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## *Inside this Issue:*



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# A Novel Cryotherapy Compression Wrap in the Management of Acute Ankle Sprains: Potential Use for Special Operators on the Battlefield

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## ABSTRACT

**Objective:** Musculoskeletal injuries related to training and operational missions frequently affect military personnel. A common treatment for these injuries is the PRICE method (protection, rest, ice, compression, and elevation), which is time consuming and impractical in the field. Therefore, the primary objective of this study was to determine the effectiveness of the cryotherapy wrap compared to a traditional treatment in the management of acute ankle sprains. **Methods:** A randomized controlled clinical trial was conducted in a university research laboratory with 13 subjects (9 males and 4 females) with the following physical characteristics: age (yr) 20.6 ± 2.2, height (cm) 177.0 ± 14.3, weight (kg) 76.6 ± 20.6, and body mass index ($kg/m^2$) 24.1 ± 3.7. Participants were instructed to perform PRICE with a traditional ice pack and compression wrap (control group) or with an Arctic Ease® cryotherapy wrap (test group) for 48 hours following enrollment in the study. The Numeric Pain Scale, Foot and Ankle Ability Measure, and ankle/foot volumetric measurement were performed at initial presentation and 24-hour, 48-hour, and 7-day follow-up intervals. **Results:** While the comparison of the Numeric Pain Scale scores, Foot and Ankle Ability Measure scores, and volumetric changes between groups revealed no statistically significant differences ($p>0.01$), there was an 86% compliance rate for subjects in the cryotherapy wrap group compared to a 17% compliance rate of subjects in the control group. **Conclusions:** The cryotherapy wraps performed comparably to ice therapy and therefore may be especially applicable to military personnel required to operate in austere and hostile environments where traditional therapies are unrealistic. Although this pilot study did not demonstrate that the cryotherapy wraps produce statistically superior results, trends emerged in the data suggesting that subject compliance rate may be improved by using an alternative form of cryotherapy compression, which could lead to better management of pain, edema, and functional recovery. Future research should include a larger sample size to verify this claim.

**Key Words:** cryotherapy, ankle sprain, ice, edema, compression

## INTRODUCTION

Musculoskeletal injuries resulting from training exercises and combat events are relatively common among military personnel. In fact, these injuries account for a large number of noncombat injuries and result in significant cost to the military through both lost duty time and medical costs. A 2010 study conducted by the Air Force Research Laboratory identified Battlefield Airmen (BA) as one of the primary groups at risk for this type of injury.[1] BA are composed of Pararescue Jumpers (PJs), Special Operations Weather Team, Combat Controllers, and Tactical Air Control Party. These individuals are considered to be an elite group of airmen, both physically and mentally, and undergo intense training lasting up to 2 years. As a result of their intense and high volume physical training regimen, many do not complete the program. Approximately 15% of those who do not complete training are due to medical-related events, which were often diagnosed as musculoskeletal diseases. Of these diseases, a large percent were "sprains and strains of joints and adjacent muscles," most of which were of the lower extremity.[2] For example, additional physical dangers contributing to lower extremity injury rates in Combat Controllers are partially attributed to carrying gear weighing between 140 to 160 pounds to high altitudes (e.g., >10,000 feet) on uneven and rugged terrain.[3] PJs are another elite group of BA who conduct combat rescue missions all over the world. PJs suffer even higher rates of lower extremity injuries partially attributed to their overall mission requirements and additional physical dangers, such as parachuting into unknown drop zones. Additionally, an estimated 60% of PJs are unable to complete their initial training phase due to a lower extremity injury.[3] The physically demanding operational missions of BA result in an increased risk of musculoskeletal injuries on the battlefield and during training.[3]

Following a musculoskeletal injury, cryotherapy is one of the first lines of treatment during the acute or post-acute stage. In the acute phase, cryotherapy's most immediate physiological effects are to decrease tissue and interarticular temperature resulting in decreased pain, tissue metabolism, muscle spasm, circulation, inflammation, edema, and sensory nerve conduction velocity.[4-9] These effects are important initially to decrease the extent of secondary injury caused by the byproducts of these physiological mechanisms that may cause further injury to the immediate surrounding area.[9-11] The effects of cryotherapy have been shown to have an enhanced physiological effect when used in conjunction with compression, which further controls excessive fluid accumulation in the interstitium.[11-13]

The most effective treatment for acute musculoskeletal injury is a combination of treatments including protection, rest, ice, compression, and elevation (PRICE).[14] The PRICE treatment has been documented and is generally accepted as the standard treatment for acute musculoskeletal injuries.[9,14,15] It is important to begin this treatment as soon as possible and to maintain the treatment through the acute phase of injury to prevent secondary injury to the injured and surrounding tissue.[9] During field training exercises and in combat situations, despite the need for continued treatment, compliance is often low due to the constraints associated with these environments (e.g., ice is not always readily available, and circumstances are not always such that the injured limb can be elevated).

Despite the widespread use of cryotherapy treatment, there is much disagreement about the most effective treatment parameters including duration, frequency, and compression.[16,17] There are several studies that report that intermittent ice and compression yield favorable results over "traditional" ice treatment.[12,18,19] Other studies found that long duration low grade cooling may be clinically valuable in improving recovery after traumatic soft tissue injury.[10,11] In recent years, new cryotherapy products introduced to the market have attempted to provide a more convenient and efficient product to treat musculoskeletal injuries. To date, little evidence has been provided to assess the effectiveness of these products for clinical use.

When evaluating an acute ankle sprain, it is important to establish the severity of the injury. Grading of an ankle sprain ranges from a grade I to grade III, with grade I being the least severe and grade III being most severe. A grade I ankle sprain presents with no structural instability, mild to moderate discomfort, mild ecchymosis, and gradual onset of edema, with full or partial weight bearing on the affected limb. A grade II ankle sprain demonstrates slight to no instability, moderate to intense discomfort, significant ecchymosis, and a sudden onset of edema with difficult or impossible independent

weight bearing. Grade III ankle sprains display gross instability, no pain or intense discomfort, severe and dispersed ecchymosis, and a sudden onset of edema that is difficult to control, while displaying the inability to bear weight on the ankle.[20,21] If the patient is unable to bear weight, it is important to rule out fracture. The Ottawa Ankle Rules are a screening tool that has been shown to be a highly sensitive test in ruling out ankle fracture.[22]

The product of interest in this study is a self-adhering cryotherapy compression wrap that provides a long duration low grade cooling to the site of injury. It is a Food and Drug Administration approved physical medicine therapeutic class 1 device approved for use as a reusable hot or cold pack (regulation number 890.5700), a disposable hot or cold pack (regulation number 890.5710), and an elastic bandage (regulation number 880.5075).[23] This product was chosen for this study because it provides both cryotherapy and compression to the injury site. The product is worn by the patient for 2 to 4 hours at a time, at which point the used wrap is rehydrated and a new wrap is applied. The proposed benefit of the cryotherapy compression wrap is that it provides cooling and compression to the injury site while providing the opportunity for increased patient compliance.

The primary objective of this study was to compare the effectiveness of the Arctic Ease® cryotherapy wrap (Arctic Ease, Phoenixville, PA) to traditional treatment in the management of acute ankle sprains. The hypothesis is that the cryotherapy compression wrap will demonstrate a significant decrease in edema and pain and an increase in functional mobility when compared to a traditional ice and compression regimen following an ankle sprain.

## METHODS

### Participants

Fourteen subjects volunteered to participate in the study. One subject fit the criteria for the Ottawa Ankle Rules[24] and was referred for radiographic testing and found to have a fracture. Therefore, 13 subjects [9 male and 4 female, age (yr) 20.6 ± 2.2, height (cm) 177.0 ± 14.3, weight (kg) 76.6 ± 20.6, and body mass index (BMI) $kg/m^2$ 24.1 ± 3.7] were included in our study. These physical characteristics are representative of a Combat Controller trainee population, which has typical physical characteristics to include mean age (yr) 28.9 ±5.7, height (cm) 179.2± 6.2, weight (kg) 84.6 ± 10.3, and BMI ($kg/m^2$) 26.3 ±2.8.[25] Nonetheless, the psychological characteristics of the population subset used in this study may not be representative of a Combat Controller trainee, and this is a heterogeneous sample. The inclusion criteria included subjects between 18-26 years of age who had suffered an acute (grade II-III) ankle sprain within 48 hours of enrollment in the study. Subjects were excluded if any of the following criteria were met: history of a previous ankle sprain in the last 6 months, Raynaud's disease or other form of cold sensitivity, age outside of the 18- to 26-year-old range, history of ankle or foot surgery on the involved lower extremity, or a positive finding on clinical exam on the Ottawa Ankle Rules or with a confirmed fracture via radiograph.

Prior to participation, the subjects were required to review and sign the informed consent form that was approved by the Saint Francis University Institutional Review Board. Next, subjects completed a demographic and injury history questionnaire and a self-reported activities questionnaire (Foot and Ankle Ability Measure, FAAM). The demographic questionnaire provided information about the subject's past medical history, injury history, and current status. The FAAM is an evaluative instrument that assesses physical function of individuals with musculoskeletal disorders of the leg, foot, and ankle.[26] Patients were also asked to report their pain on the numeric pain scale. This scale requires patients to rate their perceived pain on a scale of 0-10 with 10 being the most severe.[27]

For each test session, subjects underwent a standard clinical examination including volumetric assessment, which was performed to determine ankle volume. Volume was determined by measuring the amount of water displaced by the ankle using a volumetric measuring tank. Subjects were then randomly assigned to the wrap or control group. The control group was instructed to follow a traditional program to self-manage the ankle sprain for the next 48 hours according to the PRICE protocol. They were issued a 4-inch compression bandage to wear for 48 hours and instructed in appropriate application of the device

using a figure eight wrapping technique. They were instructed to elevate the involved lower extremity above the heart as often as possible and to apply a traditional ice pack to the injured ankle for up to 20 minutes every 2 to 3 hours.

The wrap group was instructed to follow the same instructions, with a cryotherapy compression wrap being substituted for the ice and compression bandage in the treatment protocol. Subjects in this group were instructed to utilize the cryotherapy compression wrap for 2 to 4 hours before removing the wrap to rehydrate the product. During this time, a second cryotherapy compression wrap was applied. Subjects were instructed to continue this treatment for 48 hours. The cryotherapy compression wrap used in this study is the Arctic Ease® Cryotherapy Wrap, which is a compression wrap type device 4 inches in width by 60 inches in length. The product is a polymer-treated wrap that absorbs heat energy, creating a thermodynamic cycle in which heat is removed from tissue, thus causing it to be cooled. It is reusable, odorless, and latex and adhesive free and also allows the user to maintain mobility during use. The product may be applied at either room temperature or precooled. In either application, the manufacturer states the product provides a low grade cooling effect at approximately 20.1-22.8 °C.[28]

Both groups were asked to complete a journal outlining their compliance to the prescribed treatment during the first 48 hours. Subjects in both groups were reevaluated at the 24-hour, 48-hour, and 7-day mark after the initial assessment. Data were then analyzed to compare the effectiveness of the cryotherapy compression wrap to the PRICE method. Response variables for this study include the Numeric Pain Scale, volumetric measurements, FAAM score, and compliance.

**Numeric Pain Scale**

Subjects completed the Numeric Pain Scale during the initial assessment and at each follow-up session described previously. Subjects were asked to choose a number on a scale from 0 (no pain) to 10 (severe pain) that corresponded to their current pain level.[27]

**Volumetric Measurements**

At each testing interval, ankle volume was determined by measuring the amount of water displaced by the ankle in a volumetric measuring tank. The reliability of this method of volumetric measurement has been demonstrated in previous literature.[29,30] The procedure for using this device was operationally defined and understood by all investigators prior to data collection. The subjects were instructed to slowly lower their ankle into the tank from a seated position (hips flexed to 90°, knees flexed to 90°, ankles at neutral) until the foot was resting flat on the bottom of the tank and the shaft of the tibia was in a vertical position. Water displaced was collected and measured using a graduated cylinder in milliliters. The water temperature was between 20.0 °C and 22.2 °C.

**Foot and Ankle Ability Measure**

The functional ability of subjects was assessed at each testing interval using the FAAM Activities of Daily Living (ADL) subscale. This outcome measure has demonstrated good reliability and validity and has been shown to be more responsive to changes in functional status than other instruments.[26] The assessment requires subjects to rate their functional abilities in 21 different ADLs on a scale ranging from 4 to 0, with 4 being "no difficulty" and 0 being "unable to do." Responses marked as not applicable are not counted in the total score. The number of items with a response was multiplied by 4 to obtain the maximum potential score. The total score is then divided by the maximum potential score and multiplied by 100 to determine the FAAM ADL subscale score.

**Statistical Analysis**

Statistical analyses were performed using Minitab® 16.1.1 software (Minitab Inc., State College, PA). Descriptive statistics include mean and standard deviation. Independent *t*-tests were used to compare mean scores between the wrap and control groups to determine if statistically significant differences existed.

## RESULTS

The control and wrap groups' demographics are presented in Table 1. There were no significant differences noted in any of the demographics between groups.

**Table 1. Subject Demographics**

| Demographic | Control Group (n=6) | | Experimental Group (n=7) | | p-value | 95% Confidence Interval |
|---|---|---|---|---|---|---|
| | Mean | Standard Deviation | Mean | Standard Deviation | | |
| Age (yr) | 21.17 | 1.60 | 20.14 | 2.67 | 0.417 | (-1.70, 3.75) |
| Height (cm) | 180.34 | 16.62 | 174.17 | 12.52 | 0.475 | (-12.54, 24.88) |
| Weight (kg) | 84.40 | 25.90 | 70.20 | 13.60 | 0.266 | (-13.60, 42.0) |
| BMI ($kg/m^2$) | 25.39 | 4.75 | 22.93 | 2.39 | 0.288 | (-2.60, 7.52) |

The mean differences of the measurements taken at each testing interval are noted in Table 2. When comparing the control group to the wrap group, there were no significant differences when examining FAAM scores or volume changes at any of the testing intervals. However, the change in Numeric Pain Scores at 7 days was statistically significant.

**Table 2. Mean Difference in Outcome Measures Between Testing Interval and Baseline – Comparison of Control Group vs. Wrap Group**

| Outcome Measure | Control Group | | Cryotherapy Compression Wrap Group | | p-value | 95% Confidence Interval |
|---|---|---|---|---|---|---|
| | Mean Difference | Standard Deviation | Mean Difference | Standard Deviation | | |
| Change of pain 24 hours | 2.17 | 1.47 | 2.14 | 1.07 | 0.974 | (-1.61,1.66) |
| Change of pain 48 hours | 3.00 | 1.67 | 2.00 | 2.12 | 0.421 | (-1.76, 3.76) |
| Change of pain 7 days | 3.50 | 1.87 | 3.67 | 2.07 | 0.886 | (-2.74, 2.41) |
| Change of FAAM score 24 hours (%) | 10.33 | 6.53 | 10.00 | 8.52 | 0.938 | (-8.99, 9.65) |
| Change of FAAM Score 48 hours (%) | 20.30 | 15.80 | 13.60 | 9.10 | 0.403 | (-10.87, 24.34) |
| Change of FAAM score 7 days (%) | 29.3 | 14.30 | 23.33 | 9.99 | 0.423 | (-10.38, 22.39) |
| Change of volume 24 hours (mL) | 82.0 | 140.0 | 68.4 | 89.7 | 0.834 | (-157.0, 129.4) |
| Change of Volume 48 hours (mL) | 12.2 | 53.6 | -80.0 | 241.0 | 0.407 | (-353.0, 169.0) |
| Change of Volume 7 days (mL) | 58.3 | 52.8 | -62.0 | 256.0 | 0.311 | (-395.0, 154.0) |

Finally, the groups' mean measurements for each response variable (Numeric Pain Score, FAAM, volume reduction) are presented in Figures 1-3, respectively.

**Figure 1. The mean Numeric Pain Scores at each testing interval**

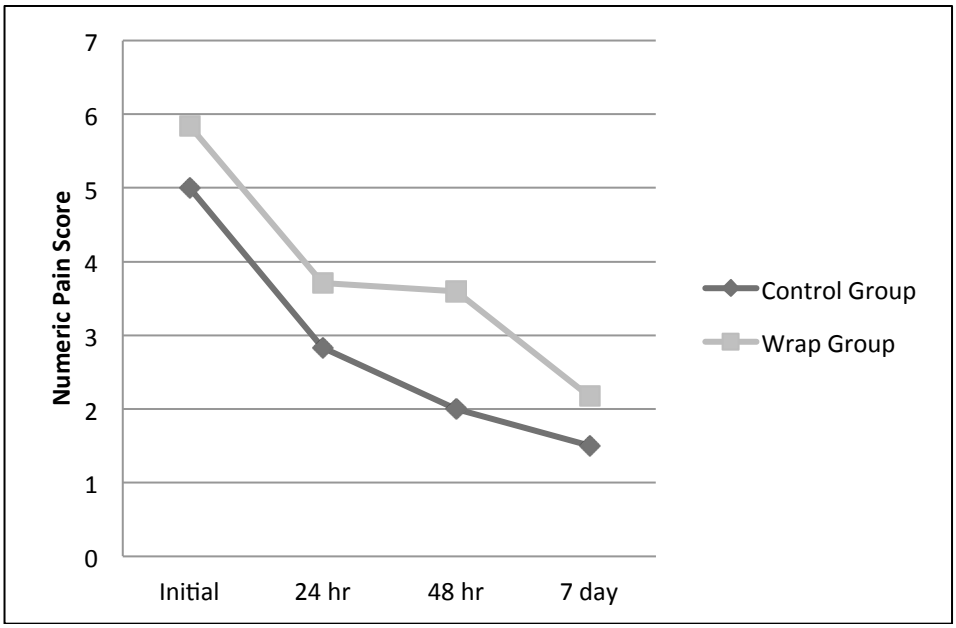



**Figure 2. The mean FAAM scores at each testing interval**

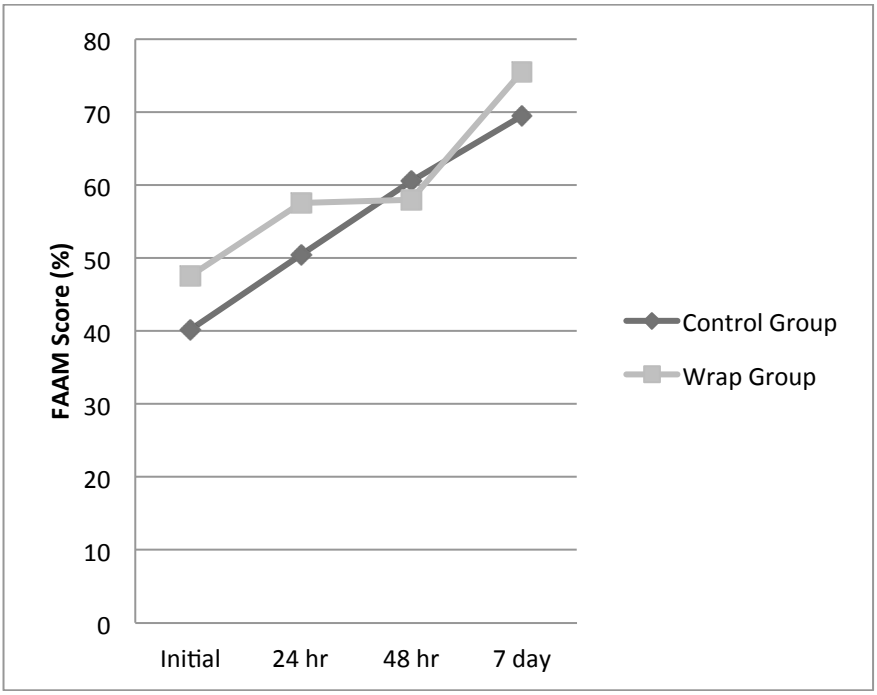
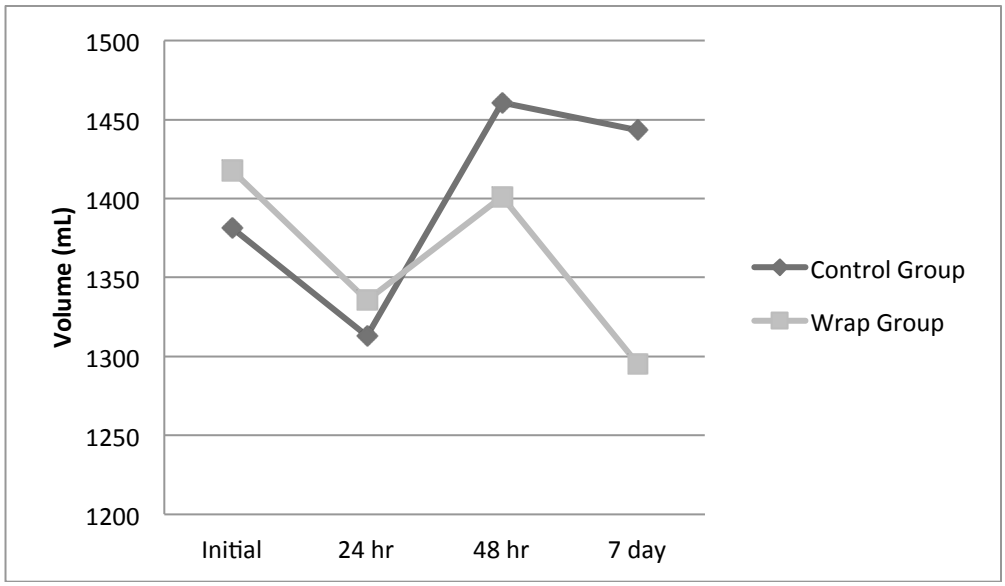


**Figure 3. The mean volume measurements at each testing interval**




Patient compliance to the prescribed treatment assessed by a compliance journal completed by the subjects varied greatly between groups. In the wrap group, 86% (6/7) demonstrated compliance to the prescribed treatment, while 17% (1/6) demonstrated compliance in the control group.

**DISCUSSSION**

This study examined the effectiveness of a novel cryotherapy treatment on pain, edema, and self-reported functional activities. Both the control group and the cryotherapy compression wrap group demonstrated a similar decrease in pain. The minimum detectable difference that indicates a meaningful difference in Numeric Pain Score has been identified as 1.39.[27] Both groups demonstrated over a three-point change after 7 days, suggesting that either treatment was effective in decreasing subjective reports of pain.

This study also examined functional improvement using the FAAM outcome measure. This measure has been demonstrated as reliable and valid in physical therapy literature.[26] The minimal detectable difference indicating a clinically significant improvement is eight points or greater. As shown in Table 2, both groups demonstrated a change in the FAAM score that exceeded the minimal detectable change, suggesting either treatment is effective.

Although not statistically significant, the volumetric changes demonstrated a slight downward trend, indicating the cryotherapy compression wrap group had a greater decrease in edema as compared to the control group (Figure 3). The control group demonstrated an increase in edema 48 hours and 7 days after the injury. These results may suggest that the cryotherapy/compression wrap may be more effective for controlling edema. Alternatively, these results may be related to a decrease in subject compliance among the subjects in this group. In this study, only 17% of the subjects in the control group were compliant with the prescribed treatment, while the cryotherapy wrap group demonstrated 86% compliance. These findings suggest that compliance may be improved by using an alternative cryotherapy/compression product, which may create potential for improved clinical outcomes.

Given these findings, it may be suggested that the Arctic Ease® product would be an effective alternative to the standard PRICE protocol in the management of pain, edema, and functional recovery following ankle sprains. More importantly, the cryotherapy compression wrap could be used in the field because it does not require ice and the wrap's cooling effect can be reactivated by rerolling it and then placing it inside a zip-lock bag with 2 teaspoons of water. Due to the wrap's lightweight features and its

advanced reactivation cooling technology, it could be considered as an alternative form of cryotherapy for military special operators during training and in the battlefield. Nonetheless, this novel form of cryotherapy has not been tested in the field on this population but may be worth examining in the future. The limitations of this study included a small sample, which limits the generalization of the results to a similar population. Further research with a larger sample size and other populations would be needed to determine if the trends noted in this study are reproducible. It would also be beneficial to compare this method of treatment to other accepted methods including continuous cold water therapy and intermittent compression to fully examine its efficacy. Additionally, all subjects in this study did not complete the journal indicating how they used the interventions described in the wrap and control group. For this study, this group of investigators only examined collegiate-aged subjects. Therefore, it is unknown if these results would be reproduced in other subject populations.

When treating these injuries, the clinician may surmise that as function improves swelling would decrease. This was not seen in our study. Although edema improved in the wrap group and increased in the control group, both groups demonstrated a notable change in function as reported on the FAAM. This is consistent with other research examining the relationship between edema and functional activity level. Man et al. reported there was no relationship between ankle-foot swelling and self-assessed ankle function.[31]

Researchers have demonstrated that combining cryotherapy and compression provides better results than cryotherapy alone.[12] Additionally, research conducted by Merrick et al. suggested that continuous cryotherapy may reduce the magnitude of secondary tissue injury.[11] The product tested in this study provides both continuous cryotherapy and compression, which may explain why the wrap group demonstrated a greater decrease in swelling as compared to the PRICE protocol.

Traditionally, when an individual sustains a soft tissue injury, specifically an ankle sprain, the initial management includes PRICE. Cryotherapy is usually recommended for 20 minutes every 2 to 3 hours.[14] Although this is the most widely accepted method to treat this injury, it is not always practical, especially in an operational environment. Since the cryotherapy wraps do not require refrigeration and are light weight, they offer an ideal treatment option that is feasible for use in the field.

Because this product is portable, easy to apply, and seems to provide an effective cryotherapy and compression intervention, it may be a convenient and appropriate product for use in the military domain. It could be easily utilized by injured military members without impacting mission requirements, which sometimes make compliance to prescribed treatment difficult in this population. In particular, Special Operations forces could greatly benefit, due to isolated missions where immediate medical care is not always possible.

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