure
PPT	Pain Pressure Threshold
PU	Perfusion Units
QST	Quantitative Sensory Testing
S-ACU	Sham Acupuncture (Non-Penetrating)
SC	Skin Conductance
SNS	Sympathetic Nervous System
ST	Skin Temperature
STD	Skin Temperature (Distal)
STP	Skin Temperature (Proximal)
TB	Total Backscatter
VAS	Visual Analogue Scale
WHO	World Health Organization

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Dedication:

As the first person in my family to reach post-secondary education, I am immensely proud to be completing my third university degree. I would like to dedicate this thesis to "the village" comprised of every individual or group who has helped me along my

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Introduction

Pain

Pain is a major factor for most people at some point in their lives. A common reason people seek physiotherapy treatment is because of pain. Pain has been defined as a subjective, unpleasant emotional or sensory experience that can be related to tissue damage or potential tissue damage (Merskey, 1994). Distinctions have been made between acute and chronic pain. Acute pain is thought to occur in response to tissue injury due to activation of local sensory nociceptors which have connections with the central nervous system (CNS). In addition to pain, injury to the tissue can cause stress, which is regulated by the autonomic nervous system (ANS). Tissue healing is thought to take days or weeks and the perception of acute pain can resolve before completion of the healing process (Loeser & Melzack, 1999). In contrast, chronic pain can last months or years, persisting after the tissue has healed and out of proportion with the actual amount of damage. It is believed that chronic pain occurs when the ANS is unable to restore itself to normal after an injury has healed. Chronic pain can be influenced by emotional and environmental factors through altered stress regulation by the ANS (Loeser & Melzack, 1999).

Lateral Epicondylosis

Lateral epicondylosis, also known as Tennis Elbow, is a common condition affecting up to 3% of the population (Buchbinder, Green, & Struijs, 2008). Tennis elbow is characterized by pain and tenderness of the common extensor tendon, pain that radiates into the dorsal forearm and weakness of the wrist extensor muscles (Slater, Arendt-

Nielsen, Wright, & Graven-Nielsen, 2005). Although usually self-resolving, lateral epicondylosis has been shown to become chronic, or persist for longer than 12 months in 20% of individuals (Buchbinder et al., 2008). Treatments for lateral epicondylosis can range from exercise, bracing and acupuncture to corticosteroid injection and even surgery (Buchbinder et al., 2008). Acupuncture has been shown in some trials to have a short-term benefit in the treatment of lateral epicondylosis; however, there is conflicting evidence in the literature (Buchbinder et al., 2008; Haker & Lundeberg, 1990). The evidence for acupuncture in the treatment of lateral epicondylosis has been described as low quality due to small sample sizes and inconsistent methodology between studies (Buchbinder et al., 2008).

Acupuncture

Acupuncture is a long-standing, useful modality in the treatment of pain and is becoming more recognized by Western medical practitioners. Acupuncture is also a growing area of medical research. In the ten years since the landmark 1997 National Institute of Health (NIH) Consensus statement on acupuncture was released, the quality and quantity of research studies have increased (NIH, 1997; NIH, 2008). Several advancements have led to a better understanding of the properties of acupuncture points and meridians as well as the mechanism of acupuncture, although further research is still needed (Napadow et al., 2008). While our understanding of acupuncture is improving, there remains a lack of consensus regarding its efficacy in the treatment of pain. Studies into acupuncture analgesia have shown little consistency in their terminology, methodology and placebo selection. In order to address the methodological challenges that face the design of

acupuncture studies, the Society for Acupuncture Research recently produced a set of guidelines to unify research in the area. A more consistent approach to clinical trials would be beneficial to increase the number of meta-analyses and systematic reviews (Napadow et al., 2008).

Sympathetic Nervous System and Pain

It has been suggested that the sympathetic nervous system (SNS) plays a role in acute and chronic pain; however, there is a lack of research pertaining to the response of the SNS to acupuncture and other pain treatments. Outcome measures such as perfusion, skin conductivity and skin temperature can used to quantify SNS activity (Jänig & Kollmann, 1984; Morrison, 2007). Measurement of any SNS response to acupuncture will add to the body of knowledge surrounding the physiological effects of treatment.

Experimental Model of Pain

Emotional and environmental factors can influence clinical pain and make it inconsistent between individuals. Pain has been described as a subjective and multidimensional experience that is unique to each person (Clark, Yang, Tsui, Ng, & Bennett Clark, 2002). As such, the measurement of pain in a way that takes into account all dimensions can be challenging using traditional on dimensional pain scales (Clark et al., 2002). Experimental models of pain are believed to be less affected by biopsychosocial influences than clinical pain (Svensson & Arendt-Nielsen, 1995). Several advantages to the use of experimental pain have been identified including the ability to select the time of onset and location of the pain as well as offering a quantifiable and reproducible

stimulus (Svensson & Arendt-Nielsen, 1995). The elicitation of delayed onset muscle soreness (DOMS) is emerging as a model of experimental pain for lateral epicondylosis (McRae, 2006; Slater, Arendt-Nielsen, Wright, & Graven-Nielsen, 2003). As such, there are very few studies involving this model of pain to study acupuncture analgesia. Previous experiments have involved DOMS in the elbow flexors and showed little consistency in their results. However, the studies utilized different outcome measures and different acupuncture treatment protocols. To date, no studies investigating the effect of acupuncture on DOMS in the forearm extensor muscles have been performed (Lin & Yang, 1999; Hübscher, Vogt, Bernhörster, Rosenhagen, & Banzer, 2008).

Study Description

The study explored the effects of acupuncture on an experimental model of lateral epicondylosis. The specific objectives of the study were:

-To create a model of forearm muscle pain that is valid, reliable and reproducible in healthy human participants.

- To compare the effects of real and placebo acupuncture in relieving muscle pain.

-To use quantitative sensory testing (QST) methods to provide objective measures of pain relief.

- To quantify the response of the SNS to ACU and S-ACU.

Review of literature

Introduction

Acupuncture originated in China and has been practiced for over 2500 years (World Health Organization, 2002). It became popular in the United States after President Nixon visited China in the early 1970's. While on this trip, an American reporter received acupuncture treatment for complications following an appendectomy and wrote about his experience in the New York Times (Reston, 1971). The article increased interest in acupuncture and its use has gained in popularity. The National Institutes of Health (NIH) released a position statement reporting that acupuncture had been shown to be effective in the treatment of pregnancy-related nausea, chemotherapy-related nausea and vomiting, post-operative pain and dental pain (NIH, 1997). This position statement served as a significant contribution to the acceptance of acupuncture by medical practitioners in the United States. Today, acupuncture is a common treatment administered by doctors, physiotherapists, traditional acupuncturists and other healthcare professionals worldwide (Ernst, 2006). The World Health Organization considers acupuncture to be part of 'Complimentary and Alternative Medicine' and implemented a comprehensive traditional medicine strategy in 2002 to encourage a stronger evidence-base for quality, safety and efficacy (World Health Organization, 2002).

Although a long-standing and popular treatment, the mechanism and efficacy of acupuncture remain controversial. A number of limitations to acupuncture research have been identified including poorly described studies with inconsistent terminology, an unconventional conceptual framework, a lack of understanding regarding properties of

acupoints, meridians and the mechanisms of acupuncture as well as the absence of an accepted placebo.

Terminology and Study Design

One element of the controversy surrounding the study of acupuncture is the lack of consistent terminology. In general, the term acupuncture refers to a therapy involving the insertion of fine needles into acupuncture points (Langevin & Yandow, 2002). Once inserted, the needles can be stimulated manually or with electronic current (electro-acupuncture) or laser light (laser-acupuncture). In addition, treatments can involve electrical or laser light stimulation over acupuncture points without the use of needles (Ceniceros & Brown, 1998; Ernst, 2006; Napadow et al., 2008). The wide variety of techniques attributed to the term acupuncture has made the comparison between research studies difficult. Consequently, more specific and consistent terminology in future research has been recommended to address this obstacle (Schnyer, 2008).

Another criticism of many acupuncture studies has been the scant details pertaining to the interventions of treatment and control groups. Poorly described treatment methodology limits the reproducibility of experiments (Ernst, 2006; MacPherson et al., 2002). It has been recommended that future clinical trials should be more consistent and that a more unified approach amongst the acupuncture research community would allow for more meta-analyses, systematic reviews and replication of studies (NIH, 2008). The "Standards for Reporting Interventions in Controlled Trials of Acupuncture: The STRICTA Recommendations" is a guideline for planning and describing acupuncture

research studies. The recommendations suggest that all studies related to acupuncture should include standard information regarding treatment rationale, needling details, treatment regimen, co-interventions, practitioner background and control selection (MacPherson et al., 2002).

Conceptual Framework of Acupuncture

Traditional acupuncture theory is difficult to reconcile with the current conventional medical model. This is due, in part, to the differing philosophies of Eastern and Western medicine. Traditional acupuncture theory states that health is obtained by balancing the Yin (female) and Yang (male) forces in the body. The goal of acupuncture treatment is to balance Yin and Yang by manipulating acupuncture points. Organs are viewed as energetic and the energy is known as 'de qi' (Ceniceros & Brown, 1998). The presence of 'de qi' is a phenomenon that is difficult to describe in western medical terms. Many acupuncturists claim to recognize 'de qi' by the sensation of the needle being 'grasped' by the underlying tissue while patients may describe sensations such as 'dull,' 'ache,' 'numb,' 'heavy' or 'spreading' (Langevin, Churchill & Cipolla, 2001; Park, White, Stevinson, Ernst & James, 2002). Acupuncture points are believed to be areas where 'de qi' is superficial and are linked together into 'meridians,' or channels, which run longitudinally along the body surface (Langevin & Yandow, 2002). There are three classes of acupoints: 'channel points' (along meridians), 'extra points' (off of meridians) and less used 'a shi points' (points which are painful on palpation). 'Channel' and 'extra points' are always present in individuals, while 'a shi points' are situational and not always present (Birch, 2003).

Recently, the term 'Western medical acupuncture' has been coined. This evidence based style of acupuncture is practiced by Western medical practitioners. It does not take into account the eastern concepts of 'de qi' or the balance of Yin and Yang. Although the treatment techniques involved with western medical acupuncture are similar to traditional Chinese acupuncture, the indications differ. The primary use of Western medical acupuncture is the treatment of symptoms such as pain or nausea whereas traditional acupuncture is used to maintain good health or to treat overall poor health (White, Lewith, Hopwood & Prescott, 2003). Western medical acupuncture may more easily reconcile with current scientific thinking (White et al., 2003).

Acupoints, Meridians and Mechanistic Models

Many efforts have been made to study acupoints and meridians; however, the anatomical and physiological properties remain unclear (NIH, 2008). Numerous attempts have been made to explain these structures within the Western biomedical framework. Early studies in the 1970's and 1980's related acupuncture points and meridians to a number of neural structures including peripheral nerves, free nerve endings, neurovascular bundles, mechanoreceptors and motor points (Bossy, 1984; Ciszek, Szopinski & Skrzypulec, 1985; Dung, 1984; Liu, Varela & Oswald, 1975; Napadow et al., 2008). It has been suggested that these studies were poor in quality due to a lack of good controls, small sample sizes and poor descriptions of acupoint localization. Therefore, to date, no one anatomical neural structure can be attributed to acupuncture points or meridians (Napadow et al., 2008).

Recently, the association between loose connective tissue and acupoints has been studied. Many acupuncture points and meridians have been found to align with intermuscular and intramuscular loose connective tissue in the upper limb (Langevin & Yandow, 2002). Meridians appeared to run along fascial planes and acupoints appear to be located where fascial planes converge. The overlap between connective tissue planes and acupoints and meridians is intriguing and warrants further research (Langevin & Yandow, 2002). The results of Langevin & Yandow (2002) are in keeping with the clinical technique of locating acupuncture points by palpating for a 'depression' under the skin. The concept of the 'needle-grasp' effect has been explained as a tissue/needle mechanical coupling whereby the tissue winds around the needle during needle rotation. It has been hypothesized that needle manipulation transmits a mechanical signal to connective tissue cells via mechanotransduction (Langevin, Churchill & Cipolla, 2001). This proposed mechanism may explain local and remote, as well as long-term effects of acupuncture. However, this theory is still evolving and the clinical significance is unclear (Napadow et al., 2008).

Another model of the mechanism of acupuncture, involving the role of nitric oxide, has been suggested (Tsuchiya, Sato, Inoue & Asada, 2007). Nitric oxide is a known second messenger in the regulation of local circulation and it has been suggested that circulation can play a role in pain (Tsuchiya et al., 2007). Acupoints have been shown to have increased nitric oxide activity and acupuncture has been shown to increase blood flow to the area of treatment. The increase in circulation associated with acupuncture is thought to promote healing of tissue (Tsuchiya et al., 2007). Acupuncture treatment has been

found to increase nitrite and nitrate levels in the blood, which are end products of nitric oxide metabolism. In contrast, sham acupuncture was found to have no effect (Tsuchiya et al., 2007). Nitric oxide has been theorized by Tsuchiya et al. (2007) to play a role in analgesia by inhibiting substance P and it has been suggested that individuals who respond strongly to acupuncture, do so because they generate more nitric oxide in response to treatment. The mechanism by which acupuncture leads to an increase in nitric oxide remains unknown and this mechanistic model requires further study (Tsuchiya et al., 2007).

Sympathetic Nervous System and Pain

The measurement of changes in the SNS has been suggested as an objective measure of pain (Jänig & Kollmann, 1984; Morrison, 2007). The sympathetic nervous system (SNS) in animals functions to prepare the body to react efficiently to threatening environmental stimuli (Jänig & Kollmann, 1984). When faced with a stressor, such as pain, the SNS has been shown to respond with a predictable pattern known as the 'affective defense reaction.' Physiological changes include sweating, increased cardiac output, piloerection, decreased blood flow to the skin and viscera, increased blood flow to the skeletal muscles, as well as the release of catecholamines, vasopressin and ACTH (Hess, & Brugger, 1943; Jänig & Kollmann, 1984). Consequently, skin conductivity, skin temperature and perfusion can serve as indicators of SNS activity.

The SNS is believed to play a role in pathological pain such as central and peripheral sensitization, although the exact mechanism is unclear (Jänig & Kollmann, 1984;

Morrison, 2007). It is also believed that the SNS may play a role in acupuncture analgesia; however, there is a lack of research pertaining to the response of the SNS to acupuncture and other pain treatments. Very few studies have looked specifically at the SNS response to acupuncture in human participants. In one study involving 19 normal participants, acupuncture was shown to produce a long lasting and generalized warming suggestive of a reduction of SNS activity (Ernst & Lee, 1985). An acupuncture needle applied to the left Large Intestine 4 point (see figure 1) and manually stimulated for 15 minutes was shown to increase skin temperature in the face, hands and feet, but not locally around the needle. In contrast, the control group showed a decrease in skin temperature at the same sites (Ernst & Lee, 1985). Ernst & Lee (1985) attributed the generalized increase in skin temperature to a reduction of SNS activity and suggested that the effect of acupuncture treatment was central in origin. One limitation of the study noted by the authors was that the body sites selected for skin temperature measurement did not allow segmental participation to be ruled out (Ernst & Lee, 1985).

In another study, acupuncture was shown to have the opposite effect by temporarily increasing activity the SNS (Kimura, Masuda, & Wakayama, 2006). An acupuncture needle inserted into the right Large Intestine 4 point of 7 participants for two minutes was shown to increase activity in cutaneous fascicles of the median nerve and to decrease blood flow to the left volar index finger tip for one minute after insertion. A subsequent return to baseline levels for the second minute of insertion and for five minutes after needle removal was noted. In contrast, the 5 participants in the control group showed no significant change in skin sympathetic nerve activity or blood flow in the experiment

(Kimura et al., 2006). Kimura et al. (2006) acknowledged that it was difficult to compare the outcomes with Ernst & Lee (1985) due to the different acupuncture treatment regimes (Ernst & Lee, 1985; Kimura et al., 2006). In addition, the short needle insertion time used by Kimura et al. (2006) does not reflect the insertion times used in practice and therefore limits the clinical relevance of the results. Further study into the response of the SNS to acupuncture is required to enhance understanding of acupuncture analgesia.

Measurement of Autonomic Nervous System Function

Skin Perfusion: The laser doppler perfusion meter (LDPM)(Perimed, Stockholm, Sweden) is a widely used clinical and research tool for the measurement of local microcirculatory blood perfusion in capillaries, venules and shunting vessels (Brown, Rice & Bennett, 1998; Murray, Herrick & King, 2004; Perimed, n.d.; Picart, Carpentier, Brasseur, Galliard & Piau, 1998). The LDPM has been described as a non-invasive, continuous and sensitive measure of microvascular blood flow (Leahy, de Mul, Nilsson & Maniewski, 1999). The device has been used in studies to quantify blood flow in individuals with Raynaud's phenomenon (Murray et al., 2004). It has also been used to investigate perfusion in patients with neuropathies, tumors, vasospastic vascular disorders, or those who have undergone plastic or orthopedic surgery (Schabauer & Rooke, 1994).

The LDPM consists of a photo detector connected to a probe tip containing optical fibres that transmit and receive laser light. When the laser light enters the tissue, blood cells moving past the beam will cause the light to change frequency, an effect known as the

Doppler Shift. Non-moving tissue will not shift the frequency of the light. The ratio of shifted light to non-shifted light corresponds to the number of moving blood cells encountered by the light path. A portion of the light in the tissue will scatter back to the probe and be carried along the receiving optical fibre until it reaches the photo detector where it is converted into electrical signals (Choi & Bennett, 2003; Perimed, n.d.). The electrical signals are separated into several parameters including blood perfusion, velocity, concentration of moving blood cells (CMBC) and total backscatter (TB). Blood perfusion has been defined as the product of CMBC and the mean velocity of the cells within the measured volume and is measured in perfusion units (PU). The CMBC value demonstrates the number of moving cells in the measured volume. The velocity pertains to the average velocity of the blood cells in the measured volume. The TB value refers to the amount of shifted and un-shifted light measured by the system. The TB value can be affected by the colour of the tissue, the number of blood cells present, technical parameters and even dust in the optical system (Perimed, n.d.).

Although widely used in a number of applications, the LDPM has not gained universal acceptance for any one application. Several limitations of the LDPM have been identified, particularly pertaining to the probe. The probe has been found to be very sensitive to vibration and motion. It has also been suggested that probe contact with the skin could alter the blood flow in the underlying tissue. In addition, the probe restricts measurements to a 1mm by 1mm area at a time (Choi & Bennett, 2003). It has been suggested that forearm skin motion can be misinterpreted as blood flow since the spectra of blood flow and skin motion overlap (Oberg, 1999). It has also been noted that

examining the perfusion of a small area does not necessarily represent the surrounding area (Murray et al., 2004).

The validity of the LDPM has been described as difficult to assess because there is no 'gold standard' to calibrate perfusion. When compared with other techniques for measuring perfusion including fluoroscein, the Xenon isotope and microspheres, a high correlation with the LDPM has been found. However, the correlation coefficients were variable depending on the site being tested (Choi & Bennett, 2003). It has also been noted that the microvascular blood flow of a tissue can be somewhat unpredictable. Therefore, quantifying perfusion should involve the change in perfusion in response to a physiological stimulus and be normalized to baseline values (Leahy et al., 1999). Limitations aside, the LDPM is a sensitive, non-invasive and continuous measure of relative blood flow.

Skin Temperature: The temperature unit (Thought Technology, New York, USA) measures skin surface temperature. The temperature sensing portion of the unit is known as a thermistor which is an electronic resistor made from small beads of complex materials. The resistance of the thermistor changes in response to temperature changes and the signals are converted into temperature readings. The manufacturing standard of such devices is cited as ±1°C accuracy with an operating range between 25°C and 45°C (Crawford, Hicks & Thompson, 2006).

Several advantages of contact electronic thermometers have been identified including the compact size, non-invasive application with no special preparation, fast reading times and the ability to obtain continuous temperature monitoring at a number of body sites simultaneously. Disadvantages of this device have also been described. Longer reading times may occur on dry skin as more time is required to obtain balance with the sensor. Readings with the contact electronic thermometer may be affected by ambient temperature and may experience electronic interference with other devices such as mobile phones (Crawford et al., 2006; Kelechi & Michel, 2007; Ninet & Fronek, 1985).

The 'gold standard' of body temperature has been defined as core temperature. An invasive method involving the placement of a temperature probe internally into locations such as the bladder or esophagus is required in order to obtain core temperature. However, skin temperature is a more common, non-invasive and clinically practical measure of body temperature. Normal skin temperature, taken at the axilla, has been considered to be a range between 35.5°C and 37°C in adults and between 35.6°C and 37.2°C in children. Several factors for varied body temperature have been identified including gender (increased in females around ovulation), age (decreased about 0.5°C in the elderly), time of day (increased about 0.5°C in the afternoon) and the use of medications such as antipyretics or thyroid preparations (Crawford et al., 2006).

The temperature of the skin surface has been described as representative of the microcirculation to the level of the papillary dermis. Warmer skin temperature correlates to a vasodilated state whereas cooler skin temperature correlates to a vasoconstricted state

(Kelechi & Michel, 2007). Increased skin temperature has also been associated with inflammatory processes due to increased local perfusion (Kelechi & Michel, 2007). Skin temperature changes occur very slowly in relation to that of the vascular system. It has been suggested that the large heat capacitance of skin tissue can interfere with the actual temperature changes occurring in the area of the vascular bed (Ninet & Fronek, 1985). A twenty minute rest period has been suggested to establish a baseline for skin temperature (Ernst & Lee, 1985).

The measurement of changes in skin temperature has been described as a non-invasive way to measure cardiac output with pale, cold skin acting as a marker for physiological adaptation to reduced cardiac output. When compared with the more invasive core-peripheral temperature gradients (CPTGs), skin temperature readings obtained with adhesive electrical probes were found to have a strong correlation the former. Although it was suggested that the use of CPTGs was unnecessary, it was recommended that further study involving a larger sample be completed to provide further validation (Schey, Williams & Bucknall, 2009).

Skin Conductance: A skin conductivity algesimeter (Thought Technology, New York, USA) measures changes in skin conductivity, which can be used to quantify pain. Sweating can occur as an emotional response, controlled by the cerebral cortex via sympathetic nerves in the skin. These nerves release acetylcholine, which binds to muscarinic receptors causing the glands in the palms and soles to produce sweat. A reduction in skin resistance occurs as a result of sweating and a subsequent increase in

skin conductance occurs within a few seconds. Once the sweat is reabsorbed, skin conductance will once again decrease. The skin conductance response has been described as a good indicator of pain, especially in individuals such as infants or patients under general anesthesia, who cannot communicate their perception of pain intensity (Storm, Shafiei, Myre & Raeder, 2005; Storm, 2008). The skin conductance algesimeter has been shown to have high specificity and sensitivity for pain in anesthetized and post-operative patients (Storm, 2008).

Greater skin conductance response values have been shown in the dominant hand compared to the non-dominant hand. A difference in skin conductance response has not been shown between men and women (Román, García-Sánchez, Martínez-Selva, Gómez-Amor & Carrillo, 1989; Román, Carrillo & García-Sánchez, 1992). The presence of nerve damage in the area under the electrodes has been cited as having an influence on reliability (Storm, 2008). Also, skin conductance values can be affected by anxiety and by body temperature changes (Berde 2009). To date, there appear to be no studies investigating the use of skin conductance response values as an indicator of pain due to musculoskeletal injury.

Selection of Acupuncture Control

Sham Acupuncture: A significant challenge in studying the effectiveness of acupuncture is the lack of a standard control or placebo. Earlier studies used 'sham' acupuncture as a control. Sham acupuncture is often described as the insertion of a needle into a point near a known acupuncture point, but not located on the meridian (Melchart et al., 2005;

Langevin et al., 2011; World Health Organization, 2002). There is no consensus on the best way to select sham points. In addition, sham acupuncture seems to have a similar or slightly muted effect on pain when compared to real acupuncture (Melchart et al., 2005; Langevin et al., 2011). There appears to be some response with the insertion of needles regardless of location (Melchart et al., 2005; Langevin et al., 2011). Interestingly, when sham acupuncture has been compared to a no treatment control, larger effect sizes have been shown than when conventional placebos are compared to a no treatment control (Langevin et al., 2011). Consequently, the use of sham acupuncture at non acupoints as a control is disputed (Melchart et al., 2005; NIH, 2008; Langevin et al., 2011).

Non-Penetrating Acupuncture Needles: Recently, non-penetrating acupuncture needles have become available and are inconsistently referred to as 'sham needles' or 'placebo needles' in the literature. The ideal sham needle has been described as having the same appearance as a real acupuncture needle and having the ability to be applied at any acupuncture point. The needle must also appear to penetrate the skin and be convincing to the patient. Non-penetrating needles have a tip that presses against the skin and a shaft that telescopes into the handle, much like a stage knife. This allows for the sensation and appearance of needle insertion (McManus et al., 2007). Three types of non-penetrating needles have been described including the 'Park-Sham Device,' the 'Double Blind Needle' and the 'Streitberger Needle' (McManus et al., 2007; Park et al., 2002; Takakura & Yajima, 2007).

Park Sham Device: The Park Sham Device (Dong Bang Acupuncture Inc., Boryeong, Korea) is one type of non-penetrating needle that has been developed as a potential placebo control for acupuncture. The non-penetrating needle contains a blunt tip and a needle shaft that slides up into the handle when pressed against the skin. Both the real and non-penetrating needles are contained within a guide tube with an adhesive base. An initial validation study for the Park Sham Device involved testing on the Large Intestine 4 point of 58 patients with recent stroke (Park et al., 2002). The 0.35mm gauge of the needles was slightly larger than the 0.25mm-0.30mm gauge needles commonly used clinically (AFCI, 2007). The Park Sham Device was shown to be indistinguishable from the real needle for every participant. However, a possible lack of sensation may have contributed to this finding (Park et al., 2002). A subsequent validation study involved 63 healthy acupuncture naïve adults who were informed of the possibility of receiving real or sham acupuncture at the Large Intestine 4 point and asked to report the sensations they felt with needle application (Park et al., 2002). Participants were significantly more likely to report sensations associated with 'de qi' with the real needle versus the Sham Park Device. The authors concluded that the device was shown to be clinically inert by taking the presence of 'de qi' sensations as a surrogate measure of effectiveness (Park, et al., 2002). This rationale could be challenged by the observation that presence of 'de qi' has not been shown to correlate with the therapeutic benefit of acupuncture treatment (AFCI, 2007). A reasonable level of inter-rater reliability was found with the Sham Park Device, which was measured by having blinded assessors view a videotape of the participants being interviewed after needle application and guessing whether 'de qi' had been experienced. However, the answers provided by the participants may have been

affected by the wording of the questions asked (Park et al., 2002). One challenge to this method of determining inter-rater reliability is the fact that 'de qi' is not always elicited with real needle insertion (AFCI, 2007).

The results of validation testing of the Sham Park Device on the Large Intestine 4 point with acupuncture-experienced participants have been less favourable, although the sample size of 21 participants was small (Tsukayama, Yamashita, Kimura & Otsuki, 2006). Furthermore, the gauge of needle tested (0.18mm) was thinner than the 0.25mm-.30mm gauge often used clinically and thinner than the gauge used in initial validation testing of the Park Sham Device (AFCI, 2007; Park et al., 2002). In participants who received real needles, 100% reported the sensation of needle penetration and 71% reported a 'dull sensation.' In contrast, in participants who received the Sham Park device, only 35% reported the sensation of needle penetration and 20% reported a 'dull sensation.' The results were less striking when tested at the Urinary Bladder 23 point (located approximately 1-1/2" laterally from the lower border of the L2 spinous process). In participants who received real needles, 50% reported the sensation of needle penetration and 40% reported a 'dull sensation.' In contrast, in participants who received the Sham Park device, 50% reported the sensation of needle penetration and 20% reported a 'dull sensation.' The discrepancy between the findings at the Large Intestine 4 point and the Bladder 23 point suggest that visual impact as well as acupoint selection may play a role in the ability of participants to discriminate between needle types (Tsukayama et al., 2006). The Park Sham device is currently under development and not available commercially at this time (Dongbang, n.d.).

The Double Blind Needle: Recently, a more sophisticated non-penetrating acupuncture needle called 'the Double Blind' needle has been designed (Takakura & Yajima, 2007). The matching 0.16mm gauge real and non-penetrating needles are both contained in a guide tube with an adhesive pedestal at the base for adhering to the skin. The opaque guide tubes allow the needle tips to be hidden from view throughout the treatment and contain a layer of 'stuffing' in the upper portion, which serves to give the needle resistance as it is applied. The guide tube of the non-penetrating needle contains an additional layer of 'stuffing' in the lower portion, which serves to give a sensation similar to skin puncture and tissue penetration for the practitioner. The body of the non-penetrating needle is just long enough to allow the blunt tip to press against the skin, while the body of the real needle is longer than the guide tube by the length of the insertion depth and both needles contain a stopper to prevent the needle handle from advancing further when the tip reaches the desired position (Takakura & Yajima, 2007).

In validation testing of the Double Blind Needle, practitioners were not able to consistently distinguish between the real or non-penetrating needles that were applied in random order to the Large Intestine 4 point. The possibility of practitioner masking with the Double Blind Needle is supported by the observation that practitioners correctly identified needles in only 50% of cases (Takakura & Yajima, 2007). Another validation study further supported the potential for practitioner masking whereby one practitioner who applied 114 pairs of randomly shuffled real and non-penetrating needles into the Triple Warmer 5 acupoint (see figure 1) correctly identified 97 needles, incorrectly identified 122 needles and was unable to provide a guess for 9 needles (Takakura &

Yajima, 2008). The conclusion that patient masking is possible with the Double Blind Needle based on an initial validation study involving the Large Intestine 4 point can be questioned. Firstly, the acupuncture-experienced participants were not informed of the possibility of receiving a non-penetrating needle rather, they were told that they would receive two needles that may or may not be different. When one of each needle was applied on each arm at the same time, none of the patients indicated that they suspected a non-penetrating needle was used. However, it is unlikely that patients would suspect that a non-penetrating needle was used if they were not informed of this possibility. Furthermore, the needles used in the study had a gauge of only 0.16mm whereas the gauge used clinically for the Large Intestine 4 acupoint is 0.25mm-0.30mm and the depth of insertion was 10mm whereas the depth used clinically is 12-24mm (AFCI, 2005; AFCI, 2007). In addition, the needles were immediately removed, whereas acupuncture needles are usually left in place for 15-30 minutes in the clinical setting. A longer insertion time may have given patients the opportunity to detect a difference between the needle types (AFCI, 2005; AFCI, 2007). Furthermore, a statistically significant difference was found in terms of reported sensation of skin penetration and 'de qi' sensation, which was less common with the non-penetrating needles (Takakura & Yajima, 2007).

A more recent validation study involved testing at the Triple Warmer 5 acupoint (see figure 1) with acupuncture-experienced participants were informed of the possibility of receiving a non-penetrating acupuncture needle (Takakura & Yajima, 2008). When one of each needle was randomly applied to each forearm, patients were asked to guess the

type of needle, report the pain of needle penetration on a VAS scale and report if 'de qi' sensation was felt. As with previous validation testing of the Double Blind Needle, the 0.16mm gauge was not consistent with the 0.25mm-0.30mm gauge used clinically for the Triple Warmer 5 acupoint and the insertion depth of 10mm was not consistent with the 12-24mm depth used clinically (AFCI, 2005; AFCI, 2007). The reports of skin penetration pain and 'de qi' sensations were not statistically different between the real and non-penetrating needles suggesting that the sensations of the two needles are comparable. The authors further concluded that effective patient masking was achieved because 56% of the non-penetrating needles were incorrectly identified. However, since only 32% of real needles were correctly identified there appears to be a significant difference in the likelihood of successfully identifying real versus non-penetrating needles. Further validation testing for this type of non-penetrating needle is required, especially involving a more clinically relevant gauge, depth of insertion and length of insertion time. Furthermore, while the developers of this type of non-penetrating needle hold patents in China and the United States, they are not available commercially at this time (Takakura & Yajima, 2008).

Streitberger Needle: The Streitberger needle (Asiamed, Pullach, Germany) is the most commonly used non-penetrating acupuncture needle in research studies (McManus et al., 2007; White et al., 2009). It was one of the first non-penetrating needles to be designed and tested (Streitberger & Kleinhenz, 1998). The Streitberger kit contains matching real and non-penetrating needles with similar appearances. The 0.30mm gauge of the needles is similar to the 0.25mm-0.30mm gauge needles commonly used clinically (AFCI, 2007). The real needle has a sharp penetrating tip, while the non-penetrating needle has a blunt

tip and the shaft moves up into the handle when pressed against the skin. Application of the needles involves placing a small plastic ring over the acupoint and holding it in place with tape (see Figure 2). The ring and tape conceal the tip of the needle as it reaches the skin. The tape also serves to hold the needle in place once it is inserted.

The developers of the Streitberger needles performed validation testing with a crossover study involving the Large Intestine 4 point (see figure 1)(Streitberger & Kleinhenz, 1998). The 60 participants were acupuncture naïve and were not informed of the possibility of receiving a non-penetrating acupuncture needle. Rather, they were told they were testing a new type of acupuncture needle to see if it was more or less painful than a traditional needle. Participants were asked to report whether they felt the needle puncture the skin, to rate the pain of needle penetration using a Visual Analogue Scale (VAS) and to report whether they felt a dull pain (de qi). Most participants reported the feeling of needle penetration regardless of whether they received the real or non-penetrating needle and regardless of the order the needles were applied. None of the participants suspected that the skin had not been punctured. However, it is unlikely that any of the participants would suspect that the needles had not pierced the skin if they were not informed of this possibility prior to treatment. The differences in the VAS scores between the real and non-penetrating acupuncture needles were not significant. Participants were significantly more likely to report 'de qi' with the real acupuncture needle than with the non-penetrating needle. In cases where 'de qi' was reported with non-penetrating needle, the authors offered pressure from the plastic ring, pain by pressure on a skin receptor or psychological influences as possible explanations

(Streitberger & Kleinhenz, 1998). It has been suggested that further testing of inter-rater reliability of the Streitberger needle is required (White et al., 2009).

Several practical difficulties with use of the Streitberger non-penetrating needle kits have been identified related to use of the tape as well as needle insertion, stimulation and removal (McManus et al., 2007). The tape included in the kit does not always adhere to the skin. Penetrating the tape with a blunt needle tip can be difficult to do in a way that does not appear different from the more easily inserted real needle. The tape and ring make it difficult for the practitioner to view needle insertion through them. Furthermore, it can be challenging to advance the non-penetrating needle into the handle by the desired length while maintaining a similar speed to real needle insertion. Also, the shaft and handle of the non-penetrating needle can easily separate and fall apart. It is often necessary for the practitioner to grasp the non-penetrating needle at the junction of the handle and needle shaft. In real acupuncture, the practitioner does not touch the needle shaft at all. When stimulating the non-penetrating needle manually, the practitioner must avoid accidentally advancing the shaft further into the needle handle. In addition, it can be difficult to remove the non-penetrating needle in a way that does not reveal that it is shorter than the real needle. There may be some bleeding at the sites after removal of real acupuncture needles, which would compromise patient blinding. Consequently, it has been recommended that the patient's view of the needle insertion be shielded to enhance blinding. Since practitioners are required to use special technique to make the insertion of the non-penetrating needle appear similar to the real needle, practitioner masking is not possible with the Streitberger needle (McManus et al., 2007). A practical guide for researchers using the Streitberger needle, offering advice regarding several

techniques to address the limitations of the non-penetrating needle and maintain the patient blinding, has become available (McManus et al., 2007). Limitations aside, the Streitberger needle has been described as the best option for a convincing acupuncture-like control currently available (White et al., 2009).

To date, the extent to which individual aspects of acupuncture treatment (such as needle location and depth of penetration) are associated with therapeutic benefit remain unclear (Langevin et al., 2011). It has been suggested that the therapeutic effect of acupuncture and sham acupuncture may be due to non specific effects such as patient expectancy of benefit and the interaction between patient and practitioner (Langevin et al., 2011). The Society for Acupuncture Research has suggested that future acupuncture research studies provide a more detailed study of the specific parameters of acupuncture treatment, such as location and depth of penetration, as well as their physiological response. As such, it has been recommended that future studies simultaneously investigate the effects of acupuncture and sham acupuncture on local tissues and on the nervous system (Langevin et al., 2011).

Delayed Onset Muscle Soreness (DOMS) Pain Model

The advantage of an experimental muscle pain model is the ability to select the location and time of onset of the pain which can then be used to investigate pain modulation. An emerging model of experimental muscle pain is the elicitation of DOMS, which is described as a type I muscle strain (Slater, Arendt-Nielsen, Wright & Graven-Nielsen, 2003; Slater, Arendt-Nielsen, Wright & Graven-Nielsen, 2005; Slater, Arendt-Nielsen,

Wright & Graven-Nielsen, 2006). DOMS is commonly elicited by performing an unaccustomed eccentric exercise protocol (Hübscher, Vogt, Bernhörster, Rosenhagen & Banzer, 2008; Slater et al., 2003).

DOMS is characterized by deep tenderness as shown by a reduction in pain pressure threshold (PPT) (McRae, 2006; Slater et al., 2003) with the most sensitive sites of the wrist extensors being the extensor carpi radialis longus and brevis muscles (Slater et al., 2003). It has been suggested that the presence of DOMS in the forearm extensors can be demonstrated by a reduction in PPT, grip strength and wrist extension force (Slater et al., 2005; Slater et al., 2006). Muscle soreness has been shown to increase over the first 24 hours after exercise, peak at 24-72 hours after exercise and resolve within 5-7 days (Hübscher et al., 2008; McRae, 2006; Slater et al., 2003; Slater et al., 2005; Slater et al., 2006).

Acupuncture may be effective in the treatment of DOMS by contributing to tissue healing and analgesia. Since acupuncture is thought to increase local perfusion, it is possible that DOMS may resolve more quickly with acupuncture treatment due to enhanced tissue healing as a result of the increased circulation (Tsuchiya et al., 2007).

The efficacy of acupuncture in the treatment of DOMS in the wrist extensors has not been studied. Studies involving acupuncture treatment of DOMS in the elbow flexors have yielded mixed results. In one study, acupuncture was more effective than sham acupuncture and no treatment in improving VAS scores; however, no significant

differences in mean pressure threshold or maximum isometric voluntary force values were found between the three groups (Hübscher et al., 2008). In another study, acupuncture was shown to significantly reduce VAS scores, but not creatine kinase levels, when compared to no treatment (Lin & Yang, 1999).

Tools to Measure the Signs and Symptoms of DOMS

Visual Analogue Scale (VAS): The VAS (see appendix A) is a widely used assessment tool for pain measurement, particularly in research pertaining to treatment outcome (Jensen & Karoly, 1993). The VAS is made up of a vertical or horizontal line that begins at 0 cm (no pain) and ends at 10 cm (worst pain imaginable) (Jensen & Karoly, 1993; Katz & Melzack, 1999). Patients are instructed to select a point along the line that corresponds to the intensity of their pain. It has been recommended that patients be given the opportunity to practice using the VAS to increase their understanding of the task (Jensen & Karoly, 1993). The distance from 0 cm to the point on the line selected represents the pain intensity score. Since each mm increment on the line can be selected, there are 101 points on the scale. It has been suggested that the large number of possible responses may make the VAS more sensitive to changes than rating scales with four or five points (Jensen & Karoly, 1993). Several advantages of the VAS have been identified including the conceptual simplicity and ease of administration and scoring of the VAS (Katz & Melzack, 1999; McGuire, 1984). In addition, it is possible to determine percentage differences between VAS values over time since each ratio on the scale is presumed equal. The ratio scale properties of the VAS also make it possible to compare the VAS measurements of independent samples (Katz & Melzack, 1999).

However, limitations for the VAS have also been identified. Some patients, such as individuals with perceptual-motor problems, may have difficulty understanding the instructions and require more lengthy directions. Also, the VAS involves more steps for scoring than other pain outcome measures. Therefore, it can be prone to more opportunity for error and may be impractical in the clinical setting (Jensen & Karoly, 1993; Katz & Melzack, 1999). It has also been suggested that use of the VAS should be limited to the measurement of pain intensity as there is little evidence available for other dimensions of pain (McGuire, 1984).

The majority of validation studies for the VAS have involved the adult population and it has been shown to be appropriate to measure pain. Good test-retest and inter-rater reliability have been shown for the VAS in adults (McGuire, 1984; Summers, 2001). The VAS for pain has been shown to correlate with observed pain behaviour and other self-report measures. It has also been shown that the VAS is sensitive to treatment effects (Jensen & Karoly, 1993).

Jamar Dynamometer: The computerized Jamar dynamometer (Biometrics, Gwent, UK) is a commonly used tool for the assessment of grip strength (see figure 3). Grip strength has been shown to be reduced in individuals with conditions such as lateral epicondylosis or DOMS of the forearm extensor muscles (Slater et al., 2005; Slater, Arendt-Nielsen, Wright, & Graven-Nielsen, 2006). The results of grip strength testing can be used by clinicians to assess treatment outcomes and to set realistic therapeutic goals (Hamilton,

McDonald & Chenier, 1992). The Jamar dynamometer has been shown to be reliable and valid when testing healthy adults (Hamilton, McDonald & Chenier, 1992; Mathiowetz, Weber, Volland & Kashman, 1984).

The Jamar dynamometer consists of a sealed hydraulic system, a gauge in pounds and kilograms and an adjustable handle with settings at 1, 1.5, 2, 2.5 and 3 inches. The device measures the force generated by the muscles involved in grip and is considered an isometric contraction as the handles move together by less than one eighth of an inch during testing (Bechtol, 1954). The Jamar dynamometer is easy to operate and the test for grip strength requires little time to perform. A number of recommendations have been made to ensure accurate results with the Jamar Dynamometer. The American Society of Hand Therapists has supported the use of standard patient positioning with the shoulder adducted and in neutral rotation, the elbow at 90 degrees of flexion, the forearm in neutral and the wrist in a self selected position (Fess, 1992). The use of standard patient instructions has also been recommended to increase accuracy (Crosby, Wehbé & Mawr, 1994). A protocol of alternating between the right and left hands while testing has been suggested to reduce the effect of muscle fatigue (Bechtol, 1954). Acceptable reliability has been shown with several testing methods including one trial, the mean of two or three trials and the highest of three trials (Crosby et al., 1994; Hamilton, Balnave & Adams, 1994; Mathiowetz, Weber, Volland & Kashman, 1984). Maximum grip strength can usually be obtained with the second, or 1.5 inch setting on the dynamometer handle, but some researchers prefer to test at all five settings to account for differences in hand size in participants (Bechtol, 1954; Crosby et al., 1994).

Achieving full effort from the participant is important for obtaining accurate results with the Jamar Dynamometer. Pain has been shown to have a variable effect on grip strength, with hand or wrist pain having a greater effect than forearm pain and pain above the elbow having little effect. Feigned weakness has also been identified as having a negative influence on grip strength and it has been suggested that there should be less than 20% variation between repeated tests if full effort is given (Bechtol, 1954).

Several factors have been identified as predictive of maximum grip. Men have been shown to have greater grip strength than women and maximum grip strength in both sexes has been found between the ages of 25 and 40. Occupations or hobbies involving repeated gripping or grasping have been shown to influence grip strength in men. Handedness has been demonstrated as an influence on maximum grip and it is generally accepted that the dominant hand should show 10% greater grip strength than the non-dominant hand (Anakwe, Huntley & McEachan, 2007; Bechtol, 1954; Crosby et al., 1994).

Pressure Algometry: A pressure algometer (Somedic, Horby, Sweden) is a non-invasive handheld device which measures pain sensitivity. The device consists of a pistol-shaped handle with a strain gauge located at the tip (see figure 4). Three pressure application surfaces, sized $0.5cm^2$, $1cm^2$ and $2cm^2$ can be applied to the tip of the algometer, which allows for measurement at a number of body sites (Kosek, Ekholm & Nordemar, 1993). The device includes a removable patient switch, which is comprised of a handle with a

button at the top which serves to record the level of pressure. The pressure algometer can be used to measure Pain Pressure Threshold (PPT) which has been defined as the point at which an applied pressure is perceived as painful. It has been shown that healthy women have lower PPT values than healthy men. In one study involving 120 males and 120 females, there was a highly significant ($p<0.0005$) difference, with females showing a 28% lower mean PPT at a test site over the first dorsal interosseous muscle (Chesterton, Barlas, Foster, Baxter & Wright, 2003). It has also been shown that hyperalgesia can be determined through measurement of PPT. Changes in PPT values can be recorded over time and used to trace recovery (Kinser, Sands & Stone, 2009).

Validation testing of pressure algometry has been favourable, although it has been suggested that investigators should take time to become familiar with the device through practice to enhance validity. Furthermore, application of the device perpendicular to the body surface has been recommended to increase the reliability of readings. The pressure algometer has been shown to be valid when compared to a force plate and reliable if repeat measurements are taken within one week (Kinser et al., 2009; Kosek et al., 1993). High inter-rater reliability has also been shown with pressure algometry in trained observers (Chesterton, Sim, Wright & Foster, 2007). It has been shown that a consecutive measurement of PPT can be 8% lower than the first if taken immediately. It has been suggested that this finding may be due to irritation, central summation, or even due to the participant having focused attention on the test site (Kosek et al., 1993). Therefore, the collection of three consecutive PPT measurements has been recommended (Chesterton et al., 2007).

Summary

The conceptual framework for traditional Chinese acupuncture is difficult to reconcile with the conventional medical model. Consequently, Western Medical Acupuncture is emerging as an evidence-based style of acupuncture practiced by Western medical practitioners. Previous research into the efficacy and mechanism of action of acupuncture treatment has lacked consistency in terminology and study design. As a result, comparison between studies is difficult and the number of meta-analyses is limited. The STRICTA guidelines serve as a framework to unify future acupuncture research (MacPherson et al., 2002).

There is currently no universally accepted control for acupuncture. The use of sham acupuncture as a control in acupuncture research studies has been disputed. Sham acupuncture has been shown to demonstrate some analgesia effect, albeit not as pronounced at the effect seen with acupuncture. The Streitberger non-penetrating needle has been shown to allow for patient masking; however, the special application technique required does not allow for practitioner masking. Practical difficulties with the use of Streitberger needles have been identified and a guide pertaining to use of the needles has become available (McManus et al., 2007). The Streitberger needle has been described as the best option for a placebo in single-blind acupuncture research studies. The 'Double Blind' and 'Sham Park' non-penetrating acupuncture needles currently in development offer potential for both patient and practitioner masking which may allow for double blind studies in the future.

The mechanism of action for acupuncture analgesia remains unclear. The SNS is believed to play a role in acupuncture analgesia; however, there are few studies in this area of research and the results have been conflicting. Further study into the response of the SNS to acupuncture and placebo acupuncture would be beneficial. Acupuncture is also thought to improve healing by enhancing local circulation, although few research studies have investigated the effect of acupuncture on blood flow.

Experimentally induced DOMS is emerging as a model of pain in research studies. DOMS in the forearm extensor muscles has been shown to be associated with a reduction in PPT and a reduction in grip strength. Little work has been done to study the efficacy of acupuncture in the treatment of DOMS. Studies involving acupuncture treatment of DOMS in the elbow flexors have yielded mixed results. To date, there are no studies investigating the efficacy of acupuncture in treating DOMS in the forearm extensor muscles.

Purpose, Objectives and Hypotheses

Purpose

To further explore DOMS as an experimental model of lateral epicondylosis. To determine the efficacy of acupuncture versus non-penetrating sham acupuncture in the treatment of DOMS involving the forearm extensor muscles. To quantify the SNS response to acupuncture and non-penetrating sham acupuncture.

Objectives

- To create a model of forearm muscle pain that is valid, reliable and reproducible in healthy human participants.
- To compare the effects of real and non-penetrating sham acupuncture in relieving muscle pain.
- To use quantitative sensory testing (QST) methods to provide objective measures of pain relief.
- To quantify the SNS response to ACU and S-ACU

Hypotheses

- Participants will show reduced grip strength and reduced PPT with the presence of DOMS. Acupuncture will be more effective than S-ACU in improving grip strength and PPT recovery after the onset of DOMS.

- Participants will show increased VAS for pain values with the presence of

DOMS. Acupuncture will be more effective than S-ACU in decreasing VAS values immediately post treatment and 24-hours post treatment.

- Participants in the ACU group will show greater SNS activation than the S-ACU group during treatment. Activation of the SNS will be indicated by an increase in blood flow, SC and proximal skin temperature (STP) as well as a decrease in distal skin temperature (STD).

Rationale of Study

Clinical Relevance

The use of acupuncture as a treatment modality is believed to produce several physiological changes. In addition to decreasing the sensation of pain, acupuncture is thought to promote healing of tissue through increased circulation. However, there is currently little evidence to support or refute the effect of acupuncture on circulation. This study approach represents a new direction in research towards the possible influence of acupuncture not only on decreasing pain but also in helping promote healing. This study utilizes an acupuncture treatment protocol that is clinically relevant as the needle gauge, acupoints, frequency of manual needle stimulation and treatment time is often used for forearm pain (AFCI, 2007). This study provides valuable information regarding the efficacy of an accepted modality used for pain control. The efficacy of acupuncture towards increasing blood perfusion and skin temperature thus increasing the tissue healing process was also investigated. The results of this study provide information regarding the response of the SNS to acupuncture.

Limitations, Delimitations and Assumptions

Limitations

This study is a single-blind design because practitioner masking is not possible with Streitberger acupuncture needles. In order to achieve a double-blind design, it would be necessary to employ a separate acupuncture practitioner and assessor, which would be beyond the scope and budget of the project. Therefore, the possibility of practitioner bias cannot be eliminated. More sophisticated non-penetrating acupuncture needles with the potential for practitioner masking are still in development and are not available commercially.

Delimitations

This study is limited to an experimental model of lateral epicondylosis and forearm extensor muscle pain. Chronic lateral epicondylosis and forearm muscle pain may not respond to acupuncture in the same way as the type of muscle pain induced in the study. Participants in the study were limited to healthy adults between the ages of 18 and 50. As the study population may differ from the demographic of patients more commonly affected with lateral epicondylosis, the results may not be more broadly applicable. Furthermore, participants in the study were asked to avoid anti-inflammatory medications and the use of ice during the study as they may affect the speed of recovery from DOMS. This may not reflect the reality that anti-inflammatory medications and ice are often used along with acupuncture treatment for forearm muscle pain in the clinical setting. Although the acupuncture treatment regimen selected for the proposed study is clinically relevant in terms of needle gauge, depth of insertion, amount of manual stimulation and

insertion time, it does not reflect the reality that several acupuncture treatments are usually performed. To follow participants for several acupuncture treatment sessions would be beyond the scope and budget of the project.

Assumptions

This study included the following assumptions: the exercise protocol would consistently elicit DOMS, participants in the acupuncture and non-penetrating sham acupuncture groups would remain unaware of the style of acupuncture they received, and the time allotted for monitoring of the SNS response to treatment would be sufficient to demonstrate an effect.

Design and Methodology

Introduction

The experimental design of this study was a single-blinded, randomized controlled descriptive study. The design of this study adheres to the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines to unify research in the area of ACU (MacPherson et al., 2002). The methodology of the study also adheres to the recommendations outlined in the practical guide for use of Streitberger needles to enhance patient blinding (McManus et al., 2007). This project was approved by the Health Research Ethics Board (HREB) from the University of Manitoba, Bannatyne Campus (H2009:180) (see Appendix B).

Participants

Prior to recruitment, a sample size analysis was performed based on the difference in PPT values of a previous study involving DOMS of the forearm extensor muscles (Slater et al., 2003). The power calculation involved a difference in PPT values ($\mu 1 - \mu 2$) of 93.7, an α value of 0.05 and a β value of 0.80. The minimum sample size result of the power calculation was 12 participants per group, or 36 participants in total.

Thirty-six healthy adult participants (29.78 +/- 4.96 years of age) (17 men, 19 women) (5 left, 31 right hand dominant) participated in this study. The age (years), gender (male/female) and hand dominance (right/left) for all participants were documented. Table 1 outlines the demographic information for all study participants. Chi-square testing revealed no significant difference between the three groups in terms of gender. In

contrast, Chi-square testing did reveal a significant difference between the three groups in terms of handedness, with more people being left handed in the sham acupuncture group.

Participants were asked to refrain from the use of analgesics, anti-inflammatory medications or cryotherapy during the study. In addition, participants were asked to refrain from any vigorous physical exercise involving the non-dominant upper extremity during the experimental period. All participants reviewed and signed an information and consent form (See Appendix C).

Inclusion / Exclusion Criteria

Participants were recruited from the staff and students of the University of Manitoba by word of mouth and posters placed around campus. For convenience, individuals between the ages of 18 and 50 years were recruited. All potential participants were asked to complete a screening questionnaire (Appendix D). In order to minimise the possible confounding variables with respect to SNS activity, individuals with an alcohol or tobacco addiction, taking medications affecting the central or peripheral nervous system (ie. beta blockers, anti-depressants, analgesics), or women who were pregnant or lactating were excluded from the study. In order to avoid complications, individuals with hemophilia or other bleeding disorders were also excluded. To ensure that forearm curls were a novel exercise to the participants, only those who had not participated in forearm strengthening exercises (weight training) or were not involved in occupations/hobbies involving repeated forceful wrist flexion/extension (such as racquet sports and carpentry) in the last three months were included. Participants were advised of the possibility of

receiving acupuncture treatment, or treatment with needles that do not pierce the skin, prior to the study.

Selection

Participants were allocated to each of the three study groups using an online random numbers table resulting in an equal number of participants per group. Group one was assigned to the control group and received no treatment. Group two was assigned to the acupuncture group and received acupuncture (ACU) treatment. Group three was assigned to the sham group and received non-penetrating sham acupuncture (S-ACU) treatment. Figure 5 provides an overview of the study design.

Instrumentation and Measures

Baseline Measurements

Prior to starting the exercise protocol, baseline grip and pain/discomfort measurements were collected from each participant (see Appendix E).

Grip strength measurements were made using a calibrated G100 electronic dynamometer (Biometrics, Gwent, UK). Figure 3 illustrates the set up for grip testing used in the study. The grip strength testing protocol used in the study reflects a protocol that is commonly used in clinical practice. Participants were seated in an office chair with the shoulder positioned in neutral rotation and adduction, the elbow in 90° of flexion, the forearm in neutral and the wrist in a self-selected position. A series of three grip strength measurements for the non-dominant hand were performed with 30 seconds of rest

between each trial (Crosby, Wehbé, & Mawr, 1994). For each trial, participants were instructed to grip the dynamometer as hard as possible for a total of three seconds. Grip strength measurements were collected at every study session.

Several measures of pain/discomfort were used in the study and were divided into two categories, those that measured pain at rest and those that measured pain with provocation. The list of pain measures is as follows:

- No provocation:
    - Pain at rest (VAS-R)
- Provocation with mechanical pressure:
    - Pain pressure threshold with mechanical algometer (PPT)
    - Pain with mechanical algometer applied pressure (VAS-P)
    - Pain with custom algometer applied pressure (VAS-C)

For all but PPT, pain was measured using visual analogue scales (VAS). The VAS consisted of a 10cm horizontal line with 'no pain' as the left anchor and 'worst pain imaginable' as the right anchor. Participants were asked to mark a vertical tick on the VAS to indicate their perceived level of pain/discomfort. For VAS-R, participants were asked to indicate the level of pain/discomfort while at rest (Appendix A). For VAS-P, participants were asked to indicate the level of pain/discomfort associated with pressure applied with a mechanical algometer (Appendix A). For VAS-C, participants were asked to indicate the level of pain/discomfort associated with pressure applied with a custom algometer (Appendix A). VAS measurements were taken at every study session.

A calibrated pressure algometer (Somedic, Horby, Sweden) with a 2cm ^{2} probe tip was used to obtain the PPT measurements at the Large Intestine 10 (LI10) acupuncture point on the non-dominant forearm. The LI10 point is located on the proximal dorsal radial forearm between the extensor carpi radialis longus and extensor carpi radialis brevis muscles, which are often involved in lateral forearm pain (see figure 1). The LI10 point was located by having each participant flex their non-dominant elbow in full pronation to reveal the transverse cubital crease. The LI10 point was located 3 fingers breadth distal to the end of the crease in line with the anatomical snuff box of the wrist (AFCI, 2005; AFCI, 2007). Figure 4 depicts the PPT testing used in the study. PPT measurements were obtained by applying an increasing amount of pressure with the algometer at the test site until the participant pressed the stop button. Each participant was instructed to press the stop button "at the first instant that the pressure becomes painful." Three PPT recordings were obtained with a 30-second rest period between each trial. PPT values were recorded at every study session.

For VAS-P testing, the Somedic algometer was also used to deliver a consistent amount of pressure to the LI10 test site. The amount of pressure delivered to each participant was determined by calculating the mean of the three PPT values recorded at their baseline. The examiner applied the amount of pressure corresponding to the baseline mean PPT of each participant. Each participant was then asked to complete the VAS scale to indicate the level of discomfort associated with the pressure applied. Each

participant received the same amount of pressure for VAS-P testing throughout the study. VAS-P values were recorded at every session.

It was not feasible to provide each participant with a Somedic algometer for follow up testing at home. Consequently, a custom algometer was created for participants to take home for VAS-C testing (figure 11). The custom algometer consisted of a 1.5L water bottle, filled with 1402g of salt, with a $2cm^2$ diameter wooden dowel glued to the lid. The LI10 point was marked on the non-dominant forearm of each participant for testing with the custom algometer. Participants were instructed to hold the algometer tip on the test site with the forearm in full pronation and then complete the VAS to indicate the amount of discomfort associated with the pressure. VAS-C values were recorded at 24 and 60-hours after baseline as well as at every session.

For VAS-R testing, participants were asked to complete a VAS to indicate the level of discomfort in the non-dominant forearm when seated comfortably with forearms positioned in neutral rotation on the armrests of the chair. VAS-R values were recorded at every session.

DOMS Pain Model

Prior to this study, a small pilot study was performed in order to determine an exercise protocol that could elicit DOMS. The pilot study involved 4 right hand dominant participants (3 women, 1 man) with a mean age of 33.25 years.

The following exercise protocol was used during the pilot study (see Appendix E). Each participant was seated in an office chair with their non-dominant forearm resting in pronation on the armrest. The armrest was positioned to place the elbow at approximately 90 degrees of flexion. A 5-lb dumbbell was placed into the participant's non-dominant hand. Each participant was instructed to keep pace with an electronic metronome set to beep at a rate of 15 repetitions per minute. Each participant competed three sets of wrist curls with one minute rest between sets. The investigator held the dumbbell during the rest period. For the first two sets, participants were instructed to try to perform 75 repetitions. If they could not complete the full set, they were advised to continue until they felt they "could not do one more repetition." For the final set, participants were advised to perform as many repetitions as they could until they felt they "could not do one more repetition."

After 48+/-2 hours, each of the participants was asked to report whether they had discomfort with gentle finger pressure at the Large Intestine 10 acupoint (see figure 1). All four participants reported tenderness with light finger pressure.

The exercise protocol used in the pilot study was also used in this study to elicit DOMS in the non-dominant forearm extensor muscles.

SNS Response to ACU

The SNS response to treatment was determined by monitoring skin conductance (SC), skin temperature (ST) and perfusion (BF) during the control, ACU and S-ACU

treatments (see Appendix E). Figure 6 depicts the placement of the SC, ST and BF sensors.

SC values were measured with calibrated Flexicomp Infiniti SC-Flex/Pro skin conductance sensors (Thought Technology, New York, USA) placed on the bilateral index and ring fingers of each participant. The sampling rate used in the study was 32Hz and SC values were recorded in micro-siemens (μS). The Flexicomp Infiniti encoder was linked to a PC where values were stored in Biograph Infiniti software (Thought Technology, New York, USA).

ST values were measured with calibrated Flexicomp Infiniti skin temperature sensors (Thought Technology, New York, USA). Proximal skin temperature (STP) was measured at the LI10 point of each forearm. Distal skin temperature (DST) was measured at the tip of the middle finger bilaterally. The sampling rate used in the study was 32Hz and ST values were recorded in degrees Celsius (°C). The Flexicomp Infiniti encoder was linked to a PC where values were stored in Biograph Infiniti software (Thought Technology, New York, USA).

Perfusion (BF) values were measured with a calibrated laser doppler perfusion meter (LDPM) (Perimed, Stockholm, Sweden). A perfusion sensor was placed at the LI10 point of each forearm. BF was values were recorded in perfusion units (pu). The LDPM was linked to a PC where values were stored in Perisoft software (Perimed, Stockholm, Sweden).

Figure 6 depicts the equipment set-up used for SNS monitoring in the study. When monitoring SC, STP, STD and BF, each participant was positioned comfortably in a recliner. The SNS was monitored for a baseline period of 20 minutes prior to treatment, for the 15 minute treatment and for a 10 minute recovery period after treatment.

Acupuncture Protocol

This study utilized a treatment protocol involving four acupoints that would be used clinically to treat lateral forearm pain (AFCI, 2007). The acupoints chosen for the study were Large Intestine 4, 10 and 11 (LI4, LI10 and LI11) was well as Triple Warmer 4 (TW4) and were selected based on Western Medical acupuncture philosophy (see figure 1). All acupoints were selected as treatment for lateral epicondylosis based on their proximity to the forearm extensor muscles or location within the radial nerve distribution. The acupoints LI11 and LI10 are located near the common extensor tendon and the extensor carpi radialis longus and brevis muscles respectively. The LI11 acupoint was landmarked by locating the end of the lateral elbow crease and the LI10 acupoint was landmarked by measuring 3 fingers breadth distal to the LI11 acupoint (AFCI, 2005; Langevin & Yandow, 2002; World Health Organization, 1993). The TW5 acupoint is located between the tendons of extensor digitorum communis and was landmarked by measuring 3 fingers breadth proximal to the midline of dorsal wrist crease . The LI4 acupoint is located within the sensory distribution of the radial nerve, which also provides motor innervation to the forearm extensor muscles. The LI4 acupoint was landmarked by locating the midpoint on the first dorsal web space between the middle of the first and second metacarpal bones. The acupuncture practitioner in the study (KP) was a licensed

physiotherapist who primarily treats hand & upper limb conditions. The practitioner certified to practice acupuncture with the College of Physiotherapists of Manitoba. The practitioner located the acupoints on all participants in all three groups. The Streitberger protocol was used (Streitberger & Kleinhenz, 1998). Briefly, the acupoints were marked with a small plastic ring and fixed to the skin with paper tape (Transpore, Minneapolis, USA). The needles for the ACU and S-ACU treatments were administered through the plastic ring and tape to make the two treatments appear as similar as possible. The needles used for the ACU treatments were 0.30 gauge and 30mm in length (Asiamed, Pullach, Germany). The Streitberger needles used for the S-ACU treatments were 0.30 gauge and 30mm in length (Asiamed, Pullach, Germany) and do not pierce the skin. The ring and tape at each acupoint served to hold the S-ACU needles in place.

All participants were seated comfortably in a recliner for the treatment session (Session 2A). Individuals in the control group rested comfortably in the recliner for the entire treatment period. The needles for the ACU treatments were inserted to a depth of approximately 15mm. The needles for the S-ACU treatments were administered to appear to be inserted at a depth of approximately 15mm (with 15mm of the needle pressed up into the handle). All needles were left in place for 15 minutes and were stimulated manually by the practitioner at 5 and 10 minutes into the treatment period. Manual stimulation of all ACU needles was achieved by grasping the handle and performing a piston motion (twisting while pulling up and down approximately 5mm five times). The practitioner grasped the S-ACU needles at the junction of the shaft and handle while manually stimulating the needles in order to prevent separation of the two

parts. The practitioner took care to shield the participant's view of needle insertion, needle stimulation and needle removal by holding one hand in front of the needle. When the rings and tape were removed at the end of the 10 minute post treatment monitoring period, the practitioner again shielded the participants view with one hand and wiped the area with a swab moistened with alcohol to remove any presence of blood on the skin.

Immediately after the treatment session (Session 2B), the grip strength, VAS-R, VAS-P, VAS-C and PPT values were reassessed for each participant with the same methodology as the baseline measurement and the pre-treatment reassessment. Each participant was given a custom algometer to take home and asked to complete the VAS-C test 12-hours later (60 hours after baseline).

Participants returned to the lab 24 +/- 2 hours after the treatment session for final reassessment (Session 3). At the final session, the grip strength, VAS-R, VAS-P, VAS-C and PPT values were reassessed for each participant with the same methodology as the baseline measurement (session 1), the pre-treatment reassessment (Session 2A) and the post-treatment reassessment (session 2B).

Figure 5 depicts an overview of the timing of the study sessions. Session 2A took place 48+/- 2 hours after session 1. Session 2B took place immediately after the completion of session 2A (approximately 1 hour later). Session 3 took place 24+/- 2 hours after session 2B.

Description of Paper

The methods, results, discussion and conclusion sections of this thesis are presented in two separate manuscripts. The first manuscript is entitled Sympathetic Nervous System Response to Acupuncture and Non-Penetrating Sham Acupuncture and the second manuscript is entitled Delayed Onset Muscle Soreness in Healthy Human Adults: An Experimental Model of Pain.

Sympathetic Nervous System Responses to Acupuncture and Non-Penetrating Sham Acupuncture

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Introduction

Acupuncture originated in China and has been practiced for over 2500 years (World Health Organization, 2002). Today, acupuncture is a common treatment administered by doctors, physiotherapists, traditional acupuncturists and other healthcare professionals worldwide (Ernst, 2006). The World Health Organization considers acupuncture to be part of 'Complimentary and Alternative Medicine' and implemented a comprehensive traditional medicine strategy in 2002 to encourage a stronger evidence-base for quality, safety and efficacy (World Health Organization, 2002).

Although a long-standing and popular treatment, the mechanism and efficacy of acupuncture remain controversial. A number of limitations to acupuncture research have been identified including poorly described studies with inconsistent terminology, poorly described study methodology, the absence of an accepted placebo and a lack of understanding regarding the mechanisms of acupuncture.

One element of the controversy surrounding the study of acupuncture is the lack of consistent terminology. In general, the term acupuncture refers to a therapy involving the insertion of fine needles into acupuncture points (Langevin & Yandow, 2002). Once inserted, the needles can be stimulated manually or with electronic current (electro-acupuncture) or laser light (laser-acupuncture). In addition, treatments can involve electrical or laser light stimulation over acupuncture points without the use of needles (Ceniceros & Brown, 1998; Ernst, 2006; Napadow et al., 2008). The wide variety of techniques attributed to the term acupuncture has made the comparison between research

studies difficult. Consequently, more specific and consistent terminology in future research has been recommended to address this obstacle (Schnyer et al., 2008).

Another criticism of many acupuncture studies has been the scant details pertaining to the interventions of treatment and control groups. Poorly described treatment methodology limits the reproducibility of experiments (Ernst, 2006; MacPherson et al., 2002). It has been recommended that future clinical trials should be more consistent and that a more unified approach amongst the acupuncture research community would allow for more meta-analyses, systematic reviews and replication of studies (NIH, 2008). The "Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) Recommendations is a guideline for planning and describing acupuncture research studies. The recommendations suggest that all studies related to acupuncture should include standard information regarding treatment rationale, needling details, treatment regimen, co-interventions, practitioner background and control selection (MacPherson et al., 2002).

A significant challenge in studying the effectiveness of acupuncture is the lack of a standard control or placebo. Earlier studies utilized a style of sham acupuncture whereby real acupuncture needles were inserted at non-acupuncture points as a control (Melchart et al., 2005; World Health Organization, 2002; Langevin et al., 2011). There is no consensus on the best way to select sham points. Sham acupuncture with real needles at non-acupuncture points has been shown to demonstrate some analgesia effect, albeit not as pronounced at the effect seen with acupuncture needles inserted at acupuncture points

(Melchart et al., 2005; Langevin et al., 2011). There appears to be some response with the insertion of needles regardless of location (Melchart et al., 2005; Langevin et al., 2011). Interestingly, when sham acupuncture has been compared to a no treatment control, larger effect sizes have been shown than when conventional placebos are compared to a no treatment control (Langevin et al., 2011). Consequently, the use of this style of sham acupuncture as a control in acupuncture research studies has been disputed (Melchart et al., 2005; NIH, 2008; Langevin et al., 2011).

Recently, non-penetrating acupuncture needles have become available and are inconsistently referred to as 'sham needles' or 'placebo needles' in the literature. The ideal sham needle has been described as having the same appearance as a real acupuncture needle and having the ability to be applied at any acupuncture point. The needle must also appear to penetrate the skin and be convincing to the patient. Non-penetrating needles have a tip that presses against the skin and a shaft that telescopes into the handle, much like a stage knife. This allows for the sensation and appearance of needle insertion (McManus et al., 2007). The Streitberger needle (Asiamed, Pullach, Germany) is the most commonly used non-penetrating acupuncture needle in research studies (McManus et al., 2007; White et al., 2009). The Streitberger kit contains matching real and non-penetrating needles with similar appearances. The real needle has a sharp penetrating tip, while the non-penetrating needle has a blunt tip and the shaft moves up into the handle when pressed against the skin. Application of the needles involves placing a small plastic ring over the acupoint and holding it in place with tape.

The ring and tape conceal the tip of the needle as it reaches the skin. The tape also serves to hold the needle in place once it is inserted.

It has been shown that patient masking in acupuncture naïve individuals is possible with the Streitberger needles. Validation testing in a crossover design study at the Large Intestine 4 acupoint (LI4) showed that most participants reported the feeling of needle penetration regardless of whether they received the real or non-penetrating needle and regardless of the order the needles were administered (Streitberger & Kleinhenz, 1998). None of the participants suspected that the skin had not been punctured. However, participants were not informed of the possibility of receiving a non-penetrating needle at the beginning of the study. Therefore, it is unlikely that any of the participants would suspect that the needles had not pierced the skin if they were not informed of this possibility prior to treatment. It has been suggested that further testing of inter-rater reliability of the Streitberger needle is required (Adrian White and Editorial Board of Acupuncture in Medicine, 2009).

Since practitioners are required to use special technique to make the insertion of the non-penetrating needle appear similar to the real needle, practitioner masking is not possible with the Streitberger needle (McManus et al., 2007). Several practical difficulties with use of the Streitberger non-penetrating needle kits have also been identified (McManus et al., 2007). The tape included in the kit does not always adhere to the skin. Penetrating the tape with a blunt needle tip can be difficult to do in a way that does not appear different from the more easily inserted real needle. The tape and ring make it difficult for

the practitioner to view needle insertion through them. Furthermore, it can be challenging to advance the non-penetrating needle into the handle by the desired length while maintaining a similar speed to real needle insertion. Also, the shaft and handle of the non-penetrating needle can easily separate and fall apart. It is often necessary for the practitioner to grasp the non-penetrating needle at the junction of the handle and needle shaft. In real acupuncture, the practitioner does not touch the needle shaft at all. When stimulating the non-penetrating needle manually, the practitioner must avoid accidentally advancing the shaft further into the needle handle. In addition, it can be difficult to remove the non-penetrating needle in a way that does not reveal that it is shorter than the real needle. Although not always, there may be some bleeding at the site after removal of a real acupuncture needle. Therefore, it has been recommended that needle insertion be shielded from the patient's view to enhance blinding. A practical guide for researchers using the Streitberger needle, offering advice regarding several techniques to address the limitations of the non-penetrating needle and maintain the patient blinding, has become available (McManus et al., 2007). Limitations aside, the Streitberger needle has been described as the best option for a convincing acupuncture-like control currently available (Adrian White and Editorial Board of Acupuncture in Medicine, 2009).

To date, the extent to which individual aspects of acupuncture treatment (such as needle location and depth of penetration) are associated with therapeutic benefit remain unclear (Langevin et al., 2011). It has been suggested that the therapeutic effect of acupuncture and sham acupuncture may be due to non-specific effects such as patient expectancy of benefit and the interaction between patient and practitioner (Langevin et al., 2011). The

Society for Acupuncture Research has suggested that future acupuncture research studies provide a more detailed description of the specific parameters of acupuncture treatment, such as location and depth of penetration, as well as their physiological response. As such, it has been recommended that future studies simultaneously investigate the effects of acupuncture and sham acupuncture both on local tissues and on the nervous system as a whole (Langevin et al., 2011).

The mechanism of action for acupuncture analgesia remains unclear. The sympathetic nervous system (SNS) is believed to play a role in acupuncture analgesia; however, there are few studies in this area of research and the results have been conflicting. Further study into the response of the SNS to acupuncture and non-penetrating sham acupuncture would be beneficial. Acupuncture is also thought to improve healing by enhancing local circulation,although few research studies have investigated the effect of acupuncture on blood flow.

One of the common reasons individuals seek acupuncture treatment is for pain. Pain is a major factor for most people at some point in their lives. Pain has been defined as a subjective, unpleasant emotional or sensory experience that can be related to tissue damage or potential tissue damage (Merskey H, 1994). The experience of pain has been described as unique to each individual (Clark et al., 2002). Acute pain is thought to occur in response to tissue injury due to activation of local sensory nociceptors which have connections with the central nervous system (CNS). In addition to pain, injury to the tissue can cause stress, which is regulated by the autonomic nervous system (ANS).

The measurement of changes in the SNS has been suggested as an objective measure of pain (Jänig & Kollmann, 1984; Morrison, 2007). The sympathetic nervous system (SNS) in animals functions to prepare the body to react efficiently to threatening environmental stimuli (Jänig & Kollmann, 1984). When faced with a stressor, such as pain, the SNS has been shown to respond with a predictable pattern known as the 'affective defense reaction.' Physiological changes include sweating, increased cardiac output, piloerection, decreased blood flow to the skin and viscera, increased blood flow to the skeletal muscles, as well as the release of catecholamines, vasopressin and ACTH (Hess, WR, & Brugger, M, 1943; Jänig & Kollmann, 1984). Consequently, skin conductivity, skin temperature and perfusion can serve as indicators of SNS activity.

The SNS is believed to play a role in pathological pain such as central and peripheral sensitization, although the exact mechanism is unclear (Jänig & Kollmann, 1984; Morrison, 2007). It is also believed that the SNS may play a role in acupuncture analgesia; however, there is a lack of research pertaining to the response of the SNS to acupuncture and other pain treatments. Very few studies have looked specifically at the SNS response to acupuncture in human participants. In one study, acupuncture was shown to produce a long lasting and generalized warming with increased skin temperature at the face, hands and feet, suggesting a reduction of SNS activity (Ernst & Lee, 1985). The acupuncture protocol used in the study involved the application of an acupuncture needle to the left large intestine 4 (LI4) acupoint with manual stimulation for 15 minutes. The authors suggested that the effect of acupuncture treatment was central in

origin but did acknowledge that the body sites selected for skin temperature measurement did not allow segmental mechanisms of pain modulation to be ruled out (Ernst & Lee, 1985). In the study, the temperature sensors were placed in the same location bilaterally, thus on the same dermatome. The addition of additional sensors on each limb at sites located within different dermatomes would be required to determine whether the skin temperature response to acupuncture was central or segmental in origin.

In another study, acupuncture was shown to have the opposite effect by temporarily increasing activity the SNS as shown by increased in activity in cutaneous fascicles of the median nerve and decreased blood flow to the index finger (Kimura et al., 2006). It is difficult to compare the outcomes of the two studies due to the different acupuncture treatment regimes (Ernst & Lee, 1985; Kimura et al., 2006). In addition, the short needle insertion time of two minutes used by Kimura et al. (2006) does not reflect the insertion times used in practice and therefore limits the clinical relevance of the results. Further study into the response of the SNS to acupuncture is required to enhance understanding of acupuncture analgesia.

Currently, the effect of acupuncture on the SNS remains poorly studied in the literature. It remains uncertain whether acupuncture consistently increases or decreases SNS activity. It is unclear whether the response of the SNS to acupuncture is dependent on the acupuncture protocol used. Furthermore, the response of the SNS to acupuncture may be dependent on whether the system is perturbed by a painful stimulus.

Emotional and environmental factors can influence clinical pain and make it inconsistent between individuals. Pain has been described as a subjective and multidimensional experience that is unique to each person (Clark et al., 2002). As such, the measurement of pain in a way that takes into account all dimensions can be challenging using traditional on dimensional pain scales (Clark et al., 2002). Experimental models of pain are believed to have less biopsychosocial influences than clinical pain (Svensson & Arendt-Nielsen, 1995). The advantage of an experimental muscle pain model is the ability to select the location and time of onset of the pain which can then be used to investigate pain modulation. An emerging model of experimental muscle pain is the elicitation of delayed onset muscle soreness (DOMS) (McRae, Sheila, 2006; Slater et al., 2003; Slater et al., 2005; Slater et al., 2006). DOMS has been described as a type I muscle strain and is commonly elicited by performing an unaccustomed eccentric exercise protocol (Hübscher et al., 2008; McRae, 2006; Slater et al., 2003). Muscle soreness after a novel eccentric exercise session has been shown to increase over the first 24 hours after exercise, peak at 24-72 hours after exercise and resolve within 5-7 days (Hübscher et al., 2008; McRae, 2006; Slater et al., 2003; Slater et al., 2005; Slater et al., 2006). It has been suggested that the elicitation of DOMS via novel eccentric exercise in the forearm extensor muscles can mimic two of the three main characteristics of lateral epicondylosis; the deep tissue hyperalgesia and reduced muscle force but not the pain at rest (Slater et al., 2003).

Little work has been done to study the efficacy of acupuncture in the treatment of DOMS. Studies involving acupuncture treatment of DOMS in the elbow flexors have yielded

mixed results. To date, there are no studies investigating the efficacy of acupuncture in treating DOMS in the forearm extensor muscles. Since DOMS is an emerging model of experimental pain, there are very few studies involving DOMS to study acupuncture analgesia. Previous experiments have involved DOMS in the elbow flexors and showed little consistency in their results. However, the studies utilized different outcome measures and different acupuncture treatment protocols. In one study, acupuncture was more effective than sham acupuncture and no treatment in improving VAS scores; however, no significant differences in mean pressure threshold or maximum isometric voluntary force values were found between the three groups (Hübscher et al., 2008; Lin & Yang, 1999).

The effect of acupuncture on chronic lateral epicondylosis has been studied. Two studies investigating the effectiveness of acupuncture in lateral epicondylosis utilised similar acupuncture protocols (Davidson, J., Vandervoort, A., Lessard, L., & Miller, L., 2001; Fink et al., 2002). In one study, the acupuncture protocol included the LI4, TW5, LI10, LI 11 and large intestine 12 (LI12) acupoints. The needles were inserted for 20 minutes and manually stimulated every five minutes, with eight treatment sessions delivered at a frequency of two to three times a week. Acupuncture was shown to reduce pain scores, reduce disability of the arm, shoulder and hand (DASH) scores as well as increased pain-free grip (Davidson, J., Vandervoort, A., Lessard, L., & Miller, L., 2001). In another study involving a similar acupuncture protocol, acupuncture was also shown to be favourable. The acupuncture protocol included the LI4, TW5, LI10, LI11 and lung 5 (LU5) acupoints. Needles were manually stimulated immediately after insertion and left

in place for 25 minutes. A penetrating sham acupuncture style was used, with needles applied at least 5cm away from the classical acupuncture points used in the study. Acupuncture was shown to be more effective than penetrating sham acupuncture in relieving the pain associated with chronic lateral epicondylosis (Fink et al., 2002).

The purpose of this study is to quantify the response of the SNS to acupuncture (ACU) and non-penetrating sham acupuncture (S-ACU) in a system perturbed by experimentally induced pain using a clinically relevant acupuncture protocol. We hypothesize that participants who receive ACU will show greater SNS activation than those who receive S-ACU as indicated by an increase in blood flow, skin conductance and local skin temperature as well as a decrease in distal skin temperature.

Methods

This study was a single-blinded, randomized controlled study. The design of this study adheres to the guidelines outlined in STRICTA to unify research in the area of acupuncture (MacPherson et al., 2002). The methodology of the study also adheres to the recommendations outlined in the practical guide for use of Streitberger needles to enhance patient blinding (McManus et al., 2007).

Participants

Thirty-six healthy adult participants (29.78 +/- 4.96 years of age) (17 men, 19 women) (5 left, 31 right hand dominant) participated in this study. The age (years), gender (male/female) and hand dominance (right/left) for all participants were documented. Chi-

square testing revealed no significant difference between the three groups in terms of gender. In contrast, Chi-square testing revealed a significant difference between the three groups in terms of handedness, with more people being left handed in the sham acupuncture group.

Table 1 outlines the demographic information for all study participants. Prior to participation, all participants signed a written consent form according to a protocol approved by the University of Manitoba Faculty of Medicine Health Research Ethics Board (Appendix B).

All potential participants were asked to complete a screening questionnaire (Appendix D). In order to minimise the possible confounding variables with respect to SNS activity, individuals with an alcohol or tobacco addiction, taking medications affecting the central or peripheral nervous system (ie. beta blockers, anti-depressants, analgesics), or women who were pregnant or lactating were excluded from the study. In order to avoid complications, individuals with hemophilia or other bleeding disorders were also excluded. To ensure that forearm curls were a novel exercise to the participants, only those who had not participated in forearm strengthening exercises or were not involved in occupations/hobbies involving repeated forceful wrist flexion/extension (such as tennis, carpentry) in the last three months were included.

Participants were asked to refrain from taking pain or anti-inflammatory medications or participation in any exercises involving the forearms during the study. Participants were

advised of the possibility of receiving acupuncture treatment, or treatment with needles that do not pierce the skin, prior to the study. All participants reviewed and signed an information and consent form (See Appendix C).

Exercise Protocol

The following exercise protocol was used to elicit delayed onset muscle soreness in the non-dominant forearm extensor muscles (See appendix E):

Each participant was seated in an office chair with their non-dominant forearm resting in pronation on the armrest, which was positioned to place the elbow at approximately 90 degrees of flexion. Each participant was instructed to keep pace with an electronic metronome set to beep at a rate of 15 repetitions per minute. Each participant competed three sets of wrist curls using a 5 pound (lb) dumbbell with one minute rest between sets. The investigator held the dumbbell during the rest period. For the first two sets, participants were instructed to try to perform 75 repetitions. If they could not complete the full set, they were advised to continue until they felt they "could not do one more repetition." For the final set, participants were advised to perform as many repetitions as they could until they felt they "could not do one more repetition."

SNS Monitoring

Sensors for monitoring skin conductance (SC), skin temperature (ST) and perfusion (BF) were attached (See appendix E). SC values were measured with calibrated Flexicomp Infiniti SC-Flex/Pro skin conductance sensors (Thought Technology, New York, USA) placed on the bilateral index and ring fingers of each participant. ST in degrees Celsius

(°C) was measured with calibrated Flexicomp Infiniti skin temperature sensors (Thought Technology, New York, USA). Proximal skin temperature (STP) was measured at the LI10 point of each forearm. Distal skin temperature (STD) was measured at the tip of the middle finger bilaterally. Both temperature and skin conductance were sampled at 32 Hz.

Perfusion (BF) values were measured with a calibrated laser doppler perfusion meter (LDPM) (Perimed, Stockholm, Sweden). A perfusion sensor was placed at the LI10 point (see figure 6) of each forearm. BF values were recorded in perfusion units (pu). The LDPM was linked to a PC where values were stored in Perisoft software (Perimed, Stockholm, Sweden).

Figure 6 depicts the equipment set-up used for SNS monitoring in the study. A pillow case was placed gently over each participant's fingers after the SC and STD sensors were attached. The SNS was monitored for a baseline period of 20 minutes prior to treatment, for the 15 minute treatment and for a 10 minute recovery period after treatment.

Acupuncture Protocol

Participants returned to the lab 48 ± 2 hours after the exercise session to attend a treatment session. Participants of the study were randomly assigned to one of three groups. Group one was assigned to the control group and received no treatment. Group two was assigned to the acupuncture group and received acupuncture (ACU) treatment. Group three was assigned to the sham group and received non-penetrating sham acupuncture (S-ACU) treatment.

Figure 1 depicts the acupoints used in the study. The acupoints chosen for the study were large intestine 4, 10 and 11 (LI4, LI10 and LI11) as well as triple warmer 4 (TW4) and were selected based on Western Medical acupuncture philosophy. All acupoints were selected based on their proximity to the forearm extensor muscles or location within the radial nerve distribution. The acupoints LI11 and LI10 are located near the common extensor tendon and the extensor carpi radialis longus and brevis muscles respectively. The TW5 acupoint is located between the tendons of extensor digitorum communis. The LI4 acupoint is located within the sensory distribution of the radial nerve, which also provides motor innervation to the forearm extensor muscles (AFCI, 2005; Langevin & Yandow, 2002; World Health Organization, 1993). The acupuncture practitioner in the study (KP) was a licensed physiotherapist who primarily treats hand & upper limb conditions. The practitioner is certified to practice acupuncture with the College of Physiotherapists of Manitoba. The practitioner located the acupoints on all participants in all three groups. The Streitberger protocol was used (Streitberger & Kleinhenz, 1998). Briefly, the acupoints were marked with a small plastic ring and fixed to the skin with paper tape (Transpore, Minneapolis, USA). The needles for the ACU and S-ACU treatments were administered through the plastic ring and tape to make the two treatments appear as similar as possible. The needles used for the ACU treatments were 0.30 gauge and 30mm in length (Asiamed, Pullach, Germany). The Streitberger needles used for the S-ACU treatments were 0.30 gauge and 30mm in length (Asiamed, Pullach, Germany) and do not pierce the skin. The ring and tape at each acupoint served to hold the S-ACU needles in place.

All participants were seated comfortably in a recliner for the treatment session. Individuals in the control group rested comfortably in the recliner for the entire treatment period. The needles for the ACU treatments were inserted to a depth of approximately 15mm. The needles for the S-ACU treatments were administered to appear to be inserted at a depth of approximately 15mm (with 15mm of the needle pressed up into the handle). All needles were left in place for 15 minutes and were stimulated manually by the practitioner at 5 and 10 minutes into the treatment period. Manual stimulation of all ACU needles was achieved by grasping the handle and performing a piston motion (twisting while pulling up and down approximately 5mm five times). The practitioner grasped the S-ACU needles at the junction of the shaft and handle while manually stimulating the needles in order to prevent separation of the two parts. The practitioner took care to shield the participant's view of needle insertion, needle stimulation and needle removal by holding one hand in front of the needle. When the rings and tape were removed at the end of the 10 minute post treatment monitoring period, the practitioner again shielded the participants view with one hand and wiped the area with a swab moistened with alcohol to remove any presence of blood on the skin.

Data Analysis

The BF recordings were visually inspected for obvious movement artefact. Any data points associated with obvious movement artefact were removed. The BF, SC, STP and STD recordings were divided into five minute intervals: baseline 0-5, baseline 5-10, baseline 10-15, baseline 15-20, insertion – stimulation 1, stimulation 1-2, stimulation 2-removal, removal to recovery 5 and recovery 5-10. The mean BF, SC, STP and STD

values were calculated for each interval and the values from the baseline 15-20 interval were chosen as baseline values for comparison.

The changes in BF, SC and ST over time were determined using a Friedman repeated measures analysis of variance on ranks (see Appendix G). Post-hoc analysis for changes in blood flow, skin conductance and skin temperature over time were completed using Tukey's test. At each individual time point, the differences between the control, ACU and S-ACU groups were determined using a Kruskal-Wallis one way analysis of variance on ranks. Post-hoc analysis for differences between groups was completed using Tukey's test for BF and ST. Post hoc analysis for differences between groups was completed using Holm-Sidak's test for SC. The significance level was set at $p<0.05$ for all analyses. The Sigma Stat program (Systat Software, San Jose, USA) was used for the above statistical analysis.

In addition, to determine if gender or handedness impacted the results, three-way repeated measures ANOVA testing was performed for each of the outcome variables: BF, ST and SC (see Appendix G). The significance level was set at $p<0.05$. This analysis was performed using SAS software version 9.2 (SAS Institute Inc., Cary, USA).

Results

Figure 7 presents the change in ipsilateral BF over time, represented as a percentage of perfusion measured at baseline. When compared with the control and S-ACU groups, the ACU group demonstrated a significant increase in ipsilateral BF (median (Inter Quartile

Range: 25%, 75%))(see Appendix F). Five minutes into the treatment period, ipsilateral blood flow increased to (135.219:115.552, 192.878) in the ACU group. By the end of the recovery period, the increase in ipsilateral BF seen in the ACU group had decreased significantly ($p<0.05$) and returned to baseline (100.331: 87.261, 109.808).

Figure 7 also presents the change in contralateral BF over time, represented as a percentage of perfusion measured at baseline. No significant different differences were noted between the ACU, S-ACU and control groups at any interval throughout the experiment. All three groups demonstrated a slight, gradual decline in contralateral BF throughout the recording period. By the end of the recording period, the reduction in contralateral BF seen in the control (89.383: 77.613, 102.766) and S-ACU group became significant (71.901: 60.766, 98.422) ($p<0.05$). Gender or handedness was not found to be associated with a significant change in BF.

Skin conductance is illustrated in Figure 8. Figure 8 presents the change in ipsilateral SC over time, represented as a percentage of SC measured at baseline. When compared with the control group, the ACU group demonstrated a significant increase in ipsilateral SC five minutes into the treatment period and remained increased throughout the remainder of the treatment period (144.332: 107.955, 192.914) ($p<0.05$)(see Appendix F). By the end of the recovery period, the increase in ipsilateral SC seen in the ACU group had decreased significantly and returned to baseline (104.730: 94.417, 136.806) ($p<0.05$). No significant differences were noted between the ACU, S-ACU and control groups during the recovery period.

Figure 8 also presents the change in contralateral SC over time, represented as a percentage of SC measured at baseline. When compared with the control group, the ACU group demonstrated a significant increase in contralateral SC five minutes into the treatment period (146.835: 112.272, 206.265) ($p<0.05$). The increase in contralateral SC seen in the ACU group had decreased significantly but not returned to baseline five minutes into the recovery period (116.152: 98.010, 145.525) ($p<0.05$). No significant differences were noted between the ACU, S-ACU and control groups for the remainder of the treatment period or during the recovery period. Gender or handedness was not found to be associated with a significant change in SC.

Figure 9 presents the change in ipsilateral STD over time, represented as a percentage of STD measured at baseline. When compared to the control group and the S-ACU group, the ACU group showed a significant reduction in ipsilateral STD five minutes into the treatment period (98.830: 98.276, 99.383) and remained decreased throughout the remainder of the treatment period (98.806: 96.761, 99.647) (98.800: 96.643, 99.370) ($p<0.05$)(see Appendix F). The ACU group also continued to show a significant reduction in ipsilateral STD throughout the recovery period (97.786: 96.742, 99.246) (97.618: 97.107, 99.037) ($p<0.05$).

Figure 9 also presents the change in contralateral STD over time, represented as a percentage of STD measured at baseline. When compared to the control group and the S-ACU group, the ACU group showed a significant reduction in contralateral STD five

minutes into the treatment period (98.830: 98.276, 99.383) and remained decreased throughout the remainder of the treatment period (98.806: 96.761, 99.647)(98.800: 96.643, 99.370) ($p<0.05$). The ACU group also continued to show a significant reduction in contralateral STD throughout the recovery period (97.786: 96.742, 99.246) (97.618: 97.107, 99.037) ($p<0.05$). Gender or handedness was not found to be associated with a significant change in STD.

Figure 10 presents the change in ipsilateral STP over time, represented as a percentage of STP measured at baseline. The ACU group showed a significant reduction in ipsilateral STP by the end of the treatment period (99.145: 98.122, 99.738) which continued throughout the recovery period ($p<0.05$) (98.997: 97.565, 99.595) (98.986: 97.747, 99.461)(see Appendix F). Likewise, the S-ACU group showed a significant decrease in ipsilateral STP by the end of the treatment period (99.345: 98.856, 99.718) and five minutes into the recovery period (99.410: 98.865, 99.733) ($p<0.05$). No statistically significant differences were shown between the ACU, S-ACU or control groups at any interval throughout the treatment or recovery periods.

Figure 10 presents the change in contralateral STP over time, represented as a percentage of STP measured at baseline. No statistically significant differences were shown between the ACU, S-ACU or control groups at any interval in the treatment or recovery periods. The control, ACU and S-ACU groups showed a significant decrease in contralateral STP by the end of the recovery period respectively (99.256: 99.120, 100.501) (98.986:

97.747, 99.461) (99.359: 98.873, 99.869) ($p<0.05$). Gender or handedness was not found to be associated with a significant change in STP.

Discussion

The primary objective of this study was to use BF, SC and ST measurements to evaluate the SNS response to ACU and S-ACU in healthy human participants with experimental muscle pain. The results of this study show a significant ipsilateral increase in BF and a significant increase in SC bilaterally in the ACU condition. A significant decrease in STD is seen bilaterally with ACU, while STP decreases significantly ipsilaterally with both ACU and S-ACU but not in the control condition.

The ACU group showed a significant increase in local BF on the ipsilateral forearm within five minutes of needle insertion, while no increase was observed on the contralateral side. This unilateral increase in local perfusion suggests that the changes are mediated locally and not systemically.

The ACU group showed a significant increase in SC bilaterally within five minutes of needle insertion. The increase in SC on both the ipsilateral and contralateral side suggests that the change is mediated systemically. An increase in SC is suggestive of SNS activation. Since the SC sensors were located on the same segment bilaterally, segmental mediation cannot be ruled out. An increase in SC is suggestive of SNS activation.

ACU group showed a significant reduction of STD bilaterally within five minutes of needle insertion. The decrease in STD on both the ispilateral and contralateral side suggests that the change is mediated systemically. Since the STD sensors were located on the same segment bilaterally, segmental mediation cannot be ruled out. A reduction in STD is suggestive of SNS activation.

On the contralateral arm, the control, ACU and S-ACU groups all showed a significant decrease in STP by the end of the recovery period. The S-ACU group showed a significant decrease in ipsilateral STP by the end of the treatment period and five minutes into the recovery period. Likewise, the ACU group showed a significant reduction of STP ipsilaterally within five minutes of needle insertion which continued throughout the recovery period. The reduction of STP seen in the ACU group is the opposite of what would be expected given the significant increase in blood flow observed. It is possible that the skin temperature sensor was not placed close enough to the needle site to record any increase in STP associated with the increased blood flow.

It appears that ACU causes activation of the SNS as indicated by the increase in SC and decrease in STD observed within five minutes of needle insertion. The unilateral increase in blood flow observed near the needle site appears to be due to local circulatory modulation.

Very few studies have looked at the SNS response to ACU in human participants. To date, no studies have investigated the SNS response to ACU specifically in human

participants with experimental pain. Our findings are in contrast to those of Ernst & Lee (1985) who found that ACU produced a long lasting and generalized warming with increased ST at the face, hands and feet. A generalized increase in ST is suggestive of a reduction of SNS activity (Ernst & Lee, 1985). In contrast, our findings showed a decrease in ST with ACU, which is suggestive of an increase in SNS activity. It is difficult to compare the ST outcomes of our study to those of Ernst & Lee (1985) as different ACU protocols were utilized. Our study included four acupoints (LI4, TW5, LI10, LI11) with a 15-minute treatment period, while their study including only one acupoint (LI4) with a treatment period of the same length. The participants in our study were individuals with experimental pain while Ernst & Lee (1985) included normal participants. It is possible that the SNS responds differently to ACU in the presence of pain. The results of our study and those of Ernst & Lee (1985) both suggest that the effect of ACU on skin temperature is systemic in origin; however, the body sites selected for ST measurement did not allow segmental participation to be ruled out (Ernst & Lee, 1985).

The results of our study are in keeping with those of Kimura, Masuda & Wayakama (2006) in which ACU was shown to temporarily increase activity the SNS, although the outcome measures utilized were different. Kimura et al. (2006) demonstrated an increase in activity in cutaneous sympathetic fascicles of the median nerve and decreased BF to the index finger (Kimura et al., 2006). It is difficult to compare the BF outcomes of our study with Kimura et al. (2006) due to the different ACU treatment regimes and different locations of the BF sensors. Our study included four acupoints (LI4, TW5, LI10, LI11)

with a 15-minute treatment period, while their study included only one acupoint (LI4) with a treatment period of only two minutes (Kimura et al., 2006). Furthermore, our study placed the bilateral BF sensors proximally near the elbow while Kimura et al. (2006) placed a single BF sensor on the contralateral index finger, presumably looking for SNS activity specifically.

Limitations and Assumptions

Although participants were advised of the possibility of receiving acupuncture or treatment with needles that do not pierce the skin, they were not asked to guess which type of needle they had received after the treatment. Information regarding the participants' perception of whether they received real or non-penetrating acupuncture could have provided information about participant expectations. It has been suggested that the muted effect noted with sham acupuncture could be due to participant expectation (Langevin et al., 2011).

Conclusions

The results of this study add to the scant body of literature investigating the SNS response to ACU. It appears that ACU causes activation in the SNS as indicated by a bilateral increase in SC and a bilateral decrease in STD after needle insertion. It appears that the unilateral increase in BF near the needle site observed with ACU treatment is due to local circulatory control, rather than systemic control.

It is clear that further study into the response of the SNS to ACU is required to enhance understanding of ACU analgesia. To date, it is difficult to determine whether the effect of ACU on the SNS is central or segmental in origin. As such, further study should include the placement of SC and ST sensors at non-segmental locations.

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Delayed Onset Muscle Soreness (DOMS) in Healthy Human Adults: An Experimental Model of Pain

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Introduction

Pain is a major factor for most people at some point in their lives. One of the most common reasons people seek physiotherapy treatment is because of pain. Pain has been defined as a subjective, unpleasant emotional or sensory experience that can be related to tissue damage or potential tissue damage (Merskey H, 1994). Distinctions have been made between acute and chronic pain. Acute pain is thought to occur in response to tissue injury due to activation of local sensory nociceptors, which have connections with the central nervous system (CNS). In addition to pain, injury to the tissue can cause stress, which is regulated by the autonomic nervous system (ANS). Tissue healing is thought to take days or weeks and the perception of acute pain can resolve before completion of the healing process (Loeser & Melzack, 1999). In contrast, chronic pain can last months or years, persisting after the tissue has healed and out of proportion with the actual amount of damage. It is believed that chronic pain occurs when the ANS is unable to restore itself to normal after an injury has healed. Chronic pain can be influenced by emotional and environmental factors through altered stress regulation by the ANS (Loeser & Melzack, 1999).

Lateral epicondylosis, also known as Tennis Elbow, is a common condition affecting up to 3% of the population (Buchbinder et al., 2008). Tennis elbow is characterized by pain and tenderness of the common extensor tendon, pain that radiates into the dorsal forearm and weakness of the wrist extensor muscles (Slater et al., 2005). Although usually self-resolving, lateral epicondylosis has been shown to become chronic, or persist for longer than 12 months in 20% of individuals (Buchbinder et al., 2008). Treatments for lateral

epicondylosis can range from exercise, bracing and acupuncture to corticosteroid injection and even surgery (Buchbinder et al., 2008). Acupuncture has been shown in some trials to have a short-term benefit in the treatment of lateral epicondylosis; however, there is conflicting evidence in the literature (Haker & Lundeberg, 1990). The evidence for acupuncture in the treatment of lateral epicondylosis has been described as low quality due to small sample sizes and inconsistent methodology between studies (Buchbinder et al., 2008).

Emotional and environmental factors influence clinical pain and make it inconsistent between individuals. Experimental models of pain are believed to be less affected by biopsychosocial influences than clinical pain (Svensson & Arendt-Nielsen, 1995). Another advantage of an experimental muscle pain model is the ability to select the location and time of onset of the pain which can then be used to investigate pain modulation (Svensson & Arendt-Nielsen, 1995). An emerging model of experimental muscle pain is the elicitation of delayed onset muscle soreness (DOMS) (Hübscher et al., 2008; McRae, 2006; Slater et al., 2003; Slater et al., 2005; Slater et al., 2006). DOMS has been described as a type I muscle strain and is commonly elicited by performing an unaccustomed eccentric exercise protocol. Muscle soreness after a novel eccentric exercise session has been shown to increase over the first 24 hours after exercise, peak at 24-72 hours after exercise and resolve within 5-7 days. Previous studies have attempted to experimentally mimic the characteristics of lateral epicondylosis in participants. It has been suggested that the elicitation of DOMS via novel eccentric exercise in the forearm extensor muscles can mimic two of the three main characteristics of lateral epicondylosis:

the deep tissue hyperalgesia and reduced muscle force attenuation (Slater et al., 2003; Slater et al., 2005). The exercise protocol utilized in previous studies involved the use of KinCon dynamometer set to the isokinetic mode. Participants completed a 25-minute exercise session including five sets of five minutes of exercise with one minute of rest between sets. Each eccentric contraction was four seconds in length with one second of rest between contractions (Slater et al., 2003; Slater et al., 2005). The presence of DOMS in the forearm extensor muscles can mimic the deep tissue hyperalgesia associated with lateral epicondylosis, with the most sensitive sites being the extensor carpi radialis longus and brevis muscles (Slater et al., 2003). The deep tenderness associated with DOMS can be shown by a reduction in pain pressure threshold (PPT) (Slater et al., 2003). In addition, the presence of DOMS in the forearm extensor muscles mimics the reduced muscle force seen in patients with lateral epicondylosis and be demonstrated by a reduction in grip strength (Slater et al., 2003). In order to elicit the third characteristic of lateral epicondylosis, pain at rest, injection of hypertonic saline into the extensor carpi radialis brevis muscle approximately 24-hours after the novel eccentric exercise program is required (Slater et al., 2005).

Since DOMS is an emerging model of experimental pain, there are very few studies involving DOMS to study acupuncture analgesia. Previous experiments have involved DOMS in the elbow flexors and showed little consistency in their results. However, the studies utilized different outcome measures and different acupuncture treatment protocols. In one study, acupuncture was more effective than sham acupuncture and no treatment in improving VAS scores; however, no significant differences in mean pressure

threshold or maximum isometric voluntary force values were found between the three groups (Hübscher et al., 2008). In another study, acupuncture was shown to significantly reduce VAS scores, when compared to no treatment (Hübscher et al., 2008; Lin & Yang, 1999).

The purpose of this study was to further explore DOMS as an experimental model for some of the characteristics of lateral epicondylosis. Our goal was to develop an exercise protocol that was less time consuming and required less specialized equipment than the protocols described in the current body of literature. In addition, this study sought to determine the efficacy of acupuncture (ACU) versus non-penetrating sham acupuncture (S-ACU) in the treatment of DOMS involving the forearm extensor muscles.

Methods

This study was a single-blinded, randomized controlled descriptive study. The design of this study adheres to the guidelines outlined in STRICTA to unify research in the area of ACU (MacPherson et al., 2002). The methodology of the study also adheres to the recommendations outlined in the practical guide for use of Streitberger needles to enhance patient blinding (McManus et al., 2007).

Participants

A sample size calculation was performed prior to the study and yielded a result of 12 participants group. Thirty-six healthy adult participants (29.78 +/- 4.96 years of age) (17 men, 19 women) (5 left, 31 right hand dominant) participated in this study. The age

(years), gender (male/female) and hand dominance (right/left) for all participants were documented. Chi-square testing revealed no significant difference between the three groups in terms of gender. In contrast, Chi-square testing revealed a significant difference between the three groups in terms of handedness, with more people being left handed in the sham acupuncture group. Table 1 outlines the demographic information for all study participants. Prior to participation, all participants signed a written consent form according to a protocol approved by the University of Manitoba Faculty of Medicine Health Research Ethics Board (Appendix C).

All potential participants were asked to complete a screening questionnaire (Appendix D). In order to minimize the possible confounding variables with respect to SNS activity, individuals with an alcohol or tobacco addiction, taking medications affecting the central or peripheral nervous system (i.e. beta blockers, anti-depressants, analgesics), or women who were pregnant or lactating were excluded from the study. In order to avoid complications, individuals with hemophilia or other bleeding disorders were also excluded. To ensure that forearm curls were a novel exercise to the participants, only those who had not participated in forearm strengthening exercises (weight training) or were not involved in occupations/hobbies involving repeated forceful wrist flexion/extension such as racquet sports and carpentry in the last three months were included. Participants were asked to refrain from taking pain or anti-inflammatory medications or participation in any exercises involving the forearms during the study. Participants were advised of the possibility of receiving acupuncture treatment, or treatment with needles that do not pierce the skin, prior to the study.

Baseline Measurements

Prior to starting the exercise protocol, baseline grip and pain/discomfort measurements were collected from each participant (See appendix E).

Grip strength measurements were made using a calibrated G100 electronic dynamometer (Biometrics, Gwent, UK). Figure 3 illustrates the set up for grip testing used in the study. The grip strength testing protocol used in the study reflects a protocol that is commonly used in clinical practice. Participants were seated in an office chair with the shoulder positioned in neutral rotation and adduction, the elbow in 90° of flexion, the forearm in neutral and the wrist in a self-selected position. A series of three grip strength measurements for the non-dominant hand were performed with 30 seconds of rest between each trial (Crosby et al., 1994). For each trial, participants were instructed to grip the dynamometer as hard as possible for a total of three seconds. Grip strength measurements were collected at every study session.

Several measures of pain/discomfort were used in the study and were divided into two categories, those that measured pain at rest and those that measured pain with provocation. The list of pain measures is as follows:

- No provocation:
    - Pain at rest (VAS-R)
- Provocation with mechanical pressure:
    - Pain pressure threshold with mechanical algometer (PPT)
    - Pain with mechanical algometer applied pressure (VAS-P)

- Pain with custom algometer applied pressure (VAS-C)

For all but PPT, pain was measured using visual analogue scales (VAS). The VAS consisted of a 10cm horizontal line with 'no pain' as the left anchor and 'worst pain imaginable' as the right anchor. Participants were asked to mark a vertical tick on the VAS to indicate their perceived level of pain/discomfort. For VAS-R, participants were asked to indicate the level of pain/discomfort while at rest (Appendix A). For VAS-P, participants were asked to indicate the level of pain/discomfort associated with pressure applied with a mechanical algometer (Appendix A). For VAS-C, participants were asked to indicate the level of pain/discomfort associated with pressure applied with a custom algometer (Appendix A). VAS measurements were taken at every study session.

A calibrated pressure algometer (Somedic, Horby, Sweden) with a $2cm^2$ probe tip was used to obtain the PPT measurements at the Large Intestine 10 (LI10) acupuncture point on the non-dominant forearm. The LI10 point is located on the proximal dorsal radial forearm between the extensor carpi radialis longus and extensor carpi radialis brevis muscles, which are often involved in lateral forearm pain (see figure 1). The LI10 point was located by having each participant flex their non-dominant elbow in full pronation to reveal the transverse cubital crease. The LI10 point was located 3 fingers breadth distal to the end of the crease in line with the anatomical snuff box of the wrist (AFCI, 2005; AFCI, 2007). Figure 4 depicts the PPT testing used in the study. PPT measurements were obtained by applying an increasing amount of pressure with the algometer at the test site until the participant pressed the stop button. Each participant was instructed to press

the stop button "at the first instant that the pressure becomes painful." Three PPT recordings were obtained with a 30-second rest period between each trial. PPT values were recorded at every study session.

For VAS-P testing, the Somedic algometer was also used to deliver a consistent amount of pressure to the LI10 test site. The amount of pressure delivered to each participant was determined by calculating the mean of the three PPT values recorded at their baseline. The examiner applied the amount of pressure corresponding to the baseline mean PPT of each participant. Each participant was then asked to complete the VAS scale to indicate the level of discomfort associated with the pressure applied. Each participant received the same amount of pressure for VAS-P testing throughout the study. VAS-P values were recorded at every session.

It was not feasible to provide each participant with a Somedic algometer for follow up testing at home. Consequently, a custom algometer was created for participants to take home for VAS-C testing (figure 11). The custom algometer consisted of a 1.5L water bottle, filled with 1402g of salt, with a $2cm^2$ diameter wooden dowel glued to the lid. The LI10 point was marked on the non-dominant forearm of each participant for testing with the custom algometer. Participants were instructed to hold the algometer tip on the test site with the forearm in full pronation and then complete the VAS to indicate the amount of discomfort associated with the pressure. VAS-C values were recorded at 24 and 60-hours after baseline as well as at every session.

For VAS-R testing, participants were asked to complete a VAS to indicate the level of discomfort in the non-dominant forearm when seated comfortably with forearms positioned in neutral rotation on the armrests of the chair. VAS-R values were recorded at every session.

Exercise Protocol

The following exercise protocol was shown to be successful in pilot testing and was used to elicit delayed onset muscle soreness in the non-dominant forearm extensor muscles (see Appendix E):

Each participant was seated in an office chair with their non-dominant forearm resting in pronation on the armrest, which was positioned to place the elbow at approximately 90 degrees of flexion. Each participant was instructed to keep pace with an electronic metronome set to beep at a rate of 15 repetitions per minute. Each participant competed three sets of wrist curls using a 5 pound (lb) dumbbell with one minute rest between sets. The investigator held the dumbbell during the rest period. For the first two sets, participants were instructed to try to perform 75 repetitions. If they could not complete the full set, they were advised to continue until they felt they "could not do one more repetition." For the final set, participants were advised to perform as many repetitions as they could until they felt they "could not do one more repetition."

Each participant was given a custom algometer to take home and asked to complete the VAS-C test 24-hours later.

Acupuncture Protocol

Participants returned to the lab 48 ± 2 hours after the exercise session to attend a treatment session. Participants of the study were randomly assigned to one of three groups. Group one was assigned to the control group and received no treatment. Group two was assigned to the acupuncture group and received acupuncture (ACU) treatment. Group three was assigned to the sham group and received non-penetrating sham acupuncture (S-ACU) treatment.

The acupoints chosen for the study were Large Intestine 4, 10 and 11 (LI4, LI10 and LI11) was well as Triple Warmer 4 (TW4) and were selected based on Western Medical acupuncture philosophy. All acupoints were selected as treatment for lateral epicondylosis based on their proximity to the forearm extensor muscles or location within the radial nerve distribution. The acupoints LI11 and LI10 are located near the common extensor tendon and the extensor carpi radialis longus and brevis muscles respectively. The LI11 acupoint was landmarked by locating the end of the lateral elbow crease and the LI10 acupoint was landmarked by measuring 3 fingers breadth distal to the LI11 acupoint. The TW5 acupoint is located between the tendons of extensor digitorum communis and was landmarked by measuring 3 fingers breadth proximal to the midline of dorsal wrist crease. The LI4 acupoint is located within the sensory distribution of the radial nerve, which also provides motor innervation to the forearm extensor muscles. The Li4 acupoint was landmarked by locating the midpoint on the first dorsal web space between the middle of the first and second metacarpal bones (AFCI, 2005; Langevin & Yandow, 2002; World Health Organization, 1993). The acupuncture practitioner in the

study (KP) was a licensed physiotherapist who primarily treats hand & upper limb conditions. The practitioner certified to practice acupuncture with the College of Physiotherapists of Manitoba. The practitioner located the acupoints on all participants in all three groups. The Streitberger protocol was used (Streitberger & Kleinhenz, 1998). Briefly, the acupoints were marked with a small plastic ring and fixed to the skin with paper tape (Transpore, Minneapolis, USA). The needles for the ACU and S-ACU treatments were administered through the plastic ring and tape to make the two treatments appear as similar as possible. The needles used for the ACU treatments were 0.30 gauge and 30mm in length (Asiamed, Pullach, Germany). The Streitberger needles used for the S-ACU treatments were 0.30 gauge and 30mm in length (Asiamed, Pullach, Germany) and do not pierce the skin. The ring and tape at each acupoint served to hold the S-ACU needles in place.

All participants were seated comfortably in a recliner for the treatment session. Individuals in the control group rested comfortably in the recliner for the entire treatment period. The needles for the ACU treatments were inserted to a depth of approximately 15mm. The needles for the S-ACU treatments were administered to appear to be inserted at a depth of approximately 15mm (with 15mm of the needle pressed up into the handle). All needles were left in place for 15 minutes and were stimulated manually by the practitioner at 5 and 10 minutes into the treatment period. Manual stimulation of all ACU needles was achieved by grasping the handle and performing a piston motion (twisting while pulling up and down approximately 5mm five times). The practitioner grasped the S-ACU needles at the junction of the shaft and handle while manually

stimulating the needles in order to prevent separation of the two parts. The practitioner took care to shield the participant's view of needle insertion, needle stimulation and needle removal by holding one hand in front of the needle. When the rings and tape were removed at the end of the 10 minute post treatment monitoring period, the practitioner again shielded the participants view with one hand and wiped the area with a swab moistened with alcohol to remove any presence of blood on the skin.

Immediately after the treatment session, the grip strength, VAS-R, VAS-P, VAS-C and PPT values were reassessed for each participant with the same methodology as the baseline measurement and the pre-treatment reassessment. Each participant was given a custom algometer to take home and asked to complete the VAS-C test 12-hours later (60 hours after baseline).

Participants returned to the lab 24 ±2 hours after the treatment session for final reassessment. At the final session, the grip strength, VAS-R, VAS-P, VAS-C and PPT values were reassessed for each participant with the same methodology as the baseline measurement, the pre-treatment reassessment and the post-treatment reassessment.

Statistical Analysis

At each individual time point, the differences between grip strength and VAS-P values for the control, ACU and S-ACU groups were determined using a one way ANOVA (see Appendix G). At each individual time point, the differences between VAS-R, VAS-C and PPT for the control, ACU and S-ACU groups were determined using a Kruskal-

Wallis one way analysis of variance on ranks. The changes in VAS-R, VAS-C and PPT over time were determined using a Friedman repeated measures analysis of variance on ranks. The changes in grip strength and VAS-P over time were determined using repeated measures one way ANOVA. Post-hoc analysis for changes in grip strength, VAS-R, VAS-P, VAS-C and PPT over time were completed using Tukey's test. The significance level was set at $p<0.05$ for all analyses. The Sigma Stat program (Systat Software, San Jose, USA) was used for this statistical analysis.

In addition, to determine if gender or handedness impacted the results, three-way repeated measures ANOVA testing was performed for each of the outcome variables: grip strength, PPT, VAS-R, VAS-C or VAS-P (see Appendix G). The significance level was set at $p<0.05$. This analysis was performed using SAS software version 9.2 (SAS Institute Inc., Cary, USA).

Results

Grip Strength: Figure 12 illustrates the mean maximum grip strength findings for the three groups. The control group demonstrated a significant reduction in the (mean +/- (standard deviation)) grip strength in the time span from session 1 (32.682(9.171)) to session 2B (28.344 (10.315)) as well as from session 2A (32.516 (10.019)) to session 2B (28.344 (10.315)) ($p\leq0.05$)(see Appendix F). The acupuncture group demonstrated a significant reduction in grip strength in the time span from session 1 (27.199 (12.872)) to session 2A (24.534 (12.780), from session 2A (24.534 (12.780) to session 2B (24.072 (12.361)) and an increase in grip strength from session 2B (24.072 (12.361)) to session 3

(27.968 (12.126)) ($p \leq 0.05$). No significant differences were found between the control, ACU or S-ACU groups at any time point in the experiment. Gender or handedness was not found to be associated with a significant change in grip.

PPT: Figure 13 illustrates the mean PPT findings for the three groups. The control group demonstrated a reduction in PPT (median (Inter Quartile Range: 25%, 75%)) from session 1 (baseline) (252.833: 210.833, 307.167) to session 2A (48-hours post exercise) (207.667: 162.833, 266.167); however, the finding was not significant (see Appendix F). A significant reduction in PPT for the control group was seen between session 1 (baseline) (252.833: 210.833, 307.167) and session 2B (49-hours post exercise) (205.833: 165.500, 248.500) ($p \leq 0.05$). The control group showed an increase in PPT from session 2B (49-hours post exercise) (205.833: 165.500, 248.500) to session 3 (72-hours post exercise) (226.667: 173.500, 249.833); however, the results were not significant. The ACU group demonstrated a significant reduction in PPT from session 1 (baseline) (263.667: 191.667, 327.333) to session 2A (48-hours post exercise) (177.000: 152.833, 264.167), from session 1 (baseline) (263.667: 191.667, 327.333) to session 2B (49-hours post exercise) (163.167: 121.833, 251.667) and a significant increase in PPT from session 2B (49-hours post exercise) (163.167: 121.833, 251.667) to session 3 (72-hours post exercise) (225.667: 158.167, 296.833) ($p \leq 0.05$). The S-ACU group demonstrated a significant reduction in PPT from session 1 (baseline) (237.500: 213.333, 340.833) to session 2A (48-hours post exercise) (173.500: 138.667, 356.333) ($p \leq 0.05$). No significant differences were found between the control, ACU or S-ACU groups at any

session in the experiment. Neither gender nor handedness was significantly associated with the change in PPT.

VAS-R: Figure 14 represents the VAS-R findings for the three groups. No significant differences in VAS-R were seen over time in the control group or the sham group (see appendix F). The acupuncture group showed a significant increase in VAS-R (median (Inter Quartile Range: 25%, 75%)) from session 1 (0.000: 0.000, 0.000) to session 2A (10.000: 2.000, 34.000). No significant differences in VAS-R were found between the control, acupuncture and sham groups at any session in the experiment. Gender or handedness was not found to be associated with a significant change in VAS-R.

VAS-C: Figure 15 represents the VAS-C findings for the three groups. The control group showed a significant increase in VAS-C (median (Inter Quartile Range: 25%, 75%)) from session 1 (baseline) (3.500: 1.500, 5.00) to 24-hours post exercise (19.00: 10.500, 26.00)(see Appendix F). The VAS-C finding for the control group then continued to decrease over time from session 2A (48-hours post exercise) to session 3 (72-hours post exercise) but had not returned to baseline. Likewise, the sham group showed a significant difference in VAS-C from session 1 (baseline) (5.000: 2.500, 11.500) to 24-hours post exercise (18.00: 6.500, 37.00) and from 24-hours post exercise (18.00: 6.500, 37.00) to session 3 (72-hours post exercise) (4.000: 0.500, 17.500). In contrast, the acupuncture group showed no significant differences in VAS-C over time. No significant differences in VAS-C were found between the control, acupuncture and

sham groups at any session in the experiment. Gender or handedness was not found to be associated with a significant change in VAS-C.

VAS-P: Figure 16 represents the VAS-P findings for the three groups. No significant differences in VAS-C were found between the control, acupuncture and sham groups at any session in the experiment (see Appendix F). Gender or handedness was not found to be associated with a significant change in VAS-P.

Discussion

Grip strength: The control group showed no significant reduction in grip strength between session 1 (baseline) and 2A (48-hours post exercise); however, a significant reduction in grip strength was seen between session 1 (baseline) and 2B (49-hours post exercise) as well as between session 2A (48-hours post exercise) and 2B (49-hours post exercise). It appears that DOMS in the control group had not set in by 48-hours after exercise (session 2A) but had significantly set in by 49-hours after exercise (session 2B). The control group showed a non-significant increase in grip strength between session 2B (49-hours post exercise) and session 3 (72-hours post exercise) which suggests that DOMS had started to resolve sometime between 49-hours (session 2B) and 72-hours (session 3) post exercise. The acupuncture group showed a significant reduction in grip strength between session 1 (baseline) and session 2A (48-hours post exercise) which suggests that DOMS had significantly set in by 48-hours post exercise. The reduction in grip strength seen in the acupuncture group between 48-hours (session 2A) and 49-hours (session 2B) post exercise could be due to DOMS continuing to peak, or due to reduced

muscle force as a result of needle insertion during acupuncture treatment. The increase in grip strength seen in the acupuncture group between 49-hours (session 2B) and 72-hours (session 3) post exercise could be due to DOMS starting to resolve or could be due to the acupuncture treatment. The sham group demonstrated no significant differences in grip strength over time; however, the results were underpowered at 0.389. It is possible that differences in grip strength over time for the sham group were present, but not detected due to low power.

No significant differences were shown between the control, acupuncture and sham-acupuncture groups at any session; however, the results were underpowered at 0.049, 0.051 and 0.049 respectively. It is possible that differences between the three treatment groups were present, but not detected due to the low power. A larger sample size may be needed to detect significant differences between the grip strength measurements of the control, acupuncture and sham-acupuncture groups.

PPT: The findings for the control group suggest that DOMS had set in significantly by 49-hours post exercise (session 2B) and started to resolve by 72-hours (session 3) post exercise. The findings for the acupuncture group suggest that DOMS had set in significantly by 48-hours post exercise (session 2A). The reduction in PPT seen in the acupuncture group between 48-hours (session 2A) and 49-hours (session 2B) post exercise could be due to DOMS continuing to peak or could be due to sensitivity at the test site due to needle insertion during the acupuncture treatment. The increase in PPT seen in the acupuncture group between 49-hours post exercise (session 2B) and 72-hours

post exercise (session 3) could be due to DOMS starting to resolve, or could suggest a late analgesic effect of the acupuncture treatment. The sham group showed a significant reduction in PPT between session 1 and session 2A suggesting that DOMS had significantly set in by 48-hours post exercise. No significant differences were found between the control, ACU or S-ACU groups at any session in the experiment.

The results of our study are partly in keeping with a previous investigation of DOMS in the elbow flexors, where PPT was shown to reach the lowest point at approximately 24-hours post exercise, was increased by 48-hours and had returned to baseline by 72 hours post exercise (Hübscher et al., 2008). We did not measure PPT in our study at 24-hours post exercise. The results of our study showed that PPT was reduced at 48-hours post exercise (session 2A), had increased by 72-hours post exercise (session 3), but had not returned to baseline. In our study, only one acupuncture treatment was administered at 48-hours post exercise (session 2A) whereas Hübscher (2008) administered three acupuncture treatments immediately post exercise, at 24-hours and 48-hours post exercise. The differences in PPT results between the two studies could be due to the differing acupuncture protocols or a differing recovery from DOMS in the elbow flexors versus the wrist extensors.

VAS-R: Only the acupuncture group showed a significant increase in VAS-R between session 1 and 2A, suggesting the onset of DOMS by 48-hours post exercise. The lack of significant changes in VAS-R for the control and sham groups over time is in keeping

with the previous findings that DOMS does not consistently elicit pain at rest (Slater et al., 2003; Slater et al., 2005).

VAS-C: Individuals in the control and S-ACU groups had significant increases in VAS-C between session 1 and 24-hours post exercise, suggesting that DOMS had significantly set in by this time. There was also a significant reduction in VAS-C seen in the control and sham groups between 24-hours post exercise and 72-hours post exercise (session 3), suggesting that DOMS had begun to resolve. In contrast, participants in the ACU group showed no significant change over time. This finding suggests that the exercise protocol selected does not consistently elicit DOMS in all participants.

VAS-P: No significant differences in VAS-P were found between the three groups at any session of the experiment; however, the results were underpoweredat 0.049. It is possible that a difference was present, but not detected due to low power. No significant differences in VAS-P were seen over time in any of the three treatment groups. This finding suggests that the exercise protocol selected was not successful in eliciting DOMS consistently in all participants.

Conclusions

The sample size of 12 per group selected for the study was not large enough to allow sufficient statistical power when comparing grip strength or VAS-P results. A larger sample size may be required in order to detect any differences in grip strength or VAS-P between groups.

Our choice to test PPT at the same location as the LI10 needle insertion location may have introduced a confounding variable to the experiment. It is possible that the decrease in PPT seen in the acupuncture group after treatment could have been due to irritation at the needle site. In a future study, it may be beneficial to select a test site away from any needle insertion site. It has been suggested that the muscle belly of the extensor carpi radialis brevis muscle, located midway between the radial head the dorsal distal radio-ulnar joint, serves as a good site for testing PPT in experimental forearm extensor muscle pain (Slater et al., 2003).

Our goal was to develop an exercise protocol that was less time consuming and required less specialized equipment than the protocols described in the current body of literature; however, it is likely that the exercise protocol selected for the study was not challenging enough to consistently elicit DOMS in all participants. While the exercise protocol selected for the study was successful in eliciting DOMS during pilot testing, it did not consistently do so during the study. The pilot testing used for the study may not have involved enough participants and may not have adequately tested for the presence of DOMS. Future studies involving DOMS of the non-dominant forearm extensor muscles may require a more challenging dumbbell exercise protocol with more sets and repetitions or the use of a Kin Con dynamometer as already established in the literature (Slater et al., 2003; Slater et al., 2005).

Not withstanding the limitations, there were several strengths to the study. An acupuncture protocol that is reflective of clinical practice was used. The study is one of

the first acupuncture studies to include three treatment groups: acupuncture, non-penetrating sham acupuncture and a control. Since there is currently no true placebo for acupuncture, the use of both a sham and control group allow for better comparison with acupuncture than a study with only two groups.

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Overall Contributions and Future Directions

Overall Contributions

Previous ACU studies have been criticized for having poorly described methodology and inconsistent terminology. This study adheres to the STRICTA recommendations for unifying ACU research including information regarding treatment rationale, needling details, treatment regimen, co-interventions, practitioner background and control selection (MacPherson et al., 2002).

Previous ACU studies have included protocols which were not reflective of the number of needles or treatment times commonly used in clinical practice. The current research study utilized a clinically relevant ACU protocol that is reflective of treatment for forearm pain.

There is currently no true placebo for acupuncture. This study is one of the first acupuncture studies to include three treatment groups: acupuncture, non-penetrating sham acupuncture and a control. The use of both a sham and control group allow for better comparison with acupuncture than a study with only two groups.

There is limited information pertaining to the SNS response to ACU and S-ACU in the literature, as such, this study provides valuable information. The outcome of this research study indicates that ACU causes activation in the SNS as indicated by a bilateral increase in SC and a bilateral decrease in STD after needle insertion. It appears that the

unilateral increase in BF near the needle site observed with ACU treatment is due to local circulatory control, rather than systemic control.

Future Directions

The current research project provides valuable information regarding the SNS response to ACU and S-ACU. The findings of this project provide a basis for a number of different directions for future research.

It may be beneficial to further explore the use of DOMS elicited in the forearm extensors via eccentric exercise as an experimental model of lateral epicondylosis; however, more robust pilot testing may be required prior to proceeding. The exercise protocol utilized in a future study may need to include additional sets and repetitions of eccentric wrist curls. Furthermore, the pilot study should include grip, PPT, VAS-P and VAS-C testing to determine the success of the protocol in eliciting DOMS before proceeding.

An interesting question to pursue may be to investigate how the SNS responds to ACU and S-ACU in participants with actual, rather than experimental, lateral epicondylosis. The results of the current study could then be compared to those of the future study to determine if the SNS responds similarly to ACU and S-ACU with experimental and actual lateral epicondylosis.

The results of the current study did not allow us to determine whether the SNS response to ACU and S-ACU was segmental or central in origin due to the placement of the SC,

STD and STP sensors on the same segment bilaterally. It would be interesting to use a similar methodology in a future study, but to include more SC and STP sensors. If the additional SC and STD sensors were placed on the feet, on a different segment, it may be possible to determine whether the SNS response to ACU and S-ACU is segmental or central in origin.

The role of participant expectation regarding ACU was not explored in the current research study. In a future study using similar methodology, it may be beneficial to ask participants to guess whether they had ACU or S-ACU immediately after the treatment. The results of the future study may then provide information regarding how participant expectation influences the SNS response to ACU and S-ACU.

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Table 1: Demographic Information for Study Participants

Treatment Group	Gender	Age (years)	Hand Dominance
Control	Male	28	Right
	Male	23	Right
(6 male, 6 female)	Female	35	Right
	Female	34	Right
(29.17 +/- 4.8 years)	Male	30	Left
	Female	31	Right
(1 left, 11 right)	Female	23	Right
	Male	28	Right
	Female	36	Right
	Male	31	Right
	Female	21	Right
	Male	30	Right
Acupuncture	Female	26	Right
	Male	30	Right
(2 male, 10 female)	Female	24	Right
	Male	33	Right
(29.75 +/- 4.73 years)	Female	32	Right
	Male	24	Right
(12 right)	Female	32	Right
	Female	22	Right
	Female	32	Right
	Female	37	Right
	Female	35	Right
	Female	30	Right
Non-Penetrating Sham Acupuncture	Male	34	Right
	Male	34	Right
	Male	32	Left
(8 Male, 4 female)	Male	26	Left
	Female	26	Left
(30.42 +/- 5.63 years)	Male	27	Right
	Female	44	Right
(4 left, 8 right)	Female	34	Right
	Male	23	Right
	Female	28	Right
	Male	27	Left
	Male	30	Right

Figure 1: Acupoints Used in the Study

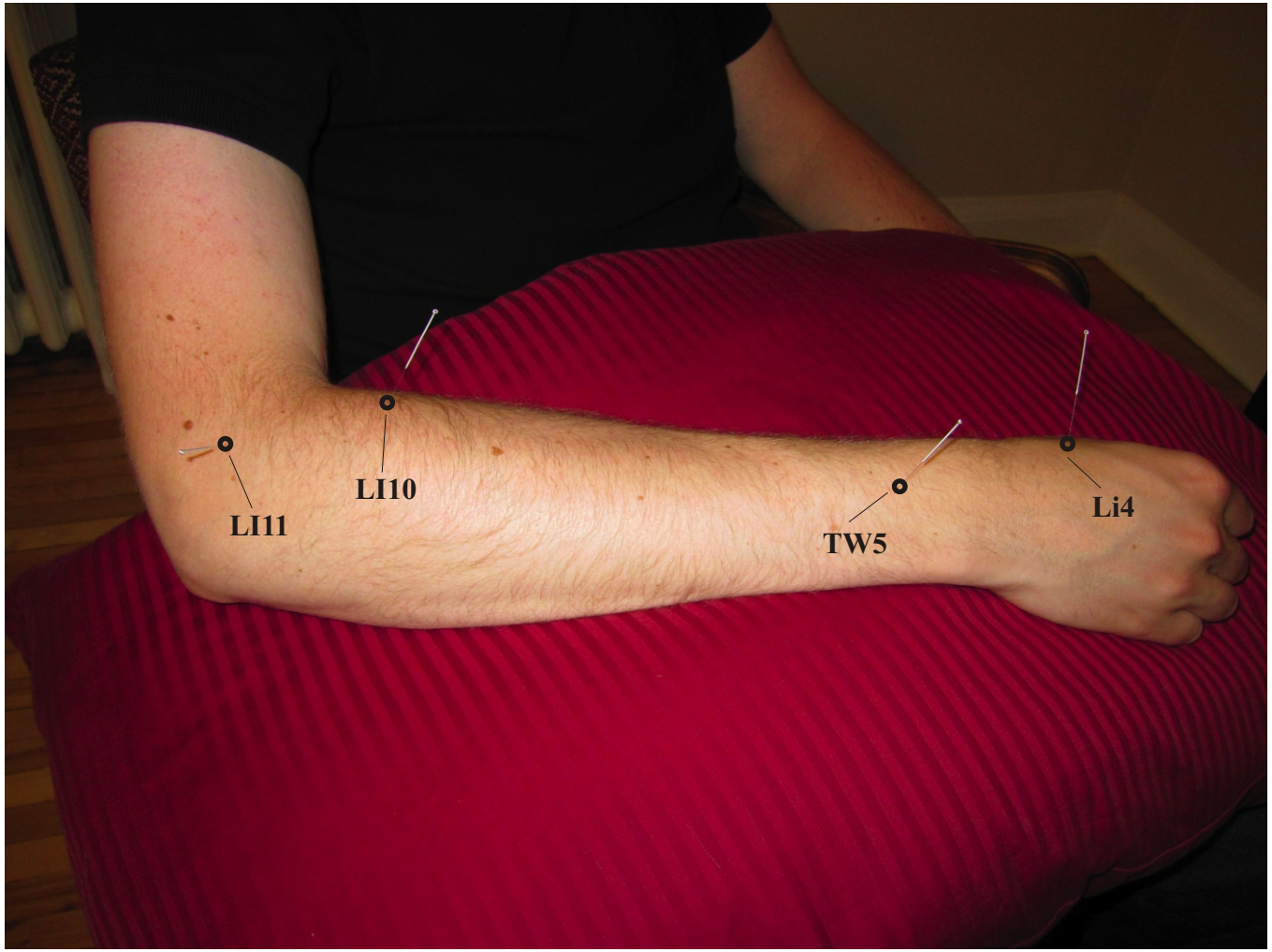


Figure 2: Real and Streitberger Non-Penetrating Acupuncture Needles

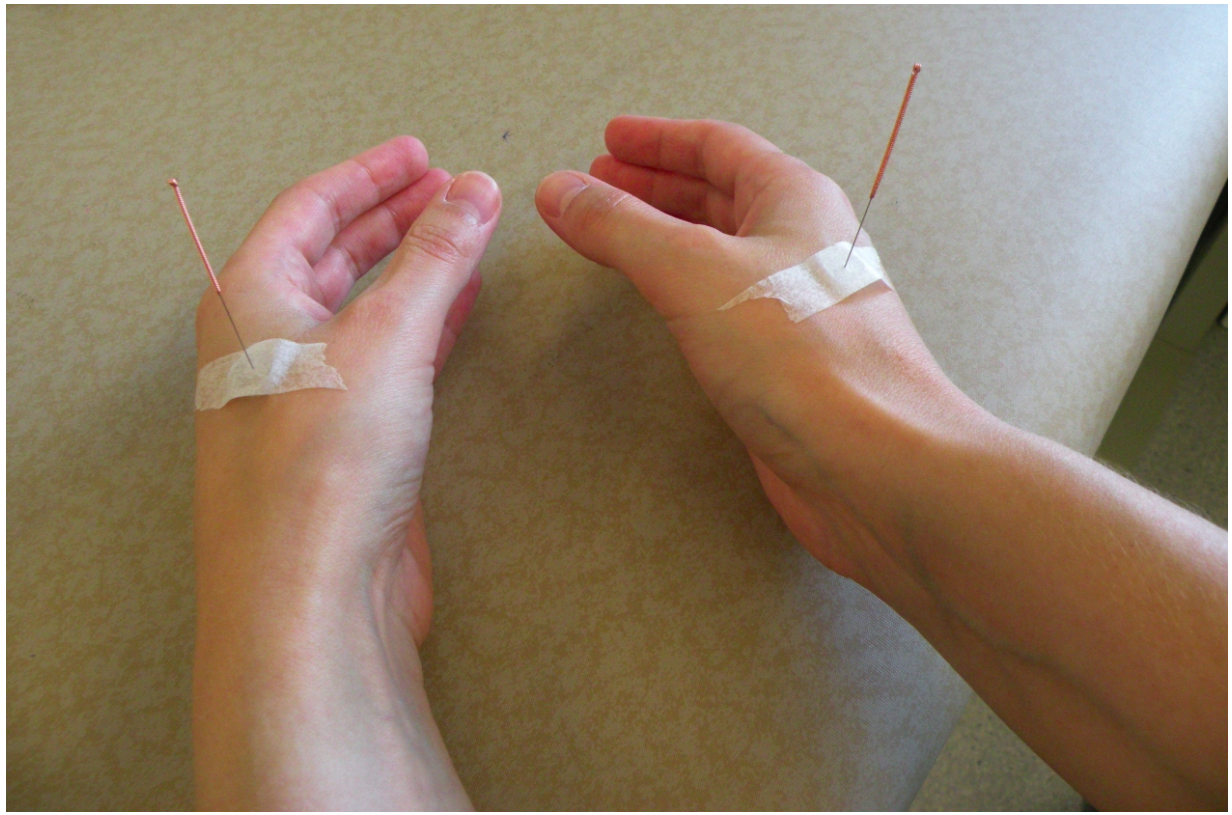


Figure 3: Grip Testing With the Biometrics Electronic Dynamometer (Gwent, United Kingdom)

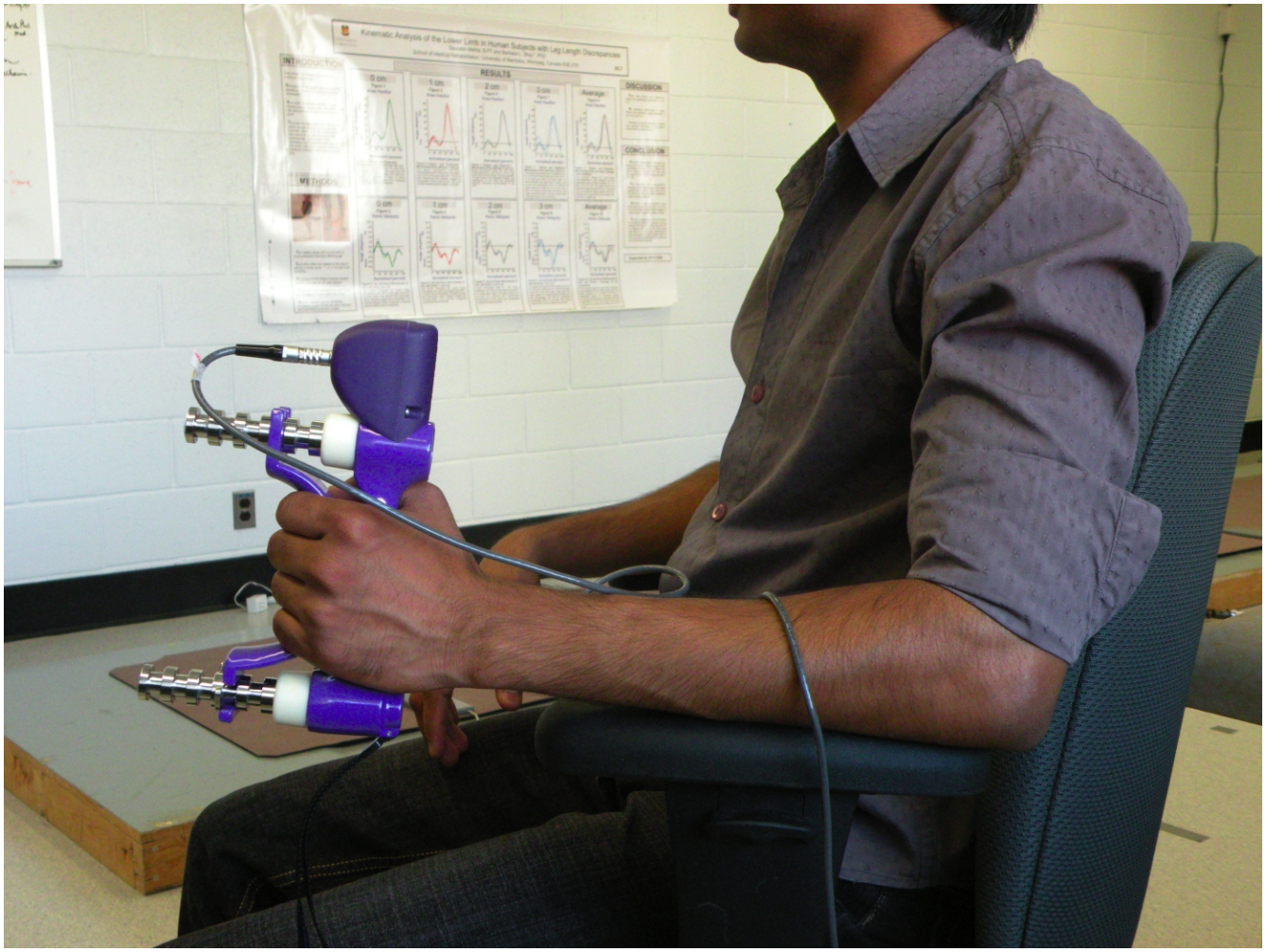


Figure 4: Pain Pressure Testing (PPT) With the Somedic Algometer (Horby, Sweden)

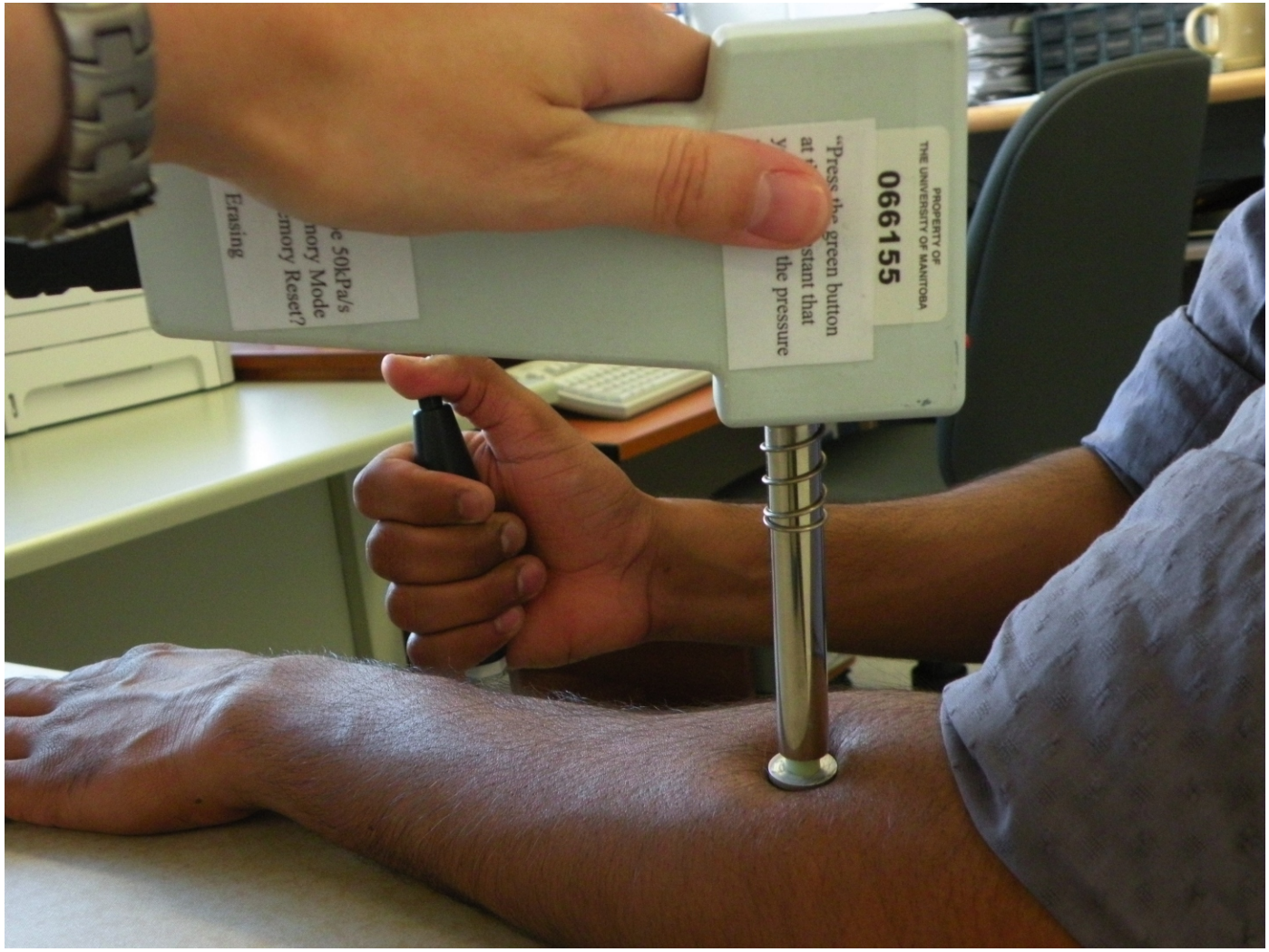


Figure 5: Overview of the Study

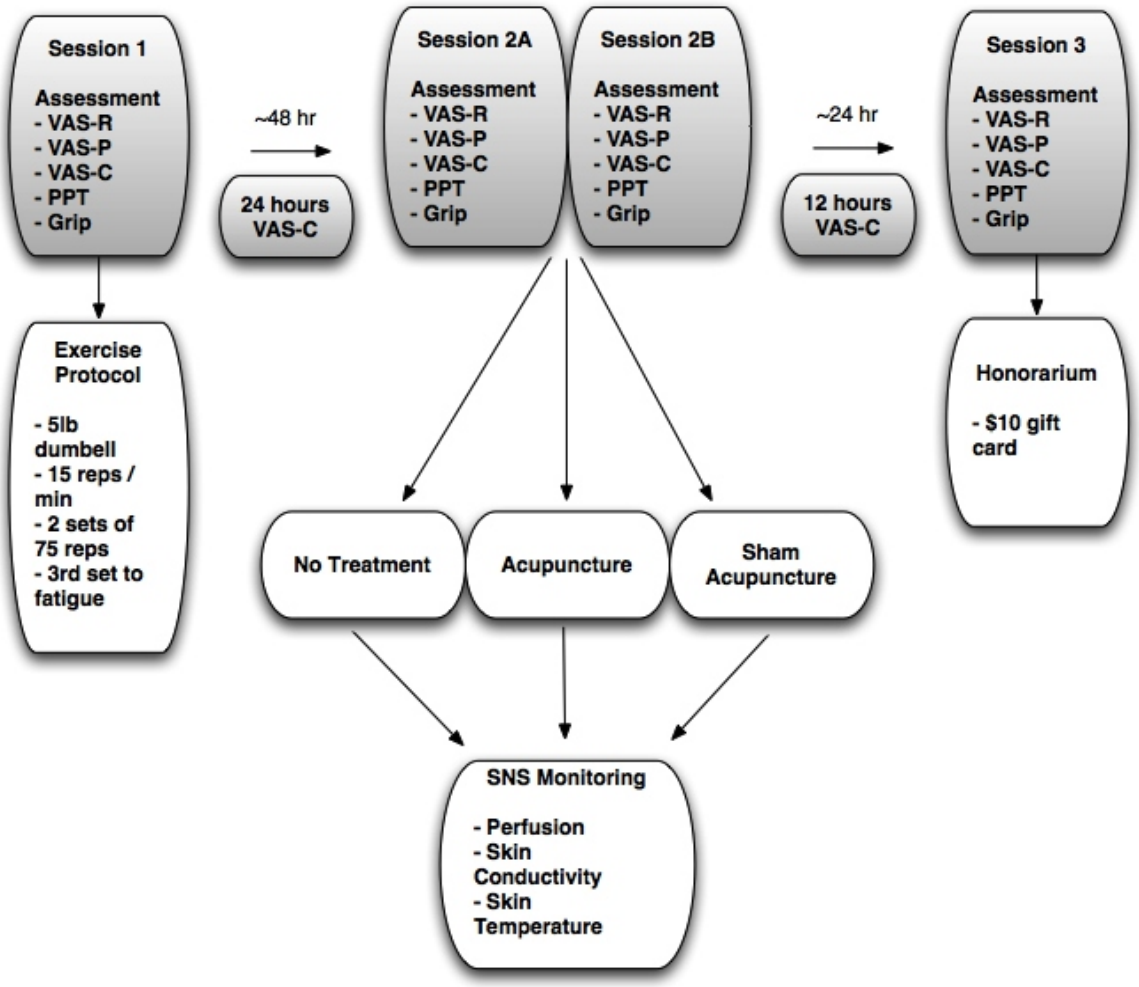
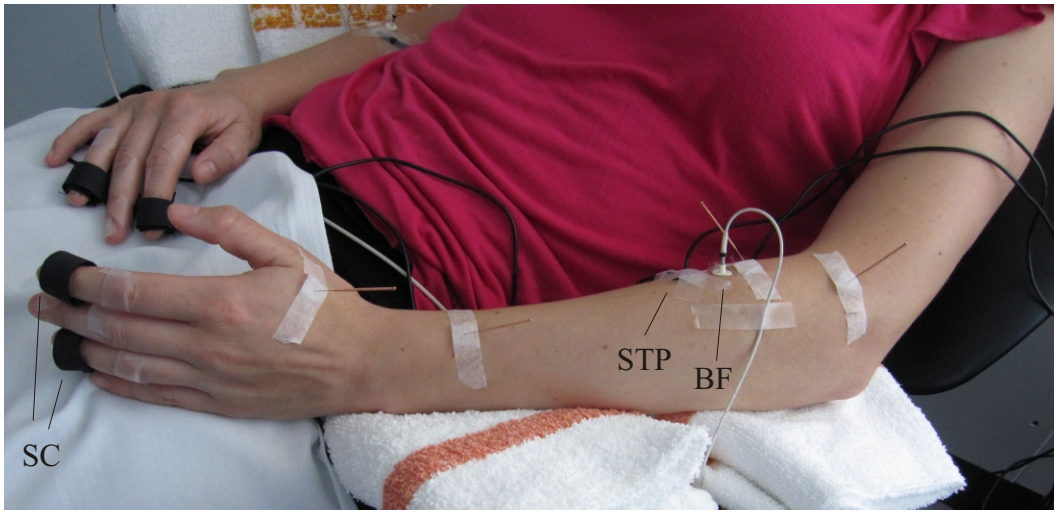
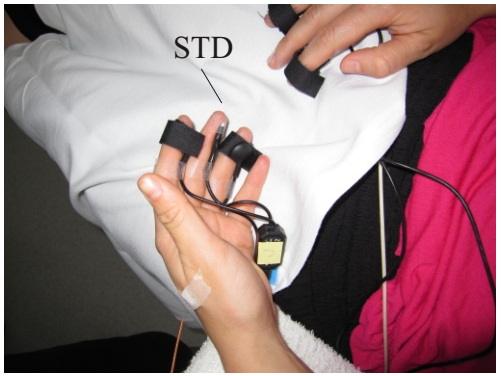


Figure 6: Experimental Set-up for Sympathetic Nervous System Monitoring





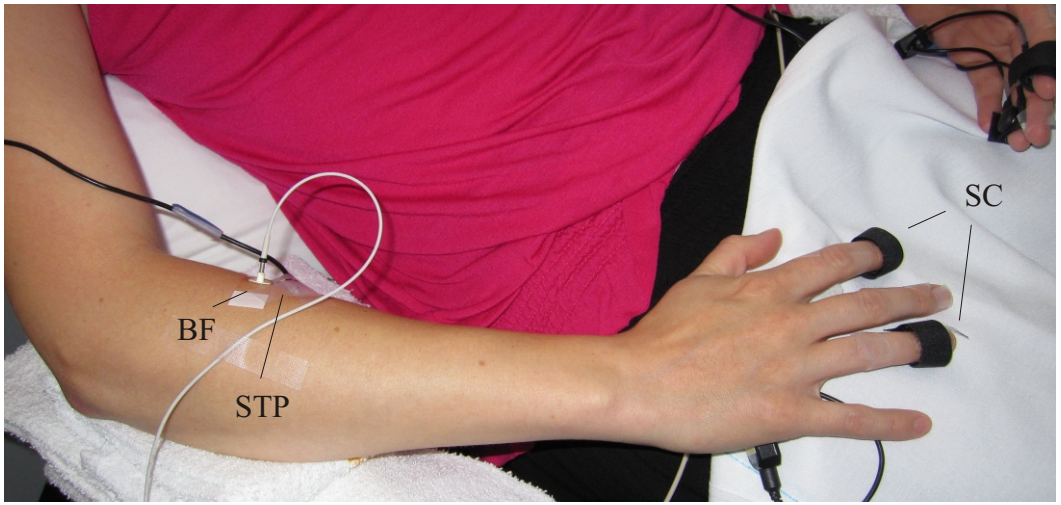


Figure 7: Blood Flow

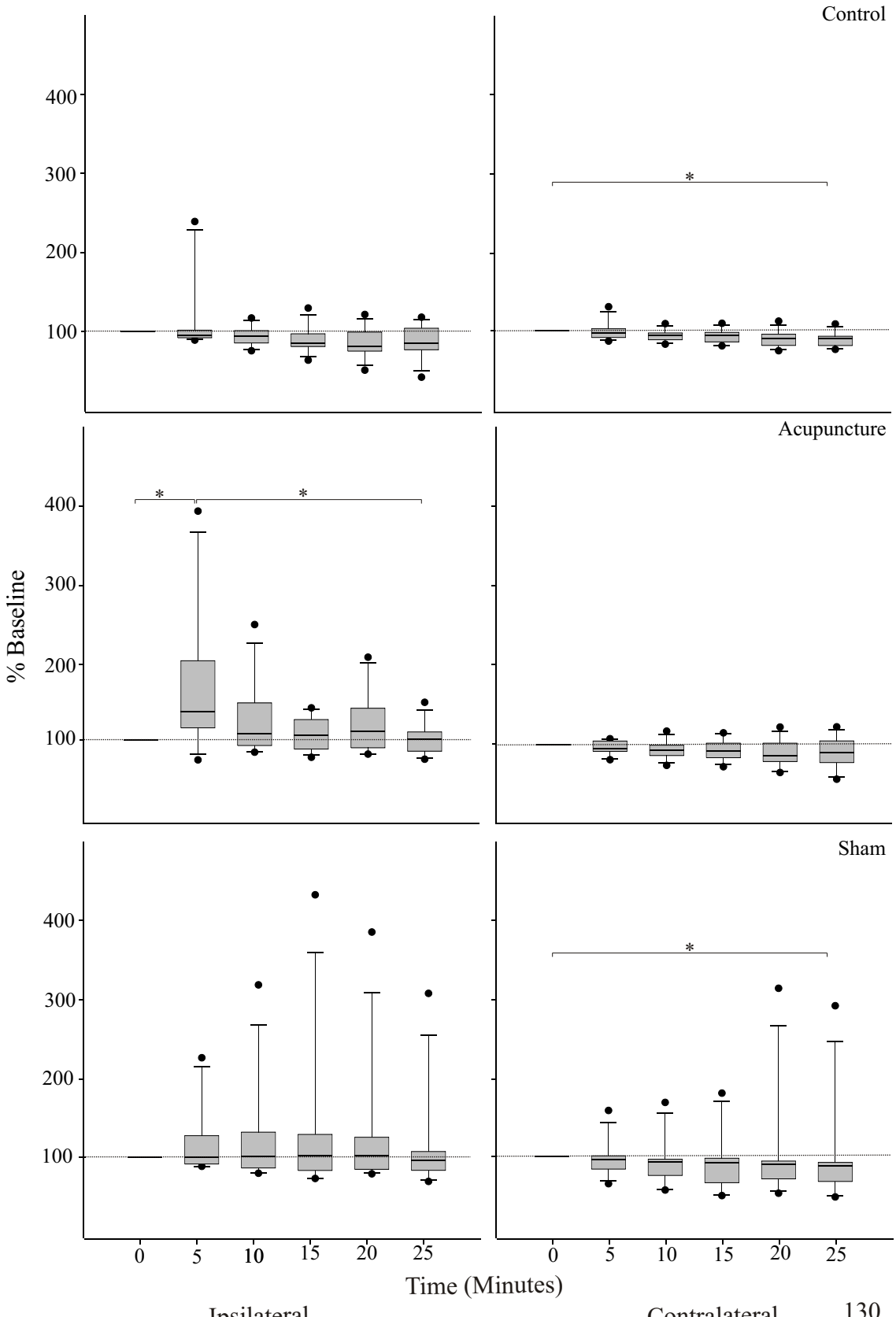


Figure 8: Skin Conductance

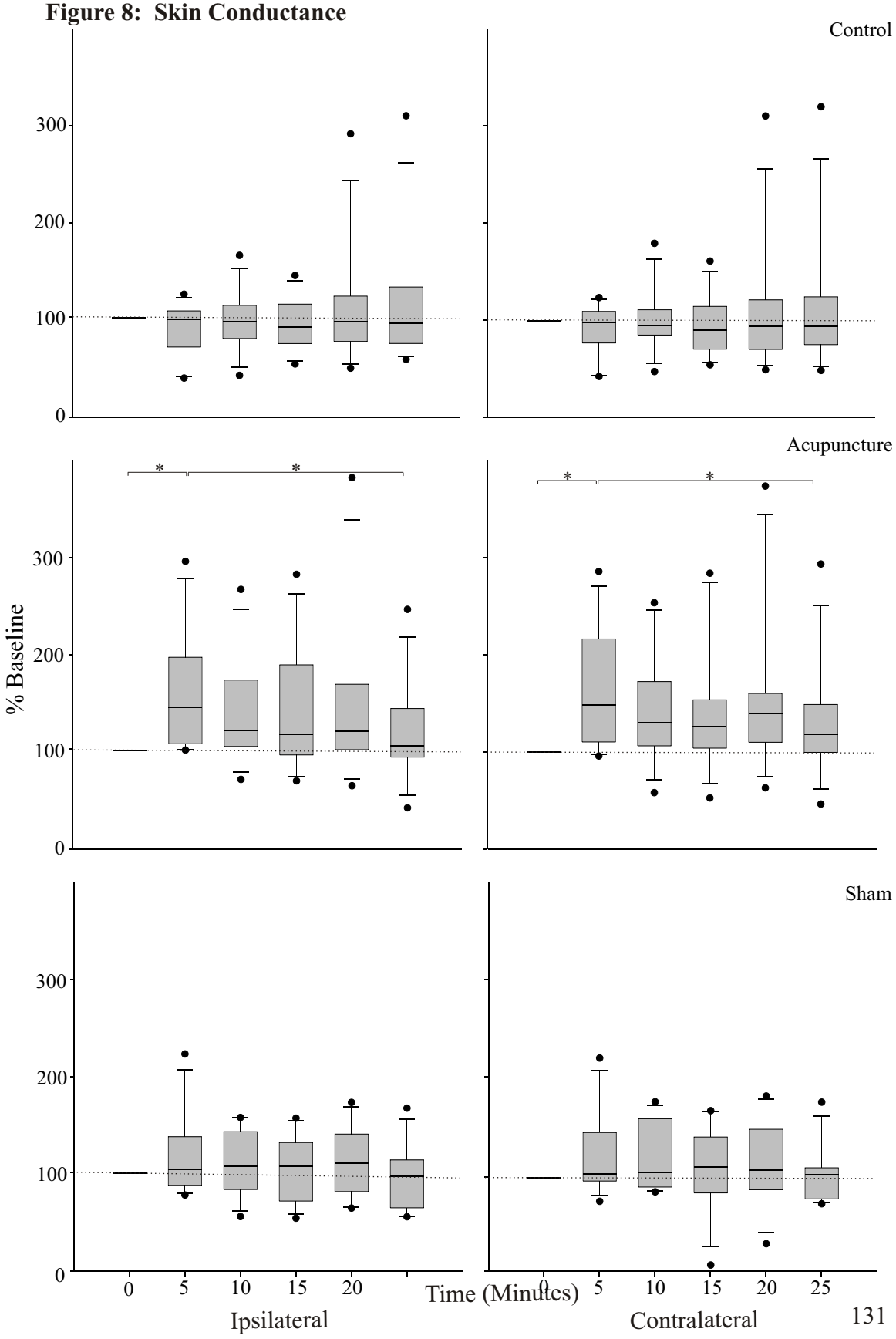


Figure 9: Distal Skin Temperature

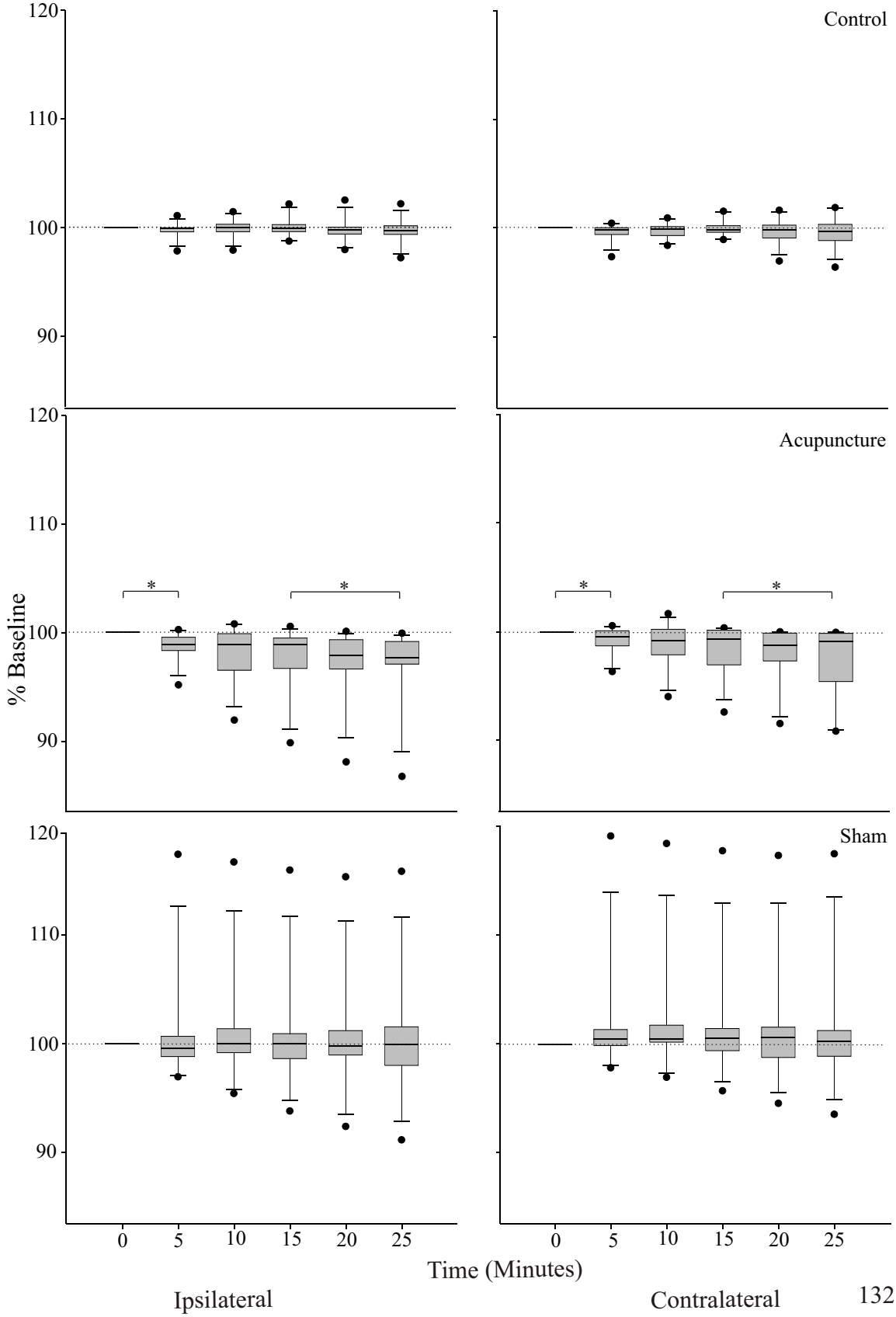


Figure 10: Proximal Skin Temperature

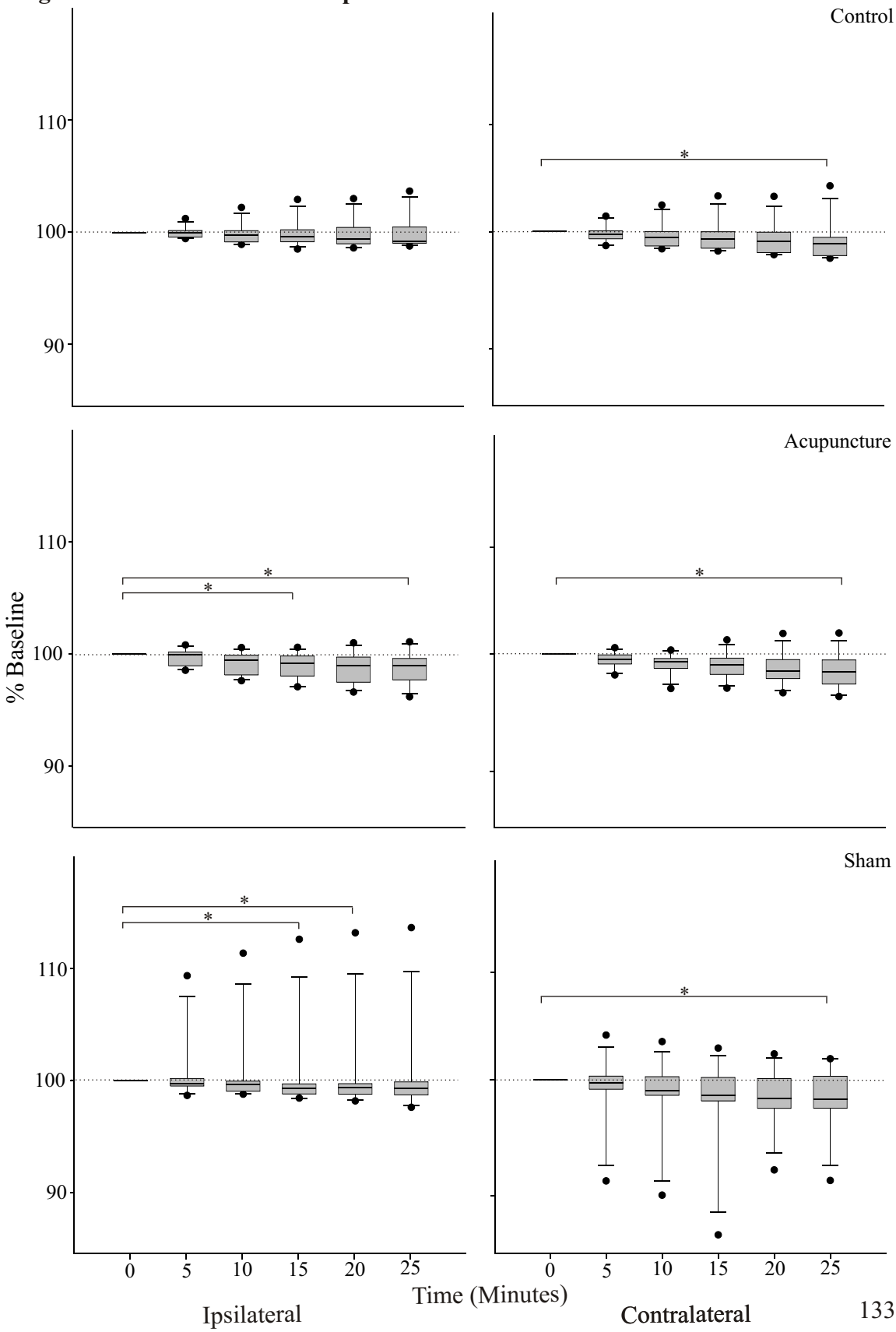


Figure 11: Custom Algometer Testing Used in the Study

Figure 12: Grip Strength

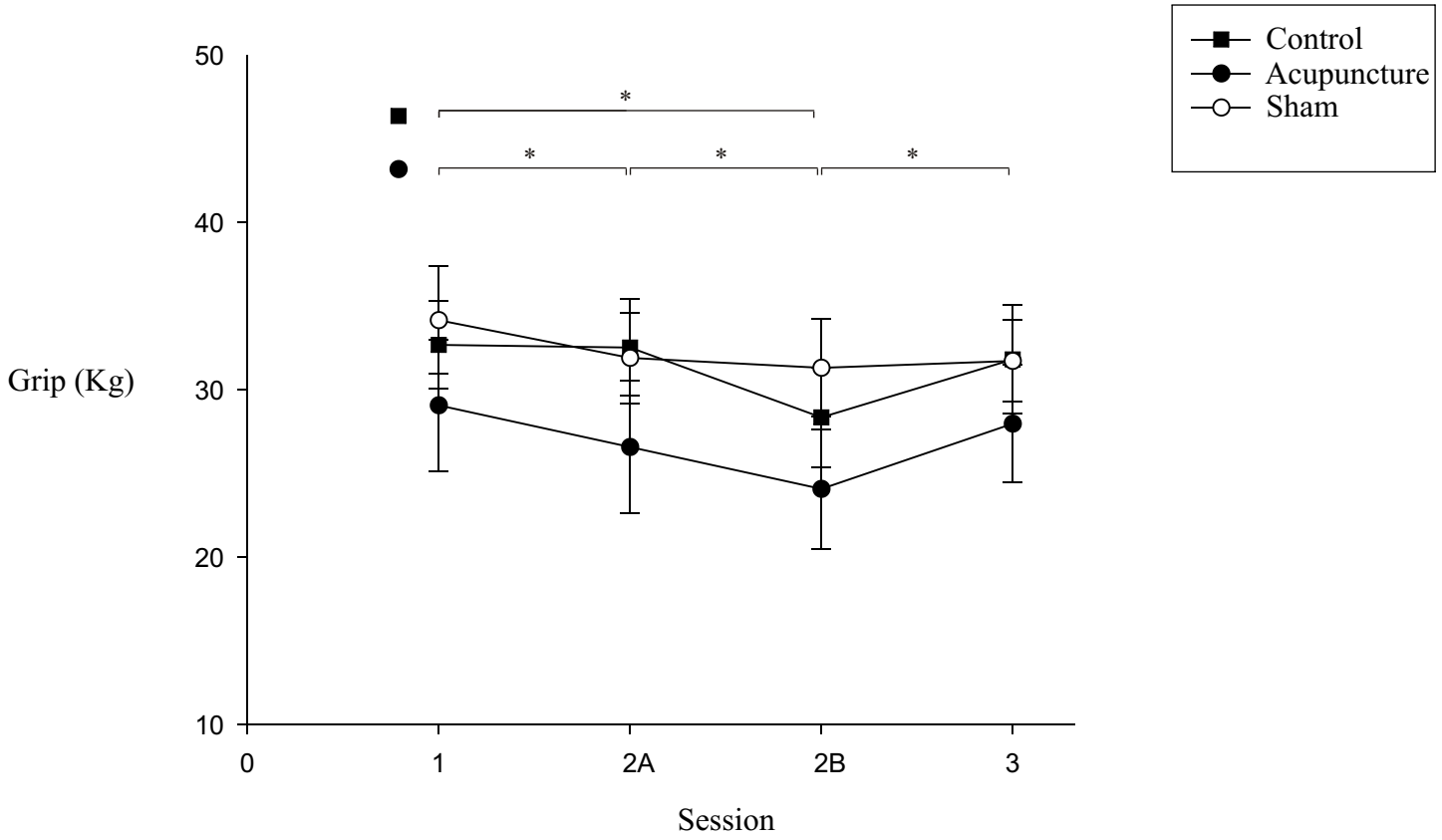


Figure 13: Pain Pressure Threshold

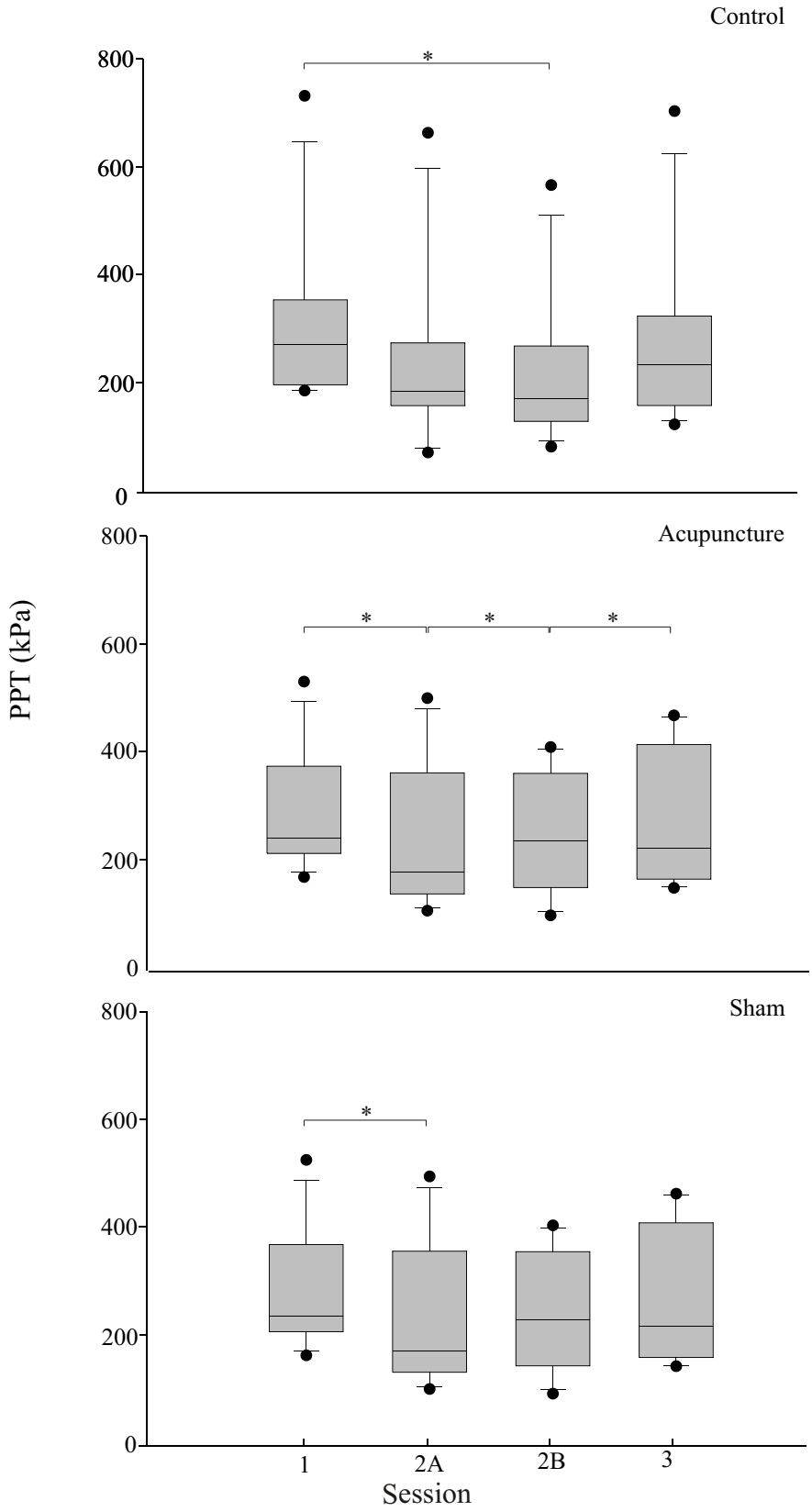


Figure 14: VAS for Pain at Rest

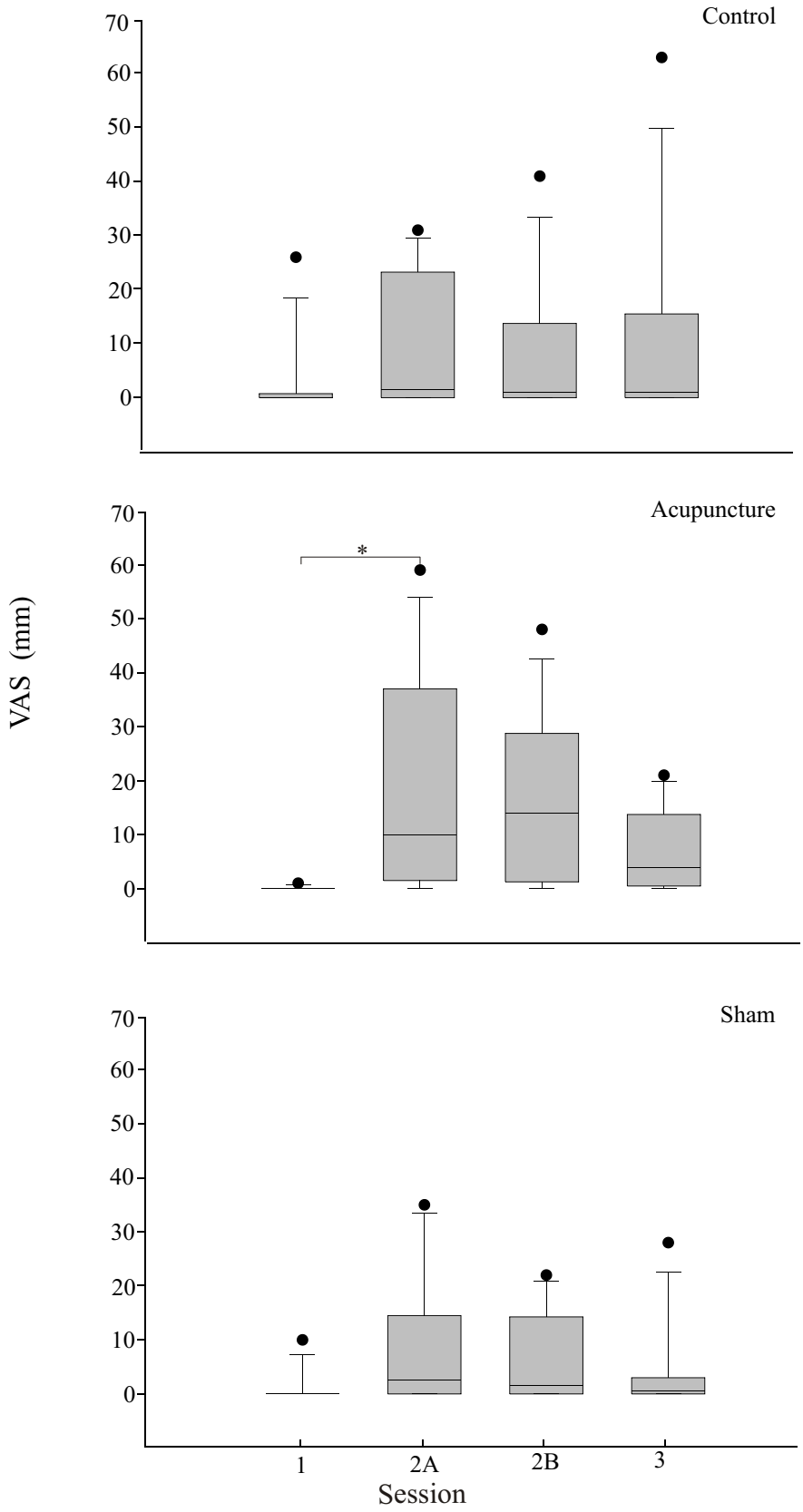


Figure 15: VAS for Pain with Custom Algometer

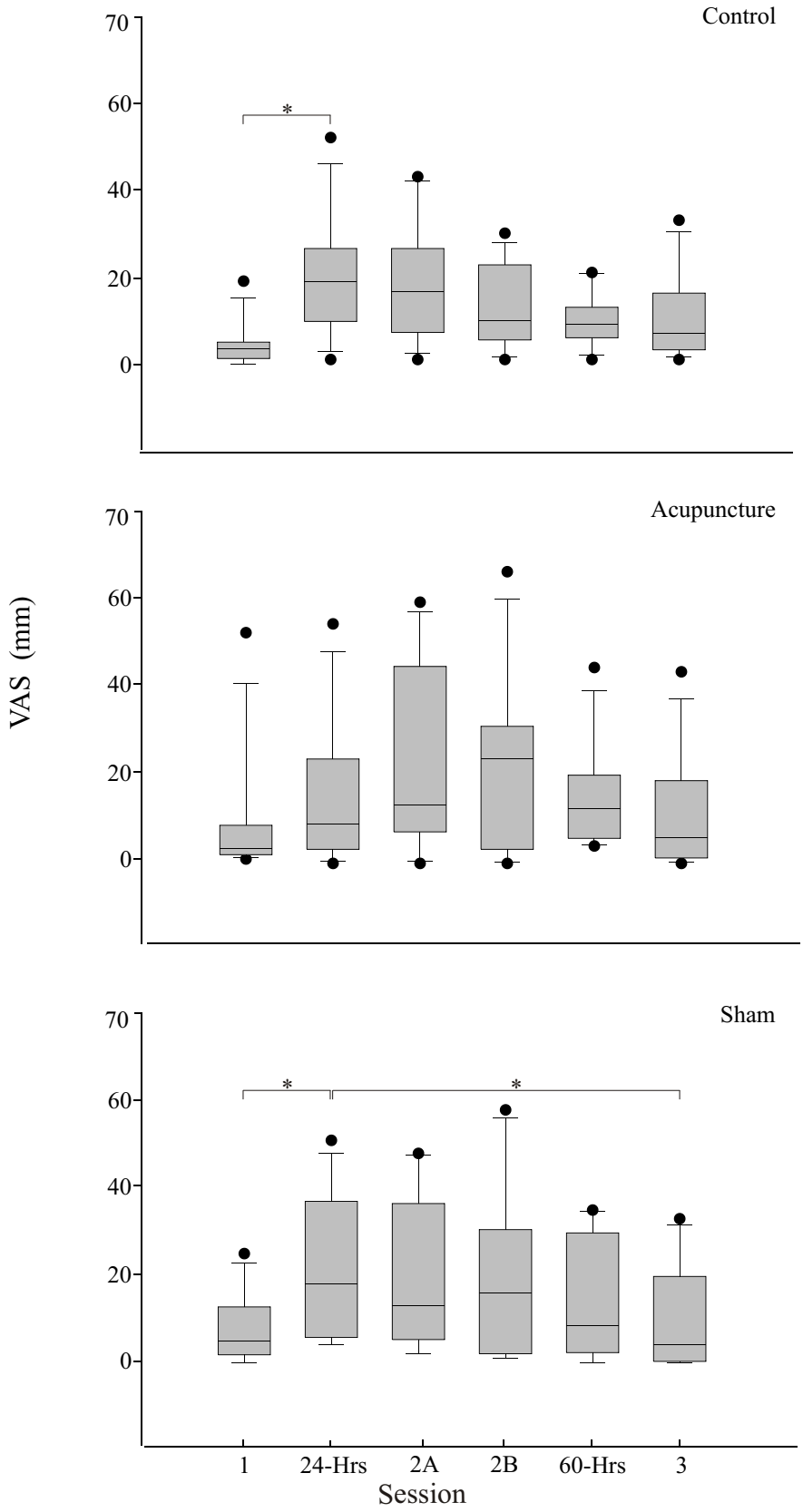


Figure 16: VAS for Pain at Pain Pressure Threshold (VAS-P)

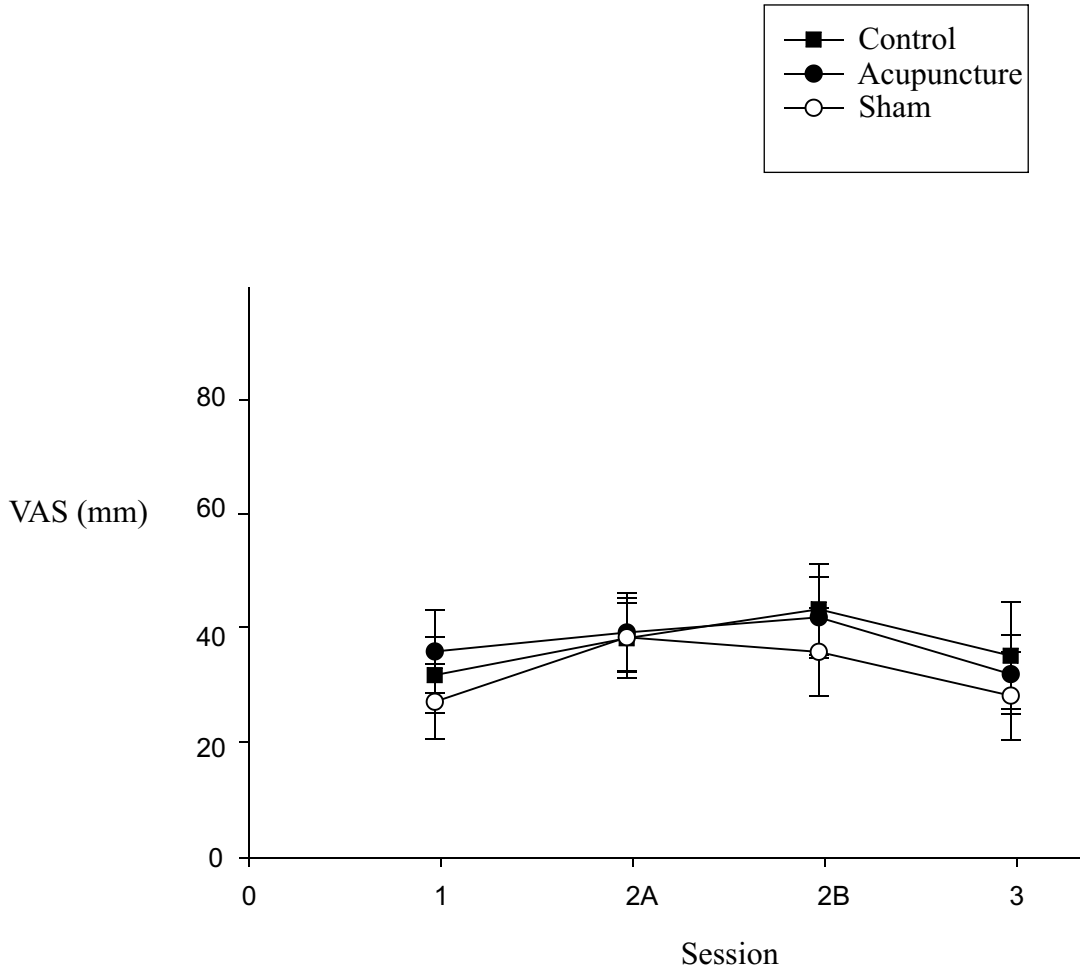


Figure Legends

Figure 1: Acupoints Used in the Study: The acupoints used in the study were Large Intestine 4 (LI4), Large Intestine 10 (LI10), Large Intestine 11 (LI11) and Triple Warmer 5 (TW5).

Figure 2: Real and Streitberger Non-Penetrating Acupuncture Needles: The real and Streitberger (Asiamed, Pullach, Germany) non-penetrating acupuncture needles in situ, left and right respectively.

Figure 3: Grip Testing With the Biometrics Electronic Dynamometer (Biometrics, Gwent, UK): The set-up for grip testing is depicted. Participants were positioned with the non-dominant shoulder positioned in neutral rotation and adduction, the elbow in 90° of flexion, the forearm in neutral and the wrist in a self-selected position. Measurements were made using a calibrated G100 electronic dynamometer.

Figure 4: Pain Pressure Threshold Testing (PPT) With the Somedic Algometer (Horby, Sweden): The set-up for PPT testing is depicted. PPT measurements were obtained by applying an increasing amount of pressure with the algometer at the test site until the participant pressed the stop button. Each participant was instructed to press the stop button "at the first instant that the pressure becomes painful." Three PPT recordings were obtained with a 30-second rest period between each trial. A calibrated Somedic pressure algometer (Horby, Sweden) with a $2cm^2$ probe tip was used to obtain the PPT

measurements at the Large Intestine 10 (LI10) acupuncture point on the non-dominant forearm.

Figure 5: Overview of the Study: An overview of the study sessions is depicted.

Figure 6: Experimental Set-up for Sympathetic Nervous System Monitoring: The experimental set-up for a right hand dominant participant is presented with the left upper extremity referred to as the ipsilateral side and the right upper extremity referred to as the contralateral side. The blood flow (BF) sensors of the laser doppler perfusion meter (Perimed, Stockholm, Sweden) were placed just distal to the Large Intestine 10 (LI10) acupoint location bilaterally. The Flexicomp Infiniti SC-Flex/Pro skin conductance (SC) sensors (Thought Technology, New York, USA) were placed on the palmar tips of the second and fourth digits bilaterally. The Flexicomp Infiniti distal skin temperature (STD) sensors (Thought Technology, New York, USA) were placed on the palmar tips of the third digits bilaterally. The proximal skin temperature (STP) sensors were placed just distal to the BF sensors bilaterally.

Figure 7: Blood Flow: The change in perfusion over time is represented as a percentage of blood flow (BF) measured at baseline. The X axis is the time expressed in five minute intervals. The Y axis is the BF expressed as a percentage of baseline in perfusion units. The dots represent the highest and lowest outliers. The top and bottom of the shaded box represent the upper and lower quartiles respectively. The median is represented as a line

in the shaded box between the upper and lower quartiles. The top and bottom whiskers represent the maximum and minimum values respectively. When compared with the control and non-penetrating sham groups, the acupuncture group demonstrated a significant increase in ipsilateral BF five minutes into the treatment period ($p \leq 0.05$). By the end of the recovery period, the increase in ipsilateral BF seen in the ACU group had decreased significantly ($p \leq 0.05$) and returned to baseline. All of the treatment groups demonstrated a slight, gradual decline in contralateral BF throughout the recording period. By the end of the recording period, the reduction in contralateral BF seen in the control and S-ACU groups became significant ($p \leq 0.05$). No significant differences were noted between the acupuncture, non-penetrating sham and control groups at any interval throughout the experiment. (*= significance at $p \leq 0.05$)

Figure 8: Skin Conductance: The change in skin conductance (SC) over time is represented as a percentage of SC measured at baseline. The X axis is the time expressed in five minute intervals. The Y axis is the SC expressed as a percentage of baseline in micro-siemens (μS). The dots represent the highest and lowest outliers. The top and bottom of the shaded box represent the upper and lower quartiles respectively. The median is represented as a line in the shaded box between the upper and lower quartiles. The top and bottom whiskers represent the maximum and minimum values respectively. When compared with the control group, the acupuncture group demonstrated a significant increase in ipsilateral SC five minutes into the treatment period and remained increased throughout the remainder of the treatment period ($p \leq 0.05$). No significant differences were noted between the acupuncture, non-penetrating sham acupuncture and control

groups during the recovery period. When compared with the control group, the acupuncture group demonstrated a significant increase in contralateral SC five minutes into the treatment period ($p \leq 0.05$). The increase in contralateral SC seen in the acupuncture group had decreased significantly, but not returned to baseline five minutes into the recovery period ($p \leq 0.05$). No significant differences were noted between the acupuncture, sham acupuncture and control groups for the remainder of the treatment period or during the recovery period. (*= significance at $p \leq 0.05$)

Figure 9: Distal Skin Temperature: The change in distal skin temperature (STD) over time is represented as a percentage of STD measured at baseline. The X axis is the time expressed in five minute intervals. The Y axis is the STD expressed as a percentage of baseline. The dots represent the highest and lowest outliers. The top and bottom of the shaded box represent the upper and lower quartiles respectively. The median is represented as a line in the shaded box between the upper and lower quartiles. The top and bottom whiskers represent the maximum and minimum values respectively. When compared to the control group and the sham acupuncture group, the acupuncture group showed a significant reduction in ipsilateral STD five minutes into the treatment period and remained decreased throughout the remainder of the treatment period. The acupuncture group also continued to show a significant reduction in ipsilateral STD throughout the recovery period ($p \leq 0.05$). When compared to the control group and the sham acupuncture group, the acupuncture group showed a significant reduction in contralateral STD five minutes into the treatment period and remained decreased throughout the remainder of the treatment period ($p \leq 0.05$). The acupuncture group also

continued to show a significant reduction in contralateral STD throughout the recovery period ($p \leq 0.05$). (*= significance at $p \leq 0.05$)

Figure 10: Proximal Skin Temperature: The change in proximal skin temperature (STP) over time is represented as a percentage of STP measured at baseline. The X axis is the time expressed in five minute intervals. The Y axis is the STD expressed as a percentage of baseline. The dots represent the highest and lowest outliers. The top and bottom of the shaded box represent the upper and lower quartiles respectively. The median is represented as a line in the shaded box between the upper and lower quartiles. The top and bottom whiskers represent the maximum and minimum values respectively. The acupuncture group showed a significant reduction in ipsilateral STP by the end of the treatment period which continued throughout the recovery period ($p \leq 0.05$). Likewise, the sham acupuncture group showed a significant decrease in ipsilateral STP by the end of the treatment period and five minutes into the recovery period ($p \leq 0.05$). No statistically significant differences were shown between the acupuncture, sham acupuncture or control groups at any interval throughout the treatment or recovery periods. No statistically significant differences were shown between the acupuncture, sham acupuncture or control groups at any interval in the treatment or recovery periods. The control, acupuncture and sham acupuncture groups showed a significant decrease in contralateral STP by the end of the recovery period respectively ($p \leq 0.05$). (*= significance at $p \leq 0.05$)

Figure 11: Custom Algometer Testing Used in the Study: The custom algometer consisted of a 1.5L water bottle, filled with 1402g of salt, with a $2cm^2$ diameter wooden dowel glued to the lid. Participants were instructed to hold the algometer tip on the test site (Large Intestine 10 Acupoint) with the forearm in full pronation and then complete the VAS to indicate the amount of discomfort associated with the pressure.

Figure 12: Grip Strength: The X axis is the session number with session 1 serving as baseline, session 2A at 48-hours post exercise, session 2B at immediately after treatment (49-hours post exercise) and session 3 at 72-hours post exercise. The Y axis is the mean grip strength expressed in kg. The control group demonstrated a significant reduction in mean grip strength in the time span from session 1 (baseline) to session 2B (49-hours post exercise) as well as the time span from session 2A (48-hours post exercise) and session 2B (49-hours post exercise) ($p \leq 0.05$). The acupuncture group demonstrated a significant reduction in mean grip strength in the time span between session 1(baseline) and session 2A (48-hours post exercise), from session 2A (48-hours post exercise) to session 2B (49-hours post exercise) a significant increase from session 2B (49-hours post exercise) to session 3 (72-hours post exercise) ($p \leq 0.05$). The sham group demonstrated no significant differences in grip strength over time.

Figure 13: Pain Pressure Threshold: The X axis is the session number with session 1 serving as baseline, session 2A at 48-hours post exercise, session 2B at immediately after treatment (49-hours post exercise) and session 3 at 72-hours post exercise. The Y axis is the mean pain pressure threshold (PPT) expressed in kilopascals (kPa). The dots

represent the highest and lowest outliers. The top and bottom of the shaded box represent the upper and lower quartiles respectively. The median is represented as a line in the shaded box between the upper and lower quartiles. The top and bottom whiskers represent the maximum and minimum values respectively. The control group demonstrated a reduction in PPT between session 1 and session 2B ($p \leq 0.05$). The acupuncture group demonstrated a significant reduction in PPT from session 1 to session 2A and a significant increase in PPT from session 2B to session 3 ($p \leq 0.05$). The non-penetrating sham acupuncture group demonstrated a significant reduction in PPT from session 1 to session 2A ($p \leq 0.05$).

Figure 14: VAS for Pain at Rest: The X axis is the session number with session 1 serving as baseline, session 2A at 48-hours post exercise, session 2B at immediately after treatment (49-hours post exercise) and session 3 at 72-hours post exercise. The Y axis is the mean VAS score expressed in mm. The dots represent the highest and lowest outliers. The top and bottom of the shaded box represent the upper and lower quartiles respectively. The median is represented as a line in the shaded box between the upper and lower quartiles. The top and bottom whiskers represent the maximum and minimum values respectively. The acupuncture group showed a significant increase in VAS for pain at rest (VAS-R) between session 1 and 2A ($p \leq 0.05$). There were no significant changes in VAS-R for the control and sham groups over time.

Figure 15: VAS for Pain with Custom Algometer: The X axis is the session number with session 1 serving as baseline, 24-hrs as 24 hours after baseline, session 2A at 48-

hours post exercise, session 2B at immediately after treatment (49-hours post exercise), 60-hrs as 60 hours after baseline and session 3 at 72-hours post exercise. The Y axis is the mean VAS score expressed in mm. The dots represent the highest and lowest outliers. The top and bottom of the shaded box represent the upper and lower quartiles respectively. The median is represented as a line in the shaded box between the upper and lower quartiles. The top and bottom whiskers represent the maximum and minimum values respectively. The control and S-ACU groups showed significant increases in VAS for pain with custom algometer (VAS-C) between session 1 and 24-hours post exercise as well as significant reductions in VAS-C 24-hours post exercise and 72-hours post exercise ($p \leq 0.05$). Participants in the ACU group showed no significant change in VAS-C over time.

Figure 16: Pain at Pain Pressure Threshold (VAS-P): The X axis is the session number with session 1 serving as baseline, session 2A at 48-hours post exercise, session 2B at immediately after treatment (49-hours post exercise) and session 3 at 72-hours post exercise. The Y axis is the mean VAS score expressed in mm. No significant differences in pain at pressure threshold (VAS-P) were found between the three groups at any session of the experiment.

APPENDIX A

Visual Analogue Scale for Pain

How severe is your pain today? Place a vertical line on the line below to indicate how bad you feel your pain is today.

No Pain — Worst Pain Imaginable

How severe is your pain when this amount pressure is applied? Place a vertical line on the line below to indicate how bad you feel your pain is when the pressure is applied.

No Pain — Worst Pain Imaginable

APPENDIX B

Health Research Ethics Board Approval

UNIVERSITY OF MANITOBA

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Research Ethics Boards

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APPROVAL FORM

Principal Investigator: Ms. K. Paulson
Supervisor: Dr. B. Shay

Ethics Reference Number: H2009:180
Date of REB Meeting: June 22, 2009
Date of Approval: July 10, 2009
Date of Expiry: June 22, 2010

Protocol Title: The Efficacy of Acupuncture Versus Placebo Acupuncture in Relieving Delayed Onset Muscle Soreness (DOMS) in Health Human Adults

The following is/are approved for use:

- **Protocol, Version dated 04/06/09**
- **Appendix 1, Visual Analogue Scale for Pain, submitted June 4, 2009**
- **Research Participant Information and Consent Form, Version dated 06/07/09**
- **Recruitment poster, Version submitted June 4, 2009**

The above was approved by Dr. John Arnett, Ph.D., C. Psych., Chair, Health Research Ethics Board, Bannatyne Campus, University of Manitoba on behalf of the committee per your letter dated July 7, 2009. The Research Ethics Board is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement, and the applicable laws and regulations of Manitoba. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the *Food and Drug Regulations of Canada.*

This approval is valid for one year from the date of the REB meeting at which the study was reviewed. A study status report must be submitted annually and must accompany your request for re-approval. Any significant changes of the protocol and informed consent form should be reported to the Chair for consideration in advance of implementation of such changes. The REB must be notified regarding discontinuation or study closure.

This approval is for the ethics of human use only. For the logistics of performing the study, approval must be sought from the relevant institution, if required.

Sincerely yours,

John Arnett, Ph.D., C. Psych.
Chair, Health Research Ethics Board
Bannatyne Campus

Please quote the above Ethics Reference Number on all correspondence.
Inquiries should be directed to the REB Secretary **Telephone**: (204) 789-3255 / Fax: (204) 789-3414

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APPENDIX C

Research Participant Information and Consent Form

Title of Study: "The Efficacy of Acupuncture Versus Placebo Acupuncture in Relieving Delayed Onset Muscle Soreness (DOMS) in Healthy Human Adults."

Principal Investigator: Krista Paulson, R106-771 McDermot Avenue
Winnipeg, MB R3E 0T6

Co-Investigator: Dr. Barbara Shay, R106-771 McDermot Avenue
Winnipeg, MB R3E 0T6

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your friends, family or (if applicable) your doctor before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

Purpose of Study

This research study is being conducted to study acupuncture and its effectiveness in treating delayed onset muscle soreness. A total of thirty participants will participate in this study.

Study procedures

Once you decide to participate, you will then be asked to attend the laboratory on three separate visits. In this preliminary trial, we will ask you to complete a visual analogue scale to indicate your perceived level of pain at that moment. We will then measure the grip strength of your non-dominant hand with a measuring device called a dynamometer by having you squeeze the device three times. We will also measure your pain-pressure threshold by applying pressure to your non-dominant forearm with a device called a pressure algometer. Gradually increasing amounts of pressure will be applied to your forearm until you state that the amount of pressure applied is perceived as painful. This will be done three times. You will then perform wrist curl exercises with a dumbbell using your non-dominant hand. The total time of the preliminary trial should be less than 45 minutes.

After the preliminary trial is complete, you will then be given information regarding the second and third visits, which should take place 24 and 48 hours after the preliminary trial.

In this study, you will be "randomized" into one of three study groups described below. "Randomized" means that you are put into a group by chance, like flipping a coin. You will have an equal, one in three chance of being placed in any group. Group one will receive no treatment at the second visit. Group two will receive acupuncture treatment, with needles that pierce the skin, at the second visit. Group three will receive acupuncture treatment, with needles that do not pierce the skin, at the second visit.

In the second trial, you will complete the visual analogue scale to indicate your perceived level of pain at that moment. You will have your grip strength and pain-pressure threshold measured as in the first trial. You will then be seated in a chair in a reclined position with your arms resting on a pillow on your lap for the duration of the second trial. We will attach a device which measures blood flow on each forearm. We will also attach a device which measures skin temperature on each middle finger. You will rest in the chair for 10 minutes to ensure a resting heart rate is attained. We will then take a five minute baseline measurement of your blood flow and skin temperature.

If you are in group one, you will rest in the chair for 25 minutes while the devices record your blood flow and skin temperature.

If you are in group two, you will have four acupuncture needles applied, which will pierce the skin. One needle will be applied on the web space between your thumb and index finger on the back of your hand. The other three needles will be applied to your arm near your outer elbow. The needles will remain in place for a period of 15 minutes while we continue to record blood flow and skin temperature. We will then remove the needles and will continue to record blood flow and skin temperature for an additional ten minutes.

If you are in group three, you will undergo the very same protocol as for group two except needles that do not pierce the skin will be used.

After the blood flow and skin temperature monitoring devices are removed, you will complete the visual analogue scale to indicate your perceived level of pain at that moment. You will then have your grip strength and pain-pressure threshold measured as in the first trial. The second trial will take approximately 60 minutes to complete.

In the third trial you will complete the visual analogue scale to indicate your perceived level of pain at that moment. We will also measure your grip strength and pain-pressure threshold as in the first trial. The third trial will take approximately 20 minutes to complete.

The investigators may decide to take you off this study if they feel that you may have problems tolerating the exercise program, or acupuncture treatment, if they feel that they pose a harmful effect above and beyond that of which is expected in a normal situation.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study staff first.

Risks and Discomforts

Measurement of your pain pressure threshold will create mild discomfort as the algometer is pressed onto your skin. The testing will stop at the very first level of pressure that your report as painful. The exercise program in this study is expected to create 'delayed onset muscle soreness' approximately 24 hours after completion. This is usually characterized by mild discomfort and tenderness. You have probably felt

‘delayed onset muscle soreness’ in the past after an unfamiliar exercise or activity such as the first game of a golf season. The ‘delayed onset muscle soreness’ should resolve within 72 hours after completion of the exercise program. If you are in group two or three, you may experience a pinching sensation or mild ache as the needles are placed and while they are in place. If you are in group two, a small risk of infection may accompany the insertion of acupuncture needles. Normal use of the arm should not be affected after the experiment series in complete.

Benefits

There may or may not be direct benefit to you from participating in this study. We hope the information learned from this study will benefit our understanding of the potential benefits acupuncture has to offer in regards to its ability to increase blood flow to injured tissue and its ability to affect the rate of healing of injured tissue.

Costs

All the procedures, which will be performed as part of this study, are provided at no cost to you.

Payment for participation

You will be given a gift card after completing all three study visits for your participation in this research study.

Confidentiality

Information gathered in this research study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law.

The University of Manitoba Health Research Ethics Board may review records related to the study for quality assurance purposes.

All records will be kept in a locked secure area and only those persons identified will have access to these records. If any of your medical/research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave the University of Manitoba.

Participants wishing to view results of the experiments once they are finished may do so by contacting the principle investigators for further details.

Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your care at this centre. If the study staff feel that it is in

your best interest to withdraw you from the study, they will remove you without your consent.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study. Participants who are students or employees of the University of Manitoba or who are associated professionally with any of the investigators can be assured that the decision not to participate will in no way affect any performance evaluations.

Medical Care for Injury Related to the Study

In the case of injury or illness resulting from this study, necessary medical treatment will be available at no additional cost to you.

You are not waiving any of your legal rights by signing this consent form nor releasing the investigator(s) or the sponsor(s) from their legal and professional responsibilities.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact the principle investigator: Krista Paulson at 204-470-5354 or Dr. Barbara Shay at 204-787-2856.

For questions about your rights as a research participant, you may contact The University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Krista Paulson and Dr. Barbara Shay and or her study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

I agree to be contacted for future follow-up in relation to this study,

Yes ___ No ___

Participant signature_____Date _____

(day/month/year)

Participant printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent.

Printed Name: _____ Date _____

(day/month/year)

Signature: _____

“Role in the study:

Relationship (if any) to study team members:_____

APPENDIX D

Participant Screening Questionnaire

Exercise History:

1. Which hand do you write with (please circle):
   Right Left

2. Do you currently have an injury in your non-dominant hand or arm (please circle):
   Yes No

3. In the last three months, have you participated in any activities involving forceful, repeated wrist flexion/extension of your non-dominant wrist, such as carpentry or tennis (please circle):
   Yes No

4. Have you completed any forearm strengthening exercises with your non-dominant arm in the last three months (please circle):
   Yes No

5. Do you have pain in your non-dominant hand/arm at rest, or with activity (please circle):
   Yes No

6. Do you have any restriction in movement of your non-dominant hand/arm (please circle):
   Yes No

Acupuncture History:

7. Have you had acupuncture treatment in the past (please circle):
   Yes No
   If yes, how did you respond?
   _____
   _____
   _____
   _____

8. Do you have a fear of needles (please circle):
   Yes No

Medical History:

9. Do you have an addiction to alcohol or tobacco (please circle):
   Yes No

10. Are you currently pregnant or breastfeeding (please circle):
   Yes No

11. Do you have hemophilia or another bleeding disorder (please circle):
   Yes No

12. Do you have HIV or AIDS (please circle):
   Yes No

13. Are you taking any medications (please circle):
   Yes No
   If yes, please indicate your medications:
   _____
   _____
   _____
   _____
   _____

Participant Name (Print): _____

Participant Signature: _____ Date: _____

Investigator Signature: _____ Date: _____

Participant Number: _____

APPENDIX E

Testing Protocol and Participant Instructions

Pain at Rest (VAS-R) Testing

Each participant was instructed to "place a vertical line on the VAS scale to indicate how bad you feel your pain is today."

Pain Pressure Testing (PPT) With Somedic Algometer

The participant's non-dominant forearm was positioned in 90 degrees of elbow flexion and full pronation. The examiner applied a gradually increasing amount of pressure to the Large Intestine 10 point of the participant's forearm with the algometer. The participant was instructed to "press the green button at the first instant that you feel the level of pressure has become painful." The test was repeated for a total of three times with 30 seconds of rest between.

Pain at Pressure (VAS-P) Testing With Somedic Algometer

Each participant's non-dominant forearm was positioned in 90 degrees of elbow flexion and full pronation. The examiner applied a set amount of pressure (equal to the mean PPT value from the baseline measurement for that participant) to the Large Intestine 10 point of the participant's forearm. The participant was instructed to "place a vertical line

on the VAS scale to indicate how bad your pain is when the pressure from the algometer was applied."

Pain Testing (VAS-C) With Custom Algometer

The participant was instructed to "hold the custom algometer with the wooden tip over the 'X' on your non-dominant forearm. Do not press down onto the algometer. Gently hold the algometer so it stays upright and parallel to your forearm. Now place a vertical line on the VAS scale to indicate how bad your pain is when the pressure from the custom algometer was applied."

Participant Instructions for the Exercise Protocol

"You will be completing a challenging exercise session of wrist curls with your non-dominant arm. You will complete 3 sets of exercises with 1 minute of rest between sets. For the first two sets, your goal is to perform 75 repetitions. If you cannot make it to 75 repetitions, please continue until you have reached fatigue and feel as though you could not do one more repetition. For the last set, please continue until you have reached fatigue and feel as though you could not do one more repetition."

"You will keep pace with a metronome set to 15 beats per minute for the repetitions. You will start with your arm resting on the armrest of the chair holding the 5-lb dumbbell in the 'up position' (wrist extended). You will slowly lower the dumbbell to reach the

'down position' (wrist flexed) in time for the beep of the metronome. You should try to time the repetitions so that you reach the 'down position' at each beep of the metronome. During the sets, the examiner will verbally count the number of repetitions you have completed. During the rest periods, the examiner will hold the dumbbell for you."

Participant Instructions for Sympathetic System Monitoring

"Some of the sensors that will be attached to your arms are sensitive to movement. Try to remain as still as possible throughout the recording session. Recordings will be collected for a 20-minute baseline period. Recordings will continue for the 15-minute treatment period and for a 10-minute recovery period after the treatment has ended."

APPENDIX F

Results By Outcome Measure

Blood Flow (BF) (Percentage of Baseline)

Time	**Group**	**Ipsilateral BF** **Median (25% - 75%)**	**Contralateral BF** **Median (25% - 75%)**
5 minutes	Control	97.123 (93.737 - 102.371)	102.993 (84.937 - 125.360)
(Treatment)	Acu	135.219 (115.552 - 192.878)	99.450 (81.596 - 111.284)
	S-ACU	100.319 (92.455 - 126.599)	94.885 (79.510 -112.571)
10 minutes	Control	95.340 (88.699 - 102.401)	88.517 (78.348 -98.661)
(Treatment)	Acu	108.085 (94.013 - 137.316)	90.698 (89.331 - 97.310)
	S-ACU	100.927 (86.760 - 125.704)	80.198 (69.986 - 105.215)
15 minutes	Control	86.480 (83.137 - 96.332)	90.350 (84.092 - 97.733)
(Treatment)	Acu	105.411 (89.211 - 122.320)	93.188 (82.481 - 109.008)
	S-ACU	102.211 (85.814 - 122.147)	86.428 (62.706 - 104.670)
20 minutes	Control	82.763 (77.057 - 98.849)	84.015 (73.754 - 101.391)
(Recovery)	Acu	110.852 (94.641 - 136.122)	97.854 (93.129 - 103.346)
	S-ACU	102.103 (85.374 - 121.200)	82.414 (66.357 – 96.831)
25 minutes	Control	86.493 (78.738 - 105.073)	89.383 (77.613 - 102.766)
(Recovery)	Acu	100.331 (87.261 - 109.808)	100.616 (67.776 - 111.607)
	S-ACU	96.044 (84.883 - 105.663)	71.901 (60.766 - 98.422)

Skin Conductance (SC) (Percentage of Baseline)

Time	Group	Ispilateral SC Median (25% - 75%)	Ispilateral SC Median (25% - 75%)
5 minutes	Control	98.557 (75.267 -105.436)	98.065 (80.746 - 108.506)
(Treatment)	Acu	144.332 (107.955 - 192.914)	146.835 (112.272 - 206.265)
	S-ACU	103.355 (87.583 - 136.269)	101.945 (95.104 - 141.947)
10 minutes	Control	95.481 (79.226 - 111.042)	94.672 (85.609 - 110.507)
(Treatment)	Acu	120.485 (107.079 - 170.628)	128.554 (107.429 - 165.366)
	S-ACU	107.035 (82.971 - 141.072)	103.551 (88.885 - 158.140)
15 minutes	Control	90.250 (74.202 -108.137)	90.485 (73.210 - 108.144)
(Treatment)	Acu	116.603 (96.357 - 177.873)	124.348 (102.194 - 149.800)
	S-ACU	106.397 (72.552 - 130.018)	108.799 (83.085 - 135.799)
20 minutes	Control	95.470 (76.622 - 118.182)	93.954 (74.459 - 117.062)
(Recovery)	Acu	119.758 (102.897 - 167.280)	137.742 (112.542 - 153.230)
	S-ACU	110.030 (82.739 - 137.788)	106.213 (91.824 - 142.763)
25 minutes	Control	94.046 (74.288 - 124.879)	94.457 (77.770 - 118.406)
(Recovery)	Acu	104.730 (94.417 - 136.806)	116.152 (98.010 - 145.525)
	S-ACU	96.233 (65.005 - 112.179)	101.336 (76.254 - 107.586)

Proximal Skin Temperature (STP) (Percentage of Baseline)

Time	Group	Ipsilateral STP Median (25% - 75%)	Contralateral STP Median (25% - 75%)
5 minutes	Control	100.034 (99.658 - 100.200)	100.034 (99.658 - 100.200)
(Treatment)	Acu	99.910 (99.006 - 100.159)	99.910 (99.006 - 100.159)
	S-ACU	99.765 (99.552 - 100.179)	99.765 (99.552 - 100.179)
10 minutes	Control	99.796 (99.309 - 100.176)	99.796 (99.309 - 100.176)
(Treatment)	Acu	99.448 (98.320 - 99.846)	99.448 (98.320 - 99.846)
	S-ACU	99.686 (99.107 - 99.969)	99.686 (99.107 - 99.969)
15 minutes	Control	99.674 (99.235 - 100.250)	99.674 (99.235 - 100.250)
(Treatment)	Acu	99.145 (98.122 - 99.738)	99.145 (98.122 - 99.738)
	S-ACU	99.345 (98.856 - 99.718)	99.345 (98.856 - 99.718)
20 minutes	Control	99.458 (99.074 - 100.425)	99.458 (99.074 - 100.425)
(Recovery)	Acu	98.997 (97.565 - 99.595)	98.997 (97.565 - 99.595)
	S-ACU	99.410 (98.865 - 99.733)	99.410 (98.865 - 99.733)
25 minutes	Control	99.256 (99.120 - 100.501)	99.256 (99.120 - 100.501)
(Recovery)	Acu	98.986 (97.747 - 99.461)	98.986 (97.747 - 99.461)
	S-ACU	99.359 (98.873 - 99.869)	99.359 (98.873 - 99.869)

Distal Skin Temperature (STD) (Percentage of Baseline)

Time	Group	Ipsilateral STD Median (25% - 75%)	Contralateral STD Median (25% - 75%)
5 minutes	Control	99.996 (99.772 - 100.057)	99.996 (99.772 - 100.057)
(Treatment)	Acu	98.830 (98.276 - 99.383)	98.830 (98.276 - 99.383)
	S-ACU	99.549 (98.890 - 100.459)	99.549 (98.890 - 100.459)
10 minutes	Control	100.072 (99.764 - 100.324)	100.072 (99.764 - 100.324)
(Treatment)	Acu	98.806 (96.761 - 99.647)	98.806 (96.761 - 99.647)
	S-ACU	100.011 (99.176 - 101.077)	100.011 (99.176 - 101.077)
15 minutes	Control	100.040 (99.769 - 100.298)	100.040 (99.769 - 100.298)
(Treatment)	Acu	98.800 (96.643 - 99.370)	98.800 (96.643 - 99.370)
	S-ACU	100.003 (98.729 - 100.880)	100.003 (98.729 - 100.880)
20 minutes	Control	99.885 (99.494 - 100.103)	99.885 (99.494 - 100.103)
(Recovery)	Acu	97.786 (96.742 - 99.246)	97.786 (96.742 - 99.246)
	S-ACU	99.782 (99.074 - 100.808)	99.782 (99.074 - 100.808)
25 minutes	Control	99.768 (99.490 - 100.188)	99.768 (99.490 - 100.188)
(Recovery)	Acu	97.618 (97.107 - 99.037)	97.618 (97.107 - 99.037)
	S-ACU	99.909 (98.291 - 101.250)	99.909 (98.291 - 101.250)

Grip Strength (Kg)

Session	**Group**	**Mean (Standard Deviation)**
Session 1 (Baseline)	Control	32.682 (9.172)
	Acu	27.199 (12.872)
	S-ACU	34.154 (11.109)
Session 2A (48-Hours)	Control	32.516 (10.019)
	Acu	24.534 (12.780)
	S-ACU	31.904 (9.397)
Session 2B (49-Hours)	Control	28.344 (10.315)
	Acu	24.072 (12.361)
	S-ACU	31.313 (10.121)
Session 3 (72-Hours)	Control	31.814 (11.272)
	Acu	27.968 (12.126)
	S-ACU	31.718 (8.440)

Pain at Pressure Threshold (VAS-P) (mm)

Session	**Group**	**Mean (Standard Deviation)**
Session 1 (Baseline)	Control	31.833 (23.229)
	Acu	36.000 (25.085)
	S-ACU	27.167 (22.791
Session 2A (48-Hours)	Control	38.333 (24.366)
	Acu	39.333 (24.306)
	S-ACU	38.500 (20.817)
Session 2B (49-Hours)	Control	43.417 (27.665)
	Acu	42.000 (24.499)
	S-ACU	35.917 (26.736)
Session 3 (72-Hours)	Control	35.250 (32.739)
	Acu	32.000 (24.079)
	S-ACU	28.250 (26.830)

Pain With Custom Algometer Pressure (VAS-C) (mm)

Time	Group	(Median 25% - 75%)
Session 1	Control	3.500 (1.500 - 5.000)
(Baseline)	Acu	3.500 (2.000 - 8.500)
	S-ACU	5.000 (2.500 - 11.500)
24- hours	Control	19.000 (10.500 - 26.000)
	Acu	9.000 (3.500 - 22.000)
	S-ACU	18.000 (6.500 - 37.000)
Session 2A	Control	16.500 (7.500 - 26.000)
(48-hours)	Acu	13.500 (7.500 - 41.500)
	S-ACU	13.000 (5.500 - 33.000)
Session 2B	Control	10.000 (6.000 - 22.500)
(49-hours)	Acu	24.000 (4.500 - 31.000)
	S-ACU	16.000 (2.000 - 29.000)
56-hours	Control	9.000 (6.000 - 12.750)
	Acu	12.500 (6.500 - 19.500)
	S-ACU	8.500 (2.500 - 26.500)
Session 3	Control	7.000 (3.500 - 14.500)
(72-hours)	Acu	6.000 (1.500 - 19.000)
	S-ACU	4.000 (0.500 - 17.500)

Pain at Rest (VAS-R) (mm)

Time	Group	Median (25% - 75%)
Session 1	Control	0.000 (0.000 - 0.500)
(Baseline)	Acu	0.000 (0.000 - 0.000)
	S-ACU	0.000 (0.000 - 0.000)
Session 2A	Control	1.500 (0.000 - 20.500)
(48-hours)	Acu	10.000 (2.000 - 34.000)
	S-ACU	2.500 (0.000 - 11.000)
Session 2B	Control	1.000 (0.000 - 13.500)
(49-hours)	Acu	14.000 (1.500 - 28.500)
	S-ACU	1.500 (0.000 - 12.500)
Session 3	Control	1.000 (0.000 - 12.000)
(72-hours)	Acu	4.000 (1.000 - 13.500)
	S-ACU	0.500 (0.000 - 3.000)

Pain Pressure Threshold (PPT) (KPa)

Time	Group	Median (Interquartile Range)
Session 1	Control	252.833 (210.833 - 307.167)
(Baseline)	Acu	263.667 (191.667 - 327.333)
	S-ACU	237.500 (213.333 - 340.833)
Session 2A	Control	207.667 (162.833 - 266.167)
(48-hours)	Acu	177.000 (152.833 - 264.167)
	S-ACU	173.500 (138.667 - 356.333)
Session 2B	Control	205.833 (165.500 - 248.500)
(49-hours)	Acu	163.167 (121.833 - 251.667)
	S-ACU	231.167 (154.333 - 347.333)
Session 3	Control	226.667 (173.500 - 249.833)
(72-hours)	Acu	225.667 (158.167 - 296.833)
	S-ACU	218.833 (166.333 - 385.667)

APPENDIX G

Statistical Analyses

Outcome	Statistical Test	Post Test
Blood Flow	Friedman Repeated Measures ANOVA on Ranks Kruskal Wallis One Way ANOVA on Ranks	Tukey's
Blood Flow Gender Handedness	Three Way ANOVA	None
Skin Conductance	Friedman Repeated Measures ANOVA on Ranks Kruskal Wallis One Way ANOVA on Ranks	Holm Sidak
Skin Conductance Gender Handedness	Three Way ANOVA	None
Skin Temperature	Friedman Repeated Measures ANOVA on Ranks Kruskal Wallis One Way ANOVA on Ranks	Tukey's
Skin Temperature Gender Handedness	Three Way ANOVA	None

Three-way analysis of variance testing completed with SAS 9.2 (SAS Institute Inc., Cary, USA). All other analyses completed with Sigma Stat (Systat Software, San Jose, USA). Significance for all analyses was $p \leq 0.05$.

Outcome	Statistical Test	Post Test
Pain at Pressure (VAS-P)	One Way ANOVA Repeated Measures ANOVA	Tukey's
VAS-P Gender Handedness	Three Way ANOVA	None
Pain at Rest (VAS-R)	Kruskal Wallis One Way ANOVA on Ranks Friedman Repeated Measures ANOVA on Ranks	Tukey's
VAS-R Gender Handedness	Three Way ANOVA	None
Pain Custom Algometer (VAS-C)	Kruskal Wallis One Way ANOVA on Ranks Friedman Repeated Measures ANOVA on Ranks	Tukey's
VAS-C Gender Handedness	Three Way ANOVA	None
Pain Pressure Threshold (PPT)	Kruskal Wallis One Way ANOVA on Ranks Friedman Repeated Measures ANOVA on Ranks	Tukey's
PPT Gender Handedness	Three Way ANOVA	None
Grip	One Way ANOVA Repeated Measures ANOVA	Tukey's
Grip Gender Handedness	Three Way ANOVA	None

Three-way analysis of variance testing completed with SAS 9.2 (SAS Institute Inc., Cary, USA). All other analyses completed with Sigma Stat (Systat Software, San Jose, USA). Significance for all analyses was $p \leq 0.05$.