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Evaluation of comfort associated with the use of a robotic mattress with an interface pressure mapping system and automatic inner air-cell pressure adjustment function in healthy volunteers

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ABSTRACT

Aim of the study: A robotic mattress equipped with an interface pressure mapping system and an automatic inner air-cell pressure adjustment function had been developed to aid in the management of pressure ulcers, but its effects on comfort remained unclear. The present study aimed to investigate whether use of the mattress with continuous, automatic, interface pressure mapping-based regulation of inner air-cell pressure (i.e., robotic mattress) improves comfort over that provided by body weight-based pressure regulation (traditional approach) in healthy volunteers.

Materials and methods: A robotic mattress was used with two settings (i.e., interface pressure-vs. body weight-based regulation). First, 20 healthy volunteers were recruited, and the level of comfort, interface pressure distribution, body immersion, and tissue oxygenation were measured and compared between the two settings.

Results: The level of comfort (20.5 vs 47.5, $p = 0.014$), contact area (2263.9 vs 2145.2 cm^2, $p = 0.002$), and body immersion for healthy participants were significantly larger when using the interface pressure-based setting.

Conclusion: The robotic mattress provided improved comfort, which might be caused by increased contact area, and improved body immersion. The robotic mattress is expected to be effective both for managing pressure ulcers and increasing comfort.

1. Introduction

Pressure ulcer (PU) is localized injury to the skin and/or underlying tissue usually over a bony prominence [1]. Once a PU develops, it prolongs the length of hospitalization, decreases quality of life, and increases the burden of nursing care [2–4]. In addition, deterioration due to infection occasionally occurs, leading to sepsis and subsequent death [5,6]. Particularly, PU prevention for critically ill patients is quite difficult due to limited position and instable hemodynamics. To reduce prevalence of PU in intensive care unit (ICU), both prevention and treatment of PUs, which are called PU management, are extremely important.

The pressure redistribution mattress is currently the most effective solution for PU management [7]. The alternating pressure air-mattress (APAM) is one of the effective mattresses, as it spreads the contact area and reduces interface pressure (IP) by controlling the inner air-cell pressure [8]. However, although the APAM has capability of high IP redistribution, a review indicates that there was no significant difference between APAM and constant low-pressure devices [7]. In order to exert the capabilities of APAM to its full function, variable parameters of APAM such as inner air cell pressure, cell profile and cycle period needed to be optimized. These optimal parameters have already been explored in healthy participants [9]. However, fundamentally, these parameters should be adjusted based on the characteristics of lying people. In particular, the current inner air-cell pressure adjustment algorithm is based only on body weight (BW), which has two potential problems; BW-based settings cannot adapt to IP changes which occur due to repositioning; and BW-based settings do not account for individual body shapes such as bony prominence, which lead to a differential distribution of local IP for patients with the same BW. Ideally, APAM settings need to be adjusted according to IP values automatically. In the clinical setting, nurses currently measure local IP by a

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portable single-point measurement sensor [10,11]. However, this approach is sometimes unsuitable especially for ICU patients, because it is difficult to insert such sensor under the bony prominent sites of patients due to instable hemodynamics. Therefore, there is an urgent need to implement both continuous and whole-body measurement of IP distribution using a sensor inside APAM instead of the single-point manual measurement. It has been revealed that monitoring IP distribution over a long period was effective for PU prevention [12,13]. IP distribution measurement was only used for monitoring and displaying IP distribution for nurses in repositioning. Currently, there are no attempts to develop an algorithm for automated inner air-cell pressure adjusting based on the measured IP values.

We have newly developed an IP-based automatic inner air-cell pressure adjustment function for an APAM equipped with an IP distribution sensor, which is thin and flexible enough for continuous and accurate measurement of IP distribution on air-cells for ICU patients. This improved APAM is further referred to as a “robotic mattress”.

Comfort level is another aspect of APAMs [14] because decreased comfort level for the patients often disturbs the use of APAMs [15]. It is reported that the high inner air-cell pressure decreases comfort [16]. It is also known that the structure of air-cells and air systems such as inflating and deflating types affect comfort level [14]. The several known factors which may lead to comfort can be different among inner air-cell settings. The pushing feeling from APAM decreased by IP reduction in head of bed elevation [17], suggesting that decreasing maximum IP and increasing contact area may help improve comfort. A comparison of comfort associated with several inner air-cell pressure values indicated that comfort level may be related to body immersion and bending at the hip [18]. Although our robotic mattress has the potential to improve comfort level by reducing whole body IP based on appropriately-adjusted inner air-cell pressure, this remains uncertain.

Furthermore, the decreased maximum IP may improve physiological response of soft tissues. Transcutaneous oxygen and carbon dioxide values were stable in some able-bodied people using BMI-sensitive prototype mattress even if the head of the bed was elevated [19]. These values as well as comfort and maximum IP were equivalent between automatic and manual repositioning [20]. It is reported that reducing local IP tended to improve tissue oxygenation and significantly improve comfort [21]. Considering these research results, the physiological response of tissue such as transcutaneous oxygen and tissue oxygen may change through maximum IP reduction using the robotic mattress. However, these changes are still unclear.

Our research aimed to investigate whether using an IP-based, automatic inner air-cell pressure adjustment function (further referred to as IP-based setting) is superior to using BW-based adjustment (traditional approach, further referred to as BW-based setting) in terms of comfort, maximum IP, contact area, body immersion, and tissue oxygenation. Furthermore, to exclude the contribution of illness-related discomfort and solely collect feelings about mattress comfort accurately, the experiment requires healthy volunteers who can appropriately describe their experience.

2. Method

2.1. Robotic mattress and algorithm

A robotic mattress (LEIOS, Molten Corporation, Hiroshima, Japan) equipped with an IP distribution sensor and consisting of an air-cell layer, a urethane foam layer, a pump, positioning cells, and a small display to show the IP mapping (Fig. 1) was used. The mattress contains 30 air-cells sized is 67 × 5.5 × 5.5 cm, and 4 air systems for inflation and deflation. The mattress takes less than 1 min for equilibrium of air in cells in alternating. The usual cycle period is 10 min, and cell profile is 1:2 or 1:4. The mattress can control inner air-cell pressure in 0.25 kPa intervals. The IP based setting was implemented as follows (Fig. 2). First, the mattress stopped the regular air-cell pressure alternating. The mattress inflated the air cells to the maximum pressure, and measured the peak IP value (Px) from the pressure distribution sensor. After that, the mattress decreased inner air cell pressure to 0.25 kPa lower, and measured peak IP value (Py). If the peak IP value (Py) was lower than that of the previous inner air-cell pressure (Py < Px), the mattress decreased inner air-cell pressure again. The procedure was repeated until the peak IP value was higher than that of the previous inner air cell pressure. Finally, once the mattress detected this IP inflexion point, the mattress adjusted the inner air-cell pressure to 0.25 kPa above this point. After the setting was completed, the mattress restarted the regular air-cell pressure alternating. The BW-based setting, which represents the traditional approach, was also implemented so that inner air-cell pressure is non-dynamically adjusted in proportion to BW alone.

3. Experimental study in healthy volunteers

3.1. Study design

A crossover experiment was conducted to compare the effect of the two settings for inner air-cell pressure adjustment (IP- vs. BW-based setting). The inclusion criteria was: age above 20 years; and the ability to report the state of comfort or discomfort. Data were collected from September to November in 2016. The Ethical Committee of the Graduate School of Medicine, the University of Tokyo (approval number #11156) approved the study. Informed consent was obtained from all participants. During the study, the participants' safety was monitored by one of the author, a nurse.

3.2. Data collection

3.2.1. Comfort

The comfort was defined as the state free from any discomfort, which are feelings of pain or numbness in the area where contact between the mattress and body, and feelings of pain according to lying posture itself on APAMs. In this experimental study including healthy participants, we evaluated the levels of discomfort instead of comfort because it is unusual for the participants to use APAMs and therefore difficult to assess the comfort directly. Discomfort was assessed in the buttocks and in the whole body when lying in the supine position, and was evaluated on the visual analog scale (VAS), with 100 points indicating intolerable discomfort. When reporting the VAS score, the participants were asked to exclude other discomfort due to prolonged restriction of the same posture and attachment of a probe for tissue oxygenation measurement.

3.2.2. Body immersion

Body immersion was measured using a motion capture system (Flex3, Optitrak Japan, Tokyo, Japan) assessing the 3D positions of markers attached to the body in images captured by high-speed optical sensors. The sampling rate was 60 Hz and the resolution was 0.1 mm. The markers were attached to both shoulders, the manubrium sterni, both iliac crests, and both knees (Fig. 3). Although the absolute location of a marker depends on lying posture and attached position, it was confirmed through a preliminary experiment that the variance of marker locations was within 1 mm during stable lying posture after attachment. Thus, for each marker, the mean of the vertical position was computed over the first and the last 10 min, and body immersion was defined as the difference between the means. The angle of the hip joint, representing an indicator of posture change, was calculated based on the horizontal and vertical positions of three markers (right shoulder, right iliac crest, and right knee).

3.2.3. IP distribution

IP distribution was measured by IP distribution sensor inside the robotic mattress. The number of sensor cells is 21*61, sampling rate is 2 Hz, measurement range is 0–100 mmHg, and the resolution is