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Cooling System to Treat Exercise-Induced Hyperthermia

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14. ABSTRACT

Air Combat Command has designated non-invasive cooling of trauma patients to prevent hypothermia from point of injury to role 4 facilities and temperature maintenance among air evacuation patients to be a research priority. This presentation discusses findings from a study designed to determine the effectiveness of a cooling pump based patient thermal management system supplied by Aspen Systems on lowering core body temperature after temperature elevation caused by physical activity. Six active duty Air Force volunteers between the ages of 19 and 45 ingested a CorTemp® core body temperature sensor. Subjects exercised on a treadmill for 60 minutes or until core temperature elevated 1°C above baseline. Subjects then rested supine on a standard NATO litter for 60 minutes or when core temperature returned to subject's baseline. Subjects repeated the exercise-then-rest regimen a second time, except resting occurred with the Aspen litter cooling pad. A reduction in cooling time to baseline by half for each subject using the cooling pad compared with cooling naturally was determined to be a level of significance. None of the subjects showed a significant decrease in cooling time to baseline core temperature using the Aspen litter cooling pad when compared to cooling naturally. The Aspen Systems thermal management system may have a role in the prevention of hypothermia among trauma patients or with temperature maintenance among air evacuation patients. However, as utilized in this study, the system is not considered to be effective as a treatment modality for patients with hyperthermia.

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1.0 SUMMARY

Air Combat Command has designated non-invasive cooling of trauma patients to prevent hypothermia from point of injury to role 4 facilities and temperature maintenance among air evacuation patients to be a research priority. This presentation discusses findings from a study designed to determine the effectiveness of a cooling pump based patient thermal management system supplied by Aspen Systems on lowering core body temperature after temperature elevation caused by physical activity. Six active duty Air Force volunteers between the ages of 19 and 45 ingested a CorTemp® core body temperature sensor. Subjects exercised on a treadmill for 60 minutes or until core temperature elevated 1°C above baseline. Subjects then rested supine on a standard NATO litter for 60 minutes or when core temperature returned to subject's baseline. Subjects repeated the exercise-then-rest regimen a second time, except resting occurred with the Aspen litter cooling pad. A reduction in cooling time to baseline by half for each subject using the cooling pad compared with cooling naturally was determined to be a level of significance. None of the subjects showed a significant decrease in cooling time to baseline core temperature using the Aspen litter cooling pad when compared to cooling naturally. The Aspen Systems thermal management system may have a role in the prevention of hypothermia among trauma patients or with temperature maintenance among air evacuation patients. However, as utilized in this study, the system is not considered to be effective as a treatment modality for patients with hyperthermia.

2.0 INTRODUCTION

In 2003, the Department of the Army and Air Force produced guidance titled "Heat Stress Control and Heat Casualty Management" in TB MED 507/AFPAM 48-152. This emphasized that troops participating in military deployments often will encounter heat stress that requires management for successful mission accomplishment. Heat stress can be divided into compensated heat stress (CHS) and uncompensated heat stress (UCHS). CHS and UCHS are primarily determined by biophysical factors (environment, clothing, and work-rate) and are modestly affected by biological status (heat acclimatization and hydration status). CHS exists when heat loss occurs at a rate in balance with heat production so that a steady-state core temperature can be achieved at a sustainable level for a requisite activity. CHS represents the majority of military situations. UCHS occurs when the individual's evaporative cooling requirements exceed the environment's evaporative cooling capacity. During UCHS, soldiers cannot achieve steady-state core temperature, and core temperature rises until exhaustion occurs at physiological limits [1].

Heat-related illnesses exist in a spectrum of disease states, ranging from minor heat-related illnesses, such as heat edema, sunburn, and heat cramps, to heat stroke, which is life-threatening. Heat exhaustion is the most common form of heat casualty and is not associated with evidence of organ damage. It occurs when the body cannot sustain the level of cardiac output necessary to meet the combined demands of skin blood flow for thermoregulation and blood flow for the metabolic requirements of exercising skeletal muscle and vital organs. Treatment is focused on water-electrolyte replacement and active cooling. Heat stroke is characterized by elevated body temperature (>40°C or 104°F) and central nervous system dysfunction, which result in delirium, convulsions, or coma. Heat stroke is a catastrophic medical emergency resulting from a failure of the thermoregulatory mechanisms [1]. Exertional

heat exhaustion is defined as the inability to continue to exercise, which occurs with heavy exertion in all temperatures and may or may not be associated with physical collapse. Exertional hyperthermia, defined as a core body temperature above 40°C (104°F), occurs during athletic or recreational activity and is influenced by exercise intensity, environmental conditions, clothing, equipment, and individual factors. Hyperthermia occurs during exercise when muscle-generated heat accumulates faster than heat dissipates via increased sweating and skin blood flow. Heat production during intense exercise is 15–20 times greater than at rest and can raise core body temperature by 1°C (1.8°F) every 5 minutes if no heat is removed from the body. Prolonged hyperthermia may lead to exertional heat stroke if not promptly recognized and treated with body cooling. Wide variations of heat tolerance exist among athletes. It is not unusual for some athletes to experience prolonged hyperthermia without noticeable medical impairment, especially during competition [2].

During physical exercise, metabolic heat production can increase by 10- to 20-fold, but less than 30% of the heat generated is converted to mechanical energy. Conversely, more than 70% of metabolic heat generated has to be transported from the peripheral compartments of the body to the skin to be dissipated to the environment. Heat starts to accumulate in the body when the heat dissipating mechanisms are unable to cope with metabolic heat production, leading to an increase in body temperature [1]. Lim et al. found the average gastrointestinal (GI) temperature increased from 37.6°C before exercise to 39.3°C after running for 45 minutes outdoors. The highest individual GI temperature recorded was 40.3°C during the run. In addition, the mean GI temperature of soldiers marching for 12 km with the standard equipment and backpack increased from 37.5°C before the march to 39.4°C at the end of the march, and the highest individual GI temperature recorded was 40.4°C. The duration and intensity of exercise, which drive metabolic heat production, contribute significantly to the amount of heat accumulated in the body during exercise. The risk of heat injury during physical exertion is often underestimated during cooler conditions because metabolic heat production alone can generate sufficient heat to cause heat injury even in cooler conditions during intense exercise. The “fire” starts from within the body in exertional heat injury, and heat casualties have been reported in ambient temperatures <20°C [3].

Body cooling is the treatment foundation and must be initiated as soon as possible, using the most practical means available. Both cool and ice water immersion are the most effective methods in lowering body temperature. Ice water produces a slightly faster cooling; however, in the field, it is very difficult to obtain. Initial cooling methods include removing outer layers of clothing; soaking the skin with water; using wet sheets, ice packs, or spray bottles; massaging the skin; and resoaking. Another method described is digging a field-expedient immersion bath. Heat casualties are more frequently seen during intense advanced training and operations settings, where ideal treatment modalities may be lacking [1]. One potential solution in filling this treatment modality gap is the subject of this research project. Forward positioning of a thermal management system to treat heat-related illness would be significant because other treatment resources are often limited in deployed conditions. Additionally, the cooling system can remain with the patient through the aeromedical evacuation (AE) system, if needed. The Air Combat Command (ACC) has designated non-invasive cooling of trauma patients to prevent hyperthermia from point of injury to role 4 facilities and temperature maintenance among AE patients to be a research priority (Figure 1).[1]

[1] Hendricks TM. Medical Modernization Planning Division (ACC/SGR), TES Summit, Slide 8, March 2012.

ACC/SG 1 to N List

U.S. AIR FORCE

1-N	MTA	Category	Priority	Urgency	Gap Title	Gap / Shortfall Description	Requirement
1	Expeditionary Medicine	First Responder/ Resuscitation	H	U	Hemorrhage Control (Torso)	The ability to effectively control bleeding. Better capability needed to be evaluated junctional & torso (non-compressible) based injuries.	RESEARCH: Research to discover novel methods of treating non-compressible wounds. Involving damage to tissues spanning the root of an extremity and adjacent torso.
2	Expeditionary Medicine	First Responder/ Resuscitation	H	U	Coagulopathy	The ability to effectively manage the diffuse coagulopathy often associated with major trauma.	RESEARCH: To (1) identify early evidence of coagulopathy (2) determine intervention to preclude further degradation and (3) determine best practices for intervention and treatment.
3	Expeditionary Medicine	First Responder/ Resuscitation	H	U	Hemorrhage Control (Extremity)	The Air Force does not have the ability to effectively control extremity bleeding. Existing and new capabilities need to be evaluated for non-junctional bleeding. (i.e. extremity)	MATERIEL DEVELOPMENT: There is a need to standardize equipment sets. RESEARCH: Evaluate novel methods for quickly stopping life-threatening extremity bleeding. TRAINING: Need new standard for training to improve tourniquets use (tourniquets are sometimes applied too loosely or below the effected level).
4	Expeditionary Medicine	First Responder/ Resuscitation	H	U	Vascular Access	The AF does not have the ability to rapidly access vascular regions.	RESEARCH: Research is needed to (1) identify rapid reliable vascular access for first responders and (2) identify novel techniques to monitor i.e. pressure wire. MATERIEL: There is a need for a rapidly insertable, low profile percutaneous device(s) for use by a range of personnel including first responders.
5	Expeditionary Medicine	Surgery	H	U	Hypothermia / Hyperthermia prevention and treatment	No technology exists for non-invasive warming and cooling of trauma patients to prevent hypo/hyperthermia from point of injury to role 4 facilities.	MATERIEL DEVELOPMENT: Research devices that can both warm and cool patients. Devices must be small and ruggedized. RESEARCH: Research the limitations of COTS products and analyze development of COTS/modified COTS is a solution. Potential to be interoperable with device for hypothermia and hyperthermia prevention. RESEARCH: To study and evaluate novel technology/technique to reduce effects of hypothermia, i.e. new drug therapy, advanced vascular access, and fluid resuscitation. Point of injury to role IV MTFs

Figure 1. Medical Modernization Planning Division (ACC/SGR), TES Summit, March 2012.
Item 5 emphasizes the need for hyperthermia prevention.

In a prior cooling study evaluating the effectiveness of a cooling vest during intense physical fitness, Trbovich et al. utilized a 2-hour recovery to minimize temperature carryover from prior exercise, citing the Downey and Darling report that at least 1 hour is needed after exercise for T_c (core temperature) to return to baseline [4].

A National Aeronautics and Space Administration (NASA) research project comparing various temperature monitoring devices found that T_c measurement using an ingestible pill may be more appropriate in exercise testing, circadian monitoring, protective clothing monitoring and testing, and other field environments, such as microgravity, where instrumenting subjects for an esophageal thermometer or rectal thermometer may not be feasible. The ease of use of this hardware and relatively few sanitary concerns in comparison to the esophageal and rectal thermistors make it an ideal candidate for studies involving exercise or that take place in non-controlled environments [5].

3.0 METHODS

3.1 Data Collection

Six volunteer subjects were enrolled in this study. (Ten subjects were to be enrolled initially. However, after the initial six subjects showed no significant cooling effect from the cooling pad, enrollment was discontinued.) Enrollment in this protocol was limited to active duty military members between the ages of 19 and 45. Subjects completed a medical screening questionnaire (Figure 2). The inclusion and exclusion criteria are as follows:

Inclusion Criteria:

1. Age: 19-30 years
2. Must have a composite fitness assessment score ≥ 90 %
3. Must not be on a medical profile
4. Active duty military

Exclusion Criteria:

1. Subjects who have any known or suspected obstructive disease of the GI tract, including but not limited to diverticulitis and inflammatory bowel disease
2. Subjects who have a history of disorders or impairment of the gag reflex
3. Subjects with previous GI surgery
4. Subjects who might undergo nuclear magnetic resonance/magnetic resonance imaging scanning during the period that the CorTemp® (HQ Inc., Palmetto, FL) sensor is within the body
5. Subjects with hypomotility disorders of the GI tract, including but not limited to intestinal obstruction
6. Subjects having a cardiac pacemaker or implanted electromedical device
7. Subjects who have experienced swallowing disorders
8. Subjects who smoke
9. Resting T_c greater than 38°C or 100.4°F
10. Subjects who are pregnant or who may become pregnant over the course of the study period. In the event an unknowingly pregnant female should swallow the CorTemp® sensor, additional reporting may be required.
11. Subjects weighing less than 80 pounds or a body mass index (BMI) greater than or equal to 30

Table 1 shows the demographics of the six enrolled subjects.

Please answer Y or N for the following health history questions:

- Do you have a family medical history of any of the following?	**Y**	**N**
-- Father or brother suffered a heart attack, stroke, or sudden death before age 55		
-- Mother or sister suffered a heart attack, stroke, or sudden death before age 65		
- Have you used tobacco within the past 6 months?	**Y**	**N**
- Have you been diagnosed with <u>any</u> of the following?	**Y**	**N**
-- High Cholesterol (>200 mg/dL)		
-- High Blood Pressure		
-- Diabetes or Impaired Glucose Tolerance		
-- Obesity (BMI >30)		
-- Heat Illness		
- Are you currently taking any medications, herbals, or supplements?	**Y**	**N**
- Do you have a medical condition that restricts your ability to perform actions such as running/jumping/lifting?	**Y**	**N**
- Are you on a profile or waiver?	**Y**	**N**
- Do you suffer any chronic joint, muscle, or bone pain?	**Y**	**N**
- Do you have any known or suspected obstructive disease of the gastrointestinal tract, including but not limited to diverticulitis and inflammatory bowel disease?	**Y**	**N**
- Do you have a history of disorders or impairment of the gag reflex?	**Y**	**N**
- Have you had gastrointestinal surgery?	**Y**	**N**
- Are you potentially undergoing nuclear magnetic resonance/ magnetic resonance imaging scanning during the period that the CorTemp® sensor is within the body?	**Y**	**N**
- Do you have hypomotility disorders of the gastrointestinal tract, including but not limited to intestinal obstruction?	**Y**	**N**
- Do you have a cardiac pacemaker or implanted electromedical device?	**Y**	**N**
- Have you experienced swallowing disorders?	**Y**	**N**
- For females, are you pregnant or could you become pregnant over the course of the study period?	**Y**	**N**

Figure 2. Medical screening questionnaire.

Subjects' physical activity and fluid and food intake before each test were ad libitum with the exception of alcohol, which was restricted. Subjects swallowed a core body temperature sensor with a glass of tepid water at least 2 hours before testing began (Figure 3). Throughout the remainder of testing, food and water intake was ad libitum, but fluid intake was restricted to bottled water at room temperature.

Table 1. Subject Demographics

Subject	Age (yr)	Gender	Height (cm)	Weight (lb)	BMI	Pred MHR	55% MHR	75% MHR
1	42	M	172	170	26	178	98	134
2	38	M	176	184	27	182	100	137
3	36	M	180	157	22	184	101	138
4	22	M	175	159	24	198	109	149
5	44	F	150	97	20	176	97	132
6	37	F	157	124	23	183	101	137
7[a]	42	M	171	147	23	178	98	134

[a]Data not used during calculation due to protocol error. However, results referenced in Discussion.
Note: MHR = maximum heart rate.

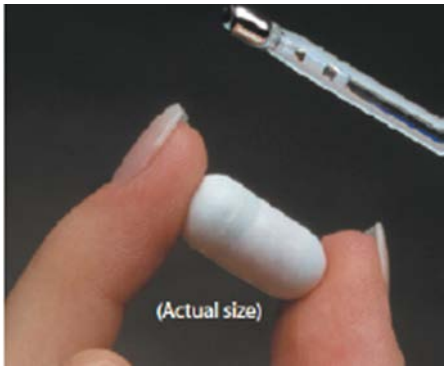


Figure 3. CorTemp® Ingestible Core Body Temperature Sensor. *Courtesy of HQ Inc.*

3.1.1 Phase 1. Prior to testing, the subject's baseline T_c was measured. The subject then began exercising on a treadmill to increase T_c. The pace of exercise was adjusted to maintain a heart rate of 65% (± 10%) MHR at a 2% incline. In a NASA research project, subjects completed a supine submaximal exercise test that consisted of 20 minutes of supine rest, 20 minutes at 40% of supine peak oxygen consumption (VO_2peak), and 20 minutes at 65% VO_2peak [6]. In our study, predicted MHR was used as a surrogate for VO_2peak level of exertion and subjects ran on the treadmill at 65% (55-75%) MHR. Predicted MHR was calculated using the following equation: MHR = 220 – Age. Subjects' exercise heart rates and T_c were captured by the CorTemp® Data Recorder (HQ Inc., Palmetto, FL) throughout the testing (recorded every 5 minutes). Telemetered signals from the CorTemp® Ingestible Core Body Temperature Sensor and Polar heart rate chest strap (Polar Electro Inc., Lake Success, NY) were received and recorded using the CorTemp® Data Recorder. Exercising was discontinued at 60 minutes or when T_c was elevated 1.0°C above baseline, whichever came first [7,8].

The subject immediately assumed a supine resting position on a standard NATO litter (Figures 4 and 5). The subjects' T_c was captured by the CorTemp® Data Recorder throughout the cooling period (recorded every 5 minutes). Monitoring was discontinued at 60 minutes or when T_c returned to subjects' baseline, whichever came first. Subjects then entered a 1-hour rest period before entering Phase 2.

Figure 4. Aspen Systems Inc. patient thermal management system. *Photo by Dr. Lloyd Tripp.*

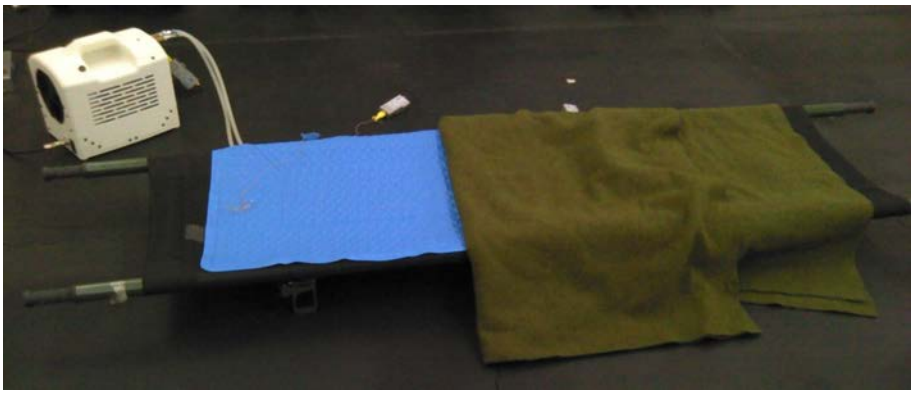


Figure 5. Patient thermal management system with cooling pad on standard NATO litter.
Photo by Dr. Lloyd Tripp.

3.1.2 Phase 2. In Phase 2, the subject exercised as before to elevate T_c. When entering the cooling portion, however, the subject assumed a supine position on the cooling pad pre-positioned on the NATO litter and set to a temperature of 40°F.

Three patients completed the testing protocol cooling naturally in Phase 1 and then with the cooling pad in Phase 2. Three patients completed the testing protocol cooling with the cooling pad in Phase 1 and then naturally in Phase 2. Tables 2-4 show individual subject results. Once data collection was completed, names and phone numbers were removed to de-identify the dataset for this study; thus, subjects were referred to by their unique identifier number.

Table 2. Cooling Temperatures by Time, Cooling Naturally First, then by Cooling Pad (Subjects 1, 3, 4)

Time (min)	Cooling Temperature (°C)					
	Subject 1		Subject 3		Subject 4	
	Natural	Cooling Pad	Natural	Cooling Pad	Natural	Cooling Pad
Start	37.96	38.26	37.49	37.97	38.01	37.89
5	37.52	38.21	37.85	38.29	36.81	36.71
10	37.23	38.12	37.58	38.10	37.11	37.07
15	37.50	38.04	37.25	38.00	37.25	37.26
20	37.45	37.86	37.16	37.86	37.30	37.35
25	37.24	37.70	37.30	37.66	37.30	37.31
30	37.24	37.67	37.22	37.29	37.27	37.29
35	37.16	37.65	37.17	37.55	37.20	37.27
40	37.13	37.59	36.92	37.52	37.13	37.16
45		37.57	36.99	37.17	37.13	37.10
50		37.53	36.87	37.39	37.15	36.99
55			36.94	37.29	37.10	37.00
60			36.87	37.28	37.12	36.93

Table 3. Cooling Temperatures by Time, Cooling Naturally First, then by Cooling Pad (Subjects 5, 6, 2)

Time (min)	Cooling Temperature (°C)					
	Subject 5		Subject 6		Subject 2	
	Cooling Pad	Natural	Cooling Pad	Natural	Cooling Pad	Natural
Start	37.97	38.24	38.35	38.55	37.82	37.94
5	38.18	38.02	38.02	38.97	37.92	38.03
10	38.04	37.92	37.78	38.10	37.94	38.02
15	37.93	37.57	37.73	37.98	37.86	37.89
20	37.77	37.78	37.73	37.86	37.75	37.75
25	37.69	37.92	37.71	37.71	37.74	37.60
30	37.61	37.61	37.66	37.73	37.68	37.57
35	37.57	37.22	37.67	38.20	37.58	37.55
40	37.49	38.24	37.71	37.62	37.50	37.52
45	37.46		37.65	37.54	37.44	37.47
50	37.40		37.46	37.22	37.38	37.45
55	37.34		37.41		37.26	37.43
60	37.33		37.45		37.22	37.43

Table 4. Cooling Temperatures by Time for Subject 7 (Cooling by Cooling Pad First, then Naturally)

Time (min)	Cooling Temperature (°C) for Subject 7[a]	
	Cooling Pad	Natural
Start	37.78	37.64
5	37.59	37.28
10	37.34	36.84
15	36.52	36.84
20		36.81
25		36.77
30		36.88
35		36.77
40		36.81
45		36.92
50		36.93
55		36.90
60		36.81

[a]This subject's results were not included in the study as the cooling pad was inadvertently not turned on prior to subject entering the cooling period (see Discussion section).

3.2 Study Design

This experimental study compared cooling rates of subjects after elevation of core body temperature by physical fitness either naturally or with the addition of a cooling pad, with subjects serving as their own control. The independent variable for this study was cooling pad application and the dependent variable for this study was core body temperature. Historically, in healthy athletes, the time to return to T_c post-exercise is approximately 1 hour [4]. The null hypothesis is that there will be a shortened time required to return to baseline T_c post-exercise for those treated with the cooling pad compared with matched counterparts.

We compared time from maximum temperature to baseline T_c when cooled naturally to time from maximum temperature to baseline T_c with the treatment of the Maxi-Therm® Lite cooling pad (Cincinnati Sub-Zero, Sharonville, OH). Subjects served as their own control.

With the significance level set at $\alpha = 0.05$, a sample size of 10 yielded a power greater than .90. A reduction in time of 30 minutes is an effect size of 0.50, a very large effect. A minimum of nine people was needed to achieve a power of .80.

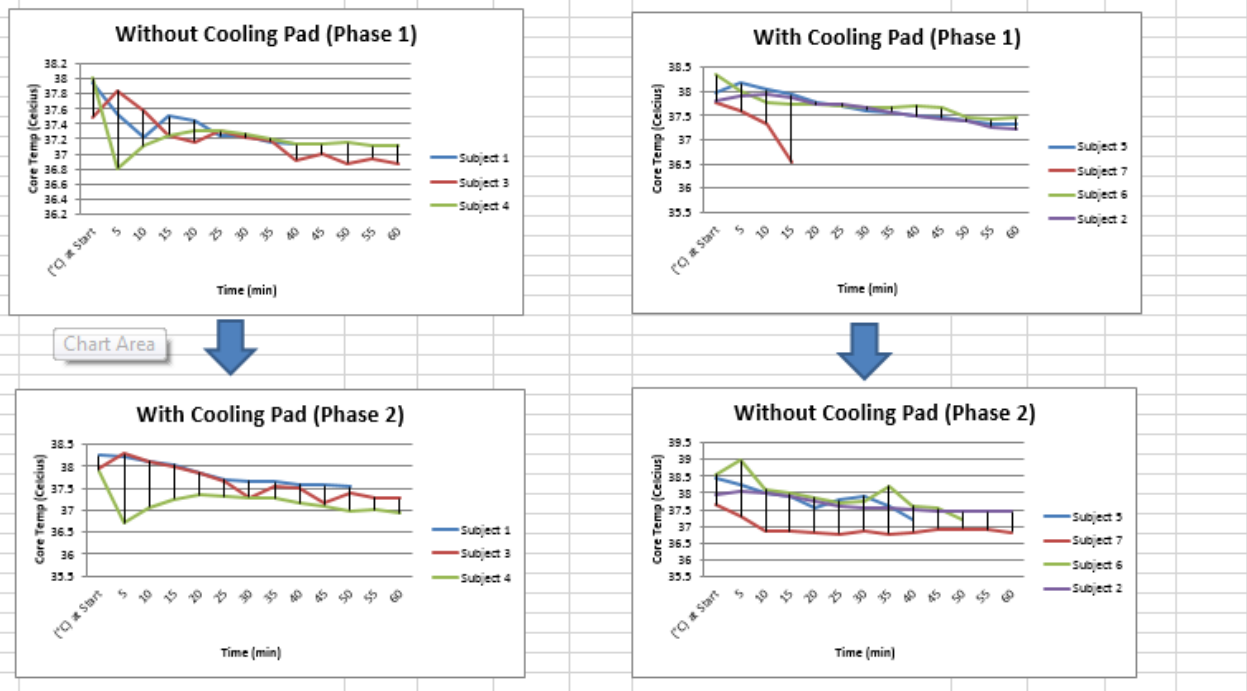
3.3 Statistical Analysis

A linear mixed model was utilized for its ability to incorporate both fixed effects and correlated errors, which are modeled through random effects. Fixed effect variables included time to cooling (T), whether the subject started with cooling naturally (Group 1) or cooling with the cooling pad (TP) (Group 2), and the interaction T x TP. Random effect variables were accounted for within subject correlation. Statistical software utilized SPSS 22 (IBM, Armonk, NY) and R 3.2.2 (https://www.r-project.org/).

The study protocol was approved by the Institutional Review Board of the Air Force Research Laboratory, Wright-Patterson Air Force Base, OH.

4.0 RESULTS

All six subjects failed to show a statistically significant difference in cooling times to baseline between the naturally cooling group and the cooling pad group (Figure 6). Additionally, although subjects were at low risk of harm due to the exercise protocol or the ingestible thermometer, the risk was not zero. Therefore, the study was discontinued after six subjects completed the established protocol.



	Subject 1	Subject 3	Subject 4
Time to Return to Baseline (min)= Tn	40	60	60
Time to Return to Baseline (min)= Tc	50	60	60
Tc/Tn	1.25	1	1

	Subject 5	Subject 7*	Subject 6	Subject 2
Time to Return to Baseline (min)= Tc	60	15	60	60
Time to Return to Baseline (min)= Tn	40	60	50	60
Tc/Tn	1.5	0.25	1.2	1

Figure 6. Cooling trends for each subject.

Both analyses (SPSS 22 and R 3.2.2) showed no significant difference between the two groups while accounting for fixed and random factors (Figures 7 and 8). Analysis also determined that there was no interaction between time and group by fitting a full and reduced model that determined the chi square and p-value as follows: chi square $\chi 2=0.1765$, $p=0.6744$. The p-value is greater than 0.05, rejecting the null hypothesis, and the Aspen cooling system as utilized in this study was not found to significantly lower core body temperature when compared to subjects cooling naturally.

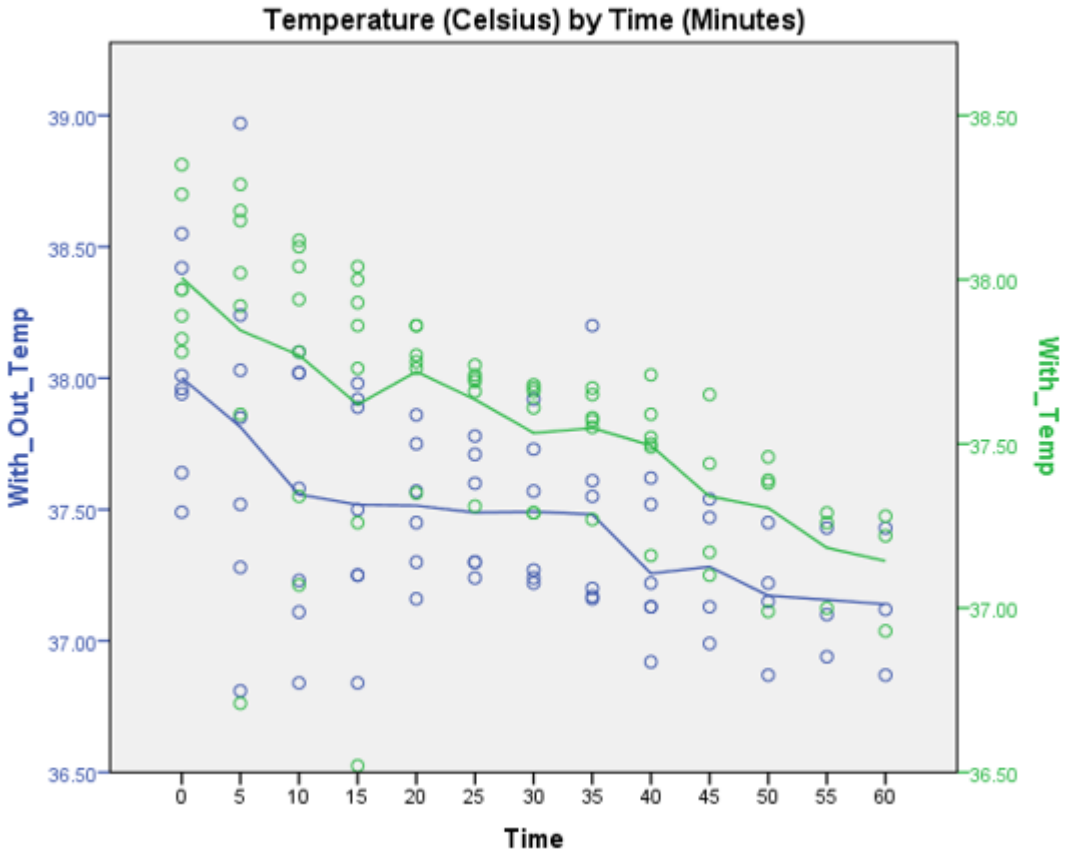


Figure 7. SPSS scatterplot with fit regression lines of temperature without (With_Out_Temp) and with (With_Temp) cooling pad measured by °C by time in minutes.

5.0 DISCUSSION

It is important to emphasize that this thermal management system *applied in the manner tested* would not have a role in initial management of heat casualties given the results of this study. With subjects laying supine on the cooling pad, the cooling pad makes direct contact over only a few points of the body, having only a small regional area of effect. This pad extended from the head to approximately the subject's buttock. Direct contact points were at the buttock, shoulder blades, and back of the head, with air space created by the body's natural curvature at the low back, between the shoulder blades, and neck. Given the pliable nature of the cooling pad, an improved study method could have been to drape the cooling pad over the top of the supine patient, covering the neck, torso, and groin, and molding the blanket to the shape of the body. This leaves the back exposed to the ambient air provided by NATO litter mesh backing, which is important to maintain avenues for body heat exchange to the environment.

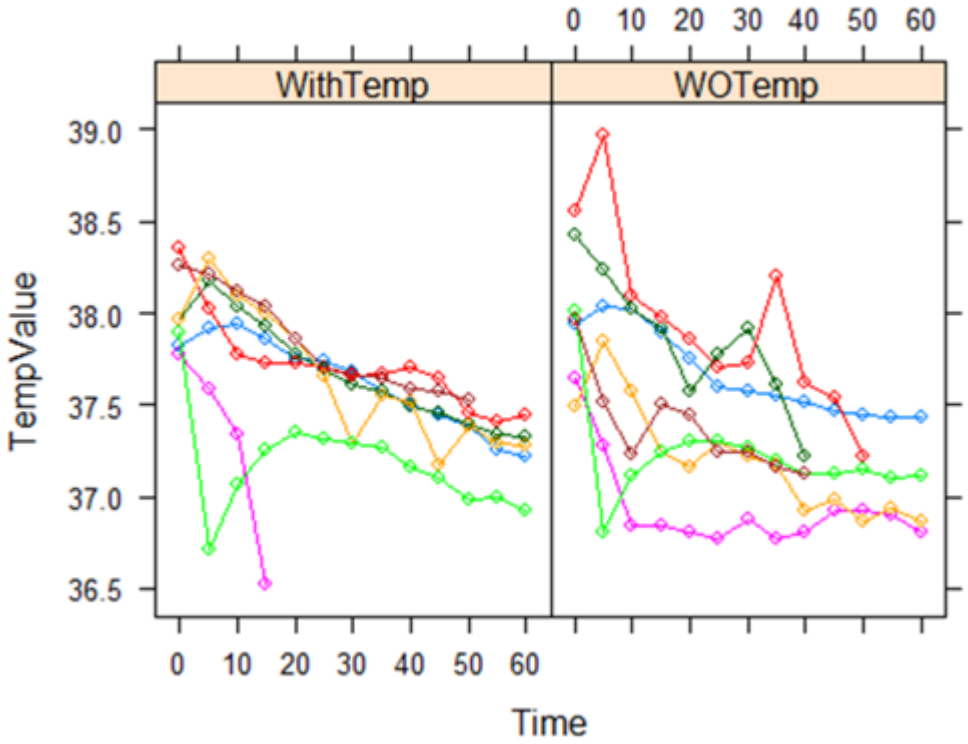


Figure 8. R 3.2.2 statistical output to determine whether slopes were equal for each group. *Temperature in °C by time in minutes; each line color represents a subject group with cooling pad vs. group without cooling pad. The pink line shows subject 7, whose results are shown for comparison but were not included due to protocol variation (see Discussion).*

During compensated heat stress, the body relies heavily on peripheral vasodilation to mobilize elevated core body heat to the periphery to be exchanged to the environment. However, the direct application of the 40°F cooling pad to the skin results in a reactionary peripheral vasoconstriction, establishing an area of insulation and slowing core temperature cooling in the short term. White and Wells found that skin temperature drops rapidly in the first 1–3 minutes and reaches minimum temperature around 8–9 minutes of cooling after direct contact with external cooling. Superficial intramuscular temperature cools in a linear pattern at a rate faster than deeper muscle tissues, with the magnitude of muscle temperature change being dependent on the thermal gradient between the muscle and cryotherapy medium. Although both superficial and deep intramuscular tissues reach a minimum temperature in the post-cooling period, deeper tissues will reach a nadir in temperature later in the post-cooling period as heat from deep tissues is lost to colder superficial tissues [5]. This suggests that more effective cooling may take place with an intermittent cooling strategy vs. continuous cooling strategy. Where this study utilized a continuous cooling strategy with an a priori level of significance set at 30 minutes of cooling to return core temperature to baseline, an alternate approach could have been 15 minutes of cooling followed by ambient temperature exposure only while measuring core temperature. White and Wells found that skin temperature reaches its nadir after 8-9 minutes of cooling; therefore, 10-15 minutes would be ample [5].

One subject after completing the exercise portion of the protocol with elevated T_c was placed on the cooling pad and NATO litter. However, the thermal management system had not been previously cooled. The system was turned on and cooled from room temperature to 40°F in 15 minutes. This subject was the only one who cooled to baseline core temperature in < 30 minutes; in fact, the subject accomplished this in 15 minutes (Figures 6 and 8). It is theorized that this subject did not experience an acute vasoconstriction as the other subjects did when placed immediately on the cooling pad preset to 40°F. This gradual cooling allowed continued circulation and exchange of core elevated temperature with the periphery and then to the environment. Because the subject did not maintain protocol, the results from this subject were not included in the study results. However, this provides another potential alternate study protocol for future studies, in addition to an intermittent cooling strategy.

There are several limitations in the resultant design of the study. The sample size is small, with a final subject count of six. The protocol only planned for a sample size of 10, which would exceed a power of 0.80 with an alpha of 0.05. However, as discussed above, given the failure of the cooling pad to achieve a rate of cooling at a level of significance for any of the subjects, the study was terminated early given there was even a small risk to subjects ingesting the CorTemp® sensor. The study needed to be completed in 1 day given the potential for subjects to pass the sensor from the body. Also, given the amount of exercise required over the study period of 7 hours, subjects needed to drink water and have some form of nutrition. It was determined that subjects could drink ad libitum throughout the study, but water would be provided at room temperature to limit the theoretical impact of cold water ingestion on the CorTemp® sensor readings. Subjects were allowed to eat a meal of their choosing between the morning and afternoon sessions during the 1-hour recovery period. The amount and character of meals taken were not recorded. It is understood that post-meal GI blood flow and thermogenesis could affect T_c as measured by the CorTemp® sensor in the GI tract. Although recorded, subject BMI was not utilized in calculations but, along with body surface area, could affect the rate of change of individual core temperatures. Additionally, individual variations in sweat rates, ventilation rates, fitness levels, and oxygen consumption were not factored into the analysis.

6.0 CONCLUSION

Current combat environments place soldiers at increased risk for heat-related illness. Non-invasive cooling of trauma patients to prevent hyperthermia from point of injury to role 4 facilities and temperature maintenance among AE patients continue to be a research priority. Forward positioning of a thermal management system to treat heat-related illness would be significant because, as cited above, other treatment resources are limited in these conditions. Additionally, the cooling system can remain with the patient through the AE system, if needed. While the Aspen cooling system was not effective at cooling subjects with exercise-induced hyperthermia in the manner applied for this study, such a system could have a role in temperature maintenance. Further studies are recommended to evaluate the effectiveness of such a cooling system if applied in a different manner, such as draped over the subject to increase direct body contact, or using different timing methods, such as the intermittent and gradual cooling strategies described above.

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LIST OF ABBREVIATIONS AND ACRONYMS

ACC	Air Combat Command
AE	aeromedical evacuation
BMI	body mass index
CHS	compensated heat stress
GI	gastrointestinal
MHR	maximum heart rate
NASA	National Aeronautics and Space Administration
T_c	core temperature
UCHS	uncompensated heat stress
VO_2peak	peak oxygen consumption