

Finite Element Analysis and Empirical Analysis of a Cost-effective Pressure Ulcer-Preventing Mattress

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Abstract: Pressure relief mattresses are recommended to prevent pressure ulcers (PU). Passive mattresses offer a cost advantage over dynamic mattresses. This study evaluates a new passive PU-preventing mattress. Finite element analysis was used to determine the curved surface design of a mushroom-shaped support. A novel mattress evaluation platform was developed integrating a pressure mapping sensor, laser doppler flowmetry (LDF) and precise temperature sensors to validate the effectiveness of the new passive mattress. Compared with standard hospital mattresses, the new passive mattress was found to provide a more even body pressure distribution (relative disparity of -0.7%) and better assisted subcutaneous blood flow (relative disparity of 18.78%). Experimental results demonstrated that the new passive mattress can provide an effective and economical solution for preventing PU.

Keywords: Pressure ulcers, pressure relief mattress, interface pressure, subcutaneous blood flow

Introduction

Pressure ulcers (PU) are common in a variety of patient settings and are also experienced by the elderly, caused by the occlusion of capillary blood flow and increased contact pressure [1]. Pressure relief mattresses are recommended to prevent PU. Mattress support surfaces are categorized as low-tech (non-powered or passive options) and high-tech (dynamic surfaces options) [2]. Different types of dynamic mattresses (e.g., alternating pressure air mattresses, low air-loss mattress) have been found to effectively reducing pressure and shearing forces [3]. However, limited medical budgets raise the need to find more economic mattresses [4]. Costeffective analyses have found that passive mattresses (e.g., high specification foam) are more effective at preventing PU than standard foam mattresses [5], while costing much less than high-tech or dynamic mattresses.

Various finite element (FE) model studies have investigated interface pressure at the buttock surface and stress at bony prominences [6, 7]. These studies focused on a single pressure-oriented cause. Although interface

pressure was commonly used to assess a support surface's pressure relief capability, focusing only on the pressure aspect cannot fully explain the physiological impact on pressure ulcers. In general, soft mattresses can reduce body pressure, but an overly soft mattress might prevent body movement as well as inhibit subcutaneous blood flow [8]. Ideal mattress design for preventing PU should not only relieve overall body pressure but promote blood microcirculation between bone and skin.

Assessments of pressure relief mattresses have to consider the aetiology of PU mechanisms [9]. PU causes can be categorized as intrinsic and extrinsic. Extrinsic factors include mechanical stress acting on the soft tissue, such as pressure, shear and friction. In addition to the pressure factor, skin temperature and humidity are strongly correlated with the onset of PU. Intrinsic factors are related to conditions leading to soft tissue failure, such as malnutrition, anemia and soft tissue infections. Simultaneously considering intrinsic and extrinsic factors in the development of PU can provide a better understanding of the comprehensive relationship between pressure, moisture, and subcutaneous blood flow.

Recently, LAIN HONG SHING YEH CO. introduced a new passive mattress (Patent NO: M427068) (Fig. 1.) featuring a mushroom-shaped support array. Adjusting the density and dimension of Ethylene vinyl acetate (EVA) material during manufacturing produces different cushion mechanisms and different degrees of resilience. Theoretically, such a passive mattress has the following advantages.

- (1) Integrated structure: Computer aided design (CAD) was used to integrate the mushroom-shaped support with the mattress base using the same material. Manufacturing and cutting require no adhesive bonding, making the product environmentallyfriendly.
- (2) Functional geometrical design: The groove around each mushroom-shaped support provides an adjustable contact area corresponding to different degrees of interface pressure. The support design can increase the immersion and envelopment effect and is more ergonomic.
- (3) Better air ventilation: Accumulated heat and moisture between the support surface and the skin can be removed by circulating air flow.

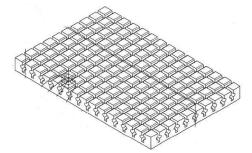


Figure 1. Schematic of the new passive mattress

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Support surface design is a key consideration for preventing PU. We examine the performance of different mushroom-shaped supports using FE analysis and empirically validate the findings with the aim to optimize passive pressure relief mattress design for the prevention of PU.

This study aims to (1) use various three-dimensional FE models to establish guidelines for optimal mattress support shape design, (2) use multiple physiological sensors to construct an integral mattress evaluation platform and verify the practical effectiveness of passive mattresses with respect to standard hospital mattresses. Figure 2 illustrates the overall design flow.

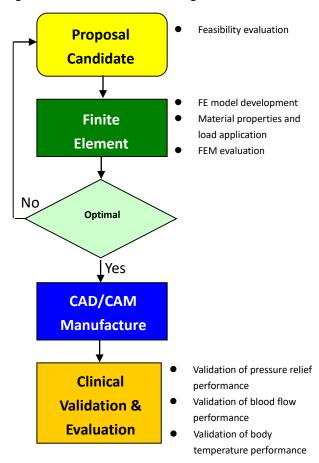


Figure 2. Passive mattress design flow

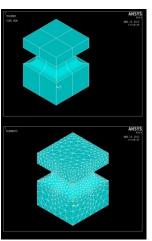
Finite element analysis

Two designs were considered. Shape A, a flat top interface with a mushroom-shaped support surface, can be fabricated using CNC milling techniques. Shape B has a curved top interface which can be manufactured using CNC wire electrical discharge machining techniques. Both support designs were modeled with a rectangular flat bottom with a surface area of 60*60mm2 and a height of 75mm.

Using ANSYS 14.0, the FE model was developed to

analyze the von Mises stress distribution on the interface of the mushroom-shaped support and validated the optimal support shape design. The elastic behaviour of the EVA mattress support is known to be highly nonlinear. However, over the range of stresses encountered in this study (3 kPa–30 kPa), the response was linear, and the Young modulus of the EVA foam was set at 30kPa, with a Poisson ratio of 0.1 based on previous findings [10]. The Shape A and Shape B models were meshed using SOLID185 elements as shown in Fig. 3.

It was assumed that the support was placed on a rigid surface so that the bottom of the support was fixed. Loading was applied by simulating the weight of the human buttocks. The Tekscan pressure mapping system was used to measure interface pressure on the mattress support surface and to obtain uniform pressure loading in the FE model. A uniform pressure load of 3.3 kPa was applied only on the right upper part of support surface. The FE-simulated stress distributions were compared between Shape A and Shape B to determine the better shape design.



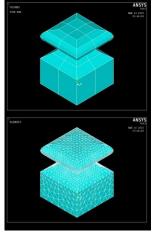


Figure 3. FE model of mattress support of Shape A (left) and Shape B (right)

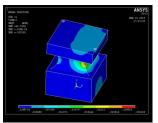
The stress distributions of the FE model are shown in Fig. 4. The higher stress area (3.6 kPa; light blue area) covers nearly the entire right upper surface of the Shape A model. The cause of minor stress redistribution capability on the support surface could be attributed to its flat surface. In contrast, the higher stress area of the Shape B model was concentrated only in a smaller section near middle upper part. The curved surface design exhibited better stress distribution performance and is thus more suitable for use in a passive mattress (Fig. 5). The effectiveness of the two designs was empirically evaluated in tests with human subjects.

Human experimental validation

Instrument

The following hardware was integrated into the novel mattress evaluation platform (Fig. 6.).

- (1) Tekscan (Tactile Pressure Sensor)- Sensor Model #5330 (47.1cm x 47.1 cm; 1024 sensors).
- (2) Laser doppler flowmetry. Oxford Optronix Ltd. (OxyLab LDF).
- (3) LM35 precision temperature sensor.



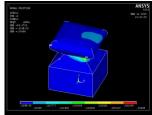


Figure 4. Stress distribution of Prototype A (left) and Prototype B (right)



Figure 5. New passive mattress

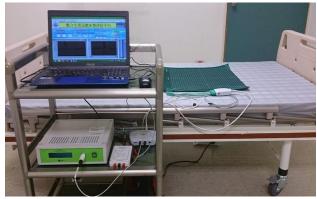


Figure 6. Mattress evaluation platform

Subjects

A total of 30 healthy adults were recruited as testers. Before the experiment, participants were asked to avoid exercise and caffeinated beverages. Table 1 summarizes participant demographic data. The population included 14 women, and excluded participants suffering from diabetes, skin conditions or cardiovascular disease. Fourteen of the 30 participants were female. The study was approved by the Institutional Review Board of Kaohsiung Medical University Hospital (KMUH-IRB-20130134).

	Male (n=16)	Female (n=14)
Age	31.31 ± 13.57	28.14 ± 13.68
Height	170.75 ± 4.49	158.43 ± 5.92
Weight	72.83 ± 11.08	55.14 ± 8.3
BMI	24.99 ± 3.77	21.88 ± 2.49

Table 1. Participant demographics

Experimental protocol

Participants were asked to wear identical T-shirt and sweat pants to eliminate any potential discrepancies caused by clothing. The order of mattresses was randomized for each subject. After calibrating the pressure sensors according to the manufacturer's recommendations, the participant lay supine on each mattress for 30 minutes. Buttock interface pressure, sacral blood perfusion and temperature were recorded simultaneously using sensors in the integrated evaluation platform. Environmental temperature was controlled at 23 \pm 2°C, the humidity was kept at 53 \pm 1%. The experiment proceeded as follows:

- (1) Participants rested for 15 minutes before measurement. During the rest, the participant was instructed in the experimental procedure.
- (2) An LDF probe and temperature sensor was fixed on the participant's sacrum. Pressure sensors were calibrated according to each participant's weight.
- (3) First, the participant was instructed to lie prone to measure heel temperature. The subject was then asked to maintain a comfortable supine position for 30 minutes. During this time, measurements of buttock pressure, sacrum blood flow and temperature were recorded. Finally, the subject returned to a prone position to re-measure heel temperature.
- (4) A 15 minutes cool-down period was used to ensure participants returned to baseline conditions. During this time, the rater swapped the mattress and recalibrated the pressure sensors.
- (5) Repeat Step 3.

Data analysis

All recorded raw data were screened and filtered using a custom-designed Matlab program. The mean contact pressure, blood flow and temperature for each minute were calculated.

Laser Doppler signals from the subcutaneous tissue were recorded in terms of BPU (Blood Perfusion Units), which are intrinsically relative as an arbitrary unit (AU). Although such measurements are proportional to flow, the factor of proportionality will be different for different tissues [11]. Because each subject showed individual variations in blood flow, the relative change from the base line measurement for each participant was used to evaluate the impact of the mattress [12].

Relative contact pressure, blood flow and temperature results were calculated by subtracting each measurement at 30 min from the participant's respective measurement at 1 min. Next, all measurement were processed at 3-minute intervals for the 30-minute period to result in 10 measurement instances, with the first 3minute interval serving as the baseline. The relative change percentage (% \triangle) was calculated as follows: [measurement at last 3-minute interval – measurement at baseline)/measurement at baseline]×100.

A paired two-tailed T-test was performed to reveal the relative differences in the buttock pressure, subcutaneous blood flow and temperature.

Experimental results

Interface pressure measurement

Table 2 shows the relative interface pressure change on the buttock over the entire measurement period. Though the new passive mattress had a higher interface pressure, the relative interface pressure change showed a minor decrease. We can see that relative interface pressure difference increased significantly over time (Table 2). The relative change percentage was -0.7%. In comparison with the standard mattress, the relative change percentage was 12% (Fig. 7).

	1 min	30 min	Relative	Р
			Difference	value
New	31.51	31.17	-0.33	0.25
mattress	(5.22)	(4.49)	(1.58)	
Standard	21.73	24.34	2.61	0.0001*
mattress	(2.44)	(2.71)	(1.11)	

pair t test: * p<0.05; Unit: mmHg

Table 2. Relative pressure change of buttock measurement

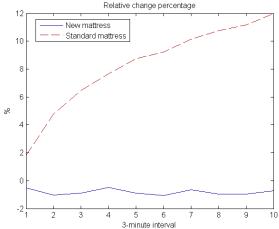


Figure 7. Relative pressure change percentage

Subcutaneous blood flow measurement

Table 3 shows the relative subcutaneous blood flow change under the sacrum over the entire measurement period. With the new passive mattress, blood flow perfusion increased over time. However, the relative blood flow change in both mattresses was not significant. The relative change percentage in the new mattress (18.78%) was higher than that in the standard mattress (2.32%) (Fig. 8). Figure 9 presents a multiple line plot for each participant for the two mattresses.

	1 min	30 min	Relative	P
			Difference	value
New	26.22	29.79	3.58	0.12
mattress	(8.92)	(15.36)	(12.12)	
Standard	29.27	28.32	-0.95	0.74
mattress	(9.69)	(16.67)	(15.69)	

pair t test: * p<0.05; Unit: AU

Table 3. Relative blood flow change of sacral measurement

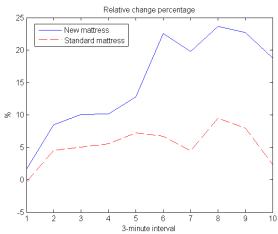


Figure 8. Relative blood flow change percentage

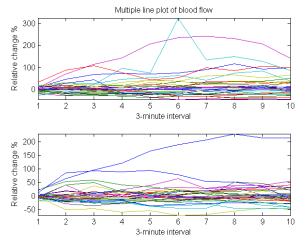


Figure 9. Multiple line plot for each participant using the new mattress (top) and the standard mattress (bottom)

Skin temperature measurement

Table 4 shows the relative temperature change on

sacral skin over the entire measurement period. Relative skin temperature change in both mattresses increased significantly over time. The relative change percentage was 7%.

	1 min	30 min	Relative	Р
			Difference	value
New	32.77	35.19	2.42	0.0001*
Mattress	(0.95)	(0.67)	(0.55)	
Standard	32.91	35.28	2.37	0.0001*
Mattress	(0.97)	(0.67)	(0.49)	

pair t test: * p<0.05; Unit: °C

Table 4. Relative sacral temperature change

Discussion

The Japanese Society of Pressure Ulcers suggests a threshold of 32 mmHg/cm² average body pressure value for all medical mattresses [8]. Both mattresses used in this study satisfied the threshold. The standard hospital mattress used two layers of polyurethane-based foam material, with a softer upper layer and a firmer bottom layer. Although the interface pressure in the standard mattress was less than that in the new passive mattress, the standard mattress exhibited an increase in relative pressure over time. Previous studies have found that polyurethane-based foams are subject to deformation depending upon the loading, time, and temperature [6, 13]. Using ergonomic measures and Kansei engineering evaluation, Nagamachi et al. claimed the high rebound mattress was superior to soft mattresses, with the former providing more even body support and more comfortable bed rest. They found the latter made it hard for patients to roll over on the bed and contributed to the onset of PU [8]. Our results are consistent with previous findings regarding pressure measurements of polyurethane-based foam mattress. The weak support mechanism of standard mattresses causes the relative pressure to increase over time, while the new passive mattress exhibited no increase in interface pressure, had a better support mechanism and allowed the body to move smoothly.

The tissue ischemia induced by applied external pressure is the primary aetiology of PU. Subcutaneous microcirculation can be assessed by quantifying changes in skin blood flow response to a variety pressure load [14]. The new passive mattress was found to increase relative sacral blood flow, possibly due to two vasodilatory mechanisms (pressure-induced vasodilation (PIV) and reactive hyperemia) [12, 15]. PIV reflected the phenomenon in which skin blood flow increased in a certain range of locally applied pressure. Responding to interface pressure and maintaining constant vascular tone, skin blood vessels had to compensate through

vasodilatation. Compared with PIV, reactive hyperemia exhibited an increase in blood flow after the removal of externally applied pressure. The array of the mushroomshaped supports on the new passive mattress allowed for smooth body movement. Combined with the grooved design, it facilitated forming dynamic pressure loading in weight-bearing tissues and enhancing skin perfusion. On the other hand, the standard mattress exhibited a smaller relative blood flow change. In [8], the lower rebound of a soft mattress also showed little blood flow change. Our results are consistent with previous findings.

Environmental heat and moisture also contribute to the onset of PU. While we hypothesized that the grooved design around the mushroom supports could facilitate air ventilation, the new passive mattress did not show any advantage in terms of cooling skin temperature. Relative skin temperature change was found to increase 2.4 °C in both mattresses. Lying supine on the mattress was found to raise skin temperature by 2-3 °C, approaching the body's core temperature [16]. In our experimental protocol, both mattresses were covered with an identical standard mattress cover. We hypothesize the limited breathability of the mattress cover and increased sacral skin temperature most likely resulted from heat accumulation between the subject and the mattress cover. In Figliola's study, low air loss mattress was found to provide a continuous flow of air across the surface of the mattress, thus preventing moisture build-up on the skin [17]. Using the available air flow groove, low air loss design can be easily integrated into the modified mattress design to improve air flow circulation. However, the effectiveness of active "low air loss" design in the new mattress needs be investigated further.

Limitations

Given limitations in measuring depth and reliability problems of available LDF measuring techniques, the measuring depth of the microcirculation perfusion was likely to be in the range 1.0-1.5 mm under the sacrum skin site only. Although the effectiveness of the new passive mattress was evaluated using objective FE simulation and empirical experiments, methods to investigate the subject's subjective evaluation (e.g. Visual Analog Scale or Kansei engineering process) were not applied in this study. In addition, additional experiments are needed to verify the practical effectiveness of the new mattress in preventing PU in the future.

Conclusion

This study evaluated the potential of a new passive mattress in preventing PU. The shape of mattress support surface was determined by using FE analysis. Empirical experiments found the mattresses' mushroom-shaped support structure maintained an even body pressure distribution. The new mattress was found to outperform standard hospital mattresses in terms of promoting subcutaneous blood flow. Improved breathability of the mattress cover is needed to strengthen the grooved geometrical structure. In addition, the mattress evaluation platform developed in this study can allow technicians to automatically measure physiological signals and properly adjust mattress properties in response to measured data. This would be particularly convenient for users who may not be experts in FEM for mattress design.

Many commercial dynamic mattresses exist to prevent the onset of PU. But the high cost of such mattresses raises the need for developing a new costeffective mattress given rapidly aging societies. The findings of this study suggest the new passive mattress can provide an economical solution to preventing PU.

Acknowledgments

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