**Exploring the impact of a new clinical mattress solution on interface pressure and comfort when lying.**

**Short title: Are you lying comfortably?**

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**Conflicts of interest**

The authors have no conflicts of interest. This is an independent research study; however all mattresses were provided by Levitex Foams, UK.

**ABSTRACT**

**Objective:** Effective pressure management for patients is critical for hospital and community-based care, to prevent the occurrence of pressure ulcers. This study explores the impact of a new mattress and topper solution on interface pressure and comfort in lying.

**Methods:** In this quantitative, healthy cohort study, patient-surface interface pressures were calculated for three mattresses (Standard hospital, new solution, Air)with and without an innovative topper solution (Levitex foams, UK). Subjective comfort, surface area, peak and mean pressure and peak pressure index (head, sacrum, heels) were calculated for all conditions for a 20-minute period.

**Results:** 27 healthy volunteers took part in this study. The new mattress solution decreased peak pressure significantly compared to hospital and air mattresses. Lower peak pressures were seen for the hospital compared to air mattress. The new mattress solution improved comfort and significantly lowered (>30%) heel and head pressure compared to other surfaces. Both hospital and air mattresses significantly reduced pressure and improved comfort with the addition of the new topper solution.

**Conclusion:** This new mattress solution offers a potentially improved pressure management solution for patients. Implementation of the topper may also prove to be an improved solution when used with existing standard or air flow mattresses.

**Key words:** mattress, pressure ulcer, prevention, sleep surface, tissue health,

**Key Messages:**

* A new mattress or topper solution has the potential to improve pressure management for patients.
* The new mattress solution decreased peak pressure significantly compared to hospital and air mattresses.
* Air mattresses do not necessarily reduce peak pressure index compared to standard solutions.
* Addition of a new alternative topper may help to reduce pressure and subsequently pressure ulcer incidence on hospital and air mattresses.

**INTRODUCTION**

A pressure ulcer is defined as a localised injury to the skin or underlying tissue, occurring due to pressure, or pressure in combination with shear and usually over a bony prominence. 1 Pressure ulcers are a common, expensive, and physically debilitating health complication, affecting people in both acute care and the community. Any patient can develop a pressure ulcer, however they are more likely to occur in people who are seriously ill, have a neurological condition, reduced sensation, limited mobility, nutritional deficiency, an inability to reposition themselves or significant cognitive impairment. 2-4 Bony prominences, such as the sacrum, elbows and heels are common sites for pressure ulcers. The development of a pressure ulcer can impact an individual’s rehabilitation process, leading to extended hospital stays. In 2017-18 the United Kingdom National Health Service (NHS) safety thermometer5 recorded 18,789 incidents of pressure ulcer development despite extensive preventative programmes and initiatives. The economic burden of pressure related wounds on the NHS UK currently stands at £5 billion annually.6

Evidence based guidelines for the treatment and prevention of pressure ulcers give detailed guidance when caring for people in bed.7 This focuses on regular posture change and consideration of support surfaces including pressure reducing mattresses and overlays, recommending an individualised risk assessment to meet specific needs.1 The evidence suggests that high pressures for a short time are just as damaging as low pressures over a long time. Guidance from the National Institute for Health and Care Excellence 2 is similar encouraging regular risk assessment, positional changes and use of pressure reducing mattresses and overlays.

There are over 200 pressure redistributing devices on the market for people with reduced mobility who are often confined to their chairs or beds.3,4,8 “Low tech” devices are commonly mattresses or overlays and can be gel-filled or contain air pockets, memory foam, or flotation type cells or indeed, a combination of these.9 “High tech” devices are available for the at-risk bed fast patient and include dynamic systems of alternating pressure mattresses(APM), constant low pressure (CLP) or rolling systems to constantly redistribute the patients’ weight, therefore reducing peak pressure areas.2 A Cochrane systematic review 10 identified that a “low tech” mattress type of High Specification Foam (HSF) demonstrated an overall risk reduction of 60% when compared with “standard” hospital foam. The same systematic review found no evidence of a difference in the relative risk of developing a PU between a range of “high tech” interventions including APM, CLP and HSF when carrying out a meta-analysis. Provision of this specialist “high tech” equipment within health and social care is costly and despite the lack of evidence, APM’s are in common use. Feedback from the Pressure Ulcer Research Service User Network suggests that some patients do not like the APM’s due to pump noise, and the soft air cells impacting sleep, restricting movement and reducing the ability to self-reposition, therefore increasing the care burden. 11 A further extensive randomised control trial by Nixon and colleagues12 went on to demonstrate no differences in the safety profile of APM’s and HSF but highlighted the fact that more patients requested a change from APM due to comfort or to assist with repositioning on the bed.

Research is therefore needed to evaluate the effect that any innovations in pressure relieving systems may have on redistribution of pressure, comfort and positioning to provide a robust evidence base prior to provision.4 This study explores the efficacy of a new clinical mattress solution on pressure relief and comfort when compared to existing clinical solutions in healthy individuals..

**METHOD**

**Participants**

All volunteers to the study were screened to ensure they met the eligibility criteria. All were adults who were able to transfer on and off a bed independently without an existing PU or any condition that prevented them from lying flat for 21 minutes without a break. All participants were within weight restrictions for the beds and able to give informed consent to participate.

All data collection conformed to the declaration of Helsinki and data protection principles (GDPR), volunteers gave written informed consent prior to participation. Full ethical approval was granted by the University Ethics Committee (**HSR1718-001**). A convenience sample of individuals was recruited through staff and students of the University and through the snowballing effects of the study.

**Procedure**

This study was a within subject comparative design, exploring the effect of lying surface on interface pressures and subjective comfort

Each participant attended data collection sessions at the University. Total time for data collection on the three different surface iterations was approximately 1.5 hours including completion of the qualitative questionnaires in between each surface session. Data collection in each condition was 21 minutes in total, allowing for a 6 minute “settling time”. Interface pressure readings were collected at the key pressure points of heels, sacrum, and occiput on each mattress surface and recorded in the X-sensor software (<http://www.sumed.co.uk>). The sensor mat was linked to X-sensor PRO v6.0 software from SUMED International, has excellent calibration stability leading to consistent data collection with high reliability particularly where high repeatability and minimal creep characteristics are important.13 The materials used and the method of assembly creates a robust, pliable and conformable sensor pad which minimises any distortion of the true interface pressure. The mat was flexible, with a 61 cm x 183 cm sensing area, 12.7mm resolution, 6,912 sensing points, and 5-50 mmHg & 10-200 mmHg pressure ranges (Sumed, UK), with an accuracy rate of ±10% of the calibrated values.14 The mat was used to measure: Surface area of the body in contact with the mattress surface (in cm2), Mean interface pressure across total body contact area (in mmHg) and peak pressure index (PPI) in specific regions of interest including the heels, sacral region (lower back) and head (in mmHg). These specific areas of interest are common areas for PU development when lying supine, with the sacrum and heels being identified as most vulnerable sites with prevalence rates of PU’s varying between 34.8% and 51.7% for the sacrum and between 26.7% and 38.4% for the heels.15

Data were recorded as colour coded maps of pressure distribution as well as specific peak pressure and mean pressure readings given at specific timed stages, recorded in mmHg (See Figure 1). It has been argued that X-sensor appears to be a gold standard technology16 for pressure mapping in humans. Manufacturer product literature outlines performance characteristics, including precision and reliability. Manufacturer calibration and quality control data, prior to sales, confirm a high level of precision and reliability.

The conditions for this study were: (a) Mattress Surface 1: *Hospital Mattress* (200cm x 88cm x 15cm; Invacare Essential basic profiling mattress, UK) (b) Mattress Surface 2: *A* unique formulation, polyurethane foam mattress (190cm x 90cm x 20cm; Levitex foams Ltd, UK) (c) Mattress Surface 3: *Air Mattress* (200cm x 88cm x 15cm; Drive Devilbiss, Simple Air dynamic mattress, UK). All surfaces were also tested with a 5cm unique formulation, polyurethane foam mattress topper layer (Levitex Foams Ltd, UK).

**Data Analysis**

Pressure data recorded in mmHg stored in the X-sensor pressure system and transferred to secure laptops to allow analysis using the X-sensor advanced software technology. Data was merged using the average peak pressures for all 900 frames, then regions of interest were placed around the heels, the sacrum and the head to calculate peak pressure index (PPI) of each region. The entire activated area was also compared to explore impact of mattresses on overall contact surface area. A numerical rating scale (0-10: where 0 = Extremely uncomfortable and 10 = Extremely comfortable) was used to assess the comfort of each clinical sleep surface, combined with a General comfort/discomfort questionnaire adapted from previous work. 17

Results for all data were analysed using SPSS v.28 for Windows (IBM Corp., USA). A 3 (Mattress Surfaces) x 2 (Topper/No Topper) ANOVA was run to explore the differences between conditions followed by post hoc pairwise comparisons with Bonferroni correction (significance level α = 0.05). Violations of Mauchly’s sphericity assumption were accounted for using the Greenhouse-Geiser correction where required, to avoid a type one error. Significant interactions between Mattress and topper were further explored using a paired sample t-test for each surface with and without the topper (significance level α = 0.05).

**RESULTS**

A total of 27 healthy participants (24 females, 3 males; mean age: 30.1±7.4 years; mean height: 164.6±7.6cm; mean weight 77±22.2kg; Mean Body Mass Index: 28.2±6.8 kg/m2), were included in this study. Mean data for all measures in each condition are reported in Table 1.

**Surface Contact Area**

A significant difference was seen between the mattress conditions for surface area (p<0.001) and topper conditions (p=0.001). Average surface contact area was significantly higher in both Surface 2 and 3, compared to surface 1 (Table 1 and 2). No significant difference was seen in surface contact area between surface 2 and 3. A significant difference was also noted between the topper conditions (p=0.001), with the addition of a mattress topper significantly increasing surface contact area for all mattresses.

**Mean Pressure**

No significant difference was seen between mattresses for overall mean pressure (Table 1 and 2). However, addition of the topper led to a significant decrease in mean pressure for both surface 1 and 3 (Table 3), with surface 3 showing the decrease in mean pressure. No significant difference was seen for surface 2 with and without the mattress topper.

**Peak Pressure**

Peak pressure was significantly different between mattress conditions (p<0.001). Participants showed significantly lower peak pressure on surface 2 compared to both surface 1 (p=0.031) and 3 (p<0.001). Peak pressures were approximately 3 times higher on surface 3 compared to Surface 2 and almost 50% higher on surface 1 compare to surface 2 (Table 1). In addition, significant differences were noted between surface 1 and 3 (p<0.001) with peak pressures over twice as high on surface 3.

Addition of a topper to the three surfaces created significantly different responses. Surface 1 and 3 showed a significant decrease in peak pressure (Table 1-3) with the inclusion of a topper. In contrast, peak pressure increased significantly with the addition of a topper to Surface 2 (p=0.015).

**Peak Pressure Index (PPI)**

PPI at the head, showed a significant difference between mattresses (p=0.002). Whilst no significant difference was seen between surface 1 and 2 (p=0.217), there was a significantly lower PPI (14%🡫) noted at the head on surface 2 compared to surface 3 (p=0.005). Addition of a topper did not significantly change PPI at the head.

At the sacral region, PPI was not significantly different between the mattress conditions (p=0.20). The addition of the topper significantly decreased the sacral PPI for surface 3 (>29%🡫), however no significant change was seen when a topper was added to surface 1 and 2.

At both the right and left heels, a significant difference was seen between mattresses (p<0.001). Surface 2, showed a significantly lower PPI at the heels compared to surface 1 and 3 (>30%🡫; Table 1 and 2). Surface 1 also showed a significantly lower (>20%🡫) heel PPI compared to surface 3. The addition of the topper significantly reduced the PPI at the heels on surface 1 (>30%🡫) and 3(>40%🡫) but not on surface 2.

**Subjective Comfort**

A significant difference was seen between the 3 mattress conditions and between topper conditions (Table 1 and 2). Surface 2 showed a significantly higher comfort rating than that of both surface 1 and 3 by over 2.5 points. No significant difference was seen between surface 1 and 3.

There was a significant difference between topper and no topper conditions (p=0.002). Results indicated that the comfort score for both surface 1 (1.9 point 🡩) and 3 (1.4 point 🡩) improved significantly (p<0.03) with the topper. Surface 2 did not show any significant improvement with the addition of a topper of the same material.

**DISCUSSION**

This study explored the impact of a new hospital mattress and topper solution on interface pressure and comfort when lying.

The overall average surface contact area was recorded as being significantly higher in both the new mattress solution and the air mattress when compared to a commonly used mattress used in acute hospital environments. Air mattresses are a “high tech” mattress,2 specifically designed to redistribute pressure for the “high risk” patient and these surface area results would support the fact that weight is distributed over a larger surface area using the air-filled tube design. Subjective comfort scores indicated a correlation with increasing surface area comfort scores when comparing the new mattress with an air mattress (p=0.001), despite both these mattresses increasing the surface area when compared to the standard hospital mattress. Despite air mattresses being an expensive tool used for the more “at risk” patient the mean comfort score for this mattress was the lowest of all surfaces, supporting previous findings12 that reported patients often requested a change from the air mattress due to discomfort. Whilst this brings in to question the cost utility of an air mattress, more pertinent to the clinical environment, is the patient’s ability to gain comfortable sleep and promote healing and recovery.

The addition of the topper demonstrated a significant increase in surface area for all mattresses, again this is reflected in higher comfort scores with the addition of the topper. The topper increased comfort on both the hospital and the air mattress significantly, suggesting it may be a potential solution to the improve comfort without compromising pressure redistribution.

The mean pressures recorded across the whole contact area were not significantly different. However, with the addition of the topper, mean pressure led to a significant decrease in mean pressure for both mattresses used in the acute setting. The significant reduction in mean pressure when adding the topper to an air mattress, reducing from 23.26mmHg (highest mean score recorded of the 3 mattresses) to 16.7mmHg is supported by a significant increase in the subjective comfort score. The new foam mattress mean pressures were not impacted by the addition of the topper, suggesting perhaps that the foam mattress alone was sufficient or an optimum depth.

The International Best Practice Guidelines for pressure mapping,18 define PPI as the pressure average value calculated within a 10cm2 area (i.e. the approximate contact area of the ischial tuberosity) around the highest recorded peak pressure values. Although this study reports significant differences in the peak pressure between all three mattresses, previous work19 studied reliable metrics for interface pressure mapping, identifying non-repeatability of single peak measures. The result was that researchers recommended the use of Peak Pressure Index as a more reliable metric.

A standardised pillow (Levitex, UK) was used on each mattress surface to reduce variables but also to explore the perceived comfort of the pillow when used in combination with a range of base mattresses. Despite this standardisation, PPI at the head, showed a significant difference between mattresses. The new mattress showed the lowest PPI at the head in contrast to the hospital and air mattresses. Additional subjective perceptions of comfort and positioning of the head and neck appeared to support that the pillow used in this study was perceived as more comfortable when used on a firmer surface (i.e. hospital and new mattresses). These findings are limited and require further investigation over longer periods of time and with a range of people to allow them to reposition throughout the period of data collection and be flexible to apply to side sleepers as well as back sleepers. With the increasing burden of pressure ulcers globally,3 to reduce incidence, there is a need to give consideration to resting patient positioning and the support afforded by lying surfaces.4

The sacral region is a very common site for the development of pressure ulcers for the less mobile person who spends a lot of time in bed.7 However exploration of the sacral PPI did not identify any significant differences between the mattress conditions, although the highest mean PPI was recorded on the air mattress. Addition of the topper significantly decreased the sacral PPI this surface, significantly increasing comfort. Clinical implications of introducing a topper when using such a high tech/high-cost mattress following reports of discomfort would improve a patient’s comfort, facilitating better sleep without “stepping down” onto a low tech mattress and associated increased pressure ulcer risk.12 In contrast to the air mattressand the standard hospital no significant changes were seen when a topper was added to the new foam mattresses.

Additional common sites for discomfort and subsequent pressure ulcer development are the heels with numerous strategies applied in nursing and hospital environments to “off load” pressure from the heels using inflatable devices, intermittent pneumatic pressure cuffs and airflow systems.8 At both the right and left heels, a significant difference was seen between mattresses, with the new surface, affording lower PPI at the heels compared to the standard and air mattresses. Again, the standard hospital mattress also showed a significantly lower heel PPI compared to the air mattress, calling into question the true pressure redistribution benefits these mattresses may provide. The addition of the topper significantly reduced the PPI at the heels on both the hospital (>30%🡫) and air mattress (>40%🡫). These findings suggest that the provision of a low-tech foam topper over the hospital mattress may be a simple and relatively inexpensive recommendation to reduce risk and increase comfort and bed mobility for an individual in an acute hospital setting. The application of the topper over an existing mattress may also be a low cost, low waste clinical recommendation to reduce pressure risk when a patient is transferre within the community or care home setting. In addition, the provision of the topper on an airflow system may significantly reduce the risk of heel pressure ulcers whilst increasing comfort promoting better sleep and the potential for improved recovery and rehabilitation for anyone within hospital or rehabilitation environment. It is acknowledged that further work is required to truly explore the potential wider clinical benefits of pressure redistribution and patient benefit to healing, pressure ulcer prevention and comfort. Whilst the present study did not note any change in skin temperature, it is possible that in a clinical setting patient sweat and moisture may be factors requiring further exploration. Future laboratory and long term clinical studies may wish to also consider moisture in clinical settings through patient sweat as this can also lead to additional issues.

**CONCLUSION**

This new mattress solution offers a potentially improved pressure management solution for patients. Implementation of the topper may also prove to be an improved solution when used with existing standard or air flow mattresses.

The evidence presented from the analysis of the interface pressure data provides a sufficient evidence base to categorise the innovative foam mattress and topper as a “low tech” pressure redistributing surface that should be considered when providing an alternative mattress surface to any individual with limited mobility or who needs assistance to move on the bed and may be considered at risk of pressure ulcer development. Given the identified advantages of the new foam mattress and topper, it is apparent that this new foam mattress provides improved redistribution of pressure, whilst increasing comfort. As a low-tech alternative to expensive, high maintenance pressure redistribution systems used within health and social care, the new mattress solution may offer an alternative to improve health and well-being for patients within community and acute care environments.

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**Figure 1**

Pressure mapping system (XSensor, Sumed, UK) in situ over Mattress 1 (Hospital mattress)



**Table 1:**  **All Mean (standard deviation) data for surface area, pressure and comfort.**

|  |  |  |
| --- | --- | --- |
|  | Mattress | Mattress + topper |
| Surface 1 | Surface 2 | Surface 3 | Surface 1 +topper | Surface 2 +topper | Surface 3 +topper |
| Average Surface Contact Area (cm2) | 3561.24 (917.9)A | 4178.33(1005.96) A | 4306.28(1055.81) A | 3925.09(782.58)B | 4487.90(1289.57) B | 4470.96(1093.66) B |
| MeanPressure (mmHg) | 22.69(3.45) | 21.63(3.06) | 23.26(2.73) | 20.87(3.11) B,C | 20.48(3.59) B,C | 16.70(2.06) B,C |
| Peak pressure (mmHg ) | 73.40(16.55) A | 49.56(7.62) A | 156.91(55.72) A | 52.09(10.17) B,C | 58.80(13.04) B,C | 82.79(29.23) B,C |
| Head PPI(mmHg ) | 33.37 (5.2) A | 31.80(5.7) A | 36.19(6.9) A | 34.88(6.0) | 32.19(5.3) | 36.51(6.9) |
| Sacrum PPI(mmHg) | 36.77 (8.1) | 40.84(6.34) | 43.84 (13.29) | 35.51 (4.60) B,C | 38.96 (8.44) B,C | 33.69(9.16) B,C |
| Right heel PPI (mmHg) | 45.67 (17.11) A | 26.79(7.14) A | 55.62 (22.87) A | 28.87 (8.10) B,C | 29.73 (10.89) B,C | 35.62(9.67) B,C |
| Left heel PPI(mmHg) | 43.30 (15.6) A | 26.83(9.07) A | 58.29 (10.08) A | 28.04 (8.39) B,C | 27.95 (9.46) B,C | 34.50(10.08) B,C |
| Comfort score(0-10) | 5.96 (1.99) A | 8.46(1.14) A | 5.50(2.55) A | 7.85(1.44) B,C | 8.00(1.67) B,C | 6.96(2.66) B,C |

ASignificant effect between mattresses, BSignficant effect between topper condition, cMattress\*Topper interaction

**Table 2: Pairwise comparisons data for all outcome measures**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Contact Surface Area | Mean Pressure | Peak Pressure | HeadPPI | SacrumPPI | Right HeelPPI | Left HeelPPI | Comfort Score(0-10) |
| Mattress 1 vs Mattress 2 | 0.001\* | 1.000 | 0.031\* | 0.217 | 0.125 | 0.002\* | 0.005\* | 0.003\* |
| Mattress 1 vs Mattress 3 | 0.000\* | 0.106 | 0.000\* | 0.173 | 0.897 | 0.021\* | 0.048\* | 0.123 |
| Mattress 2 vs Mattress 3 | 1.000 | 0.372 | 0.000\* | 0.005\* | 1.000 | 0.000\* | 0.001\* | 0.001\* |
| No topper vsTopper | 0.001\* | 0.000\* | 0.000\* | 0.354 | 0.000\* | 0.000\* | 0.000\* | 0.002\* |

\* significant difference P<0.05

**Table 3: T-test data Mean and (Standard deviation) for Mattress topper interaction**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Mean Pressure | Peak Pressure | Sacrum | Right Heel | Left Heel | Comfort Score |
| Surface 1 vsSurface 1 + Topper | 2.28 (2.80)\* | 28.16(37.44)\* | 1.91(8.66) | 15.36 (18.37)\* | 14.40 (16.29)\* | -1.648(1.99)\* |
| Surface 2 vsSurface 2 + Topper | 0.60(3.81) | -7.17(13.32)\* | 0.75(6.58) | -1.81 (11.03) | -0.33 (12.44) | 0.577(1.63) |
| Surface 3 vsSurface 3 + Topper | 6.56(1.61)\* | 69.85(50.25)\* | 10.14(8.52)\* | 21.47 (20.46)\* | 25.03 (25.80)\* | -1.40(2.89)\* |

\* significant difference P<0.05

---------------------This is the author’s accepted version----------------------