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TITLE:	Effects of Burn Injuries on Thermoregulatory and Cardiovascular Responses in Soldiers:Implications for the Standards of Medical Fitness
PRINCIPAL INVESTIGATOR:	Craig G. Crandall, Ph.D.
CONTRACTING ORGANIZATION:	University of Texas Southwestern Medical Center Dallas, TX 75390-7208
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U.S. Army Medical Research and Materiel Command
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The aim of this study was to investigate whether the absolute effective body surface area (BSA) or the %BSA burned best predicts the core temperature response to exercise in the heat. Sixteen healthy non-burned individuals [8 large (LG) and 8 small (SM)] were recruited. On separate occasions, subjects cycled at ~100 W for 1 h in a 39°C, 20% relative humidity environment with a simulated burn injury of 0% or 40% total BSA. A simulated 40% burn injury reduced the effective BSA to 1.35±0.05 m_2 and 1.01±0.07 m_2 in LG and SM groups, respectively. Greater elevations in core temperature were observed in SM, irrespective of condition. For both groups, the elevation in core temperature was exacerbated by the 40% simulated burn ($P<0.01$), yet the magnitude of the increase in core temperature from 0% to 40% simulated burn was not different between groups ($P=0.37$). Despite the same 40%BSA burned, smaller individuals showed an ~0.75 °C greater elevation in core temperature during exercise. In exercise-based rehabilitation or physically demanding occupational settings, activities performed at the same absolute intensity will place burn survivors of smaller body size, but with the same %BSA burned, at greater risk for hyperthermia.

15. SUBJECT TERMS

Army's Standards of Medical Fitness; burn injury; thermoregulation; sweating; heat dissipation; environmental temperature; body surface area burned; donor site

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1. INTRODUCTION

The U.S. Army's Standards of Medical Fitness pertaining to a prior burn injury is based upon the findings of only three studies, from a total of 9 subjects with burns of >40% body surface area (BSA; N=4, 3, and 2), and report contradictory findings. Equally low number of subjects were assessed in individuals with <40% BSA burned in those studies. Notably, we know nothing about the interactive effects of differing workload requirements (e.g., metabolic heat generation associated with military service) and the environmental conditions soldiers often operate in on the safety and well-being of a soldier with a prior burn injury. Further, we know nothing about the effects of differing body sizes, location of burn injury, and/or how a soldier's uniform/body armor may affect thermoregulatory and cardiovascular responses during military operations of a soldier with a burn injury. Clearly, there is insufficient information to make conclusions regarding the potential detrimental effects of a prior burn injury at the level necessary to include such recommendations in the Standards of Medical Fitness. The proposed work will provide clear and scientifically-supported guidelines that will culminate in recommendations for a revision of the US Army's Standards of Medical Fitness for burn injuries to more accurately predict the consequences of the injury on the safety and wellbeing of the burned soldier. This information will also have direct impact on the accession/retention of the burned soldier, potentially allowing highly trained, but burned, soldiers to remain in service and thereby realizing cost savings to the Army that would otherwise be spent on training replacements. Finally, the obtained information will benefit the civilian burn community, and those who treat such individuals, through specific recommendations that are dictated in part by the activity level and/or environmental conditions such individuals participate in, with a goal of mitigating the risk of heat-related injuries in this population.

2. KEYWORDS

Army's Standards of Medical Fitness; burn injury; soldier; thermoregulation; sweating; heat dissipation; exercise; metabolic heat generation; environmental climate; temperature; humidity; body surface area burned; donor site; fitness.

3. ACCOMPLISHMENTS

What were the major goals of the project: For year 3 of this project (October 1, 2017 – September 30, 2018) the Statement of Work indicates that (i) we will complete data collection for protocol 2A and will reduce these data such that the results could be disseminated to the scientific community via national meetings and publications, (ii) we will initiate data collection for protocol 2B and 2D, while continuing to collect data for protocol 2C, and (iii) we will obtain IRB and HRPO approvals for protocols in Aim 3. Protocol 2A evaluates the effect of ambient temperature on individuals exercising in thermoneutral and hyperthermic environments, with simulated burns covering 0, 20%, 40%, and 60% of their body surface area. Protocol 2B evaluates the effect of exercise intensity on individuals exercising in hyperthermic environments, simulated burns covering 0, 20%, 40%, and 60% of their body surface area. We would like to note that to complete the battery of tests required for Protocols 2A and 2B, each subject visits the laboratory on 9 occasions. Protocol 2C assesses the relationship between one's maximal evaporative capacity and body surface area burned. For this protocol, subjects exercise at a fixed workload, having simulated burns covering 0, 20%, 40%, and 60% of their body surface area, which is

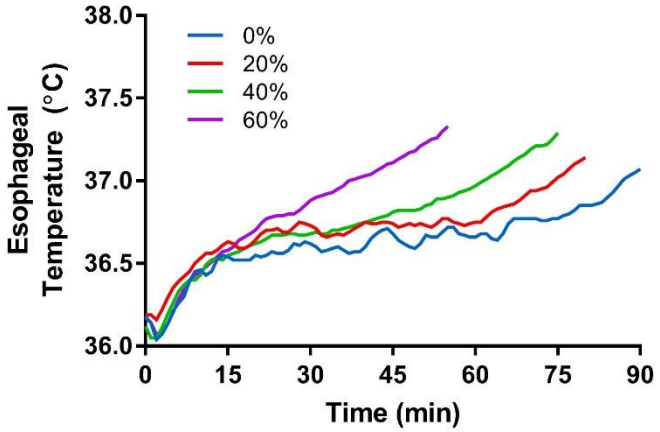
followed by escalating humidity to identify the relative humidity at which core temperature inflection point occurs. To complete this protocol, subjects visit the laboratory on 5 occasions. Protocol 2D evaluates the effects of the size of the burn injury on an individual's maximum ability to dissipate heat from burned individuals, and requires 4 visits to the laboratory.

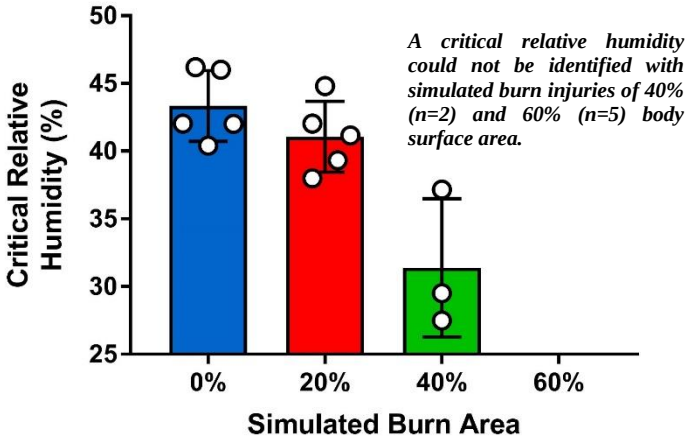
What was accomplished under these goals?:
We continue to collect data for Aim 1B (assessment of the impact of large/small body size on thermoregulatory responses in actual burn victims with an injury spanning 40% of total body surface area).

We are pleased to say that we have nearly completed Aims 2A and 2C. We are in the midst of collecting data on the final subject for each protocol, so we anticipate that data collection for these Aims will be complete in the next quarter. Preliminary data from Aim 2C was presented at the annual Experimental Biology meeting. Below is the submitted abstract of that work as well as the primary findings. These data confirm that individuals with 20% and 40% body surface area burn working at a moderate exercise intensity (5 W/kg) are able to regulate core body temperature at a similar level as that observed in non-burned while exposed to both thermoneutral and hyperthermic environmental conditions. However, individuals with a 60% body surface area burn are at a greater risk for a hyperthermic injury when performing moderate exercise in the heat, but not in thermoneutral conditions.

ABSTRACT TITLE: **Critical Environmental Limits for Prolonged Work in the Heat Using a Simulated Burn Injury Model**
Following a deep burn injury, excision of devitalized skin and subsequent grafting impair sweat production within grafted sites. Since the capacity for whole-body evaporative heat dissipation is dependent on sweat production and the total non-injured skin area available for heat dissipation, burn injuries likely reduce the capacity for whole-body heat dissipation in proportion to the size of the burn injury during heat stress. To test this possibility, four healthy subjects (1 female; 28 ± 7 years, 71.1 ± 9.0 kg, 1.87 ± 0.12 m^2) visited the laboratory on separate days to complete an incremental humidity protocol while cycling at a fixed metabolic heat production (5 W/kg, equivalent to ~35% maximum oxygen uptake) in 40°C with and without simulated burn injuries of 20%, 40%, or 60% of total body surface area. During each trial, exercise was performed at an initial relative humidity (RH) of 25% for 30 min to achieve thermal equilibrium, after which exercise continued as RH was increased by 3% every 5 min up to 90 min. A 'critical' RH was identified as the RH value above which a steady-state esophageal temperature could no longer be maintained, thus providing an indication of maximum evaporative heat dissipation. Burn injuries were simulated by covering skin on the torso, arms, and legs with highly absorbent, vapor-impermeable material that prevents sweat evaporation. The results show that the average critical RH declined with the size of the simulated burn injury up to 40% (0%: 44.1 ± 2.4%; 20%: 41.8 ± 2.3%; 40%: 31.4 ± 5.1%), with significant reductions in the critical RH at 40% vs. 0% and 20% simulated burn injuries (P=0.009). However, a critical RH value could not be discerned in one subject with a 40% simulated burn injury or in any subject with a 60% simulated burn injury, indicating physiologically uncompensable conditions throughout the experimental protocol. These preliminary data suggest that under the current

environmental conditions, burn survivors with injuries of ≥40% have a substantially attenuated capacity for heat dissipation, placing them at greater risk of heat-related illness during prolonged work and heat stress. Such information may be incorporated into exposure guidelines for burn survivors working under severe occupational heat stress such as military personnel.





Data collection for Aim 2D is ongoing. This protocol compares thermoregulatory responses to exercise in hyperthermia conditions between groups of burn survivors with burn injuries spanning 20%, 40%, or 60% of total body surface area. Data collection for the 20% group is complete, and are halfway through data collection for the 40% and 60% groups. Preliminary data from this protocol were recently presented at the Physiology and Pharmacology of Temperature Regulation meeting. Below is the submitted abstract of that work.

ABSTRACT TITLE: **Thermoregulation in severely burned individuals**
Surgical treatment of deep burn injuries involves the excision of devitalized tissue from the wound followed by transplantation of a skin graft from a donor site onto the excised area. Together, these procedures disrupt the cutaneous vasculature, sweat glands, and associated neural connections within the grafted area, resulting in suppressed or severely attenuated elevations in skin blood low and sweating in grafted skin, a reduced capacity for whole-body heat dissipation, and an exacerbated rise in core temperature during a

thermoregulatory challenge. While extensive skin grafting may predispose burn survivors to heat illnesses, the risk will be dependent on a variety of physical and physiological factors affecting human heat exchange. This presentation will cover recent research into the thermoregulatory consequences of burn injuries during prolonged physical activity, with emphasis on: (i) heat loss responses in grafted vs. donor sites, and (ii) the effects of various physical factors (work intensity, body size, environment) on core temperature regulation. Presentation attendees will gain a greater understanding of the extent to which thermoregulatory function is impaired in burn survivors, and the implications for heat illness risk in occupational settings.

IRB and HRPO approvals have been obtained for Aims 3A and 3B.

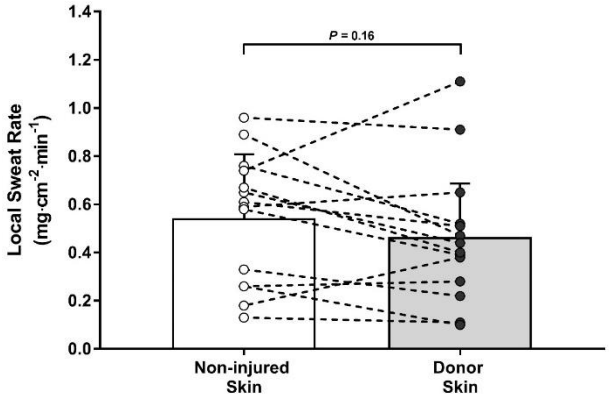
Data collection for Aim 4 has concluded. These data were presented at the American College of Sports Medicine annual meeting. Below is the abstract of that work, as well as the preliminary findings. These data confirm that donor sites do not exhibit any thermoregulatory dysfunction compared to non-injured, healthy skin sites in burn survivors during exercise-heat stress.

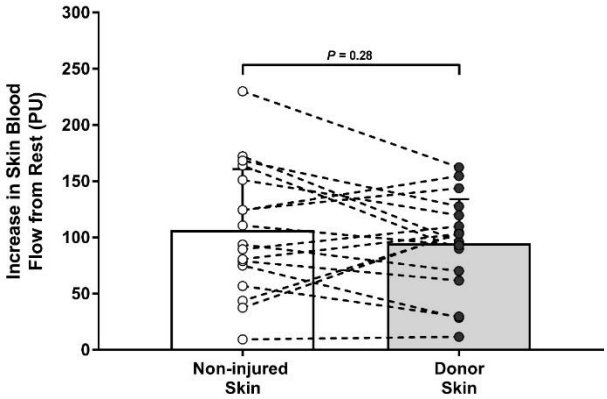
ABSTRACT TITLE: **No Evidence of Thermoregulatory Impairment in Donor Skin during Exercise-induced Hyperthermia**

According to the US Army's Standards of Medical Fitness (AR 40-501), "Prior burn injury (to include donor sites) involving a total body surface area of 40 percent or more does not meet the standard". While the Standard implies that elevations in skin blood flow and sweating are impaired within donor skin during an exercise-induced hyperthermic challenge, this has not been experimentally verified.

PURPOSE: This study tested the hypothesis that human donor skin retains the capability to increase skin blood flow and sweat production in response to exercise-induced hyperthermia. METHODS: Thirteen burn survivors (11 males; aged 36±12 years) with well-healed burn injuries spanning 36.4±17.5% of body surface area (BSA), as well as donor sites covering 18.0±9.8% BSA, cycled for 60 min at a workload eliciting ~50% of maximal aerobic capacity. Environmental conditions were set at 39.5±0.2°C and 21.8±3.8% relative humidity. Immediately prior to and upon completion of exercise, skin blood flow was assessed via laser-Doppler imaging from donor sites and adjacent non-injured skin (n=12). Local sweat rate was also assessed at the same skin sites at 45 min of exercise using absorbent material (n=10).

Gastrointestinal temperature was measured using an ingestible temperature sensor. RESULTS: At 60 min of exercise, the elevation in gastrointestinal temperature averaged 0.8±0.3°C ($P<0.01$). At the end of this exercise bout, the magnitude of the increase in skin blood flow was similar between donor and non-injured sites (donor: 103±45 flux units; non-injured: 123±58 flux units; $P=0.21$). Similarly, local sweat rate did not differ between sites (donor: 0.54±0.29 mg/cm^2/min; non-injured: 0.62±0.26 mg/cm^2/min; $P=0.27$). CONCLUSION: These data suggest that well-healed donor skin retains the capability to elevate skin blood flow and sweating during exercise in the heat. Therefore, the US Army should exclude donor skin when determining whether the size of a burn injury meets the Standards of Medical Fitness.





What opportunities for training and professional development has the project provided?:
Though the project was not intended to provide training or professional development opportunities, training has nonetheless taken place as a result of the performed work. Specifically, Matthew Cramer, Ph.D., Gilbert Moralez, Ph.D., and Mu Huang, Ph.D. are postdoctoral fellows working on this project. As a result of this project, all three received training in the following areas: IRB approvals, subject recruitment (both uninjured and burned subjects), data collection and management, data analysis and reporting, and presentation of the data. Regarding the last point, data from these studies have been presented by trainees at weekly "Works in Progress" meetings, at the American Burn Association annual meeting (2017-2018), at the World Burn Congress (2017), at Experimental Biology (2017-2018), and at the American College of Sports Medicine Annual General Meeting (2017-2018).

How were the results disseminated to communities of interest?:
The obtained data have been presented at the following local, national, and international meetings in verbal or poster formats: internal "Works in Progress" meetings, the American Burn Association, the World Burn Congress, the Military Health System Research Symposium, Experimental Biology, the American College of Sports Medicine, and the Physiology and Pharmacology of Temperature Regulation meetings. The manuscript for Aim 4 is presently under review for publication in the journal Medicine and Science in Sports and Exercise. We anticipate that three more publications will originate from Aims 1A, 2A, and 2C within the next year.

What do you plan to do during the next reporting period to accomplish the goals?:
Over the next 12 months, we need to continue with enrollment and data collection for the studies that are already initiated (i.e., Aims 1B, 2B, and 2D). As mentioned above, these studies take a tremendous effort from both the research subject and the research team to complete, with some protocols requiring upwards to 9 unique laboratory visits to complete data collection from each subject for a specific protocol. Additionally, we will commence enrollment and data collection for the Aim 3A/3B protocols, which were recently approved by the IRB and HRPO.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

The obtained data in Aim 1A indicate that the thermoregulatory consequence of a burn injury of a given relative size (e.g., 40% of total body surface area) is heavily influenced by the overall size of the individual. That is, a smaller individual having the exact same percentage of his/her body surface area burned is at a greater risk for a hyperthermic injury relative to a larger individual having the exact same percent body surface area burned during prolonged exercise with the same absolute metabolic cost. These data alone are sufficient to question the Army's Standard of Medical Fitness requirement of a single qualifier stating that >40% body surface area burned "does not meet the standard", since if the burned individual is large s/he will be better able to tolerate a hyperthermic insult relative to if s/he were small.

Data from Aim 2A (although preliminary, the findings are robust) will inform the military that individuals with a 20% and 40% body surface area burns are fully capable of regulating their internal temperature, when compared to a non-burned individual, exercising at moderate intensities in both normothermic and hyperthermic environments. However, individuals with 60% body surface area burn are at a greater risk for a hyperthermic injury, but only when exercising in conditions of elevated environmental temperatures.

Data from Aim 2C (although preliminary, the findings are robust) will inform the military that maximum evaporative heat dissipation decreases as the size of a burn injury increases. Individuals with a burn injury of 40% are still able to thermoregulate appropriately during prolonged moderate-intensity work in hot conditions at a relative humidity of ~30%.

Data from Aim 4 will inform the military that donor sites (skin areas harvested for skin grafts) contribute normally to thermoregulatory function during exercise in hyperthermic conditions, and should therefore not be included when determining whether a burned soldier meets the Standards of Medical Fitness.

What was the impact on other disciplines?

The obtained data will be of interest to the civilian burn rehabilitation community. Exercise is critical for appropriate rehabilitation. That said, burned individuals are often hesitant to perform aerobic exercise training for fear that they may experience a heat-related injury. The information presented above will be very beneficial to the rehabilitation community by instructing them that a larger person with the same percent body surface area will be better able to "thermally" tolerate exercise at a given rate of metabolic heat generation relative to a smaller person, thereby improving the safety of the rehabilitation of individuals with these injuries. The obtained data will also inform the rehabilitation community that individuals with burns up to (and including) 40% body surface area are fully capable of regulating body core temperature during moderate exercise in both normothermic and hyperthermic environmental conditions. However, individuals with 60% of their body surface area burned should be cautious when exercising at a moderate intensity in hyperthermic environmental conditions.

What was the impact on technology transfer?: Nothing to report.

What was the impact on society beyond science and technology?:

Nothing to report.

5. CHANGES/PROBLEMS

Changes in approach and reasons for change:
None

Actual or anticipated problems or delays and actions or plans to resolve them:
None

Changes that had a significant impact on expenditures:
None

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents: No significant changes were enacted. The IRB protocols for Aims 1 and 2 were approved and renewed on 05/09/2018, with an annual expiration date (requiring submission of continuing renewal) of 05/16/2019.

Significant changes in use or care of human subjects
The IRB protocol for Aim 3 was approved on 08/30/2018, with an annual expiration date (requiring submission of continuing renewal) of 08/09/2019. Given the completion of data collection for Aim 4, the IRB protocol for Aim 4 remains open for analysis only as of 07/19/2018.

Significant changes in use or care of vertebrate animals:
None

Significant changes in use of biohazards and/or select agents:
None

6. PRODUCTS

Publications, conference papers, and presentations:

Journal publications**:**

1. Cramer MN, Moralez G, Huang M, Crandall CG. No Evidence of Thermoregulatory Dysfunction within Donors Site of Burn Survivors. Med Sci Sports Exerc, 2018. Manuscript under review (Manuscript ID: MSSE-D-18-00976). Federal support acknowledged.
2. Cramer MN, Moralez G, Huang M, Crandall CG. No evidence of thermoregulatory impairment in donor skin during exercise-induced hyperthermia. Med Sci Sports Exerc 49(5) Supplement 1: 622, 2018. Conference abstract; published. Federal support acknowledged.

3. Cramer MN, Moralez G, Huang M, Crandall CG. Critical Environmental Limits for Prolonged Work in the Heat Using a Simulated Burn Injury Model. FASEB J 32 (Meeting Abstract Supplement): 590.15, 2018. Conference abstract; published. Federal support acknowledged.
4. Crandall C, Cramer MN, Moralez G, Huang M. Donor Sites Appropriately Contribute to Whole-body Thermoregulation During an Exercise-induced Hyperthermic Challenge. J Burn Care Res 39 (suppl 1): S55, 2018. Conference abstract; published. Federal support acknowledged.

Books or other non-periodical, one-time publications: Oral and poster presentations from this project were given at the following meetings during the prior 12 months:

Experimental Biology
American College of Sports Medicine
American Burn Association
Military System Health Research Symposium
Physiology and Pharmacology of Temperature Regulation

Other publications, conference papers, and presentations: Data from these projects were presented (in either oral or poster formats) at the meetings indicated above, as well as the World Burn Congress. Moreover, Matthew Cramer, Ph.D. has presented data originating from this work internally at our "works in progress."

Website(s) or other Internet site(s):
None

Technologies or techniques:
None

Inventions, patent applications, and/or licenses:
None

Other Products:
None

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Dr. Craig Crandall
Project Role: PI
Researcher Identifier:
Nearest person month worked: 4
Contribution to Project: Dr. Crandall has worked extensively with the lab team while planning and implementing data collection and analysis.
Funding Support: Dr. Crandall receives extramural funding from the Department of Defense and the NIH

Name: Matthew Cramer, Ph.D.
Project Role: Postdoctoral fellow
Researcher Identifier:
Nearest person month worked: 9
Contribution to Project: Dr. Cramer assists with all aspects of the study, from recruitment through data analysis. This contribution has been quite extensive as each subject requires multiple visits to the laboratory to accomplish the stated aims.
Funding Support: Dr. Cramer receives extramural funding support from grants to Dr. Crandall from the NIH and the Department of Defense. He also receives salary support through the Natural Sciences and Engineering Research Council of Canada.

Name:Gilbert Moralez, Ph.D.
Project Role: Postdoctoral fellow
Researcher Identifier:
Nearest person month worked: 1
Contribution to Project: Dr. Moralez assists with data collection.
Funding Support: Dr. Moralez receives extramural funding support from grants to Dr. Crandall from the NIH.

Name: Mu Huang, Ph.D., DPT
Project Role: Postdoctoral fellow
Researcher Identifier:
Nearest person month worked: 1
Contribution to Project: Dr. Huang assists with data collection.
Funding Support: Dr. Huang receives salary support from the School of Health Professions at the University of Texas Southwestern Medical Center.

Name:Naomi Kennedy RN, BSN
Project Role: Research Nurse
Researcher Identifier:
Nearest person month worked: 3
Contribution to Project: Naomi has assisted with subject screening and consenting, data collection, and subject safety.
Funding Support: Ms. Kennedy receives extramural funding support from grants to Dr. Crandall from the NIH and the Department of Defense

Name:Sarah Bailey Adams, M.S.
Project Role: Research Associate
Researcher Identifier:
Nearest person month worked: 3
Contribution to Project: Ms. Bailey assists with subject recruitment, scheduling, and with data collection and reduction.
Funding Support: Ms. Adams receives extramural funding support from grant to Dr. Crandall from the NIH and the Department of Defense

Name:Manall Jaffrey, M.S.
Project Role: Research Associate
Researcher Identifier:
Nearest person month worked: 3
Contribution to Project: Ms. Jaffrey assists with subject recruitment, scheduling, and assisted with data collection and reduction.
Funding Support: Ms. Jaffrey receives extramural funding support from grant to Dr. Crandall from the NIH and the Department of Defense

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
Yes, Dr. Crandall has recently received support from the Department of Defense for a new project titled “Analgesics in the pre-hospital setting: Implications on hemorrhage tolerance (W81XWH1820012). This new grant does not impact the support for the present project.

What other organizations were involved as partners?:
Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS**:**
Not applicable

QUAD CHART:
See attachment

9. APPENDICES

Not applicable

Effects of Burn Injuries on Thermoregulatory and Cardiovascular Responses in Soldiers: Implications for the Standards of Medical Fitness

BA150093

W81XWH-15-1-0647

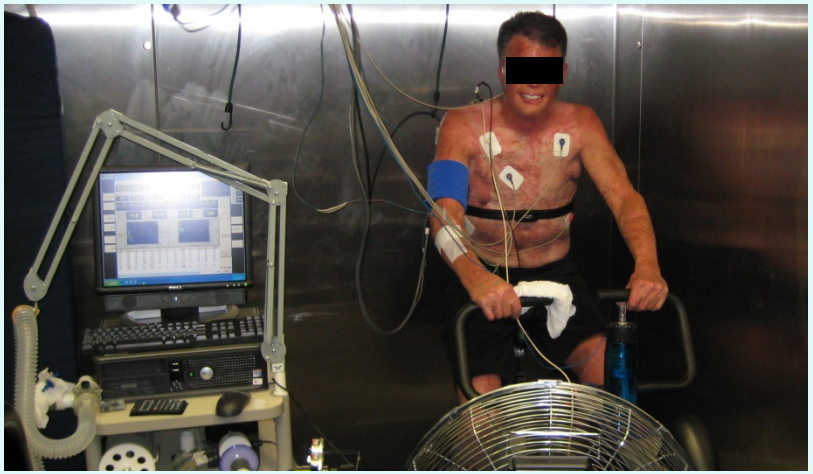
PI: Craig Crandall, Ph.D. **Org:** Univ of Texas Southwestern Medical Center **Award Amount:** $2,017,168

Study/Product Aim(s)

- Aim 1: Absolute body surface area (BSA) available for heat dissipation (i.e., uninjured skin) more accurately predicts thermoregulatory and cardiovascular consequences during a thermal stress relative to the current standard of using %BSA burned.
- Aim 2: The extent to which a burn injury is detrimental to an individual is dependent on the ambient temperature at a given exercise intensity and the exercise intensity within a given environment.
- Aim 3: Does the location of the burn injury influence thermoregulatory responses?
- Aim 4: Does the donor site contribute to compromised thermoregulatory responses in burned individuals.
- Aim 5: Identification of an upper limit for which a soldier with a prior burn injury could be expected to maintain a safe core body temperature across differing metabolic demands and environmental conditions.

Approach

The above questions will be addressed primarily by measuring thermoregulatory responses (e.g., core and skin temperatures) during exercise in neutral and hyperthermic environments at various workloads (e.g. rate of metabolic heat generation) in individuals with simulated burn injuries and in actual burn patients.



Accomplishment: We continue to collect data for Aims 1 and 2. We completed data collection for Aim 4, and received IRB and HRPO approvals for Aim 3.

Timeline and Cost

Activities CY	16	17	18	19	20
Aim 1: Body surface area					
Aim 2: Effect of workload and climate					
Aim 3: Burn location					
Aim 4: Donor site					
Aim 5: Compilation					
Estimated Budget ($K)	**$431**	**$375**	**$395**	**$399**	**$419**

Updated: 10/24/2018

Goals/Milestones

CY16 Goal – Obtain IRB and HRPO approvals. Initiate data collection for Aim 1A.

CY17 Goals – Complete Aims 1A and initiate Aims 2.

CY18 Goal – Continue data collection for Aims 1B, all Aim 2s, and Aim 4.

CY19 Goal – Complete data collection for Aim 2 and initiate data collection for Aim 3.

CY20 Goal – Complete data collection for Aims 1B, 3, and 4. Complete the synthesis of the obtained data and provide guidelines regarding burn injury size/location, environmental condition, and workload by which a burned soldier could safely perform his/her duties.

Comments/Challenges/Issues/Concerns

- We have done an exceptional job at recruiting subjects and accomplishing the grant's objectives. We remain on track relative to our expected goals.

Budget Expenditure to Date

Projected Expenditure: $1,199,846

Actual Expenditure: $1,007,159.52