A phantom-based method to assess X-ray table mattress interface pressures.

Nadi Alresheedi ¹ Lucy Anne Walton ¹ Andrew Tootell¹ Jo-Anne Webb ¹ Peter Hogg¹

¹ School of Health and Society, University of Salford, Salford M5 4WT, United Kingdom.

Corresponding author: **Nadi Alresheedi** L629 Allerton building University of Salford Salford M5 4WT n.alresheedi@edu.salford.ac.uk +447947355537

Abstract

Background

Pressure redistribution performance of X-ray table mattresses can influence the development of pressure ulcers in at risk populations. Interface pressure analysis, with human participants, is a common method to assess mattresses. This approach has limitations that relate to the lack of standardisation between and within humans.

Aim

To develop and validate an anthropomorphic phantom-based method to assess X-ray table mattress interface pressures as an index of mattress performance.

Methods

A phantom simulating an adult head, pelvis and heels, was 3D printed from X-ray Computed Tomography image data and attached to a metal frame 175cm in length. Dry sand was added to the phantom head, pelvis and heels to represent a range of human weights. Pressure distribution was assessed using XSensor. Phantom validation was achieved by comparing phantom mattress interface pressure characteristics, for 5 human equivalent weights, against 27 sets of human mattress interface pressure data.

Results

Using the correlation coefficient R, phantom and human pressure data showed good correlation for the five phantom weights (R values: head=0.993, pelvis=0.997 and heels= 0.996).

Conclusion

A novel method to test X-ray mattresses for interface pressure was developed and validated. The method could have utility in the testing of X-ray mattresses that are in routine use and for new mattress development. Phantom interface pressure data could be provided by manufacturers to help inform procurement decisions when matching mattress characteristics to medical imaging demands and the underlying patient populations.

Introduction

Pressure ulcers are injuries that occur on the subcutaneous layer of skin and its underlying tissues [1]. They are a common, costly and physically debilitating health complication, affecting people in acute care and the community. Anybody can develop a pressure ulcer. However, pressure ulcers are more likely to occur in people who are seriously ill, have a neurological condition, reduced sensation, limited mobility, nutritional deficiency, significant cognitive impairment and an inability to reposition themselves [2], [3]. Pressure ulcers often occur on skin that overlies bony prominences [4], with common sites including the sacrum, elbows, and heels. The development of a pressure ulcer can affect an individual's rehabilitation process, leading to extended hospital stays. The annual cost of treating pressure ulcers in the UK is estimated to be between £1.4 and £2.5 billion [5]. The UK Department of Health [6] proposed that pressure ulcers could be eliminated in 95% of NHS patients; DoH identified pressure ulcers as one of the four harms that should be monitored using the NHS Safety Thermometer [7].

A predisposing factor to pressure ulcer development is prolonged (>20 minutes) pressure imposed on the skin [8], the time it takes for X-ray procedures varies, a lower limb X-ray would typically take 10 mins, whilst an interventional procedure, for example peripheral angioplasty or stent insertion can take 2 hours or more. Consequently bed mattress and X-ray table mattress design can influence the development of pressure ulcers in at risk populations [9], [10]. Mattresses that are used in medical imaging departments are no different to those used on beds - X-ray table mattresses have also been identified to have the potential to contribute to the development of pressure ulcers and, importantly, this is an under-researched area [11]. It is worth noting that X-ray table mattresses have additional characteristics compared with beds - they are thinner, should not impose image artefacts and should not overly attenuate the radiation beam. X-ray table mattresses are typically 2.5 cm thick, in comparison a standard hospital bed mattress is around 20 cm thick and a bed with a memory foam topper around 30 cm thick. With the aim of minimising pressure ulcers in mind, these characteristics increase X-ray mattress design complexity.

Interface pressure measurement is the most common measure adopted in research and clinical practice to provide an indication of pressure ulcer risk with the assumption that higher interface pressures are associated with increased risk of pressure ulcers [12] [13] [14]. In clinical practice interface pressure is used to identify sites of higher interface pressure in order to ensure adequate off loading during repositioning to reduce pressure ulcer incidence. Several research studies have measured interface pressure and pressure ulcer incidence demonstrating positive correlation[15][16][17]. However, interface pressure measurements are not necessarily transferable from patient to patient because other factors influence pressure ulcer risk aside from the surface the patient rests on- this makes developing a threshold for pressure ulcer incidence incredibly difficult to establish from interface pressure measurements in human studies. It has previously been suggested that incidence of pressure ulcers only generally occurs above an interface pressure of 60mmHg [16]; this finding appears to be consistent with data presented [15]. An anthropomorphic phantom-based method could be beneficial as it would enable a standardised approach for cross-sectional and longitudinal interface pressure analysis; it would have the added benefit of not needing human participants who might be difficult to access. Almost no work has been published on anthropomorphic phantom-based approaches to assess interface pressure for mattresses, however [12] outlined a sophisticated approach. Whilst Bain's work has many benefits, it is likely to have limited value because of phantom complexity and production costs.

In this paper we report a method for developing a novel inexpensive anthropomorphic phantom and validate the phantom against human volunteer data for a range of equivalent body weights. We demonstrate that the phantom can be used to assess mattress interface pressures as an index of mattress performance in terms of its ability to support pressure ulcer prevention.

Method

The methods are presented in two phases: Phase 1 outlines the development of the phantom; Phase 2 describes the steps taken to validate the phantom, this includes how phantom pressure data were analysed and presented.

Phase 1: phantom development

A phantom was created to represent the common jeopardy areas of pressure ulcer development (the head, pelvis and heals). An overview of the phantom development process is displayed using a flow chart (Figure 1).



Figure 1. Flow chart displaying the phantom development process.

Commercially available anthropomorphic X-ray phantoms, which represented an adult head, pelvis and heels (Figure 1A, [18]) were scanned using a Toshiba 16 slice CT scanner [19]. The scanner passed relevant quality performance tests in advance of imaging (Institute of Physics and Engineering in Medicine (IPEM) Report number 91; ICRP, 2007; Toshiba, 2014). CT data were captured using the following acquisition settings; 0 gantry tilt, 5 mm slice thickness, 1.5

pitch, field of view (FOV) $\frac{1}{4}$ 20.8 cm, grid 512x512, 120 kVp and 100 / 150 mA. Example images of the acquired data are seen in Figure 1B.



Figure 2: (A) Head and pelvis anthropomorphic phantoms that were used to acquire CT image data. (B) Examples of their CT images.

X-ray phantom Digital Imaging and Communications in Medicine (DICOM) format CT image data were converted to Nearly Raw Raster Data (NRRD) file format using Slicer Software (<u>https://www.slicer.org/</u>). The NRRD file was then converted to Standard Triangle Language (STL) format using embodi3D.com. Prior to printing, STL data were processed using MeshLab (version 1.2.3-64; <u>http://meshlab.sourceforge.net</u>) to correct for 3D surface anomalies. Subsequently, four 3D printing sessions occurred to develop anthropomorphic phantoms for the head, pelvis, and left heel and right heel. Only the posterior sections of the head, pelvis and heels were required, as only the posterior surfaces would make contact with the mattress. By only printing the posterior regions, it also enabled a flat surface to be left to the anterior, which enabled weight to be added with ease.

The 3D printer for larger prints (pelvis / head) was *BigRep One* (<u>https://bigrep.com/bigrep-one/</u>) and the printing material was MonsterFil 2.85mm PLA in 2.26kg spools (e.g. <u>https://monsterfil.com/monsterfil-red-2-85mm-5-lbs-2-26-kg.html</u>). For this printer, the print files were prepared using *Simplify3D Slicing Software* (<u>https://www.simplify3d.com/</u>). The 3D printer for the smaller prints (heels) was *Ultimaker 2* (<u>https://ultimaker.com/3d-printers/ultimaker-2-plus</u>). The software to prepare the files for this printer was Ultimaker Cura

(https://ultimaker.com/software/ultimaker-cura). All four 3D prints were hollow (without infill).

Once printed, the four components were linked together to represent the human body (Figure 2A). To join components together a custom-made frame, of 25mm x 25mm x 1.5mm box aluminium 175cm long (the average height of a human), was used. The box aluminium was fixed by plastic connectors to maintain rigidity. The plastic connectors for knee and elbow 'positions', allowed the structure to bend in order to simulate potential human limb motion, this provided a degree of flexibility to the frame which enabled the jeopardy areas to submerge into the mattress when weight was added. Finally, urethane foam was used to fill the 4, 3D-printed components to give them adequate rigidity to make them strong enough to withstand weight that was applied to the upper surface during experimentation. Once assembled (Figure 2B), the phantom, which represents pressure ulcer jeopardy areas in a human body, could be placed on an X-ray table / mattress and kiln-dried sand could be added to it to represent a range of human weights. Measurement of interface pressure occurring through the interaction between the mattress surface and the phantom jeopardy areas can be collected using XSensor technology. XSensor technology uses sensors in a mat (Figure 3B) interfaced to a computer to provide a digital profile or map of interface pressure (Figure 5).



Figure 3: 3D Phantom: (A) top – plan view; bottom – side view; (B) 3D phantom placed on an XSensor Px100 on an X-ray table mattress

In order to establish the weight of sand necessary to be added to the phantom to simulate a range of human weights, XSensor [20] interface pressure data from a published study with 27 volunteers was used [16]. A summary of the volunteer characteristics is included in Table 1.

For our phantom work, the 27 volunteers were grouped into 5 weight categories (Table 2 & 3). To represent these 5 categories, average weights for each were calculated from XSensor data to determine the amount of sand to be added to phantom heels, pelvis and head (see Table 2, final column – 'weight for 3D phantom').

Table 1. Displays a summary of the volunteer characteristics (27 volunteers, 24 female and 3 male) from the volunteer study [16] from which human XSensor pressure data was utilised to validate the phantom. The data display's the average \pm the standard deviation.

Weight (kg)	Height (cm)	BMI		
77.04 ± 22.18	164.63 ± 7.64	28.18 ± 6.75		

Phase 2: phantom validation

For the pelvis, heels and head, Peak Pressure Index (PPI) and interface pressure profiles were compared between the 3D phantom and the human volunteer study. The same mattress was used to collect interface pressure data for the phantom and human volunteer study [21]. The mattress was a standard single size, $90 \times 190 \times 20$ cm in width, length and depth respectively. The mattress was composed of 10cm of conventional foam and 10cm of memory foam.

XSensor Technology was used to record mattress interface pressure readings (Figure 2B). To minimise measurement error in humans, data is often acquired for 20 minutes, following a settling time of 6 minutes [22]. However, the 3D phantom does not contain soft tissue materials and so it only required 3 minutes settling time to achieve stabilised pressure readings, and only 15 minutes was needed for data collection. A range of human equivalent weights were added to the phantom at the head, pelvis and heels as indicated in Table 2. To minimise random error, interface pressure measurements for each weight were repeated 3 times and averaged.

Prior to conducting phantom experiments, a quality control step was taken to determine whether weights placed on one 'body part' had an impact on the XSensor interface pressure reading of another 'body part', e.g. whether weight placed on the pelvis impacted on readings taken at the heels and head. It was essential to ensure this did not occur as the weights added to the pelvis, head and heels had been calculated to mimic those which would be expected for each respective weight group. This experiment involved placing the maximum sand weights on head, then pelvis, then heels, one at a time, and to determine whether a change in interface pressure at the other locations had occurred (see Figures 3A, 3B, and Table 3). Percentage difference in weights were calculated by the following equation

Percentage difference = $\frac{V1-V2}{\{\frac{V1+V2}{2}\}} * 100$

Where: V1 is PPI without weight, V2 is PPI after applied the weight.

The results show that the percentage differences varied from 1.3% to 5.8%. As seen, weight transference is quite small, suggesting minor errors are imposed.



Figure 4: (A) Maximum weight on head, and (B) Maximum weight on pelvis.

The method of calculating and analysing Peak Pressure Index and Interface Pressure Ratio

Peak Pressure Index

Peak Pressure Index data, recorded in mmHg saved in the X-sensor system, was transferred to laptop for analysis using X-sensor software. Data was merged using the average peak pressures for all frames, then regions of interest were placed around the heels, the pelvis and the head to calculate the highest Peak Pressure Index (PPI) in middle of 9 cells of each region; the mean values were calculated for each region. This method is widely reported in the literature [13].

Interface Pressure Ratio

Using phantom data, a novel Interface Pressure Ratio (IPR) was developed to indicate mattress interface pressure redistribution efficiency. IPR serves as a simple indicator to compare between mattresses and for the same mattress over time. IPR uses phantom PPIs from the head, pelvis and heels when a 'used mattress' (experimental condition) is compared against 'no mattress' (control condition). This calculation is repeated for all five weights, such that for one

mattress there are 5 IPR values for head, 5 for pelvis and 5 for heels (where only one average value for both heels is presented). The formula for IPR is indicated below.

PPI when Mattress is used PPI for no mattress

IPR varies between 0 and 1. '1' implies the mattress has the same interface pressure distribution properties as a hard surface (e.g. X-ray table surface). As the ratio approaches '0', the interface pressure redistribution properties of the mattress improve. To illustrate its use, Table 2 shows IPRs from a 15-year-old X-ray table mattress that is in current clinical use. For the 5 weight categories, the IPR indicates the mattress interface pressure redistribution properties are similar to the X-ray table itself (i.e. approaching '1', which is very poor).

Table 2: Interface Pressure Ratio (IPR, the peak pressure index when a mattress is used divided by the peak pressure index without mattress) from a 15-year-old X-ray table mattress and their corresponding Peak Pressure Index for the for the 5 weight categories.

Weight category	Peak Pressu	ıre Index (mı	nHg)	Interface Pressure Ratio			
	Head	Pelvis	Heels	Head	Pelvis	Heels	
Maximum (148kg)	88.5	110.7	97.3	0.93	0.85	0.95	
Third							
quartile (84kg)	68.9	93.4	78.1	0.92	0.78	0.90	
Mean (76kg)	60.6	79.2	70.2	0.85	0.78	0.86	
First							
quartile (64kg)	55.4	62.5	53.9	0.84	0.70	0.94	
Minimum (50kg)	50.1	47.5	35.1	0.83	0.93	0.92	

Results

Comparison of human volunteer and phantom PPIs

Table 3 shows the average (and SD) PPIs for the phantom and human volunteers. There was strong positive correlation between the PPI for the phantom and the human volunteers for the head, sacrum and heels respectively (R^2 =0.993, 0.997 and 0.996).

Table 3: Pea	k Pressure Index for phantom	and humans			
Weight category	Peak Pressure Index for Human volunteer data (average and SD) mmHg	Peak Pressure Index for 3D phantom data (average and SD) mmHg	Weight added phantom (kg)	to	3D

	Head	Pelvis	Heels	Head	Pelvis	Heels	Head	Pelvis	Heels	
Maximum	47.3	54.6	56	46.6	57.4	55.4	6	37	3	
(148kg)	(148kg)	±1.18	±1.24	±3.49	±2.76	±2.41	±1.38		57	5
Third	38.7	44.1	34.7	39.1	47.1	37.6	3	30	13	
quartile (84kg)	±2.02	±2.67	±2.00	±2.33	±1.75	±1.93		50	1.5	
Mean (76kg)	33.6	39.6	29.8	35.3	41.5	31	2.5	24	1	
	±1.66	±1.00	±1.25	±2.08	±2.52	±2.60		24	-	
First	30	34.3	22.5	30.3	35.9	24.9	2	21	0.8	
quartile (64kg)	±1.77	±2.40	±2.21	±2.31	±1.81	±1.66	4	21	0.0	
Minimum (50kg)	22.1	25.4	18.8	22.5	24.9	22.5	15	10	03	
	±1.32	±2.61	±0.50	±1.34	±1.10	±1.67	1.5	10	0.5	



Figure 5. Displays the interface pressure map of a human (above) and the phantom (below). The interface pressure values are mapped as a colour gradient. The scale to the right of the maps displays the interface pressure for the corresponding colours of the scale ranging from 0 mmHg up to 120 mmHg.

Discussion

For the purpose of testing interface pressure distribution properties of X-ray mattresses, the results suggest the 3D phantom is a reasonable representation of the human body. Unlike humans, the phantom's standardised characteristics do not change over time and because of this a high level of confidence can be placed on phantom interface pressure data as it will not suffer from confounding repeatability problems that can be seen when human volunteers are used. Additionally, there will be no access and ethical issues, unlike human volunteers.

The method proposes two metrics for assessing mattress performance – PPI and IPR. PPI is a widely reported metric for assessing mattress performance, but the added benefit of our approach relates to the standardisation imposed by the phantom. This standardisation allows for objective repeatable PPI comparisons for the same mattress across time and between mattresses at the same point in time. The controllable phantom characteristics allow further analysis to be done with the interface pressure data, hence the introduction of IPR. IPR can be presented as an array of data (see Table 2, 'Interface Pressure Ratio') for sacrum, head and heels in the 5 weight categories. IPR is a simple metric that permits quick and objective comparisons to be made between mattresses at a given point in time and for the same mattress across time. Manufacturers might consider providing this sort of data to assist consumers make more informed procurement decisions at the point of purchase. If this occurred, each mattress would then have known 'baseline' anthropomorphic phantom IPR and PPI data and, if needed, repeat testing using the method could be conducted to see whether the mattress continues to perform adequately over time. Such data, provided by manufacturers, could help inform procurement decisions for matching mattress characteristics to imaging demands / frequency and underlying patient populations.

Whilst many X-ray imaging examinations are short (<20 minutes) and potentially induce no detrimental effects with respect to pressure ulcer formation, some radiological procedures are lengthy, where patients may lie in one position for 2 hours or more [8]. Such lengthy radiological studies occur within operating theatres, interventional imaging rooms and on emergency department trolleys. Intermediate length imaging studies exist, for example in MR and hybrid imaging, where the patient may have to lie perfectly still for 30 minutes or more. These radiological procedures have the potential to induce pressure ulcers, due to the length of time a potential at risk patient must remain very still or even motionless [23],[24]. Furthermore, mattresses used in imaging contexts need further consideration, in terms of usage frequency and variation in the sizes of patients who use them. Consequently, deterioration over time should be considered as a mattress in one locality could remain serviceable for years whereas the same mattress in a different locality might not [25].

Our phantom has advantages over the one produced by Bain, Ferguson-Pell and McLeod (2003). First, the simple design of our phantom combined with the availability of 3D printing allows it to be produced quickly, cheaply and easily. Second, our phantom allows a range of human weights to be simulated. Limitations of our phantom include lack of deformability and its singular size. For the latter, size variations could be introduced by using a range of human CT images. For the former, a suitable deformable material needs identifying and including onto the external inferior surfaces. Aside having suitable soft tissue characteristics, the material would need to maintain the same deformable characteristics over a sustained period for studies that may need to occur over years. If studies examining the interface pressure properties of mattresses move towards the use of anthropomorphic phantoms, then how humans are involved in mattress testing would need some thought. It could be that subjective measures only might be needed from human volunteers (e.g. comfort/ quality of sleep/pain scales), on the other hand

it could be, in addition to subjective measures, interface pressure mapping using humans needs to continue but only in quite specific circumstances.

One of the questions which remains unanswered is which PPI or IPR value identifies a mattress as being ineffective at supporting the prevention of pressure ulcer development and therefore is in need of replacement? An IPR value closer to 1 approaches the equivalent performance of a hard surface whilst a value closer to 0 reflects a better performing mattress in terms of its redistribution properties. Further research is necessary to identify the appropriate IPR index above which a mattress warrants replacements. However, in relation to the performance of X-ray mattresses this is not the only indicator of performance which needs to be considered. X-ray mattresses also need to be radiolucent in order to ensure image quality is of diagnostic quality and radiation dose is as low as reasonably possible. Further research is necessary to develop an index which considers all three properties.

Further research utilising the methods described in this paper are underway in order to: compare the performance of X-ray table mattresses in several hospitals together with an analysis of new commercially available X-ray table mattresses; determining whether, because of thinness, X-ray mattresses might have maximum (patient) weights beyond which bottoming out would occur; designing a new X-ray table mattress. Finally, it is worth noting our method and phantom could have utility in assessing bed mattresses and mattresses used in Magnetic Resonance Imaging, Computed Tomography and Nuclear Medicine and further work would be needed to assess this proposition.

Conclusion

A novel method to test X-ray mattresses for interface pressure was developed and validated, as an index of mattress performance. This method could have utility for assessing bed mattresses. Phantom interface pressure data could be provided by manufacturers to help inform procurement decisions when matching mattress characteristics to medical imaging d

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