THE EFFECTS OF THE SPACE CORRECTION KINESIO TAPING METHOD® ON THE PATELLOFEMORAL JOINT MEASURED BY DIAGNOSTIC ULTRASOUND

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Title

The Effects of the Space Correction Kinesio	Taping Method® on the
Pattellofemoral Joint Space as Measured by I	Diagnostic Ultrasound.

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North Dakota State University's regulations and meets the accepted

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MASTER OF SCIENCE

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ABSTRACT

Background: There is limited quantitative research on joint space measurements to support the use of Kinesio Tape Space Correction Method®. There is limited to no research regarding the use of diagnostic ultrasound to take a measurement of specific joint spaces.

Methods: 32 subjects with bilaterally-healthy knees, no reported surgeries or reported allergies to Kinesio Tape®, reported their dominant knee to the researcher, who then measured their patellofemoral joint space with diagnostic ultrasound. Measurements were taken, the Kinesio Tape Space Correction Method® was applied, and left on for 10 minutes with the patient in a non-weight-bearing position. After 10 minutes, the joint space was re-measured.

Results: There was a statistically significant difference (t[31]=2.823, p=.008) between pre-and post-taped patella to femur measurements.

Conclusion: Results indicate that patellofemoral joint spaces can be increased by the Kinesio Tape Space Correction Method® after 10 minutes of application.

Keywords: Kinesio Tape®, Diagnostic Ultrasound, Patellofemoral Joint Space

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CHAPTER 1. INTRODUCTION

Overview of the Problem

Kinesio® Tape is a widely used modality which has limited quantitative research to back the claims of the Kinesio Taping Association International (KTAI). These claims include that the tape has the ability to "re-educate the neuromuscular system, reduce pain, optimize performance, prevent injury, and promote improved circulation and healing" (p.23)¹. The technique being tested in the current study is the Space Correction Kinesio Tape Method® over the patella. The idea behind this technique is that the tape application creates a suction force that helps increase the space around the patella, hence increasing the space at the joint¹. To date, after an exhaustive literature review, no research has been published regarding the topic of the Space Correction Kinesio Tape Method® on the patellofemoral joint. It is rare to find support for altering the space in the joint though there are studies that have positive results for pain control with Kinesio Tape®²-⁴.

Diagnostic ultrasound is used for guided injections of joints, observe the degeneration of structures, or to analyze an area of pain in real time. Research is limited in regards to specifically measuring joint spaces ⁵⁻⁹. Research is limited in regards to specifically measuring joint spaces with diagnostic ultrasound. There appears to be no standard for measuring a joint space in the literature, but there are some common anatomical landmarks which are referenced. Therefore, using diagnostic ultrasound to look at the patellofemoral joint space has not occurred in published literature that includes joint space measurements or a standard to find these measurements.

Understanding if a Space Correction Kinesio Tape Method® increases the space within a joint could benefit clinicians in treating some injuries which may cause reported pain. Some

pathologies which occur at the knee and could be observed with diagnostic ultrasound include plica syndrome, chondromalacia, or even patella tracking. The ability to record joint space measurements could assist clinicians make evidence-based medicine decisions when working with patients who report joint pain².

Statement of Purpose

The purpose of this study was to determine if the Space Correction Kinesio Tape Method® created a statistically significant difference in the pre-taped versus post-taped patellofemoral joint space when measured by diagnostic ultrasound.

Research Questions

The research questions that guided this research were:

- Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring the patellofemoral joint space as determined by diagnostic ultrasound?
- 2) Does an individual's dominate leg have a statistically significant difference patellofemoral joint space compared to the non-dominate leg?
- 3) Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring from the skin to the patella as determined by diagnostic ultrasound?
- 4) Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring from the skin to the patella tendon as determined by diagnostic ultrasound?

Dependent Variable

The dependent variable in this study was the joint space measurement post application of the Space Correction Kinesio Tape Method®.

Independent Variable

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

Limitations

This study was limited by a number of components. The major limitation was that the study was performed on individuals with healthy, pain free, and non-surgical knees. Therefore, any conclusions made from this data may not be transferable to individuals with injured and painful knees. Future research will utilize the current project for specific details of the Kinesio® Tape and diagnostic ultrasound methods. Another limitation may have been the placement of the Kinesio® Tape. In order for the space correction technique to work correctly it must be applied in a specific spot which could interfere with the placement of the diagnostic ultrasound and alter the picture. This study should allow for the focus on the diagnostic ultrasound measurement of the patellofemoral space with and without Kinesio® Tape but will not allow for comparison of other taping techniques that may claim a similar idea as Kinesio® Tape.

Delimitations

The aspects of this study which were not included as a part of the current research project included: any possible abnormalities seen on the diagnostic ultrasound image, and joint space differences in populations. For example the differences in joint spaces based on age range, past sport experiences or profession. This study did not research participants with patellofemoral joint space problems. The literature on Kinesio® Tape seems to be primarily focused on pain control, which is also not a part of the research questions.

Significance of the Study

Kinesio® Tape is a widely used modality for athletic trainers, massage therapists, physical therapists, and others. There is limited research supporting the use of Kinesio® Tape for anything other than pain, hence the need for quantitative research involving Kinesio® Tape. In

some studies, strength and balance measurements occurred with the use of Kinesio® Tape but some of the information is contradictory²⁻⁴. The literature shows support for the use of Kinesio® Tape for pain, but there is limited quantitative data to show the support for use of Space Correction Kinesio Tape Methods®.

Definitions

Diagnostic Ultrasound: a non-invasive imaging technique used for the assessment of musculoskeletal conditions as well as for guided needle injections ¹⁰

Kinesio Tape® & Kinesio FP® Tape: a latex-free tape with acrylic adhesive that is heat activated. The adhesive is applied to the tape in a wave like pattern to mimic the qualities of a finger print. Kinesio FP Tape® can stretch up to 60 percent of its resting length, which gives the opportunity to use the elastic qualities for a patients benefit with different Kinesio Tape Methods®¹.

Patellofemoral Joint Space: The space between the patella bone and femur bone in the knee¹¹.

Kinesio Tape Space Correction Method®: the Kinesio® Tape Method that uses 10-35% tension in the tape and specific cuts in the tape to increase space between tissues. This increase in space is caused by a lifting recoil in the tape from the cuts and the tension on the tape.

CHAPTER 2. LITERATURE REVIEW

The purpose of this literature review is to give background information on musculoskeletal diagnostic ultrasound as well as Kinesio® Tape. Diagnostic ultrasound is most commonly used for guided injections, but more uses are being explored. These uses include; real time muscle and tendon analysis, analyzing the structure of tissue, boney abnormalities, as well as others. There is limited research regarding diagnostic ultrasound of the knee, especially in regards to measuring specific joint spaces. Kinesio® Tape is a therapeutic tape used for musculoskeletal conditions. Commonly, Kinesio® Tape is used for pain management and the facilitation or inhibition of muscles. However, many techniques are not well researched for quantitative data. The Space Correction Kinesio Tape Method® is used to increase space between skin and muscle, as well as at the joint space level. To date, there have been no published articles which specifically study the quantitative measurements of the effects of Kinesio® Tape.

Diagnostic Ultrasound

Diagnostic ultrasound is an imaging technique which produces an image via a transducer that contains a crystal which, in turn, creates sound waves. These sound waves penetrate into tissue through transmission gel and interact by reflecting off of or continuing past structures. These reflections or continuations of the sound wave create the image that a trained individual is able to utilize to make clinical decisions⁵. There are many purposes for the use of diagnostic ultrasound. Mainly, diagnostic ultrasound is used to help guide physicians for injections into joints because it gives them the opportunity to see the structure in which they are injecting⁵. The advantages of diagnostic ultrasound versus magnetic resonance imaging (MRI) and X-ray include: low cost for the patient, images in real time, side by side comparison, ability to change the pressures over fluid filled areas, also in many cases diagnostic ultrasound is pain free^{5,6,9,10}.

Though MRI and X-ray can be pain free as well, clinicians are able to use diagnostic ultrasound with patients in a pain free positions while still gaining a quality image which may differ from MRI and X-ray.

Friedman, Finlay and Jurriaans discussed the advantages of using diagnostic ultrasound as well as explained what the researchers believe the best scanning technique is for the knee using ultrasound. They included their best descriptions as to what normal anatomy should look like via diagnostic ultrasound. Friedman, Finlay and Jurriaans successfully reviewed different techniques with the sound head as well as patient positions, and were able to create their own guide for a review of the knee using diagnostic ultrasound. The main conclusion in completing this ultrasound technique review was that experience in acquiring a valid clear picture and being able to correctly read the image for assessment along with understanding the anatomy is key in using diagnostic ultrasound in this knee⁹. In order for a correct diagnosis and/or assessment, knowing what normal structure appears like is key. Overall, the researchers concluded that with growing interest in the realm of diagnostic ultrasound, the acceptance of a diagnosis via diagnostic ultrasound will become more common.

For diagnostic ultrasound purposes, the frequency ranges between seven megahertz (MHz) and 13 MHz depending on what structure the clinician is trying to observe⁸. When looking at the patellofemoral joint or more superficial parts of the knee, research shows that clinicians mainly use high resolutions between 7-10 MHz⁹. Carr, Hanly, Griffin and Gibney (2001) explained that some transducer frequencies are available up to 20 MHz. They show in high resolution, but are not widely available partially because penetration is limited, so the use for these high frequency transducers is limited. They also stated that the patella tendon is seen clearly with a 7-10 MHz transducer⁷. Pacnesny and Kruczynski (2011) state that when looking at

deep regions of the knee such as the popliteal area, 5 MHz may be most appropriate⁸. Brussaard used a transducer with a frequency set to 7.5 MHz to examine chondromalacia of the femoropatellar joint, while a text book written by Jacobson stated that the frequency simply had to be less than 10 MHz^{5,6}.

Diagnostic Ultrasound in the Knee

There is little research using diagnostic ultrasound as a tool to measure spaces in the knee at either the patellofemoral joint or the tibiofemoral joint. There have been studies completed on the techniques for the best ultrasound images of these joints. In the study completed by Friedman, Finlay and Jurriaans (2001), it was noted that unlike x-ray, diagnostic ultrasound is able to assess circumference in bone, as well as assess the exact spot of pain⁹. Because of the ability to assess bone circumference, the possibility of measuring joint space with diagnostic ultrasound is high⁹. This could be key for the assessment of patella femoral pain syndrome, chondromalacia, arthritis and plica syndromes.

A study completed by Yanagisawa, Kobayashi, Oshawa, Saito, Yaamoto, Tajika, and Takagishi (2015) on osteoarthritis in the knee used diagnostic ultrasound to measure the peripheral joint space in the medial knee to observe the size of osteophytes. Bilateral knee measurements in a total of 225 participants (males= 72, females= 154) were recorded in both weight-bearing and non-weight-bearing positions. Participants were divided into groups based on age; 40-49 years, 50-59 years, 60-69 years, 70-79 years and 80 plus years. The researchers measured the displacement of the medial meniscus, the osteophytes, and the joint space in both knees of the subjects. They determined three landmarks for repeatable placement of the transducer to measure the joint space. These three landmarks included the anterior surface of the medial femoral condyle, the medial patellar boarder, and the medial retinaculum. It is key to note the landmarks they used for repeatable measurements for joint space measurements in the knee

such that other researchers are able to perform similar studies. The peripheral joint space was measured from the edge of the medial femoral condyle to the medial tibial condyle or wherever the osteophytes were located. The distance was measured with electronic calipers. The differences between the 60-69 and 80 plus age groups for meniscus displacement and joint spaces were statistically significant $(p < 0.01)^{9,12}$. Overall, this study helps support the use of diagnostic ultrasound in measuring specific anatomical landmarks in joint spaces, specifically the knee. This is valuable information because clinicians are able to see what is occurring at the joint space in real time and possibly able to conclude a diagnosis.

A study completed by Paczesny and Kruczynski was used to determine if diagnostic ultrasound was a feasible diagnostic technique for medial plica syndrome in the knee. The study included 88 participants (males= 32; females= 56) with a mean age of 20-years-old who all had a history of pain and a palpable medial band. While the authors do not explain their definition of a medial band, based on the explanation, we can assume the authors were referring to tissue felt between the patella and the medial joint line. A 12 MHz high frequency transducer was used for the ultrasound, which was placed over the anteromedial aspect of the knee with the knee in full extension. The purpose of full extension was so that the quadriceps muscle group was fully relaxed. The ultrasound image revealed the medial patella, the patellar cartilage, and the medial femoral condyle. Researchers measured both the problematic or painful knee as well as the uninjured, non-painful knee. Then an arthroscopic evaluation was completed with the purpose of observing the plica and possible impingement occurring between the patella and femoral condyle. Researchers were able to compare the plica syndrome diagnosed with ultrasound to a gold standard of arthroscopy. According to this study, the accuracy of diagnostic ultrasound for detecting medial plica syndrome, was 88 percent, 90 percent sensitive, and 83 percent

specific^{8,9,13}. These published conclusions indicate diagnostic ultrasound does a better job of ruling out medial plica syndrome than it does ruling it in.

Brussaard, Naudts and Schepper completed a study which observed chondromalacia of the "femoropatellar" joint. The researchers defined chondromalacia as an anatomic lesion on the patellar cartilage or the femoral cartilage. In order to observe this, they compared the femoropatellar joint with diagnostic ultrasound as well as with contrast computed arthrotomograpy (contrast CT scanning). 35 participants ranging from 18-66 years of age, were included in this research project. These participants suffered from femoropatellar arthralgia on the medial or both sides of the knee, as well as knee pain which was worse with resisted knee flexion. The diagnostic ultrasound set at 7.5 MHz for observing the knee while it was in 110 degrees of flexion. It was noted that ultrasound was diagnostically useful when compared to CT scanning except for in patients with cartilage issues on the deep patellar surface $(p<0.0001)^6$. It was found that in a knee with cartilage damage and tendon abnormalities, it was more common for the ultrasound picture to be distorted. The distorted image may occur because of the reflectivity during the ultrasound off of the tendon and cartilage damage. They found in this case the diagnostic ultrasound had higher diagnostic value than a computed arthrotomography scan in the femoropatellar joint⁶. If clinicians are unsure of what condition is affecting the patient, a combination of diagnostic ultrasound and CT may be most appropriate to gain the best understanding of the joint space. With more information on the accuracy of diagnostic ultrasound, clinicians are better able to make proper judgement for surgical intervention or more conservative treatments by use of diagnostic tests that are non-invasive such as diagnostic ultrasound.

A study completed by Stubbings and Smith found that in the case of medial patella plica syndrome, ultrasound is superior to MRI for diagnostic purposes. This study compared literature on the accuracy of clinical tests including MRI, ultrasound, and a surgical reference test as the gold standard. Stubbings and Smith found that diagnostic ultrasound was 90% sensitive, and 83% specific for the diagnosis of medial patella plica syndrome, while MRI was 77% sensitive and 58% specific for the diagnosis of medial patella plica syndrome. This is important to note because when discerning between conditions involving the patella, it is important for clinicians to know which diagnostic tool may give them the best information. The sensitivity and specificity for ultrasound are the same as what Paczesny and Kruczynski found, but are different than what Brussaard, Naudts and Shepper found in their study on ultrasound diagnosis of chondromalacia. Brussaard, Naudts and Shepper found diagnostic ultrasound to be 77% sensitive and 100% specific. Other studies did not report the specificity and sensitivity of diagnostic ultrasound. Therefore, publishing more research is needed on this topic in order to find the best diagnostic tool for the knee.

According to Friedman, Finlay and Jurriaans, the medial knee evaluation should include the assessment of the femoro-tibial joint space and meniscus. They also stated that the patellar retinaculum should be examined at the thickest margin of the patella. There was no mention of measuring the patellofemoral joint space with regards to diagnostic ultrasound in the knee⁹. This is a cause of concern for conditions such a chondromalacia patella or a plica syndrome, as well as possible arthrosis at either surface. If clinicians were able to have a quantifiable measurement of the patellofemoral joint space, the understanding of what was occurring in the joint may be more accurate and possibly better treated.

Kinesio® Tape

Kinesio® tape was first introduced by Dr. Kenzo Kase, who has a background in chiropractic and acupuncture. One of his main goals when he was developing this tape was to create a product which had similar elastic properties as healthy human tissue. The goal of creating it to be similar to the epidermis was to limit the body's perception of weight and avoid sensory stimuli when properly applied¹⁵. Kinesio® tape can stretch up to 55-65% of its resting length, but while on the paper is on a 10 percent stretch¹⁵. Kinesio® tape is extremely adhesive, yet breathable, allowing it to stay on the skin for multiple days with minimal irritation. It is a polymer elastic strand wrapped in cotton fibers. The cotton is used in order for moisture from the body to be absorbed, as well as for the tape to dry more quickly since it can be left on the skin for up to 72 hours. The adhesive in the tape is heat activated, and is in a wave pattern to mirror that of human fingerprints. Dr. Kase thought that using this product on a muscle in order to achieve the best joint position could be more beneficial than using a rigid tape to stabilize a joint. Kinesio® Tape claims to "re-educate the neuromuscular system, reduce pain, optimize performance, prevent injury, and promote improved circulation and healing." (p.23)¹⁵.

There are six application techniques used for correction. These include; mechanical correction or recoiling, fascia correction or holding, space correction or lifting, ligament/tendon correction or pressure, functional correction or spring, and lymphatic correction also called channeling¹⁵. The recoiling method includes facilitating or inhibiting muscles. To facilitate muscles, the tape is applied distal to proximal with 15-25% tension on the tape. To inhibit a muscle, the tape is applied proximally to distal with 15-35% tension on the tape, both making sure the recoil is towards the anchor point. The holding method is used to inhibit pathological movements and influences the body to a desired resting position such as better posture. The tape is applied with 50-75% tension, in order to hold the joint in the spot that the clinician places it.

The space correction method uses different tensions depending on the cuts that create the lifting recoil. This can range from 10-35% tension in the tape. The ligament correction is stretched to 100% tension to give the perception of support and to decrease stress on the ligament. The functional correction, also named the spring-assist correction, has 50-75% tension and is applied to either assist a motion or limit a motion. It is commonly used for the stimulation of the mechanoreceptors in the joint that will help limit the amount of stretch on the joint. The channeling method is commonly used for lymph edema. This method uses 0-20% tension on the tape. The tape helps pull exudate from the congested areas to the less congested area using lymphatic pathways¹.

Though Kinesio Tape® is widely used, it is not well researched with objective measurements. The theory behind Kinesio Tape® is that it can improve circulation, assist with healing, and finally optimizes performance. These occur because of the increase in space between skin and connective tissue due to the elasticity of the tape, which in effect increases blood flow and lymph drainage¹⁵. With the increase in blood flow and lymph drainage, metabolic activity increases which can decrease healing time and makes normal function possible more quickly¹⁶. Also with the increased interstitial space, the pressure on pain receptors should decrease causing a pain reduction. To date, an exhaustive literature review did not reveal any published studies specifically examining the use of the Space Correction Kinesio Tape Method®. *Kinesio Tape*® *on the Knee*

A study completed by Akbas, Ozgur and Yuksel was completed to evaluate the use of Kinesio Tape® on patellofemoral pain syndrome. Though this study was based more on pain relief, the authors did measure the position of the patella in relation to the medial femoral condyle after Kinesio Tape® was applied. This study was performed on 31 female patients with a mean age of 44 years. Participants had to have a diagnosis of unilateral patella femoral pain

syndrome, but were excluded if they had tendonitis, Osgood-Schlatter, meniscus or ligament issues or patellar problems other than pain (such as patella subluxation). The authors measured the position of the patella by use of caliper with the knee in 20 degrees of flexion. The caliper jaws were fixed on the femoral condyles and the patellar medial and lateral edges. Kinesio Tape® was applied on an individual basis depending on what their pain was stemming from. Some patients received a facilitation technique on the quad and some were taped for tightness relief of the IT band and hamstring, a fascial technique was not mentioned. The analysis of the before and after Kinesio Tape® measurements were not significant (p>0.05) stating that the location of the patella did not change, but it is unknown how long the tape was left on the subjects².

The results of the Akbas, Ozgur and Yuksel study did not explain if the tape was still on the patient during the measurement or if it had been removed, which leaves unanswered questions. The tape may have had a significant effect while it was on the patient in regards to this caliper measurement, but it is unknown. Though the measurement may not have been statistically significant, it was reported that pain decreased, which is considered clinically relevant². The same study explored the performance differences of the patella tracking between a Kinesio tape® application and a McConnell's patellar positioning tape application. It was found that there were positive effects with Kinesio Tape® on healthy individuals, but no positive effects with either McConnell's or Kinesio Tape® on individuals suffering from patellofemoral pain syndrome². The types of positive effects were not described, and may have been focused on pain instead of a quantitative measurement of the patella.

Ibrahim and Atya performed a study that assessed Kinesio Tape® and sensory motor training for patients with knee osteoarthritis. Sixty patients with knee osteoarthritis were

evaluated and randomized into three equal groups. The first group received traditional physical therapy, the second received the same physical therapy as well as Kinesio Tape® for the knee, and the third group received the same physical therapy and sensory motor training. Baseline tests were taken prior to any treatments, and again at the eight week mark. The baselines included a visual numeric scale for pain, a passive active joint position reproduction method using an isokinetic dynamometer, and a functional disability level for activity of daily living. They did not use a space correction technique, but rather a facilitation technique on the quadriceps and then a mechanical correction with tension on the tail of the "I strip" for patella tracking. In the group that had both sensory-motor training and physical therapy, joint dysfunction lessened, as well as an increase in accurate proprioception (p=0.001). Pain was reduced significantly in the Kinesio® Tape group, but no statistics were given³. The authors' main conclusion regarding Kinesio® Tape, is that pain is reduced due to the stimulated nerve endings from the adhesion of Kinesio® Tape to the skin³. According to this study, sensory motor training with physical therapy seemed to more beneficial than Kinesio® Tape with physical therapy for patients with osteoarthritis for proprioception, but the opposite for pain control. This does not mean Kinesio Tape® is a poor treatment option for these patients especially if pain is a major limitation.

A similar study was conducted but examined the initial effects of Kinesio Tape® in patients with patellofemoral pain syndrome. Aytar, Ozunlu, Surenkok, Baltaci, Oxtop and Karatas were interested in the acute effects of Kinesio® Tape on pain, strength, proprioception and balance of 22 female subjects with patella femoral pain syndrome. Subjects were arranged in two groups, a Kinesio® Tape group and a placebo tape group. The Kinesio® Tape group was taped according to Dr. Kenzo Kase's manual with a Y shaped strip over the quadriceps for facilitation. In addition, two "I-strips" were applied around the patella for a mechanical

correction with the knee at 45 degrees and 50-75% of tension on the tape. The placebo tape was a plaster with no stretch that was placed in a similar technique as the Kinesio Tape® group. In the case of muscle strength, measured with a Biodex, and balance measured by a balance plate KAT 300, Kinesio Tape® had a positive effect in the initial evaluation after tape was applied as well as 45-minutes after the tape was applied (p<0.05). Pain also improved with the tape applications, but none of these were statistically significant (p<0.05). Authors credit this positive effect to the possible increase in feedback from adhesion to the skin without limiting motions from more rigid tapes 4 . The authors did not state what occurred during the 45 minute waiting period, therefore it is unknown if movement or activity could have altered results of this study. Also, research is limited on the longer term effects of the tape, so it is unknown if leaving the tape on longer with additional activity affects how the tape works.

Howe, Campbell, Hall and Hopper facilitated the quadriceps in 29 female recreational runners. The participants repeated running trials for three different tape applications. Two mechanical correction tape techniques were applied around the patella to assist with patellar tracking. The knee was flexed to 90 degrees for the first. The Kinesio® Tape was cut into a Y with the anchor being the origin of the vastus medialis oblique, continuing on a 25-50% stretch along the lateral border of the vastus medialis oblique muscles. The second piece of tape was applied with the knee in extension on a 75-100% stretch around the inferior and medial border of the patella to force a medial glide. A Mulligans tape application was applied for one trial with the knee in 25 degrees of flexion and the hip in internal rotation. The purpose was to add a tibial torsion internally to help with tracking of the knee. The last trial was one with no tape. Balance, proprioception, pain, and muscle strength were measured in this study. The participants ran trials at 5 m/s (plus or minus 0.5 m/s) and had to hit a specific force plate. It was found that Mulligans

tape job was associated with a smaller knee flexion velocity than the Kinesio® Tape. This is most likely due to the rigidness of the tape used as well as the location of the tape, which only helps support the use of Kinesio® Tape, as it does not limit body motions like more rigid tapes do. Overall, authors concluded Mulligan tape was more of a limiter compared to Kinesio® Tape. They noted that pairwise comparisons showed that Mulligan tape had a smaller hip flexor and extensor motion during running (p = 0.001). They also noted that there was no significant difference between Kinesio® Tape and no tape during the running trials¹⁷. Information is limited on the specifics of how long the Kinesio® Tape was left on prior to any trials. Though this research does not support the use of Kinesio® Tape for much more than pain control, there were some positive effects. The positive effects could be clinically important, even if they are not statistically significant. Therefore, clinicians should not rule out Kinesio® Tape completely. *Conclusion*

Based on the literature reviewed, there are published articles regarding the use of diagnostic ultrasound to visually analyze the patellofemoral joint. Though few researchers have researched the patellofemoral joint space specifically, there have been similar methodologies to measure the patella. Many of these methodologies or techniques to observe the patella include using the medial femoral condyle as a landmark, creating an opportunity to examine the joint space, and take a measurement. The pitfall with this technique was highlighted as user error of the diagnostic ultrasound, not knowing what correct anatomy should look like when deciphering the image, or the lack of anatomical knowledge creating an incorrect picture. The literature seems to be conflicting on the use of Kinesio® Tape for purposes other than pain reduction, but is also limited on certain Kinesio® Tape techniques. Though many researchers found positive effects from mechanical correction Kinesio® Tape applications on the knee, there did not appear to be many statistically significant studies with outcomes other than pain control. Research is,

again, very limited in this aspect. It is also unknown if the positive effects that researchers found can translate into clinically applicable or positive effects. The purpose of the literature review was to see what information is available to analyze on the subject of Kinesio® Tape space correction techniques as well as observing the patellofemoral joint space with diagnostic ultrasound. This information can help support researching the use of diagnostic ultrasound specific to Kinesio Tape Methods®.

CHAPTER 3. METHODOLOGY

Statement of Purpose

The purpose of this study was to evaluate the effectiveness of the Space Correction Kinesio Tape Method®, via diagnostic ultrasound, over the patellofemoral joint in healthy individuals. This study is guided by the following research questions:

- Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring the patellofemoral joint space as determined by diagnostic ultrasound?
- 2) Does an individual's dominate leg have a statistically significant difference patellofemoral joint space compared to the non-dominate leg?
- 3) Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring from the skin to the patella as determined by diagnostic ultrasound?
- 4) Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring from the skin to the patella tendon as determined by diagnostic ultrasound?

Participants

Participants for this study included 16 males and 16 females (n=32) between the ages of 18 and 30. Each participant had bilateral, healthy knees as each person served as his/her own control. Participants were recruited via email listserv and word-of-mouth in the North Dakota State University (NDSU) community. Exclusion criteria for this study included: 1) past knee surgery; 2) non-surgical knee injury in the past 6 months; 3) prior history of general medical conditions involving joints, muscles, bones, or connective tissue (examples included

osteoporosis, fibromyalgia, etc.); 4) reported allergies to Kinesio Tex Tape®. All participants had equal opportunity to win a cash drawing at the closing of the study for their participation. *Setting*

This study took place at Bentson Bunker Fieldhouse on the NDSU campus, room 14.

This was the best place for the study to take place because the supplies (Kinesio Tex Tape®) and equipment (Diagnostic Ultrasound) necessary for this study are stored in this location.

Participants had easy access to the building as most will be members of the NDSU community.

Equipment

The examination of the patellofemoral joint space was completed with the Terason 3200 diagnostic ultrasound unit. The examination was completed by a certified athletic trainer who has experience with the diagnostic ultrasound unit. The Space Correction Kinesio Tape Method® was completed by a Kinesio Taping Instructor who is also faculty at NDSU. The tape used was the Kinesio Tex Gold FP 2" tape®. Each Space Correction Kinesio Tape Method®, as well as goniometry measurement was completed by the same individual for internal consistency. *Procedures*

Prior to data collection, this research project was approved by the North Dakota State University Institutional Review Board (IRB). Research was conducted fall of 2015 in the Bentson Bunker Fieldhouse; room 14 on the NDSU campus, 1301 Centennial Blvd. Fargo, ND 58102. Upon arrival of the participants to the lab, each individual signed necessary paperwork. Paperwork included the Informed Consent and Health History Questionnaire.

Raw data was taken via diagnostic ultrasound of the patellofemoral joint spaces in bilateral knees. The analysis was completed using the Treason t3200 ultrasound unit on high frequency. The tibiofemoral joint was positioned in slight flexion with a half roam roller positioned directly under the popliteal space to hold the joint in slight flexion (5-15 degrees).

Because the anatomy differs in each participant the baseline position may have been changed, more or less flexion was used per individual basis to achieve a good image of the patellofemoral space. Because each subject served as their own control, the difference in joint angle was not significant to the final results. The ultrasound probe was placed in a long axis view over the patellar tendon in order to ensure viewing of the lower aspect of the patella, were observed. From the initial position, the probe was moved medially making sure that the patella's medial border was apparent on the image. Movement of the ultrasound head (distal aspect) continued until the medial femoral condyle came into view. Once the medial femoral condyle was observed, the screen was frozen and the joint space was measured from the medial aspect of the patella to the medial femoral condyle (patellofemoral joint space). The measurement was taken with the caliper function in the ultrasound software, done perpendicular to the screen for a consistent reading (Figure 1). Sharpie marks were placed where the ultrasound probe was placed so that the joint space was able to be re-measured in the same place after the tape had been applied.



Figure. 1 Diagnostic Ultrasound Caliper Measurements

The Kinesio Tape Space Correction Method® as described in published Kinesio Tape® manuals was applied to the clean skin of the patient. Skin was cleaned using an alcohol prep pad

and excess hair was trimmed. The dominate knee was taped, according to the participants' determination. The Space Correction Kinesio Tape Method® is referenced on the Kinesio Tape® database; however, the anatomical description is of the elbow and not the knee. Tape was applied according to the Kinesio Tape® database written by Dr. Kase. The tape was cut approximately two inches longer than the patella, or 4 squares in the tape (when looking on the underside of the tape). The tape also had 3 cuts longitudinally, keeping the ends intact. The patellofemoral joint was flexed to 120 degrees, which was confirmed via a goniometer read by an experienced certified athletic trainer. The Kinesio Tape® text states that the reason for the knee flexion position, was to increase the tissue tension under the tape to assist with lifting. The paper was torn from the back of the tape in the middle portion of it and applied over the patella. The middle third portion was applied with light to moderate tension (approximately 35% tension) over the patella and then the ends had no tension and were anchored in neutral (Figure 2.). Lastly the tape was rubbed to activate the adhesive¹⁵. The knee was returned to the original slightly flexed position that the initial joint space measurement was taken from. The subject sat, non-weight bearing for ten minutes. During this ten minutes, the non-dominate joint space measurements were taken. A measurement of the dominate joint space was taken ten minutes after the tape was applied with the ultrasound probe placed in the same spot as the baseline spot, signified by the original marks, with the tape still on the subject. The joint space was measured in the same manner as previously described for the baseline measurement.



Figure 2. Kinesio® Tape Space Correction Method over the Patellofemoral Joint *Data Analysis*

Statistical analysis for the approved research questions was computed using the latest SPSS software. Paired t-tests were conducted for all research questions since only one variable was being compared in each respective research question.

CHAPTER 4. RESULTS

Introduction

Kinesio Tape, though a widely used modality, has limited quantitative research to support its use clinically. Kinesio Taping Association International (KTAI) claims that have been previously discussed include; the ability to "re-educate the neuromuscular system, reduce pain, optimize performance, prevent injury and promote healing"(p.23)¹. Ideally the Space Correction Kinesio Tape Method® creates a suction force that lifts the structures under which the tape is applied. Specifically at the knee when the Space Correction Kinesio Tape Method® is applied at the patella, the suction force should increase the space between the underside of the patella and the femur. The lack of quantitative research to support the use of Kinesio Tape®, as well as the limited research involving the measurement of joint spaces with diagnostic ultrasound were the primary topics in this research project. The research questions which guided this research were:

- Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring the patellofemoral joint space as determined by diagnostic ultrasound?
- 2) Does an individual's dominate leg have a statistically significant difference patellofemoral joint space compared to the non-dominate leg?
- 3) Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring from the skin to the patella as determined by diagnostic ultrasound?
- 4) Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring from the skin to the patella tendon as determined by diagnostic ultrasound?

Participant Demographics

Thirty two healthy individuals participated in this study (16 females, 16 males). Data that was collected was analyzed using SPSS version 23 (SPSS Software 23^{rd} edition, IBM, Upper Saddle River, NJ). Descriptive statistics were performed for age, with the mean age being 20.69 \pm 2.681, and dominate pre- tape patellofemoral measurement with the mean 2.405 \pm .241. See Table 1 for descriptive statistics.

Table 1. Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation	
Age	32	18	29	20.69	2.681	
Dominate Pre-						
Patella to Femur	32	1.73	3.03	2.4050	.24105	
measurement						
Valid N (listwise)	32					

Methods

Subjects arrived at the research site and completed an informed consent and medical history questionnaire. Once this was completed and any questions they may have had were answered, the data was collected. First, the dominant knee (as determined by the subject) was measured via diagnostic ultrasound. The landmarks that were used for repeatable measures were the medial patellar border and the medial femoral condyle^{9,12,13}. When these landmarks were clearly visible on the ultrasound output; the superior and inferior borders of the ultrasound head were delineated with visible marks on the skin for repeatable measures. Once the ultrasound measurement was taken (with the caliper function on the ultrasound unit), the dominant patellofemoral joint was taped with the Space Correction Kinesio Tape Method®. The tape was

cut approximately two inches longer than the patella, or four squares in the tape, with three cuts longitudinally through it, keeping the ends intact.

The patellofemoral joint was flexed to 120 degrees, which was confirmed via a goniometer measurement. The paper was torn from the back of the tape in the middle portion of and applied over the patella from the center of the tape. The middle third of the tape was applied with light to moderate tension (35%) over the patella and then the ends or tails had no tension and were anchored in neutral. Lastly the tape was rubbed to activate the adhesive 15. Once the tape was applied and activated, the non-dominate patellofemoral joint space was measured using diagnostic ultrasound.

Ten minutes after the tape was applied, the dominant patellofemoral joint space was measured for the second time duplicating the original measurement. A local diagnostic ultrasound expert requested caliper measurements of the skin to patella (measured from the top layer of adipose to the inferior angle of the patella), as well as a skin to patella tendon (measured from the top layer of adipose to the inferior border of the patella tendon just distal to the patella) measurement. These anatomical features were easily identified in the view previously established by the patellofemoral joint space measurement.

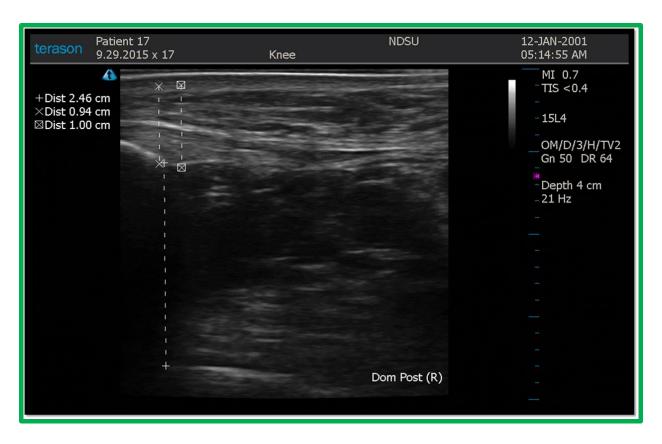


Figure 3. Diagnostic Ultrasound Caliper Measurements showing Patella to Femur, Skin to Patella and Skin to Patella Tendon Measurements

Statistical Analysis

A paired sample dependent t-test was performed with the significance level set at $p \le .05$. The paired sample t-Test compared the dominate patella femoral space measurement via diagnostic ultrasound prior to being taped and 10 minutes after being taped with the Kinesio Tape Space Correction Method®. There was a statistically significant difference (t[31]=2.823, p=.008) between pre-taped (M=2.405 \pm .241) and post-taped (M=2.515 \pm .23) patella to femur measurements with a mean difference of M= .11. These results support that the use of the Kinesio Tape Space Correction Method® can increase the patellofemoral joint space. Table 2 provides a summary of the results for male and female patella to femur measurements pre- and post- tape application.

Table 2. Group Statistics: Dominant Patella to Femur Measurements

					Std. Error
	Sex	N	Mean	Std. Deviation	Mean
DOMPrePF	Male	16	2.4069	.28161	.07040
	Female	16	2.4031	.20191	.05048
DomPostPF	Male	16	2.5581	.25370	.06342
	Female	16	2.4713	.20324	.05081

A second paired sample t-test was performed with the significance set at $p \le .05$ to compare non-taped dominant and non-dominant (non-taped) patella femoral joint spaces. There was no statistically significant difference (t[31]=.274 p=.786) in dominant (M=2.405 \pm .241) and non-dominant (M=2.417 \pm .242) patella femoral joint spaces (Table 3). The mean difference between the two was M=.012.

Table 3. Paired Samples Statistics Dominant to Non-dominant Patella to Femur Measurement

					Std. Error
		Mean	N	Std. Deviation	Mean
Pair 1	DOMPrePF	2.4050	32	.24105	.04261
	NonDomPF	2.4166	32	.24212	.04280

A third paired sample t-test was performed with the significance level set at $p \le 0.05$ to compare the dominant pre- and post- taped skin to patella measurement. There was no statistically significant difference (t[31] =.1.211 p=.235) between pre-taped (M=.745 ± .250)

and post-taped (M= $.700 \pm .164$) skin to patella measurements (Table 4). The mean difference between the two was M= .045.

A fourth paired sample t-test was performed with the significance level set at $p \le 0.05$ to compare the dominant pre- and post- taped skin to patella tendon measurement. There was no statistically significance difference (t[31] =.017 p=.987) between pre-taped (M=.856 \pm .149) and post-taped (M=.856 \pm .170) skin to patella tendon measurements (Table 4). The mean difference between the two was M= 0.

Table 4. Paired Samples Tests

			Paired Differences						
					95% Con Interval Differ	of the			Sig. (2-
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t	df	taile d)
Pair 1	DOMPrePatella to Femur – DomPostPatella to Femur	- .1096 9	.21980	.03886	18893	03044	2.823	31	.008
Pair 2	DOMPreSkin to Patella – DomPost Skin to Patella	.0450	.21018	.03715	03078	.12078	1.211	31	.235
Pair 3	DOMPre Skin to Patella Tendon – DomPost Skin to Patella Tendon	.0003	.10378	.01835	03773	.03711	017	31	.987

CHAPTER 5. CONCLUSIONS

Statement of Purpose

The purpose of this study was to determine if there is a significant difference in the patellofemoral joint space pre- and post- Space Correction Kinesio Tape Method® measured by diagnostic ultrasound. Researchers used the following questions to guide the study:

- 1) Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring the patellofemoral joint space as determined by diagnostic ultrasound?
- 2) Does an individual's dominant leg have a statistically significant difference patellofemoral joint space compared to the non-dominant leg?
- 3) Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring from the skin to the patella as determined by diagnostic ultrasound?
- 4) Does the Space Correction Kinesio Tape Method® create a statistically significant change when measuring from the skin to the patella tendon as determined by diagnostic ultrasound?

Literature Review Summary

Though quantitative research is limited regarding the use of Kinesio® Tape, specifically the Space Correction Kinesio Tape Method®, the statically significant findings of this research (t[31]=2.823, p=.008) supports the use of the Space Correction Kinesio Tape Method® to increase the patellofemoral joint space in healthy individuals. It is logical that if Kinesio Tape® does increase the space between skin and connective tissue, the likelihood of the femur and patella degenerating due to friction could decrease. Also this space created by the Space Correction Kinesio Tape Method® could potentially help increase range of motion, thus

increasing functionality of the knee. This concept came from Dr. Kase's 2nd edition of the Kinesio Taping Manual which stated that Kinesio® Tape improves circulation, increased healing and optimizes performance¹⁵.

While the literature review for the current research project is limited, there is a small amount of research involving different Kinesio® Tape methods. Because there was no literature supporting the Space Correction Kinesio Tape Method®, researchers determined that this technique could be quantitatively measured, specifically with diagnostic ultrasound to provide evidence based research. Other researchers have performed studies using different Kinesio® Tape methods, as well as different outcome measures. Limited research has been completed to give guidelines for joint space measurement with diagnostic ultrasound, specifically the use of specific landmarks. The small amount of research as well as differing tape methods helped guide the current research project by use of methodology, statistical analysis, and some clinical relevance.

Ibrahim and Atya observed pain in patients with osteoarthritis. They used a Manual Correction Kinesio Tape Method® over the patella to assist with patellar tracking, as well as the facilitation technique on the Vastus Medialis. This study compared proprioception training and sensory motor training to the Kinesio Tape® group and found that for pain management, Kinesio Tape® was beneficial; however, overall proprioception and sensory motor training was most beneficial for osteoarthritis patients 3 . Though the research completed by Ibrahim and Atya did use a specific Kinesio® Tape Method, the focus of their study as well as the specific patient population differ from the current study. The current research did not measure pain and included only healthy patellofemoral joints. Ibrahim and Atya used paired t-tests (p=0.05) to detect

differences between baseline and post treatment values. This data analysis was also used for the current research study, with the pre- and post-measurement research design.

Akbas et al. observed the effects of Kinesio Tape® on patella tracking in participants with patellofemoral pain syndrome. They measured the IT band tension, hamstring tension, and the location of the patella. Thirty-one women were split into two groups based on random selection. Each group performed both stretching and strengthening protocols. Again, based on random assignment, participants in one group received a Kinesio Tape® application based on specific needs of each individual. The researchers found that pain was decreased and hamstring flexibility had increased in the Kinesio Tape® group. One problematic area of this study was the Kinesio Tape® applications were applied on an individual basis which may skew results. Over all it was stated that Kinesio Tape® did not have a positive effect on participants with patella femoral pain syndrome, but Kinesio Tape® did have positive effect on increasing hamstring length². After reviewing Akbas et. Al.'s research, it was found that the methodology could not be replicated based on the individualized applications of Kinesio® Tape as well as the large amount of variables. This study was the most appropriate that was found for a fair representation of clinical application. This was because of the individualized treatment plan with the Kinesio® Tape, but from a research standpoint, it may not be the best methodology for repeatable measures. The current researchers decided to create a methodology that could be replicated for future studies. One thing which was similar from this study was the sample size; the current research had a sample size of 32, with 16 females and 16 male.

Aytar et al. used a quadriceps facilitation and a patella Mechanical Correction Kinesio

Tape Method® on twenty-one female participants with patellofemoral pain syndrome. They

measured muscle strength, joint position, static and dynamic balance, and pain intensity for two

groups; Kinesio Tape® and placebo tape. Over all they found a decrease in pain that was not statistically significant, as well as a lack of statistically significant difference in joint position in participants with patellofemoral pain syndrome. The researchers did find the Kinesio Tape® group had statistically significant findings for muscle strength (p=0.028 at 60 degrees of flexion and p=0.012 at 180 degrees), static balance (p=0.012), and dynamic balance (p=0.046) forty-five minutes after the tape had been applied⁴. Aytar et al. had a very detailed methodology, and although the current study did not follow it directly, due to the differing tape methods as well as outcome measures, the exclusion criteria was something that the current researchers were interested in. The specific exclusion criteria included; current knee pain, a past trauma or surgery, joint disease, and any allergy to adhesive tapes. The current researchers also chose to stray from a placebo tape application due to the discussion aspect held by Aytar et al. Atyar et al., wrote, "A strong placebo effect of taping has been well documented in subjects with patellofemoral joint pain. The application of elastic tape may affect by mediation through cutaneous mechanoreceptors which could enhance proprioception and facilitate motor activity" (p. 141). This deterred current researchers from using a placebo tape method as to not skew results.

Little research had been completed to create a specific protocol for observing and measuring joint spaces. According to Friedman and Finlay, the possibility to measuring joint spaces is high because of the ability to position patients to get a clear image in real time⁹. Two research teams used the medial patellar border and the medial femoral condyles as landmarks. Yanagisawa et al. used diagnostic ultrasound to measure if the osteophytes in the medial knee had enlarged and used the above landmarks as well as the medial retinaculum. They concluded that after the age of 60 the number of osteophytes significantly increased⁹. Paczesny et al. used

diagnostic ultrasound to research the ability to diagnose medial plica syndrome better than MRI could. They used the previously listed landmarks as well as the medial cartilage as their guide. They found that diagnostic ultrasound was better at diagnosing medial plica than MRI¹³. Since the previously stated anatomical landmarks have been the most common stated in the literature for repeatable measures, the current study also used them. Neither Yanagisawa et al. nor Paczesny et al. specifically reported any anatomical landmarks for a measurement between the skin and patella or skin and patella tendon. Because the medial patellar border and patellar tendon were seen in the same image as the patellofemoral joint space, the current research team decided to add additional landmarks. These landmarks were the inferior aspect of the medial patellar border as well as the inferior aspect of the patella tendon just distal to the patella. The researchers measured from the superior aspect of the adipose tissue right below what would be the skin to the patella and the patella tendon.

Current Research Summary

In order to determine if a significant change resulted in the patellofemoral joint space from a Space Correction Kinesio Tape Method®, current researchers completed a pretest-posttest research design. Thirty-two healthy participants' knees were scanned using the caliper function on a diagnostic ultrasound machine (Terason 3200) to measure the patella femoral joint space. The landmarks used for repeatable measure included the medial patellar border and the medial femoral condyle^{9,12,13}. Following the initial dominate patellofemoral space measurement, the subjects received the Space Correction Kinesio Tape Method® over the patellofemoral joint space. Ten minutes after the Kinesio Tape was applied, they were scanned again to identify any changes in patellofemoral joint space. During the 10 minutes the participants were seated and not allowed to bear weight, and their non-dominate patellofemoral joint space was also measured.

The major limitations of this involved the methodology and design of the study. Since there is such a limited amount of research involving Kinesio® Tape the current study chose to keep the subjects non-weight bearing. This non-weight bearing position is not realistic nor transferrable to an active population. Having the subjects weight bearing could possible alter the statistical significant findings of the current research. Another limitation includes not having a specific evidence based protocol used for the measurement of the patellofemoral joint space with diagnostic ultrasound. The literature did not state a specific way to not only measure the joint space, but also the best limb position to find the joint space and measure the space. The current research did not standardize any exercise performed prior to the measurements being taken. This also may have affected the joint space. For example high impact athletic involvement may cause a decrease in the joint space while low impact may not, but the current research did not control or standardize athletic participation prior to the research being completed. The two major strengths of the current research involved having consistency. The current research was consistent with the tape application. The person who measured the 120 degrees of flexion with a goniometer was the same for each participant. This was also the Certified Kinesio Faculty Member, who completed all of the Space Correction Kinesio Tape® applications. A different researcher was consistent with using the diagnostic ultrasound to find and measure the patellofemoral joint space. Though a strength of the study is consistency, a pitfall was not having any blinding. The current study could have had one person take the diagnostic ultrasound image and another researcher complete the measurements. Another strength of the current research is the possibility for repeatable measures with the methodology.

Conclusions

The primary conclusion drawn from the results of this study indicate that patellofemoral joint space is increased by the Kinesio Tape Space Correction Method® after 10 minutes of application (t[31]=2.823, p=.008). Increasing joint spaces creates opportunity for an increase in range of motion, as well as for a potential positive treatment of plica syndrome, chondromalacia of the patella, patellofemoral pain syndrome, possibly other patellofemoral related injuries, and overall pain relief. Previous research indicates that Kinesio Tape Methods® have helped reduce pain at the knee, but none have explored the Space Correction Kinesio Tape Method® and the benefits that could come from that method²⁻⁴. Our results show that there is a statistically significant increase in the dominate patellofemoral joint space after a 10 minute Space Correction Kinesio Tape Method® application in a non-weight bearing position. Because this study was performed on healthy individuals with non-injured knees, it is unknown if these results are transferable to an injured population, but ideally they would be.

Diagnostic ultrasound was selected as the way to measure the joint space because it was non-invasive and clinically applicable in the orthopedic settings. It is difficult to record quantitative measurements in regards to Kinesio® Tape, and this was a way that made it possible. Though no studies have observed and measured the patellofemoral joint space specifically, diagnostic ultrasound has been used to observe the knee. The present study is hard to compare to previous studies using diagnostic ultrasound mainly because the lack of protocol in place for measuring the joint space. It is unknown what the best patient position is for a quality, concise and repeatable measurement is.

Research Question 1 was determined to be statistically significant (t[31]=2.823, p=.008); therefore, the space between the patella and femur increases with the use of Kinesio® Tape.

Research Question 2 was determined to be not statistically significant (t[31]=.274 p=.786) thus concluding that the patellofemoral joint spaces do not differ from dominant to non-dominant knees. This was key for the current research findings. If there was a statistically significant difference, the population being research may not have had bilateral healthy knees thus skewing the results that were found.

Research Question 3 was determined to be not statistically significant (t[31] = .1.211 p=.235); therefore, saying there was not a large difference in skin to patella measurements preand post-taped.

Research Question 4 was determined to be not statistically significant (t[31] = .017 p=.987); concluding that there was no difference between pre- and post-taping of the skin to patella tendon measurement.

The findings of this research could act as a catalyst for future research endeavors. This research could benefit and help guide future research that creates a protocol for measuring patellofemoral joint spaces with diagnostic ultrasound. Also, it could help guide further research to standardize a general measurement range for healthy non-painful patellofemoral joint spaces. This research may also act as a guide for a continuation of quantitative Kinesio Tape® research based on the differing methods of Kinesio Tape® application.

Clinically, this information provides evidence to support the use of diagnostic ultrasound to measure joint spaces, specifically the patellofemoral joint space. Also, this research provides evidence to support the use of the Kinesio Tape Space Correction Method® at the patellofemoral joint space, potentially reducing pain and increasing function. Even if the patellofemoral joint space had not had a statistically significant change, the Space Correction Kinesio Tape Method®

may still be clinically relevant, similar to many other modalities that do not have statistically significant findings to back them but are still used and useful in a clinical setting.

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APPENDIX A. IRB APPROVAL

NDSU NORTH DAKOTA

September 22, 2015

Katie Lyman

Department of Health, Nutrition & Exercise Science

RB Approval of Protocol #HE16052, "The Effects of the Space Correction Kinesio Taping Method® on the Patellofemoral Joint Measured by Diagnostic Ultrasound"

Co-investigator(s) and research team: Kara Gange, Kassian Keister

Approval period: 9/22/2015 to 9/21/2016 Continuing Review Report Due: 8/1/2016

Research site(s): NDSU Funding Agency: n/a

Review Type: Expedited category #4

RB approval is based on the original protocol submission —with revised Methods section (received 9/21/2015).

Additional approval is required:

o prior to implementation of any changes to the protocol (Protocol Amendment Request Form).

o for continuation of the project beyond the approval period (Continuing Review/Completion Report Form). A
reminder is typically sent 4-6 weeks prior to the expiration date; timely submission of the report is your responsibility. To avoid a lapse in approval, suspension of recruitment, and/or data collection, a report must be received, and the protocol reviewed and approved prior to the expiration date.

A report is required for:

o amy research-related injuries, adverse events, or other unanticipated problems involving risks to participants or others within 72 hours of known occurrence (Report of Unanticipated Problem or Serious Adverse Event Form). o any significant new findings that may affect risks to participants.

o closure of the project (Continuing Review/Completion Report Form).

Research records are subject to random or directed audits at any time to verify compliance with IRB regulations and NDSU policies.

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

Sincerely.

Krily Studey

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult www.ndsu.edu/irb. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

INSTITUTIONAL REVIEW BOARD

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Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

MONThur IDM private

APPENDIX B. RECRUITMENT LETTER

Recruitment Letter:

My name is Kassiann Keister, and I am a Certified Athletic Trainer in the Master of Science Program in the Department of Health Nutrition, and Exercise Sciences at NDSU.

I would like to invite you to participate in my research study titled "The Effects of the Space Correction Kinesio Taping Method® on the Patellofemoral Joint Measured by Diagnostic Ultrasound". Kinesio Tape® is becoming a more popular tape used by competitive and recreational athletes. Most commonly it is used for pain, but can be used for muscle facilitation, inhibition, and certain correction techniques such as the Space Correction Kinesio Tape Method®. The space correction technique is one that creates a suction cup effect over the area it is places, possibly increasing the space in tissue beneath it. Diagnostic ultrasound is a non-invasive imaging technique. It is most commonly used for guided injections in joints, to observe the degeneration of structures, and to look at an area of pain in real time. It can also be used to measure anatomical spaces, such as the space between the femur and patella in the knee.

If you choose to participate in this study, you will report to only one data collection session that should last approximately thirty minutes. During the thirty minute session both of your knees joints will be measured with the diagnostic ultrasound. After the first measurement your dominate knee will be Kinesio Taped ® with the Space Correction Kinesio Tape Method®. You will also be asked to sit for 10 minutes with the tape on, and then the joint space will be remeasured.

I am in need of 30 individuals, 15 males and 15 females, between the ages of 18 and 30 years old. In order to participate, you must be recreationally active, and a non-NCAA athlete with two healthy knees. You may not participate in the study if you have suffered from1) past knee surgery; 2) non-surgical knee injury in the past 6 months; 3) prior history of general medical conditions involving joints, muscles, bones, or connective tissue (examples include osteoporosis, fibromyalgia, etc.); 4) reported allergies to Kinesio Tex Tape®.

To compensate you for your time and participation in this study, you and all other participants will have the opportunity to win one of fifteen 10\$ drawings.

If you have further questions or wish to participate in this study, please contact me at kassiann.keister@ndsu.edu or (763) 300-0852. This research has been approved by NDSU IRB #HE16052.

APPENDIX C. INFORMED CONSENT

Health, Nutrition, and Exercise Sciences Department # 2620, PO Box 6050 Fargo, ND 58108-6050 701-231-5590

Title of Research Study: The Effects of the Space Correction Kinesio Taping Method® on the Patellofemoral Joint Measured by Diagnostic Ultrasound

This study is being conducted by:

Dr. Katie Lyman, HNES Assistant Professor, <u>Katie.Lyman@ndsu.edu</u>, office number: 701-231-8208.

Kassiann Keister, HNES Advanced Athletic Training Masters Student, Kassiann.Keister@ndsu.edu, cell number: 763-300-0852.

Why am I being asked to take part in this research study? We are looking for 15 males and 15 females between the ages of 18-30 years in the Fargo-Moorhead area with two healthy knees. You will not be allowed to participate if you have had: 1) past knee surgery; 2) non-surgical knee injury in the past 6 months; 3) prior history of general medical conditions involving joints, muscles, bones, or connective tissue (examples include osteoporosis, fibromyalgia, etc.); 4) reported allergies to Kinesio Tex Tape®

What is the reason for doing the study? The purpose of this research is to study the effects of Kinesio Taping® Methods on the patellofemoral joint space via diagnostic ultrasound. Kinesio Tape® is a widely used modality for athletic trainers, massage therapists, physical therapists, and others. There is limited research supporting the use of Kinesio Tape® for anything other than pain, hence the need for quantitative research involving Kinesio Tape®. In some studies, strength and balance measurements occurred with the use of Kinesio Tape®, but some of the information is contradictory. The findings from this study could help clinicians treat knee pain more effectively.

What will I be asked to do? You will come to the Bentson Bunker Fieldhouse, room 14, wearing shorts. You will be asked to read the consent from, ask any questions you may have, sign the consent form, and complete the Health History Questionnaire. Next, both of your knees will be cleaned and excess body hair will be trimmed. Then an ultrasound probe with ultrasound gel will be placed on your medial knee area. After both knees have been measured, you will identify your dominant leg. Your dominant leg will be cleaned again if necessary and then taped with Kinesio Tape®. After 10 minutes of sitting with tape on your knee the ultrasound probe will be placed on you knee to measure the space between your patella and femur again.

The researchers have been trained and are qualified to perform all of the techniques (Diagnostic ultrasound use and Kinesio Taping® Methods).

Where is the study going to take place, and how long will it take? The study will be completed on the North Dakota State University campus in the Bentson Bunker Fieldhouse

Research Laboratory in room 14. Filling out all of the paperwork (consent form, Health History form) and all of testing will be completed in one visit and should last no more than 30 minutes.

What are the risks and discomforts? You may feel slight physical discomfort after the Kinesio Tape has been applied. Since the study is being conducted on healthy joints, the anticipated physical discomfort will be minimal. The session will be stopped at any time and tape removed upon request.

What are the benefits to me? This study could yield useful information, however you are not expected to get any benefit from being in this research study.

What are the benefits to other people? This study could be useful information for athletic trainers and any other health care professionals who use the Kinesio Taping® Methods.

Do I have to take part in the 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 research study? Instead of being in this research study, you can choose not to participate.

Who will see the information that I give? We will keep private all research records that identify you. Your information will be combined with information from other people taking part in the study. When we write about the study, we will write about the combined information that we have gathered. We may publish the results of the study; however, we will keep your name and other identifying information private.

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. Your name and research records will be stored 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.

Will I receive any compensation for taking part in this study? You will have the opportunity to win one of fifteen 10\$ drawings for your participation in the study.

What happens if I am injured because of this research? If you receive an injury in the course of taking part in the research, you should contact Dr. Katie Lyman at the following phone number 701-231-8208, or Kassiann Keister 763-300-0852. If needed, she may refer you to local care facilities. Payment for this treatment must be provided by you and your third party payer (such as health insurance or Medicare). 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 your participation in this research.

What if I have questions?

Before you decide whether to accept this invitation to take part in the research study, please ask any questions that might come to mind now. Later, if you have any questions about the study, you can contact the researcher, Kassiann Keister at 763-300-0852 or kassiann.keister@ndsu.edu.

What are my rights as a research participant?

You have rights as a participant in research. If you have questions about your rights, or complaints about this research, you may talk to the researcher or contact the NDSU Human Research Protection Program by:

- Telephone: 701.231.8995 or toll-free 1-855-800-6717
- Email: ndsu.irb@ndsu.edu
- Mail: NDSU HRPP Office, NDSU Dept. 4000, PO Box 6050, Fargo, ND 58108-6050.

The role of the Human Research Protection Program is to see that your rights are protected in this research; more information about your rights can be found at: www.ndsu.edu/irb.

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	Date
Your printed name	
Signature of researcher explaining study	Date
Printed name of researcher explaining study	_

APPENDIX D. KINESIO TAPING® RESEARCH PROPOSAL

KINESIO TAPING® ASSOCIATION

3901 GEORGIA ST NE, BUILDING F SUITE F2, ALBUQUERQUE, NM 87110 • TELE. 505-797-7818 FAX. 505-856-2983

Kinesio Taping® Research Proposal

KTAI Research Committee

- 1. PROJECT TITLE: The Effects of the Space Correction Kinesio Taping Method® on the Patellofemoral Joint Measured by Diagnostic Ultrasound
 - a. PROPOSAL PREPARED BY: Kassiann Keister, Katie Lyman
 - b. INSTITUTION/DEPARTMENT: North Dakota State University
 - c. ADDRESS: Katie Lyman, PhD, ATC, NREMT, CKTF & Kassiann Keister, ATC, CKTP, ROT

North Dakota State University PO Box 6050 Dept 2620 Fargo, ND 58108

- d. PHONE CONTACT NUMBER: 763-300-0852
- e. CONTACT EMAIL: Kassiann.keister@ndsu.edu; Katie.lyman@ndsu.edu
- f. DATE OF PROPOSAL: August 31, 2015
- g. DATE TO BEGIN: September, 18, 2015
- h. EXPECTED COMPLETION: November 15, 2015
- 2. LIST PRIMARY INVESTIGATOR AND CO-INVESTIGATORS/OTHER RESEARCH PERSONNEL: Please list all participating co-investigators and other research personnel and specific years of experience and role in the project.

Katie Lyman: Committee Chair (Focusing on Kinesio Tape®)

CKTP= 2010; CKTI= 2011; CKTF= 2015

*Over ten years of research experience.

Kassiann Keister: NDSU Graduate Student (research for thesis)

CKTP= 2015

Kara Gange: Committee Member (focusing on Diagnostic Ultrasound) 3 years of experience and research with Diagnostic Ultrasound Elizabeth Blodgett Salafia: Committee Member (focusing on statistics)

3. PURPOSE OF STUDY: An additional page may be attached fully describing the section below. Please summarize the purpose of the study using non-technical language. The information must include 1, a brief statement of the problem and related theory supporting the intent to study, and 2, a brief but specific description of the procedure(s) involving the subjects in 200 words or less.

The purpose of this study is to determine if the Space Correction Kinesio Tape Method® increases the patella femoral joint space when measured by diagnostic ultrasound. The literature shows support for the use of Kinesio Tape® for pain, but there is limited quantitative data to show the support for use of space correction Kinesio Tape® methods. There also is limited research in regards to measuring joint spaces with diagnostic ultrasound. Both patella femoral joint spaces of the subjects will be measured with diagnostic ultrasound and recorded. Then a certified athletic trainer (ATC) who is a Certified Kinesio Taping Practitioner (CKTP) will tape the subjects dominant knee with the Space Correction Kinesio Tape Method® over their patella. Once the tape has been applied, they will rest for ten minutes. Then their patella femoral joint spaces will be re-measured to observe if the joint space has changed from their initial measurement.

4. DESCRIPTION OF SUBJECT POPULATION: Number of subjects to be enrolled, age range, describe populations to be included/excluded from the research.

Participants for this study will include 15 males and 15 females (n=30) between the ages of 18 and 30. Each participant must have bilateral, healthy knees as each person will serve as his/her own control. Participants will be recruited via email listserv and word-of-mouth in the North Dakota State University community. Exclusion criteria for this study include: 1) past knee surgery; 2) non-surgical knee injury in the past 6 months; 3) prior history of general medical conditions involving joints, muscles, bones, or connective tissue (examples include osteoporosis, fibromyalgia, etc.); 4) reported allergies to Kinesio Tex Tape®.

While this research project will be measuring healthy tissue, the research will serve as baseline data for future research projects. Because there is limited objective research with the Space Correction Method, a pilot project is necessary for future studies.

5. DESCRIPTION OF STUDY (an additional page should be attached fully describing the section below)

Describe the tasks/tests or procedures subjects will be asked to complete or undergo using non-technical language. Describe the study design and all methods and procedures (sequentially) to which the subjects will be involved in. (Suggestion: explain step by step what the subject will be asked to do and/or procedure performed exclusively for research purposes.) Include duration, intervals of administration and overall length of participation and how evidence will be collected and evaluated.

See attached Type of Study:	Evaluation Measure:	Control:
Case Study	Subjective	_xYes
X Case Control	Visual Analog Skill	No
Cohort	Range of Motion	
Randomize Control	_x Objective	
_Other (Specify)	Other(Specify)	

6. Materials & Support: COSTS (what you are requesting from KTAI) Please give a general description of the estimated amount of product needed and any additional support requested. Approval of these requests is on a case-by-case basis.

I believe this study will need one bulk pack of Kinesio® Tex classic 2" tape (69.99\$).

- 7. LITERATURE REVIEW: Please include your bibliography or attach the results of a literature search, which justify the involvement of human subjects in this research project.
- **1.** Kase K, Wallis J, Kase T. *Clinical Therapeutic Applications of the Kinesio Taping Method*. 2nd ed. Tokyo, Japan: Ken Ikai Co.; 2003.
- **2.** Akbas E, Ozgur A, Yuksel I. The Effects of additional kinesio taping over exercise in the treatment of patellofemoral pain syndrome. *Turkish Association of Orthopaedics and Traumatology*. 2011;45(5):335-341.
- **3.** Ibrahim A, Atya A. Kinesio Taping Versus sensorymotor training for patients with knee osteoarthritis. *International Journal of Terapies and Rehabilitation Research.* 2015;4(3):9-14.
- **4.** Aytar A, Ozunlu N, Surenkok O, Baltaci G, Oztop P, Karatas M. Initial effecs of Kinesio taping in patients with patellofemoral pain syndrome: a randomized, double-blind study. *Isokinetics and Exercise Science*. 2011;19:135-142.

- **5.** Jacobson JA. *Fundamentals of Musculoskeletal Ultrasound*. 2 ed. Philadelphia, PA: Elsevier Saunders; 2013.
- **6.** Brussaard C, Naudts P, De Schepper A. Ultrasonographic diagnosis of chondromalacia of the femoropatellar joint. *J Belge Radiol*. 1991;74(4):303-306.
- 7. Carr JC, Hanly S, Griffin J, Gibney R. Sonography of the patellar tendon and adjacent structures in pediatric and adult patients. *AJR Am J Roentgenol*. Jun 2001;176(6):1535-1539.
- **8.** Paczesny L, Kruczynksi J. Ultrasound of the Knee. *Seminars in Ultrasound CT and MRI*. 2011;32:114-124.
- **9.** Friedman L, Finlay K, Jurriaans E. Ultrasound of the knee. *Journal of Skeletal Radiology*. 2001;30:361-377.
- **10.** Razek A, Fouda N, Elmetwaley N, Elbogdady E. Sonography of the knee joint(). *J Ultrasound*. Vol 122009:53-60.
- 11. Lee D, Bouffard JA. Ultrasound of the knee. European Journal of Ultrasound. 2001;14:57-71.
- **12.** Yanagisawa S, Kobayashi T, Ohsawa T, et al. Sonographic evaluation of the medial aspect of the knee in a population-based cohort study. *J Clin Ultrasound*. Jun 2015;43(5):318-321.
- **13.** Paczesny L, Kruczynski J. Medial plica syndrome of the knee: diagnosis with dynamic sonography. *Radiology*. May 2009;251(2):439-446.
- **14.** Stubbings N, Smith T. Diagnostic test accuracy of clinical and radiological assessments for medial patella plica syndrome: a systematic review and meta-analysis. *Knee*. Mar 2014;21(2):486-490.
- **15.** Kase K, Wallis J, Kase T. *Clinical Therapeutic Applications of the Kinesio Taping Method Book.* 2 ed2011.
- **16.** Yoshida A, Kahanov L. The effect of Kinesio taping on Lower Trunk Range of Motions. *Research in Sports Medicine: an International Journal.* 2007;15(2):103-112.
- 17. Howe A, Campbell A, Hall T, Hopper D. Effects of two different knee tape procedures on lower-limb kinesmatics and kinetics in recreational runners. *Scandinavian Journal of Medicine and Science in Sports.* 2014:1-7.
 - 8. BENEFITS: Describe the probable benefits of the research for KTAI. Describe the benefits of the
 - knowledge gained to KTAI, advancement of scientific knowledge and/or benefits to future patients/subjects.

The benefits of this study for KTAI include more quantitative data regarding Kinesio Tape® techniques that does not focus on pain control. The results of this study will help be a stepping stone for other research regarding diagnostic ultrasound and Kinesio Tape®. Clinicians will be able to possibly use this research to create more beneficial treatment options.

In addition, this topic has been accepted for the Kinesio Taping Association International Research Symposium as a poster presentation. Dr. Katie Lyman will be in attendance to answer questions and present the research findings.

6. Description of the Study Attachment

Research will be conducted fall of 2015 in the Bentson Bunker Fieldhouse; room 14 on the NDSU campus, 1301 Centennial Blvd. Fargo, ND 58102. Upon arrival of the participants to the lab, each individual will sign necessary paperwork. Paperwork includes the; Informed Consent, Health History Questionnaire, and PAR-Q. Participants' height and weight will be measured prior to testing procedures. Raw data will be taken via diagnostic ultrasound of patellofemoral joint spaces in bilateral knees. The analysis will be completed using the Treason t3200 ultrasound unit. The ultrasound probe will be placed in a long axis view over the patellar tendon in order to ensure specific anatomical features, such as the lower aspect of the patella, is observed. From there the probe will be moved medially making sure that the patella's medial border is apparent on the image. Once the medial femoral condyle is observed; the screen will be frozen and the joint space will be measured from the medial aspect of the patella to the medial femoral condyle. The measurement will be taken with the caliper function in the ultrasound software, done perpendicular to the screen for a consistent reading. Sharpie marks will be placed where the ultrasound probe was placed so that the joint space can be measured in the same place after the tape has been applied.

The Kinesio Tape Space Correction Method® commonly used will be applied to the clean skin of the patient. Skin will be cleaned using an alcohol prep pad. The dominate knee will be taped, according to the participants determination. The Space Correction Kinesio Tape Method® is referenced on the Kinesio Tape® database and is shown over the elbow. Tape will be applied according to the Kinesio Tape® database written by Dr. Kase. The tape is to be cut approximately two inches longer than the patella. The tape also should have 3 cuts longitudinally through it, keeping the ends intact. The knee should be flexed fully (into its full range of motion). The Kinesio Tape® text states that the reason for this was to increase the tissue tension under the tape to assist with lifting. The paper is to be torn from the back of the tape in the middle portion of it and applied over the patella. The middle third portion should be applied with light to moderate tension (25-50%) over the patella and then the ends should have no tension and should be anchored in neutral. Lastly the tape should be rubbed to activate the adhesive 1. A measurement of the joint space will be taken ten minutes after the tape is applied with the ultrasound probe placed in the same spot as the baseline spot, signified by the original marks. The joint space will be measured in the same manner as previously described for the baseline measurement. In total each data collection section should take approximately 30 minutes.

APPENDIX E. HEALTH HISTORY QUESTIONNAIRE

Health History Questionnaire

Please answer the following questions to the best of your ability. For the following questions, unless otherwise indicated, circle the single best choice for each question. As is customary, all of your responses are completely confidential and may only be used in group summaries and/or reports. All information collected is subject to the Privacy Act of 1974. If you have any physical handicaps or limitations that would require special assistance with this questionnaire, please let your trainer know. This form is in accordance with the American College of Sports Medicine guidelines for risk stratification when followed correctly by your trainer. Your trainer should be certified with a national organization in order to use these forms correctly.

					Ht.:	
Ge	ender:	Age:	Birthdate:			
Ad	ldress:				10 F	
Cit	ty:		State:	ZIP:	Phone:	
En	nergency Contact:				Phone:	
Pe	ersonal Physician:				Phone:	
E-	mail:					
1.	Have you ever had a de	finite or suspecte	ed heart attack or s	troke?	Yes	No
2.	Have you ever had coro	nary bypass surg	gery or any other ty	pe of heart surg	gery?Yes	No
3	Do you have any other	cardiovascular or	pulmonary (lung)	disease		
0.	(other than asthma, all				Yes	No
4.	Do you have a history o	f: diabetes, thyro	id, kidney, liver dise	ease	Yes	No
	(circle all that apply)					
5.	Have you ever been told					
	an abnormal resting or	exercise (treadm	ill) electrocardiogra	am (EKG)?		No
6.	If you answered YES to	any of Questions	s 1 through 5, plea	se describe:		
	70					
_						
_						

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a. pain or discomfort in the chest or surrounding areas that occurs	
when you engage in physical activity?	No
b. shortness of breathYes	No
c. unexplained dizziness or fainting Yes	No
d. difficulty breathing at night except in upright positionYes	No
e. swelling of the ankles (recurrent and unrelated to injury)Yes	No
f. heart palpitations (irregularity or racing of the heart on more than one occasion)Yes	No
g. pain in the legs that causes you to stop walking (claudication)Yes	No
h. known heart murmurYes	No
lave you discussed any of the above with your personal physician?	No
Are you pregnant or is it likely that you could be pregnant at this time?	No
Have you had surgery or been diagnosed with any disease in the past 3 months?	No
Have you had high blood cholesterol or abnormal lipids within the past 12 months	
or are you taking medication to control your lipids?	No
Do you currently smoke cigarettes or have quit within the past 6 months?	No
2. Have your father or brother(s) had heart disease prior to age 55 OR	
mother or sister(s) had heart disease prior to age 65?	No
3. Within the past 12 months, has a health professional told you that you	
have high blood pressure (systolic ≥ 140 OR diastolic ≥ 90)?	No
4. Currently, do you have high blood pressure or within the past 12 months,	
have you taken any medicines to control your blood pressure? Yes	No
5. Have you ever been told by a health professional that you have a fasting blood glucose greater than or equal to 110 mg/dl?	No
6. Describe your regular physical activity or exercise program:	
type:	<u></u>
frequency: days per week	
duration: minutes	
intensity: low moderate high (circle one) BMI:	
7. If you have answered YES to any of questions 7-16, please describe:	
,	

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			Vaa	No
	atment for any blood clots?			No
Do you have problems with bone	es, joints, or muscles that may be aggravated	d with exercise?	Yes	No
20. Do you have any back/neck prol	blems?		Yes	No
21 Have you been told by a health	professional that you should not exercise? .		Yes	No
22. Are you currently being treated f	or any other medical condition by a physiciar	n?	Yes	No
 Are there any other conditions (r asthma, cancer, anemia, hepatit 	mitral valve prolapse, epilepsy, history of rheuis, etc.) that may <i>hinder</i> your ability to exerci	ımatic fever, ise?	Yes	No
	e you experienced any <i>unexplained</i> weight l known reason)?		. Yes	No
25. If you have answered YES to a	ny of questions 18-24, please describe:			
6. Please list below all prescription	and over-the-counter medications you are co	urrently taking:		
Medicine:	Reason for taking:	Dosage:	Amount/F	requency:
	ey.			
27. Are there any medicines that you 12 months which you are currer If so, please list:	ur physician has prescribed to you in the pas	t	Yes	No
12 months which you are currer	ur physician has prescribed to you in the pas ntly not taking?	t	Yes	No
12 months which you are currer If so, please list:	ntly not taking?			
12 months which you are currer If so, please list:	Ouestionnaire questions accurately and com	pletely. I understand that	my medical	history is a
12 months which you are currer If so, please list: have answered the Health History very important factor in the develop	Questionnaire questions accurately and comment of my fitness/wellness program. I under	pletely. I understand that restand that restand that certain medica	my medical I or physical	history is a
12 months which you are currer If so, please list: have answered the Health History very important factor in the developing which are known to me, but that I developed the source of t	Ouestionnaire questions accurately and com	pletely. I understand that stand that certain medica	my medical I or physical of the above	history is a conditions conditions
12 months which you are currer If so, please list: have answered the Health History very important factor in the develop which are known to me, but that I dichange, I will immediately inform my failure to disclose accurate, con	Questionnaire questions accurately and comment of my fitness/wellness program. I under to not disclose to my trainer, may result in sey trainer of those changes. I, knowingly and applete, and updated information in accordance.	pletely. I understand that of the stand that certain medical rious injury to me. If any of willingly, assume all risks be with the attached ques	my medical I or physical of the above of injury res tionnaire. I a	history is a conditions conditions sulting from
12 months which you are currer If so, please list: have answered the Health History very important factor in the develop which are known to me, but that I dehange, I will immediately inform my failure to disclose accurate, constand that in order to properly risk st	Questionnaire questions accurately and comment of my fitness/wellness program. I under to not disclose to my trainer, may result in sey trainer of those changes. I, knowingly and inplete, and updated information in accordance tratify my Health History Questionnaire, my tr	pletely. I understand that of the stand that certain medical rious injury to me. If any of willingly, assume all risks be with the attached questainer should have a mining	my medical I or physical of the above of injury res tionnaire. I a num of a na	history is a conditions conditions sulting from
12 months which you are currer If so, please list: I have answered the Health History very important factor in the develop which are known to me, but that I dhange, I will immediately inform mmy failure to disclose accurate, constand that in order to properly risk stication as a personal trainer. My trainers with the current of the control of the current of the c	Questionnaire questions accurately and comment of my fitness/wellness program. I under o not disclose to my trainer, may result in sey trainer of those changes. I, knowingly and nplete, and updated information in accordance tratify my Health History Questionnaire, my trainer also verbally explained this statement to	pletely. I understand that istand that certain medicarious injury to me. If any cwillingly, assume all risks be with the attached quesainer should have a mining me to my understanding.	my medical I or physical of the above of injury res tionnaire. I a num of a na	history is a conditions conditions ulting from also under- tional certi-
12 months which you are currer If so, please list: I have answered the Health History very important factor in the develop which are known to me, but that I dichange, I will immediately inform my failure to disclose accurate, constand that in order to properly risk stication as a personal trainer. My tra	Questionnaire questions accurately and comment of my fitness/wellness program. I under to not disclose to my trainer, may result in sey trainer of those changes. I, knowingly and inplete, and updated information in accordance tratify my Health History Questionnaire, my tr	pletely. I understand that estand that certain medica rious injury to me. If any owillingly, assume all risks be with the attached ques ainer should have a mining me to my understanding.	my medical I or physical of the above of injury res tionnaire. I a num of a na	history is a conditions conditions sulting from also under tional certi

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eck the identified ACSM major coronary risk factors b Lipids (TCH ≥ 200 OR HDL < 35)	Cigarette Smoking (or quit within the past 6 months)		
Eamily History	High Blood Pressure/Blood Pressure Medications		
Diabetes/glucose ≥ 110 mg/dl	Sedentary		
BMI ≥ 30	Pregnancy		
Metabolic Disease	Respiratory Disease (asthma, emphysema, chronic bronchitis		
Signs or Symptoms of Cardiovascular Disease Cardiovascular Disease	se		
sk Stratification	Factors		
Apparently Healthy	One or No Risk Factors (No medical clearance required)		
Apparently Healthy Male \geq 45; Female \geq 55	One or No Risk Factors (Initial medical clearance required)		
High Risk, No Signs or Symptoms	Two or More Risk Factors (medical clearance required)		
High Risk, with Signs and Symptoms	One or More Signs/Symptoms With or Without Risks (medical clearance required)		
Known Disease	Diagnosed Cardiopulmonary/Metabolic Disease (annual medical clearance required		
Pregnancy	Medical Clearance Required		
_	clearance from their personal physician must give it to to beginning their exercise program.		

Health History Questionnaire follows the American College of Sports Medicine recommendations for risk stratification. This must be performed on all clients in order to determine the need for medical clearance and/or exercise modifications. Any trainer or those making exercise recommendations should be certified in the proper use of the risk stratification process through a national organization.

If a client has a YES response to anything on page 1, he/she has KNOWN DISEASE, and must have medical clearance prior to beginning exercise.

If he/she has a YES response to anything on #7 a-h on page 2, your client is HIGH RISK WITH SIGNS/SYMPTOMS and must have medical clearance prior to exercise. If your client has a YES response to questions # 8 or 9, he/she must have medical clearance.

YES responses to two or more on questions 10-16 on page 2, your client is HIGH RISK WITHOUT SIGNS OR SYMPTOMS and must have medical clearance (unless he/she also has a YES answer in question #7 making them still HIGH RISK WITH SIGNS/SYMPTOMS).

All other questions on page 3 are at your own discretion. Remember, when in doubt, refer out. Please also refer to the most recent edition of ACSM's Guidelines for Exercise Testing and Prescription (Williams & Wilkins) as well as the most recent edition of the ACE Personal Trainer Manual (American Council on Exercise) for more explanations on the risk stratification. It is your responsibility as a trainer to remain updated on all changes or modifications for risk stratification in determining the need for medical clearance and exercise modifications/recommendations.

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