Preventing Hypothermia: Comparison of Current Devices Used by the U.S. Army with an *In Vitro* Warmed Crystalloid Fluid Model

CPT Paul B. Allen Sr.
Brooke Army Medical Center
MCHE-DEM (Attn: CPT Paul Allen)
3851 Roger Brooke Drive
Fort Sam Houston, TX 78234-6200
USA

paul.b.allen@us.army.mil

Steven W. Salyer
Brooke Army Medical Center
MCHE-DEM (Attn: Steve Salyer)
3851 Roger Brooke Drive
Fort Sam Houston, TX 78234-6200
USA

steven.w.salyer@us.army.mil

Michael A. Dubick
US Army Institute of Surgical Research
Fort Sam Houston, TX 78234
USA

michael.dubick@us.army.mil

Lorne H. Blackbourne
US Army Institute of Surgical Research
Fort Sam Houston, TX 78234
USA

lorne.h.blackbourne@us.army.mil

John B. Holcomb
University of Texas Health Science Center
6410 Fannin Suite 1100 Houston, TX 77030
USA

ABSTRACT

Background

Multiple methods are utilized for thermoregulation of combat wounded as they proceed from the point of injury until their arrival in the United States. The purpose of this study was to develop an in vitro torso model constructed with fluid bags and to determine whether this model could be used to differentiate between the heat prevention performance of devices with active chemical or radiant forced-air heating systems compared with passive heat loss prevention devices.

Methods

We tested two groups of hypothermia prevention products: Group 1, which consisted of three devices with actively heated systems (either chemically or electrically); and Group 2, which consisted of five methods of passive heat loss prevention. Both groups were tested on a fluid model of truncal dimensions (45 liters PrismaSate® dialysate solution, approx 60% of 70 kg, or 48.6 kg) warmed to 37° C versus a control with no warming device. Core temperatures were recorded every 5 minutes for 120 minutes total, based on the controls achieving a clinically significant drop from 37°C to 34°C consistently over 2 hours.

Results

The wool blanket provided no significant prevention of heat loss compared with the controls. Products that prevent heat loss with an actively heated element performed better than most passive prevention methods. The

Report Documentation Page		*Form Approved* *OMB No. 0704-0188*

1. REPORT DATE **APR 2010**	2. REPORT TYPE **N/A**	3. DATES COVERED **-**	
4. TITLE AND SUBTITLE **Preventing Hypothermia: Comparison of Current Devices Used by the U.S. Army with an In Vitro Warmed Crystalloid Fluid Model**		5a. CONTRACT NUMBER	
		5b. GRANT NUMBER	
		5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)		5d. PROJECT NUMBER	
		5e. TASK NUMBER	
		5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **Brooke Army Medical Center MCHE-DEM (Attn: CPT Paul Allen) 3851 Roger Brooke Drive Fort Sam Houston, TX 78234-6200 USA**		8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)		10. SPONSOR/MONITOR'S ACRONYM(S)	
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT **Approved for public release, distribution unlimited**			
13. SUPPLEMENTARY NOTES **See also ADA564622. Use of Advanced Technologies and New Procedures in Medical Field Operations (Utilisation de technologies avancees et de procedures nouvelles dans les operations sanitaires). RTO-MP-HFM-182**			

14. ABSTRACT

Multiple methods are utilized for thermoregulation of combat wounded as they proceed from the point of injury until their arrival in the United States. The purpose of this study was to develop an in vitro torso model constructed with fluid bags and to determine whether this model could be used to differentiate between the heat prevention performance of devices with active chemical or radiant forced-air heating systems compared with passive heat loss prevention devices.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT **SAR**	18. NUMBER OF PAGES **22**	19a. NAME OF RESPONSIBLE PERSON
a. REPORT **unclassified**	b. ABSTRACT **unclassified**	c. THIS PAGE **unclassified**			

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std Z39-18

*original HPMK™ achieved and maintained significantly higher temperatures than all other methods and the
controls at 120 minutes (p < 0.05). None of the devices with an actively heated element achieved the sustained
44 °C that would damage human tissue if left in place for 6 hours. The best passive methods of heat loss
prevention were the Hot Pocket and Blizzard™ blanket, which performed similarly as two out of three active
heating methods tested at 60 and 120 minutes.*

Conclusions

*Our in vitro fluid bag "torso" model appeared sensitive to detect heat loss in the evaluation of several active
or passive warming devices. All active and most passive devices were better than wool blankets. Under
conditions near room temperature, passive warming methods (Blizzard™ blanket or the Hot Pocket) were as
effective as active warming devices other than the original HPMK™. None of the devices with an actively
heated element achieved the sustained 44 °C temperature that would damage human tissue if left in place for a
6-hour period. Further studies are necessary to determine how these data can translate to field conditions in
preventing heat loss in combat casualties.*

1.0   INTRODUCTION

Hypothermia, defined as a core temperature of less than 35 °C [1- 3] secondary to hemorrhagic shock or
trauma [4, 5], is as difficult for medical providers to treat today as it was in World War I [6]. It is an often
overlooked and sometimes fatal complication of trauma.

1.1   Physiology

Core temperature is controlled by the hypothalamus with 80 % of its input coming from peripheral neuron-
receptors [3, 6, 7]. The human body maintains core temperature at approximately 37ºC +/- 1.0ºC [3, 6, 7].
Depending on which reference you read, hypothermia is variously defined as a core temperature of less than
35-36ºC [3, 4, 7]. Non-shivering thermogenesis begins at 36ºC, and shivering at 35-35.5ºC [4, 6]. Shivering
generates heat, but increases glucose and energy consumption. Substrates for this heat generation rely heavily
on metabolism of glucose at 2-5x the basal metabolic rate [7]. Shivering also increases oxygen consumption,
further worsening the condition of patients who are already hypoxemic at the cellular level which may further
worsen shock [4, 8, 9].

Hypothermia may be exacerbated by catecholamine release, steroid release, and release of tissue thromboplastin
from ischemic tissues [4]. Adrenergic-mediated vasoconstriction occurs at 36.7˚C and couples with shivering as
the main defenses against temperature loss for a time [6]. As core body temperature decreases, the adrenergic,
cardiovascular and metabolic compensatory mechanisms begin to fail [4]. When the body is cooled below 32˚C
shivering stops, leaving vasoconstriction as the only defense against continued temperature drop [4, 7]. Previous
studies assert that 100% mortality occurs in trauma patients with core temperatures at 32˚C or below [8, 10, 11].
This is in contrast to patients suffering from accidental hypothermia, where severe hypothermia is defined as less
than 28˚C, but is associated with mortality of only 10% [11].

Because of these differences, a separate classification scheme for hypothermia has been proposed in patients
suffering from trauma where mild hypothermia is defined as core temperature from 34-36ºC, moderate 32-
34ºC, and severe <32ºC [11]. Most studies advocate what is termed "active rewarming" below 32ºC at which
point injury or illness prevents normal thermogenesis [7]. Viscous bronchorrhea, decreased ciliary motility,
non-cardiogenic pulmonary edema, and decreased renal blood flow by 50% occur at 27 to 30ºC [4]. This
decreased blood flow causes an increased loss of fluid through cold induced diuresis, but without nitrogenous

waste removal [4, 9]. At temperatures less than 32ºC the body experiences a severe decrease in intrinsic metabolic rate. At less than 24ºC endocrine modulation fails, and the risk of spontaneous ventricular fibrillation increases [4, 9], although this may occur at earlier temperatures in trauma patients.

1.2   Combat Trauma

Although the pre-hospital civilian or casualty care curriculum stresses the importance of preventing heat loss and keeping multisystem trauma patients warm, sometimes this critical step is overlooked during care of trauma patients. One study observed that 43% of trauma patients arriving at a hospital have core temperatures of less than 36 °C [12]. These data suggest a need for increased focus on thermoregulation of the combat casualty.

There are many implications of hypothermia in multisystem trauma patients. Because every body system is affected by hypothermia, there are strong relationships among sepsis, coagulopathy, acidosis, and multiorgan failure in these critically injured patients [12]. Hypothermia's relationship to coagulopathy and shock has been well documented [1, 2, 4-6, 12-19]. This "triad" is a significant contributing factor to the mortality of trauma patients and has been noted as a major reason for resistance to resuscitation after trauma [6, 8, 10, 16, 18]. This acquired coagulopathy, particularly in trauma patients who require massive transfusion, accounts for a large percentage of early trauma deaths among both civilians and military personnel [2, 3, 13].

1.3   Current Data from the Field

The triad of hypothermia, coagulopathy, and acidosis may be more difficult to reverse in a desert environment [6, 20]. In addition, a coagulopathy of trauma, perhaps arising from a separate mechanism, affects at least 1 in 4 seriously injured trauma patients; and etiologies include direct effects of hemorrhage and subsequent shock, hemodilution, hypothermia, and acidosis [16]. Data suggest a possible correlation with survival associated with hypothermia. For example, one study in particular showed that in normothermic patients, the survival rate was 97.5%, whereas in hypothermic patients it was 75% [7]. Another conclusion from the same study observed that 87.5% of patients who were hypothermic upon arrival needed surgery versus 64.5% of normothermic patients. Eastridge et al. showed a correlation between hypothermia and the need for massive transfusion in multiple trauma victims and asserted that blood transfusion requirements are directly proportional to core temperature [17]. Even mild hypothermia (34 to 36 °C) has multiple untoward physiologic effects; and studies demonstrated an increased incidence of post-operative wound infections, coagulopathy, myocardial ischemia, and a decrease in peripheral circulation (which may increase tissue hypoxia, thus making wounds more susceptible to infection) [1, 2, 21]. Arthurs et al. looked retrospectively at one year's worth of trauma patients presenting to their combat support hospital in Iraq and found data that associated temperatures of 33 °C or less with 100% mortality [11]. These data suggest that a critical temperature range for the multisystem trauma patient was 34 to 36 °C [11].

1.4   Importance to the Military

Combating hypothermia in the pre-hospital setting (U.S. Army levels I and II for the military) has plagued medical providers since the discovery of this metabolic derangement [22]. Hypothermia by itself presents treatment challenges. Combined with a shock state and hypovolemia, it can be a disastrous event that will worsen and quickly lead to decompensation in critically injured patients.

Since the U.S. Army developed the Tactical Combat Casualty Care (TCCC) model, casualty evacuation (CASEVAC) care has presented a challenge for providers to prevent hypothermia in trauma patients [11, 22]. TCCC advances have driven medical device markets to make products whose performances have not been

validated by independent studies. Medical providers in the field are thus forced to base their procurement decisions on either personal anecdotal experience or manufacturer claims of performance or simply to rely on old methods of passive prevention of heat loss.

1.5   Current Devices Commonly in Use

In the current conflict, many methods of both active and passive hypothermia prevention are employed. In the active group, the Hypothermia Prevention Management Kit (HPMK™) (Fig 1) is a small, lightweight device, which uses an active chemical heating element placed on the patient, and surrounded by an outer blanket. This active element, called the Ready Heat™ (Fig 1), is also available through military supply channels as a single item. These devices require no external power source, and are becoming widely used by our forces. Additionally, the Bair Hugger 505® forced warm air patient warming system (Fig 1) is available at most level II/role II facilities. This device is purpose built to prevent hypothermia in patients undergoing surgery, but must have a power supply to operate.

Original HPMK™

New HPMK™

Ready Heat™

Bair Hugger 505®

Figure 1: Pictures of the active heating products used in this study.

There are several passive methods available as well. The standard US Army wool blanket (Fig 2) is still in use today, and its design has changed little throughout history. More modern passive prevention methods such as the space blanket (Fig 2), and the Blizzard Blanket™ (Fig 2), which is a component of the HPMK™, represent more modern lightweight solutions to the problem of hypothermia prevention. Some passive methods have come into wide use through Soldier innovation, such as the human remains pouch (Fig 2). This device has been used alone, and in combination with the space blanket and wool blanket during the current conflict with great success, earning the nickname "Hot Pocket".

Wool Blanket

Space Blanket

Blizzard Blanket™

Human Remains Pouch

Figure 2: Pictures of the passive heating products used in this study.

Like the devices in the active group above, many devices used today to maintain patient temperatures utilize the application of heat directly to the patient's skin. These devices use either forced warmed air, warmed fluid or dry powder chemical reactants to provide the heat source. There have been anecdotal reports of patients sustaining thermal burns from some of these products during the current conflict. Regarding surface temperatures, research in this area done in the 1940's utilized an apparatus that passed warm fluid through a brass container in direct contact with both porcine tissue, and the tissue of human volunteers [23]. In their experiments, Moritz and Henriquez found that the lowest surface temperature responsible for cutaneous burning was 44˚C, and the time required to cause irreversible damage to epidermal cells at this temperature was approximately 6 hours [23].

They also found that the rate at which irreversible cellular injury was sustained increased rapidly as the surface temperature was raised, and for each degree rise in surface temperature between 44 and 51˚C, the time required to produce such injury was reduced by approximately one-half [23].

1.6   Study Purpose

Using laboratory testing, we rated the performance parameters of various hypothermia prevention methods currently available in the U.S. Army medical supply system for TCCC on a torso fluid model constructed from nine 5000-cc bags of warmed PrismaSate® (Gambro, Lakewood, CO) dialysate solution. We had three main research questions: 1) Are devices with active chemical or radiant forced air heating systems better than passive prevention of heat loss? 2) Do passive heat loss prevention systems prevent heat loss over 120 minutes that are comparable to systems with an actively heated component? 3) Do any of the devices with an actively heated component achieve temperatures known to cause burns on human skin? This study attempted to quantify the efficacy between the main hypothermia prevention kits available at the point of injury and role I and role II facilities and to establish a rank order of greatest to least in terms of loss of temperature, gain of temperature, or no change in our fluid model. The results of this study should also apply to treating hypothermia in the civilian community.

2.0   MATERIALS AND METHODS

This study was a prospective laboratory trial designed to evaluate current products used to prevent hypothermia. Our fluid model consisted of nine 5000-cc bags of PrismaSate® (Gambro, Lakewood, CO) dialysate solution used for continuous renal replacement therapy. This fluid was composed of 3.05 g magnesium hydrochloride, 5.4 g lactic acid, 7.08 g sodium chloride, 2.21 g sodium bicarbonate, and 0.314 g potassium chloride in a total volume of 5000 cc. These bags were configured to the size and weight of an adult human torso (approximately 60% of 70 kg, or 48.6 kg) and heated to 38.5 °C (Fig 3).

Figure 3: Arrangement of the PrismaSate® bags to develop the fluid model used in this study.

Our initial assumption was that there would be a very large, rapid drop in temperature in our untreated control model. However, after preliminary testing it was apparent that the model cooled slower than expected. A control model was heated to 37 °C and allowed to cool at ambient temperature to provide baseline negative

control values without hypothermia prevention. Average time for this model to cool from 37 to 34 °C was 2 hours, so this became our testing time.

Fluid models had one indwelling thermistor probe in a representative "core" bag, and surface temperature probes were attached dorsally and ventrally to track changes in temperature every 5 minutes for 2 hours.

We tested two broad groups of hypothermia prevention: active and passive. In the active group, we evaluated two Hypothermia Prevention Management Kits (HPMK™) (North American Rescue Products, Greer, SC)– the original and a newer version introduced during the course of our study. We also evaluated the Ready Heat™ (RH) blanket (TechTrade LLC, New York, NY) and the Bair Hugger® Model 505 (Arizant Inc., Eden Prairie, MN) forced air warmer (Fig 1). The HPMK™ consists of the RH™ blanket and either the Blizzard™ blanket or heat reflective shell (HRS™) described below. The Bair Hugger® is a forced air warming device consisting of a warming unit and telescoping hose that attaches to a reinforced paper blanket with cells that provide venting of the warmed air. The device requires electrical power and the high setting of the device is listed as 40 °C. These products are the standard active hypothermia prevention devices currently being used by the U.S. military and are listed in the Joint Theater Trauma System Clinical Practice Guidelines on Hypothermia Prevention, Monitoring, and Management (November 2008) for hypothermia prevention in trauma patients from the current war in Iraq. The NSN (national stock number) for each item available in the U.S. Army Inventory is listed in Table 1. We also evaluated surface temperatures in the active group to determine whether temperatures achieved might cause damage to human skin.

Table 1: Device Information.

Hypothermia Prevention Product			
Name	NSN*	Dimensions	Weight
Original HPMK	6515-01-532-8056	6.75" H x 10.5" W x 5.5" D	3 lbs 8 oz
New HPMK	6515-01-532-8056	6.75" H x 10.5" W x 5.5" D	3 lbs 8 oz
New Ready Heat	6532-01-525-4062	36" W x 48" L	2 lbs
Ready Heat	6532-01-525-4062	36" W x 48" L	2 lbs
Blizzard Blanket	6532-01-524-6932	20 x 11 x 4.5 cm.	1.16 lbs
Heat Reflective Shell	Pending	43" W x 78" L	
Human Remains Pouch	9930-01-331-6244	36" W x 96" L	14 oz
Space Blanket	7210-00-935-6666 or 7210-01-463-5431	56" W x 84" L	2 oz
Wool Blanket	7210-00-282-7950 or 7210-00-935-6665	62" W x 80" L	2.75 lbs
Bair Hugger	6530-01-463-6823	13" H x 10" W x 11" D	13.6 lbs

*NSN is the NATO (North Atlantic Treaty Organization) stock number assigned to products.

In the passive group (Fig 2), we compared the U.S. Army standard issue wool blanket, space blanket, Human Remains Pouch (HRP), Blizzard Blanket™ (Performance Systems Medical Division, Houston, TX), and Heat Reflective Shell (HRS™). The Blizzard™ and the HRS™ are components of the original and the new HPMK™, respectively. Since both are available as single units without the Ready Heat™, they were also evaluated alone. Additionally, the HRP, wool blanket, and space blanket were evaluated as a passive system in combination, known as the Hot Pocket. The space blanket, also known as the combat casualty care blanket has a reflective side. The blanket used in this study was a heavier plasticized tarpaulin version which has cross-hatched plastic thread reinforcements to confer strength. The Blizzard Blanket™ is a large reflective wrap designed to cover most adults completely and is made from a proprietary material called Reflexcell™. The HRP or body bag is the current device used in the military and is constructed of an outer plastic or canvas cover with a rubber leak proof inner core. The HRS™ is constructed from a polyolefin, 4-ply, composite fabric with a protected non-conductive thermal reflective layer that is waterproof and windproof. We compared products within their group and then in relation to an untreated control group, evaluating their abilities to prevent a core temperature drop in our model. Each device was tested five times. Table 1 shows the dimensions and weight of all products evaluated.

During preliminary test runs, we denoted exact times relevant to degradation of temperature upon removal of the fluid bags from the warming cabinet to account for initial radiant and convective heat losses prior to model setup. No test began until indwelling temperatures were at exactly 37° C. This study was conducted in an operating suite of the US Army Institute for Surgical Research (ISR), suitable to control ambient temperatures tightly. Internal room temperature was maintained between 22.3 and 22.7°C, and verified with both digital and mercury type thermometers placed throughout the room. Temperatures were checked every 15 minutes and never varied outside this range.

Bags were placed in the center of a calibrated warming cabinet, model 5618 (Getinge, Rochester, NY), and set to a temperature of 37.8 °C. This temperature setting actually achieved a core temperature closer to 38.5 °C consistently, so the experiment was started when the bags had cooled to 37 °C.

Two groups of 9 bags were heated simultaneously in the warming cabinet and randomly selected for each test to decrease variability. Only two tests were done per day on bags warmed continuously in the cabinet for 12 hours. The fluid bags were placed on a stainless steel operating table. The bags were then stacked in the configuration of a torso (Fig 3).

Temperature measurements of the dorsal surface, ventral surface, and core were obtained every 5 minutes during test runs with the Omega® HH 84 Thermo Collector. The manufacturer's specifications list variance as 0.1 °C for accuracy. The devices self-calibrate upon powering up and run self-diagnostic tests. If the probes are not functioning, the temperature will not be displayed; and a message reading "over" will be visible. Probes were replaced if temperature monitoring malfunctioned. Two Omega® hypodermic probes (model number HYP1-30-1/2T-G-60-SMP-WM) were used for each test for core measurements, and two probes (model number HYP2-21-1-1/2-T-G-48-OSTW-M) were used to monitor surface temperatures.

A mercury thermometer was then compared to ensure that all devices were within reasonable variance as listed by Omega. No variation was detected between probe readings, and minimal variation was detected between the digital and the mercury thermometers (0.1 to 0.2 °C).

The core probe was placed on a 6-inch rod and inserted by using a luer adapter to ensure that the probe was in the center of the representative core bag. Surface probes were placed directly underneath actively heated elements and not on air bubbles once the model was placed on the table.

Alternating ends of the table were used between runs to account for conduction of heat to the table, and table temperature was checked to ensure equilibrium with the room environment prior to each test. The table was turned during each consecutive trial so the head of the model was farthest away from the air flow of the air conditioning unit to control for convective forces.

2.1   Statistical Analysis

Data were compiled with the Thermocollector® program, which accompanied the Omega thermistor temperature collection devices. Our sample size calculation was originally based upon a non-matched, two-tailed comparison of average core temperature. We presumed an average end-state core temperature of 26.7˚C for the control, with a 0.5˚ C standard deviation among samples, and wished to detect a minimum statistically-significant difference of 1˚C between experimental groups.

We calculated that a sample size of 5 per group would detect significance at an alpha error level of 0.05 with a power of greater than 90%. From control testing we discovered an average core drop of 3°C in 2 hours time. Our post-test power analysis determined that 2 runs per device would have been sufficient to detect significance at the same alpha error. Although a temperature drop of 1˚C was of statistical significance based on our design, this test attempted to detect a more clinically significant drop in temperature from 37˚C to 34˚C as a measure of efficacy in hypothermia prevention.

Core temperatures were compared among all devices relative to the untreated controls. Surface temperatures were evaluated to determine whether devices with an actively heated component reached temperatures known to be capable of causing tissue damage in humans.

Data are presented as mean $\pm$ standard deviation (SD). A p value of <0.05 was considered statistically significant. Selection of times listed in table 2 reflect reference times for medical personnel treating casualties in the field. An evacuation time of 30 minutes might apply to some situations, whereas 120 minutes may be more realistic in others. For combined core temperature results, data were analyzed using repeated measures with two-way analysis of variance (ANOVA) with time and device as the variables. Tukey-Kramer adjustment was used for multiple comparisons at each time point. To determine whether there was a significant drop in temperature at the end of the experiment compared to baseline for each individual device, a one-way ANOVA with repeated measures was used.

3.0   RESULTS

3.1   Control

In the untreated control group, the average time for our model to cool from 37 °C to 34 °C in an ambient controlled room temperature of 22.3 to 22.7 °C was 2 hours (Fig. 4). In this group, the mean temperature was 36.2 °C at 30 minutes, 35.44 °C at 60 minutes, and 33.9 °C at 120 minutes.
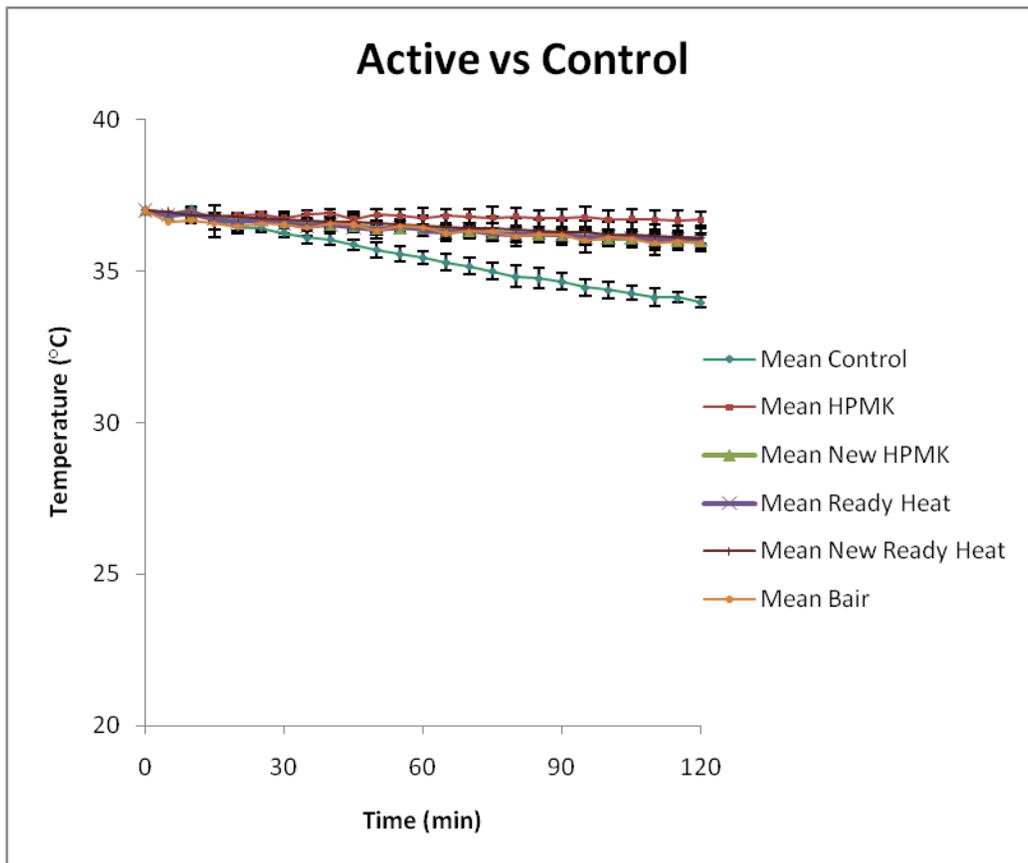
**Figure 4: Temperature maintenance of active heating products (HPMKs, Bair Hugger, and
Ready Heat) over the 2-hr period compared to untreated controls. The original HPMK
maintained the highest temperatures compared to the others. Data represent
the mean $\pm$ SD of five determinations for each product.**

3.2   Active Group

A comparison of the active hypothermia products versus the control group is shown in Figure 4. All active
warming devices maintained core temperatures in the fluid model significantly better than controls or the wool
blanket from 60 min or earlier (see below) to the end of the 120-min experimental period (Fig 4, Table 2).

**Table 2: Mean Core Temperatures of the Model at Times after Wrapping in Hypothermia Prevention Products
[Data represent the means$\pm$ SD of five determinations at each time point].**

Hypothermia Prevention Product	Mean Core Temperature, °C			
Name	At 30 Minutes	At 60 Minutes	At 90 Minutes	At 120 Minutes
Original HPMK	36.76 ± 0.11	36.76 ± 0.23	36.74 ± 0.33	36.7 ± 0.32
New Ready Heat	36.72 ± 0.22	36.5 ± 0.37	36.28 ± 0.38	36.08 ± 0.38
Ready Heat	36.56 ± 0.15	36.34 ± 0.17	36.18 ± 0.24	36.06 ± 0.29
New HPMK	36.6 ± 0.14	36.4 ± 0.14	36.18 ± 0.18	35.98 ± 0.23
Hot Pocket	36.66 ± 0.15	36.42 ± 0.13	36.18 ± 0.16	35.94 ± 0.15
Bair Hugger	36.54 ± 0.24	36.44 ± 0.25	36.18 ± 0.37	35.92 ± 0.37
Blizzard Blanket	36.48 ± 0.18	36.1 ± 0.12	35.86 ± 0.11	35.6 ± 0.10
Human Remains Pouch	36.14 ± 0.23	35.6 ± 0.26	35.08 ± 0.24	34.56 ± 0.09
Heat Reflective Shell	36.46 ± 0.11	36.02 ± 0.20	35.58 ± 0.26	35.16 ± 0.35
Space Blanket	36.34 ± 0.15	35.96 ± 0.31	35.58 ± 0.30	35.12 ± 0.18
Wool Blanket	35.9 ± 0.1	35.26 ± 0.09	34.86 ± 0.17	34.44 ± 0.15

3.2.1   Hypothermia Prevention Management Kit™ (HPMK™)

Once the fluid model was constructed and core temperature of 37 °C was assured, the kit was wrapped in sequence, Ready Heat™ heating blanket over the dorsal surface, reflective shell over heating blanket, and sealed according to its recommended use. Recording began at a core temperature of 37 °C. Mean core temperature was 36.76 °C at 30 and 60 minutes, and fell only to 36.70 °C at 120 minutes (Fig 4). The HPMK™ maintained temperature better than controls or the wool blanket from 20 through 120 min (Fig 4). In addition at 120 min, the HPMK™ maintained a significantly higher core temperature than all other devices evaluated.

During the course of our study, a new version of the HPMK™ was introduced; so we included that kit in our evaluation, as well as comparisons between the two Ready Heat blankets and two outer shells (see below). Mean core temperature in the new HPMK™ at 30 minutes was 36.6 °C, falling only to 35.98 °C at 120 minutes (Fig 4, Table 2). This newer HPMK™ was better than controls in maintaining temperature from 35 to 120 minutes of the experimental period. The average core temperature maintained by the new HPMK™ was

significantly less, statistically, than the original HPMK™, only at 120 min (Fig 5). However, differences in the actual temperature maintained between the two kits did not achieve our definition of a clinically significant 3° C drop in temperature.
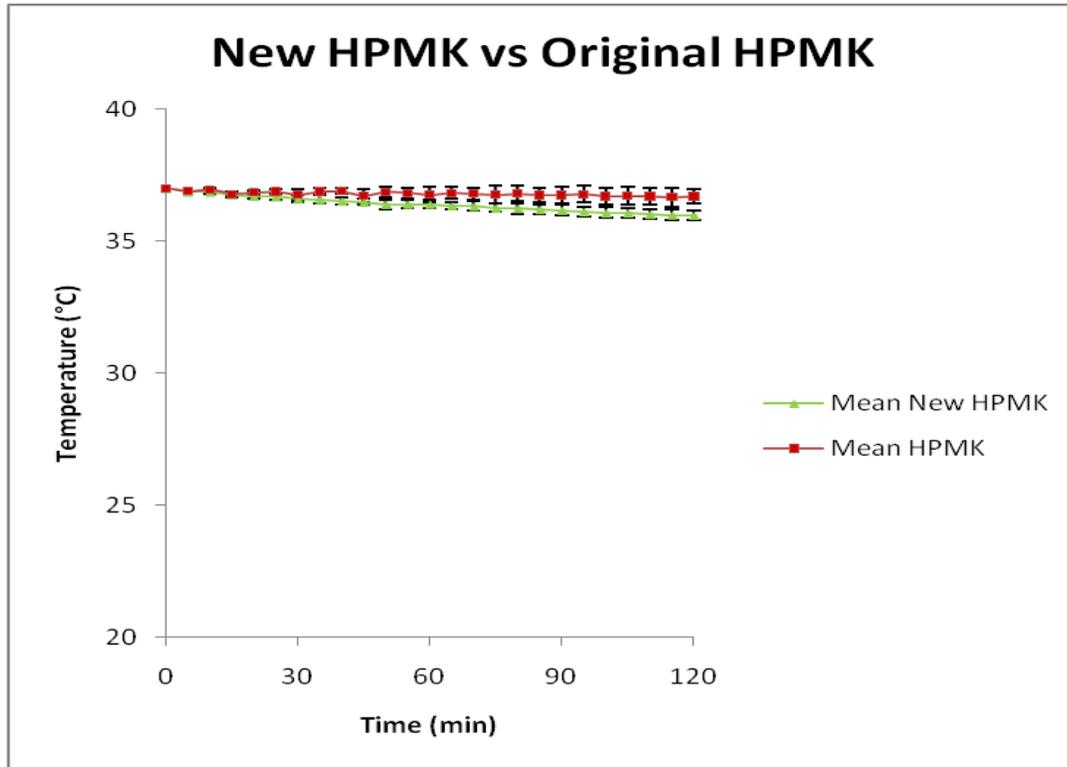

Figure 5: Temperature maintenance in the model of the two HPMK versions examined. Significant differences in the rate of heat loss in the model between the two products was only observed at 120 min. Data represent the mean $\pm$ SD of five determinations for each product.

3.2.2   Bair Hugger® (Model 505) Patient Warming Device

The fluid model was placed on the table, allowed to cool to 37 °C, and then covered with the full-body blanket component of the Bair Hugger®. The device was set on high for the duration of the test. Average mean core temperature at 30 minutes was 36.54 °C and dropped to 35.92 °C at 120 minutes (Fig 4, Table 2).

3.2.3   Ready Heat™ Heated Medical Disposable Blanket

The Ready Heat™ blanket was opened, and 30 minutes was chosen as the time within the manufacturer's instructions to allow the device to heat properly. The model was covered as one would cover a patient in the supine position. A standard Soffe (Fayetteville, NC) tan U.S. Army issue T-shirt was placed on the fluid model between the heating elements and the device as per manufacturer's guidance and in accordance with what would be readily available to a provider placing this device on a combat casualty. Mean core temperature was 36.56 °C at 30 minutes, 36.34 °C at 60 minutes, and 36.06 °C at 120 minutes (Fig 4, Table 2). The Ready Heat™ maintained temperature better than controls or the wool blanket from 35 minutes to the end of the experiment.

On initial observation, the new Ready Heat™ seemed to perform differently than the original. The standard deviation observed in the temperature measurements was less compared to that of the original device, suggesting more uniform warming. Thus, the new Ready Heat™ was better than controls or the wool blanket as early as 20 min after the start of the experiment and remained so throughout the rest of the experimental period (Fig 4, Table 2). Mean core temperature observed was 36.72 °C at 30 minutes, 36.5 °C at 60 minutes, and 36.08 °C at 120 minutes (Figs 4 and 6 and Table 2). As shown in Figure 6, there were no statistical or clinically significant differences between the two Ready Heat products.
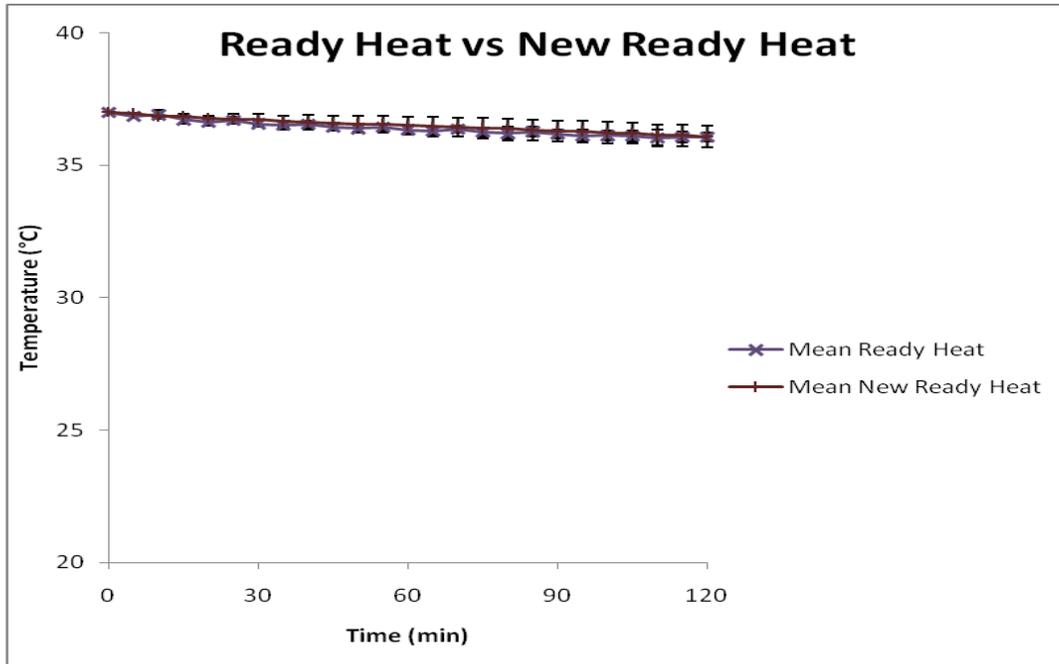

Figure 6: Temperature maintenance between the Ready Heat blankets in the original and the new HPMK. There was no statistical difference in the rate of heat loss in the model between the two products. Data represent the mean ± SD of five determinations for each product.

3.3   Passive Group

A comparison of the passive devices evaluated to the control group is illustrated in Figure 7. All devices other than the wool blanket and the human remains pouch (HRP) maintained core temperature better than controls from 60 min or earlier (see below) to the end of the experiment (Fig 7, Table 2).
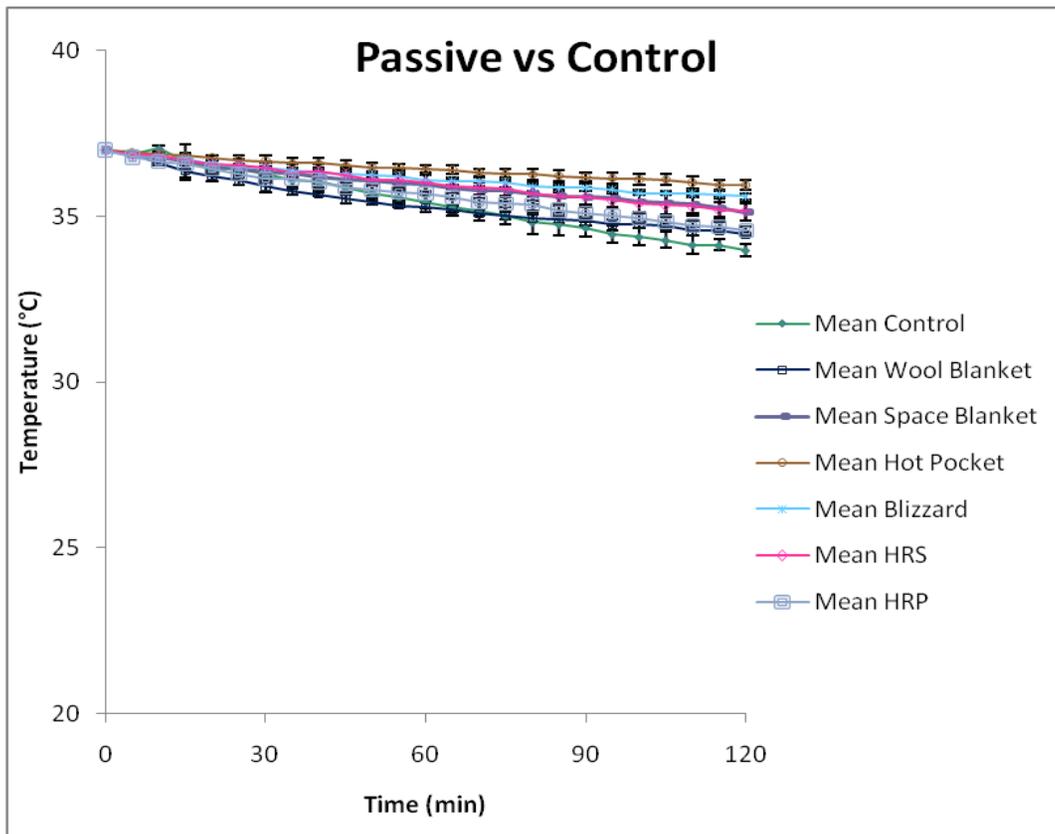
**Figure 7: Temperature maintenance of passive warming products (wool blanket, space blanket,
Human Remains Pouch, Hot Pocket, Heat Reflective Shell, and Blizzard) over the 2-hr period
compared to untreated controls. The Hot Pocket maintained the highest temperatures
compared to the others, and the wool blanket was not better than the untreated
controls. Data represent the mean $\pm$ SD of five determinations for each product.**

3.3.1   Wool Blanket

For its ubiquitous presence, this product was also the poorest performer, with a temperature drop similar to that of the control group (Fig 7). Mean core temperature was 35.9 °C at 30 minutes, 35.26 °C at 60 minutes, and 34.44 °C at 120 minutes (Table 2). Given this poor performance, one must wonder about its utility given the advanced technologies available today.

3.3.2   Blizzard Blanket

This product performed well by itself, even matching the performance of the Bair Hugger® as well as the Ready Heat™ over the first hour. Mean core temperature was 36.48 °C at 30 minutes, 36.10 °C at 60 minutes, and 35.6 °C at 120 minutes (Fig 7, Table 2). The Blizzard™ blanket maintained temperature better than the wool blanket as early as 15 min after the start of the experiment and maintained statistically higher temperatures for the remaining time (Fig 7, Table 2). In addition, at the end of the study, the core temperature maintained by the Blizzard™ Blanket was not significantly different from that maintained by the active warming devices, new or original Ready Heat™ or the new HPMK™.

3.3.3   Blanket, Combat Casualty, Type II (Space Blanket)

This blanket was placed over the fluid model and tucked in both sides for each test. Mean core temperature was 36.34 °C at 30 minutes, falling to 35.12 °C at 120 minutes (Fig 7, Table 2). The Space Blanket also outperformed the wool blanket from 30 min until the end of the experiment (Fig 7, Table 2).

3.3.4   Human Remains Pouch (HRP)

The HRP was wrapped over the fluid model in the manner it has been used to prevent hypothermia. The mean core temperature was 36.14 °C at 30 minutes and fell to 34.56 °C at 120 minutes (Fig 7, Table 2). The HRP did not maintain core temperatures significantly better than controls or the wool blanket in this study.

3.3.5   Hot Pocket (Combination of Two Wool Blankets, One Space Blanket, Inside Human Remains Pouch)

Our model was placed in the above listed configuration with wool blankets closest to the fluid bags, then space blanket, then HRP. The mean core temperature was 36.66 °C at 30 minutes, 36.42 °C at 60 minutes, and 35.94 °C at 120 minutes (Fig 7, Table 2). The Hot Pocket was very effective and maintained core temperatures better than controls, the wool blanket, or HRP as early as 15 min after the start of the experiment and maintained this advantage for the remaining time (Fig 7, Table 2). Also, at the end of the experiment, the Hot Pocket maintained core temperature of the fluid model as well as all active warming devices except for the original HPMK™.

3.3.6   Heat Reflective Shell (HRS™)

This blanket was the passive warming component in the newer version of the HPMK™ we evaluated. Mean core temperature was 36.46 °C at 30 minutes, 36.02 °C at 60 minutes, and 35.16 °C at 120 minutes (Fig 7, Table 2). The HRS™ maintained temperature better than the wool blanket from 15 to 120 min of the experimental period (Fig 7, Table 2). As we compared the original to the new HPMK™, we also evaluated any differences between its passive components. There were no statistically significant differences between the Blizzard™ and the HRS™ (Fig 8).
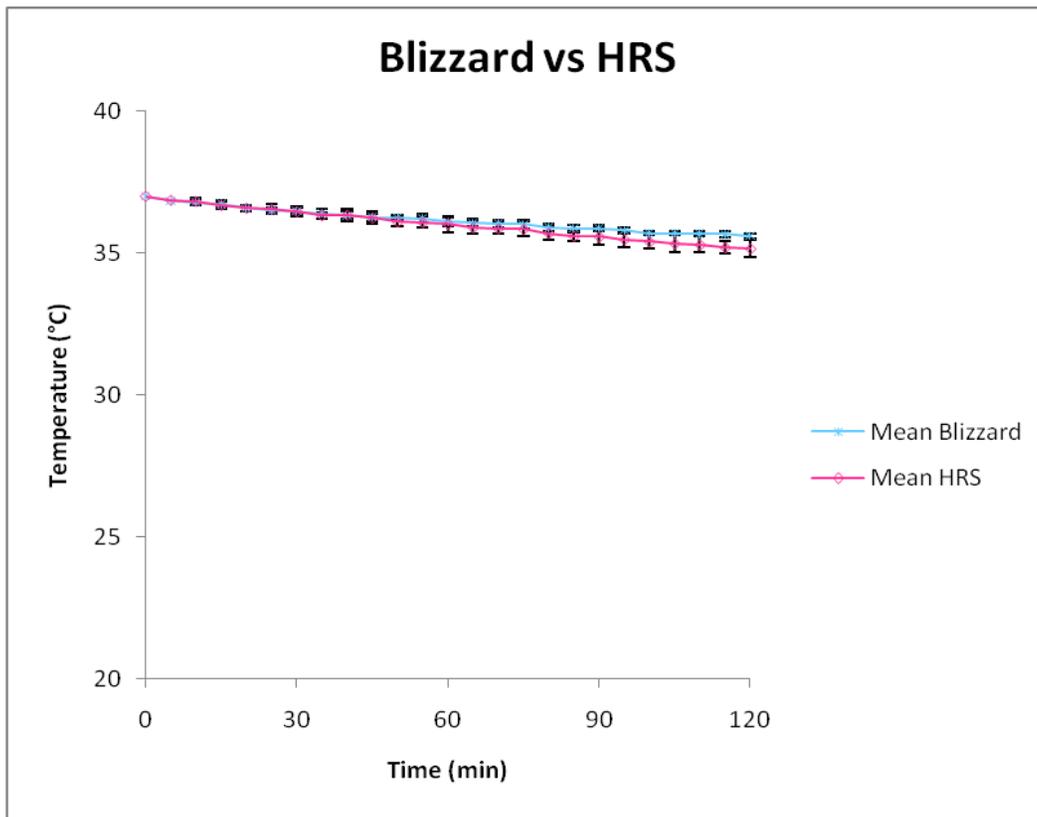
**Figure 8: Temperature maintenance in the Blizzard blanket versus the Heat Reflective Shell in the
original and the new HPMKs, respectively, over the 2-hr period. Although there was some
divergence of the temperature maintenance curve at 60 min between the two products,
the rate of heat loss from the model was not significantly different in the two groups.
Data represent the mean + SD of five determinations for each product.**

3.4   Surface Temperature Evaluation

Surface temperatures were evaluated in products with an actively heated element (HPMK™, Ready Heat™, Bair Hugger® 505). Our interest was specifically in temperatures known to be dangerous to human skin through prolonged exposure. Maximum mean surface temperatures achieved for the original HPMK™ system was 41.68 °C at 90 minutes. Maximum mean surface temperature achieved for the original Ready Heat™ blanket alone was 40.24 °C at 5 minutes. Maximum mean surface temperature achieved for the Bair Hugger® 505 was 35.56 °C at 5 minutes.

4.0   DISCUSSION

At the point of injury, combat casualties or trauma patients suffering from acute blood loss are physiologically more susceptible to hypothermia, even in the hot desert environments our forces find themselves in during the current conflict [3, 10, 19]. Providers at the point of injury must actively prevent hypothermia or keep it from worsening in acutely traumatized patients [21].

Vital signs become misleading, and injuries may be masked by hypothermia [2]. Pulse oximetry is not accurate in the face of hypothermia due to decreased perfusion in peripheral limbs [2]. Many traumatic mechanisms will impair thermoregulation in patients at the point of injury such as spinal cord injury, trauma to the central nervous system, burns, multisystem trauma, and shock [2, 10].

Iatrogenic factors such as exposure of body surfaces for inspection of wounds; lack of body movement for thermogeneration; and radiant, conductive, and convective heat loss mechanisms make this subset of patients, once injured, particularly susceptible to the induction or worsening of hypothermia and worsening shock [3, 10, 15, 24-26].

Massive volume resuscitation with room temperature crystalloid fluids further exacerbates this hypothermia and induces hemodilution, which further affects coagulation [4, 10]. Blood loss with massive traumatic injury, coupled with shock, and acidosis from traumatic wounds, hypoxia, and physiologic derangement may both initiate and/or potentiate hypothermia. Space blankets, which are in common supply across the battlefield and in prehospital civilian settings, have been shown to reduce heat loss by only 30% [1].

In the present study, all products tested prevented the full 3°C drop we predetermined to be clinically significant based on the literature. Even the poorest performer (wool blanket) ended at a mean temperature of 34.44 °C at 120 minutes. Some products, however, maintained higher temperatures. The question of product efficacy, then, hinges on individual casualty circumstances. If a patient is injured in a wilderness setting, such as an engagement in the mountains of Afghanistan during the winter months and a first responder cannot make it to the casualty in a timely manner, the patient is susceptible to developing hypothermia over the course of the combat action. If this patient's starting temperature at the beginning of resuscitation is at 33.5 °C, then only 0.5 °C becomes vitally important, since the current data portends for poor outcomes below 33 °C. So in this case, a device that allows for little heat loss would be critical, and use of a device such as the wool blanket would be inadequate.

The original HPMK™ maintained the highest temperatures compared to all other methods (p<0.05) with the narrowest margin of heat loss, while the newer HPMK™ achieved similar temperatures, until 120 min compared to the original HPMK™ we evaluated. In addition, comparisons between the Ready Heat™ blankets in the original and new HPMK™ systems, as well as comparisons between the Blizzard™ and the HRS™ blankets, indicated that they performed similarly to each other in maintaining temperature over the 2-hour experimental period. Since the completion of our study, a new water-resistant shell was introduced into the HPMK™ which may offer better performance than the HRS™ we evaluated when used with the Ready Heat™ blanket as part of the HPMK™. Preliminary data indicate that the RH™ blanket will not generate heat well if it becomes wet before activating (data not shown). Thus, a new water-resistant shell should improve the overall performance of the HPMK™, but it should be noted that this new shell or the newest system was not evaluated in the current study.

For up to 1 hour, the rate of temperature loss between the original and the new outer blanket appeared identical. After 1 hour, there was some divergence suggesting that the Blizzard™ blanket may perform slightly better; but results were not statistically significant. One problem commonly noted with the Blizzard™ is that once the casualty or trauma patient is wrapped in it, you must open the blanket completely to re-examine the patient, reinforce dressings, or provide treatments. Also there are no access points to run intravenous lines, or tubes outside of the device. It took an average of 3 minutes to open the Blizzard™ blanket completely and to set it up for the fluid model under our experimental conditions. Despite its drawbacks, it was one of the top-performing products in our testing. The reflective skull cap provided with the

original HPMK™ system was not evaluated as a part of testing in our fluid model but is designed to prevent heat loss in the trauma patient from that area.

There were no significant differences in the rate of loss of core temperature between the Ready Heat blankets in the original and new HPMK™ evaluated. However, the new Ready Heat™ did not perform exactly like the original. Preparation time for the heating element to begin its chemical reaction is required with the Ready Heat™. This time needs to be considered when using these devices on patients in the field. The Ready Heat™ uses a metalloid exothermic reaction as the source of heat generation; and as a result, if particles are not agitated prior to placement and/or as particles become static, the heat generation properties are affected. Thus, in training of first responders, recommending agitating the blanket periodically during the pre-warming period to maximize mixing of the components for even heat generation would be beneficial. The individual unit's standard operating procedures and immediate action drills should include this time for preparing and agitating the heating element for this system at the first notification or realization of significant trauma-related casualties who will need to be evacuated for further care. For testing purposes, 30 minutes was chosen as the time for maximal heat generation in the current study.

Regarding surface temperature among all the devices evaluated, none of them achieved the threshold temperatures considered to cause thermal injury [26]. Several anecdotal reports of thermal burns from the original HPMK™ have circulated. It is possible that compression of these devices might increase heat transfer, and some anecdotal reports related to thermal injury with the original HPMK™ refer to objects directly on the heating element which may have increased pressure over the patient's skin. Further study is needed to determine whether environmental or patient factors are responsible, seems warranted.

4.1   Limitations

Because this fluid model did not consist of a biological organism and had no basal metabolic activity, extrapolation to efficacy in humans may be limited. This study looked at a very narrow focus of parameters with reference to surface heat and reduced rate of heat loss as measures of performance, and any data derived which are known to harm humans (e.g., absolute surface temperatures which would cause injury to tissue) were noted. Despite these limitations, the fluid model was effective in detecting drops in temperature among the different devices. Therefore, we believe our model would be useful to screen potential new products or combinations claimed to prevent hypothermia. Since we only studied these products at one environmental temperature, it is also unknown whether cooler ambient room temperatures would have produced different results. In the passive group, almost any single coverage device can be used by Soldiers or first responders in the field, but we purposely limited our evaluation to devices available within the medical supply system that are purpose built for casualties.

5.0   CONCLUSIONS

From this testing, we cannot definitively conclude that all active methods are better than passive methods, nor can we rank their performance as originally intended. Given the poor performance of the wool blanket when used alone over the course of this study, one must wonder about its utility given the advanced technologies available today. Traditional single coverage passive products like the wool blanket and the space blanket may be adequate for 30 minutes; but if evacuation times exceed 30 minutes, the HPMK™, Ready Heat™, or Bair Hugger 505® may be a better choice. The observations that chemically heated devices performed as well or better than the Bair Hugger® that requires electrical power, and that some passive prevention products (Blizzard™, Hot Pocket) performed as well as the Bair Hugger® system and the Ready Heat™, is useful information for first responders who may need to keep casualties warm in the field or during evacuation;

situations where power is unavailable. Also, we did not detect surface temperatures produced by the active warming devices that would indicate they would burn human skin.

The original HPMK™ maintained the highest temperatures to the starting 37 °C compared to the other methods tested in preventing heat loss from this fluid model. This exact product is no longer available. However, the newer HPMK™ performed similarly to the original, and the slight difference may be an issue only in evacuation times exceeding several hours. However, a further refinement in the HPMK™ has been made to improve the product, which should continue to make it a valuable option for reducing heat loss.

Trauma patients undergoing longer evacuation and transport should have an active warming method (HPMK™, Bair Hugger®, Ready Heat™), a Blizzard™ blanket, or the Hot Pocket applied for thermoregulation. The data suggested that traditional single-coverage devices such as space blanket and wool blanket would be inadequate for preventing significant heat loss over long periods, but these methods may still be effective for very short evacuation times.

This study should be repeated in a biological model to validate these results. Additional investigation is also needed to determine whether devices with an actively heated component cause thermal burns in patients. Taken together, this study will serve as a guide to providers for selecting a hypothermia prevention system. Although the study was designed for evaluating products available in the US Army supply system, the results should be applicable to all first responders, whether military or civilian, who are concerned with preventing further heat loss in trauma patients.

5.1 Acknowledgments

6.0 REFERENCES

[1] Taguchi A, Kurz A. Thermal management of the patient: where does the patient lose or gain temperature. *Current Opinion in Anaesthesiology*. 2005; 18:632-639.

[2] Danzl D. Hypothermia. *Semin Respir Crit Care Med*. 2002 Feb; 23(1):57-68.

[3] Derr Robert D. Hypothermia, Threat to Military Operations. *Mil Med*. 1991 Mar; 156, 3:140.

[4] Farkash U, Lynn M, Scope A, et al. Does pre-hospital fluid administration impact core body temperature and coagulation functions in combat casualties? *Injury*. 2002 Mar; 33(2):103-110.

[5] Carr ME Jr. Monitoring of hemostasis in combat trauma patients. *Mil Med*. 2004 Dec; 169(12 Suppl):11-15, 4. Review.

[6] Holcomb J. The 2004 Fitts lecture: Current perspective on Combat Casualty Care. *J Trauma*. 2005; 59:990-1002.

[7] Eastridge BJ, Owsley J, Sebesta J, et al. Admission physiology criteria after injury on the battlefield predict medical resource utilization and patient mortality. *J Trauma.* 2006 Oct; 61 (4):820-823.

[8] Eiseman B, Moore EE, Meldrum DR, et al. Feasibility of damage control surgery in the management of military combat casualties. <u>Arch Surg.</u> 2000 Nov; 135(11):1323-1327.

[9] Aragon D. Temperature management in trauma patients across the continuum of care: the TEMP Group. Temperature Evaluation and Management Project. <u>AACN Clin Issues.</u> 1999 Feb; 10(1):113-123.

[10] McDonald V, Ryland K, Coagulopathy in trauma: optimizing haematological status. *Trauma.* 2008; 10:109-123.

[11] Arthurs Z, Cuadrado D, Beekley A, et al. The impact of hypothermia on trauma care at the 31st combat support hospital. Am J Surg. 2006 May; 191(5):610-614.

[12] McArthur BJ. Damage control surgery for the patient who has experienced multiple traumatic injuries. *AORN J.* 2006 Dec; 84(6):992-1000; quiz 1001-1002. Review.

[13] Brohi K, Cohen MJ, Davenport RA. Acute coagulopathy of trauma: mechanism, identification and effect. *Curr Opin Crit Care.* 2007; 13 (6): 680-5.

[14] Hammond, KL, Margolin DA. Surgical Hemorrhage, Damage Control, and the Abdominal Compartment Syndrome. *Clin Colon Rectal Surg*. 2006; 19:188-194.

[15] Insler SR, Sessler, DI. Perioperative thermoregulation and temperature monitoring. *Anesthesiol Clin*., 2006 Dec; 24 (4): 823-837.

[16] Kauvar DS, Lefering R, Wade CE. Impact of hemorrhage on trauma outcome: an overview of epidemiology, clinical presentations, and therapeutic considerations. *Trauma*. 2006 June;60(6 Suppl):S3-11.

[17] Eastridge BJ, Malone D, Holcomb JB. Early predictors of transfusion and mortality after injury: a review of the data-based literature. *J Trauma.* 2006 June; 60(6 Suppl):S20-25. Review.

[18] Kauvar DS, Holcomb JB, Norris GC, et al. Fresh whole blood transfusion: a controversial military practice. *JTrauma.* 2006 July; 61(1):181-184.

[19] Marshall TJ Jr. Combat casualty care: the Alpha Surgical Company experience during Operation Iraqi Freedom. *Mil Med.* 2005 June; 170(6):469-472.

[20] Gamble WB. Recent advances made in wartime medical care. *J Craniofac Surg.* 2006 Nov; 17(6):1033-1034.

[21] Knappe T, Mittlmeier T, Eipel C., et al. Effect of systemic hypothermia on local soft tissue trauma-induced microcirculatory and cellular dysfunction in mice. *Crit Care Med*. 2005, Aug; 33(8):1879-1881.

[22] Beekley AC, Watts DM. Combat trauma experience with the United States Army 102nd Forward Surgical Team in Afghanistan. *Am J Surg.* 2004 May; 187(5):652-654.

[23] Moritz A, Henriques F. Studies of thermal injury II. The relative importance of time and surface temperature in the causation of cutaneous burns. *Am J Pathol.* 23:695, 1947.

[24] Beekley AC, Starnes BW, Sebesta JA. Lessons learned from modern military surgery. *Surg Clin North Am.* 2007 Feb; 87(1):157-184,vii. Review.

[25] Aragon D. Temperature management in trauma patients across the continuum of care: the TEMP Group. Temperature Evaluation and Management Project. *AACN Clin Issues.* 1999 Feb; 10(1):113-123. Review.

[26] Shafi S, Elliott AC, Gentilello L. Is hypothermia simply a marker of shock and injury severity or an independent risk factor for mortality in trauma patients? Analysis of a large national trauma registry. *J Trauma.* 2005 Nov; 59(5):1081-1085.