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Evaluation of Four Portable Cooling Vests

for Workers Wearing Gas Extraction Coveralls in Hot Environments

by

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A thesis submitted in partial fulfillment
of the requirements for the degree of
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microclimate cooling, heat strain

DEDICATION

I dedicate this work to my family. The completion of this thesis would not have been possible without the encouragement and love of my wife Tiffany, nor the inspiration provided by our daughter Paige.

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ABSTRACT

Excessive exposure to heat stress can cause a host of heat-related illnesses. For laborers, job specific work demands and protective garments greatly increase the risk of succumbing to the effects of heat stress. Microclimate cooling has been used to control heat stress exposure where administrative or engineering controls are not adequate. This study tested the performance of four personal cooling vests for use with insulated protective clothing (gas extraction coveralls) in warm-humid (35^{0}C, 50% relative humidity) and hot-dry (40^{0}C, 30% relative humidity) conditions. On 10 separate occasions, 5 male volunteers walked on a treadmill to elicit a target metabolic rate of 300 watts, for 120 minutes, while wearing a (a) water cooled vest, (b) air cooled vest, (c) frozen polymer vest (FP) (d) liquid CO2 cooling (LCO_2) vest, or (e) no cooling (NC). A three-way mixed effects ANOVA was used to assess the results and a Tukey's Honestly Significant Difference multiple comparison test was used to identify where significant differences occurred ($\rho < 0.05$). The air, water, and FP systems produced significantly lower heat storage rates compared to NC. To the extent that the gas extraction coverall is worn in an environment between 30^{0}C and 45 ^{o}C and the rate of work is moderate, the FP, air and water vest were shown to manage heat storage well, reducing storage rate by about 48%, 56% and 65% respectively.

CHAPTER 1: INTRODUCTION

Problem Statement

Laborers exposed to an excessive amount of heat stress are at risk for heat-related illnesses such as heat cramps, heat exhaustion, and heat stroke. The extent of heat stress exposure depends on the environment, work demands, and clothing. Heat stress may also impair cognitive function, leading to poor decision-making and careless work practices.(1)

Of primary consideration in assessing heat stress are the environmental factors of air temperature, humidity, air movement, and radiant heat. High air temperature and radiant heat load can add heat to the body while excessive humidity can lower the rate of evaporation, the body's primary means of heat dissipation. The physiological impact of these environmental related heat stress factors can be greatly amplified by clothing and work demands. When physiological adaptations to heat have reached their limits uncompensable heat stress ensues.

Personal protection ensembles, such as those used by firefighters and gas utility workers, reduce water vapor permeability and increase insulation. Under such conditions the body cannot compensate for the lack of cooling, heat storage ensues, and the body has a reduced physiological tolerance to heat stress.(2) Gas utility linemen, who are repairing or maintaining gas transmission pipelines, rely on flame resistant gas extraction coveralls for protection when there is the potential of blowing gas ignition and explosion. These coveralls are constructed entirely of flame resistance materials and incorporate fitted ankle, wrist, and neck cuffs to prevent flammable gas from entering. The coveralls are designed to be worn over a harness, and are built with a lanyard port in the back, necessary to extract workers if a flash fire occurs. The gas extraction coverall, related flame resistance balaclava sock hood, and multilayer heat protective gloves protect workers by insulating them against heat long enough to egress from the area in the event of an explosion.

The extent of heat stress is difficult to appraise when protective ensembles are donned for protection from physical, chemical, or biological hazards.(3-5) The National Institute for Occupational Safety and Health (NIOSH) and ACGIH® (American Conference of Governmental Industrial Hygienist) publish guidelines for heat stress evaluation, however; these guidelines are only applicable to workers that are not wearing barriers which significantly restrict evaporation. Inability to evaluate heat stress means employers and employees have to rely on physiological monitoring to avoid heat related illness.(6) Thus, gas utility crews and employers are confronted with the competing task of managing heat stress via physiological monitoring, reducing risk of fire related injuries, and completing the assigned job in an economically feasible timeframe. Moreover, the small size of the crews, requisite specialized training, and mobility of the gas utility crews also limits the usefulness of administrative controls such as work-rest cycles.

Strategies to control exposure to heat stress in protective ensembles include intermittent work cycles (vary duration with conditions), intermittent work coupled with cooling system during the rest phase, continuous cooling during uninterrupted work, continuous cooling coupled with intermittent work, and self-limiting work breaks. One approach is to remove the protective clothing during the rest phase and rely on natural cooling, but this tactic assumes that the ambient environment is conducive to adequate heat exchange during rest periods when the ensemble is removed.(7) Using natural cooling or cooling systems during rest periods does not diminish the discomfort of wearing protective ensembles during work nor does it reduce cardiovascular strain or sweat production during work cycles.(8) Such administrative strategies may provide a false sense of protection from heat related illness; rest cycles merely oscillate the cumulative heat storage in conditions conducive to heat stress.(9) The cooling approach examined in the present study is continuous cooling during uninterrupted work.

Providing cooling during continuous work relies on portable systems to create a microclimate inside the protective ensemble such that thermal balance is achieved. Microclimate cooling is usually achieved by circulating air or liquid to and from a heat sink or by wearing phase changing materials. The former is referred to as active cooling while the latter is referred to as passive cooling. Regardless of system design, the goal of personal cooling is to reduce heat storage, increase comfort, and lower the physiological strain of working in protective clothing in uncompensable conditions.

Estimating the cooling power of a cooling device for use with a protective ensemble of particular design is best accomplished through physiological monitoring during human trials.(4) Other methods of evaluating physiological impact of an protection ensemble are mathematical modeling, and use of thermal manikins.(4) Methods of monitoring heat stress include rectal temperature, heart rate, sweat rate, and metabolic rate. In addition, exposure time is used to express increase in subject tolerance and/or control of heat storage in uncompensable conditions.

Differences in cooling system performance can be observed as differences in the rate of increase of body core temperature (T_{re}). Therefore, the cooling rate (CR) of a particular cooling device can be estimated by calculating the difference between the metabolic heat (M) generation measured during a controlled trial and the observed rate of heat storage (S) during the same trial. That is CR = M – S. In this study, CR is used as a means for comparing cooling vest performance to previous studies.

The purpose of this research was to examine the performance of four commercially available personal cooling systems in controlling heat strain in people wearing gas extraction ensembles during continuous exercise in standard dessert or standard subtropical conditions.

Research Question

What are the differences among the cooling systems on safe exposure time and the rate of change of body temperature? The null hypothesis of this study is that there is no difference among commercially available cooling systems with respect to the cooling rate.

CHAPTER 2: LITERATURE REVIEW

Types of Cooling Devices

A recent description of the categories of personal cooling devices by Yang, Stapleton, Diagne, Kenny, and Lan (2012) described the following three categories; phase change materials (PCMs), fluid cooled garments (FCGs), and evaporative devices.(10) A description of each cooling garment category follows, with emphasis on FCGs and PCM, as the present study examined the performance of three FCGs and one PCM.

Phase Change Material Cooling Systems

PCM garments rely on a frozen substance to absorb heat during phase change, most commonly from solid to liquid. Exploiting the latent heat of sublimation of dry ice is a less common method. (11) Since PCM garments do not rely on a power source to move the coolant, such garments are also called passive cooling systems.(12) Among microclimate cooling systems, PCM garments have long been extolled as the cheapest, most mobile, and easiest to don.(13-15)

To date, the materials used in human trials involving PCM cooling garments have included; frozen water, frozen CO_2 (dry ice), paraffin wax and various frozen aqueous solutions. The heat sinks in most commercially available PCM garments consist of sealed plastic packets filled with water or gelling agents.

Regardless of chemical composition, cooling packs act as heat sinks by way of conduction. For conduction to take place the garment must be designed to ensure adequate contact between the skin and heat sink in a manner that does not hinder mobility. This is most commonly accomplished with vest. Other methods of providing PCM cooling during work include direct insertion of heat sinks into specially adapted coveralls, head coverings, neck coverings, and ponchos.(13, 16, 17)

During fusion, water ice transfers about 80 kcal (335 kJ) of heat per kg of ice and an additional transfer of 36-38 kcal (150-159 kJ) occurs due to the specific heat of water.(13) The rate of heat transfer at the interface is directly proportional to the quantity of skin in contact with the heat sink.(11, 13, 18, 19) Total service time depends directly on the heat absorbing capacity of the coolant, which is the total amount of ice in the ice vests.(11, 13, 19, 20) One drawback of using PCMs with low staring temperatures is that garment manufacturers must provide insulation between the skin and cooling surface to prevent discomfort or skin injury. This barrier reduces cooling efficiency.

PCM cooling systems are vulnerable to reduced service time due to losses of capacity to the environment. However, the greater the clothing insulation over the passive system, the more it is protected from the outside environment. Wearing ice vest underneath protective ensembles may create cooling by convection as cool air is trapped in the suit, although the contribution to total cooling has not been quantified by experimental data.(14)

The need for unrestrictive cooling garments for maintenance crews at nuclear power plants led Kamon et al.(13) to the evaluation of a frozen water shirt and jumpsuit. The jumpsuit, loaded with ice packets which were in contact with the trunk, buttocks, and upper thigh, covered 75% of the body surface and was tested with loads of 7.2 kg of ice (70 gm packets) and 6.2 kg of ice (60 gm packets). The shirt covered approximately 40% of the body and was loaded with 3.8 kg of ice (70 gm packets). Significantly longer stay times, slower rise in core temperatures, and slower increase in heart rates were a linear function of ice weight.(13) What's more , Kamon et al.(13) found that none of the aforementioned designs hindered movement, even allowing workers to gain access to crawl under pipe and work in a confined space.

Since 1984, several ice vests have used gelling agents to reduce the likelihood of cooling pack leaks.(15) Using a calorimetric method, Coleman(15) compared the cooling capacity of three commercial ice vests containing frozen gelled coolant materials to the heat storage capacity of pure water-ice vest and found that gelled coolant had heat storage capacity of approximately 60% that of distilled water. Although the chemical composition of each gelling agent was proprietary, Coleman posited that the reduction in coolant heat storage capacity was due to the loss of water available for phase change. Since the gelling agents do not undergo phase change it follows that the gelling agents contribute little with regards to providing actual storage capacity and generally consume < 1 cal/g ^{0}C.(15)

Use of commercial ice vest with and without personal protective ensembles has been well evaluated. A recent investigation of the efficacy of one such ice vest (Climatech® CM 2000) found that the vest significantly reduced the level of thermal strain for subjects wearing insulated protective clothing (nuclear, biological, chemical [NBC] suit) during exercise in a thermal chamber heated to 35^{0}C and RH of 65%.(14) Wearing the ice vest under the NBC suit lowered HR from minute 60 to 100 of exercise and attenuated the increase of esophageal temperature (T_{es}). This slowing of T_{es} extended exercise time by 11.9 min ±.4%.(14) Although the ice vest was able to slow the increase in T_{es} compared to the control, uncompensable heat stress was still apparent in the continual rise in temperature during the course of the 120 minute trials.(14) Unfortunately, metabolic rate was not one of the metrics; therefore, cooling rate cannot be estimated.

Muir, Bishop, and Ray (1999), adapted Saranex® coated Tyvek® fabric suits to hold six frozen gel-packs inserts (78% water) directly against the wearer via built in pouches, they effectively obviated removal of personal protection clothing to replace the heat sink.(17) This ice-cooling technique used nylon straps on the outside of the suit to ensure two gel-packs placed on the pectoral region, shoulder blades, and lumbar region were held against the body. When compared to controls, this six cooling packs configuration extended work time among men conducting moderate work at a rate of 450 W in the two highest of three test conditions of 28^0C, 23^0C, and 18^0C. Mean work time increase was 71% and 88% at WBGTs of 23^0C and 28^0C, respectively.(17)

Gao, Kuklane, and Holmer(20) used a thermal manikin to demonstrate that the cooling rate of a PCM depends on the temperature gradient between the skin temperature and melting temperature of the PCM. Testing salt mixtures consisting of sodium sulphate decahydrate and water at three melting temperatures (24, 28 and 32 ^{0}C), showed that the vest with the lowest melting temperature had the higher cooler rating.(20) Gao et al. also demonstrated that PCM mass determines cooling duration while mainly covering area dictates cooling rate.

Paraffin wax has also been used as the heat sink in PCM garments. Cooling is provided as the paraffin changes from solid to liquid. Parrafin has been shown to absorb approximately 200 kJ/kg of heat during the melting process.(21) However, since paraffin is flammable it is not ideal for use in industries with an increased risk of exposure to fire. Chou, Torchihara, and Kim(22) found that paraffin with a starting temperature of 20^0C and melting temperature of 28^0C was more effective than frozen water in slowing the rate of heat storage in subjects wearing firefighting ensembles. Chou et al. opined paraffin is more efficient for use in cooling garments because 1) the higher starting temperature obviates a protective barrier between the skin, thus providing a more efficient heat exchange and 2) paraffin is more pliable than ice as it melts which increases surface area contact with the skin.(22) However, their comparison was confounded by the fact that the ice and paraffin had different surface area (1,310 cm^2 vs 1,792 cm^2) and mass (1,050 g vs 1,344 g).(22)

Review of the literature reveals that PCM cooling garments, when used with personal protective ensembles, are capable of slowing heat storage rate but are incapable of halting heat storage in hot environments. Due to alteration of heat sink mass, coverage area, and heat sink starting temperature, the investigators for passive cooling reported cooling rates from 90 to 520 W. Previous studies have shown that the cooling effect of frozen water-garments is a linear function of the mass of the ice.(13, 23) However, with more than 500 natural and synthetic know PCMs(24), cooling systems using PCMs have the largest potential for future adaptation and study among all the types of cooling devices used in the present study.

Fluid Cooled Garments

Fluid cooled garments include the use of water, air, or aqueous solutions as the coolant.(10) The general subclasses of FCGs are liquid cooling systems (LCS) and air cooling systems (ACS). FCGs rely on a heat sink attached to the cooling garment with a supply hose and a means of providing pressure to circulate the air or liquid through the garment. A majority of FCGs rely on ice water and a heat exchange coil to either cool liquid in a closed loop water pump system or cool the air as it is supplied from either a compressor or air pressure vessel. ACSs have also provided cooling with forced ambient air(25), breathing apparatus exhalation air(26), vortex devices, and air conditioner chilled air.(7, 27) LCS garments have also used a vapor compression system to supply a liquid consisting of water and glycol mixtures.(7, 28) A benefit common to both LCSs and ACSs is the ability to adjust the flow rate and temperature of the cooling medium. Compared to passive cooling methods, FCGs also provide cooling longer without heat sink replenishment.

A review of the literature reveals that LCSs and ACSs are not significantly different in performance, but LCSs are widely regarded as the most capable personal cooling method to use with protective clothing because LCS coverage area can effectively be increased to cover the limbs.(29) Notwithstanding, some comparative studies found that ACS vest were slightly superior to LCS vest in reducing cardiovascular strain and elicited more positive user feedback, with no significant difference between overall cooling performance.(8, 28, 30) Vallerand et al. posited that one reason for this unexpected difference could be that air is able to cool an area beyond the vest coverage; i.e. neck and non-vest covered portion of the torso.(28) Despite physiological performance differentiation between FCGs, some users may favor ACSs because they are generally lighter, keep the user drier, and leaks are less problematic.(7)

Several authors found no difference in ACS or LCS performance for participants wearing nuclear, biological and chemical (NBC) ensembles and exercising intermittently at low to moderate paces.(7, 28, 30) Based on these findings, McLellan, Frim and Bell tested continuous application of an ACS and LCS with participants wearing NBC and exercising at 500 W and 350 W.(31) They found both ACS and LCS changed the conditions from uncompensable to compensable during light exercise and produced heat strain comparable to the light exercise sans cooling during heavy exercise. The McLellan, Frim, and Bell study was congruent with the previous NBC findings that there was no “compelling physiological evidence to favor the selection of one cooling method”.(31)

Liquid Cooling Systems

Like PCM cooling garments, LCSs rely on close contact between the coolant and the skin to transfer heat. In the case of LCSs, conduction is the primary mode of heat transfer as liquid is circulated near the skin through a system of plastic tubing (typically polyvinyl chloride) and then back to the heat sink via an electric motor driven pump. The coolant remains at a constant inlet temperature as long as the heat sink maintains cooling capacity. A LCS’s thermal capacity may be altered by changing the flow rate and specific heat of the coolant.(32) In addition, heat transfer rate can be increased by increasing tubing coverage area, unlike ACSs which are more restricted to body coverage.(18, 27, 32)

The heat exchange across a LCS is shown to be proportional to the inlet temperature of the cooling liquid.(32) Inlet temperature can be altered by environmental temperature, length of the heat exchange tubing, and insulation value of the clothing over the LCS.(32) Several studies have shown that LCS contact with the skin is an important factor and garment fit may significantly affect system efficiency because a loose fit reduced skin-to-tubing contact area.(29)

The most commonly used heat sink is ice water but compression cooling offers a lower inlet temperature (below 0 °C) when a mixture of water and propylene or ethylene glycol is used. A 2002 study by Caderette et al. compared the performance of ice-based and vapor compression (18°C) based liquid cooling systems for use with impermeable protective clothing and found they were equally effective during heat exposure.(27) The same study also reinforced the idea that cooling rate was significantly increased by enlarging cooling garment coverage area.(27)

Air Cooling Systems

ACSs remedy the lack of heat dissipation through convection cooling and fostering the body's natural evaporative cooling mechanism. This is accomplished through use of powered air which is either cooled prior to input into the garment or the use of ambient air. The most typical method of heat exchange is air coil immersion in an ice water reservoir. Another common method uses a vortex tube, which decreases the inlet air temperature by separating the warm air from the higher density cool air.

Several authors have posited that ACSs may be superior to LCSs because air cooling fosters evaporation, which is the body's primary natural means of heat dissipation.(7, 30) Indeed, evaporation has a high capacity for heat dissipation; each liter of sweat transfers approximately 2,400 kJ of heat energy.(29) However, efforts to quantify the extent of evaporative cooling contribution to cooling system performance have been unsuccessful.(30, 31)

The inconvenience of using tethered sources has spurred the development and study of several non-tethered ACSs which provide continuous cooling. The most widely studied is use of ambient air supplied via a belt or pack mounted air intake (without vortex tube). Chen, Constable and Bomalaski found that use of ambient air during work periods was effective when used in conjunction with conditioned air delivered during rest periods during.(25) One study circulated exhalation air from a full face respirator into the user's fully enclosed protective ensemble but found the humidity of the exhaled air and lack of temperature gradient did not provide cooling.(33)

Shapiro et al. found that using ambient air to supplied air vest (ventilation) in a hot-dry environment (49^0C, 205%RH, 68^0C T_g) could damage the skin, and in the hot-wet environment (35^0C, 75%RH) had low effectiveness.(30) In the same study there was no significant difference between an air cooled vest and water cooled vest with regards to heat storage or physiological metrics, except that the air cooled vest produced significantly lower cardiovascular strain.

Zhang, Bishop and Green found that a portable cooling vest designed to vent gaseous CO_2 over the skin, facilitated a higher sweat evaporation rate, and created positive subjective response, however; the cooling device was found to have no significant cooling impact during work of less than 50 minutes.(34) The liquid CO_2 cooling system (Porticool Personal Cooling System, Porticool, Inc.) consisted of a regulator and CO_2 bottle (worn with nozzle facing down to release liquid CO_2 into the regulator), connected via flexible tubing to a vest designed to vent the vapor over the subjects skin.(34) During trials with participants dressed in jeans and tee shirts, an environment of 30^0C WBGT (75% RH), with workloads of 465 W; the liquid CO_2 vest increased work time (97 ± 36 min) compared to no cooling (74 ± 26 min) and decreased heat storage (54 ± 41 W) compared to no cooling (72 ± 40 W).(34) Use of the liquid CO2 vest fostered sweat evaporation from the skin (60 ± 10% vs. 51 ± 10%) but had no impact on sweat production rate.(34) As stated by Zhang et al.(34) the evaporative cooling benefit from this device may be diminished or completely negated by protective clothing.(34)

Evaporative Cooling Garments

Evaporative cooling garments (ECGs), a type of passive cooling device, freely evaporate water or other coolant from their fabric to the surrounding environment when wetted. A study by Heled, Epstein, and Moran, showed that evaporative cooling garments can successfully be placed over protective suits made out of polyvinyl chloride and polyethylene to reduce heat storage rate.(35) Because gas extraction ensembles consist of multilayered cloth, use of evaporative cooling garment is not an option for gas utility workers.

Recently, researchers designed and tested a vacuum desiccant cooling (VDC) prototype which successfully exploited the cooling power of evaporation within specially designed cooling packs. Human trials revealed a cooling capacity of 373W/m^2.(10) This cooling method integrates vacuum cooling, desiccant cooling, and membrane technology to yield a device that employs the latent heat of water evaporation which is approximately seven times of the latent heat of ice melting.(10) Each pad consisted of a cooling core (water bag), a spacer, an absorption core (LiCl powder), and an outer bag. A vacuum is applied to activate the pouches prior to use, but after initial activation cooling was provided for 60 minutes. Total weight of the system was 3.4 kg.

Table I. Reports of cooling system performance, factors that were reported as affecting performance and the reported or estimated cooling rate.

Study (Authors)	Type	Style	Area^{a}	Flow rate^{c}	Inlet Temp^{d}	Heat capacity^{e}	Work rate^{f}	Clothing and Tdb^{g}	Cooling Rate [W]
Zhang, Y. et al.	ACS	Vest (CO2)	–	–	–	–	–	–	411*
Muir, I., Bishop, P., & Ray, P.	PCS	Ice pack coveralls	–	–	–	–	–	Yes	428*
			–	–	–	–	–	Yes	412*
			–	–	–	–	–	Yes	373*
Kamon, E. et al.	PCS	Jacket	Yes	–		Yes	–	–	80 to 150
Shipiro et al.	LCS	Vest	–	–	–	–	–	Yes	79 to 121
	ACS	(Ambient)	–	–	–	–	–	Yes	32
Bennett et al.	PCS	Ice Vest	Yes	–	–	Yes	–	–	150
Cadarette et al.	LCS	Shirt w/hood	Yes	–	–	–	–	–	281
	LCS	Body suit	Yes	–	–	–	–	–	362
Nag et al.	LCS	Jacket	–	Yes	–	–	–	Yes	165
Bomalaski, S., Chen, Y., & Constable, S.	ACS	Vest	–	–	Yes	–	–	–	185*
	ACS	Vest	–	–	Yes	–	–	–	160*
Harrison & Belyavin	LCS	Suit-60 m	Yes	–	Yes	–	–	Yes	290
	LCS	Suit-120 m	Yes	–	Yes	–	–	Yes	460
Konz, S. et al.	PCS	Vest (Dry ice)	Yes	–	–	Yes	–	Yes	90
White et al.	LCS	Suit	–	–	–	–	–	–	210
	PCS	Vest-Freon	–	–	–	–	–	–	210
Tayyari, F. et al.	PCS	Vest-Ice	–	–	–	–	Yes	–	260 to 335*
Coleman, S.	PCS	Vest	–	–	–	Yes	–	–	–
Speckman, K.	LCS	Various	Yes	Yes	Yes	–	Yes	Yes	150 to 400
	PCS	Vest	Yes	–	–	Yes	–	Yes	190 to 400
	ACS	Vest	–	Yes	Yes	–	Yes	Yes	50 to 700
Yang et al.	PCS	(Vacuum dessicant)	–	–	–	–	–	–	150
Kenny, G.P et al.	PCS	Vest	–	–	–	–	–	–	250*
Vallerand, A. et al.	ACS	Vest	–	–	–	–	–	–	181
	LCS	Vest	–	–	–	–	–	–	164
McLellan, T., Frim, J., & Bell, D.	ACS	Vest	–	–	–	–	Yes	–	280 to 435*
	LCS	Shirt	–	–	–	–	Yes	–	280 to 435*

a	Increase in body surface area coverage increases performance
b	Increase in flow rate increases performance
c	Decrease in inlet temperature increases performance
d	Increase in heat capacity of the heat sink increase performance
e	Increase in metabolic rate decreases performance
f	Increase in clothing insulation and/or decreases in air temperature increases performance.
*	Estimated Cooling Rate

CHAPTER 3: METHODS

Overview

A variation of the US Army Research Institute for Environmental Medicine's (USARIEM) recommended approach of evaluating the physiological effects of protective clothing by fixed environmental condition(s) and at a fixed metabolic rate was used to test the cooling systems. At the University of South Florida, this method of evaluation is the Short-term Protocol. The aim of the Short-term Protocol is to create condition(s) conducive to body heat storage by manipulating environment, work demands, and clothing.(36) The present study held clothing and metabolic rate constant, and the cooling systems were treatments in the experimental design. The primary metric was the average heat storage rate.

Equipment

The experiments were conducted in a climatic chamber. The internal dimensions of the chamber are 2.7 m wide, 3.0-m deep and 2.2 m high. Heat rate was monitored with a wireless chest strap heart rate (HR) monitoring system. Core temperature (T_{re}) was continuously monitored by means of a flexible thermistor inserted 10-cm beyond the anal sphincter muscle. The thermistor was calibrated prior to each trial in a stirred water bath. Skin temperature was continuously monitored using surface thermistors taped to the right triceps, pectoralis major, quadriceps femoris, and gastrocnemius. In addition, ingestible body core thermometer pills were used. The pill was swallowed either the night before or upon reporting to the lab for a trial.

Metabolic rate was assessed from oxygen consumption using an open circuit method. During the measurement, the subject breathed through a mouthpiece while wearing a nose clip. The expired air was collected for three minutes into a collection bag fitted with a quick turn valve and the volume of air expired was measured using a dry gas meter. Prior to volume measurement, a small sample was drawn into an oxygen analyzer to determine exhaled air's oxygen content. Oxygen consumption was computed following standard methods.(37) This process was carried out 30 minutes, 60 minutes, and 90 minutes into the study and was done without stoppage of treadmill walking.

Participants

Five male participants completed the trials; their age, weight, height, and the mean metabolic rate across all trials are described in Table 1. The study protocol was approved by the University of South Florida Institutional Review Board. Participants provided written informed consent following university policy and underwent a physical examination by a licensed physician. Qualifying for participation entailed physical examination for evidence of disorders of the vestibular system, pulmonary system, cardiovascular system, gastrointestinal system, genitourinary system, musculoskeletal system, and neurological system. Participants also underwent a resting 12-lead electrocardiogram. All of the participants were healthy with no chronic disease required medication.

Participant pre-session weights were tracked to assure no progressive loss of water and the pre- and post-session weight loss was used to guide subject rehydration for the remainder of the day. A day-to-day or pre-to-post net loss of 1.5% of body weight was used as a trigger point to advise more aggressive fluid replacement. Participants were asked not to consume caffeine or participate in vigorous exercise prior to their trial. The participants were not acclimatized as part of the protocol. There were at least 40 hours between trials to reduce the effects of acclimation.

Table II. Physical Characteristics of Five Male Participants

Code	Age [yr]	Weight [kg]	Height [cm]	Mean Metabolic Rate [W]
S1	22	74	179	263
S2	22	81	201	293
S3	25	80	183	252
S4	30	83	178	295
S5	23	88	185	337
Average	24	81	185	288
Std. Dev.	3.0	4	8	30

Protocol

There were two environmental conditions; a standard desert condition of T_{db}= 40^0C (104^0F) and 30% RH, and a standard subtropical environment of T_{db}=35^0C (95^0F) and 50% RH. Air motion for both environments was 0.5 m/sec , there was no radiant heat load, and temperatures were held constant within ± 0.5 ^{0}C. Five participants completed trials for four cooling vests plus no-cooling while wearing the gas extraction coveralls in both environments for a total of 10 trials per participant. The order of the cooling system was randomized and partially balanced among participants within an environmental condition. Environmental conditions (T_{bd} and T_{pwb}) were recorded 5 minutes every intervals.

The standard protective clothing was a gas extraction coverall (Gas Extraction Suit ® GES8, Oberon Co., New Bedford, MA) and related flame resistance balaclava sock hood and multilayer heat protective gloves (Figure 1). Nomex® coveralls, gym shorts, and tee shirt were worn under the protective ensemble. Footwear consisted of athletic socks and running shoes. All cooling vests were worn under the Nomex® coveralls and over a tee shirt.

Participants prepared for the trial by inserting the rectal thermistor, and dressing in gym shorts and shoes. After recording the semi-nude weight (sans tee-shirt and shoes), surface thermistors were taped to the skin and a heart rate monitor was strapped around the chest. If applicable, a cooling vest was donned over the tee shirt before donning the protective ensemble. Prior to entering the climatic chamber, fully clothed weight was recorded. During the trial, participants were provided water and/or a commercially available fluid replacement beverage as requested. Total fluid consumed was recorded. After termination of the trial, fully clothed and semi-nude weight was again recorded.

Participants walked on a motorized treadmill set to elicit a moderate metabolic rate of 300 W for 120 minutes or until volitional fatigue, heart rate reached 95% of age-predicted maximal heart rate, or internal body temperature of $>39^{o}C$. Walking pace with no incline was selected independent of participant aerobic capacity to elicit about 300 W. Data (T_{re}, HR, T_{sk}, T_{pwb}, T_{db}) were monitored continuously throughout the trial and recorded every five minutes.

Figure 1. Protocol clothing consisted of gym shorts, shoes, and a tee-shirt worn under Nomex® coveralls and the flame resistant Gas Extraction Suit ® (with gloves and balaclava).

Personal Cooling Systems

Four personal cooling systems plus a control (no cooling) were tested. All cooling systems covered the torso, providing cooling to the front and back. Figure 2 shows the frozen polymer vest, and Figure 3 shows the heat sink and tether of the FCGs. A description of each system follows.

Frozen Polymer Vest

The frozen polymer vest, marketed under the name Stacool Industrial Vest, is manufactured by StaCool Industries Inc. (Brooksville, FL). Cooling is accomplished by three frozen polymer panels inserted into the front and back of the vest (Figure 2). The frozen panels consist of 12 individual cells that contain a non-flammable and non-toxic polymer material. Stacool utilizes 3M Thinsulate ™ to insulate the frozen panels from the wearers body and nylon on the exterior. The vest is designed with two Velcro® straps around the waist and one over each shoulder to ensure the polymer panels maintain contact with the skin.

Figure 2. The front side of the StaCool Industrial Vest ® with three of the six 12-cell frozen polymer panels exposed.

The polymer panels were prepared per manufacture instructions by soaking them in warm water to allow the polymer to hydrate and then placing them in the freezer. Upon hydration, the cells took on a gel consistency, and did not require rehydration after use. The polymer panels were kept in a freezer with a temperature of -11 ^{0}C (12 F) and weighted 2.4 kg (5.29 lbs). The polymer panels were not replaced during the trial.

Liquid Cooling Vest

The liquid cooling vest, produced by Shafer Enterprises (Stockbridge, GA) under the trade name CoolShirt ® Aqua Vest, was used with a 24 quart (22.7 L) cooling reservoir produced by the same company. The cooling water is supplied through a 20 ft (6 m) long supply hose, runs through about 50 feet (15.2 m) of capillary tubing inside the vest, and returns to the reservoir under power of a 110 V submersible electric pump (1360 L/hr). The rubber supply and return hose were covered with neoprene insulation and encased within a layer of foam insulation. The cooling reservoir was filled with 4.5 kg (10 lbs) of ice and 4.5 L of water. The ice was not replenished throughout the trial, but ice was present in the cooler at trial end. Per the manufacturer's instructions, the vest was soaked with water prior to each use. The vest weighted about 1.8 kg (4 lbs).

Air Cooling Vest

The air cooling system was a flame retardant cooling vest (Part No. 8450) manufactured by Allegro Industries (Piedmont, SC). Compressed air was provided with air tanks (breathing quality) and cooled with a Cool-Box® (Model No. BACB-196) produced by Air Systems International (Chesapeake, VA). The Cool-Box® (Figure 3) was filled with 20 lbs of ice and 21 liters of water and has a capacity of 37.8 L. Ice was not replenished throughout the trial, but ice was present in the cooler at each trial end. For all trials the compressed air was regulated to maintain at supply pressure of 90 psi. To measure total flow rate, a dry gas meter was used to measure the volume discharge from the vest into a sample bag during a 30 s interval where the supply pressure to the cooler was 90 psi; the mean of four measurements was .24 m^3 per minute. Each 8.5 m^3 air tank lasted about 35 minutes. The air vest weighted 0.68 kg (1.5 lb).

Liquid Carbon Dioxide Vest

The liquid CO_2 (LCO_2) vest, known as the Porticool II® is marketed by CoolShirt, Inc. (Stockbridge, GA). This system consists of a 20 oz CO_2 bottle threaded into a regulator which supplies liquid CO_2 to a supply hose attached to a network of ventilation hose sewn into the vest. As the liquid CO_2 exits the regulator it vaporizes and the flow of gaseous CO_2 travels from the regulator through the connection hose and vest tubing, and finally vents over the body. To supply liquid CO_2, the bottle must be carried upside down. Because our protocol entailed walking, a paintball CO_2 canister belt (NX$^{e®}$ Paintball SP Series 2+1 harness) was used to secure the CO_2 bottle and regulator around the waist. The system arrived with a belt attachment clip but it could not support the weight of the system, which was 1.3 kg (2.9 lbs). The CO_2 canister was changed every 25 minutes and the flow valve was always set to fully open.

Figure 3. Pictured from left to right: 1) CoolShirt® Aqua Vest system, 2) Allegro® air vest with Cool-Box air cooling system (Air Systems Inc.), and 3) Porticool II ® cooling system secured to the participant with a paintball bottle belt (NX$^{e®}$). Each cooling vest was worn under the Gas Extraction Suit® and Nomex® coverall and over a T-shirt.

Determination of Dependent Data

The baselines for the computations of the rates were the values of rectal temperature (T_{re}), average skin temperature (T_{sk}) and heart rate (HR) at 5 minutes into the trial. The changes in the first 5 minutes represent an adjustment to work rather than any effects due to heat stress. The final values of these measures and the elapsed time (e.g., 115 min = 1.92 hr) were used to compute the rate of change.

Heat storage rate (S) was calculated as:

$$S[W] = (\Delta T_{re}/\Delta t)[^0C/hr] \text{ x Body weight [kg] x } 0.971\ [W \cdot hr / kg \cdot {}^0C] \tag{1}$$

Where Δt was the trial time in hours, and 0.971 $W \cdot hr \cdot kg^{-1} \cdot {}^0C^{-1}$ is the body specific heat.

Change in core temperature (ΔT_{re}), heart rate (ΔHR), and skin temperature (ΔT_{sk}) were calculated as:

$$\Delta Tre = T_{re\ final} - T_{re\ 5\ min} \tag{2}$$

$$\Delta HR = HR_{final} - HR_{5\ min} \tag{3}$$

$$\Delta Tsk = Tsk_{final} - T_{sk\ 5\ min} \tag{4}$$

Where average skin temperature was calculated as:

$$T_{sk} = 0.3\ (T_{Chest} + T_{Arm}) + 0.2\ (T_{Thigh} + T_{Calf}) \tag{5}$$

While heat storage rate is indicative of the increase in body core temperature, cooling rate (CR) is used to quantify the heat diminishing capacity of cooling devices. Where CR is the metabolic rate (M) minus the heat storage rate (S). That is, CR= M-S.

Data Analysis

The primary dependent variable was heat storage rate (S). Other dependent variables were change of body core temperature (ΔT_{re}), heart rate (ΔHR) and average skin temperature (ΔT_{sk}). Data were analyzed using JMP ® (version 9) statistical software (SAS, Cary, North Carolina). To analyze the relationships among cooling systems and environment, a three-way mixed effects ANOVA (analysis of variance) was performed in which cooling system and environment (plus cooling system x environment) were fixed effects and the participants were treated as a random effect. A Tukey's Honestly Significant Differences (HSD) multiple comparison test was used to identify where significant differences occurred between cooling system performance ($p < 0.05$).

CHAPTER 4: RESULTS

All trials lasted 120 minutes with one exception where a frozen polymer (FP) trial in desert condition was terminated at 100 minutes due to reaching the body core temperature threshold. Two LCO_2 trials were not completed due to technical problems, resulting in four LCO_2 trials in each environment. One NC trial in the desert condition was repeated for one participant. Table III provides the number of trials and the mean values for M and heat S. Table III also lists the mean change in T_{re}, HR, and T_{sk}.

Table III. Summary of experimental results.

Environment	Cooling	N	M [W]	S [W]	ΔT_{re} [°C]	ΔHR [bpm]	ΔT_{sk} [°C]	Cooling Rate [W]
Desert	NC	6	296	35	0.9	33	1.34	261
40 °C	LCO_2	4	283	25	0.6	32	1.25	258
30% RH	FP	5	291	19	0.48	15	1.54	272
	Air	5	294	15	0.38	5	0.52	279
	Water	5	304	5	0.14	3	0.17	299
Subtropical	NC	5	284	21	0.53	33	1.52	263
35 °C	LCO_2	4	288	25	0.63	26	2.46	263
50% RH	FP	5	284	10	0.25	9	1.53	274
	Air	5	253	11	0.27	5	-0.58	243
	Water	5	295	14	0.36	6	0.38	281
Combined	NC	11	290	29	0.73	33	1.42	261
	LCO_2	8	286	25	0.62	29	1.86	261
	FP	10	288	15	0.37	12	1.53	273
	Air	10	273	13	0.33	5	-0.03	260
	Water	10	299	10	0.25	5	0.27	289

Note: Change (Δ) in physiological metrics was calculated as the difference between the values at 5-minutes and end of trial. Cooling Rate = M – S. M is metabolic rate and S is storage rate.

There were no significant differences due to environment, and no interaction. Therefore, the reported data that follow are the combined results of both environments. In all cases, there were significant differences among the cooling conditions. Metabolic rate was consistently achieved with an (average of 287 W) with no significant difference among cooling or environmental conditions.

Heat Storage Rates

Figure 4 illustrates the combined mean storage rate of trials with each cooling system. Mean storage rate ranged from approximately 10 W to 29 W, and there was no statistically significant difference between NC (28.2 ± 3.8 W) and LCO_2 (24.6 ± 4.3 W) for storage rate ($\alpha < 0.05$). The same was true for the LCO_2, FP (14.7 ± 3.9 W), and air (12.6 ± 3.9 W). FP, air and water (9.9 ± 3.9 W) systems were not significantly different but were all significantly lower than NC and LCO_2.

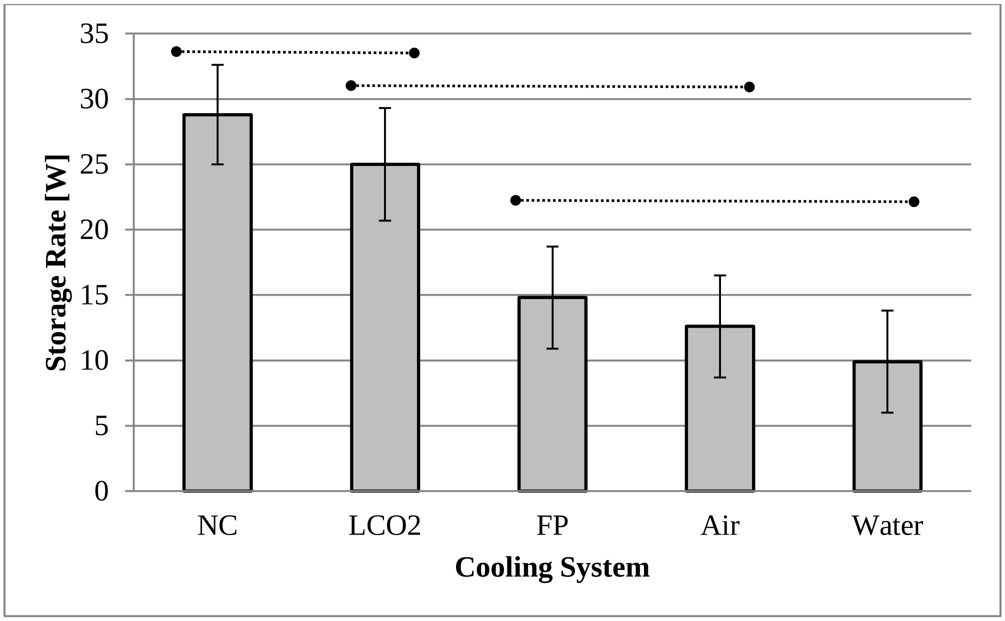

Figure 4. Mean heat storage rates [W] and standard deviation whiskers for each cooling system. Horizontal lines indicate that there is no statistically significant difference.

Body Core Temperature

Figure 5 illustrates the mean difference between core temperature (T_{re}) at end of trial and T_{re} at minute 5, which ranged from 0.25 to 0.72 ^{o}C. There was no statistically significant difference between change in T_{re} during the NC (.72 ± .09 ^{o}C) and LCO_2 (.61 ± 0.10 ^{o}C) cooling conditions. The same is true for $LCO_{2,}$ FP (.37 ± 0.09 ^{o}C), and air (.33 ± 0.09 ^{o}C). FP, air, and water (.25 ± 0.09 ^{o}C) were significantly lower than NC and CO_2 but were also not significantly different. Figures 6 shows the combined mean changes in T_{re} across time for the desert condition and sub-tropical condition.

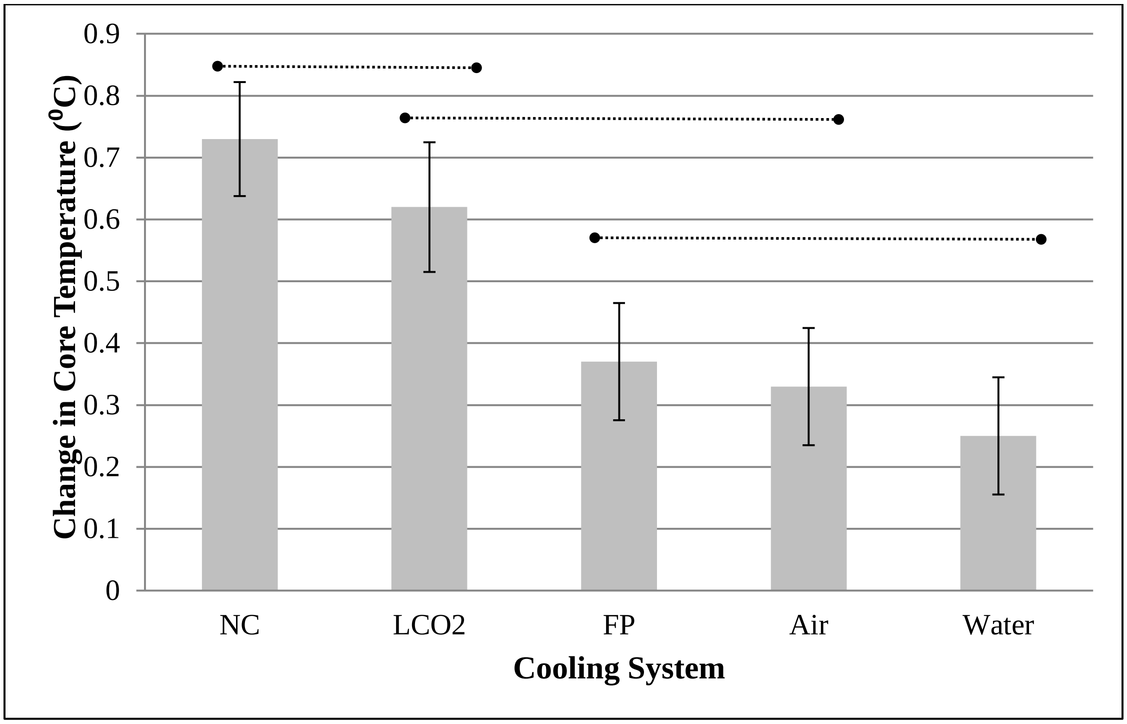

Figure 5. Mean change in core temperature and standard deviation whiskers for each cooling system. Horizontal lines indicate that there is no statistically significant difference.

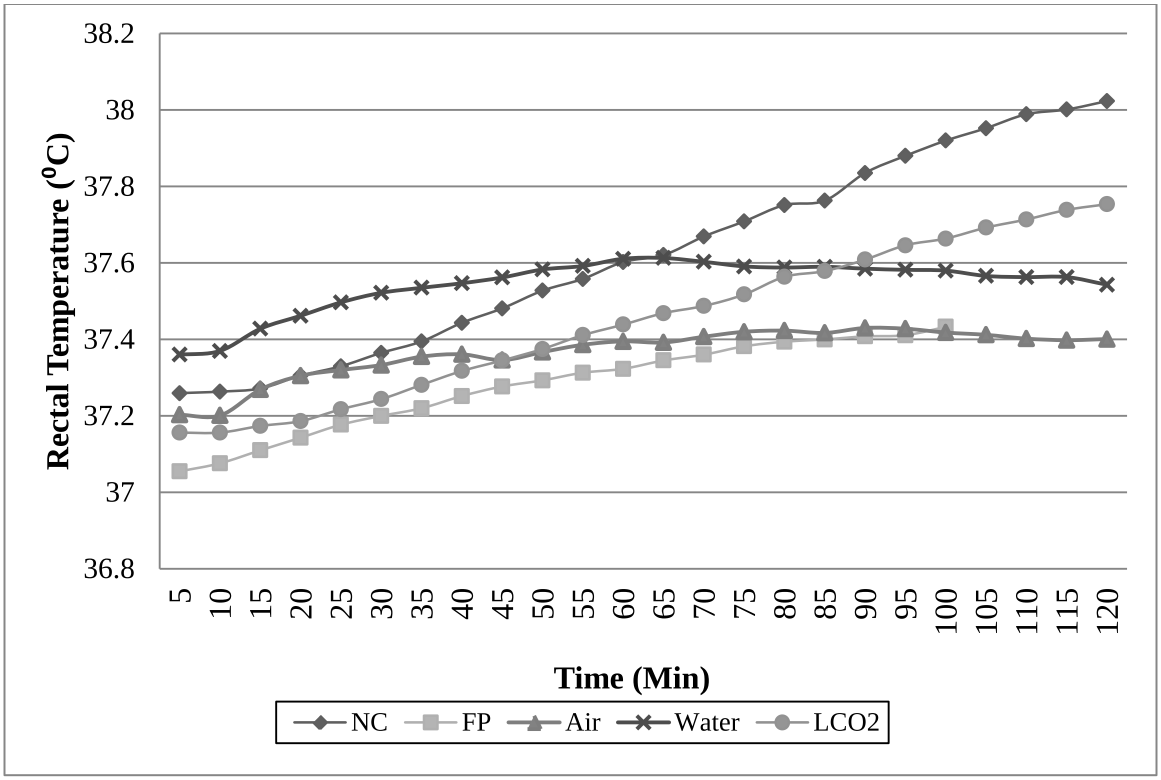

Figure 6. Mean core temperature across time.

Skin Temperature

Figure 7 illustrates the mean difference between skin temperature (T_{sk}) at end of trial and T_{sk} at minute 5. Change in T_{sk} ranged from -.03 to 1.8 ^{o}C. Figure 8 is the mean change in T_{sk} across time starting at 5 minutes until the end of each trial for both environmental conditions combined. There was no statistically significant difference in change of T_{sk} between LCO_2 (1.8 ± .32 ^{0}C), FP (1.5 ± .31^{0}C), or NC (1.5 ± .29 ^{0}C). FP, NC and water were not differentiated but were lower than the LCO_2 condition. Water and air (-.03 ± .31^{0}C) were not differentiated; however air was the lowest of all conditions. The rise of skin temperature associated with air and water (.27 ± .31^{0}C) were not significantly different but were significantly lower the other conditions.

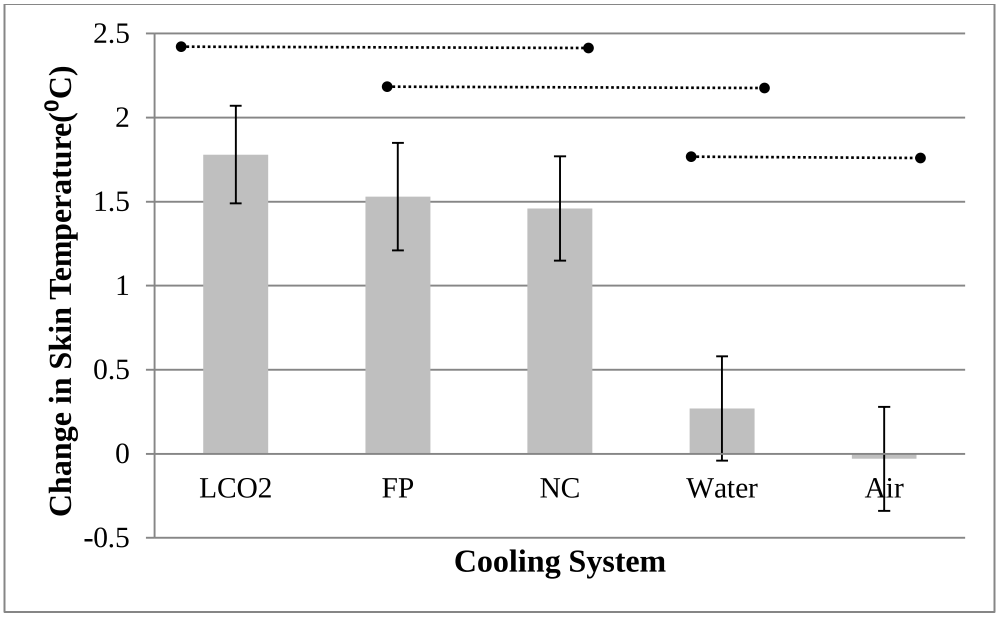

Figure 7. Mean change in skin temperature and standard deviation whiskers for each cooling system. Horizontal lines indicate that there is no statistically significant difference.

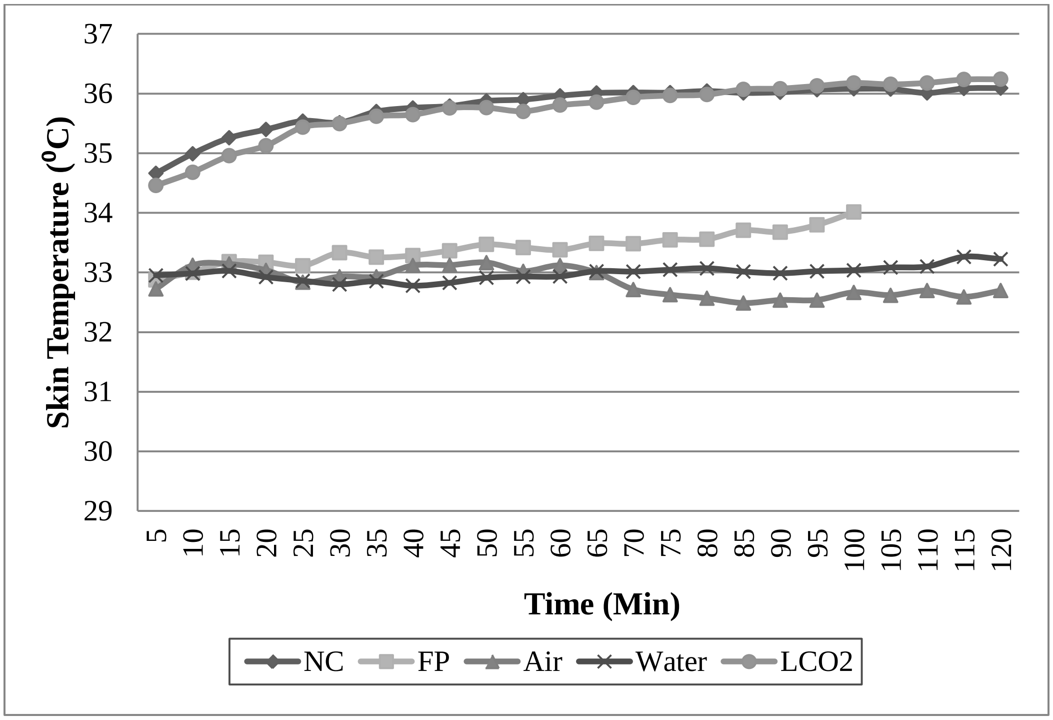

Figure 8. Mean skin temperature across time.

Cardiovascular Strain

Figure 9 illustrates the mean change in heart rate (ΔHR) from minute 5 of each trial to end of trial. ΔHR ranged from 5 to 33 beats per minute (bpm). No statistically significant difference in ΔHR exists between the NC (33.3 ± 2.8 bpm) and LCO$_2$ (27 ± 3.1 bpm). FP (12 ± 2.8 bpm), air (5 ± 2.8 bpm) and water (4.6 ± 2.8 bpm) were not differentiated but had a significantly lower ΔHR compared to NC and CO$_2$. Figure 10 shows the mean change in heart rate across time.

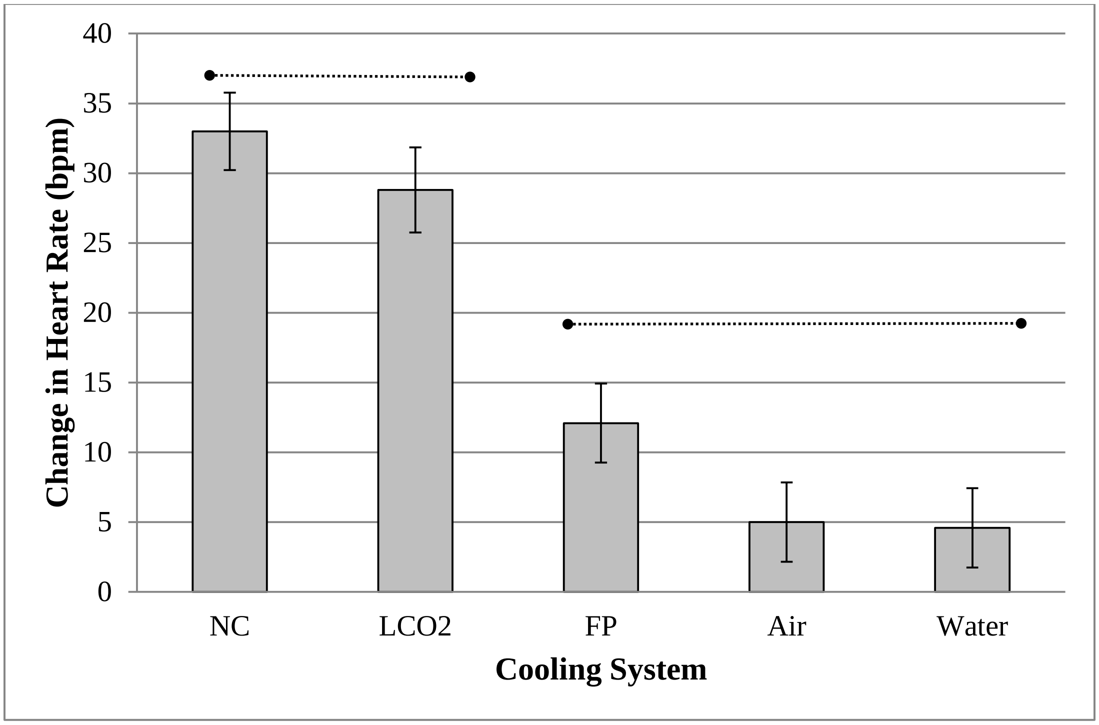

Figure 9. Mean change in heart rate and standard deviation whiskers for each cooling system. Horizontal lines indicate that there is no statistically significant difference.

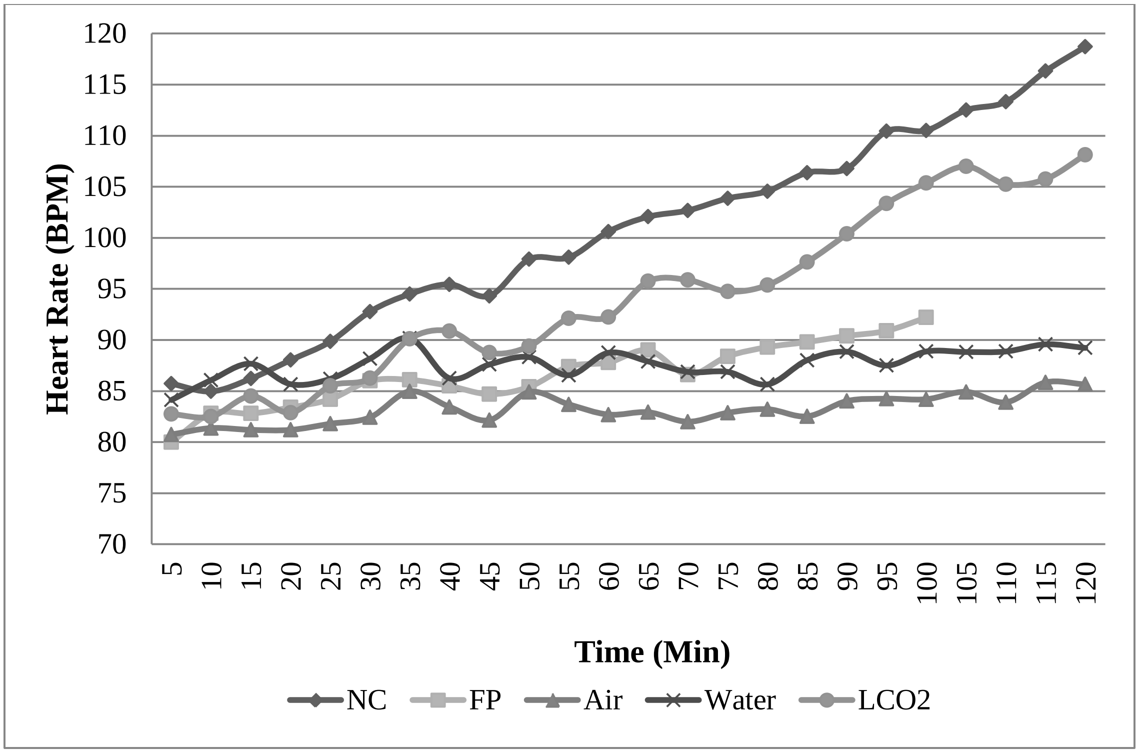

Figure 10. Mean heart rate across time.

CHAPTER 5: DISCUSSION

The purpose of the present study was to compare the performance of a frozen polymer vest, air vest, water vest, and LCO_2 vest during continuous exercise to discern if one cooling system was more effective than another in aiding heat transfer from the body while wearing a gas extraction coverall. The physiological data collected over the 120 minute work session provided cooling vest differentiation by way of heat storage rate and heat strain. If storage rate is near zero, then the person is in equilibrium and can safely work for an extended period of time. As the storage rate increases the work time decreases.

There were no statistically significant differences in measured metabolic rate among cooling systems or environmental conditions (Table I). Consistent metabolic rates confirm that similar work demands were established across all trials, which means comparison among devices and environments are meaningful. Differences among participant responses to heat stress were acceptable because the data analysis methods controlled for those differences. There were no differences between the two environments. In practice, the protective clothing probably isolated the user from the external thermal environment between 30 and 45 °C (86 and 113 °F), and the work demand (i.e., metabolic rate) was the major contributor to heat storage rate. Montain et al. also found that participants had similar physiological tolerance when wearing protective clothing in desert and tropical climates.(2)

As seen in Figures 6 and 7, the T_{re} over time alone may not necessarily provide a clear depiction of the cooling power among cooling devices. However, ΔT_{re} is indicative of the body's ability to maintain a homeostasis. In this regard, heat storage rate does provide the most apparent indication of cooling device performance (Figure 5) and indicates that FP, air, and water were all significantly lower than NC.

The air and water vest performed well with heat storage rates of about 43%, and 34% of the control. That air and water cooling were not significantly differentiated is congruent with previous comparisons of ACS and LCS for use with personal protective ensembles.(7, 28, 30, 31) McLellan, Frim, and Bell found that an air vest and water vest provided a cooling rate of about 280 W and 279 W for participants with a work rate of 300 W in a standard desert (40°C and 30% RH) condition.(31) The present study showed a mean cooling rate of 279 W for air vest and 299 W for water vest in the desert condition (Table III).

The FP Vest exhibited good performance with a heat storage rate of about 51% of the control. The mean cooling rate was 273W (Table III). In comparison, a study by Tayarri, Burford, and Ramsey found a cooling rate of 260 W for participants exercising at a rate of 300 W (no protective garments) in an environment of 40 °C and 75% RH.(16) Similar results were also reported by Kenny et al., who reported a cooling rate of about 250 W for workers wearing NBC and exercising at a pace of about 300 W in a hot environment (35°C, 65% RH).(14)

Performance of the LCO_2 system was not differentiated from the control. This was the first study to test the use of the LCO_2 with a protective ensemble. A previous study of the LCO_2 system by Zhang et al., found it was effective in increasing work time and attenuating heat stress in an environment of 33 °C T_{db}/75% RH with a time-weighted workload of 465 W, for study participants wearing jeans and tee-shirts.(34) Both Zhang et al.(34) and the present study applied the LCO_2 vest over a tee shirt, changed the bottles out at about 25 minutes, and used a continuous exercise protocol. Conversely, in the present study the flow rate was set to maximum, while Zhang et al.(34) set the flow at a moderate rate. Our results suggest that the cooling rate was not adequate to compensate for a moderate rate of work while wearing the gas extraction suit.

It should also be noted that the manufacturer supplied clip-on style bottle harness did not sufficient secure the CO_2 bottle and regulator, therefore; a paint ball CO_2 bottle harness (NXe Paintball SP Series 2+1 harness) was purchased to provide adequate holding capacity. Changing the 20 oz CO_2 bottles was relatively easy, taking about 3 minutes on average. However, the manufacturer instructions must be followed carefully to avoid malfunction of the regulator. For instance, over treading or under treading the bottle into the regulator assembly could result in lack of liquid CO_2 flow.

The polymer was melted at the end of the trials, which means that the heat sink was exhausted and that the service life was just under two hours. Unlike some other phase change materials, such as paraffin, the heat sinks used in this garment cannot be recharged in a cooler with water ice. The effects of the storing the FP heat sinks in a cooler prior to use were not examined in this study (they were inserted directly from the freezer). However, the polymer vest may be favorable over other PCMS because the material is non-toxic (in case of leaks) and is not flammable.

Practical considerations of the tethered systems include power supply for the water vest and a source of compressed air for the air vest. In addition the weight of the heat sink may be of concern. The Air Vest heat exchange cooler weighed about 41 kg (90 lb) once loaded with 21 liters of water and 9.1 kg (20 lb) of ice. The heat exchange cooler had wheels but the design of the cooler is of standard domestic food cooler variety, therefore may have less mobile on rugged terrain. In contrast, the water vest cooling water reservoir weighed about 12 kg (26 lb) when loaded with 4.5 kg of ice and 4.5 L of water.

Regarding ease of wear, the water vest's insulated supply and return hose was awkward to don because the tether attachment is located on the side of the water vest. This arrangement required that the hose be fed through the back of the flash gear and then around the wearer to the connection near the left hip; however no participants complained of discomfort during the trials. This connection arrangement was similar to the air vest, only the air hose was of much smaller circumference.

Limitations

Modification of the study protocol would allow further differentiation of the cooling systems by way of exposure time. This can be achieved by adjusting workload with input from biomedical modeling.(4, 36)

Another weakness of this study is the small number of participants. Although similar trials have used small sample sizes, using more subjects would further differentiate the heat storage results.

Conclusion

The mechanisms of heat retention caused by the Gas Extraction Suit® occur as a result of increased insulation and decreased permeability. It can be concluded that water, air, and FP cooling vest can be beneficial in that they have the capability of decreasing the physiological strain of working in hot environments and the ability to ease the employee discomfort during continuous work. Where being free of tether is important, use of FP is an effective alternative to powered cooling vest, but the heat sink was depleted after the two hour trials and requires removal of the coverall to replenish the heat sink. Because FP packs must be frozen to be effective, FP may have limited application for faraway or protracted jobs because chilling the polymer packs in an iced cooler will reduce effectiveness (according to manufacturer). Conversely, as evidenced by the ice remaining in the air and water vest heat sinks, air and water are capable of continuous cooling beyond two hours and can be replenished with ice as needed.

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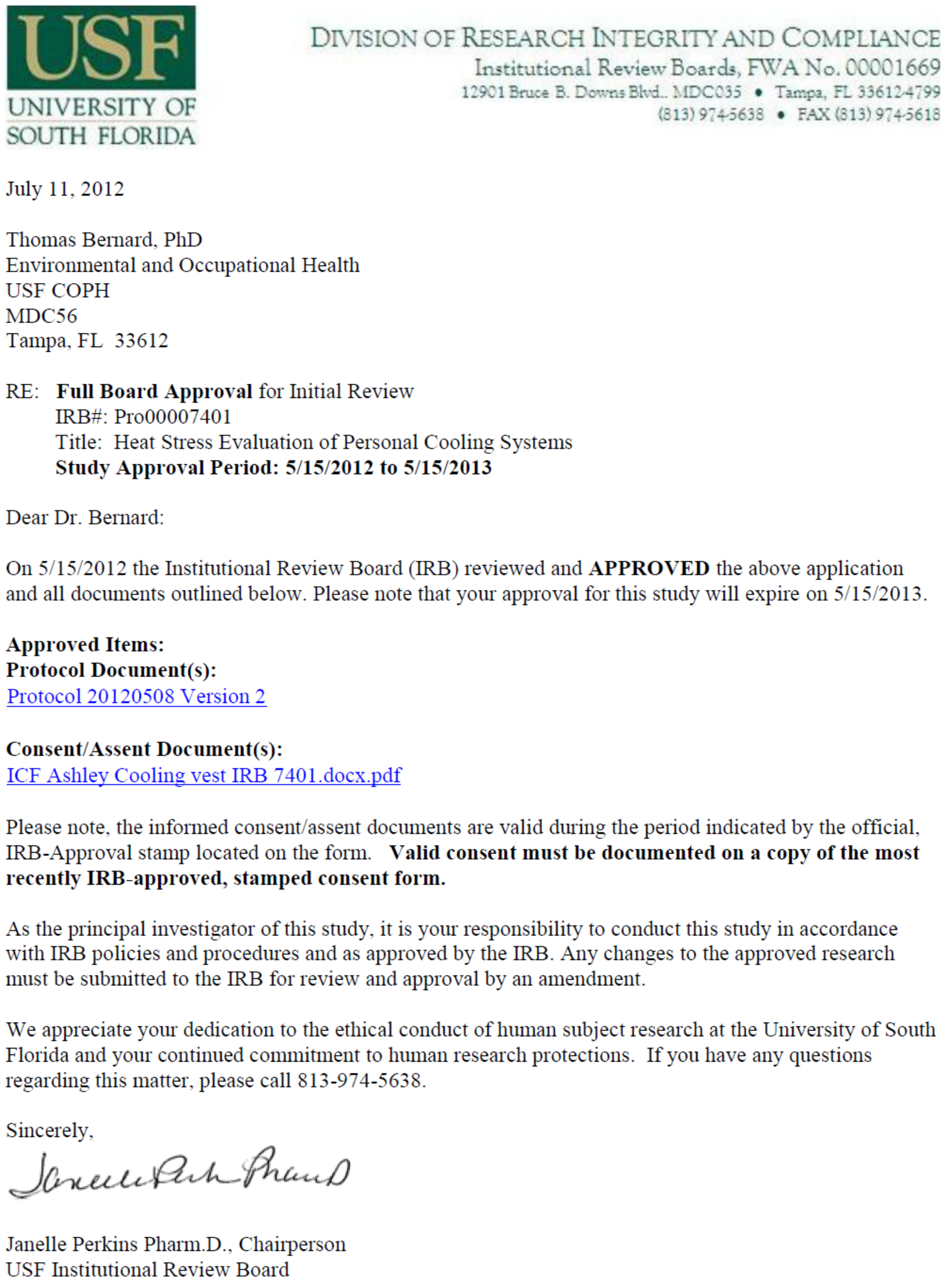
APPENDICES

Appendix A: Tukey's HSD results.

Table AI: Means differences Tukey's Honestly Significant Difference multiple comparison test results.

Storage Rate (minute 5 to 120)					
Device	Level			Least Square Mean (W)	Standard Error
NC	A			28.24	3.80
CO2	A	B		24.64	4.29
Frozen		B	C	14.76	3.90
Air		B	C	12.58	3.90
Water			C	9.89	3.90
Change in Core Temperature (minute 5 to 120)					
Device	Level			Least Square Mean (^{0}C)	Standard Error
NC	A			0.715	0.092
CO2	A	B		0.615	0.105
FP		B	C	0.366	0.096
Air		B	C	0.325	0.096
Water			C	0.251	0.096
Change in Heart Rate (minute 5 to 120)					
Device	Level			Least Square Mean (bpm)	Standard Error
NC	A			33	2.49
CO2	A			26.4	2.61
FP		B		12.1	2.61
Air		B		5	2.61
Water		B		4.6	2.61
Change in Skin Temperature (minute 5 to 120)					
Device	Level			Least Square Mean (^{0}C)	Standard Error
CO2	A			1.78	0.324
FP	A	B		1.53	0.311
NC	A	B		1.46	0.291
Water		B	C	0.27	0.311
Air			C	-0.031	0.311

Appendix B: Institutional Review Board Approval



USF
UNIVERSITY OF
SOUTH FLORIDA

DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd.. MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-5618

July 11, 2012

Thomas Bernard, PhD
Environmental and Occupational Health
USF COPH
MDC56
Tampa, FL 33612

RE: **Full Board Approval** for Initial Review
IRB#: Pro00007401
Title: Heat Stress Evaluation of Personal Cooling Systems
Study Approval Period: 5/15/2012 to 5/15/2013

Dear Dr. Bernard:

On 5/15/2012 the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents outlined below. Please note that your approval for this study will expire on 5/15/2013.

Approved Items:
Protocol Document(s):
Protocol 20120508 Version 2

Consent/Assent Document(s):
ICF Ashley Cooling vest IRB 7401.docx.pdf

Please note, the informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on the form. **Valid consent must be documented on a copy of the most recently IRB-approved, stamped consent form.**

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

Janelle Perkins Pharm.D., Chairperson
USF Institutional Review Board