THE EFFECTS OF KINESIO® TAPE STAR TECHNIQUE IN INDIVIDUALS WITH CHRONIC NON-SPECIFIC LOW BACK PAIN: A PILOT STUDY

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Title

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ABSTRACT

Kinesio® Tape is theorized to reduce pain and aid with movement during treatment of chronic non-specific low back pain. This study investigated the effect that Kinesio® Tape has on patient-reported outcome measures and on disability in patients with chronic non-specific low back pain. Six volunteers exhibiting chronic non-specific low back pain, based on an included questionnaire, were recruited for this study. Patient-reported visual analog scores (VAS), Oswestry Disability (ODI) scores, Tampa Scale of Kinesiophobia (TSK) scores and postural stability measured by the Biodex balance system, as well as timed up and go scores were recorded over two randomized sessions with Kinesio® Tape star technique and with a sham taping. Upon conclusion of this study there was significance found when looking at the pain, timed up and go, and ODI scores but there were not any differences found between the two different Kinesio® Tape taping techniques.

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LIST OF ABBREVIATIONS and ACRONYMS

ANOVA	Analysis of Variance
BMI	
DNA	Deoxyriboneucleic Acid
FBSTI	Forward Backward Stability Index
FBSWI	Forward Backward Sway Index
FSST	Four Square Step Test
IRB	Institutional Review Board
L5	Fifth Lumbar Vertebrae
LCD	Liquid Crystal Display
LRSTI	Left Right Stability Index
LRSWI	Left Right Sway Index
LOS	Limits of Stability Test
mCTSIBModif	ied Clinical Test of Sensory Interaction in Balance
mfMRI	Muscle Fun
ODI	Oswestry Disability Index
OSTI	Overall Stability Index
OSWI	Overall Sway Index
ROM	
RMDQ	
SI Joint	Sacroiliac Joint
TSK	
TENS	Transcutaneous Electrical Nerve Stimulation

TUG	
VAS	Visual Analog Scale
	visual Allalog Scale

LIST OF SYMBOLS

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CHAPTER 1: INTRODUCTION

1.1. Overview of the Problem

Chronic low back pain is the third most common reason for physician visits.¹ Chronic low back pain also accounts for 13% of work-related injuries and the leading cause of sick leaves.¹ Diagnosis of this condition relies more on the ruling out of injuries than a specific list of criteria to define it. In fact, chronic non-specific low back pain is often characterized by pain in the low back that has lasted for at least three months with or without radiating into the buttocks or leg.^{1,2} Once other conditions have been ruled out treatment of chronic low back pain often consists of exercise therapy, transcutaneous electrical nerve stimulation, superficial heat or cold, low-level laser therapy, massage, behavioral treatment, lumbar supports, traction, multidisciplinary rehabilitation.³ Another common, but sometimes controversial, treatment includes Kinesio® Tape.

Kinesio® Tape is a commonly used therapy for many conditions. It was first created in the 1970s by Dr. Kenzo Kase.⁴ With many theorized benefits but minimal evidence supporting or refuting them its use remains controversial. Among the theorized benefits is the ability of the tape to create space by lifting through a space correction application. The claim is that the tape when allowed to create recoil provides lift over tight tissue and offers fascial mobilization, increasing range of motion (ROM) and decreasing pain. Kinesio® Tape, applied using the space correction application, may increase the space in the fascia resulting in relief of pain and decrease in the disability related to chronic non-specific low back pain.⁴

1.2. Statement of Purpose

The purpose of this study was to determine the effectiveness of the Kinesio® Tape star space correction application in reducing pain in individuals with chronic non-specific low back

pain. Furthermore, it investigated the effectiveness of Kinesio® Tape on reducing disability using the Biodex balance system.

1.3. Research Questions

1) How did the star space correction Kinesio® Tape technique affect an individual's low back pain?

2) How did the star space correction Kinesio® Tape technique affect an individual's postural stability?

1.4. Dependent Variables

The primary dependent variable of this study was the disability of the participants measured with the Oswestry Disability Index (ODI) and the Biodex Balance System after Kinesio® Tape was applied. A secondary dependent variable of this study was the pain of participants measured with the visual analog scale (VAS).

1.5. Independent Variable

The independent variable of this study was the application of Kinesio® Tape.

1.6. Limitations

This research study was not without limitations due to numerous variables present. One limitation included that the participants of this study ages were restricted to between 18 and 50, hence the results are not generalizable to populations outside of this range. Another limitation was that there is no specific diagnosis of chronic low back pain and is more of a condition that is used when there is absence of other conditions. The literature lacks a definitive etiology and diagnostic criteria for the condition. Thirdly, the participants presented with varying degrees of symptom severity and condition duration, which might be another limitation. A final limitation

was the small sample size (n=6) of this study. Thus, this study should be considered a pilot study.

1.7. Delimitations

To be included in this study, participants had to have been symptomatic for at least three months. Another delimitation of this study, due to time constraints, was that this study was conducted over two sessions and did not include any long-term follow-up.

1.8. Significance of Study

Kinesio® Tape is a therapy used by a multitude of healthcare workers. However, it remains controversial due to a lack of consistent evidence. Kinesio® Tape is a frequent topic for the treatment of low back pain. However, there is limited evidence on the effect the space correction application has on the objective of balance in individuals experiencing symptomatic chronic non-specific low back pain. Overall, this study will help clinicians determine if the space correction technique is a viable therapy option to be used in patients with chronic non-specific low back pain.

1.9. Definitions

Chronic non-specific low back pain: the absence of other pathologies but the experience of chronic pain for at least three months, with or without radiation to the buttocks or legs.^{1,2}

Kinesio® Tape: a kinesthetic tape composed of either 100% cotton and elastic fibers or a blend of cotton/polyester and elastic. It's able to stretch 40-60% of its resting length. Kinesio® Tape is used to restore space, movement and cooling.⁴

Kinesio® Tape Space Correction Method: a Kinesio® Tape application used to create recoil and lift. The tape is applied with 10-35% of its available tension through the center of the tape.⁴

Biodex Balance System: a non-invasive measuring tool that uses a machine that calculates the amount of movement applied to the balance portion of the machine.

Magnetic resonance imaging (MRI): a medical imaging technique that uses a magnetic field and computer-generated radio waves to create detailed images.

Functional magnetic resonance imaging (mfMRI): technique used for measuring and mapping brain activity, through the blood flow, in a non-invasive and safe manner.

Electromyography (EMG): a procedure used to assess how the muscles and nerves function through the use of needles or surface electrodes.

CHAPTER 2: LITERATURE REVIEW

It is estimated that over 80 percent of the United States population will experience low back pain at some point in their life.² Many recover within a few months. However, some will develop chronic low back pain.² Chronic low back pain is the third most common reason for physician visits.¹ Chronic non-specific low back pain is defined as consistent pain occurring in the lumbar or waist region with or without radiation into the buttock or leg lasting for at least three months or occurs repeatedly over a period of six to twelve months.^{1,2} Because of the costliness and commonness of this condition there are many treatments that are being used and investigated for this condition. Kinesio® Tape has become a common therapy for the treatment of chronic low back pain. The purpose of this literature review is to give background information on chronic non-specific low back pain, cover the related anatomy, etiology, Kinesio® Tape, and the Biodex Balance System.

2.1. Low Back Anatomy

Understanding the underlying musculoskeletal anatomy of the low back is vital to comprehension of the etiology of chronic non-specific low back pain. The low back provides many muscle attachments, bony articulations and nerves, ligamentous attachments, and produces multiple motions. Of particular importance to this research study is how the bony and muscular anatomy can contribute to symptoms of chronic non-specific low back pain.

2.1.1. Bony Anatomy

In relation to the low back the bony anatomy consists of the lumbar, sacral and coccyx regions of the spine.⁵ Additionally, it also encompasses the crest and fossa of the ilium. The bony anatomy in the lumbar region consists of five vertebrae and their corresponding intervertebral joints. Of importance to this paper there are major components of the lumbar vertebrae relevant

to chronic non-specific low back pain. These components include the spinous processes, the superior and inferior articular facets and the transverse processes. Each vertebrae forms a joint with the vertebrae beneath it at the articular facets. The spinous processes serve as landmarks when palpating the spine, making it possible to count vertebrae to know approximately where the issues may lie. The transverse processes serve as attachment sites for muscles, tendons and ligaments associated with the lumbar region of the back. The bony anatomy of the sacral region is composed of five fused vertebrae called the sacrum and both superior articular processes and the articular surface with which the sacrum and the illuim form the sacroiliac joint (SI joint). The sacrum serves as attachment for muscles, tendons, and ligaments. Additionally, it serves as a pathway for the spinal cord to exit and branch into peripheral nerves. The articular processes serve as areas where L5 joins with the sacrum to create a joint allowing for movement of the trunk. The SI joint serves as a means of trunk and pelvic motion. The bony anatomy of the coccyx region includes four or more fused vertebrae. These vertebrae serve as attachments for muscles of the pelvis.⁵

2.1.2. Soft Tissue Anatomy

Because there is no known cause of chronic non-specific low back there could be any number of specific soft tissue involvement. However, the specific soft tissues that will be discussed in this section include muscles, ligaments, and the related fascia. The muscles that will be discussed in this section include those that act directly on the vertebrae/spine, those that act on the pelvis and those that simply originate or insert in the lumbar region. The muscles that directly act on the spine include the quadratus lumborum, the erector spinae (specifically the spinalis branch), the multifundi, the rotatores, the intertransversarii, and the interspinalis.⁶ The muscles that have actions in the pelvis relevant to low back pain may include the psoas major, the gluteus

maximus, and the piriformis. Other muscles that may be involved include the abdominal muscles. The ligaments that are relevant to this topic include the supraspinous ligament, the anterior longitudinal ligament, posterior longitudinal ligament, the ligamentum flavums, the interspinous ligaments, the iliolumbar ligament, posterior sacroiliac ligament, posterior sacroccygeal ligaments, sacrotuberous ligament, iliolumbar ligament, anterior sacroiliac ligament, anterior sacroiliac ligament. There is one large fascial structure of importance in regard to chronic non-specific low back pain, that being the thoracolumbar aponeurosis.⁶

Muscles mentioned in the previous section are important for movement of the trunk and spine. For example, the quadratus lumborum, originating on the posterior iliac crest and inserting on the twelfth rib and the transverse processes of the first through fourth lumbar vertebrae, not only serves to laterally flex and assist in extension of the vertebral column but also to stabilize the last rib during forced inhalation and exhalation.⁶ Similarly, the erector spinae, the spinalis branch to be specific, laterally flexes and extends the vertebral column. Another muscle that serves to laterally flex and extend the spine is the intertransversarii. That being said the interspinalis muscles are the main muscles involved in the extension of the vertebral column. Two other muscles that aid in movement and stabilization of the spine include the multifundi and the rotatores muscle groups. They originate inferiorly on the sacrum and transverse processes of the lumbar through cervical vertebrae, as well as the transverse processes of the lumbar through cervical vertebrae column.⁶

Muscles of the pelvis also aid in the movement and stabilization of the trunk. For example, the psoas major originating proximally on the bodies and transverse processes of the lumbar vertebrae and running distally to insert the lesser trochanter of the femur, plays an

important role in the stabilization of the low back.⁶ A special quality of the psoas major is that when a specific section of the muscle is fixed the muscle can act on different areas, i.e. when the origin is fixed the psoas acts on the hip (coxal joint) allowing it to flex. However, when the insertion is fixed the psoas acts on the trunk, specifically flexing the trunk toward the thigh. Another muscle found in the pelvis that is relevant to movement of the trunk is the gluteus maximus. The gluteus maximus, running from the coccyx, edge of the sacrum, and posterior iliac crest to the iliotibial tract and gluteal tuberosity, serves to extend, laterally rotate and abduct the hip (coxal joint). The last muscle found in the pelvis of importance for this literature review is the piriformis muscle. This muscle laterally rotates the hip (coxal joint).⁶

Other muscles that while they aren't directly related to the low back, as they are located more laterally and anteriorly, they do produce motion of the vertebral column. They are the abdominal muscles.⁶ The first one that will be discussed is the external oblique muscles. These muscles, while again located more anteriorly and laterally than previous muscles, serve to produce lateral flexion to the same side and rotation to the opposite side of the vertebral column, as well as flexion of the vertebral column if both the muscles contract at the same time. The other abdominal muscles that produces motion is the internal oblique muscle. This muscle, originating at the lateral inguinal ligament, iliac crest and thoracolumbar fascia and inserting on the lower three ribs, abdominal aponeurosis to linea alba, also produces lateral flexion to the same side of the vertebral column when the muscle contracts unilaterally. However, when the muscles contract together they produce flexion of the vertebral column.⁶

The stability of the spine and low back depends on the ligamentous connections. One of these ligaments includes the supraspinous ligament.⁶ This ligament runs the length of the

posterior vertebral column along the spinous processes of the vertebrae. The anterior longitudinal ligament is another ligament that provides stability to the vertebral column. It runs along the anterior surface of the vertebral bodies. Similarly, the posterior longitudinal ligament is a ligament that runs along the posterior surface of the vertebral bodies. Another group of ligaments that provide stability to the vertebral column is the ligamentum flavums. These ligaments run from the distal anterior side of the spinous process of one vertebra to the proximal anterior side of the spinous process of one vertebra ligaments run from between the spinous processes from posterior to anterior to the ligamentum flavums.⁶

The rest of the ligaments mentioned in the paragraph above provide connections between the bones of the pelvis, providing stability to the joints of the pelvis.⁶ The first ligament is the iliolumbar ligament, which runs from the L4 and L5 transverse processes to the medial iliac crest. The posterior sacroiliac ligaments connect the posterior sacrum to the iliac crest. Another ligament is the posterior sacrococcygeal ligament that connects the posterior coccyx bone to the posterior sacrum above it. The sacrotuberous ligament which connects the sacrum to the ischium posteriorly. Other ligaments on the anterior side of the sacrum and coccyx also serve to provide support the vertebrae/spine. The anterior sacroiliac ligaments connects the anterior sacrum to the iliac crest. The other ligament on the anterior side is the sacrospinous ligament which connects the anterior sacrum to the ilium as well. A final soft tissue structure that, as mentioned earlier is of importance to chronic non-specific low back pain, includes the thoracolumbar aponeurosis. This aponeurosis attaches to the spinous processes of the thoracic and lumbar vertebrae. It is specifically a thick diamonded shaped tendon lying superficially across the posterior thorax, across the sacrum to the posterior iliac crest. It serves to provide an anchor for several muscles including the erector spinae group.⁶

2.2. Chronic Non-Specific Low Back Pain

Chronic non-specific low back pain was the third most common reason for physician visits in 2003.¹ Chronic non-specific low back pain is responsible for high treatment costs, sick leave, and individual suffering, meaning that it is also one of the main reasons that people seek health care. It is also the second most common cause of disability in the United States.² Chronic non-specific low back pain is often defined as pain in the low back for three months or longer, with or without radiating into the buttocks or leg. This diagnosis is often made when an individual experiences prolonged pain in the lumbar or pelvic regions without a discernable cause. There are many theorized causes of chronic non-specific low back pain however, there is no constants in all cases. Therefore, the factors of chronic non-specific low back pain must be analyzed on an individual basis.

2.2.1. Etiology

Low back pain is the leading cause of disability worldwide since 1990.⁷ Some cases of low back pain can be traced to an understood pathological cause. However, in many cases a source cannot be identified and is then termed nonspecific low back pain.^{7–15} When this pain lasts longer than three months, it is termed chronic non-specific low back pain. ^{7–15} There are many theories as to the cause behind chronic non-specific low back pain, some of these include muscle degeneration/deconditioning,^{7,11,14} kinematic/movement imbalances,^{13,15} demographic and social factors,^{8,10} genetics,^{8,12} and psychological factors.^{10,16} Though none of these have been shown to be a single cause, or even causative in, chronic low back pain.

One factor that is theorized to play a role in non-specific chronic low back pain is muscle degeneration and or deconditioning. ^{7,11,14} In a study by Rose-Dulcina et. al. it is stated that deconditioned lumbar extensor muscles have been identified as a risk factor for chronic non-

specific low back pain, though it is difficult to establish any characteristics of deconditioning as a cause of non-specific chronic low back pain or as a result of the pain.⁷ There is also evidence that shows a strong relationship between pain and the location of muscular atrophy, a characteristic of deconditioning.^{7,17} However, there has also been evidence that are contradictory in patients with unilateral pain. This was contradictory because while they had unilateral pain there was presence of either bilateral¹⁸ or ipsilateral muscle atrophy¹⁹⁷. There has also been greater evidence of fiber-type transformations, as opposed to size transformations, in those with nonspecific chronic low back pain.²⁰ Evidence of the other studies have also shown that lower level of back extensors endurance²¹ and higher-level back of extensor fatigue²², these also being a characteristic of deconditioning.⁷ This evidence also suggested that the reduced back extensor endurance is a characteristic of deconditioning that leads to the development of non-specific chronic low back pain. In studies mentioned in Rose-Dulcina, there has been evidence of asymmetrical lumbar erector spinae contraction patterns in non-specific chronic low back pain individuals. This can lead to imbalances in spinal loading and potential spinal injuries.²³ Asymmetrical lumbar muscle fatiguability could contribute to asymmetric back movements and create pain during daily activities. This is the rationale for why Rose-Dulcina et. al. examined individuals with chronic non-specific low back pain and the asymmetry of the lumbar muscles fatiguability when compared to asymptomatic individuals. They used a visual analog scale to measure pain, the Oswestry Disability Index, and the Pain Catastrophizing scale to measure functional disability and pain catastrophizing respectively. The participants were asked to perform the trunk extensor endurance test, also known as the Sorenson test, where they begin in a prone position on an examination couch with their iliac crests aligned with the couches edge, their lower limbs attached to the couch, and their arms folded across their chest. Then, they were

asked to maintain a horizontal position as long as they could. The participants were also asked to rate their perceived exertion every 15 seconds on the Borg CR-10 scale. EMG signals were assessed using active surface electrodes, bilaterally placed on the erector spinae longissimus muscle and the lumbar multifundi muscles. The results of this study revealed that the non-specific chronic low back pain participants had significant shorter endurance than the asymptomatic participants. Although there was no significance found in the measures of fatiguability between the participants, there was also no differences in the asymmetry parameters of the study. Meaning that while non-specific chronic low back pain participants it didn't appear to be due to fatiguability.⁷

In an article by Valdivieso et. al. it is stated that muscle deconditioning can be due to congenital or acquired lowering of muscle activity.¹¹ This can cause a constant overloading of the lumbar muscles and increase fatigue within these muscles, ultimately leading to chronic non-specific low back pain. However, muscle deconditioning can also be a consequence of chronic low back pain. It is believed that the lumbar trunk muscles undergo an acute-to-chronic phase remodeling that ends with reduced cross-sectional area of these muscles.²⁴ The decreased usage of the muscles result in reductive remodeling of tissue leading to a shift from slow to fast twitch muscle fiber type, decreased force output and fatigue resistance, a lower neural activation, reduced metabolic supply and diminished local oxidative capacity.²⁵ It is understood that primary effect of mechanical stimuli, i.e. muscle contraction, produce a significant increase in cardiac output followed by increase in blood volume. Back muscle strength and endurance through the use of dependent vascular profusion may be a critical event in the etiology and progression of chronic low back pain. It is also suggested that lack of dynamic back muscle work is a possible

causal factor leading to deconditioning through rarefaction of capillaries and reduced aerobic capacity.¹¹

In another study by Goubert et. al. researchers divided low back pain patients into two groups, a chronic low back pain group and a recurrent low back pain group.¹⁴ The participants underwent 3-Tesla Siemens Trio-Tim whole-body MRI to acquire T-1 weighted and T-2 weighted images. T-1 weighted images were used to evaluate muscle cross-sectional area and fat infiltration, and mfMRI was also used to evaluate muscle activity. T-2 weighted images were taken after 20 minutes of rest and immediately after an exercise was performed. After the exercise the participants were asked to rate their perceived exertion. They assessed these images and activity within the lumbar multifundi and erector spinae muscles. Results of this study indicated that there were no differences in left and right multifundi or erector spinae crosssectional are or muscle fat infiltration. There were however differences found between groups for fat cross-sectional area in the multifundi and erector spinae and for muscle fat infiltration in the multifundi and erector spinae. There were significant differences found between groups in the T2-rest images of the multifundi muscle. Fat cross-section area was significantly higher in chronic low back pain when compared to recurrent low back pain. Another result indicated that there was a difference in the rate of perceived exertion, which was significantly lower in the recurrent low back pain group than in the chronic low back pain group. This all correlates with other studies in that no difference in overall cross-sectional area has been observed in chronic low back pain patients. However, there is greater fat infiltration and therefore decreased muscle quality in chronic low back pain.¹⁴

A study by Haj et. al. focused less on intricate muscle deconditioning factors and more on kinematic muscle movements, the researchers observed fifty males total for lumbar axial

rotation.¹³ The study consisted of 25 chronic low back pain participants and 25 control participants. Chronic low back pain patients were asked to quantify pain level on visual analog scale and complete a Rolland Morris Disability Questionnaire before completing the evaluations. Wireless industrial lumbar motion monitors were used to assess axial ROM velocity and angular acceleration of lumbar rotation in an upright standing position and with full forward bending. All values were significantly lower in non-specific chronic low back pain participants than in the healthy participants, asymmetry in lumbar rotation only found in neutral stance in chronic nonspecific low back pain. In most cases there was also a significant decrease in lumbar rotation demonstrated when moving from a neutral stance to a fully forward bending stance. This is later discussed in the discussion portion of the article, and it's stated that these results can all be explained on a mechanical basis, meaning that chronic low back pain can result from ongoing postural deficit creating an abnormal movement resulting in repeated low intensity overloads, mechanical instability, increased spinal tissue tension, spinal muscle spasms, back pain ending with limited ROM. These results also indicated that velocity of rotation can be affected by neuromuscular coordination, individual motivation, skill, muscle power and physiological flexibility.¹³

Another study that investigated kinematic differences in chronic low back pain is by Rum et. al.¹⁵ This study has a total of 22 participants, 11 chronic low back pain and 11 healthy controls. They evaluated chronic pain with the use of a visual analog scale. The Oswestry Disability Index and Tampa Scale of Kinesiophobia were used to assess disability related to daily activities and fear of self-damaging during movement. Kinematic movement was assessed using a motion capture system that had seven infrared cameras that could reconstruct 3-D positioning of 35 retro-reflective markers placed on bone landmarks. They also used a dynamometric

platform embedded in the floor to measure ground reaction forces. Surface EMG was used to record muscular activity of lumbar erector spinae and external obliques of participants. The participants were asked to walk straight at a comfortable pace while fixing gaze on black target on the end of a 10-meter walkway. The participants performed ten unconstrained walking trials at most comfortable speed and then a block of 60 walking trials during which a stopping signal was randomly delivered, requiring the sudden termination of gait. The results of this study indicated that there were similar walking speeds between the groups. During the walking at a comfortable pace phase of the study thorax sagittal ROM and lumbar transverse ROM were greater in the chronic low back pain group. Another main finding was that there was greater upper body movement variability during both walking and gait termination in the chronic low back pain group, paired with altered bilateral coactivation of the lumbar erector spinae in gait termination. The differences in chronic low back pain neuromuscular activation appeared to be due to the mechanical requirements of gait termination, likely due to the participant attempting to increase spinal stiffness before stopping action.¹⁵

Another theorized cause of chronic non-specific low back pain is social and demographic causes.^{8,10} In a case-crossover study analyzed by Hartvigsen et. al., they found that work exposures of lifting, bending, awkward postures and tasks considered physically demanding and increased the risk of develop low back pain.⁸ There was also evidence of chronic low back pain affecting low income and those individuals who didn't finish school/had a short education disproportionately. This may be explained by environmental and lifestyle exposures in lower socio-economic groups, lower health literacy and less availability or access to health care. There is also evidence that as mentioned earlier being in routine and manual occupations are associated with chronic low back pain.⁸ Other factors may include having a less satisfying job/work or

having higher physical workloads are also associated with development of disabling chronic low back pain. Other social factors that have been theorized to be associated with chronic pain includes the individuals work compensation system, workplace disputes, work and or family tensions and cultural tensions affecting beliefs. Again, the evidence cannot differentiate whether these factors are the cause of chronic low back pain or whether it is caused by chronic low back pain.¹⁰

A more recent theorized cause of low back pain includes a genetic component.^{8,12} In a systematic review analyzed by Hartvigsen et. al. they found a range of genetic influence from 21-67%, with a greater incidence for more chronic and disabling low back pain.⁸ In an article from Aroke et. al., there is an estimate that about 46-75% of low back pain is inheritable.¹² Evidence attests to the role of epigenetics in many chronic pain conditions. Epigenetics is a mechanism in which environment can directly enhance or suppress gene expression without changes to the DNA sequence. Epigenetics underlie the development of many chronic pain conditions such as fibromyalgia, chronic postoperative pain and possibly chronic low back pain. Hartvigsen analyzed the whole blood of about 50 participants in a separate study about low back pain. Pain severity assessed using Brief Pain Inventory – Short Form. Forty-eight pain free controls were also enrolled in the study. Venous blood samples were collected using ethylenediamine-tetra-acetic acid tubes. The samples were then centrifuged for ten minutes at room temperature, the plasma and buffy coat were isolated, aliquoted and stored at -80 degrees Celsius until DNA extraction. Genomic DNA was then extracted and quantified on NanoDrop 2000. The DNA was then digested by enzymes and fragments were ligated with adaptors and C to T converted strands sequenced on NextSeq 500 to generate raw reads. Raw reads were then cleaned and adapters removed, then aligned and mapped to human reference genome. Reads with

multiple mapping were discarded and reads with unique alignments were identified, used kits to identify CpG sites, normalize, and perform differential methylation. Results indicated that samples show clustering especially among individuals with chronic low back pain. A principal component analysis was performed and was found that two major principal components were indicated where two potential DNA methylation patterns were identified. 159 DMRs were identified and the genomic distribution of the DMRs were also identified and then annotated. A majority of the DMRs located on chromosome 1 followed by chromosome 19 and chromosome 2. Functional genomic analyses were performed and indicated that a majority of differentially methylated CpGs in protein encoding genes, specifically the genes CELSRI, KIFFI, MINKI, and NAVI. Most of these were found to be hypomethylated in individuals with chronic low back pain. Hypomethylation being associated with gene expression and hypermethylation has been associated with gene silencing. Findings of this study suggested increased expression of NAVI and KIFFI affects chronic low back pain. This study found that regions of the CELSRI and MINKI genes were hypermethylated in the chronic low back pain group when compared to the healthy control groups. This is all important because the vertebral column is formed through differentiation of chondrocytes and bone mineralization. This study found that the pathways associated with negative regulation of chondrocyte development and bone mineralization are differentially enriched in individuals with chronic low back pain. With the study article in the discussion section, it is stated that it is possible that chronic non-specific low back pain may be associated to epigenetic modifications that alter chondrocyte to osteoblast ossification. There was also evidence in samples of the SPARC gene of hypermethylation in individuals with chronic low back pain, suggesting that epigenetic changes of the matrix of the vertebral column may play a role in chronic low back pain. It is stated that environmental factors that may occur during an individual's lifespan that may influence normal physiology and increase disease risk.¹²

A final theorized factor of chronic low back pain are psychological factors.^{10,16} There has been evidence that factors such as maladaptive coping strategies, (i.e. negative thinking), pathological fear and abnormal anxiety regarding pain, avoidant behavior, catastrophizing and hyper-vigilance have been associated with high levels of pain, disability and muscle guarding.¹⁰ A study by Shanbehzadeh et. al. assessed the attention demands of postural control in chronic non-specific low back pain. Moreover, they also assessed the difference between individuals with high and low pain-related anxiety.¹⁶ The human body is inherently unstable in standing positions. The human body maintains a standing position through the integration of sensory input from vestibular, visual and proprioception systems. During challenging conditions, the central nervous system relies on the most reliable sense to provide optimized control. Previous studies have shown that impaired proprioception inputs from the lumbo-pelvic region in chronic low back pain. Studies reporting on postural control impairments in chronic low back pain emphasize the impact of psychological aspects of pain as factor of pain intensity, suggesting that higher pain intensities and threat value of pain could affect motor control and therefore incidence and chronicity of low back pain. In the study by Shanbehzadeh et. al. they recruited patients who were 18-45 with no history of vestibular, cognitive or anxiety disorder, previous spinal surgery, radicular pathology musculoskeletal problems and not taking any medications that alter postural control or cognitive processes. The chronic low back pain participants were divided into two groups: individuals with low pain-related anxiety and individuals with high-pain related anxiety based on a cut-off score of 30 on the Pain Anxiety Symptom Scale. A visual analog score, the Oswestry Disability Index, and the State-Trait anxiety inventory were also used to assess pain,

disability and anxiety. Participants rated their pain before and after testing on a visual analog scale and rate the intensity of pain that the participants anticipated with performing the test. The test included custom-vibrators attached to the participants Achilles tendon and tibialis anterior tendon. A cognitive task was also performed during the postural task. Postural sway data were collected using force platforms while an auditory stroop task was performed, specifically a recording of the words high and low was played and the participant was asked to identify what pitch the word was said as quickly and accurately as possible. Four postural conditions were completed with and without the cognitive task. In all conditions the participants stood relaxed with toes and heel touching, head erect, and arms hanging at their sides on a force plate and were asked not to move limbs and head during testing. The conditions included eyes open with and without vibration, eyes closed with and without vibration, all of these performed with and without the cognitive task. This study found the participants in the high pain-related anxiety group anticipated greater pain than what they felt during the testing. They also indicated that regardless of test condition participants in the high pain-related anxiety group had smaller and greater amounts of postural sway than the other group. This may be explained by the effect of anxiety on the threat assessment system. Participants with high pain-related anxiety anticipated greater pain seeming to have modified postural control strategy in a manner to protect the spine through adopting a stiffening strategy. Participants with low pain-related anxiety show now postural control changes during dual tasking and participants with high pain-related anxiety showed longer reaction times with increasing difficulty of standing postural task indicating that anxiety may have affected postural control as the postural tasks became more difficult.¹⁶

With the articles reviewed it became apparent that while there are many theorized causes with some evidence that might support those theories. Almost all the literature states that there

was no indication whether the theorized causes were causes of chronic low back pain or whether the chronic low back pain results in the theorized causes. There has also been speculation that the causes of low back pain, especially chronic non-specific low back pain is a multifactorial issue and cannot be boiled down to a single factor.¹⁰ However, there is very little research behind this theory.

2.3. Kinesio® Tape

Kinesio® Tape was first invented in the 1970's by Dr. Kenzo Kase.⁴ It was initially used in Japanese rehab hospitals. It gained traction quickly, especially after its use in the 1988 Olympics. However, it wasn't introduced into the United States until 1995.⁴

2.3.1. Characteristics

Kinesio® Tape is different than conventional taping methods in multiple ways. Unlike Athletic and McConnel taping, where the goal is to limit motion of all tissues in an area whether they are injured or healthy using compressive forces, Kinesio® Tape allows a clinician to target specific tissues depending on the cut and tension of the tape.⁴ Kinesio® Tape also allows a normal ROM and has benefits achieved through both compressive and decompressive forces.⁴

Specific unique qualities of Kinesio® Tape include that the tape, depending on its type, is made of either 100% cotton and elastic fibers or a blend of cotton/polyester and elastic fibers making it possible for the tapes weight and thickness to resemble the skin.⁴ Kinesio® Tape uses 100% medical grade acrylic for the adhesive, is latex free and heat activated. Another unique quality of Kinesio® Tape is that on the paper backing of the roll there are lines dividing it into two inch by two inch boxes, called blocks, allowing for easy measurement. The tape is applied to the paper backing with a 10% stretch. More importantly the tape can stretch 40-60% of its resting length along its longitudinal axis.⁴

Claims of the Kinesio® Tape method is that it is effective because of its ability to restore space, movement, and cooling.⁴ The tape can create space because of the lift created when the tape is applied to the skin. This creates separation of tissues and allows for movement of the fluid, specifically lymph and blood, that were trapped in the compressed tissues. The movement of these fluids and the space produced by the removal of these fluids provides a cooling effect.⁴

There are different kinds of Kinesio® Tape, each slated for a specific use.⁴ These include the Kinesio Tex Classic, Kinesio Tex Classic Performance Plus, Kinesio Tex Gold FP, and Kinesio Tex Gold Light Touch Plus (LT). Because the Kinesio Tex Classic is best used for high tension applications on healthy skin, this is the type of Kinesio® Tape that will be used in this study. Unique qualities of the Kinesio Tex Classic includes that it is made with 100% high grade cotton allowing both breathability and comfort. Another feature allowing for breathability and comfort is that of the wave pattern of the adhesive on the tape.⁴

2.3.2. Methods of Application

There are many ways to apply Kinesio® Tape to the body. The application is dependent on what tissues the clinician wishes to target and their treatment goal.⁴ Kinesio® Tape is claimed to be able to target different types of tissues including the tissues of the epidermis and dermis including fascia, circulatory and lymphatic tissue, nervous system tissue, and muscle, tendon and ligamentous tissue.⁴ There is evidence that different cuts of Kinesio® Tape and different tensions applied to Kinesio® Tape will dictate how and what kind of tissues the tape will affect. The basic cuts of tape include the web cut, the I strip, the Y strip, a fan cut, an X cut and a Donut Hole cut. These all produce tension over tissues in a specific way and are assigned different levels of stimulus based on the way in which the tension is disbursed through the tape.⁴

Armed with this information and looking at the existing literature on Kinesio® Tape and chronic non-specific low back pain, there was very little similarity in the methods of application throughout various studies. A systematic review conducted by Sheng et al. showed that in the eight included studies applications used were I-shaped cuts, Y-shaped cuts, and asterisk shaped cuts; however, there were eight different ways in which these cuts were applied and no tensions of the tapes were mentioned.²⁶ In a study by Castro-Sanchez et al. I-strips were used in a specific pattern, called a star pattern, over the maximum point of pain with 25% tension.²⁷ And yet in a study by Abbasi et al. the intervention was placing a waterproof adhesive tape on the participants for 72 hours, stating it was applied in a star shape but tension was given as 15-25%, there was no standardization of the tensions.²⁸ In a final study by da Luz et al. it is stated that "Kinesio Tex Classic tape was used and applied over the erector spinae muscle with 10-15% tension", but no mention of what kind of cut was used.²⁹

In conclusion there is very little standardization of procedures within the existing literature, so it is very difficult to apply results to everyday clinical application. It is difficult to state that Kinesio® Tape improves or does not improve chronic non-specific low back pain when the results cannot be compared between studies in the available literature because there is very little generalization within the procedures of said literature. With that being said the fact that with chronic, and specifically non-specific, low back pain there is not an understandable cause to the pain or disability. Maybe there isn't a way to standardize Kinesio® Tape applications and may need to be applied on an individual basis.

2.3.3. Kinesio® Tape and Chronic Non-specific Low Back Pain

Multiple studies have been conducted assessing treatment of low back pain through various Kinesio® Tape techniques.^{27,29} One study conducted in Spain evaluated people with

chronic low back pain of mechanical etiology.²⁷ The primary purpose of the study was to assess whether Kinesio® Tape applied for one week affects disability, pain, kinesiophobia, range of motion, and trunk muscular endurance. Additionally, the researchers examined residual effects of the Kinesio® Tape treatment four weeks later. Participants in this study included a total of 60 individuals between the ages of 18-65 years. Inclusion criteria were chronic low back pain for at least three months, a four or greater on the Roland-Morris Low Back Pain and Disability Questionnaire, and an inability to achieve flexion-relaxation in their lumbar muscles during trunk flexion. It is also important to note that analgesic and anti-inflammatory medications were requested to be ceased at least three days prior to baseline measurements. The participants were placed into either the experimental or placebo group. In the experimental group, the Kinesio® Tape application included four I-strips at 25% tension overlapping in a star shape, starting from the center of the strip and laying to the ends over the maximum point of pain. In the placebo group, the tape application included a single I-strip applied transversely just above the maximum point of pain. Once the appropriate Kinesio® Tape application was applied, baseline measurements were conducted.²⁷

Several tools were used to examine the effectiveness of the Kinesio® Tape applications utilized in Castro-Sanchez's study.²⁷ Two different questionnaires were used to assess disability including the Oswestry Disability Index and the Roland-Morris Disability Questionnaire. Additionally, pain was assessed using a 10-cm visual analog scale and kinesiophobia was evaluated via the Tampa Scale for Kinesiophobia. Objective measurements of trunk flexion were conducted using a fleximeter. Finally, isometric endurance was measured in seconds using the McQuade test. The McQuade test is started with the participant in a sitting position both with their hips and knees bent to 90 degrees. The participant places their arms across their chest with

hands resting on the contralateral shoulder. They are then asked to lean back against a board positioned at an incline of 60 degrees while keeping the head in a neutral position. The abdominal muscles are then engaged to maintain the position, and a neutral spine. The goal of this test was to hold the position for as long as possible, and the participant's back must not touch the board at any point in time. The test was concluded when there is any change in trunk position. The test in this study was measured in seconds.²⁷

Based on the results, it can be concluded that the Kinesio® Tape application resulted in improvements in almost all measures evaluated and by greater degree than the control group (Table 1). The experimental group improved at the one-week evaluation for every component measured, although not always at a statistically significant level.²⁷ However, all effects seem to be short-term and are not as effective four weeks post tape removal. Because there was still some improvement in the control group, there is some question as to whether the results were from the use of Kinesio® Tape itself or from the specific application technique of the tape. If a different brand of tape had been used in the control group there may have been a different degree of difference between the Kinesio® Tape group and the control group.²⁷

Μ	ean Outcomes and I	Differences Betwee	n Groups
Outcome	Experimental Group	Control Group	Difference between Groups
Oswestry Disability Index (score of 0-	Baseline: 28	Baseline: 29	
100)	W1: 26	W1: 31	W1: -4 (95% CI 2 to 6)
	W5: 26	W5: 27	W5: 1 (95% CI -1 to 3)
Roland-Morris Disability	Baseline: 10.9	Baseline: 9.8	
Questionnaire (score of 0-10)	W1: 9.5	W1: 9.6	W1: -1.2 (95% CI 0.4 to 2.0)
01 0 10)	W5: 9.8	W5: 8.6	W5: 0.1 (95% CI -1 to 1.3)
Pain Visual Analogue Scale (score of 0-10)	Baseline: 5.6	Baseline: 5.4	
	W1: 4.2	W1: 5.1	W1: -1.1 (95% CI 0.3 to 1.9)
Tampa Scale for	W5: 4.7 Baseline: 41	W5: 5.6 Baseline: 39	W5: -1 (95% CI 0.2 to1.7)
Kinesiophobia (score of 17-68)	W1: 39	W1: 38	W1: -0.7 (95% CI -1.5 to 0.2)
	W5: 39	W5: 38	W5: -0.1 (95% CI -0.9 to 0.7)
Trunk Flexion ROM (degrees)	Baseline: 94	Baseline: 90	
(8)	W1: 98	W1: 92	W1: 2.6 (95% CI 0 to5)
MaQuada tast for	W5: 97 Baseline: 41	W5: 94 Baseline: 49	W5: -0.1(95% CI -3 to 3)
McQuade test for Trunk muscle			
endurance (sec)	W1: 54	W1: 39	W1: 23(95% CI 14 to 32)
Abbreviations: B. baseline	W5: 49	W5: 39	W5: 18 (95% CI 9 to 26)

 Table 1. Mean Outcomes and Differences Between Groups

Abbreviations: B, baseline; W1, Week 1; W5, Week 5 ^aAdapted from Castro-Sánchez et al.²⁷

In a separate study, researchers evaluated the effectiveness of Kinesio® Tape for treating low back pain compared to another brand of tape.²⁹ This study included a sample of 60 participants between 18-80 years of age. Participants were referred by a physician, had no

physical therapy within the last six months, and had no prior use or knowledge of the Kinesio® Tape technique. Participants were randomized into three groups including the experimental group, a placebo group, or control group. The experimental group received Kinesio® Tape treatment in the form of I-strips applied over the erector spinae with 10-15% tension with the muscle on stretch. The placebo group received a micropore tape that was also applied over the erector spinae with the muscle on stretch. The placebo group received a micropore tape that was also applied over the erector spinae with the muscle on stretch. The control group received no taping intervention. In contrast to the previously mentioned study where researchers objectively measured muscular endurance and range of motion,³⁰ the researchers in this study only analyzed subjective measures of pain intensity and disability of participants.³¹ These qualities were evaluated through the use of numeric scale 0-10 for pain intensity and a Brazilian version of the Roland-Morris Disability Questionnaire for disability.²⁹

Researchers found that while there was a decrease in disability in the Kinesio® Tape group (Table 2), it was not enough to be considered clinically relevant after 48 hours, and pain outcomes between groups were not statistically significant.²⁹ There was no statistically significant difference between the groups, except in the disability component of this study between the Kinesio® Tape and control groups at the 48-hour evaluation (p=.003). There was no significant difference in disability at the 48-hour evaluation between the Kinesio® Tape and micropore groups (p=.08), or between the micropore and control groups (p=.22). No statistically significant difference in pain was noted at the 48-hour evaluation between the Kinesio® Tape and micropore groups (p=.82), between the Kinesio® Tape and control groups (p=.09), or between the micropore and control groups (p=.09), or between the micropore and control groups (p=.54), the Kinesio® Tape and micropore groups (p=.76), or the micropore and control groups (p=.75). No statistically

significant difference in disability was recorded at the 7-day evaluation between the Kinesio® Tape and micropore groups (p=.11), the Kinesio® Tape and control groups (p=.08), and the micropore and control groups (p=.89). This study did not record or limit medication use, and therefore stated within their article that the use of a wide range of medications by participants may have swayed the outcomes. From these results, we can see that the Kinesio® Tape outcomes were like that of the micropore tape, possibly making the inference that the effects of Kinesio® Tape are similar to that of the placebo effect.²⁹

	Mean	Outcomes	
Outcome	Kinesio [®] Tape	Micropore	Control Group
	Group	Group	
Disability	B: 12.8	B: 12.2	B: 11.8
(score out of 24)			48: 10.6
	48: 8.6	48: 9.4	7: 10.3
	7: 9.6	7: 10.2	
Pain Intensity	B: 6.6	B: 6.7	B: 6.1
(score out of 10)			48: 5.4
	48: 4.9	48: 5.1	7: 5.5
	7: 5.4	7: 6.3	

Table 2. Mean Outcomes

Abbreviations: B, baseline; 48, 48-hour evaluation; 7, 7 days later ^aAdapted from da Luz et al.²⁹

Statistically, the between-group results were not significant; however clinically they can be seen as significant because for measures of both pain and disability, the Kinesio® Tape group displayed a large decrease from the baseline measurement to the evaluation 48-hours later.²⁹ However, these results are not the same even a week later. The Kinesio® Tape group increased in both disability and pain, indicating they worsened from their 48-hour evaluation. The micropore tape group had similar results but to a lesser degree. This may be explained by the fact that the micropore tape possibly has different manufacturing regulations and qualities, therefore making the effect that it has on the body similar but not as effective. Another explanation for this difference may be that the Kinesio® Tape provides more, or different, feedback providing the participant with better results.²⁹

In another study researchers investigated the effects of Kinesio® Tape with physiotherapy on lumbar range of motion, pain and disability.³² They also evaluated the effects of Kinesio® Tape technique versus a sham taping technique. This study included participants who were 18-65 years old who were experiencing chronic, non-specific low back pain for at least three months without any leg pain and a visual analog score greater than three. The participants could not have any neurological deficits, surgical history, inflammatory low back pain, active psychiatric disease, previous low back Kinesio® Tape, skin diseases, any Kinesio® Tape contraindications or use of medications. Once criteria were met, participants were randomized into four groups via block randomization. Participants were randomized into four groups which included a control group, a placebo group, and two different experimental groups. All participants were given the same modalities and exercises. Modalities included superficial heating via moist heating pack for 20 minutes in a prone position five times a week for a total of three weeks. Also included was a 25-minute TENS treatment at a frequency of 100 Hz, pulse duration of 100 u/s at a sensory level amplitude via four electrodes over the painful area. The exercises given to the participants included trunk flexion and extension exercises, stretching and mobilization exercises, as well as postural exercises. Participants performed these exercises under the supervision of a physiotherapist five days a week for three weeks and were then instructed to continue the exercises twice a day and continue after the treatment.³²

Multiple groups received a different Kinesio® Tape application to assess the effectiveness of the different application techniques.³² The two experimental and the placebo

group received a Kinesio[®] Tape application a total of three weeks in five-day intervals. The control group received no tape, just the modalities and exercises. The placebo group received a sham taping. This taping used Kinesio® Tape (5cmx20cm) that was applied horizontally on a defined region of pain with no tension. The first experimental group received a Kinesio® Tape technique that involved four I-strips (5cmx20cm), the purpose of which is a space correction, meaning that they are creating space between tissues. The first I-strip was placed horizontally with the participant in an upright position at the highest point of pain with 25-35% tension in the center of the tape and without tension at the ends. A second I-strip was placed vertically with the participant in a forward flexed position at the highest point of pain with 25-35% tension in the center of the tape and without tension at the ends. Two final I-strips were placed in opposite oblique directions with the participant in a rotated and flexed towards the contralateral region at the highest point of pain with 25-35% tension in the center of the tape and without tension at the ends. The second experimental group received a Kinesio® Tape technique that involved two Istrips (5cmx35cm), the purpose of which is a fascial correction, meaning that they are trying to realign the fascial tissues. This was applied with the end starting on the sacral paravertebral region without tension with the participant in an upright position, the rest of the tape was then applied along the lumbar paravertebral region with 10-50% tension using oscillating motion with the participant in the max forward flexed position and the end point applied with no tension. This technique was done bilaterally.³²

Evaluations of participants were done at baseline (day 0), at the end of treatment (day 21), and one month post treatment (day 51). These evaluations included outcomes for pain severity, lumbar range of motion, and levels of disability.³² Pain outcome was measured with the use of a 10-cm visual analog scale (VAS), assessed during activity (VASactivity), at rest

(VASrest) and during the night (VASrest). Range of motion was evaluated with the modified Schober test and fingertip-to-floor distance (FTF). Disability was measured with the Oswestry Disability Index(ODI) and the Roland-Morris Disability Questionnaire (RMDQ).³²

There were 125 participants at the start of the study; however, at the conclusion of the study only 51 participants were retained. Results, shown in Table 3, for the per-protocol analysis indicated that there were statistically significant differences in all categories of time and the categories of VASactivity, FTF left lateral, ODI, and RMDQ for time group interaction.³²

Interaction Effects of Group and Time (Per-Protocol Analysis)				
	Time	Group	Time/group interaction	
VASactivity	< 0.001	0.249	0.027	
VASresting	< 0.001	0.221	0.624	
VASnight	< 0.001	0.371	0.560	
Schober	0.006	0.434	0.336	
FTF anterior	0.002	0.267	0.085	
FTF right lateral	< 0.001	0.091	0.146	
FTF left lateral	< 0.001	0.108	0.036	
ODI	< 0.001	0.321	0.003	
RMDQ	< 0.001	0.550	0.003	

Table 3. Interaction Effects of Group and Time (Per-Protocol Analysis)

Abbreviations: VAS: Visual Analog Scale; FTF: fingertip-to-floor distance; ODI: Oswestry Disability Index; RMDQ: Roland Morris Disability Questionnaire Adapted from Mengi et. al.³²

In conclusion, this study showed, like the previous studies, that time had a significant effect on Kinesio® Tape's effectiveness.³² Specifically, that over time if the tape is continually applied, and applied properly then Kinesio® Tape can have positive effects on both pain and functionality. However, once application is stopped the effects begin to taper, and eventually discontinue altogether.³²

A ranodmized control trial by Castro-Sanchez et. al. was conducted to assess the short-

term effects of Kinesio® Tape versus a placebo tape on the lumbar spine in individuals with

chronic non-specific low back pain.³³ To be included in this study individuals had to have had low back pain for at least 3 months, be between the ages of 18 and 65 years of age and score a four or greater on the Roland-Morris Disability Questionnaire, as well as the inability to achieve flexion-relaxation in the lumbar region. The participants could not have clinical signs of radiculopathy, lumbar stenosis, fibromyalgia, spondylolisthesis, previous spinal surgery or Kinesio[®] Tape therapy, corticosteroid treatment within the previous two weeks, and central or peripheral nervous system disease. Individuals that met inclusion criteria for this study were randomly assigned to an experimental group or a control group. The experimental group was asked to sit and four I-strips of Kinesio® Tape were applied to the participants back at 25% tension in an overlapping star pattern over the point of their maximum pain. The control group received a single Kinesio® Tape I-strip that was applied transversely just above the point of maximum pain. Participants were sent home and were instructed to keep the tape on for seven days, outcomes were then measured on day seven and four weeks later. The outcome measures included in this study were disability, measured through the use of the Oswestry Disability Index and The Roland-Morris Disability Questionnaire, pain, measured via a 10 cm visual analog scale. Fear of movement, measured with the Tampa Scale of Kinesiophobia, trunk flexion range of motion measured with a fleximeter and isometric endurance using the McQuade test were also included as outcome measures.³³

A total of 60 people was included in this study. Results of the one-week session indicated that there was statistically significant improvement in the disability outcome measures, though there was no statistical difference at four-week session.³³ Results also indicated that there was a significant improvement in the pain outcome for the experimental group at one week session that remained four weeks later. There were no significant differences were noted in the fear of

movement outcome, ROM motion outcome showed a three degree increase in the experimental group at one week, but it was not maintained at the four-week session. However, the endurance outcome had significant improvement at one week and was maintained at the four week session.³³

In a study conducted by Toprak et. al., like the one being proposed in chapter 3, researchers found that pain intensity of the participants decreased, static overall and frontal plane stability was improved, and dynamic overall and sagittal plane improved.³⁴ This study was designed as a case series design. The study included 101 individuals who were between the age of 20 and 65 with non-specific chronic low back pain. The researchers of this study chose to assess demographic information including age, gender, weight, height, smoking, alcohol consumption and exercise habits, as well as body mass index (BMI), postural stability and pain intensity. Postural stability and pain intensity were taken as a baseline and 45 minutes after the tape had been applied. Disability and pain intensity were assessed using the Oswestry Disability Index and postural stability was assessed using the Biodex Balance System, in both a static and dynamic mode in a bilateral standing position. The specific tape application used was a combination of muscle and ligament techniques. Two I strips were applied vertically from the lower posterior iliac crest along the paravertebral muscles to the upper twelfth rib at 10-15% tension with the participant in lumbar flexion and lumbar rotation to the opposite side. A separate two I strips were applied diagonally across the sacrum with a tension of 50-75%.³⁴

2.4. Biodex Balance System

2.4.1. Definition and Purpose

The Biodex balance system was first introduced into research and the clinic in the 1990s.³⁵ The Biodex balance system is a multiaxial device that allows clinicians quantitatively

measure the ability of an individual to maintain their posture during static and dynamic conditions.^{35–38} Biodex has a circular platform that can move in the anterior and posterior and medial and lateral directions. The Biodex allows for 20 degrees of tilt on the platform. It has five test protocols and six training modes, allowing it to be used as balance assessment tool. It also features adjustable support handles, a 12.1-inch high-resolution color touch screen with LCD display, and a color printer with stand for printing results of assessments. It produces three stability indices: mediolateral stability index, anteroposterior stability index and overall stability index. Another feature is that the stability of the platform is dependent on the amount of resistance that is offered from springs found underneath the platform. Stability of the platform ranges from one to eight with one being the greatest instability and eight being the lowest instability. It also allows for neuromuscular assessment because of its ability to quantify the individual's ability to maintain static and dynamic postural stability on both stable and unstable surfaces. ^{35–38}

2.4.2. Validity and Reliability

Validity is the ability of a test to assess what it's supposed to test. Reliability is the ability to easily repeat the test with similar results. While the Biodex balance system has been around for multiple decades there is little literature on the validity and reliability, specifically for the different tests and trainings that the Biodex offers. In one study by Dawson et. al. researchers assessed the reliability of commonly used postural stability assessment tools including the Biodex balance system.³⁵ The participants of Dawson's study performed the Timed-up-and-go (TUG) test, the FFST test, and the Biodex, specifically the Limits of Stability (LOS) and modified-Clinical Test of Sensory Organization and Balance (mCTSIB) tests of the Biodex system. Dawson found that the LOS tests overall percentage, the tug and FSST have strong to

excellent test-retest reliability. The results also showed that the mCTSIB stability indices demonstrated a strong test-retest reliability. Another outcome they were assessing was validity and, in these terms, the intercorrelations between measures indicated that poor construct validity among all measures tested meaning that each of the assessments tested are measuring different aspects of the individuals balance and cannot be used interchangeably.³⁵

Similarly, a study by Sherafat et. al. that assessed the reliability of the Biodex balance system between participants with and without non-specific low back pain.³⁷ In this study they had 15 chronic low back pain participants and 15 healthy matched individuals. The participants were asked to complete a postural task and a cognitive task in multiple conditions. The cognitive task included a modified stroop task where the participant was asked to name the pitch the words high and low were said in. The postural task included the participants standing on the Biodex balance system while experiencing eight separate conditions including: a postural task at level five platform stability with eyes open, a postural and cognitive task at level five stability with eyes open, a postural task at level five stability with eyes closed, a postural and cognitive task at level five stability with eyes closed, a postural task at level three stability with eyes open, a postural and cognitive task at level three stability with eyes open, a postural task at level three stability with eyes closed, and a postural and cognitive task at level three stability with eyes closed. The results found that there were no significant differences in the mean values of the Biodex stability indices (anteroposterior stability index, the mediolateral stability index, the overall stability index) between the test and retest sessions in most of the conditions. Also, they found that the intersession reliability of the Biodex indices had stronger values in the chronic low back pain group than the healthy individuals. A third finding was that the tests performed with eyes closed had a higher intersession and intrasession reliability than the tests with eyes open.

There were higher intersession reliability results in the level five stability versus the level three stability, and higher in chronic low back pain than in the healthy individuals. This all indicates that there is higher reliability within the Biodex balance system when certain conditions are performed and when chronic low back pain patients are assessed versus when healthy individuals are assessed.³⁷

In a third study by Pickerill et. al., researchers assessed the validity and reliability of a specific testing found in the Biodex balance system and other postural stability devices on healthy university students.³⁶ This test, termed the limits-of-stability (LOS) test. The LOS test on the Biodex balance system consists of participants moving a cursor by leaning toward a target while standing on the unstable platform. Participants are to finish the test as accurately and quickly as possible while keeping their body in a straight line. The test measures the time and accuracy with which participants can transfer their center of gravity. The LOS test from the other postural stability device selected, the NeuroCom Smart Balance Master uses a two-force plate structure connected by a pin joint with four transducers oriented vertically and one oriented horizontally. This LOS test requires participants to transfers their center of gravity while standing stable on the force plates towards targets represented on a computer monitor. Interclass correlation results of this study show that there were no differences. However, when data were collapsed across session and outcome means analyzed a moderate inverse relationship was found between the two Biodex outcome measures. There was also statistical significance in other outcome measures however those were weakly correlated. Intraclass correlations showed that there was a moderate repeatability between in the Biodex outcome measure of direction control. In their discussion they stated that LOS tests based on same dynamic principal should have outcome measures that correlate highly however the two devices that were assessed in this study

had only one similar outcome measure, that being directional control. With that and the evidence that the correlation between them was significant suggested that there is no construct validity between the two, though this could be attributed to the different testing protocols, especially the fact that the devices assess different components of postural stability.³⁶

2.5. Conclusion

Chronic low back pain is one of the leading causes of disability in the world since the 1990's. There is limited literature on the exact cause of chronic low back pain, specifically non-specific chronic low back pain is unknown and there is little evidence supporting any theory. There is no conclusive evidence that the theorized causes are causes or results of chronic low back pain.

Kinesio® Tape is a therapeutic modality used by clinicians since the 1970s in Japan and since 1995 in the United States. Kinesio® Tape is a stretchy adhesive tape with manufacturer claims of the ability to restore space within the tissues, aid in movement of those tissues and provide cooling. Current literature on non-specific chronic low back pain and Kinesio® Tape suggests that Kinesio® Tape is effective in reducing pain for a short period of time, up to about 48 hours. There is very little literature on Kinesio® Tapes effect on the disability of someone with non-specific chronic low back pain. One problem encountered when analyzing the existing literature is that there is little to no standardization of protocol, i.e. Kinesio® Tape technique used, parameters of the technique, the measurements taken, the nomenclature surrounding chronic low back pain. This makes it very difficult to generalize the results of these studies to everyday clinical practices.

The Biodex balance system is a machine used in clinical practices to assess the ability of an individual to maintain posture on varying degrees of an unstable surface. The Biodex is made

up of a base that houses a circular platform that is able to produce varying degrees of stability dependent on the rigidity of the springs underneath the platform. There are several different tests and trainings that can be utilized on the Biodex, however there is little research on the reliability and validity of all these tests/trainings. This is mainly since the different programs measure different components of postural stability. The reliability of validity of the Biodex is also dependent on other clinical tests and balance devices like it, of which they are few and the results are generalizable to all balance devices and tests because all of them again test different components of postural stability and balance.

CHAPTER 3: METHODOLOGY

The purpose of this study was to determine the effectiveness of the Kinesio® Tape star space correction application on individuals with chronic non-specific low back pain. Furthermore, it investigated the effectiveness of Kinesio® Tape on reducing disability using the Biodex balance system. The research was guided by the following questions:

1) How did the star space correction Kinesio® Tape technique affect an individual's low back pain?

2) How did the star space correction Kinesio® Tape technique affect an individual's postural stability?

3.1. Participants

Six individuals between the ages of 18 and 50 were included in this study. Participants were included if they had low back pain for three or more consecutive months, can read and write in English, as well as score at least an 8 on the Oswestry Disability Index (ODI). Participants were excluded from the study if they had a history of any disc or spine disease or condition, any neurological disease or symptoms, any balance disorders or conditions, and any previous back surgery. Participants were also excluded if they had any contraindications of Kinesio® Tape, including allergies to adhesives, active malignancy site(s) – cancer diagnosis, cellulitis, skin infection, open wounds, or fragile skin. Tape application was randomized to participants. Participants with an odd number received the experimental tape, in that tension was applied to the tape, at their first session and the sham, in that no tension was applied to the tape, at their first session and the sham, in that no tension was applied to the tape, at their first session and the sham, in that no tension was applied to the tape, at their first session and the sham, in that no tension was applied to the tape, at their first session and the sham, in that no tension was applied to the tape, at their first session and the sham at their second session.

3.2. Setting

The study took place on the North Dakota State University campus, in Room 14 of the Bentson Bunker Fieldhouse, at 1301 Centennial Blvd. Fargo, ND 58102. This location stores the necessary equipment to conduct this study including the Kinesio® Tape and the Biodex Balance System.

3.3. Equipment

Pain of the individuals was assessed using a visual analog scale (VAS). Disability of the participants was assessed subjectively using the ODI and objectively through the use of the Biodex Balance System (Biodex Medical Systems, Inc., Shirley, NY). The researchers have chosen to use Kinesio® Tex Classic Tape. The tape was applied according to the methods described in the Kinesio® Taping Assessments, Fundamental Concepts and Techniques book for the space correction star cut. The researchers chose to use the Postural Stability Test of the Biodex Balance System SD (Biodex Medical Systems, Inc., Shirley, NY). The postural stability test required that the participant stand so that their center of gravity was in the middle of the position patient page. Once the position was accepted a testing options screen appeared where the researcher set the test trial time (30 seconds), the number of trials (3), and a rest countdown (10 seconds). There is also the option of changing the platform stability on this screen, for this study level 7 was chosen, as 1 is the most stable and 12 is the least stable.³⁹ The participants remained standing in the accepted position in a bipedal stance and their eyes remaining open. They were allowed two practice trials, for familiarization, and then completed the test trial to be used as a baseline measurement.

3.4. Procedure

Prior to data collection, this study was approved by the North Dakota State University Institutional Review Board (IRB) and all participants provided written informed consent. All participants and researchers were required to wear masks during the data collection for COVID 19 safety. Participants were recruited via email listserv and word-of-mouth. Prior to the first session an individual interested in the study was sent an email with a link to a survey with inclusion and exclusion questions, as well as the ODI. Once participants met inclusion criteria the researcher emailed the participant about setting a time for their first session, at the end of this email researcher asked the participant to refrain medication use at least six hours prior to their session. For the first session, the participants reported to room 14 of the Bentson Bunker Fieldhouse on the NDSU campus. Upon arrival participants were asked COVID 19 symptom questions and completed the necessary paperwork including the Informed Consent, VAS, ODI, and Tampa Scale of Kinesiophobia (TSK).

Once these forms were completed participants were asked to perform the timed up and go test, followed by the postural stability test of the Biodex balance system. Following the baseline measurements, the researcher prepared the participants skin for application by shaving the area if necessary and wiping it with an isopropyl alcohol pad. The star taping technique required the use of 4 2x8 inch (4block) I strips. Prior to application the tape was folded into thirds, with the paper backing still present, ensuring the anchors remained long enough. For the first strip, participants were asked to stand in a forward bended position that did not elicit pain, the middle of the paper backing was removed, and the tape was applied with 10-35% tension over the greatest point of pain running medial to lateral. The ends of the tape were applied with no tension and the adhesive was activated by the researcher rubbing the tape to create heat. The participant was then

asked to straighten slightly to stretch the target tissue differently. The second I strip was applied in the same fashion as the first strip running proximal to distal. The ends were again applied with no tension and the adhesive activated. The participant then positioned themselves in a flexed and rotated position. The third I strip was applied the same as the previous two I strips, running at a 45-degree angle to the first two strips. For the final position the participant flexed and rotated to the opposite side. The fourth and final I strip was applied in the same fashion as the previous three pieces, running at the opposite 45-degree angle, with the ends applied without tension and the adhesive activated. For those with an odd number tension was applied, for those with an even number tension was not applied to the tape for this session. The participant then sat and allowed the tape to adhere for 45 minutes.

Following the waiting period, with the tape remaining intact, the participant was asked to perform the timed up and go test, followed by the postural stability test again. Completion of the session commenced once the participants completed the VAS, ODI, and TSK another time, and the tape was removed from the participants back. Participants were instructed to continue with their daily activities as normal.

The participants were asked to return for a second session at least one week later. During this session the participant completed the VAS, ODI and TSK forms. The participant's skin was again prepared for tape application by shaving the area if necessary and cleaning it with an isopropyl alcohol prep pad. The tape was applied in the same fashion as it was in the first session, however those with an odd number received tape without tension and those with an even number received tape with tension. The tape will again be allowed to adhere for 45 minutes. Following the waiting period, the participant completed the timed up and go test followed by the postural stability test on the Biodex balance system one more time, followed by completing the

VAS, ODI, and TSK one final time, followed by the removal of the Kinesio® Tape, cueing the end of the study.

3.5. Data Analysis

Statistical analysis of the research questions was computed with the SPSS software. Demographics were examined using mean and standard deviation. All outcomes, VAS, ODI, TSK, TUG, Biodex (stability indices and sway indices) were analyzed using a 2x2 repeated measures ANOVA. An alpha level of less than 0.05 was used to determine statistical significance. If a significant tape and time interaction occurred, differences were analyzed using a Tukey's post hoc correction.

3.6. Conclusion

The purpose of this study was to investigate if the star space correction Kinesio® Tape technique would decrease the pain and disability in an individual with chronic non-specific low back pain. The VAS was used to assess pain and TSK was used to assess fear of movement and ODI was used to assess the disability of participants. Disability of participants was also assessed using the Biodex balance system before and after the tape application. Results were interpreted to confirm or refute if the star space correction Kinesio® Tape technique would be an effective treatment for clinicians to use for patients with chronic non-specific low back pain.

CHAPTER 4: MANUSCRIPT

4.1. Abstract

[Study Design] Cross-over experimental.

[Background] Chronic non-specific low back pain has become one of the leading causes of disability worldwide and its costs rise all year. However, it is complex and not well understood. Kinesio® Tape has been theorized to aid in reduction of pain and increased motion of individuals with chronic non-specific low back pain.

[Objectives] To determine the effect Kinesio® Tape has on patient-reported outcomes and balance in patients with chronic non-specific low back pain.

[Methods] This study consisted of six volunteers exhibiting chronic non-specific low back pain. Participants completed two separate sessions at least one week apart, in which they received the same Kinesio® Tape star technique, one with tension (experimental) and one without tension (sham). Patient reported VAS, ODI, and TSK scores and balance measured by the Biodex balance system were recorded multiple times during the testing session.

[Results] There was significance found within the VAS time comparison and group time effect, the ODI time comparison and the TUG time comparison. Within the VAS time comparison both groups showed decreased scores from pre to post treatment (p=0.007). The group x time comparison showed that SHAM group scores were significantly greater at baseline when compared to the STAR group scores (t (5) = -2.712; p=0.611). ODI analyses indicated that both the STAR and SHAM groups had a significant decrease in scores from pre to post treatment in the time comparison (p=0.029). Another finding of this study was in the TUG time comparison. There was significance found in this comparison however times were essentially the same between the STAR and SHAM.

[Conclusions] Use of the star Kinesio[®] Tape technique on the low back decreased pain related to chronic non-specific low back pain and disability as reported by the patient outcome survey, however, this may have been due to other factors, such as a placebo effect or some other unknown pathway, as both the STAR and SHAM scores decreased the same. Additionally, there was no significance seen within any subjective measure such as outcomes from the Biodex balance system.

4.2. Introduction

There is an estimated 80 percent of the United States population that will experience low back pain at some point in their life.² Many recover within a few months. However, some will develop chronic low back pain.² Chronic non-specific low back pain is defined as consistent pain occurring in the lumbar or waist region with or without radiation into the buttock or leg lasting for at least three months or occurs repeatedly over a period of six to twelve months.^{1,2} Because chronic non-specific low back pain is responsible for high treatment costs, sick leave and individual suffering this condition has many treatments that are being used and investigated. Kinesio[®] Tape has become a common therapy for the treatment of chronic low back pain. However, the research is back and forth on whether there is a physiological effect, and what kind of effect, when using Kinesio® Tape or if there is a larger part due to a placebo effect. The Biodex Balance System is used as a measuring tool for balance/stability. However, there is very limited studies using the Biodex Balance System paired with the use of Kinesio® Tape, making it hard to make comparisons of results seen in this study. With that this study's purpose is to assess Kinesio® Tape's star correction application on individuals with chronic non-specific low back pain

4.3. Methods

4.3.1. Participants

Twenty-one individuals completed the pre-screening survey for the project. Of these individuals twelve were excluded for various reasons. Of the remaining ten participants, two did not respond to further communications or were no longer interested. Eight adults ranging from age 19-48 volunteered for this study through word-of-mouth and email recruitment. Six of these adults completed both sessions of the study, two dropped out due to scheduling issues. Inclusion criteria for this study were any individual between the ages of 18 and 50 who had been experiencing low back pain for three months or more, could read and write English and scored at least an eight on the Oswestry Disability Index. Exclusion criteria included having a history of disc or spine disease, a history of any neurological disease, any balance disorders, any previous back surgery, and allergies to adhesives, any active malignancy site, any cellulitis, skin infection or open wounds in the area or having skin that is fragile. This study was approved by the University's Institutional Review Board. Prior to initiation of the study, all participants were provided and signed a written informed consent outlining the procedures and risks involved.

4.3.2. Procedures

This study utilized a cross-over experimental design with subjects receiving two separate Kinesio® Tape applications, one experimental (tape applied with tension) and one sham (tape applied without tension). The tape application was randomized in that odd numbered participants received the experimental application at their first session and the control application at their second session. At pre-testing, all participants completed a pain visual analog score (VAS), the Oswestry Disability Index (ODI) and the Tampa Scale of Kinesiophobia (TSK) as baseline measurements. Next, the participants performed the timed up and go test followed by a trial run

on the Biodex balance system serving as their final baseline measurement. The clinician prepared the participants skin and applied the appropriate Kinesio® Tape technique. The experimental taping included four strips of Kinesio® Tape measuring eight inches (four blocks). Each piece of tape was folded into thirds and the participant was asked to bend forward at the hips as far as possible without pain. The tape was then applied with 10-35% tension in the middle and applied over the area of maximum pain running medial to lateral. The second piece of tape was applied with the participant in a slightly straighter position; the same procedure was followed with the tape only having the tape running from cephalic to caudal. The participant was then asked to maintain a flexed and rotated position; the same procedure was also followed for the third piece of tape with it running at a 45-degree angle to the other two strips. The fourth and final piece of tape was applied with the same procedure at the opposite 45-degree angle and the patient flexed and rotated to the opposite side. The sham taping was applied with no tension on any parts of the tape. The participant then sat for 45 minutes, allowing the tape to properly adhere to the skin. Following this, the participant performed post-testing which consisted of another timed up and go test, Biodex balance system testing, and the completion of the VAS, ODI, and TSK one final time. The participants then came back for a second session at least one week later and completed the same protocol but with the opposite taping intervention performed in trial 1.

4.3.3. Statistical Analysis

Statistical analysis for the approved research was performed using SPSS software. Demographics were examined using mean and standard deviation. All outcomes, VAS, ODI, TUG, TSK, Biodex (stability indices and sway indices) were analyzed using a 2 x 2 repeated measures ANOVA. An alpha level of less or equal to 0.05 was used to determine statistical

significance. If a significant group and time interaction occurred, differences were analyzed using a Tukey's post hoc correction.

4.4. Results

Though there was a small sample size (N=6) for this study analyses indicated that there was significance in a couple of different categories. Table 4 shows demographic descriptives for the six participants of this study and Table 5 shows data descriptives, specifically the means and standard deviations pre and post STAR and SHAM technique, respectively. There was a significant group x time interaction effect for VAS [F(1,5)=10.00; p = 0.025, Table 6]. Post-hoc analysis to determine the interaction effect further, determined that at the pre-testing the SHAM VAS scores were higher than the STAR VAS technique (t(5)= -2.712, p=0.042). There was not a significant difference between SHAM and STAR VAS at the post-testing (t(5)=-0.542,p=0.42). There was a significant time effect for VAS [F(1,5)=19.29; p = 0.007]. Both groups decreased their scores from pre to post testing. There was also a significant time effect for the ODI [F(1,5)=9.28; p = 0.029, Table 7], whereby SHAM decreased by 2.8 points and STAR decreased by 1.7 points. However, there were no significant differences between the two groups (t(5)=-0.67, p=0.532).

There was a significant time effect for TUG [F(1,5)=6.65; p = 0.050, Table 8]. Both STAR and SHAM decreased the TUG time by 0.92 and 0.91 seconds, respectively (t(5)=0.054, p=0.959).

No group [F(1,5)=0.470; p = 0.523], time [F(1,5)=0.934; p = 0.378] or group x time [F(1,5)=0.095; p = 0.770] effects were found for the TSK [Table 9]. No group [F(1,5)=0.728; p = 0.433], time [F(1,5)=0.022; p = 0.887], or group x time [F(1,5)=0.728; p = 0.433] effects were found for OSTI component of the Biodex Balance System test [Table 10]. No group

[F(1,5)= 0.550; p = 0.492], time [F(1,5)= 0.004; p = 0.952], or group x time [F(1,5)= 0.550; p = 0.492] effects were found for OSWI component of the Biodex Balance System test [Table 11]. No group [F(1,5)= 0.413; p = 0.549], time [F(1,5)= 0.209; p = 0.666], or group x time [F(1,5)= 0.734; p = 0.431] effects were found for FBSTI component of the Biodex Balance System test [Table 12]. No group [F(1,5)= 0.386; p = 0.561], time [F(1,5)= 0.051; p = 0.830], or group x time [F(1,5)= 0.341; p = 0.585] effects were found for FBSWI component of the Biodex Balance System test [Table 13]. No group [F(1,5)= 0.933; p = 0.378], time [F(1,5)= 0.375; p = 0.567], or group x time [F(1,5)= 0.933; p = 0378] effects were found for LRSTI component of the Biodex Balance System test [Table 14]. No group [F(1,5)= 0.830; p = 0.404], time [F(1,5)= 0.004; p = 0.954], or group x time [F(1,5)= 0.798; p = 0.413] effects were found for LRSWI component of the Biodex Balance System test [Table 14]. No group [F(1,5)= 0.830; p = 0.404], time [F(1,5)= 0.004; p = 0.954], or group x time [F(1,5)= 0.798; p = 0.413] effects were found for LRSWI component of the Biodex Balance System test [Table 14]. No group [F(1,5)= 0.830; p = 0.404], time [F(1,5)= 0.004; p = 0.954], or group x time [F(1,5)= 0.798; p = 0.413] effects were found for LRSWI component of the Biodex Balance System test [Table 15].

Demographic Descriptives					
	N	Minimum	Maximum	Mean	Standard Deviation
Age (yr)	6	19	48	26.33	10.97
Height (ft)	6	5.5	6.30	5.73	0.30
Weight (lb)	6	135	294	195.50	54.59

 Table 4. Demographic Descriptives

	Data Descriptive Statis	stics	
	Pre	Post	% Change
STAR			
VAS (1-10 scale)	4.50 ± 1.97	3.33 ± 1.63	-26%
ODI (points)	15.00 ± 4.19	12.17 ± 5.60	-19%
TUG (sec)	8.82 ± 1.52	7.89 ± 1.04	-11%
TSK (points)	41.67 ± 6.98	41.00 ± 4.19	-2%
OSTI (score)	1.59 ± 0.45	1.72 ± 0.83	8%
OSWI (score)	1.49 ± 0.41	1.66 ± 1.28	11%
FBSTI (score)	1.48 ± 0.39	1.53 ± 0.61	3%
FBSWI (score)	1.36 ± 0.38	1.40 ± 0.87	3%
LRSTI (score)	0.33 ± 0.16	0.47 ± 0.42	42%
LRSWI (score)	0.61 ± 0.26	0.82 ± 1.01	34%
SHAM			
VAS (1-10 scale)	5.33 ± 1.97	3.50 ± 1.64	-34%
ODI (points)	15.17 ± 2.93	13.50 ± 4.23	-11%
TUG (sec)	8.82 ± 1.52	7.92 ± 1.48	-10%
TSK (points)	42.67 ± 3.27	41.17 ± 4.36	-4%
OSTI (score)	1.59 ± 0.45	1.43 ± 0.42	-10%
OSWI (score)	1.48 ± 0.40	1.26 ± 0.54	-15%
FBSTI (score)	1.49 ± 0.38	1.37 ± 0.45	-8%
FBSWI (score)	1.33 ± 0.38	1.89 ± 0.54	42%
LRSTI (score)	0.33 ± 0.16	0.30 ± 0.63	-9%
LRSWI (score)	0.61 ± 0.26	0.42 ± 0.18	-31%

Table 5. Data Descriptive Statistics

Tests of Within-Subject Effects - VAS					
	df	F	Significance	Partial Eta Squared	
Group	1,5	3.00	0.144	0.375	
Time	1,5	19.286	0.007	0.794	
Group x Time	1,5	10.00	0.025	0.667	

Table 6. Test of Within-Subject Effects VAS

Table 7. Test of Within Subject Effects ODI

Tests of Within-Subject Effects ODI					
	df	F	Significance	Partial Eta Squared	
Group	1,5	1.031	0.357	0.171	
Time	1,5	9.275	0.029	0.650	
Group x Time	1,5	0.450	0.532	0.082	

Table 8. Test of Within Subject Effects TUG

Tests of Within-Subject Effects TUG					
	df	F	Significance	Partial Eta Squared	
Group	1,5	0.003	0.959	0.001	
Time	1,5	6.646	0.050	0.571	
Group x Time	1,5	0.003	0.959	0.001	

Tests of Within-Subject Effects TSK				
	df	F	Significance	Partial Eta Squared
Group	1,5	0.470	0.523	0.086
Time	1,5	0.934	0.378	0.157
Group x Time	1,5	0.095	0.770	0.019

Table 9. Tests of Within-Subject Effects TSK

Table 10. Tests of Within-Subject Effects OSTI

Tests of Within-Subject Effects OSTI					
	df	F	Significance	Partial Eta Squared	
Group	1,5	0.728	0.433	0.127	
Time	1,5	0.022	0.887	0.004	
Group x Time	1,5	0.728	0.433	0.127	

Table 11. Tests of Within-Subject Effects OSWI

Tests of Within-Subject Effects OSWI				
	df	F	Significance	Partial Eta Squared
Group	1,5	0.550	0.492	0.099
Time	1,5	0.004	0.952	0.001
Group x Time	1,5	0.550	0.492	0.099

Tests of Within-Subject Effects FBSTI				
	df	F	Significance	Partial Eta Squared
Group	1,5	0.413	0.549	0.076
Time	1,5	0.209	0.666	0.040
Group x Time	1,5	0.734	0.431	0.128

Table 12. Tests of Within-Subject Effects FBSTI

Table 13. Tests of Within-Subject Effects FBSWI

Tests of Within-Subject Effects FBSWI					
	df	F	Significance	Partial Eta Squared	
Group	1,5	0.386	0.561	0.072	
Time	1,5	0.051	0.830	0.010	
Group x Time	1,5	0.341	0.585	0.064	

Table 14. Tests of Within-Subject Effects LRSTI

Tests of Within-Subject Effects LRSTI						
	df	F	Significance	Partial Eta Squared		
Group	1,5	0.933	0.378	0.157		
Time	1,5	0.375	0.567	0.070		
Group x Time	1,5	0.933	0.378	0.157		

Tests of Within-Subject Effects LRSWI						
	df	F	Significance	Partial Eta Squared		
Group	1,5	0.830	0.404	0.142		
Time	1,5	0.004	0.954	0.001		
Group x Time	1,5	0.798	0.413	0.138		

Table 15. Tests of Within-Subject Effects LRSWI

4.5. Discussion

Given chronic non-specific low back pain affects so many people, upwards of 80% of the US population, there is a need for new treatments, which could include Kinesio® Tape in conjunction with other typical therapies. This is one of multiple studies that has looked at the tapes effect on disability, though this is the first to use the Biodex Balance system in conjunction with the TUG and TSK tests. The results of this study may help practitioners have a better understanding of how this therapy may help patients with chronic non-specific low back pain.

Because this study ran repeated measures ANOVA's for statistical analyses, partial eta squared was given as the indicator for effect size. SPSS defines a partial eta squared small effect size as 0.01-.059, a medium effect size as 0.06-0.13, and a large effect size as greater than 0.14.⁴⁰ These were used to assess the effect sizes of this study.

Participants in both STAR and SHAM groups reported a reduction in pain after tape application. This was also observed in Castro Sanchez et al.'s study, where tape was applied for one week before reassessing measures.²⁷ Contrarily, this study was more acute and there was only 45 minutes from application to reassessment in both sessions. While statistical significance was not found a large partial eta squared (effect size estimate) effects were indicated through analyses in all components of the pain analyses. While there was a large effect in all components, the effect in the time and group x time analyses was larger than the group analyses. This indicates that there may be practical applications for Kinesio® Tape in the reduction of pain in the treatment of chronic non-specific low back pain. However, the Kinesio® Tape (STAR or SHAM) did not appear to influence pain reduction differently.

Similarly, there was significance found within the time analyses of the ANOVA for the ODI component. An overall reduction of scores was observed when analyzing the data. However, there were a large to medium effect seen within the group, time, and group x time analyses for the ODI component (0.171, 0.650, 0.082, respectively). This indicates that there may be practical application for Kinesio[®] Tape in the reduction of disability, subjectively seen in the ODI, in the treatment of chronic non-specific low back pain. However, in the group x time analyses the effect was closer to a medium effect (0.08) meaning there is less applicability and or the effect of the Kinesio® Tape when comparing sham taping and comparing over time, indicating that there may have been a placebo effect that took place. This may also be due to the reduction of pain that was reported. A potential limitation was the time allowed for this study that there was not a significant enough amount of time between individuals reassessing while filling out the ODI. With questions of the ODI including the ability to sit for periods of time without pain, ability to stand for periods of time without pain, ability to walk a specific distance without pain, paired with the short amount of time allowed for this study an individual's ability to subjectively judge how the tape affected the questions of the ODI in the time allowed.

There was also significance found within the time analyses of the ANOVA for the TUG component of this study as well. There was an overall reduction of time in TUG, indicating improved performance for both STAR and SHAM. There was a small effect observed in the group analyses (0.001), a large effect observed within the time analyses (0.571), and a small

effect in the group x time analyses (0.001). This indicates that there may be practical application of taping in reducing the effect that chronic non-specific low back pain plays on individuals' free movement, however, the method of taping did not affect the improvement in performance.

There was no significance found in any of the analyses for the TSK component of this study. However, there was a large effect (0.157) observed in the time analyses. This indicates that there may be clinical application in that Kinesio® Tape may be used to improve an individual who is suffering from chronic non-specific low back pain, fear of movement. Though because there was only a large effect found in the time analyses Kinesio® Tape may need to be applied for a longer period of time prior in order for effects to be felt by individuals. Since this study only allowed for 45 minutes of application prior to reassessment, there may be future need to allow a longer period of time in order to reach significance and find lasting effects. There were medium-large effects (0.86, 0.19) found in the group analyses and in the group by time analyses. There may have been skewed results for this component of the study because of the amount of time allotted from application to reassessment. Since the statements presented in the TSK, for example "people aren't taking my medical condition seriously enough" or "simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening", it may have been difficult for patients to reassess how they were feeling after application without having the tape applied for a longer period of time and or being able to perform their activities of daily living.

Additionally, there was no significance found when comparing groups for any of the postural stability measures assessed by the Biodex Balance system. The components include Overall Stability Index (OSTI), Overall Sway Index (OSWI), Forward Backward Stability Index (FBSTI), Forward Backward Sway Index (FBSWI), Left Right Stability Index (LRSTI) and Left

Right Sway Index (LRSWI). There was a medium effect found in the group (0.127) and group x time (0.127) analyses and a small effect in the time (0.004) analyses for the OSTI. This suggests that there is a slight chance of a clinical application of Kinesio® Tape in the use of decreasing the overall amount of disability in an individual produces on the Biodex Balance System. However, the small time effect indicates that Kinesio® Tape makes no difference over time when comparing groups. Additionally, there were large effects found in the group (0.99) and group x time (0.99) and a small effect (0.001) seen in the time analyses of the OSWI. This indicates that there may be a practical application supporting the use of Kinesio® Tape in reducing overall disability in individuals with chronic non-specific low back pain. The FBSTI component of the Biodex Balance System had small to medium partial eta squared effects. The group analyses showed a medium effect (0.076), the time analyses showed a small effect (0.040), and the group x time analyses showed a medium effect (0.128). This is an indication that there may be practical applications for the use of Kinesio® Tape in treating chronic non- specific low back pain. However, being that there are only small or medium effects it may have been due to the reduction of pain that was seen within this study, making participants fear movement, specifically forward and backward sway. The FBSWI component had small to medium partial eta squared effect. The group analyses indicated a medium effect (0.072), time analyses indicated a small effect (0.010) and the group x time analyses indicated a medium effect (0.064). Again, this could indicate that there are some practical applications of Kinesio® Tape in treating disability in individuals with chronic non-specific low back pain, however it could also be due to the reduction of pain observed within this study or a placebo effect. The last two components of the Biodex Balance System indicated = small to large partial eta squared effect size. The group analyses for both components indicated large effect sizes LRSTI 0.157 and LRSWI 0.142, while

the time analyses for LRSTI indicated a medium effect (0.070) and a small effect (0.001) in the LRSWI component. The group x time analyses, however indicated a large effect size (0.157) for the LRSTI component and a medium effect size (0.138) for the LRSWI component. All these indicate that there is a large chance of a practical application of Kinesio® Tape in treating disability, specifically side to side (left and right) sway, in individuals with chronic non-specific low back pain. Though there are large effects observed this again may have been due to the reduction of pain observed within this study creating less fear of movement and loss of balance allowing individuals to balance better on the Biodex Balance System.

All these suggest that while Kinesio® Tape did not affect many dependent measures of this study, but it did by some other pathways reduce pain. These result findings only allow for speculation on what these pathways may be, however, other authors suggest that pain modulation occurs due to the gate control theory or because of increased afferent feedback. Also, with the reduction of pain there may be improvement observed in many of the other components analyzed in this study due to the individual's feeling less fear of movement and disability.

This research study is not without limitations due to the numerous variables present. First, this study was only able to recruit a total of six participants, severely limiting the statistical analysis and the generalizability of these data. With that being said, a second limitation of this study was that it was restricted to participants between the ages of 19 and 48; therefore, results cannot be generalized to a population outside this range. Thirdly, the participants presented with low back pain caused by no known pathology, meaning that these results cannot be generalized to a healthy population or a population in which pain has a diagnosable cause. Their scores varied widely upon entry using the ODI as well, making it difficult to subjectively assess

disability scores for a requirement of inclusion, specifically what score is best to be used for including an individual with chronic non-specific low back pain.

Future research on this topic should aim to either refine the inclusion and exclusion criteria to increase the number of participants recruited and or increase the time the researchers recruited to increase the number of participants recruited. Additionally, since there was no statistical significance found within any of the disability components and a small significance within the pain component, future research may consider using various Kinesio® Tape techniques and or tension to explore if any techniques or tension difference(s) decrease either of these. Furthermore, future research may consider a longer time frame from application to reassessment, as 45-minutes may not have been a time frame long enough to affect any changes and or at the very least reach statistical significance.

4.6. Conclusions

While the sample size of this study was small, taping (STAR or SHAM) decreased the pain of patients with chronic non-specific low back pain. ODI scores were lower when the experimental tape was used than when the sham taping was used. Disability, measured via multiple Biodex Balance System components, showed no significance in any of the components measured. While the way in which Kinesio® Tape decreases the pain of patients remains a question, Kinesio® Tape can be used confidently in patients with chronic non-specific low back pain to aid with pain reduction, and therefore possibly reduction of some disability.

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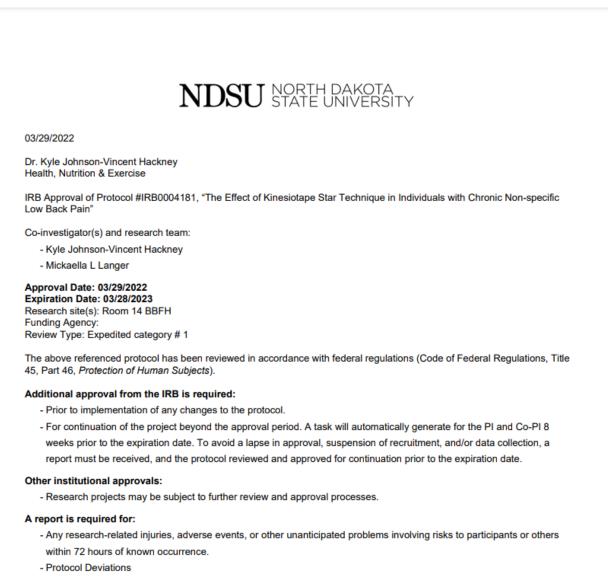
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APPENDIX A. IRB Approval Letter



- Any significant new findings that may affect risks to participants.

Thank you for cooperating with NDSU IRB procedures, and best wishes for a successful study.

NDSU has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

APPENDIX B. Informed Consent

NDSU NORTH DAKOTA

Health, Nutrition, and Exercise Science 1301 Centennial Blvd Fargo, ND 58108-6050 701-231-6706

The Effects of Kinesio[®] Tape Star Technique in Individuals with Chronic Non-specific Low Back Pain

This study is being conducted by: Dr. Kyle Hackney, PhD, Associate Professor in Health,

Nutrition and Exercise Sciences (HNES), North Dakota State University. Phone: ###-#####.

Email: kyle.hackney@ndsu.edu and Mickaella Langer, HNES Advanced Athletic Training

Masters Student, Phone:#-###-####. Email: mickaella.langer@ndsu.edu.

Key Information about this study:

This consent form is designed to inform you about the study you are being asked to participate in. Here you will find a brief summary about the study; however, you can find more detailed information later on in the form.

- Masks will be worn for all sessions
- This study is being conducted to investigate the effects that Kinesio[®] Tape has on the pain and postural stability of individuals with non-specific chronic low back pain
- You may participate in this study if you
 - Are between the ages of 18 and 50
 - Have had low back pain for three months or longer
- You may not participate in this study if you
 - Have a history of disc or spine disease or condition
 - Have a history of any neurological disease or condition
 - Have any balance disorder or condition
 - Have had any previous back surgery
 - Have any allergies to adhesives
 - Have any active malignancy site
 - Have cellulitis, any skin infection, or any open wounds on your lower back
 - Have skin that is easily cut or torn (fragile)
- All participants who meet the above stated criteria and agree to participate in this study are subject to being taped with Kinesio[®] Tape and performing tests on the Biodex balance system.
- Risks: you may experience an increase in pain or no relief of pain; allergic reaction to Kinesio[®] Tape; mild discomfort with tape removal may occur
- Benefits: you may experience some pain relief

- You will be asked to complete two separate sessions spaced at least one week apart. The first session will be about an hour and a half, and the second session will be about an hour, for a total time commitment of approximately two and a half hours.
- All identifiable information will be kept private and confidential. Paper forms will be entered into a computer without any identifiable information and stored in a password protected data file.

Why am I being asked to take part in this study?

Chronic low back pain is one of the leading causes for physician visits and days missed in the workplace. There are claims that Kinesio® Tape helps with pain reduction and can even help with movement. We are asking people to participate so we can evaluate Kinesio® Tape effects on the pain and disability caused by chronic low back pain.

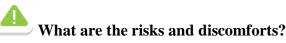
What will I be asked to do?

You will be asked to attend two sessions in total. COVID-19 screening will take place at both sessions. The first session will start with the study being explained to you and you signing the informed consent. You will then be asked to complete demographic information, a pain scale, and a form called the Tampa Scale of Kinesiophobia (TSK). You will then be allowed familiarization trials on the Biodex Balance System, followed by a baseline testing. Following completion of the baseline measurement Kinesio® Tape will be applied to your back and will be allowed to adhere/sit for 30 minutes. Following the waiting period, you will once again be asked to complete a pain scale and the TSK and will then be asked to again perform a test on the Biodex balance system. One last pain scale and TSK will be completed prior to termination of the first session.

You will be asked to come back at least one week later. This second session will consist of the completion of the pain scale and TSK upon arrival. Kinesio® Tape will again be applied to your back and allowed to adhere for 30 minutes. You will then complete the pain and TSK again, followed by Biodex testing and the completion of the pain scale and TSK one final time. Completion of these will end the second and final session.

Where is the study going to take place, and how long will it take?

This study will take place at North Dakota State University in Bentson Bunker Fieldhouse room 14 on the North Dakota State University campus at 1301 Centennial Blvd. Fargo, ND 58102. If you agree to this study, you will be asked to attend two sessions total. Though it is difficult to estimate the time of these session, as it depends on the individuals and equipment working properly, we expect the first session to take about one and a half hours to complete and the second session to take about one hour to complete.



It is not possible to identify all potential risks in the research procedures, however, the researchers have taken reasonable actions to minimize any known risks. Although this study has minimal risk to you, the most common risks and discomforts include an increase in pain or no

change in pain. Another possible risk is allergic reaction to Kinesio® Tape. Mild discomfort with tape removal may also occur. If new findings develop during research which may change your willingness to participate, we will tell you about these findings.

What are the expected benefits of this research?

Individual Benefits: You may experience some pain relief, but no other benefits are expected to be obtained from this research study.

Societal Benefits: Gaining a better understanding of how Kinesio® Tape affects not only pain but disability in chronic low back pain could help improve clinical treatments for chronic low back pain, and therefore individuals suffering from chronic low back pain.

Do I have to take part in this study?

Your participation in this research is your choice. If you decide to participate in the study, you may change your mind and stop participating at any time without penalty or loss of benefits to which you are already entitled.

What are the alternatives to being in this study?

Instead of being in this research, you may choose not to participate.

i) Who will have access to my information?

We will keep all identifying records private and confidential. Your information will be combined with the information from other participants and stored in a password protected data file. You will be assigned a participant number and that number will be associated with your information. When the study is written only the combined information gathered will be included, all identifying information will remain private and password protected.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example, your name will be kept separate from your research records and these two things will be kept in different places under lock and key. If you withdraw before the research is over, your information will be removed at your request, and we will not collect additional information about you.

Can my participation in the study end early?

Your participation in this study may end whenever you wish.

Will I receive any compensation for participating in the study? No compensation is currently available for this study.

the study? What happens if I am injured because of the study?

If you are injured during the course of this study, you should contact Dr. Hackney at ###.####.#### or ###.####. Treatment for the injury will be available including first aid, emergency treatment, and follow-up care as needed. Payment for this treatment must be provided by you and your third-party payer (such as health insurance or Medicaid). This does not mean that you are releasing or waiving any legal right you might have against the researcher or NDSU as a result of you participation in this research.

• What if I have questions?

Before you decide whether you'd like to participate in this study, please ask any questions that come to mind now. Later, if you have questions about the study, you can contact Dr. Kyle Hackney at ###.##### (office) or ###.##### (cell) or kyle.hackney@ndsu.edu, or Mickaella Langer at ###.##### or mickaella.langer@ndsu.edu.

What are my rights as a research participant?

You have rights as a research participant. All research with human participants is reviewed by a committee called the *Institutional Review Board (IRB)* which works to protect your rights and welfare. If you have questions about your rights, an unresolved question, a concern or complaint about this research you may contact the IRB office at 701.231.8995, toll-free at 855-800-6717 or via email (ndsu.irb@ndsu.edu).

Documentation of Informed Consent:

You are freely making a decision whether to be in this research study. Signing this form means that

- 1. you have read and understood this consent form
- 2. you have had your questions answered, and
- 3. you have decided to be in the study.

You will be given a copy of this consent form to keep.

Your signature

Your printed name

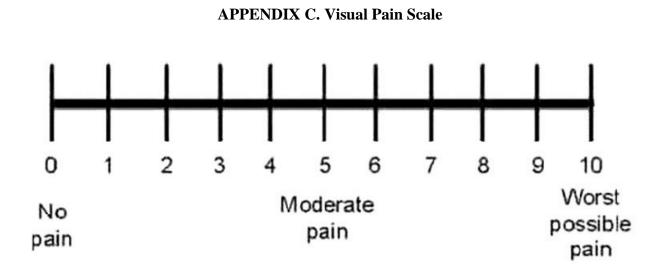
Signature of researcher explaining study

Printed name of researcher explaining study

Date

Date

Date



APPENDIX D. Oswestry Disability Index

Oswestry Low Back Disability Questionnaire

Oswestry Low Back Pain Disability Questionnaire

Instructions

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

Section 1 - Pain intensity

- I have no pain at the moment
- The pain is very mild at the moment
- The pain is moderate at the moment
- The pain is fairly severe at the moment
- The pain is very severe at the moment
- The pain is the worst imaginable at the moment

Section 2 – Personal care (washing, dressing etc)

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- It is painful to look after myself and I am slow and careful
- I need some help but manage most of my personal care
- I need help every day in most aspects of self-care
- I do not get dressed, I wash with difficulty and stay in bed

Section 3 – Lifting

- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives extra pain
- Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
- Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- I can lift very light weights
- I cannot lift or carry anything at all

Section 4 - Walking*

- Pain does not prevent me walking any distance
- Pain prevents me from walking more than 1 mile
- Pain prevents me from walking more than 1/2 mile
- Pain prevents me from walking more than 100 yards
- I can only walk using a stick or crutches
- I am in bed most of the time

Section 5 – Sitting

- I can sit in any chair as long as I like
- I can only sit in my favourite chair as long as I like
- Pain prevents me sitting more than one hour
- Pain prevents me from sitting more than 30 minutes
- Pain prevents me from sitting more than 10 minutes
- Pain prevents me from sitting at all

Section 6 - Standing

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- Pain prevents me from standing for more than 1 hour
- Pain prevents me from standing for more than 30 minutes
- Pain prevents me from standing for more than 10 minutes
- Pain prevents me from standing at all

Section 7 – Sleeping

- My sleep is never disturbed by pain
- My sleep is occasionally disturbed by pain
- Because of pain I have less than 6 hours sleep
- Because of pain I have less than 4 hours sleep
- Because of pain I have less than 2 hours sleep
- Pain prevents me from sleeping at all

Section 8 - Sex life (if applicable)

- My sex life is normal and causes no extra pain
- My sex life is normal but causes some extra pain
- My sex life is nearly normal but is very painful
- My sex life is severely restricted by pain
- My sex life is nearly absent because of pain
- Pain prevents any sex life at all

Section 9 - Social life

- My social life is normal and gives me no extra pain
- My social life is normal but increases the degree of pain
- Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- Pain has restricted my social life and I do not go out as often
- Pain has restricted my social life to my home
- I have no social life because of pain

Section 10 – Travelling

- I can travel anywhere without pain
- I can travel anywhere but it gives me extra pain
- Pain is bad but I manage journeys over two hours
- Pain restricts me to journeys of less than one hour
- Pain restricts me to short necessary journeys under 30 minutes
- Pain prevents me from travelling except to receive treatment

APPENDIX E. Tampa Scale of Kinesiophobia

1 = strongly disagree

2 = disagree 3 = agree 4 = strongly agree

 I'm afraid that I might injury myself if I exercise 	se 1	2	3	4
 If I were to try to overcome it, my pain would increase 	1	2	3	4
 My body is telling me I have something dangerously wrong 	1	2	3	4
 My pain would probably be relieved if I were to exercise 	o 1	2	3	4
 People aren't taking my medical condition seriously enough 	1	2	3	4
My accident has put my body at risk for the res of my life	t 1	2	3	4
7. Pain always means I have injured my body	1	2	3	4
 Just because something aggravates my pain doe not mean it is dangerous 	es 1	2	3	4
 I am afraid that I might injure myself accidentally 	1	2	3	4
 Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening 	n 1	2	3	4
 I wouldn't have this much pain if there weren't something potentially dangerous going on in m body 		2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
 Pain lets me know when to stop exercising so that I don't injure myself 	1	2	3	4
 It's really not safe for a person with a condition like mine to be physically active 	n 1	2	3	4
 I can't do all the things normal people do because it's too easy for me to get injured 	1	2	3	4
 Even though something is causing me a lot of pain, I don't think it's actually dangerous 	1	2	3	4
 No one should have to exercise when he/she is pain 	in 1	2	3	4