THE RATE OF INTRAMUSCULAR TISSUE TEMPERATURE REDUCTION BETWEEN WETTED ICE WITH ELASTIC WRAP AND GAME READY®

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

By

Courtney Rae Anderson

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

Major Program:
Advanced Athletic Training

February 2020

Fargo, North Dakota

North Dakota State University
Graduate School

Title

The Rate of Intramuscular Tissue Temperature Reduction Between Wetted Ice with Elastic Wrap and Game Ready®

By

Courtney Rae Anderson

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:

Dr. Kara Gange
Chair

Dr. Bryan Christensen

Dr. Rachelle Vettern

Approved:

02/27/2020
Date

Dr. Yeong Rhee
Department Chair

ABSTRACT

In recent years, the Game Ready® unit has become a popular cryotherapy modality to treat musculoskeletal injuries. The purpose of this study was to determine which cryotherapy method, wetted ice bag with elastic wrap or Game Ready®, decreases triceps surae intramuscular tissue temperature the most during a 30-minute treatment. The independent variables were the cryotherapy modalities (Game Ready® and wetted ice with elastic wrap) and time (baseline, 10, 20, and 30 minutes).

Twenty patients participated in this study. Wetted ice with elastic wrap decreased tissue temperatures significantly greater than Game Ready® at 20 minutes ($P = 0.03$), and 30 minutes ($P = 0.02$). Since wetted ice with elastic wrap produced a greater and faster decline in intramuscular tissue temperature compared to Game Ready® on medium pressure, this cryotherapy modality should be utilized in the immediate care phase of the injury repair process.

ACKNOWLEDGEMENTS

I would like to extend a thank you to my advisor, Dr. Kara Gange, as well as my committee members, Dr. Rachelle Vettern and Dr. Bryan Christensen, for their help and support along the way. In addition, I would like to thank my parents, Rollie and Denise Anderson, for always encouraging me throughout this process. I would also like to extend a special thank you to Kathleen Vesta, ATC and Jenna Treloar, ATC for continuing to hold me accountable and encouraging me to push through challenges throughout this long journey. Without all of their support and expertise, this study would not have been possible.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDIX FIGURES

Figure Page

CHAPTER 1. INTRODUCTION

Cryotherapy, or cold therapy, is a frequently chosen intervention by clinicians for the treatment of musculoskeletal injuries.[1-3] Cold therapy produces a decline in tissue temperatures as the body responds to the transfer of heat, resulting in a decrease in cell metabolism,[4-6] muscle spasm,[7,8] pain,[7,8] and edema prevention.[9,10] Several types of cryotherapy treatments exist including ice bag, cold whirlpool, ice massage, Game Ready®, and any other form of cold modality applied to the body that causes therapeutic effects.[11] The primary goal immediately (first 24 hours) after an injury occurs is to lower tissue temperature, ultimately resulting in decreased cellular metabolism to reduce the risk of secondary hypoxic injury.[12,13]

For several decades, ice has been combined with compression to initiate a greater tissue temperature reduction, as well as rid the injured site of inflammation.[4] The majority of research performed on ice with compression compared to ice alone has supported ice combined with compression results in a greater, and faster, decline in intramuscular tissue temperature.[4,12] Clinically, ice bags combined with either flexi-wrap or elastic wrap are a commonly used cold modality for providers during the immediate care of musculoskeletal injuries. Generally, providers select either cubed ice or crushed ice bags. While wetted ice (ice and water added to an ice bag and used together with a dry interface[10]) is another option for clinicians, it is not often chosen. However, based on minimal research, wetted ice has been shown to be more effective at decreasing intramuscular tissue temperature compared with crushed ice and cubed ice.[10]

Similar to wetted ice, limited research exists on the Game Ready® modality. In recent years, the clinical use of Game Ready® has become a growing phenomenon within the athletic training population. The Game Ready® is a unit that combines intermittent compression with cold to provide a cooling effect on the body. Currently, the minimal research on Game Ready®

has shown the medium pressure setting decreases tissue temperature more than the high, low, or no pressure settings.[3,13,14] However, Game Ready® set on medium pressure is less effective at reducing intramuscular temperature compared with an ice bag treatment.[3,13,14] Clinically, Game Ready® is being used as an immediate care modality due to its convenience, but the evidence supporting the use of Game Ready® as an immediate care intervention is not well supported in the literature. No evidence exists to support the optimal tissue temperature decrease for specific physiological results with cryotherapy. However, the literature is consistent with modalities producing colder temperatures are considered a better immediate care modality to decrease cell metabolism as much as possible.[10,12,15] Currently, no research has been performed comparing a wetted ice bag and elastic wrap versus Game Ready® to determine which causes a greater reduction in tissue temperature.

Statement of Problem

Due to the convenience of Game Ready®, it is being used as an immediate care intervention. Findings in the literature have indicated wetted ice cools tissue temperature more than cubed or crushed ice based on the assumption that colder is better.[10,12,15] Conversely, research on Game Ready® has revealed ice bags and slush buckets cause a greater reduction in tissue temperature compared to Game Ready®.[3,13] However, no study exists comparing the effects of Game Ready® versus wetted ice on intramuscular tissue temperature reduction as immediate care interventions.

Purpose of the Study

The purpose of this study was to determine which cryotherapy method, wetted ice bag with elastic wrap or Game Ready® set at medium pressure, was most effective at decreasing tissue temperature during a 30-minute treatment. Based on the results, this study may help contribute to the existing literature on tissue temperature reduction of both Game Ready® and wetted ice to determine the better modality to use for immediate care.

Research Questions

1. Which cryotherapy method, Game Ready® or wetted ice with elastic wrap, was the most effective at decreasing intramuscular tissue temperature during a 30-minute application in patients aged 18-40 years old?
2. Which cryotherapy method, Game Ready® or wetted ice with elastic wrap, achieved an intramuscular tissue temperature reduction the fastest?

Definition of Terms

Cryotherapy: therapeutic use of cold; the application of a device or substance with a temperature less than body temperature, thus creating heat to pass from the body to the cryotherapy device.[16]

Game Ready®: unit that combines intermittent compression with cold therapy.[17]

Wetted Ice: ice and water added to an ice bag and used together with a dry interface.[10]

Chemical Mediators: chemicals, such as histamine, bradykinin, and cytokines, that mobilize the body's resources after injury to neutralize the cause of the injury and to begin removing the cellular debris so repair can take place.[16]

Primary Injury: cellular damage caused by an acute traumatic force.[16]

Secondary Injury: cellular injury caused by enzymatic action and metabolic deficiency.[16]

Modality: application of a form of energy to the body that elicits an involuntary response.[18]

Secondary Enzymatic Injury: cellular damage resulting from enzymes, such as those in lysosomes, released from damaged cells.[16]

Secondary Metabolic Injury: cellular damage resulting from a metabolic imbalance secondary to an acute traumatic orthopedic injury.[16]

Hypoxia: inadequate oxygen in body tissue, often resulting from prolonged ischemia.[16]

Ischemia: local and temporary deficiency of blood supply caused by obstruction of circulation to a body part.[18]

Importance of the Study

The importance of this project was to provide clinicians with an understanding of whether Game Ready® or wetted ice is better at temperature reduction. Therefore, the findings of this study will help providers determine which cryotherapy method is the best option for immediate care treatments. Clinically, these results could potentially change the way providers are currently choosing to treat immediate and acute injuries.

Limitations of the Study

1. Thermocouple insertion was completed by a researcher limited to only months of experience with the technique, potentially skewing the intramuscular temperature readings due to improper insertion depth.
2. The elastic wrap was applied by the same researcher trying to apply approximately 75% tension starting distal to the treatment area and gradually decreasing the tension as it was applied proximally. To maintain pressure consistency, the researcher practiced applying the elastic wrap on simulated patients prior to performing the application on the study participants.
3. The study was limited to healthy participants only, making the data hard to generalize to an injured population.

4. The Game Ready® sleeve used on each subject was one size fits all, which may have impacted tissue cooling.

Delimitations of the Study

1. Participants were 18-40 year-old healthy males and females without a dominant lower leg injury within the past 6 months.
2. Subjects were excluded if they had a triceps surae adipose thickness ≥ 1 cm, a history of cardiovascular problems, any abnormalities found using diagnostic ultrasound over the treatment area, any contraindications to cryotherapy, infections over the treatment area, and any allergies or sensitivities to betadine.
3. Two interventions were used: wetted ice bag filled with 300 mL of water and 1 kg of cubed ice wrapped on with an elastic wrap; and a Game Ready® unit set at medium pressure.
4. All subjects received both interventions separated by a minimum of two days and a maximum of 10 days between treatments.
5. The total treatment duration consisted of a baseline period until the temperature stayed consistent for a minimum of 1 minute, followed by a 30-minute cryotherapy treatment.

CHAPTER 2. LITERATURE REVIEW

The purpose of this study was to determine which cryotherapy method, wetted ice bag with elastic wrap or Game Ready® set at medium pressure, decreased tissue temperature the most during a 30-minute treatment. The research questions guiding this study were: 1) Which cryotherapy method, Game Ready® or wetted ice with elastic wrap, was the most effective at decreasing intramuscular tissue temperature during a 30-minute application in patients aged 18-40 years old? 2) Which cryotherapy method, Game Ready® or wetted ice with elastic wrap, achieved an intramuscular tissue temperature reduction the fastest? This literature review discusses information about the injury repair process, cryotherapy, and specific types of cryotherapy applications, including Game Ready® and wetted ice. The review of literature is organized into the following areas: cryotherapy and the injury repair process, specific heat and law of thermodynamics, and Game Ready®.

Cryotherapy, or cold therapy, has been a commonly used modality for clinicians for the management of musculoskeletal injuries.[1-3] Cold therapy produces a decline in tissue temperature as the body responds to the transfer of heat, resulting in a decrease in cellular metabolism,[4-6] muscle spasm,[7,8] pain,[7,8] and edema prevention.[9,10] Various forms of cryotherapy treatment exist including cold whirlpool, ice bag, Game Ready®, ice massage, and gel packs.[11] The primary goal immediately after an injury occurs is to lower tissue temperature, ultimately resulting in decreased cellular metabolism to reduce the risk of secondary hypoxic injury.[19,20] Ice combined with compression is a routinely used modality for decreasing tissue temperature and inflammation.[3,9] Game Ready® is a unit that combines intermittent compression with cold therapy and has become a popular treatment among clinicians; however, limited research has been conducted on the effectiveness of Game Ready® on tissue temperature reduction compared to other cryotherapy treatments.

Cryotherapy and The Injury Repair Process

Cryotherapy is a modality used to treat injuries immediately after they occur because of its effects on decreasing secondary injury.[21,22,23] However, the physiology of injury is a complex process and is not well understood by clinicians. Initially when tissue damage occurs to the musculoskeletal system as a result of trauma, this is termed the primary injury.[22] During the primary injury, ultrastructural changes occur.[16] Knight[16] describes ultrastructural changes as the breakdown and eventual disruption of the cellular membrane and its organelles of the uninjured tissues around the primary injury. This physiologic response causes changes in metabolic processes thus, resulting in secondary injury.

Chemical mediators, such as histamine, bradykinin, and cytokines are activated to alert the body that tissues have been damaged and further resources are needed to respond to help regulate the inflammatory process.[16] Chemical mediators protect the body from invading organisms, reduces blood loss, and promotes healing.[24] The purpose of chemical mediators being released is to attract neutrophils and macrophages to damaged tissue. Neutrophils control acute inflammation, and macrophages control chronic inflammation and may remain at damaged tissue sites for extended periods of time.[24] After the primary injury takes place, arterial dilation occurs and an increase in blood flow to the injured area follows, resulting in cellular oncosis and pain.[16,22,24] Blood flow to the injured tissue increases, causing leukocytes to travel to the vessel walls.[16] Then, leukocytes attach to the endothelium to help with coagulation, a necessary process responsible for producing a clotting mechanism to reduce excess blood loss and prevent further tissue damage.[16,24] These hemodynamic changes lead to ischemia, or a decrease in cellular oxygen known as hypoxia.[21] Thus, the cellular membrane disruption alerts chemical mediators to respond in an attempt to maintain a level of homeostasis.

The body is made up of two major compartments, extracellular and intracellular fluid compartments. Sodium is the major ion responsible for maintaining extracellular fluid while potassium is responsible for maintaining intracellular fluid.[24] Healthy cells require oxygen and adenosine triphosphate (ATP) for proper functioning of the sodium potassium pump and is typically supplied by aerobic metabolism. Consequently, anaerobic metabolism is required to achieve normal energy requirements when cells are in a hypoxic state.[16] Anaerobic metabolism produces a buildup of lactic acid and nitric oxide in the cellular membrane.[16,24] This overproduction of lactic acid leads to a decrease in cellular energy and a decline in function of the sodium potassium pump, which is vital in maintaining minimal amounts of intracellular sodium.[16,22] In addition, the calcium pump also declines in function leading to an increase in intracellular calcium and increasing the chances of cell death.[24] Prolonged states of hypoxia produce acidosis, resulting in ruptured lysosome membranes, and ultimately leading to an increase in tissue destruction.[16,22] As a result, increased intracellular sodium and calcium initiate metabolic changes during the inflammatory process leading to secondary tissue injury.

Histamine and bradykinin are chemical mediators that travel to the injured tissue to regulate the inflammatory process, but they also trigger permeability changes. Permeability changes cause a decline of fluid within the blood vessels, ultimately blocking circulation to the injured site.[16] This becomes problematic when protein-rich fluids escape outside of the injury site and become too big to be reabsorbed into the blood stream. Protein-rich fluids increase oncotic pressure and cause a larger hematoma, ultimately resulting in edema in the interstitial space.[16,22,24] Then, protein enzymes break down the cellular membrane by splitting hydrocarbon bonds from membrane phospholipids.[21] After injury has occurred, the small vascular structures, such as capillaries, arterioles, and venules, become damaged. This can then lead to damage of the larger vascular structures, such as arteries and veins, potentially resulting in further blood loss.[25] These permeability changes within the cell membrane eventually lead to cellular necrosis.[21]

While permeability changes are transpiring, leukocyte migration towards the damaged tissue is happening simultaneously. Leukocytes are white blood cells that respond to an injured area to help fight off infection and inflammation.[26] Leukocyte migration tends to be higher in areas where more tissue damage has occurred and lower where minimal tissue damage has occurred.[16]

Typically, two types of white blood cells are involved in the inflammatory process, neutrophils and macrophages.[16,26] Neutrophils are the first leukocytes to arrive at the injury site and are the first line of defense against harmful organisms.[16,26] Generally, neutrophils are small in diameter, fast traveling, non-reproducible, and short-lived cells.[16] Although neutrophils play a significant role in limiting infection and inflammation, they also have tissue destroying potential; thus, excess amounts may cause harm to adjacent cells.[26] Alternatively, macrophages are larger in diameter, reproducible, and longer lasting. The primary function of macrophages is to control acute inflammation and clean tissue debris, but they can remain in an injured site for extended periods of time to assist in controlling chronic inflammation.[24] In addition, their reproducible nature permits them to release necessary growth factors to impaired cells allowing tissue repair and regeneration to take place. Thus, neutrophil and macrophage migration plays a vital role in the inflammatory process to aid in cellular regeneration and repair by cleaning tissue debris and controlling edema formation.

Lastly, phagocytosis is another process ensuing as part of the injury repair process. Phagocytosis is the process of removing damaged tissue from an injured area.[27] For phagocytosis to occur, neutrophils have to be present; but excess neutrophil invasion has been proposed to be a cause of secondary injury.[27] In addition, macrophages also have to be present for phagocytosis to occur and they require neutrophils to be present. As both types of leukocytes respond to damaged tissue, they begin to clean up debris and other harmful organisms by enclosing the particles in a sac called a phagosome.[16] After the leukocytes break down the foreign substances and debris, the contents are then released as free proteins into the interstitial space. These proteins pull fluid and waste products from the capillary beds into the tissue's interstitial spaces.[16] The additional free proteins accumulating in the tissue results in more fluid pulled out of the capillary beds and into the interstitial spaces. This results in an increase in edema. To conclude, phagocytosis cleans up foreign debris from injured tissue sites and expels the contents as free proteins, which may be a factor in initiating secondary injury.

Secondary injury is theorized to occur from two mechanisms, enzymatic or hypoxic.[21,22] Secondary enzymatic injury occurs when dead and dying cells around the primary injury site release enzymes. Enzymes released to the surrounding tissue are theorized to be phospholipases, proteases, and hydrolases; although, the specific identification of these enzymes has not been discovered.[21,22] The release of enzymes produces changes to the cellular membrane, resulting in hydropic swelling and eventually, cell death.[22]

Secondary hypoxic injury occurs as a result of ischemia, defined as the local and temporary deficiency of blood supply caused by obstruction of circulation to a body part.[18,21,22] Ischemia develops from a number of factors, such as damaged blood vessels, reduced blood flow, and increased extracellular pressure.[22] Prior to ischemia development, blood supply is reduced and intracellular edema forms and results in cellular damage.[24] Due to a lack of blood flow, oxygen and nutrients are not being delivered to cells. Since oxygen is no longer being supplied to the mitochondria, the production of ATP is stopped and anaerobic metabolism takes over.[16,22] After the tissues have been deprived of oxygen, cellular death occurs and leads to further swelling and hematoma formation around the damaged site.[16] Researchers have discovered hypoxia leads to mitochondrial damage and is typically observed within the first six hours after primary injury has occurred.[21] Thus, clinicians should be aware of the ischemia time frame after the primary injury to use modalities which limit the amount of secondary hypoxic injury from occurring.

Specific Heat and Law of Thermodynamics

For a cooling effect to take place in the body, a transfer of heat must occur first. The energy transfer of heat during cryotherapy applications can occur through conduction, convection, evaporation, or a combination of all three.[15] Ice bags and gel packs commonly absorb heat through conduction, or the transfer of heat occurring between two objects in contact with one another.[15,18] As long as water is continuously circulating, cold whirlpools absorb heat through convection, the transfer of heat through a medium.[15,18] Heat transfer can also occur when liquids change to gases, which is known as evaporation. Wet-Ice® is an example of a cold modality that changes from a liquid to gaseous state.[15] The transfer of heat only occurs in one direction making cryotherapy efficient because it transfers heat from the body tissues toward the cold modality, giving it the ability to absorb the heat and produce a greater reduction in tissue temperature.[15] Different types of cryotherapy can affect how much heat the modality can absorb.

The goal of cryotherapy is to reduce intramuscular temperature; however, the rate of muscle cooling could be delayed by the amount of adipose thickness present. The skin is the first to lose heat to the modality, followed by the adipose tissue, fascia, and then the muscle.[18] Adipose is a factor that slows the rate of tissue temperature reduction, and this is true based on the law of thermodynamics.[20,28] The thicker the adipose tissue, the longer it takes the heat from the muscle to move to the modality. Since muscle is the final tissue to decrease in temperature, clinicians need to make conscious choices regarding the duration of cryotherapy treatments.

In addition, thermal energy must be transferred from an area of higher temperature to an area of lower temperature, which then leads to the heat transfer from the skin to the modality.[15,29] However, different cold modalities have different thermodynamic properties. An ice bag goes through what is commonly known as a phase change, which means the ice will go from a solid to a liquid state without changing temperature or chemical composition.[16] This phase change allows more heat absorption to occur and causes tissue temperature to decline more rapidly.[10]

On the contrary, frozen gel packs do not go through a phase change; thereby, limiting the amount of heat absorption and slowing the rate of intramuscular tissue cooling.[15,16] Frozen gel packs are stored at low temperatures making the skin susceptible to frostbite if a barrier, such as a towel or cloth, is not applied over the treatment site. However, adding a barrier to conserve the skin decreases the effectiveness of temperature cooling.[16] Typically, ice bags can be applied directly to the skin without causing harm since they go through a phase change. Adding a dry or damp towel between the ice bag and skin provides an insulating effect on the skin and impedes the modality's effectiveness of heat transfer.[16] Thus, if the cryotherapy treatment goal is temperature reduction, clinicians should be aware of which cold modalities require the use of a barrier, as well as which ones go through a phase change.

Another factor influencing the rate of heat transfer is specific heat. Specific heat is the amount of heat needed to raise the tissue temperature a specific number of degrees.[15] The effectiveness of heat transfer depends largely on the differences in temperatures between the cryotherapy method and the skin. If the temperature gradient is high between the skin and the modality, the faster heat is transferred, causing tissue cooling to go deeper.[18] On the other hand, if the temperature gradient between the skin and cold modality is low, the slower the exchange of heat transfer, resulting in more superficial tissue cooling. The cryotherapy method chosen will proceed to transfer heat from the body until the tissue temperature of the skin and modality are relatively proportionate. When utilizing cryotherapy as a means of tissue temperature reduction, one must also consider the environmental temperature as the cold modality will gain heat from the outside air, potentially causing a smaller drop in temperature.[18]

Factors Affecting Cryotherapy

Specific to considerations on intramuscular tissue temperature reduction, researchers have reported a variety of factors can impede tissue cooling. Some of these factors are identified as the type of cold modality,[18] specific heat,[18] insulating medium between modality and skin,[18] treatment duration,[18] treatment area,[18] compression wrap usage,[4,12] post-treatment activity,[18] adipose,[7,20] target tissue depth,[4] vascularity of target tissue,[18] cell metabolism,[18] sympathetic nervous system,[18] and resting muscle temperature.[18] While all of these are factors that may hinder intramuscular temperature reduction, only compression wrap usage, adipose thickness, and target tissue depth are of importance in this literature review.

For several decades, ice has been combined with compression to initiate a greater tissue temperature reduction, as well as to rid the injured site of inflammation.[4] Merrick et al[4] examined intramuscular temperature responses to ice combined with compression wraps at various tissue depths. This study was a 3 x 4 repeated measures design; thus, each participant underwent all four treatments (crushed ice bag alone, elastic wrap alone, ice + elastic wrap, and no treatment).

Eleven subjects (age = 23.5 ± 2.1) participated in this study. Each participant had a mark placed within a 6 x 6-centimeter area on their anterior thigh halfway between the patella and anterior superior iliac spine (ASIS) to mark the thermocouple insertion site. Two thermocouples were inserted 1 cm medial and 1 cm lateral to the pen mark using 21-gauge hypodermic needles at three different tissue depths (skin surface, adipose + 1 cm, adipose + 2 cm). Skinfold measurements were taken to determine each participant's adipose thickness. Researchers considered 1 cm below adipose to be superficial tissue depth and 2 cm below adipose to be deep intramuscular tissue depths. The researchers applied a manometer and adjusted the pressure between 42 mmHG and 48 mmHG to ensure pressure consistency of the elastic wraps. Each person underwent all four interventions separated by a minimum of one day between treatments.

During each of the four treatments, temperatures were recorded every 30 seconds during a five-minute pre-application, 30-minute treatment application, and a 20-minute post-application. Crushed ice alone reduced temperatures by almost 10˚C at a depth of 1 cm below adipose and approximately 8˚C at a depth of 2 cm below adipose. Ice combined with compression reduced tissue temperatures approximately 13˚C at a depth of 1 cm below adipose and reduced tissue temperature approximately 10˚C at a depth of 2 cm below adipose. Compression alone had little effect on increasing tissue temperature compared to baseline; however, temperatures did rise slightly, supporting compression is an insulator. The specific temperature differences are presented in Table 2.1.

Table 2.1. Average Temperatures at Time of Greatest Treatment Effect (Temperature ± SD).

Treatment	**Adipose + 1 cm**	**Adipose + 2 cm**
Preapplication	36.28 ± 0.74	36.59 ± 0.71
Control (No Treatment)	36.13 ± 0.62	36.38 ± 0.52
Compression Only	36.25 ± 0.51	36.47 ± 0.47
Crushed Ice Only	26.58 ± 3.66	28.21 ± 2.34
Ice + Compression	23.54 ± 3.33	26.46 ± 3.04

In addition to investigating adipose, the researchers also compared the rate at which ice combined with compression versus crushed ice alone cooled tissue temperature the fastest. Ice combined with compression decreased tissue the most after approximately 32 minutes at 1 cm below adipose and nearly 35 minutes at 2 cm below adipose. The average time to achieve the greatest treatment effect with ice alone took approximately 36 minutes at 1 cm below adipose and approximately 39 minutes at 2 cm below adipose. Specific variations in treatment times are listed in Table 2.2. Overall, the results of this study supported ice combined with compression significantly ($P < 0.05$) reduced tissue temperature more than ice alone and at a faster rate.

Table 2.2. Average Time of Greatest Treatment Effect (Minutes ± SD).

Treatment	**Adipose + 1 cm**	**Adipose + 2 cm**
Control (No Treatment)	30.32 ± 1.95	30.32 ± 1.95
Compression Only	30.73 ± 6.40	31.41 ± 6.38
Crushed Ice Only	35.95 ± 3.75	39.23 ± 5.09
Ice + Compression	32.86 ± 1.93	35.32 ± 4.72

General practice from athletic trainers typically consists of using some type of external compression wrap to secure an ice bag to the skin. Elastic wrap has historically been a common form of external compression; however, due to its convenience, flexi-wrap is being used more often. In spite of this, no evidence existed supporting flexi-wrap cools tissue more than elastic wrap, so Tomchuk et al[12] explored which type of external compression wrap produced a greater tissue temperature reduction. This study was a 2 (tissue depth: skin surface and IM depth at 2 cm) x 3 (compression: no compression, flexi-wrap, and elastic wrap) x 13 (treatment time in minutes: 0, 5, 10, 15, 20, 25, 30, 40, 50, 60, 70, 80, 90) repeated measures design that included 14 subjects (age = 22.4 ± 1.8 years). Researchers stated each type of wrap was applied circumferentially, from distal to proximal, so 2 layers of the wrap covered the ice. Thermocouples were inserted into each participant's right posterior calf using a 21-gauge needle at an absolute tissue depth of two centimeters.

One of the three interventions was applied per day with a minimum of 24 to 48 hours in between treatments. Each participant rested for 15 minutes prior to the treatment to gain a baseline temperature reading. Then, the intervention was applied for 30 minutes. After the treatment concluded, the ice bag and compressive wrap were removed. All participants were instructed to remain in the prone position for one-hour post treatment to record tissue temperature changes at rest. The researchers concluded at 10 minutes of ice application, both the elastic and flexi-wrap application produced statistically significant differences in intramuscular temperature changes compared with no compression ($P < 0.001$). After 25 minutes, ice combined with elastic wrap produced a statistically significant difference in intramuscular temperature reduction compared to ice combined with flexi-wrap ($P = 0.03$). Exact temperature changes at specific time points are listed in Table 2.3. The researchers concluded elastic wrap provided a greater insulation effect than flexi-wrap; thus, the ice bag treatment with elastic wrap produced greater changes in temperature reduction compared to ice with flexi-wrap. The results of this study support ice combined with elastic wrap produces a greater reduction in tissue temperature compared to ice and flexi-wrap, which is clinically significant in the initial management immediately after injury occurs.

Table 2.3. Intramuscular Temperature Changes Between Three Compression Types (˚C).

Time (min)	Ice Only	Ice with Flexi-Wrap	Ice with elastic wrap
Baseline	35.12 ± 0.63	35.04 ± 0.58	34.93 ± 0.65
10 min	33.78 ± 0.77	32.58 ± 1.20	32.20 ± 0.86
20 min	31.52 ± 1.05	29.67 ± 1.52	28.45 ± 1.42
30 min	29.52 ± 1.18	27.17 ± 1.77	25.53 ± 1.56

Comparison of Intramuscular Tissue Temperature Changes with Cryotherapy

Historically, clinicians have used cryotherapy to treat acute musculoskeletal injuries due to the physiologic responses it produces. Thus, understanding how these changes occur prior to cold application is beneficial.[4,7,20] Cryotherapy is any therapeutic application of cold on the body ranging between approximately 0-18°C (32-65 °F) that initiates the transfer of heat, ultimately leading to a reduction in tissue temperature.[1,18] When cold therapy is applied, it causes a decline in blood flow,[1,12] cellular metabolism,[4-6] pain,[7,8] muscle spasm,[7,8] and tissue extensibility[1] in the body's response to heat loss. Heat transfer from skin to the cryotherapy modality allows these physiologic effects to occur.[18] The goal of immediate care after an injury is to decrease the cellular metabolism to decrease or prevent as much secondary injury as possible.[19,20] No evidence exists to support the optimal tissue temperature decrease for specific physiologic results with cryotherapy. However, the literature supports a greater and faster decline in intramuscular tissue temperature results in reduced cellular metabolism, causing less secondary injury.[15] Since the goal is to reduce as much secondary injury as possible after an injury is sustained,[19,20] research suggests cryotherapy application in the immediate stages of healing is beneficial due to its effects on reducing cellular metabolism.[15] Therefore, a greater decline in tissue temperature results in greater physiologic effects.[10,12,15]

Although ice bags filled with either crushed or cubed ice are typically applied by clinicians with the goal of reducing tissue temperature, wetted ice bags have also been used.

Wetted ice has been theorized to produce a greater decline in temperature because adding water fills in the spaces between the pieces of ice in the bag, resulting in increased contact between the skin and modality.[10,30] Ice bags without water transfers energy by air in the spaces between the ice. Water is a better conductor of thermal energy than air, making wetted ice bags a more efficient source of heat transfer, theorized to result in greater temperature reductions.[10,30] Wetted ice is not only a better conductor of thermal energy, but it is also hypothesized to go through a phase change quicker than ice alone. As discussed earlier, objects that go through a phase change allow more heat absorption to occur, leading to a more rapid drop in tissue temperature.[10] Thus, wetted ice is theorized to reduce tissue temperatures faster than other cryotherapy modalities.

Currently, only two studies have been performed comparing the effectiveness of wetted ice on decreasing intramuscular tissue temperature. Dykstra et al[10] compared the effects of cubed ice, crushed ice, and wetted ice on intramuscular tissue temperature. Six healthy men (Age = 23.7 ± 1.0 years) and six healthy women (Age = 22.8 ± 0.8 years) participated in this study. The averages of three skinfold measurements (Men: lateral calf skin fold = 12.8 ± 4.1 mm; Women: lateral calf skin fold = 17.3 ± 3.4 mm) were taken over the largest girth measurement of the lateral posterior calf in each participant. A 26-guage, 4-cm microprobe was used to measure intramuscular temperature changes. Each participant received the crushed ice, cubed ice, and wetted ice interventions, separated by a minimum of four days between each treatment. Both the crushed and cubed ice packs were filled with 2000 mL of the corresponding ice in a clear ice bag, and the wetted ice was filled with 2000 mL of cubed ice in a clear ice bag with 300 mL of room temperature water.

The researchers stated they chose 300 mL of water for the wetted ice group because that was the approximate amount of water left in the bag after a 20-minute cubed ice treatment during their pilot study. Temperatures were recorded every 30 seconds during a 20-minute baseline, 20-minute application, and 120-minute recovery period. The researchers discovered wetted ice produced the greatest decline in tissue temperature during the 20-minute treatment, followed by cubed ice and then crushed ice. Researchers also reported tissue temperatures remained cooler in the wetted ice group after the 120-minute recovery period, followed by the cubed ice group and then the crushed ice group. Dykstra et al[10] concluded wetted ice produced intramuscular temperature changes that were most similar to cubed ice, as seen in Table 2.4. In addition, the greatest intramuscular temperature decrease occurred with wetted ice (6.0˚C), followed by cubed ice (4.8˚C), and then crushed ice (4.3˚C).

Table 2.4. Intramuscular Temperature Changes During Treatment and Recovery.

	Cubed Ice	**Crushed Ice**	**Wetted Ice**
Treatment (20 minutes) Temperature, mean ± SD	32.9 ± 2.0	34.0 ± 1.8	32.8 ± 2.5
Recovery (120 minutes) Temperature, mean ± SD	30.9 ± 1.6	31.8 ± 1.6	30.4 ± 2.1

Furthermore, a second study conducted by Hunter et al[31] investigated the effects of wetted ice bags versus salted ice bags on intramuscular tissue temperature reduction. This study included 24 healthy subjects (13 men, 11 women; age = 22.46 ± 2.33; subcutaneous thickness = 0.63 ± 0.27 cm). A repeated measures cross-over design was used, and each subject had all three cryotherapy applications applied to their medial gastrocnemius muscle during three separate sessions. The treatment order was randomized. The three cryotherapy treatments included: a wetted ice bag containing 2000 mL of cubed ice combined with 300 mL of water, a salted ice bag containing 2000 mL of cubed ice and a half tablespoon of salt, and a salted ice bag containing 2000 mL of crushed ice and a half tablespoon of salt. Each session included a 10-minute baseline, 30-minute treatment, and a 45-minute rewarming period. A 26-guage hypodermic needle was inserted into each participant's medial gastrocnemius muscle with the thermocouple threaded a depth of 2 cm below adipose to record tissue temperature changes. Temperatures were recorded every 30 seconds during the treatment and every minute during the rewarming period.

The researchers discovered both the wetted ice bag and salted cubed ice bag produced significantly greater declines in intramuscular tissue temperatures compared with the salted crushed ice bag ($P < 0.001$). However, no statistical or clinical differences were observed between the salted cubed ice and wetted ice bag treatments ($P = 1.000$). During the 30-minute treatment, intramuscular temperatures declined 4.7˚C ± 1.56˚C in the wetted ice group and 4.5˚C ± 1.83˚C in the salted cubed ice group. Temperatures continued to cool for approximately 22 minutes post-treatment in all three groups; however, the wetted ice (6.6˚C ± 1.71˚C) and salted cubed ice (6.4˚C ± 1.60˚C) groups produced the greatest declines in intramuscular temperature. This study produced results similar to the Dykstra et al[10] study signifying wetted ice causes a greater reduction in tissue temperature compared to crushed ice bags. The treatment time in the Dykstra et al[10] study was 20 minutes and reduced tissue temperature 6˚C, while the treatment time in Hunter et al[31] was 30 minutes and reduced tissue temperature 6.6˚C. The results of these two studies indicate there is a correlation between treatment time and temperature reduction. In addition, the results of this study indicate wetted ice bags and salted cubed ice bags are equally effective in decreasing intramuscular tissue temperatures; however, adding salt to an ice bag is typically not used in an athletic training setting.

The effectiveness of wetted ice versus a traditional ice bag on skin temperatures was further explored by de Carvalho et al[32] Eighteen participants between the ages of 18 and 25 years old participated in the repeated measures study. Each subject had an ice bag containing 1 kg of ice applied to the left quadriceps, while an ice bag containing 760 g of ice and 240 g of water was simultaneously applied to the right quadriceps. The type of ice used, either crushed or cubed, was not specified. Superficial tissue temperatures were simultaneously recorded in each subject's left and right rectus femoris muscle using a Therma CAM® infrared camera at 0 minutes, 15 minutes, and 30 minutes post treatment. Each participant had to be acclimatized to the environment for 15 minutes prior to receiving the cryotherapy applications and tissue temperatures were recorded every 30 seconds during a 15-minute cryotherapy treatment.

Carvalho et al[32] reported wetted ice induced a statistically significant difference in tissue temperature decline than the ice bag treatment immediately after ($P = 0.0017$), 15 minutes after ($P = 0.0013$), and 30 minutes after ($P = 0.001$). The researchers reported wetted ice produced greater declines in tissue temperatures, but only superficial skin temperatures were measured. Since a very low correlation between skin and intramuscular temperatures exists, the results of this study cannot be generalized to intramuscular tissue, indicating the need for further studies. While three studies reported wetted ice produced a greater decline in tissue temperature, minimal evidence exists to support wetted ice is a better cryotherapy treatment during the immediate care of injury.

Clinically, cubed ice bags are common cryotherapy treatments used to reduce intramuscular temperature in the immediate stage after an injury occurs, whereas ice massage treatments are common in acute care. Zemke et al[19] examined intramuscular temperature responses between two cryotherapy treatments: a cubed ice bag and an ice massage. Seven males and seven females (age = 20.4 ± 1.3 years, percent body fat = 12.5 ± 7%) participated in this study. Four males and three females received the ice bag treatment, and four females and three males received the ice massage treatment. Adipose thickness in each participant was measured by calipers over the right posteromedial calf. A thermistor probe was inserted into each participant's medial calf at 1 centimeter below the adipose tissue. After five minutes, a baseline resting temperature for each participant was recorded, and the cryotherapy treatment was administered. The ice bag group consisted of an ice bag containing two cups of cubed ice placed on the posteromedial calf of each participant. During the treatment, temperature readings were recorded every 30 seconds over a 15-minute period. Participants assigned to the ice massage group underwent the same preparation and treatment as the ice bag group, with the only difference being the type of cryotherapy administered. A 4 x 4 cm area was marked 2.5 cm lateral to the thermocouple insertion site, and the ice cup was administered over the treatment site using overlapping horizontal strokes for 15 minutes. The treatment area was equal distance above and below the insertion site on the gastrocnemius muscle. Independent t-tests were completed for each group to determine the temperature differences.

The researchers concluded ice massage produced a 0.5˚C greater decrease in temperatures at the 5-minute mark, nearly a 1.5˚C greater decrease at the 10-minute mark, and approximately a 2˚C greater decrease at the 15-minute mark compared to the cubed ice treatment. In addition, ice massage achieved the greatest reduction in tissue temperature approximately 10.5 minutes faster than the ice bag treatment attaining statistical significance ($p \leq 0.05$). Specific temperature changes and times are presented in Table 2.5. The results supported both the ice bag and the ice massage decreased intramuscular tissue temperatures with no statistically significant difference ($P > 0.05$) between the two interventions. The actual p-value was not reported; however, the researchers stated they set the alpha level to 0.05.

Although ice massage achieved a reduction in intramuscular temperature faster than the ice bag treatment, it is not always feasible for an athletic trainer to provide ice massage treatments to all injuries. Ice massage treatments are typically performed for 5-10 minutes and ice bags are typically left on for a minimum of 20 minutes. In addition, ice massage is not used in the immediate care of injury since massages are contraindicated immediately after injury due to the increase in blood flow to the injured area, resulting in an increase in swelling. Therefore, ice bags would be a better treatment option to use immediately after injury.

Table 2.5. Intramuscular Temperature Changes During Treatment and Recovery.

Variable	**Ice Massage**	**Ice Bag**
Δ at 5 min	1.07 ± 0.64	0.64 ± 0.70
Δ at 10 min	3.09 ± 0.78	1.76 ± 1.37
Δ at 15 min	4.33 ± 0.10	2.30 ± 1.86
Time to lowest temp. (min)	17.86 ± 2.40	28.21 ± 12.50

Crushed ice bags and cold whirlpools are two of the most common cryotherapy interventions used by clinicians for the management of musculoskeletal injuries. Myrer et al[2] investigated which cryotherapy method, a crushed ice bag or cold whirlpool, decreased intramuscular temperature the most. Seventeen men (age = 25.2 ± 2.6 years) and 15 women (age = 21.7 ± 2.3 years) participated in this study equaling a total of 32 subjects. The intramuscular tissue temperature was measured using a 26-guage hypodermic needle microprobe that was inserted 1 cm below the adipose tissue. A baseline tissue temperature measurement was taken after three minutes of rest. Then, each subject was randomly assigned to either the crushed ice pack group or the cold whirlpool group. Nine men and seven women were assigned to the crushed ice pack group, while the cold whirlpool group had eight men and eight women. The ice pack contained 1.8 kg of crushed ice and was applied over the medial triceps surae muscle group for 20 minutes. Each subject in the cold whirlpool group immersed his/her left lower leg in the 244-L whirlpool to a depth of 5 cm below the knee joint for 20 minutes. The airflow of the whirlpool was kept on low and the left leg was kept 15-20 centimeters away from the airflow with a water temperature maintained at 10˚C. Temperature changes were recorded every 30 seconds during the 20-minute treatment time and 30-minute recovery time.

The researchers concluded both an ice bag with crushed ice and a cold whirlpool are effective at reducing intramuscular tissue temperatures. Although not statistically significant (P = 0.09), the crushed ice pack decreased tissue temperatures 2˚C more than the cold whirlpool (Table 2.6). Another discovery was the cold whirlpool continued to reduce tissue temperatures 30 minutes post treatment, while the tissue significantly rewarmed in the crushed ice group 30 minutes post treatment. The difference in the rewarming rates was statistically significant (P = 0.0001). Although the cold whirlpool maintained a greater reduction in tissue temperature post treatment, this intervention is typically not an immediate care treatment due to the patient being in a gravity dependent position rather than elevating the injured area. Based on the RICE (rest, ice, compression, elevation) protocol[16] for immediate care of injuries, elevation is used to help prevent edema formation. Therefore, cold whirlpool treatments are not typically used as an immediate care intervention.

Table 2.6. Intramuscular Temperature Changes.

Time Points (5 min intervals)	**Ice Pack**	**Cold Whirlpool**	**P-Values**
Baseline Temp.	34.9 ± 1.4	33.3 ± 2.1	0.01
Treatment 20 min - baseline	-7.1 ± 4.1	-5.1 ± 1.8	0.09
30 min. Post Treatment 50 min – 20 min	2.0 ± 3.1	-1.8 ± 1.4	0.0001

Clinically, several forms of cryotherapy, such as crushed ice, cubed ice, ice massage, and cold whirlpool are used to treat musculoskeletal conditions to produce a reduction in tissue temperature. Based on the three previous studies discussed, the use of cubed ice bags in the immediate care of injury is supported due to its effectiveness at decreasing intramuscular tissue temperature.[10,19] However, Dykstra et al[10] reported the wetted cubed ice bag was the most effective at decreasing intramuscular temperatures compared to a cubed ice bag and a crushed ice bag, which is clinically significant when immediate care is the primary concern.[19,20] Although cold whirlpool treatments maintained a greater reduction in tissue temperatures compared to a crushed ice bag, this is not a typical immediate care intervention.[2] Furthermore, crushed ice is being used more frequently for immediate care in athletic training rooms due to its convenience; however, wetted ice and cubed ice produced a greater decline in tissue temperatures.[10] Therefore, providers should be cognizant of which cryotherapy method they are utilizing during the immediate care of injury to achieve the greatest reduction in tissue temperatures.

Game Ready

In recent years, the clinical use of Game Ready® has become an evolving phenomenon within the athletic training population. Clinically, Game Ready® is being used as an immediate care modality due to its convenience, but the evidence to use Game Ready® as an immediate care intervention is not well supported in the literature.[3,13,33] The Game Ready® is a unit that combines intermittent compression with ice to provide a cooling effect on the body. Each unit has four adjustable pressure settings: no pressure, low pressure, medium pressure, and high pressure. Flexible wraps and sleeves are available for each of the major body parts including the knee, ankle, shoulder, elbow, wrist, back, hip/groin, and a cooling vest.[34] During a Game Ready® treatment, water continuously circulates through the flexible wrap or sleeve allowing the temperature to remain cold throughout the duration of the intervention.[34] Although Game Ready® claims it is “an easy-to-use system, making it easy for you to apply the two most difficult-to-manage aspects of the RICE (rest, ice, compression, and elevation) regimen” immediately after injury,[17] limited evidence exists to support the use of Game Ready® as an immediate care intervention.

Game Ready® claims it is a faster, deeper-penetrating, and longer-lasting cold device compared to other cryotherapy devices.[17,34] Game Ready® also states it is an easy to apply device used for the management of RICE (rest, ice, compression, and elevation) treatments in the early stages of injury.[17] As of June 2015, Game Ready® reported a 96% better post-surgical recovery compared to other cryotherapy devices, and an 87% greater reduction in pain enabling patients to stop taking pain medication sooner.[34] One case study published by Dr. Steven Sampson, Doctor of Osteopathic Medicine, discovered the use of Game Ready® helped maintain patient comfort without taking pain medication, minimized swelling, and increase the healing process in patients receiving Platelet Rich Plasma injections (PRP).[35]

Similar to the previous case study, Game Ready® published another case study involving a patient who underwent three different shoulder surgeries and discovered the use of Game Ready® enabled a quicker recovery and controlled pain better than other cryotherapy devices.[36] The patient reported he was "weeks ahead of progress compared to his other surgeries with Game Ready®" and he would request a Game Ready® unit after future surgeries to help speed up the healing process.[36] Although Game Ready® seems to be an effective modality to treat pain and speed up the healing process, the evidence is based on case studies, which have a low level of evidence and methodological quality, indicating the need for further research to support these claims.

To date, only four studies exist regarding Game Ready's® effectiveness at decreasing intramuscular tissue temperatures. Researchers studied whether the Game Ready Accelerated Recovery System™ versus the Grimm CRYOpress™ achieved a greater reduction in intramuscular tissue temperatures.[33] The Grimm CRYOpress™ is a refrigerated sequential cryo-compression system which can range between 20 to 100 mmHG of pressure during a treatment. The difference between this and the Game Ready® device is the Grimm CRYOpress is typically only used on the lower extremities and is a much larger device, whereas the Game Ready® unit can be used on all parts of the body and is a smaller and more easily portable. This study was a 2 (temperature: baseline and end of treatment) x 2 (tissue depth: skin and 1 cm below adipose) repeated measures factorial design. Six females and four males (Height = 170 ± 11.9 cm; Weight = 67.1 ± 12.2 kg) participated in this study. Skin and intramuscular temperatures were recorded using surface and implantable thermocouples, respectively, into each participant's left thigh. The implantable thermocouples were inserted to a depth of 1 cm below adipose. Temperatures were recorded every 30 seconds throughout a 20-minute treatment of either the Game Ready Accelerated Recovery System™ or the Grimm CRYOpress™. Each patient underwent both interventions separated between 24 and 48 hours between treatments. Data was analyzed using a repeated measures ANOVA design with an alpha level set at 0.05. The average skin temperature decrease for the CRYOpress™ treatment was 17.3 ± 2.3˚C and 18.4 ± 2.6˚C for the Game Ready™ interventions. In addition, the mean intramuscular temperature decrease using the CRYOpress™ was 9.5 ± 2.3˚C, whereas the Game Ready™ was 10.2 ± 2.5˚C. Although the Game Ready™ treatment caused a greater reduction in both skin and intramuscular tissue temperatures, no statistically significant differences ($P = 0.223$) existed between interventions. However, the researchers concluded the more convenient Game Ready Accelerated Recovery System™ will achieve an equal or greater decline in tissue temperature compared to the Grimm CRYOpress™.

In addition to the previous study, Holwerda et al[3] conducted an experiment investigating which cryotherapy method, crushed ice bag with elastic wrap or Game Ready®, produced a greater decline in intramuscular tissue temperatures. Ten subjects (Age = 23 ± 3 years, thigh skinfold = 11.3 ± 3.6 mm) participated and intramuscular temperatures were measured using an IT-18 implantable thermocouple 1.5 cm below the subcutaneous adipose of the distal thigh. All subjects were required to lie supine for 30 minutes to record a baseline tissue temperature. Then, temperatures were recorded every five seconds throughout the 30-minute treatment duration, followed by a 30-minute passive recovery period. A repeated measures experimental crossover design was utilized with the treatment order randomized between all participants. Treatments consisted of a crushed ice bag with an elastic wrap, Game Ready® set at no pressure, Game Ready® set at medium pressure, and Game Ready® set at high pressure. The researchers inflated a blood pressure cuff to 30 mmHG and placed it under the elastic wrap and on top of the ice bag to maintain pressure consistency in the crushed ice bag with elastic wrap treatment group.

The researchers concluded Game Ready® set at no pressure produced significantly less muscle cooling than all other treatments from the 10 to 40-minute mark. ($P < 0.05$). Holwerda et al[3] also reported crushed ice bags with an elastic wrap produced significantly greater decreases in intramuscular temperatures from the 10 to 45-minute mark when compared to Game Ready® set at medium or high pressure ($P < 0.05$). Other outcomes included the crushed ice bag with elastic wrap produced statistically significant decreases in intramuscular temperatures at both the 50 and 55-minute marks compared to Game Ready® set at medium pressure ($P < 0.05$). Although statistical power of this study was low due to the small sample size, the results supported crushed ice bags with an elastic wrap achieved a greater reduction in intramuscular temperature faster and longer than Game Ready® set at no pressure, medium pressure, and high pressure. These results support the use of ice bags with an elastic wrap during the immediate care after injury, providing clinical significance to providers if intramuscular temperature reduction is their primary goal in the immediate management of injuries.[10,12,15,19,20]

Similar to the methodology described in the previous study, Hawkins et al[13] explored whether a crushed ice bag with elastic wrap, a slush bucket, or a Game Ready® treatment produced the greatest decline in sinus tarsi tissue temperature. A slush bucket is a bucket filled with water and ice, where patients typically submerge a limb, for therapeutic benefit.[13] This treatment is typically used on patients after the acute stage of injury has passed (48-72 hours after initial injury) due to the gravity dependent position the patient is put in. This study was a 3 (ice with compression, slush bucket, Game Ready®) x 3 (time: 10-minute baseline, 20-minute treatment, 20-minute re-warming period) crossover repeated measures design that included 20 healthy participants (10 females: age = 22.0 ± 1.6 years; 10 males: age = 22.9 ± 2.4 years). All three treatments were performed at the same time of day with a maximum of one week between treatments. An IT-18 implantable thermocouple was inserted into each participant's sinus tarsi to a depth of 2 mm, near the depth of the anterior talofibular ligament (ATF). The ice bag treatment contained 1 kg of crushed ice and was secured on each patient with a 6″ ace bandage. To maintain pressure consistency, the researchers practiced applying the ace wrap using a blood pressure cuff during a pilot study; however, they did not use the blood pressure cuff during the original study due to a potential increased insulation effect from the cuff. The slush bucket treatment contained half water and half ice to a depth of 51 cm, while the Game Ready® treatment was set on the medium pressure setting.

The researchers reported ice with elastic wrap and the slush bucket produced statistically significant decreases in sinus tarsi temperatures compared to Game Ready® ($P < 0.001$). Ice with an elastic wrap (7.4˚ ± 3.2˚C) produced nearly an 11˚C difference in tissue temperatures compared to the Game Ready® treatment (18.6˚ ± 2.8˚C), and the slush bucket intervention (8.5˚ ± 3.4˚C) produced nearly a 10˚ C difference in tissue temperatures compared to the Game Ready® treatment (18.6˚ ± 2.8˚C). Although Game Ready® has been suggested for use in the immediate care of injury, the results of this study support using an ice bag with elastic wrap to achieve a greater reduction in tissue temperature compared to the Game Ready®. Though the slush bucket did produce a statistically significant decrease in tissue temperatures compared to the Game Ready® treatment, this is typically not an immediate care intervention due to the gravity dependent position of the patient. However, crushed ice bags with an elastic wrap also produced a statistically significant decrease in tissue temperatures, supporting its use after injury to reduce cell metabolism to prevent secondary injury.

Lastly, Simonson et al[14] studied the effects of an ice bag, ice bag with an Ace wrap, and Game Ready® set at no, low, medium, and high pressure at decreasing intramuscular and skin temperatures in the quadriceps muscle. This was a 6 x 7 factorial crossover study with repeated measures design. The independent variables were the cryotherapy modalities (ice, ice with ace wrap, Game Ready® no, Game Ready® low, Game Ready® medium, and Game Ready® high) and time (0, 1, 5, 10, 15, 20, and 30 minutes). The dependent variable was the quadriceps intramuscular tissue temperature measured 1.5 cm below adipose. Fifteen patients (Age = 20.87 ± 2.29 years, Adipose = 1.03 ± 0.29 cm) with no history of a thigh injury within the past six months participated in this study. Each subject received all six treatments on six different days.

The researchers found significant differences in absolute intramuscular tissue temperatures at 10 minutes ($P = 0.004$), 15 minutes ($P = 0.003$), 20 minutes ($P = 0.003$), and 30 minutes ($P = 0.001$). In addition, they found ice and ace wrap caused the greatest decline in tissue temperature compared to all other modalities. Ice and ace wrap produced a mean change of -10.76°C ± 4.71 compared to ice without an ace wrap of -8.95°C ± 4.19. They also found Game Ready® medium produced a greater decline in intramuscular tissue temperature compared to all other Game Ready treatments. Game Ready® medium produced a mean change of -8.39°C ± 2.74, whereas Game Ready® high produced a mean change of -7.00°C ± 2.80, Game Ready® low produced a mean change of -5.63°C ± 2.69, and Game Ready® no produced a change of -5.03°C ± 2.57. Based on the results of this study, it supports the theory that ice with ace wrap produces greater declines in tissue temperature compared to the Game Ready® unit. Therefore, these results support the use of ice with ace wrap in the immediate care stage of the injury repair process.

Summary

In summary, cryotherapy is frequently used in the treatment of musculoskeletal injuries to decrease cell metabolism to prevent further tissue damage. After an injury has taken place, primary injury occurs resulting in disruption of the cellular membrane around the damaged site.[16] This leads to secondary tissue damage, resulting in chemical mediators traveling to the injured site to help rid the dead debris and prevent further tissue damage.[24] Minimal research exists supporting ice bags produce a greater reduction in tissue temperature compared to the Game Ready®, indicating ice bags are the better cryotherapy choice in the immediate stages of injury.[3,13,33] While there are only two studies performed on wetted ice, both demonstrated wetted ice decreased tissue temperatures more than a traditional ice bag treatment. However, no study has compared the effects of tissue temperature decreases between a wetted ice bag with an elastic wrap and a Game Ready® treatment.

CHAPTER 3. METHODOLOGY AND PROCEDURES

The purpose of this study was to determine which cryotherapy method, wetted ice bag with elastic wrap or Game Ready®, was the most effective at decreasing tissue temperature during a 30-minute treatment. Based on the results, this study may help contribute to the existing literature on tissue temperature reduction of both Game Ready® and wetted ice. The research questions guiding this study were: 1) Which cryotherapy method, Game Ready® or wetted ice with elastic wrap, was the most effective at decreasing intramuscular tissue temperature during a 30-minute application in patients aged 18-40 years old? 2) Which cryotherapy method, Game Ready® or wetted ice with elastic wrap, achieved an intramuscular tissue temperature reduction the fastest? This chapter focuses on the experimental design, population, instruments for data collection, procedures, and data analysis procedures of this study.

Experimental Design

A 2 x 4 repeated measures design to determine decreases in posteromedial gastrocnemius intramuscular tissue temperature was used for this study. The independent variables were the cryotherapy modalities (Game Ready® and wetted ice bag with elastic wrap) and time (baseline, 10 minutes, 20 minutes, and 30 minutes). The dependent variable was the medial triceps surae intramuscular tissue temperature.

Population of the Study

Twenty healthy, college-aged individuals were recruited to participate in this study through the institution's list serve. The inclusion criteria included participants aged 18-40 years old with no prior injury to the dominant lower leg within the past six months. The exclusion criteria included any abnormalities found while scanning the treatment and thermocouple area with diagnostic ultrasound; adipose thickness ≥1 cm over the treatment area; any contraindications to cryotherapy such as Raynaud's phenomenon, cold-induced urticaria, peripheral vascular disease, lupus, open wounds, circulatory insufficiency, and myocardial ischemia; and any allergies or sensitivities to betadine. All participants signed an informed consent form after all questions were answered to their satisfaction. This study was approved by North Dakota State University's Institutional Review Board (IRB).

Instruments for Data Collection

A standard ice bag filled with 1kg of cubed ice and 300 mL of tap water from the research lab sink, was applied using an elastic wrap to each participants' lower leg for 30 minutes. The water and ice measurements were kept consistent based on what previous researchers have used in wetted ice and standard ice bag studies. The colder the water, the quicker a phase change will occur, and this theoretically, will produce a faster decline in tissue temperature. For the other treatment, a Game Ready® device (CoolSystems, Inc., Alamda, CA) was used for this study. The unit's half leg boot sleeve was applied to each participants' lower leg and ankle for 30 minutes set on the medium pressure setting (5-50 mmHG).

The posteromedial gastrocnemius intramuscular tissue temperature was recorded using 16-lead Iso-Thermex electro thermometers (Columbus Instruments, Columbus, OH). Temperatures (baseline, 10 minutes, 20 minutes, and 30 minutes) were measured using implantable IT-21-gauge thermocouples (Physitemp Inc., Clinton, NJ). A 20-gauge x 1.16 in. needle catheter (Cardinal Health) was inserted into the medial gastrocnemius muscle with the needle retracted and then the 1 ft. long thermocouple was threaded through the catheter. The Terason uSmart® 3300 Diagnostic Ultrasound (MedCore LLC., Tampa, FL) with a 15L4 transducer (4.0-15.0 MHz) and Aquasonic® ultrasound gel (Parker Laboratories, Inc, Fairfield, NJ) was used to measure adipose thickness over the treatment area and scan for any abnormalities.

Procedures

All subjects reported to the test site on two separate days. Both days were testing days with one consisting of a 30-minute wetted ice bag with elastic wrap treatment and the other consisting of a 30-minute Game Ready® application. The treatment order was randomized, and a minimum of two days and a maximum of 10 days were between the two treatments.

Prior to the cryotherapy application, the treatment area was marked with a black dot placed in the middle of the medial gastrocnemius muscle to serve as a landmark for the needle insertion. The treatment depth was 2 cm below the adipose. Therefore, the adipose thickness was measured with diagnostic ultrasound to determine the target tissue depth by placing the transducer over the mark, freezing the screen, and using the caliper function to measure the skin, adipose, and top of the muscle fascial layer. Each thermocouple was soaked in a MetriCide 28-day solution for at least 12 hours prior to insertion. The thermocouple was removed from the MetriCide and wiped dry with gauze. Then, marks were made at 5 cm and the target depth (2cm + adipose thickness).

The area of the thermocouple that was inserted into the tissue was cleaned and wiped with alcohol and then wrapped in a sterile gauze. Next, the patient was prepped, which included shaving of any hair over the treatment site, cleaning the treatment area with betadine and allowing it to dry, and then cleaning the area with isopropyl alcohol. To insert the thermocouple, the needle catheter was first inserted into the medial gastrocnemius muscle and the needle was retracted so only the catheter was left in place. Next, the IT-21 intramuscular thermocouple was threaded through the needle catheter to a target tissue depth of 2 cm below adipose and was secured to the lower leg using medical tape. Then, the thermocouple was attached to a calibrated 16-Lead Iso-Thermex electro thermometer to record decreases in tissue temperature.

Participants laid prone on the treatment table until the tissue temperature remained stable for one minute. Depending on the pre-determined treatment, either the wetted ice bag with elastic wrap or the Game Ready® treatment was administered. The treatment order was randomized by the researcher using an electronic random number generator. The wetted ice bag treatment was applied directly over the thermocouple insertion area and secured using an elastic wrap applied at approximately 75% percent tension starting distal to the treatment area and moved proximally overlapping by half. To maintain pressure consistency, the researcher practiced applying the elastic wrap on simulated patients prior to performing the application on the study participants. Former studies have commonly inflated a sphygmomanometer blood pressure cuff and placed it under the elastic wrap to maintain pressure consistency.[3,8,13] The elastic wrap practice applications consisted of applying a sphygmomanometer to the lower leg, pulling the elastic wrap to its full tension, measuring the length of the wrap, and calculating 75% of the total length to apply to the body part until the researcher was able to maintain a consistent pressure. Once consistent pressure was observed with the sphygmomanometer, the researcher removed it and practiced applying the elastic wrap to maintain consistency prior to performing the application on study participants. However, the use of a sphygmomanometer is not commonly performed in clinical practice and could potentially skew the results due to the potential for an increased insulation effect from the cuff. Therefore, the use of a sphygmomanometer was not used for pressure consistency in this study.

For the Game Ready® treatment, the half leg boot sleeve was secured around each patient’s calf and ankle by the same researcher, and the hose was connected from the Game

Ready® unit to the sleeve. Then, the power cord was plugged into the unit, the pressure was adjusted to the medium pressure setting, and the time was set for 30 minutes. Tissue temperatures were recorded at 0, 10, 20, and 30 minutes during the treatment.

Following the treatment, all materials were removed from the participant, the treatment area was cleaned using alcohol wipes, and a Band-Aid was applied over the insertion site. The subjects were given instructions on how to watch for signs of infection following the procedure and were given an icing schedule for soreness from the thermocouple insertion. The subjects were advised to ice as needed for soreness every few hours throughout the day for 30 minutes at a time following the treatment. Each subject returned for their second, and final, treatment session a minimum of two days and a maximum of ten days between treatments to aid in tissue recovery. Upon completion of the second session, all subjects were paid a total of $20 for their participation in the study.

Data Analysis Procedures

Descriptive statistics (Mean and Standard Deviation) were included for age, adipose thickness, water temperature, ambient air temperature, and tissue temperature at each time point. A 2 x 4 repeated measures ANOVA was performed at all four time points with the independent variables being the modalities (Game Ready® and wetted ice) and time (0, 10, 20, and 30 minutes), while the dependent variable was the posteromedial gastrocnemius intramuscular tissue temperature. Significance levels were determined using Bonferroni adjustments. The SPSS version 23 was used to perform all statistical analyses with a significance level set at $P \leq 0.05$.

CHAPTER 4. MANUSCRIPT

Abstract

Cryotherapy is a popular treatment chosen by providers to treat musculoskeletal injuries. The purpose of this study was to determine which cryotherapy method, Game Ready® or a wetted ice bag with elastic wrap, caused a greater and faster decline in tissue temperature during a 30-minute treatment. At 2cm below adipose, intramuscular tissue temperatures significantly decreased more and faster with the wetted ice treatment compared to the Game Ready® treatment at all four time points ($F_{3,57} = 10.98$, $P = 0.002$). Wetted ice significantly decreased temperature more than Game Ready® at 20 minutes ($t_{19} = 2.38$, $P = 0.03$), and 30 minutes ($t_{19} = 2.53$, $P = 0.02$). Since the primary goal after injury is to lower tissue temperature to decrease cellular metabolism to reduce the risk of secondary hypoxic injury, these findings suggest wetted ice would be the more effective treatment in the immediate care phase.

Introduction

Cryotherapy, or cold therapy, is the application of a device or substance with a temperature less than body temperature, causing heat to pass from the body to the cryotherapy device.[16] This is a frequently chosen intervention by clinicians for the treatment of musculoskeletal injuries.[1-3] Cold therapy produces a decline in tissue temperatures as the body responds to the transfer of heat, resulting in a decrease in cell metabolism,[4-6] muscle spasm,[7,8] pain,[7,8] and edema prevention.[9,10] Several types of cryotherapy treatments exist including ice bag, cold whirlpool, ice massage, Game Ready®, and any other form of cold modality applied to the body that causes therapeutic effects.[11] The primary goal immediately after an injury occurs is to lower tissue temperature, ultimately resulting in decreased cellular metabolism to reduce the risk of secondary hypoxic injury.[12,13]

For several decades, ice has been combined with compression to initiate a greater tissue temperature reduction, as well as rid the injured site of inflammation.[4] The majority of research performed on ice with compression compared to ice alone has supported ice combined with compression results in a greater, and faster, decline in intramuscular tissue temperature.[4,12] Clinically, ice bags combined with either flexi-wrap or elastic wrap are a commonly used cold modality for providers during the immediate care of musculoskeletal injuries. Generally, providers select either cubed ice or crushed ice bags. While wetted ice (ice with water and a dry interface[10]) is another option for clinicians, it is not often chosen. However, based on minimal research, wetted ice has been shown to be more effective at decreasing intramuscular tissue temperature compared with crushed ice and cubed ice.[10]

Similar to wetted ice, limited research exists on the Game Ready® modality. In recent years, the clinical use of Game Ready® has become a growing phenomenon within the athletic training population. The Game Ready® is a unit that combines intermittent compression with cold to provide a cooling effect on the body[17]. Currently, the minimal research on Game Ready® has shown the medium pressure setting decreases tissue temperature more than the high, low, or no pressure settings.[3,13,14,37] However, Game Ready® set on medium pressure is less effective at reducing intramuscular temperature compared with a crushed ice bag treatment.[3,13] Clinically, Game Ready® is being used as an immediate care modality due to its convenience, and the company stating it is an effective RICE (rest, ice, compression, elevation) treatment. However, the evidence supporting the use of Game Ready® as an immediate care intervention is not well supported in the literature. No evidence exists to support the optimal tissue temperature decrease for specific physiological results with cryotherapy. However, the literature is consistent with modalities producing colder temperatures being considered a better immediate care modality to decrease cell metabolism as much as possible.[10,12,15] Previous researchers have discovered wetted cubed ice produces lower tissue temperatures compared to both cubed ice and crushed ice, suggesting wetted ice cools tissue more than cubed ice and crushed ice alone.[10,31] Furthermore, researchers have also discovered cubed ice and crushed ice decrease tissue temperature more than Game Ready®.[3,13,14] Currently, no research has been performed comparing a wetted ice bag with elastic wrap versus Game Ready® to determine which causes a greater reduction in tissue temperature. Therefore, the purpose of this study was to determine the difference in tissue temperature decline between a wetted ice bag with elastic wrap and the Game Ready®.

Methods

Design

A 2 x 4 repeated measures design to determine decreases in triceps surae intramuscular tissue temperature was used for this study. The independent variables were the cryotherapy modalities (Game Ready® and wetted ice bag with elastic wrap) and time (baseline, 10 minutes, 20 minutes, and 30 minutes). The dependent variable was the posteromedial gastrocnemius intramuscular tissue temperature.

Participants

Twenty healthy, college-aged individuals (Age = 21.55 ± 2.11 years; posteromedial gastrocnemius adipose = 0.61 ± 0.18 cm) were recruited to participate in this study through the institution's list serve. The inclusion criteria included participants aged 18-40 years old with no prior injury to the dominant lower leg within the past six months. The exclusion criteria included any abnormalities found while scanning the treatment and thermocouple area with diagnostic ultrasound; adipose thickness ≥1 cm over the treatment area; any contraindications to cryotherapy such as Raynaud's phenomenon, cold-induced urticaria, peripheral vascular disease, lupus, open wounds, circulatory insufficiency, and myocardial ischemia; and any allergies or sensitivities to betadine. All 20 patients met the inclusion criteria and completed both sessions without having to exclude anyone from the study. All participants signed an informed consent form after all questions were answered to their satisfaction. This study was approved by the University's Institutional Review Board (IRB).

Procedures

All subjects reported to the research lab on two separate days. Both days were testing days with one consisting of a 30-minute wetted ice bag with elastic wrap treatment and the other consisting of a 30-minute Game Ready® application. The treatment order was randomized, and a minimum of two days and a maximum of 10 days were between the two treatments.

Prior to the cryotherapy application, the treatment area was marked with a black dot placed in the middle of the posteromedial gastrocnemius muscle to serve as a landmark for the needle insertion. The treatment depth was 2 cm below the adipose. Therefore, the adipose thickness was measured with diagnostic ultrasound to determine the target tissue depth by placing the transducer over the mark, freezing the screen, and using the caliper function to measure the skin, adipose, and top of the muscle fascial layer. Each thermocouple was soaked in a MetriCide 28-day solution for at least 12 hours prior to insertion. The thermocouple was removed from the MetriCide and wiped dry with sterile gauze. Then, marks were made on the thermocouple at 5 cm and the target depth (2cm + adipose thickness).

The posteromedial gastrocnemius intramuscular tissue temperature was recorded using a 16-lead Iso-Thermex electronic thermometer (Columbus Instruments, Columbus, OH). Temperatures (baseline, 10 minutes, 20 minutes, and 30 minutes) were measured using implantable IT-21-gauge thermocouples (Physitemp Inc., Clinton, NJ). The area of the thermocouple inserted into the tissue was cleansed and wiped with alcohol and then wrapped in a sterile gauze. Next, the patient was prepped, which included shaving of any hair over the treatment site, cleaning the treatment area with betadine and allowing it to dry, and then cleaning the area with isopropyl alcohol. To insert the thermocouple, the needle catheter was first inserted into the medial gastrocnemius muscle and the needle was retracted so only the catheter was left in place. Next, the IT-21 intramuscular thermocouple was threaded through the needle catheter to a target tissue depth of 2 cm below adipose and was secured to the lower leg using medical tape. Then, the thermocouple was attached to a calibrated 16-Lead Iso-Thermex electro thermometer to record decreases in tissue temperature.

Participants laid prone on the treatment table until the tissue temperature remained stable for one minute. Depending on the pre-determined treatment, either the wetted ice bag with elastic wrap or the Game Ready® was administered. The treatment order was randomized by the researcher using an electronic random number generator. For the wetted ice treatment, a standard ice bag filled with 1kg of cubed ice and 300 mL of tap water from the research lab sink, averaging 22.65 ± 3.88°C. Previous wetted ice studies used 300 mL of water and former studies done on standard ice bag treatments chose 1 kg of ice; therefore, we chose these numbers based on previous literature.[10,13,31] The wetted ice bag treatment was applied directly over the thermocouple insertion area and secured using an elastic wrap applied at approximately 75% percent tension starting distal to the treatment area and moving proximally overlapping by half. To maintain pressure consistency, the researcher practiced applying the elastic wrap on simulated patients prior to performing the application on the study participants. Former studies have commonly inflated a sphygmomanometer blood pressure cuff and placed it under the elastic wrap to maintain pressure consistency.[3,8,13] The elastic wrap practice applications consisted of applying a sphygmomanometer to the lower leg, pulling the elastic wrap to its full tension, measuring the length of the wrap, and calculating 75% of the total length to apply to the body part until the researcher was able to maintain a consistent pressure. Once consistent pressure was observed with the sphygmomanometer, the researcher removed it and practiced applying the elastic wrap to maintain consistency prior to performing the application on study participants. The use of a sphygmomanometer is not commonly performed in clinical practice and could potentially skew the results due to the potential for an increased insulation effect from the cuff. Therefore, the use of a sphygmomanometer was not used for pressure consistency in this study.

For the Game Ready® treatment, a Game Ready® device (CoolSystems, Inc., Alamda, CA) was used for this study. The unit's chamber was first filled with water to the maximum fill line, and the remaining part of the chamber was filled with ice, as shown in the user manual. The unit's half leg boot sleeve was applied to participants' dominant lower leg and ankle for 30 minutes set on the medium pressure setting (5-50 mmHg) by the same researcher, and the hose was connected from the Game Ready® unit to the sleeve. Then, the power cord was plugged into the unit, the pressure was adjusted to the medium pressure setting, and the time was set for 30 minutes. Tissue temperatures were recorded at baseline, 10, 20, and 30 minutes during the treatment.

Following the treatment, all materials were removed, the treatment area was cleaned using alcohol wipes, and a Band-Aid was applied over the insertion site. The subjects were given instructions on how to watch for signs of infection following the procedure and were given an icing schedule for soreness from the thermocouple insertion. The subjects were advised to ice as needed for soreness every few hours throughout the day for 30 minutes at a time following the treatment. Each subject returned for their second, and final, treatment session a minimum of two days and a maximum of ten days between treatments to aid in tissue recovery. Upon completion of the second session, all subjects were paid a total of $20 for their participation in the study.

Statistical Analysis

Descriptive statistics were included for age, adipose thickness, ice bag water temperature, and tissue temperature at each time point (Table 4.1). A 2 x 4 repeated measures ANOVA was performed at all four time points with the independent variables being the modalities (Game Ready® and wetted ice with ace wrap) and time (baseline, 10, 20, and 30 minutes) while the dependent variable was the posteromedial gastrocnemius intramuscular tissue temperature. Significance levels were determined using Bonferroni adjustments. The SPSS version 23 was used to perform all statistical analyses with a significance level set at $P \leq 0.05$.

Table 4.1. Descriptive Statistics.

	N	**Min**	**Max**	**Mean ± SD**
Age (years)	20	18	28	21.85 ± 2.11
Adipose (cm)	20	0.32	0.94	0.61 ± 0.18
Ice Bag Water Temp (°C)	20	18	30	22.65 ± 3.88
W Ice Baseline (°C)	20	34.04	38.13	36.62 ± 1.11
W Ice 10 min (°C)	20	23.94	36.61	33.64 ± 3.26
W Ice 20 min (°C)	20	19.54	34.59	30.48 ± 4.04
W Ice 30 min (°C)	20	16.95	33.62	27.95 ± 4.29
GR Baseline (°C)	20	35.28	37.90	36.36 ± 0.74
GR 10 min (°C)	20	32.80	37.02	35.20 ± 1.11
GR 20 min (°C)	20	26.28	35.70	32.96 ± 2.27
GR 30 min (°C)	20	22.90	34.74	30.75 ± 2.90

W Ice, Wetted Ice; GR, Game Ready; SD, standard deviation

Results

Intramuscular Temperature

Since sphericity was not met, we corrected for it using Greenhouse-Geisser corrections. At 2cm below adipose, tissue temperatures decreased from 36.36°C at baseline during the Game

Ready® treatment to 35.20°C, 32.96°C, and 30.75°C at 10, 20 and 30 minutes. During the wetted ice with elastic wrap treatment, tissue temperatures decreased from 36.62°C at baseline to 33.64°C, 30.48°C, and 27.95°C at 10, 20, and 30 minutes (Figure 4.1). A significant main effect existed between time and modality ($F_{3,57}$ = 10.977, P = 0.002). Using a paired samples t-test, although not statistically significant (t_{19} = 1.894, P = 0.074), wetted ice decreased 1.6°C more than Game Ready® at 10 minutes. Wetted ice significantly decreased temperature more than Game Ready® at 20 minutes (t_{19} = 2.380, P = 0.028), and 30 minutes (t_{19} = 2.525, P = 0.021). Although statistical significance was not achieved at 10 minutes between the two modalities, clinical significance was achieved as the wetted ice bag with elastic wrap decreased 1.6°C more than the Game Ready® treatment. Interestingly, 10 minutes into the treatment, intramuscular tissue temperature for the wetted ice with elastic wrap group was approximately 33.64°C; whereas, tissue temperature at the 20-minute mark during the Game Ready® treatment was approximately 32.96°C. This means the Game Ready® treatment was approximately only 0.68°C cooler after 20-minutes compared with the wetted ice bag treatment after 10 minutes. Additionally, tissue temperature during the wetted ice treatment at 20 minutes was approximately 30.48°C, and tissue temperature during the Game Ready® treatment at 30 minutes was approximately 30.74°C. Therefore, wetted ice had already achieved a greater decline in tissue temperature at 20-minutes compared to the completed Game Ready® treatment at 30 minutes.

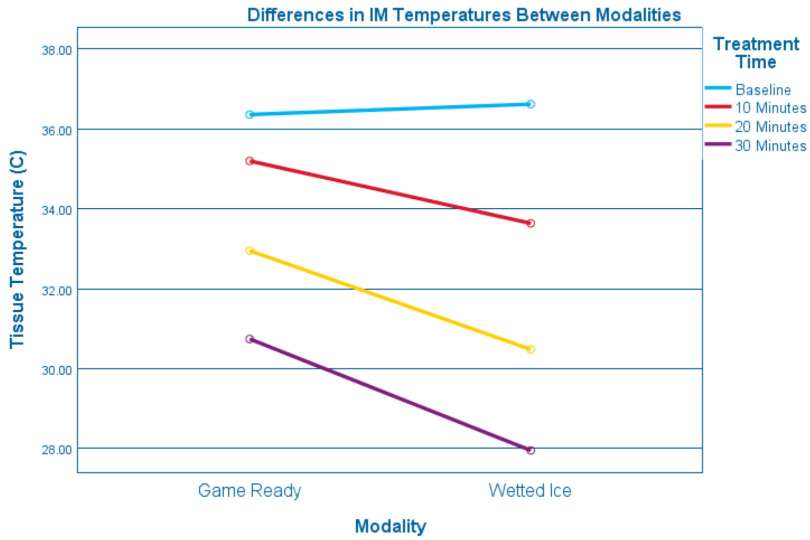

Figure 4.1. Intramuscular Tissue Temperature Decreases (°C) at Each Time Point.

Ambient Air and Water Temperature

We ran a pairwise comparison between ambient air temperature and tissue temperature at each of the four time points. For the Game Ready® treatment, the correlation coefficient at baseline was 0.146, at 10 minutes was -0.030, at 20 minutes was -0.233, and at 30 minutes was -0.313, suggesting a weak negative correlation between air temperature and tissue temperature. For the wetted ice treatment, the correlation coefficient at baseline was 0.479, at 10 minutes was 0.442, at 20 minutes was 0.392, and at 30 minutes was 0.358, suggesting a weak to moderate positive correlation between air temperature and tissue temperature. Furthermore, we ran an additional pairwise comparison for each subject on ambient air temperature and tissue temperature between both modalities at the 30-minute mark, or end of the treatment. The correlation coefficient was 0.179, suggesting a very weak correlation between air temperature and tissue temperature.

Furthermore, we wanted to know how much, if at all, the ice bag water temperature affected tissue temperature. Therefore, a general linear model at each time point (baseline, 10, 20, and 30 minutes) was performed to observe if there was a significant effect between water and tissue temperature. After running the model, there was no evidence suggesting water had an impact on tissue temperature at baseline ($F_{12,7}$ = 3.011, P = 0.076), 10 minutes ($F_{12,7}$ = 1.513, P = 0.299), 20 minutes ($F_{12,7}$ = 1.298, P = 0.377), and 30 minutes ($F_{12,7}$ = 1.055, P = 0.493). These results support the use of room temperature water as the temperature of the water has little effect on tissue temperature changes.

In addition, we wanted to find at which time point statistical significance among the two modalities was achieved between the 10 and 20-minute mark of the treatment. After running a paired samples t-test at each minute between the 10 and 20-minute mark, statistical significance occurred at the 13-minute mark of the treatment (t_{19} = 2.156, P = 0.044), where the wetted ice tissue temperature was approximately 1.95°C colder than Game Ready®. Actual tissue temperature for the wetted ice treatment at the 13-minute mark was 32.66 ± 3.58°C compared to Game Ready® temperature of 34.61 ± 1.38°C At each time point throughout the treatment, wetted ice decreased tissue temperature more than Game Ready® (Table 4.2). Pairwise comparisons computing the differences for absolute intramuscular temperatures were taken at each time point between the modalities (Table 4.3).

Table 4.2. Intramuscular Temperatures (°C) at Each Time Point.

Time Points	Wetted Ice	Game Ready®
Baseline	36.62 ± 1.11	36.36 ± 0.74
10 minutes	33.64 ± 3.26	35.20 ± 1.11
13 minutes*	32.66 ± 3.58	34.61 ± 1.38
20 minutes	30.48 ± 4.04	32.96 ± 2.27
30 minutes	27.95 ± 4.29	30.75 ± 2.90

*****Time point when statistical significance was achieved.

Table 4.3. Intramuscular Temperatures (°C) at Each Time Point.

Time Points	Mean Difference	P-Values
Baseline	-0.261 ± 1.35	0.399
10 minutes	1.561 ± 3.68	0.074
13 minutes	1.950 ± 4.05	0.044*
20 minutes	2.472 ± 4.64	0.028*
30 minutes	2.790 ± 4.94	0.021*

*Indicates significant time point difference.

Discussion

The primary goal immediately after an injury occurs is to lower tissue temperature, ultimately resulting in decreased cellular metabolism to reduce the risk of secondary hypoxic injury.[19,20] Adding an elastic wrap provides compression, ultimately resulting in greater contact between the skin and modality. Theoretically, the increased contact between the modality and the skin will produce a greater decline in tissue temperature. In addition to compression, different forms of ice can be used, most commonly, cubed or crushed ice. Wetted ice is another form of ice that can be used in a clinical setting; however, this is not commonly used. Previous research has shown cubed ice produces a greater decline in tissue temperature compared to crushed ice. Furthermore, wetted cubed ice has been shown to decrease tissue temperature more than both cubed and crushed ice.[10]

Previous researchers have reported ice bags with and without elastic wraps decrease tissue temperature more than Game Ready®.[3,13,14] Holwerda et al[3] also reported crushed ice bags with an elastic wrap produced significantly greater decreases in intramuscular temperatures from the 10 to 45-minute mark when compared to Game Ready® set at medium or high pressure ($P < 0.05$). They found ice bags decreased tissue temperature approximately 13°C at the end of the 30-minute mark, compared to 10.6°C with Game Ready® high pressure, 9.8°C with Game Ready® medium pressure, and 6.7°C with Game Ready® no pressure. Our study produced similar results, apart from using cubed wetted ice rather than crushed ice with elastic wrap. We found wetted ice with elastic wrap cooled tissue more than Game Ready® set on medium pressure from the 10 to 30-minute mark. We discovered tissue temperatures decreased approximately 9°C in the wetted ice group compared to approximately 6°C with Game Ready® medium pressure. Holwerda et al[3] performed a 30-minute treatment followed by a 30-minute passive recovery period. During the passive recovery period, tissue temperatures continued to stay cooler with the ice bag treatment compared to all Game Ready® treatments at no, medium, and high pressure.

We believe their change in tissue temperature of 13°C with the ice treatment and 9.8°C with Game Ready® on medium pressure treatment compared to our 9°C difference with wetted ice with elastic wrap and 6°C with Game Ready® on medium pressure, is contributed to the difference in target tissue depths. They inserted thermocouples to a depth of 1.5 cm below adipose compared to our depth of 2 cm below adipose. Therefore, the muscle cooling occurred more superficial compared to ours, resulting in a greater decline in temperature. In addition, we found differences in temperature decreases between modalities of 1.56 ± 3.68°C at 10 minutes, 2.47 ± 4.64°C at 20 minutes, and 2.79 ± 4.94°C at 30 minutes. We believe the reason for the greater decline in tissue temperature compared to the Game Ready® unit is due to the addition of water to the ice bag, filling in the spaces between the ice cubes. Water is a better conductor of heat than air,[10,30] ultimately resulting in increased contact between the modality and the skin. This theoretically, will result in a greater and faster decline in tissue temperature, as suggested by Holwerda et al[3] and our results.

In addition, Hawkins et al[13] studied the effects of Game Ready® versus a crushed ice bag and slush bucket at decreasing sinus tarsi tissue temperature. They reported both the slush bucket and crushed ice bag with elastic wrap interventions decreased tissue temperature substantially more than Game Ready® set on medium pressure after a 20-minute treatment. Crushed ice with elastic wrap cooled sinus tarsi temperature approximately 11°C more than the Game Ready® treatment, and the slush bucket cooled temperatures approximately 10°C more than Game Ready®. In our study, the wetted ice bag with elastic wrap cooled intramuscular tissue temperature approximately 3°C more than the Game Ready® on medium pressure after the 30-minute treatment. Our belief as to why Hawkins et al[13] reported significantly more temperature cooling than our study is the difference in target tissue depth used. They inserted thermocouples into the sinus tarsi of the right ankle to a depth of 2 mm. Our study used the posteromedial gastrocnemius muscle on the calf, and thermocouples were inserted to a depth of 2 cm below adipose thickness. The sinus tarsi temperature is closely related to skin temperature, which cools more and faster than intramuscular tissue temperature, as supported in the literature.[3,30] Since skin is the first tissue and muscle is the last tissue to lose heat to the modality, tissue cooling will occur faster and will decrease more in skin.[18] Therefore, this likely explains the difference in tissue cooling found between Hawkins et al[13] and our study.

Furthermore, Dykstra et al[10] discovered cubed wetted ice decreased intramuscular tissue temperature, 2 cm below adipose, approximately 6°C, followed by cubed ice decreasing temperature 4.8°C, and crushed ice decreasing temperature 4.3°C after a 20-minute treatment. In addition, they used 2000 mL (2 kg) of ice and 300 mL of water in the wetted ice treatment group. We used 1 kg (1000 mL) of cubed ice and 300 mL of water in our study. We found tissue temperatures decreased approximately 9°C after a 30-minute treatment, producing similar decreases in tissue temperature to the Dykstra et al[10] results. Our study was 10 minutes longer and used an elastic wrap to secure the ice bag to the leg, likely explaining the additional 3°C decrease in intramuscular tissue temperature compared to Dykstra et al.[10] An elastic wrap provides an insulation effect on the modality, preventing the ice bag from gaining heat from the air. Additionally, this affects the amount of heat transfer that can occur between an ice bag versus an ice bag with an elastic wrap, ultimately limiting the amount of muscle cooling.

On the contrary, the phase change in the Game Ready® occurs within the unit's chamber, causing the phase change to occur away from the body. Therefore, the transfer of heat is unable to occur directly on the skin, thus resulting in less tissue temperature cooling. Although our study only studied the effects of Game Ready® set on medium pressure, the existing literature supports ice bags cool tissue temperature more than Game Ready® set on no, low, medium, and high pressure.[3]

Furthermore, the differences in which modality, wetted ice with elastic wrap or Game Ready® set on medium pressure, produces lower intramuscular tissue temperatures can be contributed to phase change. An ice bag goes through a phase change, which means the ice will go from a solid to a liquid state without changing temperature or chemical composition.[16] For a phase change to take place, a transfer of heat must occur first. In addition, thermal energy must be transferred from an area of higher temperature to an area of lower temperature, which then leads to the heat transfer from the skin to the modality.[15,29]

In the wetted ice bag with elastic wrap group, the transfer of energy (heat) takes place directly on the skin, allowing the amount of heat required for the phase change to occur to be available from the body. The addition of an elastic wrap provides compression and increases the contact between the skin and modality, resulting in a greater transfer of heat and decline in intramuscular tissue temperature.[4,12] Furthermore, the water in the wetted ice bag fills in the spaces between the cubed ice, and water is a better conductor of heat than air. Adding water to an ice bag may potentially cause the phase change to occur sooner than an ice bag without water. A greater amount of heat transfer, or muscle cooling, will occur the longer a modality is in a phase change.[10] Ultimately, this phase change allows more heat transfer to occur and causes tissue temperature to decline more rapidly.[10] Additionally, the previous wetted ice studies[10,31] state the water added to the ice bag was room temperature, suggesting the actual temperature would be approximately 22°C. While we originally had planned on using water as close to 0°C, the university research lab tap water ranged from 18°C to 30°C with the average being 22.65 ± 3.88°C. We wanted to know how much, if at all, water temperature affected tissue temperature. Therefore, a general linear model at each time point (baseline,10, 20, and 30 minutes) was performed to observe if there was a significant effect between water and tissue temperature. After running the model, there was no evidence suggesting ice bag water temperature had an impact on tissue temperature at baseline. These results support the use of room temperature water as the temperature of the water has little effect on tissue temperature changes.

In addition to water temperature, we wanted to know if ambient air temperature influenced tissue temperature. The research lab fluctuated between 16.61°C to 27.30°C throughout the span of data collection. This study was conducted during the Fall, and the heat was turned on in the building during data collection, which accounts for the wide range in ambient air temperature. Therefore, we wanted to see if these changes in air temperature had any effect on tissue temperature. We found weak correlations between ambient air temperature and tissue temperature. The weak correlation may be contributed to the elastic wrap and Game Ready® sleeve, as both prevent outside air temperature from coming into contact with the modality and skin. However, due to the small sample size of our study, we cannot be certain how much of an effect air temperature had on tissue temperature.

While we found wetted ice with elastic wrap decreased intramuscular tissue temperatures significantly more than Game Ready®, a few limitations of our study exist. Both Holwerda et al[3] and Hawkins et al[13] found similar results to our study. However, the sample size of each of these studies was relatively low with only 10, 20, and 20 patients, respectively. In addition, each of these studies focused only on healthy tissue rather than pathologic tissue, making this hard to generalize to an injured population. In our study, thermocouple insertion was completed by a researcher limited to only months of experience with the technique, potentially skewing the intramuscular temperature readings due to improper insertion depth. Furthermore, the elastic wrap was applied by the same researcher trying to apply approximately 75% tension starting distal to the treatment area and gradually decreasing the tension as it was applied proximally. To maintain pressure consistency, the researcher practiced applying the elastic wrap on simulated patients prior to performing the application on the study participants. However, there was no way to record the pressure consistency of the elastic wrap during each treatment, potentially causing an increase in contact between the skin and modality and possibly resulting in greater tissue temperature cooling between participants. Although the use of a sphygmomanometer is an option to measure pressure consistency, this was not used in our study due to the potential for an increased insultation effect, and because this is not used clinically. In addition, the half leg boot Game Ready® sleeve is only one size fits all, potentially impacting muscle cooling due to the decreased contact with the skin due to differing calf girth between subjects. Therefore, future studies should be conducted on pathologic patients, include a larger sample size, and thermocouple insertion should be completed by researchers with more than a few months of experience.

Conclusion

Although no evidence exists to support the optimal tissue temperature decrease for specific physiological results with cryotherapy, the literature is consistent with modalities producing colder temperatures are considered a better immediate care modality to decrease cell metabolism as much as possible.[10,12,15] Since the tissue in the wetted ice with elastic wrap group is able to go through a phase change on the body and quicker than Game Ready®, this results in a faster and greater decline in intramuscular tissue temperature. In theory, this decline in temperature decreases the chances of secondary cell death occurring. The importance of our study was to determine which cryotherapy modality would be the better option in the immediate care of injury to prevent this secondary cell death from occurring, by determining which treatment would decrease intramuscular tissue temperature the most. More commonly, the Game Ready® unit is being used in the immediate care of injury due to its compression and cooling effect; however, research has suggested this unit does not provide as much tissue cooling as compared with a traditional ice bag treatment. Clinically, ice bag treatments are much more feasible for sideline use in the immediate care of injury compared to the Game Ready® unit. Therefore, clinicians should use wetted ice bags with elastic wrap in the immediate care of injuries rather than the Game Ready® unit to achieve optimal results of cryotherapy. Our results support our hypothesis that wetted ice with elastic wrap would produce a greater and faster decline in tissue temperature compared with the Game Ready®. On the contrary, Game Ready® should be used in the post-acute stage of the injury repair process for compression for edema reduction and prevention. The results of this study are important for clinicians to optimize their treatment and rehabilitation plans following an injury by determining which cryotherapy method is best to use during each stage of the injury repair process.

REFERENCES

1. Nadler SF, Weingand K, Kruse RJ. The physiologic basis and clinical applications of cryotherapy and thermotherapy for the pain practitioner. *Pain Physician.* 2004;7(3):395-399.
2. Myrer JW, Measom G, Fellingham GW. Temperature changes in the human leg during and after two methods of cryotherapy. *J Athl Train.* 1998;33(1):25-29.
3. Holwerda SW, Trowbridge CA, Womochel KS, Keller DM. Effects of cold modality application with static and intermittent pneumatic compression on tissue temperature and systemic cardiovascular responses. *Sports health.* 2013;5(1):27.
4. Merrick MA, Knight KL, Ingersoll CD, Potteiger JA. The effects of ice and compression wraps on intramuscular temperatures at various depths. *J Athl Train.* 1993;28(3):236.
5. Janwantanakul P. Different rate of cooling time and magnitude of cooling temperature during ice bag treatment with and without damp towel wrap. *Phys Ther Sport.* 2004;5(3):156-161.
6. Bender AL, Kramer EE, Brucker JB, Demchak TJ, Cordova ML, Stone MB. Local ice-bag application and triceps surae muscle temperature during treadmill walking. *J Athl Train.* 2005;40(4):271-275.
7. 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.
8. Long BC, Cordova ML, Brucker JB, Demchak TJ, Stone MB. Exercise and quadriceps muscle cooling time. *J Athl Train.* 2005;40(4):260.
9. Dolan MG, Thornton RM, Fish DR, Mendel FC. Effects of cold water immersion on edema formation after blunt injury to the hind limbs of rats. *J Athl Train.* 1997;32(3):233-237.
10. 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 Athl Train.* 2009;44(2):136.
11. 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(1):26.
12. Tomchuk D, Rubley MD, Holcomb WR, Guadagnoli M, Tarno JM. The magnitude of tissue cooling during cryotherapy with varied types of compression. *J Athl Train.* 2010;45(3):230.
13. Hawkins J, Shurtz J, Spears C. Traditional cryotherapy treatments are more effective than Game Ready on medium setting at decreasing sinus tarsi tissue temperatures in uninjured subjects. *J Athl Enhanc.* 2012;1:2.
14. Simonson J. Ice and ace wrap and Game Ready® in decreasing quadriceps temperature. *ProQuest.* Health, Nutrition, and Exercise Sciences, North Dakota State University; 2014.
15. Merrick MA, Jutte LS, Smith ME. Cold modalities with different thermodynamic properties produce different surface and intramuscular temperatures. *J Athl Train.* 2003;38(1):28.
16. Knight K, Draper D. *Therapeutic Modalities.* Philadelphia, PA: The Art and Science; 2008.

17. *Game Ready: The power to accelerate recovery.* Game Ready. http://www.gameready.co.uk/Images/Manuals/Game_Ready_Brochure.pdf. Accessed February 5th, 2020.
18. Starkey C. *Therapeutic Modalities.* 3rd Edition ed. Philadelphia, PA: F.A. Davis Company; 2004.
19. Zemke JE, Andersen JC, Guion WK, McMillan J, Joyner AB. Intramuscular temperature responses in the human leg to two forms of cryotherapy: Ice massage and ice bag. *J Orthop Sports Phys Ther.* 1998;27(4):301-307.
20. Myrer WJ, Myrer KA, Measom GJ, Fellingham GW, Evers SL. Muscle Temperature Is Affected by Overlying Adipose When Cryotherapy Is Administered. *J Athl Train.* 2001;36(1):32.
21. Merrick MA, Rankin JM, Andres FA, Hinman CL. A preliminary examination of cryotherapy and secondary injury in skeletal muscle. *Med Sci Sports Exerc.* 1999;31(11):1516-1521.
22. Merrick MA. Secondary injury after musculoskeletal trauma: A review and update. *J Athl Train.* 2002;37(2):209-217.
23. Oliveira NM, Rainero EP, Salvini TF. Three intermittent sessions of cryotherapy reduce the secondary muscle injury in skeletal muscle of rat. *J Sports Sci Med.* 2006;5(2):228-234.
24. Edwards SL. Tissue viability: understanding the mechanisms of injury and repair. *Nursing Standard.* 2006;21(13):48-56.
25. Denegar C. *Therapeutic Modalities for Athletic Injuries.* Humans Kinetics; 2000.
26. Davison Joseph S, Befus A, Mathison Ronald D, Woodman Richard C. Modulation of neutrophil function by the tripeptide feG. *BMC Immunology.* 2003;4(1):3.
27. Butterfield TA, Best TM, Merrick MA. The dual roles of neutrophils and macrophages in inflammation: A critical balance between tissue damage and repair. In. *J Athl Train.* Vol 41: NATL ATHLETIC TRAINERS ASSOC INC; 2006:457-465.
28. 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.
29. Enwemeka SC, Allen SC, Avila SP, Bina SJ, Konrade SJ, Munns SS. Soft tissue thermodynamics before, during, and after cold pack therapy. *Med Sci Sports Exerc.* 2002;34(1):45-50.
30. Hamid NA, Nawawi MF, Abdullah NM, Latif RA. Efficacy of cubed-ice and wetted-ice as a cryotherapeutic agent in the Malaysian climate. *Procedia Soc Behav Sci.* 2013;105:211-219.
31. Hunter EJ, Ostrowski J, Donahue M, Crowley C, Herzog V. Effect of salted ice bags on surface and intramuscular tissue cooling and rewarming rates. *J Sport Rehabil.* 2016;25(1):70-76.
32. Rodrigo de Carvalho A, Lazzeri de Medeiros D, Tibes de Souza F, et al. Temperature variation of the quadriceps femoris muscle exposed to two forms of cryotherapy by means of thermography. *Rev Bras Med Esporte.* 2012;18(2):109-111.
33. Seamon C, Merrick M. A comparison of intramuscular temperatures of the thigh during treatments with the Grimm CRYOpress and the Game Ready Accelerated Recovery System. *J Athl Train.* 2005;40(2):S99.

34. *Clinical Information.* Game Ready. https://gameready.com/clinical-evidence-2/. Accessed February 5th, 2020.
35. Sampson, Steven. *Avoiding the knife.* Game Ready. https://gameready.com/wp-content/uploads/2017/08/GR-CS-SS-0311SSCS-PainManagement.pdf. February 2011. Accessed February 5th, 2020.
36. *One patient, three shoulder surgeries- the third with a very different outcome.* Game Ready. https://nzsportshealth.co.nz/wp-content/uploads/2017/08/GR-CS-BK-0311BKCS-BetterOutcome.pdf. March 2011. Accessed February 5th, 2020.

APPENDIX. INSTRUMENTS USED

Figure A1. Game Ready Treatment.

Figure A2. Wetted Ice Treatment.

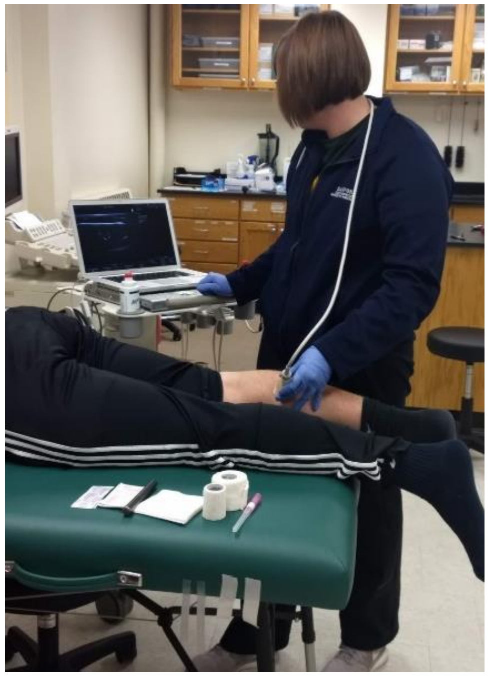

Figure A3. Diagnostic Ultrasound Measuring Adipose Thickness.

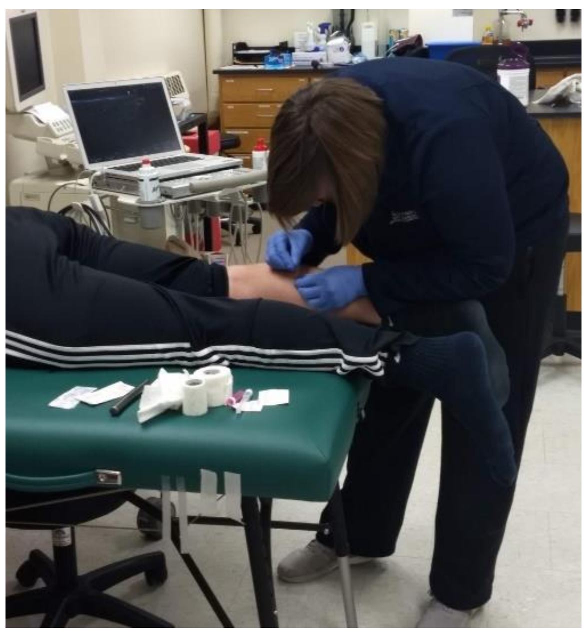

Figure A4. Thermocouple Threaded Through Needle Catheter.

Figure A5. Thermocouple Secured to Leg and Plugged into 16-Lead Iso-Thermex Thermometer.