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**Design and Clinical Evaluation for Patient Status Monitoring System of Air-Mattress**

Chiou-Fan Chen¹  Jer-Junn Luh¹  Yao-Ming Cheng²  Ching-Liang Yu²  Shu-Fen Chen²  Chun Yu³

¹ School and Graduate Institute of Physical Therapy, College of Medicine, National Taiwan University

² Apex Medical Corporation

³ Institute of Biomedical Engineering, National Taiwan University

**Correspondence to:**

Jer-Junn Luh, PhD

School and Graduate Institute of Physical Therapy, National Taiwan University

College of Medicine

Floor 3, No. 17, Xuzhou Rd., Taipei City 100, Taiwan

+886-2-33228133 (voice)

+886-2-23313598 (fax)

jjluh@ntu.edu.tw (e-mail)
Abstract

Pressure ulcers are commonly seen in long-term-care and bedridden patients. A common strategy to prevent pressure ulcer is the use of air mattress system. However, the effectiveness of the air mattress system is still under debated. In this study, we tried to design a system to collect the data of temperature, humidity and interface pressure from the interface between patient and mattress. This system contained maximal ten sets of sensor which combined a thermistor, a humidity sensor, and a force sensitivity resistor in a socket and controlled by a MPS430 microcontroller. Data were transmitted to host computer by RS232 interface. To validate this system, a clinical evaluation experiment was performed using two different mattresses—a standard hospital mattress and a low-air-loss mattress. Twenty subjects lied on two different mattresses each for two hour while monitoring temperature, humidity and interface pressure at the sacral region continuously with 0.5Hz sampling rate and averaging each 5minute epochs. The results showed that using a low-air-loss air mattress could reduce about 9 mmHg and 1℃ in interface pressure and temperature (p<0.05). However, there was no significant difference in humidity between two mattress systems.

Keywords: Pressure ulcers, temperature, humidity, interface pressure, low-air-loss mattress.
Introduction

Pressure ulcers are commonly seen in long-term-care and bedridden patients, such as spinal cord injured, stroke, or vegetative patients. It is a painful situation for patient, such as prolonged hospitalization, higher risk of infection, even threatening live, and also requiring extra medical resources, in case of complications. The risk factors for pressure ulcers can be divided into two groups, extrinsic and intrinsic [1] [2]. The extrinsic factors are interface pressure, shear and friction forces, surface temperature and humidity. The intrinsic factors consider the individual’s conditions: for example, grade of immobility and activity, age, nutrient intake, skin condition, loss of sensation, incontinence, and general physical condition, etc.

Focus on extrinsic factors, the interface pressure is the primary factors. The most common places for pressure ulcers to develop are over bony prominences. The pressure or shear forces squeeze and distort of tissues between bone and the bed or chair surface. They occlude capillaries that supply $O_2$ and nutrients to the tissues. This occlusion leads to ischemia within the tissues and worse of pressure ulcers [3].

The environmental factors, including temperature and humidity, also influence the skin tissue strength [4]. Elevating body temperature increases the metabolic activity of the tissues by 10% per degree Celsius of temperature rise, thus increasing the need for oxygen and energy source at the cellular level. A porcine research, which
applied pressure (100mmHg) on pigs for five hours in different surface temperature (25°C, 35°C, and 45°C), showed that pressure induced tissue injury accelerates with increasing temperature[5]. Skin maceration caused by sweating or incontinence results in the reduction of stiffness, nearly complete loss of connective tissue strength and in erosion of the dermis under the action of shear forces. It also increase the coefficient of friction of the epidermis, which promotes adhesion of the skin to the support surface and produces elevated shear, easy sloughing and ulceration.

Common clinical strategies for pressure ulcer prevention include changing patients’ position routinely, monitoring patients’ skin integrity regularly, and using support surface systems [1]. Support surface can divide into two groups, static (including foam, fluid-filled products, and air-fluidized products) and dynamic (low-air-loss mattress, alternating mattress). In general, dynamic mattresses are better than static mattress and also more expensive [6].

Some systems were designed to measure the interface pressure in the market. However it still lacks some devices to measure the local pressure, temperature, and humidity in the interface between patients and supporting surface. In this study, we tried to design a measurement system to evaluate the effect of support surface. This system could monitor the temperature, humidity and interface pressure in the same time. A clinical validation of this system was also performed by recording these three
parameters of the patients who were at pressure ulcer risks.

Materials and Methods

System Designs

The temperature-humidity-pressure measurement system (THP system) diagram was showed as figure 1. The thermistor (TDS503D1, Sen-Tech Co. Ltd, Taichung, Taiwan), humidity sensor (ALH-3ES, Centenary Materials Co., Ltd. HsinChu, Taiwan) and force sensitive resistor (FSR-402, Interlink Electronics Inc, CA) were assembled in a 15cmX15cm cloth socket to measure the interface temperature, humidity, and pressure of subjects lying on a mattress system. All the signals were amplified and transmitted to a data acquisition system which contained a MSP430 (Texas Instrument Inc, TX, USA) micro-controller on 0.5 Hz sampling rate. The host computer could obtain the data from the data acquisition system via a standard RS-232 interface.

In the host computer, recording software provides some useful functions including system setup, data storage and archive, graphing, and alarm setting. In the system setup, we can assign the sampling rate of system and perform the system calibration with reference temperature, humidity, and pressure. In the data storage and
archive, the data from this monitoring system could be stored in an Access 2000
database and retrieve the historical data in different records. Graphing function
allowed the user to observe the recording. The alarm system will show the alarm
signal on the screen and buzzing if the hazard of over-pressure or over-heat were
detected. The flow-chart of monitoring software was showed as figure 2.

Calibration was performed once a month during the experiment period to
guarantee the accuracy of this system. However it only less than 5% system error
could be found.

Clinical Evaluation

Patients, who were aged over 20, lay in bed over 12 hours a day and evaluated
with Braden scale less than 18 points, were invited to participate. Those who fulfilled
one of following criteria were excluded: a grade 3 pressure ulcer or grade 2 pressure
ulcers in two different sites, over two wounds except pressure ulcers, a wound size
over 10% of the whole body surface area, had pressure ulcers with medical history of
diabetes, take steroids for long term, with medical history of acute cutaneous or
subcutaneous dermatosis, such as cellulitis, with infectious disease except
catheter-associated urinary tract infections, or peripheral vascular disease.

Twenty subjects were recruited in the clinical evaluation study. All subjects read
the agreements and signed before the research.

Equipments

We chose a low-air-loss air mattress (9C060001, Apex Medical Corp., Taiwan) and a standard hospital mattress to use in this experiment. The sensor pad of the THP system was put in the sacral region to monitoring the physical parameters in the interface between the mattress and patients. The sensor pad contained nine sensor points to measure temperature, relative humidity, and interface pressure at the same time (figure 3.).

Evaluation Protocol

The subject was asked to lie on a standard hospital mattress (SHM) in supine position comfortably for two hours. The sensor pad was placed in the bottom of the buttock which the center of the sensor pad was right down on the sacrum and smoothened the clothes to avoid crumples. The temperature, relative humidity, and interface pressure were acquired continuously through the two hours in 0.5Hz. Room temperature and relative humidity were also recorded for the baseline calibration. The next day, the subject was asked to perform the same protocol but lie on the low-air-loss mattress (AM).
Data analysis

The data from each sensor was averaged in a five minutes epoch for two hours. Physical parameters from all sensors were evaluated as the maximum value and average value in the same epoch. Considering the environment bias in temperature and humidity, the calibrated temperature (△T) and calibrated humidity (△H), which were the raw data minus the room temperature and humidity respectively, were used in this study. Paired-samples T test was used to compare the three parameters between SHM and AM.

Results

Twenty subjects, 10 male and 10 female, were recruited in our research (Table 1). The scores of Barden Scale were 13.58±2.32 points (8~17 points), which was at the moderate risk (Table 2).

The change values ("24th five-minute"−"1st five-minute") of temperature, relative humidity, and pressure showed a raising trend during the bed time in two different mattress conditions (Table 3). It accumulated 0.99±0.46°C in temperature, 1.96±2.09% in relative humidity, 9.30±4.6 mmHg in average pressure (AP), and 23.05±11.08 mmHg in maximum pressure (MP) in hospital mattress condition. It
accumulated 0.45±0.29℃, 1.57±1.20%, 5.67±3.98mmHg (AP) and 9.63±4.42 mmHg (MP) in AM condition. There were significant difference in temperature and pressure (P<0.05), but wasn’t in relative humidity (P>0.05).

The average parameters in AM condition was lower in 1.07±0.14℃, 2.21±0.06%, 8.94±0.61mmHg (AP), 16.59±1.88mmHg (MP) than that in SHM condition, and there were significant differences in temperature and pressure (P<0.05), but wasn’t in relative humidity (P>0.05). The change curve during data collecting of temperature, humidity, and interface pressure were showed as figure 4, figure 5 and figure 6.

Discussion

Temperature, humidity, pressure were important pressure ulcer risk factors. There were many journal researches mention the effect of each of those [2]. There were no equipments which can collect these three parameters at the same time from now on. So we expected the THP system to be an application of clinical monitor device, providing an objective database to assess patients’ conditions.

The results showed the temperature in sacral region was higher in 9~11℃ than room temperature. The temperature in sacral region of AM was significant lower in 1℃ than that of SHM. In addition, it showed the humidity in sacral region was higher in 8~10% than room humidity. The humidity in sacral region of AM was lower in 2%
than that of SHM, but no significant difference due to large standard deviation. It also showed the AM can significantly decrease the interface pressure and reduce the accumulation during a period of time. Moreover, it was obviously showed in the maximum pressure.

The design of low-air-loss air mattress should distribute pressure with a series of connected air-filled cushions or compartments, and control moisture with high moisture vapor permeability of cover and continuous flow of air through the device. The result didn’t showed well benefit on controlling moisture [7]. The reason could possibly be the poor moisture vapor permeability of the THP sensor pad. In addition, the pressure seemed to increase with time through fluctuation was noticed when plotted with pressure-to-time illustration in individual cases (figure 7). The reason could be the voluntary or involuntary movements of the subjects, such as tremor, coughing, or small turning. These movements such as coughing during data collecting might cause dramatic pressure increase, which might lead to unsuspected shut-down of the machine. It would be a problem for users.

Conclusion

This pilot study showed THP system was a well assessment device for support surfaces. The clinical evaluation of THP system was found significant pressure and
temperature reduction of the air mattress using, but no significant difference in humidity. It should change the material of the cover of sensor pad and enhance system stability for dramatic pressure increase by program design. We expect to build up a database for assessment of support surface in the future.
References


Skin Wound Care. 18(3):151-7, 2005
Acknowledge

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Figure Captions:

Figure 1. The THP system diagram

Figure 2. The flow-chart of monitoring software

Figure 3. The sensor position of measuring pad. The distance between two sensors was 4.5cm. The diameter of sensor was 2.8cm.

Figure 4. The comparison of calibrated temperature between SHM and AM.

Figure 5. The comparison of calibrated humidity between SHM and AM.

Figure 6. The comparison of interface pressure between SHM and AM.

Figure 7. The illustration of interface pressure of three typical subjects (subject 3, 13, and 16) in 2 hours.
Table Captions

Table 1. Basic data of Subjects

Table 2. Barden scale of Subjects

Table 3. The comparison of the average data of 1st 5-min., 12th 5-min., and 24th 5-min. between SHM and AM.
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## Table 1. Basic data of Subjects

<table>
<thead>
<tr>
<th></th>
<th>Subjects : 20</th>
</tr>
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<tbody>
<tr>
<td>Gender (M/F)</td>
<td>10 / 10</td>
</tr>
<tr>
<td>Age (y)</td>
<td>80.53 ±10.52 (50~94)</td>
</tr>
<tr>
<td>Height(cm)</td>
<td>157.11 ±9.62 (143~182)</td>
</tr>
<tr>
<td>Weight(kg)</td>
<td>56.7 ±9.19 (40~84.9)</td>
</tr>
<tr>
<td>Body mass index (kg/cm²)</td>
<td>22.86 ±1.96 (19.42~28.04)</td>
</tr>
<tr>
<td>Room temperature (℃)</td>
<td>22.24±0.84(20~24)</td>
</tr>
<tr>
<td>Room relative humidity (%)</td>
<td>51.68±4.87(41~60)</td>
</tr>
</tbody>
</table>
Table 2. Barden scale of Subjects

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Score (Mean ± SD, Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total score</td>
<td>13.58±2.32 (8~17)</td>
</tr>
<tr>
<td>Sensory perception</td>
<td>2.63±0.67 (1~4)</td>
</tr>
<tr>
<td>Moisture</td>
<td>3±0.92 (1~4)</td>
</tr>
<tr>
<td>Activity</td>
<td>1.68±0.57 (1~3)</td>
</tr>
<tr>
<td>Mobility</td>
<td>1.74±0.78 (1~3)</td>
</tr>
<tr>
<td>Nutrition</td>
<td>2.84±0.67 (2~4)</td>
</tr>
<tr>
<td>Friction and shear</td>
<td>1.68±0.46 (1~2)</td>
</tr>
</tbody>
</table>

Score classification:
At risk: 15-18; moderate risk: 13-14; high risk: 10-12; very high risk: 9 or below.
Table 3. The comparison of the average data of 1\textsuperscript{st} 5-min., 12\textsuperscript{th} 5-min., and 24\textsuperscript{th} 5-min. between SHM and AM

<table>
<thead>
<tr>
<th></th>
<th>SHM</th>
<th>AM</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calibrated temperature (\Delta T) (\degree C)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1\textsuperscript{st} -5-min</td>
<td>10.41±0.62</td>
<td>9.73±0.98</td>
<td>0.020 *</td>
</tr>
<tr>
<td>12\textsuperscript{th} -5-min</td>
<td>11.19±0.69</td>
<td>10.0±0.96</td>
<td>0.001 *</td>
</tr>
<tr>
<td>24\textsuperscript{th} -5-min</td>
<td>11.38±0.70</td>
<td>10.1±0.97</td>
<td>&lt;0.001 *</td>
</tr>
<tr>
<td>change value</td>
<td>0.99±0.46</td>
<td>0.45±0.29</td>
<td>0.001 *</td>
</tr>
</tbody>
</table>

| **Calibrated humidity \(\Delta H\) (%)** |                   |                   |         |
| 1\textsuperscript{st} -5-min | 11.57±4.31        | 9.42±3.93         | 0.119   |
| 12\textsuperscript{th} -5-min | 11.52±4.92        | 9.28±3.39         | 0.144   |
| 24\textsuperscript{th} -5-min | 11.51±5.52        | 9.26±3.14         | 0.163   |
| change value         | 1.96±2.09         | 1.57±1.20         | 0.432   |

| **Interface pressure (mmHg)** |                   |                   |         |
| 1\textsuperscript{st} -5-min | 15.47±6.75        | 8.24±3.51         | <0.001 *|
| 12\textsuperscript{th} -5-min | 17.69±7.16        | 8.41±5.08         | <0.001 *|
| 24\textsuperscript{th} -5-min | 18.14±8.31        | 9.39±6.88         | <0.001 *|
| change value         | 9.30±4.64         | 5.67±3.98         | 0.01    |

| **The maximum interface pressure (mmHg)** |                   |                   |         |
| 1\textsuperscript{st} -5-min | 31.19±9.17        | 16.8±5.00         | <0.001 *|
| 12\textsuperscript{th} -5-min | 36.06±12.87       | 18.8±7.77         | <0.001 *|
| 24\textsuperscript{th} -5-min | 32.74±16.34       | 19.1±9.34         | 0.006   |
| change value         | 23.05±11.08       | 9.63±4.42         | 0.001   |

Data: average ± standard deviation

* P value < 0.05

Change value: “maximum 5-min data” minus “minimum 5-min data”.