RESEARCH PROTOCOL

July 13, 2017

1. Protocol Title: The Effects of Kinesio Tape® on Arthrogenic Muscle Inhibition and Rate of Torque Development

PERSONNEL

2. Principal Investigator: Marc Norcross, PhD, ATC
3. Student Researcher(s): Yu-Lun Huang, MS, ATC
4. Co-investigator(s): Sam Johnson, PhD, ATC, CSCS; Cathleen Brown Crowell, PhD, ATC
5. Study Staff: Whitley Nelson
6. Investigator Qualifications

The PI, Dr. Norcross, and Dr. Crowell both have a Ph.D. in Human Movement Science (Biomechanics) and extensive experience in neuromechanics research including research on lower extremity injury prevention. Dr. Johnson has a Ph.D. in Exercise Science and has previously conducted multiple research investigations using the methodology that will be employed in this investigation.

7. Training and Oversight

Yu-Lun Huang is a doctoral student in Kinesiology under the direction of Dr. Norcross. She is a certified athletic trainer, and has experience providing treatment and injury prevention protocols to athletes. Ms. Nelson has been/ will be trained by the PI, co-Investigator, or Ms. Huang prior to performing any data collection, reduction, or analysis, and have completed the research ethics and compliance training. Ms. Nelson will be under direct supervision by either the PI, a co-Investigator, or Ms. Huang during all testing sessions to oversee and direct their involvement in the project.

If additional study staff is recruited to assist in this project throughout data collection, reduction, and analysis, the PI will ensure that:

1) they complete ethics and compliance training

2) they undergo rigorous training on the study procedures

3) a project revision form is submitted and approved by the IRB before any contact with participants or participants' data.

8. Conflict of Interest

There are no conflicts of interest to disclose.

FUNDING

9. Sources of Support for this project (unfunded, pending, or awarded)

This project is unfunded.

DESCRIPTION OF RESEARCH

10. Description of Research

Decreased ability to voluntarily activate the entire motoneuron (MN) pool following joint injury is known as arthrogenic muscle inhibition (AMI), which is commonly quantified by measuring central activation ratio (CAR). AMI is not only observed immediately after joint injury, but has been shown to persist during and after rehabilitation. It is proposed that AMI, by negatively impacting neuromuscular factors such as muscle strength, muscle activation, and rate of torque development (RTD), contributes to a prolonged rehabilitation process and higher risk of re-injury. Unfortunately, AMI cannot be reduced by traditional rehabilitation interventions such as strength training alone. Therefore, it is necessary to identify an intervention that can effectively decrease AMI in order to facilitate improvements in muscle function in individuals with AMI.

Kinesio Tape® is commonly used to facilitate muscle contraction in athletic populations. This elastic therapeutic tape is popular in the athletic setting because it can be applied and used continually during exercise and activities of daily living for up to 2-3 days without restricting movement. It has been suggested that Kinesio Tape® facilitates muscle contraction by inducing increased sensory input via skin stimulation. The tape activates cutaneous mechanoreceptors with the greater afferent feedback thought to improve the efferent output from the central nervous system to the target muscles (Akbaş, Atay, & Yüksel, 2011; Yoshida & Kahanov, 2007). While this technique is widely used in the clinical setting to improve muscle function, the facilitative effect of Kinesio Tape® has not been demonstrated- perhaps due to three key limitations of previous investigations. First, previous studies have predominantly recruited healthy participants without muscle function deficits. Therefore, there could have been a ceiling effect whereby there was no observable effect of Kinesio Tape® due to a lack of muscle dysfunction in these healthy individuals. Second, most investigators have generally taken outcome measurements immediately before Kinesio Tape® application and less than 24 hours later. This is much shorter than the 2-3 days that Kinesio Tape® is used clinically and may not be long enough to induce an observable, facilitative effect. Finally, the protocols utilized in previous investigations also failed to mimic clinical practice by not combining Kinesio Tape® application with a therapeutic exercise protocol targeting the inhibited muscle.

Therefore, the purpose of this study is to investigate the effects of prolonged application (> 48hours) of Kinesio Tape® incorporated with a therapeutic exercise protocol on AMI and muscle function. To do so, we will use the peroneus longus muscle in individuals with functional ankle instability (FAI) as a model, given that AMI has been shown to exist in this muscle in individuals with FAI (McVey, Palmieri, Docherty, Zinder, & Ingersoll, 2005).

The following specific aims will be tested:

Aim#1. To investigate the effect of prolonged application (> 48hours) of Kinesio Tape® incorporated with a therapeutic exercise protocol on AMI of the peroneus longus in individuals with FAI.

Aim#2. To investigate the effect of prolonged application(> 48hours) of Kinesio Tape® incorporated with a therapeutic exercise protocol on peroneus longus muscle function in individuals with FAI.

Our central hypothesis is that prolonged application of Kinesio Tape® in combination with therapeutic exercise will diminish AMI and improve muscle function of the inhibited peroneus longus muscle.

The results of this study will be submitted for publication to a clinical, peer-reviewed journal and/or presented at scientific meetings. In addition, the results of this study will guide clinicians who work with patients with joint injuries to have a better understanding of whether Kinesio Tape® is a beneficial intervention to reduce AMI, and whether any facilitative effect of the motor neuron pool results in greater muscle function. If Kinesio Tape® is shown to be an effective intervention for reducing AMI and increasing muscle function, this investigation would provide a much-needed evidence base regarding the clinical usefulness of Kinesio Tape® during rehabilitation for patients with AMI.

11. Background Justification

Muscle weakness and joint instability resulting from alteration of neuromuscular control have been reported following joint injury (Delahunt, 2007; McVey et al., 2005). This protective response adapted following injury is known as arthrogenic muscle inhibition (AMI) (Palmieri et al., 2005; Pietrosimone, Hertel, Ingersoll, Hart, & Saliba, 2011). Unfortunately, traditional rehabilitation and strength training are unable to reduce AMI (Palmieri-Smith, Hopkins, & Brown, 2009). As a result, AMI not only causes muscle strength deficits, prolongs the rehabilitation process, and delays time to return to play, but also may predispose patients to further injury (J T Hopkins & Ingersoll, 2000; Suter & Herzog, 2000). Therefore, effective interventions for reducing AMI should be identified.

Kinesio Tape® is widely used to treat neuromuscular injuries in athletic populations. Kinesio Tape® is proposed to facilitate muscle activation by stimulating cutaneous mechanoreceptors, which may reduce AMI and further improve muscle contraction (Akbaş et al., 2011; Yoshida & Kahanov, 2007). However, the effect of Kinesio Tape® on reducing AMI has not been established in previous studies.

Introduction and negative effects of AMI

It has been suggested that following joint injury, swelling and damage to joint structures causes a continuing presynaptic inhibition of muscles, even though these muscles are not necessarily injured (J T Hopkins & Ingersoll, 2000). AMI compromises the ability to fully contract inhibited muscles voluntarily, and will lead to muscle weakness and strength deficits over time (Arnold, Linens, De La Motte, & Ross, 2009). Previous studies have shown that AMI has negative effects on muscle strength (Mizner, Stevens, & Snyder-Mackler, 2003) as well as RTD. Kline et al. reported that 6 months after anterior cruciate ligament reconstruction, patients had lesser RTD of the quadriceps on their injured side compared to the uninjured side (Kline, Morgan, Johnson, Ireland, &

Noehren, 2015). Residual symptoms and complaints following injury including pain, swelling, and joint instability may be highly related to AMI. Unfortunately, despite the completion of a rehabilitation program following joint injury, AMI is a significant barrier to restoring function and can lead to atrophy, poor muscle function, and a prolonged rehabilitation process because of not being able to fully contract the inhibited muscles during therapeutic exercise (J T Hopkins & Ingersoll, 2000). Without full recovery of muscle function, patients are more susceptible to recurrent injury (Fyfe, Opar, Williams, & Shield, 2013) and joint instability (Delahunt, 2007; Gutierrez, Kaminski, & Douex, 2009). For instance, AMI has been found in the peroneal muscle group in individuals with functional ankle instability (FAI) (McVey et al., 2005). Following lateral ankle sprains, greater than 39% of patients have residual complaints such as instability, pain, or giving-way (Verhagen, De Keizer, & Van Dijk, 1995) that may be related to AMI of the peroneal muscle group. Hence, identifying interventions that can diminish AMI is important to improve the effectiveness of rehabilitation.

Mechanism of AMI

In order to develop interventions addressing AMI, it is important to understand the underlying mechanism. Supraspinal centers play a critical role in modulating signals from different sensory afferent receptors and controlling the motor response (D. A. Rice & McNair, 2010). Supraspinal centers receive information provided by local joint receptors regarding the environment- including joint position and movement-, summarize and process that information, and coordinate a proper motor response by sending an efferent output to muscles surrounding the joint. However, if the afferent input from local receptors is changed due to distension from swelling or damage to structures due to a current or previous joint injury (J T Hopkins & Ingersoll, 2000), the abnormal afferent stimuli will activate an inhibitory response and decrease the ability to voluntarily recruit the motoneuron (MN) pool of the muscles surrounding the joint. In consequence, lesser efferent output is delivered to muscles by the MN pool, which leads to weaker muscle contraction and impaired muscle function.

Treatment of AMI

Previous studies have shown that AMI cannot be overcome by traditional rehabilitation and strength training alone (Gutierrez et al., 2009; Palmieri-Smith et al., 2009). Recent years has seen increased attention being given to interventions for AMI because AMI plays such an important role in a patient's recovery following joint injury with a wide range of interventions including cryotherapy, transcutaneous electrical nerve stimulation (TENs), and joint manipulation evaluated (Doeringer, Hoch, & Krause, 2010; Grindstaff et al., 2011; J Ty Hopkins & Stencil, 2002; Nishikawa & Grabiner, 1999; Pietrosimone, Hart, Saliba, Hertel, & Ingersoll, 2009). The basic concept of these interventions is to decrease presynaptic inhibition, and to increase efferent motor output by stimulating sensory receptors so that inhibitory interneurons are no longer activated (J T Hopkins & Ingersoll, 2000).

There is conflicting evidence regarding the use of cryotherapy to reduce AMI. While cryotherapy effectively increased the motor excitability of inhibited muscle in effusion model studies by stimulating thermoreceptors around the joint (J. T. Hopkins, Ingersoll,

Edwards, & Klootwyk, 2002; D. Rice, McNair, & Dalbeth, 2009), it did not improve motoneuron excitability in individuals with functional ankle instability (Doeringer et al., 2010). Further, Doeringer et al. reported that cyrotherapy had a negative effect on muscle strength evidenced by reduced eversion torque after icing. Thus, the effect of cryotherapy on reducing AMI is still not clear.

Instead of stimulating thermorecepteors, the following interventions target other sensory receptors. TENs has been shown to increase quadriceps activity in patients with knee osteoarthritis by inducing afferent stimuli (Pietrosimone et al., 2009). Similarly, the effect of joint manipulation on reducing AMI has also been reported (Grindstaff et al., 2011). By stimulating sensory receptors, distal tibiofibular joint manipulation increased motoneuron excitability in the soleus, but not the peroneus longus muscle (Grindstaff et al., 2011). However, there is a drawback of joint manipulation and TENs treatments with respect to the length of time over which these interventions can provide sensory stimulation. There is evidence to support that the effects of joint manipulation last 30 minutes after treatment, but whether the effects last more than 30 minutes is unknown (Grindstaff et al., 2011). Further, the residual effects of a TENs treatment on AMI have not been reported. Therefore, having an intervention, such as Kinesio Tape®, that can provide uninterrupted sensory stimulation for a longer period of time while also allowing for rehabilitative exercise to be performed concurrently may be highly effective for reducing AMI.

Introduction of Kinesio Tape®

Kinesio Tape® is commonly used to decrease pain (Aytar et al., 2011; Campolo, Babu, Dmochowska, Scariah, & Varuhese, 2013; Kuru, Yaliman, & Dereli, 2012; Parreira, Costa, Hespanhol, Lopes, & Costa, 2014), swelling, and facilitate muscle contraction in the athletic population (Kamper & Henschke, 2013). This elastic therapeutic tape is popular in the athletic field because it can be applied before and during exercise (up to 2-3 days) without restricting movement. In theory, Kinesio Tape® is believed to increase muscle excitability because it induces sensory input via skin stimulations. The stimuli activate cutaneous mechanoreceptors to provide afferent input. As a result, this feedback is thought to improve efferent output from the central nervous system to the targeted muscles (Akbaş et al., 2011; Yoshida & Kahanov, 2007). Thus, due to the increased sensory feedback provided by Kinesio Tape®, this intervention may increase muscle activation, and improve muscle function and performance (Kase K, Wallis J, 2003). While the facilitative effects of Kinesio Tape® have not been demonstrated in previous investigations, one study investigating the effect of an ankle brace on muscle excitation found that stimulation of cutaneous mechanorecepters around the ankle joint increased H-reflex amplitude in the peroneal muscle group (Nishikawa & Grabiner, 1999). Though it is still unknown if Kinesio Tape® can increase muscle excitability, it is possible that Kinesio Tape® might provide the same positive effect by stimulating sensory receptors in a similar manner as an ankle brace.

A number of studies have investigated the effects of Kinesio Tape® on muscle strength and functional performance. However, the results are inconsistent. Some studies showed that Kinesio Tape® has positive effects on muscle function, including an

increase in hop distance and knee extension peak torque (Aktas & Baltaci, 2011), quadriceps eccentric muscle strength (Vithoulka et al., 2010), and explosive power of the gluteus maximus (Mostert-Wentzel et al., 2012). In contrast, the results from other studies indicate that Kinesio Tape® does not increase knee extension torque (Serra et al., 2015) and muscle strength (Fu et al., 2008; Gómez-Soriano et al., 2014). Recently, one meta-analysis summarized the effect of Kinesio Tape® on muscle function. It reported that Kinesio Tape® had some positive effects on muscle strength, but that the changes were negligible (Williams, Whatman, Hume, & Sheerin, 2012). In addition, this meta-analysis indicated that the long-term effects of Kinesio Tape® on muscle strength and the underlying mechanism of potential facilitative effects are still unclear. The authors concluded that small effects might result from insufficient application duration, which is less than 24 hours in most previous studies (Aktas & Baltaci, 2011; Fu et al., 2008; Serra et al., 2015). Thus, the researchers recommended future studies to investigate the long-term effects of Kinesio Tape® application on muscle function (Williams et al., 2012). The authors also identified a common weakness in previous studies was the inclusion of healthy subjects instead of subjects with AMI (Williams et al., 2012). In the clinical setting, it is recommended to apply Kinesio Tape® for up to 2-3 days, and Kinesio Tape® is usually coupled with therapeutic exercises and active movements to increase the effect of skin stimulation. As a result, it is critical that future studies recruit individuals exhibiting AMI to determine whether Kinesio Tape® has a facilitative effect that can reverse muscle inhibition.

Gap in Knowledge

The effectiveness of Kinesio Tape® to reduce AMI and improve muscle function is unknown. According to previous studies, the treatment approach that has been used to reduce AMI is to increase sensory input to eliminate the inhibitory response that occurs following joint injury. Given this rationale and the fact that Kinesio Tape® can stimulate cutaneous mechanoreceptors, this intervention may be effective for increasing efferent output and muscle performance. It is also apparent that it is critical to recruit individuals exhibiting AMI and replicate clinical practice by coupling Kinesio Tape® with therapeutic exercise when determining the facilitative effects of Kinesio Tape®. Individuals with functional ankle instability are known to exhibit AMI of their peroneal muscles. Therefore, by using this injured population as a model, we can investigate the effects of a combination of prolonged Kinesio Tape® application (>48 hours) and therapeutic exercise on AMI and muscle function.

12. Subject Population

The total enrollment number will be up to 70 participants with unilateral functional ankle instability (FAI). Age of the participants will be between 18 and 35 years-old. A minimum age of 18 has been selected to minimize the potential confounder of physical maturation. Participation in this study is restricted to individuals with FAI because previous research has demonstrated that AMI is present in the peroneal muscles of this specific population. FAI is common in both males and females (Gribble et al., 2014).

Individuals will be eligible to participate in this study if they meet the following inclusion criteria which are endorsed by the International Ankle Consortium (Gribble et al., 2014):

1. A history of at least one significant ankle sprain on the involved (injured) limb
    i. The initial sprain must have occurred at least 12 months prior to the study enrollment
    ii. Was associated with inflammatory symptoms (pain, swelling, etc.)
    iii. Created at least one interrupted day of desired physical activity.
2. The most recent injury on the involved (injured) ankle must have occurred more than 3 months prior to the study enrollment.
3. A history of the involved (injured) ankle joint 'giving way', and/or recurrent sprain and/or 'feelings of instability' on the involved (injured) limb

    Participants should report at least 2 episodes of 'giving way' in the 6 months prior to the study enrolment.
4. Be 18-35 years of age
5. Have not had a past allergic reaction to Kinesio Tape®

The definition of an ankle sprain as "An acute traumatic injury to the lateral ligament complex of the ankle joint as a result of excessive inversion of the rear foot or a combined plantar flexion and adduction of the foot. This usually results in some initial deficits of function and disability" (Delahunt et al., 2010). The definition of 'giving way' is "The regular occurrence of uncontrolled and unpredictable episodes of excessive inversion of the rear foot (usually experienced during initial contact during walking or running), which do not result in an acute lateral ankle sprain" (Delahunt et al., 2010). The definition of 'recurrent sprain' as "Two or more sprains to the same ankle". The definition of feeling of ankle joint instability is "The situation whereby during activities of daily living (ADL) and sporting activities the subject feels that the ankle joint is unstable and is usually associated with the fear of sustaining an acute ligament sprain" (Delahunt et al., 2010).

Individuals will be ineligible to participate if they:

1. Have a history of previous surgeries to the musculoskeletal structures (i.e., bones, joint structures, nerves, etc.) in either lower extremity.
2. Have a history of a fracture in either lower extremity requiring realignment.
3. Had acute injury to the musculoskeletal structures of other joints of either lower extremity in the previous 3 months which impacted joint integrity and function (i.e., sprains, fractures, etc.) and resulted in at least 1 interrupted day of desired physical activity.
4. Are not able to be matched according to our group allocation procedure
5. Have had a past allergic reaction to Kinesio Tape®
6. Currently display symptoms of an acute sprain including swelling, heat, redness, pain, discoloration, and/or loss of range of motion or function

7. Any diagnosed vestibular disorder, Charcot-Marie-Tooth disorder, Ehlers-Danlos, or other hereditary nerve, balance or connective tissue disorder
8. Report a possibility that they may be pregnant as hormonal changes may affect ligamentous laxity
9. Have suffered more than one ankle sprain on the uninvolved limb
10. Have had an ankle sprain on the uninvolved limb within the past 12 months
11. Have episodes of giving way of the ankle on the uninvolved limb besides the single time when they may have sprained this ankle.

Participants in this investigation will be matched by gender and whether the limb with FAI is the dominant or non-dominant leg. Limb dominance will be identified by asking which leg will be used to kick a soccer ball for distance during the initial screening via phone, and will be confirmed during the in-depth screening and familiarization session. Twenty individuals will be allocated to the control and Kinesio Tape® intervention groups, respectively. Given our inclusion criteria, there are four possible sub-classifications of participants: 1) female with FAI of the dominant limb, 2) female with FAI of the non-dominant limb, 3) male with FAI of the dominant limb, and 4) male with FAI of the non-dominant limb. To ensure balanced and matched control and intervention groups, we will only schedule for an in-depth eligibility screening (please see Section 14) participants who: 1) can be matched on gender and limb dominance to a participant who has already been enrolled in the study, or 2) can be matched by a future participant of the same sub-classification without exceeding our target sample size of 20 per group. During the in-depth screening and familiarization session, three FAI self-report questionnaires (see Attachment A: Screening Questionnaires) and two clinical tests of the ankle (please see Section 14) will be implemented to determine if participants have unilateral FAI and a clearly uninvolved, uninjured "control" limb. If participants do not meet the criteria of the three FAI self-report questionnaires and two ankle tests, the participant will be excluded from further participation in the study.

We aim to enroll 40 subjects (20 individuals per group) that will successfully complete all study procedures. This sample size is based upon an a priori power analysis that indicated that 20 participants per group is necessary to detect a medium size interaction effect (f = .23) with a power of 0.80 and an alpha level of 0.05 (G*Power 3.1.9.2). However, our total enrollment will be to up to 70 participants to account for participant drop-out and withdrawals due to failed eligibility screening or an inability to match participants using the process described above.

Recruitment:

Participants will be recruited through the posting of fliers in on-campus buildings (see Attachment B: Recruitment Flier); through brief presentations made to Oregon State University classes that are not taught by any of the research team after obtaining the instructor's permission (see Attachment C: Recruitment In-Class Guide); and by word of mouth. Additionally, we will post fliers (see Attachment B: Recruitment Flier) in local physical therapy clinics, medical offices, and fitness clubs, after obtaining appropriate

approval from these entities, in order to increase the potential participant pool to include active individuals in the community who may not be reached via on-campus recruitment methods. Interested individuals will be instructed to contact the research staff either by telephone or e-mail. We will not perform any direct recruitment of employees, students, or community members except for the in-class method previously described.

13. Consent Process

Individuals that respond to recruitment will go through an oral consent process via phone followed by a short screening process. These procedures will be used to eliminate the burden of time and expense associated with coming to the Women's Building on the OSU campus for individuals who are either ineligible to participate in the study or who will not be able to be matched to enrolled study participants according to our group allocation procedures.

Potential participants responding to recruitment via phone will complete the oral consent and initial screening process either immediately or at a time that is scheduled with the research staff during the initial call. Potential participants that respond to recruitment via email will receive an email response (see Attachment D: Email Response to Recruitment) requesting to schedule a phone conversation. During the oral consent process, a researcher will explain the study, the criteria for eligibility, and the rights of participants to the interested individual (see Attachment E: Oral Consent Guidelines and Screening). If the potential participant is still interested in participating, he/she will provide oral consent and then be screened for eligibility. Participants will be asked questions to determine if they meet the initial screening criteria and are able to be matched based upon the group allocation plan. Participants meeting these criteria will then be scheduled for a 60 minute in-depth eligibility screening and familiarization session (please see Section 14) and will be sent an email to confirm their appointment (see Attachment F: Confirmation of In-depth Eligibility and Familiarization Session). If a participant is unable to schedule the in-depth screening and familiarization session immediately following the initial phone screening, he/she will be asked to email available dates and times to the research staff. If additional communication with participants is needed, we will only contact them via phone or by email using the contact information that they have provided.

Written consent will be obtained from participants at the start of their in-depth eligibility screening and familiarization session in the Women's Building on the OSU campus. In order to obtain written consent from participants, the following steps will be taken:

- Step 1: They will read the informed consent document by themselves (Attachment G: Written Consent Form).
- Step 2: The participant will be asked to verbally summarize the contents of the consent document to make sure the participant fully understands the procedures.
- Step 3: The researcher will clarify if any misunderstanding of the concepts or questions exist, and will ask the participant if he or she has any questions and answer those questions until the participant fully understands the study procedures.
- Step 4: The participant will be informed that their participation is voluntary and they

have the right to withdrawal from this study without any consequence.

- Step 5: Subject signatures indicate that the study has been explained to them, all of their questions have been answered, and they agree to be in the study. Researcher signatures indicate that the study was explained to the subject, comprehension was assessed and found to be sufficient, and the subject provided consent to participate in the study. If they do not consent to being in the study, no other information will be collected.

Over the course of the study, testing will be stopped immeditaely if the participant is not willing to continue.

14. Eligibility Screening

All study participants will complete an in-depth eligibility screening in the Women's Building on the Oregon State University campus.

To be eligible to continue participating in the study, the individual must meet the specific criteria for FAI and be deemed to not have mechanical ankle instability on the involved (injured) limb. In addition, the individual must meet the specific criteria for lack of FAI on the uninvolved (control) limb. First, the individual will complete the general checklist (see Attachment H: General checklist) and Tegner Activity Scale (see Attachment I: Tegner Activity Scale) by themselves to confirm if he/she meet the general inclusion criteria. He/she will also complete the Functional Ankle Instability Questionnaire (FAIQ), Ankle Instability Instrument (AII) and the Cumberland Ankle Instability Tool (CAIT) (see Attachment A: Screening Questionnaires). Lastly, the talar tilt test and anterior drawer test will be performed by student researcher, Yu-Lun Huang, who is a certified athletic trainer and qualified to perform these tests.

The talar tilt and anterior drawer are two commonly-used clinical special tests that have previously been used to identify mechanical ankle instability (Palmieri-Smith et al., 2009). We will use the talar tilt test to check the integrity of the calcaneofibular ligament, and the anterior drawer test to check the integrity of the anterior talofibular ligament. The procedures for conducting these special tests are fully described in section 15.

Specific criteria for determining FAI on the involved (injured) limb:

- Functional Ankle Instability Questionnaire (Hubbard & Kaminski, 2002):
  - i. "Yes" for questions 3, 5, 6, 7, and 9
  - ii. "No" for questions 4, 8, and 10
  - iii. No clinical signs of mechanical instability can be present (see below).
- Ankle Instability Instrument (Gribble et al., 2014):
  - i. "Yes" for question 1
  - ii. "Yes" for at least 4 other questions.

- Cumberland Ankle Instability Tool (CAIT) (Gribble et al., 2014):
  i. Total score < 24

Specific criteria for determining lack of FAI on the uninvolved (control) limb:

- Functional Ankle Instability Questionnaire (Hubbard & Kaminski, 2002):
  i. ”Yes” to question 1
  ii. “No” to question 4
  iii. No clinical signs of mechanical instability can be present (see below).
- Ankle Instability Instrument (Gribble et al., 2014):
  ii. “No” to all questions
- Cumberland Ankle Instability Tool (CAIT) (Gribble et al., 2014):
  i. Total score ≥ 28

Specific procedure for ruling out mechanical ankle instability

i. Talar tilt test and anterior drawer test will be performed as described in Section 15 to detect and rule out individuals with mechanical ankle instability
ii. If both or one of these tests is positive, the participant will be excluded

Potential participants that are determined to be ineligible by the screening will be thanked for their participation and withdrawn from the study. They will be asked not to provide any further information, and will not be scheduled for future testing sessions. The researcher will retain the individual’s name, contact information, and reason for ineligibility in a secure document that will be retained along with the documentation of consent that was provided.

Participants that are determined to be eligible by the in-depth screening will immediately complete a familiarization session as described in Section 15 below and be scheduled for two additional testing sessions.

15. Methods and Procedures

Study Overview:

Participants will complete an initial phone screening and report to the Women’s Building at Oregon State University for three different study sessions:

ii. Session 1: Written consent, in-depth eligibility screening, and familiarization session
iii. Session 2: Testing session A
iv. Session 3: Testing session B

Protocol

Session 1:

- Participants will complete the written consent
- Eligibility screening
  i. Complete the general checklist (see Attachment H: General Checklist) and the Tegner Activity Scale (see Attachment I: Tegner Activity Scale)
- Complete the Functional Ankle Instability Questionnaire, the Ankle Instability Instrument and the Cumberland Ankle Instability Tool (see Attachment A: Screening Questionnaires). These are patient-reported outcome measures from self-report questionnaires that indicate the perceived level of function, pain, etc. These are not medical records from a physician or other provider.
- Talar tilt test and anterior drawer test will be performed on both ankles. The testing procedures and the signs of positive test are described below (Starkey et all., 2015) :

Talar tilt test:

- Participant position: sitting with legs over the edge of a table
- Procedure: the examiner will first use one hand to stabilize the leg, and use the other hand to grasp the calcaneus and talus and provide an inversion stress by rolling the calcaneus medially to evaluate the integrity of the calcaneofibular ligament. During the testing, the ankle will be maintained in approximately 10 degrees of dorsiflexion (Figure 1).
- Positive test: if the talus tilts excessively compared with the uninvolved ankle or lacking of end feel, the result will be determined as positive.

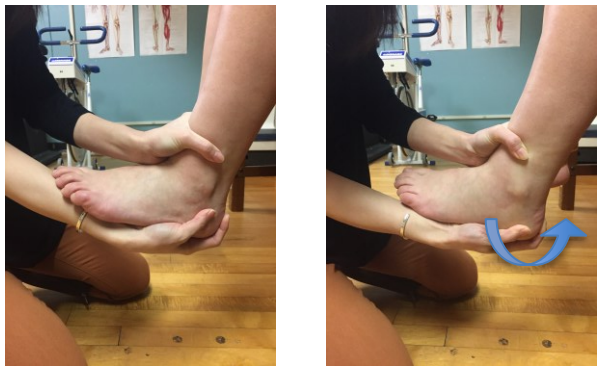

Figure 1: the left picture is the starting position and the right picture is the end position

Anterior drawer test

- Participants position: sitting over the edge of the table with the knee flexed
- Procedure: the examiner will first use one hand to stabilize the leg, and use the other hand to cup the calcaneus while the forearm supports the foot in a position of slight plantarflexion. The examiner will then draw the calcaneus and talus forward while stabilizing the distal leg to evaluate the integrity of the talofibular ligament. (Figure 2).
- Positive test: if the talus slides anteriorly from under the ankle mortise compared with the uninjured side, the talus subluxates and relocates, or there is a lack of a firm end feel, the result will be determined as positive.

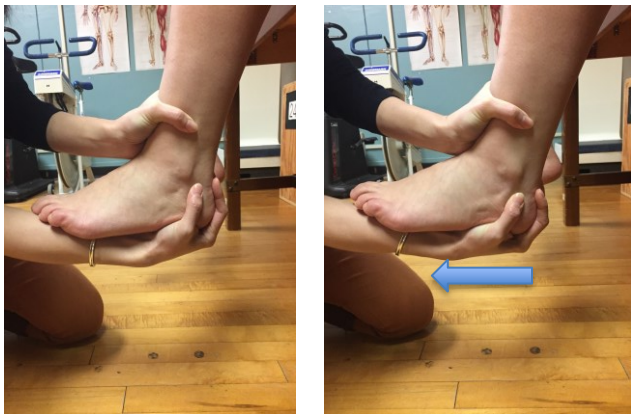

Figure 2: the left picture is the starting position and the right picture is the end position

Familiarization session:

The following steps will be taken:

A. Position the participant on the Biodex dynamometer (Figure 3)

Participants will be asked to sit on the chair of the dynamometer (Biodex) with the hip angle set at 70 to 80 degrees flexion, and straps placed over the chest, waist, and tested leg to prevent extra movement during testing. The knee will be extended, and the participant's foot strapped to the footplate with a Velco strap in ≈10 degrees of plantar flexion (Willems, Witvrouw, Verstuyft, Vaes, & De Clercq, 2002) and ≈7 degrees of inversion (Aydoğ, Aydoğ, Çakci, & Doral, 2004). The thigh will be supported by a supportive bar. The contralateral limb will not be restricted.

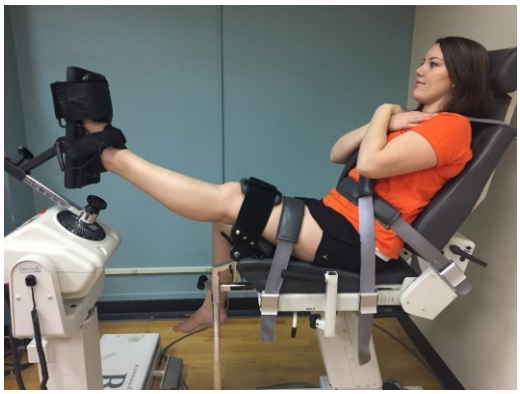

Figure 3. Testing position on the Biodex dynamometer

B. RTD familiarization

Participants will be asked to have their arms crossed over their chest to perform isometric eversion against the footplate of the dynamometer.

i. They will be instructed to push against the footplate by everting the ankle as hard and fast as possible, and maintain the maximum isometric contraction for 3 seconds. Sixty second rest intervals will be given between each trial to minimize the potential for muscle fatigue (Aydoğ et al., 2004).

ii. The participant will be instructed to only contract their peroneal muscles to evert the foot without compensating by using other body parts. The research staff will monitor for compensatory movements during the task and if any compensation is observed, we will instruct the participant in how to eliminate the compensation.

iii. Approximately three to six practice RTD trials will be performed and torque data recorded using the Biopac software. Extra practice may be performed if necessary until the participant can perform the motion correctly.

C. Maximal Voluntary Isometric Contraction (MVIC) familiarization

MVICs will be performed with the participant postioned on the Biodex as described above (Figure 3). Participants will be asked to have their arms crossed over their chest during these contractions.

i. Participant will be asked to push against the footplate of the Biodex dynamometer by contracting his/her foot evertor gradually until reaching their maximal effort and to maintain their maximal effort for at least 3 seconds.

ii. The participant will be instructed to only contract their peroneal muscles to evert the foot without compensating by using other body parts. The research staff will monitor for compensatory movements during the task and if any compensation is observed, we will instruct the participant in how to eliminate the compensation.

iii. Approximately three to six practice MVIC trials will be performed and torque data recorded using the Biopac software. Extra practice may be performed if necessary until the participant can perform the motion correctly.

D. Repeat RTD familiarization and MVIC familiarization on the other leg.

E. Ankle exercise protocol familiarization

Participants will be shown a video to assist in teaching them how to correctly perform the below ankle exercises that will be completed during Session 2 of the protocol. Approximately three to six practice reptitions will be performed for each exercise. Extra practice may be performed if necessary until the participant can perform the exercises correctly.

The descriptions of the ankle exercises are listed below:

1. The participant will be instructed to stretch his/her gastrocnemius muscle on the FAI limb by keeping a straight knee in a lunge position and to stretch the soleus by bending the knee slightly in the same postion (Figures 4 and 5).

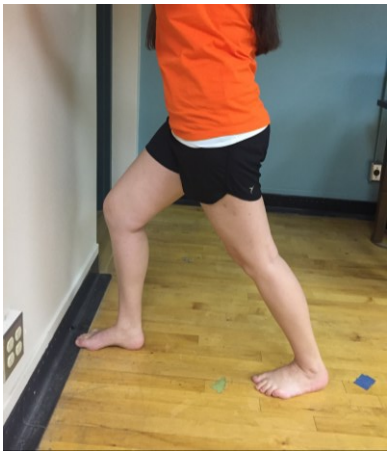

Figure 4: gastrocnemius muscle stretching

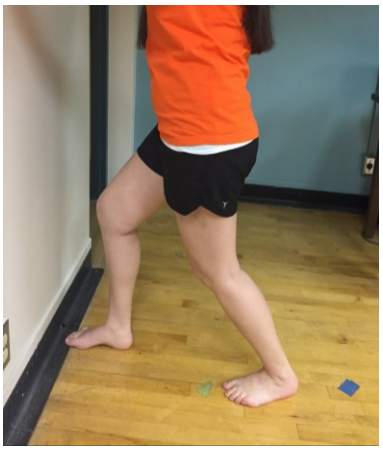

Figure 5: soleus muscle stretching

2. The participant will be instructed to perform a single-limb calf raise on the FAI limb with the knee straight using only body weight for resistance (Figure 6).

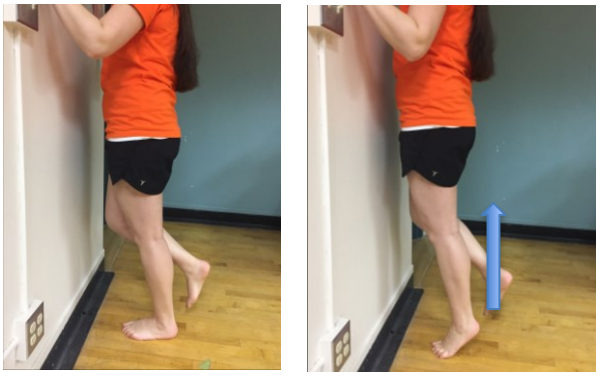

Figure 6: the left picture is the starting position and the right picture is the end position

3. The participant will be instructed to perform anke dosiflexion exercises on the FAI limb with theraband (Figure 7). Participants will select the theraband color that provides the participant a moderate resistance while still being able to maintain good quality muscle contraction throughout the whole range of motion.

Figure 7: ankle dosiflexion exercises

4. The participant will be instructed to perform anke inversion and eversion exercises on the injured limb with self-selection theraband (Figures 8 and 9). To select a proper resistance of theraband, the particiant should feel moderate resistance while still be able to maintain good quality muscle contraction throughout whole range of motion.

Figure 8: inversion

Figure 9: eversion

5. The participant will be instructed to stand on his/her FAI limb while barefoot and eyes closed, put the hands on the iliac crests, and maintain his/her balance for 30 seconds (Figure 10).

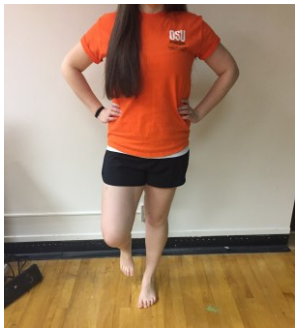

Figure 10: closed eyes single-limb stance with barefoot

6. The participant will be instructed to stand on his/her FAI limb while barefoot. The research staff will toss a ball to the participant in random directions to create an external perturbation, and the participant will toss the ball back immediately after they catch it (Figure 11). The number of toss in low-left, low-right, high-left, hight-right and short toss will be evenly distributed. He/she will be instructed to attempt to maintain balance throughout. If the participant's foot touches the ground, the trial will not be counted as a successful trial. The participant will practice ten successful catch-toss trials or up to 15 catch-toss trails total.

Figure 11: single-limb stance ball toss with barefoot

Total time Session 1 = ~60 minutes

Session 2.

- Height and weight without shoes will be measured (~ 5 minutes)

  Participants will remove their shoes. A wall mounted stadiometer will be used to measure height, while weight will be measured using a standard scale.

- Range of motion of both ankles will be measured (~ 5 minutes)

  A goniometer will be used to measure inversion, eversion, dorsiflexion and plantarflexion angles of both ankles.

- Position the participant on the Biodex dynamometer (~ 5 minutes)

  The participant will be postioned the same as they were during the familiarization session (Figure 3).

- Electrode placement (~ 5 minutes)

  i. Prior to application of the following electrodes, participant's skin will be cleaned with alcohol and excess hair shaved. *One* stimulating electrode will be placed behind the head of the fibula over the location of the common peroneal nerve to deliver a small shock. *One* dispersive electrode will be placed over the posterolateral surface of the lower leg (Figure 12).

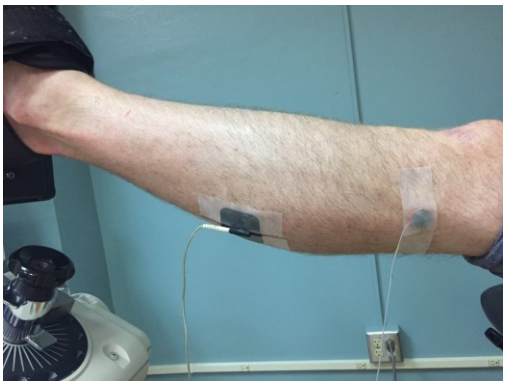

Figure 12 Electrode placement

  ii. We will identify the precise location for the stimulating electrode by delivering stimuli to the participant as the electrode is moved slighlty over the area behind the head of the fibula (i.e., the location of the common peroneal nerve). During each stimulus, the participant will feel a shock behind the head of the fibula and a muscle contraction of the peroneal muscles, and we will record the torque produced by this contraction. Between each shock there will be at least 10 seconds of rest. We will identify andmark with a permanent marker the location of the stimulating electrode that induced the largest eversion torque and use this location of the stimulating electrode for both testing sessions. In total, participant will receive ≈ 5–10 shocks to locate the optimal stimulating electrode location.

  iii. The stimulating and dispersive electrodes will be secured with tape to minimize the movement of the electrodes during testing.

- Measurement of RTD (~10 min)

  The participant will perform 2-3 practice trials, if necessary, and 3 testing

trials using the methods described previously and practiced during the familiarization session.

- Measurement of MVIC (~ 10 minutes)

  Testing of MVIC will be done with the participant postioned on the Biodex as described previously. Participants will be asked to have their arms crossed over their chest during the measurement.

  iv. The participant will perform 2-3 MVIC practice trials, if necessary, and 3 testing trials using the methods described previously and practiced during the familiarization session. A total of 3 successful trials will be measured to obtain the MVIC.

- Measurement of superimposed burst (SIB) (~ 10 minutes)

  The average peak torque recorded during the 3 MIVC trials will be used as the threshold for triggering an exogneous electircal stimulus delivered through the stimulating electorde during SIB trials. The participant will be asked to perform 3 more MVICs as they had done previously. However, during these trials, an exogenous stimulus will be delivered by the data collection system when the participant reaches the defined threshold torque. This stimulus is intended to fully activate the enitre motor unit pool and the torque produced during this supramaximal voluntary contraction will be recorded. This procedure will be performed three times with 60 seconds rest between each trial.

Measurements during session 2 will be taken on both limbs in a counterbalanced order so that we may compare AMI and muscle function between the FAI and uninvolved sides.

- Repeat participant positioning on the Biodex dynamometer (~ 5 minutes) and electrode placement (~ 5 minutes) on the other leg. Measure RTD (~ 10 minutes), MVIC (~ 10 minutes), and SIB (~ 10 minutes) on the other leg.

Following completion of the above testing, participants will be assigned to either the Kinesio Tape® intervention group or the control group using randomization without group replacement. As noted previously, sub-groups for the purpose of randomization and insuring equal intervention and control group sizes will be based on gender and whether FAI is on the dominant or non-dominant leg.

- Apply Kinesio Tape® on FAI limb (treatment group) or sit quietly (control group) (~10 minutes)

  The application of Kinesio Tape® is according to the guidelines provided by the Kinesio Taping Association (Kase, K. 2016). For preparing for placement of the Kinesio Tape®, each participant will be shaved (if necessary), and cleaned with alcohol pre pads over the peroneus longus from the origin to the insertion. Participants will be positioned in ankle inversion to place the peroneus longus on stretch. A 5 cm width strip of Kinesio Tape® (Kinesio TEX Products, NKT-050, Japan) will be applied from origin (the head of the

fibula) to insertion (the medial cuneiform and first metatarsal) of the peroneus longus in a longitudinal direction (Figure 13). The proximal anchors will be applied without tension, and the Kinesio Tape® placed on approximately 50% stretch before being applied over the peroneus longus and the distal anchor point.

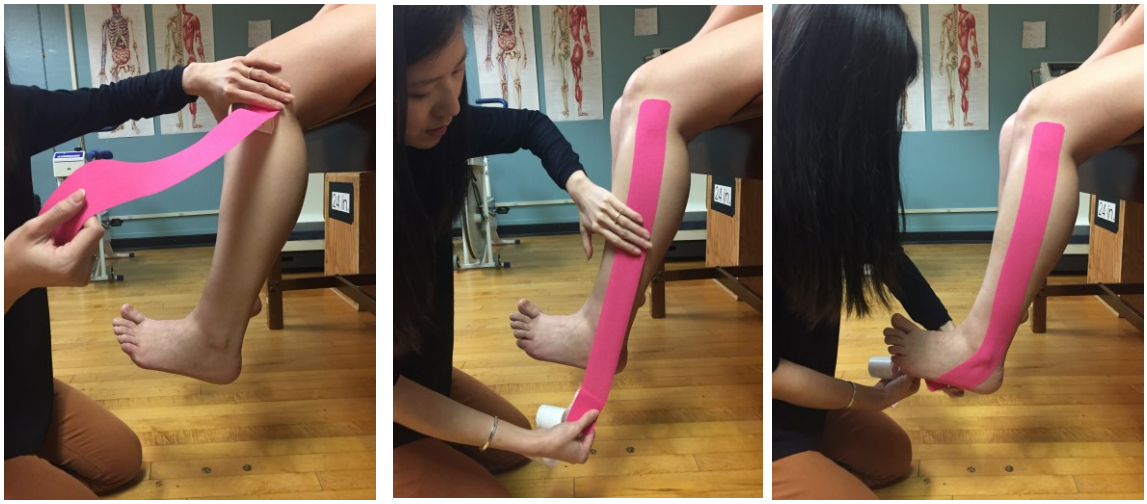

Figure 13: Kinesio tape application

- Exercise protocol (~20 minutes)

  Following 10 minutes of stationary bicycle (Monark Bicycle Ergometer) riding at a self-selected resistance, all participants will perform a standardized set of therapeutic exercises that are commonly implemented in ankle rehabilitation programs. The ankle exercises have been fully described previously in Section 15. Table 1 lists the specific number of sets and repetitions for each exercise.

Table 1. Standard Ankle Exercise Protocol		
Tasks	Sets/Repetitions	Limb
Warm-up: • Stationary bicycle ride at a standard light resistant (Monark Bicycle Ergometer)	10 minutes	N/A
Stretch • Gastrocnemius (stretch with straight knee) • Soleus (stretch with knee slightly bent)	3 sets x 20 seconds each	FAI limb only
Strengthening exercise: • Single-limb calf raise with bodyweight • Ankle dorsiflexion with self-selection theraband • Ankle inversion with self-selection theraband • Ankle eversion with self-selection theraband	3 sets x 15 reps each	FAI limb only
Neuromuscular control: • Closed eyes single-limb stance with barefoot • Single-limb stance ball toss with barefoot	2 sets x 30 seconds, 2 sets x 10 reps	FAI limb only

Participants in the Kinesio Tape® group will be instructed to keep the tape in place until they have completed session 3. All participants will be asked to maintain their normal activity and to report back to the laboratory two days later for their final scheduled testing session.

Total time Session 2 = ~120 minutes

Session 3.

All testing will be completed in the Women's Building using previously described methods. However, during session 3, measurements will only be taken on the limb with FAI and the Kinesio Tape® will be left in place during testing.

- Position the participant on the Biodex dynamometer (~ 5 minutes)
- Electrode placement (~ 5 minutes)
- Measurement of RTD (~10 min)
- Measurement of MVIC (~ 10 minutes)
- Measurement of SIB (~ 10 minutes)

Total time Session 3 = ~40 minutes

16. Compensation

Participants will not be compensated for their participation in this investigation.

17. Costs

The participants will be responsible for their own transportation to and from the testing site and any fees associated with parking. There will be no other costs borne by participants for participating in this study except for their time.

18. Medical Devices

- Indication if data related to the safety or efficacy of the device will be collected: This investigation will evaluate the effectiveness of the combination of a prolonged Kinesio Tape® application (>48 hours) and therapeutic exercise for reducing AMI and improving muscle function.

- Rationale for choosing the device to be used: As described in Section 11, Kinesio tape is popular in the athletic field because it can be applied before and during exercise (up to 2-3 days) without restricting movement. In theory, Kinesio Tape® is believed to increase muscle excitability because it induces sensory input via skin stimulations. The stimuli activate cutaneous mechanoreceptors to provide afferent input. As a result, this feedback is thought to improve efferent output from the central nervous system to the targeted muscles (Akbaş et al., 2011;

Yoshida & Kahanov, 2007). Thus, due to the increased sensory feedback provided by Kinesio Tape®, this intervention may increase muscle activation, and improve muscle function and performance (Kase K, Wallis J, 2003).

- Device description:

Kinesio Tape, as shown above and in Figure 13, is classified as a “Tape and Bandage, Adhesive” medical device by the Food and Drug Administration. It is manufactured by the Kinesio Holding Corporation, which is registered with the FDA>

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A to Z Index | Follow FDA | En Español

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Establishment Registration & Device Listing

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Classification Name:	TAPE AND BANDAGE, ADHESIVE
Product Code:	KGX
Device Class:	1
Regulation Number:	880.5240
Medical Specialty:	General Hospital
Registered Establishment Name:	KINESIO HOLDING CORPORATION
Registered Establishment Number:	3000214922
Owner/Operator:	Kinesio Holding Corporation
Owner/Operator Number:	10027689
Establishment Operations:	Specification Developer

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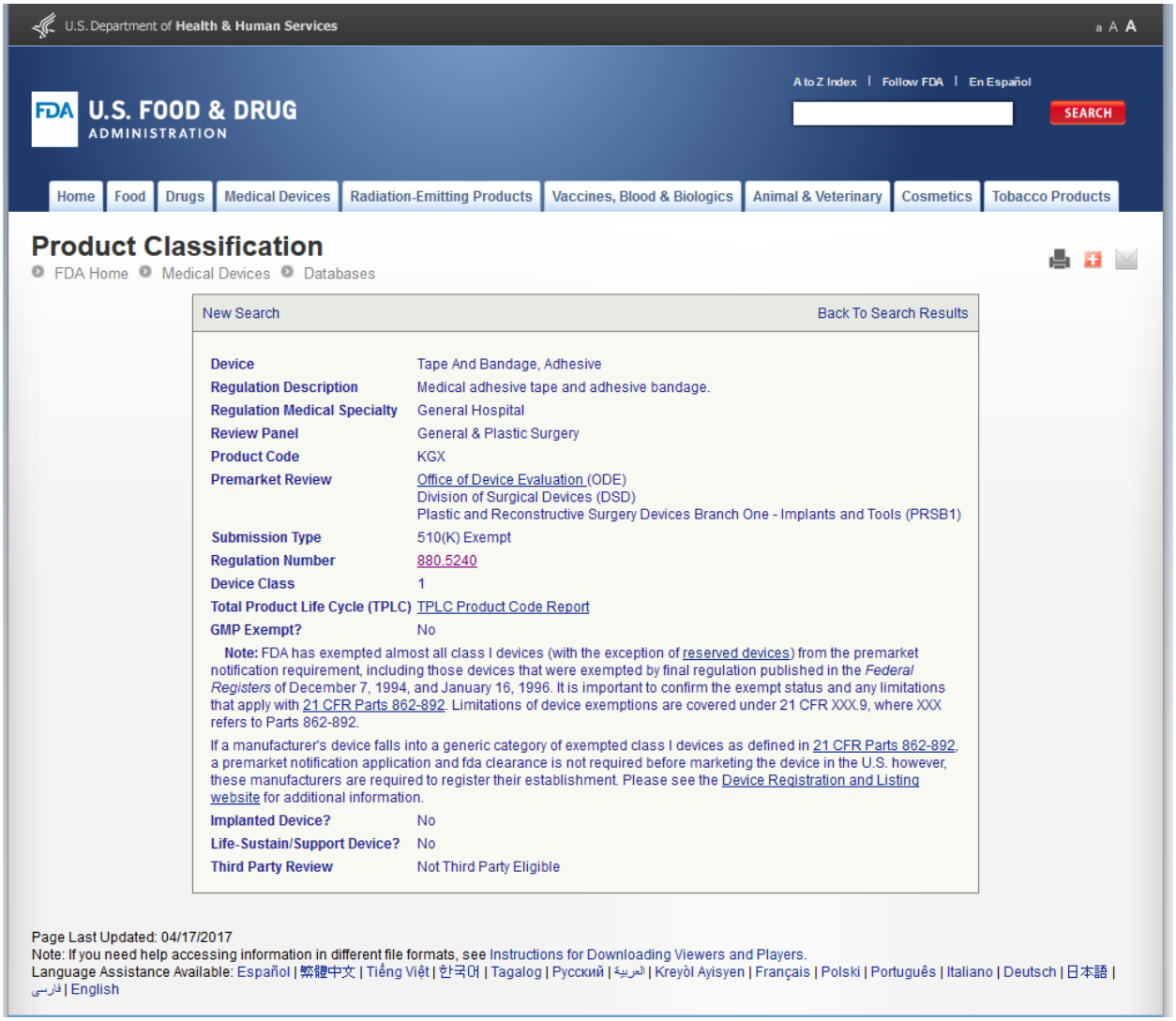

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Product Classification

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Device	Tape And Bandage, Adhesive
Regulation Description	Medical adhesive tape and adhesive bandage.
Regulation Medical Specialty	General Hospital
Review Panel	General & Plastic Surgery
Product Code	KGX
Premarket Review	Office of Device Evaluation (ODE) Division of Surgical Devices (DSD) Plastic and Reconstructive Surgery Devices Branch One - Implants and Tools (PRSB1)
Submission Type	510(K) Exempt
Regulation Number	880.5240
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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A description of how the device will be used is provided in Section 15 and based upon the instructions set forth in Illustrated Kinesio Taping 4th ed. Written by the developer fo the technique, Kenzo Kase, D.C.

- Proposed Intended Use/Indications for Use:
    - As described in the methods and procedures, we propose to apply this device to the lateral aspect of the lower leg in individuals with FAI for approximately 48 hours. Participants will complete a standard ankle exercise program immediately after tape application and indicators of muscle inhibition and performance at 48 hours post-treatment will be compared to participants with FAI that only completed the exercise protocol. A copy of the product labeling is provided below.

- We have no intent to commercialize or patent the device.

19. Though the medical device that we propose to use in this study is not exempt from the specified requirements described in 21 CFR 812, we believe that this investigation qualifies as a Nonsignificant Risk device study because the device is: not implanted; not used to support or sustain human life; nor does it present a potential for serious risks to the health, safety, or welfare of participants.Anonymity or Confidentiality

An electronic spreadsheet, known as the “Master List” will contain the name and contact information of each individual who responds to recruitment. To protect the confidentiality of the participants, their data will be identified by an assigned code. The code will be linked to their data. The Master List will document the identification code, whether the individual met the eligibility criteria, the scheduled test date and time, and the reason for ineligibility, if applicable.

With the exception of the Master List, all other forms, files, and recordings will be coded using the assigned identification code without names or contact information.

All study related materials will be stored in a secure manner, either on a computer belonging to the researchers that is password protected or on a computer or locked file cabinet that is in the researchers’ laboratory or office for a minimum of three years post study termination. Data from individuals who are found to be ineligible for participation during the screening process will also be stored with an identification code assigned following the oral consent process. All computers on which data will be stored that are connected to a network have fully patched operating systems and applications, and current antivirus software with current virus definitions. No information will be stored in cloud-based servers. Any document that includes the participants’ name will be stored separately from any coded information.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify individual participants and at most, the Web site will include a summary of the results.

Results in the form of research manuscripts will be submitted to OSU scholars' archives and for peer-reviewed publication. Results will also be presented at scientific meetings. In all cases, a participant's identity will not be disclosed. Results will be reported in a summarized manner such that participants cannot be identified.

20. Risks

No more than minimal risk is expected. The possible risks and/or discomforts include:

As with any physical activity, participation in this study carries a risk of bodily injury such as muscle strain, ligament sprain, or (in rare instances) a potentially disabling injury. The motions that participants will be asked to perform are ones that repeatedly occur during physical activity and performance testing. Following testing and exercises, participants may experience muscle soreness and/or fatigue. To minimize these risks, they will be instructed to warm up with practice trials to prepare for testing and will be provided with 60 seconds of rest between trials.

The electrical stimulation may cause some discomfort. In rare situations, the electrical stimulation could cause a participant to feel dizziness, nausea, and/ or faint. The researchers will closely monitor the participants throughout the testing to ask how they are feeling. The participants will be able to tell the researcher if they are not willing to continue the testing session. The following study personnel (Dr. Norcross, Dr. Johnson, Dr. Brown Crowell and Ms. Huang) are certified athletic trainers trained in emergency response. At least one of them will be present at all testing sessions, and in the event of an injury, will evaluate the situation and either activate the emergency medical system (EMS) or assist the participant in seeking medical assistance for non-life threatening injuries. All adverse events will be reported immediately to the appropriate IRB official.

Although Kinesio Tape® is latex-free and rarely irritates the skin, some individuals may have an allergy to Kinesio Tape®. To minimize this risk, we will exclude participants that report having an allergic reaction to Kinesio Tape® and we will instruct participants to remove the tape and immediately seek medical attention if they suspect that they are having an allergic reaction. Every participant has the right to stop participation anytime with no negative consequences. In the chance that a participant experiences discomfort or allergic reaction, the event will be documented and reported to the OSU IRB.

21. Benefits

It is unlikely that the participants will experience any noticeable benefits from their participation in this study. However, it is possible that the Kinesio Tape® intervention may facilitate muscle activation and reduce AMI in the peroneal muscles of participants who receive this intervention.

Society will benefit from this study because the results of this study may provide clinicians and patients with evidence supporting a therapeutic treatment option to reverse AMI and facilitate muscle function.

22. Assessment of the risks and benefits

Although some risks and/or potential discomforts are associated with this study, they are minimal due to the protective measures taken against them. It is expected that the

knowledge to be gained from the completion of this investigation with respect to whether Kinesio Tape® is a useful intervention to reduce AMI following joint injuries or surgeries is a benefit to society that outweighs the risks.

23. Attachments:

- Attachment A: Screening Questionnaires
- Attachment B: Recruitment Flier
- Attachment C: Recruitment In-Class Guide
- Attachment D: Email Response to Recruitment
- Attachment E: Oral Consent Guidelines and Screening
- Attachment F: Confirmation of In-depth Eligibility and Familiarization Session
- Attachment G: Written Consent Form
- Attachment H: General Checklist
- Attachment I: Tanger Activity Scale