THE EFFECTS OF A KINESIO® TAPE APPLICATION ON INTRAMUSCULAR TISSUE TEMPERATURE CHANGE DURING A 20-MINUTE CRYOTHERAPY APPLICATION

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

By

Michael Samuel McCrone

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

Major Program:
Advanced Athletic Training

March 2017

Fargo, North Dakota

North Dakota State University
Graduate School

Title

The Effects of a Kinesio® Tape Application on Intramuscular Tissue Temperature Change During a 20-Minute Cryotherapy Application

By

Michael Samuel McCrone

The Supervisory Committee certifies that this ***disquisition*** complies with North Dakota State University's regulations and meets the accepted standards for the degree of

MASTER OF SCIENCE

SUPERVISORY COMMITTEE:

Katie Lyman
Chair

Kara Gange

Jay Albrecht

Michael Kjellerson

Approved:

March 28th, 2017
Date

Yeong Rhee
Department Chair

ABSTRACT

The methodology for this research study was specifically designed to investigate whether or not Kinesio® Tape would act as a barrier during a cryotherapy application. Previous research has concluded that certain dressings can act as a barrier and impede the decrease in temperature in the underlying tissue. However, the properties of Kinesio® Tape are supposed to mimic the properties of skin. The thickness of Kinesio® Tape is miniscule compared to other barriers such as a plaster cast or an ace bandage. Due to this property, there were no statistically significant results found in intramuscular tissue temperature change comparing the use of the tape application and no application. This research has provided evidence-based support that the use of cryotherapy over a Kinesio® Tape application will have no adverse effects.

ACKNOWLEDGEMENTS

I want to start by thanking my family, especially for my Mom and Dad. The constant support and reminders to “Be myself” and “Do my best” have made me the person I am today. They always pushed me to be better and expand my knowledge and skills. I am so grateful to call you both my role models and can’t thank you enough for always being there. I love you both very much!

To my wife Chelsea, I can’t give enough gratitude to you. The sacrifices you have made to help me on this project are invaluable. Thank you for putting up with my late nights and stress-relieving vent sessions. Thank you for never allowing me to get down and for always continuing to make me strive for more. You are my rock and my best friend. I couldn’t ask for anyone better and I love you to the moon and back!

Dr. Katie Lyman has been the back-bone of my whole thesis. She has given me valuable guidance and has allowed me to enjoy this journey. She provided guidance and advice to give me the confidence to be able to complete graduate school and still balance a personal life. Her knowledge and wisdom has been unparalleled. I am so grateful for the time and support that you have given me over the past two years.

I want to thank my other committee members as well, Dr. Kara Gange, Michael Kjellerson, and Dr. Jay Albrecht, for taking time out of your busy schedules to serve on my committee. I appreciate all off your help and individual expertise.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1. INTRODUCTION

1.1. Overview of the Problem

Kinesio® Tape is a modality that is becoming more popular in use for the athletic and medical settings.[1-3] Kinesio® Tape is proposed to assist with the inhibition/facilitation of muscles, correction of fascial abnormalities, provide mechanical support, improve lymphatic drainage and circulation, and postural support.[4] However, due to poor study designs, there is a lack of quantitative research to support the uses of the Kinesio® Tape. The properties of Kinesio® Tape are supposed to mimic the properties of skin; therefore, Dr. Kenzo Kase, the inventor of Kinesio® Tape, claims that it can be used in combination with cryotherapy.[4] To date, after an extensive literature review, no research has been completed to support or refute this claim.

Cryotherapy is the most common modality used for orthopedic injuries[5] and acute management of musculoskeletal injuries.[6] There are many factors that can alter the effectiveness of cryotherapy, one of which is barriers.[7-10] Studies have provided evidence that different barriers, such as ace bandages and other casting materials, have adverse effects on the cooling properties that occur in the underlying intramuscular tissue temperature during a cryotherapy application. In addition, achieving desired intramuscular tissue temperatures required additional time with the cryotherapy application.[7-10]

Treatments in the medical field are forever progressing. As new techniques emerge, it is important research follows suit. The goal of every medical professional is to provide the best care available, as determined by evidence-based research. Even though the quantitative effects of Kinesio Tape® are not consistent, its popularity continues to increase. Understanding how

Kinesio Tape® might affect cryotherapy will allow medical professionals to continue to provide optimal care for patients.

1.2. Statement of Purpose

The purpose of this study was to investigate the intramuscular tissue temperature change during a cryotherapy application that is applied over a Kinesio® Tape application. Because there are different methods of applying Kinesio® Tape, dependent upon the goal of the treatment, different widths were studied in order to provide conclusions to practitioners. This study also determined if the width of Kinesio® Tape would alter the change in the underlying intramuscular tissue temperature. After an extensive literature review, there is no research to quantify the effects Kinesio® Tape has on the change of intramuscular tissue temperature during a cryotherapy application.

1.3. Research Questions

The research questions that guided this study were:

Q1: What is the impact of Kinesio® Tape application on the temperature of intramuscular tissue in the presence of a cryotherapy application?

Q2: What is the impact of the width of Kinesio® Tape on the temperature of intramuscular tissue in the presence of a cryotherapy application?

Q3: What is the difference in subjective reporting of participants' discomfort with the application of cryotherapy with and without Kinesio® Tape applied?

1.4. Dependent Variable

The dependent variables in this study were the temperature recordings during the 20-minute cryotherapy application.

1.5. Independent Variable

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

1.6. Limitations

The limitation in this study was the use healthy individuals with healthy tissue. Therefore, the results of this study may not be transferable to individuals who have injured tissue. In addition, the small sample size of 20 individuals is a limitation for making generalizations for all individuals.

1.7. Delimitations

The study was performed with a population consisting of males only using the dominant quadriceps. There are multiple Kinesio® Tape applications which could have been investigated. A "Y" strip was chosen over an "I" strip because it is most commonly used on the quadriceps. There was also a seven-day window between the first and second session. During this time, the participants were asked not to vary from their current exercise program if they were currently partaking in one. Also, they were asked not to start a new workout regime during the duration of the study. However, the researchers were not able to control the amount of activity performed during the research timeframe.

1.8. Significance of the Study

Cryotherapy is the most commonly used modality for musculoskeletal injuries.[11] In order for cryotherapy to be effective, there has to be a decrease in intramuscular tissue temperature.[11] There are many factors which influence the change in tissue temperature, such as barriers.[7-10] With Kinesio® Tape becoming more popular in health related fields, [1-3] undoubtedly it has been and will continue to be used in combination with cryotherapy. However, there have been no previous studies to support or refute the claims Dr. Kenzo Kase has made on Kinesio® Tape

acting as a barrier to intramuscular tissue temperature with the application of cryotherapy. The effects of barriers have been documented in the research,[7-10] but Kinesio® Tape has not been researched as a potential barrier.

1.9. Definitions

Kinesio® Tape- A kinesthetic tape that mimics the thickness and flexibility of skin. It helps aid with muscle activation and force production, pain levels, aid the lymphatic system, improve circulation, increase range of motion, reduce delayed onset muscle soreness, and provide mechanical support.[4]

Thermocouples- There are many different types of cryotherapy used in order to reduce the metabolic process: cold-water immersion, ice bag, gel pack, ice massage, or any other application of cold for the purpose of therapeutic effects.[12] Measure intramuscular tissue temperature during various modalities.[13]

Kinesio® Tape Facilitation Technique- This technique is applied along the muscle length starting at the origin and pulled towards the insertion. The ends of the tape act as anchors and are applied with no tension. The tape covering the treatment area is applied with 15-35% tension.[4]

Cryotherapy- The purpose of a cryotherapy application is to decrease intramuscular tissue temperature.[14] By doing so, the enzymatic response is delayed decreasing the chance of secondary injury to the uninjured tissue.[15] Clinicians must be aware of the duration, amount of adipose tissue, type of cryotherapy, and anatomical location when applying an application.

CHAPTER 2. REVIEW OF LITERATURE

The purpose of this literature review is to give background information on cryotherapy, Kinesio® Tape, and the use of thermocouples. Cryotherapy is most commonly applied for musculoskeletal injuries to help reduce pain, edema, nerve conduction and local blood flow. There are many factors that can influence the effects of cryotherapy. Parameters clinicians must consider are: duration of treatment, amount of adipose tissue and anatomical location, and mode of cryotherapy. Kinesio® Tape is a therapeutic tape used for musculoskeletal injuries. Commonly, it is used to facilitate or inhibit muscles. Personnel and authors at Kinesio Taping Association International (KTAI) claim that the application of Kinesio® Tape will not affect a cryotherapy treatment. To date, there is no published research investigating the effects of cryotherapy on intramuscular tissue temperature with a Kinesio® Tape application.

2.1. Cryotherapy

Cryotherapy is the most common modality used for orthopedic injuries[5] and the acute management of musculoskeletal injuries.[6] Cryotherapy is used to help reduce pain, edema, nerve conduction, and local blood flow.[14] The primary use of cryotherapy is to reduce the metabolic process of an injured tissue in order to help the uninjured tissue survive the enzymatic reactions that occur with an injury.[12] It is theorized that applying ice immediately is more beneficial than delaying the application.[6] In addition, using techniques which cool the tissue more rapidly and produce lower temperatures are theorized of being more beneficial in slowing the metabolic process more effectively.[6]

There are many factors which can affect the effectiveness of cold modalities: duration,[6] amount of adipose tissue and anatomical location,[1] and type of cryotherapy used.[6] Even though there have been no parameters set for time or intramuscular tissue temperature, most clinicians

apply cryotherapy for 20 to 30 minutes.[11,12,14,16] However, a barrier between the ice and skin, such as a cast, splint, or tape, could require longer treatment applciations.[7-10] There are many different types of cryotherapy used in order to reduce the metabolic process: cold-water immersion, ice bag, gel pack, ice massage, or any other application of cold for the purpose therapeutic effects.[12]

2.1.1. Thermodynamics

To understand how ice changes intramuscular temperature, one must understand thermodynamics. Heat is transferred in one direction only, high heat to low heat.[6] Cold modalities do not transfer cold to the tissues but absorb the heat from the underlying tissues.[6] In order to decrease intramuscular tissue temperature, the superficial epidermis must be cooled first; this will allow heat to be transferred out of intramuscular tissue and essentially decrease temperature.[6] The transferring of heat depends on the mass, size of contact area, difference in starting temperatures, heat capacity, and the rewarming properties of the tissue through metabolic processes.[6]

There are different types of heat transfer that occur with cold modalities: conduction, convection, evaporation, or a combination.[6] Conduction is the absorption of heat from the underlying tissue due to direct contact such as using an ice bag.[6] Convection is the use of water to absorb heat, such as a cold whirlpool. Evaporation is allowing the ice to change state from a solid to a liquid; this occurs in certain commercial products such as Wet-Ice.[6] For the majority of cryotherapy applications, conduction is the reason for heat transfer. It is theorized that there would be a greater cooling effect from modalities which uses a combination of types of heat transfer and undergo a phase change (solid to liquid).[6,14] However, skin temperature rapidly

drops in the first three minutes and will be at its minimum temperature around the nine minute mark no matter which application is used.[12]

The process of cooling intramuscular tissue temperature is a linear pattern.[15] Skin temperature is reduced the fastest and will reach a minimum temperature first. Superficial intramuscular tissue temperature cools slower than skin temperature but at a more rapid pace than deeper muscle tissues. Deeper tissues do not reach a minimum temperature until after the treatment time has concluded because heat from the deeper tissues is lost to the more superficial. If the duration of a cryotherapy application is too short, the deeper tissues may not receive any of the treatment. If the duration is too long, the superficial tissues are at risk for damage. Therefore, clinicians must be aware of how long an application should be applied to obtain the greatest effects without causing harm to the patient.

2.1.2. Factors Affecting Ice: Duration

The clinical standard for cryotherapy treatments ranges from 20 to 30 minutes. However, there is little published research supporting the time frame clinicians most often utilize for patients.[3-6] Kuo et al[17] performed a study comparing the change in skin temperature during a 10-minute, 20-minute, and 30-minute cryotherapy application. The study was performed on a population that had sustained injuries either in an automobile accident or during activity. The extent of the injuries included sprains, strains, contusions, or hematomas. An ice bag (20 X 25 cm) was filled either half way or two-thirds full depending on the size of injury. After the treatment time was complete, the skin temperature was recorded using a TES-1306 thermometer with a measurement range of -200°C to 760°C. The 10-minute group had a decrease of skin temperature of -9.22°C ± 4.38°C, the 20-minute group decreased -9.77°C ± 4.73°C, and the 30-minute group was a change of -10.39°C ± 5.07°C. Even though a decrease of skin temperature

was observed for each treatment time, none of them were significant when comparing the results to the pretest temperatures ($P = .6055$, $P = 3.896$, $P = .1614$, respectively). However, a significant difference was shown across time in each group ($P < .0001$).[11] Even though the mean temperature change for 30 minutes was larger, it was not statistically significant ($P > 0.05$). When comparing different treatment times, this authors concluded that the duration of the ice application did not have a significant effect on the decrease of skin temperature.

Duration is one component of a cryotherapy application that can help predict intramuscular tissue temperature change. Jutte et al[11] investigated the best predictor of intramuscular tissue temperature change during a 30-minute cryotherapy application. The authors recruited 15 participants with skin fold measurements of the mid-thigh under 40 mm. Skin temperature was recorded using three surface thermocouples and a fourth thermocouple was inserted 2 cm below the adipose tissue. There was a three-minute pretreatment time to record baseline temperatures, followed by a 30-minute application time, and finishing with a 120-minute rewarming time frame. Temperatures were recorded every 30 seconds for the duration of the study. Pearson's product-moment correlations were developed for each variable and the change of intramuscular tissue temperature. Duration was found to have a Pearson's r value of -.59 during the cryotherapy application and .76 during the rewarming period. Therefore, the duration of an application is the strongest predictor of intramuscular tissue temperature decrease. Clinicians should focus on duration of cryotherapy and time in-between treatments in order to provide the best evidence-based treatment to all patients.

Due to the conflicting evidence in the literature, it is hard to generalize the optimal duration for a cryotherapy application. Kuo et al[17] found no statistical significance when comparing intramuscular tissue temperature change between 10-minute, 20-minute, and 30-

minute applications in contrast to researched published by Jutte et al,[11] indicating tissue temperature could continue to decrease after 30 minutes of a cryotherapy application. One factor which the aforementioned researchers did not discuss was the role of adipose tissue and the potential for a lack of intramuscular tissue temperature decrease dependent upon the amount in each individual.

2.1.3. Factors Affecting Ice: Adipose Tissue

The literature has suggested adipose tissue affects the cooling of intermuscular tissues.[5,11,16,18] Mryer et al[18] investigated the relationship between the amount of overlying adipose tissue and intramuscular tissue temperature with a 20-minute ice bag application. Thirty healthy college students (12 females and 18 males) were placed into three groups based on skinfold measurements: 8 mm or less (group 1), 10-18 mm (group 2), and 20 mm or more (group 3). Thermocouples were inserted at 1 cm and 3 cm below the adipose level. Baseline measurements were taken for three minutes followed by a 20-minute ice application, measurements were taken to the nearest 0.01°C every 10 seconds. Myrer et al[18] found that there is an inverse relationship between adipose tissue amount, tissue temperature change, and the rate at which the temperature changes at 1 cm below adipose. Group 1 had a total change of 14.43°C temperature and a cooling rate of 0.72°C/min. Group 2 had a smaller temperature change of 9.06°C, compared to group 1, with a rate of 0.45°C/min. Group 3 had a temperature change of 5.00°C with a rate of 0.25°C/min. The intramuscular tissue temperature that had less overlying adipose tissue cooled at a much quicker rate compared to more adipose tissue; overlying adipose tissue has a larger effect on decreasing more superficial tissues. After a 20-minute application, the temperature decrease at 3 cm into the intramuscular tissue was 45% less than that at 1 cm. At 3 cm, there were statistically significant decreases ($P < .05$) comparing group 1 to group 2 and 3.

This study supports that with less adipose tissue, there is a greater magnitude of cooling. Myrer et al[18] supports that different amounts of adipose tissue can affect the cooling rate and magnitude of cooling of the underlying intramuscular tissue temperature.

Similar to Myrer et al[18], Otte et al[16] found that with an increase in adipose tissue, there is an increase of treatment time to reach desired effects. Otte et al[16] compared the amount of time it takes for tissue temperature to decrease 7°C for different amounts of adipose tissue: 0-10 mm, 11-20 mm, 21-30 mm, and 31-40 mm. The researchers chose a 7°C decrease because it is a fairly typical effect, even though no optimal tissue temperature change has been discovered. Table 1 offers the treatment times needed dependent on the amount of adipose tissue. These results refute the normal protocol of 20-30 minutes for an ice bag. The normal protocol would only include those with adipose tissue less than 30 mm.

The scapula, deltoid, ulnar groove, midforearm, midthigh, medial aspect of the knee, midcalf, and lateral aspect of the ankle are some of the most popular anatomical locations for ice.[5] Jutte et al.[5] hypothesized sex, activity level, and treatment site would affect skinfold measurements. Three hundred eighty-nine college students (157 male Division I athletes, 39 Female Division I athletes, 108 male recreational athletes, and 85 female recreational athletes) were recruited to participate in a study comparing skin fold measurements at the most popular anatomical areas for an ice application. Two trained investigators, who were not authors, performed three skinfold measurements at each location. Female athletes were found to have a higher skinfold measurement at the deltoid, midforearm, midthigh, medial aspect of the knee, and the midcalf compared to males.[5] Recreational athletes were found to have higher skinfold measurements at the scapula, midforearm, midthigh, medial aspect of the knee, and the midcalf.[5]

It is important to consider sex, activity level, and anatomical location when applying cryotherapy due to the effects of adipose tissue on cryotherapy.[5]

Myrer et al[18] and Otte et al[16] concluded that the amount of adipose tissue has an effect on intramuscular tissue temperature change during a cryotherapy treatment. Different anatomical positions have different amounts of adipose tissue.[5] Gender and activity levels can play a role in the amount of adipose tissue present at anatomical locations that are more likely to have a cryotherapy application.[5] When applying cryotherapy, clinicians need to be aware of not only the amount of adipose tissue underneath the application site, but also the type of ice.

Table 1. Treatment Time Recommendations to Produce Typical Effects in Most Patients

Reference	Skinfold Thickness	Treatment Time
Otte et al[16]	0-10 mm	12 minuets
	11-20 mm	30 minutes
	21-30 mm	40 minutes
	31-40 mm	60 minutes

2.1.4 Factors Affecting Ice: Type of Ice

Various types of cryotherapy modalities are available to be used in the clinical setting.[19] Ice packs are used the most due to their effectiveness, convenience, low cost, and ease of transport.[14] Ice packs are made by including cubed ice, crushed ice, or wetted ice.[14] Dykstra et al[14] compared crushed ice, wetted ice, and cubed ice with a 20-minute protocol using six males and six females. Each participant received each type of cryotherapy intervention with at least four days in between. Upon the completion of the cryotherapy protocol, wetted ice resulted in the greatest temperature decrease at the skin surface (17.0°C) and intramuscularly (6.0°C). Crushed ice caused a temperature decrease of 14.1°C at the skin surface and 4.8°C intramuscularly. Crushed ice influenced the smallest temperature changes, decreasing 15.0°C at the skin surface and 4.3°C intramuscularly. Even though the wetted ice produced a greater decrease at the skin

surface compared to cubed ice, the intramuscular tissue decrease was similar and no statistical significance was determined ($P > .05$). Wetted ice produced the greatest temperature decrease during a 20-minute application for skin surface and intramuscular tissue temperature, but cubed ice is just as effective for intramuscular tissue temperature. Therefore, clinically speaking, cubed ice is just as effective as wetted ice when the goal is to reduce intramuscular tissue temperature.

Kanlayanaphotporn et al[19] preformed a study comparing an ice pack, gel pack, frozen peas, and a mixture of alcohol and water (4:1 ration of water and 70% alcohol). Fifty women between the ages of 20 and 23 were recruited to participate in the study. Each participant completed a 20-minute application of each different mode of cryotherapy with a 24-hour window between each session. Skin temperature was recorded during the treatment time by a surface thermocouple probe that was taped onto the treatment area. The mean temperature for each participant before the ice pack was applied was 31.9°C to 32.1°C. The ice pack and water with alcohol mixture resulted in the greatest decrease in skin temperature. The skin temperate after the ice pack and alcohol was 10°C ± 3.5°C and 10°C ± 4.5°C respectively. Skin temperatures were 13.9°C ± 4.1°C and 14.4°C ± 3.0°C after the gel pack and frozen peas. There were statically significant results for the decrease of skin temperature over time for each mode of cryotherapy ($P < 0.001$). However, when comparing the changes between the ice pack versus alcohol/water mixture and the frozen peas versus the gel pack, there were no statically significant results in skin temperature change ($P > 0.05$). Even though the ice pack and alcohol/water mixture produced the greatest temperature change, there was no statistical significance ($P > 0.05$) to conclude which one was more effective. The same results could be found when comparing the frozen peas and the gel pack. Each type of cryotherapy produced a decrease in skin temperature, but there was no one mode that was more effective than another.

Wet-Ice, a commercially made ice pack, and Flex-i-Cold, a commercially available frozen gel pack hasve also been compared to an ice bag made of crushed ice.[6] Merrick et al[6] completed a study to compare the effects of Wet-Ice, Flex-i-Cold, and an ice bag had on surface and intramuscular tissue temperature change. Each patient received all three cryotherapy interventions for 30 minutes with a 48-hour window in between each intervention.[6] Each patient had thermocouples on the skin surface, 1 cm subadipose, and 2 cm subadipose.[6] Temperature measurements were taken every 30 seconds for the duration of the treatment.[6] At each depth, there was a decrease in temperature observed by all three interventions.[6] There were significant effects observed for the temperature changes at all three depths ($P < 0.005$) and with each type of cryotherapy modality ($P < 0.005$).[6] At the skin surface and 1 cm subadipose, the ice bag and Wet-Ice produced colder temperatures than Flex-i-Wet, but there was no statistical significance ($P > 0.05$). Ice based cryotherapy product, such as ice bags and Wet-Ice, might be more efficient in lowering more superficial tissues.

Different modes of cryotherapy can produce different temperature changes on various tissues depths. Table 2 represents the decrease in tissue temperature for different modes of cryotherapy. The negative numbers are representative of the decrease in tissue temperature from the baseline established in each study. Every type of cryotherapy produced a decrease in tissue temperature with some having a greater impact than others. Although there are no guidelines set for the optimal tissue temperature change, cryotherapy is still an effective treatment no matter what type is being used.

Table 2. The Decrease of Various Tissue Temperatures for Different Modes of Cryotherapy

Mode	Duration	Measurement	Results
Dykstra et al[14]			
Wetted Ice	20 Minutes	Intramuscular/Skin Surface Temperature	-6°C/-17°C
Cubed Ice	20 Minutes		-4.8°C/-14.1°C
Crushed Ice	20 Minutes		-4.3°C/-15°C
Kanlayanaphotporn et al[19]			
Ice Pack	20 Minutes	Skin Surface Temperature	-22°C
Alcohol/Water	20 Minutes		-22°C
Gel Pack	20 Minutes		-18°C
Frozen Peas	20 Minutes		-18°C
Merrick et al[6]			
Ice Bag	30 Minutes	Skin Surface/1cm/ 2cm subadipose Temperature	-25°C/-8°C/-5°C
Wet Ice	30 Minutes		-25°C/-8°C/-6°C
Flex-i-Cold	30 Minutes		-22°C/-6°C/-4°C

2.1.5. Effects of Cryotherapy over Barriers

Cryotherapy is often used with various compressive wraps, dressings, and bandages.[7] Tsang et al[7] investigated the differences between applying an ice bag over a dry towel, a dry elastic wrap, and ice applied directly to the skin (control group). Nine university students received each protocol over a day span with 24 hours in-between each treatment session. Each participant had a 10-minute pretreatment to obtain a baseline of the skin temperature and a 20-minute protocol for the treatment.[7] The towel was a single layered 100% cotton and the dry elastic wrap was a 3 in MBM Econowrap. Pretreatment temperature measurements were recorded for each group: 31.19 ± 0.93°C for the towel group, 30.72 ± 1.86°C for the elastic wrap, and 31.52 ± 1.12°C for the control group. During the treatment, the towel group recorded a temperature of 23.84 ± 2.88°C, the elastic wrap 27.47 ± 2.36°C, and the control 12.50 ± 4.39°C. For each group, there were statistically significant decreases ($P < .05$) in skin temperature during the protocol. Even though the temperature decrease was not as large in the two groups with barriers compared to the control group, there was still a significant decrease. The results of the

study conclude that barriers do affect the reduction of skin tissue temperature in the underlying tissue.

A dry washcloth, a damp washcloth, ace bandage, and a padded ace bandage can also be used at barriers. However, LaVelle et al[8] found that a padded ace bandage does not allow for any temperature decrease in tissue temperature; therefore it was excluded from the results of the study. There was a 30-minute ice bag application applied over each barrier. Mean skin temperature decreases were calculated for each barrier: -11.3 ± 2.4°C for the dry washcloth, -18.7 ± 2.1°C for the wet wash cloth, -9.7 ± 2.5°C for the ace bandage, and -18.6 ± 2.3°C for no barrier. Even though some barriers had a greater effect on the decrease in skin temperature, each barrier had a statically significant decrease ($P < .05$) in skin temperature over time. The wet wash cloth was able to produce a decrease similar to no barrier. Certain barriers affect the decrease of the underlying tissue temperatures, but some, like a wet wash cloth, produces a decrease similar to not having barrier.

Okcu et al[9] and Weresh et al[10] performed studies investigating the effects on skin temperature of ice packs over plaster casts, synthetic casts, an ace wrap, and a Robert Jones bandage. Both studies concluded that skin temperature could be decreased over all barriers.[9,10] The plaster cast showed a decrease of 15°C and reached a minimum skin temperature of 16°C.[9,10] Okcu et al[9] reported this temperature change after 30 minutes of application whereas Weresh et al[10] reported the findings after 90 minutes of application. The synthetic cast had a decrease of 13^0C and reached a minimum temperature of 17°C after 38 minutes.[9] After 90 minutes the synthetic cast produced a decrease of 4°C and reached a minimum temperature of 18°C.[10] The ace bandage produced a decrease of 9°C with a minimum temperature of 20°C after 42 minutes[9] but a 11°C decrease with a minimum temperature of 21°C after 90 minutes of an ice

pack application.[10] The Robert Jones bandage produced the lowest temperature decrease of 8°C[9] and 5°C.[10] The minimum temperature that the skin below the bandage was 22°C after 48 minutes[9] and 28°C after 90 minutes.[10] The tissue under a barrier will have a decrease in temperature; however, the normal 20 to 30 minute application practiced by most clinicians will not allow for the greatest decrease in tissue temperature.

The previous studies support the idea that the effects of cold can be transferred through barriers and change the surface temperature of skin.[7-10] A damp wet cloth was shown to be best at decreasing skin temperature compared to other barriers.[7,8] However, there was a decrease with each application over all the barriers.[7-10] The barriers, however, may have led to an increase of treatment time for the cryotherapy application.[7-10] One study even had to extend a couple of the treatment times because the temperature was still continuing to decrease after 30 minutes due to a slower cooling rate. Table 3 displays the decrease in tissue temperature underneath the barriers for the previous studies listed. The research has concluded that barriers alter the effectiveness of a cryotherapy application.

Table 3. The Effects of Various Barriers on the Decrease of Tissue Temperature

Mode	Duration	Measurement	Results
	Tsang et al[7]		
Dry Towel	20 minutes	Skin Surface Temperature	-8°C
Elastic Wrap	20 minutes		-3°C
No Barrier	20 minutes		-19°C
	LaVelle et al[8]		
Dry Washcloth	20 minutes	Skin Surface Temperature	-11 ± 2.4°C
Wet Washcloth	20 minutes		-18.7 ± 2.1°C
Ace Bandage	20 minutes		-9.7 ± 2.5°C
No barrier	20 minutes		-18.6 ± 2.5°C
	Okcu et al[9]		
Plaster Cast	30 minutes[a]	Skin Surface Temperature	-15°C
Synthetic Cast	30 minutes[a]		-13°C
Ace Wrap	30 minutes[a]		-9°C
Robert Jones	30 minutes[a]		-8°C
	Weresh et al[10]		
Plaster Cast	90 minutes	Skin Surface Temperature	-15°C
Synthetic Cast	90 minutes		-4°C
Ace Wrap	90 minutes		-11°C
Robert Jones	90 minutes		-5°C

[a] Represents that some treatments were extended until a minimal temperature was reached

2.1.6. Cryotherapy: Conclusion

With very little information to support the parameters of cryotherapy, it is still one of the most commonly used modalities to treat pain, swelling, and musculoskeletal injuries. The most widely used application time of 20-30 minutes may be arbitrary based on existing, published literature. Otte et al[16] concluded that depending on adipose tissue, some people might have to have a treatment time of up to 60 minutes. Adipose tissue may be a major limiting factor of the effectiveness of a cryotherapy application but there are other factors to consider. The type of ice and different barriers can affect the efficacy of cryotherapy as well. Barriers influence the amount of tissue cooling during a cryotherapy application.[7-10] Barriers also increase the duration of applications in order to record results comparable to no barrier. All of these factors influence how effective the cryotherapy application will be at decreasing the underlying intramuscular tissue temperature.

2.2. Thermocouples

2.2.1. Introduction

Thermocouples are used in research to measure tissue temperature during different modality applications.[13] There is a lack of research which includes the technique of inserting thermocouples. Although there is no literature which describes the step-by-step procedures for inserting thermocouples, several publications have incorporated thermocouples as the instrument of choice when measuring intramuscular tissue temperature.

2.2.2. Reliability and Validity

The majority of validity and reliability tests for thermocouples have been performed using room temperature and not at temperatures that occur during different modality applications.[13] Therefore, the results are not representative of the validity and reliability of

thermocouples for intramuscular and modality temperatures. Long et al[13] investigated the validity and reliability of three different types of thermocouples (PT-6, IT-18, and IT-21) in five different water bath temperatures (5°C for cryotherapy, 15°C, 18.4°C for room temperature, 25°C, and 35°C for normal intramuscular tissue temperature). Three different electrothermeters were used in order to record the temperature readings of the thermocouples, (1) a 6-channel Data-logger with a temperature range of -250°C to 350°C, (2) a 16-channel Iso-Thermex with a temperature range of -50°C to 50°C (Iso -50:50), and (3) a 16-channel Iso-Thermex with a temperature range of -20°C to 80°C (Iso -20:80). Six thermocouples (2 of each type) were plugged into each electrothermometer. The thermocouples and a mercury thermometer were inserted into the different water temperatures for four minutes. The thermocouples took temperature measurements every 10 seconds and the mercury thermometer was read by the same investigator every 10 seconds for 4 minutes. This process was repeated for every water temperature. The thermocouples used with both the Iso-Thermex units were more valid than the Datalogger ($p<.05$). Refer to Table 4 for the validity and reliability for the Iso -50:50 unit. For this unit, the PT-6 thermocouples were more valid than the IT-18s and both thermocouple types were more valid than the IT-21s at every temperature ($P < .001$). The PT-6 thermocouples were more reliable than the IT-21s at 5°C, 25°C, and 35°C ($P < .001$). The IT-18s were also more reliable than the IT-21s at 25°C and 35°C ($P < .001$.)

Table 4. Validity and Reliability of Thermocouple Types Across Different Water Bath Temperatures for the Iso -50:50[a] Electrothermometer (n = 162 Measurements)[13]

		Thermocouple Type[b]		
	Temperature, °C	**PT-6**	**IT-18**	**IT-21**
Absolute thermocouple-mercury thermometer differences, mean (validity) ± SD	5	0.13[c] ± 0.02	0.14 [c] ± 0.10	0.17 [c] ± 0.07
	15	0.12[c] ± 0.02	0.14 [c] ± 0.01	0.13 [c] ± 0.09
	18.4	0.12[c] ± 0.04	0.16 [c] ± 0.02	0.13 [c] ± 0.09
	25	0.05[c] ± 0.05	0.08 [c] ± 0.02	0.33 [c] ± 0.22
	35	0.06[c] ± 0.04	0.09 [c] ± 0.03	0.20 [c] ± 0.16
Thermocouple Measurement reliability, mean ± SD	5	4.87 ± 0.02	4.84 ± 0.10	4.94 ± 0.17[d]
	15	14.88 ± 0.02	14.85 ± 0.01	14.92 ± 0.13
	18.4	18.27 ± 0.04	18.24 ± 0.02	18.24 ± 0.14
	25	24.95 ± 0.05	24.92 ± 0.02	25.20 ± 0.34[d,e]
	35	34.94 ± 0.04	34.90 ± 0.03	35.01 ± 0.25[d,e]

[a] Iso-Thermex calibrated from -50°C to 50°C (Columbus Instruments, Columbus, OH).
[b] Physitemp Instruments Inc, Clifton, NJ.
[c] Indicates PT-6 thermocouples were more valid than IT-18 thermocouples, and both PT-6 and IT-18 thermocouples were more valid than IT-21 thermocouples.
[d] Indicates PT-6 thermocouples were more reliable than IT-21 thermocouples at 5°C, 25°C, and 35°C.
[e] Indicates IT-18 thermocouples were more reliable than IT-21 thermocouples at 25°C and 35°C.

Table 5 displays the reliability and validity of the Iso -20:80. The thermocouples validity differed for each water bath temperature for this unit ($P < 001$). The IT-21s were less valid at 35°C compared to the temperature readings at 15°C and 18.4°C ($P < .05$). When comparing the three different types of thermocouples, the IT-21s at 35°C were less valid than the PT-6 at 15°C, 18.4°C, 25°C, and 35°C and the IT-18s at 15°C, 18.4°C and 25°C ($P < .05$). The PT-6 and IT-18 thermocouples were more reliable than the IT-21 thermocouples at 25°C and 35°C ($P < .001$).

Table 5. Validity and Reliability of Thermocouple Types Across Different Water Bath Temperatures for the Iso -20:80[a] Electrothermometer (n = 162 Measurements)[13]

		Thermocouple Type[b]		
	Temperature, °C	**PT-6**	**IT-18**	**IT-21**
Absolute thermocouple-mercury thermometer differences, mean (validity) ± SD	5	0.18 ± 0.02	0.16 ± 0.02	0.15 ± 0.05
	15	0.08[c] ± 0.02	0.11 [c] ± 0.02	0.03 ± 0.02[d]
	18.4	0.05[c] ± 0.02	0.12 [c] ± 0.02	0.02 ± 0.01[d]
	25	0.07[c] ± 0.04	0.03 [c] ± 0.02	0.71 ± 0.42
	35	0.11[c] ± 0.06	0.02 ± 0.02	0.10[c,d] ± 0.82
Thermocouple Measurement reliability, mean ± SD	5	4.82 ± 0.02	4.84 ± 0.02	5.05 ± 0.15
	15	14.92 ± 0.02	14.89 ± 0.02	14.98 ± 0.03
	18.4	18.35 ± 0.03	18.28 ± 0.02	18.39 ± 0.02
	25	25.06 ± 0.05[e]	24.98 ± 0.03[e]	25.71 ± 0.42[e]
	35	35.11 ± 0.06[e]	34.99 ± 0.03[e]	36.02 ± 0.83[e]

[a] Iso-Thermex calibrated from -20°C to 80°C (Columbus Instruments, Columbus, OH).
[b] Physitemp Instruments Inc, Clifton, NJ.
[c] Indicates IT-21 thermocouples were less valid at 35°C than PT-6 thermocouples at 15°C, 18.4°C, 25°C, and 35°C and IT-18 thermocouples at 15°C, 18,4°C, and 25°C.
[d] Indicates IT-21 thermocouples were less valid at 35°C than at 15°C and 18.4°C.
[e] Indicates IT-21 thermocouples were less reliable at 25°C and 35°C than PT-6 thermocouples at 25°C and 35°C and IT-18 thermocouples at 25°C and 35°C.

Table 6 summarizes the validity and reliability of the Datalogger. The IT-21 thermocouples at 35°C were less valid than the PT-6s and IT-21s at 18.4°C ($P < .05$). The IT-21s at 25°C and 35°C were also less valid than the IT-18s at 15°C and 18.4°C ($P < .05$). PT-6 thermocouples at 25°C and IT-18 thermocouples at 25°C and 35°C were more reliable than the IT-21 thermocouples at the same temperatures ($P < .001$). The study concluded that the PT-6 and IT-18 thermocouples used with the two Iso-Thermex units had similar reliability and validity. The PT-6 thermocouples with the Datalogger were the least reliable and valid. There were also differences between the thermocouple type and temperature of the water. The PT-6 thermocouples were more valid than the IT-21s in the coldest and the warmest water temperatures. However, the IT-21 thermocouples were more reliable and valid with temperatures

around body temperature (18.4°C). Therefore, they are most commonly used to record intramuscular tissue temperature. Different thermocouple types and electrothermometers have different reliabilities and validities. To ensure the most accurate results, reliability and validity measurements should be performed at temperatures similar to those during the experiment. The type of thermocouple and electrothermometer being used plays a factor in the reliability and validity of the temperatures being recorded.

Table 6. Validity and Reliability of Thermocouple Types Across Different Water Bath Temperatures for the Datalogger[a] (n = 162 Measurements)[13]

		Thermocouple Type[b]		
	Temperature, °C	**PT-6**	**IT-18**	**IT-21**
Absolute thermocouple-mercury thermometer differences, mean (validity) ± SD	5	0.93 ± 0.04	0.87 ± 0.05	0.96 ± 0.16
	15	0.75 ± 0.05	0.69[c] ± 0.03	0.82 ± 0.18
	18.4	0.71[d] ± 0.03	0.65[c,d] ± 0.05	0.67 ± 0.10
	25	0.79 ± 0.02	0.79 ± 0.04	1.00[c] ± 0.20
	35	0.80 ± 0.15	0.80 ± 0.04	1.00[c,d] ± 0.82
Thermocouple Measurement reliability, mean ± SD	5	5.93 ± 0.04	5.87 ± 0.05	5.95 ± 0.16
	15	15.75 ± 0.05	15.69 ± 0.03	15.81 ± 0.18
	18.4	19.11 ± 0.03	19.05 ± 0.05	19.07 ± 0.10
	25	25.79 ± 0.02[e]	25.79 ± 0.04[e]	26.00 ± 0.21[e]
	35	35.79 ± 0.15	35.80 ± 0.04[e]	36.00 ± 0.20

[a] Commtest Instruments Ltd, Christchurch, NZ.
[b] Physitemp Instruments Inc, Clifton, NJ.
[c] Indicates IT-21 thermocouples were less valid at 25°C and 35°C than IT-18 thermocouples at 15°C and 18.4°C.
[d] Indicates IT-21 thermocouples were less valid at 35°C than PT-6 and IT-21 thermocouples at 18.4°C.
[e] Indicates IT-21 thermocouples were less reliable than PT-6 thermocouples at 25°C and IT-18 thermocouples at 25°C and 35°C.

Thermocouple leads are often too short to reach the electrothermometer and extension leads must be used.[20] Jutte et al[20] performed a two-part study to determine if extension leads or the temperature of the extension leads could alter the reliability and validity of thermocouples.

The first test compared the temperature measurements of 10 IT-21 thermocouples inserted directly into the Iso-Thermex (5) and IT-21 thermocouples inserted via extension leads (5). Each thermocouple was placed in a cooler of water (17.2°C) that sat in a room that was 18.1°C for 24 hours before. A mercury thermometer was used to determine the temperature of the water and used to compare the results of the readings from the thermocouples. Readings were taken every 20 seconds for five minutes and recorded for two trials. For the second trial, the extension leads were switched and PT-6 and IT-21 thermocouples were used. The methodology was the same as previously mentioned but without the use of extension leads. During the data collection time, an ice bag was placed on the thermocouple lead to see if it would have any effect on the temperature readings. The collection time was also 10 minutes (2.5 minute pre-application, 5 minute ice application, 2.5 minute post application). It was found that the ice application did effect the validity of the temperature measurements ($P = 0.001$). However, extension leads did not influence the validity ($P = .46$) or the reliability ($P = .10$).

2.2.3. Conclusion

Thermocouples are used to measure intramuscular tissue temperature during cryotherapy applications.[13] However, there is very little published literature on the proper insertion technique and most do not describe the precise methodology. When inserting the thermocouples, it is important to ensure the treatment area and thermocouples are disinfected to reduce the risk of infection. Many factors go into the reliability and validity of thermocouples and the electrothermometers. Outside factors, such as putting ice on the thermocouple lead, can also affect the validity and reliability of the measurements.[20]

2.3. Kinesio® Tape

Kinesio® Tape was developed by Dr. Kenzo Kase, a Japanese chiropractor, during the 1970s.[21,22] Popularity began to grow after its first public appearance in the 1988 Seoul Summer Olympic games.[21] Kinesio® Tape became even more popular after the 2008 Beijing Summer Olympic games due to professional athletes playing while wearing it.[21,23] Kinesio® Tape is a type of kinesthetic tape that mimics the thickness and flexibility of the skin, which limits the body's sensory stimuli to the tape.[1,4] The purpose of Kinesio® Tape is to aid muscle activation and force production,[1,2] decrease pain levels,[21-23] aid the lymphatic system,[1,2,23] improve circulation,[21,22] increase range of motion,[2] reduce delayed onset muscle sorenss,[21] and provide mechanical support[1,2] without restricting movement by creating micro convolutions that lift the skin away from the tissue beneath.[1] In order to achieve these goals, different types of strips can be applied, for example: a "Y" strip.[4] The "Y" strip is the most commonly used method to help facilitate or inhibit a muscle.[4] When it is applied from the insertion to the origin of the muscle it inhibits the muscle, and if it is applied from the origin to the insertion of a muscle it helps facilitates the muscle.[2] When applying an application, the target tissue must be on a stretch; this will create convolutions to help blood flow and lymphatic systems.[4] However, contradictory results have been concluded with pain reduction, muscle force, and changes in range of motion, and there is very little evidence to support the effectiveness and how Kinesio® Tape works due to poor study designs.[2]

2.3.1. Uses of Kinesio® Tape: Musculoskeletal Facilitation

Kinesio® Tape is often applied to inhibit or facilitate a muscle to assist muscles with optimal sarcomere length. Lumbroso et al [2] recruited 36 participants (21 females and 18 males) to compare the effects of Kinesio® Tape on range of motion and muscle force. The participants

either received a facilitation hamstring Kinesio® Tape application (n=18) or an inhibition of the gastrocnemius (tendon correction of the Achilles) Kinesio® Tape application (n=18). For the hamstring group, the participant was standing with forward trunk flexion. An "I" strip was applied starting at the ischial tuberosity and ending on the lateral aspect of the popliteal fossa. A second "I" strip was applied from the ischial tuberosity to the medial aspect of the popliteal fossa. The tape was applied with approximately 30% tension. To treat the Achilles Tendon and the subsequent muscle belly of the gastrocnemius, the foot was placed into dorsiflexion and the tape was applied starting at the base of the calcaneus with no tension as an anchor. The following portion of the tape was applied to the musculotendinous junction with a tension of 50-75%. After the junction, the tape was applied at a 15-25% tension until the end which had no tension applied. Both groups resulted in statically significant increases ($P = 0.006$) for range of motion, measured by goniometer, and for muscle force, measured using a Biodex ($P < 0.001$ for the gastrocnemius group and $P < 0.028$ for the hamstring group). Kinesio® Tape can help increase range of motion and muscle force in the lower extremities. Even though comparisons cannot be made between the groups, due to the two different application techniques, both techniques were effective in increasing range of motion and muscle force.

Similar to the aforementioned study, Vered et al[22] investigated the effects of a facilitation of biceps brachii had on peak force measure by a hand hand-held digital dynamometer. Kinesio® Tape was applied in one of four ways: distal-to-proximal, proximal-to-distal, two horizontal "I" strips applied across the muscle belly at 30% tension, or no tape. The distal-to-proximal application was a "Y" strip applied with 30% tension starting just distal to the radial tuberosity with the tails being applied around the muscle belly to the anterior aspect of the shoulder. The proximal-to-distal application was a "Y" strip applied with 30% tension starting with the two

tails at the anterior aspect of the shoulder. The tails were then applied around the muscle belly with the other anchor just distal to the radial tuberosity. Each participant performed a maximal contraction with each type of application. There was no statistical difference ($P > 0.05$) in force when comparing the proximal-to-distal, distal-to-proximal, and no tape. However, the two horizontal "I" strips produced statically significant higher muscle peak forces than no tape ($P = 0.003$), proximal-to-distal group ($P = 0.001$), and distal-to-proximal group ($P = 0.001$). The study concluded that two horizontal "I" strips applied to the biceps brachii was more effective at increasing peak force compared to applying tape distal-to-proximal or proximal-to-distal. Although the researchers used the correct tension as described by Dr. Kenzo Kase, KTAI does not recognize the two horizontal I strips as an approved methodology. Further research should be conducted to understand the physiological changes of the muscle when the tape is applied across a muscle as opposed to a longitudinal application.

2.3.2. Facilitation of Rectus Femoris

Kinesio® Tape has also been studied to determine its role in preventing injuries. Aktas et al[24] performed a study to determine if a knee brace or Kinesio® Tape is more effective on muscular strength and functional performance to help reduce the prevalence of injuries. Twenty physically active, (11 females and 9 males) university students were recruited to participate. Each participant had both knees tested four times including a control, knee brace, Kinesio® Tape, and a knee brace with Kinesio® Tape. A "Y" strip was used for the application with the base starting at the anterior inferior iliac spine (AIIS) and ending just proximal of the patella. While the two tails were being applied to the medial and lateral border of the patella, the participants were instructed to fully flex their hip and knee. Another "Y" strip was used for a patellar mechanical correction. The base was applied to the lateral border of the patella and the

tails were applied at 50-75% tension to cover the superior and inferior borders of the patella. The participants were tested on isokinetic knee strength, vertical jump, and a one leg hop test. Males having Kinesio® Tape on their dominant leg and females with it on the non-dominant leg had significant increases ($P = 0.007$) in the one leg hop test compared to no Kinesio® Tape. There were significant increases in isokinetic strength between the control and the tape application ($P = 0.031$) and also, the group with both the brace and tape ($P = 0.041$). However, there were no significant differences noted during the vertical jump ($P > 0.05$) even though isokinetic strength was increased. The researchers concluded that Kinesio® Tape improved muscle function which has the possibility to lead to a decrease of injury severity and prevalence. In summary, the application can aid in preventing an injury by helping support the knee musculature, encourage tissue heeling, and supporting knee muscle performance.

Similar to Aktas et al,[24] Vithoulka et al[25] investigated the effect of Kinesio® Tape on the quadriceps muscle. Vithoulka et al[25] used the same application technique as Aktas et al,[24] but examined the effects it had on quadriceps strength, determined by isokinetic concentric-eccentric strength, as measure by a Biodex. There was no statistical significance ($P > 0.05$) difference in peak concentric strength due to the application. However, the application did lead to a statistically significant ($P < 0.05$) increase in peak eccentric torque. It can be concluded that a facilitation application of the rectus femoris can help increase eccentric strength. Increasing eccentric strength might help reduce the risk of injury because it allows the muscle to absorb more strength.[26]

During walking, the quadriceps muscles play an important role on knee kinematics and kinetics. Guner et al[27] compared the effects of an inhibition and a facilitation application of the quadriceps femoris had on knee kinematics and kinetics during walking. The facilitation

application was applied from the AIIS to the medial and lateral borders of the patella while the knee was in 60° of flexion. The participants walked 10 meters barefoot at a comfortable pace while wearing 16 reflective markers. Force plates were embedded in the middle of the walkway and the participants performed the walk at least five trials. A good trial was determined by the participant's foot completely striking the force plate. Upon conclusion, the study determined that there were statistically significant ($P < 0.05$) increases with walking speed and stride length with a facilitation application when compared to no tape. However, contrary to Vithoulka et al,[25] there was no statistical significance ($P > 0.05$) found with the difference between eccentric strength among groups.[27]

2.3.3. Conclusion

There are controversial results determining the effectiveness of Kinesio® Tape on the facilitation of muscles. Vithoulka et al[25] concluded that a facilitation application can increase the eccentric strength of muscle, however research performed by Guner et al[27] resulted in no increase in eccentric strength. As the popularity continues to increase, the proper application technique must be utilized in research methodologies in order for the uses to be effective. Kinesio® Tape has the ability to help the rehabilitation process of injured athletes with the proper application and guidance. Overall, Kinesio® Tape can be used to help decrease pain levels and increase muscular functionality. In the previous studies, Kinesio® Tape was used alone on different strength exercises. Further research needs to test the effects of Kinesio® Tape on every aspect of the rehabilitation aspect. Kinesio® Tape can help decrease muscular pain just like cryotherapy. With the increase of popularity for the use of Kinesio® Tape and with cryotherapy being the most commonly used modality, it is inevitable that the two will be used together. Barriers have been found to affect a cryotherapy application. However, after an

extensive literature review, there is no research if Kinesio® Tape acts as a barrier during a cryotherapy application.

CHAPTER 3. METHODOLOGY

3.1. Purpose

The purpose of this study was to determine if the application of Kinesio® Tape acts as a barrier to the effects of intramuscular tissue temperature change during a cryotherapy application. The study compared intramuscular tissue temperature change in the dominant quadriceps muscle with and without a Kinesio® Tape application. This chapter describes the population of the study, setting of the study, data collection instrumentation, procedures, and the data analysis. The research was guided by the following research questions:

Q1: What is the impact of Kinesio® Tape application on the temperature of intramuscular tissue in the presence of a cryotherapy application?

Q2: What is the impact of the width of Kinesio® tape on the temperature of intramuscular tissue in the presence of a cryotherapy application?

Q3: What is the difference in subjective reporting of participants' discomfort with the application of cryotherapy?

The independent variable of the study was the Kinesio® Tape quadriceps facilitation application. The dependent variable was the temperature recordings from the cryotherapy application as measured by the Iso-Thermex electronic thermometer (Columbus Instruments, Columbus, OH 43204 U.S.A.).

3.2. Participants

A convenience sample of 20 males between the ages of 18 and 50 were recruited from email listserv and by word-of-mouth at North Dakota State University and the surrounding Fargo-Moorhead area. Participants were excluded from the study if they had any contraindications to cryotherapy: decreased sensation or blood flow over the area, Raynaud's

phenomenon, cold urticaria, cryoglobulinemia, paroxysmal cold hemoglobinuria, angina pectoris, or any other severe heart condition. The previous cases are determined by having a previous reaction to cryotherapy or have been diagnosed by a doctor. Additional exclusion criteria included any contraindications for Kinesio® Tape, which included malignancy sites, cellulitis, skin infection, open wounds, Deep Vein Thrombosis, diabetes, kidney disease, congestive heart failure, coronary artery disease, or fragile skin.[4]

3.3. Setting

The research was conducted in the Research Laboratory in the Bentson Bunker Field House on the campus of North Dakota State University. The laboratory was used because the equipment (Kinesio® Tape, Terason t3200™ Diagnostic Ultrasound, and Iso Thermex unit) for this study are located at this site. The room is also temperature controlled during the summer months; therefore, any environmental influence would be eliminated.

3.4. Equipment

MetriCride® 28-Day High Level Disinfectant/Sterile solution (Cardinal Health) was used to sterilize the IT-21 one foot thermocouples (Physitemp Instruments, Clifton, NJ) for at least 12 hours prior to insertion. The thermocouples were inserted 1 cm below the adipose tissue into the rectus femoris and vastus medialis oblique muscle bellies using a 20 gauge x 1.16-inch needle catheter (Cardinal Health). The thermocouples were attached to the Iso-Thermex electronic thermometer (Columbus Instruments, Columbus, OH 43204 U.S.A.). The electrothermometer has a temperature range of 0-50°C with an accuracy of ± 0.1°C.[28]

Kinesio® Tex Tape is a latex-free tape made of 100% cotton and elastic fibers, which allows it to stretch up to 60% of its resting length.[1-3,21,24,25,27] The thickness and weight of the

tape were developed to mimic the properties of skin. [1-3,21,24,25,27] The adhesive of Kinesio Tape® mimics the pattern of a fingerprint and is heat activated. [1-3,21,24,25,27]

In order to determine the musculotendinous junction and amount of adipose tissue present in each participant, the Terason t3200™ Diagnostic Ultrasound (MedCorp, LLC., Tampa, FL) and the 15L4 Linear transducer (4.0-15.0 MHz) (MedCorp, LLC., Tampa, FL) was used with Aquasonic® 100 ultrasound gel (Parker Laboratories, INC., Fairfield, NJ) as the coupling medium. The musculotendinous junction was in a different place on each participant; therefore, the process was performed for each participant.

3.5. Procedures

3.5.1. Thermocouple Insertion Guided by Diagnostic Ultrasound

For this study, the thermocouples were inserted into the rectus femoris muscle belly just proximal to the musculotendinous junction and into the vastus medial oblique. The musculotendinous junction was determined by diagnostic ultrasound. After an extensive literature review, there are no studies reporting the proper protocol to insert themocouples. However, the researcher attended a 16-week course taught by an individual trained in thermocouple insertion.

Diagnostic ultrasound was used in order to determine the location of the musculotendinous junction of the rectus femoris. The junction was marked using a Sharpie and a measuring tape was used to measure 2.5 cm proximal to the junction. This was used as the insertion point for the first thermocouple. The second thermocouple insertion site was the largest aspect of the vastus medialis oblique, as determined by the largest observable aspect of the muscle. Again, a Sharpie was used to make a mark representing the thermocouple insertion site.

The thermocouples were inserted 1 cm below the adipose tissue into the belly of the muscles. To determine the depth of the thermocouple, each thermocouple was laid down next to a ruler and a mark was made on the thermocouple representing the amount of adipose tissue plus 1 cm. Another mark was made on the thermocouple at 5 cm to represent the farthest depth a thermocouple should be inserted. This also acts as a guide to the clinician to ensure the safety of each participant.

Each thermocouple was soaked in a cleaning solution, Metricide, for at least 12 hours before being inserted into the quadriceps. The thermocouple was wiped using sterile gauze and isopropyl alcohol and wrapped in sterile gauze until inserted. The participants were asked to take two deep breaths and upon the exhale of the second breath, the 20 gauge 1.16-inch needle catheter was inserted into the muscle belly as marked by the Sharpie. The needle was retracted by a spring-loaded mechanism, leaving the catheter in the muscle belly. The thermocouple was then removed from the sterile gauze and inserted through the catheter to a depth of 1 cm below the adipose tissue as portrayed by the Sharpie mark on the thermocouple. Once the thermocouple was inserted to the appropriate depth, the catheter was removed and the thermocouple was stabilized and helped in place by the 1st and 2nd metacarpals of the clinician. Transparent surgical tape was applied over the thermocouple in order to ensure that it remained stable throughout the rest of the study. The thermocouple lead was taped to the back of the participant's knee using Powerflex self-adhering tape and attached to the Iso-Thermex electronic electrothermometer (Columbus Instruments, Columbus OH).

3.5.2. Kinesio® Tape

The Kinesio® Tape application was a quadriceps facilitation application, performed by a Certified Kinesio® Tape Practitioner (CKTP). A "Y" strip with 15-35% tension was applied

over the rectus femoris and vastus medialis oblique.[4,24,25,27] The tape started at the anterior inferior iliac spine with no tension. Tension was then applied as the tape was pulled inferiorly by the clinician. The tape split 2.5 cm past the musculotendinous junction as determined by the Sharpie mark on the skin as originally identified by diagnostic ultrasound. The two tails were placed on the medial and lateral aspects of the patella over the vastus lateralis and vastus medialis oblique. The application ended at the tibial tuberosity with no tension.[4,24,25,27]

3.5.3. Cryotherapy

Two cubed ice bags were the mode of cryotherapy for each session. Because there were two thermocouples, two ice bags were used to ensure that both muscle bellies were affected by the application. One ice bag was placed over the thermocouple inserted into the muscle belly of the rectus femoris, and the second ice bag was applied over the thermocouple in the vastus medialis oblique. A pillow was used to hold the second ice bag in place. Cubed ice was used because there is no statistical significance between different types of ice bags during a 20-minute application.[14] A 20-minute application is the standard treatment time issued by clinicians.[14] Also, there is no statistical difference between intramuscular tissue temperature change between different application durations.[14]

3.6. Experimental Procedure

3.6.1. Introduction

Participants were recruited via email listserv and word-of-mouth at North Dakota State University and the surrounding Fargo-Moorhead area. The participants signed up for two, one-hour time slots that were exactly one week apart. Once the participants were screened for exclusion criteria and agreed to participate in two separate treatment times, they were randomized into one of two groups. Half of the participants received cryotherapy on the rectus

femoris and vastus medialis oblique without Kinesio® Tape during the first session. The other half the participants had Kinesio® Tape applied prior to the cryotherapy application. Participants switched conditions during the second session. At least 12 hours before each participant reported, the researcher placed the thermocouples in Metricide, a cleaning solution. Upon arrival, the participant completed an Informed Consent and Health History Questionnaire (HHQ).

3.6.2. Methods Without Kinesio® Tape

The participants were supine on a treatment table with their dominant quadriceps exposed. The dominant quadriceps muscle was determined by subjective reporting of the participants as the leg they would use to kick a ball. Diagnostic ultrasound was used to locate the musculotendinous junction. The diagnostic ultrasound unit was set to the knee function.[29] The transducer was placed in short axis on the superior aspect of the patella.[29] The quadriceps tendon was visible on the center of the screen with the vastus medialis oblique and vastus lateralis visible on either side of the tendon.[29] The probe was slid anteriorly until the tendon faded away.[29] Once the tendon faded out of the screen the researcher deemed the anatomical location as the musculotendinous junction and used a measuring tape to measure 2.5 cm proximal to this point to act as the insertion point. The researcher then determined the amount of adipose tissue over the insertion point by freezing the screen and measuring from the skin to the most superior aspect of the muscle, using the caliper function. The amount of adipose tissue was recorded in centimeters.

The patient was then asked to contract the quadriceps muscle and the largest observable aspect of the vastus medialis oblique was marked with a Sharpie to be the second thermocouple insertion point. The same process was repeated to determine the amount of adipose tissue as stated previously. The measurements were recorded into the same document as the previous

measurements. Once the measurements were recorded, the two thermocouple insertion sites were trimmed of excess hair and cleaned using Betadine and 70% isopropyl alcohol. The thermocouples were removed from the cleaning solution and prepped for insertion.

Once the thermocouples had been removed from the cleaning solution, they were dried using sterile gauze. The thermocouple was placed next to a ruler and marked with a Sharpie at the depth of insertion. Because the thermocouple was inserted 1 cm below the adipose tissue, the amount of adipose must be added to 1 cm. For example, if there was .5 cm of adipose tissue, the thermocouple was marked at 1.5 cm in order to place the thermocouple 1 cm below the adipose tissue. Once the thermocouple was marked, it was cleaned with 70% isopropyl alcohol and wrapped in sterile gauze until it was time to insert.

The participant was asked to take two deep breaths and upon the exhale of the second breath, the 20 gauge 1.16-inch needle catheter was inserted into the muscle belly, as marked by the Sharpie. The needle was retracted by a spring-loaded mechanism, leaving the catheter in the muscle belly. The thermocouple was then removed from the sterile gauze and inserted through the catheter to the depth portrayed by the Sharpie mark on the thermocouple. Once the thermocouple was inserted to the appropriate depth, the catheter was removed and the thermocouple was stabilized and helped in place by the 1st and 2nd metacarpals of the clinician. Transparent surgical tape was applied over the thermocouple in order to ensure that it remained stable throughout the rest of the study. The thermocouple lead was taped to the back of the participant's knee using Powerflex self-adhering tape and attached to the Iso-Thermex electronic electrothermometer (Columbus Instruments, Columbus OH). This process was performed for the thermocouple in the rectus femoris and in the vastus medalis oblique.

Once the thermocouples were secured, baseline temperature readings were recorded every 30 seconds throughout a three-minute period.[11] The average temperature for the three minute baseline was recorded. During the first three minutes, the clinician made two ice bags to cover both thermocouples. The ice bags were made with cubed ice because that was what was available at the location. The first ice bag (1 kg) was placed over the rectus femoris thermocouple. The second ice bag (0.5 kg) was placed over the vastus medialis oblique and a pillow was used to hold the ice bag in place. The application lasted 20 minutes with temperature recordings every 30 seconds as described by Merrick et al.[6] The lowest temperature and total decrease in intramuscular tissue temperature was recorded and saved.

Based on literature provided by other studies which included cryotherapy applications, the researcher asked participants to rate their discomfort from the cryotherapy application.[2,11,30] Using the Borg Scale of Perceived Pain, participants reported their pain on a scale from 0-10. The researcher recorded the verbal response during the following time frames: pre-thermocouple insertion, post-thermocouple insertion, immediately after the ice bag was applied, and at 1, 2, 4, 6, 8, 10, 15, and 20 minutes.

Upon the completion of the cryotherapy application, the thermocouples were removed and placed into a cleaning solution. The area was cleaned with alcohol and then Band-Aids were placed over the insertion sites in case of any bleeding that might occur. The participant then registered for another session exactly one week later. Acute wounds take five to 10 days to heal; therefore, a seven day window allowed the thermocouple insertion sited to completely heal before the second insertion.[31]

3.6.3. Methods with Kinesio® Tape

The same protocol for the thermocouple insertion for the session without Kinesio® Tape was followed. The two insertion points were determined using diagnostic ultrasound and by the largest observable aspect of the vastus medialis oblique. Another mark was made 2.5 cm distal to the insertion point on the rectus femoris. The second mark represented where the Kinesio® Tape will split. The same process was used to determine the amount of adipose tissue over the insertion points and was recorded. The insertion process of the thermocouples was exactly the same as the first session. In order to have intra-rater reliability compared to the first session, the same clinician performed the procedure. The only difference in procedure was the application of Kinesio® Tape after the thermocouples were inserted and secured.

Kinesio® Tape was applied by a CKTP. A quadriceps femoris facilitation application was conducted according to the Kinesio® Tape guidelines starting at the anterior inferior iliac spine with no tension.[4,24] The tape was applied with a 15-35% tension through the treatment area, which was placed on a stretch by flexing the knee. The tape split 2.5 cm past the musculotendinous junction around the medial and lateral side of the patella.[4] The application ended at the tibial tuberosity with no tension. The thermocouple insertion sites were just before the musculotendinous junction and the vastus medialis oblique. The application technique allowed the researcher to record temperature change under different widths of the Kinesio® Tape. Because the application was a “Y” strip, the first thermocouple was under the full width of the tape and the second thermocouple was under roughly one-half the width of Kinesio® Tape. Once the application was complete, the three-minute baseline recording began.

The same three-minute baseline with a 20-minute application time was used. Again, the lowest temperature and total decrease of intramuscular tissue temperature was recorded for each

thermocouple. The same process occurred for the removal of the thermocouples. At the completion of this session, the participant received compensation for their time.

3.7. Statistical Analysis

Descriptive statistics (mean ± SD) were employed on all anthropometric data for each participant and each participant served as his own control. To determine if the Kinesio® Tape had an effect on the intramuscular tissue temperature changes, a one-way MANOVA was used with 40 temperature readings as the dependent variable and the tape application as the fixed factor. The research was also able to determine if the width of the tape, due to the type of Kinesio® Tape cut (e.g., "I-"versus "Y"- strip), by performing a one-way MANOVA using the temperature readings as the dependent variable and muscle location as the fixed factor. To determine if the tape had any effect on perceived pain, a one-way MANOVA with the pain scale was the dependent variable and the tape application as the fixed factor was used.

CHAPTER 4. MANUSCRIPT

4.1. Abstract

4.1.1. Context

Cryotherapy is the most commonly used modality for managing musculoskeletal injuries. The effectiveness of a cryotherapy application is variable and there are many factors that affect the outcomes. One factor that can alter the effectiveness of cryotherapy on intramuscular temperature is a barrier (e.g., tape) placed between the skin and cryotherapy mechanism. Kinesio® Tape is commonly used in combination with cryotherapy; however, the effects of the tape on cryotherapy are poorly characterized. Research is warranted to investigate the claim by the manufacturer that Kinesio® Tape is not a barrier for cryotherapy treatment.

4.1.2. Objective

To compare intramuscular temperature change during a 20-minute cryotherapy session with and without Kinesio® Tape application.

4.1.3. Design

Randomized, within subject, experimental.

4.1.4. Setting

Laboratory at a research university.

4.1.5. Subjects

Twenty males (Age: 21.3 ± 2.83).

4.1.6. Interventions

Participants were asked to report for two separate sessions one week apart. Participants served as their own control and were randomized into two groups in which either Kinesio® Tape was applied during the first session or second session. The Kinesio® Tape was applied from the

origin to insertion of the rectus femoris and vastus medialis oblique (VMO) muscles to cover thermocouples inserted into each muscle belly. Two separate ice bags were placed over each thermocouple and temperature recordings of intramuscular tissue temperature 1 cm below the adipose tissue of the recuts femoris and VMO were recorded. Temperatures were recorded every 30 seconds for a three-minute baseline prior to the cryotherapy application and over 20-minutes of treatment time.

4.1.7. Main Outcome Measures

Intramuscular tissue temperature change for the rectus femoris and vastus medialis oblique with and without Kinesio® Tape, perceived pain scale with and without Kinesio® Tape

4.1.8. Results

A one-way MANOVA revealed a nonsignificant effect for tape over the rectus femoris thermocouple, Wilks' $\lambda = 0.035$, $F(38, 1) = 0.730$, $P = 0.75$, the VMO Wilks' $\lambda = 0.100$, $F(37, 2) = 0.486$, $P = 0.858$, and perceived pain, Wilks' $\lambda = 0.770$, $F(9, 30) = 0.997$, $P = 0.463$.

4.1.9 Conclusion

Results indicate the application of Kinesio® Tape do not lead to a difference in intramuscular temperature recordings. Intramuscular temperature for each group fell over time, but the pattern between the groups was indistinguishable. This result lends credence to the claim that ice can be applied over Kinesio® Tape without substantial differences in cryotherapy effectiveness.

4.2. Introduction

Cryotherapy is the most common modality used to treat orthopedic injuries[5] and the acute management of musculoskeletal injuries.[6] Clinicians choose this particular modality to help reduce pain, edema, nerve conduction, and local blood flow.[14] Ice reduces the metabolic process

of an injured tissue in order to help the uninjured tissue survive the enzymatic reactions that occur with an injury.[12] There are many factors which can affect the effectiveness of cold modalities, including but not limited to: duration of treatment, amount of adipose tissue and anatomical location, and type of cryotherapy used.[1, 6] A barrier between the ice and skin, such as a cast, splint, or tape require longer treatment applciations.[7-10]

Cryotherapy is often used in combination with various compressive wraps, dressings, and bandages.[7] Statistically significant decreases ($P < .05$) in surface temperature during a 20-minute cryotherapy application has been found with the use of barriers, but are not comparable to the surface temperature change that occurs without a barrier.[7] Some barriers, such as a padded elastic bandage, are too thick to allow a cryotherapy application to have any effect on the underlying tissue.[8] Even though intramuscular tissue temperatures under a barrier decrease, increased cryotherapy application time may be required in order to reach a clinically significant decrease in temperature change.[7-10] The thickness of a barrier is the key factor in affecting the underlying tissue temperature change during a cryotherapy application. The thickness of tape used by medical professionals is much thinner compared to other barriers. Therefore, the intramuscular tissue under a tape application is hypothesized to have a greater decrease compared to tissue under a thicker barrier (i.e. cast or splint). After an extensive literature review, there is no specific research investigating the role tape has as a potential barrier to cryotherapy techniques.

Kinesio® Tape is one type of tape which practitioners use for a wide variety of musculoskeletal conditions. The tape was specifically designed to mimic the thickness of the epidermis in order to limit the body's sensory stimuli to the application. Based on the properties of the product, the creator of the tape has claimed a cryotherapy application (i.e. ice bag) can be placed over the tape without deleterious effects.[4] However, this claim has been largely

unsubstantiated and needs further investigation prior to allied health care professionals using the combination of treatments to provide optimal care for athletes or patients.

4.3. Methods

4.3.1. Design

The study was a randomized, within subject experimental design. The independent variable is the application of Kinesio® Tape and the dependent variables are the baseline temperature measurement and the temperature recordings taken every 30-seconds during the 20-minute cryotherapy application.

4.3.2. Participants

Twenty males (age: 21.3 ± 2.83; height: 72 ± 2.64 in; weight 182.05 ± 23.246 lbs) participated in this IRB-approved research protocol. Participants were excluded if there were contraindications to cryotherapy (i.e. decreased sensation or blood flow over the area, Raynaud's phenomenon, cold urticaria, cryoglobulinemia, paroxysmal cold hemoglobinuria, angina pectoris, or any other severe heart condition) or Kinesio® Tape (i.e. malignancy sites, cellulitis, skin infection, open wounds, Deep Vein Thrombosis, diabetes, kidney disease, congestive heart failure, coronary artery disease, or fragile skin). Participants were also excluded if there was more than 1.5 cm of adipose tissue as quantified by musculoskeletal diagnostic ultrasound or injury to the quadriceps within the previous six months.

4.3.3. Procedures

Each participant reported for two sessions exactly one week apart. The participants were randomly assigned to receive Kinesio® Tape either in the first or second session. The dominant leg of each participant was used by asking the participants to subjectively report the leg that they would use to kick a ball. Thermocouple insertion locations were then determined on the VMO,

as determined by the largest observable aspect of the muscle, and the rectus femoris, 2.5 cm proximal to the musculotendinous junction. In order to determine the insertion point of the rectus femoris, diagnostic ultrasound was used (Terason t3200™ Diagnostic Ultrasound, MedCorp, LLC., Tampa, FL). The transducer was placed in the long axis view and placed just anteriorly to the patella so that the tendon and patella were visible on the screen. The transducer was slid anteriorly along the tendon until the disappeared revealing the muscle belly. At this point, a mark was made using a Sharpie to represent the musculotendinous junction. A tape measure was then used to measure 2.5 cm anteriorly to the junction and marked using an "X" to act as the thermocouple insertion site. The VMO thermocouple insertion site was determined by asking the participant to flex his quadriceps. The largest observable aspect was marked by a Sharpie to act as the insertion point. See Figure 1 for the thermocouple insertion locations. Once both thermocouple insertion points were determined, the diagnostic ultrasound was used to determine if there were any abnormalities of the muscle and to measure the amount of adipose tissue underlying each thermocouple insertion point. To measure the amount of adipose tissue, the transducer was placed over the thermocouple insertion point and the screen was frozen. The caliper function was then used to measure the distance between most superior aspect of the muscle to the skin in centimeters. The amount of adipose tissue was used to calculate the accurate placement of the thermocouples 1 cm below the adipose tissue.

Thermocouple preparation included a submersion in Metricide for a minimum of 12 hours before insertion into the participants' muscles. The thermocouple was wiped using sterile gauze and isopropyl alcohol and wrapped in sterile gauze until inserted. The participants were asked to take two deep breaths and upon the exhale of the second breath, the 20 gauge 1.16-inch needle catheter was inserted into the muscle bellies of the rectus femoris. The needle was

retracted by a spring-loaded mechanism, leaving the catheter in the muscle belly. The thermocouple was then removed from the sterile gauze and inserted through the catheter to a depth of 1 cm below the adipose tissue. Once the thermocouple was inserted to the appropriate depth, the catheter was removed and the thermocouple was stabilized. Transparent surgical tape was applied over the thermocouple in order to ensure that it remained stable throughout the rest of the study. The thermocouple lead was taped to the back of the participant's knee using Powerflex self-adhering tape and attached to the Iso-Thermex electronic electrothermometer (Columbus Instruments, Columbus OH). The same process was used to insert the second thermocouple into the VMO.

The Kinesio® Tape application condition consisted of a "Y" strip application over the quadriceps encompassing both thermocouple insertions sites (Figure 2). The tape started at the anterior inferior iliac spine with no tension. Tension (15-30%) was then applied as the tape was pulled inferiorly by the clinician. The quadriceps muscle was placed on a stretch by flexing the knee during the application. The tape was split 2.5 cm past the musculotendinous junction and the two tails were placed on the medial and lateral aspects of the patella over the vastus lateralis and vastus medialis oblique. The application ended at the tibial tuberosity with no tension.[4,24,25,27] A three-minute baseline was recorded to determine an initial tissue temperature without the cryotherapy application. After the three-minute baseline, a 1 kg and a 0.5 kg ice bag were placed over the rectus femoris and VMO respectively (Figure 3). Temperature recordings were taken every 30 seconds for 20 minutes for both sessions. Patients were asked to rate their perceived pain during the 20-minute cryotherapy session on a scale of 0-10 based on the Borg Scale of Perceived Pain.

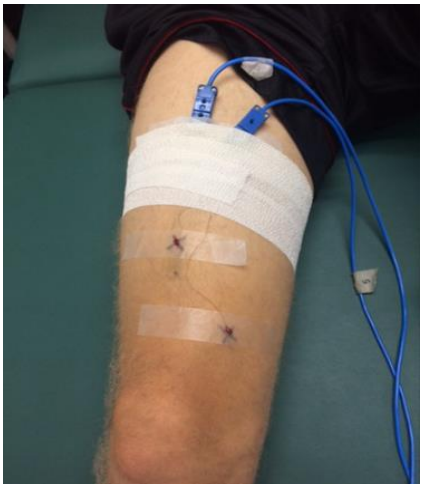

Figure 1. Thermocouple Insertion

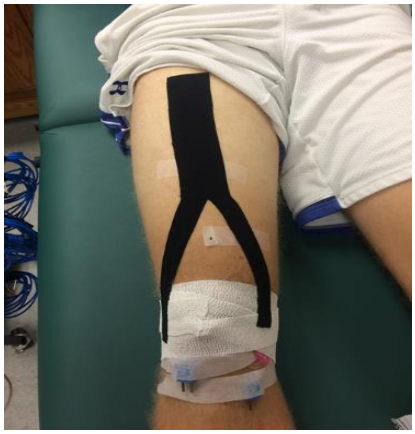

Figure 2. Kinesio® Tape Application

Figure 3. Ice Application

4.4. Statistical Analyses

Descriptive statistics (mean ± SD) were employed on all anthropometric data for each participant. To determine if the Kinesio® Tape had an effect on the intramuscular tissue temperature changes, a one-way MANOVA was used with 40 temperature readings as the dependent variable and the tape application as the fixed factor. The research determined if the width of the tape, due to the type of Kinesio® Tape cut (e.g., "I-"versus "Y"- strip), by performing a one-way MANOVA using the temperature readings as the dependent variable and muscle location as the fixed factor. To determine if the tape had any effect on perceived pain, a one-way MANOVA with the pain scale was the dependent variable and the tape application as the fixed factor was used.

4.5. Results

Table 7 presents the means (±SD) of the anthropometric data for all participants, including age, height, weight, and amount of adipose tissue. The baseline mean temperature for the rectus femoris with a Kinesio® Tape application was 33.93 ± 1.22°C compared to 34.48 ± 1.41°C without the tape application. Table 8 presents the mean temperature recordings of the rectus femoris over the 41 data collection points during the cryotherapy application. The baseline mean temperature for the VMO was 34.19 ± 1.24°C with a Kinesio® Tape application compared to 34.41 ± 1.37°C without the application. Table 9 presents the mean temperature recordings of the VMO over the 41 data collection points during the cryotherapy application. Overall, there was a 5.96 ± 2.17°C decrease in tissue temperature for the rectus femoris with the presence of Kinesio® Tape and a 5.94 ± 2.57°C decrease without the application. The VMO resulted in decreases of 4.00 ± 1.89°C with the presence of Kinesio® Tape and 4.41 ± 2.61°C without the

application. Table 10 presents the overall changes noted during the 20-minute cryotherapy application.

A one-way MANOVA revealed a nonsignificant effect for tape over the rectus femoris, Wilks' $\lambda = 0.035$, $F(38, 1) = 0.730$, $P = 0.751$. For the VMO, a nonsignificant effect was found for the tape as well, Wilks' $\lambda = .100$, $F(37, 2) = .486$, $P = .858$. Due to the Kinesio® Tape application resulting in nonsignificant results, the width of the tape had no statistically significant effect on the underlying intramuscular tissue temperature change tape, Wilks' $\lambda = 0.42$, $F(38, 1) = .597$, $P = .796$. Also, there was no statistically significant difference in perceived pain scale with or without the Kinesio® Tape application, Wilks' $\lambda = .770$, $F(9, 30) = .997$, $P = .463$. Table 11 presents the multivariate results for each one-way MANOVA in regards to temperature change for the rectus femoris and VMO, the effects of the width of Kinesio® Tape, and perceived pain scale.

Table 7. Means (±SD) of Anthropometric Data

	Mean	**SD**
Age (yrs.)	21.3	2.83
Height (in.)	72.0	2.636
Weight (lbs.)	182.05	23.246
Adipose (cm)	0.30	0.22

Table 8. Means (±SD) of Tissue Temperature of Rectus Femoris

	Tape		No Tape	
Time (min)	**Mean**	**SD**	**Mean**	**SD**
0.0	33.93	1.22	34.48	1.41
0.5	33.92	1.24	34.42	1.41
1.0	33.88	1.26	34.41	1.80
1.5	33.79	1.33	34.43	1.30
2.0	33.69	1.40	34.20	1.69
2.5	33.68	1.38	34.14	1.64
3.0	33.50	1.58	34.00	1.76
3.5	33.32	1.68	33.86	1.89
4.0	33.17	1.79	33.67	2.05
4.5	32.95	1.84	33.51	2.16
5.0	32.81	1.97	33.33	2.30
5.5	32.62	2.07	33.15	2.40
6.0	32.42	2.16	32.44	3.54
6.5	32.22	2.21	32.79	2.62
7.0	32.10	2.33	32.57	2.69
7.5	31.86	2.40	32.43	2.82
8.0	31.67	2.49	32.25	2.91
8.5	31.49	2.56	32.07	2.99
9.0	31.30	2.63	31.85	3.00
9.5	31.12	2.71	31.73	3.11
10.0	30.97	2.67	31.56	3.17
10.5	30.47	2.82	31.37	3.24
11.0	30.55	2.88	31.25	3.32
11.5	30.36	2.92	31.16	3.30
12.0	30.23	2.96	30.90	3.43
12.5	30.02	3.03	30.74	3.47
13.0	29.86	3.10	30.58	3.52
13.5	29.67	3.13	30.42	3.57
14.0	29.50	3.17	30.25	3.62
14.5	29.38	3.20	30.12	3.64
15.0	29.20	3.23	29.98	3.68
15.5	29.10	3.25	29.82	3.72
16.0	28.91	3.27	29.69	3.76
16.5	28.82	3.28	29.56	3.79
17.0	28.70	3.30	29.41	3.80
17.5	28.56	3.31	29.27	3.82
18.0	28.43	3.34	29.14	3.85
18.5	28.30	3.36	29.01	3.86
19.0	28.17	3.39	28.86	3.89
19.5	28.06	3.40	28.72	3.91
20.0	27.97	3.40	28.54	3.98

Table 9. Means (±SD) of Tissue Temperature of VMO

	Tape		No Tape	
Time (min)	**Mean**	**SD**	**Mean**	**SD**
0.0	34.27	1.24	34.41	1.37
0.5	34.32	1.24	34.40	1.36
1.0	34.25	1.31	34.37	1.37
1.5	34.30	1.34	34.33	1.44
2.0	34.30	1.44	34.26	1.52
2.5	34.21	1.47	34.17	1.60
3.0	34.09	1.49	33.99	1.70
3.5	34.08	1.63	34.00	1.85
4.0	33.98	1.73	33.90	1.97
4.5	33.91	1.83	33.78	2.12
5.0	33.75	1.93	33.66	2.25
5.5	33.69	2.00	33.54	2.38
6.0	33.59	2.10	33.41	2.49
6.5	33.44	2.23	33.26	2.62
7.0	33.35	2.30	33.16	2.72
7.5	33.22	2.35	33.02	2.82
8.0	33.11	2.41	32.90	2.92
8.5	32.96	2.50	32.79	3.03
9.0	32.84	2.61	32.63	3.12
9.5	32.75	2.69	32.48	3.21
10.0	32.67	2.78	32.45	3.40
10.5	32.50	2.80	32.31	3.37
11.0	32.37	2.88	32.04	3.45
11.5	32.16	2.89	31.95	3.50
12.0	32.14	2.99	31.84	3.55
12.5	32.02	3.02	31.71	3.62
13.0	31.88	3.07	31.60	3.67
13.5	31.77	3.11	31.49	3.69
14.0	31.65	3.13	31.24	3.70
14.5	31.51	3.15	31.22	3.78
15.0	31.43	3.19	31.10	3.82
15.5	31.50	3.08	30.97	3.84
16.0	31.42	3.08	30.87	3.87
16.5	31.32	3.08	30.76	3.88
17.0	31.20	3.07	30.66	3.89
17.5	31.11	3.08	30.04	4.57
18.0	31.00	3.10	30.93	4.46
18.5	30.90	3.10	30.35	3.94
19.0	30.39	3.11	30.21	3.97
19.5	30.30	3.12	30.11	3.98
20.0	30.19	3.13	30.01	3.98

Table 10. Mean (±SD) Overall Tissue Temperature Change

	Tape		No Tape	
Location	**Mean**	**SD**	**Mean**	**SD**
Rectus Femoris	5.96	2.17	5.94	2.57
VMO	4.00	1.89	4.41	2.61

Table 11. Multivariate Results

	Wilks' Lambda	F-Value	Hypothesis df	Error df	Sig.
Rectus Femoris	.035	.730	38.000	1.000	.751
VMO	.100	.486	37.000	2.000	.856
Width of Tape	0.42	.597	38.000	1.000	.796
Perceived Pain	.770	.997	9.000	30.000	.230

4.6. Discussion

The purpose of this study was to determine the impact of Kinesio® Tape on tissue temperature changes and the paresthesia effects associated with cryotherapy. The optimal temperature decrease for an ideal healing process is uncharacterized in research, however, one study reported a decrease of 7°C is therapeutic.[16] There are factors that have been investigated which can impede the underlying tissue from reaching a therapeutic level; these factors include, casting material,[7-10] the amount of adipose tissue,[5,11,16,18] and the mode of cryotherapy.[6,14,19]

Studies have provided evidence that different barriers, such as ace bandages and other casting materials, have adverse effects on the cooling properties that occur in the underlying intramuscular tissue temperature during a cryotherapy application.[7-11] Barriers obstruct the transfer of heat out of the muscles and into the cryotherapy application. Previous research has investigated the effect of a variety of different barriers such as a towel,[7] elastic wrap,[7] padded ace bandage,[8] dry and damp washcloth,[8] normal ace bandage,[8,9,10] plaster cast,[9,10] and a synthetic cast.[9,10] Each study concluded that every barrier, except a padded ace bandage, allowed for a

decrease in the underlying tissue temperature. However, the temperature decreases were not as large as those recorded without a barrier during a 20 to 30-minute application. Therefore, the application of barriers impacts the healing process by creating a less than optimal environment to stimulate the normal cellular metabolic process.

Some barriers are too thick to allow for an optimal decrease in tissue temperature; however, Kinesio® Tape was created with skin-like properties in order to nullify these effects. By comparing the tissue temperature change with and without an application, and by comparing perceived pain during the cryotherapy application, we were able to investigate the role Kinesio® Tape may have in preventing optimal tissue cooling. Contrary to other types of barriers, the temperature decreases associated with applying cryotherapy over Kinesio® Tape are comparable to temperatures without the tape. The participants reported, through a perceived pain scale, that the discomfort associated with cryotherapy was the same for both sessions. Therefore, the temperature changes and perceived pain scale support the claims that cryotherapy can be applied over Kinesio® Tape without affecting the physiological effects associated with cryotherapy.

The effects of adipose tissue altering intramuscular tissue temperature change during cryotherapy is well documented in research.[5,11,16,18] Adipose tissue decreases the rate at which the underlying tissue temperature decreases.[5,11,16,18] Otte et al[16] determined that different amounts of adipose tissue will affect the duration of application needed to reach a tissue temperature decrease of 7°C. Due to the amount of adipose tissue (0.33 ± 0.20 cm) of the participants in this research, a 30 to 60 minute application duration would have been needed to reach a decrease of 7°C.[16] Research has also determined that recreational athletes, such as the participants in this study, have a larger amount of adipose tissue in the thigh compared to an athletic population.[5] In our study, each participant served as their own control to account for the effects of adipose tissue

on a cryotherapy application. Consistent with previous findings, we found the amount of adipose tissue impacted the level of tissue cooling; however, this had no effect on determining if Kinesio® Tape would act as a barrier to the cryotherapy application.

Previous research has been unable to characterize a tissue temperature decrease that is optimal for the healing process to occur during a cryotherapy application due to inconsistencies in methodologies and results. Our research resulted in a 5.96 ± 2.17°C (Kinesio® Tape group) and a 5.94 ± 2.57°C tissue temperature decrease 1 cm subadipose in the rectus femoris, and a 4.00 ± 1.89°C (Kinesio® Tape group) and a 4.41 ± 2.61°C tissue temperature decrease 1 cm subadipose in the VMO. Previous research has observed a temperature decrease of 7.85 ± 2.52°C at 1 cm subadipose in the thigh with a 30-minute application duration.[6] However, the total amount of adipose tissue was not reported and a longer duration has been found to result in a larger decrease of tissue temperature.[17] Myrer et al[18] recorded a similar temperature decrease, 7.1 ± 4.1°C, 1 cm subadipose. However, the cryotherapy application was applied over the gastrocnemius not the thigh. Other aspects such as the size of the ice bag and the use of compression differed in each research methodology. Inconsistent methodologies do not allow comparisons to be made of tissue temperature decrease recoded in previous research. Therefore, an optimal tissue temperature decrease during cryotherapy cannot be characterized by research.

Various types of cryotherapy modalities are applied in the clinical setting.[19] Different types of cryotherapy affect the overall tissue temperature decrease observed in the underlying tissue.[6,14,19] Research has shown that cubed ice produces a larger decrease in the underlying tissue compared to crushed ice during a 20-minute application.[14] Cubed ice was used included in the methodology of this research because it is commonly available in a clinic setting. Each participant received the same size ice bag (1 kg over the rectus femoris and 0.5 kg over the

VMO) in both sessions to increase the inter-rater reliability of the temperature changes. The type of ice being used was a factor explaining why the temperatures did not decrease 7°C and not a factor in determining if Kinesio® Tape would act as a barrier.

There are various factors within the research that do not allow for the transferability of the results. The study was conducted on healthy individuals and healthy tissue; therefore, the results of this study may not be transferable to individuals who have injured tissue. Previous studies have also included healthy tissue in their research protocol in order to study the physiological effects on undamaged tissue in order to understand potential impacts on injured structures.[2,22,23,25] To the knowledge of the researchers, this is the first study to determine if Kinesio® Tape acted as barrier during a cryotherapy application. Not only should research continue to test Kinesio® Tape but also other brands (e.g. Rock Tape, Mueller, etc.) because the results of this study may not be transferable due to a difference in properties.

4.7. Conclusion

Kinesio® Tape has become a tool for a variety of orthopedic objectives. The purpose of using the tape during rehabilitation is that the patient can go home with the application still applied and continue to have relief from pain or other symptoms. The manufacturer claims that patients and clinicians can apply cryotherapy over the application without any adverse effects. The results of this study provide support to this claim because there was no statistically significant difference found between tissue temperature change and perceived pain between groups. The effects of a cryotherapy application were not impeded due to the application of Kinesio® Tape. A clinician can now use Kinesio® Tape and cryotherapy in combination to help reduce symptoms knowing that there will be no impedance of the effects of a cryotherapy application.

CHAPTER 5. DISCUSSION

The purpose of this study was to determine if Kinesio® Tape would act as a barrier to intramuscular tissue temperature change during a cryotherapy application. A secondary purpose was to determine if different width of a Kinesio® Tape application would have different effects on intramuscular tissue temperature change. While not a primary goal of the research, the methodology included a perceived pain score from the cryotherapy application in order to compare differences between the treatment and control groups. Even though there is an increase in popularity of Kinesio® Tape,[1-3] there is a lack of evidence-based quantitative research to determine its effects on intramuscular tissue temperature change during a cryotherapy application. The lack of research has left clinicians applying cryotherapy over Kinesio® Tape without understanding the physiological effects of the treatment.

5.1. Research Findings

The baseline mean temperature for the rectus femoris with a Kinesio® Tape application was 33.93 ± 1.22°C compared to 34.48 ± 1.41°C without the tape application. The VMO location the baseline mean temperature was 34.19 ± 1.24°C with a Kinesio® Tape application compared to 34.41 ± 1.37°C without the application. A one-way MANOVA revealed a nonsignificant effect for tape over the rectus femoris, Wilks' $\lambda = 0.035$, $F(38, 1) = 0.730$, $P = 0.751$. For the VMO, a nonsignificant effect was found for the tape as well, Wilks' $\lambda = .100$, $F(37, 2) = .486$, $P = .858$. Considering presence of the tape was nonsignificant, there was no statistically significant difference between the width of tape, Wilks' $\lambda = 0.42$, $F(38, 1) = .597$, $P = .796$. Also, there was no statistically significant difference in perceived pain scale with or without the Kinesio® Tape application, Wilks' $\lambda = .770$, $F(9, 30) = .997$, $P = .463$.

5.2. Utilization for Athletic Trainers

As treatment of care continues to progress toward newer techniques, evidence-based research is needed to help support the new techniques. There is a lack of evidenced-based research to support the many uses of Kinesio® Tape, but there is an abundance of anecdotal evidence. The same can be said about the use of cryotherapy and Kinesio® Tape in combination. The results of this study provide quantitative evidence which confirms previously unsubstantiated claims that cryotherapy could be applied over Kinesio® Tape with no ill effects on intramuscular tissue temperature.

Kinesio® Tape was created to mimic the thickness of skin to reduce the body's sensation to an application.[4] By comparing the tissue temperature change with and without an application, and comparing perceived pain during the cryotherapy application, the researchers were able to test how similar the properties are to skin. Contrary to other types of barriers, the temperature decreases associated with applying cryotherapy over Kinesio® Tape are comparable to temperatures without the tape. The participants reported, through a perceived pain scale, that the discomfort associated with cryotherapy was the same for both sessions. Therefore, the temperature changes and perceived pain scale from this study support that the properties of Kinesio® Tape are similar to skin. The results provide evidence-based support that Kinesio® Tape is not a barrier to effects of a cryotherapy application when used in combination.

5.3. Limitations

This research contains limitations due to the numerous variables involved. One limitation was that the study was conducted on healthy individuals and healthy tissue. Therefore, the results of this study are not transferable to individuals who have injured tissue. Previous studies have also included healthy tissue in their research protocol in order to study the physiological effects

on undamaged tissue in order to understand potential impacts on injured structures.[2,22,23,25] The type of application, facilitation of the quadriceps, is another limitation. A facilitation application is applied with a 15-35% stretch.[4] The results of this study are not transferable to other types of Kinesio® Tape applications. To the knowledge of the researchers, this is the first study to determine if Kinesio® Tape acted as barrier during a cryotherapy application. Not only should research continue to test Kinesio® Tape but also other brands (e.g. Rock Tape, Mueller, etc.) because the results of this study cannot be transferable due to a difference in properties. The mode of cryotherapy, cubed ice, was another limitation of this research study. Other modes of cryotherapy (i.e. ice cup, crushed ice, wetted ice) have different cooling rates.[6]

5.4. Future Research

Future research should focus on the limitations within this study. To the knowledge of the researchers, this was the first study completed to determine if Kinesio® Tape would act as a barrier to a cryotherapy application. There are many different types of tape that mimic the properties of Kinesio® Tape, but are not exactly the same. Therefore, the results of this study cannot be generalized to the other brands. Future research should determine the effects of the other brands on cryotherapy and compare to the results of this study on Kinesio® Tape.

5.5. Conclusions

Kinesio® Tape has become a vital aspect of the rehabilitation process throughout the medical field. The purpose of using the tape during rehabilitation is that the patient can go home with the application still applied and continue to have relief from pain or other symptoms. The manufacturer claims that patients and clinicians can apply cryotherapy over the application without any adverse effects. The results of this study provide support to this claim because there was no statistically significant difference found between tissue temperature change and

perceived pain between groups. The effects of a cryotherapy application were not impeded due to the application of Kinesio® Tape. A clinician can now use Kinesio® Tape and cryotherapy in combination to help reduce symptoms knowing that there will be no impedance of the effects of a cryotherapy application.

REFERENCES

1. Morris D, Jones D, Ryan H, Ryan CG. The clinical effects of Kinesio® Tex taping: A systematic review. *Physiother Theory Pract.* 2013;29(4):259-270 212p.
2. Lumbroso D, Ziv E, Vered E, Kalichman L. The effect of kinesio tape application on hamstring and gastrocnemius muscles in healthy young adults. *J Bodyw Mov Ther.* 2014;18(1):130-138.
3. Merino-Marban R, Fernandez-Rodriguez E, Mayorga-Vega D. The Effect of Kinesio Taping on Calf Pain and Extensibility Immediately After Its Application and After a Duathlon Competition. *Res Sports Med.* 2014;22(1):1-11.
4. Kase K, Wallis J, Kase T. *Clinical Therapeutic Applications of the Kinesio Taping Method.* 2nd Edition ed. Tokyo, Japan2003.
5. Jutte LS, Hawkins J, Miller KC, Long BC, Knight KL. Skinfold Thickness at 8 Common Cryotherapy Sites in Various Athletic Populations. *J Athl Train.* 2012;47(2):170-177.
6. Merrick MA, Jutte LS, Smith ME. Cold Modalities With Different Thermodynamic Properties Produce Different Surface and Intramuscular Temperatures. *J Ath Train.* 2003;38(1):28-33.
7. Tsang KKW, Buxton BP, Guion WK, Joyner AB, Browder KD. The effects of cryotherapy applied through various barriers. *J Sport Rehabil.* 1997;6(4):343-354.
8. LaVelle BE, Snyder M. Differential conduction of cold through barriers... ace bandages, padded ace bandages and compression dressings in the management of acute soft tissue trauma. *J Adv Nurs.* 1985;10(1):55-61 57p.
9. Okcu G, Yercan HS. Is it possible to decrease skin temperature with ice packs under casts and bandages? A cross-sectional, randomized trial on normal and swollen ankles. *Arch Orthop Trauma Surg.* 2006;126(10):668-673.
10. Weresh MJ, Bennett GL, Njus G. Analysis of cryotherapy penetration: a comparison of the plaster cast, synthetic cast, Ace wrap dressing, and Robert-Jones dressing. *Foot Ankle Int.* 1996;17(1):37-40.
11. Jutte LS, Merrick MA, Ingersoll CD, Edwards JE. The relationship between intramuscular temperature, skin temperature, and adipose thickness during cryotherapy and rewarming. *Arch Phys Med Rehabil.* 2001;82(6):845-850.
12. White GE, Wells GD. Cold-water immersion and other forms of cryotherapy: physiological changes potentially affecting recovery from high-intensity exercise. *Extrem Physiol Med.* 2013;2:26-26.
13. Long BCbloe, Jutte LS, Knight KL. Response of Thermocouples Interfaced to Electrothermometers When Immersed in 5 Water Bath Temperatures. *J Ath Train* 2010;45(4):338-343.
14. Dykstra JH, Hill HM, Miller MG, Cheatham CC, Michael TJ, Baker RJ. Comparisons of Cubed Ice, Crushed Ice, and Wetted Ice on Intramuscular and Surface Temperature Changes. *J Ath Train.* 2009;44(2):136-141.
15. White GE, Wells GD. Cold-water immersion and other forms of cryotherapy: physiological changes potentially affecting recovery from high-intensity exercise. *Extrem Physiol Med.* 2013;2:26-26.
16. Otte JW, Merrick MA, Ingersoll CD, Cordova ML. Subcutaneous adipose tissue thickness alters cooling time during cryotherapy. *Arch Phys Med Rehabil.* 2002;83(11):1501-1505.

17. Kuo CC, Lin CC, Lee WJ, Huang WT. Comparing the antiswelling and analgesic effects of three different ice pack therapy durations: a randomized controlled trial on cases with soft tissue injuries. *J Nurs Res.* 2013;21(3):186-194.
18. Myrer WJ, Myrer KA, Measom GJ, Fellingham GW, Evers SL. Muscle Temperature Is Affected by Overlying Adipose When Cryotherapy Is Administered. *J Ath Train.* 2001;36(1):32-36.
19. Kanlayanaphotporn R, Janwantanakul P. Comparison of skin surface temperature during the application of various cryotherapy modalities. *Arch Phys Med Rehabil.* 2005;86(7):1411-1415.
20. Jutte LS, Long BC, Knight KL. Temperature Measurement Reliability and Validity With Thermocouple Extension Leads or Changing Lead Temperature. *J Ath Train.* 2010;45(6):642-644.
21. Csapo R, Alegre LM. Effects of Kinesio® taping on skeletal muscle strength—A meta-analysis of current evidence. *J Sci Med Sport.* 2015;18(4):450-456.
22. Vered E, Oved L, Zilberg D, Kalichman L. Influence of kinesio tape application direction on peak force of biceps brachii muscle: A repeated measurement study. *J Bodyw Mov Ther.* 2016;20(1):203-207.
23. Yeung SS, Yeung EW, Sakunkaruna Y, et al. Acute effects of kinesio taping on knee extensor peak torque and electromyographic activity after exhaustive isometric knee extension in healthy young adults. *Clin J Sport Med.* 2015;25(3):284-290.
24. Aktas G, Baltaci G. Does Kinesiotaping increase knee muscles strength and functional performance? *Isokinetics and Exercise Science.* 2011;19:149-155.
25. Vithoulka I, Beneka A, Malliou P, Aggelousis N, Karatsolis K, Diamantopoulos K. The effects of Kinesio-Taping® on quadriceps strength during isokinetic exercise in healthy non athlete women. *Isokinet Exerc Sci.* 2010;18(1):1-6.
26. LaStayo PC, Woolf JM, Lewek MD, Snyder-Mackler L, Reich T, Lindstedt SL. Eccentric muscle contractions: their contribution to injury, prevention, rehabilitation, and sport. *J Orthop Sports Phys Ther.* 2003;33(10):557-571.
27. Guner S, Alsancak S, Koz M. Effect of two different kinesio taping techniques on knee kinematics and kinetics in young females. *J Phys Ther Sci.* 2015;27(10):3093-3096.
28. *Iso-Thermex Electronic Thermometer Instruction Manual.* Columbus, OH: Columbus Instruments International Corp; 1992.
29. Fundamentals of musculoskeletal ultrasound. In. *Scitech Book News.* Vol 31. Portland: Ringgold Inc; 2007.
30. Galvan HG, Tritsch AJ, Tandy R, Rubley MD. Pain Perception During Repeated Ice-Bath Immersion of the Ankle at Varied Temperatures. *J Sport Rehabil.* 2006;15(2):105-115.
31. Velnar T, Bailey T, Smrkolj V. The wound healing process: an overview of the cellular and molecular mechanisms. *J Int Med Res.* 2009;37(5):1528-1542.

APPENDIX A. NORTH DAKOTA STATE UNIVERISTY INSTITUTIONAL REVIEW BOARD APPROVAL

NDSU NORTH DAKOTA STATE UNIVERSITY

August 31, 2016

Dr. Katie Lyman
Department of HNES

IRB Approval of Protocol #HE17002, "The Effects of a Kinesio Tape® Application on Intramuscular Tissue Temperature Change During a 20-Minutes Cryotherapy Application"
Co-investigator(s) and research team: Michasel McCrone, Kara Gange

Approval period: 8/31/2016 to 8/30/2017 Continuing Review Report Due: 7/1/2017

Research site(s): NDSU Funding agency: MAATA
Review Type: Full Board, meeting date – 8/26/2016
Risk Level: A minor increase over minimal risk
IRB approval is based on original submission, with revised: protocol, recruitment messages, consent and funding information (received 8/29/2016).

Additional approval is required:
o prior to implementation of any proposed changes to the protocol (Protocol Amendment Request Form).
o for continuation of the project beyond the approval period (Continuing Review/Completion Report Form). A reminder is typically sent two months prior to the expiration date; timely submission of the report is your responsibility. To avoid a lapse in approval, suspension of recruitment, and/or data collection, a report must be received, and the protocol reviewed and approved prior to the expiration date.

A report is required for:
o 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).
o any significant new findings that may affect risks to participants.
o closure of the project (Continuing Review/Completion Report Form).

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

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

Kristy Shirley
Digitally signed by Kristy Shirley
DN: cn=Kristy Shirley, o=NDSU, ou=Institutional Review Board, email=kristy.shirley@ndsu.edu, c=US
Date: 2016.08.31 10:09:30 -05'00'

Kristy Shirley, CIP
Research Compliance Administrator

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

INSTITUTIONAL REVIEW BOARD
NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 701.231.8995 | Fax 701.231.8098 | ndsu.edu/irb
Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

APPENDIX B. INFORMED CONSENT

NDSU North Dakota State University
Department of Health, Nutrition, and Exercise Science
Bentson Bunker Field House
NDSU Dept. 2620
Fargo, ND 58108-6050
978.790.8218

The Effects of a Kinesio® Tape Application on Intramuscular Tissue Temperature Change During a 20-Minute Cryotherapy Application

This study is being conducted by: Michael McCrone, graduate student in the Post Professional Advanced Athletic Training Master's Program at North Dakota State University, (701)-730-6249, michael.mccrone@ndsu.edu and advisor Katie Lyman, Katie.lyman@ndsu.edu, (218)-443-6446

Why am I being asked to take part in this research study? Because you are a male between the ages of 18-50 years old, you are invited to take part in this research. We are looking for 20 participants. The study is trying to determine the effects Kinesio Tape® has on cryotherapy and not gender differences. Cryotherapy is the use of ice to help muscle soreness or injury. An example would be using an ice bag or frozen gel pack.

You should not participate in this study if:

- You have experienced a thigh injury within the last six months, or are currently injured.
- Decreased sensation or blood flow to the thigh,
- Any conditions related to exposure to cold, such as:
    - Raynaud's phenomenon (a condition where extremities turn blue and are painful when exposed to cold)
    - Cold-induced hives,
    - Blood conditions related to cold exposure (e.g. cryoglobulinemia, paroxysmal cold hemoglobinuria),
- Angina pectoris (chest pain, or any other sever heart condition, Deep Vein Thrombosis, Diabetes, Kidney disease, congestive heart failure, or coronary heart disease,
- malignancy sites, cellulitis, skin infection, open wounds or fragile skin.

You will also be excluded if you have more than 1.5 cm of adipose (fat) tissue

What is the reason for doing the study? The reason for doing this study is to see if Kinesio® Tape will act as a barrier to temperature changes in the underlying a cryotherapy application. The use of Kinesio® Tape is becoming very popular and Dr. Kenzo Kase, the founder, claims that it will not affect a cryotherapy application. However, there is no research to back this claim.

What will I be asked to do? You will be asked to come to room 14 in the Bentson Bunker Fieldhouse for 2 sessions and wear clothing that will allow for the quadriceps on your dominant leg to be exposed. You should not exercise 2 hours before your appointment. You will be split

into one of two groups, 1) receiving Kinesio Tape® on the first session or 2) receiving Kinesio Tape® during the second session. You will lie down on your back and 2 small dots will be made on your quadriceps using a Sharpie, the area around the dots will be cleaned with Betadine and isopropyl alcohol. A small needle will then be inserted into both of the dot marks and then quickly removed leaving a small catheter. Two small thermocouples will then be placed through the catheter into the muscle and then the catheter will be removed leaving the thermocouple in the quadriceps. Thermocouples are little thermometers that can be used to measure muscle tissue temperature. Once the thermocouples are secured in place you will have Kinesio® Tape applied depending on what group you are in and what session you are in. The tape will be applied from your hip to your knee. There will be a split in the tape about half way down your leg leaving two tails. The two tails will then be applied around the inside and outside of your knee. You will then be asked to lay as still as you can while two ice bags are placed on your leg for 20 minutes. During this time, you will be asked about how cold the ice bag feels. Upon completion, the thermocouples will be removed and you will be asked to sign up for a second session exactly one week later. At the end of the session additional ice will be made available if you feel sore.

Where is the study going to take place, and how long will it take? The study will take place on the North Dakota State University Campus. The study will be done in 2 sessions. Each session should take approximately one hour. The second session must be completed exactly one week of the first session.

What are the risks and discomforts? It is not possible to identify all potential risks in research procedures, but we have taken reasonable safeguards to minimize any known risks. There are four stages of discomfort with an ice bag application. You will feel coldness right away when the bag is applied, then the intensity of the cold will increase, then it will feel like "pins and needles" (the same feeling if your foot falls asleep), and finally, it will be numb. With the insertion of the thermocouple there is slight discomfort as a result of the needle catheter being inserted into the muscle and zero to minimal bleeding during the insertion of the thermocouple. Individuals who have had this procedure performed on them have rated the discomfort between a 1-3 out of 10. There is the potential for residual soreness in the quadriceps that feels similar to the soreness after working out. Rarely, slight bruising at the injection site may occur. If soreness occurs, it typically lasts 12-24 hours after the procedure. There is a small possibility of an infection at the needle catheter insertion site or allergic reaction to the betadine used to clean the area before insertion. If an infection or reaction occurs (redness, swelling, warmth over the area), please contact Michael McCrone at 608-295-9988 or michael.mccrone@ndsu.edu or my advisor, Dr. Katie Lyman at Katie.lyman@ndsu.edu or (218)-443-6446. We will look at the site and refer you to the NDSU Student Health Services, if necessary. If you are a non-NDSU student, you will be referred to the hospital under the coverage of your personal insurance. If a severe allergic reaction occurs (rash, hives, tightness in the chest, difficulty breathing, swelling of the face, mouth, lip or tongue) 911 will be called and the investigator will monitor and provide any first responder care to the subject. The researchers are Certified Athletic Trainers and certified in first aid and CPR/AED. If new findings develop during the course of this research which may change your willingness to participate, we will tell you about these findings.

What are the benefits to me? You are not expected to get any benefit from being in this research study.

What are the benefits to other people? The information from this study will benefit healthcare providers who use Kinesio® Tape and the patients they serve.

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

What will it cost me to participate? There is no cost to you as the participant in this study.

What are the alternatives to being in this research study? Instead of being in this research study, you can choose not to participate.

Who will see the information that I give? We will keep private all research records that identify you. Your information will be combined with information from other people taking part in the study, we will write about the combined information that we have gathered. You will not be identified in these written materials. We may publish the results of the study; however, we will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example, your name will be kept separate from your research records and these two things will be stored in different places under lock and key. If you withdraw before the research is over, your information will be retained in the research record or removed at your request, and we will not collect additional information about you.

Can my taking part in the study end early? If you fail to show up to all sessions, you may be removed from the study. You may also request to be removed from the study.

Will I receive any compensation for taking part in this study? You will be compensated for your participation of the study. The total compensation for successfully completing the study will be $30. You will receive your compensation at the end of the second session. If you do not complete both sessions, you will not be compensated for your time.

What happens if I am injured because of this research?
If you receive an injury in the course of taking part in the research, you should contact Katie Lyman at the following phone number (218)-443-6446. If needed, you may be referred for outside treatment at Student Health Services or your primary provider. Treatment for the injury will be available including first aid, emergency treatment and follow-up care as needed. Payment for this treatment must be provided by you and your third party payer (such as health insurance or Medicare). This does not mean that you are releasing or waiving any legal right you might have against the researcher or NDSU as a result of your participation in this research.

What if I have questions?
Before you decide whether to accept this invitation to take part in the research study, please ask any questions that might come to mind now. Later, if you have any questions about the study, you can contact the researchers: Michael McCrone at (608)-295-9988, or michael.mccrone@ndsu.edu; and Katie Lyman, Katie.lyman@ndsu.edu, (218)-443-6446.

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

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

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

Documentation of Informed Consent:
You are freely making a decision whether to be in this research study. Signing this form means that

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

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

_____ _____
Your signature Date

_____
Your printed name

_____ _____
Signature of researcher explaining study Date

_____
Printed name of researcher explaining study

APPENDIX C. HEALTH HISTORY QUESTIONAIRE

Health History Questionnaire

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

Name:_____ Ht.:_____ Wt.:_____

Gender:_____ Age:_____ Birthdate:_____

Address: _____

City:_____ State:_____ ZIP:_____ Phone:_____

Emergency Contact:_____ Phone: _____

Personal Physician:_____ Phone:_____

E-mail:_____

1. Have you ever had a definite or suspected heart attack or stroke? .....Yes No

2. Have you ever had coronary bypass surgery or any other type of heart surgery? .....Yes No

3. Do you have any other cardiovascular or pulmonary (lung) disease (***other than*** asthma, allergies, or mitral valve prolapse)? .....Yes No

4. Do you have a history of: diabetes, thyroid, kidney, liver disease. .....Yes No **(circle all that apply)**

5. Have you ever been told by a health professional that you have had an abnormal resting or exercise (treadmill) electrocardiogram (EKG)? .....Yes No

6. If you answered YES to any of Questions 1 through 5, please describe:

_____

_____

_____

_____

7. Do you currently have any of the following:
   a. pain or discomfort in the chest or surrounding areas that occurs when you engage in physical activity? ..... Yes No
   b. shortness of breath ..... Yes No
   c. unexplained dizziness or fainting ..... Yes No
   d. difficulty breathing at night except in upright position ..... Yes No
   e. swelling of the ankles (recurrent and unrelated to injury) ..... Yes No
   f. heart palpitations (irregularity or racing of the heart on more than one occasion) ..... Yes No
   g. pain in the legs that causes you to stop walking (claudication) ..... Yes No
   h. known heart murmur ..... Yes No

Have you discussed any of the above with your personal physician? ..... Yes No

8. Are you pregnant or is it likely that you could be pregnant at this time? ..... Yes No
   If yes, what is your expected due date?_____

9. Have you had surgery or been diagnosed with any disease in the past 3 months? ..... Yes No
   If yes, please list date_____ and surgery/disease_____

10. Have you had high blood cholesterol or abnormal lipids within the past 12 months or are you taking medication to control your lipids? ..... Yes No

11. Do you currently smoke cigarettes or have quit within the past 6 months? ..... Yes No

12. Have your father or brother(s) had heart disease prior to age 55 OR mother or sister(s) had heart disease prior to age 65? ..... Yes No

13. Within the past 12 months, has a health professional told you that you have high blood pressure (systolic $\geq$ 140 OR diastolic $\geq$ 90)? ..... Yes No

14. Currently, do you have high blood pressure or within the past 12 months, have you taken any medicines to control your blood pressure? ..... Yes No

15. Have you ever been told by a health professional that you have a fasting blood glucose greater than or equal to 110 mg/dl? ..... Yes No

16. Describe your regular physical activity or exercise program:
    type:_____
    frequency: _____ days per week
    duration: _____ minutes
    intensity: *low* *moderate* *high* **(circle one)**
    BMI: _____

17. If you have answered YES to any of questions 7-16, please describe:

_____

_____

_____

P04-020

18. Are you currently under any treatment for any blood clots? ..... Yes No

19. Do you have problems with bones, joints, or muscles that may be aggravated with exercise? ..... Yes No

20. Do you have any back/neck problems? ..... Yes No

21 Have you been told by a health professional that you should not exercise? ..... Yes No

22. Are you currently being treated for any other medical condition by a physician? ..... Yes No

23. Are there any other conditions (mitral valve prolapse, epilepsy, history of rheumatic fever, asthma, cancer, anemia, hepatitis, etc.) that may ***hinder*** your ability to exercise? ..... Yes No

24. During the past six months, have you experienced any ***unexplained*** weight loss or gain (greater than ten pounds for no known reason)? ..... Yes No

25. If you have answered YES to any of questions 18-24, please describe:

_____

_____

_____

26. Please list below all prescription and over-the-counter medications you are currently taking:

Medicine:	Reason for taking:	Dosage:	Amount/Frequency:

27. Are there any medicines that your physician has prescribed to you in the past 12 months which you are currently not taking? ..... Yes No
If so, please list:

_____

_____

_____

I have answered the Health History Questionnaire questions accurately and completely. I understand that my medical history is a very important factor in the development of my fitness/wellness program. I understand that certain medical or physical conditions which are known to me, but that I do not disclose to my trainer, may result in serious injury to me. If any of the above conditions change, I will immediately inform my trainer of those changes. I, knowingly and willingly, assume all risks of injury resulting from my failure to disclose accurate, complete, and updated information in accordance with the attached questionnaire. I also understand that in order to properly risk stratify my Health History Questionnaire, my trainer should have a minimum of a national certification as a personal trainer. My trainer also verbally explained this statement to me to my understanding.

Client's Signature:_____ Date:_____

Trainer's Signature:_____ Date:_____

For Use by the Personal Trainer ONLY

Check the identified ACSM major coronary risk factors below:

_____ Lipids (TCH ≥ 200 OR HDL < 35)
_____ Family History
_____ Diabetes/glucose ≥ 110 mg/dl
_____ BMI ≥ 30
_____ Metabolic Disease
_____ Signs or Symptoms of Cardiovascular Disease_____
_____ Cardiovascular Disease_____
_____ Cigarette Smoking (or quit within the past 6 months)
_____ High Blood Pressure/Blood Pressure Medications
_____ Sedentary
_____ Pregnancy
_____ Respiratory Disease (asthma, emphysema, chronic bronchitis)

Risk Stratification	Factors
_____ Apparently Healthy	One or No Risk Factors (No medical clearance required)
_____ Apparently Healthy Male ≥ 45; Female ≥ 55	One or No Risk Factors (Initial medical clearance required)
_____ High Risk, No Signs or Symptoms	Two or More Risk Factors (medical clearance required)
_____ High Risk, with Signs and Symptoms	One or More Signs/Symptoms With or Without Risks (medical clearance required)
_____ Known Disease	Diagnosed Cardiopulmonary/Metabolic Disease (annual medical clearance required)
_____ Pregnancy	Medical Clearance Required

All clients needing written medical clearance from their personal physician must give it to their trainer prior to beginning their exercise program.

Additional Comments: _____

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

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

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

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

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

Premier Performance, Inc.
1457 Cambridge Common
Decatur, Georgia 30033
404-406-2873
pperform@bellsouth.net

American Council on Exercise
4851 Paramount Dr.
San Diego CA 92123
800-825-3636
www.ACEfitness.org