THE EFFECT OF ELECTRICAL INTRAMUSCULAR STIMULATION ON SUB ACUTE AND CHRONIC HAMSTRING MUSCLE STRAIN INJURIES

by

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Abstract

Muscle strain injuries affect a wide range of physically active people around the world and are reaching epidemic proportions. Despite the variety of treatment options available in rehabilitation, there are no clear guidelines for electrical stimulation that provide effective reproducible results that address the underlying cause of these injuries. For instance, electrotherapy is inefficient at stimulating muscles, because of imprecise parameters and an ability to target particular muscles. The difference between this study and previous research is the precise delivery of electrical stimulation (intramuscular) at two different frequencies (2 Hz and 50 Hz) and comparing it a control group.

Objective: To determine the difference on muscle strength and functional status between three treatments modalities for sub acute and chronic hamstring strains.

Design: A randomized experimental design was used to compare the effects of low (2 Hz), high (50 Hz) and no-electrical (control) intramuscular stimulation on muscle strength and mental and functional status (AMSMC HEALTH STATUS INDEX). Each group consisted of 18 subjects.

Main Outcome: The difference in treatment modalities was evaluated by comparing the muscle strength test (Biodex Dynamometer) results and the AMSMC HEALTH STATUS INDEX results in pretest and post-test conditions.

Results: The AMSMC HEALTH STATUS INDEX, but not muscle strength test (Biodex), changed significantly after 2-Hz electrical intramuscular stimulation (pre-test $\mu = 66.56$, Std= 11.92, post-test $\mu = 92.89$, Std= 6.25), whereas no statistically significant changes in health status index and muscle strength test occurred with 50-Hz (pre-test = 69.22, Std= 11.31, post-test $\mu =$ 70.22, Std= 12.27)) and no-electrical stimulation groups (pre-test $\mu = 69.11$, post-test $\mu = 73.39$, Std= 13.18).

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES:

PREFACE

During this past decade, there have been many changes to our leisure and workplace activities. The growing interest in fitness and changes to the work environment – increased work pressure, use of computer and longer work hours have increased the incidence of muscle injuries due to sport and work related activities[1-6]. The long recovery period associated with these injuries results in lost productivity and participation in sports. This has compelled health care professionals to search for more efficient and effective methods, such as electrical intramuscular stimulation therapy, for treating such injuries. Despite the fact that electrical therapy has been used for over 100 years, its application remains unspecific which influence the efficacy of this treatment. However, these limitations can be improved with this study which compares the response of three treatment modalities which are low frequency (2Hz), high frequency (50 Hz) and no-electrical stimulation.

The confirmed efficiency of a particular modality provides a means to expedite recovery and improve both the short and long-term prognosis of the injury.

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DEDICATION

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Chapter 1 Introduction

The use of electrical stimulation for pain relief is not a new phenomenon. The first account of such application traces back to 63 A.D. An ancient Greek physician, Scribonius Largus, reported that pain was relieved by standing on an electric fish at the seashore[7]. The interest in electrical stimulation revived in 16th through the 18th century with the advent of the electrical generator and the discovery that an electric current could imitate the signals sent along the nervous system. Experiments were conducted using various electrostatic devices for headache and pain relief. They rested on the theory that an electric current could block the pain from reaching the brain. In the 1900's a device called the Electreat, along with numerous other devices was used for pain control and other quack applications such as cancer cures. However, they were not portable, and had limited control of the stimulus.

In 1974, the TENS (Transcutaneous Electrical Nerve Stimulation) device improved on the previous limitations of electrical stimulation[8]. The unit is connected to the skin using two or more electrodes. A typical battery-operated TENS unit consists of a pulse generator, small transformer, frequency and intensity controls, and a number of electrodes. It was initially used for testing the tolerance of chronic pain patients to electrical stimulation before implantation of electrodes in the spinal cord dorsal column[9]. The electrodes were attached to an implanted receiver, which received its power from an antenna worn on the surface of the skin. Although intended only for testing tolerance to electrical stimulation, many of the patients got so much pain relief from the TENS that they never returned for the implant.

1.1 Transcutaneous and Percutaneous Electrical Stimulation for myofascial pain.

TENS is now accepted as a method of pain relief, and has a wide following for use in obstetric care, particularly labour[10]. In palliative care and pain medicine, TENS units are sometimes used in an attempt to alleviate neuropathic pain (pain due to nerve damage) or post operative pain. The goal of stimulation in any pain of neurological origin is suppression of signals through a reflex arc. In addition to functioning as an alternative method of pain relief, there is evidence that electrical stimulation encourages muscle contractions and increased blood flow to the targeted tissues[11-16]. Results of various investigations suggest that TENS can trigger various circulatory alterations. For example, TENS applied at intensities that evoke muscle contractions increases blood flow velocity in the artery supplying the stimulated muscles and leads to a decreased blood flow velocity in arteries to non-stimulated muscles in humans[16]. Results of recent studies also indicate that TENS evokes muscle contraction capable of increasing the degree of microvascular perfusion in the stimulated skeletal muscle[17]. It is still debated whether the increase in blood flow during electrical stimulation is attributed to muscle contraction or to circulatory changes due neurological stimulation via a reflex arc. Understanding the nature of this process is the key factor in determining parameters for electrical stimulation and the scale of frequency in each case. If an electrical stimulation modality triggers circulatory responses, then an intact peripheral nervous system is necessary for TENS to enhance peripheral circulation. Consequently, such treatment would be of limited use in conditions such as diabetes mellitus and peripheral neuropathies, accompanied by impaired peripheral circulation and consequent impaired tissue and vascular denervation. However, if a modality capable of increasing blood supply were

delivered to the given tissue, it would help its rehabilitation[18]. This suggests that different modalities should be applied for treating conditions such as diabetic neuropathy and overuse injuries.

Percutaneous Electrical Nerve Stimulation (PENS) or Electro acupuncture is another type of electrical stimulation. During PENS needles are attached to a device that generates a small electric current that flows between pairs of needles. This form of treatment rests on the traditional acupunctural beliefs that needles inserted in specific points on the human body help restore health and well being[19 20]. The practice of augmenting this stimulation with electrical current is believed to enhance the effect of traditional acupuncture by increasing the stimulus[21-25]. The electrical current is delivered using a device that is capable of adjusting the frequency and intensity of the stimulation. Several pairs of needles can be stimulated simultaneously, usually for no more than 30 minutes at a time. Although this practice has gained a wide following, there is still insufficient scientific evidence regarding the efficiency of PENS.

Weiner et al[26] reported that that PENS reduces pain intensity and improved self-reported disability and physical performance in adults with low back pain. The treatment involved needles insertion to 2-4 cm and frequencies from 4 to 200 Hz. The authors recommended larger studies with longer duration of follow-up to validate these findings and support the use of PENS in clinical practice.

A study by Ghoname et al[27] illustrated that PENS is of value in treating lower back pain. The study utilized PENS for lower back pain and demonstrated PENS to be more effective in decreasing visual analog scale (VAS) pain score compared to sham, TENS and exercise. Additional benefits included decreased medication use and improved

physical activity, quality of sleep, and sense of well-being. In another study, Meng et al[28] compared medical treatment (NSAIDs, muscle relaxants, paracetamol and back exercises) to acupuncture for patients with low back pain. The acupuncture group showed significant improvement in the Roland Disability Questionnaire. Effects were maintained for up to four weeks after treatment. Kerr et al[20] et al conducted a study of similar design comparing TENS and acupuncture. The result showed overall improvement of back pain in both groups. However, no difference between TENS and acupuncture were observed. Both studies failed to control for potential placebo effects resulting from needle insertion. The fact that both acupuncture and TENS benefited back pain patients, and no difference was observed between groups, indicates both may be acceptable for treating back pain. Other studies document similar findings[19 20 23 24 29-33].

Gadsby and Flowerdew[33] in Cochrane Database System Review concluded that PENS and TENS reduce pain and improve range of motion in chronic back pain patients on short term at list. Carlsson and Sjolund[19] conducted a randomized controlled trial comparing acupuncture, electroacupuncture and mock TENS. They reported that a significant decrease in pain intensity occurred at one and three months in the acupuncture group compared to the mock TENS group.

The summary of above studies demonstrates that;

1) electrical stimulation is superior over conventional acupuncture and
2) PENS is superior TENS in clinical trials.

The difficulty of conducting a clinical trial using acupuncture lies in the variability of the method and "state-of-art" practices which are difficult to standardize and translate to a scientific language. Acupuncturists differ widely in their comfort levels

with the research methods used, their adherence to the study protocol, and their expectations of trial outcomes. Such difficulties can be solved by applying different modalities of acupuncture serving specific conditions on specific grounds. In their review, on effect sizes of non-surgical treatments for low-back pain Keller et al[34] conclude that TENS, manipulation, acupuncture, behavioral therapy, exercise therapy, and NSAIDs have only small to moderate effect of treatments for LBP. The author[34] suggests a search for developing more effective interventions.

1.2 Epidemiology of muscle strain injuries

Muscle strains are amongst the most common injuries in football players and sprint athletes[35-38]. The most common strains are to the long muscles of the lower limb, particularly the hamstring muscle group, the rectus femoris (quadriceps group) and gastrocnemius (calf group).

A study[36] of the Australian Football League (AFL) between 1992 and 2000 analyzed, 2255 matches involving 1607 individual players. During matches under study, 672 hamstring, 163 quadriceps, and 140 calf muscle strain injuries occurred[36]. The information was confirmed in other sudies[39-41].

Work and lifestyle related muscle injuries

The exact data on work related muscle injuries is not collected, but it is possible to get the approximate information by analyzing musculoskeletal data. According to the 1997 report from the National Arthritis Data Workgroup, a working group of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, 37.9 million people, or 15

percent of the entire U.S. population, suffered from one or more chronic musculoskeletal disorders in 1990[42]. Moreover, given the increase in disease rates and the projected demographic shifts, they estimate a rate of 18.4 percent or 59.4 million people with these disorders by the year 2020. Results of the National Health Interview Survey for 1995 showed a 13.9 percent prevalence of impairment from musculoskeletal disorders[5].

Other estimates were generated from the Health and Retirement Survey (1992-1994)[43], which found a rate of 62.4 percent among men and women between ages 51 and 61 reporting one or more musculoskeletal disorders; 41 percent of these reported work disability as a consequence. Among all disabled workers in that age group, almost 90 percent reported one or more musculoskeletal disorders, making musculoskeletal disorders overwhelmingly the largest reason for disability.

1.3 Terminology

Work Related Musculo-Skeletal Disorders, Repetitive Strain Injuries, Soft Tissue Injuries are names for different types of muscle strain injuries. These names include conditions like low back pain, whiplash injury, tennis elbow, swimmer's shoulder, runner's knee. These physical impairments differ only in location and symptoms related to the injured part. The physiology of the injury and the consequences remain the same. A strain which occurred during one event is referred to as an acute type of injury and a strain related to a number of events is usually called a repetitive strain injury. The difficulty in repetitive strain injuries is tracking the number of events before developing a clinical picture of these symptoms. Muscle strain injuries may be classified by time frame of recovery into acute, sub acute and chronic types. Acute muscle strain injury is

usually a single event without a history of the event in the past. Such an injury is usually direct and improves in a relatively short (7-15 days) period of time with rest and anti-inflammatory medication[44]. Sub acute muscle strain injury is an injury which heals in a longer period of time – approximately 30 days. The statement is based on observation of Jarvinen et al[45] and Kaarinen et al[46] that a regeneration of myofibrils is complete by day 21 when intervening scar diminished in size. A chronic muscle injury is an injury not healed in two months. Usually it is reoccurring type of event and is characterized by very limited response to anti-inflammatory medication[47]. The most common causes of muscle strain injuries are mechanical stressors[48]. Therefore contact injuries such as contusions were excluded. The degree of injury was limited to first or second where first degree muscle injury is strain represents a tear of only a few muscle fibers with minor swelling and discomfort accompanied by no or only minimal loss of strength and restriction of the movements. Moderate (second-degree) strain, in turn, is a greater damage of the muscle with a clear loss in function (ability to contract), whereas a tear extending across the entire cross section of the muscle and, thus, resulting in a virtually complete loss of muscle function is termed severe (third-degree) strain/contusion[45].

1.4 The study's theory

The offered treatment is an application of electric current to the contractile muscle elements by acupuncture needles to evoke muscle contractions. The contraction of the injured muscle will be stimulated by needles placed at the site of the injury and myotome's innervation to ensure painless but powerful contraction. The use of needles, which carry out the function of electrodes, is imposed by the need to avoid natural body

insulators such as skin, adipose tissues, fascia and superficial muscles as well. The device uses low intensity, low frequency waveform impulses to provide periods of contraction and relaxations necessary for the restoring blood circulation.

Both inflammatory and chronic stages are associated with diminished performance, which can be measured. The positive changes in the performance of the muscles after the treatment program will be used to evaluate treatment efficiency and discuss the results. This study will evaluate the outcome of electrical intramuscular stimulation in treating muscle strain injuries.

The study's treatment target groups are patients who obtained a hamstring injury between 1 to 6 months before the trial and whose hamstring injury is the first incident in the last 12 months. The time frame is chosen to separate an acute stage from a sub acute one and a chronic stage from advanced tissue degeneration. The inflammation (acute) stage is accompanied by an increase of inflammation markers and good recovery is achieved with non-steroid anti-inflammatory medication. The sub acute/chronic stages are characterized by a reduction in the number of inflammation markers, increased proliferation of collagen and fibroblasts which begin producing a gel-type matrix that surrounds the connective tissue, leading to fibrosis and scarring. Other methods than anti-inflammatory medication are required for the recovery during these stages where an electrical stimulation may be one of them.

1.5 Hypothesis

The purpose of this study was to determine whether low frequency (2 Hz) electrical intramuscular stimulation is more efficient compared to the control group

(intramuscular needling without electrical stimulation) and high frequency (50 Hz) electrical intramuscular stimulation and will

1. Increase in the AMSMC health status index after intervention
2. Increase in the eccentric muscle strength (Biodex) after intervention conditions

1.6 Assumptions

The following assumptions were made when designing the study:

1. All subjects respond honestly, to the best of their knowledge, regarding the amount of activity that they perform on a weekly basis as well as their involvement in competitive sporting activities.
2. All subjects report accurate scores, to the best of their ability, when filling out the health status index.
3. All subjects complied honestly with the trial requirements (no anti-inflammatories or pain-killers on test day).

1.7 Limitations

The study, at the present time, was limited by the following:

(1) The age (19-54) is chosen to make random sample groups more homogeneic to increase statistical power.

(2) The study did not apply to such injuries as acute hamstring injuries, contusions, lacerations, abrasions or injuries due to a fall or an accident as well as hamstring

injuries out of time frame 1- 8 months of existing symptoms.

(3) The power analysis of the study is to be based on differences that are assumed and not directly determined through the literature.

(4) The muscle strength test is affected but not limited only to a damage of muscle cells. Neurological strength can not be controlled in the study because of insufficient amount of research on the topic and study design.

Chapter 2 Review of literature

Muscle Strain Injuries

2.1 Pathophysiology, signs and prognosis of muscle strain injuries

Acute Muscle Strain Injury

Computed tomography of human athletes reveals that inflammation and edema play a large role in acute muscle strains[49-53]. Muscle disruption and minor hemorrhages are present immediately following an injury. Inflammation becomes pronounced in the following days and by one week the inflammation is beginning to be replaced by fibrous tissue (8-35 days)[51 52 54 55].

Many injuries result from rapid loading and follow a well defined and often relatively short course to recovery. The exact moment and how they occurred is often remembered. There are four classic signs of inflammation presence: redness, swelling, heat, and pain with impaired function[56]. The stage is linked with increases in plasma inflammatory indicators, myeloperoxidase and interleukin-6 on a molecular level and neutrophils on a cellular level[56].

The mechanism of recovery goes through specific stages. Acute injuries incurred to muscle tissue involve processes of healing and repair similar to those of other tissues[45]. Initially bleeding following trauma is associated with platelet aggregation, degranulation and vasoconstriction of blood vessels[45]. An inflammatory process occurs next, triggered by growth factors and cytokines initiating a cascade of events[56]. The leucocytes recruited in the injury environment are observed to include neutrophils in the first few hours followed by monocytes at 18 hours and T cells and macrophages at 36 to 48 hours[56]. Within a few days there is a proliferation of ground substance, and fibroblasts begin

producing a gel-type matrix that surrounds the connective tissue, leading to fibrosis and scarring[45]. At the same time, myoblastic cells form in the area of trauma, which eventually lead to the regeneration of new myofibrils. Thus, the regeneration of both connective tissue and muscle tissue has begun[57]. Collagen fibers undergo maturation and orient themselves along the lines of tensile force according to Wolff's Law[58]. Active contraction of muscle fibers and their linear orientation are critical in regaining normal tensile strength[58].

The inflammatory response, which is necessary to initiate growth and healing, involves chemoattractants and cytokines that recruit and activate leukocytes to remove injured tissue and release growth factors to stimulate tissue rejuvenation[45]. This response is weakened with aging, as plasma cytokines are elevated and leukocyte phagocytic activity to infectious challenges is reduced. It is not known if age affects the inflammatory response to functional overload-induced skeletal muscle injury.

Sub acute and chronic muscle injuries

Injuries other than acute or single event injuries (e.g., ACL rupture, meniscus tear) are "non-contact" injuries. It is characteristic of some injuries (e.g., tenosynovitis, muscular strains, etc.) that only the general time frame (day, week) is remembered because of the insidious nature of the onset. These injuries are long lasting and/or subject to reoccurrence. They are often the result of overuse in which repeated stress does not allow the body to complete the repair process. The injured tissue may merely remain static or suffer the cumulative effects of repetitive micro trauma with eventual tissue deterioration to the point of gross failure (e.g., Achilles/patellar tendonitis, rotator cuff tendonitis, tennis elbow).

The signs of sub acute and chronic muscle injuries are not like the 4 classic signs of acute injuries (inflammation - redness, swelling, heat, pain). Only two signs remain out of four: – swelling and pain. Despite the lack of evidence that heat and redness are present during a repetitive strain injury, the majority of physicians maintain that these factors are present and warrant the prescription of anti-inflammatory medication[59 60]. There is a growing opposition to this belief based on lack of significant improvement with anti-inflammatory treatment for chronic muscle strain injuries[59 61-64].

The difference in pathophysiology and the signs of acute and sub acute/chronic muscle strain injuries encourages the search for another contributing factor to the impairment. Research has shown that increased intramuscular pressure[65-67] may disturb the blood flow to myotendinous junction. The role of intramuscular pressure at the injured muscle remains unanswered. The two signs (pain and swelling) suggest that excess of intramuscular pressure may be more significant than currently recognized.

2.2 Prevalence and biomechanics of hamstring injury

The pathogenesis of hamstring muscle injuries has been studied as extensively as any other single sports injury, but it is remains unclear[1 61 68 69]. Sports medicine dogma advises that low muscle strength, poor flexibility, lack of warm-up, failure to stretch, and muscle fatigue are risk factors for muscle strains, and that these injuries can therefore be prevented[48 55 69-71]. The scientific evidence to support these beliefs is insufficient[6 41 55 71-74]. The only reversible risk factor for hamstring muscle injuries for which there is good degree of clinical evidence is low strength[6 55 71 74]. Past injury history is a recognized risk factor but it is not reversible. There are a number of prospective studies suggesting that

low hamstring muscle strength is associated with future injuries, but one study[75] in Australian football contradicts these. It is likely that injury history, age, muscle fiber type, and player speed are all confounders of hamstring and quadriceps muscle strength, and no study to date has been able to take account for all of these factors together.

Based on the analysis of Orchard et al study[71], intrinsic (player related) factors are more predictive of muscle strain injury than are extrinsic (environment-related) factors. This study confirms previous findings that a history of injury to a muscle group (hamstring, calf, or quadriceps) is the most important risk factor for a future injury of that group. A history of previous calf muscle injury was independently predictive of hamstring muscle injury, and a history of quadriceps muscle injury was independently predictive of calf muscle injury[71]. A recent hamstring muscle injury was a risk factor for quadriceps muscle injury[35]. This may be explained by the fact that after an injury, changes occur in the biomechanics of running or muscle pathophysiology that predispose athletes to an injury in a different muscle[73]. The finding that injury history is such a strong risk factor for muscle strains shows that this factor must be considered with other variables.

Player maximum speed is a likely risk factor for all muscle strain injuries, and there may be genetic types that are at increased risk for all muscle strains; for example, blood group O has been associated with tendon rupture, low hamstring muscle strength and hamstring injury[38 76-78]. Past injury has also been associated with low hamstring muscle strength[79] and may be a confounder. Muscle strength (particularly of type II fibers) is known to decrease with age[80], with the implication that age may be a confounder of low muscle strength, or that relative weakness may be a mechanism by

which older players are more prone to sustain hamstring and calf muscle injuries. A contracted muscle is known to resist more force than a relaxed muscle[81], partially explaining why low muscle strength may be a risk factor for muscle strain injuries. There is only a few studies[69 75 79] suggesting that correcting muscle strength deficits can lower the injury rate[77]. In this study, age (when considered independently of past history) was a risk factor for hamstring and calf muscle strains but not for quadriceps muscle strains. Crosier et al study[69] is consistent with the theory that abnormalities of the lumbar spine are implicated in the development of muscle strains, since the lumbar nerve roots of L5 and S1, which supply the hamstring and calf muscles, are more likely to be affected by age-related spinal degeneration than the nerve supply of the quadriceps muscles (L2, L3, and L4)[82]. The age-related loss of muscle strength is known to be caused by denervation of type II muscle fibers[80]. A possible mechanism for the increased age-related susceptibility is low lumbar degeneration leading to L5 and S1 nerve impingement, leading to hamstring and calf muscle fiber denervation, and then leading to decreased muscle strength.

2.3 Current treatment options for muscle injuries

Physiotherapy

The main tools in the physiotherapy treatment for muscle strain injury are exercise, ultrasound, TENS (Transcutaneous Electrical Nerve Stimulation) and interferential TENS, high voltage galvanic current and ice/heat application. Eccentric stretching is well recognized modality if rehabilitation of muscle strain injuries[55 82-84].

Skeletal muscle blood flow is controlled by an array of neural, humoral, metabolic, mechanical, and myogenic mechanisms during rest and exercise[14 15 85-89]. There is hypothesis that TENS may influence blood circulation in soft tissues[12 13 15 16 90]. A number of researchers[12 13 15-17 33 90-96] report that muscle contraction has been shown to cause dilation of resistance vessels in the active muscle with subsequent changes in local hemodynamic. Likewise, an increase in the density of perfused micro vessels in the vascular bed of contracting muscles has been noted in other investigations[97]. The reports from the literature mentioned above suggest that, when the neuromuscular mechanism is intact, muscle contraction does cause acute adjustments in blood flow and microvascular perfusion[97]. However these studies did not specify the frequency of the electrical signals. Most electrotherapy protocols[90 93-95 98] are focused on temporarily analgesia and use frequencies of 100 Hz and above. The factors that reduce efficiency of electrotherapy are adipose tissue, dryness of the skin and depth of the injured muscle[99]. Both skin and adipose tissues are rather insulators than conductors; therefore, a weakened electrical impulse can only reach superficial muscles[99].

Ultrasound therapy is popular for treating soft tissue injuries[100]. It is frequently prescribed for soft tissue injuries. Most frequent application of ultrasound (shock wave) is for treating plantar fasciitis, epicondylitis and other tendinous tissues impairments. Heat/ice application is the most popular recommendation for muscle strain injuries. An ice application is more indicated for pain suppression by diminished nerve sensitivity during the acute inflammation stage (4-7 days)[101]. A heat application is more often used for sub acute and chronic stages because it encourages vasodilatation and increased blood circulation[1 29 61 102]. Again skin and adipose tissues significantly reduce the healing effect

of the application[1 61]. There are no clear guidelines where an ice or heat should be applied in a case of chronic overuse pain.

Medications: Pain killers, anti-inflammatory medication and muscle relaxants

The most common reason for prescribing anti-inflammatory medication is an assumption that every case of myofascial pain has an inflammation factor[59]. As said above, it is beneficial in an acute stage and it is not beneficial in sub-acute and chronic type of muscle strain injury. The more chronic the pain is the less beneficial is the use of anti-inflammatory medication[59 61 102]. A number of studies report that non-steroidal, anti-inflammatory medications are effective in treating acute low back pain, but become less effective a week after the injury has occurred[47 61 102]. The reoccurrence of, for example, low back pain, remains high and increases with worker's age or amount of working hours[4 43].

Excess of intramuscular pressure (edema) has suggested being a key factor in sub acute and chronic muscle strain injury. However, anti-inflammatory medication[44 59] and muscle relaxants are not designed to reduce edema.

Analgesics are good for pain management, but only in a short term because of increased risk of re-injury of the injured muscle due to a higher pain threshold[41 55 102 103].

Prescription of *muscle relaxants* is based on the view myofascial pain as muscle spasm and only weakly supported by results from controlled clinical trials[60]. Muscle strain injury created in a lab on an animal model reveals that most frequently damaged are is musculo-tendinous units[47 51 52 81]. The damage is not a spasm but a hemorrhage[47].

Massage (active release technique, acupressure, shiatsu, etc).

Treatment is restricted to sub acute and chronic stages only because of hematoma

associated with muscle injury. The modality is favored by patients because of obtained relaxation feelings after session. There are study claiming that massage in a combination with exercise and education is more effective[104] than acupuncture or TENS for low back pain.

Alternative treatments for Muscle Strain Injuries

Acupuncture

Acupuncture has a few very important advantages[30 99 105-107]:

a) direct treatment
b) may reach a muscle on any depth
c) no use of medication
d) minor side effects such as small bleeding,

The universally recognized theory behind acupuncture efficiency is endorphin release during treatment[56].

Disadvantages of acupuncture:

Since acupuncture diagnostic tools are based on pre-scientific ideas their methods are difficult to comprehend and apply from the modern medicine perspective. Therefore the treatment is non-standardized and the results are highly dependent on the skills of the practitioner. Some researches do not recommend acupuncture for myofascial pain treatment[51 52 56 57]. Results are often not reproducible and their controversy decreases the value of acupuncture and sometimes discredits it.

Modified acupuncture

Dr. Gunn's Intramuscular Stimulation (IMS)[107] is a treatment for muscle spasm or shortened muscle by desensitizing muscle trigger point. The treatment is based on a

neurological approach to the problem. Dr. Gunn states that the injured nerve is hypersensitive (Cannon and Rosenblueth' Law of Denervation[108]) and can be desensitized by needle insertion and manipulation[107]. A needle is inserted into the spasm and followed by needle grasp and muscle's fasciculation. Visually it appears as a muscle twitch. The treatment requires needle manipulation on each shortened muscle. It is difficult to employ the technique on shortened, deep muscles near vertebra under blind control. The treatment is claimed to be effective for local muscle spasms[109]. The theory of muscle spasm seems fading and there is no clinical trails supporting the view point.

Dr. Chu offers *twitch obtaining intramuscular electrical stimulation* (United States Patent 6,058,938 et al. May 9, 2000). Dr. Chu found that the acu-needle inserted once into a muscle does not provide the desired stimulation. She developed an electrical twitch obtaining intramuscular stimulation (ETOIMS) [105 106 110-112] technique which is performed by motor end-plate employment. The rate of stimulation is 2 Hz. Both electrodes (Teflon coated needles) are placed subcutaneously about 15-25 mm away from each other into multiple motor points at 2 Hz for two seconds, using unipolar negative wave of 20 mA and 0.5 ms pulse duration, supplied by the EMG machine. It elicits "twitches in a small portion of muscle, visible as fine jerking of the stimulating needle or as fasciculation-like twitches." The technique produces local intra-muscle stimulation, and claimed that it is working well because muscles spasms elimination[105 112].

Percutaneous Electrical Nerve Stimulation

One study reported that PENS is more effective[92] in myofascial pain control rather than TENS in providing long-term pain relief and improved physical function in

patients with chronic low back pain. But recommendations regarding the impulse frequency and location of the needles are not consistent. Low frequency (4 Hz and higher), high (100 Hz and higher) and combinations of them are used for treatments with various results. The mechanism of the treatment is blockage of nerve pathway (dorsal horn neurons) and the results are short-term and not cumulative [91 93].

Acupuncture-Like-TENS (technique similar to PENS)

AL-TENS is an electro-acupuncture performed by a TENS device. Acupuncture needles are placed at key points along the nerve pathway. Hi-frequency current impulse or burst mode is applied for the purpose of analgesia of the painful area. The method is used for pain control, but the results are short term. Recent research on the efficacy of TENS and AL-TENS concluded that they are not effective for treatment of low back pain (muscle strain injury type)[91 93 94 113 114]. This conclusion could be attributed to the method of stimulation used in the study. Sherry et al[12] in her study of electrical burst-mode stimulation found that muscle contraction is positively correlated with the local increase in blood flow. However, electrical burst-mode stimulation is ineffective at stimulating the type of muscle contractions that encourage blood flow[12]. This explains why in this trial neither TENS nor AL-TENS in this study had a significant effect.

Treatment for musculo-skeletal injury (MSI) in the sub acute or chronic stage should have a long term recovery and well grounded explanation for it. The lack of success may be explained by the lack of knowledge in pathophysiology of muscle strain injuries (overuse) and therefore lack of successful experimental design.

2.4 Difficulties in applying percutaneous or transcutaneous electrical stimulation for muscle strain injuries

The practitioners and researchers faced three major obstacles:

a) parameters of the stimulation

b) goal of the stimulation:

-analgesia versus treatment

c) delivery method of electrical current to the target.

The parameters of electrical stimulation used for analgesia purposes in human subjects seem quite standard:

TENS treatment goes with high frequency or low frequency of 40-150/4 Hz and low intensity in burst mode and PENS (AL-TENS) goes with low frequency 4 Hz and high intensity.

Both frequencies high (100 Hz) and low of 4 Hz are found to be similarly effective in a burst mode[12]. All other parameters are constant, as follows: 100-micro-second pulse duration, asymmetrical biphasic square wave, 20-minute duration, and sensory amplitude. Sensory amplitude was determined by increasing the amplitude until a motor contraction was observed and then decreasing the amplitude to just below the motor contraction threshold. The summary of reviewed articles on the topic is presented below:

Table 2.1: Parameters of electrical stimulation

Human subjects

Author	Frequency	Pulse duration µS	Intensity mA	Duration	Wave
Rakel and Frantz[98] (TENS)	4 Hz 100 Hz	100 pulses per second for 0.5 seconds and then 50 pulses per second for 0.5 seconds was used with a pulse width of 150 microseconds.	sensory amplitude	20 min	asymmetrical biphasic square wave
Moore[115] et al TENS NMES, NMES/TENS,	100 70	100 200	0-60 0-100	5 consecutive hours a day, for 2 consecutive days, with a 2-day hiatus between treatment conditions to minimize carry-over effects.	asymmetrical biphasic square pulse symmetrical biphasic square pulse
Ghoname[27] et al PENS TENS	4 4	0.5 milliseconds. 0.1 milliseconds.	<25 maximum tolerable "tapping" sensation		unipolar squarewave
Yokoyama[92] et al PENS TENS	4/30 Hz	n/a	sensory amplitude	20 min (16 sessions)	n/a

The number of treatment sessions and the period of treatment required to sustain analgesia after PENS are unclear.

Conventional TENS is associated with a faster onset and shorter duration of analgesia compared with acupuncture-like TENS.

Animal subjects:

Author	Frequency (Hz)	Pulse duration	Intensity	Duration min	Wave
Vance et al[95] TENS	4 Hz 100 Hz	100 µs	sensory amplitude	20	asymmetrical biphasic square wave.
Ma et al[116]	4 Hz 100 Hz	100 µs	15-25 mA	20	asymmetrical biphasic square wave.
Ainsworth et al[91]	4 100	n/a	sensory amplitude	20	n/a

The conclusion from the reviewed articles suggest that for analgesia purpose it is not necessary to have specific requirements regarding the frequency, pulse width or intensity, both in human and animals subjects. The animal studies were set up to provide most evident explanation for analgesia after deliberately induced inflammation (kaolin injection). The effect of analgesia was detected in all studies and remained from 2 to 8 hours[95].

The studies in human subjects have more variety in conditions treated in TENS/PENS studies. There three most frequent conditions tested TENS efficiency are postoperative management, low back pain and osteoarthritis[32 33 96 98].

Again the tests were done for confirming the benefits of electrical stimulation for a particular condition. The intensity in human subjects varied more than in animal subjects from 0-25 and to 100 mA and the frequency remained similar where 4 Hz was defined as low and 70 and 100 Hz as high frequency stimulation. Both high and low frequencies were found to be effective for the analgesia purpose[91 95]. The explanation why both frequency modes were effective is provided by Lieber[117]. He writes that "the stimulation patterns designed in physiological amounts of electrical activity to the muscles and mimic the activity of motor nerves normally activating "fast" (by high frequency) and "slow" (by slow frequency) muscles".

However there is some degree of inconsistency between the studies where

- the purpose of animal studies were *analgesia* on deliberately induced inflammation with consequential limb functionality and
- the purpose of electrical stimulation in human studies frequently claimed as a *therapeutic* modality.

It is assumed that therapeutic modality and analgesia modality are supposed to be different from each other.

Another difference is that studies on human subjects are commonly performed for lower back pain or osteoarthritis which is considered as chronic conditions, where animal studies were performed on induced acute inflammation. The analgesia stimulation in animal and human studies did not vary except the definition of low frequency which is 4 Hz in animal studies and 50 Hz in human post operative management. There is no mentioning of "tapping" contractions and no cumulative effects in animal studies, where studies in humans for low back pain and osteoarthritis always mentioning the "tapping" as a marker of intensity stimulation in humans. For example there is no difference in efficiency for analgesia purpose in animals but in humans Walsh et al[118] reported that the hypoalgesic effect of TENS on experimentally induced ischaemic pain was more effective at 4 Hz than 110Hz. In confirmation, another study states also that low frequency is more effective than high, but adds that muscle contraction plays significant role in the blood circulation enchancement[12]. Some studies[27 92] report that PENS in human subjects is more effective than TENS. The difficulty with PENS is the belief that needles have to be applied to acu-points in order to be effective. However the most important factor is the muscle contraction, not the point location[92 99]. Studies[27 92] comparing the effect of TENS and PENS in low back pain utilize different methods of applying electrodes. PENS has also another parameter rarely mentioned in many studies - the depth of the needling. TENS stimulation does not require it and therefore the treatment may be compared to a two-dimensional model (+/- electrodes lay flat on the skin) were PENS is a three-dimensional (+/- electrodes placed in particular depth) model

and absence of the information makes reviewing the information of PENS effectiveness more challenging. Yokoyama et al[92] mentioned depth of needle insertion as 2-4 cm but do not specify the target (ie. acu-point, connective/adipose tissues or a back erectors muscles). The majority of studies on TENS/PENS application seen intensity of stimulation that results in muscle contraction (tapping)[26 27 31 32 92 94-96 116 119]; where PENS requires 15-30 mA and TENS up to 60 mA in human subjects. The explanation of the phenomena is quite obvious: the closer the stimulation to the muscle the less electrical current is needed to employ the contraction. The contracting muscles were never identified in any studies however it very clear that Ghoname et al[27] electrically stimulated back erectors muscles for low back pain because of needle (PENS) or electrodes (TENS) placement. It is an assumption that if muscle contraction (tapping sensations) is so important in electrical stimulation, that more precise (targeted needling) of particular muscle (back erectors for example) will be more efficient. Perhaps such stimulation will provide more consistent results. Also the reason for improvement with PENS is still a mystery, as well as the frequency of sessions to maintain the improvement[92] which is usually subside a week after cessation of treatment. There are several studies reporting pain reduction in osteoarthritis[31 32] after PENS application. It is interesting that application of acupuncture compared with PENS is less beneficial for osteoarthritis[31 32].

The conclusion on electrical stimulation it is a potential tool for acute and chronic pain reduction. Analgesia lasts up to 24 hours[94] and the treatment effect is assumed to be longer than analgesia.

The key factor that summed to influence the success of treatment is the frequency of stimulation which affected blood flow.

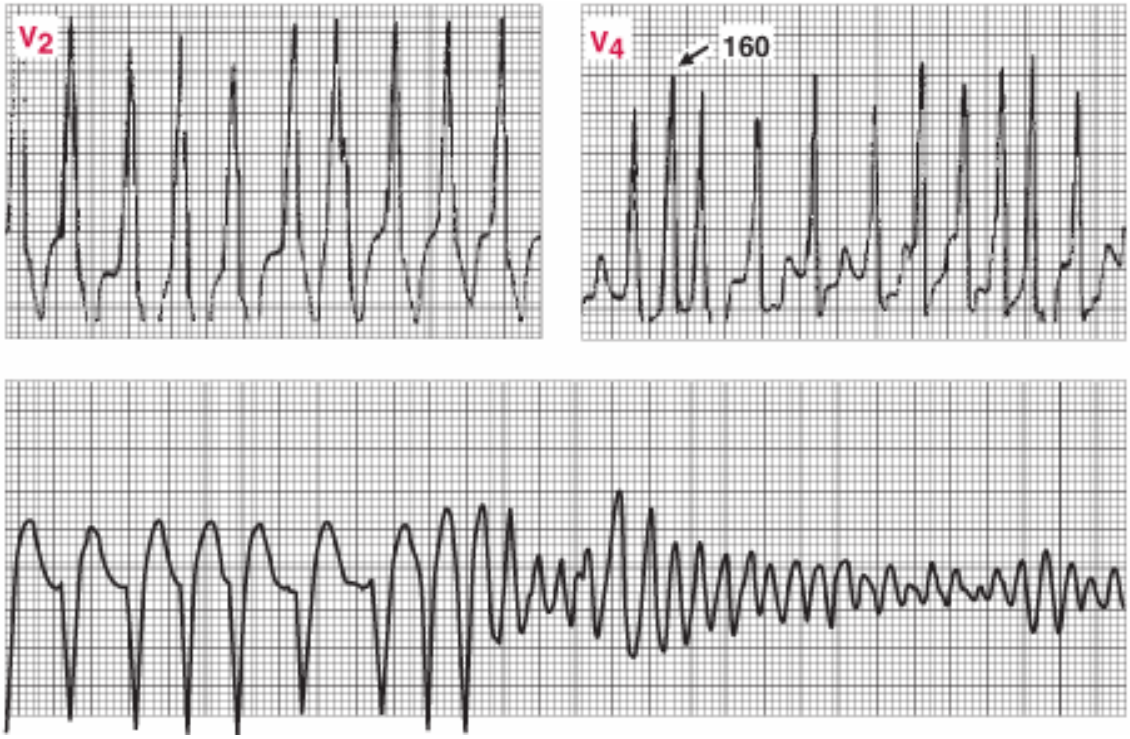
Many authors[14 15 17 85 88 90 93-95 97 120-122] agree on fact that electrical stimulation may influence the blood flow in muscle. Despite numerous studies on electrical tetanic or twitch contractions there is still no commonly shared viewpoint on what frequency of electrical stimulation (not intramuscular) is beneficial for muscle blood flow or rehabilitation of muscle injury[11-16 85 90 123]. "Although studies in humans are scarce, the effect of twitch versus tetanic muscle contractions in animals has been studied elaborately[16 17 91 93-95 116 122 124]. Brechue et al[85] reported a higher blood flow increase after 50Hz compared with 1 to 4Hz in the dog's hind limb while Wakim[123] reported highest blood flow values between 8 and 32Hz in dogs. Mohr et al[16] reported that 20Hz was the most efficient stimulation frequency for blood flow increase in rat's hind limb. In contrast, Hawker and Egginton[90] and Folkow and Halicka[125] showed that maximal flow in rat and cat skeletal muscles, respectively, occurred around 1 to 4Hz"[11].

The issue of frequency is the major focus of this study because of the focus on defining low and high frequency electrical stimulation. The expected difference in results may support or reject the "blood flow" theory. The reasons why frequency may benefit a blood circulation are physiological boundaries of muscle contraction, where blood flow goes in the muscle during a relaxation period and leaves within a contraction. It seems that the time frame for contraction and relaxation is well defined and has certain limits. For example longer muscle contraction period (tetanus) will increase demand for energy wise blood flow and may results in muscle damage.

One of skeletal muscle working with great rhythm capacity is the heart muscle.

The most common ventricular frequency before a heart goes into ventricular fibrillation and cardiac arrest is ~ 6 Hz.

Figure 2.1: Atrial fibrillation ECG



Merck Manuals, Fig. 14 Atrial Fibrillation and Wolff-Parkinson-White (WPW) Syndrome: Ventricular response is very fast (RR intervals minimum of 160 msec). Shortly thereafter, ventricular fibrillation develops (lead II continuous rhythm strip at bottom).

Note: One hertz simply means one impulse per second or 60 impulses per min. Therefore 160 msec is 1000/160 =6.25Hz.

An addition to the example, a short self-study was performed by the author on the maximum characters typed by point or middle finger during one minute with the help of keyboard and MS Word (counted characters). The number of typed characters did not exceed 360 which mean that average finger motion frequency did not exceed 6 Hz.

These above mentioned information make the statement of Folkow and Halicka[125] (1-4 Hz is more effective in terms of blood circulation) is more grounded in terms of blood circulation and muscle contraction.

Since there is some sort of uncertainty on parameters of electrical stimulation, it would make sense to run an experiment with a single impulse and frequency of 1-4 Hz first and, after it's proven to be effective, an experiment with tetanic mode of contraction

may be conducted.

2.5 The Role of eccentric muscle strength measurement in the assessment of muscle strain injuries

Muscle strength testing is frequently used in examining the effect of treatment modality. However the difficulty of the test is that muscle strength is a result of four factors that overlap[126]:

1) physiological strength (muscle length, cross sectional area, available crossbridging, responses to training),
2) neurological strength (how strong or weak is the signal that tells the muscle to contract),
3) mechanical strength (muscle's force angle on the lever, moment arm length, joint capabilities) and
4) metabolic conditions

Loss of muscle strength is a marker of exercise-induced muscle damage; however, there is a large variability in the measurement, even when subjects are exposed to standardized exercise protocols[126]. Despite the known effect of CNS on muscle strength this study focused only on impaired peripheral muscle function which could result from many different mechanisms, including damaged contractile proteins, damaged sarcolemma and altered intracellular environment. Most research involving excentric muscle strength measurements are done in studies of acute muscle injuries such as DOMS[127]. Also muscle strength is one factor correlated with reoccurrence of hamstring injuries[36 55 69 75]. However the reason for the lack of restoration of muscle strength

remains unclear.

Eccentric strength was measured using the Biodex Dynamometer (model 900-240). The Biodex Dynamometer is a hydraulically powered, computer controlled exercise-testing device. This apparatus was used to measure and record the eccentric torque (Newton - meters, Nm) of the hamstring muscle in each subject. The subjects sat on the dynamometer, with their hips at 80° of flexion, their back supported and their pelvis stabilized on the seat with three seatbelts (waist belt, left shoulder and right shoulder belt). The author set the lever arm length to line up the rotational axis point of the machine with the lateral malleolus. The subject's test leg was secured by a Velcro strap on the distal thigh and around the ankle during the exercise protocol. The subjects held the sides of the seat for additional stability. The angular velocity was set at 60° of sec through a range of 75° at a long muscle length (110° - 35° of knee flexion). Subjects were given a practice trial consisting of two sub maximal eccentric contractions. Immediately after practice, the subject underwent 3 test sets. Each set consisted of three maximal trials. There was a three minutes recovery period between sets. The highest torque (Nm) of each test set was kept for analysis.

2.6 Muscle pain and the AMSMC health status index

Pain is very subjective in nature, and it's very difficult to measure objectively and quantify it[23 27 30 32 115 118 119 128]. The AMSMC health status index consists of a few blocks of questions and Visual Analog Scale (Appendix B). The validity of pain measurement with VAS is well documented[129-131]. The questionnaire added to VAS section quantified function and performance. There are 10 questions for physical function

with maximum total scores of 30. Each answer has 3 different grades. There are two questions for physical activity with maximum total scores of 30. Each answer has 4 different grades. There are 5 questions for emotional/mental behavior with maximum total scores of 30. Each answer has 4 different grades. The Visual Analog Scale consists of three parts:

1) influence of pain on daily living,
2) physical activity and
3) sleep deprivation.

Each part has a 5 cm line with marked endings indicating absence of complaints (mark 5) at one end and extreme presence at the other end (mark 0). In order to quantify and objectively measure pain, subjects are asked to place a mark along this line with respect to their level of pain at the time of measurement. Therefore, higher mark will indicate less significant pain. Although a great deal of criticism exists in the literature with respect to the high variability inherent in this pain rating system, the visual analog scale has been found to bring greater sensitivity and statistical power to data collection and analysis by allowing a broader range of responses than traditional categorical responses[132]. It also removes the bias brought on by examiner questioning and allows for graphical temporal comparisons, thus minimizing bias and boosting statistical power.

CHAPTER 3 METHODOLOGY

3.1 Frequency of electrical stimulation

Despite numerous researches[16 27 32 33 91 92 95 133 134] on electrical tetanic or twitch contractions there is still no commonly shared viewpoint on what frequency of electrical stimulation (not intramuscular) is beneficial for muscle blood flow or rehabilitation of muscle injury. Although studies in humans are scarce, the effect of twitch versus tetanic muscle contractions in animals has been studied elaborately. Brechue et al[85] reported a higher flow increase after 50Hz compared with 1 to 4Hz in the dog's hind limb, while Wakim[123] reported highest blood flow values between 8 and 32Hz in dogs. Mohr et al[16] reported that 20Hz was the most efficient stimulation frequency for blood flow increase in rat's hind limb. In contrast, Hawker and Egginton[90] and Folkow and Halicka[125] showed that maximal flow in rat and cat skeletal muscles, respectively, occurred around 1 to 4Hz[11]. The frequency of 2 Hz is chosen for low frequency definition because of 2 reasons:

1. the mean for 1-4 Hz is 2.5 Hz
2. the half Hz is rejected for calibration simplicity

The high frequency definition is chosen for 50 Hz as highest mentioned frequency in the mentioned above review.

In this study, two steps have been taken to standardize strength testing. The lever arm of test device was maintained constant for each subject. The same muscle of each subject was tested before and after the intervention.

3.2 Experimental design

Three groups (N=54) of subjects were treated with use of electrical stimulation and two acupuncture needles.

The study sample

The research protocol was a randomized double-blind design. Subjects were brought into the Buchanan Lab (Aquatic centre) where they were screened and examined thoroughly to ensure that all the inclusion and exclusion criteria had been met and that they were not at any risk by undergoing electrical stimulation with acu-needles.

The study design

Every subject condition was evaluated for the severity of hamstring injury and matched a subject in two other groups. The randomization performed on every small group of subjects multiple of three and matched for age, gender and severity of hamstring injury (time frame). The subjects were then randomly assigned to one of three groups: a control (N=18), Low Frequency (N=18) and High Frequency (N=18) blinded to their specific treatment and group assignment. Eccentric torque (strength) was taken at Pre-Treatment (Day 1) and Post-Treatment conditions (Days 11). Both volunteers and acupuncturist were blinded. Every individual with a hamstring Injury not less than 4 weeks and not more than 6 months prior the trial signed to one of the groups. The subjects were instructed to do the treatment in the morning, afternoon, and evening at relative times throughout the program.

During the treatment, subjects lay on a massage table (Richmond clinic site) with needles inserted within the same muscle tissues, close to but not into the sore spots of the target-muscle (not a trigger points) and wires were securely connected to needles by “alligators”

in order to achieve good contact. After the wires were in place, the thirty minute treatment commenced. The assistant provided the blind control for the acupuncturist by employing the frequency specific to the group and treatment protocol.

The experiment was divided into three stages:

STAGE 1 (baseline/pre-treatment)

Evaluation period

- Height
- Weight
- AMSMC health status index (VAS, functional and mental status)
- Eccentric strength (torque) assessment

STAGE 2 (Treatment x 3 times a week for 30 min, total number of sessions is 10)

-Group 1 (N=18) receives needles with electrical stimulation of 2 Hz

-Group 2 (N=18) receives needles with electrical stimulation of 50 Hz

-Group 3 (N=18) receives needles without electrical stimulation

STAGE 3 (post-treatment evaluation)

Evaluation period (post-exercise)

- Eccentric strength assessment
- Questionnaire on pain, physical, functional and mental status (AMSMC)

3.3 Subjects

The proposed study recruited 54 subjects of 19-54 years old who have experienced a hamstring injury not less than 1 month (4 weeks) and not longer than 6 months before. The subjects were assigned to one of 3 experimental groups (n=18). Every group was

matched with two others in sense of age and condition severity. The subject matching was focused mostly on age and timeframe of the injury

a) All individuals were chosen based on the nature and time frame of the request for the first appointment.
b) Subjects accepted for the study were given a consent form beforehand, which was signed in accordance with the standards of the University of British Columbia Clinical Screening Committee for Research Involving Human Subjects.
c) Exclusion in the study was based on certain criterion that was followed. Those excluded from taking part in this study are subjects:
    i. Who did have a hamstring injury in past 12 month prior the trial or has recently low back pain, sciatica or other conditions which may possibly compromise muscle strength measurements.
    ii. Who experienced muscle strain injury symptoms in less than 1 month or more than 6 months,
    iii. Taking medication such as analgesics, NSAID, muscle relaxants or any other treatment protocol
    iv. ..... Bleeding or autoimmune disorders.
    v..... Unable to compile with treatment

3.4 Procedure

Low Frequency Electrical Intramuscular Stimulation:

The set of two acupuncture needles (invasive device) conducted electrical power to a treatment target on an injured muscle and provided powerful and visible muscle contraction with frequency 2 (Hz) and adjustable micro-current output (mA). The

electrical impulse generator was able to provide frequency range between 2Hz and 50 Hz and electrical output from 5 to 50 mA. The criterion for the electrical intramuscular stimulation was comfort level for each individual (sensory amplitude). The set of two acu-needles provided painless but powerful muscle contraction in the individual comfort zone. Each electrical impulse was a modified waveform called monophasic. The electrical impulse generator (TENS) had an output voltage of 60 mAmp, an LED indicator for power on, and nine volt alkaline battery power source.

Stage 1

Initially subjects were given a brief explanation of the experimental process. The subjects were then evaluated. Height, weight and hamstring eccentric strength were taken, including eccentric muscle strength (torque). The testing occurred before the treatment and after. The height and weight of each subject was also recorded on the muscle strength measuring day. Subjects were requested to give a subjective rating of affected hamstring muscle by filling out the AMSMC health status index. The ratings included visual analog scale (VAS). The VAS consisted of three parts regarding influence of pain on daily living, physical activity and sleep deprivation. Each part is a 5 cm long line with marked endings indicating absence of complains at one end and extreme presence at the other end. In order to quantify and objectively measure pain, subjects are asked to place a mark along this line with respect to their level of discomfort at the time of measurement (APPENDIX B).

Stage 2

Upon completion of measurement the subjects were scheduled for the treatment

appointments. The procedure was explained previously.

A subject lies on an examination table face down and needles were inserted - one in osseous spinosus of L5 and the other one in the affected hamstring muscle (not necessary the most painful spot) and the treatment modality was applied regarding the protocol X 3 times a week, 30 min for each session and 10 sessions in total.

Stage 3

The subjects were measured for muscle strength (eccentric torque, Nm) of the affected leg (Hamstring). The researcher set the lever arm length to line up the rotational axis point of the machine with the lateral malleolus. A special attention was applied to the length of the arm lever of the Biodex to make sure that the same length of arm lever was used in post-treatment measurement. Subjects were requested to give a subjective rating of muscle pain in their treated hamstring muscle together with mental and functional status in pre- and post-treatment time.

3.5 Statistical Analysis

One-way ANOVA with Tukey's HSD post hoc comparison

Dependent variables: AMSMC and muscle strength test, where each DV has 2 levels before and after the intervention (10 sessions)

Independent variables: frequency with three levels (2 Hz, 50 Hz and 0 Hz)

Diagrammatic representation of study design:

SAMPLE	AMSMC		Muscle strength	
	Before	After	Before	After
Low frequency (2 Hz) group (n=18)	X	X	X	X
High frequency (50 Hz) group (n=18)	X	X	X	X
Control (0 Hz) group (n=18)	X	X	X	X

3.6 Statistical Power

Power for the study (0.76) was based on calculations of Cohen's Dc (delta/s(1-r)$^{1/2}$). Calculations were based on an alpha level set at 0.05, a 20% expected change, correlations of 0.6 and a standard deviation of 33% for the individual variables. These values were determined from previous literature on transcutaneous stimulation with different parameters[26 27 92 94 96 104] and assumptions were based on clinical significance.

CHAPTER 4 --- RESULTS

Three equal groups of subjects (36 males, 18 females) with sub acute and chronic hamstring injuries (time frame is 1≥6 months) were tested under three different treatment modalities. Group 1(N=18) was stimulated with 2 Hz frequency electrical intramuscular stimulation; group 2 (N=18) was influenced with 50 Hz (N=18) frequency electrical intramuscular stimulation and group 3 did not receive any electrical stimulation. The subjects were normally distributed in pre-treatment condition regarding an age, gender and scores in muscle strength and AMSMC Health Status Index.

Table 4.1:

Case Processing Summary

			Cases					
			Valid		Missing		Total	
gender		group	N	Percent	N	Percent	N	Percent
male	gender	2 Hz	12	100.0%	0	.0%	12	100.0%
		50 Hz	12	100.0%	0	.0%	12	100.0%
		0 Hz	12	100.0%	0	.0%	12	100.0%
female	gender	2 Hz	6	100.0%	0	.0%	6	100.0%
		50 Hz	6	100.0%	0	.0%	6	100.0%
		0 Hz	6	100.0%	0	.0%	6	100.0%

Table 4.2:

Descriptive Statistics

		N	Mean	Std.	Variance	Skewness		Kurtosis	
frequency		Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
2 Hz	StrengthBefore	18	131.144	9.4559	89.413	1.088	.536	1.961	1.038
	AMSMCBefore	18	66.56	11.917	142.026	-.060	.536	-.955	1.038
	Valid N (listwise)	18							
50 Hz	StrengthBefore	18	130.028	9.5629	91.449	-1.374	.536	3.454	1.038
	AMSMCBefore	18	69.22	11.306	127.830	-.415	.536	-1.239	1.038
	Valid N (listwise)	18							
0 Hz	StrengthBefore	18	133.572	12.0050	144.120	.753	.536	.354	1.038
	AMSMCBefore	18	69.11	11.303	127.752	-1.471	.536	1.715	1.038
	Valid N (listwise)	18							

The violation of normality (Kolmogorov-Smirrnov) was observed in AMSMC scores of 0 Hz group, but normal distribution of scores in box-plot (Fig. 1 & 2), skewness values (Table 3) between -0.6 and 0.6 and Rule of Thumb suggests that the assumption of

normality has not been violated and therefore has continued.

Note: The Rule of Thumb suggest that **equal variances could be assumed** if no one variance is more than 3-4 times larger than any other variance.

Table 4.3

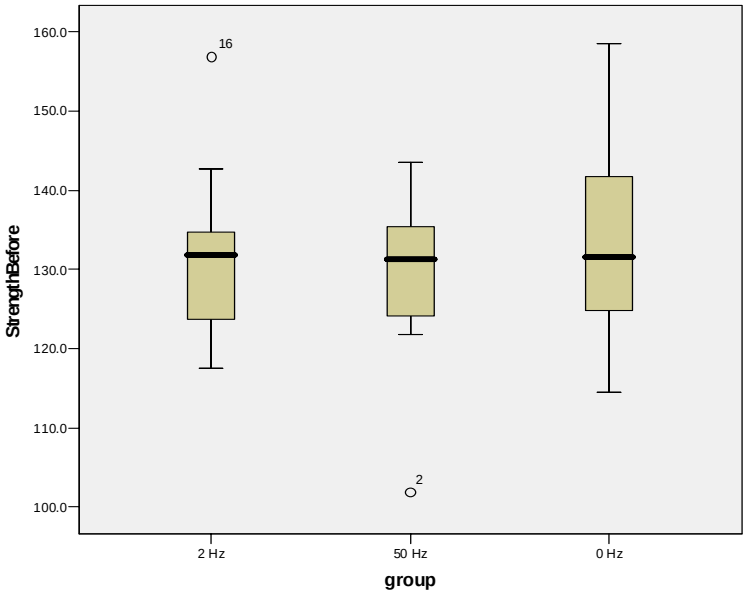
Tests of Normality

		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	frequency	Statistic	df	Sig.	Statistic	df	Sig.
StrengthBefore	2 Hz	.128	18	.200*	.925	18	.161
	50 Hz	.139	18	.200*	.895	18	.048
	0 Hz	.149	18	.200*	.940	18	.293
AMSMCBefore	2 Hz	.124	18	.200*	.959	18	.575
	50 Hz	.140	18	.200*	.922	18	.141
	0 Hz	.246	18	.005	.835	18	.005

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

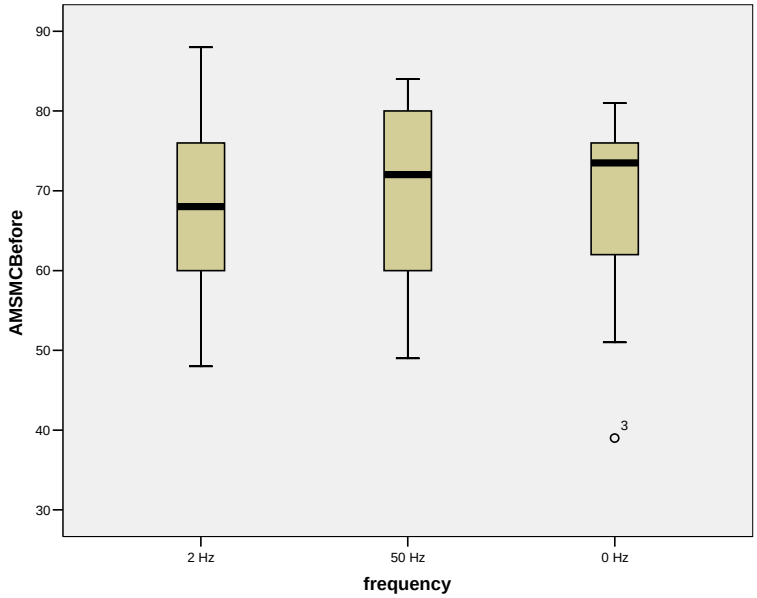
Figure 4.1: Boxplots for muscle strength (Nm) data before intervention:



The Boxplots shows one outlier in groups 2 Hz and 50 Hz each and no extreme values in 0 Hz group. Histograms show that the scores are reasonably normally distributed.

Figure 4.2

Boxplots for AMSMC HEALTH STATUS INDEX data before intervention



The Boxplots shows one outlier in group 0 Hz each and no extreme values in 2 and 50 Hz groups. Histograms show that the scores are reasonably normally distributed.

Table 4.4

Test of Homogeneity of Variances

	Levene Statistic	df1	df2	Sig.
StrengthBefore	.654	2	51	.524
AMSMCBefore	.273	2	51	.762

The Sig .52 and .76 suggest that homogeneity for *StrengthBefore* and *AMSMCBefore* is not violated and one way ANOVA's test was conducted.

Table 4.5 One –way ANOVA test on AMSMC and eccentric muscle strength (Nm) between and within groups before and after intervention

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
StrengthBefore	Between Groups	118.225	2	59.112	.546	.583
	Within Groups	5524.697	51	108.327		
	Total	5642.921	53			
AMSMCBefore	Between Groups	81.926	2	40.963	.309	.735
	Within Groups	6759.333	51	132.536		
	Total	6841.259	53			
StrenghtAfter	Between Groups	209.929	2	104.965	.876	.423
	Within Groups	6109.812	51	119.800		
	Total	6319.741	53			
AMSMCAfter	Between Groups	5424.333	2	2712.167	22.407	.000
	Within Groups	6173.167	51	121.042		
	Total	11597.500	53			

One way ANOVA was conducted on eccentric muscle strength and AMSMC under influence of three treatment modalities such as electrical intramuscular stimulation with the frequency 2 Hz (N=18, μ=131.14, Std= 9.46), 50 Hz (N=18, μ= 130.03, Std= 9.56) and control group (0 Hz) (N=18, μ= 133.57, Std= 12) for *Strength Before* (Nm) and *AMSMCBefore* scores 2 Hz (N=18, μ=66.56, Std= 11.92), 50 Hz (N=18, μ= 69.22, Std= 11.31) and control group (0 Hz) (N=18, μ= 69.11, Std= 11.3).

ANOVA test revealed statistically significant difference after intervention in AMSMC score only F (2,5) = 22.41, Sig=.00 and Part Eta^2 = 0.47 (large effect size) were α =.05 (Table 6).

Note: Part Eta^2 was calculated from sum of squares between/total sum of squares =

= 5424.333/ 11597.500=0.47

The One-Way ANOVA revealed that there is statistically significant difference between groups but doesn't tell where the difference is. Post hoc multiple comparisons was made to explore the difference between groups.

Table 4.6: Post hoc Tukey's HSD

Multiple Comparisons

Tukey HSD

Dependent Variable	(I) frequency	(J) frequency	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
StrengthBefore	2 Hz	50 Hz	1.1167	3.4693	.945	-7.258	9.492
		0 Hz	-2.4278	3.4693	.765	-10.803	5.947
	50 Hz	2 Hz	-1.1167	3.4693	.945	-9.492	7.258
		0 Hz	-3.5444	3.4693	.567	-11.919	4.830
	0 Hz	2 Hz	2.4278	3.4693	.765	-5.947	10.803
		50 Hz	3.5444	3.4693	.567	-4.830	11.919
AMSMCBefore	2 Hz	50 Hz	-2.667	3.837	.768	-11.93	6.60
		0 Hz	-2.556	3.837	.784	-11.82	6.71
	50 Hz	2 Hz	2.667	3.837	.768	-6.60	11.93
		0 Hz	.111	3.837	1.000	-9.15	9.37
	0 Hz	2 Hz	2.556	3.837	.784	-6.71	11.82
		50 Hz	-.111	3.837	1.000	-9.37	9.15
StrenghtAfter	2 Hz	50 Hz	3.9167	3.6484	.535	-4.891	12.724
		0 Hz	4.4056	3.6484	.454	-4.402	13.213
	50 Hz	2 Hz	-3.9167	3.6484	.535	-12.724	4.891
		0 Hz	.4889	3.6484	.990	-8.318	9.296
	0 Hz	2 Hz	-4.4056	3.6484	.454	-13.213	4.402
		50 Hz	-.4889	3.6484	.990	-9.296	8.318
AMSMCAfter	2 Hz	50 Hz	22.667*	3.667	.000	13.81	31.52
		0 Hz	19.500*	3.667	.000	10.65	28.35
	50 Hz	2 Hz	-22.667*	3.667	.000	-31.52	-13.81
		0 Hz	-3.167	3.667	.666	-12.02	5.69
	0 Hz	2 Hz	-19.500*	3.667	.000	-28.35	-10.65
		50 Hz	3.167	3.667	.666	-5.69	12.02

*. The mean difference is significant at the .05 level.

The result of Tukey's HSD (table 7) is:

1) *AMSMCAfter* scores in group 1(2 Hz) (μ= 92.89, Std= 6.25) are significantly different than results of group 2 (50 Hz) (μ= 70.22, Std= 12.27) or results of group 3 (0 Hz) (μ= 73.39, Std= 13.18) and there is no statistically significant difference between groups 2 (50 Hz) and group 3 (0 Hz). Graphic representation of means as bars shown in Table 10.

Figure 4.3: Graphic presentation of AMSMC scores after intervention

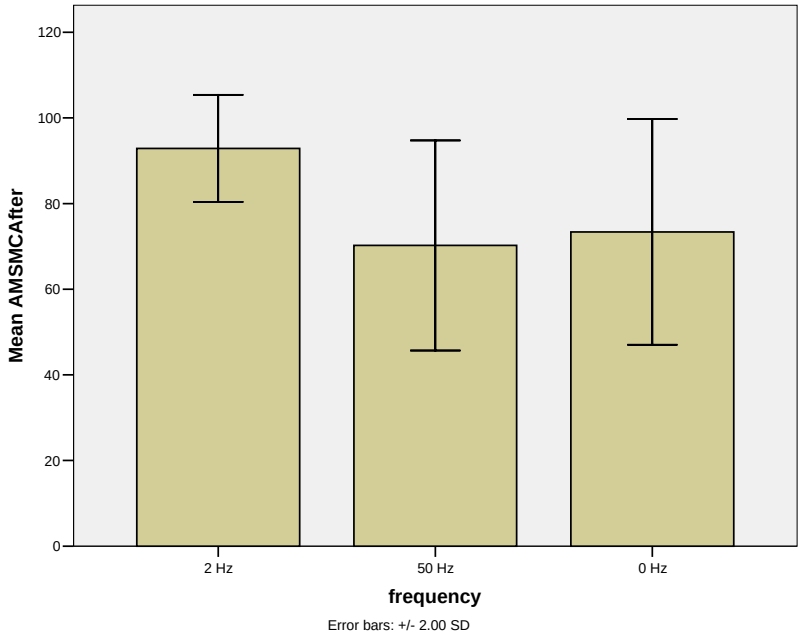


Table 4.7: Paired samples T-test on physical function, physical activity, mental behavior and pain in AMSMCBefore and after 2 Hz electrical stimulation

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PhysFunctionBefore	25.22	18	3.574	.842
	PhysFunctionAfter	29.06	18	1.434	.338
Pair 2	PhysAcitvityBefore	14.33	18	6.791	1.601
	PhysActivityAfter	27.00	18	2.910	.686
Pair 3	MentalBehavBefore	18.61	18	3.013	.710
	MentalBehavAfter	23.67	18	1.414	.333
Pair 4	PainBefore	8.39	18	1.975	.465
	PainAfter	13.17	18	2.383	.562

Table 4.8: Paired samples T-test for AMSMC HEALTH STATUS INDEX

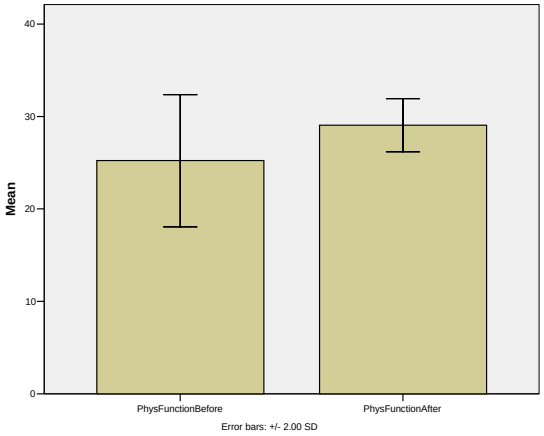
Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	PhysFunctionBefore - PhysFunctionAfter	-3.833	2.956	.697	-5.303	-2.364	-5.503	17	.000
Pair 2	PhysAcitvityBefore - PhysActivityAfter	-12.667	6.553	1.545	-15.925	-9.408	-8.201	17	.000
Pair 3	MentalBehavBefore - MentalBehavAfter	-5.056	2.817	.664	-6.457	-3.654	-7.613	17	.000
Pair 4	PainBefore - PainAfter	-4.778	2.922	.689	-6.231	-3.325	-6.938	17	.000

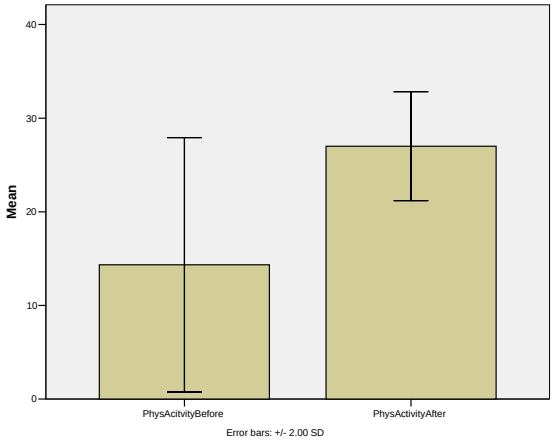
The conducted T-test on paired samples before and after intervention revealed statistically significant paired difference for all four pairs with largest mean difference in pair 2-PhysicalActivity.

Figure 4.4 Graphic presentations of paired samples T-test on physical function, physical activity, mental behavior and pain in AMSMCBefore and after 2 Hz electrical stimulation.

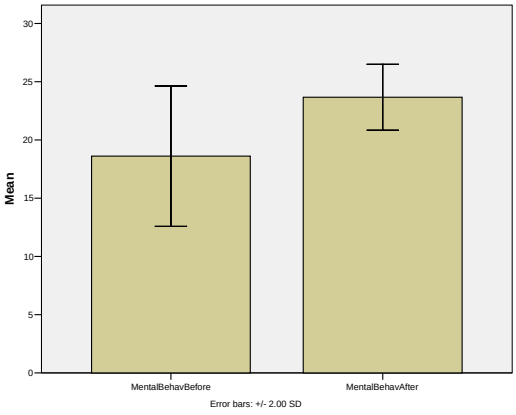
a) Physical function



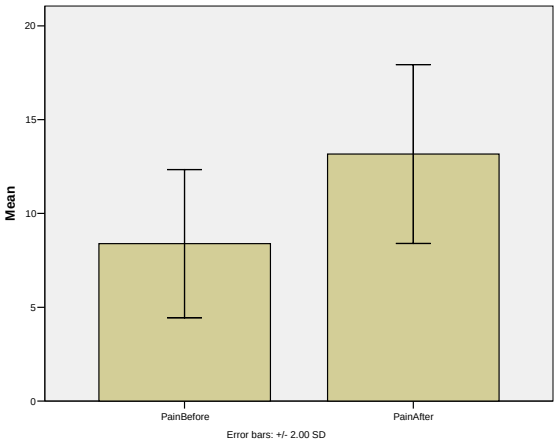
b) Physical activity



c) Mental behavior



d) Pain



CHAPTER 5 – DISCUSSION

This study demonstrated superior AMSMC score results using 2 Hz electrical intramuscular stimulation for the treatment of chronic hamstring strain versus 50 Hz electrical stimulation and needling without electrical stimulation. The subjects in the 2 Hz electrical intramuscular stimulation group reported improvement in physical function, activity level, emotional/mental behavior and pain level in daily living, during and after activity or sport and sleep disruption because of pain. The improvements had a cumulative effect and became more obvious toward the last treatment. The AMSMC scores for 50 Hz and control group were also superior after intervention but were not statistically significant.

This study supports the author's theory that low frequency (2 Hz) is more effective compared to higher frequency (50 Hz) and the control group. The frequency choice was based on a literature review of previous studies with attention to blood circulation factors. The stimulation was applied to the affected (unilateral) hamstring (biceps, semimebranosus or semitendinosus) above or below tenderness area and the duration was the most commonly recommended (30 minutes).

The patients have been told that the main goal of the study was the intensity of stimulation not the frequency. The author was blinded the particular frequency used on each patient.

The mechanism of the long-term effect of PENS was not clearly explained in previous studies due to lack of randomization and defined treatment parameters. It has been shown that acupuncture needles placed in non acupuncture points lead to pain reduction because of stimulation of endorphin release via a mechanism called diffuse

noxious inhibitory control[135]. One significant consequence of electroacupuncture is the release of endogenous opioids such as β-endorphin, which generally produces analgesia for up to two hours [24]. Therefore, the short-term analgesic effects of PENS on chronic pain are known, but the explanation for any long term effect is difficult. The circulatory disturbances and intramuscular pressure may be one of possible reasons.

The primary reason why electrical stimulation remains a controversial treatment is the lack of defined treatment parameters. For example, the main complaint in a low back pain is difficulty to erect the spine. The major muscles responsible for this function are the back erectors. Therefore trials comparing PENS and TENS in patients with low back pain have to target the back erectors as a major pain source. Ghoname[27] and Yokoyama[92] used the identical treatment protocol but did not provide information on needled tissues. Both studies reported that PENS was more effective than TENS, but failed to provide a reason. The major factors influence the response to PENS are location[134], frequency[33], and duration[133] of electrical stimulation. A clearly defined treatment location will enable other treatments' providers to make a frequency choice based on tissue involved (e.g. nerve or skeletal muscle).

The most important treatment parameter to differentiate between analgesia and treatment is blood flow and frequency of stimulation. Violation of the laws of muscle physiology during electrical stimulation may lead to damage of muscle tissues. Studies by Ghoname[27] and Yokoyama[92] applied electrical stimulation at 4 Hz. The upper limit of frequency sufficient for blood flow detected by Folkow and Halicka[125] was also 4 Hz. They reported that the oxygen delivery was barely sufficient to cover the aerobic demands at the rates of contractions as low as 4–5 Hz. A frequency of 2 Hz frequency

provides a sufficient ratio of muscle contraction and relaxation whereas frequencies above 4 Hz lead more toward tetanic contraction and reduce muscle blood flow. Stimulation below 2 Hz will increase the relaxation time and diminish muscle contraction. Tetanic contraction wasn't a goal of this study, but tetani may increase the efficiency of electrical intramuscular stimulation if the contraction time and relaxation time are within a certain ratio. The duration and frequency of tetanic "train impulses" should not exceed the demand for blood supply during contraction or the ability to supply blood flow during relaxation.

The effect of the low frequency electrical stimulation can be explained from the muscle relaxation/contraction pressure point of view. The increase in muscle relaxation pressure interferes with blood flow during exercise and inversely related to exercise tolerance.

The mechanism for increased relaxation pressure in the repetitive strain injured muscle is not well documented. It is a theory that 2 Hz intramuscular stimulation lowers the muscle relaxation pressure.

One explanation for increased muscle relaxation pressure is that a ruptured myofibril adheres to neighboring myofibrils shortly after the artificially induced muscle injury[29]. The adhesion prevents the gap between the stumps of ruptured myofibrils from widening during a muscle contraction. Repetitive muscle strain injury may produce enough adhesions to increase muscle relaxation pressure. Low frequency electrical stimulation may disrupt the bond between myofibrils and restores normal muscle relaxation pressure.

However, the "adhesion" theory may explain muscle stiffness in repetitive muscle injuries but can not explain pain increase during physical activity in same subject. A

combination of intramuscular edema and adhesion formation may be provide the complete picture. This combination suggests that the degree of edema and adhesion formation may vary depending on the stage of injury. For example, during chronic repetive muscle strain injury adhesion formation may be more prominent than edema and both will interfere microcirculation during exercise.

Another interesting observation of the study was the muscle strength data. Group 1 (2Hz), which dramatically improved in AMSMC score, demonstrated no statistically significant changes in muscle strength after intervention. This could be explained from a neurological standpoint described below.

Kaariainen et al[92] and Jarvinen et al[29] examined lateral adhesion of myofibers to the extracellular matrix during the healing of muscle subjected to shear forces. Adhesion formation in repetitive type of muscle injury may be the reason for muscle stiffness, reduced muscle elasticity, and reduced muscle strength. It is reasonable to assume that restoration of muscle strength in the healing process is the final stage of recovery, whereas pain improvement is just the beginning of recovery. The post-treatment muscle strength tests were performed 1-3 days after the last treatment. This short interval may not have allowed enough time for strength to return. It is also possible that the lower motor neuron did not have enough time to recover completely to get the conductivity back. Jarvinen et al[29] reported that regeneration of intramuscular nerves follows the regeneration and revascularization of the myofibers. Therefore, even though the muscle tissue has recovered, strong contraction will not occur without a recovered neurological pathway. The elimination of chronic pain and its origins may provide an environment for a complete recovery and restoration of muscle strength.

CHAPTER6 - SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

Summary

The treatment parameters for electrical intramuscular stimulation remain controversial. The variety of studies that have been published, differ in results as to whether this form of therapy proves to be effective in treating sport and exercise-related injuries. The PENS is a subject of more controversy since such factors as depth of needling and muscle recognition are often ignored. The purpose of this study was to determine whether intramuscular electrical stimulation of a particular frequency for a particular muscle will provide different results in improvement in AMSMC and muscle strength testing test (Biodex) in the recovery from a sub-acute and chronic muscle injury. The subjects (n=54) were randomly assigned to one of three groups (2 Hz, 50 Hz electrical stimulation and control group). The subjects performed an eccentric muscle strength test (Nm) and filled out the AMSMC questionnaire (pain, mental, physical and functional status) before and after the intervention.

Statistically significant difference ($p<0.05$) in the AMSMC scores was observed between those treated with 2 Hz electrical intramuscular stimulation and those that received 50 Hz electrical stimulation and the control group (no electrical stimulation).

Conclusions

From a review and analysis of pain, mental and functional status (AMSMC HEALTH STATUS INDEX) scores and the results of muscle strength test (Biodex) obtained before and after an intervention, it appears that AMSMC scores were statistically different in

physical activity (*before* μ = 14.33, *after* μ =27), physical function (*before* μ = 25.22, *after* μ =29.06), mental behavior (*before* μ = 18.61, *after* μ =23.67) and pain (*before* μ = 8.39, *after* μ =13.17) with large effect size (Part Eta² = 0.47) in group 1 (2 Hz) compared to group 2 (50 Hz) and control group (0 Hz) after intervention. The pain scores were measured on reversed scale thus the upper number 5 is associated with no pain at all during daily living, physical activity or sleeping time.

The AMSMC scores for 50 Hz (pre-test = 69.22, post-test μ= 70.22) and control group (pre-test μ= 69.11, post-test μ= 73.39) were higher after intervention but not statistically significant. The intervention treatment did not have any effect on the muscle strength test.

Recommendations for future studies

The present study supports the efficacy of using 2 Hz electrical intramuscular stimulation in sub-acute and chronic muscle strain injuries. However, a more focused study on a blood flow and intramuscular pressure in injured muscles may shed light on the mechanism of this effect. The cost of doing the recent study was quite inexpensive and therefore, more deep and extended study is recommended to explore the role and reasons of change in blood flow and muscle relaxation pressure which is believed to be a reason for transforming acute and sub-acute injuries into chronic ones.

Future studies should:

1. Focus on certain important variables such as intramuscular pressure, intramuscular muscle relaxation, and blood microcirculation right after the intervention with changes detected by pain, mental and functional status, and muscle strength test (Biodex) and MRI or infrared spectroscopy over longer time periods. These variables do not carry the subjective component and will provide high quality data. Muscle strength test is one that

has the potential for errors. A change in lever arm length may produce a measurement error in results before and after intervention.

2. Caution should be applied when interpreting muscle strength tests. The data should be analyzed and correlated with the time frame of the existing injury, tests and the time frame after the intervention

3. Three months follow-up study is recommended to discover if muscle strength test scores eventually will go up and if the AMSMC scores after intervention will remain same for extended period of time (1-2 months) and if the treatment have be repeated later in time i.e. in 1or 2 months.

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Appendix A:

SUBJECT AND CONTROL INFORMATION AND CONSENT FORM

THE EFFECT OF ELECTRICAL INTRAMUSCULAR STIMULATION ON SUB ACUTE AND CHRONIC HAMSTRING MUSCLE STRAIN INJURIES

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1. INTRODUCTION-"The invitation to participate"

The research is focused on muscle strain injuries. A hamstring injury is one of most frequent injury among sport athletes.

You are being invited to take part in this research study because you are male/female found to found to be suffering a Hamstring Injury with the same age and activity level as another participant suffering from a hamstring injury.

2. YOUR PARTICIPATION IS VOLUNTARY

Involvement in this research study is entirely up to you, so it is up to you to decide whether or not to participate. Before you decide, you must understand what this study involves. This consent form will explain to you why the research is of importance, what procedures will be carried out during the study, and possible benefits, risks, and discomforts.

If you decide to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any point and without giving any reason to your decision.

If you do not wish to participate, you do not have to provide any reasoning for your decision, nor will you lose the benefit of any medical care to which you are entitled or are presently receiving.

Please take time to read over the following information carefully and discuss it with your family, friends, and doctor before you decide.

3. WHO IS CONDUCTING THE STUDY?

The study is being conducted by Primary Care Physician, Acupuncturist and Physiotherapist at Allan McGavin Sports Medicine Clinic and Muscle & Tendon Strain Injury Clinic.

4. BACKGROUND

Hamstring Injury is a condition currently accounting for 41% of all lower extremity injuries in sport active population, and studies are showing a trend of increasing prevalence.

This irritation and subsequent pain in the hamstring muscles area is associated with overuse and repetition of the injury. However, the incidence of injury is also related to not efficient enough treatment of previous injury. Therefore an effective treatment option will not only treat a recent injury but help to prevent the reoccurrence of other injuries.

Typical treatment of Hamstring Injuries involves rest, ice, compression, physiotherapy treatment and a gradual introduction to an eccentric strengthening program of the hamstring muscles. The treatment focuses on the injured area alone, and not on the associated factors or biomechanical deficits related to the injury. Without an early diagnosis, and effective treatment, clinical resolution of Hamstring Injuries may well be longer than three months. More chronic Hamstring Injury cases may require an intense rehabilitation program of up to six months.

The best way to treat Hamstring Injuries remains unclear.

5. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to aid rehabilitation professionals to establish a more effective therapy option, which will be able to focus not only on the Hamstring Injury, but any muscle strain injury related to work, sport or accident. The particular study is designed to collect data and observe possible difference between three treatment groups. One of the main hypotheses is that the role of inflammation in sub-acute and

chronic muscle strain injuries may not be as significant as is generally accepted.

Group 1 is group of subjects under low frequency electrical intramuscular stimulation**.**

Group 2 is group with subjects under high frequency electrical intramuscular stimulation.

Group 3 is group with subjects under sub sensory electrical intramuscular stimulation.

6. WHO CAN PARTICIPATE IN THIS STUDY?

You are invited to participate as a subject in this study if you are a person, found to be suffering from Hamstring Injury not less than 3 weeks ago and not more than 6 months ago. If Injury occurred previously, this must have been at least one year ago. Age of participant: 19 – 54 years old.

7. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

Hamstring Injury patients who

- experienced muscle strain injury symptoms in less than 1 month or more than 6 months,
- taking medication such as analgesics, NSAID, muscle relaxants during the trial
- have bleeding or autoimmune disorders

Subjects who have had previous Hamstring Injury /surgeries/pain should not participate in this study.

In addition, you should not participate in this study if you cannot, for any reason, have an acupuncture needle inserted into your affected leg.

8. WHAT DOES THE STUDY INVOLVE?

Location: This study is taking place at Allan McGavin Sports Medicine Clinic University of British Columbia, in Vancouver, Canada. It is anticipated that 54 subjects will be enrolled in the study with electrical intramuscular stimulation treatment. Subjects will form 3 groups with 18 individuals in each group.

Prior to the study: On your first visit to the Sports Medicine Centre a medical history (time frame of symptoms) and a physical examination will be collected. There are no blood tests during this exam. You will be asked to complete a questionnaire and to evaluate your pain level in the beginning and end of the trial. You will be randomly assigned (“like a flip of a coin”) to one of the three treatment groups. This means you

have equal chance to be placed in any of the treatment groups.

EXPERIMENTAL PROCEDURE:

If You Decide to Join This Study: Specific Procedures

If you agree to take part in this study, the procedures and visits you can expect will include the following:

Before any procedure is carried out, the researcher will measure your muscle strength of hamstring muscle with an instrument for measuring the degree of muscular power called dynamometer and will record both your age and an estimate of your activity level.

Three groups (n=18) subjects treated with use of electrical stimulation with 3 different frequency mode and two acupuncture needles.

During the electrical intramuscular stimulation treatment, subjects lay on a massage table. Needles are inserted in strategically chosen spots of the target-muscle (**not a trigger points**) and wires are securely connected to needles by "alligators" in order to achieve good contact. After the wires are in place the thirty minute treatment commences. If the pain source is localized in a single muscle only the treatment may be shorter, because the single muscle injury requires 5-7 minutes of treatment per session. The acupuncturist will be blinded on electrical frequency choice. The assistant will choose what frequency to employ regarding the belonging to the group and treatment protocol.

All groups are subjectively tested for pain and muscle strength with BioDex dynamometer before the first session and in the end of the study.

OVERALL DURATION OF THE STUDY

All subjects will be seen at the Muscle & Tendon Strain Injury Clinic 3 times every week for 10 session total. Every visit will take 30 min. In these visits you will be asked to fill out a discomfort questionnaire and the Primary Care Physician will do a history and examine your affected muscle. Visits will take approximately total 600 min of your time in the study

9. WHAT ARE MY RESPONSIBILITES?

In order to participate, you must let the investigators know all treatment recommendations given to you to treat your Hamstring Injury, and any exercises or therapies carried out to treat your injury.

You should follow recommendations of trial practitioner regarding the sport activity level and stop using any pain killers, muscle relaxants or anti inflammatory medication

10. WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

Side effects of electrical intramuscular stimulation may include, but are not limited to:

- A bruise from inserting a needle into a blood vessel. Usually it is temporary cosmetic damage only because applied finger pressure for a few minutes is sufficient to stop bleeding.

- Muscle soreness on the next day after the first session of Electrical Intramuscular Stimulation. The muscle soreness is similar to sensations of DOMS (Delayed Onset of Muscle Soreness) and usually disappears in 24-48 hours.

- A recipient may faint if the fear of needles is severe. Proper recipient screening will help to recruit right volunteers. If faintness occurs, a lying position with the legs elevated will solve the problem.

- A needle inserted into a nerve may cause a pain. The needle will be removed immediately if it occurs. No treatment is required because some techniques even recommend this for quicker improvement.

There is also a small risk of infection (needles are single use only) and may be feeling of lightheadedness for up to 5-15 min.

11. WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Personal Benefit: No one can guarantee that you will benefit from this study. The study will test 3 types of treatment and their effectiveness. At the end of the study we will provide the most effective treatment method free of charge to the volunteers who have participated in the study. We hope that the information regarding possible associations and/or causes of this injury learned from this study can be used in the future to benefit other people with a similar injury. If you wish, we can provide you with the results from this study after it are completed.

Societal Benefit: A long-term benefit arising from this study is that it may provide a treatment option for any muscle strain injury. This may in turn lead to an improvement in rehabilitation techniques through the establishment of a more appropriate and effective therapy treatment plan.

12. WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?

The trial involves improvement of hamstring muscles strength, and does qualify as a 'treatment'.

. You can discuss you options with your doctor before deciding whether or not to participate in this research project.

13. WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?

If new information arises during the study that may affect your willingness to remain in the study, you will be advised of it. Such a situation would arise if risks were identified in relation to your participation in this study.

13. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You may stop participating in the study at any time. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

The study investigators may decide to discontinue the study at any time, or withdraw you from the study at any time, if they feel that it is in your best interests.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis. By law, this data cannot be destroyed.

15. WHAT HAPPENS IF SOMETHING GOES WRONG?

You do not waive any of your legal rights by signing this consent form.

16. CAN I BE ASKED TO LEAVE THE STUDY?

If you are not complying with the requirements of the study or for any other reason, the study investigator may withdraw you from the study. On receiving new information about the treatment, your research investigator might consider it to be in your best interests to withdraw you from the study without your consent if they judge that it would be better for your health.

17. AFTER THE STUDY IS FINISHED

Study results are likely to be available in September 2007. If desired, you can be informed of them by contacting an investigator.

18. WHAT WILL THE STUDY COST ME?

You will not incur any personal expenses as a result of participation, nor will you receive payment for participation.

19. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records identifying you may be inspected in the presence of the investigator or his or her designate, and the UBC Research Ethics Board for the purpose of monitoring the research. However, no records that identify you by name or initials will be allowed to leave the Investigators' offices.

20. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions or desire further information about this study before or during participation, you can contact Dr. Jack Taunton at (604) 822-3614 or Dr. Nikolay Yelizarov at (604) 818-3462.

21. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT DURING THE STUDY?

If you have any concerns about your rights as a research subject an/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services at 604-822-8598.

22. SUBJECT CONSENT TO PARTICIPATE

1 I have read and understood the subject information and consent form.

2 I have had the opportunity to ask questions and have had satisfactory responses to any my questions.

3 I have had sufficient time to consider the information provided and to ask for advice if necessary.

4 I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objectives.

5 I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.

6 I understand that I am not waiving any of my legal rights as a result of signing this consent form.

7 I understand that there is no guarantee that this study will provide any benefits to me.

8 I have read this form and I freely consent to participate in this study.

9 I have been told that I will receive a dated and signed copy of this form.

SIGNATURES

Printed name of subject	Signature	Date
_____	_____	_____
_____	_____	_____
Printed name of Witness	Signature	Date
_____	_____	_____
Principal Investigator or Designate	Signature	Date
_____	_____	_____

Appendix B: AMSMC HEALTH STATUS INDEX (Questionnaire)

Name_____ Date_____

THE A.M.S.M.C. HEALTH STATUS INDEX

Physical Function

1. The following question lists activities you might do during a typical day. **Does your injury limit you** in these activities? (*Please mark a (✓) in the appropriate column)*

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) Strenuous activity (i.e. moving furniture, lifting heavy objects)	____	____	____
b) Moderate activity (i.e. raking leaves, household cleaning)	____	____	____
c) Lifting or carrying groceries	____	____	____
d) Dressing yourself	____	____	____
e) Bathing and self-care	____	____	____
f) Sexual function	____	____	____
g) Climbing/descending stairs	____	____	____
h) Walking 2 km	____	____	____
i) Walking one block	____	____	____
j) Crouching or kneeling	____	____	____

/30

Activity/Role Physical

2. How has your injury affected your ability to perform duties at your workplace? (*Please mark a (✓) in the appropriate column)* If you are **retired**, tick 'My work is unaffected'.

Not able to work	Restricted duties	Same duties, they just take longer	My work is unaffected
_____	_____	_____	_____

3. This question will assess how your injury is affecting your ability to participate in sport or physical activity. If you enjoy your main sport/activity on a recreational (non-competitive) level please **complete 3a only.**
If you do compete in your main sport/activity, please **complete 3b only and indicate your competitive level here:**
Provincial ___ National ___ International ___ Professional ___

3a.	Not able to participate	Reduced volume or hours of activity	Same volume as before, w/ less intensity	Full participation
	_____	_____	_____	_____

3b.	I can't compete	Participate in less events/season	Same # of events/season but compete @ lower intensity	Full competition
	_____	_____	_____	_____

4. Have you stopped participating in your main activity completely? Have you changed your main activity to compensate for your present injury (i.e. "I have given up running and have taken up cycling instead to avoid my running related pain.")? If the answer to either of these questions is 'yes', tick yes. Otherwise, mark 'no'.

Yes _____
No _____

/30

Emotional/Mental Behavior

5. This question is to help us understand how your injury has affected you on an emotional/mental level. Over the last **4 weeks** how much time...*(Please mark a (✓) in the appropriate column)*

	All the Time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt lethargic and without energy?	____	____	____	____	____
b) Did you feel sad or depressed by your inability to fully participate in sport/ activity and/or work?	____	____	____	____	____
c) Have you felt that your self-image is lower?	____	____	____	____	____
d) Have you felt irritable or had mood swings?	____	____	____	____	____
e) Have you been unhappy or in a bad mood?	____	____	____	____	____

/25

Pain

6. *Please mark a (X) on the scale that corresponds to your level of pain, from 'no pain' to 'severe pain'.*

a) How would you rate your level of pain during daily living?

No pain |——————| Strong, Severe pain

b) How would you rate your level of pain during and after activity or sport?

No pain |——————| Strong, Severe pain

c) How would you rate your level of sleep disruption due to pain?

No pain |——————| Very Difficult to sleep, constant pain

/15

Total Score /100