



A Comparison of Hybrid and Crossover Airflow Mattresses

An Independent Report

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LITERATURE REVIEW

Pressure Ulcers

Pressure ulcers are areas of localised damage to the skin and underlying tissue caused by pressure, friction or shear (McInnes, et al., 2015). The formation of pressure ulcers remain a problem within acute care settings, with approximately 57-60% of all pressure ulcers occurring within hospitals (Shahin, et al., 2009). From this, 13% of those are patients in intensive care units (ICUs), (Shahin, et al., 2009) and have been deemed the most vulnerable to develop hospital-associated pressure ulcers (HAPUs) (Behrendt, et al., 2014). More specifically, the lower extremities of ICU patients are particularly at high risk of developing pressure ulcers (Burdette-Taylor & Kass, 2002).

Problem with Pressure Ulcers

Pressure ulcers, also known as bedsores, pressure sores/injuries and decubitus ulcers, have a detrimental effect on health status, health care costs and quality of life (Qaseem, et al., 2015). The treatment of pressure ulcers is essential in order to promote healing and avoid complications but often a multidisciplinary approach with nurses, physicians and other members of a care team are required (Qaseem, et al., 2015). The cost associated with treating pressure ulcers varies in the UK from grade 1 at £1,064 to grade 4 at £10,551; totalling an estimated 1.4-2.1 billion annual expenditure for the NHS for ulcer treatment alone (McInnes, et al., 2015). This expense is emphasised with pressure ulcers being described as the most physically debilitating and costly complications in the 20th Century (Shahin, et al., 2009). The complications can include higher hospital-expenses, increased duration of stay, risk of developing osteomyelitis, sepsis or multi-organ failure, higher amputation rate and mortality rate (Burdette-Taylor & Kass, 2002).

Typically, the ulcers develop over bony prominences (Masterson & Younger, 2014), due to prolonged pressure over a small contact area with high local pressures and restricted blood flow (Burdette-Taylor & Kass, 2002). Hospital-acquired pressure ulcers at the sacrum and heel are the most common type of pressure-related ulcers, along with the ischium (Shahin, et al., 2009).

Heel Pressure Ulcers

The heel has been reported to account for 25-30% of all pressure ulcers (McGinnis, et al., 2014). Due to the heel's unique anatomical structure, it is at high risk of ulceration due to the limited surface area, lack of supporting large muscles to further minimise the pressure and the thin layer of tissues overlaying the calcaneus (Masterson & Younger, 2014). Further to this, the fat pad between connective tissue is believed to be almost avascular (Cichowitz, et al., 2009).

Patients with diabetes, oedema or arterial disease are at particular risk of heel pressure ulceration due to peripheral neuropathy, essentially resulting in continued pressure and trauma to the area because of the loss of protective sensation (Masterson & Younger, 2014).

Interventions

The European and US National Pressure Ulcer Advisory panels (EPUAP and NPUAP) have previously advised that pressure ulcers at the heel could be prevented by avoiding contact with the mattress (McGinnis, et al., 2014). However, this is not always a suitable option **Support Surfaces**

Disclaimer: This final independent report recognises the agreement established in the contract between Select Medical Limited and the University of Central Lancashire (Allied Health Research Unit). This report discusses all the main outcome measures of this study including all data and meets the full contractual obligation between the parties.



Support Surfaces

Healthcare professionals often use a variety of support surfaces in order to reduce either the magnitude or duration of the interface pressure and essentially prevent or treat pressure ulcers (McInnes, et al., 2015). These interventions vary financially from over £30,000 for bed replacements, to less than £100 for some foam overlays. Constant low-pressure (CLP) surfaces (foams, water, air and elastomeric mattresses) are commonly used as interventions.

Regular repositioning of the patient is also another common and effective strategy to prevent the formation of pressure ulcers (Behrendt, et al., 2014). Although it is unclear which repositioning regime is the most successful, it is usually most effective when used in conjunction with a CLP surface (Behrendt, et al., 2014).

CLP surfaces, which mould around the individual's body as a mechanism to distribute the pressure over a larger area can be described as "low-tech" CLP devices (McInnes, et al., 2015). Air-fluidised beds, low-air-loss beds and alternating-pressure devices, are classed as "high-tech" CLP devices (McInnes, et al., 2015).

Standard hospital mattresses have been found to be inferior in the prevention of pressure ulcers in comparison to a range of CLP surfaces such as foam based, low-pressure mattresses/overlays and higher-specification devices. ICU patients are regularly provided a continuous low-pressure air mattress (CLPAMs) or alternating-pressure mattress (APMs) (Masterson & Younger, 2014). However there are currently conflicting views on the effectiveness of APMs, so the National Institute of Health and Care Excellence (NICE) in 2014 called for more independent research to confirm the overall efficacy and effectiveness in comparison to high-specification foam mattresses (Masterson & Younger, 2014).

Current Solutions

A particularly advanced product, the Nimbus 4, provides active pressure redistribution via a 'figure 8' air-filled cells system; where 1 cell in 2 alternately inflate and deflate so that during the deflation cycle tissue reperfusion is enabled (McGinnis, et al., 2014). More specifically to the heel pressures, five cells with Wound Valve Technology are located near the feet so that the heel can be completely offloaded from contacting the mattress by deflating these cells directly beneath the heel (McGinnis, et al., 2014). A study was carried out by Masterson & Younger (2014) to evaluate the Nimbus 4 at Chelsea and Westminster ICU during a 10-week period. The nurses were encouraged to use the Wound Valve Technology and the study reported zero pressure ulcers were developed during the course of the study when using the Nimbus 4 mattress system. Alternative solutions such as air filled, disposable foam or padded boots had found similar findings but conflicting findings have also been published, so it has been suggested that more in depth research is required to determine their effectiveness (McGinnis, et al., 2014). However, there are limitations to both solutions. It has been reported that the boots can be hot and uncomfortable for patients and awkward for skin assessments for nurses (Masterson & Younger, 2014). The Nimbus 4, special heel cells are only located in a specific place so the product does not account for any movement of the patient (Masterson & Younger, 2014).

Hybrid support surfaces, those that can act as a static surface mattress or an alternating pressure mattress, combine foam and air to maximise benefits of both mattress types. These mattresses should allow use with a broader range of patients (Fletcher et al., 2015). By offering pressure distribution and pressure relief, a hybrid mattress may be an effective intervention in patients at risk of ulceration (Fletcher et al., 2015).

Micro-movements

Pressure is defined as the force of an object on another over a set area. Movement is necessary in the redistribution of pressures on the body. As a person's size and weight cannot be immediately changed the overall pressure on the body cannot be changed. By altering the distribution of forces, the pressure can be reduced in one area and built up in another. An example of this is the build-up of pressure when sitting down on a chair; a person will naturally wriggle to relieve pressure in the area where they perceive a high force, and redistribute the pressure across the body. Alternating pressure mattresses do this in much the same way without the person moving by filling and emptying air cells within the mattress. However, a person will also make small postural adjustments (micro-movements) whilst lying down. By encouraging these micro-movements in areas of increased pressure or where this build up could be potentially harmful, would be beneficial to the patient by redistributing the forces. This would allow blood to return to an area and re-oxygenate the tissue where the blood supply may have temporarily been restricted due to the high pressure.

The FLEXI by Pure Air is a mattress designed for use by a range of individuals including those who are at very high risk of developing a pressure ulcer. It is a dynamic pressure redistribution mattress system targeting areas of the clinical care sector looking for a solution to prevent pressure ulcer development. Patient support is provided through a combination of air-cells containing foam of varying density across three different zones, head, torso and heel.

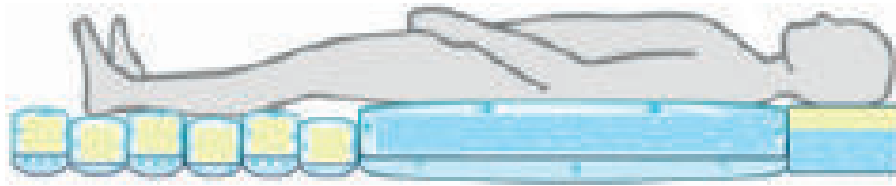


Figure 1: Diagram of three different regions of support in the FLEXI by Pure Air mattress (head, torso & heel).

AIMS

This study aimed to:

- Identify differences in buttock and heel pressure during long sitting between the FLEXI by Pure Air mattress and a market leading competitor
- Identify any differences in buttock micro-movements during long sitting between the FLEXI by Pure Air mattress and a market leading competitor
- Obtain subjective feedback relating to firmness and comfort of the FLEXI by Pure Air mattress compared to a market leading competitor.

METHOD

Participants

16 healthy participants aged between 18 and 55 were recruited for this study. Participants were recruited from within the University of Central Lancashire. Each participant was screened for any health issues that may be adversely affected by the testing and eligible participants then gave written consent to be part of the study.

Procedure

This study conformed to the Declaration of Helsinki and was approved by the University of Central Lancashire Research Ethics Committee (STEMH 720). This study took place in the Movement Analysis Laboratory at the University of Central Lancashire.

Each participant was randomly assigned an order of mattress to be used in the study. Participants were positioned on a bed in a long sitting position (Figure 2), with two pressure mats, (Conformat, Tekscan, MA, USA) (Figure 3) placed under their buttocks and heels. Participants were required to remain in this position for 20 minutes (approximately 2 of the mattresses inflation/deflation cycles).

Following each trial, the participant was asked to complete a series of short simple questions related to the mattress tested.

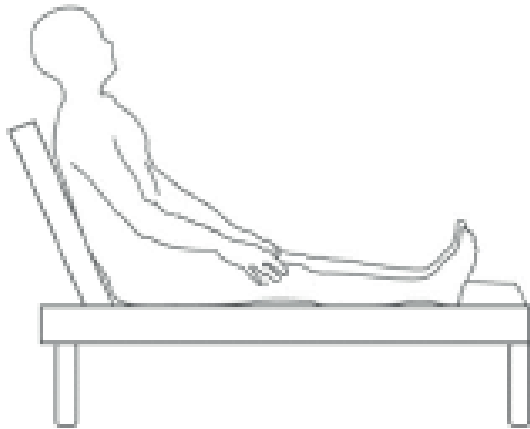


Figure 2: Long sitting position. Backrest at 60° and legs straight out in-front

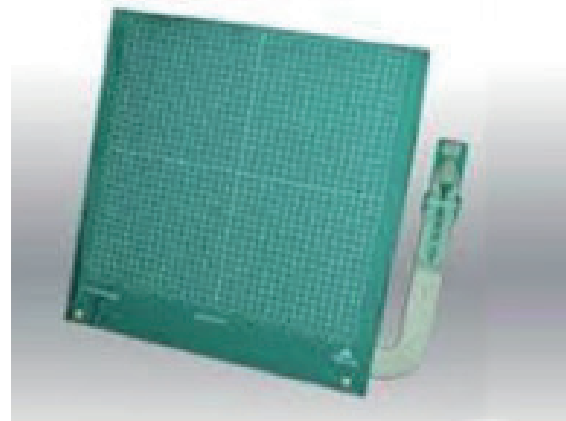


Figure 3: Pressure sensors to be placed on the bed beneath the buttocks and heels of participants

Data analysis

Peak contact pressure (KPa) and centre of pressure velocities data were exported and analysed in FScan Researcher (Version 7.0) (Tekscan, Boston, United States), EMGworks Analysis (Delsys Inc., Boston, USA) and Microsoft Excel (Microsoft Limited, Berkshire, UK).

Statistical analysis

All data was entered into IBM SPSS statistics 24 (IBM, New York, USA), pressure and time data was analysed using a repeated measures ANOVA and questionnaire data was analysed using a Friedman test.

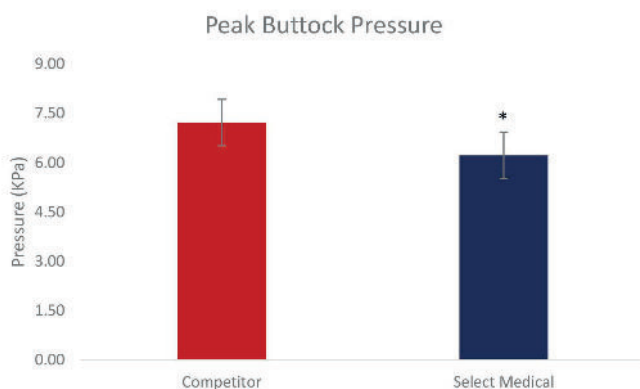


Figure 4: Mean peak pressure under the buttocks during long sitting. * denotes a significant difference ($p < 0.05$).

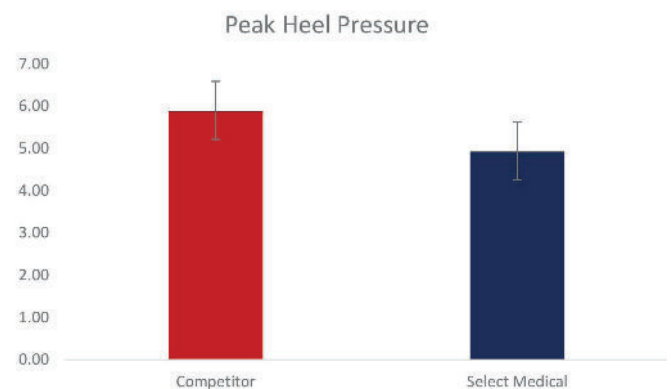


Figure 5: Mean peak pressure under the heels during long sitting

Figure 5 reports the mean peak heel pressure. The FLEXI by Pure Air mattress did produce an overall lower mean peak pressure, however this was not found to be statistically significant ($p > 0.05$).

Further analysis was performed investigating the median energy of the individuals in order to determine the micro-movements performed whilst sitting on each mattress. There was a 1.7% difference in the median frequencies of the energy observed. However, looking at the confidence interval of the results there was a trend to the FLEXI by Pure Air mattress. This may indicate that there were more micro-movements occurring when using the FLEXI by Pure Air mattress compared to the competitor.



Questionnaire Feedback

Participants were asked to rate their levels of comfort using a Numeric Rating Scale (NRS) in order to understand perceived levels of comfort and firmness of the two different mattresses. There was no significant difference ($P>0.05$) found between the perceived comfort of each mattress. When looking at the firmness of each mattress, although the FLEXI by Pure Air mattress is fully adjustable, it was set to a medium firmness as the competitor had only two firmness settings high and low. During testing, the competitor mattress was set to low. There was no significant difference ($P>0.05$) found between the perceived firmness of each mattress.

DISCUSSION

This study explored the differences between the FLEXI by Pure Air mattress and a market competitor by observing the mean peak pressures at the buttocks and the heel and the differences in micro-movements during long sitting.

It has been previously accepted that pressure between 30-35 mmHg can cause ischemia (Reswick & Rogers, 1976), a term used to describe inadequate blood supply to tissues, which can lead to ulceration or gangrene (Bradbury, et al., 2005). Further to this, pressure of 70mmHg applied for 2 hours, can cause dermal damage and pressure exceeding 80 mmHg could cause necrosis (Parish & Witkowski, 1994). Reswick & Rogers (1976) previously proposed that the projected area of support yields an average pressure of approximately 20 mmHg when lying face down and 50 mmHg when sitting (excluding the back). The pressure at the projected area of support that is produced when sitting is above the 30-35 mmHg 'ischemia pressure' and studies have shown that during sitting the tissue (subcutaneous adipose) covering the bony prominence of the ischial tuberosity becomes ischaemic (Thorfinn, 2009).

The Winnicare and competitor mattresses produced mean peak pressures of 6.22 kPa and 7.22kPa respectively. For the FLEXI by Pure Air mattress, this equates to a pressure of 46.65mmHg. This is above the pressure values suggested to cause ischemia but is below the point at which dermal damage may occur. Patients using these sorts of mattresses therefore should still be encouraged to move or if unable, regular repositioning would still be advisable. Whilst on the FLEXI by Pure Air mattress, there was a trend towards people producing more micro-movements.

The pressures seen at the heel were lower than those seen in the market competitor, but this was not found to be significant with the FLEXI by Pure Air mattress producing what equates to 36.9mmHg and thus falling just outside the accepted range to not cause ischemia.

The perceived comfort and firmness of the two mattresses did not significantly differ, though the FLEXI by Pure Air mattress does have the ability to adapt to individual preferences, with more settings rather than just a high and low setting.

The adjustability of the firmness in the mattress would allow for individuals to personalise this more but a further study would be recommended to look at any increases or decreases in pressure, especially around the buttocks where the highest pressures were seen.

Further research is required to investigate the potential impact of crossover mattresses on the user, which may be investigated through biomechanical testing and other qualitative methods.

SUMMARY

- The FLEXI by Pure Air mattress produced significantly lower pressure under the buttocks than the market competitor
- Both mattresses produced pressure lower than those needed to cause dermal damage when applied for 2 hours
- Winnicare produced lower pressures at the heel though these were not significantly different. The pressures seen at the heel were well below the dermal damage threshold in the literature but high enough to cause ischemia
- There was no significant difference in the median frequency of the energy involved in the micro-movements but there was a positive trend towards the FLEXI by Pure Air mattress that may indicate a slight increase in these movements
- There was no significant difference between the perceived comfort and firmness of the mattresses. However, the greater adjustability of the FLEXI by Pure Air mattress would allow individuals to change these to suit their own requirements.



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