Cooling Vest May Reduce Heat Stress, Improve Thermal Comfort, and Preserve Cognitive Performance of Surgeons While Performing Surgery

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Amendments:

Protocol date changed from April 28, 2020 Version 2.0 - to July 15, 2020 Version 3.0:

Page 7 of 16 under METHOD section changed the age limit from 30-65 years of age to 25-65 years of age.

Protocol date changed from July 15, 2020 Version 3.0 – to September 3, 2020 Version 4.0

Page 7 of 16 under METHOD section changed the surgical helmet system from an exclusion to an inclusion as long as the system is consistently worn for each of the surgeon's four cases.

Page 9 of 16 under Secondary Outcome #1- mean core temperature. Oral temperatures of the participants will be measured preoperatively and postoperatively prior to completing the C3B battery assessment.

INTRODUCTION

Heat Stress is a serious problem affecting surgeons in operating facilities across the United States and throughout the world. Surgeons are literally drenched from perspiration while wearing impervious surgical gowns and protective clothing which increases the incidence of health related maladies, such as fatigue and dehydration (Satarifard, Gaeini, & Choobineh, 2012; Nerbass et al., 2017), decreased **thermal comfort**, and alterations to cognitive performance (Berg et al., 2015), potentially increasing surgical errors (Zwolinska & Bogdan, 2012). Human beings respond to heat stress via a cascade of physiological responses (increased acute circulatory system response, central nervous system activation and molecular responses increase production of heat shock proteins to protect cells). These mechanisms are activated in an effort to adapt or normalize systemic and cellular responses of the body which initially improves brain function and ideally enhances cognitive performance (Logan & Barksdale, 2008), although repeated triggers to the stress response systems have a cumulative "wear and tear" impact on body functions which contribute to cognitive decline and other health related morbidities (Satarifard, Gaeini, & Choobineh, 2012; Logan & Barksdale, 2008).

Decrements in **cognitive performance** occur when core temperature increases by about 1ºC (Reinersten et al., 2008; Simmons et al., 2008). The level of cognitive decline depends on exposure duration, the intensity and complexity of the activity, and─ importantly─ the degree of hyperthermia (Gauoa et al., 2011; Simmons et al., 2008). There have been several heat stress studies performed in industrial settings and in climatic heat chambers. Processing speed and reaction time, short-term memory, and decision are all impaired (Gaoua et al., 2011; Sun et al., 2012; Piil et al., 2017; Mazlomi et al., 2017).

Cooling the skin reduces the unpleasant sensations caused by excessive heat exposure (Simmons et al., 2008). Localized cooling of the torso during systemic heat exposure reduces physiological stress by lowering body skin and core temperatures, decreasing heart rate, reducing sweat rate, and improving perception of thermal comfort (Chang, Song, & Yang, 2015). **Cooling vests** worn under impervious surgical gowns serve as a heat sink and reduce unpleasant sensations and the symptoms of physiological stress (Smolander et al., 2004; Kenney et al., 2011; Reinersten et al., 2008).

We propose to test the primary hypothesis that ***wearing a cooling vest during surgery improves surgeons' perception of thermal comfort***. Secondary, we will test the hypothesis that ***wearing a cooling vest during surgery reduces surgeons' mean-body temperature and preserves their cognitive performance.***

Specific Aims

1. Our **primary aim** is to evaluate surgeons' self-rated thermal comfort with and without a cooling vest during prolonged and strenuous surgery.

   Primary hypothesis: Surgeons' self-rated thermal comfort is improved by wearing a cooling vest during prolonged and strenuous surgery.

2. A **secondary aim** is to evaluate surgeons' mean-body temperature with and without a cooling vest during prolonged and strenuous surgery.

Secondary hypothesis 1: Surgeons' mean-body temperature, estimated from core and mean-skin temperature, is reduced by wearing a cooling vest during prolonged and strenuous surgery.

3. Another **secondary aim** is to evaluate surgeons' cognitive performance with and without a cooling vest just after prolonged and strenuous surgery.

   Secondary hypothesis 2: Surgeons' cognitive performance is better preserved by wearing a cooling vest during prolonged and strenuous surgery compared to the same surgeons' cognitive performance without wearing a cooling vest during prolonged and strenuous surgery.

4. An additional **secondary aim** is to evaluate the surgeons' perceived ergonomic workload with and without a cooling vest during a prolonged and strenuous surgery.

   Secondary hypothesis 3: Surgeons' perceived ergonomic workload is less demanding by wearing a cooling vest during prolonged and strenuous surgery compared to the same surgeons' perceived ergonomic workload without wearing a cooling vest during a prolonged and strenuous surgery.

Background and Significance

Heat stress is a serious problem affecting the physiological and psychological responses of surgeons in operating rooms (OR) across the United States and throughout the world as body heat is trapped under protective impervious surgical gowns increasing body temperature (Satarifard, Gaeini, & Choobineh, 2012), possibly altering cognitive performance (Berg et al., 2015), and potentially increasing surgical errors (Zwolinska & Bogdan, 2012). Physical efforts of individuals to adapt to higher temperatures, or acclimate, within an occupational environment is dependent on the type of work performed, thermal condition and insulated layers of clothing worn (Zwolinska & Bogdan, 2012).

Cooling systems are sometimes used to reduce thermal discomfort and to improve comfort, decrease sweating, and increase work productivity (Lango et al., 2009). In a met-analysis by Chan, Song, and Yang (2015), the use of microclimate cooling systems in occupational settings attenuated increases in core temperature, sweat rates, and improved human performance. Research does not exist to capture surgeons' perceptions of comfort, skin and core body temperatures in *real-time* operating conditions and whether surgeons experience a degree of heat stress sufficient to impair their cognitive performance. A gap in research also exists to identify whether a cooling vest intervention worn by surgeons while performing surgery will improve comfort and/or reduce negative physiological and psychological responses to heat stress (Lango et al., 2009).

Environmental, Personal, and Situational OR Conditions Impacting Surgeons

The Facility Guidelines Institute recommends the **ambient temperature** levels in each OR are monitored and maintained at 20-24ºC (68º - 75ºF) which contributes to heat stress experienced by surgeons. AORN Standard Practice Guidelines, Safe Environment of Care Protocol states: Ambient temperature levels in each OR are monitored and maintained at 21-24ºC to reduce hypothermia and improve surgical outcomes experienced by patients (AORN, 2017). It is estimated that 20% of surgical patients experience unintentional hypothermia, core body temperature dropping below 36ºC,

potentially increasing perioperative complications including delayed wound healing, surgical site infections, and surgical blood loss (Sessler, 2016).

Regulated ambient operating room temperatures to protect vulnerable sedated patients from hypothermia may be warm for surgeons as their elevated body temperatures predispose sterile surgical fields to contamination from surgeons' sweat dripping onto the field (Berg et al., 2015). Additionally, the level and duration of discomfort experienced by surgeons at the field are also impacted by close physical proximity among operating members, patient warming devices, physical exertion, body position, and use of lead x-ray aprons which collectively contribute to elevated body temperatures, excessive fluid loss, and alterations in cognitive performance (Berg et al., 2015; Nerbass et al., 2017).

Surgical gowns and additional layers of **personal protective clothing** have a considerable impact on the body temperature and comfort of the surgeon (Zwolinska & Bogdan, 2012). Surgical gowns are medical products that comply with occupational safety regulations instituted by the Association for the Advancement of Medical Instrumentation (AAMI) to ensure barrier protection to prevent high-risk contaminations, penetration by liquids, or any microbial transmission (Reinersten et al., 2015). The gowns are manufactured from nonwoven material fibers, which are bonded to each other by friction and/or cohesion and/or adhesion (AORN, 2017). In addition to the impervious gowns, additional safety requirements stipulate surgical personnel wear goggles, glasses with side guards face masks, knee-high shoe covers, waterproof aprons, or additional sleeve layers to be worn, dependent on the type of surgery, and double gloving to reduce the risk of infection (AORN, 2017).

Physiological and Psychological Responses to Heat Stress

Human beings respond to **heat stress** via a cascade of acute physiological responses to initially enhance the body's response to heat stress in which systemic and cellular functions attempts to regulate and regain control throughout the stress event (Bouchama & Knochel, 2002). The initial reactions include an acute circulatory system response, central nervous system activation, and molecular responses to increase production of heat shock proteins which work to protect cells from damage or cell death (Bouchama & Knochel, 2002). Following the acute response, most individuals acclimate to physiologic changes to maintain a balance state within body systems. Repeated daily exposure and prolonged contact to heat stress predispose some individuals to develop adverse physiological and psychological responses to heat stress (Conrad & Bimonte-Nelson, 2010; Moran et al., 2006; Logan & Barksdale, 2008).

Initially, an **acute circulatory system response** to heat stress occurs whereby cardiovascular activity diverts blood flow to the body surfaces, increasing peripheral blood volume to bring about profuse sweating (Horowitz & Robinson, 2007) which evaporates in ambient temperatures and naturally cools the body (Amorium et al., 2015) unfortunately, not for surgeons as sweat is blocked from evaporating. At the same time the cardiovascular activity occurs, the central nervous system reacts to warm temperatures and moderate physical activity through activation of the hypothalamic-pituitary-adrenal (HPA) axis (Nater, Skoluda, & Strahler, 2013). Initial activation of the HPA axis, the body's stress response, or the fight-flight reaction, protects organs from permanent harm by increasing alertness and protecting against pathogens by boosting the immune system response (Ryann et al., 2016). Released from the HPA axis, glucocorticosteriods, primary stress hormones, are sent to bind with available glucose in the bloodstream which are routed to the brain to support ***cognitive performance*** and ***decision making functions*** during stressful situations (Ryann et al., 2016).

At the **molecular level**, cells initially respond to heat stress by synthesizing highly conserved sets of polypeptides, heat shock proteins (HSPs), the stress proteins essential for survival at normal and elevated temperatures (Kregel, 2002). Elevated levels of HSPs measured during heat exposure suggest these proteins play an important role in maintaining cellular homeostasis, or a balance state, in response to heat stress (Horowitz et al., 2004). Cell protection is a critical function of HSPs to develop thermotolerance, a defense mechanism of cells to protect tissue from damage associated with heat stress exposure by increasing transcription (production) of HSPs, creating a temporary state of heat tolerance or balance (Horowitz et al., 2004).

Following the initial rapid acute responses of the systemic and cellular processes, individuals acclimate, or acclimatize to heat stress, by increasing levels of extracellular fluid and blood plasma, activation of stress hormones, and conservation of salt by the kidneys which improve the body's ability to resist dehydration (Bouchama & Knochel, 2002) and increase a balance state of adaptation (Horowitz & Robinson, 2007). Additionally, allostasis, an advanced flexible version of homeostasis, signals the body to remain stable during exposure to stressful events. This complex process continually monitors and adapts the variability occurring among hormones, temperature, and blood pressure (Logan & Barksdale, 2008).

Chronic activation or daily exposure to heat stress threatens the body's efforts to maintain a balanced state, eventually becoming fatigued and physiological and psychological responses deteriorate with repeated exposure to heat (Logan & Barksdale, 2008). Each time the stress response is activated, physiological adjustments are made, which have a cumulative "*wear and tear*" effect on body functions (Satarifard, Gaeini, & Choobineh, 2012; Logan & Barksdale, 2008). Several adverse physiological reactions occur when permanent triggers continually activate the release of stress hormones from the neuroendocrine system resulting in elevated levels of corticosteroids, which alter the immune system, suppress the digestive system, and burden the reproductive system (Nadar Skoluda, & Strahler, 2013; Logan & Barksdale, 2008). Long-term exposure to elevated corticosteroids increases the occurrence of anxiety, depression, heart disease, and weight gain contributing to health related morbidities (Satarifard, Gaeini, & Choobineh, 2012). The effects of elevated and prolonged exposure to glucocorticosteriods may leave the hippocampus region of the brain vulnerable to potential injury neurotoxicity or metabolic challenges (Conrad & Bimonte-Nelson, 2010) potentially resulting in dysregulation of the HPA axis and ***alterations in cognitive performance*** (McEwen, 1998).

Cognitive performance is a brain function allowing individuals to use acquired knowledge to work through mental processes and exposure to stress (Berg et al., 2015). The brain controls voluntary and involuntary activities including, but not limited to; attention, perception, mood, emotion, appetite, and memory (Kamphuis et al., 2012). Alterations in voluntary and involuntary activities resulting from heat stress depend on the length and source of heat exposure, the length and complexity of the duty to be performed and the skill level of the participant (Gaoua et al., 2011). Individuals who have acquired high skill levels and experience with particular repetitive tasks may be able to tolerate subsequent effects of heat stress for a longer duration of time (Hancock, Ross, & Szalma, 2007). Several heat stress studies performed in industry and simulated climatic heat chambers, measuring processing speed and reaction time short-term or working memory, and executive function of participants, reported an increased number of errors and impairment of cognitive performance (Gaoua et al., 2011; Sun et al., 2012; Piil et al., 2017; Mazlomi et al., 2017).

Cooling the body is the most effective means of improving human performance (Chan, Song, & Yang, 2015). Cognitive functions of the brain respond to cooling by improving perceptions of thermal

comfort, decreasing cardiovascular strain, and less decrements to cognitive performance are noted (Goaua et al., 2011; Simmons et al., 2008; Chan, Song, & Yang, 2015).

Surgeons experience discomfort from elevated body temperatures while performing surgery, but the presence and/or absence and the amount of alterations to cognitive performance are not known (Berg et al., 2015; Lango et al., 2009; Zwolinska & Bogdan 2011) and if cooling the body preserves resources, reduces threats to cognitive performance, and reduces perceptions of a physically demanding ergonomic workload.

Environmental conditions (ambient OR temperatures, overhead lighting, electrical equipment), personal factors (personal protective equipment, metabolic heat, core and skin temperatures) and situational factors (type and length of a surgical procedure, perceived ergonomic workload) contribute to the presence of occupational heat stress experienced by surgeons performing surgical procedures. Surgeons' physiological and psychological responses to heat stress are measureable through a self-reported response to thermal comfort and perceived ergonomic workload, skin and core body temperature sensors, and a cognitive battery assessment. The physiological and psychological measure of surgeons' responses to heat stress can be influenced by wearing a cooling vest during the surgical procedure (Figure 1).

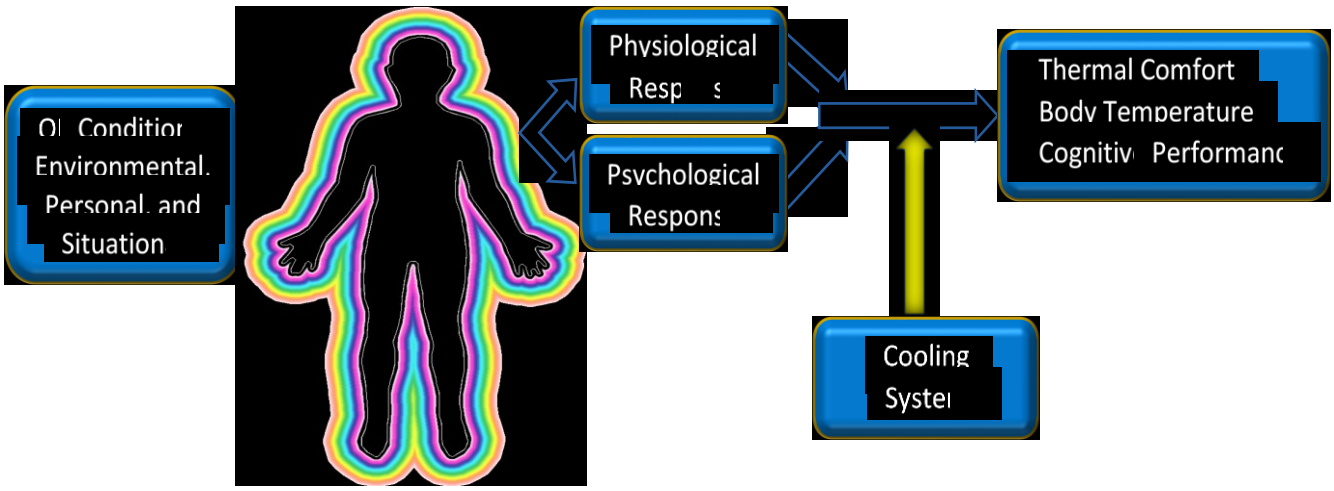

Figure 1. Conceptual Framework.

Methods

The trial will be conducted with Cleveland Clinic IRB approval and consent from participating surgeons. The trial will be registered at ClinicalTrials.gov. A full statistical analysis plan will be developed before any data are evaluated. Reporting will be consistent with the CONSORT guidelines.

Subject selection

Inclusion criteria are: 1) surgeons who perform elective major orthopedic surgery such as total hip and knee arthroplasties scheduled for 90 to 150 minutes at the Cleveland Clinic Main Campus; 2) Orthopedic surgeons ages of 25-65 years old, as body temperatures may be lower and less stable

in the elderly (Waalen & Buxbaum, 2011), who operate frequently enough to participate in four cross-over cases; 3) Surgical procedures in which surgical helmet systems or airborne barrier protection devices are worn are included as long as the surgeon wears the system for all four cases being measured.

Exclusion criteria are: 1) Surgical cases that require surgeons to sit on stools during the procedure, which may impact temperature and energy expenditure; 2) Surgeons who report having a recent illness within 24 hours prior to the surgery, symptoms producing a febrile condition; 3) Surgeons who worked the previous evening; and 4) Surgeons who wear lead X-ray gowns.

Surgeon research subjects will be recruited by posting information about the study on the Orthopedic and Rheumatology Institute website. All human subject research protocols instituted by the Cleveland Clinic will be followed and documented. Participating surgeons will be advised of all known risks and benefits of study as well as information describing the requirements of the study and data management. The surgeons will be advised of the option to stop participation at any time. Written informed consent will be obtained from each surgeon.

Participating surgeons will be assigned a study number and only this number will be included on case-report forms. A single cross-linking record will identify specific surgeons for the purpose of organizing cross-over cases. Otherwise, analysis will be based on study number and no individual data will be linked to specific surgeons. Case-report forms will be kept locked in a secure research office and data-acquisition iPads will be encrypted.

We do not plan to obtain consent from patients for this comparative effectiveness trial that evaluates an FDA exempt device designed to improve *surgeons'* comfort.

Protocol

We propose a randomized cross-over trial using a uniform and strongly balanced 4-period design in which will include four operations for each surgeon. Surgeons will be randomized to 1 of 4 sequences: ABBA, BAAB, AABB or BBAA. The design is "uniform" in that each treatment appears the same number of times within each sequence (uniform within sequence) and if each treatment appears the same number of times within each period (uniform within each period). It is strongly balanced with respect to first-order carryover effects because each treatment precedes every other treatment, *including itself*, the same number of times.

We chose this design versus a parallel group design because 1) it removed the potential for confounding, even with a small sample size, as comparisons are made within subject, and not between subjects; 2) the design is very efficient since within-subject comparisons are correlated, obviating the need for a larger study which would also not be practical in this setting. Also, no differential carryover effect is expected in this study, removing one of the main concerns with crossover trials.

Surgeons will be randomly assigned to use either the CoolSource™ cooling vest (worn between scrubs) and a conventional surgical gown for each of 4 surgeries. Sequence of treatments within surgeons will be randomized (ABBA, BAAB, AABB or BBAA), and determined using the PLAN procedure in SAS, such that each surgeon will wear vest and non-vest twice. The sequencing will not be shared with any study personnel. Allocation for each case will be concealed with a web-based system that will be accessed only shortly before surgery.

We will target an ambient temperature of 21°C ± 1°C, and try to maintain the same temperature of each of the four study cases for each surgeon. The CoolSource vest holds six reusable cooling packs

located bilaterally on the shoulders, angled flank along the base of the rib cage, and along each side of the spine, mid-back. The vest will be donned over hospital-issued scrubs after all temperature sensing devices have been applied and before surgical hand scrubbing. Surgeons will wear the vest throughout surgery, and for a few additional minutes while postoperative assessments are made (details below).

The weight of the disposable cooling vest is 1 kg which is evenly distributed over both shoulders. The cooling packs have an insulated cover to reduce condensation or sweating while seated inside the vest pocket. The flexible frozen reusable cooling packs will be inserted into each of the six pockets and the vest belt will be tied to hold the cooling packs securely. The disposable cooling vests will be discarded after each case, and the cooling packs returned to a freezer.

Measurements

A questionnaire detailing demographic information (age, height, weight, age, ethnicity, and education level) training level, specialty program, and estimated past case volume will be completed by participating surgeons before their first case.

Temperature of the freezer holding the cooling packs will be assessed before randomization to confirm that the temperature is <0°C.

Before every surgical case starts the time the surgeon dons the cooling vest and the time the surgeon dons the sterile surgical gown will be recorded.

Primary Outcome will be self-rated thermal comfort. Immediately after surgery, *while still gowned*, surgeons will rate their thermal comfort on a 0-10 Likert scale, with 0 representing extreme cold, 5 being thermal comfort, and 10 representing extreme heat. Two points on the 11-point Likert scale will be considered a clinically important difference.

Secondary Outcome #1 - mean core temperature. The first secondary outcome will be the mean core temperature for a case, calculated as the time-weighted average over the taken measurements. The surgeon's core body temperature will be monitored by a validated wireless wearable iThermonitor WT701 biosensor which estimates core temperature within ±0.5ºC (Pei et al., 2018). The sensor will be applied to the surgeon's right axilla 15-20 minutes prior to the surgical hand scrub performed at the start of surgery and secured with an adhesive cover. A small patch of axillary hair will be clipped or shaved as necessary. After the temperature sensors are applied, the surgeon's oral temperature will be measured by the Femometer adult digital oral thermometer which meets professional accuracy standards for digital thermometers (ASTM E1112-00) to support the accuracy of the iThermonitor core body temperature measurement. The surgeon's oral temperature will be measured for a second time when the surgeon exits the surgical field prior to taking the C3B battery assessment.

Secondary Outcome #2 - mean skin temperature. The second secondary outcome will be the mean skin temperature for a case, calculated as the time-weighted average over the taken measurements. Mean skin temperature will be estimated from skin temperature from the back of the upper chest, deltoid arm, thigh, and calf using the formula [$MST_R = 0.3\ t_{chest} + 0.3\ t_{arm} + 0.2\ t_{thigh} + 0.2\ t_{leg}$ or $0.3(t_{chest} + t_{arm}) + 0.2(t_{thigh} + 0.2\ t_{leg})$] (Ramanathan, 1964). Skin temperature will be continuously measured using wireless patches, TempTraq, which meet professional accuracy standards for digital thermometers (ASTM E1112-00). The sensors will remain affixed with adhesive dressing on the surgeon's body surface throughout surgery and approximately 10 minutes required for post-operative testing.

Secondary Outcome #3 will be surgeons' cognitive performance, measured with the C3B battery. The self-administered C3B is a performance-based battery of cognitive tests which measure visual memory; episodic learning and delayed memory (five learning trials with a total score of 70) and processing speed; information processing speed and incidental memory (15 symbols repeated for 120 seconds). Also, relevant distractions or interruptions (phone call, pager, staff, equipment, and other) will be recorded and the frequency in which they occur during the C3B battery test. Both tests will be aggregated using z-scores and summing the z-scores within patient. A greater than 10% within-subject difference in total scores will be considered significant. Testing will take place right after surgery with surgeons still gowned. The surgeons will sit with the iPad touch screen placed on a desk in front of them for approximately 10 minutes to complete the cognitive test. To minimize learning during the trial, participating surgeons will complete the cognitive assessment battery before the first study day. For subsequent cases, the test will be administered prior to the surgical hand scrub and after the end of surgery. The C3B test modules use auditory test instructions and on-screen visual test stimuli consistent with symbols, single digits, and single letters.

Secondary Outcome #4 will be surgeon' perceived ergonomic workload measured with Borg CR_{10} scale of exertion and the rating-of-fatigue (ROF) scale.

Immediately after surgery, *while still gowned*, surgeons will rate their perceived exertion on a 1-10 Borg CR_{10} scale, with 1 representing very slight exertion, 5 being severe, and 10 representing maximal exertion. Perceived fatigue will be rated on a 0-10 ROF scale, with 0 representing not fatigued at all, 5 moderately fatigued, and 10 total fatigue & exhaustion. Two points difference on either scale will be considered a clinically important difference. Time the surgeon removes the sterile surgical gown and the cooling vest after completing the C3B will be recorded. Also, total amount of time the surgeon wore the sterile surgical gown / cooling vest in minutes will be calculated.

Ambient operating room temperatures will be monitored at ≤15-minute intervals with an electronic thermometer positioned eight feet from the base of the OR table, outside of the surgical field on the circulating nurses' workstation.

Data Analysis

Participants' age, weight, height, and other continuous demographics and baseline characteristics will be summarized using descriptive statistics (n, mean, median, standard deviation, minimum and maximum), while race, surgical specialty, as well as other categorical variables will be summarized with frequency tabulations. The 4 sequence groups will be compared on baseline variables descriptively.

Specific Aim 1) Evaluate the difference between surgeons' self-rated thermal comfort with and without a cooling vest during prolonged and strenuous surgery. 0-10.

Perceived measure of thermal comfort for both conditions, with and without a cooling vest will be analyzed by descriptive statistics recommended for ordinal Likert scale items – i.e., frequencies and median [quartiles].

We will use a linear mixed effects model to test the treatment effect of the cooling vest on mean thermal comfort. We will adjust for treatment, sequence and period effects, and include subject as a random effect to account for the within-subject correlation. We will test for differential carryover effect by assessing the treatment-by-period interaction. If no interaction is detected the interaction term will be removed and the treatment effect assessed in a main effects model.

Specific Aim 2) Evaluate the difference between the surgeons' core, mean skin, and mean body temperatures with and without a cooling vest during a prolonged strenuous surgery.

For each temperature we will used a linear mixed effects model to test the treatment effect of the cooling vest on a subject's temperature during the case. We will adjust for treatment, sequence and period effects, and include subject as a random effect to account for the within-subject correlation. We will test for differential carryover effect by assessing the treatment-by-period interaction. If no interaction is detected the interaction term will be removed and the treatment effect assessed in a main effects model.

Specific Aim 3: Evaluate the difference between the surgeons' measure of cognitive performance with and without a cooling vest just after a prolonged strenuous surgery.

Cognitive performance will be measured by the C3B performance-based battery of cognitive tests at the end of the case. An overall score for a subject after a particular case will be calculated by first rescaling (e.g., so that each item ranges from 0 to 100) and then averaging the scores across the battery. Treatment effect will be assessed using a linear mixed effects model as described for Aims 1 and 2.

The significance level will be 0.05 for the primary outcome (Aim 1) and 0.05 across the 3 secondary outcomes (2 temperatures, cognitive function), such that the secondary outcomes will be assessed at a significance criterion of 0.05/3=0.017. SAS statistical software version 9.4, Carey, NC, will be used for all analyses.

Specific Aim 4: Evaluate the difference between the surgeons' perceived ergonomic workload with and without a cooling vest during a prolonged and strenuous surgery.

Perceived ergonomic workload will be measured by duration of the surgical procedure recorded in minutes, surgeons' report of the number of hours slept prior to the study day, Borgs' visual analog scale for exertion (0-10), and the Rating of fatigue scale (0-10).

Perceived ergonomic workload for both conditions, with and without a cooling vest will be analyzed by descriptive statistics recommended for ordinal measured items – i.e., frequencies and median [quartiles].

We will use a linear mixed effects model to test the treatment effect of the cooling vest on mean perceived levels of exertion and fatigue. We will adjust for treatment, sequence and period effects, and include subject as a random effect to account for the within-subject correlation. We will test for differential carryover effect by assessing the treatment-by-period interaction. If no interaction is detected the interaction term will be removed and the treatment effect assessed in a main effects model.

Sample Size Justification.

Sample size calculation is based on having 90% power at the 0.05 significance level to detect a difference of 2 or more (on a scale of 0-10) on surgeons' self-rated thermal comfort with and without a cooling vest. With an estimate SD (s) of 3 for thermal comfort in each group, and an assumed within-subject correlation (ρ) of 0.5, the estimated SD of the within-subject difference would be $\sqrt{s_1^2 + s_2^2 - 2\rho s_1 s_2}$, or $\sqrt{2(3^2) - 2(0.5)(3)(3)} = 3$. Within these assumptions we would need a total of 26 subjects to have 90% power to detect a difference of 2 or more on mean thermal comfort in this crossover design. The detectable difference corresponds to an effect size (Cohen's D) of 0.66, which is medium to large. For the 3 secondary outcomes each using a significance criterion of 0.05/3=0.017, we would have 90% power to detect an effect size of 0.76.

Our assumptions of variability and within-subject correlation for the primary aim will be reassessed in an internal pilot study after 13 subjects have competed the 4 cases, and the total sample reassessed based on the findings.

To ensure that sensors, iPad, and wireless technology can be monitored during a real-time surgical procedure, a small trial of two or three case studies will be conducted to ensure all processes work properly, which will not be included in the final data analysis. Periods of poor data or lead disconnection will be marked for exclusion in analysis.

Innovation

The discomfort surgeons experience during long surgical procedures combined with an inability to evaporate sweat through impervious surgical gowns prompted the innovative design of the disposable CoolSource™ Cooling System. The cooling vest is worn by surgeons under the impervious gown to reduce heat and improve comfort while performing surgery. The positive changes in mood, attention, and productivity have been reported by staff and surgeons in a product trial which supported the need for research to investigate the impact heat stress has in which supported the need for research to investigate the impact heat stress has in *real-time* operating conditions.

The **innovative** design of this study measures data by wireless sensor technology during *real-time* surgical procedures without disrupting the surgery, as previous studies utilized simulated conditions. Furthermore, limitations are numerous when trying to generalize findings discovered in structured simulated studies as there is a wider range of effecting factors in *real-time* investigations (Mazlomi et al., 2017). Information obtained from this study will support the development of prescriptive measures and standards to address heat stress in surgeons to alleviate perceptions of discomfort and improve physiological and psychological well-being.

Protection of Human Subjects

The research study is being conducted according to the purposes outlined in the research protocol and the primary responsibility of the informed consent is designed to protect the rights, welfare, and well-being of the participants. The risks and benefits of the study are reasonable to the anticipated benefits and the importance of generalizable knowledge that is expected to result.

Identified Risks:

- Risks to breach of confidentiality: The records of this research will be kept confidential and every effort will be made to protect participants' confidentiality through encrypted coded data and will not include any information that will make it possible to identify a participant. Any reports that may be published will not include any information that will make it possible to identify a participant. Research records will be kept in a locked file and access will be limited to the researchers and hospital review board responsible for protecting human participants.
- Participants will be advised of the entire protocol as well as the voluntary option to withdraw from the study at any time.
- Shaving small skin areas (approximately 2" x 2") for temperature sensor placement may be necessary for adhesive cover to adequately adhere to skin surfaces which could cause mild discomfort, redness, or itching as the body hair regrows.

- Potential risks to comfort, elevated body temperatures, and cognitive performance (e. g. short-term memory and/or processing speed) in occupational heat stress studies naturally occur while surgeons are operating, however, the cooling vest intervention administered in the study may reduce these potential risks.
- There is no evidence that OR personnel wearing the cooling vest under the impervious sterile surgical gown offer any risk to patients as there is no direct contact.

Steps to minimize risks:

- Attenuate first-time cooling-vest users' concerns for perception of discomfort related to cooling packs or added weight, all participants will have the opportunity to wear the cooling-vest prior to any of the randomized trials.
- All members of the research team will be appropriately trained, maintained appropriate credentials, licensing privileges, and institutional competencies.

Identifying benefits:

- The vest design was designed to cool areas of the body that do not cause discomfort over a period of approximately two hours, and the cooling packs do not come in direct contact with participant's skin as it is worn over scrubs.
- Heat stress studies have shown that wearing a cooling garment in stressful thermal environments can decreased heart rates, reduce sweat rates, and improve human performance.
- Surgeons who routinely wear the cooling vest perspire less while operating. This is a substantial advantage because when surgeons perspire, beads of contaminated sweat can fall into the patient's open incision, contaminating the case and predisposing patients to infections.

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