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THE EFFECTS OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) USING DIFFERENT PARAMETERS AND SITE PLACEMENTS ON PERCEPTION OF PAIN IN CHRONIC LOW BACK PAIN PATIENTS

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THE EFFECTS OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) USING DIFFERENT PARAMETERS AND SITE PLACEMENTS ON PERCEPTION OF PAIN IN CHRONIC LOW BACK PAIN PATIENTS

by

KARA CHIDESTER

Presented to the Faculty of the Honors College of

The University of Texas at Arlington in Partial Fulfillment

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Thank you all for helping me achieve my academic goals in life including this project!

April 17, 2022

ABSTRACT

THE EFFECTS OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) USING DIFFERENT PARAMETERS AND SITE PLACEMENTS ON PERCEPTION OF PAIN IN CHRONIC LOW BACK PAIN PATIENTS

Kara Chidester, BSN

The University of Texas at Arlington, 2022

Faculty Mentor: Cynthia Trowbridge

A study was conducted using 10 participants and the effects of using a transcutaneous electrical nerve stimulation (TENS) unit to treat chronic lower back pain. Participants were required to have lower back pain for more than three months out of the year and the pain to be non-specific (could not be clinically diagnosed by a healthcare provider). The study focused on comparing the analgesic effects of applying TENS pads directly to the area of concern (Lower back/Gate-control) verses placing them on a kidney meridian point (Kidney meridian/Endogenous). To test this, participants were pseudo-randomly placed into one of two categories: the Lower back/Gate-control (LBGC) or Kidney meridian/Endogenous opiate (KMEO) and given different parameters to set their TENS unit.

During the first and last week of the study, participants filled out a PROMIS-29 v1.0 and Global Rate of Change Scale to measure patients' subjective data. This data was collected and analyzed at the end of the third week. Both groups demonstrated some overall improvement with a reduction in pain, improvement of physical function, decrease in fatigue, and less pain interference; however, only the meridian group demonstrated a statistically significant decrease in pain intensity and fatigue. This suggested that placing the TENS pads on a meridian location and using an endogenous opiate setting rather than placing pads directly on the site of pain with a gate control setting, has a larger reduction in pain intensity and fatigue indicating a decreased perception in pain.

Previous research by Chesterton and colleagues (2002; 2003) demonstrated that pad placement and TENS parameters matter. When placing the pads on the meridian and stimulating the body's natural endogenous opiate mechanism, longer lasting pain relief was experienced. The results of our study supported the findings in Chesterton (2002; 2003) indicating that more effective TENS treatments are experienced when pad placement and parameters are experienced together.

There were two limitations of our study including a small sample size and corrupted data for our physical range of motion measurements.

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CHAPTER 1

INTRODUCTION

1.1 Pain and Pain Theories

Affecting nearly 100 million Americans each year,[1,2] pain is one of the most debilitating diseases in the world resulting in high health care costs, loss in productivity,[3] and numerous physical and/or mental conditions.[1,4] Chronic pain has also been linked to limitations in mobility, daily activities, opioid dependence, anxiety, and depression.[4] These often lead to socioeconomic stresses including, but not limited to, a burden on taxpayers and interference in activities of daily living like family and work responsibilities or recreational and social interests. [1,3] With the prevalence of pain increasing significantly each year in the United States,[4,5] it is important that the U.S. is able to properly prevent, assess, treat, and understand pain of all types to decrease or stop this spreading debilitating disease.[1]

Before chronic pain can be treated, clinicians must identify what pain is and address any common misconceptions about it. One of the largest misconceptions is that pain is only an indicator of tissue damage.[1,6,7] Though there is still a large need for more research on the incidence, prevalence, and treatments of pain, new research is indicating this current view of pain is untrue. [1,6-8] Instead of pain being created solely in areas of tissue damage, it is believed that pain is created by the brain. This is significant because it implies that pain is not a direct indictor of tissue damage, so a patient can feel pain when there is nothing

physically wrong with them. Unfortunately, this misinterpretation can lead to chronic pain which can lead to opioid use, expensive medical bills, limited mobility, and more.[1,3,4,9]

Pain is just an opinion generated by the brain. [6] Physiologically, the brain can tune the perception of pain and make any stimulus appear more or less painful. For example, a patient can interpret chest and abdominal pain as having a heart attack rather than mild gas pains. In a paper by Paul Ingram called "Pain is Weird" [6], he discusses a variety of stories of how pain can be interpreted differently depending on the patient's circumstances. One of these stories discusses how a man went to the bathroom, noticed his stool was bright red, so he collapsed on the floor in agony. After calling the doctor and having a full assessment done, the doctor could not find anything wrong with him. The doctor went to check the toilet where the red stool had been spotted and found out it was just a lot of beets the man had eaten a few hours ago. The cause of the pain was the shock from seeing the toilet full of red: therefore, all his pain was created by his mind.[6] A similar concept can happen to patients who experience chronic pain. The brain will trick these patients into believing they are continuing to have serious health issues when there is no physical damage identified.

Why and how the brain categorizes and manages pain is not entirely understood and more research is needed to fully understand these processes. One management theory, proposed in 1996 by Walls and Melzack, is the Gate Control Theory.[8] In this theory, they propose that the body is capable of producing its own forms of analgesics by blocking pain receptors from reaching the brain. The gate control theory works by activating large sensory fibers associated with touch and vibration to overwhelm or block the spinal cord's transmission (gate) to the brain. In doing so, small pain fibers cannot get their message

through to the brain resulting in less pain perception.[10] A second pain management theory is called the endogenous opioid system. It is the body's own analgesic system where natural pain relief chemicals, including endorphins, are released when pain is perceived. This theory allows the body to regulate its own perception of pain and can also be used when a painful stimulus is applied to another part of the body stimulating the brain to release endorphins. The research team used both theories as a basis for treating lower back pain.

1.2 Why is Back Pain a Problem?

The purpose of this study is to help patients suffering from chronic pain, specifically chronic, nonspecific, lower back pain. Chronic lower back pain (LBP) is defined as "back pain lasting more than 12 weeks"[3] and nonspecific is referring to patients who do not have a clinically diagnosed back problem such as a slipped disk or stenosis. Chronic back pain is the "second most common cause of disability in US adults and a common reason for lost work days,"[11] it costs between $100 and $200 billion annually,[11] and it is experienced by 70% to 80% of adults at some point in their lives.[3,12]

According to the American College of Physicians (ACP), the first line of treatment for chronic lower back pain should be nonpharmacological treatments including but not limited to exercise, therapeutic modalities (e.g., ice, heat, laser, electrical stimulation), spinal manipulation, and cognitive behavior therapy. [3] If these fail, the ACP recommends using pharmacological methods including anti-inflammatory and analgesic medicines prior to any opioid prescription.[3] Unfortunately, these recommendations are often not followed as patients immediately request and receive opioid medications.[1] Because the risks of

opioid use tend to outweigh is benefits, it is important to find more evidence regarding nonpharmacological treatments.

1.3 Research Question

To investigate electrical stimulation as a nonpharmacological method of treatment for chronic, nonspecific, low back pain, two different treatment parameters were compared regarding their clinical effectiveness. The research question was: are there differences in the perceived recovery (subjective) and trunk range of motion (objective) from chronic low back pain when the transcutaneous electrical nerve stimulation (TENS) electrodes are placed on the site of pain using the gate control theory of pain management versus over the kidney meridian points on the ankle using the opiate control theory of pain management?

We hypothesize that both parameters and sites will achieve similar pain modulation for adults with chronic low back pain. Chesterton et al.[10,13] determined that pain relief was more significant after a 30-minute TENS treatment if unique pad placement were associated with the selected pain modulation theory. Electrodes placed at the site of pain and set to a comfortable sensory sensation (gate control theory) and electrodes placed along associated meridian energy points and set to a rhythmical acupressure like motor sensation (opiate control theory) were the best for pain modulation.

CHAPTER 2

LITERATURE

2.1 Different Ways of Treating Back Pain

There are many modalities in treating LBP and they are broken into two categories: pharmacological and nonpharmacological. Pharmacological modalities include nonsteroidal anti-inflammatory drugs (NSAIDS), Acetaminophen, opioids, benzodiazepines, antidepressants and more. The individual results of all the pharmacological methods vary greatly, so the ACP recommends that patients who have persistent chronic low back pain try "nonsteroidal anti-inflammatory drugs as first-line therapy, or tramadol or duloxetine as second-line therapy."[3] A large danger to using pharmacological methods to treating chronic pain is addiction. With opioids being the primary treatment for chronic pain in North America for over a decade, unintentional prescription overdose has significantly increased. [9,14] Within the last two decades, the opioid crisis in the United States has become a major public health problem with opioids alone making up 75% of all pharmaceutical overdose deaths. Not only does this make treating chronic pain with opioids more dangerous, providing pain relief with other methods is extremely difficult due to the misconception that there are limited alternative and affordable therapies available other than opioids. [9]

Other nonpharmacological methods include therapeutic modalities [3,12,15,16], physical exercise [3,17], herbal supplements [18], and cognitive behavior [7,19]. One of the most common therapeutic modalities used to modulate pain is a TENS device. A TENS unit is a small electrical stimulation device that is designed to deliver electrical impulses of different intensities and duration to a body part or a meridian. The body's perception of the electrical stimulation is used to activate modulation of pain in the brain. A variety of Cochrane reviews on many of these nonpharmaceutical modalities have similar results when it comes to the effectiveness in treating lower back pain. Current guidelines state that exercise therapy may be beneficial, but research supporting these methods are limited and need to be further investigated.[3,7]

In one study, which used yoga to treat lower back pain, 12 trials were reviewed on their effectiveness of treating chronic non-specific low back pain using yoga compared to no specific treatment.[17] Since there were no blinded treatments and the outcome of the results were self-assessed, the trials were at a high risk for bias. The biases and need for higher quality research made the effectiveness of using yoga to treat LBP underdetermined.[17] Another study looked at the effects of therapeutic ultrasound compared to a placebo to treat lower back pain. [15] This study also had inconclusive results stating the evidence of treating chronic lower back pain using ultrasound is "uncertain" and the "available trials were very small".[15] When looking at the use of herbal supplements used for treatment of LBP, an overview of over 14 different herbal supplements showed no concrete evidence that they are safe or efficacious for long-term use. [18] Overall, there is a need for more testing to help develop effective treatments for chronic LBP. [3,7]

2.2 TENS Unit Studies

A very common therapeutic modality to treat chronic pain is the application of electrical stimulation via a TENS unit. Therefore, several Cochrane Systematic Reviews have investigated the effectiveness and safety of TENS units for treating chronic pain in adults. One of these studies reviewed the TENS unit's ability to reduce chronic pain in adults and its safety. [20] When reviewing its effectiveness, the "evidence within each review was consistently rated as very low quality" and there were "significant methodological limitations" including small sample sizes. These factors contributed to an inconclusive result if using a TENS unit is physically harmful or beneficial for controlling pain. [20] When looking at other studies of a TENS unit and its effectiveness of treating lower back pain, the results are similar.

The reason measuring the effectiveness of a TENS unit is so difficult is due to the variety of parameters a TENS unit can provide. Two studies[10,13] set out to test these different parameters and their effectiveness at reducing pain. Chesterton et al.[10,13] did this by using a pressure algometer and pushed on participants' hands until they felt pain and repeated this process over the course of 30 minutes. In-between each pressure stimulus, the participant would be subjected to the treatment with the TENS unit depending on their assigned group. One group was assigned to a "gate control" where the pads of the TENS unit were placed on the site where the patient was experiencing pain (in this case, their hand). They were instructed to set the intensity to a level that was comfortable and keep the machine on for a total of 30 minutes (taking short breaks to get a pain reading from the

ressure sensor). Another set of participants were assigned to a "descending" or "endogenous opiate control bias" group where the pads were places on the gallbladder meridian points. They were instructed to set the intensity to the highest setting they could tolerate and keep the machine on for 30 minutes. The results of the study were somewhat unexpected. Both groups had a similar amount of short-term pain relief after 30 minutes of using the TENS unit. Although, once the TENS unit was off, the long-term effects of pain relief were drastically different between the two groups. The group that had the pads placed directly on the source of pain had significantly less long-term analgesic effects than patients who had the pads placed on the meridian points. [10,13]

Therefore, both the "gate control" theory and the "endogenous opiate" theory provided significant short-term relief of pain, but only the endogenous opiate theory with the pads placed the meridian site resulted in long term pain relief.

CHAPTER 3

METHODOLOGY

3.1 Study Design

To investigate electrical stimulation as a nonpharmacological method of treatment for chronic, nonspecific, low back pain, two different treatment parameters were compared regarding their clinical effectiveness. The study design was a 2 x 2 (treatment group X time) randomized crossover mixed model. There were two treatment groups including the lower back/gate-control (LBGC) group and the kidney meridian/endogenous opiate (KMEO) group. Two time points were assessed including baseline and after two weeks of treatment. The dependent variables included the PROMIS-29 v1.0 patient rated outcomes scale and the Global Rating of Change scale. Evaluation of the subjects included range of motion (ROM) using an inclinometer and tape measure, PROMIS-29 v1.0, and Global Rate of Change (GROC) scale at the beginning and end of the study which lasted a total of two weeks.

3.2 Subjects

Participants were recruited via flyers around campus and email. Interested participants were given a QR link to a brief health history to see if they qualified for the study (see inclusion criteria below). A total of 251 people viewed the health history form, 100 participants filled out the response and 32 participants qualified.

Thirteen participants completed the information session but three dropped out due to time commitment issues. A total of 10 participants completed the study and each

participant was assigned pseudo-randomly to a treatment group. Of these two groups, 5 participants were assigned to the LBGC group while 5 participants were assigned to the KMEO group. Each group consisted of 1 male and 4 females and varied in severity of pain. No subjects withdrew during the study. Subject demographics are in Table 3.1.

Table 3.1: Patient Demographics

	Age	Height (cm)	Mass (kg)	Gender
Meridian	31±18	165.1±8.6	81.2±20.5	F=4; M=1
Pain Site	27±3.6	171.7±12.4	83.7±20.6	F=4; M=1
Total	29.4±12.4	168.4±10.6	82.5±19.4	F=8; M=2

3.3 Inclusion/Exclusion Criteria

Before the study began, participants completed a questionnaire to screen for inclusion/exclusion criteria. Once past the questionnaire, participants were shown a PowerPoint presentation on the inclusion/exclusion criteria and study requirements. Subjects were included if they were:

1. Experiencing or had been diagnosed with lower back pain. Lower back pain was defined as either every day or most days for at least the last 12 weeks.
    a. The participant was not taking opioids for the treatment of lower back pain
2. Over the age of 18 and under 65
3. Willing to report to lab on three different occasions for research instructions and assessment of subjective and objective measures.
4. Willing and able to apply the portable TENS unit for 30 minutes on a minimum of five days a week for two weeks.

5. Did not have any of the following conditions marked on the Health History form (Appendix A.1):
    a. Surgical history to neck or low back
    b. Diagnosis of slipped or herniated disk in neck or lower back
    c. COVID-19 or any symptoms associated with an infection
    d. Were not pregnant or did not suspect pregnancy – this was determined by self-report of female patient
    e. Epilepsy, cancer, cardiac pacemaker
    f. Skin problems such as psoriasis, eczema, swelling, infection, inflammation or skin abrasions on or around the areas we placed the TENS unit.
    g. Latex allergies as electrodes were made of latex products
    h. Current or previous neuropathology that resulted in hyper/hypo sensitivities (very sensitive or limited sensations)

3.4 Procedures and Outcomes Measured

3.4.1 Procedure Description

Subjects were asked to come to the clinic for an assessment two times: once at the beginning of the study and once at the end. During the first appointment (pre), the subject filled out one patient rated outcome form and had their back ROM measured using two different techniques. The ROM measurements included back flexion, extension, and lateral side bending. The researchers measured their ROM using a tape measure and inclinometer. Based on group assignment the subject received a TENS unit and completed one 30-minute TENS treatment to orient them to the device. Participants were taught how to use the TENS unit and given an opportunity to ask questions before being sent home to complete the

treatments on their own. They were also given a QR code to use every time they completed a TENS treatment which assessed their pain sensations before a treatment, after a treatment, and kept record of when they completed a treatment. Participants were asked to complete one 30-minute session per day, five days a week for two weeks.

After two weeks, the participants were asked to complete another appointment (post) where they filled out two patient rated outcome scales, and their ROM was measured. At the very end of the study, participants returned their TENS unit and were given information on how to purchase their own TENS device, if interested.

3.4.2 TENS Parameters

Both the LBGC and KMEO groups were given a TENS unit and asked to set the units on different parameters. The parameters are defined below:

Lower back/Gate-control (LBGC)

- Placement - on the area of concern (lower back) (Figure 3.1.).
- Settings:
    - Intensity – up to comfort with no muscle contraction (Tingly sensation which mimics a rubbing feeling)
    - Pulse Rate - 120 Hz
    - Pulse Duration - 40 μsecond
- Duration – 30min continuous
- Subjects increase sensation with tolerance

Kidney meridian/Endogenous opiate (KMEO)

- Placement - On Kidney 2, 4, 8, 9 Meridian Point (Figure 3.2.)
- Settings:

- Intensity – to tolerance (pins and needles sensation which mimics acupuncture)
- Pulse Rate - 150 Hz
- Pulse Duration - 300 µseconds

- Duration – 30min intermittent
  - TENS unit was set on strength duration 1 (SD1) which allowed for electrical impulses to be delivered in an intermittent fashion.
- Subjects increase sensation with tolerance Inclusion Criteria

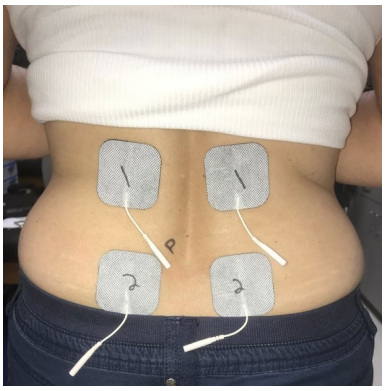


Figure 3.1. Lower Back Pad Placement

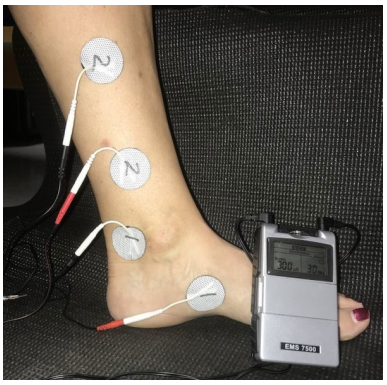


Figure 3.2. Kidney Meridian Pad Placement

3.4.3 Range of Motion Assessment

Participants completed three ROM activities during each appointment. The measurements included flexion, extension, and lateral bending of the back. A tape measure and inclinometer were both used to measure these movements but results of these measurements could not be determined due to corrupt data.

3.4.4 Patient Rated Outcome Scales

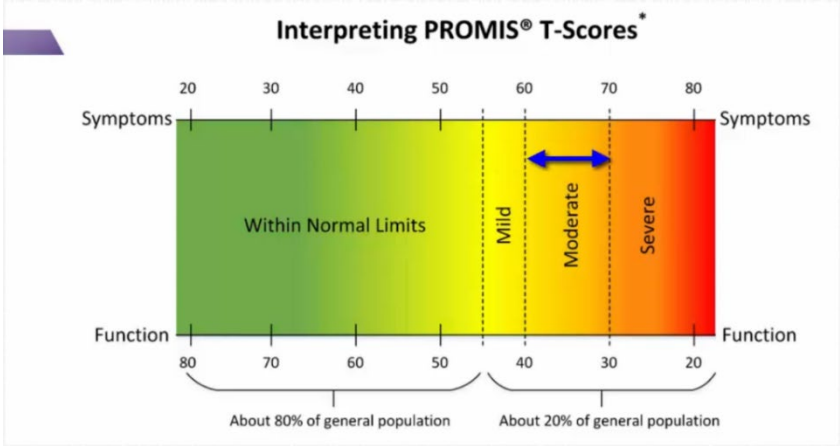
Participants completed a Patient-Reported Outcomes Measurement Information System (PROMIS-29) v1.0 form at the beginning of the pre and post appointment and a

Global Rating of Change (GROC) form at the end of treatment. These are Likert scales that allow subjects to rank different physical sensations and emotions related to their chronic lower back pain and their recovery.

The PROMIS-29 v1.0 (Figure 3.4) is a 29-question survey that asks information in three major categories: physical, mental, and social health. These categories are further broken into subcategories and are categorized as either a function or a symptom. Depending on their classification (function or symptom) the scoring changes direction where a function improves as the score gets higher, but a symptom improves as the score gets lower (see Figure 3.3).

Physical health is broken down into five subcategories: fatigue, pain intensity, pain interference, physical function, and sleep disturbance. Mental health is broken down into two subcategories: anxiety and depression. Social health has one subcategory: ability to participate in social roles and activities. Physical function, social role and sleep disturbance are all measured on the function side of the "Interpreting PROMIS T-Scores" scale. When the score gets lower, the participant experience is lower (e.g., a sleep score of 80 identifies a higher sleep quality than a sleep score of 60). The other side of the scale defines symptoms which are fatigue, pain intensity, pain interference, anxiety, and depression. When the score gets lower, the participant experience is more desirable (e.g., a depression score of 80 identifies the participant has more depression than a participant that has a depression score of 60).

Figure 3.3: PROMIS T-Score Scale



Participants scored questions within each category on a scale from either “not at all” to “very much”, “very poor” to “very good”, or “never” to “always”. Each answer choice was ranked from 1-5. An online scoring service was used to calculate T-scores for each of the subscales. A T-score uses 50 as the population mean and then provides a score for each subject relative to this benchmark. The scores for the subscales that measure symptoms (e.g., fatigue or anxiety) indicate that scores from 55 to 60 indicate mild symptoms, 60 to 70 indicates moderate symptoms, and >70 indicates severe symptoms (Figure 3.3). The scores for the subscales that measure function (e.g., physical function or sleep disturbance) indicate that scores from 40 to 45 indicate mild disability, 30 to 40 indicate moderate disability, and <30 indicate severe disability. (Figure 3.3)

Figure 3.4: PROMIS-29 v1.0

PROMIS–29 Profile v1.0

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
PFA11 1	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA21 2	Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA23 3	Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA53 4	Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
EDANX01 5	I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40 6	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX41 7	My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53 8	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Depression **In the past 7 days...**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
EDDEP04 9	I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP06 10	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP29 11	I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP41 12	I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
HI7 13	I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
AN3 14	I have trouble starting things because I am tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	In the past 7 days…					
FATEXP41 15	How run-down did you feel on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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Figure 3.4: PROMIS-29 v1.0

PROMIS–29 Profile v1.0

Fatigue

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
FATEXP40 16	How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Sleep Disturbance

	In the past 7 days…	Very poor	Poor	Fair	Good	Very good
Sleep109 17	My sleep quality was	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep116 18	My sleep was refreshing	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep20 19	I had a problem with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep44 20	I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Satisfaction with Social Role

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
SRPSAT07 21	I am satisfied with how much work I can do (include work at home)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT24 22	I am satisfied with my ability to work (include work at home)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT47 23	I am satisfied with my ability to do regular personal and household responsibilities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPSAT49 24	I am satisfied with my ability to perform my daily routines	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Pain Interference

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
PAININ9 25	How much did pain interfere with your day to day activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ22 26	How much did pain interfere with work around the home?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ31 27	How much did pain interfere with your ability to participate in social activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ34 28	How much did pain interfere with your household chores?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Pain Intensity

	In the past 7 days…											
Global07 29	How would you rate your pain on average?	☐ 0 No pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Worst imaginable pain

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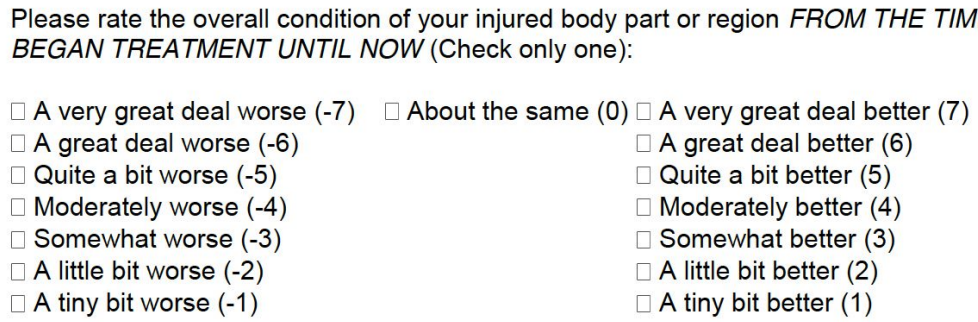
The GROC measures the patient's perception in regard to the overall condition of their injured body part (in this case the lower back). The GROC has the participant rate their change in sensations from the beginning of treatment to the present time. There are a total of 15 answer choices ranging from "a very great deal worse" (-7) to "a very great deal better" (+7). Each level is represented by a 1-point increment varying better to worse (Figure 3.5).


Please rate the overall condition of your injured body part or region *FROM THE TIME THAT YOU BEGAN TREATMENT UNTIL NOW* (Check only one):

☐ A very great deal worse (-7)	☐ About the same (0)	☐ A very great deal better (7)
☐ A great deal worse (-6)		☐ A great deal better (6)
☐ Quite a bit worse (-5)		☐ Quite a bit better (5)
☐ Moderately worse (-4)		☐ Moderately better (4)
☐ Somewhat worse (-3)		☐ Somewhat better (3)
☐ A little bit worse (-2)		☐ A little bit better (2)
☐ A tiny bit worse (-1)		☐ A tiny bit better (1)

Figure 3.5: Global Rate of Change (GROC)

3.5 Statistical Analysis

Microsoft Excel was used to perform all analysis. Descriptive Statistics were calculated for PROMIS subscales and Global Rating of Change scale. ROM data was not able to be analyzed due to corruption and loss of data files. To determine time effects of treatments, the two treatment groups LBGC and KMEO were considered separately. Each was compared within group (pre vs. post) using equal variance t-tests with an alpha set *apriori* at 0.05.

CHAPTER 4

RESULTS

4.1 PROMIS Outcomes

PROMIS T-scores for pain intensity, physical function, pain interference, and fatigue were statistically analyzed to determine pre to post time differences separately within each of two treatment groups LBGC and KMEO. The KMEO group demonstrated a significant reduction in PROMIS pain intensity score (0-10) from pre (5.0±1.2) to post (2.8±1.3) ($t(8) = 2.75$; $p=0.02$) (Figure 4.1) whereas there was no significant difference within the LBGC group from pre (4.8±1.9) to post (3.8±1.3) ($t(8) = 0.96$; $p=0.33$) (Figure 4.2). We also analyzed the percentage change from pre levels of pain intensity to post levels of pain intensity and determined that the KMEO group improved by 46.0±19.2% whereas the LBGC improved only 19.0±10.8% over the two week treatment ($t(8)=2.7$; $p=0.03$).

Neither the KMEO nor the LBGC groups demonstrated significant improvement in PROMIS physical function scores from pre to post ($p>0.05$) (Figure 4.3). The KMEO group demonstrated a significant reduction in PROMIS fatigue score from pre (55.3±6.3) to post (45.5±6.6) ($t(8) = 2.4$; $p=0.04$) whereas there was no significant difference within the LBGC group from pre (56.7±6.7) to post (52.3±6.4) ($t(8) = 1.0$; $p=0.31$) (Figure 4.4). Neither the KMEO nor the LBGC groups demonstrated significant improvement in PROMIS pain interference scores from pre to post ($p>0.05$) (Figure 4.5).

Both pain intensity and fatigue had significant and clinically meaningful improvements in the KMEO group versus the LBGC group. The threshold to evaluate within-group change in the PROMIS subscales generally ranges between 2 and 6 T-score points. [21] Our small sample size likely limited our ability to obtain statistical significance for physical function and pain interference; however, the KMEO group did have greater magnitude of change indicating more improvement in each of these variables.

4.2 Global Rating of Change (GROC)

The GROC scale allows a patient to rate their perceived feelings towards recovery with positive numbers indicating improvement. There was no statistical difference ($t(8) = 1.5$; $p = 0.15$) in GROC scores between the KMEO (4.4 ± 1.5) and LBGC (2.6 ± 2.0); however, the GROC score for the KMEO group indicates that these subjects had a "moderately better" improvement relative to the LBGC group that only improved "a little bit" (Figure 4.6).

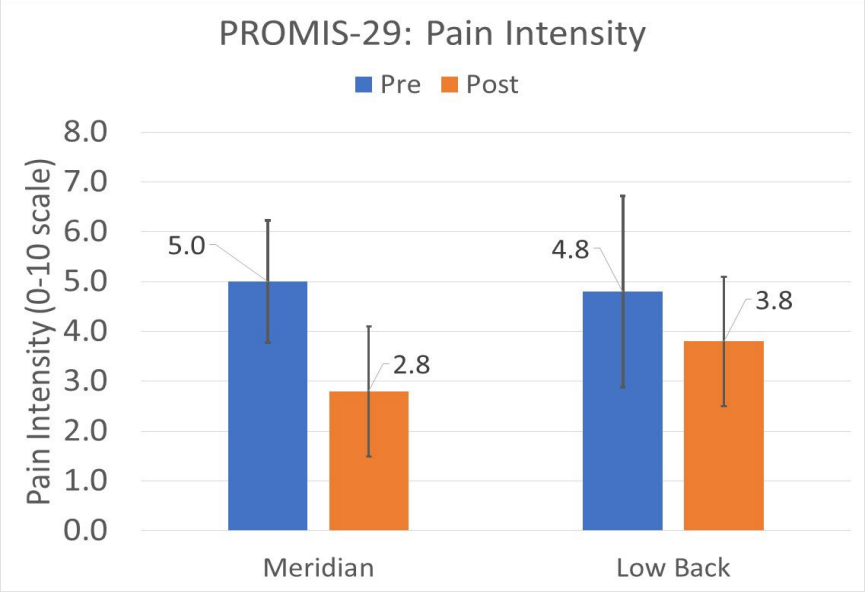


Figure 4.1: Meridian group: *Post pain intensity less than pre pain intensity (p=0.02)

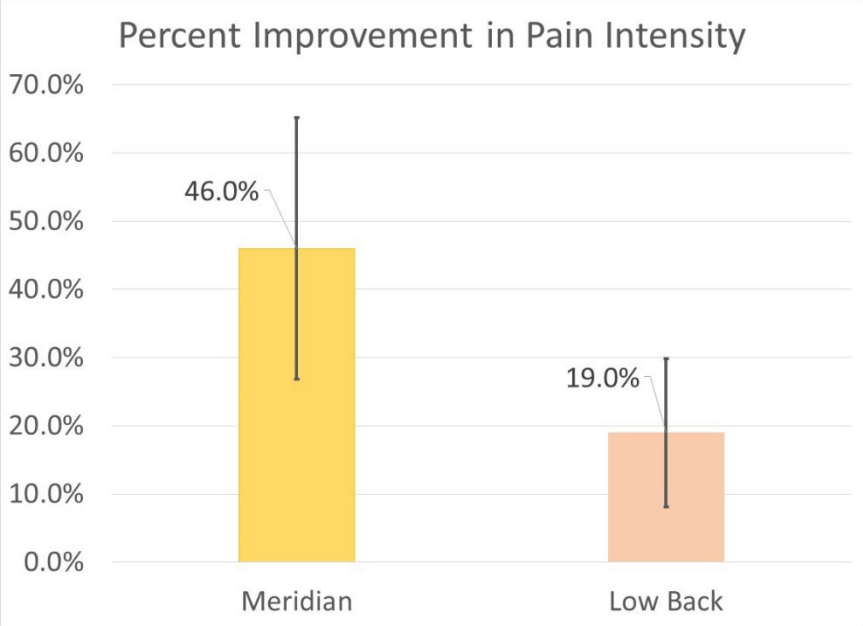


Figure 4.2: Meridian group was significantly improved compared to low back (p=0.02)

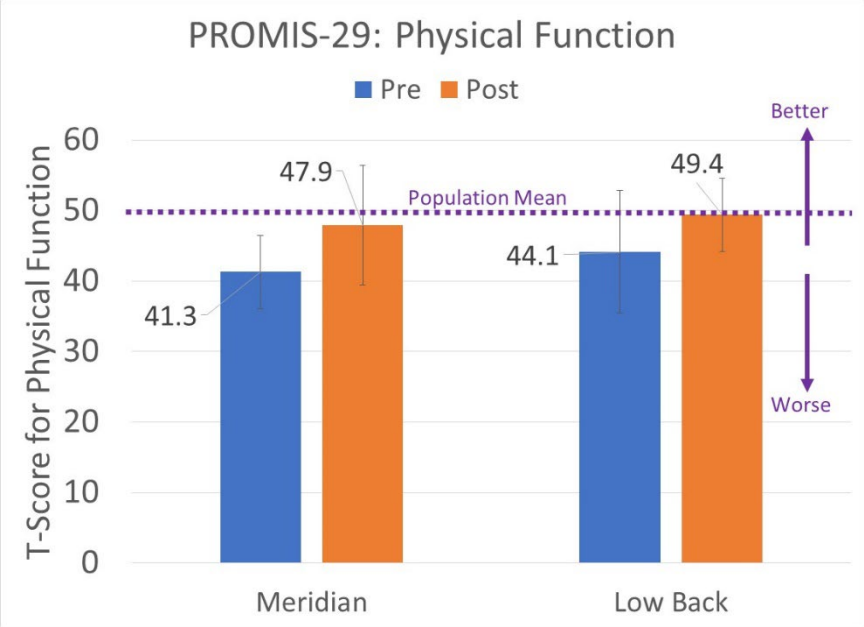


Figure 4.3: No significant difference within groups

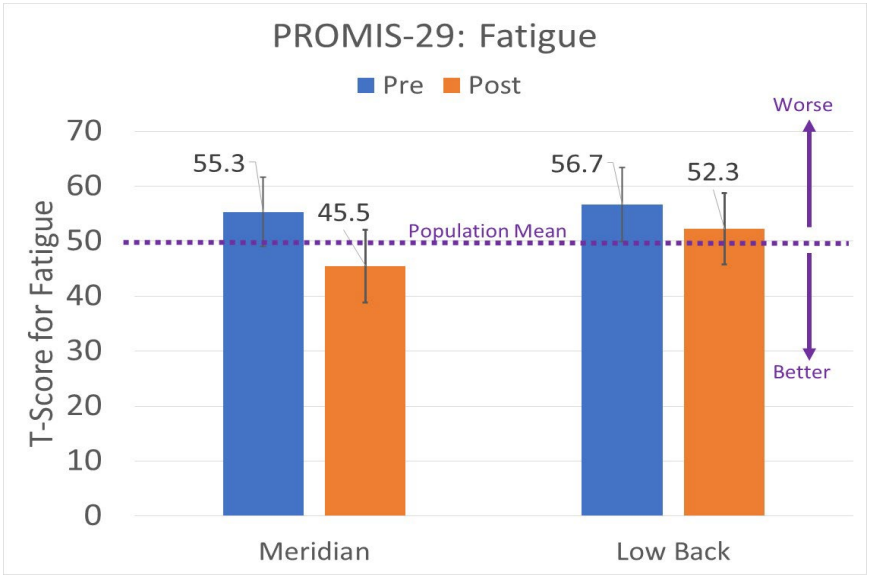


Figure 4.4: Meridian group *Post fatigue score less than pre fatigue score (p=0.04)

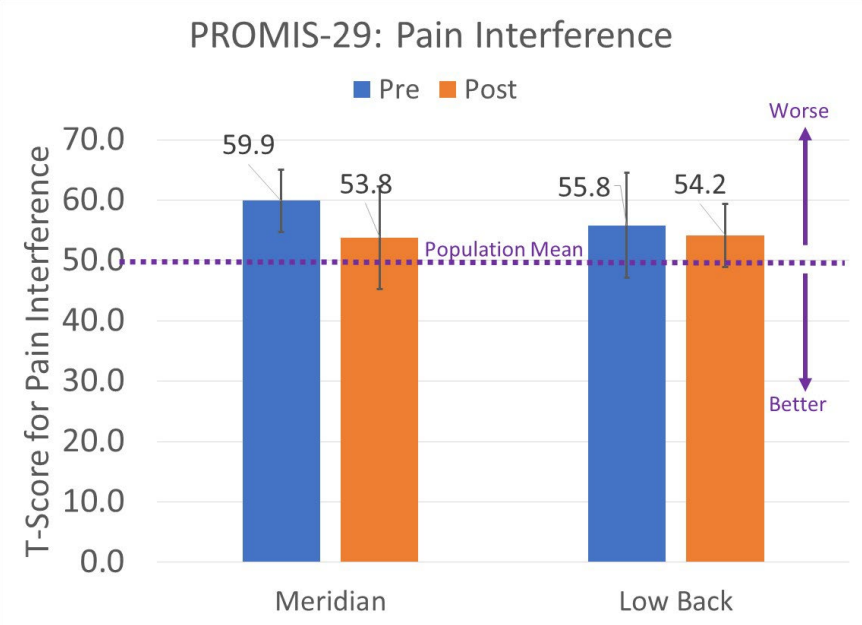


Figure 4.5: No significant difference within groups

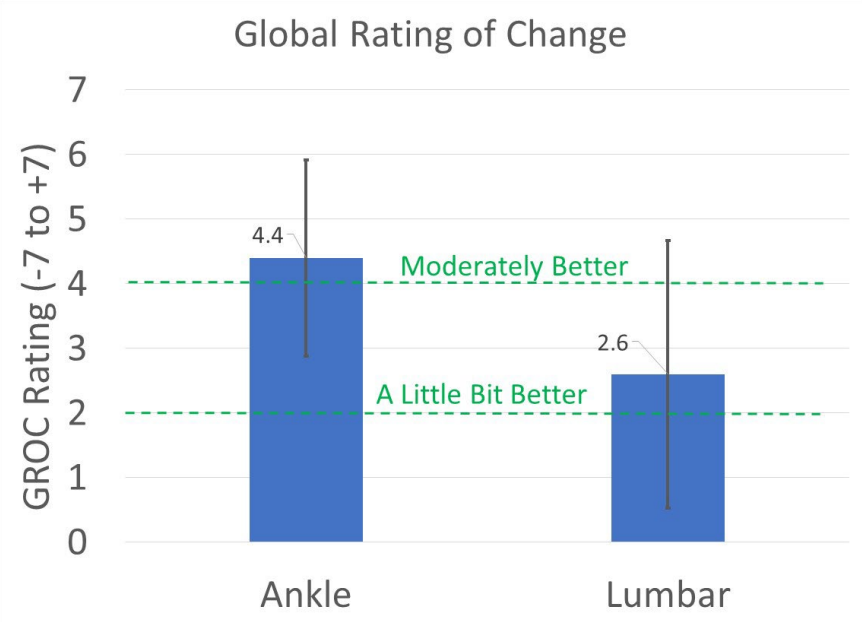


Figure 4.6: No significant difference between groups

CHAPTER 5

DISCUSSION

5.1 Practical Applications

The purpose of this study was to help patients suffering from chronic pain and specifically, chronic, nonspecific, lower back pain. In this study, we found that using a TENS unit could be an effective alternative to alleviating pain without the use of opioids, injections, or other invasive techniques. Though both groups in the study experienced a decrease in pain, placing the pads on the meridian point and using an endogenous opioid setting created more effective and longer lasting pain relief then the lower back gate-control group. The results of our study support the findings of the Chesterton [10,13] study which indicated more effective TENS treatments are experienced when pad placement and parameters are experienced together.

The results of this study should be used to help educate healthcare providers on alternative methods to pain relief. Using invasive procedures or opioids increase the patient's risk of other unintentional side effects such as infection, addiction, overdose, and dependance and can be much more costly than noninvasive procedures. The types of nonpharmacological methods to treat pain should be more widely considered in the healthcare setting and proper education on how to apply these alternative methods need to be addressed.

The common way to treat pain using a topical application is to apply the stimulus directly to the site of pain (e.g., massages, creams, or ice packs). Although, recent evidence

suggests that pain often is not fully associated with the area that hurts, but instead is incorrectly processed by the brain. This suggests that we do not always need to treat the site of pain and using other points of interests (such as meridian points) may be more effective. This study supports using other points of treatment (such as a meridian points) is more effective than applying a stimulus directly to the area of pain.

When using a meridian point to treat pain, the parameters used must be altered to engage the body's own opioid system. A common mistake made by TENS users is to set the TENS unit on a parameter that is not strong enough to cause the body to release its own opioids. Proper education is imperative to provide effective pain relief which will likely decrease the need for more invasive procedures in the future and decrease the risk of unwanted side effects for the patient.

5.2 Limitations

The major limitation to this study was our small sample size. Since the inclusion/exclusion criteria for this study was relatively difficult (patients could not be diagnosed with a back disorder yet they still needed to have back pain longer than three months), this made our subject pool limited. We were also limited to participants' availability on when they could come into the clinic to have their range of motion measured and have time to complete their TENS treatments in their daily lives. Since these treatments were completed on their own time, there was no way for us to monitor if they did the treatment correctly, completed the full 30 minutes, changed the setting, etc. These are all factors that could have played into the results without the researchers knowing.

Another limitation was that we did not have enough participants to make the groups equal in aspects such as gender, back pain severity, and age. As seen in the demographics,

the age ranges and pain severity varied between groups which could have affected the results.

5.3 Future Research

The management of pain is complicated. However, nonpharmacological resources should always be considered as a first line of musculoskeletal pain treatment. The TENS unit is affordable, easy to use, compact, and there is evidence for its effectiveness in the relief of musculoskeletal pain. Our study adds to the literature and emphasizes that clinicians should consider the pain theory, the pad placement, and parameters when using a TENS unit to manage patients' pain. Future research should continue to investigate the use of an endogenous opioid theory and pad placement for the treatment of a variety of musculoskeletal pain.

APPENDIX A

HEALTH HISTORY FORM

Filled in by investigator
Subject Number:_____

DEPARTMENT OF KINESIOLOGY

HEALTH STATUS QUESTIONNAIRE

Age_____ Gender Female / Male (Circle one)

Height _____ (ft) _____ (in) Weight _____ (lbs)

Height _____ (cm) Mass _____ (kg)

PAST TRAUMA OR SURGERY HISTORY TO LOW BACK

How long have you experienced low back pain? (Please express in months) _____

Please list all injuries and surgeries you have previously had to your low back.

CURRENT MEDICATIONS

Drug allergies: ❑ No ❑ Yes To what?
Please list any medications that you are now taking. Include non-prescription medications & vitamins or supplements:

Name of drug	**Dose (include strength & number of pills per day)**	**How long have you been taking this?**
1.		
2.		
3.		
4.		
5.		
6.		

GENERAL HEALTH STATUS

PAST MEDICAL HISTORY

Do you now or have you ever had:

❑ Diabetes
❑ High blood pressure
❑ High cholesterol
❑ Hypothyroidism
❑ Heart murmur
❑ Cancer (type) _____
❑ Pulmonary embolism
❑ Psoriasis
❑ Eczema
❑ Heart problems
❑ Hepatitis
❑ HIV/AIDS
❑ Asthma
❑ Emphysema
❑ Stroke
❑ Epilepsy (seizures)
❑ Chronic pain (last over 3 months)
❑ Acute pain
❑ Any nerve pathology

Do you currently have any wounds or cuts on your low back or ankles/lower legs?
❑ Yes ❑ No

Are you allergic to adhesives or latex?
❑ Yes ❑ No

Are you currently or have chance of being pregnant?
❑ Yes ❑ No

Other medical conditions (please list):

I hereby state that, to the best of my knowledge, my answers to the above questions are complete and correct.

Subject Code_____Date _____

APPENDIX B

LOW BACK PAD PLACEMENT MANUAL

Materials to start:

- Extra batteries
- Pads with adhesive
    - Do not use the same pads for more than one week
- 2 sets of Cords
- TENS Unit

Lower Back

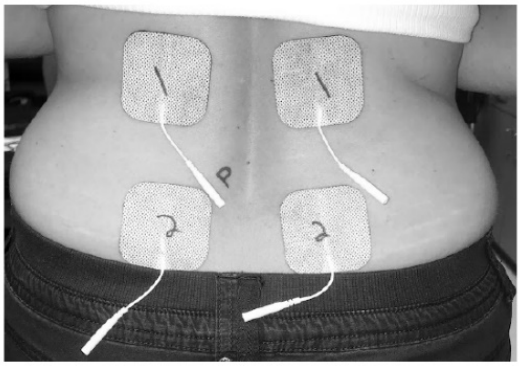
1. Identify anatomical land points and place the pads.

   1st set of pads

   - Place both pads horizontally **above** the location you have pain – the cords can be either way

   2nd set of pads

   - Place both pads horizontally **below** the location you have pain – the cords can be either way



Please Note: The P in the picture above indicated where the patient is experiencing pain. The pads should be surrounding the area that pain is felt but the pads should NOT be placed diagonally to each other. They need to be placed horizontally to each other as shown above.

2. Plug in the adapters to the 1st set of pads – Black on LEFT and Red on RIGHT

   *Please Note: each cord has a black and red adapter. One red and one black adapter should be used for one set of pads (either the 1st or 2nd). Do not cross these adapters to other pad sets as the results may be affected.

Materials to start:

- Extra batteries
- Pads with adhesive
    - Do not use the same pads for more than one week
- 2 sets of Cords
- TENS Unit

Lower Back

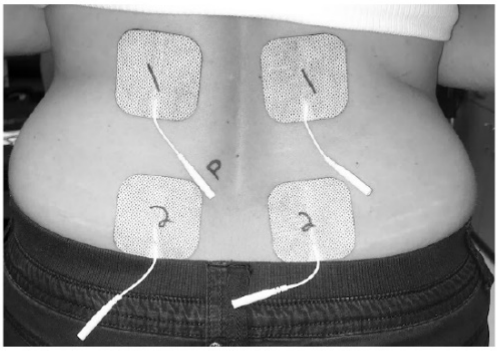
1. Identify anatomical land points and place the pads.

   1st set of pads

   - Place both pads horizontally **above** the location you have pain – the cords can be either way

   2nd set of pads

   - Place both pads horizontally **below** the location you have pain – the cords can be either way



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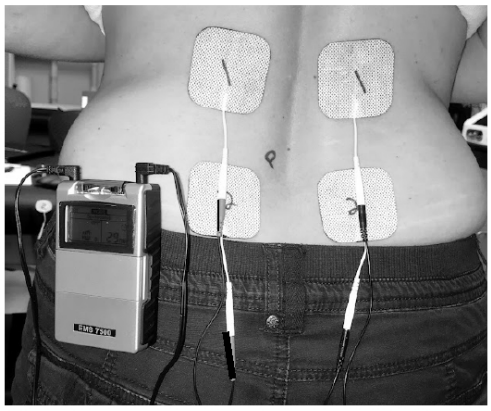
2. Plug in the adapters to the 1st set of pads – Black on LEFT and Red on RIGHT

   *Please Note: each cord has a black and red adapter. One red and one black adapter should be used for one set of pads (either the 1st or 2nd). Do not cross these adapters to other pad sets as the results may be affected.

3. Plug the other end of the cord into channel 1 of the TENS unit.
    - The channel is located on top of the TENS unit and is labeled #1.
4. Repeat steps 2 & 3 for the 2nd set of pads.



5. Once all the pads are secure and all cords are plugged in, DO NOT CHANGE ANY SETTING ON THE TENS UNIT. All setting will be preselected in the TENS unit and opening of the device will not be necessary.
6. To turn the TENS unit on, simply slowly turn the volume knob location next to channel one to a comfortable level.
    - Once you turn the volume knob on you may here a small beep and the screen turn on. This means you have successfully turned on the TENS unit.
    - The TENS unit will start working immediately once the volume knob has been turned on.
7. Attach the TENS unit to a comfortable location and keep it on for the required duration.

Normal

120 Hz

50 microseconds

30 minutes

SENSATIONS:

PINS and NEEDLES – heavy buzzing with no muscle twitching. You can turn up until twitch and then turn back down.

Adjust at least every 10 minutes or as needed to maintain heavy buzzing sensation that is non-painful

APPENDIX C

KIDNEY MERIDIAN PAD PLACEMENT MANUAL

Materials to start:

- Extra batteries
- Pads with adhesive
    - Do not use the same pads for more than one week
- 2 sets of Cords
- TENS Unit

Instructions

Meridian Point

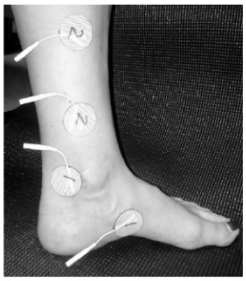
1) Identify anatomical land points and place the pads.

   1st set of pads

   - One on the interior side at the base of the patients arch on their foot. You may try putting it directly below the body prominence located in the insider portion of the arch on the foot.
   - Directly behind the ankle bone/malleolus
     - Do not put the TENS pads directly on the ankle bone.

   2nd set of pads

   - Place the first one about 2 finger distances above the malleolus or ankle bone.
   - Place the second pad about a palm's width above the first pad.



2) Plug in the adapters to the 1st set of pads

   *Please Note: each cord has a black and red adapter. One red and one black adapter should be used on one set of pads. Do not cross these adapters to other pad sets as the results will be affects.

3) Plug the other end of the cord into channel 1 of the TENS unit.
   - The channel is located on top of the TENS unit and is labeled #1.
4) Repeat steps 2 & 3 for the 2nd set of pads.

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BIOGRAPHICAL INFORMATION

Kara Chidester is currently a senior at the University of Texas at Arlington. She is working towards an Honors Bachelor of Science in Nursing and plans to graduate in August of 2022. She is an active member in Zeta Tau Alpha, the Honors College, and is currently interested in researching alternatives to pharmaceutical drugs for pain management. After her bachelor's degree, she would like to go on to get her doctorate in anesthesia to become a certified nurse anesthetist in the DFW area.