4-24-2020

# Safety and Feasibility of Bilateral Lower Extremity Cold-Compression Therapy for Older Adults

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April 24, 2020

A Senior Honors Thesis Presented in Partial Fulfillment of the Requirements of the Bellarmine University Honors Program

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Acknowledgements

Thank you to Dr. Jonathon Blandford and the Bellarmine Honors Program for allowing me the opportunity to develop and present this work. A special thanks to Dr. Sonja K. Bareiss for allowing me to join her research, guiding me through the research process, and advising me on writing and presenting our findings. I would like to express my gratitude to Dr. Christopher J. Wingard and Dr. Catherine Crandell for reading, editing, and providing guidance on this project. I would like to thank Bellarmine DPT students Hannah Poteet, Logan Wright, and Melissa Hammer for allowing me to partner with them on this project. Additionally, I want to thank Aquilo Sports for providing equipment; the Thrive Center for allowing us to use their resources; and all individuals who participated in this study. Lastly, thank you to my family, Rosemary, Stephen, and William, for loving and supporting me, always.

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Abstract

Older adults often suffer from diseases that cause chronic pain and swelling that have been treated using a variety of modalities, including cold therapy, compression garments, and analgesics. Cold-compression therapy combines two separate modalities to create a more comprehensive and complete therapy. Cold-compression has been shown to reduce pain and inflammation after exercise in young, healthy adults (Dupont et al., 2017). This therapy also has the potential to relieve pain and inflammation from older adults, especially those suffering from chronic conditions.

To determine if cold-compression is a safe modality for older adults, both older (65 +) and young (18-30) adults were recruited for a 15-minute bilateral lower extremity therapy session. Outcome measures include blood pressure, ankle brachial index (ABI), tactile sensory threshold, pain-pressure threshold (PPT), and cutaneous temperature. Bilateral cold compression was applied using Aquilo cryocompression pants (Aquilo Sports, Louisville, KY). Water temperature and compression of the pants were monitored during the intervention.

Our study included 25 young adults ($\bar{x}$ = 23.9 yrs. $\pm$ 1.4) and 19 older adults ($\bar{x}$ = 70.3 yrs. $\pm$ 3.7). When compared to young adults, older adults saw significantly larger differences in sensory threshold ($p$ = 0.02), PPT ($p$ = 0.02), and cutaneous temperature ($p$ = 0.01) changes in the medial thigh. Average post-intervention skin temperatures on the left medial thigh were lower in the older adults ($\bar{x}$ = 57.6°F $\pm$ 10.5) than the younger adults ($\bar{x}$ = 68.2°F $\pm$ 13.2). Based on our study, cold-compression was well tolerated in the older adults and outcome measures were within safe limits. We recommend cold-compression as a viable therapeutic modality for clinical use in older adults.

Introduction

For years, the most common methods for treating sore muscles have been cold therapy, (i.e. ice, cold water immersion) and analgesics. Stress inflicted on muscles from physical activity can cause inflammation and swelling, which leads to delayed onset muscle soreness (DOMS). DOMS has been predominantly studied in athletes and young adults, but this phenomenon can occur in an individual of any age or activity level. Older adults, especially, experience many chronic diseases such as osteoarthritis which cause musculoskeletal pain or soreness. As a result, older adults rely on analgesics to relieve pain, but not necessarily cold therapy. Because of older adults' decreased temperature regulation and increased cold sensitivity, it was generally thought that cold therapy would have adverse effects on older individuals (Alba, Castellani, & Charkoudian, 2019). However, recent studies on a wide variety of cold therapy techniques have included older adults, showing promising results for pain maintenance among older individuals (Ni et al., 2015).

*Cold therapy*

Cold therapy refers to any modality that involves decreasing the temperature of the interested region of the body (White & Wells, 2013). Methods include, but are not limited to, ice bags, gel packs, cold water immersion, aerosol gas, and whole-body chambers, with temperatures varying from 10° to -110° C (White & Wells, 2013). Cold therapy is occasionally used interchangeably with the term cryotherapy, but cryotherapy is often used to refer to cold therapy that utilizes gas (i.e. liquid nitrogen) to produce extremely cold temperatures (Costello et al., 2014). Predominantly, the scientific literature on cold therapy centers around athletes and young, healthy adults (Clifford, Abbott, Kwiecien, Howatson, & McHugh, 2018; DuPont et al., 2017; Halson et al., 2008). Subjecting the body to cold temperatures is believed to mitigate stress on the body caused by physical activity (Heiss et al., 2019). Mechanical stress to muscle cells can cause increased metabolites in the blood stream, increased temperature, excess fluids, and inflammation (White & Wells, 2013). By decreasing temperature around the affected area, cold therapy can decrease post-exercise pain and inflammation, ultimately leading to a faster and more efficient recovery.

When muscle tissue undergoes exercise-induced stress, the tissue heats up, causing an increase in local tissue temperature (White & Wells, 2013). This temperature increase causes an increase in the energy demand and metabolite production; by cooling the muscle, this energy demand and metabolite accumulation is decreased (White & Wells, 2013). Additionally, exposure to cold temperatures activates cutaneous vasoconstriction pathways that allow the body to mitigate heat loss (Alba et al., 2019). With continued cooling, however, both cutaneous vasoconstriction and vasodilation occur alternately. By altering the blood flow, blood is redirected from the skin to the underlying area, bringing oxygen and nutrients to muscle cells, while also flushing out edema (Chatap, De Sousa, Giraud, & Vincent, 2007). Ultimately, these mechanisms result in a reduction of post-exercise swelling and secondary muscle damage caused by inflammation (White & Wells, 2013).

Secondary muscle damage can cause increased soreness and reduced performance, however cold therapy has been shown to reduce these symptoms (White & Wells, 2013). Cold therapy has an analgesic effect, by slowing nociceptive conduction to reduce pain sensation and thereby reduce the perception of soreness (Halson et al., 2008). DOMS is an important consequence of exercise, because it can reduce performance and cause discomfort that may contribute to a negative attitude towards exercise. DOMS is associated with increased creatine kinase levels and edema, both of which have been shown to decrease with cold therapy (White & Wells, 2013). The literature on cold therapy is predominantly focused on treating DOMS, particularly in athletes (Beliard et al., 2017; Clifford et al., 2018; Halson et al., 2008). However, muscle soreness is an issue that affects people of all activity levels, including older adults.

*Compression*

Compression garments—articles of clothing that exert a specific amount of pressure—have been used among older adults suffering from chronic diseases (i.e. diabetes mellitus, deep vein thrombosis) to elite athletes trying to decrease performance loss (Hill, Howatson, Van Someren, Leeder, & Pedlar, 2014). From whole body garments to garments specific to certain body regions, studies on compression show benefits from pressures ranging from 15 to 46 mmHg (Heiss et al., 2019). For athletes, it is believed that compression attenuates performance loss, muscle soreness, and pain experienced after intense bouts of exercise (Brown et al., 2017). On the other hand, compression has been historically used in older adults to alleviate symptoms of chronic diseases (Hill et al., 2014).

Primarily, compression garments are utilized to improve blood circulation by increasing blood flow. Compression increases the velocity of blood flow by reducing vasodilation, which in turn increases venous return (Brown et al., 2017). This allows blood to transit the site of interest at a faster rate, bringing oxygen and nutrients while also clearing out waste. Studies have shown that creatine kinase levels decrease in the blood stream after wearing compression garments post-exercise (Brown et al., 2017). Improving blood circulation is vital for older individuals as their cardiovascular and neurological functions decrease in efficiency, compromising the ability to perfuse tissues adequately (Alba et al., 2019).

In addition to improved circulation, compression is believed to reduce swelling. Compression garments are often used both in individuals with chronic diseases that experience swelling and athletes during and post-exercise (Hill et al., 2014). The reduction of swelling occurs because the compression garment creates a pressure gradient promoting venous and lymph drainage (Heiss et al., 2019). This pressure gradient reduces the amount of osmotic pressure, reducing the chance of cell lysis (Brown et al., 2017; Heiss et al., 2019). Ultimately, this reduces edema in the interested area, which in turn reduces DOMS.

*Cold-compression*

Cold-compression, also called cryocompression, is the combination of cold and compression modalities. The theory behind cryocompression is that combing the two modalities will create a more efficient and effective treatment modality for pain and swelling (Alfuth, Strietzel, Vogler, Rosenbaum, & Liem, 2016). Using cold and compression therapy separately, but consecutively, improved performance and reduced soreness (Duffield, Murphy, Kellett, & Reid, 2014). Once technological advances allowed the two modalities to be combined into one unit, the expectation was that not only would the physiological benefits be greater, but it would also be more time- and space-efficient (Clifford et al., 2018). Cryocompression has been shown to reduce perceptions of pain and soreness faster, lower creatine kinase levels, and improve sleep quality when compared to individuals who received no treatment (DuPont et al., 2017). Additionally, cryocompression is capable of lowering skin temperatures enough to have an analgesic effect and slow nerve conduction (Ostrowski, Purchio, Beck, & Leisinger, 2018).

*Clinical Application*

To date, the research on cold and cryocompression therapy focuses on elite athletes performing high-intensity workouts (Duffield et al., 2014; DuPont et al., 2017). The benefits of these therapies, however, are not exclusive to this specific population. More recent research has explored the use of cold and cryocompression therapy in other populations, including individuals with knee osteoarthritis, multiple sclerosis, and post-operative patients (Alfuth et al., 2016; Dantas et al., 2019; Leegwater et al., 2017; Ni et al., 2015; Pawik, Kowalska, & Rymaszewska, 2019). Given the positive results in cryocompression treatment in athletes and young adults for DOMS and swelling and in post-operative patients, it could be assumed that cryocompression could be expanded to a more general population, specifically older adults (65 years or older). Older adults experience a significant decrease in participation in physical activity at an adequate level for their health and well-being (Resnick, 2002). This decrease in physical activity, often caused by the development of chronic disease and pain, can accentuate the development of chronic diseases and a lower quality of life (Nelson et al., 2007). Using cryocompression in older adults may help alleviate symptoms of chronic diseases and prevent adverse symptoms of physical activity.

By utilizing cryocompression in older adults, the negative effects of chronic pain and aging might be mitigated; however, it is imperative to ensure that combining cold and compression therapies is safe for older adults. As people age, their thermoregulatory processes slow down and become less efficient. The neurological and vascular mechanisms that react to changes in temperature either become weakened, or some pathways cease all together (Alba et al., 2019). Older adults rely more heavily on intracellular Rho-kinase (ROCK) mediated pathways for whole body temperature regulation, which can cause microvascular damage; however, the mechanisms for local cooling do not appear to alter with age, suggesting cold compression is safe for older adults (Alba et al., 2019). Additionally, blood flow is not as easily regulated, as aging causes blood vessels to stiffen. When this stiffening occurs, blood vessels cannot dilate or constrict as rapidly, which can cause a decrease in venous return. As a result, older adults tend to have elevated blood pressure and less efficient circulation throughout the body compared to younger adults (Gong et al., 2015). Due to these physiological changes in older adults, cryocompression therapy should be tested for safety in older adults before testing for positive therapeutic effects, the focus of this project.

For the purpose of our study, we compared several physiological reactions between young adults (18-39) and older adults (65+) who underwent 15 minutes of cold-compression utilizing the bilateral Aquilo cryocompression pant. During the study, we measured blood pressure, blood flow efficiency, sensory threshold, pain-pressure threshold, circumference, and temperature. By comparing these variables among younger and older adults, we attempt to assess the response to cryocompression in older adults to understand the potential safety of this therapy approach. Additionally, using the Aquilo pants, we were able to assess the feasibility of using this modality in treating older adults and made note of possible areas to improve the appliance design.

## Methods

### *Participants*

Participants were recruited form the general public and partitioned into two categories based on age: the young adults (*n* = 25, mean: 23.9 years) and the older adults (*n* = 19, mean: 70.7 years). Of the young adults, 13 were male and 12 were female, with an average height of 1.72 m, weight of 73.0 kg, and body-mass index (BMI) of 24.7. For the older adults, 10 subjects were male and 9 were female, with an average height of 1.72, weight of 82.9, and BMI of 27.8. The majority of our participants identified as white or Caucasian (*n* = 44), with the other ethnicities being Hispanic (*n* = 2) and African American (*n* = 2). We had a total of 48 participants, with 4 participants that were unable to complete the study. Two participants were turned away from the study due to a known diagnosis of diabetes. Diabetes mellitus affects nerve signaling, which may put them at risk when undergoing significantly cold temperatures. One patient experienced technical difficulty with the equipment and was unable to record sufficient data. Lastly, another individual was turned away due to a Wells score that was higher than 1.

Participants were selected based on age and a generally healthy diagnosis. Age criteria for young adults was between 18 to 30 years old, while the criteria for older adults it was 65 years or older. Both groups underwent health screenings to ensure that all participants could safely complete the study. Subjects were disqualified if they had been bedridden for at least a month, had surgery in the last 6 months, or had undergone chemotherapy in the last year. Additionally, potential subjects were turned away if they had any known vascular disease, open wounds, Reynaud’s disease, diabetes mellitus, or a neuropathy.

In addition to the health screening, participants were screened for deep vein thrombosis (DVT) using the Wells Criteria screening test. Participants who score a 1 or higher were turned away due to a moderate possibility of a DVT (Modi et al., 2016). Because this study involved subjecting participants to significantly cold temperatures, individuals with DVT were at an elevated risk of experiencing circulation problems.

*Measurements*

Temperature

To assess temperature, a non-contact digital laser infrared thermometer (ThermoWorks, Industrial IR Gun (IR-GUN-S) American Fork, UT) was utilized prior to and post-treatment at four marked areas of the lower extremity: the medial thigh, dorsal surface, first web space, and the plantar surface of the foot. These areas were chosen in order to assess the cryotherapy treatment across the entire lower extremity. The skin surface temperature was measured to both assess the effectiveness of our cryocompression treatment and compare the different areas of the lower extremity.

Circumferential Measurements

To measure any lower limb dimensional changes circumferential measure was done at five locations on the lower extremity using a tape measure. The places measured were the metatarsal heads, malleolar, mid-calf, suprapatellar, and mid-thigh. The mid-calf was defined as 10 cm below the tibial tuberosity, and the mid-thigh was defined as 10 cm above the suprapatellar. The circumference was measured for comparison between pre- and post-therapy and between young and older adults. A decrease in circumference after cryocompression treatment is associated with a reduction of swelling and edema.

Cardiovascular Function

To assess changes in cardiovascular function, the participants' blood pressure was taken before and after treatment. The participant was asked to sit down and rest their arm at heart level, and the blood pressure was taken manually with a blood pressure cuff on upper arm. The systolic and diastolic pressures were used to calculate mean arterial pressure (MAP). Additionally, the ankle-brachial index (ABI) was taken prior to and post-treatment. The systolic pressure of the brachium, dorsal pedis, and posterior tibia arteries were recorded using an ABI instrument (Newman Medical's PC based simple ABI 300 system, Arvada, CO). Once all three readings on each side were recorded, the highest of the two pressures in the lower extremity was divided by the upper extremity. An ABI ratio between 0.9 and 1.4 is considered normal; any measurement under 0.9 strongly suggests the presence of a cardiovascular disease, while a measurement above 1.4 is indicative of major cardiovascular problems (Rac-Albu, Iliuta, Guberna, & Sinescu, 2014).

Sensation (Pain Pressure Threshold and Sensory Threshold)

Pain pressure threshold (PPT) was measured using an algometer (AlgoMed; Computerized Pressure Algometer; Medoc, Israel) that was applied to the medial thigh, dorsal surface, plantar surface, and first web space. The pain algometer was applied to the specific location with constant, increasing pressure until the participant expressed discomfort (AlgoMed; Computerized Pressure Algometer; Medoc, Israel). The value at that threshold was recorded as pounds of force. Pain pressure threshold was measured before and after treatment to assess any change in pain sensory after cryocompression.

Sensory threshold was measured by using Baseline® Tactile™ Monofilaments (Fabrication Enterprises Inc., White Plains, NY) at the medial thigh, dorsal surface, plantar surface, and first web space. With the participants eyes closed, the filament was touched to one of the four areas at random, moving from smaller to larger diameter of filament until the participant said they could feel it. Sensory threshold was measured before and after treatment to assess any effect of cryocompression on tactile sensation.

Pressure

Air bladder pressure sensors were attached to both the participant's legs with medical tape at three locations: the anterior thigh, the fibular head, and the lateral calf (PicoPress, Microlab Elettronica Sas, Italy). The pants' compressive pressure was measured at the 1-minute and 10-minute mark of the intervention. Pressure was measured to assess the compressive pressure applied by the Aquilo pants, to ensure that the applied pressure levels were safe, and to determine if any change in pressure occurred over time.

*Aquilo Pants*

Aquilo cryocompression pants are manufactured by Aquilo Sports, (Louisville, KY). These pants were designed to provide both cold and compression bilaterally to the lower extremity, with a targeted audience of cyclists and marathon runners. Unlike similar cryocompression wearables (i.e. GameReady, PowerPlay), Aquilo's cryocompression pants apply a fixed, constant pressure to the entire lower extremity bilaterally, rather than to one specific area or limb (i.e.

ankle, knee, etc.). The pants consist of a stretchy polyester material to provide compression, with polyurethane meshwork on the inside to circulate the cold water from the control unit. The control unit, where the water and ice were kept, was connected to the pants via detachable hoses.

*Procedure*

Participants were given a consent form and a thorough written explanation of the procedure and verbal response to any question or clarifications. After signing consent forms participants health history was recorded, including any medications, surgeries, or significant maladies and screened for any DVT using Wells Criteria questionnaire (Figure 1). Heart rate and pulse oximetry were taken on the second toe, along with blood pressure on the upper arm, all of which were recorded while the participant was sitting for at least 5 minutes. Height and weight were then recorded, and the participant was asked to change into a pair of spandex shorts.

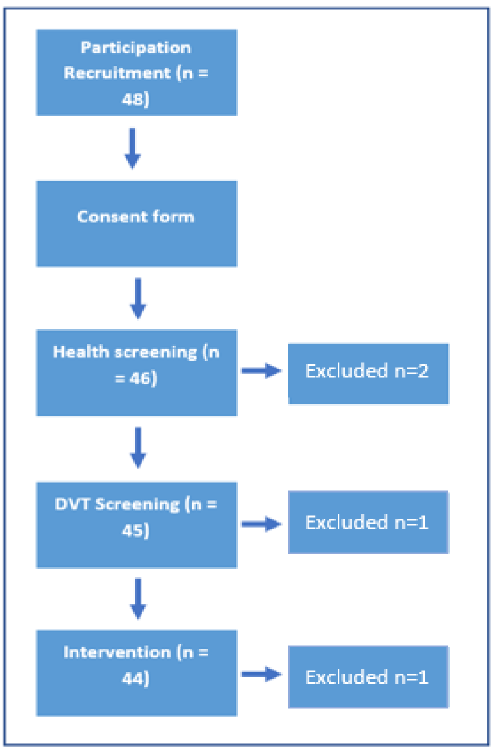


*Figure 1. Flowchart for participant screening and exclusion procedure.*

Once in the shorts, the participant's skin integrity was checked. Using washable markers, marks were made at the points of interest on the lower extremities bilaterally to ensure consistent measurements. Circumferential measurements were taken while the participant was standing, while all other measurements (i.e. temperature, PPT, sensory threshold, and ABI) were taken with the participant seated in a zero-gravity recumbent chair.

Once all measures were taken, the participant was asked to put on the Aquilo pants. Pressure sensors were then taped to each of the participant's legs at the lateral calf, fibular head, and medial thigh. Before the patient sat down, the circulating unit was turned on to ensure that equal cooling occurred on both legs. The participant, then, reclined in the zero-gravity recumbent chair with the Aquilo pants on for 15 minutes. At the 1-minute and 10-minute mark, pant compression pressure readings were taken. The participant was asked the level of pain they were sensing using a numeric 0-10 scale with 0 being none and 10 being unbearable. After 15 minutes, the pants were removed, and the previous measures were taken again; temperature was taken first, sensory second, next ABI, and lastly circumferential measures.

*Statistical Analysis*

Relationships between groups were examined using statistical software through Microsoft Excel for Windows 10, specifically QI Marcos 2020 and the Data Analysis Toolpak. Box and whisker plots were made using GraphPad by Dr. Christopher Wingard. For the statistical analysis, only values on the left leg were used for temperature, sensory threshold, and PPT, due to technical difficulties in the right leg for some participants. Chi-square tests were performed to assess the normality of changes between outcomes in older and young adults. Mann-Whitney U tests were used to compare means of older adults to young adults for changes in ABI, temperature on the left medial thigh, and sensory threshold on the left plantar surface.

Additionally, Mann-Whitney U tests were used to compare changes in ABI among males and females and on the left medial thigh. A two-sample T-Test was performed to compare older adults means to young adults for temperature changes in the left plantar surface, dorsal surface, and first web space; sensory threshold changes in the left first web space, dorsal surface, and medial thigh; and PPT changes in the left medial thigh, plantar surface, dorsal surface, and first web space. Sign tests were performed to assess the change in pre- and post-intervention ABI and blood pressure in both the young and older adults, and ANOVA tests were performed to assess changes in blood pressure across age and gender. Friedman tests were performed to determine if temperature or compression varied significantly in all groups along the left leg.

## Results

As seen in table 1, 25 young adults participated, with 13 males (23-27yrs.) and 12 females (20-27 yrs.), and 19 older adults participated, with 10 males (65-76 yrs.) and 9 females (65-79 yrs.).

| Group | Count (n) | Age (yrs.) | Height (m.) | Weight (kg.) |
|---|---|---|---|---|
| **Young Male (YM)** | 13 | 24.4 ($\pm$1.1) | 1.78 ($\pm$ 0) | 81.3 ($\pm$ 6.7) |
| **Young Female (YF)** | 12 | 23.4 ($\pm$ 1.6) | 1.65 ($\pm$ 0.1) | 64.7 ($\pm$ 9.0) |
| **Older Male (OM)** | 10 | 70.1 ($\pm$ 3.1) | 1.79 ($\pm$ 0.1) | 83.8 ($\pm$ 19.6) |
| **Older Female (OF)** | 9 | 70.6 ($\pm$ 4.4) | 1.64 ($\pm$ 0.1) | 77.1 ($\pm$ 16.2) |

*Table 1. Demographics of participants, including average age, height, and weight. Standard deviation included parenthetically*

Table 2 shows the average systolic and diastolic blood pressures before and after treatment. Pre-treatment systolic blood pressure was significantly higher in the older adults compared to the young adults ($p$ = 0.01), but it did not vary significantly based on sex ($p$ = 0.15). Older males' pre-treatment systolic pressure was 4.7% higher ($p$ = 0.11) than the younger males, while the older females' pre-treatment systolic pressure was 11.8% higher ($p$ = 0.05) than the younger females. Older males had a 4.3% increase ($p$ = 0.035) in diastolic pressure, and older females had a 3.8% increase ($p$ = 0.031) in diastolic pressure. Neither the young males ($p$ = 0.27) or young females ($p$ = 0.11) had a significant change in their systolic pressure after the treatment.

| Group | Pre-Treatment Systolic BP (mmHg) | Post-Treatment Systolic BP (mmHg) | Pre-Treatment Diastolic BP (mmHg) | Pre-Treatment Diastolic BP (mmHg) |
|---|---|---|---|---|
| **YM** | 123.4 (± 9.2) | 120.8 (± 12.0) | 77.8 (± 10.2) | 77.2 (± 7.5) |
| **YF** | 114.5 (± 5.5) | 111.2 (± 8.3) | 75.3 (± 6.1) | 74.0 (± 7.8) |
| **OM** | 129.2 (± 11.0) | 130.8 (± 7.8) | 74.4 (± 5.9) | 77.6 (± 4.4) |
| **OF** | 128.0 (± 19.8) | 126.0 (± 20.3) | 73.6 (± 7.1) | 76.4 (± 8.5) |

*Table 2. Average brachial blood pressures (BP), with standard deviations, across participants before and after treatment. YM = Young Male, YF= Young Female, OM = Older Male, OF = Older Female*

Figure 2 shows the pre- and post-treatment systolic blood pressures of the young adult males and females. These were the systolic pressures recorded during ABI tests, which includes the brachial, dorsal pedis, and posterior tibial arterial pressures. Figure 3 shows the pre- and post-treatment systolic pressures of the older male and female adults. These were the systolic pressures recorded during ABI tests, which includes the brachial, dorsal pedis, and posterior tibial arterial pressures.

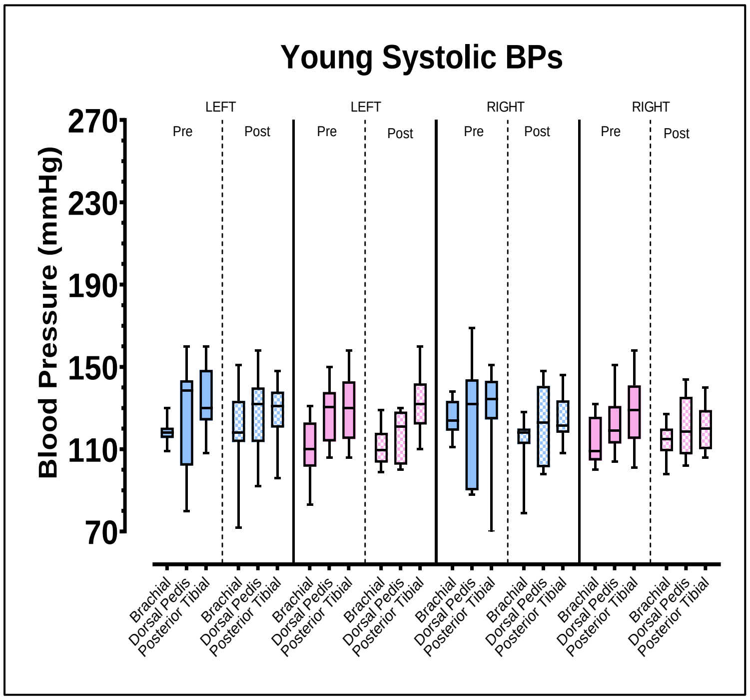


*Figure 2. Systolic blood pressure pre- and post-treatment in the Young Adults group.*

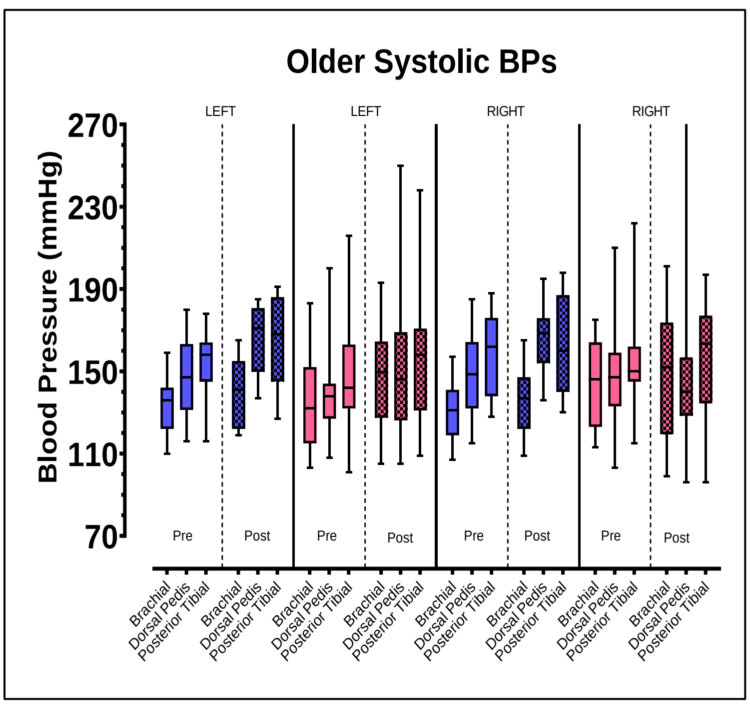


*Figure 3. Systolic blood pressure pre- and post-treatment in the Older Adults group.*

Figure 4 shows the change in ABI, including the left and right sides and the average of both sides, of the young males and females. The average ABI change in young males ($\tilde{x}$ = 0.02) was slightly higher than in the young females ($\tilde{x}$ = -0.04) but was not significant (*p* = 0.25). Figure 5 shows the change in ABI, including the left and right sides and the average of both sides, of the older males and females. The average ABI change in older males ($\tilde{x}$= 0.05) was slightly higher than in the older females ($\tilde{x}$ = 0.02) but was not significant (*p* = 0.60). The change in ABI in older adults was not significantly different from the change in ABI in younger adults (*p* = 0.41). The change in ABI was not significantly different between males and females (*p* = 0.25)

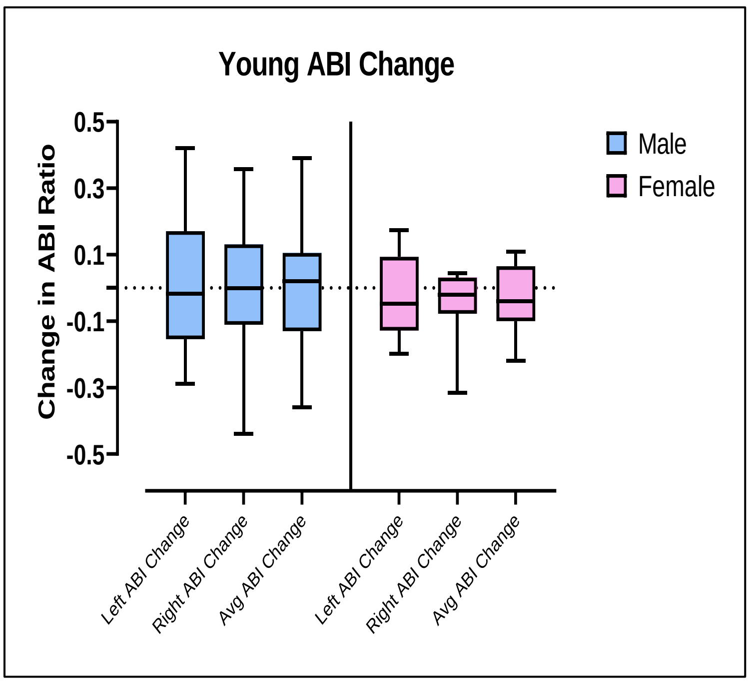


*Figure 4. Change in Ankle Brachial Index (ABI) in Young Adults.*

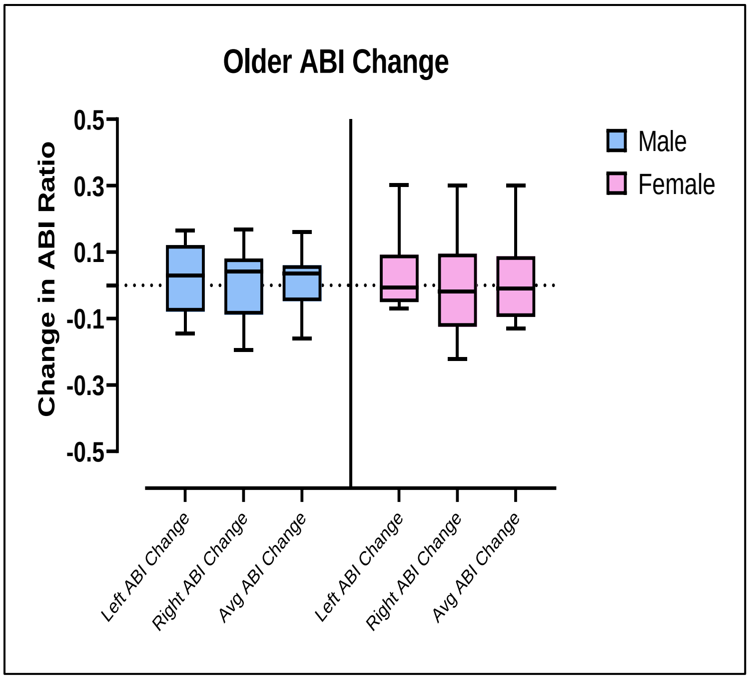


*Figure 5. Change in Ankle Brachial Index (ABI) in Older Adults.*

Table 3 shows the average skin temperature along the left leg in the four areas of interest (i.e. 1st web space, dorsal surface of the foot, plantar surface, and medial thigh). The greatest decrease in temperature (*p* = 0.007) on the left leg was seen in the medial thigh (range = -18.4 to -29.8), and the smallest decrease was in the plantar surface (range = -3.1 to -5.6). On the left medial thigh, the older adults had a 34.1% greater decrease (*p* = 0.01) in temperature ($\bar{x}$ = -29.4) compared to the young adults ($\bar{x}$ = -19.4).

| Group | 1st Web Space (°F) | Dorsal Surface (°F) | Plantar Surface (°F) | Medial Thigh (°F) |
|---|---|---|---|---|
| **YM** | 72.6 (± 4.6) | 71.5 (± 7.8) | 76.5 (± 4.2) | 67.7 (± 12.5) |
| **YF** | 69.3 (± 8.2) | 72.7 (± 5.5) | 73.9 (± 1.7) | 68.7 (± 13.9) |
| **OM** | 77.4 (± 3.4) | 73.7 (± 7.1) | 77.7 (± 3.1) | 58.7 (± 10.3) |
| **OF** | 72.7 (± 6.3) | 72.1 (± 7.9) | 75.2 (± 3.9) | 56.5 (± 10.7) |

*Table 3. Left leg average temperatures, and standard deviations, in participants after 15-minute cold compression. YM = Young Male, YF= Young Female, OM = Older Male, OF = Older Female*

Figure 6 shows the difference in temperatures along the left leg among the young adults. As also seen in Table 3, the greatest temperature change ($p$ = 2.85E-6) was seen in the medial thigh in both younger males and females. The medial thigh temperature difference was 30.5% lower in young males ($\tilde{x}$ = -20.3) than in young females ($\tilde{x}$ = -14.1) but was not significant ($p$ = 0.70). The change in temperature was not significant between young and older adult for the dorsal surface ($p$ = 0.22), web space ($p$ = 0.07), and plantar surface ($p$ = 0.90). The change in temperature was significant between young and older adults in the medial thigh ($p$ = 0.01).

Figure 7 shows the temperature difference along the left leg in the older adults in the four areas of interest (i.e. 1st web space, dorsum of the foot, plantar surface, and medial thigh). As seen in Table 3, the medial thigh had the largest decrease in both older males and females ($p$ = 1.2 E-10). Older females had a 4.5% greater decrease in the medial thigh ($\tilde{x}$= -32.6) than the older males ($\tilde{x}$ = -31.2), but that decrease was not significant ($p$ = 0.68).

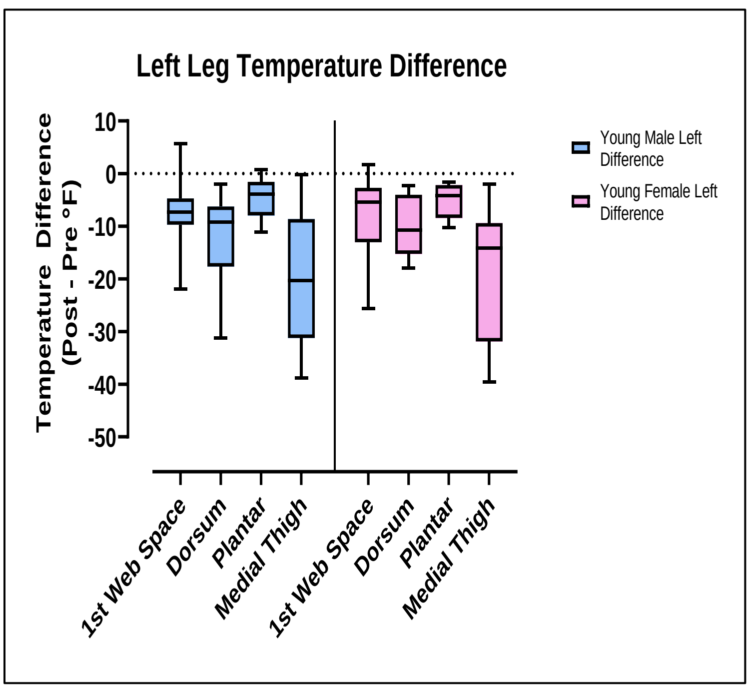


*Figure 6. Temperature differences along the left leg in the Young Adults group.*

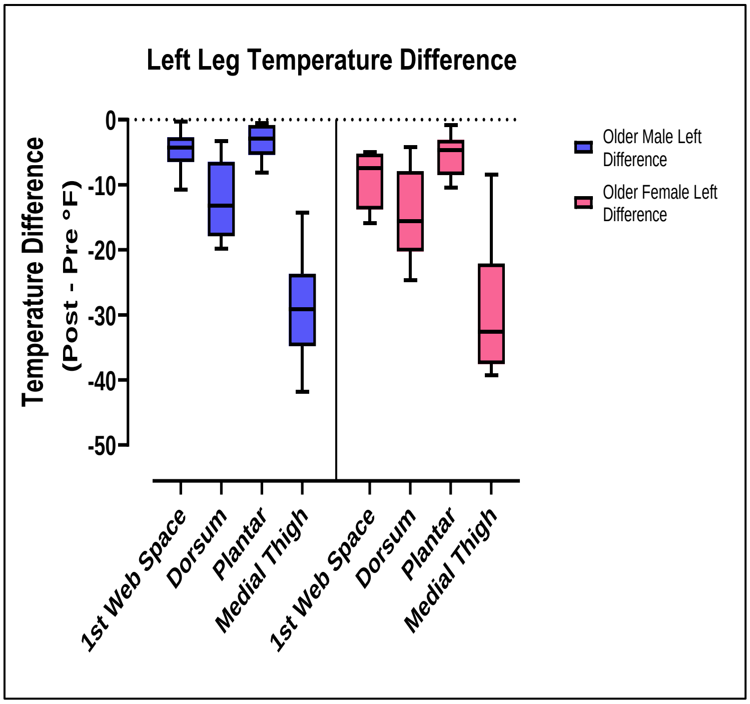


*Figure 7. Temperature differences along the left leg in the Older Adults group.*

Figure 8 shows the compression exerted on the left leg by the Aquilo pants at the 1st and 10th minute of treatment in young males and females. The greatest amount of compression was seen in the lower calf (male $\tilde{x}$= 19.5, female $\tilde{x}$ = 23.0), then the medial thigh (male $\tilde{x}$= 8.0, female $\tilde{x}$= 9.5), and the lowest compression was in the fibular head (male $\tilde{x}$= 1.0, female $\tilde{x}$= 3.0). The difference in compression on the left lower calf as compared to all other sites monitored was significant among all sex and age groups ($p$ = 0.039). Figure 9 shows the compression exerted on the left leg by the Aquilo pants at the 1st and 10th minute of treatment in older males and females. The greatest amount of compression was seen in the lower calf (male $\tilde{x}$= 21.5, female $\tilde{x}$= 19.0), followed by that at the medial thigh (male $\tilde{x}$= 3.0, female $\tilde{x}$= 4.0), and the lowest compression was at the fibular head (male $\tilde{x}$= 1.0, female $\tilde{x}$= 3.0). Older adults experienced significantly less compression on the left medial thigh, as compared to young adults ($p$ = 2.1E-8).

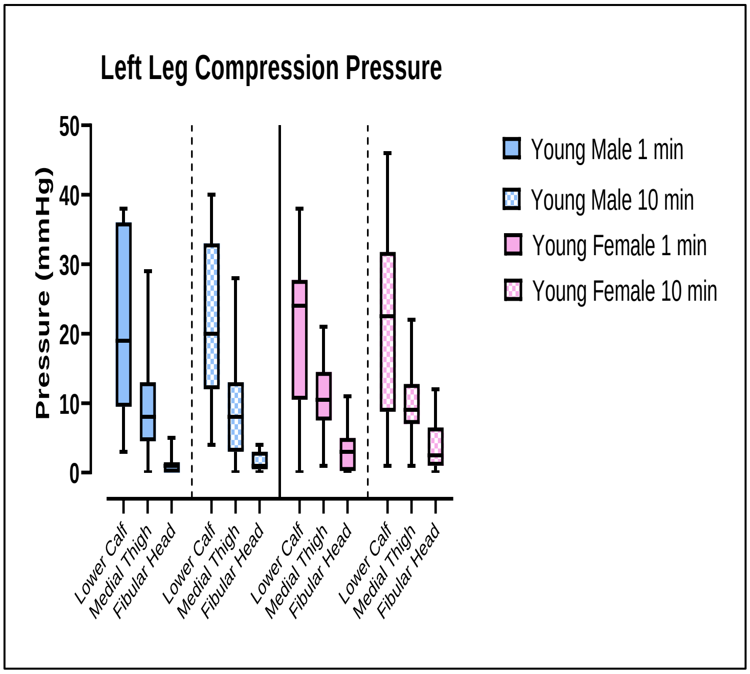


*Figure 8. Compression of the left leg at minute 1 and 10 of the treatment in the Young Adult group.*

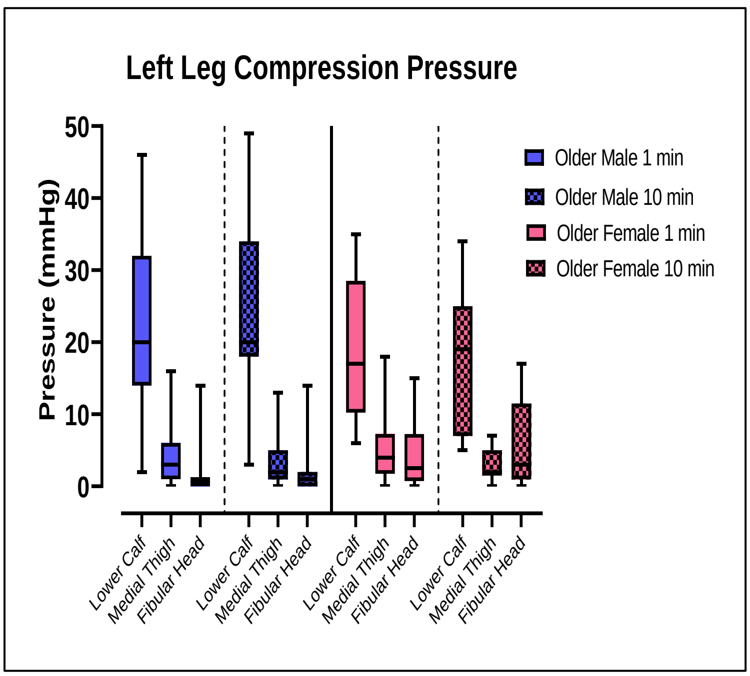


*Figure 9. Compression of the left leg at minute 1 and 10 of the treatment in the Older Adult group.*

Overall, males from both groups averaged at a level of 3.81 prior to treatment and 4.05 after; females averaged 3.71 before treatment and 3.96 after. Figure 10 shows the change in sensory threshold on the left leg in young males and females. Young males saw the greatest change at the medial thigh ($\tilde{x}$ = 0.39, $p$ = 0.15), while young females saw the greatest median change at the 1st web space ($\tilde{x}$ = 0.39, $p$ = 0.45). The change in sensory threshold was not significant between any sites the leg in the young adults ($p$ = 0.28). The average pre-treatment level for both young adult groups was 3.62, which roughly translates to a sensory threshold of 0.4 grams of force. Average post-treatment levels for young adults was 3.77, which is between 0.4 and 0.6 grams of force.

Figure 11 shows the change in left leg sensory threshold for the older males and females. The greatest change occurred at the medial thigh for both males ($\tilde{x}$= 0.67, $p$ = 0.13) and females ($\tilde{x}$= 0.47, $p$ = 0.009). The change in sensory threshold across the different sites on the left leg was significant in older adults ($p$ = 6.6E-4). There was no significant difference in left sensory threshold change between older and young adults at the first web space ($p$ = 0.62). There was a significant difference at left sensory threshold in the dorsal surface ($p$ = 0.01), plantar surface ($p$ = 0.01), and the medial thigh ($p$ = 0.02). The average pre-treatment level for both older adult groups was 3.90, which converts to about 0.6 grams of force. Post-treatment average levels for older adults was 4.23, which is roughly between 1.4 and 2.0 grams of force.

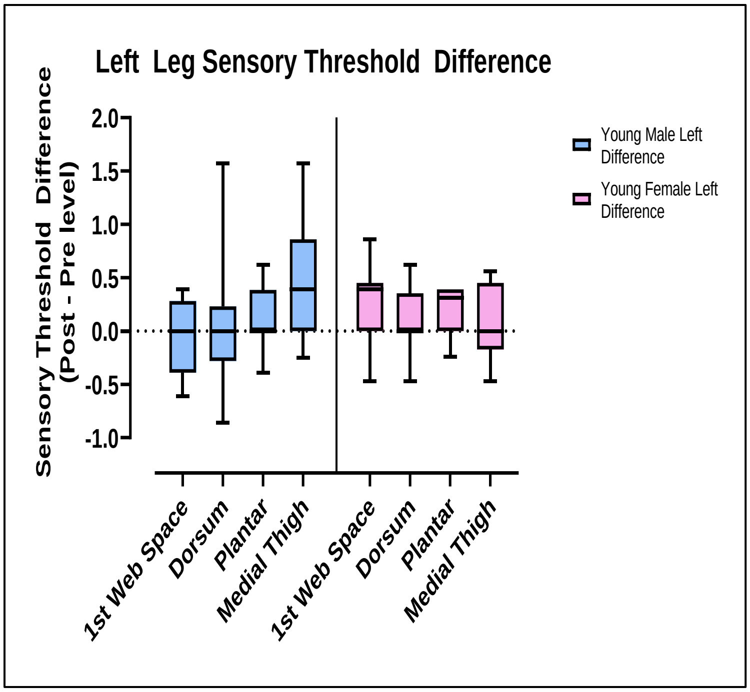


*Figure 10. Change in sensory threshold in the left leg in the Young Adult group.*

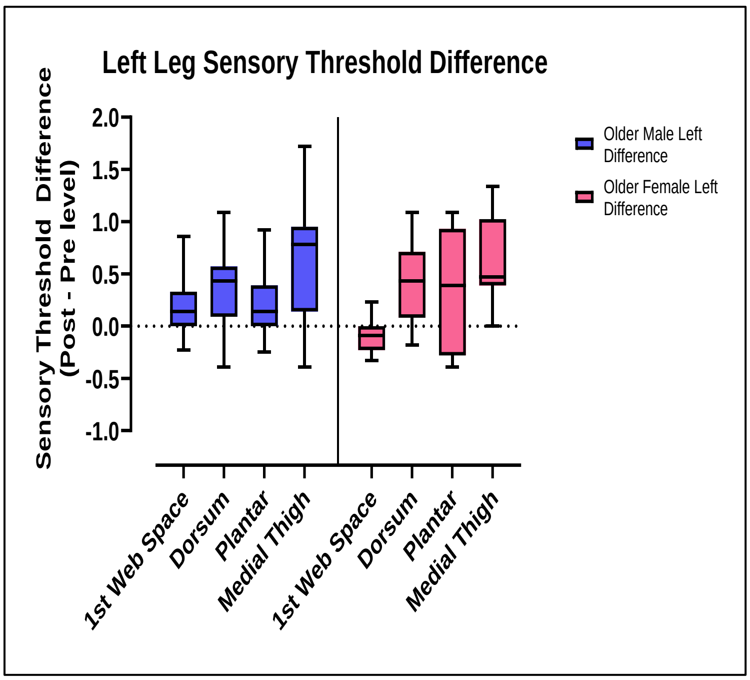


*Figure 11. Changes in sensory threshold in the left leg in the Older Adults group.*

Figure 12 shows the change of left leg pain pressure threshold (PPT) in young males and females. Young males had the greatest change at the 1st web space ($\tilde{x}$= 4.91, $p$ = 0.12), and young females had the greatest change at the dorsum of the foot ($\tilde{x}$= 2.97, $p$ = 0.52). The difference in PPT across the sites of the left leg was not significant in young adults ($p$ = 0.078). Figure 13 shows the change of the left leg pain pressure threshold (PPT) for the older males and females. Older males had a greater change at the medial thigh ($\tilde{x}$= 1.40, $p$ = 0.85), and older females had a greater change in the 1st web space ($\tilde{x}$= 3.52, $p$ = 0.92). The PPT difference across the different sites of the left leg was not significant in the older adults ($p$ = 0.88). There was no significant difference between young and older adults in average PPT change at the plantar surface ($p$ = 0.85), dorsal surface ($p$ = 0.81), and first web space ($p$ = 0.65). There was a significant difference in PPT change between young and older adults at the medial thigh ($p$ = 0.02).

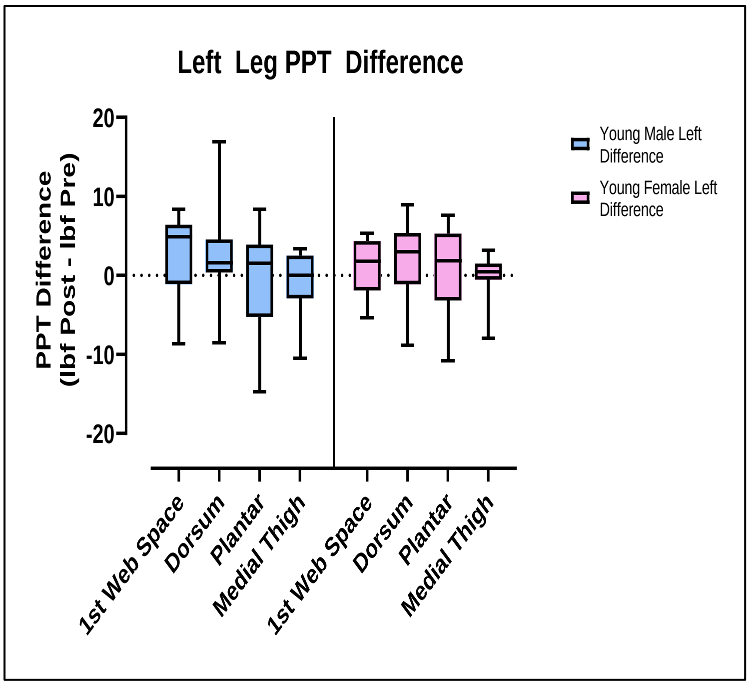


*Figure 12. Change in pain-pressure threshold (PPT) in the left leg in the Young Adults group.*

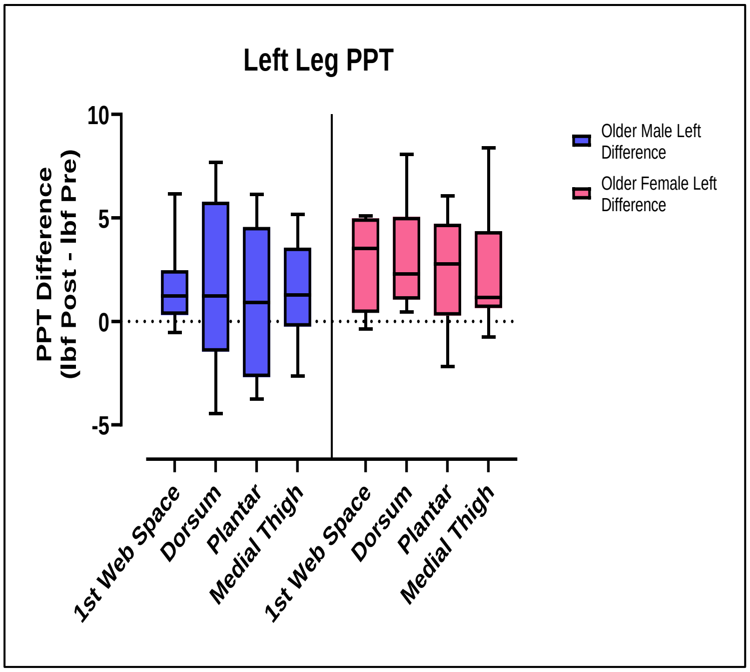


*Figure 13. Change in pain-pressure threshold (PPT) in the left leg in the Older Adults group.*

## Discussion

This study was performed to determine the safety and feasibility of bilateral cold-compression in older adults by monitoring cardiovascular, tactile sensory, pain-pressure threshold (PPT), and cutaneous temperature. Comparing pre- and post-treatment blood pressures and ABI scores, no significant differences appeared between young and older adults. Cutaneous temperatures of the lower limbs remained within safe temperatures for all participants. Additionally, post-intervention sensory threshold and PPT saw significant increases in the older adults, compared to young adults. Though further studies should be performed, this suggests that cold-compression may be an effective analgesic therapy for older adults. Our study found that cold-compression was well-tolerated in older adults, and outcome measures suggest that it is a safe intervention for this population.

*Water Temperature*

Most cold water immersion (CWI) treatments consist of water temperatures between 8-10°C, or 46.4-50°F (White & Wells, 2013). According to White and Wells, studies of CWI at 8°C (46.4°F) and 22°C (71.6°F) showed up to 40% reduction of whole limb blood flow occurred at both temperatures, but only the subjects in 22°C showed a significantly reduced cutaneous blood flow. White and Wells concluded that the cutaneous blood flow was unchanged in subjects in 8°C due to redistribution of blood flow. As blood flow is redirected to the skin and superficial tissues, flow is reduced in the deeper tissues, such as the muscles.

White and Wells also found that CWI of 5°C (41°F) for 15 minutes showed a lessened creatine kinase activity and reduced muscle edema. While we did not measure for these variables, we can extrapolate that our subjects experienced a similar change. Additionally, White and Wells saw a correlation of CWI at 15°C (59°F) with improving the parasympathetic nervous system, specifically the restoration of vagal tone and improved heart rate recovery and variability. While we might generalize that these effects occurred in our participants, due to the temperature of the water, further studies are needed to confirm those types of responses.

*Compression*

Aquilo Sports does not list a standard compression on its website, because unlike other cold-compression modalities, the Aquilo pants do not have adjustable pressure control. Other products such as GameReady, which advertises pressure ranges from 5 to 75 mmHg (Avanos Medical INC., Alpharetta, GA), and PowerPlay, which advertises pressure ranges from 50 to 70 mmHg (PowerPlay®, Tulsa, OK). According to DuPont, in a previous study, compression by the

Aquilo pants ranged from 15 to 25 mmHg on the quadricep, patella, gastrocnemius for 16 healthy, young athletic adult males (DuPont et al., 2017). Our findings showed compression ranging between 4.5-23.4 mmHg: lower calf ranging from 19.1-35.5 mmHg, medial thigh ranging from 3.3-14.3 mmHg, and femoral head 1.2-12.3mmHg (Fig. 10, 11). Because of the Aquilo pants design, the compression applied depends on body type of the participant and the fit of the pant. The difference in the pressures reported between that study and our results may reflect a mixed non-athletic population and an older adult population with significant body form differences. To address this concern, a new version of the appliance is being designed that would allow for variable pressure to be applied at different sites by adjustable Velcro pads, rather than a fixed zipper design as utilized in our study.

Studies suggest that compression garments (CG) that apply pressure between 18-21 mmHg can decrease the amount of time muscle stiffness is reduced during the inflammation phase of DOMS (Heiss et al., 2019). The only area where we observed pressures in this range was at the lower calf. Large ranges of pressure (10-21 mmHg), have shown enhanced tissue repair, attenuation of DOMS symptoms, and faster performance recovery, specifically strength and power (Hill et al., 2014). Hill et al. suggest that CGs work either by reducing inflammation and mitigating cellular damage within a 24-78-hour period, or they may increase recovery in factors key to reducing voluntary muscle activation. Additionally, they found that compression within 10-20 mmHg reduced concentrations of creatine kinase and improved venous return. Both the lower calf and medial thigh in our study had compressions within this range, suggesting these physiological changes might occur, though further research should be conducted to determine the exact changes.

*Skin Temperature*

Across all groups, the largest decrease in skin temperature occurred in the medial thigh. On the left leg, the average medial thigh temperature after 15 minutes of cold-compression was 62.9°F (17.1°C). The older adults saw a significantly larger decrease in the medial thigh temperature compared to younger adults. There did not appear to be any relationship between gender and skin temperature. The average temperature drop between the different sites on the leg revealed significant differences. Temperatures decreased the most on the medial thigh, then the dorsal surface, first web space, and lastly the plantar surface. This could be due to the connecting hose attaching closest to the medial thigh, meaning that the water cools this area first, or it could also suggest that the pant design with low compression at some sites reduces surface contact and does not provide for efficient cooling.

A previous study done with the Aquilo pants saw skin temperatures between 10-12°C (50-53.6°F) along the quadriceps and calf (DuPont et al., 2017). That study, however, was done on healthy young adults and included an exercise routine. It is believed that exercise may cause skin temperatures to decrease more, due to an improved cold-induced vasodilation (CIVD) response (Alba et al., 2019). Further studies on older adults and cold-compression should include exercise to determine if a similar result occurs.

In a study on hyperbaric cryocompression in the elderly, it was found that cutaneous analgesia is significant at 13.6°C (56.5°F) (Chatap et al., 2007). Additionally, Chatap et al. found that at 12.5°C (54.5°F) nerve conduction slowed by 10%, and at 11°C (51.8°F) enzymatic metabolism decreased by 50%. For our study, the lowest temperature average was the medial thigh in older females at 56.5°F. According to our resulting skin temperatures, 15 minutes in the Aquilo pants may cause cutaneous analgesia, but it may not significantly slow nerve conduction or decrease enzymatic metabolism. A longer treatment duration may decrease cutaneous temperatures enough to see these changes.

Other studies have shown that skin and core temperature correlate due to conductive cooling (White & Wells, 2013). White and Wells found that when cutaneous temperatures are within 12-21°C (53.6-69.8°), core temperatures decrease linearly due to vasoconstriction. This limits the amount of blood that travels to the cold area. Once the skin begins to warm again, the cutaneous vessels vasodilate, pulling that colder blood deeper into the body, causing the muscles to cool (White & Wells, 2013). The temperatures in the medial thigh post-intervention fall into this temperature range, so we can conclude that similar conductive cooling may have occurred.

One purpose of this study was to assess the safety of cold-compression in older adults. A decrease in cutaneous temperature of 5-10°C (9-18°F) causes vasoconstriction mediated by noradrenaline (NA), but at 17°C (62°F) vasoconstriction occurs via Rho-kinase (ROCK) pathway (Alba et al., 2019). Alba et al. notes that NA synthesis and release of NA is blunted in older adults, and as a result, ROCK pathways are the main pathway for older adults. Because of this, subjecting older adults to temperatures below 17°C should not be dangerous, but exposing them for long periods of time may impair these signaling pathways for regulating vasoconstriction. Additionally, temperatures at or below 6.5C (43.7F) have the potential to damage the skin (White & Wells, 2013). In our study no individuals experienced these harmful temperatures, which suggests that this procedure is safe in healthy individuals.

*Cardiovascular response*

No significant changes occurred in the systolic blood pressure (SBP) or ABI among any group. Older adults did exhibit a significant increase in diastolic blood pressure (DBP), as they averaged 74 mmHg prior to treatment and 77 mmHg after. While this increase of 3 mmHg was significant, the range of DBP post-treatment was 60-90 mmHg, which is still within the normal range (Ferrer et al., 2018; Taylor, Wilt, & Welch, 2011). The slight rise in diastolic pressure may reflect the effect of compression and cutaneous vasoconstriction shifting venous blood form the peripheral to the more central reservoir.

Both pre- and post-treatment ABI averages were within the normal values of 0.9-1.4 for all groups (Rac-Albu et al., 2014). None of the cardiovascular outcomes suggested any harmful consequences of performing cold-compression. ABI compares the blood pressures of the lower extremity with the upper, and it is often used to measure the efficiency of blood flow across the body; ABI is considered a reliable tool for peripheral arterial disease (PAD), among other cardiovascular morbidities (Rac-Albu et al., 2014). It is generally believed that blood pressure is higher in the legs compared to the arms. Rac-Albu et al. explain this higher pressure is due to vascular resistance that amplifies the pulse in the limbs, along with increased hydrostatic pressure that causes a thickening of the arterial wall. Accordingly, the ABI range for healthy individuals is 0.9 to 1.4. Values under 0.9 have a strong association with PAD and non-fatal cardiac events, while values greater than 1.4 have a correlation with major cardiac events and risk of cardiac death increases 2 times (Rac-Albu et al., 2014). Additionally, studies have shown slight differences between the left and right side, and lower ABI scores in older adults compared to young adults, as well as females compared to males (Smith, Lee, Price, van Wijk, &

Fowkes, 2003). In pre-treatment ABIs, we saw slight differences in the right and left leg among individuals, and the older adults averaged lower ABI scores, though not statistically significant.

Given the cardiovascular changes that occur with aging, the question of adverse cardiovascular effects during cold-compression is important. Research suggests that local cooling mechanisms remain largely intact in older adults, but their reliance on the ROCK pathways are associated with vascular pathology (Alba et al., 2019). This suggests that cold-compression is safe for most older adults, but caution should be used for individuals with serve vascular problems. The post-intervention ABI average among older adults was 1.13, which is within the normal range (Smith et al., 2003). In addition to ABI, we also compared SBP in both the ankle and arm. As with brachial SBP, ankle SBP tends to be higher in older adults (Gong et al., 2015). Gong et al. recommends an ankle SBP range of 100-165 mmHg in young adults, and 110-170 mmHg in older adults. The ankle SBP averages stayed within these ranges for both age groups.

*Sensory Threshold*

Except for the first web space, there were significant difference in sensory threshold changes among the two age groups. Older adults saw an average increase of 0.33 in their threshold level, while young adults only increased by 0.15. Baseline sensory threshold level was slightly higher in older adults ($\bar{x}$ = 3.9) than young adults ($\bar{x}$ = 3.6), which is consistent with previous studies (Menz, Morris, & Lord, 2006; Mildren et al., 2017; Toledo & Barela, 2014). Foot sensory is important in older adults, as it aids in posture and can help prevent falls (Viseux, 2020). Viseux found that, as people age, peripheral sensory receptors degenerate, decreasing their capacity to detect stimuli and results in a decline in foot sole skin sensitivity. Mildren et al. found that older adults had 5.5 times higher threshold levels than younger adults, which is considerably higher than our results. They suggest that the increase in sensory threshold is a result of decreased sensitivity to stimuli for fast-adapting (FA) afferents, these proprioceptive fibers are important in maintaining balance and may contribute to increased falls risk in older adults  While the sensory threshold increased the least in the plantar surface, older adults with a history of falling should be monitored when using cold-compression.

*Pain Pressure Threshold*

Older adults saw a significantly larger change in PPT than younger adults, and the older females saw a significantly higher increase over their male counterparts. PPT measures a person's response to pressure and is used to quantify pain tolerance (Park, Kwon, Weon, Choung, & Kim, 2014). Cold-compression has been shown to increase PPT, with 3 minutes of cold-compression able to maintain an increased PPT for at least 10 minutes after treatment (Park et al., 2014). Park et al. found that an increased PPT, following cold-compression, improved range of motion and decreased stretch sensitivity, thus improving a patient's flexibility by increasing pain tolerance. This is critical in treating patients, such as older adults, who may have less flexibility due to a limited range of motion or chronic pain.

As people age, PPT is believed to decrease, meaning that older adults are more sensitive to noxious stimuli (El Tumi, Johnson, Dantas, Maynard, & Tashani, 2017). According to El Tumi et al., age alters the structure, and subsequently the functionality, of nociceptors and their transmission pathways, leading to a diminished reaction time to mechanical stimuli.

Additionally, they assert that older adults have diminished endogenous pain inhibition, meaning older adults with chronic pain have an even lower PPT. El Tumi et al. also found that PPT was related to sex, with males having a higher PPT than females as young adults, but this reversed with age. It is believed that females have an increase sensitivity to pain during reproductive years, which declines post-menopause (El Tumi et al., 2017). This is also demonstrated in our results: the average PPT in young females was 5.03 lbf less than the young males, but the older females had a PPT 1.69 lbf more than the older males. Overall, though, the young adults had a higher PPT average than the older adults by almost 1.5 times. Using cold-compression to increase PPT, and thus decreasing pain sensitivity, should be studied further to determine its full effects.

## Conclusion

Given the outcomes of this study, we believe it is safe for healthy, older adults to use cold-compression modalities for therapeutic intervention. The main purpose of this study was to compare changes after cold-compression in young and older adults. Young adults served as a baseline to determine if changes experienced among older adults are unique. No significant changes in blood pressure or ABI measures suggests that cold-compression does not have an adverse effect on the cardiovascular system in older adults. Water temperature and compression of the pants were within the typical range used in clinical applications, and skin temperatures stayed above harmful levels. Sensory threshold and PPT changes suggest that cold-compression has the potential to provide pain relief in older adults.

Use of the Aquilo pants was well received by all participants, but the current pant design required assistance for all older adults to don the pants. Fitting individuals to the pants was somewhat more difficult in older adults. Most older adults had to increase pant size due to tight fitting in the waistline, which affected the compression in the medial thigh. Additionally, problems with circulation were caused by folding of the inner polyurethane layer that resulted in uneven cooling for some in the right leg. Despite these technical difficulties, we still demonstrated that most participants experienced sufficient cooling and compression.

Our study demonstrates that the use of bilateral cold compression, like the Aquilo pants, is safe and feasible in older adults. The use of cold-compression in older adults has the potential to provide an alternative therapeutic intervention in the clinical setting or home. Older adults are higher risk of suffering from chronic pain that limits their ability to exercise or even perform basic daily tasks. Additional studies should be performed to further elucidate the pain-relieving effects of cold-compression in older adults, particularly post-exercise.

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