The evaluation of medical devices with healthy people?

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1st International Comfort Congress

‘The evaluation of medical devices with healthy people?’

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Abstract

Much of the research of thermal and physical comfort is completed with healthy participants in regular life scenarios. The translation of these findings into clinical settings for people with disease, deficiency or restrictions adds a level of complexity. As an example this study evaluated the effectiveness of a patient warming mattress device on body temperature and ratings of thermal comfort/sensation.

Hypothermia has been linked to higher mortality rates in trauma patients admitted to hospital. Patient warming devices have been developed to assist the temperature of the patient and studies on these report varied effects. Laboratory trials with shivering inhibition (Goheen et al, 1997, Greif et al, 2000) found improvements from forced air and resistive blankets but without shivering inhibition (Williams et al, 2005) showed no benefit in warming from 35°C.

A physical evaluation of the warming mattress device with a thermal manikin reported an energy contribution to the user (~70W). To support the physical evaluation a user trial was conducted. Nine healthy volunteer participants (27.78 ± 4.99 Years) were exposed to three conditions using a repeated measures counterbalanced design. The participants were cooled in an environment with an air temperature of 0°C (60 minutes) then exposed to 30 minutes of a warming intervention.

1. Hot mattress HM. Mattress preheated to 18°C, under standard blankets
2. Warmed mattress WM. Mattress turned on at start of warming period, under standard blankets
3. Cold mattress CM. Control condition, no power to mattress, under standard blankets.

During the cooling phase, aural and mean skin temperature (Tsk) significantly decreased for all conditions (p<0.01). Tsk increased following each warming intervention but aural temperature continued to decline. Significant increase in overall mean thermal comfort was seen during the first ten minutes of the warming phase for HM in comparison to CM and WM (p<0.05) but not at 20 and 30 minutes. This was mirrored by the overall mean thermal sensation rating across the same timeframe. HM increased thermal sensation from very cold to cool with CM and WM showing and increase from very cold to cold.

This study revealed the effect of the device (HM) gave short term comfort and sensation gains at the start of the warming phase but the passive insulation provided (CM) also allowed re-warming to occur. This was the expected thermoregulatory response for a group of healthy participants. This group does not necessarily represent the hospital population with pathology that inhibits their normal responses to cold, e.g. circulatory shut-down, shock or trauma. For accurate application, the trial data needs to be closely matched with the limitations of the health condition in the target population.

The challenge is now to explore the relationship between data from healthy cohorts and how that can be used for groups of patients with known physical and physiological conditions and limitations. The validity of a patient’s subjective assessment of their condition lying in a hospital bed is currently unclear. Evidence needs to show whether a patient in a hospital bed can accurately report joint position, thermal comfort, skin wettedness, pressure points etc to assist in the management of their condition.
Keywords: Experimental design, Bed comfort, Thermal comfort, Warming, Healthcare.

1 Introduction

Hypothermia has been linked to higher mortality rates [1, 2, 3] and worse outcomes [4] in trauma patients admitted to hospital and is a health risk in itself. The National Institute for Health and Care Excellence (NICE) have published guidance on the management of inadvertent perioperative hypothermia [5] and on the use of a patient warming mattress in the management of the condition [6]. This study aims to evaluate the effectiveness of a patient warming mattress and the impact it has on body temperature and ratings of thermal sensation.

The human body has highly effective thermoregulatory responses to the cold [7], however, hypothermia can occur in severe environments or as a result of illness or accident [8]. The elderly are at an increased risk of hypothermia due to an elevated risk of falls [9] potentially leaving them immobile in a cold environment and a possible diminished thermoregulatory response, lowering their ability to defend their internal temperature [10, 11, 12, 13]. Medical patients are at risk from drops in internal temperature during the perioperative period as a consequence of loss of behavioural responses to cold and the inhibition of thermoregulatory response mechanisms caused by anaesthesia [5, 7].

Technology has been developed to re-warm patients already in a state of hypothermia. Resistive warming blankets [14] and hot packs [15] have been found to heat patients more effectively than control conditions, whereas heat pads [16] have previously failed to demonstrate an additional benefit. Laboratory trials investigating the use of warming devices in patient re-warming included investigations with participants shivering response inhibited through meperidine administration [17, 18]. These studies have found forced-air and resistive blankets to be more effective than control methods in re-warming participants. In comparison, a previous laboratory study without shivering inhibition [19] failed to find an additional benefit of forced air warming, compared with passive warming with blankets.

The avoidance of inadvertent hypothermia during operations has been the subject of a number of investigations and a review by NICE [5]. Forced air warming is currently the most commonly used method of warming and is supported by several studies [20, 21, 22].

Previous research has tended to concentrate on the effects warming devices have on core temperature and there is a lack of investigations into the effects on subjective measures of thermal comfort and thermal sensation, important in the consideration of overall patient comfort. Much of the research of thermal and physical comfort is completed with healthy participants in regular life scenarios. The translation of these findings into clinical settings for people with disease, deficiency or restrictions adds a level of complexity. As an example this study evaluated the effectiveness of a patient warming mattress device on body temperature and ratings of thermal comfort/sensation.

2 Methods

This study evaluated a Patient Warming Device (PWD) which constituted a heating pad and an air-filled suspension mattress. This market available device offered thermal warming and pressure reduction technology aimed at healthcare applications. The device had variable power (32°C-40°C) which were both evaluated. The study employed a two stage laboratory evaluation of the patient warming device. Firstly, a thermal manikin was used to measure the energy transfer capability of the device. Secondly, a user trial was conducted to explore the heating effects in a group of adults in a climatic chamber.

2.1 Thermal Manikin Evaluation

The PWD was evaluated using a thermal manikin (‘Newton’, North Western Measurement Technology, Seattle, USA) in a climate controlled environmental chamber in Environmental Ergonomics Research Centre at Loughborough University. The manikin has 32 individual zones; each can measure temperature and be powered to maintain a set surface temperature. The following environmental conditions were used for the evaluation:

- Air temperature (t<sub>a</sub>) 22°C, 50% Relative Humidity, Air Velocity 0.4 m/s<sup>-1</sup>
Air temperature (t_a) 10°C, 50% Relative Humidity, Air Velocity 0.4 m/s⁻¹

The thermal manikin was used in both passive and active conditions. The passive condition is when the manikin effectively acts a human shaped temperature sensor and indicates body parts which are being directly heated by the mattress. The active condition is when the manikin has a surface (skin) temperature of 34°C similar to that of a person. This gives a measure of the amount of energy required to maintain the surface temperature. The manikin was minimally clothed, (T shirt and boxer shorts) and was additionally covered with a light hospital blanket for all test conditions.

The test protocol was for the manikin to be placed on to the PWD which was unheated and then at the start of the test the PWD was switched on. Duration was for nominally 120 minutes for the passive tests and 70 minutes for the active tests. Two temperatures, 32°C (lowest) and 40°C (highest), were evaluated.

2.2 User Trial

A repeat measures within-subjects design was used for the experiment. Participants took part in three trials of different conditions; the order of the trials was counterbalanced with a Latin square design to negate order effects. All three trial conditions were preceded by 60 minutes cooling in 0°C conditions in a controlled chamber, participants were then re-warmed for 30 minutes within this chamber in one of three ways:

1. Hot mattress condition (HM). On the pre-heated warming mattress (surface temperature 17.7 ± 2.8°C) under standard blankets (pre-heat trial).
2. Warmed mattress condition (WM). On the device under standard blankets with the device turned on at the start of the warming period.
3. Cold mattress condition (CM). On the device under standard blankets with the device turned off (control trial).

2.2.1 Participants.

Nine healthy volunteers participated in the study; five males and four females. The participants were 27.78 ± 4.99 years of age, with a height of 1.70 ± 0.08m, a mass of 69.31 ± 25.36kg and a Dubois body surface area (Parsons, 2003) of 1.78 ± 0.32m². The participants wore their own clothing for the experiments and were required to dress in the following ensemble: underwear (briefs for males, bra and pants for females), socks, shorts, t-shirt, gloves. This ensemble gave an estimated clothing and thermal insulation value (CLO) of 0.26 [23].

2.2.2 Data Collection

- Climatic chamber conditions were recorded by Testo 350-454 data logger every 60 secs.
- PWD surface temperature was monitored with 6 x Grant surface temperature thermistors every 60 secs.
- Skin temperature of the participants were recorded in accordance with ISO 9886 [24] at 8 points every 60 secs.
- Internal temperature was measured aurally with Grant aural thermistors in both ears and averaged every 60 secs.
- Subjective measures were collected for thermal comfort on a 7 point scale [25] and thermal sensation on an 11 point scale [25] for overall, and thermal sensation only for chest, abdomen, upper back, lower back, hands and feet every 10 minutes.

2.2.3 Data Analysis

Analysis was conducted on the participant data to compare the start and finish of the cooling period and the effect over time of the warming period. Skin temperatures and aural temperatures were analysed using paired samples t-tests and repeated measures ANOVA, with Wilks’ Lambda used to test for significance where the assumption of sphericity was not met. Subjective measures were analysed using Friedman tests and Wilcoxon Signed Rank Tests. P <0.05 identified statistically significant differences.

3 Results:

3.1 Thermal Manikin Evaluation

The PWD had the effect of increasing the zones in contact with it by approximately 7°C for the 32°C surface temperature condition and by 10°C for the 40°C surface temperature conditions. The heating effect over
time is shown in figure 1. The graphs include all data from all the manikin zones; this is for illustrative purposes only. It can be seen that the heating of the manikin zones in contact with the PWD, (blue lines), starts almost immediately, (0 – 5 minutes). After which there is a steady increase in the temperature of the zones until approximately 65 minutes when some plateauing of the temperature increase occurs. The magnitude of the zone temperature increases were similar for both the 10 and 22°C air temperature conditions (Fig 1a, 1b).

Figure 2 present’s graphs plotting the energy required (Wm-2) to maintain a manikin surface temperature of 34°C over the duration of the test. When the PWD had a 32°C surface temperature all of the zones remained active. The effect of the PWD was seen with a reduction in the amount of power required to maintain the surface temperature of the zones in contact with it at 34°C (Figure 2a). With a surface temperature of 40°C for the PWD, a number of the zones in contact with it rose above 34°C, (Figure 2 b). This resulted in the power decreasing, if it went down to 0 Wm\(^{-2}\) then this would result in the temperature of the zone increasing beyond the set point of 34°C. Final temperatures of the back zones did get as high as 37°C after the 70 minute duration. It can be seen from the graphs that most of the zones reach a steady state by 12 to 15 minutes, with additional changes only occurring in those zones in contact with the PWD. The majority of the other zones are using approximately 50Wm\(^{-2}\) to maintain the required 34°C surface temperature; this indicates that the PWD is giving the zones in contact with it a similar amount of energy. These results match to the patterns seen in the passive tests and confirm that the PWD is capable of adding heat to a static body.

3.2 User Trial

The environmental conditions data for the three trial conditions (Cold mattress CM, Warmed mattress WM, Hot mattress HM) over the 90 minute experiment period were similar (Table 1).

<table>
<thead>
<tr>
<th>Condition</th>
<th>CM</th>
<th>WM</th>
<th>HM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air temperature (°C)</td>
<td>0.3 (±0.46)</td>
<td>0.3 (±0.38)</td>
<td>0.2 (±0.64)</td>
</tr>
<tr>
<td>Air velocity (m/s(^{-1}))</td>
<td>0.2 (±0.07)</td>
<td>0.1 (±0.03)</td>
<td>0.1 (±0.04)</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>46.9</td>
<td>45.9</td>
<td>42.4</td>
</tr>
</tbody>
</table>
The mattress temperatures were recorded (Table 2) across the area of the mattress. The HM condition showed unequal heating particularly in the lower region of the device. CM and WM were similar.

Table 2. Mattress Surface Temperatures at commencement of warming period.

<table>
<thead>
<tr>
<th>Condition</th>
<th>CM</th>
<th>WM</th>
<th>HM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>4.8 (±2.1)</td>
<td>3.6 (±1.4)</td>
<td>17.7 (±2.8)</td>
</tr>
<tr>
<td>Top (°C)</td>
<td>6.64 (±2.9)</td>
<td>4.78 (±2.0)</td>
<td>18.68 (±4.1)</td>
</tr>
<tr>
<td>Middle</td>
<td>4.48 (±1.9)</td>
<td>3.50 (±1.4)</td>
<td>24.51 (±2.4)</td>
</tr>
<tr>
<td>Bottom</td>
<td>3.30 (±1.7)</td>
<td>2.39 (±1.0)</td>
<td>9.91 (±2.3)</td>
</tr>
</tbody>
</table>

3.2.1 Skin Temperature

The skin temperatures from all 8 points were combined to give mean skin temperature. Figure 3 shows the mean of the overall skin temperature across the exposure through cooling and warming.

Figure 3 shows the mean \( T_s \) across the cooling and warming periods. There is a reduction in \( T_s \) during the cooling period, with significant differences between baseline and the end of cooling (p<0.01). There were no significant differences between \( T_s \) in the three conditions at baseline (p=0.696) or at the end of cooling (p=0.431). All three warming conditions impacted on \( T_s \), with significant differences between the 60 minute cooling point and the end of warming (p<0.05). All warming conditions significantly increased mean skin temperature across all time sections, 0-10, 10-20, 20-30 minutes (p<0.01). Though there were differences between conditions across all time sections, only significant differences found between the HM and CM trials at 20 and 30 minutes of warming (p<0.05). ANOVA analysis suggested significance between conditions for the end of cooling to start of warming sections (p<0.05), Pairwise comparison with a Bonferroni correction did not show significance.

3.2.2 Aural Temperature

The mean aural temperatures (\( T_a \)) are presented in Figure 4.

Figure 4. Mean aural temperatures (\( T_a \)) during the cooling and warming periods (n=9)

There was no significant difference in \( T_a \) between the three conditions prior to the cooling period (p=0.313), however, at the end of the cooling period WM condition (36.28°C) was lower than the CM trial (36.56°C, p<0.05). Mean \( T_a \) did not significantly change with cooling (p=0.898). There was a drop in mean \( T_a \) observed during the warming period, with differences found at the end of cooling compared with end of warming in all conditions (p<0.01). No significant differences were found between baseline and end of
warming. The drop in $T_a$ during the warming period was not significantly different between conditions ($p=0.420$). A significant effect of time was found throughout the warming period, with significant differences between all the time sections 0-10, 10-20 and 20-30 minutes of warming ($p<0.01$).

### 3.3.3 Thermal Comfort and Thermal Sensation

The participants’ ratings of thermal comfort were recorded every ten minutes throughout the trial, mean ratings of overall thermal comfort are presented in Figure 5. There were significant differences in thermal comfort ratings between the end of cooling and the end of warming in both HM and WM ($p<0.05$) but not in the CM condition ($p=0.084$). Ratings of thermal comfort at the end of cooling period and at initiation of warming were significantly different in both HM and WM conditions ($p<0.05$) but not in the CM condition ($p=0.317$). Significant differences between end of cooling ratings and ratings after 10 minutes of warming were found in all conditions ($p<0.05$), but at 20 minutes of warming, only the ratings in the HM and WM conditions were significantly different from at the end of the cooling period. Though there was an improvement in comfort across all time frames in favour of HM there was no significance other than at the start of warming ($p<0.05$).

![Fig 5. Mean overall thermal comfort during cooling and warming periods (n=9)](image)

Figure 6 shows the mean overall thermal sensation. There were no significant differences in thermal sensation between conditions at baseline. The cooling period had a significant effect on thermal sensation in all conditions ($p<0.01$) between baseline and end of cooling period. There were no significant differences between conditions at the end of the cooling period ($p=0.446$), meaning participants started in a similar state for the warming. All warming conditions had a significant impact on thermal sensation. Improvements in participants ratings were significant between conditions at the start of warming, after 10, 20 and 30 minutes of warming in all conditions ($p<0.05$). During the warming period there was a difference between HM and both of the other conditions at 10 minutes only ($p<0.05$).

![Fig 6. Mean overall thermal sensation during cooling and warming periods (n=9)](image)

### 3.3.4 Body Part Differences

The participants’ thermal sensation and thermal comfort ratings for specific areas of the body (chest, abdomen, upper back, lower back, hands and feet) were recorded. All warming conditions had an impact
on local thermal sensation e.g. Figure 7. There were expected differences between the body part locations
due to the proximity of the heat sources and blanket coverage in Table 3.

<table>
<thead>
<tr>
<th>Table 3. Body part differences in thermal sensation (n=9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Part</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Chest</td>
</tr>
<tr>
<td>Abdomen</td>
</tr>
<tr>
<td>Upper Back</td>
</tr>
<tr>
<td>Lower Back</td>
</tr>
<tr>
<td>Hands</td>
</tr>
<tr>
<td>Feet</td>
</tr>
</tbody>
</table>

4 Conclusion

The evaluation of this Patient Warming Device (PWD) has identified an interesting contradiction. The
manikin evaluation clearly identified that the PWD with its heat pad embedded next to the air-filled suspension mattress had the capability of adding heat to the individual laying on it. Both the passive and active modes of the manikin showed clear energy transfer to raise skin temperature and allow a patient to keep their core temperature at a reasonable level (Fig 1 and 2). This data lead to the second user trial evaluation to measure the effect on real people in a cold environment.

The user trial evaluation in tightly controlled environmental conditions (0°C) allowed the response in the participants to be observed. During the cooling phase, aural and mean skin temperature (Tsk) significantly decreased for all conditions (p<0.01). Tsk increased following each warming intervention but aural temperature continued to decline. Significant increase in overall mean thermal comfort was seen during the first ten minutes of the warming phase for HM in comparison to CM and WM (p<0.05) but not at 20 and 30 minutes. This was mirrored by the overall mean thermal sensation rating across the same timeframe. HM increased thermal sensation from very cold to cool with CM and WM showing and increase from very cold to cold.

This study revealed the effect of the device (HM) gave short term comfort and sensation gains at the start of the warming phase but the passive insulation provided (CM) also allowed re-warming to occur. The re-warming was particularly noted between cooling and warming phases of the protocol. This was the expected thermoregulatory response for a group of healthy participants. This group does not necessarily represent the hospital population with pathology that inhibits their normal responses to cold, e.g. circulatory shut-down, shock or trauma. For accurate application, the trial data needs to be closely matched with the limitations of the health condition in the target population.

The challenge is now to explore the relationship between data from healthy cohorts and how that can be used for groups of patients with known physical and physiological conditions and limitations. The validity of a patient’s subjective assessment of their condition lying in a hospital bed is currently unclear. Evidence needs to show whether a patient in a hospital bed can accurately report joint position, thermal comfort, skin wettedness, pressure points etc. to assist in the management of their condition.

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