COMPARING DIFFERENT BRANDS OF KINESIOLOGY TAPE FOR SUBJECTS WITH PATELLOFEMORAL PAIN SYNDROME

A Thesis
Submitted to the Graduate Faculty
of the
North Dakota State University
of Agriculture and Applied Science

By
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In Partial Fulfillment of the Requirements
for the Degree of
MASTER OF SCIENCE

Major Department:
Health, Nutrition, and Exercise Sciences

March 2019

Fargo, North Dakota
Title

Comparing Different Brands of Kinesiology Tape for Subjects With Patellofemoral Pain Syndrome

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MASTER OF SCIENCE

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ABSTRACT

Kinesiology tape is a common therapeutic intervention although inconsistent results are reported in the literature. The purposes of this research were to determine if the Kinesio® Taping Space Correction web cut increases patellofemoral joint space when applied to subjects with PFPS; to determine if this taping method affects patient outcomes; and to compare this taping method using two different brands: Kinesio® Tape and KT Tape®. In this randomized, controlled, double-blinded study, 32 participants with PFPS were placed into one of four groups; (1) Kinesio® Tape with tension, (2) Kinesio® Tape without tension, (3) KT Tape® with tension, and (4) KT Tape® without tension. After analyzing diagnostic ultrasound measurements, Visual Analogue Scale (VAS), and Kujala Patellofemoral Scoring System (KPSS), researchers concluded the tape significantly increased patellofemoral joint space after 10 minutes and effects were maintained for 24 hours. Pain and other symptoms decreased significantly although no differences were noted between groups.
ACKNOWLEDGMENTS

I would like to thank my advisor, Dr. Katie Lyman for her continued support throughout my graduate school experience. She has been tremendously helpful every step of the way. Under her guidance and assistance, I have been able to grow and improve both as a student and as a healthcare professional.

I would also like to thank Dr. Kara Gange and Dr. Thomas Hanson, for serving on my thesis committee. They both offered their knowledge and experience to allow me to develop this thesis to its full potential. I would also like to recognize Dr. Hanson for completing the statistical analysis following our data collection for a NATA abstract proposal as well as the final results of this thesis.

I want to thank the Kinesio® Taping Association International (KTAI) for their support of this project by providing the Kinesio® Tape used in this study.

I would like to thank the Health, Nutrition, and Exercise Science Department, the College of Human Development and Education as well as the Post-Professional Athletic Training Program at North Dakota State University for their financial support.

Additionally, I would like to thank all of the participants for being involved with this study. This research would not have been possible without the commitment and compliance of each participant.

Finally, I would like to thank my family for their continued love and support throughout my entire life. My parents, Stan and Wendy Marcus have given me countless opportunities to succeed and I am deeply grateful to have them as well as my two sisters, Rebecca and Rachel Marcus.
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CHAPTER 1: INTRODUCTION

1.1. Overview of the Problem

Commonly used by healthcare providers, kinesiology tape is used therapeutic intervention for treating injuries. With many different therapeutic claims, kinesiology tape is a versatile treatment option for various pathologies. Limited and inconsistent research has been conducted with regards to the physiological effectiveness of kinesiology tape. Specifically, with the Kinesio® Taping Space Correction Web Cut, only one study could be obtained. The previous study was conducted on healthy tissue and only investigated the Kinesio® Tape brand. The current study aims to investigate the Kinesio® Taping Space Correction Web Cut on subjects with Patellofemoral Pain Syndrome (PFPS). When applied to the patellofemoral joint, the Kinesio® Taping Space Correction Web Cut provides a suction-like force to lift subcutaneous structures, thereby increasing the space between the patella and the femoral condyles. The increase in patellofemoral joint space may alleviate symptoms associated with PFPS.

In the current literature, kinesiology tape is often referred to as “kinesio tape” or “KT.” These terms can easily be mistaken for different brands of kinesiology tape including Kinesio® Tape and KT Tape®. The manufacturers of each brand of kinesiology tape stake similar claims regarding its effectiveness, although the materials of each product are unique. The different manufacturing techniques and materials used in each brand of tape may cause different patient outcomes when brands are used interchangeably using the same application method.

Diagnostic ultrasound is an increasingly popular imaging method used to view subcutaneous structures. However, limited research has been published regarding the use of diagnostic ultrasound to measure the patellofemoral joint space specifically. Normative data is also unavailable with regards to adequate or ideal patellofemoral joint space measurements. The
current study may offer more information associated with the patellofemoral joint space and the relation to PFPS.

The application of the Kinesio® Taping Space Correction Web Cut may be a beneficial intervention for clinicians to utilize in the treatment of patients with PFPS. Additionally, if the different brands of kinesiology tape offer differing results, future clinicians and researchers may not be able to use different brands of kinesiology interchangeably. Future research should analyze different brands of tape as well as different taping methods.

1.2. Statement of Purpose

The primary purpose of this study was to determine if the Kinesio® Taping Space Correction Web Cut over the patellofemoral joint increased the patellofemoral joint space in subjects with PFPS. In addition, a secondary purpose was to determine if there was a difference in effectiveness between the different brands of kinesiology tape. Lastly, this study determined if the Kinesio® Taping Space Correction Web Cut alleviated patient-reported symptoms associated with PFPS.

1.3. Research Questions

1) What are the differences in patellofemoral joint space with the application of kinesiology tape on subjects with PFPS?

2) What are the differences in patellofemoral joint space when comparing two separate brands of kinesiology tape?

3) What are the differences in participants’ perceived patellofemoral joint pain and disability with and without kinesiology tape?
1.4. Dependent Variable

The primary dependent variable in this study was the patellofemoral joint space following the kinesiology tape application measured using diagnostic ultrasound. An additional dependent variable included the patient outcome measures quantified by the Kujala Patellofemoral Scoring Sheet and a Visual Analogue Scale.

1.5. Independent Variable

The independent variables for this study were the application of Kinesio® Tape or KT Tape® as well as the amount of tension applied to the tape.

1.6. Limitations

One challenge for the researchers was obtaining an accurate diagnosis of PFPS because the presence of the condition often relied on the absence of other pathologies. Additionally, the current literature lacked the definitive etiology and diagnostic criteria for the pathology. The subjects with PFPS presented with varying levels of symptom severity and pathology duration. Finally, the participant ages ranged from 18 to 60; therefore, results could not be generalized to populations of other ages.

1.7. Delimitations

Subjects were included if anterior knee pain was been present for at least three months and a score between 45 and 70 was recorded on the Kujala Patellofemoral Scoring System. Despite the wide variety of brands of kinesiology tape available to consumers, the researchers decided to examine Kinesio® Tape and KT Tape®. Both brands were commonly used by healthcare providers and the general population.
1.8. Significance of the Study

A variety of healthcare practitioners utilized kinesiology tape as a therapeutic intervention for patients. The current literature regarding the effectiveness of kinesiology tape was often inconsistent. Limited research was conducted evaluating the Kinesio® Taping Space Correction Web Cut for the patellofemoral joint. This study supported the use of kinesiology tape as a treatment option for subject with PFPS. This study also determined if there is a difference in effectiveness between brands of kinesiology tape.

1.9. Definitions

Patellofemoral Pain Syndrome (PFPS): pathology of the patellofemoral joint presenting with anterior, retropatellar or peripatellar knee pain. Symptoms are most common while ascending and descending stairs, deep squatting, kneeling, prolonged sitting with knees bent, and standing up.²

Diagnostic Ultrasound: a non-invasive, high frequency imaging technique use to view subcutaneous structures.³

Kinesio® Tape: 100% cotton kinesiology tape with latex free, acrylic adhesive. The tape can stretch up to 60% of its resting length and is designed to mimic the epidermal layer of human skin while providing a positional stimulus through the skin, aligning fascial layers, creating more space by lifting the fascia and soft tissue above the area of pain/inflammation, providing sensory stimulation to assist or limit motion, and assisting in the removal of edema by directing exudate toward a lymph duct.⁴

KT Tape®: 100% cotton kinesiology tape with latex free elastic cores for longitudinal stretching. The manufacturer claims the tape can aid in lifting the skin, decompressing fascial layers, and improving lymphatic movement under the skin (www.kttape.com).
Kinesiology tape is a commonly used therapeutic intervention for the treatment of Patellofemoral Pain Syndrome (PFPS). Although clinicians are using the tape as an ergogenic aid, the effectiveness of kinesiology tape for PFPS remains under investigation. Extensive research has been conducted attempting to prove the efficacy of kinesiology tape as a treatment for PFPS; however, conflicting results, as well as varying methodologies have been reported in the literature. The brand of kinesiology tape used in each study is not always reported and the manufacturers of each brand of kinesiology tape claim different uses and benefits. With the different materials and manufacturing methods of each brand of tape, the associated therapeutic benefits may vary. After investigating the available published literature, no studies were found comparing the differences between brands of kinesiology tape. The lack of consistency between methodologies and instrumentation may have led to the inconsistent results of previous studies.

Limited research has been conducted regarding the Kinesio® Taping Space Correction Method for the knee. Kase et al. claims the taping method lifts the skin superficial to the patella and subsequently lifts the subcutaneous structures of the patellofemoral joint. Previous research evaluating the Kinesio® Taping Space Correction Method for the knee had been conducted on healthy tissue and had only used one brand of kinesiology tape. The purpose of this literature review is to address the current published literature related to the definition and etiology of PFPS as well as the effectiveness of kinesiology tape as a treatment for PFPS.

2.1. Patellofemoral Pain Syndrome

2.1.1. Definition

Patellofemoral Pain Syndrome (PFPS) is considered one of the most common pathologies among active adults. Although more often diagnosed in females than males, PFPS accounts for
approximately 30% of all injuries reported in sports medicine clinics. The main symptom of the pathology is general anterior knee pain, which is frequently associated with daily activities such as ascending and descending stairs, deep squatting, kneeling, prolonged sitting with knees bent, and standing up. The definitive etiology of the pathology is considered multifactorial. Biomechanical dysfunction is the most common contributory factor for PFPS. Generally used as a blanket term for retropatellar or peripatellar localized knee pain, PFPS is not linked to a specific injury. Pain in the patellofemoral joint stems from general abnormalities of the patellar articulation with the femur. In order to fully understand PFPS, a knowledge of the subcutaneous anatomical structures within the patellofemoral joint is necessary.

2.1.2. Anatomy

The patellofemoral joint is defined as the articulation between the posterior surface of the patella and the trochlear surface of the distal anterior portion of the femur. The patellofemoral joint is composed of bones, cartilage, and soft tissue. The posterior surface of the patella consists of two convex facets allowing the patella to conform to the concave surfaces of the femur. Most of the patella is covered in a thick layer of cartilage to reduce joint reaction forces caused by forceful quadriceps contractions. The patella is enclosed within the patellar tendon which assists with static stability. The anterior, distal end of the femur is composed of an intercondylar groove or trochlear sulcus, and a medial and lateral facet. The concave medial and lateral facets are covered in cartilage to articulate with the patella. These facets protrude slightly from the femur to prevent patellar dislocations and to ensure patellar stability. The medial facet protrudes slightly more anterior, which is one of the reasons a lateral dislocation or subluxation of the patella has a greater occurrence compared to a medial dislocation.
Soft tissue structures also aid in the stability of the patella. On the medial side of the patellofemoral joint, the medial patellofemoral ligament (MPFL), the medial meniscopatellar ligament and the medial retinaculum provide stability and assist in the prevention of lateral translation. On the lateral aspect of the patellofemoral joint, the lateral patellofemoral ligament, joint capsule, iliotibial band, and lateral retinaculum aid in static stability of the patella within the joint. The four muscles of the quadriceps (rectus femoris, vastus medialis, vastus lateralis, vastus intermedius) all insert on the patella and form the patellar tendon. Unlike the other quadriceps muscles, the distal end of the vastus medialis, the vastus medialis oblique (VMO), has oblique fibers inserting on the mid portion of the medial patella. The location and muscle fiber alignment provide important medial stabilization to the patella to a greater effect than the other quadriceps muscles.²,¹³,¹⁴

The position of the patella within the patellofemoral joint facilitates certain movements of the knee. The patella is responsible for 31% of torque during full knee extension. The location of the patella adds protection to the trochlear groove and reduces friction between the femoral condyles and the quadriceps tendon.² In the frontal plain, the patella should be observed with the patient in a supine position with the leg extended in a relaxed position. With the lack of quadriceps activation, the patella should be located superior to the femoral condyle with minimal contact between the patella and the femur.¹⁴ In this open-packed position, the patella is hypermobile when passively manipulated.

Patellar tracking, or how the patella moves during tibiofemoral motions, can also be a contributing factor to PFPS.²,¹²,¹³ The movements of the patella are described as: superior/inferior glide, medial and lateral glide, medial and lateral tilt, and medial and lateral rotation.²,¹² The superior glide occurs when the quadriceps contract and the knee is extended,
shifting the patella proximally. The inverse condition, or inferior glide, occurs when the knee is flexed and the quadriceps relax. The patellar contact area with the femur increases during knee flexion.\textsuperscript{2,13-5} In the presence of weak quadriceps muscles, the patella may have an altered gliding path due to unbalanced or unequal pull on the patella, which may lead to pain or discomfort within the patellofemoral joint.\textsuperscript{2,14,15} Overall, clinicians should have knowledge of the subcutaneous anatomical structures and the biomechanical processes associated with them.\textsuperscript{14} Understanding the possible causes of the pathology will allow clinicians to develop a treatment plan for optimal results.\textsuperscript{2}

2.1.3. Etiology

Although PFPS is not associated with a definitive etiology, researchers have established certain anatomical factors as possible causes for the pathology. Common possible causes include quadriceps weakness, patellar malalignment, and patellar hypermobility.\textsuperscript{6,8,9,12,13,16} With regards to quadriceps weakness, the VMO has been specifically targeted based on the important role in patellar stabilization.\textsuperscript{2,6,8-10,13,14} Due to the increased incidences of PFPS in women, researchers have observed the relationship between the Q-angle and patients with PFPS.\textsuperscript{8,13,16} The Q-angle is described as the angle of intersection between a line drawn from the anterior superior iliac spine (ASIS) of the hip to the center of the patella and a line from the center of the patella to the tibial tuberosity.\textsuperscript{2,15} Due to the static nature of a Q-angle assessment, researchers have been unable to determine a consistent relationship between larger Q-angles and PFPS.\textsuperscript{2}

The perception of patellofemoral pain is due to the abnormal irritation of nerve fibers located in the supporting tissue of the knee.\textsuperscript{10} Irritation or degeneration of the articulating cartilage of the patellofemoral joint has been directly related to patellofemoral pain.\textsuperscript{2,9} The lack of congruency of the articular cartilage following degeneration may increase friction between the
posterior surface of the patella and the femoral condyle. LaBella\textsuperscript{2} reported the increase in intraosseous pressure and metabolic activity can lead to pain in the patellofemoral joint as well. In some cases, the plicae, found on the medial aspect of the knee, may become impinged between the patella and the medial femoral condyle causing PFPS symptoms and the infrapatellar fat pad is also at risk of becoming irritated due to the location under a tight lateral retinaculum.\textsuperscript{2,13}

In conclusion, PFPS is a common pathology of the knee among active individuals. Although the definition and causes of the condition are unclear, researchers agree PFPS is a multifactorial pathology with regards to causes and diagnosis.\textsuperscript{2,5,8,12-14} PFPS may be caused by trauma to the knee; however, anatomical structures and abnormalities are more commonly associated with symptoms of PFPS. The abnormal anatomical structures and movements have been directly linked to increased pressure and friction within the patellofemoral joint leading to patellofemoral pain. Knowledge of the subcutaneous structures of the knee is important in order to understand the possible causes of PFPS.\textsuperscript{2}

2.2. Kinesiology Tape

2.2.1. Properties

Many different brands of kinesiology tape are currently available for consumers to purchase, although only the two popular brands of Kinesio\textsuperscript{®} Tape and KT Tape\textsuperscript{®} will be discussed and compared. Kinesio\textsuperscript{®} Tape is a registered trademark of Kinesio Holding Corporation (Albuquerque, NM). Developed by Dr. Kenzo Kase, the tape became available to consumers in 1982. The tape is 100% cotton with a latex-free, acrylic adhesive. Similar to the thickness of the epidermal layer of the skin, the tape can be stretched longitudinally between 40 and 60 percent of the original resting length.\textsuperscript{4,17} Prior to removing the paper backing from the
tape, a ten percent stretch is already present. The adhesive pattern of the tape is designed to replicate a fingerprint to aid in circulatory, lymphatic and neurological treatments. Kinesio® Tape is also waterproof, which allows patients to shower and perform daily activities without restriction for three to five days.  

The creators of Kinesio® Tape claim the tape has five primary uses: to provide a positional stimulus through the skin; to align fascial layers; to create more space by lifting the fascia and soft tissue above the area of pain/inflammation; to provide sensory stimulation to assist or limit motion; and to assist in the removal of edema by directing exudate, toward a lymph duct.  

Additionally, Kinesio® Tape must be purchased and applied by healthcare providers trained and certified by Kinesio University™ or Kinesio Taping® Association International (KTAI) credentialed with the Certified Kinesio® Taping Practitioner (CKTP), Certified Kinesio® Taping Technician (CKTT), etc.. The versatility and durability of Kinesio® Tape have contributed to its increasing popularity among healthcare practitioners.

Similar properties exist for KT Tape®, although there are variations in the materials and uses. KT Tape® is a registered trademark of KT Health (American Fork, UT). The tape is made of 100% cotton fibers with elastic cores to allow the tape to stretch longitudinally. The adhesive is latex-free and waterproof so that it will withstand humidity, sweat, and showers for multiday use. Limited information is published pertaining to materials and uses of KT Tape®. The manufacturer claims the tape can aid in lifting the skin, decompressing fascial layers, and improving lymphatic movement under the skin. KT Tape® can also release pressure over the site of an injury thus relieving pain and discomfort without limiting range of motion (www.kttape.com). The different brands of tape may not be interchangeable as the therapeutic effects may differ due to the varying materials and manufacturing methods between brands.
2.2.2. Application

In the field of athletic training, the use of kinesiology tape is a controversial topic due to conflicting methodologies as well as inconsistent clinical effectiveness reported in the literature. A common use of kinesiology tape is to relieve symptoms associated with PFPS. A lack of standardization for the application of kinesiology tape for PFPS is reported in the existing literature, thus making it difficult for researchers to repeat studies or generalize results. The most common discrepancies between studies include the brand of kinesiology tape, the application pattern or technique, and the credentials of the clinician applying the kinesiology tape. In order to achieve valid and reliable results, the aforementioned considerations should be reported just as any other product or methodology would be described in original, scientific research. Despite the current literature evaluating the effectiveness of kinesiology tape as a treatment for PFPS, no definitive research has been obtained comparing the possible differing effects related to the brands of kinesiology tape.

The rising popularity of kinesiology tape has led to different manufacturers and companies creating unique brands of tape with similar claims of effectiveness. In some cases, the brand of kinesiology tape used in a study may be left unreported or referred to as an abbreviation. Kurt et al., Akbas et al., and Ho et al. conducted research evaluating the effect of kinesiology tape on subjects with PFPS. The authors of all three studies failed to report the brand of the kinesiology tape. The authors of these studies referred to the tape as “kinesio tape” or “KT”. These terms may be easily mistaken for two popular brands of kinesiology tape, Kinesio® Tape or KT Tape.

Although Kurt et al. did not specify the brand of kinesiology tape, the researchers used a Visual Analogue Scale (VAS) to evaluate pain intensity, a Kujala Pain Scale (KPS) specifically
for physical limitations, the Tampa Scale (TSK) to evaluate kinesiophobia or fear of re-injury, and an isokinetic dynamometer to measure quadriceps strength and joint position sense. The kinesiology tape was applied by a CKTP although a tape stretch standardization method was not reported. The researchers used a kinesiology taping method to promote Vastus Medialis Obliquus (VMO) facilitation along with patellar correction strips to assist with patella maltracking. Isokinetic strength and joint position sense were evaluated two days after the kinesiology tape was applied. Statistical significance was assessed between groups with the experimental kinesiology taping method and sham taping method for pain intensity ($p < .001$), kinesiophobia ($p < .001$), and joint position sense ($p < .001$). The researchers concluded kinesiology tape may decrease pain, enhance joint position sense, and reduce functional impairments in subjects with PFPS.

Unique to other published literature, Akbas et al. examined kinesiology taping methods individually assigned to each subject based on patient needs with regards to quadriceps muscle weakness, quadriceps muscle tightness, and patellar movement patterns. Similar to Kurt et al., Akbas et al. neglected to identify the brand of kinesiology tape. In addition, the authors did not mention the credentials of the clinician or a length/tension standardization method for applying the kinesiology tape. A VAS was used to measure pain intensity and the Anterior Knee Pain Scale (AKPS)/ Kujala Scale were used to observe functional impairments. Also, a modified Vernier caliper was utilized to evaluate patellar tilt positioning. The six-week exercise protocol consisted of activities to promote upper leg and hip muscle flexibility as well as isometric and isotonic strengthening. The researchers analyzed the long-term effects of kinesiology tape paired with exercise as opposed to other researchers who have examined the short-term or initial effects. The researchers used a Mann-Whitney U test to compare the
statistical significance between groups although no statistical significance was observed between the group with kinesiology tape and the control group. The researchers concluded adding kinesiology tape to patients with PFPS during exercise does not improve results when compared to exercise without kinesiology tape as a long-term intervention. Akbas et al. suggested future researchers should evaluate different kinesiology taping methods including patellar correction techniques for patients with PFPS. The lack of consistency between application methods between each of the 31 participants should be noted as this may have an impact on the generalizability of this study.  

Lastly, Ho et al.\textsuperscript{19} completed a study comparing the effects of two common taping methods for the patellofemoral joint while subjects were weight bearing.\textsuperscript{19} The McConnell and kinesiology taping methods were compared using Magnetic Resonance Imaging (MRI) to observe patellar angle and location within the patellofemoral joint. Imaging was completed with the affected knee positioned at 0°, 20°, and 40° of flexion with each taping method. The researchers failed to mention the brand of kinesiology tape and whether or not the tape was applied by a CKTP with a length and tension standardization method. The MRI measurements were documented prior to any intervention and immediately following each of the taping methods. Each subject received both interventions on the same day although the order for the taping methods were randomized. The researchers simulated a weight-bearing situation by loading the affected leg with 25% of the subject’s body weight during imaging. Pain intensity was also recorded using an 11-point Numeric Rating Scale (NRS). Using a two-factor repeated-measures analysis of variance (ANOVA), the researchers identified statistical significance for both taping methods regarding patellar lateral displacement from 0° to 20° of knee flexion (mean difference, 11.3% ± 12.6%; \( p = .015 \)) and from 0° to 40° of knee flexion (mean difference, 8.3%
± 10.7%; \( p = .036 \)). No statistical significance was reported between the taping methods for patellar lateral displacement, mediolateral patellar tilt angle, patellar height, or patellofemoral joint contact area \( (p = .488, p = .558, p = .062, p = .358, \text{respectively}) \). After the application of kinesiology tape, the researchers reported statistical significance with regard to pain relief \( (p = .007) \). Ho et al. concluded neither the McConnell taping nor the kinesiology taping methods have any impact on the patellofemoral contact area or joint alignment while subjects experience a weight bearing condition.\(^1\) Despite the lack of statistical significance with regards to joint contact area and joint alignment, patient-reported patellofemoral pain was reduced following the application of kinesiology tape.

Contrary to the previously mentioned researchers\(^6,18,19\), Aghapour et al.\(^5\), Kuru et al.\(^1\), Aytar et al.\(^1\), and Freedman et al.\(^2\) all reported examining a specific brand of kinesiology tape. Each of the research teams used Kinesio\(^\text{®} \) Tape to investigate the effects on subjects with PFPS. With the contrasting materials and manufacturing methods of the kinesiology tape that is currently available, the therapeutic effects may be inconsistent for each brand. The brand of the tape should always be mentioned to improve the generalizability of each study. The methodology can then be reproduced with the same product intervention, and parameters can be replicated for future research.

Although Aghapour et al.\(^5\) used the specified brand Kinesio\(^\text{®} \) Tape and the stretch length of the tape was measured and standardized, there was no mention of a credentialed practitioner (CKTP, CKTT, etc.) to apply the tape.\(^5\) The clinician used Kinesio\(^\text{®} \) Tape over the VMO with a five cm Y-strip from origin to insertion of the VMO. The taping method used was similar to the method used by Kurt et al.\(^6\) to promote VMO muscle facilitation. The researchers evaluated the efficacy of the Kinesio\(^\text{®} \) Tape using isokinetic and functional tests as well as a VAS to measure
pain intensity. Statistical significance was reported with regards to a decrease in pain intensity \( (p = .02) \), increased normalized peak torque during concentric contractions at 60 and 180°/s velocities \( (p = .032, p = .04, \text{respectively}) \) and eccentric contractions at 60 and 180°/s velocities \( (p = .017, p = .001, \text{respectively}) \). The researchers also reported statistical significance with improved functional performance of step-down \( (p < .001) \) and bilateral squat tests \( (p < .001) \).

Aghapour et al. concluded Kinesio® Tape over the VMO is a useful tool for clinicians to implement during rehabilitation of patients with PFPS to aid in pain reduction and functional improvements.\(^5\)

Differing from Akbas et al.\(^1\)\(^8\), Aytar et al.\(^1\)\(^7\) conducted research evaluating the initial effects of Kinesio® Tape on pain, strength, joint position sense, and balance in subjects with PFPS when compared to a placebo taping application.\(^1\)\(^7\) Kinesio® Tape was applied by a CKTP, although no mention of a standardization method for length and stretch of the tape was expressed. The taping application included two Y-strips originating on the thigh with the tails encircling the medial and lateral borders of the patella and anchored just below the tibial tuberosity. An isokinetic dynamometer was used to measure both strength and joint position sense and balance was tested using the Kinesthetic Ability Trainer (KAT). Pain intensity was also measured using a VAS after subjects completed activities such as walking, ascending and descending stairs. The data analysis was interpreted to reveal statistical significance for pre-post strength at 60°/s and 180°/s \( (p = .028, p = .012, \text{respectively}) \), and static and dynamic balance for both groups \( (p = .012, p = .046, \text{respectively}) \). No statistical significance was noted between the group with the Kinesio® Tape and the group with the placebo taping application for joint position sense, pain, and balance. The researchers concluded Kinesio® Tape was not an effective
treatment for decreasing pain or improving joint position sense in patients with PFPS, however; improvements in quadiceps strength were reported after the application of Kinesio® Tape.\textsuperscript{17}

In a similar study to Aytar et al.\textsuperscript{17}, Freedman et al.\textsuperscript{20} also assessed the short-term effect of Kinesio® Tape on subjects with PFPS; however, the researchers evaluated the effectiveness with regards to pain intensity and hop function.\textsuperscript{20} The Kinesio® Tape was applied with a length stretch standardization and it was applied by a CKTP. Pain was measured using the Numeric Pain Rating Scale (NPRS) and a hand-held dynamometer was used to measure muscle strength.

Subjects were taped using the Patellar Kinesio® Taping method which included two Y-strip. The base of first Y-strip was adhered to the middle of the anterior thigh with the leg fully extended. The two tails were applied with the knee flexed to 90°, encircling the patella with little to no overlap at the tibial tuberosity. The second Y-strip was applied inversely, with the base of the strip adhered to the middle of the anterior tibia. The tails were attached encircling the patella and meeting at the superior pole of the patella.\textsuperscript{4} The subjects were examined following functional testing including squatting, ascending and descending steps, and the Single-Leg Triple Jump Test (STJT). The statistical analysis of the individual paired t-tests revealed significance for the NPRS after step up ($p = .025$), step down ($p = .026$), and STJT ($p < .001$). The distances of the STJT were also significantly increased ($p = .006$) with the Kinesio® Tape application when compared to the sham taping method. The researchers interpreted the results to support the use of the patellar taping method of Kinesio® Tape when treating patients with PFPS.\textsuperscript{20}

Rather than comparing kinesiology tape to a sham or placebo taping, Kuru et al.\textsuperscript{11} evaluated the differences between Kinesio® Taping and electrical stimulation on knee pain and function in subjects with PFPS.\textsuperscript{11} The same exercise protocol was paired with both interventions. The Kinesio® Taping application pattern used was comparable to Aytar et al.\textsuperscript{17} as the tape started
on the thigh, encircled the patella and anchored below the tibial tuberosity. Statistical significance was observed for a decrease in knee pain in the Kinesio\textsuperscript{®} Tape and the e-stim groups ($p < .001$, $p < .001$ respectively), increase in muscle strength ($p = .007$, $p = .002$ respectively) and function ($p = .002$, $p = .013$ respectively), as well as quality of life ($p = .007$, $p = .016$ respectively) were observed for both treatment groups. Despite the positive findings, no statistical significance was noted between the use of Kinesio\textsuperscript{®} Tape and electrical stimulation. The researchers concluded both Kinesio\textsuperscript{®} Tape and electrical stimulation are positive treatments for PFPF when paired with exercise.\textsuperscript{11}

### 2.2.3. Kinesio\textsuperscript{®} Taping Space Correction Method

Upon investigation, only one study has been conducted evaluating the effectiveness of the Kinesio\textsuperscript{®} Taping Space Correction Method for the patellofemoral joint. Lyman et al.\textsuperscript{1} tested the claim made by Kase et al.\textsuperscript{4} that the Kinesio\textsuperscript{®} Taping Space Correction Method can lift structures of the knee to create an increase in interstitial space.\textsuperscript{1,4} Results were gathered from 32 participants and included male ($n = 16$) and female ($n = 16$) subjects with bilaterally healthy knees. Diagnostic ultrasound was used to take objective measurements of the space between the patella and the femur, the anterior skin and the patella, and the anterior skin to the patellar tendon. Kinesio\textsuperscript{®} Tape was applied by a Certified Kinesio\textsuperscript{®} Tape Faculty (CKTF) member, although no standardization of the length and tension of the tape was documented. Statistical significance was reported for the average distance between the patella and the medial femoral condyle ($t_{31} = 2.823$, $p = .008$, $g = .465$, 95\% CI [.30, 1.89]). Although the researchers found statistical significance, the clinical significance cannot be determined due to the lack of existing comparative literature. The results were also generated from subjects with healthy tissue. In conclusion, the research team stated the Kinesio\textsuperscript{®} Taping Space Correction Method can increase
the interstitial space between the patella and the medial femoral condyle, although future research should be conducted with the same taping technique on unhealthy tissue.¹

In conclusion, the current literature pertaining to the efficacy of kinesiology tape for patients with PFPS is inconclusive. A variety of studies have been conducted evaluating the effectiveness of kinesiology tape with regards to pain, function, and patellofemoral joint space. Despite the many different taping methods researched, pain relief is commonly reported after the application of kinesiology tape.⁵,⁶,¹¹,¹⁹,²⁰ Although the current literature offers several different methodologies, the lack of standardization between taping application methods decreases the generalizability of results. The brand of kinesiology tape, the credentials of the clinician applying the tape, and the method of stretch standardization should be noted to allow for other researchers to replicate methodology. Future research assessing the effectiveness of kinesiology tape on patients with PFPS must be conducted with the standardization methods remaining consistent before definitive conclusions can be drawn.

2.3. Diagnostic Ultrasound

2.3.1. Definition

Diagnostic ultrasound is a valuable tool for clinicians to use for joint imaging, specifically in this study, for observing the patellofemoral joint. Commonly compared to Magnetic Resonance Imaging (MRI) and X-Ray imaging, diagnostic ultrasound is becoming a more prominent imaging tool among healthcare professionals. Diagnostic ultrasound offers a more cost effective, mobile, and widely available method of imaging without sacrificing accuracy.²¹ The International Federation of Sports Medicine currently recognizes ultrasound imaging as a valid diagnostic method for soft tissue lesions in sports.²² Maeseneer et al.²³ stated diagnostic ultrasound can allow the clinician to observe superficial structures of the knee with
greater ease than other imaging modalities. In order to maximize the benefits of diagnostic ultrasound, the clinician operating the machine should be properly trained and should have knowledge of the human anatomy. Typically referred to as the gold standard for assessing muscle size, MRI is most often used for diagnosing musculoskeletal injuries. Despite being a commonly used tool, several factors create question regarding the efficiency of MRI. First, MRI tends to be an expensive procedure, and the size and cost of the machines often lead to the immobility, limited quantity, and limited availability of the units. The procedure can also be time consuming, as the patient will need to remain perfectly still for sessions commonly ranging 30 to 60 minutes. MRI machines may artifact in the presence of metal, meaning the images may be distorted if any metal is present in the tissue. Overall, the images produced by MRI have been proven to be accurate with regards to diagnosing musculoskeletal injuries although newer methods may be more beneficial to clinicians and patients alike.

2.3.2. Reliability of Diagnostic Ultrasound

Diagnostic ultrasound can be used to assess the size of muscles, view the integrity of ligaments and tendons, and observe general subcutaneous structures. The reliability of diagnostic ultrasound is often compared to MRI in order to determine the accuracy of the imaging technique. Zhang et al. compared high-frequency ultrasound and MRI to determine if the methods were effective in observing patellofemoral ligament tears. All subjects (n=97) had sustained an acute or reduced patellar dislocation within 15 days of the imaging. During the high-frequency ultrasound evaluation, the patients were lying supine and the Medial Patellofemoral Ligament (MPFL) was observed at the patellar insertion, femoral attachment, and mid-substance. MR imaging was conducted in the transverse, sagittal, and coronal planes.
Subjects then underwent arthroscopic surgery and surgeons evaluated the integrity of the MPFL and repaired tissue as needed. A chi-squared test was interpreted to reveal no statistical significance between the two imaging techniques. A reliability analysis using Cohen’s Kappa between the blinded clinicians indicated values of very good and good concordance for high-frequency ultrasound and MRI ($p = 0.838$, $p = 0.796$ respectively). Clinicians operating high-frequency ultrasound were able to differentiate between partial and complete tears of the MPFL better than those operating MRI, although results were not statistically significant. The researchers concluded similar sensitivity, specificity, and accuracy were noted between high frequency ultrasound and MRI as observed in Table 1, and a slightly greater interobserver agreement was interpreted with the use of high-frequency ultrasound.

Table 1. Diagnostic performance in site-based analysis of ultrasound and MR

<table>
<thead>
<tr>
<th>Imaging Study</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial tear</td>
<td>US</td>
<td>90.8</td>
<td>96.3</td>
</tr>
<tr>
<td></td>
<td>MR</td>
<td>81.6</td>
<td>95.7</td>
</tr>
<tr>
<td></td>
<td>$X^2$</td>
<td>2.707</td>
<td>0.080</td>
</tr>
<tr>
<td></td>
<td>$P$</td>
<td>0.1</td>
<td>0.777</td>
</tr>
<tr>
<td>Complete tear</td>
<td>US</td>
<td>86.3</td>
<td>96.3</td>
</tr>
<tr>
<td></td>
<td>MR</td>
<td>80.4</td>
<td>95.7</td>
</tr>
<tr>
<td></td>
<td>$X^2$</td>
<td>0.635</td>
<td>0.080</td>
</tr>
<tr>
<td></td>
<td>$P$</td>
<td>0.425</td>
<td>0.777</td>
</tr>
</tbody>
</table>

US high-frequency ultrasonography; data are presented as percentage (ratio)

Similar to Zhang et al., Chan et al. compared diagnostic ultrasound to another common imaging technique by evaluating the differences between diagnostic ultrasound and X-ray imaging in patients with osteoarthritis of the knee. The purpose of the study was to compare the relationship between ultrasonographic findings and patient-reported pain scales to the relationship between X-rays and patient-reported pain scales. A total of five VAS were given to each subject prior to imaging to assess pre-evaluation pain intensity during walking, stair climbing, lying, sitting, and standing conditions. X-ray imaging and diagnostic ultrasound were used to observe the medial and lateral tibiofemoral joints as well as the patellofemoral joint of
the subjects in a weight-bearing position. The researchers used Pearson product-moment correlation coefficient and Spearman’s rank correlation to compare the two imaging techniques and the respective VAS scores. After analyzing the self-reported VAS for pain associated with knee osteoarthritis and the objective findings from both imaging techniques, the researchers concluded neither imaging modality was superior to the other when observing factors that may cause pain. The two imaging methods are complementary and should both be used in the diagnostic process. Therefore, diagnostic ultrasound can be used to view anatomical structures in order to make accurate diagnoses.³

The reliability of diagnostic ultrasound was also investigated by Bemben²¹ to determine if diagnostic ultrasound should be used for assessing muscle size.²¹ The researchers placed subjects into three groups based on age. The respective groups consisted of 38 post-menopausal women (avg. age = 58.9 ± 0.7 years), 85 older men and women (avg. age = 65.0 ± 0.4 years), and 10 younger men and women (avg. age = 26.1 ± 2.4 years). The first group received a diagnostic ultrasound assessment of both the biceps brachii and the rectus femoris. The second group underwent a diagnostic ultrasound assessment of only the rectus femoris and the third group received a diagnostic ultrasound assessment and an MRI of the rectus femoris. Cross-sectional images of the rectus femoris were observed and evaluated with subjects in a supine, relaxed position with ten degrees of knee flexion as well as the biceps brachii in 80° of shoulder abduction and slight elbow flexion. The data obtained from diagnostic ultrasound revealed a strong positive correlation with the images from MRI. The intraclass correlation coefficients (ICC) ranged from r = 0.72 (p < 0.01) to r = 0.99 (p < 0.01). No significant mean differences were noted between the two imaging techniques. The researchers concluded diagnostic ultrasound can provide a more cost effective and safe alternative method for viewing cross-
sectional images of muscles. The researchers also noted the ultrasound technician should be trained and should use caution while operating the unit to avoid potential measurement errors.\textsuperscript{21}

2.3.3. Diagnosis of Patellofemoral Pain Syndrome

After an extensive literature review, limited research exists regarding the use of radiographic imaging techniques as a method for diagnosing PFPS with definitive, reliable criteria.\textsuperscript{25} Imaging techniques such as diagnostic ultrasound may be used to rule out other conditions that cause similar symptoms to PFPS. Clinicians operating diagnostic ultrasound can detect tumors, fractures, osteoarthritis, and loose bodies, all of which can narrow the differential diagnoses.\textsuperscript{2} During the radiographic imaging assessment of the knee, images should be taken with antero-posterior views, postero-anterior views, postero-anterior views at 45° degrees of knee flexion, lateral views at 30° of knee flexion, and axial views of 30° and 45° of knee flexion. All imaging should also be conducted during both weight bearing and non-weight bearing conditions.\textsuperscript{2}

Overall, researchers have evaluated the validity and reliability of diagnostic ultrasound with regards to observing subcutaneous structures of the knee. Diagnostic ultrasound has been compared to other accepted imaging methods such as MRI, CT, and X-Ray and minimal differences between each method have been reported.\textsuperscript{3,21,24} In some cases, diagnostic ultrasound operators were able to evaluate subcutaneous structures with greater accuracy than MRI.\textsuperscript{24} Although, MRI and CT scans are considered the gold standard of imaging techniques, diagnostic ultrasound offers a more accessible, cost effective, and safer alternative for subcutaneous imaging.\textsuperscript{21} Specific criterion has been established in order to use diagnostic ultrasound as a method for diagnosing PFPS.\textsuperscript{25} Researchers have concluded diagnostic ultrasound is an accepted method of subcutaneous imaging and is a valid, reliable, and accurate tool for clinicians.\textsuperscript{24}
2.4. Conclusion

PFPS is a multifactorial pathology with a wide range of possible causes and treatments.\textsuperscript{2,6} Understanding the anatomy of the knee and determining the cause of each specific case is vital for the clinician when establishing the proper treatment plan.\textsuperscript{2,5} Researchers have evaluated different kinesiology taping application methods for PFPS and have reported inconsistent results.\textsuperscript{6} The differing results may be due to the lack of consistency between methodologies of the respective studies.\textsuperscript{7} The brand of kinesiology tape used in each study is often left unreported along with whether or not a CKTP applied the tape, or if a tape stretch standardization method was used during the application. Upon investigation, the brands of the kinesiology tape have not been compared in the published literature. Due to the varying claims of each manufacturer as well as the different materials used, each brand of tape may have different uses and benefits.

The researchers of the one study related to the Kinesio\textsuperscript{®} Taping Space Correction Method for the knee reported a significant increase in the distance between the posterior aspect of the patella and the medial femoral condyle, although the experimentation was conducted on healthy tissue.\textsuperscript{1} Since one of the purported benefits of the Kinesio\textsuperscript{®} Taping Space Correction Method is to lift deeper structures, it would follow that the tape would lift the patella from the underlying structures, mainly the superficial aspect of the femur. The kinesiology tape applied in this manner may alleviate symptoms of PFPS. Gaps in the current literature exist with regard to differentiating between brands of kinesiology tape as well as the effect of kinesiology tape on unhealthy tissue in patients with PFPS. Therefore, further research is necessary to create more definitive criteria for the use of kinesiology tape for patients with PFPS.
CHAPTER 3: METHODOLOGY

The purpose of this study was to determine the effectiveness of the Kinesio® Taping Space Correction Technique when applied to the patellofemoral joint of patients with Patellofemoral Pain Syndrome (PFPS). Furthermore, the effectiveness of the two different brands of kinesiology tape was compared and quantified using diagnostic ultrasound. The research was guided by the following research questions:

1) What are the differences in patellofemoral joint space with the application of kinesiology tape on subjects with PFPS?
2) What are the differences in patellofemoral joint space when comparing two separate brands of kinesiology tape?
3) What are the differences in participants’ perceived patellofemoral joint pain and disability with and without kinesiology tape?

3.1. Participants

The sample for this study comprised 32 participants (10 males, 22 females) between the ages of 18 and 60. Participants were randomly placed into four groups with eight subjects in each group: (1) Kinesio® Tape with tension, (2) Kinesio® Tape without tension, (3) KT Tape® with tension, and (4) KT Tape® without tension. All participants were currently experiencing symptoms of PFPS. All participants were recruited via email listserv, word-of-mouth, or referral by physicians/physical therapists of the Fargo-Moorhead area. Participants were excluded if the subject had a history of Osgood-Schlatter syndrome, patellar subluxation or dislocation, meniscus or ligament damage, or previous knee surgery. Subjects were also excluded from the study if any contraindications to kinesiology tape were previously reported, including an allergy to adhesives, malignancy sites, cellulitis, skin infection, open wounds, diabetes, or fragile skin.
3.2. Setting

The study took place on the North Dakota State University campus, in Room 14 of the Bentson Bunker Fieldhouse, at 1301 Centennial Blvd. Fargo, ND 58102. This location stored the necessary equipment and supplies to carry out the experimentation including the kinesiology tape as well as the Terason uSmart t3300® Diagnostic Ultrasound unit. The centralized location was easily accessible for researchers and participants.

3.3. Equipment

The patellofemoral joint space was examined using the Terason uSmart t3300® Diagnostic Ultrasound (MedCorp. LLC., Tampa, FL), 15L4 Linear Transducer (4.0-15.0 MHz) (MedCorp. LLC., Tampa, FL), and Aquasonic® 100 ultrasound gel (Parker Laboratories, INC., Fairfield, NJ).

In order to compare two popular brands of kinesiology tape, the researchers chose Kinesio Tex Gold FP 2” tape® (Kinesio Holding Corp., Albuquerque, NM) and KT Tape Cotton Elastic Sports Tape® (KT Health LLC., American Fork, UT). Each type of kinesiology tape was applied with the Kinesio® Taping Space Correction Web Cut pattern according to the methods described by Kase et al. with either no tension or 15% tension, dependent on group assignment.

3.4. Procedure

Prior to data collection, this study was approved by the North Dakota State University Institutional Review Board (IRB). Participants were recruited via email listserv, word-of-mouth, and physician/physical therapist referral. Participants reported to Room 14 of the Bentson Bunker Fieldhouse on the North Dakota State University campus. Upon arrival to the testing location, the participants completed a demographics form as well as the Kujala Patellofemoral Scoring System (KPSS) and a Visual Analogue Scale (VAS) to assess pain. Subjects were
included if the KPSS score was between 45 and 70 out of 95 with zero representing the most severe cases and 95 indicating no current symptoms. In the event a subject was suffering from bilateral PFPS, the limb with more severe symptoms was evaluated. All subjects also read and signed the Informed Consent form that outlined the expectations and associated risks of participating in the study. Participants were excluded from the study if the subject had a history of Osgood-Schlatter syndrome, patellar subluxation or dislocation, meniscus or ligament damage, osteoarthritis, or previous knee surgery within two years. The presence of any contraindications to kinesiology tape including an allergy to adhesives, malignancy sites, cellulitis, skin infection, open wounds, diabetes, or fragile skin also resulted in exclusion from the study. All included participants were compensated with $20 at the conclusion of the 24-hour intervention period.

After eligible participants were determined, the subjects were randomly placed into one of four treatment groups using a random number generator. Prior to any intervention, a baseline measurement of the distance between the inferior border of the patella and the superior surface of the medial femoral condyle was quantified and recorded for each subject via the Terason uSmart t3300® Diagnostic Ultrasound (MedCorp. LLC., Tampa, FL). With the subject lying supine on the treatment table, the clinician placed a bolster under the involved knee for accurate viewing purposes via diagnostic ultrasound by placing the knee in 20-30 degrees of flexion. The clinician used 15L4 transducer (MedCorp. LLC., Tampa, FL) at high frequency, with Aquasonic® 100 ultrasound gel (Parker Laboratories, INC., Fairfield, NJ) as a coupling medium. The transducer was placed longitudinally over the patellar tendon and in order to view the medial patella. The transducer was then moved medially until the medial femoral condyle and the medial border of the patella were clearly viewed. The clinician froze the screen and measured the distance
between the medial femoral condyle and the patella using the caliper tool found in the diagnostic ultrasound software. A permanent marker was used to mark the borders of the transducer for recreation purposes. The clinician reporting all of the diagnostic ultrasound measurements was blinded to the brand and tension of the tape.

Black Kinesio® Tape and Black KT Tape® were used and any branding found on the tape was removed to ensure the diagnostic ultrasound technician and participants were blinded to the brand of tape. A member of the research team with over eight years of experience as a CKTP and CKTF was the only researcher with access to the treatment group assignment and conducted the tape application on all 32 participants. The length of the tape was measured after the paper backing had been removed from each of the four tails. The length of the tails were measured with the tape under no tension and again under maximum tension. In Group 1 and Group 3, the respective brands of tape were stretched to 15% of the maximum length.

After the baseline measurements were recorded, each brand of kinesiology tape was prepared for application. Each tape was cut to a length of approximately two inches proximal to the superior pole of the patella and two inches distal to the inferior pole of the patella with the tape still adhered to the paper backing. The middle third of the tape was then cut three times longitudinally while keeping the ends intact. The skin of the subjects was sterilized with an isopropyl alcohol preparation pad and any excess hair was trimmed to ensure the tape adhered properly. The involved knee was positioned in 90-100° of flexion with the foot flat on the table to place the tissue on stretch during the tape application. With the knee flexed, the paper backing of the prepared strip of kinesiology tape was torn exposing the adhesive of the middle third of the tape. The exposed adhesive was applied directly over the patella with the tails evenly spaced under light tension (15%) or no tension (0%) depending on the treatment group. The clinician did
not apply the tape directly over the marked ultrasound measurement location to ensure imaging could be done over the same location previously imaged. Next, the paper backing was removed from the two ends and adhered to the skin without tension. Once the tape was applied, the clinician rubbed the tape to create heat, activating the adhesive. The leg was straightened, and a bolster was placed under the knee bringing the leg in the same angle of flexion in which the previous diagnostic ultrasound measurement was recorded. After the tape had been applied for ten minutes, the patellofemoral joint space was examined using the diagnostic ultrasound over the same location previously marked with permanent marker.

Following the initial treatment session, subjects were instructed to keep the tape on for 24 hours until the final treatment session had concluded on the following day. Upon arrival to the laboratory on the second day, each participant was asked to complete another KPSS and VAS in order to document patient outcomes of the taping methods. The involved knee of the subject was re-examined using the same equipment and parameters as described previously. Diagnostic ultrasound readings were recorded and analyzed in the similar manner as described previously.

3.5. Data Analysis

Statistical analysis for the approved research questions was computed using R statistical language and computing environment. A repeated measures ANOVA with a significance of $p < .05$ was conducted to compare the mean differences between the four taping methods. Additionally, patient outcomes was measured through the use of within and between subject t-tests for both the KPSS and VAS. Post hoc statistical significance was determined by the Bonferroni correction.
3.6. Conclusion

The purpose of this study was to determine if the Kinesio® Taping Space Correction Method Web Cut will increase the patellofemoral joint space in subjects with PFPS. In addition, another purpose of this study was to determine if there will be a statistically significant difference between the two brands of kinesiology tape in use. The KPSS was used to determine the severity of symptoms in subjects with PFPS. Participants completed the KPSS as well as a VAS upon arrival during the first treatment day and again during the follow up visit with 24 hours between each session. The patellofemoral joint space was observed and quantified using diagnostic ultrasound before and after the tape application. The results of the study were interpreted to confirm or refute the interchangeability of different brands of kinesiology tape with regards to the Kinesio® Taping Space Correction Web Cut over the patellofemoral joint. Furthermore, the results were interpreted to determine if the Kinesio® Taping Space Correction Web Cut will be an effective treatment for clinicians to administer for patients with PFPS.
CHAPTER 4: MANUSCRIPT

4.1. Abstract

Context: Kinesiology tape is a common therapeutic intervention for musculoskeletal injuries, although its effectiveness is disputed among healthcare providers. The primary purpose was to investigate differences between brands of tape when the Kinesio® Taping Space Correction Method was applied to subjects with Patellofemoral Pain Syndrome (PFPS).

Methods: Designed as a randomized, double-blind study in a laboratory at a research university. Thirty-two adults (10 males, 22 females; M = 24.5 ± 10.1 years) with PFPS participated. Inclusion criteria comprised the presence of PFPS quantified by a Kujala Patellofemoral Scoring System (KPSS) score between 45 and 70 out of 95. Initial baseline KPSS scores (M = 62.8 ± 8.3) outlining PFPS severity and Visual Analogue Scale (VAS) scores (M = 3.1 ± 1.7) were obtained, followed by baseline measurements of the space between the patella and medial femoral condyle (M = 23.0 ± 3.2 mm) using Terason uSmart t3300® Diagnostic Ultrasound. Participants were randomly assigned to a group with one of the following interventions: (1) Kinesio® Tape with tension, (2) Kinesio® Tape without tension, (3) KT Tape® with tension, and (4) KT Tape® without tension. After ten minutes with the tape, a second ultrasound measurement (M = 23.3 ± 3.2 mm) was recorded. Twenty-four hours later, a second KPSS score (M = 76.1 ± 9.0), VAS score (M = 1.7 ± 1.7), and a final ultrasound measurement (M = 23.3 ± 3.2 mm) were documented. Using R statistical language and computing environment, pre-/post-test measurements of the patellofemoral joint space quantified by diagnostic ultrasound and patient outcome surveys were recorded. Three separate repeated measures ANOVA were conducted to compare ultrasound measurements between groups, KPSS scores, and VAS scores (p < .005).

Results: Descriptive statistics indicate KPSS scores significantly increased after kinesiology tape
was applied (M = 76.1 ± 9.0, p = .002) although no statistically significant difference was observed across groups (p = .898). For the KPSS, an increase in score represents a decrease in pain and dysfunction. VAS scores also significantly decreased following the tape application (M = 1.7 ± 1.7, p = .001) although, again, no significant differences were noted across groups (p = .064). The ultrasound measurements significantly increased between baseline (M = 23.0 ± 3.2 mm) and 10 minutes post-tape (M = 23.3 ± 3.2 mm, p = .001) Although results were maintained, no significance was noted at the 24 hours measurement (M = 23.3 ± 3.2 mm) when compared to baseline and 10 minutes post-tape (p = .13, p = .99, respectively). At a small effect size, group assignment was statistically significant (p = .018).

**Conclusions:** The Kinesio® Taping Space Correction Method alleviated symptoms of PFPS observed with improvements in KPSS and VAS by increasing the patellofemoral joint space within 10 minutes and maintaining results for 24 hours. The current research cannot suggest overall interchangeability between brands, although for this specific application, both Kinesio® Tape and KT Tape® yielded similar positive patient outcomes. **Word Count:** 485 words.

4.2. Introduction

Kinesiology tape is a common therapeutic intervention used for various pathologies, although the effectiveness is widely disputed among healthcare practitioners. An array of variables may be linked to the discrepancies between research findings including the specific brand of kinesiology tape, the credentials of the taping practitioner, and the use of a length or tension standardization method. Several different brands of kinesiology tape are available to consumers and each manufacturer stakes claims of similar therapeutic benefits. Frequently in the literature, kinesiology tape is abbreviated as “KT” or “kinesio tape” and the registered trademark is often omitted. Both Kinesio® Tape and KT Tape® are popular brands of kinesiology tape and
although similar, there are manufacturing differences. The brand of tape should be specified in
the literature to ensure methodologies are accurately replicated. While many brands of
kinesiology tape are available to consumers in sporting goods stores, Kinesio® Tape requires a
certification to purchase.4 In many cases, the credentials of the practitioner applying the tape is
left unreported in the research. The credentials of the practitioner must be provided to ensure a
trained and qualified researcher is applying the tape properly. A final variable not often reported
in the methodology is the use of a length or tension standardization method. Researchers
commonly mention a percentage of stretch applied to the tape, although with the lack of a
numeric measurement, the researcher may be only approximating the correct tension during
application.

Specifically considering Kinesio® Tape and KT Tape®, both similarities and differences
exist between brands with regards to materials and functionality. According to each
manufacturer, both brands consist of a 100% cotton upper layer with a latex-free, hypoallergenic
adhesive surface, which allow the tape to be worn for multiple days at a time. In addition, both
manufacturers claim similar therapeutic effects involving the reduction of pain with an increase
in support for muscles, tendons, and ligaments as well as facilitating lymphatic drainage. The
tapes differ as KT Tape® also contains elastic cores for longitudinal stretching and Kinesio®
Tape is designed to mimic the properties of human skin in both thickness and adhesive pattern.
Furthermore, Kinesio® Tape is also said to aid in providing a positional stimulus through the
skin, aligning fascial layers, providing sensory stimulation to assist or limit motion, and to assist
in the removal of edema by directing exudate towards a lymph duct.4,6,17 Although similar, the
differences noted between Kinesio® Tape and KT Tape® with regards to materials and
functionality should be considered before grouping all brands of kinesiology tape together.
Patellofemoral Pain Syndrome (PFPS) is a common injury among competitive and recreational athletes accounting for 30% of all injuries reported in sports medicine clinics.\textsuperscript{2,5,8} Although the most common cause of this pathology may be biomechanical dysfunction, the definitive etiology is considered multifactorial. Despite the cause, the symptoms associated with PFPS stem from abnormalities of the articular surfaces of the patella and femoral condyles.\textsuperscript{2,5,8} Several researchers have evaluated the use of kinesiology tape as a treatment option for PFPS\textsuperscript{5,6,11,17-20} although only one study could be obtained specifically regarding the Kinesio\textsuperscript{®} Taping Space Correction Method web cut.\textsuperscript{1} The previous researchers reported a significant increase in patellofemoral joint space; however, treatments were conducted using participants with healthy knees\textsuperscript{1}. The suction-like force associated with the Kinesio\textsuperscript{®} Taping Space Correction Method web cut could theoretically alleviate symptoms associated with PFPS.\textsuperscript{1,4}

The primary purpose of this study was to determine if kinesiology tape applied with the Kinesio\textsuperscript{®} Taping Space Correction web cut over the patellofemoral joint was effective at increasing the patellofemoral joint space, as determined via diagnostic ultrasound. A secondary objective of this study was to determine if the Kinesio\textsuperscript{®} Taping Space Correction web cut was effective for alleviating symptoms associated with PFPS. The final purpose was to determine if there was a difference in effectiveness between brands of kinesiology tape, specifically Kinesio\textsuperscript{®} Tape and KT Tape\textsuperscript{®} when applied using the Kinesio\textsuperscript{®} Taping Space Correction web cut to subjects with PFPS.

4.3. Methods

4.3.1 Participants

Following approval from the Institutional Review Board, participants were recruited via email listserv at a mid-sized United States university, word of mouth, and flyers distributed to
local area fitness and health clubs. The subject population consisted of 32 individuals (10 males, 22 females) between the ages of 18 and 60 years ($M = 24.53 \pm 10.11$). Inclusion criteria consisted of individuals with the presence of PFPS quantified by a Kujala Patellofemoral Scoring System (KPSS) score between 45 and 70 out of 95. The KPSS was modified by removing one, five-point question pertaining to atrophy of the thigh. Due to the short-term nature of this study, atrophy of the thigh would likely remain unaltered during the 24-hour testing period, and untrained subjects may have had difficulty self-reporting atrophy. Subjects were excluded from participating in the study if any of the following conditions were present; a history of Osgood-Schlatter syndrome, patellar subluxation or dislocation, meniscus or ligament damage, previous knee surgery within two years. Additionally, subjects were also excluded from participation if any contraindications to kinesiology tape were present including; an allergy to adhesives, malignancy sites, cellulitis, skin infection, open wounds, diabetes, or fragile skin.

### 4.3.2. Procedures

Prior to data collection in this randomized, controlled, double-blinded study, each participant completed an informed consent form and agreed to participate in the study. Participants were randomly placed into one of the following four groups using a random number generator: (1) Kinesio® Tape with tension, (2) Kinesio® Tape without tension, (3) KT Tape® with tension, and (4) KT Tape® without tension. Participants completed baseline KPSS and VAS scores. A bolster was then placed under the affected knee, placing the knee in an open-packed position to allow for accurate diagnostic ultrasound imaging. The researcher placed the 15L4 transducer (MedCorp. LLC., Tampa, FL) at high frequency, with Aquasonic® 100 ultrasound gel (Parker Laboratories, INC., Fairfield, NJ) as a coupling medium over the patellar tendon and moved
medially until the medial femoral condyle and patella were clearly in view. Images were frozen, stored, and measured with the caliper function in the Terason uSmart t3300® software (MedCorp. LLC., Tampa, FL). The distance between the cortical layer of the patella and the anterior surface of the medial femoral condyle was measured in millimeters and compared before the tape was applied, 10 minutes later, and finally 24 hours after the initial application. The researcher used a permanent marker to mark the optimal transducer location for repeatability. After the baseline ultrasound measurement was obtained, a second researcher who was a Certified Kinesio® Taping Faculty (CKTF) applied the kinesiology tape with or without tension depending on the treatment group. The Black Kinesio Tex Gold FP 2” Tape® (Kinesio Holding Corp., Albuquerque, NM) was prepared by cutting four blocks from the roll. The tape was then folded in half and three cuts were made leaving about a one-inch anchor at each end. For the Black KT Tape Cotton Elastic Sports Tape® (KT Health LLC., American Fork, UT), the branding and rounded edges were removed from the pre-cut strip to ensure that neither the ultrasonographer nor the participant were privy to the type of tape applied. The tape was then folded and cut with the same pattern previously stated for the Kinesio® Tape. For groups 1 and 3, each brand of tape was applied with 15% tension measured using a tape measure to ensure accuracy. The leg of the participant was placed in approximately 45° of knee flexion until the foot was flat on the table to put the target tissue on stretch. The tape was applied based on the predetermined measurements and the tails were spaced evenly while still allowing access to the previously marked location of the ultrasound transducer. For groups 2 and 4, the tape was removed completely from the paper backing and applied with 0% tension while the knee of the subject was relaxed in full extension on the treatment table to ensure there was no tissue tension under the tape. Table 2 outlines the measurements associated with each strip of tape.
After the tape was applied, each subject remained in a comfortable position on the
treatment table for 10 minutes to allow for the immediate effects of the tape to occur.¹ A second
ultrasound measurement was recorded following the 10-minute rest period using the same
protocol previously discussed.

After 24 hours with the tape, the subjects returned to the testing location for the second
and final treatment session. A second set of KPSS and VAS scores was obtained followed by a
final ultrasound measurement. At the conclusion of the final ultrasound measurement, each
individual was compensated $20 for participating in the study.

4.4. Results

The data were analyzed using repeated-measures ANOVA models and the R statistical
language and computing environment."³⁸ Three models were estimated, one for each of the
dependent variables: KPSS score, VAS score, and ultrasound measurement. Group assignment
was included as a between-subjects factor. Generalized eta squared (\(\eta^2_G\)) was calculated as a
measure of effect size. Bakeman²⁶ argues that it is reasonable to use .02, .13, and .25 as
guidelines for small, medium, and large effect size, following Cohen’s similar
recommendation."²⁷

Initially, the participants’ gender and age were also considered as between-subject
covariates in ANCOVA models. However, in none of the estimated models were either of these
variables statistically significant. Therefore, they were omitted from analysis and the results
presented here.

<table>
<thead>
<tr>
<th>Brand of Tape</th>
<th>On Paper</th>
<th>0%</th>
<th>100%</th>
<th>15%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kinesio® Tape</td>
<td>20 cm</td>
<td>19 cm</td>
<td>31 cm</td>
<td>21.8 cm</td>
</tr>
<tr>
<td>KT Tape®</td>
<td>20 cm</td>
<td>19.5 cm</td>
<td>37 cm</td>
<td>22.5 cm</td>
</tr>
</tbody>
</table>
Using the KPSS score as the dependent variable, model estimation indicated a statistically significant difference between the pre and post taping scores with a large effect size ($F[1, 28] = 56.697, p < .001, \eta^2_G = .422$). Group assignment was statistically significant only at the 10% level, though the variable did have a medium effect size ($F[3, 28] = 2.334, p = .097, \eta^2_G = .135$). The interaction term was not statistically significant ($F[3, 28] = .197, p = .898$).

The second model was estimated using VAS as the dependent variable. As in the previous model, there was a statistically significant difference between pre and post observations, though with only a medium effect size ($F[1, 28] = 50.933, p < .001, \eta^2_G = .176$). Group assignment was not statistically significant and had a very small effect size ($F[3, 28] = 0.052, p = .984, \eta^2_G = .005$). Finally, the interaction term was not statistically significant ($F[3, 28] = .573, p = .064$). Descriptive Statistics for patient outcome measures can be found in Table 3.

### Table 3. Descriptive Statistics for Patient Outcomes

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>KPSS pre-tape</th>
<th>KPSS post-tape</th>
<th>VAS pre-tape</th>
<th>VAS post-tape</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8</td>
<td>65.750 ± 7.459</td>
<td>78.125 ± 8.543</td>
<td>3.125 ± 1.246</td>
<td>1.875 ± 1.727</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>67.125 ± 7.643</td>
<td>79.125 ± 6.643</td>
<td>3.250 ± 2.121</td>
<td>1.250 ± 1.389</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>57.375 ± 10.099</td>
<td>72.875 ±10.616</td>
<td>3.250 ± 1.488</td>
<td>1.688 ± 1.223</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>60.875 ± 4.734</td>
<td>74.375 ± 9.782</td>
<td>3.250 ± 2.252</td>
<td>1.875 ± 2.416</td>
</tr>
</tbody>
</table>

For the third model with ultrasound measurements as the dependent variable, data were collected at three points in time. Mauchly’s test indicated a violation of the sphericity assumption ($W = 0.618, p = .0015$), so the results are reported using the Greenhouse-Geisser correction to the degrees of freedom ($\varepsilon = .724$). Results indicate that the ultrasound measurements did differ between measurements at a statistically significant level but with a very small effect size ($F[1.45, 40.53] = 4.037, p = .037, \eta^2_G = .003$). Post hoc pairwise comparisons using a Bonferroni correction show that the pre-tape measurement and the immediate post-tape measurement differ at a statistically significant level ($p = .0017$). However, the comparison with the 24-hour measurement does not differ significantly from either the pre-tape measurement ($p = .13$) or the
post-tape measurement \( (p = .99) \). In this model, the group assignment was statistically significant only at the 10\% level and with a small effect size \( (F[3, 28] = 0.175, p = .091, \eta^2_G = .018) \).

Descriptive statistics for ultrasound measurements can be found in Table 4.

<table>
<thead>
<tr>
<th>Table 4. Descriptive Statistics (in mm) for Objective Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
</tbody>
</table>

*Objective measurements recorded with Terason uSmart t3300® Diagnostic Ultrasound

4.5. Discussion

The primary purpose of this study was to observe the differences in patellofemoral joint space when the Kinesio® Taping Space Correction web cut was applied over the patellofemoral joint. The researchers found a statistically significant increase in patellofemoral joint space after the tape had been applied for 10 minutes regardless of the brand of tape used or whether or not tension was applied to the tape or tissue stretch \( (p = .001) \). The initial findings pertaining to patellofemoral joint space measurements are consistent with previous research with regards to statistical significance; however, the previous data were collected based on subjects with bilaterally healthy knees.\(^1\) Although statistically significant, the mean change in patellofemoral joint space in this study was 0.34 mm ± 0.80 while the previous study reported a mean increase of 1.10 mm ± 0.59.\(^1\) Discrepancy in mean differences is most likely due to the differences in tension percentage. The previous study investigated this taping method with approximately 35\% tension as opposed to 15\% tension in the current study. The previous study also reported results based on participants with bilaterally healthy knees. Moreover, this phenomenon may due to the reduced tissue abnormalities and incongruities within the healthy patellofemoral joint compared to subjects with PFPS. Although the previous researchers reported statistical significance, the
clinical significance was unknown based on the subject population. The current study utilized subjects with PFPS and despite a lesser mean increase in patellofemoral joint space compared to previous literature, we documented clinical significance through the results of patient outcomes. To the knowledge of the researchers, this is the first study that explored the effectiveness of the Kinesio® Taping Space Correction web cut on subjects with PFPS. Additionally, although not statistically significant, when compared to pre-tape and post-tape conditions, the effects of the kinesiology tape were maintained 24 hours after the tape had been applied \( (p = .13, p = .99 \) respectively). Due to the nature of this application, it should be noted that the goal of the Kinesio® Taping Space Correction Method is to lift the patella to a sufficient distance from the femoral groove to alleviate pain and symptoms and improve knee function. Although normative data of patellofemoral joint space is not available, the concept of increasing the patellofemoral joint space in excess may also increase the risk of patellar subluxation or dislocation. Therefore, documenting that the patellofemoral joint space increased only with a mean change of 0.34 mm ± 0.80 and the space did not continue to increase after 24 hours, patellar subluxation or dislocation should not be an area of concern while using the Kinesio® Taping Space Correction Method on subjects with PFPS.

A secondary purpose of this study was to determine if the symptoms associated with PFPS could be alleviated after the application of kinesiology tape. The researchers found a significant increase in KPSS scores in all groups \( (p < .001) \) indicating a decrease in symptom severity as well as a significant decrease in patellofemoral pain quantified by the VAS \( (p < .001) \) indicating pain reduction following the tape application. Additionally, 30 of 32 (93.8%) of the participants experienced alleviated symptoms to some extent after the tape had been applied for at least 24 hours. Previous researchers have come to similar conclusions with regards to
kinesiology tape and pain relief. In a similar study, Freedman et al. evaluated short-term effects of Kinesio® tape for pain and hop function. Despite a different taping application, the researchers described significant pain reduction following the application of Kinesio® tape applied by a CKTP with a length/tension standardization. Comparable to the current study, the brand of kinesiology tape, credentials of the clinician, and length/tension standardization methods were specified. Although different kinesiology taping applications were used, Aghapour et al. and Kurt et al. also reported statistical significance with regards to pain and function quantified specifically by the VAS and KPSS, respectively. The clinical significance of these findings suggest kinesiology tape may offer therapeutic benefits to subjects with PFPS and should be used in conjunction with other therapies for optimal results. The symptom reduction may allow for improvements in performance as well as compliance with therapeutic exercises during the rehabilitation process.

The final purpose of this study was to determine if there was a difference in effectiveness between brands of kinesiology tape when applied using the Kinesio® Taping Space Correction web cut. Despite the current literature evaluating the effectiveness of kinesiology tape as a treatment for PFPS, no definitive research has been obtained comparing the possible effects related to the brands of kinesiology tape. Previous researchers have examined kinesiology taping for muscular facilitation/inhibition and patellar tracking corrections and compared to other taping methods such as the McConnell taping. Ho et al. compared McConnell taping to kinesiology tape when applied with the “2 overlapping Y strip technique” for VMO facilitation and patellar correction. The position of the patella was assessed using Magnetic Resonance Imaging (MRI) although neither kinesiology tape nor McConnell taping procedures significantly altered patellofemoral joint alignment or contact area. A different kinesiology taping method
was investigated in the previous study and therefore, is most likely the reason for disparities in conclusions compared to the current research. Subjects were also placed in a modified weight-bearing position during the imaging process in the previous study, which also may have contributed to the contradictory findings compared to the current study. Additionally, differences may have resulted due to the unspecified brand of kinesiology tape as well as the absence of the practitioner credentials reported. Specifically comparing Kinesio\textsuperscript{®} Tape and KT Tape\textsuperscript{®} in the current study, no statistical significance was noted between brands for any taping condition ($p = .091$). Although statistical significance was not reported across brands or taping condition, due to the statistical result ($p = .091$), the researchers may consider an increase in statistical significance to be possible given a larger subject population. Regardless of the lack of statistical significance, it should be noted that obvious differences in physical properties of each brand exist. Although the lengths of the tape on paper were the same, the measurements of each brand were different with off paper tension (0\%), maximum tension (100\%), and the treatment tension (15\%) as shown in Table 2. The current data may suggest the interchangeability between brands of tape but only for this specific application with this specific tension.

Interestingly, groups 2 and 4, supposedly control groups for each brand of tape, were also reported to have had an increase in patellofemoral joint space as well as alleviated PFPS symptoms. Placebo or sham taping applications are commonly utilized as control groups when assessing the effectiveness of kinesiology tape.\textsuperscript{6,17,20} For these two groups, there was no tension on either brand of tape and the tape was applied with the knee in full extension to ensure the tissue was not on stretch. The current recommendations for the Kinesio\textsuperscript{®} Taping Space Correction web cut is for the clinician to place the target tissue on stretch as tolerated by the patient and apply the tape with 10\%-20\% tension in the tails.\textsuperscript{4} Based on these recommendations,
researchers may presume that with 0% tension on the tape and no tissue stretch, therapeutic
effects should not have occurred. If these therapeutic effects can be observed with 0% tension,
the manufacturers of the Kinesio® Taping Method may need to reassess this space correction
application to confirm the proper tape tension percentages. Although tension in kinesiology tape
tends to be imperative to the therapeutic benefits, Epidermis, Dermis, and Fascial (EDF)
Kinesio® Taping application methods are intended to be applied with 0% tension while still
yielding the intended benefits.4 Similarly, the therapeutic benefits may have theoretically been
reported for the Kinesio® Taping Space Correction web cut even when applied with 0% tension
due to the stimulation of the EDF layers of tissue.

4.5.1. Generalizability

The Kinesio® Taping Space Correction web cut can be useful in alleviating symptoms
associated with PFPS. The results of this study are applicable for most people between the ages
of 18-65 suffering from PFPS. Our subject population included competitive and recreational
athletes with 93.8% of our subject population reporting symptom relief to some extent.
Therefore, active individuals who suffer from PFPS will likely report less pain while wearing the
tape for 24 hours.

4.5.2. Limitations

Patellofemoral Pain Syndrome is a general term typically associated with anterior,
retropatellar or peripatellar knee pain.2,10,12 The primary diagnostic tool for this condition is a
comprehensive history of the injury. The process is somewhat subjective; although, due to the
lack of normative data with regards to anatomical and biomechanical measurements, the main
goal of the physical examination and special tests is to identify a cause for the condition rather
than a diagnosis.2,15 The KPSS was used to assess the symptom severity prior to and after the
tape was applied. A score of 45-70 out of 95 was utilized to determine the presence of PFPS and most of the participants tended to self-report symptoms at the higher end of the spectrum. If lower scores were reported indicating more severe symptoms, the participant was not included as they may have sustained a more significant knee injury in addition to suffering from PFPS symptoms. Furthermore, the results from this study are limited to short-term effects within 24 hours of the taping application.

**4.5.3. Future Research**

The manufacturers of Kinesio® Tape claim the therapeutic effects of the tape should remain for approximately three to five days while the manufacturers of KT Tape® claim the therapeutic effects should last about one to three days. Based on this research, the effects of the tape were maintained for 24 hours, although further research should be conducted evaluating long-term effects and further testing the claims of three to five or one to three days, respectively, of clinical effectiveness. With the surplus of available brands of kinesiology tape, future researchers may also compare more brands of kinesiology tape. Kinesio® Tape and KT Tape® were selected due to the popularity in the fields of healthcare and athletics; however, there are different brands available to consumers that should also be investigated. Furthermore, future researchers should study the effects of the Kinesio® Taping Space Correction web cut on other knee pathologies as well such as Chondromalacia Patella or osteoarthritis.

**4.6. Conclusion**

In conclusion, the Kinesio® Taping Space Correction web cut can be used by Certified Kinesio® Taping Practitioners (CKTP) to alleviate PFPS symptoms by increasing the patellofemoral joint space. The increase in patellofemoral joint space may reduce the friction and irritation associated with abnormalities of the articular cartilage located on the posterior surface.
of the patella and the anterior surface of the femoral condyles. Healthcare practitioners may offer this non-invasive taping method to treat patients with symptoms of PFPS. Although more research is needed to determine the overall interchangeability of different brands of kinesiology tape, for the Kinesio® Taping Space Correction web cut, both Kinesio® Tape and KT Tape®, produce similar therapeutic benefits when applied using 15% tension. Both brands of tape effectively increased the patellofemoral joint space and improved patient outcomes. This taping application should be used in conjunction with other evidence-based rehabilitation methods to allow for optimal long-term benefits.
REFERENCES


May 1, 2018

Dr. Katie Lyman
Health, Nutrition & Exercise Sciences

IRB Approval of Protocol #HE18241, “A Comparison of the Effectiveness Between Different Brands of Kinesiology Tape with Regards to the Kinesio® Taping Space Correction Method in Patients with Patellofemoral Pain Syndrome”
Co-investigator(s) and research team: Benjamin Marcus, Kara Gange

Continuing Review Report Due: 3/1/2019

Research site(s): NDSU  Funding Agency: n/a
Review Type: Expedited category # 4
IRB approval is based on the revised protocol submission (rec’d 4/30/2018). Please utilize the approved consent (version rec’d 4/30/2018).

Additional approval from the IRB is required:
○ Prior to implementation of any changes to the protocol (Protocol Amendment Request Form).
○ For continuation of the project beyond the approval period (Continuing Review Report Form). A reminder is typically sent approximately 4 weeks prior to the expiration date; timely submission of the report the responsibility of the PI. 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.

Other institutional approvals:
○ Research projects may be subject to further review and approval processes.

A report is required for:
○ Any 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).
○ Any significant new findings that may affect risks to participants.
○ Closure of the project (Protocol Termination Report).

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

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

Sincerely,

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: FW00005459.