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AN INVESTIGATION INTO INTERFACE PRESSURE (IP) RISK OF HEALTHY VOLUNTEERS ON MODERN MEDICAL IMAGING AND RADIOTHERAPY TABLES

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PhD. Thesis **2016**

An investigation into interface pressure (IP) risk of healthy volunteers on modern medical imaging and radiotherapy tables

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Trainings undertaken during the course of the PhD

(All certified by the University of Salford, Manchester, UK)

Session No.	Title of training	Date
1.	Postgraduate research methods lessons: Key points include; • The principles of research • Qualitative research sampling and research methods • Quantitative research – experiments and other analytic methods of investigation • Research statistical analyses	18th October, 2013 For three months
2.	Completing a Learning Agreement & the PhD Progression Points • Postgraduate student lifecycle • Monitoring of doctoral research through the Self-Evaluation document and Annual Progress Report responsibilities of both the student and supervisor	21st October, 2013
3.	Postgraduate Research Induction Week • Introduce PGR students to doing research at the PhD level	4th November, 2013 For a week
4.	Celebrating PhD Research Day • Research methods • Research presentation and dissemination	8th November, 2013
5.	Doing literature review • How to use keywords and MeSH headings to search for published literature.	25th November, 2013
6.	Introduction to Endnote X7 Reference Manager-beginners • Creating an EndNote Library • Importing references from databases • Creating references from PDF files	27th November, 2013

7.	Training on how to use the Xsensor pressure mapping systems – organised by the Country Manager of Sumed, UK, dealers of the Xsensor pressure mapping system	28th November, 2013.
8.	Training on Endnote X7 Reference Manager-advanced • Creating groups in Endnote library • Creating in-text citations • Formatting bibliographies in Microsoft Word	18th December, 2013
9.	Seminar on doing Research – the scientific way • Ethics	10th February, 2014
10.	Seminar on Myers Briggs Type Indicator personality tool • To improve effectiveness of communication, team working, decision making and problem solving • To help researchers understand themselves, the impact they have on others, and how different personality styles and preferences can work together in complementary ways in a research environment	12th March, 2014
11.	Training on how to use the Xsensor pressure mapping system and its associated X3 Medical software for data acquisition, extracting and analysis – organised by Katy Szczepura, Medical Physicist, and lecturer, University of Salford, Manchester, UK.	12th March, 2014
12.	Using Social Media in Your Research and Career • Using social media to find experts with similar research interests • Using social media to advertise a study • Using social for recruitment • Using social media for dissemination of results	10th April, 2014

13.	Introduction to SPSS statistics package – beginners • Input primary data and excel data into SPSS • Upload previously coded data • Label and manipulate dataset to generate results and summary	17th April, 2014
14.	SPSS with Statistics – advanced • How to run parametric and non-parametric statistics • Edit graphical output from SPSS • How to report results from SPSS	18th April, 2014
15.	Writing research method section of a thesis	6th May,2014
16.	Statistics with SPSS – Questions and answers session webinar • The facilitator answered questions from the previous two SPSS sessions	23rd May, 2014
17.	International Wound Management Conference 2014 – held at the University of Salford, Manchester, UK. • At this conference, I presented two papers about my PhD.	21 - 22nd July, 2014
18.	OPTIMAX #2014 Summer School, Lisbon, Portugal. • This included lessons on research methods and statistics. In addition, there was a huge emphasis on self-directed reading and learning.	3rd- 23rd August, 2014
19.	OPTIMAX #14 Summer School Conference • How to write scientific research articles • Research statistics (quantitative and qualitative) • Research dissemination/presentation	23rd August, 2014
20.	Public Health 2014 Conference – How can pressures on the NHS be relieved?	11th November, 2014
21.	Introduction to NVivo • Using NVivo for literature review • Using NVivo for qualitative data analysis	19th November, 2014

22.	Conference: A step change is taking place in thinking and action on equality and diversity in the workplace.	25th November, 2014
23.	Salford Postgraduate Annual Research Conference (SPARC) • Forum for developing research • Networking with fellow postgraduate researchers from other disciplines • Actively engaging with Salford's PGR community • Developing confidence and presentation skills	26th-28th May, 2015
24.	Quantitative data analysis • Categorising data • Introduction to SPSS • Univariate analysis • Comparing groups and reducing complexity • Meaningful relationships • Multivariate analysis	13th January 2016.
25.	Word: Formatting your dissertation/thesis • Discover heading styles & captions to create automatic table of contents, list of figures. • Apply different page numbering formats and changes in page orientation via section breaks.	18th February, 2016
26.	An Introduction to Project Costings and Budgets • This session covered the key aspects of how to develop costs and budgets for research projects. • Provided better understanding of what funds can be applied for and how finance affects the planning and management of scientific research	23rd February, 2016
27.	Finding Journal Articles: Health and Social Care • Searching the SOLAR library catalogue • Finding journal articles for health and social care subjects • How to save favourites and search results	25th February, 2016

28.	Critical Thinking and Critical Writing at Doctoral Level • Analyse and chart professional progression using a critical reflective process and learning style analysis • Develop skills to evaluate research critically and include an evidence-based research to promote optimal findings • Examine critically reflective practice, problem solving and creative ethical decision making	18th May, 2016
29.	Developing Your Personal Brand Online Using Social Media • An overview of social media • Insight into the benefits of using social media for your career • Tips on Netiquette – the Do's and Don'ts of social media	19th May 2016

List of developed skills

No	Type of skill
1.	How to search for published literature using scientific databases
2.	How to critically analyse published literature
3.	How to use published literature for writing
4.	How to use Microsoft word, excel and powerpoint at the advanced level
5.	How to conduct scientific research at the PhD level
6.	How to use Endnote reference manager for in-text citation
7.	How to use the Xsensor pressure mapping equipment and its associate software to acquire, transmit and analyse interface pressure (IP) data.
8.	How to apply ethical principles in scientific research
9.	How to work effectively with people of different personality traits
10.	How to use social media to advertise, recruit and disseminate the findings of a study
11.	How to use the SPSS statistical software to analyse data
12.	How to present at a conference
13.	How to cost and budget for a project
14.	How to supervise and coordinate research projects
15.	How to think and write critically at the PhD level
16.	How to use the DR and CR X-ray machine
17.	How to use ImageJ software for image manipulation
18.	How to use the ImageJ software for Hounsfield unit calculation
19.	How to use parametric and non-parametric statistical tests
20.	How to develop a questionnaire

List of abbreviations

AMED – Allied and Complementary Medicine Database

ANOVA – Analysis of variance

AP – Alternating Pressure

BC – Before Christ

BED – Biological Equivalent Dose

BMI – Body Mass Index

˚C – Degrees Celsius

CCP – Capillary Closing Pressure

CI – Confidence Interval

CINAHL – Cumulative Index to Nursing and Allied Health Literature

CLP – Constant Low Pressure

cm – Centimetre

CPGQ – Chronic Pain Grade Questionnaire

CR – Computed Radiography

CR-UK – Cancer Research UK

CT – Computerised Tomography

DI – Deviation Index

DNA – Deoxyribonucleic Acid

DOH – Department of Health

DR – Digital Radiography

ECR – European Congress of Radiology

E.g. – For example

EI – Exposure Index

EPUAP – European Pressure Ulcers Advisory Panel

FSA – Force Sensing Array

GTV – Gross Tumour Volume

HSCIC – Health and Social Care Information Centre

HSE – Health and Safety Executive

HU – Hounsfield Unit

HVL – Half-value Life

ICC – Intraclass Correlation Coefficient

i.e. – That is

IG – Industrial Grade

IP – Interface Pressure

IR – Ischaemia Reperfusion

IVP – Intravenous Pyelography

Kg – Kilogram

K-S – Kolmogorov-Smirnov

KTU – Kennedy Terminal Ulcer

kV – Kilovoltage

L – Length

LLT – Left Lower Third

m^3 - Cubic Metre

mAs – Milliamperage second

MDR – Medical Device Related

MEDLINE – Medical Literature Analysis and Retrieval System Online

MeSH – Medical Subject Heading

mGy – milligray

mm – Millimetre

mmHg – Millimetres of Mercury

MPa – Megapascal

MRI – Magnetic Resonance Imaging

MS – Multiple sclerosis

nGy – Nano Gray

NHS – National Health Service

NICE – National Institute for Health and Care Excellence

NPUAP – National Pressure Ulcers Advisory Panel

NY – New York

OAR – Organs At Risk

ONS – Office of National Statistics

p – Probability

PET-CT – Positron Emission Tomography-Computerised Tomography

PhD – Doctor of Philosophy

PI – Principal Investigator

PIV – Pressure-induced Vasodilation

PMI – Polymethacrylimide

PMMA – Polymethylmethacrylate

P-P – Probability-Probability

PPI – Peak Pressure Index

PPPIA – Pan Pacific Pressure Injury Alliance

PubMed – Public/Publisher Medical Literature Analysis and Retrieval System Online

PUs – Pressure ulcers

PUPP – Pressure Ulcer Prevention Programme

QA – Quality Assurance

Q-Q – Quantile-Quantile

RAS – Risks Assessment Scale

RASs – Risks Assessment Scales

RLT – Right Lower Third

SD – Standard Deviation

SID – Source to Image-receptor Distance

SPECT – Single Photon Emission Computed Tomography

SPSS – Statistical Package for the Social Sciences

SRT – Stereotactic Radiotherapy

T – Thickness

TI – Target Exposure Index

TPM – Talley Oxford Pressure Monitor

TPS – Treatment Planning System

µGy – Micro Gray

UK – United Kingdom

UoS – University of Salford

US – United States

VCFs – Vertebral Compression Fractures

vs – Version

W – Width

WBRT – Whole Brain Radiation Therapy

2D – Two dimensional

3D – Three dimensional

Abstract

Background and Rationale

Pressure ulcers (PUs) present significant threats to patients and cost billions of total healthcare expenditure. In radiography/radiotherapy, a potential for high interface pressure (IP) on radiography/radiotherapy tables may exist, however no study has investigated this to an acceptable scientific level.

Thesis aims

This thesis involved two-phases. The primary aim of phase one was to investigate whether IP risks exist on radiography/radiotherapy tables. The secondary aim was to assess the perception of pain and comfort on radiography/radiotherapy tables. The aim of phase two was to determine the impact of pressure relieving interventions on IP at jeopardy areas.

Method and results

In the first phase, an Xsensor pressure mapping system was used to measure IP of jeopardy areas in healthy volunteers (26 females, 23 males; aged 18-59 (mean=34.6±10.5)) on three radiography/radiotherapy surfaces, after which they completed a pain and comfort questionnaire. ANOVA identified statistically significant differences in the mean IP for head, sacrum, and heels across the three surfaces ($p \leq 0.001$). Results indicated high IP values for head (75.9±6.9mmHg) on the radiotherapy table. This high IP could induce tissue breakdown, thereby increasing the risk of developing PUs in at risk populations. Volunteers experienced most pain whilst lying on the radiotherapy table. In phase two, a thin gel intervention with low radiation attenuation, which also has no impact on image quality, was assessed to reduce IP risks identified for the head. Pressure mapping was conducted on 20 healthy volunteers (14 males (70%) and six females (30%)); aged 25-53 years (mean=34.4±7.0). Paired-samples t-test indicated a statistically significant difference in the mean IP for the head with and without the intervention; both comparisons recorded mean IP values of 62.4±6.1 and 83.9±8.1 mmHg respectively, $p \leq 0.001$. Similarly, there was statistically significant difference in the PPI of the head with and without the intervention (mean=159.8±26.8, and mean=205.1±28.2mmHg respectively; $p \leq 0.001$).

Conclusion

IP risk exists for the head on radiotherapy tables. This could induce tissue injury in patients accessing prolonged interventional radiography and radiotherapy procedures for the head. A thin gel silicone intervention can reduce this risk. Further research is needed to assess its impact in at risk populations.

Overview and structure of the thesis

The structure of this thesis is presented in figure 1. The thesis consists of seven chapters. **Chapter one,** the introduction chapter, is to introduce and overview the key issues and also provide an outline of the structure of the thesis in order to orientate the reader. In this chapter, an overview of the problem of pressure ulcers and its impact on patients and the healthcare system has been provided. The chapter also contains the research problem which introduces the research being conducted and also put the problem of pressure ulcers in the medical imaging and radiotherapy context, and why it is necessary to investigate interface pressure risk on radiography and radiotherapy surfaces. The chapter also contains a summary of the radiographic and radiotherapy literature on pressure ulcers. Additionally, the purpose of this thesis has been discussed. The chapter concludes with an overview of the structure of the thesis.

In **chapter two**, a detailed literature review on pressure ulcers is conducted and will be presented in the narrative format under themes. The search strategy for conducting the review will be discussed. Some of the themes include the following: origin of pressure ulcers – contains historical perspective of pressure ulcers. Under this theme, the findings of historical and seminal studies on pressure ulcers will be critically discussed. In addition, the impact of these studies on modern methods for conducting pressure ulcers research will be presented. The chapter will also contain detailed literature review on the various definitions and categories of pressure ulcers. For the purpose of this thesis, the type of pressure ulcers likely to occur within radiographic/radiotherapy settings will be discussed.

Additionally, the incidence and prevalence data of pressure ulcers, as well as the financial implications of treating pressure ulcers will be discussed in chapter two. The causative factors of pressure ulcers will be discussed using the Defloor's conceptual scheme. The pathophysiology of pressure ulcers, pressure ulcers risks assessment scales (RASs), and the international guidelines for the prevention of pressure ulcers will be presented in this chapter. In conclusion, literature on interface pressure measurement, medical imaging and radiotherapy surfaces, and the rationale for this thesis will be presented.

Chapter three forms the beginning of the first phase of the thesis. In this chapter, the method for phase one will be discussed. The method begins with a detailed discussion on the ethical issues and principles considered when conducting the research. This is necessary because the thesis involved human subjects and as such key ethical principles have to be considered and adhered to. This is to ensure that the experiment was conducted in compliance with the University of Salford School of Health Sciences ethics code. Also, the results from the power analysis that informed the sample size for phase one of the thesis will be reported. The inclusion and exclusion criteria for this phase of the thesis will be stated and justified. Literature on the instrument – Xsensor pressure mapping system, will be critically evaluated. The procedure used for conducting the pressure mapping (i.e. measuring interface pressure) will also be reported in detail.

In **chapter four**, the results of phase one of the thesis will be presented using descriptive and inferential statistics. In addition, the demographics of the volunteers who participated in the study will be reported.

In c**hapter five,** the findings of phase one of the thesis will be discussed. The clinical implications of key findings of the experiment, and how these findings could impact on patients' risk of developing MDR pressure ulcers when lying on medical imaging and radiotherapy surfaces will be critically evaluated. The discussion will be conducted under the following sub-headings; comparing results to previous studies, clinical implications of the experimental findings on prolonged interventional radiography, radiotherapy planning and treatment procedures, and clinical implications of positive correlation between BMI and mean IP for the whole body.

Chapter six is phase two of the thesis. This chapter will discuss the intervention study that was conducted to minimise the high interface risk identified for head on the X-ray table with no mattress. The chapter will contain information on the background to phase two of the thesis, justification for choosing the gel intervention (radiation tests), the method (sample size, inclusion and exclusion criteria), as well as the procedure used to conduct the experiment. The findings of phase two will also be reported. In addition, the impact of the intervention on interface pressure, and how this could reduce patients' risk of developing MDR pressure ulcers will be discussed in this chapter.

Finally, **chapter seven,** will contain an overall conclusion of the thesis. In this chapter, a summary of the thesis will be presented in brief. In addition, the limitations of the thesis will be stated. The chapter will also contain recommendations for future work, the novelty of the thesis, and will end with a concluding statement.

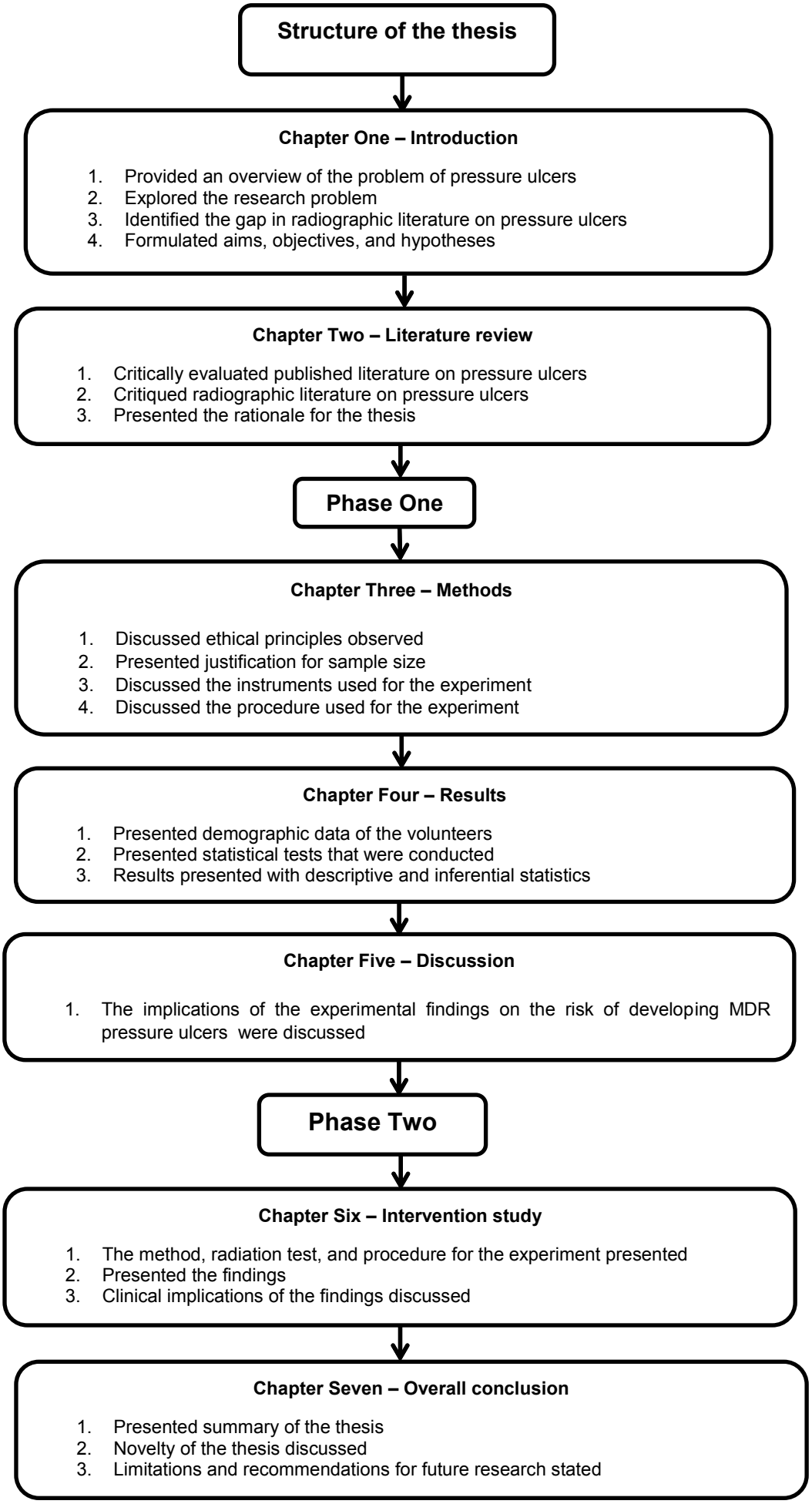

Figure 1: PhD thesis structure

1 Chapter One – Introduction

1.1 Chapter overview

This chapter will discuss the background to the study and indicate that pressure ulcers are a common health problem for patients, especially those of advanced age, and with cancer. High interface pressures are likely to result in skin tissue breakdown, which might result in pressure ulcers. It will be demonstrated that a gap in the radiographic literature does exists for pressure ulcers risk analysis on modern imaging and radiotherapy surfaces. To fill this gap, the rationale for the thesis will be discussed, from which the aims of this thesis will be stated. The chapter will conclude with an overview of the structure of the thesis, its significance, and how this research will be of clinical benefit to patients, healthcare professionals, and the research community.

1.2 Overview of the problem of pressure ulcers

Pressure ulcers are a common problem in the healthcare environment, presenting significant threat to patients especially those of advanced years or with restricted mobility or chronic diseases (Gomez-Batiste et al., 2014, Pieper, 2012, Anton, 2006). Notwithstanding the enormous efforts and international attention directed at reducing their incidence, the occurrence of hospital-acquired (nosocomial) pressure ulcers continue to rise, constituting a significant cause of complications and patient deaths (Brennan et al., 2014, Stotts et al., 2013, Goodell and Moskovitz, 2013, Stoelting et al., 2007). In the United Kingdom (UK), the Health and Social Care Information Centre (HSCIC, 2014), indicated a prevalence rate of 4.7% for pressure ulcers across a range of healthcare settings, including nursing homes, care homes, independent sector care providers as well as hospitals. In contrast, Canada has a prevalence ranging from 36.8 to 53.2% in long-term care facilities (Davis and Caseby, 2001b), whilst the prevalence of pressure ulcers among patients in Nigerian hospitals is 13.8% (Onigbinde et al., 2012). Pressure ulcers have enormous financial implications, costing between £1.8–2.6 billion in the UK (Posnett and Franks, 2008b) and between $11-17 billion in the United States (Russo et al., 2008, Gordon et al., 2004). In addition to the financial burden, pressure ulcers also have a negative physical and psychological impact on patients' quality of life (Plaskitt et al., 2015,

Kranke et al., 2015). As a result, studies have recommended that more research should be conducted into the aetiology of pressure ulcers in order to help identify methods of minimising the prevalence and incidence of pressure ulcers (NICE, 2015, Bhattacharya and Mishra, 2015, Aydin et al., 2015, Forde-Johnston, 2014).

1.3 The research problem

High interface pressure (IP) – pressure between body and support surface, can cause pressure ulcers (Raju et al., 2014, Agrawal and Chauhan, 2012). This happens when body tissues are compressed against each other (Messer, 2012, Crawford et al., 2006), mostly over bony prominences where there are less soft tissues to tolerate the compressive force brought to bear on the skin (Minnich et al., 2014, Clements et al., 2014, Levy et al., 2013). Studies have shown that interface pressures exceeding capillary closing pressures (CCP), of 32 to 47 mmHg for a period longer than two hours is most likely to compromise circulation, and may lead to tissue anoxia, and possibly cell death (Maklebust and Sieggreen, 2001, Defloor, 1999, Landis, 1930). CCP is defined as the pressure necessary to partially or completely occlude blood flow within the capillaries (McGinnis and Stubbs, 2014, Messer, 2012, Shore, 2000). Various studies into the aetiology, incidence, prevention and treatment of pressure ulcers have reported that pressure ulcers mostly occur at the head, sacrum, and heels, popularly referred to as the jeopardy areas (Casey and Gittins, 2013, Peterson et al., 2010, Regan et al., 2009, Sayar et al., 2009, Edwards, 2006, Kernozek et al., 2002). According to these studies, this is due to the prominent bony features found at these anatomical sites.

In his seminal work, Kosiak (1959) indicated that interface pressures of 60 mmHg for one hour may induce soft tissue damage. This fact is supported by an earlier study by Husain (1953), who found that sustained interface pressures of 100 mmHg for a period of two hours may induce pressure injury. Within the radiography/radiotherapy settings, the potential of high interface pressure on medical imaging and radiotherapy surfaces may exist (Justham et al., 1996). This could increase the risk of Medical Device Related (MDR) pressure ulcers among patients accessing prolonged medical imaging and radiotherapy planning and treatment procedures. However, the study conducted by Justham et al. (1996) was conducted with pressure mapping equipment that had inadequate spatial resolution, hence the reported interface pressure values may be inaccurate. In addition, limitations in the

methods used to measure interface pressure for the head exposed this study to further criticism. As such, the findings of the study cannot be easily extrapolated into modern radiography/radiotherapy surfaces.

1.4 Overview of radiographic literature on pressure ulcers

Various studies have investigated the aetiology, prevention, and treatment of pressure ulcers (McGinnis and Stubbs, 2014, Garcia-Fernandez et al., 2014a, Yap et al., 2013, Thomas, 2010, Moore, 2010). However, little has been published regarding the pressure ulcers risks to patients undergoing radiography and radiotherapy procedures. A literature search demonstrated only six studies (Messer, 2012, Justham and Rolfe, 2002, Brown, 2002, Justham and Rolfe, 2001, Howatson-Jones, 2001, Justham et al., 1996) directly or indirectly investigated pressure ulcers risks, prevalence/incidence rates, and/or pressure ulcers assessment tools in patients undergoing radiography/radiotherapy procedures. These studies are discussed and critiqued more comprehensively in chapter two (section 2.15).

Out of these studies, only one (Justham et al., 1996) investigated the interface pressures experienced by healthy volunteers on radiography/radiotherapy surfaces. Interface pressure plays a crucial role in skin damage because pressures excessively higher than 32 mmHg are considered to increase a patient's risk of developing pressure ulcers (Hollington and Hillman, 2013, Stockton and Rithalia, 2009, Reenalda et al., 2009b, Jünger et al., 2009). The longer this high interface pressure is sustained, the more harmful negative impact it will have on patients. Interface pressure values give a vivid and objective description of the pressure an area of skin is experiencing on a particular support surface. The exploratory work conducted by Justham et al. (1996) was very useful because it showed that the potential risk of high interface pressures may exist on medical imaging and radiotherapy surfaces. However, its relevance in modern radiological and radiotherapy practice is questionable because as discussed in section 2.15, the study has numerous limitations. For example, the researchers used the Talley Oxford Pressure Monitor (TPM) mark III, which has poor spatial resolution due to the wide spaces between its sensors. The implication of this is that bony anatomical areas such as the heel may only partially cover a sensor, resulting in only a fraction of the interface pressure values recorded. Additionally, the research used a poor method in measuring the interface pressure for the head by placing the head on a

pillow. The implication of this is that, the pillow provided some level of protection or cushioning for the head, thereby reducing its interface pressure values. All of these issues mean that the interface pressure values recorded cannot be considered accurate. Hence, there is a need to investigate whether interface pressure risks do exist on medical imaging and radiotherapy surfaces.

As discussed in section 2.15, although several studies investigated patients' experiences such as pain and comfort whilst undergoing radiographic and radiotherapy procedures, no study investigated patients' pain and comfort whilst lying on medical imaging and radiotherapy surfaces. There is therefore a gap in the literature as to how patients feel when they lie on radiography and radiotherapy surfaces. Hence, it is necessary to establish the impact medical imaging and radiotherapy surfaces could have on patients undergoing radiographic/radiotherapy procedures, this is because patients often spend a considerable amount of time on these surfaces (Grunheid et al., 2012, Ahmed et al., 2012).

1.5 Purpose of the thesis

The overall aim of this thesis was to investigate the interface pressures of healthy volunteers when lying on three different medical imaging and radiotherapy surfaces in order to determine whether Medical Device Related (MDR) pressure ulcers risks do exist at the jeopardy areas (head, sacrum, and heels). Also, this thesis critically assessed volunteers' perception of pain and comfort whilst lying on the medical imaging and radiotherapy surfaces. Because interface pressure risks do exist, the impact of a planned intervention was assessed in order to minimise these risks. To achieve this, the thesis comprises of phases one and two. The aims and objectives of phase one are outlined in chapter three section 3.2 and 3.3 respectively, whereas those of phase two are outlined in chapter six section 6.2.

1.6 Significance of the thesis

Pressure ulcers studies have concentrated on nursing, occupational radiotherapy and tissue viability sectors of clinical practice (Heywood et al., 2015, Manzano et al., 2013, Peterson et al., 2013a). As stated earlier, research has shown that interface pressures above capillary closing pressure play a crucial role in skin tissue damage, which could lead to developing MDR pressure ulcers (Agrawal and Chauhan, 2012, Landis, 1930). Therefore there was the need to investigate if interface pressure risks do exist on radiography and radiotherapy tables, and if they do, devise means of minimising such risks. Unfortunately, to date, no current study has successfully investigated interface pressure risks on modern medical imaging and radiotherapy surfaces with high scientific method, creating a gap in the radiographic literature on pressure ulcers.

This thesis adds to the radiographic and radiotherapy literature on pressure ulcers a significant body of work backed by two empirical studies conducted with a reliable scientific method which demonstrates that patients accessing prolonged radiography and radiotherapy planning, and treatment procedures could be exposed to high interface pressure risks for the head when the head is in direct contact with the X-ray table. Therefore this thesis fills the literature gap by demonstrating with empirical evidence that interface pressure risks do exist for the head on medical imaging and radiotherapy surfaces. This finding will create awareness among radiographers and therapy workers of the risk that patients accessing prolonged radiography and radiotherapy planning and treatment procedures could sustain skin tissue injuries as a result of the high interface pressure for the head on radiography/radiotherapy table with no mattress.

The thesis further demonstrated with reliable empirical evidence that the use of a thin silicone gel surface overlay as an intervention could significantly reduce the high interface pressure for the head. This finding could have a significant impact on clinical practice in Ghana and Portugal where prolonged radiography procedures are conducted on fluoroscopic X-ray tables with no mattress because radiographers would become aware of this risk, and provide appropriate protection for the head. In countries such as the UK where radiography procedures are conducted on surface overlays such as mattress, the findings of this thesis provided an evidence-based support for such practice. Consequently, the finding that the use of a gel surface

overlay reduced the high interface pressure for the head could have a significant impact on radiography and radiotherapy practice as radiographers, radiologists, and radiotherapists, are more likely to adopt the use of surface overlays, where necessary to minimise interface pressure when patients lie on medical imaging and radiotherapy planning and treatment surfaces.

This thesis has also proposed a unique and novel technique of assessing the quality assurance (QA) of the Xsensor pressure mapping equipment. Within the method of phase one of the thesis, a novel technique was developed which established that there was a pressure gradient between the left and right sides of the Xsensor pressure mat. This finding could have important implications for research because previous studies that used the Xsensor pressure mapping made no mention of the existence of pressure gradient with the Xsensor. Previous studies have simply relied on the manufacturer providing evidence that the pressure mapping system works correctly. This thesis has proposed a simple experiment which allows the researcher an opportunity to quality test the Xsensor pressure mapping equipment prior to and after use. Researchers using the Xsensor in future would therefore benefit from this novel method to assess the QA of their pressure mat. It is essential that the pressure mat is assessed and confirmed that it does not have a pressure gradient as the presence of a pressure gradient would invalidate the recorded interface pressure values, unless the gradient factor is factored into the calculation.

2 Chapter Two - Literature review

2.1 Chapter overview

In this chapter, the results of a literature search on the history and origins of pressure ulcers, pressure ulcer incidence and prevalence data, as well as the financial implications of treating pressure ulcers will be presented. The literature will be reviewed and critiqued for the causative factors and pathophysiology of pressure ulcers, pressure ulcer risk assessment scales and the international guidelines for the prevention of pressure ulcers. The chapter will conclude with a discussion on the effectiveness of using interface pressure measurement as a tool for predicting the risk of developing pressure ulcers, the gap in the radiographic and radiotherapy literature on pressure ulcers, which then leads to setting the rationale for the thesis. This literature review will be presented in the narrative format under themes and subheadings. Subheadings are limited to third-level headings.

2.2 Search strategy

In order to identify literature relevant to this thesis, a comprehensive literature search was conducted of scientific online databases using the following search engines: AMED, CINAHL, Ovid-Medline, Cochrane, SCOPUS, Pub-med, and Google Scholar. Grey and unpublished literatures were also searched on the internet. In addition, books, magazines, brochures and leaflets were searched for literature relevant for the purposes of this thesis. To acquire scientific literature on the history, aetiology and risk factors for pressure ulcers, the following key words were used: pressure ulcers or pressure sores or decubitus ulcers or pressure injury, combined with the following words: aetiology, epidemiology, pathophysiology, risks factors, shear, friction, tissue tolerance, tissue viability, skin damage, interface pressure, pressure induced skin damage, and skin tolerance. Until recently, pressure ulcers were also called pressure sores, pressure injury and decubitus ulcers; hence the need to include all of these terms in the search to ensure that all relevant literature on pressure ulcers were captured. To obtain relevant literature on the prevention and guidelines on pressure ulcers, the following search words were used: pressure ulcers prevention, pressure sores prevention, decubitus ulcers prevention, pressure ulcers guidelines, pressure ulcers prevention policies, pressure ulcers clinical practice, pressure ulcers treatment, pressure sore treatment, and pressure ulcers

management. For relevant literature of pressure ulcers in radiography/radiotherapy, the keywords used are pressure induced tissue damage radiography, pressure ulcers radiography, pressure ulcers radiotherapy, skin damage medical imaging, interface pressure radiography, interface pressure radiotherapy, pressure ulcers prevention radiography, and pressure ulcers management radiotherapy.

The Medical Subject Heading (MeSH) term 'Pressure Ulcers' was also used to search for relevant literature in the MEDLINE and PubMed databases, under the following subheadings: analysis, anatomy and histology, classification, complications, diagnosis, diet radiotherapy, drug radiotherapy, economics, epidemiology, aetiology, history, metabolism, mortality, nursing, pathology, physiology, physiopathology, prevention and control, psychology, radiography, radiotherapy, rehabilitation, statistics and numerical data, and radiotherapy. There was no time limit on the search. This is to ensure that important seminal studies conducted many years ago were also captured in the search results. The entire search was limited to English-language journals, and related to human and animal subjects. The search operators (AND, OR, NOT) were used where necessary to refine the search. For the purposes of this thesis, the literature review was presented in a narrative format, under themes.

2.3 History of pressure ulcers

Pressure ulcers have been recognised as a disease condition in Egyptian mummies dating back more than five thousand years (Agrawal and Chauhan, 2012). Evidence shows that ancient Egyptians treated these ulcers with honey, whilst in Persia, pressure ulcers were treated with a wide range of topical applicants (Levine, 1992). Similarly, in Arabia, nutritional support and topical remedies like honey, mouldy bread, meat, animal and plant extracts, copper sulphate, zinc oxide and alum were used to improve and promote pressure ulcer healing (Eltorai, 2003). Hippocrates (460-370 BC) reported pressure ulcers in association with other medical conditions such as paraplegia with bladder and bowel dysfunction (Levine, 1992, Adams, 1939). Levine (1992) also stated that during the 16th century, the French army surgeon, Ambrose Paré, who is regarded as the founding father of medical surgical practice, recorded cases of pressure ulcers. Ambrose Paré treated these ulcers by boosting patients' nutrition, improving pain relief and debridement; treatments that are similar to current methods of treating pressure ulcers.

Levine (2005), reported that a study conducted in the 19th century on pressure ulcers, referred to as decubitus ulcers at the time, showed that neurotrophic theory is the main cause of pressure ulcers rather than pressure. The neurotrophic theory claims that in order to ensure optimal innervation of body parts, a surplus of neurons are first produced which then compete for a small quantity of protective neurotrophic factors and only a small percentage survive while the rest die by programmed cell death (Yamaguchi and Miura, 2015, Hristova, 2013). The theory further states that predetermined factors control the amount of neurons that survive and the size of the innervating neuronal population directly correlates to the influence of their target field (Gould and Enomoto, 2009, Amen-Ra, 2007). However, various studies have opposed the position that neurotrophic theory is the main cause of pressure ulcers, and rather posited that pressure is a key factor in the incidence of pressure ulcers (Thompson and Marks-Maran, 2015, Van Gaal et al., 2014, Minnich et al., 2014, Bangova, 2013, Chauhan et al., 2005). These studies added that the absence of pressure does not only reduce drastically one's risk of developing pressure ulcers, but also helps in faster healing and treatment of existing pressure ulcers.

In the 19th century, advances in medicine such as the discovery of bacteria, antisepsis and X-rays changed the understanding, treatment and management of pressure ulcers by providing an understanding of infections and complications that can arise from pressure ulcers, and how best to deal with these complications. The 20th century brought in antibiotics, which changed the scenario further, and the later part of this century witnessed numerous studies on nutrition, trace elements, biomechanics and newer methods of treating and managing pressure ulcers (Agrawal and Chauhan, 2012).

In 1923, Carrier and Rehberg conducted an experiment in which they cannulated human capillaries, and directly measured capillary pressures. The scientific robustness of the methods used in this study cannot be critiqued because the study is not available for download in current databases. However, this study is deemed one of the pioneering studies exploring the aetiology of pressure ulcers, hence, it is often cited in the literature. Prior to this experiment, Lombard in 1912, used indirect methods to approximate capillary pressures. These two studies showed huge discrepancies in capillary pressures when they were measured directly and indirectly (Shore, 2000). In 1930, Landis, published his ground-breaking work on capillary, venules and arterioles pressures among healthy human volunteers under normal conditions, and under the influence of venous congestion, heat, cold, histamine, and inflammation. All the volunteers had a systolic blood pressure of 105-130 mmHg, and the experiment was conducted at room temperature (18-20˚C). Using a microinjection technique, Landis cannulated single capillary loops in the fingernail beds of the volunteers using a micropipette attached to a double mercury manometer that measured low and high intracapillary pressures. The manometric pressure was adjusted until blood did not enter the micropipette tip. Manometric pressure at this equilibrium point represented mean capillary pressure, and this was deemed to be 32 mmHg. Ever since, 32 mmHg is regarded as the capillary closing pressure (CCP). CCP is defined as the minimal amount of pressure necessary to cause a capillary to collapse (Agrawal and Chauhan, 2012, Landis, 1930). Pressures higher than CCP would slow down blood flow in the capillaries and lymph nodes, which might cause insufficient supply of oxygen and nutrients and may lead to inadequate removal of metabolic waste materials from the body. The scientific basis of the method used in this research have been widely criticised by several authors

because the lower pressure reading could have been due to the fact that the bleeding blood vessels were not enclosed because the capillaries were cannulated (Messer, 2012, Thompson, 2005, Defloor, 1999, Shore, 2000). Additionally, the study noted increases in capillary pressures of 60 mmHg during hyperaemia but failed to discuss and link it to the body's ability to withstand pressure through autoregulation (Thompson, 2005). As will be discussed in section 2.10.2, the body of healthy people has the capability to auto regulate itself to withstand the harmful effects of pressure in a physiological body mechanism called reactive hyperaemia in comparison to those of sick people. Lastly, Landis' *in-vitro* study did not take into account the differences in the body size, as well as the different intrinsic and extrinsic factors of the volunteers. These factors are important, as the health characteristic of the subjects could have been different from that of at risk populations, such as those of advancing age and those diagnosed with chronic disease (Thompson, 2005, Shore, 2000). Modern-day digital capillary pressure-reading techniques have shown that, the average pressure of an intact enclosed capillary is 47 mmHg (Defloor, 1999). However, 32 mmHg is widely regarded in literature as the capillary pressure threshold, above which tissue damage could occur (Manzano et al., 2013, Peterson et al., 2013a, Nayak et al., 2008, Anton, 2006, Thompson, 2005, Bouten et al., 2005).

Moving forward in time, Husain (1953), discovered that localised interface pressure (IP) of 100 mmHg applied for two hours to rats caused muscular tissue necrosis, oedema, and destruction of fibres. The aetiology of pressure ulcers has further been expanded by the classical work of Kosiak (1959). Using healthy greyhound dogs as subjects, varying intensities of pressures in millimetres of mercury (mmHg) were applied to the femoral trochanteric and lateral ischial tuberosities of the dogs. The pressures were applied for varying lengths of time. The study concluded that a pressure of 60 mmHg applied for only one hour showed evidence of tissue damage. This study has since been regarded as the basis of modern pressure ulcer research (Stojadinovic et al., 2013, Jones, 2013, Dharmarajan and Ahmed, 2003). The study by Kosiak (1959), gave rise to the top-down theory of pressure ulcer aetiology, whilst latter studies proposed the bottom-up theory (Salcido et al., 1994, Daniel et al., 1981). These theories will be discussed in detailed in section 2.11.

2.4 Definitions of pressure ulcers

Pressure ulcers can be caused by constant unrelieved pressure, they commonly occur over a bony area leading to ischaemia, tissue necrosis and cell damage (Tricco et al., 2015, Plaskitt et al., 2015, Meredith et al., 2014). In a recent document published by the National Pressure Ulcer Advisory Panel (NPUAP) of the United States, European Pressure Ulcer Advisory Panel (EPUAP), and the Pan Pacific Pressure Injury Alliance (PPPIA), edited by Haesler (2014), pressure ulcers have been defined as localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure together with shear. These organisations are the internationally recognised authorities that formulate policies on pressure ulcers. A number of contributing factors such as level of nutrition, skin type, pathological disorders and changes are also associated with pressure ulcer development (Heywood et al., 2015, Bush et al., 2015, Bishop and Droste, 2014). Some of these factors are emphasised in how some studies define pressure ulcers. Consequently, several authors have defined pressure ulcers as visible necrosis caused by pathological changes as a result of pressure-induced suppressed blood supply to the cutaneous and subcutaneous tissues (Welsh, 2014, Cremasco et al., 2013, Smith et al., 2013, Sibbald et al., 2011, Turjanica et al., 2011).

However, these definitions fall short of the complete description of pressure ulcers. Pressure ulcers should be described as an area of localised soft tissue ischaemic necrosis caused by unrelieved pressure higher than the CCP with or without shear, related to posture which commonly occurs over a bony prominence (Agrawal and Chauhan, 2012, Black et al., 2012, Beeckman et al., 2010b). This definition is supported by various studies which argued that CCP plays an integral role in the development of pressure ulcers, and that irrespective of the amount of pressure the skin is exposed to, pressure ulcers are likely to develop when the CCP is exceeded (Jones, 2013, Estilo et al., 2012, Shore, 2000, Deeth and Hamilton, 2000, Landis, 1930).

Notwithstanding the crucial role high capillary closing pressures play in the development of pressure ulcers, their impact in the formation of Kennedy Terminal Ulcers (KTU) is insignificant (Sankaran et al., 2015, Barateau and Salles, 2015). Kennedy Terminal Ulcers (KTU) are unavoidable skin breakdown or skin failure that occurs as part of the dying process (Brown and Beel, 2015, Schank, 2009). Skin failure is an event in which the skin and underlying tissue die due to hypoperfusion that occurs concurrent with severe dysfunction of other organ systems (Langemo et al., 2015, Chrisman, 2010, Langemo and Brown, 2006). Research has shown that the skin depends on the function of other organ systems for nutrition, blood circulation and the ability to fight infection, hence any dysfunction in any of the body organ systems would have a direct and visible detrimental impact on the skin (Forasassi and Meaume, 2015, White-Chu and Reddy, 2013, Dean, 2012, Reid and Shelley, 2011).

Another type of pressure ulcer has recently been identified as Medical Device Related (MDR) pressure ulcers. These are defined as localised injury to the skin or underlying tissue as a result of sustained pressure from a medical device (Pittman et al., 2015, Visscher and Taylor, 2014). MDR pressure ulcers usually occur directly under diagnostic or therapeutic medical devices such as operating theatre tables, oxygen face masks, nasal cannulae tubing and X-ray tables (Sebba Tosta de Souza et al., 2015, Baharestani, 2013). MDR tissue damage typically appears visually on the superficial skin and takes the shape of the device (Glasgow et al., 2014, Bergquist-Beringer et al., 2013, Black et al., 2010). Although most MDR pressure ulcers are preventable, not all are because they arise from therapeutic and diagnostic medical devices, which are essential part of patient management (Ambutas et al., 2014). In most instances, an improvement in the quality of life and in some instances survival of most patients is directly linked to the utilisation or application of these devices. Hence, the incidence of MDR pressure ulcers in some cases is inevitable (Makic, 2015). Irrespective of this, the incidence of MDR pressure ulcers can be reduced significantly if medical devices are carefully applied, patients using medical devices are regularly monitored for any pain arising from MDR skin damage, and frequently assessed to rule out skin injury (Fromantin et al., 2015, Calvo-Espinos et al., 2015).

In the specialised settings of radiography and radiotherapy, patients might develop MDR pressure ulcers. In view of the need to minimise error and enhance patient management, patients are usually transferred onto imaging and radiotherapy surfaces prior to a radiography and radiotherapy planning and treatment procedure (Whitley et al., 2005). These surfaces often use very thin or have no mattresses. Hard imaging and radiotherapy surfaces without any form of cushion could be harmful to the patient's skin, especially in at risk populations such older patients and those diagnosed with chronic diseases such as cancer (Stojadinovic et al., 2013, Liao et al., 2013). In addition, in most cases, prior to a procedure, patients are intentionally immobilised to minimise movement error during medical imaging and radiotherapy planning and treatment procedures. Immobilisation is more rigid during radiotherapy planning and treatment where wrong or poor delineation of the target tumour and any misdirection of prescribed radiation could be fatal (Lang et al., 2015, Li et al., 2012). In itself, the application of immobilisation devices could increase the interface pressure between the patient and the radiography/radiotherapy surface. This may induce skin injury, thereby increasing the risk of developing MDR pressure ulcers. However, the impact of immobilisation devices on the incidence of skin injury was not investigated in this thesis.

Pressure ulcers remain a common problem in health care with elderly and severely ill patients and those suffering from chronic diseases being particularly vulnerable because of poor health. Specifically, patients with chronic spinal injuries, limited trunk stability and motor function, and cancer are more prone to developing pressure ulcers (Wu et al., 2015, Meredith et al., 2014, Smit et al., 2013a). This is because of the long period of time they spend on hospital beds, wheelchairs, and radiography/radiotherapy surfaces mostly in one position (Hollington and Hillman, 2013, Marin et al., 2013). For example, most patients suffering from cancer spend long periods lying in one position on hard radiotherapy surfaces to undergo prolonged radiotherapy planning and treatment procedures. As stated earlier, this could induce tissue damage, and lead to the development of MDR pressure ulcers. Reenalda et al. (2009b) stated that staying in one position for long periods increases the likelihood of developing pressure ulcers because of the unbalanced match between the external load of body weight and the ability of the skin and subcutaneous tissues to withstand that load. This sustained interface pressure can

be very painful and uncomfortable to most patients, and could lead to the development of pressure ulcers (Vanderwee et al., 2009, Clark, 2007). The impact of this sustained pressure could be more severe in patients with neurological diseases such Parkinson's disease and brain tumours, who have no or very poor (limited) pain perception, and therefore are unable to move to relieve the pressure (Amir et al., 2013).

Moisture lesions should not be mistaken for pressure ulcers. Moisture lesions are defined as the inflammation and/or destruction of skin tissues caused by prolonged and excessive exposure to humidity or liquid which is in continuous contact with intact skin (Defloor et al., 2005b). These lesions will frequently occur as a result of acute faecal incontinence, and a patient's risk of developing moisture lesions is increased when both faecal and urinary incontinence are present (Voegeli, 2013). Moisture lesions present clinically as superficial loss of epidermis and/or dermis tissue, which may be preceded by areas of erythema on the skin (Zulkowski, 2012, Beeckman et al., 2010a). They usually occur on the buttocks, groin, inner thighs, natal cleft, skin folds, and areas where skin is in continuous contact with skin (Yusuf et al., 2015). Although moisture lesions and some pressure ulcers (category one and two; see sections 2.5.1 and 2.5.2 respectively) have some common clinical characteristics and appearances, separate categorisation, treatment, and management of moisture lesions makes sense. For example, unlike pressure ulcers, they are not found over bony prominences, and can occur in areas of low interface pressures.

2.5 Categorisation of pressure ulcers

Pressure ulcers are classified into categories to enable appropriate treatment and/or pathways to be provided (NPUAP, 2014). Although most pressure ulcers fall within the six established categories, several authors argued that there are pressure ulcers that have the characteristics of more than one particular category and may be difficult to categorise (Filius et al., 2013, Stevenson et al., 2013). Hence, healthcare professionals must be very careful when categorising pressure ulcers. This is particularly important because pressure ulcer categorisation determines the treatment and management pathway that a patient suffering from pressure ulcers receives. Using the recommendations of international organisations (EPUAP, NPUAP, and PPPIA) that formulate policies on pressure ulcers, pressure ulcers can be categorised into six main categories:

2.5.1 Category one

This presents clinically as non-blanchable erythema of intact skin (NPUAP, 2014). This category of pressure ulcers is difficult to detect in people with darker skin tones: the affected area is usually painful, firm, soft, warmer or cooler compared to surrounding areas, and takes about 28 days to heal (NICE., 2014, Bennett et al., 2004). Category one pressure ulcers have a similar physical appearance to reactive hyperaemia (discussed in section 2.10.2), hence there can be difficulties in distinguishing between the two. Also, this category of pressure ulcers must not be mistaken for a moisture lesion.

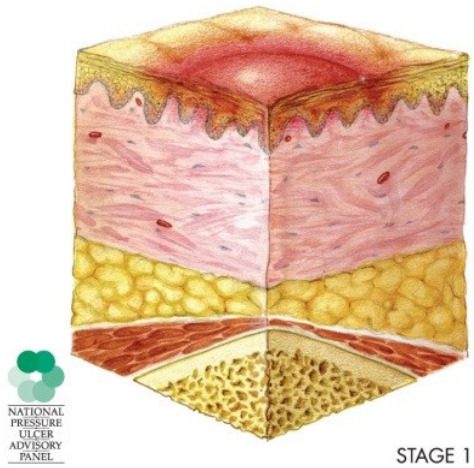

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Figure 2:1: An image of a category one pressure ulcer

(NPUAP, 2014)

2.5.2 Category two

This category of pressure ulcer presents clinically as superficial partial thickness of skin loss involving epidermis, dermis, or both (Gunningberg et al., 2013). These pressure ulcers also appear on the skin as an abrasion or blister, and have a mean expected healing time of 94 days (Bennett et al., 2004). Again, this category of pressure ulcers must not be mistaken for a moisture lesion.

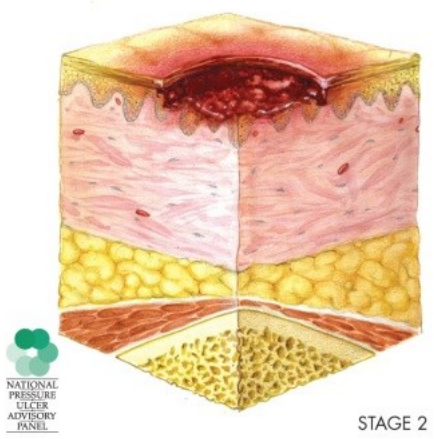


Figure 2:2: An image of a category two pressure ulcer
(NPUAP, 2014)

2.5.3 Category three

Category three pressure ulcers are classified as pressure ulcers with full thickness skin loss involving damage to or necrosis of the subcutaneous tissue that may extend down, but not through the underlying fascia (Jesada et al., 2013). Category three pressure ulcers have an average healing time of approximately 127 days (Bennett et al., 2004).

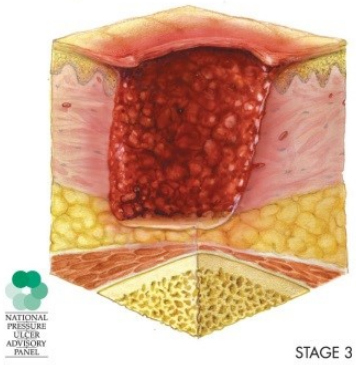


Figure 2:3: An image of a category three pressure ulcer
(NPUAP, 2014)

2.5.4 Category four

Category four pressure ulcers present clinically as extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss, and have a mean expected healing time of 155 days (Akins et al., 2011, Bennett et al., 2004).

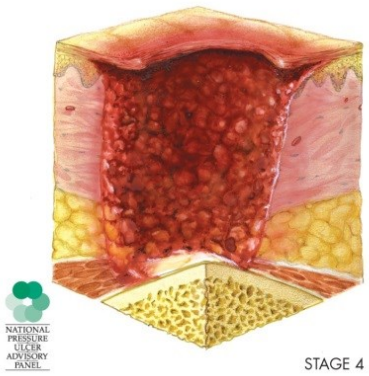


Figure 2:4: An image of a category four pressure ulcer
(NPUAP, 2014)

2.5.5 Unstageable/unclassified pressure ulcers

This category of pressure ulcers present clinically as full thickness tissue loss in which the entire ulcer is obscured by brown or black slough and/or eschar in the wound bed (NPUAP, 2014, Milne and Ousey, 2010). To ascertain the true depth of the wound, any slough and/or eschar in the wound must be removed; otherwise this ulcer may be wrongly classified as a stage three or four (NPUAP, 2014, Samuriwo, 2012).

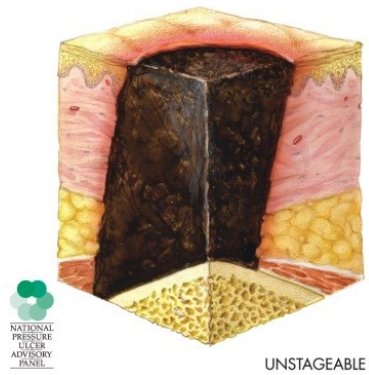


Figure 2:5: An image of an unstageable pressure ulcer
(NPUAP, 2014)

2.5.6 Suspected deep tissue injury

Backhaus et al. (2011) stated that these pressure ulcers are normally purple or maroon in colour and occur as a localised area of discoloured intact skin and/or blood-filled swelling due to damage of underlying soft tissue from pressure and/or shearing**.** Affected areas are usually painful, firm, warmer or cooler compared to adjacent skin, and are not easily visible in people with dark skin tones (NPUAP, 2014, Pieper and Kirsner, 2013).

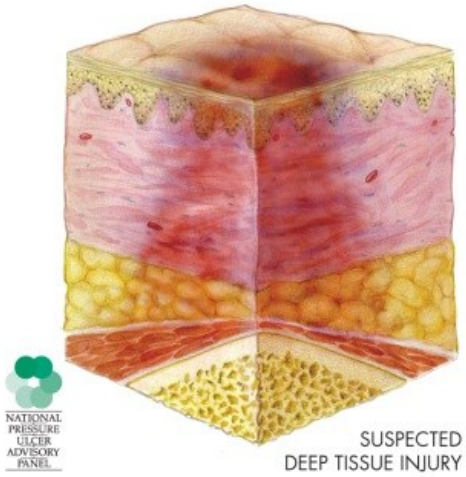


Figure 2:6: An image of a suspected deep tissue injury
(NPUAP, 2014)

As stated earlier, to better treat or manage pressure ulcers, it is important that clinicians and healthcare professionals get the categorisation of pressure ulcers correct (Theisen et al., 2012). In addition, it is important to get the categorisation of pressure ulcers correct because categorisation is useful in recording the incidence and prevalence of pressure ulcers (Mehta et al., 2015). However, studies have shown that most healthcare professionals and facilities fail to accurately categorise pressure ulcers due to insufficient knowledge (Levine et al., 2012, Demarre et al., 2012). To ensure accurate and effective categorisation of pressure ulcers, and also to enhance effective patient management, healthcare professionals require sufficient knowledge of the anatomy of the skin and sub-cutaneous tissues, and the ability to differentiate between normal and abnormal skin tissues (Ankrom et al., 2005). In addition, healthcare professional especially radiographers and radiotherapy workers must undergo training and retraining on how to categorise accurately pressure ulcers because categorisation of pressure ulcers is not a common practice in radiography.

2.6 Prevalence of pressure ulcers

To understand the magnitude of the problem of pressure ulcers, prevalence is one of the most common measures (Bredesen et al., 2015, Queiroz et al., 2014). Prevalence is defined as the number of people with pressure ulcers as a proportion of an entire patient population at a specific period of time (McGinnis et al., 2014, Stevenson et al., 2013, Leijon et al., 2013). Prevalence data is an important cross-sectional information that gives an overview of how many people have pressure ulcers in a target population (e.g. patients undergoing radiography and radiotherapy planning and treatment procedures) at a particular period of time (Bryant and Nix, 2012a). Prevalence data indicates whether pressure ulcers exist, and if they exist, the different categories, and their impact on patients' quality of life (Inan and Oztunc, 2012, Primiano et al., 2011).

Furthermore, prevalence data is a useful measure of adherence to internationally and locally recommended pressure ulcer preventive guidelines, and the use of pressure ulcer preventive interventions (Stevenson et al., 2013, McDermott-Scales et al., 2009). Prevalence data is also very useful in assessing the standard of nursing and/or medical care patients who develop pressure ulcers received (Vowden and Vowden, 2009). Nevertheless, because prevalence data only gives an overview of pressure ulcers at a specific period, it does not give a detailed description of the reasons or causes of pressure ulcers in a specific period (van Nie-Visser et al., 2013, James et al., 2010). Bryant and Nix (2012a) argued that prevalence data should not be used as a measure of the quality of care patients receive within a hospital or social care setting because different hospital and social care settings have patients with different health conditions, and at varying pressure ulcer risk levels. For example, patients in long term care homes are at high risk of developing pressure ulcers due to their age, the presence of co-morbidities, and other intrinsic and extrinsic factors such as their low level of physical activity. Therefore, these patients may be receiving the best level of nursing care but may still have high pressure ulcer prevalence, compared to younger patients in hospital settings. Consequently, comparisons cannot be made between prevalence data across different clinical settings unless the data have been collected from patients with similar health characteristics, in similar clinical or care settings, at the same period of time, using

the same pressure ulcer risk assessment scale (Milne et al., 2009, Tannen et al., 2008, Shahin et al., 2008, Maida et al., 2008, Defloor et al., 2005a).

Globally, pressure ulcers are the third most expensive medical condition after cancer and cardiovascular diseases (Agrawal and Chauhan, 2012), with varying prevalence data between countries, different clinical settings, and also between superficial and deep pressure ulcers, both having different aetiology (Plaskitt et al., 2015, Sullivan, 2014, Bennett, 2012). Deep pressure ulcers (or deep tissue injury) are caused from prolonged pressure and usually develop over bony prominences where internal pressures are mostly high (Brienza, 2007), whereas superficial ulcers are developed from shear and friction, which then causes tissue tearing (Park et al., 2014).

In the UK, the Health and Social Care Information Centre HSCIC (2014), reported that current data available for 186,000 patients indicates a pressure ulcer prevalence of 4-10% among patients in nursing homes, care homes, independent sector care providers and community nursing. However, prevalence ranges between 8 to 11% in patients admitted to acute hospitals (Defloor et al., 2005a). Another study reported that 25% of residents in ten long-term geriatric wards in Glasgow developed a pressure ulcer within six months of admission (Martin et al., 1995). The results of a pilot study conducted in five European countries, including over 2,500 patients from fifteen hospitals in the UK, found a UK prevalence of 23% or 13.9% if only including category two or above pressure ulcers (Vanderwee et al., 2007).

The Department of Health (DOH, 2010) of the UK, suggested that pressure ulcer prevalence is an excellent indicator of the quality of care delivered in a health-care setting, and recommended an annual reduction by 5%. However, as stated earlier, agreement with this recommendation is not widespread, as prevalence data alone cannot be used as a determinant of quality of care. To infer quality of care, prevalence needs to be combined with knowledge of the population's risk status and case mix (Schluer et al., 2014, Johansen et al., 2014). For example, impending death is often associated with a marked reduction in tissue tolerance and skin failure and thus an increase in pressure ulcers among patients suffering from Kennedy Terminal ulcers (Brennan and Trombley, 2010).

In the United States (US), overall pressure ulcer prevalence was 13.5% in 2008, and 12.3% in 2009 with approximately 10% of them being Medical Device Related pressure ulcers (VanGilder et al., 2009a). Current statistics on pressure ulcer prevalence in the US among patients in acute care is lacking. However, previous surveys estimated a prevalence of 14-17% among this patient population (Whittington and Briones, 2004). It must be stated that these figures are likely to rise due to population increase and an ageing population. Keelaghan et al. (2008), conducted a prevalence study in which they investigated the prevalence of pressure ulcers among newly hospitalised nursing home residents, and among newly hospitalised patients from non-nursing home settings. The study found prevalence of pre-existing pressure ulcers at the time of admission to hospitals was 26.2% among those admitted from a nursing home and 4.8% among those admitted from another living situation. The limitation of this study is that all the volunteers were at least 65 years old, an age group with a high risk of developing pressure ulcers (Chen et al., 2015, Kelly, 2014), hence conclusions from this study are restricted to an elderly population who are at heightened risk.

In Canada, prevalence figures of between 36.8-53.2% were identified in most long-term healthcare facilities (Davis and Caseby, 2001a). Woodbury and Houghton (2004), also reported a prevalence of nearly 30% in nonacute settings and concluded that the overall prevalence of pressure ulcers in all healthcare institutions across Canada is about 26%. Prevalence figures of 29.2 and 8.8% were reported in long-term care facilities in the Netherlands and Germany respectively (Tannen et al., 2006). In contrast Lahmann et al. (2006), reported a prevalence of 13.9% at a similar setting in Germany. These contrasting figures support the position that unless prevalence data is collected from patients with the same characteristics such as age and the type of hospital setting they are admitted to (i.e. acute care, long-term nursing home), at the same period in time, with the same scale, it will be difficult to compare such data.

Prevalence data across ten long-term care facilities in Italy found a mean prevalence of 27% (Capon et al., 2007). Europe has an overall average prevalence of 18.1% (Bennett, 2012, Vanderwee et al., 2007). Pressure ulcer prevalence rates in French hospitals remain stable at 8.9% over a ten year period (Barrois et al., 2008).

However, as indicated earlier, this figure is more likely to increase because of ageing population. Additionally, prevalence studies conducted in acute care facilities in Ireland concluded that prevalence ranges between 12–18.8% (Gallagher et al., 2008, Gethin et al., 2005, Moore and Pitman, 2000). A prevalence study in 12 Chinese hospitals concluded with a mean prevalence of 1.58% (Jiang et al., 2014), whilst a prevalence study conducted in one tertiary hospital in India showed a prevalence of 7.8% (Mehta et al., 2015). However, the sample size for these two studies are small, therefore the findings cannot be generalised to the wider Indian and Chinese patient population, especially when considering that each of these countries has a population of more than one billion people.

Iceland has an overall prevalence of 17% (Moore et al., 2013), whereas 9.6% of patients in Japanese long-term hospitals developed pressure ulcers (Igarashi et al., 2013). Brazil has a prevalence of nearly 17% among patients in general hospitals (Brito et al., 2013), whilst a study among patients in medical and surgical inpatient wards and critical care units in Turkey resulted in a mean prevalence of 10.4% (Inan and Oztunc, 2012). Hospitalised patients in Jordan have a prevalence between 17-24% (Aljezawi et al., 2014, Tubaishat and Aljezawi, 2013, Alja'afreh and Mosleh, 2013), and a study among stroke patients in Indonesia found prevalence to be 28% (Amir et al., 2013). Among patients in intensive care units (ICU), pressure ulcers prevalence have been identified to be 13.6% in a short stay ICU and 42.1% in a long stay ICU in the Netherlands (Weststrate and Bruining, 1996). Also, a study among 95 patients in an Italian ICU found prevalence to be 35% (Sterzi et al., 2003), whereas in a sample of 85 patients in an ICU within the USA, 56% prevalence was found (Jiricka et al., 1995). Most of these studies were conducted many years ago with very small sample sizes which may not reflect pressure ulcers prevalence in these countries. The differences in prevalence between countries may be due to the differences in patients' health characteristics, such as age and health conditions. Also, these studies were conducted at different periods, using different methods.

Pressure ulcers are common among terminally ill patients, with a prevalence rate ranging between 17-47% (Henoch and Gustafsson, 2003, Chaplin, 2000). Malignancies are a common cause of death among most patients, with cancer being the most diagnosed, which leads to patients referred to palliative care services (Sanchez-Holgado et al., 2014, Heinemeyer, 2014). The main aim of palliative services is to improve patient's quality of life, by focusing on symptoms management and control (Barateau and Salles, 2015). Pressure ulcers are a common problem in palliative care because patients referred for such services are usually of advancing age, have poor immune systems, and mostly have impaired sensory perception, making them highly susceptible of developing pressure ulcers (Sankaran et al., 2015, Gene Badia et al., 2013).

2.7 Incidence of pressure ulcers

Pressure ulcer incidence is defined as the proportion of ulcer-free patients who develop pressure ulcers within a specified period in a defined patient population (Schallom et al., 2015, Jiang et al., 2014, Moore et al., 2013). Incidence is calculated as a cumulative incidence expressed as a percentage, or as incidence density expressed as a rate (Dugaret et al., 2014, Igarashi et al., 2013). The denominator for calculating cumulative incidence is the total number of people in the patient population being observed at the beginning of the specified period of time (Eberlein-Gonska et al., 2013, Bulfone et al., 2012, Bryant and Nix, 2012b, Schoonhoven et al., 2007). Cumulative incidence measures risk, and provides an approximation of the probability of developing pressure ulcers over a time period, and therefore can be used to gauge the effects of risk factors, and the impact of pressure ulcers prevention strategies (Dugaret et al., 2014). In calculating incidence density, the denominator is the aggregate duration of exposure, hence incidence density is a rate that can be reported as patient-days (Streed and Loehne, 2007).

Cumulative incidence is commonly reported in the literature. Cumulative incidence is an effective assessment tool to determine the effects of pressure ulcer preventive interventions (Plaskitt et al., 2015, Van Gaal et al., 2014). However, it is difficult to conduct incidence studies, because such investigations require longitudinal observations usually over a long period of time (Bryant and Nix, 2012b). In the UK, statistics from NHS 'Stop The Pressure' website (NHS, 2015), indicates that about 700,000 people are affected by pressure ulcers each year. The reported annual cumulative incidence and lifelong risk of pressure ulcers among chronic spinal cord injury patients is between 23%–30%, and 70% respectively (Bishop and Droste, 2014, Eslami et al., 2012, Raghavan et al., 2003).

Cumulative incidence varies between settings: for example, in the US, Lyder et al. (2012), reported cumulative incidence of pressure ulcers ranging from 0.4-38% in acute care hospitals, 2-24% in long-term nursing facilities, and 0-17% in home care settings. Davis and Caseby (2001a) also reported that the cumulative incidence of pressure ulcers in two long-term care facilities in the US was 11.7%, whilst Japan has a cumulative incidence of 19% in a similar setting (Igarashi et al., 2013). Sweden has a cumulative incidence of 11.6% among patients in hospitals (Gunningberg et

al., 2011), Nigeria's is 13.84% in a similar setting (Onigbinde et al., 2012), and that of Spanish hospitals and nursing homes is 7.8% (Pancorbo-Hidalgo et al., 2014). Cumulative incidence of 3.3% was reported in Germany cardiological and surgical intensive care units (Shahin et al., 2009). Cumulative incidence studies are important because they give an idea of the magnitude of new pressure ulcer cases in a patient population: hence, preventive and treatment resources can be targeted at these new incidences (Mehta et al., 2015, Ghavidel et al., 2012).

However, Bryant and Nix (2012b) argued that there are considerable methodological issues surrounding the correct reporting of incidence. A classic example is the method used to define who is at risk of developing pressure ulcers. This is very important because it is the denominator used in the cumulative incidence formula, and it significantly affects the final incidence figure, and may result in an overestimation or underestimation of the true incidence (Van Gaal et al., 2014, Dugaret et al., 2014, Onigbinde et al., 2012, Bulfone et al., 2012). Nevertheless, reporting cumulative incidence is an important measure of pressure ulcers, and it is useful in designing effective pressure ulcer preventive and treatment strategies (Rich et al., 2011, Manzano et al., 2010). Currently, most incidence studies only collect data from category two and above pressure ulcers. The clinical implication of this is that, healthcare professionals and clinicians can infer from current data that the magnitude and number of people developing pressure ulcers is likely to be much more than estimated; hence, the need to ensure that patients are properly assessed, and those at risk of pressure ulcers put on an effective treatment/management pathway.

From the literature review conducted for this thesis, there seems to be controversy on whether non-blanchable erythema of intact skin (category one pressure ulcers) should be considered as a pressure ulcer or whether only categories two and beyond should be defined as pressure ulcers. Due to this confusion, some studies using pressure ulcers prevalence and incidence as outcome measure define pressure ulcers in different ways. Consequently, some of these studies did not include category one pressure ulcers (Demarré et al., 2012), whereas others (Pancorbo-Hidalgo et al., 2014, Onigbinde et al., 2012) did. This may result in underestimation and overestimation of prevalence and incidence of pressure ulcers.

The position of the author of this thesis is that category one pressure ulcers ought to be reported in all prevalence and incidence studies. However, to accurately do that, these pressure ulcers must be correctly differentiated from reactive hyperaemia (discussed in section 2.10.2), a physiological mechanism which has similar physical characteristics as category one pressure ulcers.

2.8 Cost of treating/managing pressure ulcers

The prevention of pressure ulcers has been a priority for health professionals owing to their clinical and financial implications for the individual and society (Gorecki et al., 2010). Pressure ulcers cause pain, suffering and mental stress for patients; these are difficult to quantify numerically and in monetary terms (Riordan and Voegeli, 2009, Spilsbury et al., 2007). In the UK, no current study has investigated the total cost of pressure ulcers on the National Health Service (NHS). However, a study by Guest et al. (2015) investigated the total cost of treating/managing wounds (including pressure ulcers) on the NHS, and concluded that it costs about £5.3 billion per annum. This figure is significant because pressure ulcers form a huge proportion of all wounds treated within the NHS. To really understand the financial burden of pressure ulcers, it is important to state some prominent studies conducted on this topic. Over a decade ago, the NHS spent between £1.4–2.1 billion per annum on pressure ulcers (Bennett et al., 2004). This huge sum of money amounted to approximately 4% of the total NHS expenditure at the time. A more recent study conducted by Posnett and Franks (2008a) indicated that this expenditure has increased; conservatively estimating the new cost to £1.8-2.6 billion per annum. It has also been shown that the daily cost of treating/managing pressure ulcers with complications in the UK ranges from £43 to £374, and those without complications ranges between £43 and £57 (Dealey et al., 2012). These studies have shown that pressure ulcers have huge financial cost on the taxpayer. In the US, its costs between $11-17 billion annually to treat pressure ulcers (Russo et al., 2008, Gordon et al., 2004), and about $2770 and $5630 to treat category one/two and category three/four pressure ulcers respectively (Padula et al., 2011).

However, most of these statistics do not include people with pressure ulcers who are being cared for in the community (Ousey, 2010, Posnett and Franks, 2007). This implies that the total cost of treating/managing pressure ulcers could be much more than these studies have estimated. These costs are directly linked to pressure ulcer severity and the presence of complications, which in turn affects the mean expected healing times (Raju et al., 2014, Russo et al., 2008). In other words, complications from pressure ulcers increase the length of time patients have to stay in hospitals, thereby increasing hospital cost, and preventing other patients from having access to

hospital beds (NICE., 2014, Mathiesen et al., 2013, Filius et al., 2013, Dealey et al., 2012).

The cost of nursing time dominates the resource cost of treating pressure ulcers because, the need for dressing ulcers, regular repositioning of patient, monitoring and risk assessment, makes pressure ulcer care labour intensive (Lubbe and Roets, 2014, Lyder et al., 2012). Healthcare professionals' time accounts for almost 90% of the overall cost of treating/managing pressure ulcers, and for 96% of the cost of treating/managing category one or two pressure ulcers (Dealey et al., 2012). However, the main determinant of the cost of treating/managing severe pressure ulcers (category three onwards) is the occurrence of wound complications, for example, infection, which may lead to delayed healing and the need for inpatient admission (Bishop and Droste, 2014, Krapfl and Mackey, 2008). Finally, the cost of other resources, such as dressings, antibiotics and pressure-relieving equipment, accounts for 3.3% of the overall cost of treating pressure ulcers (Dealey et al., 2012).

Most pressure ulcers are hospital acquired (nosocomial), putting more responsibility on healthcare professionals to maximise pressure ulcers preventive strategies to minimise incidence (Goodell and Moskovitz, 2013, Tzeng et al., 2013, Lyder et al., 2012). At an average 5–10 days additional length of stay per patient, hospital-acquired pressure ulcers cost thousands of excess bed delays (Orsted et al., 2009). A recent report showed that delays in discharging patients from hospital after treatment could be costing the NHS in England alone £900 million annually (Triggle, 2016). Although complications from pressure ulcers may form a small proportion of hospital delays, their contribution to increasing cost on the NHS cannot be overemphasised. Hence, reduction in pressure ulcers incidence could release beds and nursing time, allowing more patients access to hospital facilities. In addition, pressure ulcers and their associated complications could result in death, but there is no empirical evidence showing the exact nature of this relationship. To prevent and minimise the impact of pressure ulcers, and improve patient's quality of life, the NHS has invested hugely in pressure redistributing equipment, and training for health professionals (HSCIC, 2014).

Studies on the economic and financial implications of pressure ulcers should be viewed with caution, because methodologies are not the same, and therefore results of such studies cannot be compared easily. For example, some studies (NICE., 2014, Filius et al., 2013, Dealey et al., 2012) included the cost of all items of care, such as cost of bed, cost of nursing time, cost of doctors' time, medication, cost of pressure redistributing devices, and other supplies. Other studies (Black et al., 2012, Pham et al., 2011, Mistiaen et al., 2008) investigated the direct costs, such as medications and pressure redistributing devices used to manage the pressure ulcers. To compare costing, the studies should use the same costing components, and the research should be conducted on the same patient group, and also within the same period.

Apart from the cost of treating pressure ulcers and its associated complications, there is also the issue of medico-legal cost. Patients, especially in the UK, are increasingly willing to pursue a legal claim against the NHS where care is perceived to be inadequate, or where clinical negligence is deemed to occur. The NHS receives over 10,000 of such new claims annually and this number is likely to increase due to the increase number of people accessing healthcare and ageing population (Bennett et al., 2004). Data available on the website of Boyes Turner solicitors UK, indicates that their medical negligence department has successfully won pressure ulcers related claims totalling £476,000 between 2002 to date, with the highest individual claim costing £185,000 (MEDNEG, 2015).

2.9 Causative factors of pressure ulcers

From the literature on the aetiology of pressure ulcers, two conceptual schemes can be deduced: one developed by Braden and Bergstrom (1987), and the other by Defloor (1999). Braden and Bergstrom (1987), developed their scheme to serve as the basis for the Braden pressure ulcer risk assesmment scale (see section 2.12.2). In their concept, they argued that tissue tolerance is one of the causes of pressure ulcers. However, as shown in figure 2.7 and discussed in section 2.10, Defloor's concept argued that tissue tolerance is not a causative factor, rather it is an intermediary factor that affects the development of pressure ulcers. The intensity and duration of pressure needed to cause tissue damage, depends primarily on the ability of the patient's skin tissues to withstand pressure, and may vary from one patient to the other. In this thesis, the causative factors of pressure ulcers will be discussed using Defloor's concept.

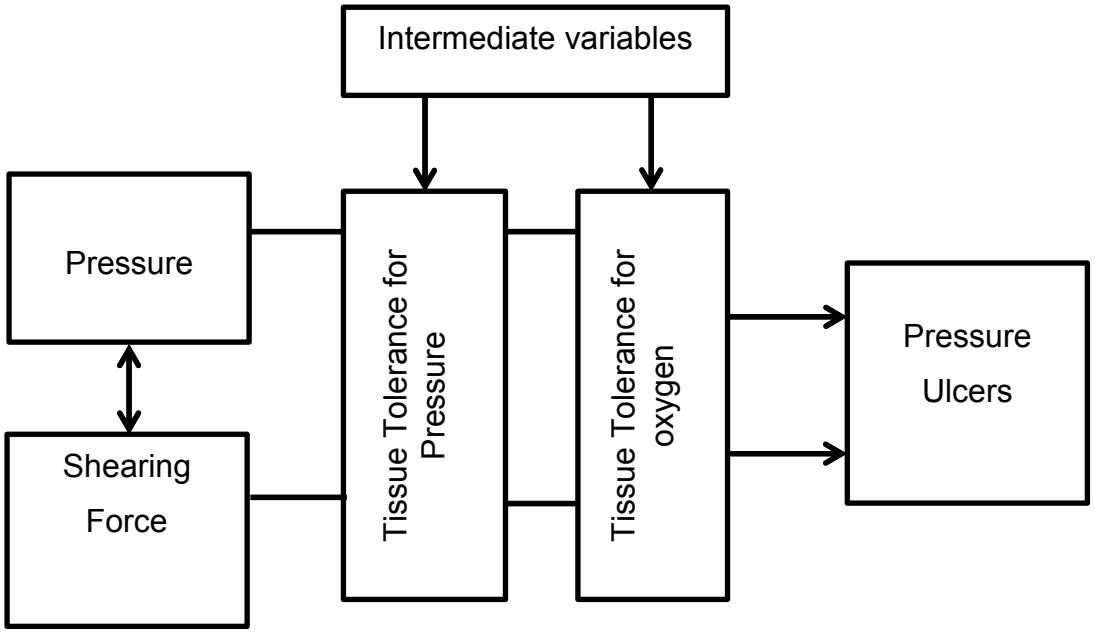


Figure 2:7: Defloor's conceptual scheme

2.9.1 Effects of pressure

Pressure, one of the major causative factors in developing pressure ulcers, is defined as the perpendicular force of a body weight exerted on a unit area of skin (Agrawal and Chauhan, 2012, Messer, 2012, Ghavidel et al., 2012, Sterner et al., 2011). Pressure remains a primary causative factor of pressure ulcers because it has a greater impact on blood flow; sometimes causing partial or complete occlusion of blood vessels (Demarre et al., 2012). This deprives tissues of oxygen, and may lead to tissue anoxia and cell death (Spilsbury et al., 2007). In addition, the presence of pressure increases significantly the risk of tissue shearing, another causative factor of pressure ulcers (Haesler, 2014). It must be stated that sustained unrelieved pressures cause consistent partial or complete occlusion of blood vessels, thereby reducing or shutting supply of vital nutrients to tissues, hence having a more damaging effect on tissues (Peterson et al., 2013b, Moore et al., 2013). Numerous studies have established that two main factors play a key role in determining if the pressure brought to bear on a skin area is necessary to cause tissue ischaemia, which may lead to pressure ulcers. These include the intensity of pressure, and the duration of pressure (Akca et al., 2015, Stojadinovic et al., 2013, Pieper, 2012, Sterner et al., 2011).

As stated earlier Landis (1930), investigated capillary closing pressure (CCP), and concluded that pressure more than 32 mmHg will impede blood flow. This may induce tissue anoxia, causing blood vessels to collapse. However, this figure has been disputed, and with the help of modern digital technology, CCP has been revised to be 47 mmHg (Defloor, 1999). To estimate the intensity of pressure applied to skin tissues at a particular time, studies measuring interface pressure, pressure between surface and body, have been conducted (Hemmes et al., 2014b, Peterson et al., 2013b, Hollington and Hillman, 2013, Peterson et al., 2010, Reenalda et al., 2009b, Justham et al., 1996, Kosiak, 1959). In an animal experiment, Kosiak (1959) illustrated the link between the duration of applied pressure and pressure ulcers. Kosiak (1959) applied pressure of different intensities for different durations to the femoral trochanteric and lateral ischial tuberosities of dogs. The researcher discovered that pressures of 60 mmHg applied for a period of one hour induced tissue damage.

Additionally, Husain (1953), indicated that pressure of 100 mmHg applied for two hours caused muscular damage, oedema, and destruction in fibres. Unfortunately, within the radiological setting, only one study has investigated interface pressure on radiography and radiotherapy surfaces. In this study, Justham et al. (1996), measured interface pressures at the head, scapulae, thoracic spine, buttocks, sacrum, and the heels, on X-ray tables with and without mattresses. They recorded mean interface pressures of 59.2±25.1 for the head, 97.7±55.9 for the sacrum, and 126.9±79.6 for the heels, all in mmHg. In healthy people with normal sensory perception, interface pressures higher than the CCP will not result in ischemia, because these people react to the discomfort arising from capillary closure and tissue anoxia by regularly shifting their position, to relieve their body of sustained pressure (Pieper, 2012, Peterson et al., 2008).

However, this is not possible during radiographic and radiotherapy planning and treatment procedures due to the need for patients to remain still. This is to eliminate patient movement and enhance diagnostic and treatment care. In addition, the utilisation of sedation for some interventional radiography procedures means that patients are unable to move. The implication of this is that, patients undergoing interventional radiography and radiotherapy planning and treatment procedures have to endure sustained interface pressure for long periods of time, thereby increasing their risk of developing pressure ulcers. The duration of sustained pressure on the skin is a very important factor that influences the degree of damage the skins suffers, and works in conjunction with intensity to cause tissue necrosis (Garcia-Fernandez et al., 2014a, White-Chu and Reddy, 2013, Agrawal and Chauhan, 2012). This pressure time-intensity relationship shows that low-intensity pressures applied to the skin over a long period of time can cause tissue damage just as high-intensity pressure can over a short period of time (Cooper, 2013, Akins et al., 2011).

2.9.2 Effects of shear

Shearing is a mechanical load arising from a combination of gravity and friction directed parallel to the skin (Lahmann et al., 2011, Akins et al., 2011). Shearing occurs from gravity pushing down on the body and friction arising from resistance between the body and a surface (Messer, 2012, Pieper, 2012). The shear between two layers of skin tissue may lead to stretching, kinking, tearing, reduced blood flow, stasis, and may distort and damage blood and lymph vessels in the subcutaneous tissues (Byrant, 2012, Defloor, 1999). Studies have shown that the effects of shear in combination with pressure is more damaging to the superficial and subcutaneous tissues than the presence of shear alone (Linder-Ganz and Gefen, 2007, Stekelenburg et al., 2007, Gefen et al., 2005, Bennett et al., 1979, Dinsdale, 1974).

Dinsdale (1974), was the first to show the impact of shear on developing pressure ulcers. Using normal and paraplegic pigs, he discovered that a pressure of 290 mmHg when used alone without shear was needed to produce pressure ulcers in the pigs. However, when pressure was combined with shear, a pressure of only 45 mmHg produced similar injuries. In addition, Bennett et al. (1979), investigated the reduction in pulsatile arteriolar blood flow over the thenar eminence and found out that pressure together with shear produced blood occlusion. However, double that pressure was required to produce the same injury without the presence of shear. These studies show that earlier interface pressure studies, such as the one conducted by Kosiak (1959), and Husain (1953), did not factor the harmful additive effects of shear stress. The implication of this is that these studies have higher capillary closing pressures; hence their findings should be taken with caution.

In radiography and radiotherapy, there is the possibility of tissue damage resulting from shearing forces. This could occur through patient transfers onto imaging and radiotherapy planning and treatment tables, and patient positioning. During handling and moving in medical imaging and radiotherapy, immobile patients are often moved over the stationary imaging/radiotherapy table, causing the patient's body to glide with gravity over the table, while the skin and the underlying tissue remain stationary. This may result in tissue damage to the underlying soft-tissue, muscles and fascia (Agrawal and Chauhan, 2012, Messer, 2012, Wurster, 2007).

As indicated earlier, Justham et al. (1996), showed that there is the possibility of high interface pressure on medical imaging and radiotherapy surfaces. The interface pressures recorded in their experiment are higher than CCP, placing patients undergoing radiographic and radiotherapy planning and treatment procedures at risk of developing MDR pressure ulcers. The presence of intrinsic factors such as poor nutrition, incontinence, and co-morbidities such as cancer and neurological disorders among most patients that undergo radiography and radiotherapy planning and treatment procedures increases significantly their risk of developing MDR pressure ulcers (Posthauer et al., 2015, Sernekos, 2013, Salcido, 2011, Thompson et al., 2005). In addition, the presence of the risk of shearing occurring during movement and handling of patients undergoing medical imaging and radiotherapy planning and treatment procedures could further increase the risk of developing MDR pressure ulcers. However, this thesis will not be investigating the impact of handling and moving on the development of pressure ulcers.

2.10 Tissue tolerance

This is an important intermediate variable that determines the pathologic effects of sustained pressure on superficial and subcutaneous tissues (Sullivan, 2014, Salcido, 2014, Levy et al., 2013). Tissue tolerance is mainly affected by the ability of the skin and supporting blood vessels, interstitial fluid, and collagen fibres, to work together to redistribute applied pressure on the skin (Stojadinovic et al., 2013, Livarinen et al., 2013, Stewart and Salcido, 2012). Any compromise made in this collaboration, will increase the detrimental impact the applied pressure could have on the skin, and its underlying tissues. However, effective redistribution of applied pressure will prevent compression of soft tissues against each other, thereby preventing, or minimising the risk of tissue ischemia (Pieper, 2012). From Defloor's (1999) concept, the factors that affect tissue tolerance can be divided into two groups (figure 2.8), the factors that affect the tissue's ability to redistribute pressure, and those that influence tissue oxygen homeostasis (oxygen distribution within the tissues, and the oxygen need of the tissue).

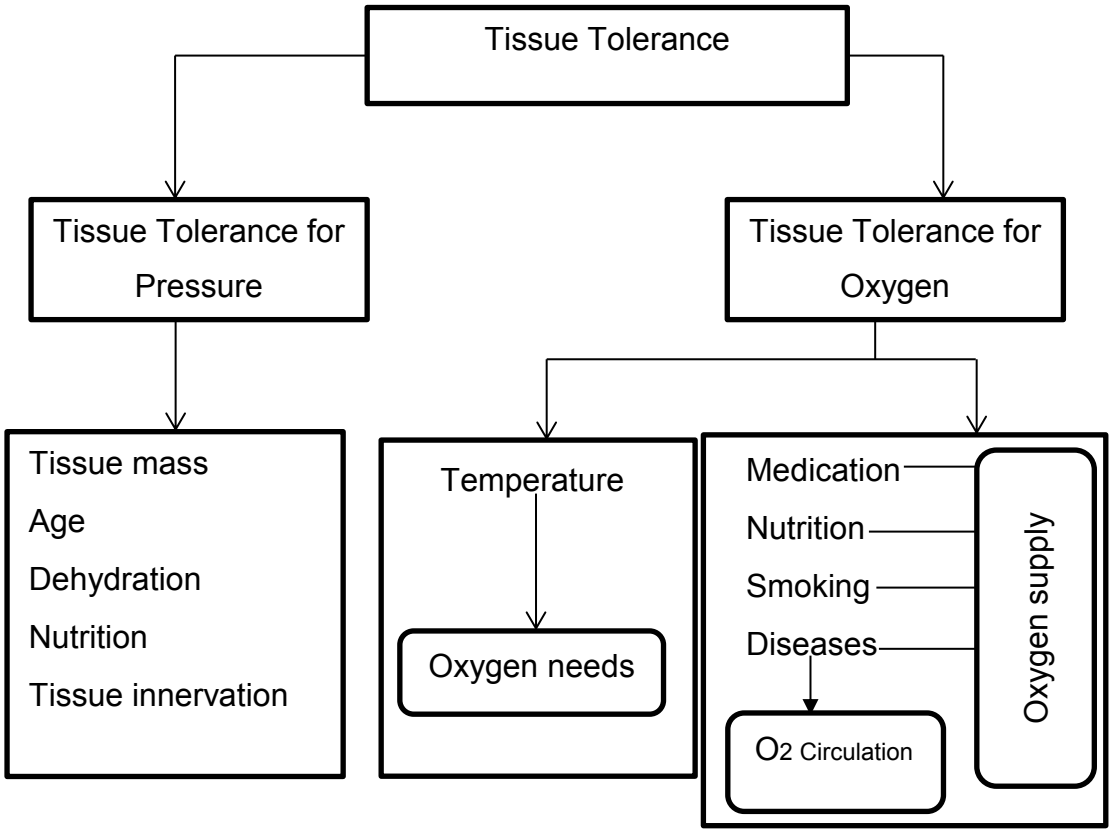


Figure 2:8: Factors affecting tissue tolerance

2.10.1 Tissue tolerance for pressure

Tissue tolerance for pressure is an important intermediary factor, because it influences whether or not applied pressure will cause pressure injury. Messer (2012), stated that normal healthy tissues have in-built protective mechanisms to protect themselves from pressure damage. This protective mechanism enables the skin and its underlying subcutaneous structures, in most instances, to withstand or tolerate pressures much greater than capillary closing pressures without suffering any injury. However, in instances where this protective mechanism is impaired, tissue damage is more likely to occur, irrespective of the intensity and duration of the applied pressure (Salcido et al., 2011, White et al., 2010, Milne and Ousey, 2010). In an animal study, Husain (1953) sensitised rat muscles to pressure, and subsequently ischaemia. Rat muscle was exposed to a pressure of 100 mmHg for two hours. Seventy-two hours later, a pressure of 50 mmHg applied to the same tissue for a period of one hour caused muscle degeneration. It is surprising that muscle damage occurred during the second application of pressure, although the intensity and duration was much lower than the pressure used in the first application. The clinical implication of this finding is that, in patients at risk of developing pressure ulcers, deep tissue damage can occur without appearing on the cutaneous tissues, and exposures to pressures can sensitise the patient's skin, thereby increasing the risk of developing pressure ulcers (Pieper, 2012).

Generally, the skin's protective mechanisms made up of elastin and collagen content, transfer and redistribute 70-80% of externally applied pressure (Kosiak, 1961, Kosiak, 1959). The combination of collagen and elastin fibres allows for extension and recoil, protecting internal structures, subcutaneous tissue and fascia, from the harmful effects of pressure (Nassaji et al., 2014, Meredith et al., 2014, Kelly, 2014, Baath et al., 2014, Thompson, 2005). However, where the superficial tissue is thin, for example as seen over bony projections such as the occiput, sacrum, and heels, a lot more pressure is transferred to the subcutaneous tissues: increasing the risk of developing pressure ulcers at these anatomical areas (Jiang et al., 2014, Briggs et al., 2013, Cooper, 2013, Regan et al., 2009, Goodell and Moskovitz, 2013). Additionally, there is an inverse relationship between ageing and collagen and elastin content found in the skin. Advancing age has been found to reduce the

elastin and collagen content in the skin, making it less pressure resistant, and more susceptible to tissue injury (Reddy, 2008, Pittman, 2007). The impact of age on developing pressure ulcers is likely to be more significant among patients who undergo radiographic and radiotherapy planning and treatment procedures because older people are more likely to undergo these procedures. Geriatric patients form the majority of patients who undertake interventional radiographic and radiotherapy planning and treatment procedures (Svensson et al., 2016, Akintade, 2015). Available statistics from Cancer Research UK, attributed to the Office of National Statistics (ONS), shows that between 2009-2011, 36% of all cancer cases occurred in older people, and 78% of cancer related deaths occurred in people aged 65 years and over, and 52% occur in those aged 75 years and over (CR-UK, 2015). Advancing age and its associated factors such as the reduction in collagen and elastic content, co-morbidities, and other age-related changes that occur in other body systems, makes older people more susceptible to having tissue damage.

Dehydration also affects the collagen and elastin content of the skin. Dehydration, a common medical problem, results from insufficient fluid intake, or excessive loss of fluid through diarrhoea and vomiting, decreases the skin's elasticity and its ability to withstand applied pressure (Posthauer et al., 2015, Wilson and Best, 2011, Collins and Claros, 2011, Campbell, 2011). Advancing age increases the risks of dehydration because older patients in declining health are more likely to have decreased thirst perception, declining ability to concentrate urine, and cognitive impairment such as an inability to ask for fluid or take fluids on their own, than younger people (Russo et al., 2009). Dehydration also changes the shape of cells, that is from turgid to flaccid, rendering them weak and prone to skin injury (Collins and Claros, 2011). It must be stated that often patients for radiography and radiotherapy planning and treatment procedures are dehydrated.

Additionally, the ability of a patient to perceive pain or discomfort arising from pressure has a direct impact on the tissues' ability to tolerate pressure (Marin et al., 2013). Normally, in reaction to pain, healthy people constantly change their posture, even when sleeping, through a sensorimotor feedback mechanism (Anton, 2006, Maklebust and Sieggreen, 2001, Allman, 1999). Barbenel et al. (1986), investigated the relationship between overnight mobility and pressure ulcers in a group of elderly

hospital patients. The study found a significant correlation between lack of mobility and an increased risk of developing pressure ulcers. The study concluded that patients assessed as being at high risk of developing pressure ulcers made fewer overnight movements. The limitation of this study is that the study was not followed up to assess if the patients regarded to be high-risk really developed pressure ulcers, hence, this study failed to clearly show the link between overnight movement and the development of pressure ulcers. However, a similar study by Allman (1999), explored this link. The study evaluated the impact of nocturnal movements in reducing the risk of developing pressure ulcers among elderly patients. Allman (1999) concluded that patients with more than 50 nocturnal movements did not develop pressure ulcers, whereas 90% of those with fewer than 20 nocturnal movements developed at least one pressure ulcer. These movements were counted using a device attached to the patients' mattresses. The limitation of this study is that the device used to measure the movement was not stated; hence, its validity and reliability cannot be established. However, this study is widely quoted in literature to illustrate that intermittent voluntary and sometimes involuntary movements help to relieve the body of sustained pressure, thereby reducing the risk of tissue damage.

The sensorimotor feedback system is usually weakened in patients diagnosed with neurological disorders such as Parkinson's disease, multiple sclerosis (MS) advanced dementia, orthopaedic injuries, and stroke (McInnes et al., 2012). These disorders impact motor neurons and pain pathways, and reduce the ability of these patients to perceive pain (Amir et al., 2013, Anton, 2006). These conditions restrict patient's mobility, hence increasing their risk of developing pressure ulcers. It must be stated that patients undergoing medical imaging and radiotherapy planning and treatment procedures do not make use of this very important body mechanism. This is because, as stated earlier, patients are required to lie still during these procedures. This is to minimise error, improve image quality, and enhance patient management. However, lying still for long periods of time, on medical imaging and radiotherapy planning and treatment surfaces that can produce high interface pressures, could be harmful to the patient's skin; especially in at-risk population such as those indicated earlier.

2.10.2 Tissue tolerance for oxygen

Pressure ulcers can arise when tissue oxygen demand outweighs supply. The presence of diseases and disorders, and other conditions, can destabilise tissue oxygen demand-supply relationship, increasing the risk of tissue damage. According to Defloor (1999), the presence of fever causes oxygen demand of cells to increase. Studies have shown that metabolism is directly affected by temperature, in that an increase of one degree Celsius of temperature increases metabolism rate by 10%, increasing the demand of cell oxygen and nutrients (Aronovitch, 2007, Berlowitz and Brienza, 2007). In an animal study, Kokate et al. (1995), illustrated the impact of temperature on the formation of cutaneous and deep tissue injury. The researchers simultaneously applied twelve metal discs on the dorsal aspect of a pig, all having an equal pressure of 100 mmHg, for five hours, while controlling the temperature of the discs at either 25, 35, 40, or 45 degrees Celsius. The study concluded that the degree of tissue injury is directly linked with an increase in applied temperature. Although no serious tissue injury was recorded in the superficial or dermal tissues underlying the sites of the 25°C disc, significant deep tissue injuries were observed from the application of a 35°C temperature. Additionally, the application of higher temperatures caused significant superficial and subdermal injuries. In another study, Grous et al. (1997) investigated the aetiology of pressure ulcers amongst 33 patients undergoing prolonged surgery. The study found that 15 patients developed pressure ulcers. Out of this number, 75% had been placed on a warming blanket during the surgery. The study concluded that the use of the warming blanket contributed to the incidence of the pressure ulcers. This supports the position that an increase in temperature results in an increased demand for oxygen, and that any mismatch between temperature-oxygen demand will increase significantly the risk of developing pressure ulcers.

Adequate diet, good nutrition, positive nitrogen balance, hydration, vitamins and trace elements are important factors that determine a tissue's tolerance to oxygen (Posthauer et al., 2015, Posthauer, 2014, Yatabe et al., 2013, Agrawal and Chauhan, 2012). Patients with eating disorders, which may result in weight loss, and poor nutritional status are associated with having higher risks of developing pressure ulcers (Fry et al., 2010). Haemoglobin level is a good factor used to determine

patient's nutritional status. It is made up of four protein chains that are present in the red blood cells, which carry oxygen from the lungs to the tissues, and takes away carbon dioxide from the tissues back to the lungs (Smit et al., 2013b). Adequate haemoglobin levels are necessary to oxygenate body tissues in order to maintain healthy cell life (Liao et al., 2013). The impact of a compromised nutritional status on developing pressure ulcers is higher in older and chronically ill patients, such as those seen within the radiography and radiotherapy settings (Edsberg et al., 2014, Lizaka et al., 2010, Shahin et al., 2010). Most patients who undergo medical imaging and radiotherapy planning and treatment procedures, have poor health conditions, such as chronic spinal cord injuries, and cancer, with multiple co-morbidities. The presence of these diseases negatively affects their immune system and nutritional status, increasing their risks of developing pressure ulcers.

Hypoproteinaemi, severe protein deficiency, changes oncotic pressure and causes oedema, which compromises oxygen diffusion and nutrient transportation within tissues (Little, 2013, Pieper, 2012, Smoliner et al., 2008). This affects the immune system, and consequently the body's ability to fight infections. According to Posthauer et al. (2015), deficiencies in vitamin A delays epithelisation, affects the collagen content in the skin, and impairs cells cohesion. Adequate levels of vitamin A are essential to maintain skin integrity and prevent the incidence of pressure ulcers, especially in at risk patients. However, there is confusion in the literature as to whether nutritional supplements play an important role in preventing pressure ulcers, and if they do, to what extent. A Cochrane review by Langer and Fink (2014), concluded that, although there is some evidence of improved pressure ulcer healing with an arginine-enriched mixed nutritional supplement compared with a standard hospital diet, there is currently no strong evidence of a benefit linked with nutritional interventions for either the prevention or treatment of pressure ulcers.

Impaired reactive hyperaemia affects tissue oxygen homeostasis, hence affecting the tissue's tolerance for oxygen. Reactive hyperaemia, an essential physiological body mechanism, is defined as a vascular flush or reddening following the release of a partial or complete occlusion of circulation, often associated with an increased volume of the pulse (Hemmes et al., 2014b, Jones, 2013, Edwards, 2006). This vasodilatory response, restores blood flow to pre-occlusion levels, replenishes

oxygen deficit, and removes toxic substances from the blood (Bhattacharya and Mishra, 2015, Messer, 2012, Stockton and Rithalia, 2008). Hyperaemic reaction also releases three important endothelial factors; endothelin, prostacyclin, and endothelial-derived relaxing factor (nitric oxide) (Bliss, 1998). Nitric oxide is crucial to wound healing and pressure ulcer prevention because it is toxic to bacteria, contributes to angiogenesis, and acts as a vasodilator, immune response mediator, and neurotransmitter (Doley, 2010, Crowe and Brockbank, 2009). However, Howatson-Jones (2001), argued that the sudden increase in blood flow can damage the endothelial lining of weak vessels, activating platelet aggregation to repair the harm, which then further block the vessels and microcirculation. Nevertheless, this argument is based on expert opinion and not supported by any empirical evidence; hence, it has very little support in the literature. Reactive hyperaemia occurs mainly in deeper tissues and structures, and occasionally appears on the dermis and epidermis as blanching hyperaemia (Thompson, 2005).

Any impairment in this important protective physiological body mechanism increases significantly patient's risk of developing pressure ulcers. The impact of impaired reactive hyperaemia can be more severe in patients undergoing some radiography procedures. For example, during intravenous pyelography procedures (IVP), an abdominal compressing band may be applied tightly across the lower abdomen to concentrate the contrast injected into the veins to fill the ureters and renal pelvis. The application of the band increases the interface pressure between the patient and the X-ray table. This is likely to partially restrict blood flow, and in severe cases, may cause ischaemia, or cell death. With the release of the compression band, a normal reactive hyperaemia response should be able to restore blood, oxygen and nutrients to the deprived tissues, restoring the tissues to normalcy. However, impaired reactive hyperaemia will deprive the tissue of these essential endothelial factors. Also blood flow to these deprived tissues will not be restored, hence depriving them of the needed oxygen to survive, and may consequently result in tissue damage or dysfunction.

Another pressure ulcer risk factor that is significant in patients accessing radiography and radiotherapy planning and treatment services is smoking. This is because most patients diagnosed with smoking related diseases such as cancer, and pulmonary diseases often require radiography and radiotherapy services for diagnosis, planning and treatment. Smoking is linked to atherosclerosis, which may result in reduced oxygen levels in tissues (Ahn et al., 2008). Nicotine, the major component of tobacco smoke, stimulates the sympathetic nervous system resulting in epinephrine that causes peripheral vasoconstriction, and subsequently decreased circulation (Nassaji et al., 2014, McDaniel and Browning, 2014). However, the claim that nicotine causes tissue hypoxia, and compromised skin integrity has been challenged but failed. A study conducted by Sorensen et al. (2009), indicated a slight increase in skin blood flow when one milligram of nicotine was infused intravenously. However, this increase was temporary. Shortly afterwards, the researchers noticed a significant decrease in blood flow to subcutaneous tissues.

The detrimental effects of smoking on skin integrity, epithelialisation, and hypoxia have been reported in several studies (McClave et al., 2009, Wong et al., 2004, Sorensen et al., 2004). According to these studies, nicotine, carbon monoxide, and hydrogen cyanide cause significant reduction in the production of erythrocytes, white blood cells, and fibroblasts, causing reduced oxygen supply to tissues. In addition, these gases also cause reduced inflammatory response, and reduced production of collagen fibronectin needed for the formation of granulation tissues and epithelialisation.

Healthy skin is protected from pressure-induced injury by an auto regulatory protective phenomenon called pressure-induced vasodilation (PIV) (Fromy et al., 2010). When pressure is applied on the body, PIV is invoked by activation of sensory C-fibres, which leads to the release of neurotransmitters that act at the level of the epithelium to cause the production of endothelial factors to induce smooth-muscle relaxation of the cutaneous micro vessels (Fromy et al., 2010). Landis (1930) discovered this mechanism when he applied 60 mmHg of pressure to the upper arm. He noticed a rapid increase in arteriolar and venous pressures within 15 to 45 seconds of applying the pressure, stabilising at an average of 10 mmHg higher than the applied pressure. Capillary pressure returned to its original level within one to

three minutes of releasing the external pressure. The presence of PIV protects the skin from applied pressure, by delaying the occurrence of tissue ischaemia, thereby preventing pressure ulcers. However, in patients with impaired PIV, such as diabetic, older patients, patients with neuropathy, and patients with spinal cord injuries, the absence of this essential protective auto regulatory mechanism exposes them to high risk of cutaneous ischaemia, which could lead to developing pressure ulcers (Gaubert et al., 2007).

Sanada et al. (1997), used laser Doppler flowmetry to investigate pre-operative and intra-operative skin blood flow over the iliac and sacral bony prominences in 24 patients undergoing prolonged surgical operations. The study concluded that patients who did not develop pressure ulcers had a 500% mean increase in intra-operative blood flow compared to pre-operative levels, whereas, there was a significant reduction in intra-operative blood flow in patients who developed pressure ulcers. These findings, clearly illustrate that skin blood flow level influences the development of pressure ulcers. This finding is significant in the radiography setting especially within interventional radiography, because of the similarity in the interventional radiography environment and the operating room, and also the similarities in the health characteristics of patients who access these facilities. The limitation of this study is that it involved a small number of patients, hence, it will be difficult to generalise the findings to all patients undergoing prolonged surgical procedures.

Using laser Doppler flowmetry, Fromy et al. (2002), measured the skin blood flow in the internal anklebone when a pressure of 5 mmHg was applied to the skin. There were 15 subjects, each in three groups of diabetic patients (one group with clinical neuropathy, another with subclinical neuropathy, and one group without neuropathy), and healthy matched control subjects. The study was conducted at room temperature. Only diabetic patients with no co-morbidities were included in the study. The study established impaired PIV in diabetic patients with subclinical or clinical neuropathy, compared to the control group, resulting in a decreased skin blood flow in these patients. Similar studies conducted in young adults with type one diabetes (Koitka et al., 2004), and one comparing neuropathic and non-neuropathic older adults (average age 60-75), with young people (20-35 years) (Fromy et al., 2010),

produced similar results. In the latter study, non-neuropathic older patients had impaired PIV response with pressure (12.0±7.0%), compared to the young subjects (62.0±4.0%, $p \leq 0.001$). Interestingly, there was no PIV response to pressure in the older patients with neuropathy, causing early cutaneous ischaemia (-31.0±10.0%, $p \leq 0.001$).

2.11 Pathophysiology of pressure ulcers

The mechanism of pressure ulcer pathophysiology is explained by two theories, the top-to-bottom theory, and the deep tissue injury (bottom-up) theory. The least favoured top-to-bottom theory proposed by Kosiak (1959), states that pressure ulcers result from skin injury that occurs at the epidermis first, and proceeds to deeper tissues. This theory proposes that compressive forces occlude dermal capillaries, causing loss of overlying epidermis. This produces superficial ulcers, which may grow deeper as compressive ischaemia of deep tissue impedes healing. The injury presents clinically as intact skin with blanchable erythema (Kosiak, 1961). The clinical implication of this theory is that, to detect pressure ulcers early, healthcare professionals should look out for visible evidence of skin injury, such as the presence of erythema, blackening or smooth shininess, and failure to do so may lead to missing these injuries. However, there is sufficient evidence in the literature indicating that superficial ulcers, which present clinically as redness, and other skin colour changes, are not easily detectable in people with darker skin tones (Bhattacharya and Mishra, 2015, Pieper, 2012, Black et al., 2007, Vanderwee et al., 2007). Therefore, this theory fails to answer an important clinical question: how can healthcare professionals identify early signs of pressure ulcers in people with darker skin tones?

Studies have shown that muscles and subcutaneous tissues are more susceptible to externally applied pressure than skin (Berlowitz and Brienza, 2007, Fleck, 2007). This gives rise to the deep tissue injury (bottom-up) theory of pressure ulcers. This model of pressure ulcer formation states that, pressure ulcers begin from the bone, and proceed outward towards the skin (Salcido et al., 1994, Daniel et al., 1981). If the pressure is persistent, ischaemic injury and tissue necrosis can progress outwardly, reaching and destroying the epidermis of the skin (Stojadinovic et al., 2013, Niezgoda and Mendez-Eastman, 2006). Many years ago, Daniel et al. (1981), illustrated this theory in an animal experiment. The researchers used a computer-controlled, electromechanical pressure applicator to produce pressure ulcers over the greater femoral trochanter in 30 normal and paraplegic pigs. Examination of the pressure site after one week of applying the pressure, revealed that muscle damage occurred when high pressure was applied for a shorter duration (500 mmHg, 4

hours), while high pressure for a longer period was needed to cause skin damage (800 mmHg, 8 hours). The study rightly concluded that muscles are more sensitive to the effects of pressure than skin. Although this is an animal study, the findings are transferable into human clinical practice because the papillary capillaries, hair follicles, collagen and elastic content, as well as the sweat glands of a pig's skin are structurally similar to that of humans (Herr, 2009).

Salcido et al. (1994) also showed that muscles and deep tissues are more susceptible to the effects of pressure than skin. In an experiment, computer-controlled pressure of 145.3 mmHg was applied for six hours at a maximum of five consecutive daily sessions, to the skin over the greater trochanter of anesthetised rats. Histological examination of the tissues, showed tissue damage were pronounced after the third, fourth, and fifth sessions as compared to the first and second. More importantly, the study showed that tissue damage occurred first in the muscle compared to the dermis or epidermis, supporting the assertion that muscles and subcutaneous tissues are more fragile and susceptible to pressure–induced injury than the epidermis. The clinical importance of these studies is that pressure ulcers are generally worse than they appear on the skin, and that the laceration that is seen on the surface of the skin may be a fraction of the magnitude of the injury that lies under the skin.

The clinical implication of the bottom-up theory is that visible signs of skin laceration should not be the basis of predicting the presence of pressure ulcers, and that other skin indicators such as changes in tissue consistency (firm versus boggy when palpated), sensation (pain), and warmer or cooler skin temperatures should be assessed and documented (Pieper, 2012, Stekelenburg et al., 2008, Nayak et al., 2008, Black et al., 2007). These two conflicting theories show that while there may be some degree of commonality in the mechanisms of pressure ulcer formation in patients, the aetiology may be different in each patient, and that each patient's unique characteristics, intrinsic and extrinsic factors, and the level of risk each patient is exposed to, should be considered when assessing and treating pressure ulcers. Also, these factors should be considered when developing pressure ulcer preventive strategies. The notion that one plan or strategy will suit all patients should be avoided.

Externally applied pressure on the skin is transferred through the epidermis and dermis of the skin towards the bone (Bateman, 2012, DOH, 2008). The impact of the pressure compresses intermediate blood vessels, subcutaneous, and muscle tissues against the bone, which also acts as counter pressure (Butcher and Thompson, 2009, Howatson-Jones, 2001). This produces a phenomenon called the McClemont cone of pressure (figure 2:9), in which externally applied pressure can increase by three to five times at the apex of the cone, located at the bone (McClemont, 1984). For example, an externally applied pressure of 32 mmHg can rise to as much as 160 mmHg at the bone, subjecting muscle and bony structures to massive pressure intensity, and possible necrosis. The pyramid shaped pressure gradient indicates that, deep pressure ulcers form at the bone-soft tissue interface, and move outwards towards the epidermis (Pieper, 2012). This high pressure at the point of contact between the soft tissue (muscle) and the bone, plus the fact that muscles are more delicate, and less tolerant to pressure, explains why pressure damage occurs first within deep tissues than the skin.

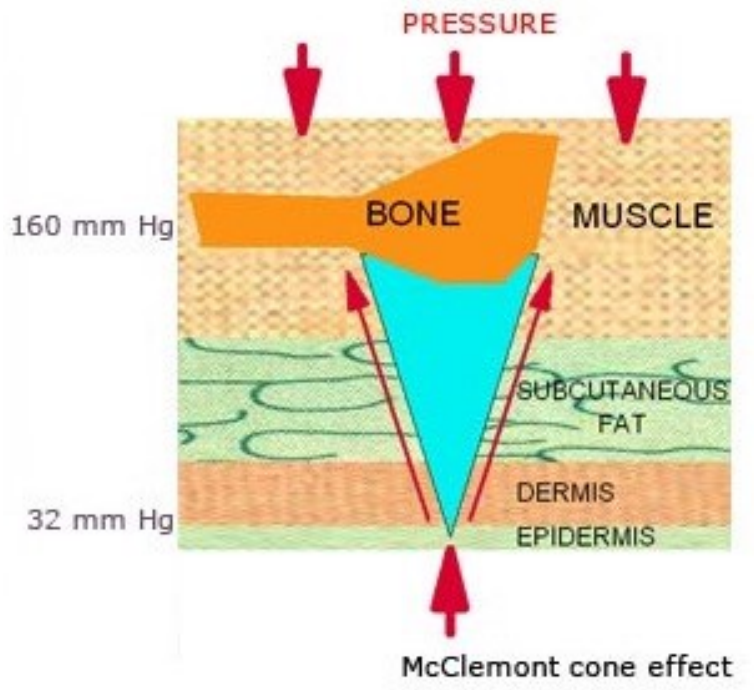


Figure 2:9: Diagram showing the McClemont cone of pressure

(Torrance, 2002)

The resultant deep tissue damage can be very harmful and extensive, and it develops at a faster rate than superficial ulcers (Bouten et al., 2003). The injury develops towards the surface of the skin, and may appear as a minor laceration on the skin surface, although massive necrosis of muscles, fascia and subcutaneous tissues might have already occurred within the deep tissues (Sullivan, 2014, Sibbald et al., 2011). The clinical implication of this is that healthcare professionals should use tactile examinations to rule out deep tissue injuries, because as stated earlier, superficial lacerations do not give a clear indication of the severity of pressure ulcers, and may show only a fraction of the magnitude of the injury.

There is significant reduction in blood flow to compressed tissue, and in some instances, blood flow ceases completely, causing cell disruption, hypertonicity, which may lead to cellular dehydration and death (Xiao et al., 2014, Smart, 2013, EPUAP and NPUAP, 2009, Thompson, 2005). Cellular damage attracts neutrophils to the site of damage, resulting in an accumulation of damaged cellular by-products and white blood cells (Pieper, 2012). When the pressure occluding blood flow to the tissue is relieved, and blood flow restored, the accumulated waste products and free radicals are released, causing an increased microcirculation activity, and reperfusion (Bansal et al., 2005, Peirce et al., 2000). The surge in blood flow, and release of oxygen-free radicals, cause oxidative stress, and inflammatory responses which destroy cellular protein, DNA, cell membrane, and contribute to cellular necrosis, resulting in a phenomenon called ischaemia-reperfusion (IR) injury (Fowler et al., 2008). IR injury is defined as the cellular injury that results from reperfusion of blood to a previously ischaemic tissue (Xiao et al., 2014). These highly toxic oxygen-free radicals are very unstable, and can cause cell death through peroxidation and propagation of more free radicals (Ceelen et al., 2008). The severity of tissue injury increases with the frequency of IR cycles, and the duration of the ischaemia (Peirce et al., 2000).

In an animal study, Peirce et al. (2000), induced IR injury in rats by applying and removing a permanent magnet which produced 50 mmHg of pressure, to the dorsal region of the rats' skin, under which a ferromagnetic steel was implanted. The study consisted of three experiments. In experiment one, 16 rats were randomly assigned into four groups (one control group, three experimental groups). The experimental groups received five IR cycles, for a total of one, two or three days, each cycle consisting of two hours of ischaemia, and thirty minutes of reperfusion, after which the magnets were removed for a final 11.5 hours of reperfusion. The rats were then sacrificed and the injury sites examined. In experiment two, 32 rats were assigned into four groups similar to experiment one. The three experimental groups received varying durations of induced ischaemia, and varying number of IR cycles. One group received five IR cycles of one hour ischaemia, followed by thirty minutes reperfusion, for five conservative days. One group also received five cycles of IR of two hours ischaemia, followed by thirty minutes of reperfusion for five conservative days. The last group had ten IR cycles of one hour ischaemia, followed by thirty minutes of reperfusion for five conservative days. After the specified cycles were completed for the day, the magnets were removed to allow reperfusion overnight. At the completion of the last IR cycle on the fifth day, the rats were sacrificed and the injury sites analysed. In experiment three, the researchers compared the injury induced by ischaemia alone, and IR-induced injury between two groups (four rats in each group). On group received a total of 10 conservative hours of ischaemia, whereas the other group had five IR cycles of two hours of ischaemia, followed by thirty minutes of reperfusion. The rats were then sacrificed and the sites examined.

Upon histological examination of the sites, the skin presented a sequence of tissue damage, similar to those seen in the formation of pressure ulcers in humans. Firstly, a blanchable hyperaemia appeared, followed by non-blanchable hyperaemia, discolouration of the skin resulting from bleeding underneath, and finally tissue necrosis. Also the study found that this sequence of tissue damage happened rapidly, and was accelerated with increases in IR cycles, duration of ischaemia, and IR cycle frequency. Additionally, histological analysis showed that recurrent IR injuries are more harmful to tissues than prolonged ischaemia alone, indicating that the reperfusion phase of the IR cycle is an essential factor that determines the severity of tissue injuries. However, the study might have underestimated the impact

of IR cycles on the formation of pressure ulcers in the long-term. Histological analysis on all the rats was conducted within 12 hours of finishing the IR routines, and therefore, the degree of tissue damage that would occur in the long term was not determined. Nevertheless, this study has important clinical implications, because, the two hours ischaemia, followed by thirty minutes reperfusion is similar to the EPUAP and NPUAP guidelines, which states that patients at risk of developing pressure ulcers should be repositioned at least every two hours when in a lying position, to relieve their body of sustained pressure (EPUAP and NPUAP, 2009). Another limitation to this study is that the implanted steel might have increased the severity of the injuries. The procedure of implanting the steel might have caused some damage to surrounding tissues, making the site at very high risk of further tissue damage. In addition, tensile strength of scar tissue is weaker than that of an intact skin, so the implantation of the steel might have scarred some tissues; weakening their strength. There is sufficient evidence in the literature to support the fact that ischaemia-reperfusion cycle plays a crucial role in the pathophysiology of pressure ulcers (Tsuji et al., 2005, Peirce et al., 2000, Daniel et al., 1981), and that healthcare professionals and researchers should focus more on developing preventive strategies to prevent the occurrence of IR injuries.

To maintain body homeostasis and health, the lymphatic system acts as a channel that directs and regulates essential processes, such as body fluid, macromolecular homeostasis, and lipid absorption (Gashev and Zawieja, 2010). It also serves as a pump that produces lymph flow, and works together with other body systems to maintain immune function (Muthuchamy and Zawieja, 2008). Lymphatic transportation happens when fluid and other lymph elements from the parenchymal interstitial spaces, crosses the lymphatic endothelium and moves into the lymphatic capillaries (Vittet, 2014). The lymphatics are also affected by externally applied pressure, and may suffer from pressure-induced ischemia, which may cease lymphatic flow in the affected tissue (Pieper, 2012). The applied pressure, and any resultant ischaemia may impede the free movement of interstitial fluid (Liao et al., 2013). Consequently, protein is retained in the interstitium, which may lead to an increase in interstitial oncotic pressure, resulting in imbalance of the transvascular exchange, oedema formation, dehydration of cells, and tissue irritation (Pieper et al., 2012).

In an experiment, Dodd and Gross (1991), demonstrated the impact of interface pressure on interstitial fluid. They applied 4 and 8 kg load over the wings of ilia, and the last dorsal spinous process of white-haired pigs. They found that the application of the loads to the hips of the pigs resulted in an interface pressure (IP) of 106.7 and 152.3 mmHg for 4.0 and 8.0 kg respectively, and 28.0% of these IP values were transferred to the tissues, leading to an increase in interstitial fluid pressure of about 28.7 and 44.1 mmHg for 4 and 8kg respectively. Whereas, when the same load was applied over the spinous process of the pigs, about 43.0% of the IP value was transferred to the interstitium. The clinical implication of this study is that the amount of load transferred to subcutaneous tissues, and its impact on interstitial fluid pressure can be predicted, hence, appropriate preventive measures, such as repositioning and the use of alternating pressure redistribution surface overlays can be used. However, the impact of applied load on interstitial fluid pressure, and its impact on efficient functioning of the lymphatic system, varies between patients, and between different anatomical areas. As a result, preventive measures should be designed and tailored to meet individual patient's needs.

2.12 Pressure ulcer risk assessment scales

Pressure ulcer risk assessment scales (RASs) are non-invasive, cost-effective, preventive tools for assessing patients' potential risk of developing pressure ulcers (Wang et al., 2014). This is done by establishing an aggregate score according to a set of parameters, deemed to be risk factors (Richardson and Barrow, 2015). Identifying a patient's pressure ulcer risk on admission is essential because it helps healthcare professionals minimise further risk by identifying priorities of care such as nutritional support, skin care and initial treatment (Balzer et al., 2013, Kottner et al., 2009b, Bell, 2005). In addition, RASs can be used to evaluate the effectiveness of pressure redistribution support surfaces (Sardo et al., 2015). Data from RASs can also serve as baseline data for future reference, and can also be used in medico-legal cases (Kumari et al., 2015). To enhance patient management, NICE recommended that systematic and comprehensive pressure ulcer risk assessment should be performed on patients admitted into hospitals, using a validated tool (NICE, 2014). The tool must also be reliable and should demonstrate an enhanced quality of care, so that patient health can be improved (Kottner et al., 2013). This is to raise the awareness of risk factors within the clinical setting, and also as stated earlier, provide a minimum standard of risk documentation. But more importantly, the use of RASs should reduce pressure ulcer incidence (Jull and Griffiths, 2010).

However, empirical evidence supporting the validity of pressure ulcers RASs is weak, with studies inundated with varying degrees of measurement errors, hence, there is no evidence that RASs reduce the incidence of pressure ulcers by themselves (Chou et al., 2013, Kottner and Balzer, 2010, Anthony et al., 2008). As a result, the clinical impact of RASs on pressure ulcer incidence should not be overemphasised. Additionally, irrespective of the recommendation that pressure ulcers RASs should be validated, there are several pressure ulcers RASs used in clinical practice worldwide that have not been properly validated. This could result in an over-prediction, and under-prediction of pressure ulcer risk, which could lead to waste of hospital resources, because patients who may not be at risk of developing pressure ulcers will receive preventive treatment, and those who are at risk may not be picked up by the RAS to be placed on preventive measures.

To enhance patient management, RASs must demonstrate an adequate level of reliability and validity. Reliability of a scale is defined as the ability of the scale to produce consistent results (Zakrasek et al., 2015). That is, if two radiographers or radiotherapy workers administered pressure ulcer RASs on the same patient around the same time using the same scale, and their aggregate scores were the same, that scale could be regarded to have 100% reliability. On the other hand, validity denotes the level of accuracy of the scale, and it is made up of two components; sensitivity which correctly predicts patients at risk, and specificity which correctly predicts patients not at risk of developing pressure ulcers (Qaseem et al., 2015, Plaskitt et al., 2015, Park et al., 2015, Garcia-Fernandez et al., 2014b). The best RAS will be the one with 100% sensitivity and 100% specificity, because this will eliminate under-prediction and over-prediction. However, because of the inverse relationship between these two components of validity, it is not possible to achieve 100% for both components (Bryant and Nix, 2012a). The evidence in the literature shows that the Norton, Braden and Waterlow pressure ulcers RASs are the most widely used worldwide (Sardo et al., 2015, Zakrasek et al., 2015, Qaseem et al., 2015, Jin et al., 2015). These RASs are discussed in sections 2.12.1, 2.12.2 and 2.12.3.

2.12.1 Norton scale

This scale, shown in table 2.1, was developed by Norton et al. (1962), specifically for an elderly care setting, or for use among patients of advancing age such as those seen within radiography and radiotherapy. Five risk factors are scored from four to one, representing the best and worst scenario respectively. A total score greater than 18 denotes low risk, 14-18 means medium risk, a score of 14 denotes high risk, and a total score less than 10 is considered a very high risk (Norton et al., 1962).

Table 2.1: Norton pressure ulcers risk assessment scale

Factor/score	**4**	**3**	**2**	**1**
Physical condition	Good	Weak	Ill	Very ill
Mental state	Alert	Apathetic	Confused	Stupour
Activity	Ambulant	Walks with help	Chair bound	Bed-ridden
Mobility	Full	Slightly impaired	Very limited	Immobile
Incontinence	Not	Occasional	Usually urine	Double incontinence

(Norton et al., 1962)

Critics of the Norton scale argue that the scale does not consider important pressure ulcer risk factors such as friction and shearing. This is a huge limitation because as stated in sections 2.9.1 and 2.9.2, friction and shearing are the two key causative factors of pressure ulcers, hence ought to be included in the Norton pressure ulcers RAS. This RAS therefore cannot be deemed to be robust enough to correctly risk assess patients for pressure ulcers. Another limitation of the Norton RAS is that it does not have a functional or specific definition of the parameters or risk factors it comprises of. This is because the one or two word descriptions used to define the variations of the risk factors lack clarity and can create confusion (Agrawal and Chauhan, 2012, Bell, 2005). As a result, healthcare practitioners are likely to misinterpret these definitions, and consequently misuse the scale. This could lead to under and over prediction of at risk patients, which may lead to placing patients on

the wrong pressure ulcer treatment and management pathway. Additionally, the Norton scale has little empirical evidence to endorse its use outside elderly patients population (Pancorbo-Hidalgo et al., 2006). However, the Norton scale has been found to be more accurate in predicting pressure ulcer risks than the clinical judgement of healthcare workers, and that it should be used to increase the effectiveness of pressure ulcers prevention measures (Terekeci et al., 2009). Studies have shown that the Norton scale has reasonable sensitivity (46.8%) and a high specificity (61.8%), and a high or substantial inter-rater reliability (Wang et al., 2014, Pancorbo-Hidalgo et al., 2006). However, the inter-rater reliability is based on the total score. These studies failed to highlight the fact that the inter-rater reliabilities of some of the individual risk factors of the scale are poor. This supports the point made earlier that some of the risk factors are ambiguous and prone to misinterpretation by different raters and different healthcare professionals. To ensure the Norton scale is properly used in the clinical settings, further research should be carried out to clarify the ambiguity surrounding the definition of these risk factors.

Norton plus scale is a revised form of the Norton scale. It includes the following: diabetes, hypertension, fever – temperature > 37°C, prescription of five or more medications. It also includes haematocrit level defined as the volume percentage of red blood cells in the blood, of ≤ 45 and ≤ 40% in males and females respectively (Berglund and Nordstrom, 1995).

2.12.2 Braden scale

The Braden RAS (Table 2.2) was developed by Bergstrom et al. (1987), based on their conceptual scheme of pressure ulcer aetiology. They posited that pressure and tissue tolerance are the two main causative factors in pressure ulcer development. Based on these two factors, six risk factors were identified as factors that could affect the tissue tolerance of the skin. These six factors are scored from one (most risk) to four (least risk), with a range of total score between six and 23; the lower the score, the greater the risk of developing a pressure ulcer. A total score greater than 18 means the patient is not at risk, 15-18 denotes mild risk, whereas 12–14, and ≤11 denotes moderate and severe risks respectively. The Braden scale is the most widely used and researched RAS in the clinical setting (Cowan et al., 2012, Stechmiller et al., 2008). Various scientific studies and meta-analysis have stated that it has the best sensitivity (57%) and specificity (68%) balance compared to other RASs (Bolton, 2007, Pancorbo-Hidalgo et al., 2006). Inter-rater reliability of the Braden RAS is also deemed very good with values ranging from 0.83-0.95, when the scale was tested on adequately trained nurses (Wang et al., 2014, Magnan and Maklebust, 2009).

Table 2.2: Braden pressure ulcers risk assessment scale

Factors	**1**	**2**	**3**	**4**
Sensory perception	Completely limited	Very limited	Slightly limited	No impairment
Moisture	Constantly moist	Very moist	Occasionally moist	Rarely moist
Activity	Bedfast	Chair-fast	Walks occasionally	Walks frequently
Mobility	Completely immobile	Very limited	Slightly limited	No limitation
Nutrition	Very poor	Probably inadequate	Adequate	excellent
Friction and shear	Problem	Potential problem	No apparent problem	

(Braden and Bergstrom, 1987)

However, just like the Norton scale, it is difficult for healthcare staff to distinguish between the meanings of the various risk factors in the Braden RAS because the risk factors have different meanings, and as such, training is required to be able to use the Braden scale accurately (Bryant and Nix, 2012a). An example is the confusion surrounding mobility and activity. Per the Braden RAS, mobility refers to the ability of a patient to change or control body position to relieve pressure, whereas activity refers to the duration and frequency a patient is in a chair, bed, or walking. As an example, a confused restless patient may be moving recurrently, but will be regarded as lacking mobility because the movements are not controlled. Although the Braden RAS is widely used among nurses and healthcare professionals, a study involving more than 2,500 nurses indicated that about 25% of the nurses showed lack of adequate knowledge and application of the scale (Maklebust et al., 2005). This makes the case for regular training and retraining of healthcare staff on the correct application of the scale very important (Magnan and Maklebust, 2009). The interpretation of scores on the Braden scale, have been revised for predicting pressure ulcer risk among paediatric patients less than nine years old. Among this patient population, a total score of 22-25 is classified as mild risk, 17–21 moderate risk, and a score ≤ 16 is deemed a high risk.

2.12.3 Waterlow scale

This is a very complex and complicated positive incremental scoring pressure ulcers RAS, developed by Waterlow (1987). Compared to the Braden and Norton RASs, the Waterlow RAS (Table 2.3) has a lot more risk factors, with total score ranging between 4 and 40. A total score of greater than 10 indicates at risk patient, 15 plus denotes high-risk patient, and a score of 20 or over denotes a very high-risk patient. This widely used scale in the UK, has been deemed to have the ability of over-prediction, because of its large number of risk factors which are not clearly defined (Kottner et al., 2009a). However, studies have shown that the Waterlow RAS has a very high sensitivity, averaging 82.4%, a moderate specificity of 50%, and an excellent inter-rater reliability score of 0.92 (Wang et al., 2014, Serpa et al., 2009, Pancorbo-Hidalgo et al., 2006, Compton et al., 2008). However, Kottner et al. (2009a), found out that the evaluation of reliability and agreement, and evaluation of the applicability of the Waterlow scale to clinical practice are limited due to the difficulty in rating items such as poor nutrition, and mobility.

Table 2.3: Waterlow pressure ulcers risk assessment scale

Build/Weight for Height	**S***	**Skin type visual risk areas**	**S***	**Sex & age (Years)**	**S***	**Special risks**	
Average (BMI=20-24.9)	0	Healthy	0	Male	1	**Tissue Malnutrition**	**S***
		Tissue paper (frail)	1	Female	2	Terminal Cachexia	8
Above average (BMI= 25-29.9)	1	Dry	1	14-49	1	Multiple organ failure	8
		Oedematous	1	50-64	2	Single organ failure (Respiratory, Renal, Cardiac)	5
Obese (BMI >30)	2	Clammy, Pyrexia		65-74	3		
Below average BMI ≤ 20	3	Clammy, Pyrexia	1	75-80	4	Peripheral vascular disease	5
		Discoloured grade 1	1	81+	5		
Below average BMI ≤ 20	3	Clammy, Pyrexia	1			Anaemia ≤ 8gm%	5
		Discoloured grade 1	2			Smoking	2
		Broken/Spots grade 2-4	3				
Continence	**S***	**Mobility**	**S***	**Appetite**	**S***	**Neurological deficit**	**S***
Complete	0	Fully	0	Normal	0	Diabetes, MS, CVA	4-6
Urine incontinence	1	Restless/Fidgety	1	Feeding tube	1	Motor/Sensory	4-6
Faecal incontinence	2	Apathetic	2	Liquid IV		Paraplegia	4-6
		Restricted	3		2	Major surgery or trauma	5
Urinary + Faecal incontinence	3	Bed bound e.g. traction	4	Anorexia/absolute diet	3		5
			5			Orthopaedic/Spinal	8
		Chair bound e.g. wheel chair				On table >2 hours	8
						On table >6 hours	

S* denotes Score.

(Waterlow, 1987)

The limitations of the Norton, Braden and Waterlow pressure ulcers RASs are that, they have been designed to be used mainly by nurses, that is, they are primarily designed for use on wards. The implications of this is that, the use of these RASs within the radiography and radiotherapy settings will be difficult because radiographers may have no training and may also not have adequate knowledge of the patient, and as a result may not be in a position to adequately risk assess patient using these scales. This is because unlike nurses who spend most of their time with patients on the wards, and have the opportunity to observe the patient for several days and weeks, the interactions between radiographers/radiotherapy workers and patients are usually brief, ranging from a few minutes to a few hours. Consequently, radiographers' and radiotherapy workers' knowledge of patients' nutritional status, level of activity, sensory perception, and all the other risk assessment factors may be very limited. Additionally, radiographers and radiotherapy workers may not be conversant with the correct application of RASs, as pressure ulcer risk assessments are not routinely done in the radiography departments.

However, in some instances, radiotherapy workers spend quite a considerable amount of time with their patients. In these instances, the therapeutic radiographer could see their patient on a very regular basis, sometimes daily, over a period of several weeks. This means they do develop long term relationships with their patients, and are in a position to observe them over this period. The clinical implication of this is that, pressure ulcer RASs can be very useful in radiotherapy because therapeutic radiographers are in a position to risk assess their patients. It is therefore hoped that radiotherapy workers could develop and use the required skills of pressure ulcer RASs as part of the care they deliver to patients. However, to ensure its effectiveness, these practitioners must be adequately trained on how best to apply RASs.

Several studies have compared the sensitivity and specificity, as well as the inter-rater reliability of pressure ulcers risk assessment scales (Park et al., 2015, Kumari et al., 2015, Sardo et al., 2015, Carreau et al., 2015, Wang et al., 2014). However, these studies are not comparable because they were conducted on different patient populations, at different periods of time, and by different raters. One RAS may exhibit high sensitivity and specificity when applied within a particular patient group,

but may show weak sensitivity/specificity balance when applied on another patient population. To get the best outcome for patient management, pressure ulcers RASs should be used together with clinical judgement, otherwise using RASs will be a waste of time because it may not have any positive clinical impact on patient management (Balzer et al., 2014).

2.13 Guidelines for preventing and treating pressure ulcers

The impact of pressure ulcers on the quality of life of patients, and the associated financial implications demand that every healthcare unit should adopt and implement pressure ulcer prevention guidelines. In 2014, the European Pressure Ulcer Advisory Panel (EPUAP), the National Pressure Ulcer Advisory Panel (NPUAP) of the US, and the Pan Pacific Pressure Injury Alliance (PPPIA), published the second edition of the prevention and treatment of pressure ulcers reference guide. This document provides evidence-based recommendations for the prevention and treatment of pressure ulcers. This document was developed using a rigorous methodology, hence the authors believed the research supporting these recommendations are accurate. For example, the document was developed by experts in pressure ulcers drawn from different countries around the world. However, guidelines may not be appropriate for use in all clinical circumstances such as in radiography and radiotherapy, and that clinical judgement of radiographers and radiotherapy workers will be required to apply pressure ulcer preventive strategies within their departments. This is because pressure ulcer prevention guidelines are not routinely implemented in medical imaging and radiotherapy.

Pressure ulcer prevention programme (PUPP) is essential for healthcare units because they are effective in reducing the incidence of hospital-acquired pressure ulcers (Sullivan and Schoelles, 2013, Allen, 2013, Wilborn et al., 2010). Bryant and Nix (2012a), advised that to create a successful PUPP, both the structure (best practice bundle) and the operations (infrastructure) of the programme must be integrated into the healthcare system. In addition, healthcare staff must agree that pressure ulcers have a negative impact on the quality of life of patients, because a multidisciplinary effort will be required to execute prevention. The 2014 guidelines published by the EPUAP, the NPUAP, and the PPPIA, contain pressure ulcer prevention components, such as skin inspection, risk assessment, nutrition and hydration, patient repositioning, intervention and treatment of MDR pressure ulcers.

To offload sustained pressure, patients ought to move to relieve their bodies of the pressure, and eliminate or reduce the interface pressure between the body and contact surface. As stated earlier, healthy people make spontaneous movements to offload applied pressure, in response to pain and discomfort but people with impaired sensory perception or those with limited mobility may not feel this pain and discomfort, and even if they do, they may not be able to reposition themselves. Sustained interface pressure for long periods may cause a reduction in tissue oxygenation and tissue damage, which may lead to pressure ulcers (Shoham and Gefen, 2012, Kaitani et al., 2010). Consequently, the EPUAP, NPUAP, and PPPIA recommended frequent turning and repositioning of patients who are immobile. This is an essential and effective method for preventing the development of pressure ulcers because it eliminates the key causative factor of pressure ulcers – sustained interface pressure. In his seminal work, Kosiak (1961) recommended that repositioning should be conducted hourly to every two hours. However, this recommendation is based on the interface pressure readings of healthy able-bodied subjects, and may not be effective when applied to patients due to the different intrinsic and extrinsic factors these two populations are exposed to. For example, healthy people are more likely to have a much better immune system, and an active, mobile lifestyle, than old frail and sick patients diagnosed with chronic diseases.

Currently, the international guidelines for pressure ulcer prevention recommend that, the frequency of patient repositioning should be determined by the individual's tissue tolerance, level of activity and mobility, general medical condition, overall treatment objectives, skin condition, and comfort (EPUAP et al., 2014). Although this recommendation is designated as a strong positive recommendation that healthcare professionals should definitely adhere to, it is supported by weak evidence, derived from indirect evidence and/or expert opinion. Due to the difficulty in measuring some of these factors, repositioning frequencies are conducted as a range of every two to four hours while lying in bed, and every 15 minutes to one hour while in a seating position (Voz et al., 2011, Bergstrom et al., 2013, Dharmarajan and Ugalino, 2002). Repositioning can be a very useful pressure ulcer preventive tool because of its ability to eliminate sustained interface pressure. However, to ensure its effectiveness, the frequency, and technique should be designed and targeted to meet each patient's needs. In other words, one repositioning technique and

frequency may be effective for one patient, but totally useless when applied to another patient. This is because different patients may have different health characteristics and may be prone to different pressure ulcer risk factors.

In radiography, the need to minimise imaging errors, and improve diagnostic image quality demands that patient movement is restricted during imaging procedures (Lang et al., 2015, Allison and McHugh, 2008). Similarly, patients undergoing radiotherapy planning and treatment procedures are required to lie still to ensure that tumours are accurately delineated during planning, and radiation doses are directed at target organs, while sparing healthy tissues during radiotherapy treatment. This means that, patients are intentionally confined to a specific position for the whole duration of imaging and radiotherapy planning and treatment procedures, some taking hours to complete. To enforce this, immobilisation devices are applied in some instances. The restriction of patient movement, plus other environmental factors specific to the radiography/radiotherapy setting, may induce tissue damage, especially in at risk patient populations. The potential impact of these on the incidences of pressure ulcers among patients undoing prolong radiography and radiotherapy planning and treatment procedures is discussed in detail in section 2.16.

As indicated earlier in section 2.4, within the radiography and radiotherapy settings, Medical Device related (MDR) pressure ulcers may occur. This is because of the need to transfer patients onto medical imaging and radiotherapy surfaces prior to and following a procedure, the application of immobilisation devices, type of surface that is used in imaging and radiotherapy planning and treatment, and the length of time patients have to remain still. To minimise error, and consequently improve diagnosis, imaging surfaces often utilise thin radiolucent mattresses. However, imaging procedures in Ghana and Portugal, and radiotherapy planning and treatment procedures are conducted on hard carbon fibre X-ray tables, without any form of cushioning.

The current EPUAP, NPUAP, and the PPPIA guidelines (EPUAP et al., 2014) on MDR pressure ulcers are grouped into four areas, namely;

- risk of MDR pressure ulcers,
- recommendations for selecting and fitting medical devices,
- recommendations for assessment of the skin and medical devices,
- recommendations for prevention of MDR pressure ulcers.

The guidelines recommend that radiographers, radiotherapists, and supporting staff should regard patients on medical devices to be at risk of developing pressure ulcers. On selecting and fitting a medical device, the recommendation is that, staff should review and select available medical devices based on the ability of the device to cause the least degree of skin damage, and that softer, and more flexible devices should be given priority, without reducing the quality of care. Also, the right size of medical device should be used, and they should be applied per the manufacturer's specification. Finally, the device should be properly secured to prevent dislodgement without creating unnecessary additional pressure.

The recommendations for assessment of the skin and medical device states that healthcare staff should inspect the skin under, and around the medical device at least twice daily for pressure-induced injury on the surrounding tissue. The frequency of observation does not apply to the radiography and radiotherapy settings because radiography and radiotherapy planning and treatment procedures do not take more than a day to complete. However, the clinical implication of the recommendation is that, radiographers and radiotherapy workers should inspect patient's skin as often as possible to identify any sign of tissue damage. This should involve both visual observations, and tactile examinations to rule out both superficial and deep tissue injuries.

In the case that MDR pressure ulcers occurred, the guideline recommended that the injury should be classified per the EPUAP/NPUAP categorisation system. However, to correctly categorise pressure ulcers, radiographers and radiotherapy workers should be adequately trained. The guidelines also recommended that to prevent MDR pressure ulcers, skin under the medical device should be kept clean and dry. This is to minimise moisture, an intrinsic factor that increases a patient's risk of

developing pressure ulcers, by creating an environment that weakens the skin's integrity, making it susceptible to injury (Tricco et al., 2015, Sardo et al., 2015, McBride and Richardson, 2015, Kim et al., 2015). Finally, the medical device should be removed as soon as possible, to minimise pressure that the device may be applying on the skin. In other words get the patient off the medical imaging/radiotherapy table as soon as possible.

2.14 Interface pressure measurement

Excessive sustained pressure on the skin for a long period of time is the most important extrinsic factor that may cause tissue damage, which may lead to developing pressure ulcers (Wininger and Crane, 2015, Hollington and Hillman, 2013). Hence, current clinical studies for assessing a patient's risk of developing pressure ulcers focus on measuring the interface pressure (IP) between the patient and a support surface (Davis and Sprigle, 2010, Reenalda et al., 2009a, Turnage-Carrier et al., 2008). Interface pressure measurement can be used in conjunction with pressure ulcer risk assessment scales to determine a patient's pressure ulcer risk level (Oomens et al., 2010, Reenalda et al., 2009b). Additionally, IP measurements can be used to evaluate the relative impact of clinical support surfaces such as hospital beds, and radiography/radiotherapy surfaces on the skin, and gives an indication as to whether these support surfaces could contribute to tissue damage (Kirkland-Walsh et al., 2015, McInnes et al., 2012). This process is called pressure mapping, and it is measured by placing a sensor or pressure sensory mat between the body and the contact surface (Nix and Mackey, 2012). A review by Cullum et al. (2004), involving 41 randomised control trials concluded that, pressure mapping can be used to reliably predict the performance of pressure redistribution surfaces in minimising a patient's risk of developing pressure ulcers. However, to get accurate results, the pressure mapping must be conducted using a valid and reliable pressure mapping system, manned by a competent operator.

The measurement of IP has been shown to have a positive impact in preventing pressure ulcers. In a systematic review, Reenalda et al. (2009a), confirmed that there is a linear relationship between IP, the contact time, and the incidence of pressure ulcers. In other words, higher IPs sustained for longer periods correlates to higher risks, which may lead to incidence of pressure ulcers. However, the authors added that this relationship is qualitative in nature, hence no definite threshold for IP can be given. This finding, together with the influence of patient's individual health characteristics like age, level of physical activity, nutritional state, the presence of comorbidities, and other risk factors, and the inverse relationship between pressure magnitude and duration, gives credence to the fact that no specific IP value can be given as the limit, beyond which tissue damage will definitely occur (Hollington and Hillman, 2013, Reenalda et al., 2009a, Gefen and Levine, 2007).

Pressure mapping can be affected by a number of factors; first, the pressure mapping equipment/technology used. This is because any malfunctioning in the pressure mapping device may render its sensors inefficient, thereby producing false results. The implication of this is that patient pressure ulcer risk levels will be wrongly assessed. As stated earlier, this may lead to over-prediction or under-prediction of at risk patients. The implication of this is that, these patients would be placed on the wrong treatment or management pathway. Over the years, a number of different pressure mapping systems have been developed, for example the pneumatic system Talley Oxford Pressure Monitor Mark 3 which is made up of 96 sensors (eight 12 cell matrices) which needs to be manually inflated (Gyi et al., 1998). Recently, the Xsensor pressure mapping system has been invented. It is designed on capacitive technology, and fitted with over ten thousand sensors giving it high spatial resolution compared with other pressure mapping systems (Sumed International, 2014, Hemmes et al., 2014b). The Xsensor technology also allows for accurate reading of IP values in real time, and produces visual IP distributions on a computer screen (Peterson et al., 2013b). Detailed characteristics of the Xsensor pressure mapping equipment/technology are provided in chapter three section 3.10.1.

The shape of a patient's body also has a direct effect on IP values. Inter-patient variability is dependent on the tone and shape of the body musculature, and the amount of fatty tissues on the body (Swain, 2005). However, studies have shown that there is no relationship between a patient's weight or height and IP (Stinson et al., 2003a). However, there is a trend between body mass index (BMI) and IP (Stinson et al., 2003a, Kernozek et al., 2002). Nevertheless, the effect of a patient's body structure on IP is very subtle, and even patients with very similar body structures can have quite different IPs. Hence, it is not possible to predict a patient's IP on a particular support surface from his body type.

The human body consists of structures of varying shapes, with different underlying bony structures. High IP pressure values are usually recorded at bony prominences such as the heels, sacrum and the occiput because of the prominent shape of these anatomical structures, and the lack of adequate muscle and fat tissues to help redistribute pressure applied on these areas (Luchi et al., 2014, Miller et al., 2014, Peterson et al., 2013a). In the supine position, the occiput and heels cover a small area, thereby increasing the IP at these areas. Confounding this is the lack of

adequate tissue, thereby increasing the IP even further. IP will vary widely between patients of different body shapes, and between different anatomical areas, and that to accurately predict the IP of a patient, pressure mapping (an objective measure) should be conducted (Wu et al., 2011, Moysidis et al., 2011).

Inter-patient pressure mapping variability can also be caused by underlying pathologies. There may be changes in body structure in immobile elderly patients and those with chronic diseases such as chronic spinal cord injuries, or disabilities. As stated earlier, these patient populations are highly at risk of developing pressure ulcers due to the loss of muscle tone, and the inferior collagen and elastic content in their skin, poor mobility, and the poor level of physical activity among these patient population (Stojadinovic et al., 2013, Agrawal and Chauhan, 2012). These factors can restrict these patients to one position for long period of time, thereby affecting their body shape and posture (Tasker et al., 2014, McInnes et al., 2012). Consequently, this affects the shape at the patient-support interface, the IP distribution, and the resultant IP values (Swain, 2005). The impact of pathology on pressure mapping variabilities has been well documented in the literature (Huang et al., 2013, Urasaki et al., 2011). This is however not the focus of this thesis.

2.15 Radiographic literature on pressure ulcers

As stated in chapter one (section 1.4), a detailed literature search on radiographic/radiotherapy literature on pressure ulcers revealed only six studies. One of these studies conducted by Messer (2012), developed an adult risk assessment and preventive intervention instrument for ancillary services patients, including those accessing radiography and radiotherapy services. This instrument, the author suggested, can be used to assess pressure ulcer risks in adult patients who undergo ancillary service procedures, such as lengthy radiography and radiotherapy planning and treatment procedures. However, this risk assessment tool is made up of a large number of risk factors, a total of 11, hence; it will be difficult to apply within the radiography/radiotherapy setting due to time constraints. Conventional imaging procedures are normally performed within very short time frames (e.g. as little as five minutes) hence it is difficult to accommodate such an elaborate tool in conventional imaging. Also due to high workload and limited time to spend with each patient, radiographers may not have the time needed to risk assess patients with this risk assessment tool. In addition, radiographers and radiotherapists will require extensive training to be able to use accurately this risk assessment scale because pressure ulcer risk assessments are not routinely done within the radiography and radiotherapy departments.

In a prospective study published as an abstract, Brown (2002) collected data from 80 patients, 20 each on four different mattresses/support surfaces used in their imaging department. Using the Braden scale, each patient was risk assessed for pressure ulcers, and the total score recorded. A skin inspection of eleven pressure areas pre and post imaging examinations were recorded, and the duration of the imaging examination was also documented. Post examination skin inspection showed that 53.8% of the patients acquired category one pressure ulcers. The conclusion of the study is very worrying, because it gives the indication that the risk of pressure ulcer development may exist within the radiographic/radiotherapy settings. However, the full study was not published, therefore, the scientific robustness of the methodology cannot be scrutinised in detail. Nevertheless, the following limitations have been observed. First, the study did not specify the types of mattress/support surfaces used. This is important because different support surfaces have direct impact on interface pressures, and some could be potential sources of tissue damage, which

may develop into pressure ulcers. Different support surfaces have different impact on patient's skin, hence it would have been very helpful if the researcher had indicated the type of support surfaces used for the experiment. For example, if the patients were made to lie on a hard X-ray table without a mattress or any form of cushion for a long time, then it would not be surprising that over half of the patients had category one pressure ulcers. This is because a hard surface fitted with carbon fibre is likely to increase patient interface pressure, which may lead to an increased risk of developing pressure ulcers. Also patient characteristics (e.g. health status, age, levels of immunity, level of nutrition, and level of physical activity) have not been reported. This is a significant limitation because studies have shown that the skin of older patients and those suffering from chronic diseases such as cancer are more prone to developing pressure ulcers (Stojadinovic et al., 2013, Liao et al., 2013). In addition, none of the 11 areas inspected were named. Although the study concluded that more than half of the patients developed pressure ulcers, these injuries cannot be attributed to the imaging surfaces. This is because the study did not investigate the interface pressures experienced by these patients whilst lying on the imaging surfaces. The implication of this is that, the observed pressure ulcers might have arisen from high radiation doses, or negligent patient transfers onto the imaging surfaces or other factors not related to the imaging process. Additionally, it is possible that this figure might have risen because studies have shown that skin damage due to pressure often does not often appear on superficial tissues until after three days post injury (Xiao et al., 2014, Stojadinovic et al., 2013, Schindler, 2010, Stekelenburg et al., 2008).

Out of the six studies which directly or indirectly investigated pressure ulcers in radiography/radiotherapy, only Justham et al. (1996), investigated the interface pressure on radiography surfaces. Interface pressure plays a crucial role in skin damage because pressures excessively higher than 32 mmHg are considered to increase patients' risk of developing pressure ulcers (Hollington and Hillman, 2013, Stockton and Rithalia, 2009, Reenalda et al., 2009b). Interface pressure values give a vivid and objective description of the pressure an area of skin is experiencing on a particular support surface. The exploratory work conducted by Justham et al. (1996) was very useful because it shows the potential risk of high interface pressures may

exist on medical imaging surfaces. However, its relevance in modern radiological and radiotherapy practice is questionable because of the following reasons.

To begin with, Justham et al. (1996), calculated the mean interface pressure of the heels, left and right buttocks, sacrum, left and right scapula, thoracic spine and occiput using the Talley Oxford Pressure Monitor (TPM) mark III made up of 12 cells, in 16 healthy volunteers. The TPM mark III is a pneumatic sensor pressure mapping system, made up of air cells connected to an air reservoir (Gyi et al., 1998). In a review to illustrate how the TPM mark III operates, Gyi et al. (1998) stated that to inflate the TPM sensor, the pressure in the air reservoir must exceed that applied to the sensor. An increase in inflation pressure above applied pressure causes the volume of the air in the sensor to increase suddenly. The pressure in the air reservoir at which there is a drop in the rate of pressure increase is noted as the applied interface pressure, and can be monitored electronically through a strain gauge diaphragm pressure transducer (Rithalia and Gonsalkorale, 2000, Bader and White, 1998, Gyi et al., 1998). The cell matrix of the TPM system has poor spatial resolution due to wide spaces between sensors, some as much as 100 mm (Gyi et al., 1998). The limitation of this is that, a bony anatomical area such as the heel and the occiput may only partially cover a sensor, hence only a fraction of the interface pressure values at these anatomical areas will be recorded.

Gyi et al. (1998), demonstrated the effects of a pressure point partially covering a sensor on the accuracy of interface pressure readings using the TPM system which has similar resolution and spacing of sensors to the one used by Justham et al. (1996). The researchers placed a sensor between two pieces of high-density foam in order to obtain a constant pressure. Three interface pressure readings were recorded with each of 100%, 75%, and 50% sensor coverage, and the means were calculated. This was repeated with three other sensors. The sensors were chosen at random to minimise bias. Using the interface pressure readings at 100% sensor coverage as the baseline, an interface pressure reading of 100 mmHg at 100% was recorded as 82 mmHg at 75% cell coverage, and 11 mmHg at 50% cell coverage. This finding depicts a significant limitation in the work of Justham et al. (1996), in that the instrument used had poor spatial resolution, with only 12 cells, which might have led to partial covering of anatomical areas, hence, inaccurate interface pressure values might have been recorded. It is therefore not surprising that the mean

interface pressure values recorded for the anatomical areas have very large standard deviations, with the head and heels having the largest standard deviations of 7.5±26.2 and 7.2±39.1 respectively. These large standard deviations might be due to the poor spatial resolution of the pressure mapping system used to conduct the study, leading to anatomical areas with pointed bony prominences being placed or partially placed on a non-recording area of the sensor matrix.

Another limitation of the study conducted by Justham et al. (1996), is that the TPM system does not record interface pressure readings in real time, and takes an average of 12 seconds to record the data from a single scan of each of the 12 sensor matrix (Wolsley and Hill, 2000, Ferguson-Pelf and Cardi, 1991, Gyi et al., 1998). Although 12 seconds may appear to be a short time, this is a very long time in pressure mapping. The implication of this is that, it is not possible to check for errors, artefacts, and changes in a volunteer's position, or movement during data acquisition. For example, unlike new pressure mapping technologies such as the Xsensor that provides an interactive system to detect movements and artefacts the very moment they occur during pressure mapping, the TPM system may detect this movement 12 seconds after it had occurred. This will affect the interface pressure values recorded because movement and artefacts have a direct impact on interface pressure, and if not eliminated will invalid the values recorded. Therefore, the interface pressure values recorded by Justham et al. (1996), cannot be deemed to be devoid of movement and artefact errors, hence might not be a true reflection of the interface pressure of healthy volunteers on medical imaging surfaces.

In the study conducted by Justham et al. (1996), the volunteers rested their head on a single foam filled pillow during data acquisition. This is a limitation which could invalidate the results. When measuring interface pressure of an anatomical area on a support surface, the pressure mat should be placed directly between the anatomical area under investigation and the support surface (Wininger and Crane, 2015, Kirkland-Walsh et al., 2015, Peterson et al., 2013a). The use of the pillow will have a direct implication on the interface pressure values for head in that it will provide some level of cushioning or protection for the head, thereby reducing the interface pressure for head. The study set out to investigate the interface pressure on the X-ray table with and without mattress. It is therefore confusing that pillows were used during pressure mapping, because as stated earlier, the use of the pillows

would likely invalidate the results. Hence the interface pressure values recorded for the head on the imaging tables can be said to be inaccurate, and not a true reflection of the interface pressure for the head on the imaging tables. More importantly, the use of the pillow might have led to an increased interface pressure for the thoracic spine, sacrum, and other parts of the body. This is because the use of a pillow will elevate the head, putting more pressure on the cervical, scapulae, and thoracic spine, which will in turn increase the interface pressures at these anatomical areas. Therefore, the use of the pillow will result in an increased interface pressure for these anatomical areas. It must be stated that it is common for patients not to be given pillows during radiographic and/or radiotherapy procedures as the pillow could induce diagnostic and radiotherapy planning and treatment errors.

Justham et al. (1996) conducted their work on a flat top imaging table that was manufactured in 1980, over three decades ago. X-ray imaging tables have undergone significant changes over the past three decades, with most having new table configurations designed with carbon fibres (Mineyuki, 2014, Tan et al., 2014, Smith et al., 2010). This is to reduce patient dose, ensure better image quality (and therefore improve diagnostic accuracy), thereby enhancing patient care and management (Ahmed et al., 2012, Brenner et al., 2011). Although the specific characteristics of the imaging table and support surfaces used were not reported in the study conducted by Justham et al. (1996), it is very likely that the imaging table/support surfaces will not be in used in modern radiography and radiotherapy departments. However, modern imaging couches are likely to be as hard and firm as old ones.

Additionally, the study was conducted on two table configurations, an imaging table with and without a mattress. Currently, radiographic procedures are conducted mainly on three table configurations: an X-ray table with a thin radiolucent mattress; computerised tomography (CT) table; and the X-ray table with no mattress (hard surface, such as the ones used in radiotherapy)(Suthar et al., 2015, Hawkes, 2015, Groheux et al., 2009, Whitley et al., 2005). The advancement in imaging equipment design has given rise to modern equipment such as the Positron Emission Tomography-computerised tomography (PET-CT) and Magnetic Resonance Imaging (MRI), which tend to have narrow, curved imaging surfaces as shown in Figure 2:10.

Figure 2:10: CT machine with a narrow curved surface and a thin mattress

Consequently, to understand the interface pressure on modern imaging and radiotherapy surfaces, it is important to use the latest pressure mapping equipment and/or technology to investigate the interface pressure on imaging and radiotherapy planning and treatment surfaces currently in use. This will provide a current objective measure of the interface pressure values on radiography and radiotherapy surfaces.

Many studies investigated patients' experiences such as pain and comfort whilst undergoing radiographic and radiotherapy procedures (Rossler et al., 2015, Weiland et al., 2014, Arunachalam et al., 2012, Goncalves et al., 2009). Comfort is defined as the absence of unpleasant feeling that could be interpreted as pain (Cox and Davison, 2005). In a recent positioning study, Rossler et al. (2015) used a MRI table top with exchangeable flat and cone-shaped inserts of varying opening diameters, to evaluate their influence on breast coverage and patient comfort in various positions. The study calculated breast length and volume to compare positioning modalities including different opening diameters and forms. The study also tested an underpressure system for its functionality and comfort on a stereotactic biopsy table mimicking a future CT scanner table. The study concluded that the cone-shaped table tops were adequate for imaging the complete breast using breast CT systems. The study also found out that, the underpressure system proved favourable for the fixation of the breast during imaging and increased breast coverage. Finally, patients' comfort was deemed adequate. Irrespective of the significance of the studies that

investigated patients' pain and comfort whilst undergoing radiographic and radiotherapy procedures, none of these studies assessed volunteers' perception of pain and comfort whilst lying on medical imaging and radiotherapy planning and treatment surfaces. There is therefore a gap in the literature as to how patients feel when they lie on radiography and radiotherapy planning and treatment surfaces. Hence, it is necessary to establish the impact radiography/radiotherapy surfaces could have on patients undergoing radiographic/radiotherapy procedures, because patients spend a considerable amount of time on these surfaces (Grunheid et al., 2012, Ahmed et al., 2012).

2.16 Rationale for the thesis

The literature review demonstrated that pressure ulcers, including hospital acquired (nosocomial) pressure ulcers are a common, severe, and costly medical problem that needs to be prevented. Medical Device Related (MDR) pressure ulcers form a large percentage of nosocomial pressure ulcers (Messer, 2012). Radiography and radiotherapy planning and treatment procedures form a significant part of all diagnostics and therapeutic procedures done within the hospital setting (Ngo et al., 2013). Notwithstanding the positive impact of radiographic and radiotherapy planning and treatment procedures in patient care and management, these procedures, plus the risk factors present within the radiography and radiotherapy environment could be contributory factors to the incidence of MDR pressure ulcers amongst patients. The impact could be severe in at risk populations, such as elderly, and those with chronic diseases, and fragile skin.

Patient transfer within the radiography/radiotherapy settings could be a potential cause of MDR pressure ulcers. Radiography and radiotherapy are specialised areas of healthcare that require specific machines and imaging and radiotherapy planning and treatment surfaces for optimum performance. In radiography, the need to maintain diagnostically acceptable image quality, warrants that imaging procedures are performed on specially designed X-ray imaging tables (Ahmed et al., 2012). Similarly, the need to minimise error demands that patients are transferred onto radiotherapy tables prior to a planning or treatment procedure. Patients with limited mobility arrive in the radiography department on trolleys and in wheelchairs, most of which may be fitted with modern pressure relieving mattresses and cushions. These mattresses are necessary to prevent tissue damage, by continuously or alternately redistributing pressure between the patient and the contact surface, thereby reducing the risk of developing pressure ulcers (Makhsous et al., 2007).

Manufacturers of these mattresses are mainly concerned with the ability of the mattress to prevent tissue necrosis, without much thought about the potential impact of the surface on radiation dose, diagnostic image quality, and the accuracy of tumour delineation during radiotherapy planning and treatment during radiotherapy treatment procedures. Some pressure redistribution technologies such as gel-filled, air-filled, and fluid-filled mattresses are not suitable for medical imaging because they could cause magnification on radiographic images, which may degrade the

diagnostic quality of that image (Amis et al., 2007). Thick pressure relieving mattresses could also cause massive attenuation, meaning less radiation dose will be hitting the detector. This may result in poor diagnostic quality and may cause an imaging procedure to be repeated. Repeating the procedure carries further risk, not just in terms of the patient having to endure staying still again, but also because of the risk of the additional dose of radiation (Admassie et al., 2010). This warrants that patients are transferred onto the imaging tables prior to a procedure.

The transfer of immobile patients from trolleys and wheelchairs onto X-ray tables can sometimes be very complicated, especially in bariatric patients, and may give rise to shearing and friction (Van Gaal et al., 2014, Pellino et al., 2006). As discussed earlier in sections 2.9.1 and 2.9.2, friction and shearing could have detrimental effects on patient's skin, especially in at risk populations such as elderly patients, and those with spinal cord injuries, and cancer (Greene and Wilkinson, 2015, Dzięgielewska et al., 2011). To minimise the impact that transfers could have on the incidence of MDR pressure ulcers among patients, most imaging and radiotherapy departments have standard protocols for moving patients from trolleys onto tables (Ngo et al., 2013). For example, the use of assistive transfer tools such as a patslide is highly recommended. Ngo et al. (2013), indicated that although most radiographers are familiar with the importance, and the use of transfer devices, some of them do not apply them in the clinical setting. Although the reasons for this are not clear, Pellino et al. (2006), stated that due to high workload, most radiographers work under considerable time pressure and are bound to make mistakes. For example, although there are strict rules on patient movement and handling in the UK such as the one developed by the Health and Safety Executive (HSE, 2015), radiographers may make mistakes when using patslide. This may cause skin injuries to patients. Griffiths (2012), added that attitudinal change, unavailability of these devices, and lack of adequate training on the use of transfer devices may account for its non-use among some radiographers. Consequently, the use of unsafe transfer methods is more likely to give rise to shearing and friction. These factors combined with the need for these patients to lie still thereby increasing the time pressure between the patient's body and the imaging/radiotherapy table is sustained could lead to pressure ulcers in the future (Lahmann et al., 2011).

The cardinal rule in medical imaging, is that images should be produced at a radiation dose as low as reasonably practicable (Whitley et al., 2005). This fundamental principle does not only inform radiographers' work but also the design of radiography equipment (Ahmed et al., 2012). The need to produce diagnostically acceptable images at the lowest dose means that no or very thin radiolucent mattresses are used in imaging (Ball et al., 2008). These radiolucent mattresses help to minimise image magnification by maintaining the body part to be radiographed as close to the image receptor as possible (Beck, 2012, Razi et al., 2009). Although magnification cannot be completely eliminated in imaging, thin mattresses help to significantly reduce its negative impact on image quality and lesion detection performance, helping to produce diagnostically acceptable images (Chida et al., 2013, Brenner and Huda, 2008). Producing radiographs with suitable image quality also means that fewer images would need repeating, and consequently, a reduction on radiation dose to both the patient and radiographer/radiologist (Ahmed et al., 2012, Engel-Hills, 2006).

The use of no or very thin radiolucent mattresses means patients undergoing imaging procedures basically have very little or no cushioning to lie on. This could increase their risk of tissue damage, and developing pressure ulcers, especially among high risk patients (Colin et al., 2013). This is because the patient's skin could be in direct contact with the hard carbon fibre imaging and radiotherapy planning and treatment table. This is likely to increase the interface pressure between the patient and the imaging/radiotherapy table and therefore increase the patient's risk of developing pressure ulcers (Stern et al., 2014). The risk is even higher if the area of contact with the imaging/radiotherapy table happens to be a bony prominence such as the head, sacrum or heels (Giuglea et al., 2010, Smart, 2013, Jiang et al., 2014). This is due to the fact that bony prominences have inadequate soft tissues to absorb, and redistribute the load of pressure, and are therefore easily prone to tissue necrosis (Kim et al., 2010, Black et al., 2012, Mehta et al., 2015). The potential impact of having no mattress on imaging/radiotherapy tables and its association to developing pressure ulcers could have a more detrimental impact in radiotherapy (Hendrichova et al., 2010). This is because of the long duration of radiotherapy planning and treatment procedures, and the high risk patient group that undergo these procedures (Brenner et al., 2011).

As stated earlier, studies have shown the direct relationship between the duration and intensity of pressure, and how sustained interface pressure for long periods of time could induce tissue damage, which may lead to pressure ulcers. It has been shown that one effective way of preventing this problem is by employing techniques that reduce the amount of time interface pressure between a body and contact surface is sustained (Hollington and Hillman, 2013, Stinson et al., 2003a). The use of repositioning techniques to periodically move patients and relieve sustained interface pressure, thereby minimising patient's risk of developing pressure ulcers has been proven to be very effective, hence it is a common standard practice in healthcare and especially nursing (Forde-Johnston, 2014, Peterson et al., 2013a, Dharmarajan and Ugalino, 2002). Unfortunately, this useful technique cannot be applied during medical imaging and radiotherapy planning and treatment procedures because as stated earlier, patients are required to lie still during imaging and radiotherapy planning and treatment procedures. Movement during imaging procedures may result in movement unsharpness of the image produced, thereby reducing the diagnostic quality of the image (Whitley et al., 2005). Movement during radiotherapy planning and treatment procedures could have serious consequences for the patient. Radiotherapy planning and treatment procedures involve accurate and precise delineation and delivery of prescribed radiation doses to a target tumour, while sparing nearby normal tissues and organs (Siva et al., 2014). Hence, patient movement during radiotherapy planning and treatment procedures may result in poorly defined gross target volume (GTV), which might lead to exposing healthy tissues and organs to harmful radiation doses (Li et al., 2012, Loch and Lima, 2010). Also, movement could result in delivering an insufficient dose to the tumour thereby failing to achieve remission (Vrana et al., 2016, Ricardi et al., 2016). As a result, patients have to endure sustained interface pressure, because some radiotherapy planning such as PET/CT and SPECT/CT and treatment procedures such as cranial stereotactic radiotherapy takes long periods to complete.

To ensure that patients do not move during radiography and radiotherapy planning and treatment procedures, they are sometimes deliberately immobilised using specific immobilisation devices. The use of immobilisation devices could increase patient's risk of developing MDR pressure ulcers because it could increase the interface pressure between the patient and the imaging/radiotherapy surface. The

application of the immobilisation device could add pressure on the already existing interface pressure between the patient body and the imaging/radiotherapy table. The impact could be very severe considering the fact that most patients who undergo radiotherapy procedures are old with fragile skin, most of them have cancer, and other co-morbidities, that might increase their risk of developing pressure ulcers (Kelly, 2014).

In summary, there is a huge gap in the literature as to the interface pressures on medical imaging and radiotherapy planning and treatment surfaces. The only study that investigated this topic was conducted on an outdated equipment manufactured over 30 years ago, using a pressure mapping technology which has been found to be less accurate due to its poor spatial resolution. The study also used flawed method in conducting the experiment. Therefore, there is the need to investigate the interface pressures on radiography and radiotherapy planning and treatment surfaces, to determine if there are interface pressure risks. Should interface pressure risks exist then an intervention study will be conducted using available pressure redistribution surface overlays to minimise the risk.

As such, this research was conducted in two phases. The first phase involved a baseline study that investigated the interface pressure of healthy volunteers on three medical imaging/radiotherapy surfaces. The study also assessed the volunteers' perception of pain and comfort whilst lying on the three different imaging and radiotherapy surfaces. For the purposes of this thesis, a healthy person is defined as any volunteer who can lie still in a supine position for 26 minutes without any difficulty. Detailed inclusion criteria have been provided in chapter three (section 3.9). Healthy adults were used for this study because this is a baseline study looking to explore new knowledge and assess the interface pressure trend on these surfaces and is also congruent with other studies in regards to sample population.

The second phase of the thesis involved an intervention study conducted to assess the impact of a thin radiolucent silicone gel surface overlay on interface pressure for the head. The was necessary because the results of the baseline study showed that high interface pressure risks do exist for the head on the radiotherapy table.

Phase One

Title:

Interface pressure (IP) risk and perception of pain and comfort on radiography and radiotherapy tables.

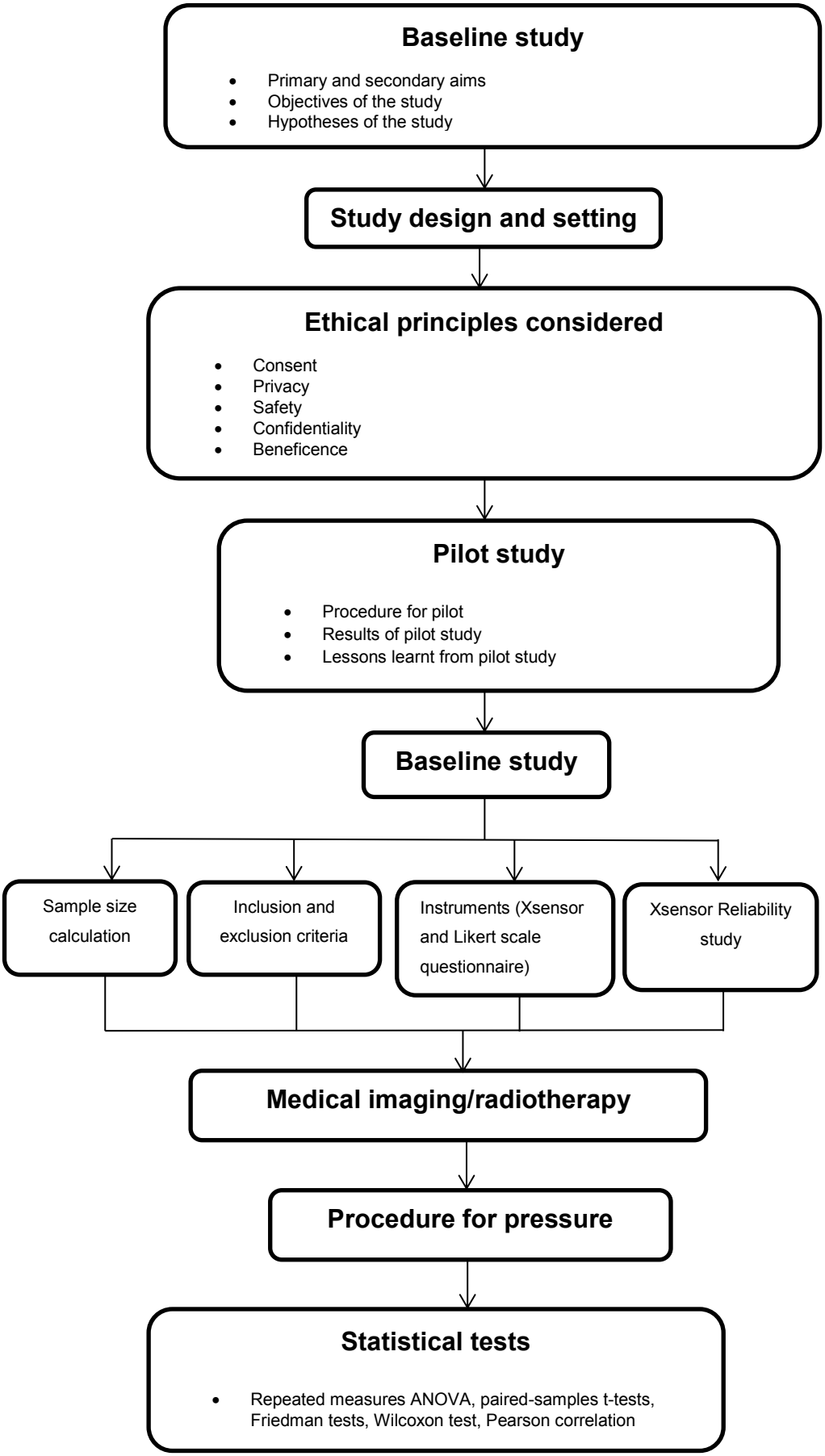
3 Chapter Three – Method for Baseline Study

3.1 Chapter overview

This chapter describes the method used for the baseline study. To achieve the aims, a set of research objectives and hypotheses have been formulated. In addition, ethical issues considered when conducting the research are discussed, followed by a section on the pilot study conducted to assess the feasibility of the method. Within the pilot, the reliability and validity of the data collection tools are also assessed so that changes could be made when necessary before the start of the baseline study. Lessons learnt from the pilot study and how these have affected the method of the baseline study have also been discussed within this chapter.

The next section of the chapter focuses on the rationale for the sample size for the study. In this section, justification is given for the sample size with evidence from a power calculation. Data collection instruments – Xsensor and 5-point Likert scale questionnaire – are then discussed. The characteristics of the Xsensor pressure mapping equipment and technology will be critically discussed in this section. The chapter concludes with information on the procedure used for measuring the interface pressures (IPs), and the statistical tests that were performed. An overview of the structure of the method is shown in figure 3.1.

Figure 3:1: Flowchart illustrating the method used for the baseline study



3.2 Aims of the baseline study

The primary aim of the baseline study is to investigate the interface pressures (IPs) of healthy volunteers whilst lying upon modern medical imaging and radiotherapy planning and treatment surfaces. The surfaces include an X-ray table with a thin mattress, a narrow curved CT surface, and an X-ray table with no mattress. The latter table is to mimic a radiotherapy planning and treatment surface. This experiment was conducted using the Xsensor pressure mapping equipment and its associated software/technology. The outcome of the baseline study will determine whether there are IP risks whilst lying upon medical imaging and radiotherapy planning and treatment surfaces currently in use in radiography and radiotherapy departments. The secondary aim is to investigate the volunteers' perception of pain and comfort whilst lying on the medical imaging and radiotherapy planning and treatment surfaces. Since this is an empirical baseline study seeking to develop new knowledge, and explore IP risks on radiography/radiotherapy surfaces, healthy volunteers were involved. To achieve the aims of the baseline study, the following objectives and hypotheses have been formulated:

3.3 Objectives of the baseline study

- Evaluate and analyse the mean IP of the whole body on the three different imaging and radiotherapy planning and treatment surfaces.
- Evaluate and analyse the mean IP of the head, sacrum, and heels on the three different imaging and radiotherapy planning and treatment surfaces.
- Evaluate and analyse the peak pressure (PP) of the head, sacrum, and heels on the three different imaging and radiotherapy planning and treatment surfaces.
- Evaluate and analyse the Peak Pressure Index (PPI) of the head, sacrum, and heels on the three different imaging and radiotherapy planning and treatment surfaces.
- Evaluate and analyse volunteers' perception of comfort on the three different imaging and radiotherapy planning and treatment surfaces.
- Evaluate and analyse volunteers' perception of pain on the three different imaging and radiotherapy planning and treatment surfaces.

- Critically analyse the relationship between BMI and mean IP on the three different imaging and radiotherapy planning and treatment surfaces.

3.4 Hypotheses of the baseline study

1. There will be statistically significant differences in the mean IP of the whole body between the three imaging and radiotherapy planning and treatment surfaces.
2. There will be statistically significant differences in the mean IP of the head, sacrum, and heels on the three imaging and radiotherapy planning and treatment surfaces.
3. There will be statistically significant differences in the mean peak IP of the head, sacrum, and heels on the three imaging and radiotherapy planning and treatment surfaces.
4. There will be significant differences in the mean Peak Pressure Index (PPI) of the head, sacrum and heels on the three imaging and radiotherapy planning and treatment surfaces.
5. There will be statistically significant differences in volunteers' perception of comfort on the three imaging and radiotherapy planning and treatment surfaces.
6. There will be statistically significant differences in volunteers' perception of pain on the three imaging and radiotherapy planning and treatment surfaces.
7. There will be a positive correlation between volunteers' BMI and mean IP of the whole body on the three imaging and radiotherapy planning and treatment surfaces.

3.5 Study design and setting

The baseline study was conducted in the medical imaging facility located within the Mary Seacole Building of the University of Salford in Manchester, United Kingdom.

3.6 Ethical considerations

The baseline study was approved by the University of Salford College of Health and Social Care Ethics Committee (Appendix 1). All the volunteers were self-selecting and participated in the study on their own free will, without any form of coercing from the researcher. The recruitment strategies used for the baseline study include placement of an advert/poster (Appendix 2) on notice boards across the University and interested volunteers were asked to contact the researcher for further information and a copy of the participants' information sheet. Also the researcher made presentations to groups of undergraduate and postgraduate students encouraging them to participate in the study. Volunteers who expressed an interest in participating in the study were then sent the participants' information sheet (Appendix 3) through an email, which contained detailed information about the study. The participants' information sheet was written in simple terms, capable to be clearly understood by non-medical or non-healthcare students and staff. The researcher was available to answer questions, and clarify issues with the potential volunteers. Volunteers who agreed to participate in the study were requested to sign a consent form (appendix 4). Records of these are kept in a locked cabinet, and can only be accessed by the researcher and members of the research supervisory team. The consent form clearly indicated that the volunteers have the right to withdraw from the study at any time, without giving any reason for doing so. In such an instance, the volunteer can request for his/her data already collected to be deleted from the study records.

The study did pose very little risk to either the volunteers or the researcher. All risk assessment requirements were fulfilled prior to data collection. The University of Salford risk assessment form (Appendix 5) was submitted to and approved by the Ethics Committee. Also the medical imaging facility (setting for the research) local rules for radiation safety compliance form (Appendix 6) was read, completed and returned to the radiation protection supervisor. On beneficence, the volunteers were given certificates (Appendix 7) for participating in the study. This was done to increase volunteers' interest and enhance recruitment. However, this is not deemed to coerce the volunteers in any way to participate in the study. The certificate of participation was signed by the researcher and his lead PhD supervisor.

The privacy of volunteers were protected in two ways. Firstly, volunteers' names, signatures and other demographic information remained confidential. This information was kept in a secured location, locked, and can only be accessed by the researcher and members of the research supervisory team. This was clearly stated in the participant information sheet prior to data collection, and agreed on during the consent process. Second, the IP data collected on the three imaging and radiotherapy planning and treatment surfaces were anonymised. Volunteers were allocated numbers by the researcher, and this coded identifier was used for the research records. None of the volunteers was named in conference presentations, and none will be named or identified in subsequent journal publications or conference papers, or in discussion with members of the research supervisory team.

3.7 Pilot study

3.7.1 Introduction

A pilot study is defined as a small-scale version of a planned study, usually conducted with a smaller sample size similar to those to be recruited later in the main study (Doody and Doody, 2015). However, as will be shown later in this section, the pilot study was conducted with a large sample size of 38 volunteers. The pilot study was conducted to allow the researcher to practice and to assess the effectiveness of the planned data collection and analysis techniques that will be used in the baseline study. In addition, the pilot study was conducted to detect any problems with the reliability and validity of the data collection tools, and methods so that changes could be made before the start of the baseline study. Finally, the pilot study was conducted to serve as reference data from which effect sizes could be calculated. This is necessary because effect size estimates will be needed to perform power analysis (discussed in section 3.8). The only study that investigated IPs on medical imaging tables is by Justham et al. (1996), and they did not report effect sizes, meaning that effect size estimates could not be calculated from that study.

Consequently, a pilot study was conducted in the medical imaging facility of the Escola Superior de Tecnologia da Saude de Lisboa, in Lisbon, Portugal. Using the same inclusion and exclusion criteria as the baseline study (section 3.9), the pilot study was conducted on 38 healthy volunteers during the 2014 OPTIMAX summer school. The participants were asked if they had any health problems that could prevent them from lying still for 26 minutes. This was made clear in the participants information sheet distributed prior to data collection. The volunteers were drawn from people participating in the summer school, hence, the large sample size, compared to that of most pilot studies. The volunteers have similar characteristics (age, and range of body mass index (BMI)), to that of the baseline study so that inferences could then be made from the results.

3.7.2 Method

Two different medical imaging surfaces were used for the pilot study. These included the Norland XR-36 bone density scanner with a radiolucent mattress and the Siemens MULTIX Pro X-ray table with no mattress. While the Norland XR-36 bone scanner is outdated and may not be in used in modern radiography departments, its thin radiolucent mattress and table are similar to the ones that come with modern radiography equipment, and are therefore comparable for this pilot study. The Siemens MULTIX Pro X-ray table surface represented a radiotherapy planning and treatment table as they have the same firm solid carbon fibre fitted table top. As stated earlier, the main aim of this pilot is not to test statistical significance, but rather to test the feasibility and the validity of the methods and data collection instrument so as to minimise error that might arise in the main study. As a result, although the two medical imaging and radiotherapy surfaces used within the pilot study are not the same as the surfaces that were used in the baseline study, they were suited for this pilot. The procedure for data collection outlined in section 3.14 was used to conduct pressure mapping of the whole body, and the jeopardy areas (head, sacrum, and heels) for 20 minutes after six minutes settling time using the Xsensor PX100:48.144.02 pressure mapping equipment and technology. See section 3.13 for justification of settling time. After pressure mapping, the volunteers completed a short Likert scale questionnaire to assess their perception of pain and comfort whilst lying on the surfaces.

3.7.3 Results

Inspection of the data prior to analyses revealed that the data of eight volunteers were affected by artefacts. These eight sets of volunteer data were consequently deleted. The demographic statistics of the remaining 30 volunteers are as follows; 24 females (80%) and 6 males (20%), aged between 19 to 51 years (mean=25.77; SD=7.72) with BMI ranging from 18.7 to 33.6 (mean 24.12; SD=3.29). Prior to statistical testing, the data was assessed for normality using histograms and Shapiro-Wilk test. The results showed normal distribution; hence parametric statistics were used. Paired samples t-test was conducted to compare the IP of the whole body and the jeopardy areas on both the mattress surface and the X-ray table

with no mattress. Also, the non-parametric Wilcoxon rank test was used to compare volunteers' perception of pain and comfort on the two surfaces.

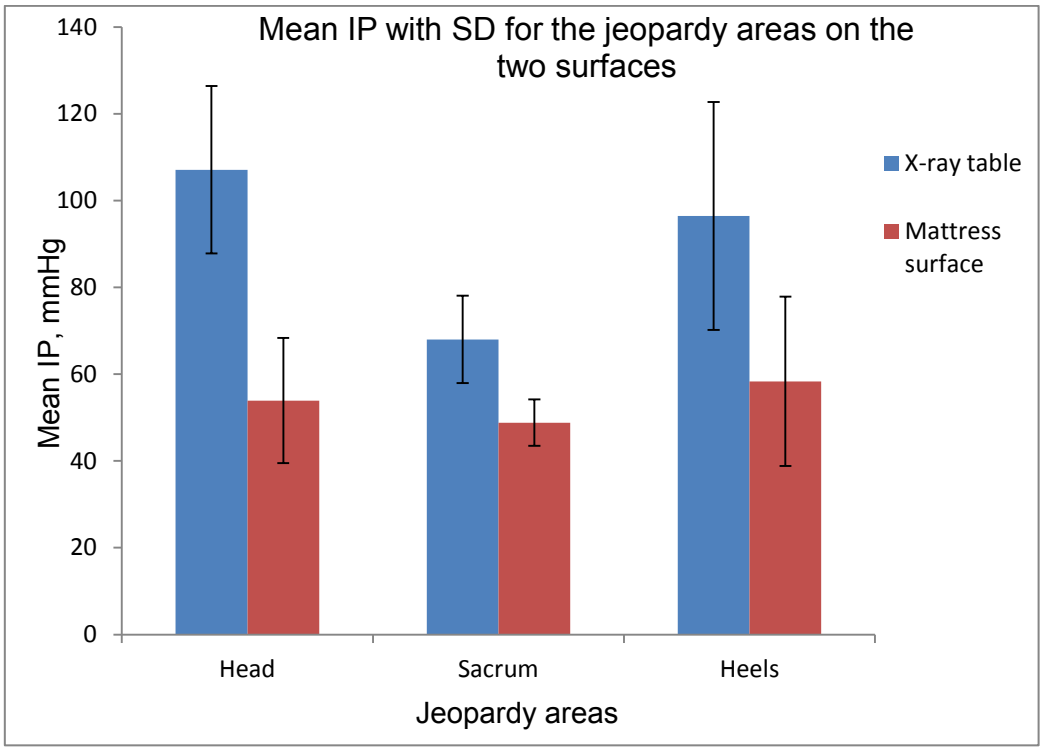
The results of a paired-samples t-test conducted to compare the mean IP for the whole body on the X-ray table and the mattress surface indicates a statistically significant difference in the mean IP on the X-ray table with no mattress (Mean = 43.05 mmHg, SD = 3.75), compared to the IP for whole body on the mattress surface (Mean = 31.10 mmHg, SD = 2.34), t (29) = 16.45, p≤0.001. The mean IP difference is 11.95 with a 95% confidence interval (CI) ranging from 10.6 to 13.34 mmHg was statistically significant, and represented a large effect size, d = 3.19.

Similarly, as shown in Table 3.1 and Figure 3.2, the results of paired-samples t-test conducted to compare the mean IP for the head, sacrum and heels on the X-ray table and the mattress surface indicates statistically significant differences. All comparisons having p≤0.001.

Table 3.1: Mean IP and standard deviation (SD) of the jeopardy areas on the two medical imaging surfaces

	IP, mean±SD (mmHg) X-ray table	IP, mean±SD (mmHg) Mattress surface	*p value*
Head	107.11±19.29	53.92±14.42	*≤0.001*
Sacrum	68.01±10.09	48.83±5.35	*≤0.001*
Heels	96.48±26.28	58.36±19.54	*≤0.001*

Figure 3:2: Bar graph comparing mean IP with SD of the jeopardy areas on the two medical imaging surfaces

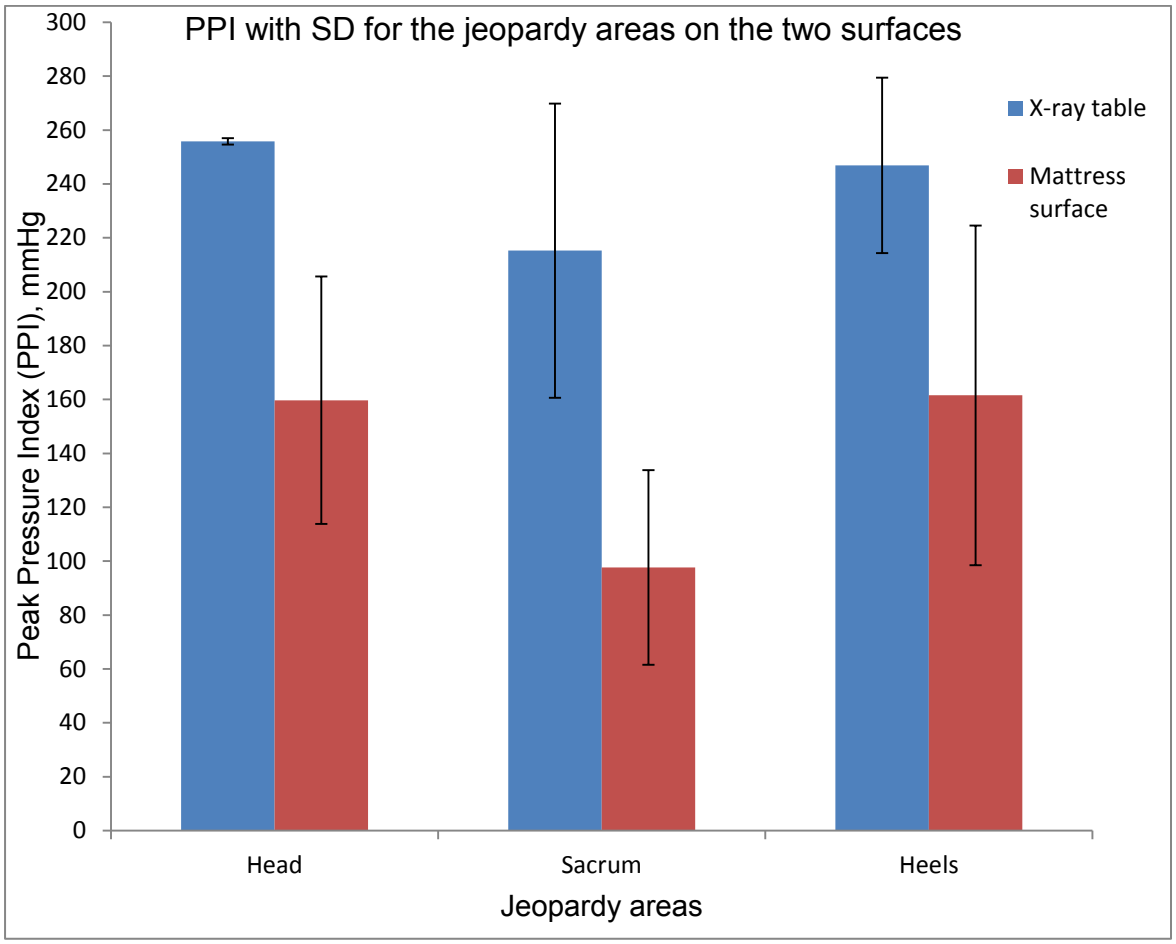


As shown in Table 3.2, the results of paired-samples t-test also indicate statistically significant differences between PPI of all the jeopardy areas on the X-ray table and the mattress surface, p≤0.001.

Table 3.2: Mean PPI and standard deviation (SD) of the jeopardy areas on the two medical imaging surfaces

	PPI, SD (mmHg) X-ray table	PPI, SD (mmHg) Mattress surface	*p value*
Head	255.78±1.2	159.7±45.9	*≤0.001*
Sacrum	215.3±54.6	97.7±36.1	*≤0.001*
Heels	246.9±32.5	161.6±63.0	*≤0.001*

Figure 3:3: Bar graph comparing PPI with SD of the jeopardy areas on the two medical imaging surfaces



The results from the Likert scale questionnaire indicated that 77% of the volunteers found the X-ray table with no mattress to be uncomfortable or very uncomfortable, compared to 23% who found it to be comfortable or very comfortable. Also, there was statistically significant difference in volunteers' perception of pain whilst lying on the two surfaces ($p \leq 0.001$) with most volunteers (71%) experiencing pain on the X-ray table with no mattress. Most of the pain occurred at the head (63%).

Results from the pilot study were presented as an electronic poster at the 2015 European Congress of Radiology (ECR) held in Vienna, Austria (Everton et al., 2015) (Appendix 8). Lastly, this pilot study has been written up into two parts – a narrative literature review paper (Everton et al., 2014a), and the other a research article (Everton et al., 2014b) – and form two chapters of a book (Hogg and Lança, 2014). In all the publications from the pilot study, the author of this PhD thesis was

named as the last author because he was the principal investigator (PI) for the study. For the purposes of the OPTIMAX summer school activity, the researcher acted as the PI because besides being a pilot study for the PhD thesis, it was also a learning experience for the international undergraduate students who participated in the summer school. As the PI directing the work and in accordance with convention he was indicated as the last author (Brennan et al., 2016, Smith and Williams-Jones, 2012).

3.7.4 Lessons learnt from pilot study

As stated earlier, the aim of the pilot study was to assess the feasibility of the baseline study, the method and the validity and reliability of the data collection instruments. From the pilot study the following lessons have been learnt. Firstly, during data acquisition, errors in the Xsensor pressure mapping equipment were detected. The errors presented visually as white artefacts on the pressure images for some of the frames of the volunteers. Detailed inspection of the data showed that no interface pressure was recorded in the affected areas, rendering the data of these frames invalid. This error might be due to the fact that the pressure mat used was old and that it had not been recently calibrated. This problem was not anticipated because the supplier of the pressure mat suggested the mat was new; post facto the supplier retracted their statement. The lesson learnt from this is that, the Xsensor pressure mat is not reliable when it is not calibrated with the latest software. Hence the need to adhere to the manufacturer's recommendation of yearly calibration (Sumed International, 2014).

Secondly, the pilot study brought to fore a pressure gradient between the left and right sides of the Xsensor pressure mat. This problem was discovered when it was realised after data collection for the pilot study that IP values of the left heels were greater than the right in all the volunteers. This would suggest in all volunteers that the left heels/feet of the volunteers are heavier than the right heels/feet. An alternative explanation is that the pressure mat may be malfunctioning. To investigate this, a novel quality assurance test was developed and performed by measuring the IP of a human dosimetry phantom at the lower third of the pressure mat. The lower third of the pressure mat was divided vertically into two sides – left and right. Ten pressure measurements each were taken on different points on the left and right sides of the mat. IP measurement was taken for two minutes at one frame per second. As shown in Table 3.3, the IP values revealed a mean percentage increase of 14% on the left side of the pressure mat compared to the right.

Table 3.3: Ten measurements comparing the IP across the lower third of the old Xsensor pressure mat

Mean IP (mmHg) RLT	Mean IP (mmHg) LLT	% increase
34.5	38.7	12.2
34.3	39.3	14.6
34.8	39.4	13.2
34.5	39.1	13.3
34.5	39.3	13.9
34.6	39.3	13.6
34.5	39.6	14.8
34.3	39.3	14.6
34.5	39.4	14.2
34.1	39.3	15.2
Mean = 34.5±0.2	39.3±0.2	14.0±0.9

RLT = right lower third; LLT = left lower third.

The pressure gradient factor was subtracted from the pressure values on the left side of the mat, and the final values used for data analysis. It should be noted that the manufacturer does not provide any guidance or method about quality control of its pressure mat, aside yearly electronic calibration checks. A consequence of this is that a novel quality control method had to be developed for this thesis.

The pilot study therefore brought to fore significant potential sources of error of the Xsensor pressure mapping equipment and technology that can render the results of pressure mapping studies invalid. The possibility of pressure gradient across different sides of the Xsensor pressure mat has never been reported in the literature. This pilot study afforded the researcher an opportunity to identify errors, and devise ways to eliminate or minimise their potential impact on the baseline study. To enhance the validity of the results of the baseline study, a brand new pressure mat was purchased from the Xsensor Company in Canada. This new mat was calibrated with the latest Xsensor software, and was certified to be in excellent working condition in line with manufacturer operating specifications. Quality assurance (QA)

testing of the new mat using the QA method developed in this thesis showed consistent results between left and right lower thirds; as shown in Table 3.4.

Table 3.4: Ten measurements comparing the IP across the lower third of the new Xsensor pressure mat

Mean IP (mmHg) RLT	Mean IP (mmHg) LLT	% increase
35.2	35.3	0.28
35.4	35.5	0.28
35.2	35.1	-0.28
34.9	34.7	-0.57
35.1	35.1	0.00
35.1	35.2	0.28
35.6	35.4	-0.56
35.0	34.9	-0.29
35.6	35.5	-0.28
35.3	35.1	-0.57
Mean = 35.1±0.2	35.2±0.3	-0.17±0.34

RLT = right lower third; LLT = left lower third.

The pilot study also brought to fore potential problems with the method. For example, as part of the initial component of the pilot study it became clear that the big toes of the volunteers had to be tied together during pressure mapping. This was to minimise movement of the feet which would invalidate the results. However, after assessing this, the volunteers found this experience to be very uncomfortable. Consequently, this procedure was not adopted into the pilot or baseline study. The pilot study was also used to check if the questionnaire used to assess the volunteers' perception of pain and comfort whilst lying on the medical imaging and radiotherapy surfaces was clearly worded and understood by the volunteers. The pilot study revealed that some of the wording of the questionnaire was not clearly understood. For example, volunteers were asked if they felt like moving whilst lying on the pressure mat. Most of them misunderstood this question to mean "itching" and "twitching". As a result, this particular question was not measuring what it was intended to measure and was consequently deleted prior to the baseline study.

Finally, the proposed statistical tests were conducted on the pilot data. This gave the researcher the opportunity to input data into the SPSS software for the first time and, clean the data, conduct paired sample t-tests, and correctly report and interpret its results.

3.8 Sample size for the baseline study

A priori power analysis was calculated using the pilot data to determine the appropriate sample size needed for the baseline study to produce valid results. Power analysis is defined as the statistical method of determining the appropriate sample size adequate to make the findings of a particular research statistically resolute (Field, 2013, Bowling, 2009, Rugg and Petre, 2007). Results from the pilot study (section 3.7) indicated a large effect size d=3.19 between volunteers' mean IP for the whole body on the two medical imaging and radiotherapy surfaces. The effect size was calculated to know the magnitude of the effect of statistical significance of the IP on the two surfaces (Bosco et al., 2015, Larner, 2014). This is important because it allows the researcher to ascertain the practical significance of the statistical significance between the IPs on the two medical imaging and radiotherapy surfaces. Effect size, Cohen's d, was calculated using the formula below:

$$d = \frac{M1 - M2}{SD1}, \text{ (Field, 2013)}$$

Where;

M1 = mean IP for whole body on the X-ray table with no mattress

M2 = mean IP for whole body on the mattress surface

SD1 = standard deviation of mean IP on X-ray table with no mattress

However, because this result was based on calculations using paired sample t-test as the pilot study was conducted on two imaging and radiotherapy surfaces, it cannot be directly extrapolated into calculating the sample size for the baseline study. This is because in the main study, the experiment will be conducted on three medical imaging and radiotherapy surfaces; hence, the parametric one way repeated measures ANOVA will be conducted if the data is normally distributed. If the data deviates from normality, the non-parametric Friedman test will be conducted. However, calculating the effect size for the pilot study gives the researcher an idea as to the category of effect size to be expected in the baseline study (i.e. small, medium, or large). Going by the widely quoted Cohen's effect size classification for ANOVA, an expected large effect size will correspond to an effect size of 0.49 or more (Cohen, 1992). Hence a power analysis using the GPower computer software was conducted. The GPower software has been shown to have excellent accuracy and has been used in sample size calculations for many studies (Faul et al., 2009,

Cunningham and McCrum-Gardner, 2007). The results from the power analysis conducted using the Gpower software showed that a sample of 42 volunteers would be needed to determine a large effect, 0.49 with 80% power, using one way repeated measures ANOVA between means with alpha at 0.05 as shown in Figure 3:4. The alpha and power levels set are in congruent with other studies (Gilcreast et al., 2005, Gunningberg et al., 2000).

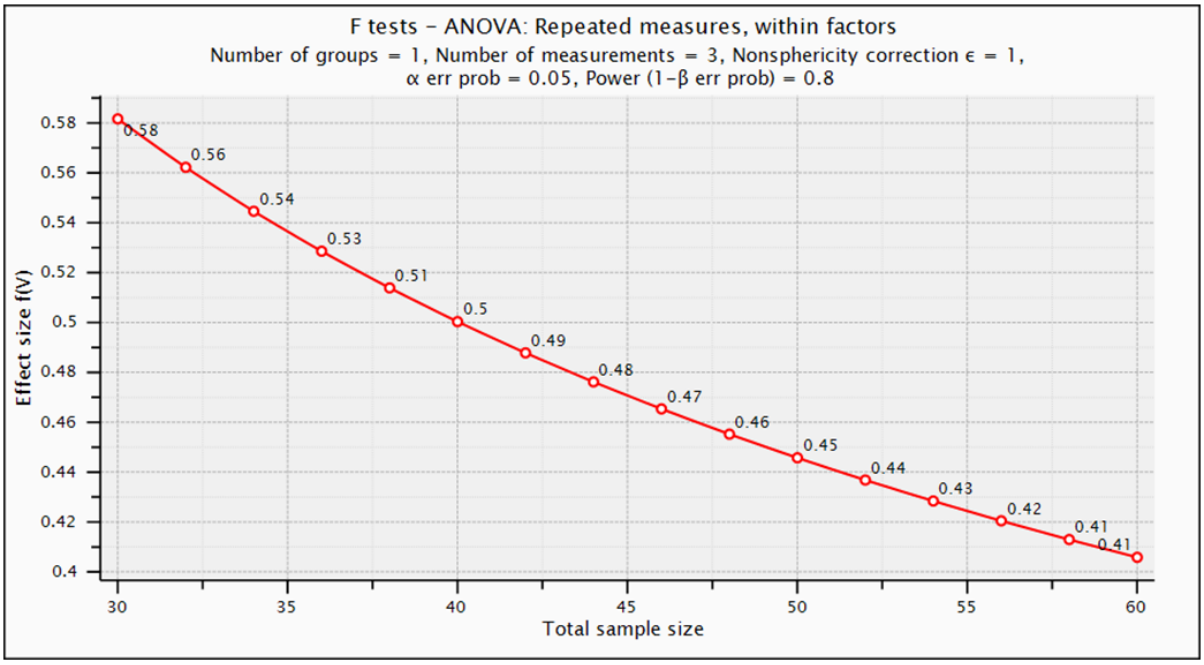


Figure 3:4: Results of power analysis using the GPower software

A disproportionate stratified random sampling method was used to recruit 49 students and staff from the University of Salford. Although this number is more than the required sample size, it was necessary to recruit more so that in the event that a volunteer withdrew from the study the sample size will still be enough to produce valid results (Bowling, 2009). This is particularly important because volunteers would be required to attend data collection on three different occasions. Disproportionate stratified random sampling method has been chosen because it enabled the researcher to recruit volunteers with a range of characteristics: gender, staff, age, students, from diverse ethnic groupings and diverse age groups and BMI (Bowling, 2009). Hence, the findings of this baseline study can be generalised to a healthy adult population.

3.9 Inclusion and exclusion criteria

Only healthy adults 18 years and older were involved in the baseline study so that the findings can be generalised to a healthy adult population (Bowling, 2009). For the purposes of this thesis, a healthy volunteer is defined as any individual who can lie still for 26 minutes without any serious difficulty. As stated earlier, healthy adults were used for this study because this is a baseline study looking to explore new knowledge and assess the IP trend on medical imaging and radiotherapy planning and treatment surfaces. The use of healthy adults is also congruent with other IP studies (Miller et al., 2014, Peterson et al., 2010, Stinson et al., 2003a, Stinson et al., 2002, Justham et al., 1996). Also, only adults were included in this study because adult population constitutes the majority of pressure ulcers cases. Various authors and researchers such as Gelis et al. (2009) and Russo et al. (2008) recommended that studies investigating IPs should be targeted at this population group so that the findings of such studies will be beneficial for clinical practice. Additionally, although the risks involved in this study are minimal, only mobile volunteers who were healthy enough to independently climb onto and off the medical imaging and radiotherapy planning and treatment surfaces with minimal or no support were involved in the study. Volunteers were asked during recruitment if they have any illness or medical condition that could prevent them from lying still for 26 minutes. This was clearly stated in the participants' information sheet (Appendix 3).

Pregnant women were excluded from the study. This was made clear in the participant information sheet distributed to volunteers during recruitment. For the purposes of this study a pregnant woman is defined as a woman who had a positive pregnancy test, missed her last menstrual period, or those who suspect that they may be pregnant. To confirm this, all female volunteers were asked prior to data collection if they think they were pregnant. Although depending solely on the word of women to rule out pregnancy may not be effective, it is the only way for the researcher to assess the pregnancy status of a woman without invading her privacy. It is worth mentioning that the issue of pregnancy is a sensitive issue that ought to be treated privately. Pregnant women were excluded on the basis that involving pregnant women in the study will have no benefit on clinical practice. Due to potential risks of foetal loss, foetal growth delay, and the possibility of causing

cancer, Positron emission tomography/computed tomography (PET-CT) and other medical imaging and radiotherapy planning and treatment procedures that involve high radiation doses, and take long time to complete, may not be justified in the pregnant patient and therefore will not be performed (Colletti, 2012). However, imaging and radiotherapy planning and treatment procedures can be undertaken on pregnant women if there is medical justification and the benefits outweigh the risk. Also, pregnant women were excluded because it might be difficult for them to lie still for 26 minutes, especially on the X-ray table with no mattress.

Secondly, volunteers who weigh more than the maximum permissible weight limit as per manufacturers specification for the relevant medical imaging/radiotherapy tables were excluded. For example CT scanner tables have a weight limit of 150 kilograms (Mutic et al., 2003). Also volunteers with a height of 190 cm or more were excluded from the study, due to the limitations of the Xsensor pressure mat dimensions. Although the pressure mat used has a sensing area of 81 x 203 cm, volunteers with height more than 190 cm were excluded to allow for space between the head and heels of the volunteer and the edge of the pressure mat so that no pressure data is lost as a result of the volunteer being too close to the edge of the pressure mat.

Finally, volunteers with any medical conditions, such as back pain, or those with spinal deformities such as scoliosis or kyphosis, that might prevent them from lying still on their back for 26 minutes were excluded from the study. This is to ensure that volunteers can lie still in a flat supine position during data acquisition. This is to avoid movement as movement could impact on the ability of the pressure mat to measure accurately the interface pressure, thereby giving false results, and render the findings of the study unreliable and invalid (Sullivan and Schoelles, 2013, Gil-Agudo et al., 2009).

3.10 Data collection instruments

Two data collection instruments were used for the baseline study. First, the Xsensor pressure mapping equipment and technology was used to provide an objective measure of IP of the whole body and the head, sacrum and heel of the volunteers on the three medical imaging and radiotherapy planning and treatment surfaces. Second, a 5-point Likert scale questionnaire was used to provide a subjective indication of volunteers' perception of comfort and pain whilst lying on the medical surfaces. These data collection instruments are discussed fully in sections 3.10.1 and 3.10.2.

3.10.1 Xsensor equipment/technology

A brand new calibrated full body Xsensor PX100.64.160.02 pressure mapping equipment with its associated software on a dedicated laptop was used for this study (Figure 3:5). Various clinical studies (Peterson et al., 2013b, King and Bridges, 2006) and academic studies (Hemmes et al., 2014b, Trewartha and Stiller, 2011) have used the Xsensor pressure mapping equipment and technology to perform pressure mapping on humans.

Figure 3:5: Xsensor equipment/technology fixed on the X-ray table

According to Hemmes et al. (2014b), the Xsensor pressure mapping system is the gold standard equipment/technology for pressure mapping. Manufacturer calibration and quality control data, prior to sales, confirm a high level of precision and reliability (Sumed International, 2014, Peterson et al., 2013b). The PX100:64.160.02 system is built using the capacitive pressure mapping technology, and was initially designed for pressure mapping in medical settings such as in rehabilitation seating, and for measuring interface pressure on hospital beds and mattresses (Sumed International, 2014). However, it has since been used in designing seats of automobiles and aeroplanes, and has also been used in research and other product design (Sumed International, 2014).

The pressure mat is designed as a conformable, flexible, and durable mat with highly sensitive sensors for measuring interface pressures in medical applications (Sumed International, 2014). The mat has a total area and a sensing area of 104.1 x 243.8 cm and 81.3 x 203.2 cm respectively, making it one of the largest pressure mapping systems available (Peterson et al., 2013b). The sensing area is defined as the area of the pressure mat that is fitted with sensors, and has the ability to record, save and transmit interface pressure (IP) values onto a handheld device or a dedicated computer fitted with the Xsensor software. The large sensing area makes this pressure mat particularly suitable for full body pressure mapping on medical imaging and radiotherapy planning and treatment surfaces (Makhsous et al., 2007).

The mat has over 10,240 sensing points, offering detailed two dimensional (2D) and three dimensional (3D) pressure images with a 1.27 cm spatial resolution, and a pressure range of 10-256 mmHg (Sumed International, 2014). Manufacturers' specification details indicate an accuracy rate of ±10 percent of the calibrated values. In addition, the Xsensor pressure mapping equipment has a maximum sampling frame rate of 17 frames per second. This wide sampling frame rate enables continuous monitoring of pressure points. This means that lots of IP data can be acquired within a short period. Manufacturer's information also indicates that the thickness of the sensing area when compressed and uncompressed is 0.081 and 0.1cm respectively. The Xsensor pressure mat also has low hysteresis, and low creep (Sumed International, 2014, Peterson et al., 2013b). Hysteresis is defined as the phenomenon exhibited by pressure mapping systems in which the systems

reaction to changes is dependent on its immediate history (Knops et al., 2010). This is mainly due to a holdup occurring between the application and removal of a force; impeding the system's ability to return to its original state (Sakai et al., 2009). Creep on the other hand is defined as an increase in pressure with constant force, and may cause the pressure mapping system to gradually deform with constant pressure (Sasaki et al., 2012).

The Xsensor equipment has a highly stable calibration and therefore does not require overly frequent re-calibration apart from the yearly calibration recommended by the manufacturers; which means that data can be collected in a fast, easy and accurate manner without the need for repeated calibrations (Hemmes et al., 2014b, Sumed International, 2014). Data from the Xsensor is recorded as colour coded maps of IP distribution in 2D and 3D, as well as numeric mean and peak IP readings given at specific timed stages, recorded in mmHg (Trewartha and Stiller, 2011). The pressure mat is connected to three X3 Pro sensor packs which are connected to the X3 Medical v6 software on a dedicated handheld device or a laptop.

There are other pressure mapping technologies available. Compared to other pressure mapping systems such as the Force Sensing Array (FSA), and the F-Scan manufactured by Tekscan, the Xsensor has been shown to perform superior. In a rigorous study comparing essential quality assurance characteristics of these three pressure mapping systems, it was proven that the Xsensor has better accuracy especially on curved surfaces, and was less affected by the radius of curvature of anatomical areas (Mitchell et al., 2005). This capability of the Xsensor is important for the purposes of this baseline experiment because the study is seeking to investigate IP values for the head, sacrum, and heels; anatomical areas of the body with very prominent bony structures, and sharp curvatures. The pressure mapping systems comparative study concluded that overall, the Xsensor has lower creep, lower hysteresis, and has much better accuracy rate especially at low pressure due to its highly sensitive capacitance sensors (Mitchell et al., 2005).

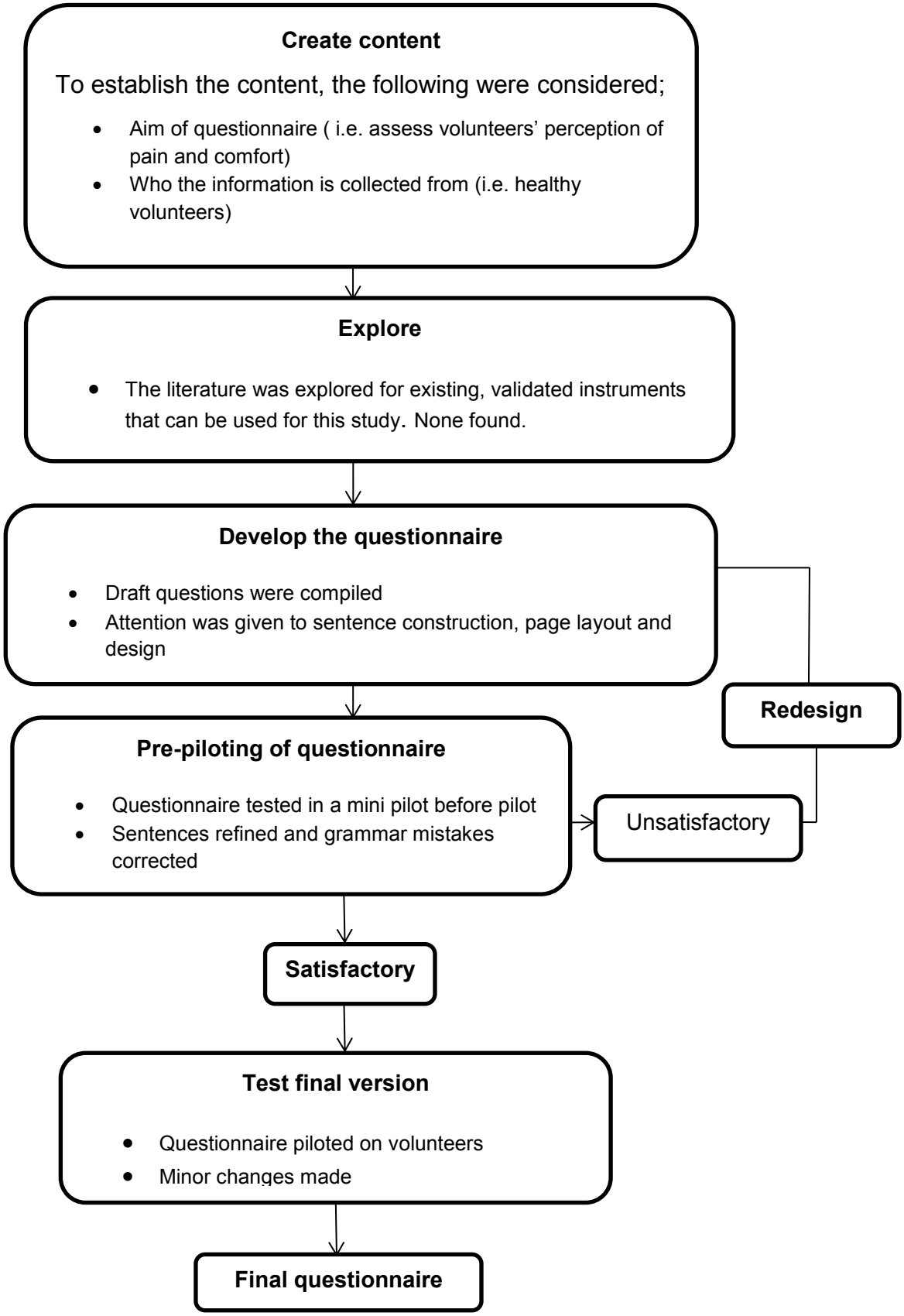
3.10.2 Questionnaire

Questionnaires are common data collection tools for measuring attitudes, perceptions and beliefs in healthcare research (Bruce et al., 2009, Bowling, 2009). As stated in section 3.2, the secondary aim of this baseline study was to assess volunteers' perception of pain and comfort whilst lying on the medical imaging and radiotherapy planning and treatment surfaces. To do this, a new short 5-point Likert scale questionnaire was developed (appendix 9). This was necessitated by the fact that there is no validated questionnaire in the literature that can easily be applied for the purposes of the baseline study. One classical example of a validated scale is the Chronic Pain Grade Questionnaire (CPGQ). The CPGQ is a very cumbersome seven item data collection tool designed to evaluate overall severity of chronic pain intensity and pain-related disability (Manraj and Saurabh, 2013). This tool has been designed to be used among people suffering from chronic pain that has lasted for at least six months. It is obvious that this tool can therefore not be applied to healthy volunteers in this study because of the large intrinsic differences in the two populations.

The methodological demands of designing, testing and using a questionnaire for research are essential if valid and reliable results are to be obtained (Artino et al., 2014, Iwasaki et al., 2013). Hence a reliable scientific process was used to develop, test, and retest the questionnaire. These processes are summarised in the flowchart in figure 3.6. A 5-point Likert scale was used for this baseline study because they are the most popular scaling method used to represent volunteers' perceptions, attitudes, and experiences in health and social care research (Bowling, 2009). There are various arguments for and against using a 5-point, 7-point or a 10-point Likert scale. However, the unanimous conclusion is that, in designing a scale, thought must be given to the simplicity of the scale. In other words, scales should be short, clearly worded, and precise without losing validity (Norman, 2010, Carifio and Perla, 2008). Also the scale should not have too many responses as this can create confusion in the minds of respondents, and may lead to volunteers providing wrong responses, and in some instances may pull out completely from the study (Rugg and Petre, 2007). The latter point is of particular interest to this research because volunteers will be required to complete the questionnaire on three different occasions, each time

after undergoing pressure mapping. As a result, a 5-point Likert scale was chosen as it provided enough responses to achieve the aims of the study.

Figure 3:6: Summary of the process for designing the questionnaire



[Adapted from Bruce et al. (2009)]

The questionnaire contains five questions/statements – three closed-ended and two open-ended questions. Two of the closed-ended questions were provided with five coded responses. For example, on a scale of 1 (very uncomfortable) to 5 (very comfortable), volunteers were asked to indicate their perception of comfort after lying on each of the three different medical imaging and radiotherapy planning and treatment surfaces. Similarly, volunteers were asked if they experienced any pain whilst lying on the medical surfaces. A 2-point response was provided for this question – yes or no. Volunteers who answered in the affirmative, were then asked to indicate the level of the pain experienced, from 1 (hardly any pain) to 5 (extreme pain).

One of the open ended questions asked the volunteers to indicate on a human diagram the anatomical area where they experienced pain. The other was seeking to solicit volunteers' comment or opinion on the overall experience of lying on the imaging and radiotherapy surfaces. This questionnaire had been assessed within the pilot study and is considered valid. However, it has limitations, which are discussed in chapter seven, section 7.3.

3.11 Reliability

The reliability of an instrument is the ability of that instrument to produce consistent results under the same measurement conditions over time (Field, 2013, Pallant, 2010). To ensure that the findings of the study are valid, and to increase confidence in the results, it is important to perform a reliability study on the Xsensor pressure mapping system. To achieve this, a test was conducted on a carbon fibre X-ray table with no mattress. This is to provide a stable surface, devoid of dent under phantom, thereby completely eliminating movement error. A one year old human phantom (Figure 3:7) was used because unlike humans, phantoms do not provide involuntary movements such as breathing and coughing which might affect the results. As the focus of this reliability study is solely to assess the validity and reliability of the Xsensor pressure mapping system, it is important to eliminate confounding variable(s) such as movement that might affect the results. The atom phantom used had a height of 91 cm and weighs 10.5 kg.

Figure 3:7: Phantom used for the reliability experiment

The reliability test was divided into three sets of ten measurements, conducted over 48 hours. On day one, the phantom was placed in a supine position on the Xsensor pressure mat and IP measurement was taken over a period of one minute at a rate of one frame per second (60 in total). Ten measurements were taken at different points of the mat. This was repeated after 24 hours, and the third IP measurement was taken after 48 hours.

The mean IP was calculated by averaging all the frames. Various authors have stated that reliability studies with intraclass correlation coefficient values of 0.7 to 0.8 indicate good reliability (Field, 2013, Kline, 1999, Pavot et al., 1991). As shown in table 3.6, the Xsensor pressure mapping system has an excellent reliability, with an intraclass correlation coefficient (ICC) of 0.93, with 95% Confidence Interval (CI) ranging from 0.81 to 0.98.

Table 3.5: Descriptive statistics of the three reliability tests

	Mean IP (mmHg)	SD	Number of test (N)
Test 1	35.49	0.02	10
Test 2	35.49	0.01	10
Test 3	35.49	0.02	10

Table 3.6: Results of intraclass correlation coefficient (ICC) test of the Xsensor

	Intraclass Correlation	95% CI	
		Lower	Upper
Single Measures	0.83	0.59	0.95
Average Measures	0.93	0.81	0.98

Although there are large differences between the body structures of the child phantom and the subjects for the baseline study (human volunteers), the use of the phantom will not have any impact on the study because as stated earlier the focus of this reliability study is to assess the reliability and validity of the Xsensor pressure mat.

3.12 Medical imaging/radiotherapy surfaces

There are various medical imaging/radiotherapy surfaces available in modern radiography/radiotherapy departments. This equipment and their accessories such as mattresses are manufactured and supplied by different companies. In some instances, one company may manufacture a piece of equipment whilst another company supply the accessories. In this research, the imaging and radiotherapy planning and treatment surfaces that were used are the Arco TN 0055 X-ray table with a thin radiolucent mattress, the CT table with a narrow curved surface, and the Arco TN 0055 X-ray table with no mattress (hard surface such as those used in radiotherapy planning and treatment). The latter surface was to mimic those used for radiotherapy planning and treatment procedures such as the KVue state of the art radiotherapy planning and treatment couch top (Figure 3:8). Although these three imaging and radiotherapy planning and treatment surfaces are not exhaustive of the available surfaces, they are representative in structure and composition of the imaging and radiotherapy table tops and surfaces available in modern radiography/radiotherapy departments. The issue here is that these three surfaces are the three main types of surfaces available in medical imaging and radiotherapy departments in worldwide.

Figure 3:8: KVue radiotherapy planning and treatment couch top

The three imaging and radiotherapy surfaces are described in this section. First, the Arco TN 0055 X-ray table (Figure 3:9) is a movable patient support system that is used for medical imaging procedures. The table is made from industrial grade (IG) Rohacell carbon fibre. The table top contains closed-cell rigid foam based on polymethacrylimide (PMI) chemistry with 0.9 mm aluminium equivalence, making the table surface hard and solid. Manufacture's characteristics indicates that the IG Rohacell table top has a density of 32 – 110 kg/m³, compressive strength of between 0.4 – 3.0 megapascal (MPa), a tensile strength of 1 to 3.5 MPa, and a shear strength ranging from 0.4 to 2.4 MPa (Evonik Industries, 2014). These characteristics provides the X-ray table top with a firm solid platform, suitable for medical imaging and similar to radiotherapy planning and treatment surfaces. However, as stated earlier, the hardness of the table could pose a threat to patients' skin, and may cause or induce Medical Device Related (MDR) pressure ulcers. Manufacturer's specification indicates that the table top is 240 cm long, 85.3 cm wide, 2.15 cm thick, and has a maximum patient weight limit of 250 kg. The table also has a vertical travel height ranging from 55.5 cm to 93.5 cm.

Figure 3:9: The Arco TN 0055 X-ray table with no mattress

The medical imaging table top is normally fitted with a thin radiolucent mattress made from combustion polyurethane modified cellular foam as shown in Figure 3:10. The foam provides some level of cushioning for patients undergoing radiography procedures without having any significant impact on dose attenuation or image quality due to their low density and high radiolucency (Guillen-Sola et al., 2013).

Figure 3:10: Arco TN 0055 X-ray table with a thin radiolucent mattress

The mattress used for this research is 213 cm long, 63 cm wide and 2 cm thick. The minimal density of this mattress may not be sufficient enough to withstand patient weight and may collapse under intense pressure exposing patients to high IP from the hard X-ray table (Howatson-Jones, 2001). Polyurethane mattresses are regulated by standards relating to physical properties. This ranges from hardness, density, thickness, ability to withstand fire, and tensile strength. However, in medical imaging, density and thickness are the main physical parameters that are most important. This is because manufacturers of medical imaging mattresses are more concerned with the ability of the mattress to have no or minimal impact on dose attenuation and image quality. To achieve this, the mattresses are very thin, and consequently may have little pressure redistributing properties. Also, polyurethane foams used in mattresses have very low densities compared to those used in seating

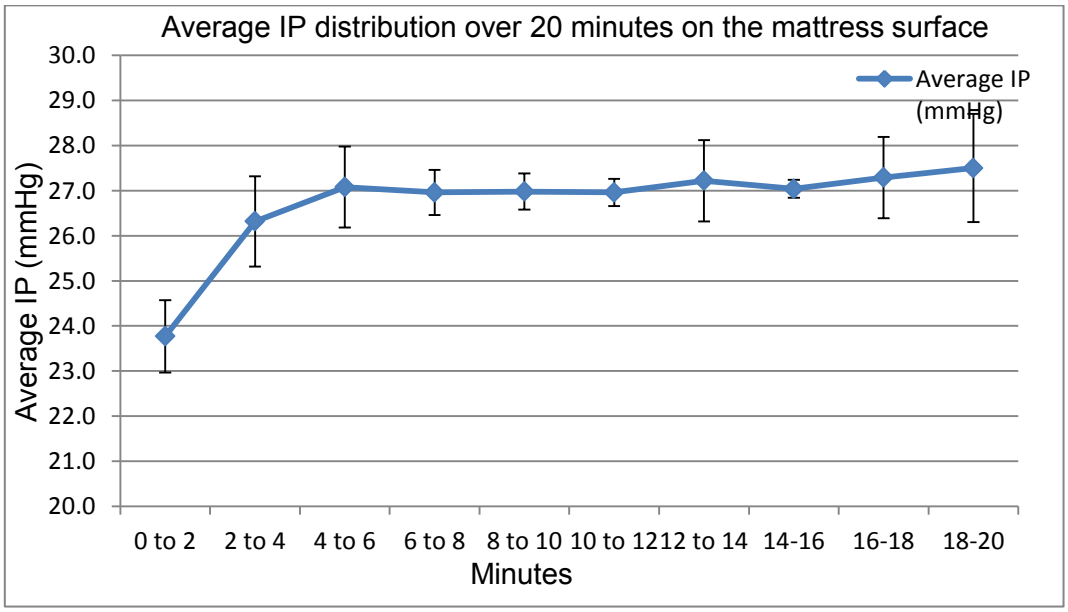
applications such as wheelchairs. This is because the weight of a patient is evenly spread over a larger surface area when lying than when seating.

The CT imaging surface used for this research has a narrow curved surface covered with a thin radiolucent mattress (Figure 2:10), with the following dimensions: 199 cm long, 46 cm wide and 1.5 cm thick. These imaging and radiotherapy surface configurations have been chosen because they are the surfaces commonly used for medical imaging and radiotherapy planning and treatment procedures in hospitals. The thesis reflects clinical reality; hence the results can therefore be extrapolated into clinical settings. Also these are the imaging/radiotherapy tables available within the University of Salford medical imaging facility and were therefore available for the researcher to use.

3.13 Settling time

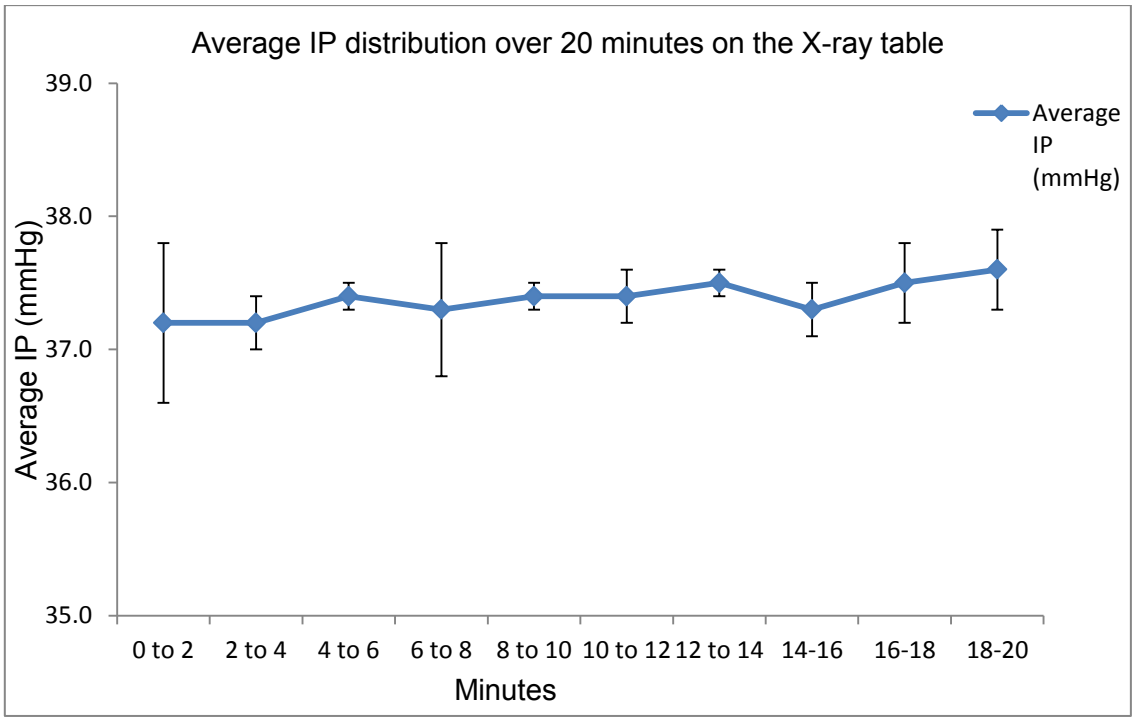
Settling time is defined as the time needed to allow a body to settle onto a contact surface (Stinson et al., 2003a). To establish the settling time necessary for this baseline study, a short experiment was conducted. The aim of this experiment was to assess the time at which the IP between a body and contact surface settles. That is to find the approximate time at which there is a rapid drop in the rate at which IP increases over time. The experiment was conduct on 10 healthy volunteers aged 22-53 years (mean = 36.4±8.6) and BMI of 21-31.5 (Mean = 23.9±3.2), on two medical imaging surface configurations – a mattress surface (the mattress surface used for the baseline study) and the X-ray table with no mattress (hard surface). All the volunteers were asked to wear a shirt and a pair of leggings to standardise clothing and reduce the impact of individual clothing on the settling time. Also, this is to eliminate the occurrence of clothing artefacts on the IP. Volunteers were in a supine position. Pressure mapping data was collected for 20 minutes, at a rate of one frame per minute. The Xsensor software was used to divide the frames into 10 parts. Part one consists of frames zero to two, part two consists of frames two to four, and so on. The average IP of each part was calculated and inputted into SPSS vs 22 for analysis. As shown in Figure 3:11, IP values on the mattress surface showed that pressure generally increased over the 20 minutes period.

Figure 3:11: Line graph showing the mean IP distribution over 20 minutes on the mattress surface.



Results from a repeated measures ANOVA test showed that there was a statistically significant difference in the mean IP over 20 minutes, Wilks' Lambda = 0.00, F (9, 1) =1025.5, p=0.024, partial eta squared = 1.0 indicates a very large effect size. Pairwise comparison using the Bonferroni confidence interval adjustment confirms a highly significant increase over the first six minutes, p≤0.001. The result of this settling time experiment conforms to that conducted by Stinson et al. (2002). However, Figure 3:12 indicates that IP has been stable over the 20 minutes on the X-ray table, hence; inferential statistics showed that there is no statistically significant difference in IP over the 20 minutes, p≥0.05.

Figure 3:12: Line graph showing the mean IP distribution over 20 minutes on the X-ray table



This is because mean IP stabilised much quicker on the X-ray table with no mattress than on the mattress surface. The firm solid surface of the X-ray table plus the absence of the thin radiolucent mattress might have contributed to this. This is because its takes quite some time for patients to settle onto mattress surfaces (Stinson et al., 2002). For the purposes of this study, a settling time of six minutes was therefore used for all three medical imaging/radiotherapy surfaces. This is to standardise the length of time volunteers have to lie on the three different imaging/radiotherapy surfaces.

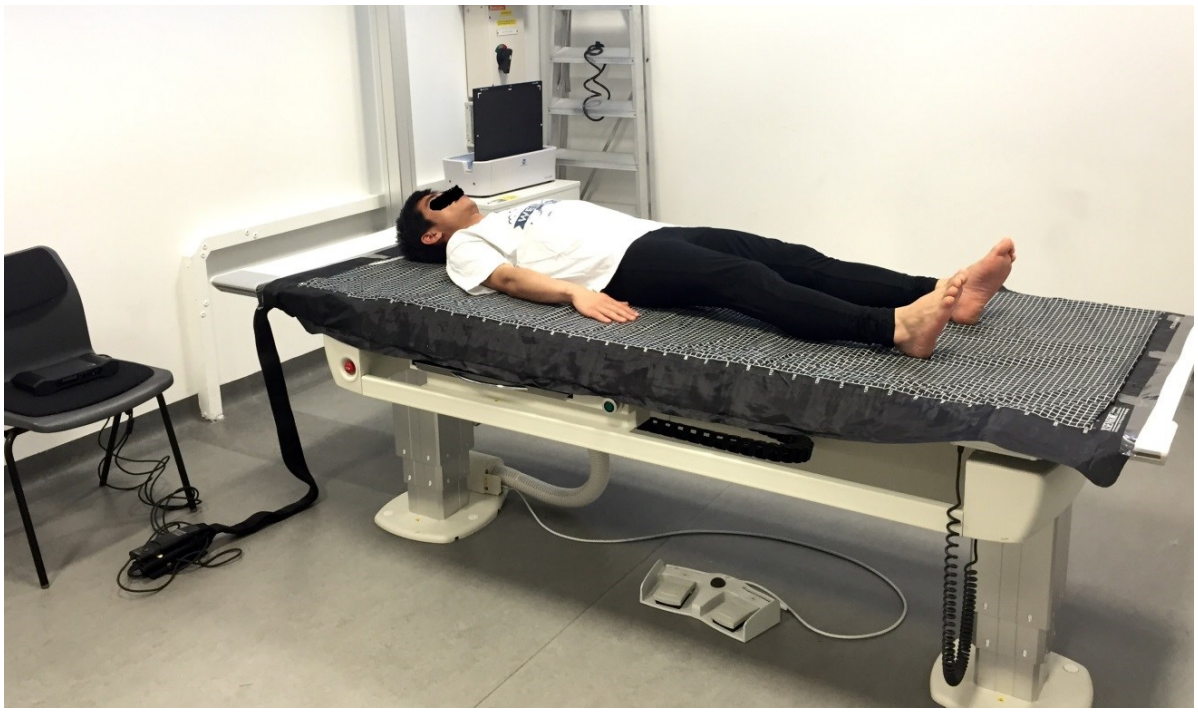
3.14 Procedure for pressure mapping

Data collection was undertaken on the three surfaces over a period of three months. In month one, data was collected on the X-ray table with no mattress, followed by the mattress surface, and in month three, data was collected on the CT surface. The sequence of the surfaces was randomly assigned through a secret ballot performed by the researcher with the permission of his research supervisors. It would have been better to randomly assign the surfaces on the day of data collection; i.e. volunteer comes in and is assigned to a particular surface. However practical problems made this otherwise laudable idea impossible. For example, due to the high demand of the medical imaging facility, at one point in time, only one imaging surface is available for this research. To ensure that one surface does not affect the IP on another surface, there was at least 48 hours resting period between data collection on one imaging/radiotherapy surface to the other. This is to enable the volunteer recover from lying down and return to baseline prior to the second pressure mapping.

Prior to data collection mutually convenient dates and times were arranged between the researcher and each volunteer. On the agreed date, each volunteer was given the opportunity to ask questions and responses/clarifications provided. Also each volunteer was screened to ensure that he/she met the inclusion criteria of the study. Those who satisfy the inclusion criteria of the study were then asked to sign a consent form. The researcher has kept records of this. These records are locked in a secured location and can be accessed only by the researcher and the members of the research supervisory team. After agreeing to participate in the study, each volunteer was directed into a cubicle to change into a new clean set of leggings and a T-shirt. This is to standardise the clothing that all volunteers wear for the study. This is very important in pressure mapping because various studies have shown that different clothing have different impact on IPs, and recommended that studies investigation IPs should have a standardised clothing for all volunteers (Fader et al., 2004, Stinson et al., 2003a).

Each volunteer was asked to take off shoes and socks, their body weight and height measured and Body-Mass Index (BMI) calculated. This is necessary to test hypothesis seven; establish whether there is a correlation between volunteers' BMI and mean IP of the whole body on the three imaging and radiotherapy planning and treatment surfaces. Prior to volunteers coming into the medical imaging lab, the Xsensor mat was placed in the middle of the imaging table. The Xsensor mat taped to one end of the imaging table and then gently stretched to smooth any folds and creases before a tape is applied on the other end. This is also to ensure that the mat is securely fixed and does not move during data acquisition. The mat is then connected via the sensor connecting packs to the Xsensor handheld display system as shown in Figure 3:13. A measurement of 2cm from the head side of the mat was taken and a tape placed there to ensure that all volunteers have their head placed on the same point of the mat. Although volunteers have different body structures and shapes, this will help standardise volunteer's positioning on the imaging/radiotherapy surfaces. This is necessary because IP results on the three surfaces can only be compared when pressure mapping is conducted under the same experimental conditions.

Figure 3:13: Volunteer lying still on the Xsensor mat securely fixed on the X-ray table



Volunteers were asked to gently lie on the mat on the imaging/radiotherapy table in a supine position (Figure 3:13). This was to avoid crumpling the mat as this could cause creasing, and creasing could result in pressure artefacts within the Xsensor data. Supine position was chosen because most radiographic, interventional radiology, and radiotherapy planning and treatment procedures require that patients lie in the supine position, making it the most common patient position in radiography and radiotherapy (Gordon et al., 2012). Volunteers' hands were pronated and the hip adjusted to ensure that they were equidistant from the edge of the mat. This position is fairly common for the supine position in radiographic imaging and in some radiotherapy procedures; hence, these position reflects patients' position in clinical settings.

Volunteers were asked if they were comfortable and whether they had any concerns and/or questions. Volunteers were covered with a lightweight blanket to keep them warm because the imaging room was quite cold. The X-ray and CT room temperatures were set via air conditioning machines at 17 and 10 ˚C respectively. This is to keep the electronics of the imaging equipment in good working condition and at the temperatures recommended by the manufacturers. The conditions of the experiments were therefore under clinical conditions and clinical room temperatures. The volunteers were then asked to remain as still as possible. This is to avoid any movement during data acquisition as movement can cause artefacts in the data, rendering it invalid (Stinson et al., 2003a). However they were reminded that should they experienced any difficulty whilst lying on the imaging/radiotherapy surface, they should inform the researcher as soon as possible. The volunteer was informed and pressure mapping was started.

During data acquisition, the researcher observed directly the volunteer to ensure that there was no movement. During data collection, access to the imaging room was restricted to ensure volunteers' privacy, and also to avoid any distraction. Pressure measurements were taken for 20 minutes (after six minutes settling time) at one frame per second. The Xsensor device was programmed to automatically start acquiring pressure measurement after the six minutes settling time. The IP data was saved onto an in-built memory card. At the end of data collection the volunteer was helped off the imaging/radiotherapy table, and then asked to complete the

questionnaire seeking to access volunteers' perception of pain and comfort whilst lying on the imaging/radiotherapy surface. The volunteers were left alone to complete the questionnaire, and were not coerced to provide specific answers/responses to the questions. After completing the questionnaire, the volunteer returned to the cubicle to change into his/her clothing. The researcher then thanked the volunteer for participating in the research and walked him/her to the door. The volunteer was reminded of the next appointment.

After each volunteer, the researcher checked to ensure that the mat was correctly positioned, crease free, and then get ready for the next volunteer. At the end of each day, the Xsensor was packed into its case as per the manufacturer's instructions, and kept safely at the medical imaging lab. This was to avoid unwanted creases and folds in the pressure mat as creases and folds can destroy the sensors and cause unusual readings in the pressure mat (Sumed-UK, 2014). To ensure high levels of infection control and hygiene, each volunteer was provided with a new clean set of leggings and t-shirt. After each session of data collection, each piece of clothing was washed thoroughly before it was used again. In some instances, a few female volunteers chose to bring their own T-shirt and leggings. This is because they felt uncomfortable wearing a piece of clothing which was not theirs, irrespective of the fact that it was clean. To ensure that this does not have any impact on the results, each individual volunteer's clothing was inspected to ensure that the material was the same as the ones used for the study. Also, to ensure hygiene, the pressure mat was cleaned in between volunteers using wet wipes as recommended by the manufacturer. This is to ensure that enough moisture was applied to the surface to remove any dirt without damaging the sensors electronics (Sumed-UK, 2014).

3.15 Statistical tests

3.15.1 Introduction

The statistical procedure used for the baseline study is summarised in figure 3.14.

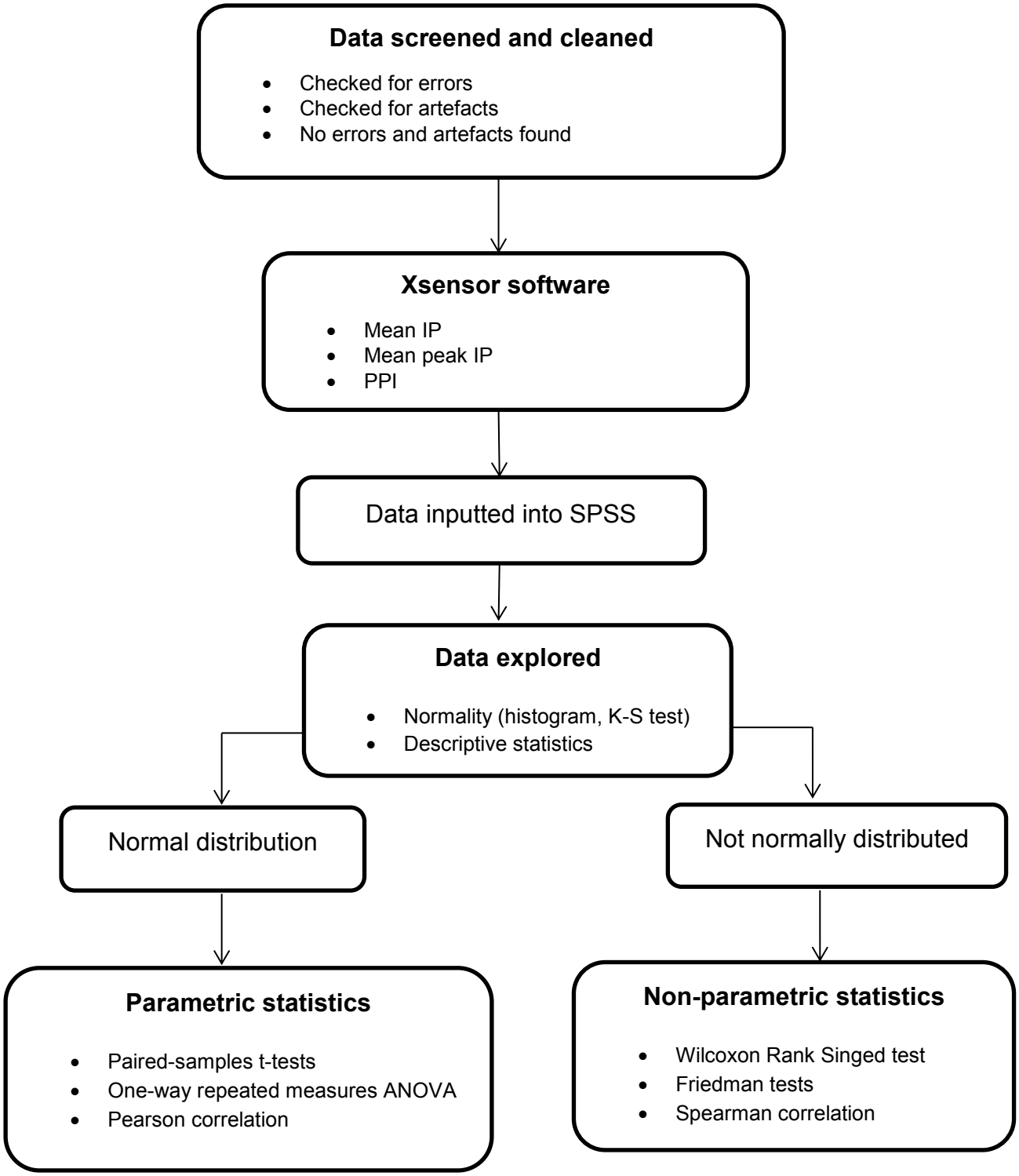


Figure 3:14: The statistical procedure used in the baseline study

The pressure mapping data for all the volunteers will be checked to ensure that they are free from artefacts. This is important because frames affected by artefacts will produce wrong results and may invalid the findings. The Xsensor X3 medical software version six will be used to calculate the PPI, mean and peak IP values of the whole body and the three jeopardy areas (head, sacrum, and heels). This will be achieved by merging all the frames and then the mean and peak interface pressure calculated. The peak pressure index (PPI) defined as the mean of the highest pressure values within a 10-12cm² area (Davis and Sprigle, 2010, Hemmes et al., 2014a) will also be calculated. According to Davis and Sprigle (2010), the number of data cells included in calculating PPI depends on the spatial resolution of the pressure mat. Studies have shown that this area (10-12cm²) is equivalent to a 3x3 cell matrix when using the Xsensor pressure mat. PPI will be calculated because it has been shown to be a reliable parameter of predicting pressure ulcers risks (Davis and Sprigle, 2010, Hemmes et al., 2014a). The values from the Xsensor X3 medical software will be inputted into SPSS version 22 (IBM Corp, Armonk, NY) for analysis.

3.15.2 Normality tests

Normal distribution of the data will be inspected visually using frequency distribution (histogram), stem and leaf plot, boxplot, P-P plot (probability-probability plot), and Q-Q plot (quantile-quantile plot). However, for accurate results, visual inspection for normality will be conducted together with objective analysis (Elhan and Tüccar, 2006, Altman and Bland, 1995). In line with the literature, Kolmogorov-Smirnov (K-S) tests will be performed to provide an objective measure of normality (Field, 2013, Cohen et al., 2011). Kolmogorov-Smirnov (K-S) test is chosen over Shapiro-Wilk, due to the latter's overly high sensitivity to detect differences from normality (Field, 2013). This means that in most instances Shapiro-Wilk tests can be significant even when the data is only slightly deviated from normal distribution. This phenomenon is more prominent in research with small sample sizes which will be the case within this research. Assessing normality is an important statistical procedure because it determines the pathway of statistical tests that should be conducted. In other words, it determines whether parametric or non-parametric statistics should be used.

3.15.3 Descriptive statistics

For the purposes of this thesis, descriptive statistics will be used to describe the sample and results. Descriptive statistics are chosen because they are very useful for summarising data to illustrate patterns. Also, they help to interpret data in a simple format, making it easier for the reader to understand (Pallant, 2010). In this thesis, descriptive statistics will be used in the form of tables, and graphical representation such as graphs, charts and scatterplots. The mean, standard deviation, minimum, and maximum values will be used to describe continuous variables such as age, BMI, mean IP, mean peak IP, and PPI. When dealing with categorical variables such as gender, perception of comfort, and pain, frequencies (percentages) will be used. The downside of using descriptive statistics is that they are not useful to make definitive conclusions. That is, inferences cannot be made from a data using descriptive statistics; hence hypotheses cannot be tested.

3.15.4 Inferential statistics

Inferential statistics will be used to test the hypotheses and make inferences from the results. One way repeated measures analysis of variance (ANOVA) will be used to test the hypotheses that there is a statistically significant difference in the mean IP and mean peak IP for the whole body, and the jeopardy areas on the three different medical imaging and radiotherapy planning and treatment surfaces. Prior to this, the assumption of sphericity will be assessed. Sphericity can be explained as the assumption that the level of dependence between experimental conditions is equal (Field, 2013). Sphericity will be assessed using Mauchly's test. Mauchly's test does this by testing the hypotheses that the variances of the difference between conditions are equal (Field, 2013, Pallant, 2010). When the data violates sphericity, Greenhouse-Geisser corrected test (ε) will be reported (Field, 2013). In addition, multivariate tests will be reported because they do not rely on the assumption of sphericity. Also, multivariate tests will be reported because the sample size for this study is greater than $a + 10$, where a is the number of levels for repeated measures (Stevens, 1992). Partial eta squared effect size will be calculated to quantify the magnitude of the statistically significant difference between the mean IP, mean peak IP for the whole body and the jeopardy areas on the three imaging/radiotherapy surfaces (Nandy, 2012, Sullivan and Feinn, 2012, Fritz et al., 2012). Lastly, post-hoc

pairwise comparisons will be conducted to establish where the statistically significant differences occur using the Bonferroni confidence interval adjustment.

Paired-samples t-tests will be used to compare across the mattress surface and the CT table for differences between PPI for the head and differences between PPI for the heels. As stated earlier, prior to this, the data will be assessed for normality. Cohen's *d* effect sizes will then be calculated to establish the magnitude of the differences between the PPI for the head and heel on the two surfaces. Cohen's *d* will be calculated using the formula below:

$$d = \frac{M1-M2}{SDpooled}, \text{ where } SDpooled = \sqrt{\frac{[(N1-1)SD1^2+(N2-1)SD2^2]}{(N1+N2-2)}},$$ (Field, 2013)

M1 = mean PPI for the jeopardy area in question on the CT table

M2 = mean PPI for the jeopardy area in question on the mattress surface

N1=N2 = sample size = 43

SD1 = standard deviation of mean PPI on CT table

SD2 = standard deviation of mean PPI on mattress surface

Cohen's classification of effect sizes for paired-samples t-tests (0.1 – small, 0.5 – medium, and 0.8 – large) will be used to interpret the effect size results (Cohen, 1988).

Non-parametric Friedman tests will be used to assess and compare volunteers' perceived level of comfort and pain on the three imaging/radiotherapy surfaces. Additionally, using a Bonferroni adjusted alpha value of 0.025 (i.e. 0.05/2) to control for type 1 error, post-hoc Wilcoxon Signed Rank Test will be conducted. Type 1 error occurs when researchers think there is an effect in the population, when in actual fact there is no effect (Harvey, 2014, Singh, 2006). In other words, the null hypothesis is rejected when in fact it is true. Lastly, effect sizes will be calculated by converting the Wilcoxon Signed Rank Test standardised test statistics *z* into an effect size *r*. This is achieved by the formula;

$$r = z/\sqrt{N}$$, (Rosenthal, 1994), *where N = number of observations*

Finally, a parametric Pearson product-moment correlation coefficient (*r*) will be used to establish the relationship between mean IP for whole body and BMI on the three imaging/radiotherapy surfaces. Prior to this, preliminary analyses will be performed to ensure no violation of the assumptions of normality, linearity, and homoscedasticity. Scatterplots will be drawn to indicate the direction of the relationship between the mean IP and BMI on the three imaging/radiotherapy surfaces. Cohen's (1988) interpretation of *r* will be used to interpret the strength of the correlation. r=0.1-0.29 (small), r=0.30-0.49 (medium), and r=0.50-1.0 (large). Also, coefficient of determination (R^2) will be calculated by multiplying *r* by itself and express it as a percentage.

4 Chapter Four – Results of baseline study

4.1 Chapter overview

This chapter contains the results of the baseline study. The results of each hypothesis stated in chapter three section 3.4 will be presented. The results will be presented in descriptive format using means and standard deviations (SD), tables, graphs and scatterplots. In addition, the results of the inferential statistics will be presented. This is necessary to indicate significant levels to show statistical differences or otherwise between the variables.

4.2 Descriptive statistics

Due to some volunteers not participating for all three imaging/radiotherapy surfaces, data was collected from 49 volunteers on the X-ray table with no mattress and 43 volunteers on all three imaging/radiotherapy surfaces. 1199 frames (instead of 1200) were used in the analysis. This was because the last frame of interface pressure (IP) data of some of the volunteers went missing due to an unexpected equipment error. When checked all the frames were free from artefacts. The sample comprised 26 females (53.1%) and 23 males (46.9%), with an age range of 18 to 59 years (mean=34.6, SD=10.5) and body mass Index (BMI) range of 19.2 to 36.7 (mean= 24.7, SD=4.0).

4.3 Results of normality tests

As stated in chapter three section 3.15.2, the data was tested for normality. This was achieved by visual observation using histograms and objective analysis using Kolmogorov-Smirnov (K-S) tests. Results from K-S tests indicated normal distribution of the data because most of the variables have non-significant p-values ($p>0.05$). In the few instances where the K-S tests indicated deviation from normality ($p\leq0.05$), visual inspection of the data using histograms, stem-and-leaf plot, boxplot, probability-probability plot (P-P plot), and quantile-quantile plot (Q-Q plot), showed normal distribution. Most studies recommend that to accurately assess the normality of data, objective analysis should be conducted in conjunction with visual inspection (Field, 2013, Ghasemi and Zahediasl, 2012, Razali and Wah, 2011). Consequently, parametric statistics were used for the data analysis.

4.4 Hypothesis one

There will be statistically significant differences in the mean interface pressure of the whole body between the three imaging and radiotherapy planning and treatment surfaces.

The mean interface pressure (IP) and standard deviations (SD) in mmHg for the whole body on the three imaging/radiotherapy surfaces are presented in Table 4.1.

Table 4.1: Mean IP and SD for the whole body across the three surfaces

Medical imaging/radiotherapy surface	Mean IP (whole body), mmHg	SD, mmHg	P value
Mattress surface	25.95	1.52	*≤0.001*
X-ray table without mattress (hard surface)	37.12	4.48	*≤0.001*
CT table	23.50	1.43	*≤0.001*

A parametric one-way repeated measures ANOVA, was conducted to compare the mean interface pressures (IP) for the whole body of the volunteers on the X-ray table without mattress, the X-ray table with a mattress, and the CT table. Mauchly's tests indicated that the assumption of sphericity had been violated, $X^2(2) = 61.89$, $p \leq 0.001$, therefore multivariate tests were reported ($\varepsilon = 0.56$). The results of the multivariate tests showed that there was a statistically significant difference in the mean interface pressure for whole body on the three medical imaging/radiotherapy surfaces, Wilks' Lambda = 0.06, $F(2, 41) = 322$, $p \leq 0.001$, with a large partial eta squared effect size of 0.94. Pairwise comparison using the Bonferroni confidence interval adjustment indicated that there were statistically significant differences between the mean IP of the whole body across the three different surfaces, all three comparisons having $p \leq 0.001$.

4.5 Hypothesis two

There will be statistically significant differences in the mean interface pressure of the head, sacrum, and heels on the three imaging and radiotherapy planning and treatment surfaces.

4.5.1 Head

The mean IP and SD in mmHg for the head on the three imaging/radiotherapy surfaces are shown in Table 4.2.

Table 4.2: Mean IP and SD for the head across the three surfaces

Medical imaging/radiotherapy surface	Mean IP, mmHg	SD, mmHg	P value
Mattress surface	37.95	4.03	*≤0.001*
X-ray table without mattress (hard surface)	75.85	6.89	*≤0.001*
CT table	38.68	4.82	*≤0.001*

Mauchly's tests indicated the assumption of sphericity had been violated, $X^2(2) = 141.13$, $p \leq 0.001$, therefore multivariate tests were reported ($\varepsilon = 0.51$). The results of the multivariate tests showed that there was a statistically significant difference in the mean interface pressure for the head on the three medical imaging surfaces, Wilks' Lambda = 0.39, $F(2, 41) = 31.66$, $p \leq 0.001$, with a large partial eta squared effect size of 0.67. Pairwise comparison using the Bonferroni confidence interval adjustment indicated that there were statistically significant differences between the means of the mean IP of the head on the X-ray table without the mattress and the other two surfaces, both comparisons having $p \leq 0.001$. However, there was no statistically significant difference in the mean IP of the head on the X-ray table with mattress and the CT table, $p=0.451$.

4.5.2 Sacrum

Table 4.3 shows the mean IP and SD in mmHg for the sacrum on the three imaging/radiotherapy surfaces.

Table 4.3: Mean IP and SD for the sacrum across the three surfaces

Medical imaging/radiotherapy surface	Mean IP, mmHg	SD, mmHg	P value
Mattress surface	28.19	2.76	*≤0.001*
X-ray table without mattress (hard surface)	44.45	7.30	*≤0.001*
CT table	26.19	2.18	*≤0.001*

Mauchly's tests indicated that the assumption of sphericity were violated, $X^2(2) = 70.24$, $p \leq 0.001$, therefore multivariate tests were reported ($\varepsilon = 0.55$). The results of the one-way repeated measures ANOVA showed that there was a statistically significant difference in the mean interface pressure for sacrum on the three medical imaging surfaces, Wilks' Lambda = 0.16, $F(2, 41) = 106.40$, $p \leq 0.001$, with a large partial eta squared effect size of 0.84. Pairwise comparison using the Bonferroni confidence interval adjustment indicated that there were statistically significant differences between the mean IP of the sacrum on the three imaging tables ($p \leq 0.001$).

4.5.3 Left heel

The mean IP and SD in mmHg for left heel on the three imaging/radiotherapy surfaces are described in Table 4.4.

Table 4.4: Mean IP and SD for the left heel across the three surfaces

Medical imaging/radiotherapy surface	Mean IP, mmHg	SD, mmHg	P value
Mattress surface	31.56	4.37	*≤0.001*
X-ray table without mattress (hard surface)	43.05	5.10	*≤0.001*
CT table	39.03	3.01	*≤0.001*

Mauchly's tests indicated that the assumption of sphericity had been violated, $X^2(2) = 52.33$, $p \leq 0.001$, therefore multivariate tests were reported ($\varepsilon = 0.58$). The results of the one-way repeated measures ANOVA indicated a statistically significant difference between the mean IP for the left heel on the three imaging surfaces, with a Wilks' Lambda value of 0.42, $F(2,41)=28.51$, $p \leq 0.001$, and a large partial eta squared effect size of 0.58. Pairwise comparison using the Bonferroni confidence interval adjustment indicated statistically significant differences between the mean IP for the left heel on two comparisons ((mattress surface versus hard surface ($p=0.002$), and mattress surface versus CT table ($p \leq 0.001$)). However, there was no statistically significant difference between the mean IP for left heel on the hard surface and the CT table ($p=0.596$).

4.5.4 Right heel

The mean IP and SD in mmHg for right heel on the three imaging/radiotherapy surfaces are described in Table 4.5.

Table 4.5: Mean IP and SD for the right heel across the three surfaces

Medical imaging/radiotherapy surface	Mean IP, mmHg	SD, mmHg	P value
Mattress surface	32.87	4.86	*0.014*
X-ray table without mattress (hard surface)	44.25	6.91	*0.014*
CT table	40.05	4.31	*0.014*

Mauchly's tests indicated that the assumption of sphericity had been violated, $X^2(2) = 30.61$, $p \leq 0.000$, therefore multivariate tests were reported ($\varepsilon = 0.66$). The results of the one-way repeated measures ANOVA indicated a Wilks' Lambda value of 0.81, $F(2,41)=4.76$, and $p=0.014$; indicating a statistically significant difference between the mean IP of the right heel across the three imaging tables. Partial eta squared effect size was large (0.19).

Pairwise comparison using the Bonferroni confidence interval adjustment indicated statistically significant differences between the mean IP of the right heel across the three imaging/radiotherapy surfaces; [(mattress surface versus hard surface (p≤0.001)), mattress surface versus CT table (p≤0.001) and hard surface versus CT table (p=0.013)].

The mean IP of the head, sacrum, and heels in mmHg and standard deviations on the three imaging/radiotherapy surfaces are presented graphically in Figure 4:1.

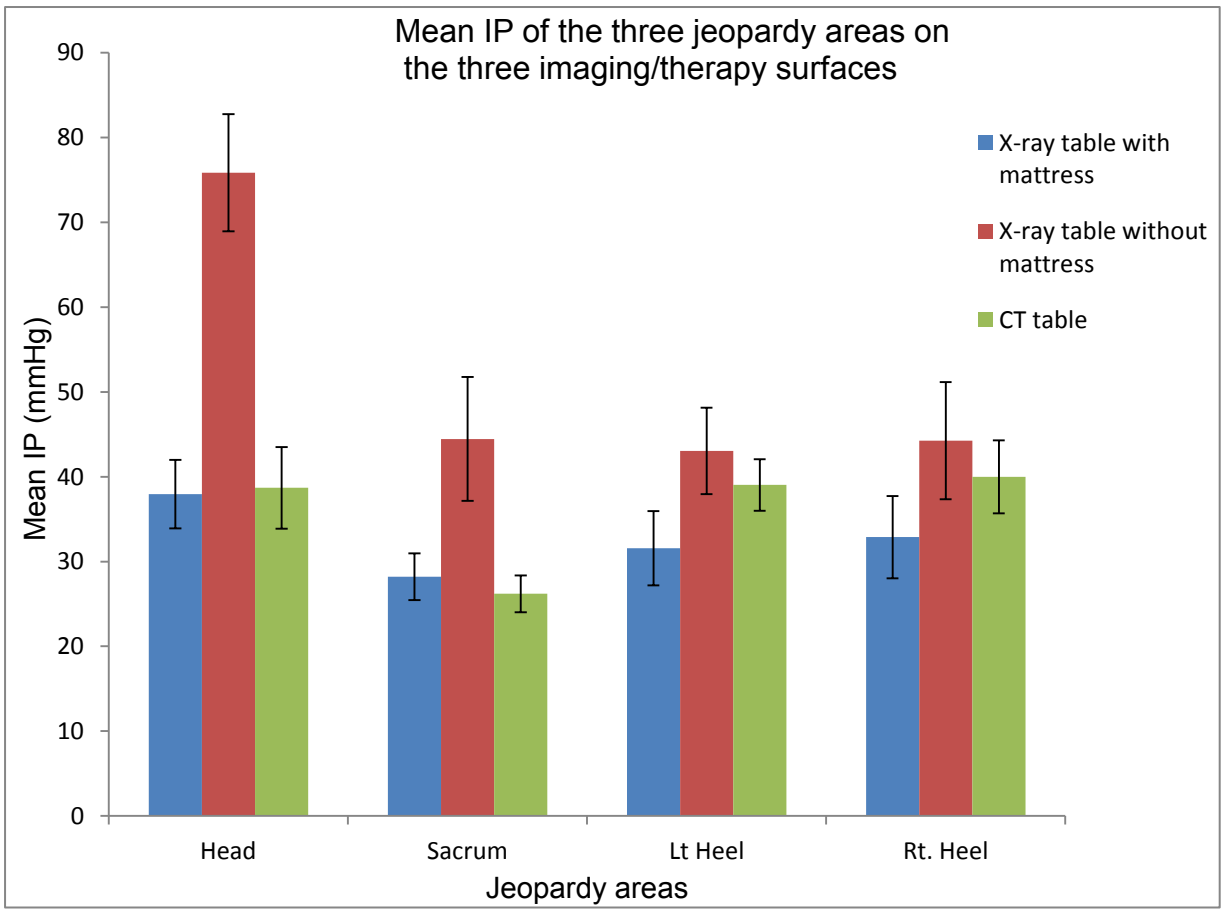


Figure 4:1: A bar graph comparing the mean IP with SD of the jeopardy areas across the three surfaces.

4.6 Hypothesis three

There will be statistically significant differences in the mean peak interface pressure of the head, sacrum, and heels on the three imaging and radiotherapy planning and treatment surfaces.

4.6.1 Head

The mean peak IP and SD in mmHg for the head on the three imaging/radiotherapy surfaces are described in Table 4.6.

Table 4.6: Mean peak IP and SD for the head across the three surfaces

Medical imaging/radiotherapy surface	Mean peak IP, mmHg	SD, mmHg	P value
Mattress surface	93.27	10.56	*≤0.001*
X-ray table without mattress (hard surface)	169.78	23.93	*≤0.001*
CT table	110.77	9.14	*≤0.001*

Mauchly's tests indicated that the assumption of sphericity had been violated, $X^2(2) = 53.32$, $p \leq 0.001$, therefore multivariate tests were reported ($\varepsilon = 0.58$). The results of the one-way repeated measures ANOVA indicated a Wilks' Lambda value of 0.45, $F(2,41)=24.90$, and $p \leq 0.001$, indicating a statistically significant difference between the mean peak IP of the head on the three imaging/radiotherapy surfaces, with a large partial eta squared effect size of 0.55. Pairwise comparison using the Bonferroni confidence interval adjustment indicated that there were statistically significant differences between the mean peak IP of the head on all the three surfaces, each comparison had $p \leq 0.001$.

4.6.2 Sacrum

The mean peak IP and SD in mmHg for the sacrum on the three medical surfaces are indicated in Table 4.7.

Table 4.7: Peak IP and SD for the sacrum across the three surfaces

Medical imaging/radiotherapy surface	Mean peak IP, mmHg	SD, mmHg	P value
Mattress surface	75.80	16.81	*≤0.001*
X-ray table without mattress (hard surface)	180.40	10.92	*≤0.001*
CT table	65.51	9.40	*≤0.001*

Mauchly's tests indicated that the assumption of sphericity had been violated, $X^2(2) = 14.99$, $p \leq 0.001$, therefore multivariate tests were reported ($\varepsilon = 0.77$). The results of the one-way repeated measures ANOVA indicated a statistically significant difference between the means of the mean peak IP of the sacrum on the three imaging/radiotherapy surfaces, Wilks' Lambda value of 0.20, $F(2,41)=82.10$, and $p \leq 0.001$, with a large partial eta squared affect size of 0.80. Pairwise comparison using the Bonferroni confidence interval adjustment indicated that there was a statistically significant difference between the mean peak IP of the sacrum on the X-ray table with mattress and the X-ray table without mattress, and also on the X-ray table without mattress and the CT table, both comparisons had $p \leq 0.001$. However, there was no statistically significant difference between the mean peal IP on the X-ray table with mattress and the CT table ($p=0.174$).

4.6.3 Left heel

The mean peak IP and SD in mmHg for the left heel on the three imaging and radiotherapy surfaces are shown in Table 4.8.

Table 4.8: Mean peak IP and SD for the left heel across the three surfaces

Medical imaging/radiotherapy surface	Mean peak IP, mmHg	SD, mmHg	P value
Mattress surface	70.26	17.13	*≤0.001*
X-ray table without mattress (hard surface)	96.14	19.30	*≤0.001*
CT table	81.40	19.41	*≤0.001*

Mauchly's tests indicated that the assumption of sphericity had been violated, $X^2(2) = 65.79$, $p \leq 0.001$, therefore multivariate tests are reported ($\varepsilon = 0.56$). The results of the one-way repeated measures ANOVA indicated a statistically significant difference between the means of the peak IP of the left heel on the three imaging tables: Wilks' Lambda value of 0.36, $F(2, 41)=36.90$, $p \leq 0.001$, and a large partial eta squared effect size of 0.64. There was a statistically significant difference between the mean peak IP of the left heel on the X-ray table with mattress and the hard surface ($p \leq 0.001$). Nevertheless there was no statistically significant difference between the mean peak IP on the X-ray table with mattress and the CT table ($p=0.909$), and the X-ray table without mattress and the CT table ($p=0.585$). Pairwise comparisons were calculated using the Bonferroni confidence interval adjustment.

4.6.4 Right heel

Table 4.9 shows the mean peak IP and SD in mmHg for the right heel on the three imaging/radiotherapy surfaces.

Table 4.9: Mean peak IP and SD for the right heel across the three surfaces

Medical imaging/radiotherapy surface	Mean peak IP, mmHg	SD, mmHg	P value
Mattress surface	75.38	16.22	*≤0.001*
X-ray table without mattress (hard surface)	104.84	24.72	*≤0.001*
CT table	84.27	12.31	*≤0.001*

Mauchly's tests indicated that the assumption of sphericity had been violated, $X^2(2) = 58.74$, $p \leq 0.000$, therefore multivariate tests were reported ($\varepsilon = 0.57$). The results of the one-way repeated measures ANOVA showed a Wilks' Lambda value of 0.37, $F(2,41)=35.41$, and $p \leq 0.001$, indicating a statistically significant difference between the means of the peak IP of the right heels on the three imaging/radiotherapy surfaces. The results indicated a large partial eta squared effect size of 0.63. Pairwise comparison using the Bonferroni confidence interval adjustment indicated statistically significant difference between the mean peak IP of the right heel on the X-ray table with mattress and hard surface ($p \leq 0.001$). However, there were no statistically significant differences between the mean peak IP on the X-ray table with

mattress and the CT table, and the X-ray table without mattress and the CT table, both comparisons had p=1.000 and p=0.258 respectively.

The mean peak IP of the head, sacrum, and heels in mmHg and SD on the three imaging/radiotherapy surfaces are presented in Figure 4:2.

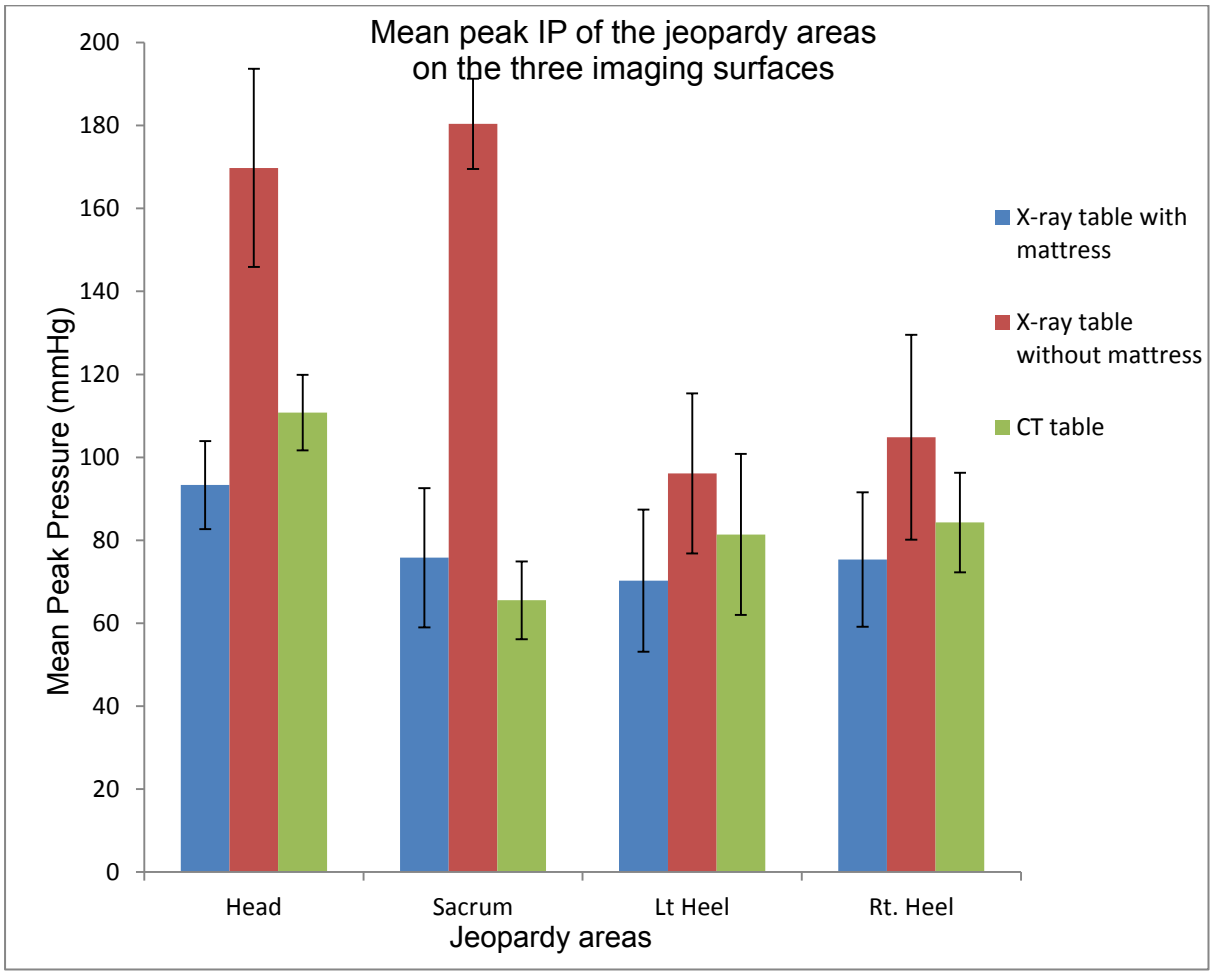


Figure 4:2: A bar graph comparing the mean peak IP with SD of the jeopardy areas across the three surfaces

4.7 Hypothesis four

There will be significant differences in the means of the Peak Pressure Index (PPI) of the head, sacrum and heels on the three imaging and radiotherapy planning and treatment surfaces.

PPI for the head and the heels could not be calculated for the X-ray table without mattress (radiotherapy surface) because these anatomical areas covered an area less than the 3x3 data matrix area needed to calculate PPI (Figure 4:3). This was due to the prominent bony prominences at the anatomical areas and the absence of a mattress.

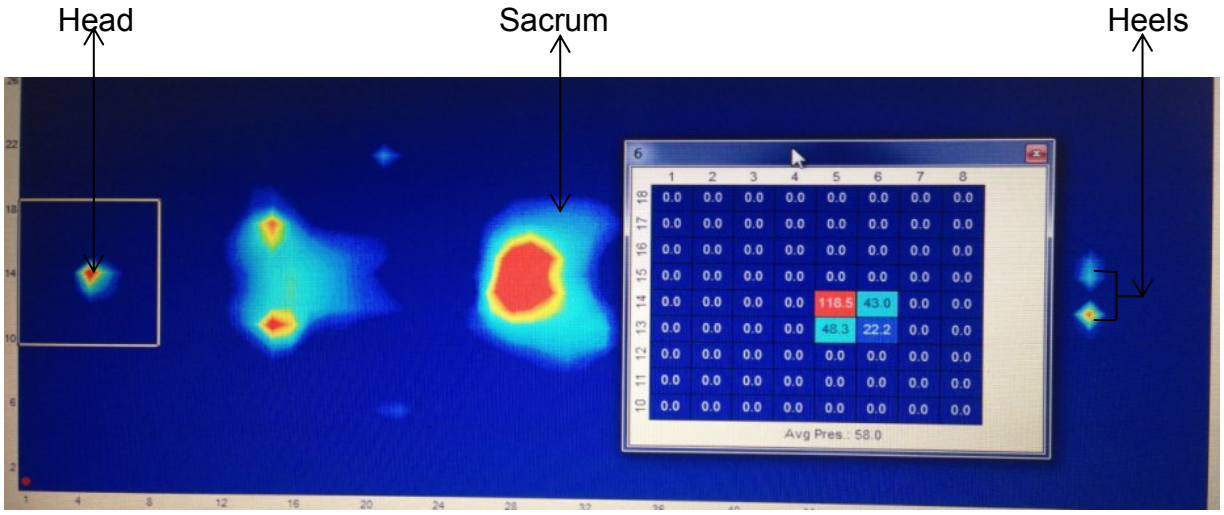


Figure 4:3: A 2D pressure image of the whole body on the hard surface showing only 2x2 cell area was covered by the head

As a result, PPI was calculated for the head and heels on the CT table and the X-ray table with mattress, and the means compared using a paired-samples t-test. However, PPI was calculated for the sacrum on the three imaging and radiotherapy surfaces and the results compared using one-way repeated measures ANOVA. The PPI was calculated using 3x3 data matrix, with the highest individual peak IP in the middle (Figure 4:4).

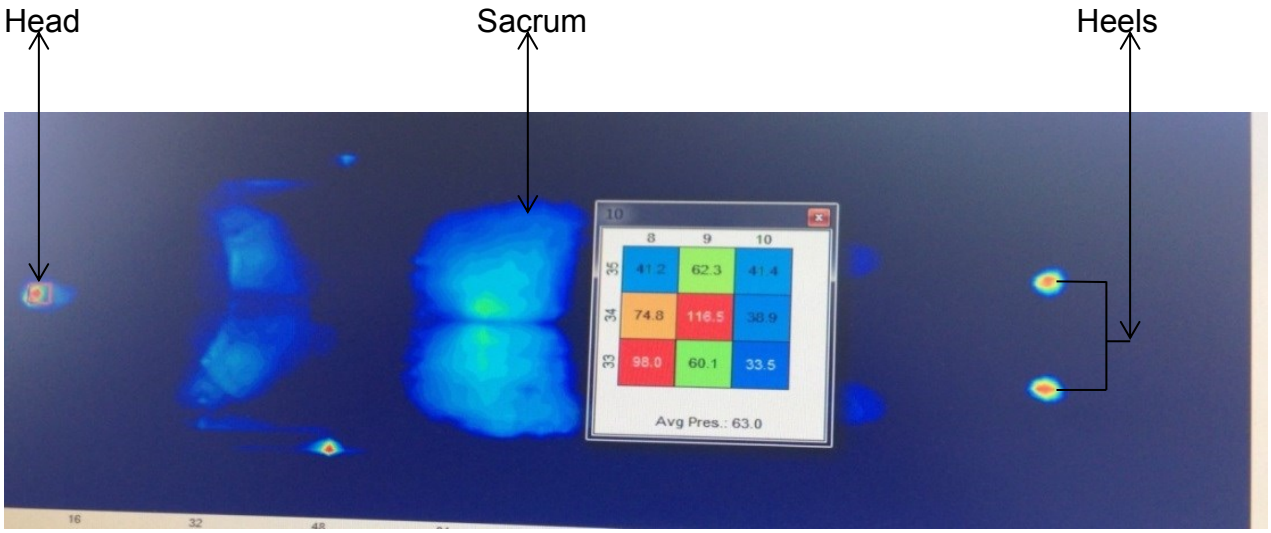


Figure 4:4: A 2D pressure image of the whole body on the mattress surface, showing how the PPI for head was calculated (3x3 cells, with highest peak IP value in the middle)

4.7.1 Head

A paired-samples t-test was conducted to compare the means of the PPI for the head on the CT table and the X-ray table with mattress. There was a statistically significant difference in the PPI for the head on the CT table (Mean=65.30, SD=6.62), and the X-ray table with mattress (Mean=62.50, SD=4.21), t (42) =2.2, p=0.033. The mean PPI difference was 2.80 with a 95% confidence interval ranging from 0.24 to 5.34, and a medium effect size, Cohen's d = 0.5.

4.7.2 Sacrum

The mean PPI and SD in mmHg for the sacrum on the three imaging/radiotherapy surfaces are stated in Table 4.10.

Table 4.10: Mean PPI and SD for the sacrum across the three surfaces

Medical imaging/radiotherapy surface	Mean PPI, mmHg	SD	P value
Mattress surface	52.34	9.21	*≤0.001*
X-ray table without mattress (hard surface)	121.85	26.9	*≤0.001*
CT table	58.86	10.8	*≤0.001*

Mauchly's tests indicated that the assumption of sphericity had been violated, $X^2(2) = 33.37$, $p \leq 0.001$, therefore multivariate tests were reported ($\varepsilon = 0.64$). The results of the one-way repeated measures ANOVA indicated a Wilks' Lambda value of 0.19, $F(2,41)=89.91$, and $p \leq 0.001$. These results indicated a statistically significant difference between the mean PPI for sacrum on the three imaging/radiotherapy surfaces and a large partial eta squared effect size of 0.81. Pairwise comparison using the Bonferroni confidence interval adjustment indicated that there were statistically significant differences between the mean PPI for the sacrum across the three surfaces [(mattress surface versus hard surface ($p \leq 0.001$), mattress surface versus CT table ($p=0.020$) and hard surface versus CT table ($p \leq 0.001$)].

4.7.3 Left heel

A paired-samples t-test was conducted to compare the means for the PPI of the left heel on the CT table and the X-ray table with mattress. There was a statistically significant difference in the PPI for the left heel on the CT table (Mean=47.8, SD=5.92), and the PPI for the left heel on the X-ray table with mattress (Mean=41.3, SD=4.45), $t(42) = 5.8$, $p \leq 0.001$. The mean PPI difference was 6.5 with a 95% confidence interval ranging from 4.2 to 8.7, and a very large effect size, Cohen's $d = 1.24$.

4.7.4 Right heel

The results of a paired-samples t-test conducted to compare the means of the PPI for the right heel on the CT table and the X-ray table with mattress indicated a statistically significant difference in the PPI for the right heel on the CT table (Mean=57.8, SD=5.41), and on the X-ray table with mattress (Mean=43.0, SD=9.0), t (42) =2.3, p=0.025. The mean PPI difference was 14.8 with a 95% confidence interval ranging from 2.0 to 27.7, and a very large effect size, Cohen's d = 1.99.

The PPI of the head, sacrum, and heels in mmHg and standard deviations on the mattress surface and the CT table are presented in Figure 4:5.

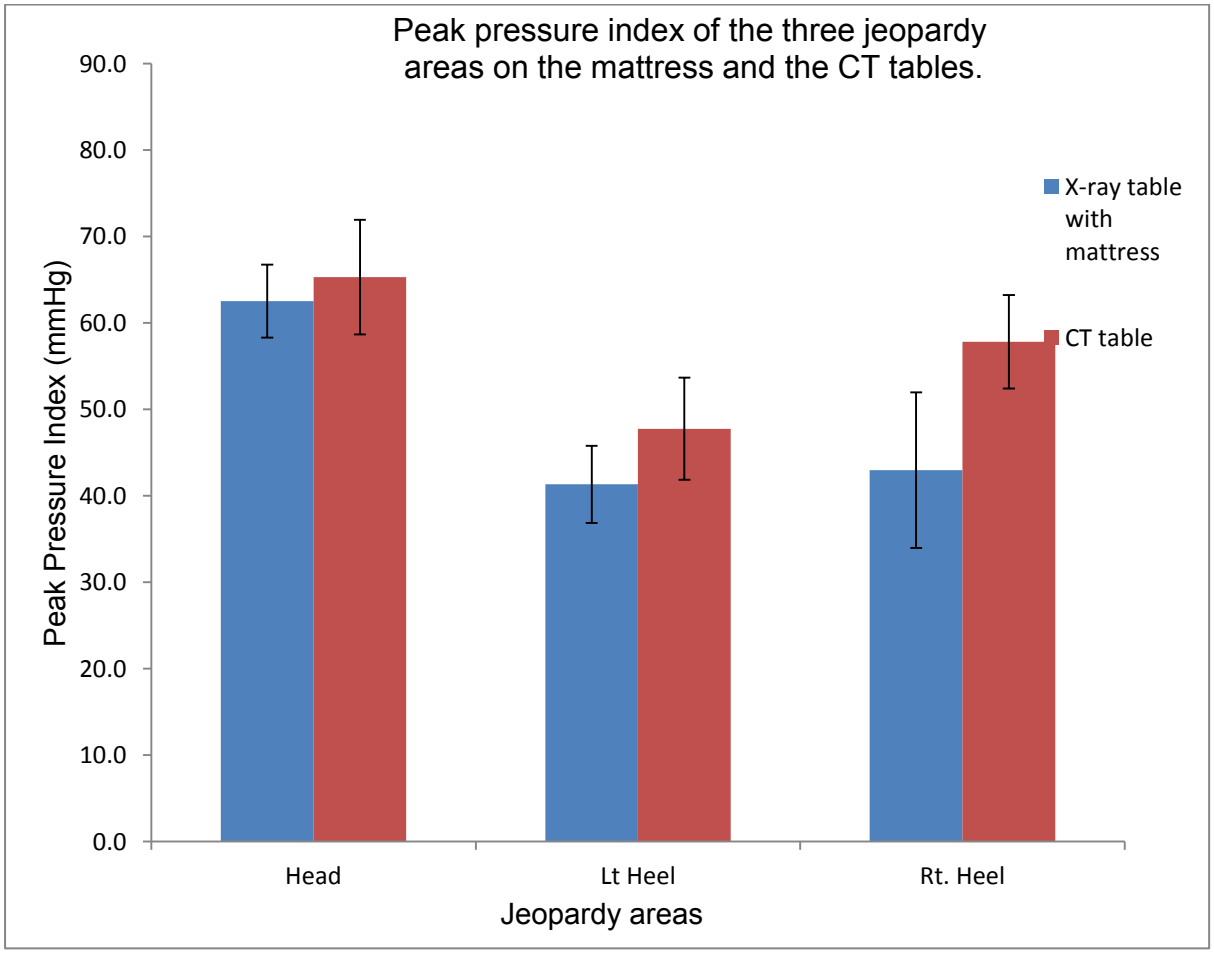


Figure 4:5: Bar chart comparing the peak pressure index and SD for the jeopardy areas on the CT table and mattress surface.

4.8 Hypothesis five

There will be statistically significant differences in volunteers' perception of comfort on the three imaging and radiotherapy planning and treatment surfaces.

Figure 4:6 shows volunteers' perception of comfort on the three imaging and radiotherapy surfaces.

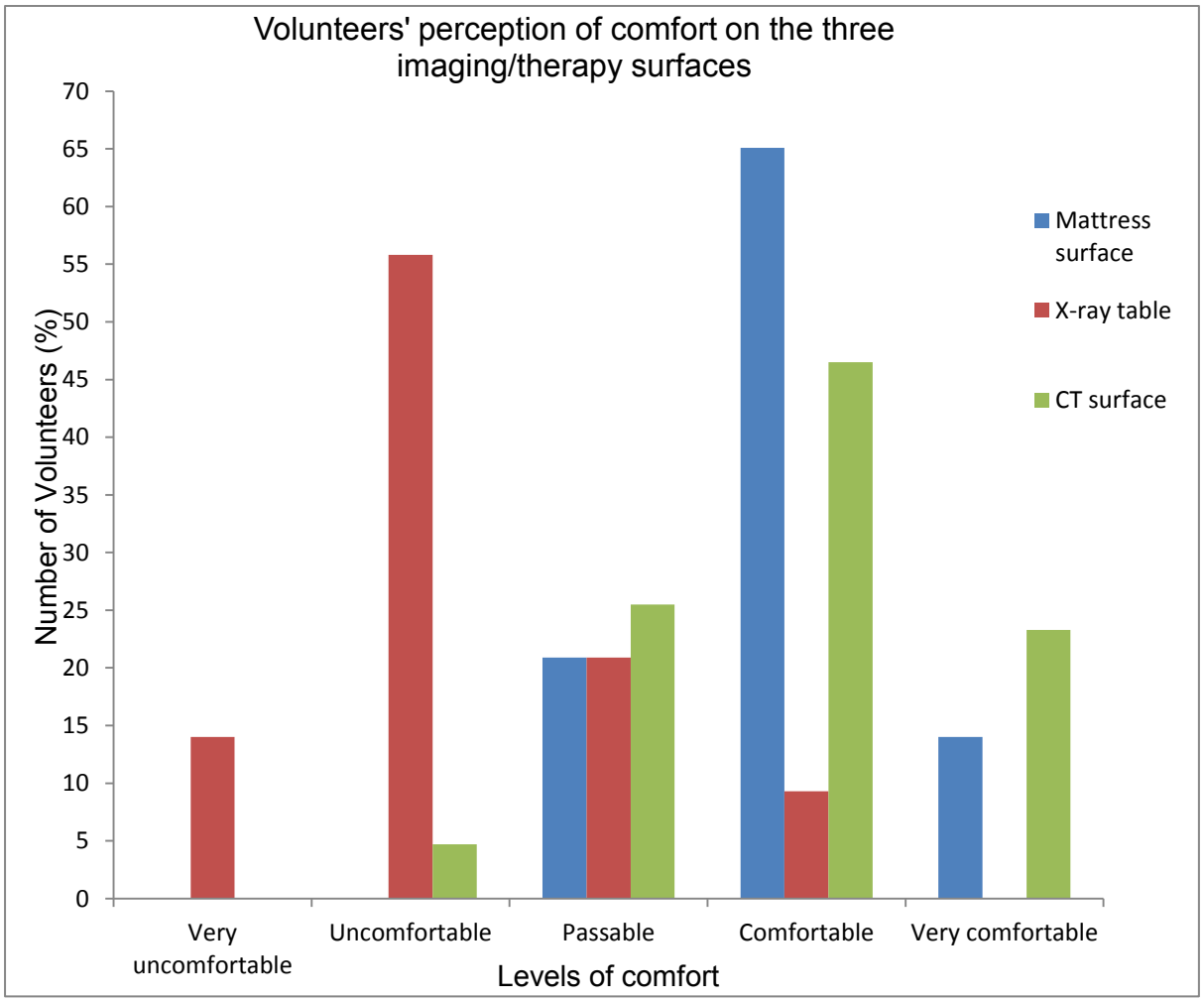


Figure 4:6: Bar graph indicating volunteers' perception of comfort on the three surfaces.

Inspection of the bar graph showed volunteers experienced the least level of comfort on the X-ray table without mattress (radiotherapy surface), compared with the mattress surface and the CT table. Similarly, the results of non-parametric Friedman test which indicated a statistically significant difference in volunteers' perception of comfort on the three imaging/radiotherapy surfaces, χ^2 (2, n = 43) = 58.4, p≤0.001). Using a Bonferroni adjusted alpha value of 0.025 (i.e. 0.05/2) to control for type 1

error, the results of post-hoc Wilcoxon Signed Rank Test revealed a statistically significant difference in volunteers' perception of comfort on the mattress table compared to volunteers' perception of comfort on the X-ray table, $z = 5.7$, $p \leq 0.001$, with a medium effect size ($r = 0.6$). Additionally there was a statistically significant difference in volunteers' perception of comfort on the CT table and the X-ray table without mattress, $z = 5.3$, $p \leq 0.001$, with a medium effect size ($r = 0.6$).

4.9 Hypothesis six

There will be statistically significant differences in the volunteers' perception of pain on the three imaging and radiotherapy planning and treatment surfaces.

The frequency of volunteers who experienced pain and those who did not experience pain on the three imaging/radiotherapy surfaces are presented in Figure 4:7.

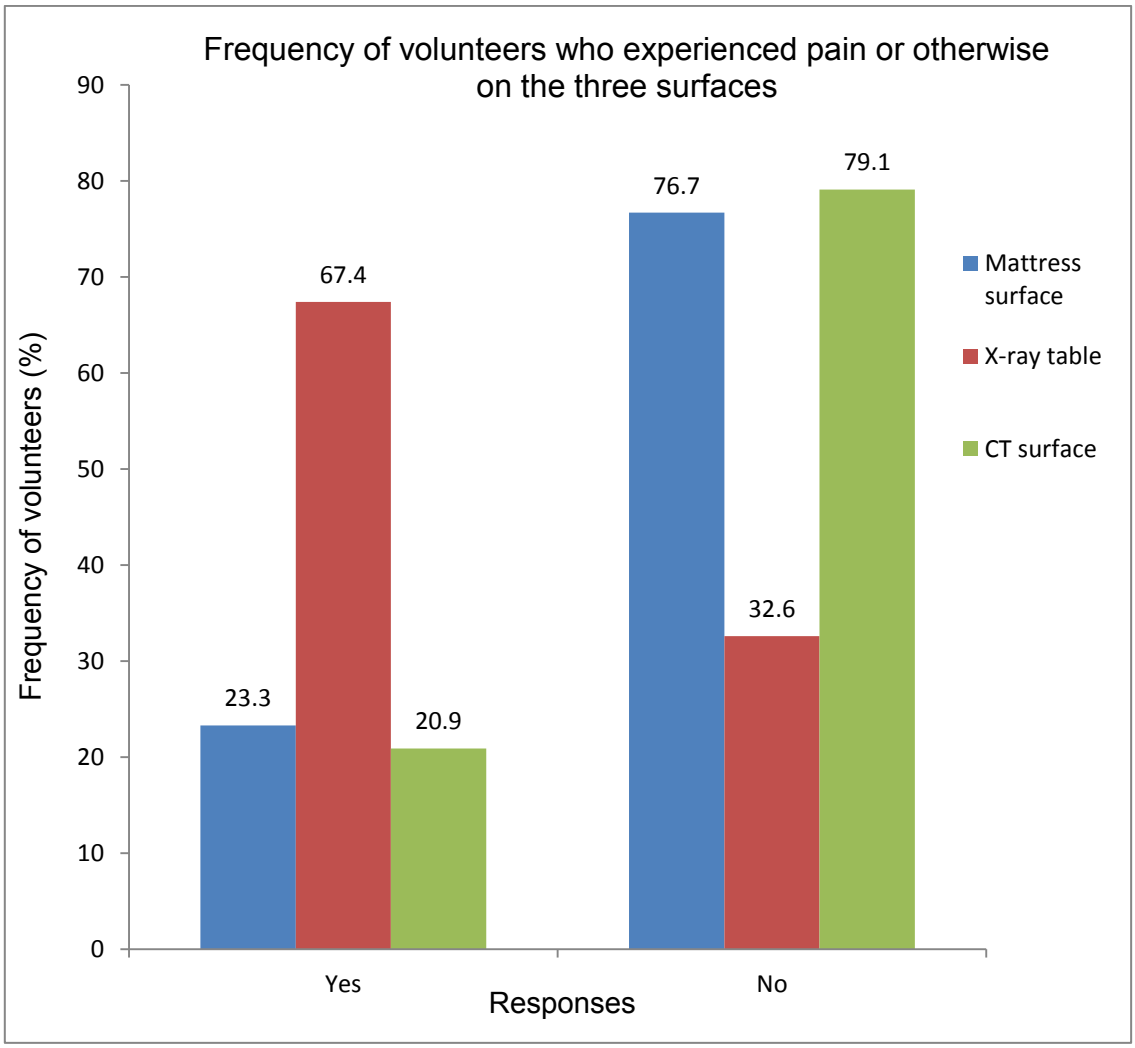


Figure 4:7: Bar chart showing the frequency of volunteers who experienced pain on the three surfaces.

The results of non-parametric Friedman test indicated a statistically significant difference in the level of pain experienced by the volunteers on the three imaging tables, $\chi^2(2, n=43) = 23.1$, $p \leq 0.001$). Post-hoc Wilcoxon Signed Rank Test showed a statistically significant difference in the volunteers'' perception of pain on the X-ray table and the mattress table, $z = 3.96$, $p \leq 0.001$, with a small effect size ($r = 0.4$). Similarly, there was a statistically significant difference in volunteers' perception of pain on the X-ray table without mattress and the CT table, $z = 3.78$, $p \leq 0.001$, with a small effect size ($r = 0.4$).

4.10 Hypothesis seven

There will be a positive correlation between volunteers' BMI and mean interface pressure (IP) for the whole body on the three imaging and radiotherapy planning and treatment surfaces.

4.10.1 Correlation between mean IP on the mattress surface and BMI

The relationship between BMI and mean IP for the whole body on the X-ray table with mattress was investigated using a Pearson product-moment correlation coefficient (r). Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity, and homoscedasticity. There was a very small positive correlation between the two variables, r = 0.1, n = 43, p=0.55, and 0.01 coefficient of determination (R^2). The small correlation resulted in a 1% shared variance between BMI and mean IP on the X-ray table with mattress. The small positive correlation between mean IP for whole body in mmHg on the mattress surface and BMI is shown in the scatterplot in Figure 4:8.

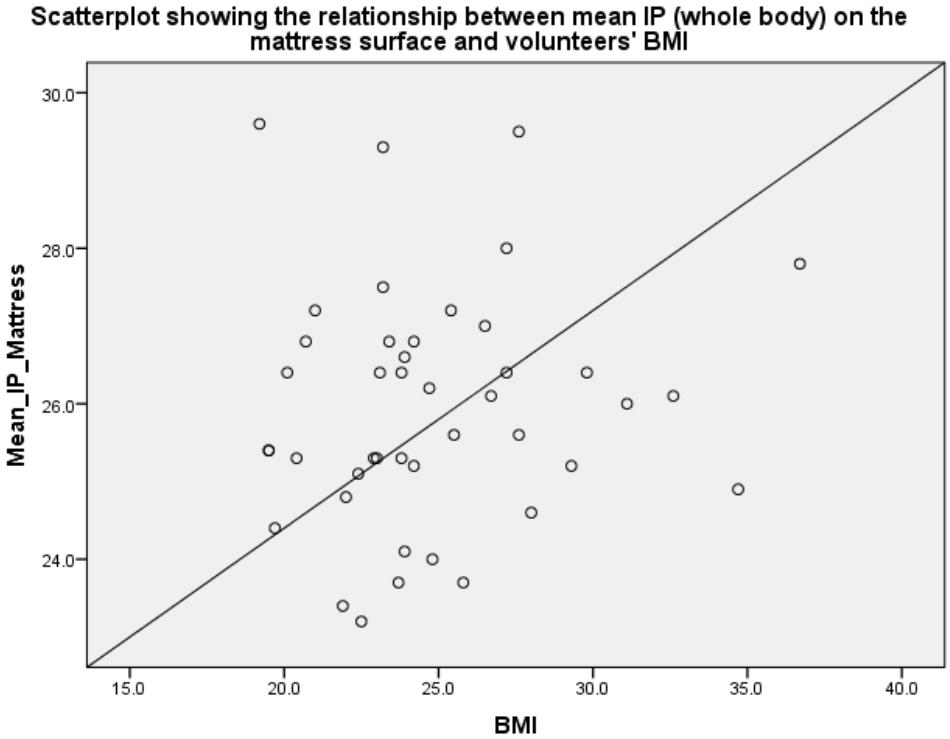


Figure 4:8: Scatterplot showing the correlation between mean IP for the whole body on the mattress surface and BMI

4.10.2 Correlation between mean IP on the X-ray table with no mattress (hard surface) and BMI

The results of the Pearson product-moment correlation (r) between mean interface pressure (IP) for the whole body on the X-ray table and BMI indicates that there was a small positive correlation between the two variables, r = 0.23, n = 49, p=0.12, and 0.1 coefficient of determination (R^2). Consequently, the small correlation resulted in a 10% shared variance between the two variables. The positive correlation between mean IP for whole body in mmHg on the X-ray table and BMI is shown in the scatterplot in Figure 4:9.

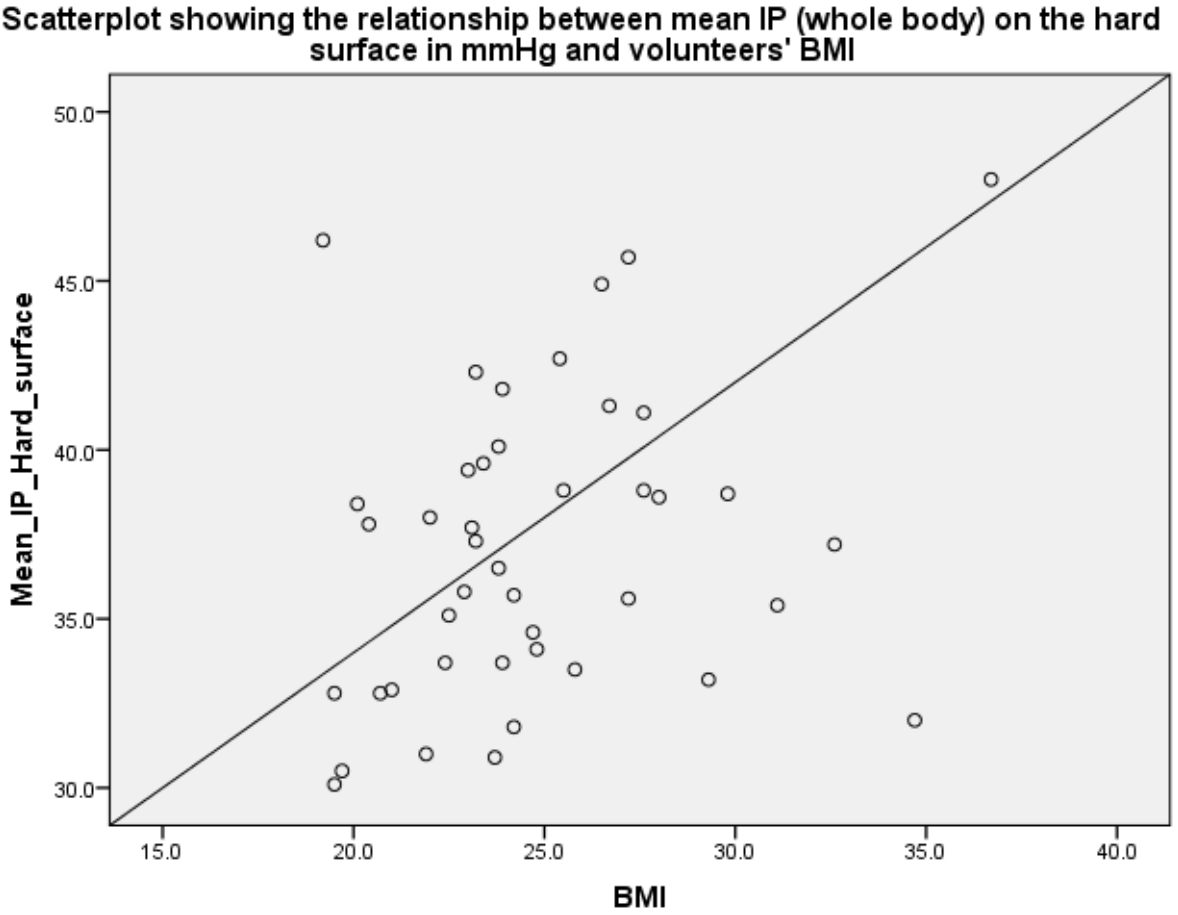


Figure 4:9: Scatterplot showing the correlation between mean IP for the whole body on the hard surface and BMI

4.10.3 Correlation between mean IP on the CT table and BMI

The relationship between BMI and mean interface pressure for the whole body on the CT table was investigated using a Pearson product-moment correlation coefficient (r). Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity, and homoscedasticity. There was a medium positive correlation between the two variables, r = 0.4, n = 43, p=0.02, and 0.16 coefficient of determination (R^2). The medium correlation resulted in a 16% shared variance between mean IP on this surface and volunteers' BMI. The positive correlation between mean IP for whole body in mmHg on the CT table and BMI is shown in the scatterplot in Figure 4:10.

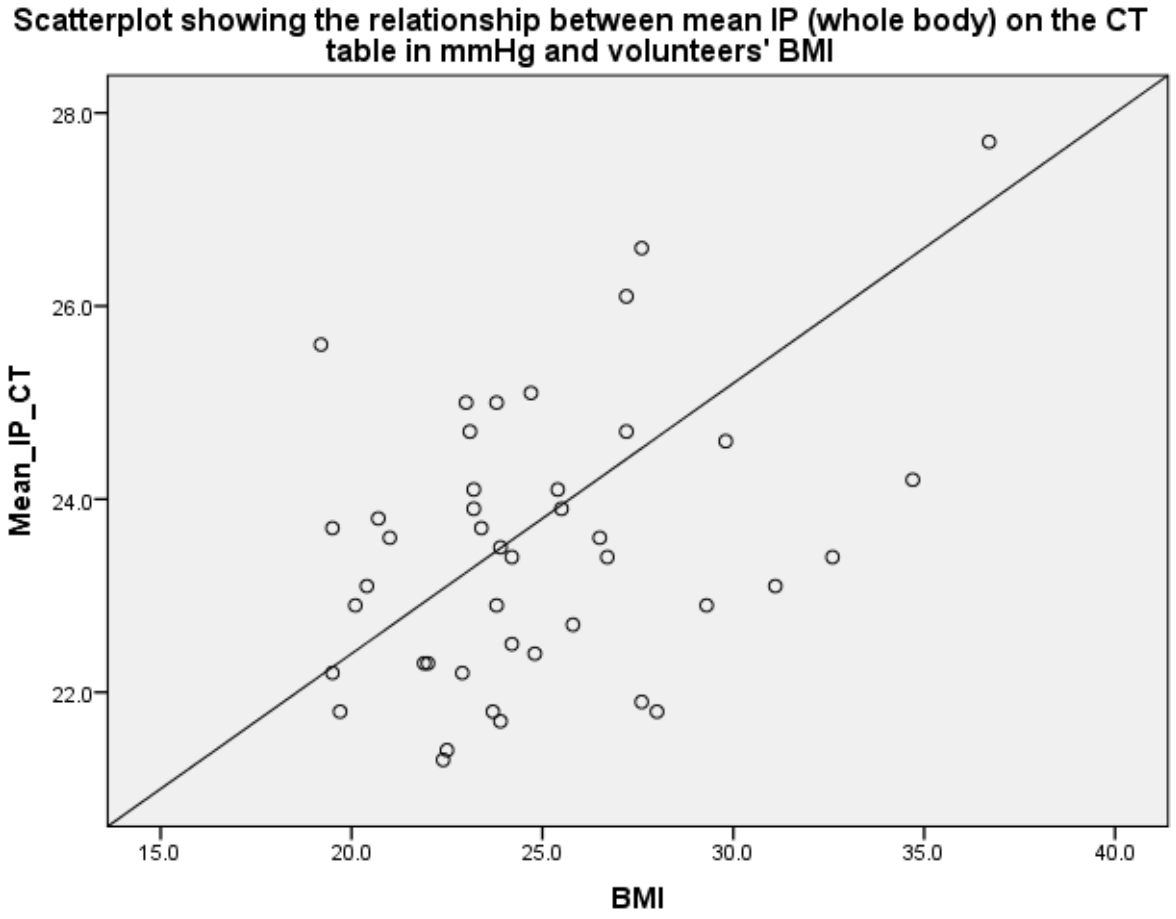


Figure 4:10: Scatterplot showing the correlation between mean IP for whole body on the CT table and BMI

The correlation statistics between mean IP for the whole body on the three imaging and radiotherapy surfaces and BMI are presented in Table 4.11.

Table 4.11: Correlation statistics between mean IP for the whole body and BMI

Mean IP for whole body	Mean±SD*	Mean BMI		
		R	R^2 (%)	P value
X-ray table with mattress	25.95±1.52	0.1	1	0.55
X-ray table without mattress	37.12±4.48	0.23	10	0.12
CT couch	23.50±1.43	0.4	16	0.02

*SD = standard deviation

5 Chapter Five – Discussion for baseline study

5.1 Chapter overview

The primary aim of the baseline study of this thesis was to investigate the interface pressures (IPs) of healthy volunteers whilst lying on three different modern medical imaging and radiotherapy surfaces. This was to ascertain whether there were IP risks whilst lying on medical imaging and radiotherapy surfaces currently in use in radiography and radiotherapy departments in hospitals. The secondary aim of this baseline study was to investigate volunteers' perception of pain and comfort whilst lying upon the imaging and radiotherapy surfaces. To achieve these aims, a set of objectives were formulated (chapter three, section 3.3). From these objectives, seven hypotheses were proposed (chapter three, section 3.4). These hypotheses have been tested and the results presented in chapter 4.

In this chapter, the results of the hypotheses will be discussed. The discussion will be conducted in two parts. First, the results of each hypothesis will be compared to previous studies. This will examine potential trends, patterns and relationships between the findings of this thesis and previous studies. In instances where the results differ from previous studies, reasons will be explored. The second part of the discussion will examine the clinical implications of the results of the baseline study. To achieve this, the clinical implications of the hypotheses that investigated the potential of interface pressure risks on medical imaging and radiotherapy surfaces will be discussed together under four sub-headings. These will include the clinical implications of the baseline study findings on prolonged interventional radiography, radiotherapy planning, and prolonged radiotherapy treatment procedures.

The implication of the findings of these hypotheses on the risk of Medical Device Relayed (MDR) pressure ulcers among patients accessing prolonged radiography and radiotherapy procedures will be discussed. In writing this chapter, data from the baseline study will be introduced and used to support and illustrate the narrative. The discussion will also focus on the clinical implications of the results in relation to the type of patients that are likely to undergo prolonged radiography and radiotherapy procedures. The peculiar health characteristics among this patient population will be

stated and discussed. Also, the implications of these health conditions combined with the presence of high interface pressure on the hard surface and how these could induce MDR pressure ulcers among this patient population will be discussed. Additionally, the results of the baseline study will be discussed in line with the strict immobilisation applied during prolonged radiotherapy and radiography procedures. The clinical implication of this together with other factors (e.g. high IP for head, hard surface, prolonged procedures, and high-risk patients) on MDR pressure ulcers will be discussed. Lastly, the results of hypotheses five and six (volunteers' perception of pain and comfort respectively), and seven (relationship between volunteers' BMI and IP for whole body) will be discussed. The clinical implications of these will be explored and discussed to indicate how they could impact on radiography and radiotherapy procedures and allow for optimisation of patient care.

5.2 Comparing results of baseline study to previous studies

Hypothesis one – there will be statistically significant differences in the mean IP of the whole body between the three imaging and radiotherapy planning and treatment surfaces.

The results of hypothesis one confirm that there were statistically significant differences in volunteers' mean IP for the whole body ($p \leq 0.001$), with volunteers experiencing the highest IP on the X-ray table without mattress (37.12 ± 4.48, in mmHg) and the lowest IP on the X-ray table with mattress (23.50 ± 1.43 mmHg). This finding cannot be compared to the previous study that investigated IP on medical imaging surfaces (Justham et al., 1996), because Justham and his colleagues did not assess IP for the whole body. However, this finding is comparable to the widely held position within the literature that support surfaces with cushion surface overlays, such as the mattresses used on the X-ray table, provide some level of cushioning and envelopment to patients resulting in a larger contact area and consequently lower interface pressure (Higer and James, 2016, Zemp et al., 2015, Yusuf et al., 2015, Kirkland-Walsh et al., 2015, Hemmes et al., 2014b, Peterson et al., 2013a, Trewartha and Stiller, 2011, Moysidis et al., 2011).

Hypothesis two – there will be statistically significant differences in the mean IP of the jeopardy areas (head, sacrum, and heels) on the three imaging and radiotherapy planning and treatment surfaces.

The key finding when the differences in mean IP for the head was compared was that there were statistically significant differences between the mean IP for the head on the three surfaces ($p \leq 0.001$). The mean IP for head on the X-ray table without mattress recorded the highest IP (75.85±6.89, mmHg) compared to the mean IP for the head on the mattress surface (37.95±4.03) and the CT surface (38.68±4.82 mmHg). The finding that the volunteers experienced the highest mean IP for the head whilst lying on the X-ray table without mattress was consistent to the results of the pilot study conducted prior to the baseline experiment (Everton et al., 2015). In the pilot study, the recorded mean IP for the head on the mattress and the hard surface were 53.93±14.42 and 107.11±19.29 mmHg, respectively ($p \leq 0.001$). From the results of these two studies (pilot and baseline study), a clear pattern was established in that the mean IP for the head was much higher on the hard surface

than on the other surfaces which were covered with thin radiolucent mattresses. This trend was also supported by the study conducted by Justham et al. (1996) in which the recorded mean IP for head on the hard surface was 59.2±25.1 mmHg compared to 48.0±25.5 mmHg recorded on a 25 mm thick mattress.

However, as expected, the mean IP for head on the hard surface recorded in this study (75.85±6.89, mmHg) was much higher than that recorded by Justham and his colleagues (59.2±25.1 mmHg). Considering the fact that these two experiments were conducted on healthy adult volunteers of similar body build, and the experiments were conducted on hard firm X-ray tables of similar characteristic one would expect that the results should be similar. This discrepancy could be attributed to the fact that the pressure mapping system and the method used by Justham et al. (1996) had numerous limitations (discussed in chapter two section 2.15). More specifically, the recorded lower mean IP for the head in Justham's study could be as a result of the head being rested on a single foam filled pillow during the pressure mapping. The use of the pillow might have provided some level of cushioning for the head, hence the lower mean IP for the head. This position is supported by the results of the baseline study in this thesis which showed that the mean IP for head on the mattress surface (37.95±4.03 mmHg) was lower than that recorded for the head on the hard surface.

As expected, when the mean IP for the sacrum was compared on the three surfaces, there were statistically significant differences ($p \leq 0.001$) between the recorded values; 28.19±2.76, 44.45±7.30, and 26.19±2.18 mmHg for mattress, hard surface and CT surface respectively. Similarly, there were statistically significant differences between the mean IP for the heels ($p \leq 0.001$). The heels experienced the highest mean IP on the hard surface. For example the mean IP for the right heels were 32.87±4.86, 44.25±6.91, and 40.05±4.31 mmHg for mattress, hard surface and the CT surface, respectively. This finding followed the trend that mattress surfaces produce less IP at jeopardy areas; a position widely supported by various studies (Hemmes et al., 2014b, Bush et al., 2015).

When the volunteers laid on the hard surface, the mean IP for the sacrum (44.45±7.30, mmHg) and the heels (44.25±6.91 mmHg) recorded in the baseline study was different from those recorded by Justham et al. (1996) for the same anatomical areas (97.7±55.9 and 126.9±79.6 mmHg for the sacrum and heels, respectively). These values were much higher than those recorded in the baseline study of this thesis; especially considering the fact that the value of the mean IP for the sacrum on the hard surface was more than double that recorded in the baseline study. These differences might be attributed to the differences in the methods used for the two studies. For example, as stated earlier, Justham and his colleagues rested the head of the volunteers on a pillow during pressure mapping. This might have elevated the head, the neck and the upper chest of the volunteers which might increase the IP for the sacrum. The linear relationship between head of bed elevation and increased sacral IP is well documented in the literature (Peterson et al., 2008, Harada et al., 2002, Sideranko et al., 1992). To this extent, the findings of the baseline study in this thesis can be deemed to be a true reflection of the mean IP for the sacrum on medical imaging and radiotherapy surfaces because of the rigorous scientific method, and the reliable and valid pressure mapping system used to conduct the experiment in this thesis.

The mean IP for the heels recorded in this baseline study (32.87±4.86, 44.25±6.91, and 40.05±4.31 mmHg for mattress, hard surface and the CT surface, respectively) were not comparable to those of Justham et al. (1996) (126.9±79.6 for no mattress, 100.5±50.0 mmHg for 25 mm thick mattress and 7.2±79.1 for 55 mm thick mattress). The results of the latter study should be interpreted cautiously because of the large standard deviations (SDs). The large SDs might be due to the poor spatial resolution of the Talley Oxford Pressure Monitor (TPM) used to conduct the research. The poor spatial resolution of the TPM means that there were large distances between the cells which might result in the heels being placed on active (recording) and inactive (non- recording) pressure mapping cells. As a result, the recorded data may not truly reflect the interface pressure for the heels. The research implication of this is that the pressure mapping cells used by Justham et al. (1996) cannot be relied upon to produce accurate results, hence the high IP values recorded for the heels may be inaccurate. Also, unlike the baseline study in this thesis where the mean IP for both heels were measured separately, the study conducted by Justham et al. (1996) did

not state whether this was the case or whether the IP for the heels were measured together. This is important because recording the IP for the heels together may mask artefacts that might occur during data acquisition. This is particularly important when the TPM pressure mapping systems used by Justham et al. (1996) does not allow real-time visual monitoring of IP, hence pressure mapping artefacts are not easily detectable.

Hypothesis three – there will be statistically significant differences in the mean peak IP of the head, sacrum, and heels on the three imaging and radiotherapy planning and treatment surfaces.

There were statistically significant differences between the mean peak IP for the head, sacrum and heels. The recorded mean peak IP for the head was 93.27±10.56 mmHg for mattress surface, 169.78±23.93 mmHg for the hard surface, and 110.77±9.14 mmHg for the CT surface ($p \leq 0.001$). The mean peak IP for the sacrum (75.80±16.81 mmHg for mattress surface, 180.40±10.92 mm Hg for the hard surface, and 65.51±9.40 mmHg for the CT surface) also indicated significant differences ($p \leq 0.001$). It is clear from these results that the recorded mean peak IP values have very large standard deviations. These large standard deviations mean that there was wide dispersion within the reported mean peak IP values. To demonstrate this take the following example; the mean peak IP for the head for volunteer 5 was 87 mmHg after 60 seconds of pressure mapping, however the recorded peak IP for the same volunteer after 120 seconds was 250 mmHg. This drastic increase in peak pressure is interesting and should not have occurred because the weight of the volunteer remained constant during pressure mapping. This inconsistency in peak IP values resulted in a mean peak IP that may not be reliable. Consequently, there were significant differences between the mean peak IP of the volunteers.

This volatile change in peak IP was comparable to other studies which indicate that peak pressure, the highest individual sensor value, is not a reliable pressure analysis parameter due to its sensitivity to random error because of erroneous electric charge fluctuations (Higer and James, 2016, Hemmes et al., 2014b, Davis and Sprigle, 2010, Bain et al., 2003). However, other studies argued that mean peak IP is a reliable parameter and reported it in their studies (Keller et al., 2005, Stinson et al., 2003b, Stinson et al., 2002, Twiste and Rithalia, 2008, Crawford et al., 2005, Stinson et al., 2008). The results within the baseline study of this thesis supported the former position that mean peak IP cannot be deemed a stable reliable parameter to assess pressure ulcers risk among patients undergoing prolonged radiography and radiotherapy planning and treatment procedures. As a result, clinical implications will not be drawn from the mean peak IP results.

Hypothesis four – there will be significant differences in the mean Peak Pressure Index (PPI) of the head, sacrum and heels on the three imaging and radiotherapy planning and treatment surfaces.

As indicated in chapter four section 4.7, PPI for the head and the heels could not be calculated on the X-ray table without mattress (hard surface) because these anatomical areas covered an area less than the 3x3 data matrix area needed to calculate PPI. This was due to the bony prominences at these areas and the absence of a mattress. As a result, PPI was calculated for the head and heels on the CT table and the X-ray table with mattress, and the means compared. The results indicated that the volunteers experienced higher peak pressure index (PPI) for the head (65.30±6.62 mmHg) on the CT surface compared to the mattress surface (62.50±4.2 mmHg). There were statistically significant differences between the two; $p \leq 0.001$. Also, mean PPI for the heel was higher on the CT surface (57.8±5.41 mmHg) than on the mattress surface (43.0±9.0 mmHg), and $p \leq 0.001$. These findings were expected because the mattress used on the X-ray table was a thicker, higher specification mattress which may distribute IP more evenly. This is because it has better pressure redistribution properties than the thin radiolucent mattress used on the CT surface. The finding that PPI is higher on the CT couch than the mattress surface is comparable to previous studies (Manzano et al., 2013, McInnes et al., 2012, Moysidis et al., 2011). These findings are also comparable to the experiment conducted by Justham et al. (1996) in which they showed that thicker mattresses have an inverse relationship with IP (i.e. the thicker the mattress the lower the recorded IP).

When the mean PPI for the sacrum on the three imaging/radiotherapy surfaces were compared, the finding showed that IP risk does exist on the X-ray table without mattress (hard surface), with a mean PPI of 121.9±26.9 mmHg, compared to 52.34±9.21 for the mattress surface, and 58.86±10.8 mmHg for the CT surface; $p \leq 0.001$. This extremely high mean PPI for the sacrum on the hard surface is similar to the results of an experiment conducted by Hemmes et al. (2014b). The surface used in Hemme's experiment is comparable to the one used in the baseline study of this thesis. As indicated in chapter three section 3.15.1, several studies posited that PPI is a stable parameter for reporting IP risks; hence should be reported and relied upon in preference to mean peak IP. However, the results from this study prove the

opposite due to the large standard deviations within the recorded PPI. The baseline study of this thesis had shown that just like peak pressure, PPI is prone to electrical charge volatility, and therefore is not a reliable parameter to predict pressure ulcers risk in patients.

When volunteers' perception of comfort whilst lying on the three different imaging/radiotherapy surfaces were assessed, the striking but expected finding was that approximately 70% of the volunteers found lying upon the X-ray table without mattress (hard surface) very uncomfortable or uncomfortable. This finding is comparable to the results of studies that investigated patients' perception of comfort whilst lying upon a hard spine board (Hemmes et al., 2010, Keller et al., 2005); a spine board is a support surface with similar characteristics as the X-ray table without mattress. Similarly, 67.4% of the volunteers indicted that they experienced pain whilst lying upon the X-ray table without a mattress, with over 81.3% of the pain occurring at the head. These findings are similar to that of Cordell et al. (1995) who investigated perception of pain on a spine board, a surface similar to an X-ray table with no mattress.

The results of the baseline study in this thesis indicated a small positive correlation between mean IP and BMI on all the three imaging/radiotherapy surfaces (1, 10, and 16% shared variance between BMI and mean IP for the whole body on the mattress surface, hard surface and CT couch respectively). These results are comparable to those of Stinson et al. (2003a). By contrast, the results of the baseline study in this thesis differ from that of Kernozek et al. (2002). These differences could be attributed to the large differences in the intrinsic factors present within the volunteers who participated in this baseline study and the one conducted by Kernozek et al. (2002). Whilst the volunteers used for this thesis were healthy, mobile and able-bodied, those of Kernozek et al. (2002) were elderly patients aged between 65-95 years suffering from spinal cord injuries. Spinal cord injuries may result in chronic spinal deformities which might affect the patients' ability to lie straight. The peculiar health conditions of the patients used for the experiment might have contributed to the results in the study conducted by Kernozek et al. (2002) which concluded that peak seat-interface pressure was highest in the patients with the lowest BMI.

5.3 Clinical implications of baseline study findings on prolonged interventional radiology procedures

The main issues from the baseline study were twofold. First, there were interface pressure (IP) risks on the X-ray table without mattress (hard surface) which could cause tissue damage and lead to Medical Device Related (MDR) pressure ulcers among patients undergoing prolonged radiography, radiotherapy planning and treatment procedures. Second, the specific health characteristics of patients who are likely to access these prolonged procedures makes the interface pressure risks more likely to predispose them to the formation of pressure ulcers. The baseline research in this thesis has demonstrated that mean IP for the whole body on the X-ray table with no mattress exceeds the threshold (32 mmHg) above which IP may induce occlusion of capillary blood flow, which may cause reduced tissue perfusion, ischemic injury, and therefore increase the risk of pressure ulcer development (Dharmarajan and Ugalino, 2002, Thomas, 1997). However, using mean IP for the whole body as a parameter to predict patient risk of developing pressure ulcers would be of little if any clinical significance. This is because mean IP for the whole body does not give a clear indication of the IP distribution across the entire skin surface of a patient's body. That is, it fails to give a clear indication of the pressure brought to bear on specific anatomical areas.

To illustrate this point, consider volunteers three and fifteen who participated in the baseline study in this thesis. These volunteers, both males, had similar ages (26 and 28 years respectively); body mass indexes (25.4 and 23.2, respectively); and approximately the same mean IP for the whole body on the X-ray table without mattress (42.7 and 42.3 mmHg, respectively). However, when the pressure mapping data of volunteer three was analysed, the results showed large differences in the IP distribution across the jeopardy areas; mean IP for the head, sacrum, right and left heels were 138.0±2.5, 50.8±1.8, 43.2±2.1 and 24.9±1.2 mmHg, respectively. Compared to the IP distribution for the head, sacrum and heels of volunteer fifteen, the results showed a fairly homogenous IP distribution across the jeopardy areas ((head (53.6±1.3), sacrum (56.8±2.6), right heel (30.1±4.2) and left heel (21.0±2.1) mmHg). Therefore to conclude that volunteers three and fifteen have the same risk of developing pressure ulcers because they experienced the same mean IP for the whole body will not be accurate. This is because as demonstrated, the IP brought to

bear on the jeopardy areas were different. The implication of the differences in IP distribution in these two volunteers is that, all other factors being equal, the risk of volunteer three developing a pressure ulcer at the head is significantly higher than that of volunteer fifteen. Using the mean IP for the whole body as a parameter to assess the risk of developing pressure ulcers would result in an over-prediction, or an under-prediction of pressure ulcer risk. This could lead to waste of hospital resources, because patients who may not be at risk of developing pressure ulcers may be placed on pressure ulcers preventive programmes, and those who are at risk may not be picked up to be placed on preventive measures.

The results of the baseline study in this thesis had demonstrated that mattress surface overlays help to redistribute interface pressure, thereby helping to reduce volunteers' risk of developing Medical Device Related (MDR) pressure ulcers. This could have a significant clinical implication for radiography practice in Ghana and Portugal because they do not use mattresses on X-ray tables. If the findings of this thesis are applied into conventional radiography practice in these countries, practice could change for the better, in the sense that patients will be provided with mattresses. This will enhance patient care and improve patient management because the introduction of a mattress will reduce IP, thereby reducing the risk of developing MDR pressure ulcers from medical imaging and radiotherapy planning and treatment surfaces.

Although high interface pressure risks have been identified for the head on the X-ray table with no mattress (hard surface), it is unlikely to induce tissue ischaemia, which would lead to pressure ulcers in patients undergoing conventional radiography procedures. This is because most conventional imaging procedures take a very short time to complete, mostly less than ten minutes (Ball et al., 2008, Whitley et al., 2005). Additionally, most conventional radiography procedures require at least two projections, usually anterioposterior (AP) and lateral projections (Whitley et al., 2005). As different patient positions are required during imaging protocols the patient often has to move, thereby relieving pressure on jeopardy areas. This means that IP between the anatomical part being x-rayed and the imaging surface will not be sustained long enough to induce tissue ischaemia. Consequently, patient movement between projections will reduce the risk of developing pressure ulcers (Dharmarajan and Ugalino, 2002). Also, during conventional radiotherapy procedures, patients are

provided with pillows when the head is not in the radiation field. This will provide some level of cushioning to the head, which will lower the IP between the head and the X-ray table thereby reducing the risk of developing pressure ulcers.

However, high interface pressure risk on X-ray tables with no mattress could induce tissue ischaemia which may lead to developing pressure ulcers in patients undergoing lengthy imaging procedures, for example interventional radiography procedures. This is because these procedures take a long time to complete, some taking several hours. In countries that do not use mattresses for imaging procedures, patients undergoing prolonged intervention radiography procedures such as cervical vertebroplasty would be required to lie on a hard imaging surface without any form of cushioning for long periods of time. Cervical vertebroplasty is a percutaneous minimally invasive interventional radiography procedure used to treat painful cervical vertebral compression fractures (VCFs) (Zhao et al., 2016a, Yang et al., 2016). Cervical VCFs can be defined as fractures involving the vertebral bodies of the cervical spine, and are common among patients of advancing age (Yan et al., 2016). Cervical vertebroplasty takes over an hour to complete, and sometimes longer if several cervical fractures are present (Wong and McGirt, 2013).

The treatment goals of cervical vertebroplasty are to relieve pain, restore mobility, restore vertebral body height, avoid new fractures, improve physical function, and enhance patient's quality of life (Alexandru and So, 2012). The presence of cervical vertebral fractures can cause a radical change in the rectangular shape of the affected cervical vertebra, causing it to compress against each other and/or surrounding tissues and nerves (Noriega et al., 2016). This results in most patients experiencing long-lasting, high pain intensity, and disabling condition resulting in impaired physical function and reduced quality of life (Svensson et al., 2016, Suzuki et al., 2008). Osteoporosis, a systemic bone disease that results in a loss of normal bone density, mass, strength, and a degradation of vertebral skeletal microarchitecture, leading to a condition in which bones are increasingly weak, and porous, making them susceptible to fracturing easily, is the common cause of cervical VCF (Zhao et al., 2016a). However, primary and metastatic malignancies, trauma, hemangioma, and osteonecrosis are other aetiologies of cervical vertebrae fractures (Jay and Ahn, 2013).

Most patients suffering from cervical VCF can be successfully managed with traditional treatments, including bed rest, analgesics, brace, and physical therapy (Sebaaly et al., 2016). However, older age is one of the risk factors for traditional treatments failure (Lee et al., 2012), and in some instances, these traditional treatments are associated with higher rates of pneumonia, venous thromboembolism, and even death in patients of advancing age (Yang et al., 2016). Cervical vertebroplasty has therefore become widely accepted as a treatment for cervical VCF especially among older patients (Yang et al., 2016).

During cervical vertebroplasty, fluoroscopic X-ray machines are used to provide image-guidance whilst orthopedic barium-opacified polymethylmethacrylate (PMMA) cement is injected into the fractured vertebrae (Nakamae et al., 2015). The orthopedic cement can easily been seen on the fluoroscopic image, and hardens soon after injection into the vertebrae (Saracen and Kotwica, 2014). The injected orthopaedic cement stabilises pathological micro fractures and reduces mechanical forces that affect nervous structures and causes pain (De la Garza-Ramos et al., 2016, Burton et al., 2005). Considering the fact that fluoroscopic X-ray machines in Ghana do not use mattresses, patients undergoing cervical vertebroplasty would be required to lie on hard rigid fluoroscopic X-ray surfaces throughout the duration of the procedure. It must be stated that patients' head are not supported on pillows during cervical vertebroplasty due to the possibility that the pillow might elevate the head above the level of the cervical spine, thereby putting pressure on the already distressed cervical spine. This might increase the pain in the cervical spine, and also increase cement leaks within the vertebrae (De la Garza-Ramos et al., 2016). Additionally, the proximity of the cervical vertebrae to the head demands that the head is not supported on pillows because the use of pillows could produce artefacts, which might affect the diagnostic quality of the fluoroscopic image. It is a common practice in radiography that any anatomical area to be irradiated and its immediate surrounding are kept free of foreign materials (Whitley et al., 2005). The absence of pillow or any form of cushioning at the head could induce tissue damage at the head because the head will be in direct contact with the rigid fluoroscopic surface for prolonged period of time.

5.4 Clinical implications of baseline study findings on radiotherapy planning

The finding that there were high interface pressure risks for the head on the X-ray table with no mattress could have clinical implications for patients undergoing radiotherapy planning. Prior to radiotherapy treatment, patients have to undergo a planning scan; typically these use computerised tomography (CT) (Nestle et al., 2009). CT scan provides an anatomical image of body parts with a high level of resolution (Smulders and Fog, 2012). However, current developments in radiotherapy treatment procedures demands for more accurate planning. These developments include the move towards more accurate and precise radiotherapy treatment procedures such as stereotactic radiotherapy which delivers radiation doses precisely to target tumours whiles sparing healthy tissues (Federspiel and Hogg, 2012). Therefore, it is important to ensure that the radiotherapy treatment field is planned accurately to maximise the benefits of the treatment and minimise its potential risks (Hogg, 2013). As stated earlier, anatomical imaging such as CT has played a pivotal role in radiotherapy planning but has numerous limitations. For example, tumours are not accurately presented on anatomical imaging when the tumour and surrounding healthy tissues have similar density or similar contrast enhancement (Mazza et al., 2013). Additionally, CT imaging gives no information about important biological characteristics of tumours, making CT insufficient for the delineation of target volume (Hicks and Hofman, 2012).

These limitations have led to the use of CT together with single-photon emission computed tomography (SPECT) or positron emission tomography-computerised tomography (PET) to provide accurate target delineation prior to radiotherapy treatment. The use of these integrated systems (SPECT/CT and PET/CT) is commonly referred to as hybrid imaging (Kashyap et al., 2013). Hybrid imaging is developed based on the idea that the fusion of SPECT or PET together with CT will demonstrate structural and functional characteristics of tumours (Federspiel and Hogg, 2012). This vital information can then be entered into a radiotherapy treatment planning system (TPS) for evaluation and for gross tumour volume (GTV) delineation (Sergieva et al., 2014). PET/CT and SPECT/CT have better sensitivity and specificity than CT alone in radiotherapy planning (Sergieva et al., 2014). The use of hybrid systems in radiotherapy planning provides an understanding of both the distribution

and size of tumours, as well as the metabolic activity of the tumours (Viti et al., 2014). SPECT/CT and PET/CT scans have been shown to help increase inter-rater agreement in GTV delineation in radiotherapy planning (Götz and Spehl, 2012). The vital information from SPECT/CT and PET/CT can be used in making very important decisions prior to the radiotherapy treatment procedure; thereby enhancing better patient management.

Irrespective of the huge clinical benefits of PET/CT and SPECT/CT in radiotherapy planning, they could be potential sources of Medical Device Related (MDR) pressure ulcers among patients because of the long time it takes to complete these procedures, and also because of the conditions under which these procedures are conducted. PET/CT and SPECT/CT scan for the purposes of radiotherapy planning takes between 40-60 minutes to complete (Townsend et al., 2004, Slomka et al., 2015). It must be stated that these times depend on the specifications of the machine, the capability of the clinical staff and complexity of the case as variations do occur between patients. CT scans are usually conducted on a narrow couch with a thin radiolucent mattress. These surfaces could reduce the risk of MDR skin injuries by providing some level of cushioning to the skin of patients accessing CT procedures (Zemp et al., 2015). However, these surfaces are soft and have the ability to sag under patient weight, making them unsuitable for the purposes of radiotherapy planning. Radiotherapy planning is performed on firm hard surfaces with no mattress similar to treatment surfaces. Therefore when conducting a SPECT/CT or a PET/CT scan for the purposes of radiotherapy planning, it is very important that the planning is conducted on a rigid surface with no mattress to replicate that of the radiotherapy treatment machine. This is crucial because the use of mattress may result in different patient geometry between planning and treatment due to the potential of bending/flexing of the mattress on the CT couch (Abrahamsson, 2012). This could result in poor delineation of the GTV and consequently suboptimal treatment (Vrana et al., 2016). Therefore to achieve the same geometry as the radiotherapy treatment surface, the normal CT mattress must be replaced with a flat carbon fibre top.

The introduction of modern radiotherapy techniques such as cranial stereotactic radiotherapy (SRT) demands even more precise tumour delineation (Berthelsen and Loft, 2012). This is essential because if the defined GTV is too small, parts of the tumour might not be irradiated; whereas if the GTV is too large, surrounding healthy tissues might be exposed to a higher radiation dose, increasing the risk of complications (Berthelsen and Loft, 2012). Sparing of healthy organs from high radiation doses is even more important in cranial SRT due to the presence of very sensitive brain structures such as the optic nerve, which when exposed to higher radiation doses can led to loss of sight (Götz and Spehl, 2012). Implementation of hybrid-based planning demands that patients lie completely still on the hard carbon fibre couch top to eliminate movement between the PET or SPECT and CT images. This is to avoid misregistrations, which could affect image interpretation and treatment plans (Delbeke et al., 2009).

Additionally, to eliminate patient movement and ensure correct target definition, patients undergoing radiotherapy planning are immobilised for the entire duration of the planning. In the instances of those undergoing planning prior to receiving treatment for head and neck cancers, they are fitted with personalised thermoplastic immobilisation masks or molds (Wahl et al., 2011). This is to ensure that the patient remains in the same position during CT and PET or SPECT scanning to ensure accurate integration of the images can be automatically applied into the treatment planning system (Berthelsen and Loft, 2012). The application of strict individualised immobilisation during SPECT/CT or PET/CT for radiotherapy planning could increase the high interface pressure identified for the head. The implication of this is that the limited skin tissue on the head may not withstand this high interface pressure. This could lead to tissue ischaemia, which might lead to MDR pressure ulcers.

5.5 Clinical implications of baseline study findings on prolonged radiotherapy treatment procedures

The finding that there is high interface pressure risks for the head on the X-ray table with no mattress could have clinical implications for patients undergoing prolonged radiotherapy procedures. Radiotherapy treatment procedures are generally delivered in less than ten minutes (Beadle et al., 2014). However, recent developments in radiotherapy treatment procedures demand that treatment times are significantly increased. A classic example is during stereotactic radiotherapy (SRT) for the treatment of cranial cancers such as brain metastases. Unlike conventional radiotherapy treatment times, cranial SRT can take between 45-60 minutes, with some lasting longer (Rieber et al., 2016, Franks et al., 2015). This is because SRT treatment delivers larger fractions of radiation more precisely and over fewer days than standard fractionated radiation (Vrana et al., 2016, Ricardi et al., 2016, Yu and Sandler, 2015). Cranial SRT treated brain metastases account to between 20-40% of adult cancer cases and their incidence has quadrupled over the last four decades (Lin and DeAngelis, 2015, Patchell, 2003). The treatment options for large brain metastases, (i.e. brain metastases bigger than 2.1 cm), include surgery and whole-brain radiation therapy (WBRT) (Pessina et al., 2016). However, current clinical literature indicates that SRT represents a feasible and safe technique for the management of brain metastases and therefore recommends SRT treatment for multiple brain metastases and also when the target is exceedingly large or close to critical brain structures (Nardone et al., 2016).

Cranial SRT involves delivering high treatment doses to a target over fewer days compared to conventional radiotherapy (Franks et al., 2015). Cranial SRT is a focal radiotherapy technique that uses stereotactic coordinates and multiple, tightly collimated, convergent high-energy beams to deliver high radiation doses and high biological equivalent dose (BED) to tumours (Nardone et al., 2016, Zheng et al., 2016). This demands the addition of multiple scans before and during the radiotherapy session to ensure adequate targeting of the radiation beams. Cranial SRT entails high level of precision through the use of image guidance to clearly define the target tumours so as to spare the numerous organs at risk (OARs) within the skull (Martin et al., 2016).

SRT is widely used as a precise and effective treatment option with minimal morbidity for patients with intracranial tumours (Rieber et al., 2016). For patients with multiple brain metastases, SRT is preferred over conventional whole brain radiotherapy due to its ability to minimise neurocognitive side effects and improved patient's quality of life (Vrana et al., 2016). Unlike conventional brain radiotherapy, cranial SRT can be applied to any location in the brain, and to very small brain metastases that are inaccessible surgically (Romagna et al., 2016, Pontoriero et al., 2016).

Irrespective of the clinical benefits of cranial SRT, this prolonged radiotherapy treatment procedure has the potential to induce MDR pressure ulcers in patients due to the conditions under which the procedures are conducted. As stated in chapter two section 2.16, it is essential that patients undergoing cranial SRT are positioned to restrict motion and ensure that normal healthy organs are not exposed to the radiation beams (Barrett et al., 2009). To enforce this, the procedure is conducted on rigid carbon fibre couch top such as the KVue state of the art radiotherapy couch top (chapter three, Figure 3:8). This versatile couch top ensures low attenuation and surface dose, precise and repeatable patient positioning each time (Soliman et al., 2016). The use of the rigid carbon fibre couch tops mean that patients undergoing cranial SRT would experience high interface pressure which could increase their risk of developing pressure ulcers. The use of the rigid carbon fibre couch top is necessary to provide the stability of patient needed during cranial SRT. To ensure effective treatment during cranial SRT, it is essential that patient position during daily treatment is the same as patient position and tumour delineation during planning to ensure their reproducibility and accuracy (Barrett et al., 2009, Beadle et al., 2014). This means that patients would have to endure lying on the hard rigid couch tops during prolonged cranial SRT procedures.

The impact of prolonged interventional radiography procedures and prolonged radiotherapy treatment procedures could have on inducing MDR pressure ulcers among patients is more severe if one considers the characteristics of the patients who normally undergo these procedures. For example, cervical vertebroplasty are usually performed on patients of advancing age, those suffering from cervical vertebral compression due to a malignant tumor, those on long-term steroid treatment, and those suffering from a metabolic disorder (Zhao et al., 2016b). Studies have shown that elderly patients form the majority of patients suffering from osteoporosis, and subsequently cervical vertebral fractures due to older frail bones, and the presence of comorbidities among the geriatric patient population (Svensson et al., 2016, Akintade, 2015). Additionally, elderly patients form the majority of patients who undertake prolonged radiotherapy treatment procedures such as cranial SRT. This is because available statistics showed that the geriatric patient population accounts for about half of all cancer cases (CR-UK, 2015).

Coincidentally, the geriatric patient population is also highly susceptible to developing pressure ulcers due to their poorer skin conditions. As stated in chapter two section 2.11, advancing age is linked with a significant reduction in the elastin and collagen content in the skin (Reddy, 2008). The significant reduction in these all important skin protective fibres reduces the ability of elderly patient's skin to extend and recoil, in order to protect the superficial skin and subcutaneous tissue from the harmful effects of pressure (Kelly, 2014). Also, the elderly patient population has also been shown to account for the bulk of patients suffering from neurological disorders such as chronic spinal cord injuries, Parkinson's disease, and multiple sclerosis (MS) that might compromise their immune system, making them more susceptible to developing pressure ulcers. Also, the presence of these disorders negatively affects their nutritional status and general well-being. This significantly increases the risk of the elderly patient population of developing pressure ulcers. Therefore, the findings of the baseline study of this thesis that there are high interface pressure risks for the head on the X-ray table with no mattress means that elderly patients who undergo prolonged interventional medical imaging procedures such as cervical vertebroplasty, and extended radiotherapy planning and treatment procedures (e.g. cranial SRT) would have to sustain high interface pressures for very

long periods. This could result in skin tissue damage, which might lead to pressure ulcer development.

The application of very strict patient immobilisation during cranial SRT is another factor that could increase patients' risk of developing MDR pressure ulcers. Patients assessing cranial SRT procedures are fitted with a personalised thermoplastic mask, to restrict patient's head movement and minimise treatment errors (Abrahamsson, 2012). The baseline study of this thesis has shown that volunteers experienced high interface pressures when lying on the hard surface. Immobilisation could further increase the high IP between the head and the radiotherapy surface. Extrapolating the findings of this experiment into clinical practice would mean that patients will also experience high interface pressure on a similar surface. The application of the head immobilisation masks during cranial SRT will increase the already high mean interface pressure between the patient's head and the rigid couch top. As a result, radiotherapy treatment of cranial tumours such as multiple brain metastases would force patients to spend hours lying on rigid and uncomfortable couch tops fitted with scotch cast masks (White and Swanson, 2016).

As indicated earlier, the findings of this study showed that most of the volunteers (70%) found the X-ray table with no mattress to be very uncomfortable or uncomfortable. Similarly, 67.4% of the volunteers indicted that they experienced pain whilst lying upon the X-ray table with no mattress, with over 81.3% of the pain occurring at the head. These findings could have clinical implication for patients accessing prolonged radiography imaging and radiotherapy planning and treatment procedures because a recent study had shown that there is a direct link between patient comfort and/or pain and accuracy of radiotherapy treatment procedures (Bartlett et al., 2015). This is due to the fact that patients who feel pain during radiotherapy procedures will find the procedure uncomfortable. Consequently, these patients may not cooperate adequately during the procedure, in so doing may reduce the accuracy of the treatment. Errors during radiotherapy treatment procedures could have serious consequences on a patient's health in the sense that the target organ may be missed and healthy surrounding tissues may be exposed to harmful radiation doses (Siva et al., 2014). Although comfort and pain are more of a subjective physical measure, there is a link between these two measures and anxiety, which is a psychological measure (Cox and Davison, 2005, Goldsworthy et

al., 2016). For example, a patient with high levels of anxiety might find the X-ray table with no mattress very painful and/or very uncomfortable. However, this might be due to the psychological state of the patient and not because of the physical demands that the hard surface placed on his/her skin.

5.6 Clinical implications of positive correlation between BMI and mean IP

The results of the baseline study of this thesis had demonstrated that there were small positive correlations between BMI and mean IP for the whole body on the mattress, hard surface and the CT tables (1, 10, and 16% shared variance respectively). The clinical implication of this finding is that patients of higher BMI are more likely to have higher IP. BMI is defined as a measure of body size, and it is calculated by dividing a person's weight in kilograms by the square of his/her height in meters (Hyun et al., 2014). BMI less than 18.5 is considered underweight, between 18.5 and 24.9 is considered a healthy weight range, between 25 and 29.9 is considered overweight, and between 30 and 39.9 is considered obese (NHS, 2016). Although high IP is not the only causative factor of pressure ulcers, it is shown to be a key predictor for pressure ulcers (Wininger and Crane, 2015). Most obese people are less active and some may be immobile. Immobility may contribute to poor blood flow within the skin tissues, which may increase the risk for pressure ulcer formation (Agrawal and Chauhan, 2012). Also, obesity is associated with the presence of other diseases such cardiovascular disease, type 2 diabetes, hypertension, and stroke (Stojadinovic et al., 2013). The presence of these comorbidities may contribute to the risk and/or severity of pressure ulcers among obese patients (VanGilder et al., 2009b).

Currently, there is confusion in the literature as to the link between BMI and the incidence of pressure ulcers. Whereas some studies indicate that high BMI leads to an increased pressure ulcer risk (Hyun et al., 2014, Kumari et al., 2015, Gallagher, 2005a, Gallagher, 2005b, Knudsen and Gallagher, 2003), others argue that low BMI leads to an increased risk in pressure ulcers development (Compher et al., 2007, Kernozek et al., 2002, Baumgarten et al., 2006, Casimiro et al., 2002, VanGilder et al., 2009b, Uzun and Tan, 2007). The differences in the conclusions from these studies could be attributed to the huge differences between the patient populations that were used for their studies. For example, Hyun et al. (2014) conducted their study on patients in medical and surgical intensive care units with a mean age of 58 years, but Compher et al. (2007) conducted their study on an elderly hospitalised patient population with a mean age of 77 years.

In contrast to the position that high BMI and its associated high body fat increases the risk of developing pressure ulcers, there is another school of thought which argues that the presence of the extra body fat and adipose tissues, rather than adding pressure on superficial and deep tissues, provide an enhanced subcutaneous protection to ease the pressure. The argument that low BMI is associated with the occurrence of pressure ulcers may arise from the fact that very low BMI is an indicator for poor health in most patients (Drake et al., 2010). It is therefore not surprising that in a study investigating the link between BMI and pressure ulcers incidence, the correlation of pressure ulcers with BMI was reduced after controlling for other indicators of poor health, such as admission from nursing home, recent hospitalisation, and poor nutritional status (Baumgarten et al., 2006).

Irrespective of the confusion in the literature, there seems to be an agreement on the fact that patients on either end of the BMI spectrum (low and high BMI) have a higher risk of developing pressure ulcers than patients with whose BMI fall within the healthy range (Drake et al., 2010, VanGilder et al., 2009b). To apply the findings that there is a positive correlation between BMI and average IP for the whole body in radiography imaging and radiotherapy treatment would mean that radiographers and therapy staff should be mindful that patients of different BMI will be exposed to different IP risk levels whilst lying upon imaging/radiotherapy surfaces. As a result, any pressure ulcer prevention plan should be specifically targeted to need individual patient's needs. For example, a thin radiolucent mattress that may reduce IP for a patient with lower BMI may not necessarily reduce IP when used on a patient with much higher BMI. Such a patient would need a higher specification pressure redistribution surface overlay in order to effectively protect the skin from tissue ischaemia.

5.7 Conclusion

The baseline study in this thesis had demonstrated that the risk of Medical Device Related (MDR) pressure ulcers do exist for the head on X-ray tables with no mattress. This is due to the high interface pressure found for the head on this surface. This finding could have severe impact among patients accessing prolonged interventional radiography procedures in countries where these procedures are conducted on X-ray tables with no mattress. These countries include Ghana and Portugal, by way of example. The presence of high interface pressure for the head on the X-ray table with no mattress could induce skin injuries among patients undergoing radiotherapy planning prior to receiving a radiotherapy treatment. As has been discussed, recent advancements in radiotherapy such as cranial stereotactic radiotherapy have increased treatment times from about ten minutes to almost an hour. This means that patients would have to lie still under strict immobilisation through the course of this prolonged treatment procedure. The application of an immobilisation device could increase the already high interface pressure between the head and the hard carbon fibre couch top. This could significantly increase patients' risk of developing pressure ulcers.

Confounding this are patient characteristics. Most patients accessing radiotherapy planning and treatment procedures are old, and usually of poorer health. Most of these are geriatric patients who are suffering from chronic diseases such as cancer and neurological disorders. Research has shown that advancing ages comes with an associated reduction in the skin's collagen and elastin contents. This means that the skin of these elderly patients accessing prolonged interventional radiography, radiotherapy planning and treatment procedures lack the vital protective mechanisms that protect the skin from injury. This increases their risk of developing MDR pressure ulcers. It is therefore important that further research is conducted to find ways of minimising the high interface pressure risks identified for the head on the X-ray table with no mattress. Consequently, phase two of this thesis will involve an intervention study with the primary aim of minimising the high IP risk identified for head in the baseline study by using a thin silicone gel surface overlay as an intervention.

Phase Two

Title:

Intervention study assessing the impact of a thin silicone gel surface overlay on interface pressure (IP) risk for the head.

6 Chapter Six – Intervention study

6.1 Chapter overview

This chapter contains the second phase of this thesis. Phase one of this thesis involved an empirical piece of work that investigated the interface pressure of healthy volunteers on modern radiography and radiotherapy surfaces. This was to critically assess and evaluate if there were interface pressure risks for the whole body, head, sacrum and heels on the three different surfaces; X-ray table with a mattress, X-ray table with no mattress, and a CT surface. The main outcome of the study concluded that there are high interface pressure risks for the head on the X-ray table with no mattress. The clinical implication of this is that patients having prolonged medical imaging and radiotherapy planning and treatment procedures could be exposed to an increased risk of developing pressure ulcers at the head. To minimise or eliminate this risk, an intervention study was conducted using a thin silicone gel surface overlay. The full intervention study is reported in this chapter.

The chapter will begin with a rationale for the study followed by the aim and objectives of the study. A set of hypotheses have been formulated from the objectives. Since this intervention study involved human volunteers, the ethical principles that were considered have also been discussed in this chapter. A section with a comprehensive discussion on the various types of surface overlays available for pressure redistribution will be provided in this chapter. The processes used to decide which of the surface overlays would best serve as an intervention within the radiography and radiotherapy settings will be discussed and presented. These processes include detailed information on a series of image assessment, radiation and dosimetry tests that were conducted on the surface overlays. The final part of this chapter includes the method used for this intervention study. This includes justification for the sample size, the pressure mapping equipment, and the procedure for data collection. Finally, the results will be presented in mean interface pressure and peak pressure index (PPI) for the head in mmHg. Prior to this, the statistical procedures used to analyse the results will be presented in a flowchart and also in text. In conclusion, a discussion section will be provided to link the findings of this intervention study to previous ones, and discuss the clinical implications and importance of the results.

6.2 Rationale for intervention study

As indicated in phase one of this thesis, pressure ulcers are a common problem in healthcare, presenting substantial threat to patients especially geriatric patients, those with restricted mobility, and patients suffering from chronic diseases such as cancer (Gomez-Batiste et al., 2014, Pieper, 2012). Irrespective of the significant effort and international attention directed at reducing the incidence of pressure ulcers, their incidence continues to rise, affecting a large proportion of patients worldwide (Brennan et al., 2014, Stotts et al., 2013). The high prevalence of pressure ulcers across a range of healthcare settings, including nursing homes, care homes, independent sector care providers as well as hospitals, is unacceptable. Making matters worse is the huge financial burden that pressure ulcers place on healthcare authorities, costing billions of pounds to treat in some countries (Reddy et al., 2006, Filius et al., 2013, Dealey et al., 2012). Apart from the financial burden that pressure ulcers place on both patients and healthcare authorities, there is also the issue of the negative physical and psychological impact that pressure ulcers have on patients (Plaskitt et al., 2015). Consequently, pressure ulcers reduce the quality of life of its patients (Kranke et al., 2015). Due to the harmful effects of pressure ulcers, researchers have been encouraged to conduct more research of rigorous scientific methodology into the aetiology of pressure ulcers to help identify ways of minimising the incidence and prevalence rates of pressure ulcers (NICE, 2015).

In radiography and radiotherapy, patients are likely to be exposed to Medical Device Related (MDR) pressure ulcers. These are defined as localised injury to the skin or underlying tissue as a result of sustained pressure from a medical device, and usually occur directly under diagnostic or therapeutic devices, and typically appears visually on the superficial skin and takes the shape of the device (Pittman et al., 2015, Visscher and Taylor, 2014, Manzano et al., 2014,). In radiography, because of the need to maintain diagnostically acceptable image quality and minimise error, patients are usually transferred onto imaging surfaces prior to a procedure (Whitley et al., 2005). These surfaces often use thin radiolucent mattresses. However, in Portugal and Ghana, diagnostic radiography procedures are conducted on hard carbon fibre X-ray tables with no mattress. These table conditions are similar to those used in radiotherapy. In radiotherapy, because of the need to maintain

reproducibility of patient position during planning and treatment, patients are positioned on hard couch surfaces with no mattress (Barrett et al., 2009). It is very important that the daily radiotherapy treatment position is the same as patient position and tumour delineation during planning to ensure accuracy of radiotherapy procedure (Beadle et al., 2014). Lying on hard imaging and radiotherapy treatment surfaces with no mattress could be harmful to patient's skin, especially in at risk populations such as elderly patients and those suffering from cancer because of their fragile skin (Stojadinovic et al., 2013). Confounding this is the fact that some of these procedures take a very long time to complete. For example cranial stereotactic radiotherapy takes between 40-60 minutes to complete (Rieber et al., 2016), whereas cervical vertebroplasty, an interventional radiography procedure takes over an hour to complete, and sometimes longer when several cervical fractures are present (Wong and McGirt, 2013). Another confounding factor is that patients are intentionally immobilised to minimise error during the procedure. Immobilisation is more rigid in radiotherapy because patient positioning is a crucial part of treatment and the use of immobilisation devices such as full head masks to reduce positioning errors and limit patient motion are necessary to eliminate any misdirection of prescribed radiation doses (Beadle et al., 2014). All these factors could contribute to high interface pressure between the head and the radiography/radiotherapy surface.

Interface pressure which is defined as the pressure between body and contact surfaces, plays a crucial role in skin damage (Hollington and Hillman, 2013). This usually occurs when body tissues are compressed against each other, mostly over bony prominences where there is less soft tissues to tolerate the compressive force brought to bear on the skin (Clements et al., 2014). Research has shown that interface pressure greater than capillary closing pressures (CCP), of 32-47 mmHg for a period longer than two hours is most likely to compromise circulation, and may cause tissue ischaemia, which may lead to pressure ulcers (Landis, 1930, Defloor, 1999). These injuries are prone to occur at the head (occiput), sacrum, and heels, popularly referred to as the jeopardy areas, due to the prominent bony features found at these anatomical sites (Casey and Gittins, 2013).

A study conducted by Justham et al. (1996) many years ago has indicated that there is the potential of high interface pressure on medical imaging and radiotherapy surfaces. This assertion could have negative implication for patients accessing prolonged imaging and radiotherapy procedures if it is confirmed because it could increase the risk of developing pressure ulcers among these patients (Pernik et al., 2016). To confirm this assertion, the first phase of this thesis involved an empirical baseline study with reliable scientific method, with the primary aim of assessing the interface pressure risk of healthy volunteers on modern radiography/radiotherapy tables. The study was conducted using the Xsensor pressure mapping technology/equipment and on three different imaging and radiotherapy tables. These surfaces include the X-ray table with a thin radiolucent mattress, the X-ray table with no mattress (such as the ones used for radiotherapy planning and treatment), and the narrow curved CT couch covered with a thin radiolucent mattress. Using a short 5-point Likert scale questionnaire, the study also investigated the volunteers' perception of pain and comfort whilst lying on the three different radiography and radiotherapy planning and treatment surfaces.

Results from the first phase of this thesis (baseline study) indicated the healthy volunteers experienced high IP for the head on the X-ray table with no mattress (75.9±6.9 mmHg). Also, there were statistically significant differences between the mean IP for the head across the three surfaces ($p \leq 0.001$). These results confirm the assertion that high interface pressure risks do exist on the X-ray table with no mattress. As discussed in chapter five sections 5.3, 5.4 and 5.5, the clinical implication of this finding is that patients accessing prolonged interventional radiography and radiotherapy planning and treatment procedures for the head that are conducted on these hard surfaces with no mattress could be exposed to high interface pressure risks. This could increase significantly their risks of experiencing skin injuries at the head which might lead to developing pressure ulcers. This risk could have a more severe impact among geriatric patients and those suffering from chronic diseases such as cancer. This is because as stated earlier these patient populations are at high risks of developing pressures ulcers due to the poor collagen and elastin content in their skin, and the presence of comorbidities (Forasassi and Meaume, 2015).

When the volunteers' perception of comfort and pain was assessed, it was found that most of them found the X-ray table with no mattress to be the least comfortable of the three surfaces, with over 70% indicating that lying on the X-ray table with no mattress for 26 minutes was very uncomfortable or uncomfortable. Volunteers also experienced much pain on the X-ray table with no mattress, with over 81.3% of the pain occurring at the head. These results were reported in chapter four, sections 4.8 and 4.8 respectively. These findings could have negative implications on patient management in radiography and radiotherapy as research has shown that there is a link between comfort and accuracy of radiotherapy procedures (Bartlett et al., 2015). It is therefore important that further research is conducted to find ways of minimising the high interface pressure risks identified for the head on the X-ray table with no mattress. Therefore, this empirical intervention study, which forms phase two to this thesis, was conducted with the primary aim of minimising the high IP risk identified for the head in the baseline study by using a thin silicone gel surface overlay as an intervention.

6.3 Aim of intervention study

The aim of this intervention study was to minimise the high interface pressure risk identified for the head in phase one of this thesis using a thin silicone gel surface overlay. A successful completion of this study will provide an insight into the impact of thin surface overlays on reducing the pressure ulcers risk of patients accessing prolonged interventional radiography and radiotherapy planning and treatment procedures. To achieve the aim of the intervention study, the following objectives and hypotheses were formulated:

6.4 Objectives of intervention study

- Evaluate and analyse the mean interface pressure (IP) for the head on the X-ray table with and without the silicone gel surface overlay.
- Evaluate and analyse the Peak Pressure Index (PPI) for the head on the X-ray table with and without the silicone gel surface overlay.

6.5 Hypotheses of intervention study

- Mean interface pressure (IP) for the head on the X-ray table will be statistically higher than the mean IP for the head on the silicone gel surface overlay.
- Peak Pressure Index (PPI) for the head on the X-ray table will be statistically higher than the PPI for the head on the silicone gel surface overlay.

6.6 Study design and setting

This empirical intervention study was conducted in the medical imaging facility located within the Mary Seacole Building of the University of Salford (UoS) in Manchester, United Kingdom.

6.7 Ethical considerations

This intervention study was approved by the University of Salford College of Health and Social Care Ethics Committee (Appendix 10). The volunteers willingly participated in the study. The recruitment procedures outlined in chapter three section 3.6 were used to recruit volunteers for this study. The volunteers who agreed to participate in the study were requested to sign a consent form (Appendix 13). Records of these are kept in a locked cabinet, which can only be accessed by the researcher and members of the research supervisory team. As in the baseline study, the consent form for this intervention study clearly indicated that the volunteers have the right to withdraw from the study at any time, without giving any reason for doing so. In such an instance, the volunteer can request for his/her data already collected to be deleted from the study records.

This intervention study did not pose any obvious risk to either the volunteers or the researcher. All risk assessment requirements were fulfilled prior to commencing the study. The University of Salford risk assessment form (Appendix 14) was submitted to and approved by the ethics committee. In addition, the medical imaging facility local rules for radiation safety compliance form (Appendix 6) was read, completed and returned to the radiation protection supervisor.

The names, signatures and other demographic information of the volunteers who participated in this study are kept confidential. This information is kept in a secured location, locked, and can only be accessed by the researcher and his supervisors. Additionally, the IP data collected were anonymised. Volunteers were allocated numbers and this coded identifier was used for the research records. None of the volunteers was named in conference presentations, and none will be named or identified in subsequent journal publications or conference papers, or in discussion with members of the research supervisory team.

6.8 Pressure redistributing surface overlays

Historically, pressure redistributing surface overlays are characterised by design, by materials in the finished product and as dynamic (alternating) or static (constant) (NPUAP, 2007). A surface overlay is defined as a specialised device or material for pressure redistribution designed to manage applied pressure, micro-climate and/or other pressure ulcer prevention and healing functions (NPUAP, 2007). Also, pressure redistribution support surfaces are defined as pressure support surfaces or overlays that minimises interface pressure from different areas of the body at regular intervals, or moulds or contours around the body, spreading the load and redistributing interface pressure over anatomical areas (NICE, 2005). The primary aim of pressure redistributing support surfaces such as mattresses, surface overlays and cushions is to relieve interface pressure so as to provide some level of cushioning to high risk parts of the body, and distribute the interface pressure more evenly. To reduce interface pressure two things ought to be done; first the area of the body in contact with the surface overlay can be increased through immersion and envelopment to protect skin tissues, and second the contact can be momentarily removed or transferred to surrounding areas by changing the area of contact over time (McInnes et al., 2015).

Pressure redistributing support surfaces that continuously change the interface pressure between a body and contact surface mechanically thereby reducing the duration of the applied pressure are called alternating pressure (AP) support surfaces, whereas those that mould around the shape of the body to distribute the body weight over a larger contact area are referred to as constant low-pressure (CLP) support surfaces, (McInnes et al., 2015). AP support surfaces are manufactured with high technological specification (popularly referred to as high-tech) and CLP support surfaces are referred to as low-tech (McInnes et al., 2015, NICE, 2005). These two categories of pressure-redistributing support surfaces are discussed in sections 6.8.1 and 6.8.2.

6.8.1 Alternating pressure (high-tech) support surfaces/overlays

Alternating pressure (AP) support surfaces which are widely used in both hospital and community settings are designed on the principle of generating alternating high and low interface pressures between body and support surface (McInnes et al., 2015, Zemp et al., 2015, Wu et al., 2015). These support surfaces aim to increase perfusion in superficial and deep tissues, which are under compression due to body weight, by redistributing interface pressure from the skin (Twiste and Rithalia, 2008). This is achieved by cyclical inflation and deflation of air-filled cells to reduce the effects of sustained interface pressure on soft tissues overlying bony prominences such as the head (Chai and Bader, 2013). The effectiveness and the efficacy of AP support surfaces depends primarily on the depth of the air-cells, the pressure within the air cells, cell inflation and deflation cycle time and the mechanical robustness of the support surface (Twiste and Rithalia, 2008). For best results, AP support surfaces must be properly inflated per the manufacturer's specification. Additionally, cell pressure within the support surface should be proportional to the weight of the user (Manzano et al., 2013, Chai and Bader, 2013). This is necessary because if the air cell pressure within the AP support surface is too high, then the surface becomes too hard, giving high interface pressures, which could in turn increase the user's risk of developing pressure ulcers (Chai and Bader, 2013). However, an AP support surface with low cell pressure will bottom out under user's weight. To ensure effective interface pressure redistribution, the rate of inflation and deflation of the air cells within the AP support surface must be identical (Demarré et al., 2012). Cycle times for inflation and deflation are on average 10-12 minutes (Demarré et al., 2012). Demarré et al. (2012) stated that a sensor must be attached to the support surface to accurately measure the pressure within the air cells at both inflation and deflation stage.

Currently, there are many new AP support surfaces on the market. These support surfaces differ significantly in their design, cost, reliability, maintenance and ease of use (Chai and Bader, 2013, Macens et al., 2011, Malbrain et al., 2010). Although all AP support surfaces work on the same principle (i.e. alternately pumps in air into air cells within the support surface at a pre-set rate and time to produce inflation of the cells, then deflate the cells also at a pre-set rate and time), there are differences in AP support surfaces. For example, there are AP support surfaces that operate on a

single, double or triple cell system, with single or multi-stage inflation and deflation of the air cells (Demarré et al., 2012, Rithalia and Gonsalkorale, 2000).

Various studies investigating the effectiveness of AP support surfaces indicated that they are useful for redistributing interface pressure, thereby reducing one's risk of developing pressure ulcers (Malbrain et al., 2010, Jans et al., 2007, Vanderwee et al., 2005, Clark, 2001, Brem et al., 2000, Phillips, 2000). However, most of these studies are outdated and were conducted among patients who are at high risk of developing pressure ulcers; hence high–quality scientific studies with rigorous methodologies supporting the notion that AP support surfaces effectively reduce the risk of developing pressure ulcers is lacking. As a consequence, the conclusion that they reduce the risk of pressure ulcer development is not based on sound empirical evidence. By contrast, some studies have failed to link AP support surfaces to a reduction in the incidence of pressure ulcers (Goossens and Rithalia, 2008, Vanderwee et al., 2008, Rithalia, 2004), clearly showing that there is lack of consensus on this topic. It must be stated that the effectiveness of AP support surfaces in reducing interface pressure and the risk of pressure ulcers development is not the focus of this thesis.

The periodic alternating changes between high and low pressures in AP support surfaces cause periodic high and low movement within the air cells. High movement occurs during inflation whereas low movements occur within the deflation stage. This means that AP support surfaces cannot be applied in medical imaging and radiotherapy planning and treatment. As indicated earlier in this thesis (section 2.15), movement during radiography and radiotherapy planning and treatment procedures could lead to errors which could have severe negative implications for patient management. For example, movement during radiotherapy treatment could lead to radiation doses missing the target tumour. The implication of this is that healthy surrounding tissues would be exposed to harmful doses of radiations. As a result, for the purposes of this intervention study, alternating pressure support surfaces have not been used as intervention. Therefore, to reduce the high interface pressures identified for the head on the X-ray table with no mattress during the first phase of this thesis, a constant low-pressure surface overlay will be considered as an intervention. This category of surface overlays is discussed in detail in section 6.8.2.

6.8.2 Constant low-pressure (low-tech) surface overlays

Constant low-pressure surface overlays are used to redistribute interface pressure by conforming to the body, thereby increasing the contact surface area between the body and a support surface (Cavicchioli and Carella, 2007). As contact area is inversely related to interface pressure (i.e. larger contact area leads to lower interface pressure), an increased contact area as a result of the surface overlay conforming to the body, will result in a decrease in interface pressure if the body weight remains constant. This could reduce the risk of tissue damage and pressure ulcers development. Constant low-pressure overlays produce static pressures and can be applied on the top of a support surface. They are filled with air, gel, foam, sheepskin, or beads, and in some instances a combination of these materials (Reddy et al., 2006). To work effectively, these surface overlays must mould to the body to maximise contact, then redistribute the body's weight as evenly as possible (Maklebust, 2005). Also, the surface overlay must be capable of deforming enough to permit body parts with prominent bony prominences to sink into the surface overlay. This is to transmit and evenly redistribute the applied pressure from one body area to surrounding tissues.

Foam, gel, and air-filled overlays form the majority of static pressure redistribution overlays used within health and social care (Miller et al., 2015, van Leen et al., 2013, Kim and Chang, 2013, Maklebust, 2005). Many years ago, standard mattress overlays made of low specification foams were deemed the gold standard of static foam pressure redistribution surfaces. It must be stated, however, that there is no international description of what constitutes a standard foam surface overlay, and, indeed, standard foam overlays varies over time between countries, hospitals, and departments (McInnes et al., 2015, Gunningberg et al., 2000). Studies have shown that high specification foams such as viscoelastic polyurethane foams, with high conformable properties are much more effective in redistributing interface pressure than standard foams (Gunningberg et al., 2000, Berthe et al., 2007, van Leen et al., 2011, Donnelly et al., 2011, Defloor and De Schuijmer, 2000). As a result, these studies have recommended the use of viscoelastic foams in health and social care settings.

The National Pressure Ulcer Advisory Panel (NPUAP, 2007) of the US defined viscoelastic foam as a porous polymer material that conforms to the body in proportion to the applied weight. Viscoelastic foam overlays are made of polyurethane foam, and have elastic properties that enable them to mould almost perfectly to the body anatomy, providing the needed conformity to redistribute interface pressure (Woodford, 2016, Freeto et al., 2016, Haesler, 2014). It must be stated that viscoelastic properties are also found in gel surface overlays. Viscoelastic gel-filled surface overlays reduce shear and supports weight without bottoming out. Most are self-sealing if punctured and can be reused. However, gel does not deform easily and may become stiff over time. Most viscoelastic gel-filled surface overlays require sealed covers. These surface overlays are called viscoelastic because of their ability to resist applied pressure, and their ability to return to their original state when the applied pressure is removed (Clancy, 2013, Wu et al., 2011). These two properties – high viscosity and elasticity – are vital in pressure redistribution because they enable the body weight to be evenly spread across large surface area without the foam deforming under the weight of the body. According to Engels et al. (2013), polyurethane viscoelastic surface overlays are made of very wide-ranging, modular-like polymer cells, providing soft but firm cushioning to body weight.

Although most studies recommend the use of viscoelastic pressure redistribution surface overlays, there is little empirical evidence available regarding the pressure reducing characteristics of these overlays. Also, there is very little evidence illustrating the magnitude of interface pressure reduction when viscoelastic surface overlays are used. The recommendation therefore that viscoelastic surface overlays effectively redistribute interface pressure, thereby reducing one's risk of developing pressure ulcers is based primarily on expert opinion, and on the belief that the use of such overlay will provide some level of padding to the body, relieves pressure and prevents pressure ulcers (King and Bridges, 2006).

Air-filled static low-pressure surface overlays are also widely used pressure redistribution devices among patients in hospitals and care settings. Air-filled surface overlays have multiple air chambers that easily allow air to flow between cells when a person lies on the surface overlay (Moody et al., 2004). The air exchange between cells allows the surface to deform and permits the body to sink into the surface,

reducing interface pressure on the skin. These surface overlays provide effective immersion and envelopment of anatomical areas especially prominent bony structures (Heyneman et al., 2009, Trewartha and Stiller, 2011). This results in better contact of the surface overlay over a larger skin area, resulting in an even redistribution of the applied pressure. The implication of this is that, the skin is exposed to reduced interface pressure, and this could consequently reduce the risk of tissue damage.

In summary, there are two main types of air-filled surface overlays; those that come with pre-filled air volume (i.e. the volume of air cannot be adjusted) and those that must be pumped up (Moody et al., 2004, Nemunaitis et al., 2015, McGinnis and Stubbs, 2014). In the latter ones, the volume of air can be adjusted to the body weight of the individual. To ensure adequate air volume within the surface overlay, inflation or deflation devices are used. To ensure effective pressure redistribution, the surface overlay must not be filled with too much air. In order words, it must not be pumped too hard because when that happens, the surface overlay becomes too hard and may not effectively redistribute pressure (McGinnis and Stubbs, 2014). To avoid this, some air-filled surface overlays are fitted with an inflation valve to prevent over and under inflation. It is important to ensure that the inflation valve works properly as an improperly inflated surface overlay will not effectively redistribute interface pressure. When this happens, the main reason of using the surface overlay (i.e. protect the body from the underlying surface) will be defeated. This could expose the patient to the risk of skin tissue damage which might lead to developing pressure ulcers.

For the purposes of this intervention study, different static low-pressure surface overlays were sought. These surface overlays were drawn from the three main types (i.e. foam, gel, and air), from different manufacturers within and outside the UK. This was necessary to provide a broad range of surface overlays from which a suitable one was selected to be used as an intervention.

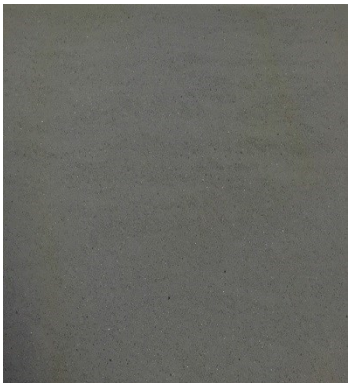
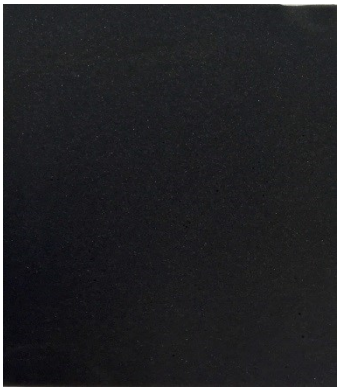
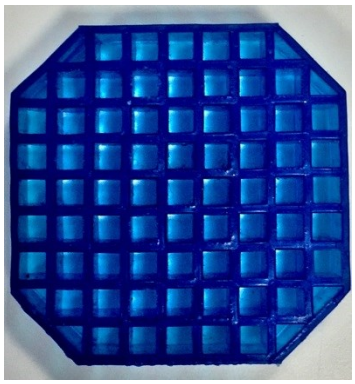
6.9 Radiation tests

6.9.1 Aim of radiation tests

The main aim of the radiation tests was to assess which of the pressure redistribution surface overlays had the least impact on radiation dose attenuation and image quality. This was necessary because to apply such an intervention in interventional radiography, radiotherapy planning and treatment, the intervention should be radiolucent, and also should not have a significant impact on radiation dose attenuation. This is vital because any significant reduction in radiation dose would mean less radiation will be reaching the detector which may result in diagnostically unacceptable images. Also, the impact of each surface overlay on image quality was assessed. To achieve these aims, the radiation tests were conducted in three parts. First a dosimetry test which involved assessing the impact of each surface on radiation attenuation. The second part assessed the impact of each surface overlay on image quality, and the last part involved CT scanning of each surface overlay. This provided a detailed visualisation of the internal three-dimensional structure of each surface overlay. The information from the CT images was used to calculate the Hounsfield unit. In other words, the information from the CT images allowed the linear attenuation coefficient of each surface overlay to be assessed.

Following extensive searching and contact with clinicians, tissue viability nurses, occupational therapists, manufacturers and distributors of pressure redistribution surface overlays, nine constant pressure redistribution surface overlays were identified. These surface overlays are illustrated in Table 6.1.

Table 6.1: The nine constant pressure redistribution surface overlays

 Gel table/Hip Pad	 Silicone Gel Flat Pad	 Grade Rf40 145 foam
 Repose air cushion	 Waffle original air cushion	 Foam
 Blue hollow surface	 Sundance SUN Z3-S	 Small round gel

These surface overlays were drawn from the three main types of pressure redistribution surface overlays (i.e. foam, gel, and air). The physical characteristics of these surface overlays are indicated in the Table 6.2.

Table 6.2: Physical characteristics of the surface overlays

Name	Material	Dimension (L x W x T in cm)*	Weight (kg)
Gel table/Hip Pad	gel	45 x 45 x 1.4	3.4
Silicone Gel Flat Pad	silicone gel	45 x 45 x 0.7	1.4
Grade Rf40 145 foam	foam	35 x35 x 1.1	<0.09
Repose air cushion	air	30 x 27 x 1.8	N/A**
Waffle cushion	air	35 x 35 x 1.5	0.2
Foam	foam	30 x 22 x 1.2	<0.09
Blue hollow overlay	elastic	6 x 6 x 1.6	<0.09
Sundance SUN Z3-S	fluidised	18 x 18 x 1.7	0.2
Small round gel	gel	8.5 x 8.5 x 0.6	<0.09

*L = length, W = width, T = thickness.

**N/A implies surface overlay recorded no weight on the scale

6.9.2 Dosimetry test

The X2 R/F dosimeter was used to assess the impact of each surface overlay on radiation dose attenuation. The X2 R/F dosimeter (Figure 6:1) is a modern equipment fitted with high sensor technology that ensures accurate measurement of radiation dose. Manufacturers' specifications indicated that the dosimeter weighs 42 grams, and has the following physical dimension: 14 x 22 x 79 mm. The dosimeter has a dose range of 40-150 kVp, and can detect dose from 1 nGy to 9999 Gy, with an accuracy of ±5% of calibrated values. The X2 R/F dosimeter has the ability to measure dose rate, kVp, HVL, total filtration, exposure time, pulses, pulse rate and dose/pulse in one exposure.

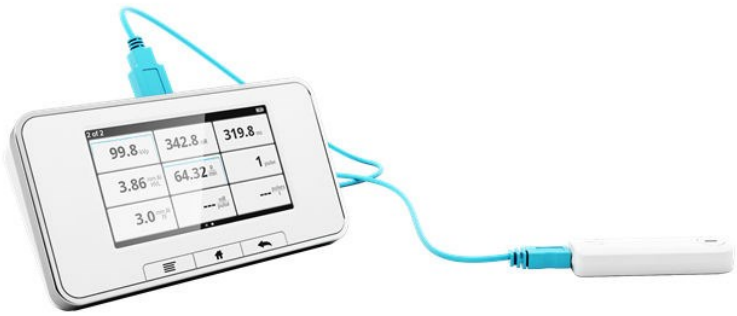


Figure 6:1: X2 R/F dosimeter

The method used for this dosimetry test involved placing the X2 R/F dosimeter on an X-ray table. The radiation field was tightly collimated to the edges of the dosimeter. Using a standard 100 cm source to image-receptor distance (SID), three exposures were made at both high kilovoltage (kV) (75kV, 2 mAs) and low kV (50kV, 2 mAs) with a fine focal spot. The average recorded dose for high and low kV were 37.28 and 10.72 mGy, respectively. These values served as the control. To assess the impact of each surface overlay on radiation dose attenuation, each surface overlay was placed on the dosimeter. Three exposures were made using the same exposure parameters as the control. The mean recorded dose for each surface overlay and the percentage difference from the control at low and high kVs are reported in Table 6.3 and Table 6.4 respectively.

Mean recorded dose for control at 50 kV 2mAs is **10.74 mGy**

Table 6.3: Mean recorded dose at low kV and percentage decrease

Surface overlay	Mean dose in mGy at low kV	Percentage decrease (%)
Gel table/Hip Pad	8.22	23.46
Silicone Gel Flat Pad	9.63	10.34
Grade Rf40 145 foam	10.64	0.93
Repose cushion	10.68	0.56
Waffle original cushions	9.72	9.50
Foam	10.71	0.28
Blue hollow overlay	10.26	4.47
Sundance SUN Z3-S	7.84	27.00
Small round gel	9.66	10.06

Mean recorded dose for control at 75 kV 2mAs is **37.28 mGy**

Table 6.4: Mean recorded dose at high kV and percentage decrease

Surface overlay	Mean dose in mGy at high kV	Percentage decrease (%)
Gel table/Hip Pad	32.06	14.00
Silicone Gel Flat Pad	34.22	8.21
Grade Rf40 145 foam	37.16	0.32
Repose cushion	37.18	0.27
Waffle original cushions	34.39	7.75
Foam	37.20	0.21
Blue hollow overlay	35.05	5.98
Sundance SUN Z3-S	29.95	19.66
Small round gel	34.29	8.02

The second part of this dosimetry test involved assessing the impact of each surface overlay for image quality. Each pressure redistribution surface overlay was placed on a 17x14 inch Aero digital radiography (DR) cassette. An adult hand anthropomorphic phantom weighing 0.79 kg and 23 cm long was placed in the middle of the surface overlay on the cassette. The radiation field was collimated to an area of 20 x 25 cm. Using an SID of 100 cm, two exposures were made at high kV (120 kV, 1.2 mAs), and low kV (60 kV, 1.2 mAs) using fine focus. Fine focus was used to enhance visualisation of fine detail (Whitley et al., 2005). This is congruent to imaging extremities such as the hand in the clinical setting. The hand phantom was then removed and another set of two exposures were taken using the same high and low kV exposure factors. In all, four exposures were taken for each surface overlay – two with the hand phantom placed on the surface overlay at high and low kVs, and another two with just the surface overlay placed on the cassette, also at high and low kVs. The images were obtained and processed on AeroDR system (Konica Minolta, Inc.) and its workstation and exposure-monitoring quality-assurance software. This software allowed automatic storage of the exposure index for every image. The acquired radiographic images are presented in Table 6.5 –Table 6.13.

Table 6.5: Radiograph of the gel table/hip pad at high and low kVs with and without adult anthropomorphic hand phantom

			
High kV	Low kV	High kV with hand	Low kV with hand

Table 6.6: Radiograph of the silicone gel flat pad at high and low kVs with and without adult anthropomorphic hand phantom

			
High kV	Low kV	High kV with hand	Low kV with hand

Table 6.7: Radiograph of the grade Rf40 145 foam at high and low kVs with and without adult anthropomorphic hand phantom

			
High kV	Low kV	High kV with hand	Low kV with hand

Table 6.8: Radiograph of the repose air cushion at high and low kVs with and without adult anthropomorphic hand phantom

			
High kV	Low kV	High kV with hand	Low kV with hand

Table 6.9: Radiograph of the waffle air cushion at high and low kVs with and without adult anthropomorphic hand phantom

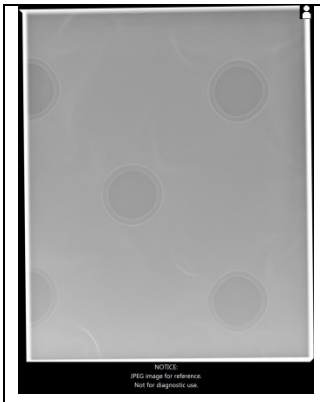
			
High kV	Low kV	High kV with hand	Low kV with hand

Table 6.10: Radiograph of the foam at high and low kVs with and without adult anthropomorphic hand phantom

			
High kV	Low kV	High kV with hand	Low kV with hand

Table 6.11: Radiograph of the blue hollow gel overlay at high and low kVs with and without adult anthropomorphic hand phantom

			
High kV	Low kV	High kV with hand	Low kV with hand

Table 6.12: Radiograph of the Sundance SUN Z3-S fluidised positioner at high and low kVs with and without adult anthropomorphic hand phantom

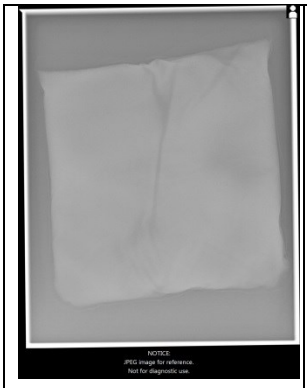
			
High kV	Low kV	High kV with hand	Low kV with hand

Table 6.13: Radiograph of the small round gel at high and low kVs with and without adult anthropomorphic hand phantom

			
High kV	Low kV	High kV with hand	Low kV with hand

From the hand radiographic images produced with the surface overlays at high and low kVs, a table was produced indicating which of the surface overlays produced artefacts on the hand radiograph. This information is illustrated in Table 6.14.

Table 6.14: Table indicating whether an artefact was present when the hand phantom was x-rayed with the various surface overlays

Surface overlay	Artefact present
Gel table/Hip Pad	Yes
Silicone Gel Flat Pad	No
Grade Rf40 145 foam	No
Repose air cushion	No
Waffle original cushions	Yes
Foam	No
Blue hollow overlay	Yes
Sundance SUN Z3-S	Yes
Small round gel	Yes

To objectively determine the amount of radiation incident on the detector when the various pressure redistribution surface overlays were used, the exposure index (EI) and the deviation index (DI) of each of the radiographs with the hand phantom were assessed. This was necessary because low energy photons will be absorbed as they pass through the part being irradiated (in this case the hand phantom) and the surface overlay (Whitley et al., 2005). The EI is an international standard to measure the radiation exposure to a digital detector (Shepard et al., 2009). EI gives an indication of the amount of radiation exposure on a digital image receptor. A target exposure index (TI) value is set by the manufacturer for each examination, and it is different for each anatomical part (Cohen et al., 2011). The TI is also affected by equipment characteristics such as filtration, and sensitivity of detector plate (Takaki et al., 2016). The manufacturer of the X-ray machine used for this experiment has set the TI for the hand at 250 µGy. The deviation index (DI) calculates the difference between a desired TI and the actual exposure (Mothiram et al., 2014). DI estimates how much the actual EI varies from the TI (Don et al., 2012). In the perfect situation (i.e. if EI and TI are the same), DI will be zero. Because the radiographs were

acquired using a digital radiography (DR) system, the system has the ability to assess the impact each surface overlay had on attenuating the beam as it passes through it. This is reflected in the amount of radiation incident on the digital detector plate. These numbers are illustrated in Table 6.15.

Table 6.15: Exposure and deviation indices for the surface overlays at high and low kVs

	High kV (120, 1.2 mAs)	Low kV (60, 1.2 mAs)
Control	EI – 2940.10 TI – 250 DI – 10.70	EI – 224.47 TI – 250 DI – -0.46
Gel table/Hip Pad	EI – 2705.38 TI – 250 DI – 10.34	EI – 195.26 TI – 250 DI – -1.07
Silicone Gel Flat Pad	EI – 2926.91 TI – 250 DI – 10.68	EI – 213.16 TI – 250 DI – -0.69
Grade Rf40 145 foam	EI – 3075.34 TI – 250 DI – 10.89	EI – 241.76 TI – 250 DI – -0.14
Repose air cushion	EI – 2881.20 TI – 250 DI – 10.61	EI – 227.52 TI – 250 DI – -0.40
Waffle air cushions	EI – 2785.64 TI – 250 DI – 10.46	EI – 202.41 TI – 250 DI – -0.91
Foam	EI – 3089.20 TI – 250 DI – 10.91	EI – 2241.76 TI – 250 DI – -0.14
Blue hollow surface	EI – 2842.58 TI – 250 DI – 10.55	EI – 207.48 TI – 250 DI – -0.80
Sundance SUN Z3-S	EI – 2773.14 TI – 250 DI – 10.45	EI – 197.91 TI – 250 DI – -1.01
Small round gel	EI – 3020.51 TI – 250 DI – 10.82	EI – 222.46 TI – 250 DI – -0.50

EI, TI and DI all in units of Microgray (μGy)

The third and final stage of the radiation test involved assessing the density of the various surface overlays to evaluate their Hounsfield unit (HU) measurements. This was important because surface overlays with higher HU will absorb more X-rays, thereby reducing the quality of the radiation reaching a detector (Pauwels et al., 2015). The HU of a surface overlay is defined as a standardised linear attenuation coefficient of that surface overlay that represents the density of the surface overlay (Johnson et al., 2016, Loveless et al., 2015). HU are linear transformations of measured X-ray attenuation coefficients of a surface overlay with reference to water (Johnson et al., 2016, Razi et al., 2014). HU scale is based on the HU value for water and air; which has a HU value of 0 and -1000, respectively (Johnson et al., 2016, Pauwels et al., 2015, Spettel et al., 2013).

To determine the HU of each surface overlay, unenhanced CT of each surface overlay was performed without contrast using a 16 slice multi-detector CT scanner (Toshiba Medical Systems, Japan). Manufacturer's specification indicated that the scanner is capable of sequential and helical scanning and reconstruction, producing high quality, essentially artefact-free images, at dose levels which are as low as reasonably practicable. Literature suggests that the linear attenuation coefficient of a material can be determined by using diagnostic CT scans to measure HU (Johnson et al., 2016, Boomsma et al., 2015, Pauwels et al., 2015, Zurl et al., 2014, Lamba et al., 2014, Ruder et al., 2012).

To calculate the mean HU of each surface overlay, an area corresponding to a number of pixels was chosen depending on the length and thickness of the surface overlay. For example, when calculating the HU for the silicone gel flat pad (surface 2), 12 areas of 0.2 cm^2 (averaging 40 pixels) were chosen. The HU for each area was calculated and the mean HU for the entire silicone gel surface overlay was calculated. This procedure was replicated to calculate the HU for the other surface overlays. However, due to the differences in length and thickness, the number of circles and the area used to calculate the HU for each surface overlay were different. The procedure used to calculate the mean HU for the silicone gel surface overlay and the foam surface overlay are illustrated in Figure 6:2 and Figure 6:3 respectively.

Figure 6:2: A CT image showing how the mean Hounsfield unit (HU) for the silicone gel overlay was calculated

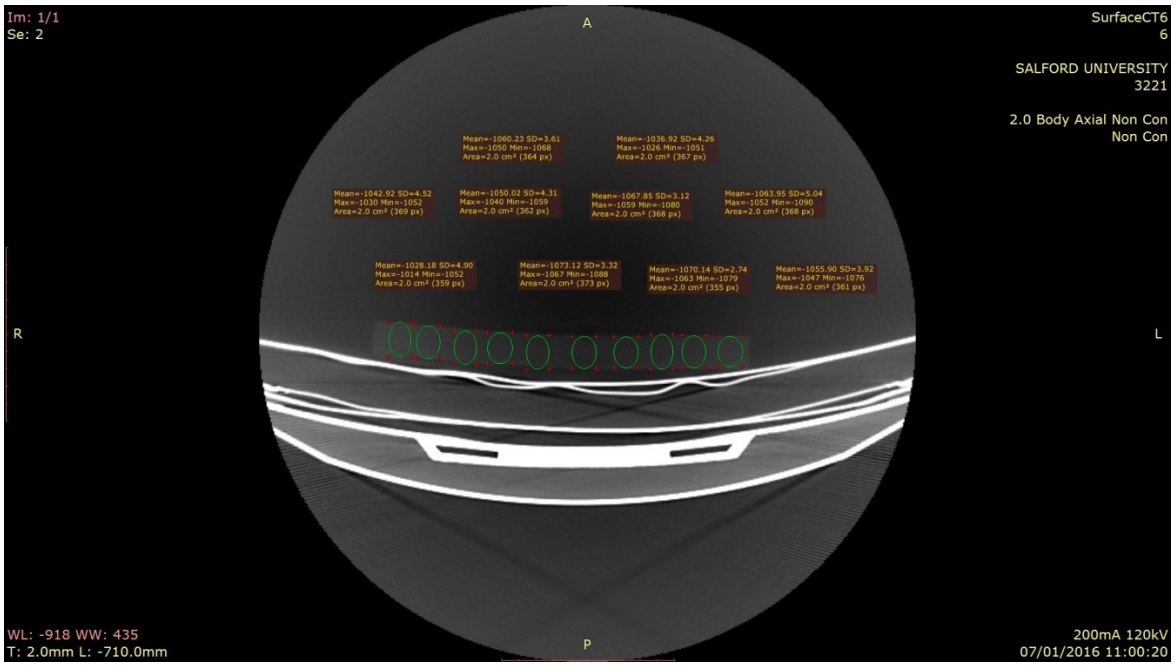


Figure 6:3: A CT image showing how the mean Hounsfield unit (HU) for the foam was calculated

The recorded mean HU and standard deviation (SD) of the surface overlays are presented in Table 6.16.

Table 6.16: The mean Hounsfield unit (HU) with standard deviation (SD) for the various surface overlays

Surface No	Surface overlay	Mean HU and SD
1	Gel table/Hip Pad	-0.67 ± 22.93
2	Silicone Gel Flat Pad	-12.54 ± 26.80
3	Grade Rf40 145 foam	-1010.45 ± 22.80
5	Waffle air cushions	-1058.20 ± 26.34
6	Foam	-1054.92 ± 14.31
7	Blue hollow surface	-508.96 ± 37.93
8	Sundance SUN Z3-S	-630.32 ± 22.11
9	Small round gel	-18.17 ± 7.06

6.9.3 Conclusion of radiation tests

The main aim of conducting the radiation tests was to assess out of the nine surface overlays, the best intervention that could be used to reduce the high interface pressure identified in the baseline study (phase one of the thesis). The intervention ought to be able to be used during interventional radiography and radiotherapy planning and treatment procedures. Due to this, the intervention should have little or no impact on image quality and radiation attenuation. Because of the need of such an intervention to be applicable in radiotherapy, the foam and air surface overlays used for this radiation test were not chosen as a possible intervention for the second phase of this thesis. This was because foam and air-filled overlays did not provide a solid firm support that is required during radiotherapy planning and treatment procedures. Foams and air-filled overlays have the tendency to squeeze and sometimes collapse under patient weight. This can induce movement during radiotherapy planning and treatment procedures. During radiotherapy treatment procedure, patients are positioned to replicate patient position during the planning. It is important that there is no difference between patient positon pre-treatment and during treatment because patient positioning is an essential factor that determines the success of any radiotherapy treatment. For example, differences between pre-

treatment and during treatment may result in wrong tumour delineation and subsequently may result in misdirecting prescribed radiation doses to wrong organs.

The thick gel table/hip pad surface overlay (surface 1) was also rejected for the purposes of this intervention study because as shown in Table 6.5 and Table 6.14, this surface overlay produced artefacts on the radiographic images. If this happens in the clinical setting, it could affect the diagnostic quality of radiographic images. Also, this surface overlay recorded a much greater impact on radiation dose attenuation. This was reflected in the bigger differences between its EI (2705.38) and DI (10.34) at high kVp and EI (195.26) and DI (-1.07) all in µGy at low kVp compared to the control [EI (2940.10), DI (10.70)] and [EI (224.47), DI (-0.46)] for high and low kVp respectively. Finally, as shown in Figure 6:4, the CT scan of this surface overlay showed significant heterogeneity within its internal structures making it unsuitable to be applied in radiotherapy.

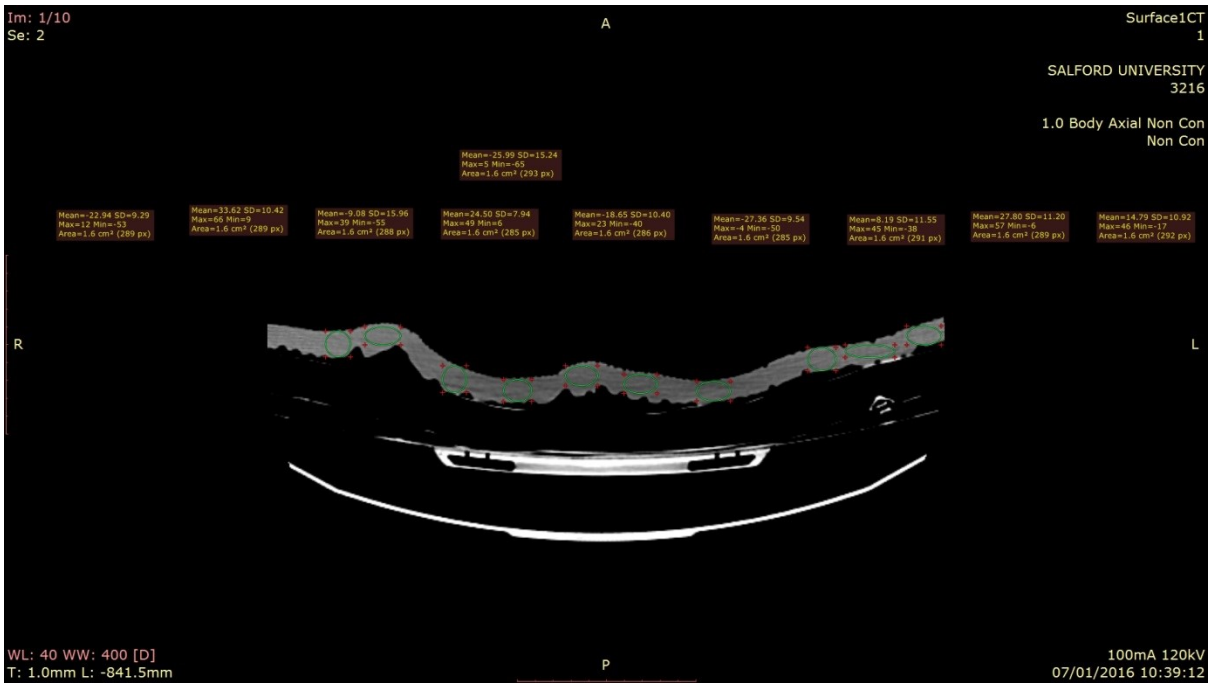


Figure 6:4: A CT image of the thick gel surface overlay showing massive heterogeneity in its internal structures

The results from the radiation tests have shown that the thin silicone gel flat pad (surface 2) is the best suited intervention for this intervention experiment. This surface overlay provided a stable firm solid support that can support patients of varying weights without any noticeable movement. It is thin with a thickness of 0.7 cm. The implication of this very small thickness is that it is not likely to cause magnification in diagnostic images. The dosimetry test indicated that the silicone gel flat pad had little impact on dose attenuation, causing only about 9.3% reduction in radiation dose at both high and low kVs compared to 23.3% of the Sundance SUN Z3-S surface overlay. The idea that the silicone gel flat pad has little impact on radiation dose attenuation was further supported by the results of the exposure index (EI) and deviation index (DI). As stated earlier in Table 6.15, the silicone gel surface overlay recorded an EI of 2926.9 and a DI of 10.68 µGy at high kVp (120, 1.2 mAs), and an EI of 213.16 and DI of -0.69 µGy at low kVp (60, 1.2 mAs). These values were similar to those recorded for the control which recorded an EI value of 2940.10 and DI of 10.70 µGy at high kVp, and an EI of 224.47 and DI of -0.46 µGy at low kVp. Additionally, the thin silicone gel flat pad had no negative impact on diagnostic quality. At both high and low kVp parameters, the hand radiograph produced using the silicone gel pad was free from artefacts, making the image diagnostically acceptable. Consequently, for the purposes of this intervention study, the thin silicone gel flat pad surface overlay was used as an intervention. The impact of such an intervention on reducing the high interface pressure identified for the head was assessed. A summary table highlighting the reasons why the various surface overlays were accepted or rejected are illustrated in Table 6.17.

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Table 6.17: A summary table highlighting the reasons why the various surfaces overlays were accepted or rejected.

Surface overlay	Status	Reason(s)
Gel table/Hip Pad	Rejected	• Produced artefact • Significant impact on radiation dose attenuation • High linear attenuation coefficient • Significant heterogeneity within its internal structures
Silicone Gel Flat Pad	Accepted	• No artefact • Minimal impact on radiation dose attenuation • Low linear attenuation coefficient • Fairly homogenous internal structures
Grade Rf40 145 foam	Rejected	• Foam not applicable for radiotherapy planning and treatment
Repose air cushion	Rejected	• Air-based cushion not applicable for radiotherapy planning and treatment
Waffle original cushions	Rejected	• Air-based cushion not applicable for radiotherapy planning and treatment
Foam	Rejected	• Foam not applicable for radiotherapy planning and treatment
Blue hollow overlay	Rejected	• Produced artefact
Sundance SUN Z3-S	Rejected	• Produced artefact • Significant impact on radiation dose attenuation • High linear attenuation
Small round gel	Rejected	• Produced artefact • Significant impact on radiation dose attenuation

6.10 Method for the intervention study

6.10.1 Sample size calculation

A priori power analysis was calculated to determine the appropriate sample size required for the intervention study. Power analysis as indicated previously is defined as the statistical method of determining the appropriate sample size needed to make the findings of a particular experiment statistically resolute (Field, 2013, Bowling, 2009). When the mean IP for the head was compared across the three medical imaging and radiotherapy surfaces, the results indicated a large partial eta squared effect size of 0.67. This effect size figure was used to conduct a power analysis using the GPower computer software. As indicated before, the GPower software has been shown to have excellent accuracy and has been used in sample size calculations for many studies (Faul et al., 2009, Cunningham and McCrum-Gardner, 2007). The results from the power analysis showed that a sample of 20 volunteers would be needed to determine a large effect, 0.67 with 80% power, using a two tailed repeated measures paired samples t-tests between means with alpha at 0.05 as shown in Figure 6:5.

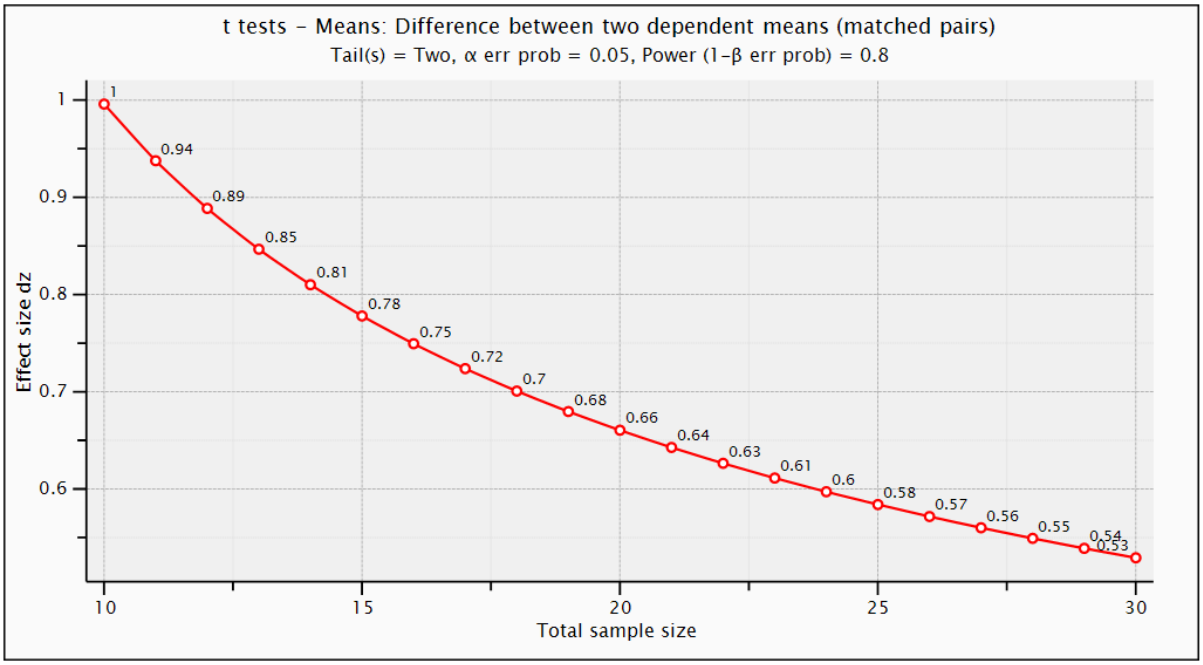


Figure 6:5: Results of power analysis indicating the sample size for the intervention study

6.10.2 Sampling

In recruiting the 20 volunteers, a disproportionate stratified random sampling method was used. The volunteers include students and staff of the University of Salford. Disproportionate stratified random sampling method was chosen because it enabled the researcher to recruit volunteers from diverse ethnic groupings, different age groups and a range of BMI. This was necessary because as this intervention study was seeking to minimise the high IP risk identified in the baseline study, it is important that the volunteers had similar characteristics to those that participated in the baseline study so that the findings can be compared. Also, it was important to include volunteers from different ethnicities and age groups so that findings of this intervention study can be generalised to the wider healthy adult population.

6.10.3 Inclusion and exclusion criteria

The volunteers for this intervention involved only healthy adults 18 years and older. As stated in the baseline study, for the purposes of this thesis, a healthy volunteer is defined as any individual who could lie still for the entire duration of pressure mapping without any serious difficulty. In this case, the duration of lying down was six minutes (two minutes for pressure mapping after six minutes settling time). The use of healthy adults is consistent with the volunteers involved in the baseline study as well as other clinical and academic IP studies (Miller et al., 2014, Peterson et al., 2010, Stinson et al., 2003a, Stinson et al., 2002, Justham et al., 1996). Also, only adults were included in this intervention study because of the reasons stated in chapter three section 3.9. Apart from one, all the exclusion criteria used for the baseline study (chapter three section 3.9) were also applied for the intervention study. The one exception was the criterion that volunteers with a height of 190 cm or more were excluded from the baseline study due to the limitations of the whole body pressure mat. This criterion did not apply for the intervention study because the pressure mapping was conducted for only the head, hence a smaller Xsensor pressure mat was used for the experiment. As a result, volunteers taller than 190 cm can were allowed to participate in the study.

6.10.4 Xsensor pressure mapping equipment/technology

For this intervention study, the PX100.100.100.05 Xsensor pressure mat was used to conduct the experiment. This pressure mat was much smaller than the whole body mat used in the baseline study making it suitable for pressure mapping of the head. This pressure mat was designed as a conformable, flexible, and durable mat with highly sensitive sensors for measuring IPs in medical applications such as assessing the IP distribution among wheelchair users (Sumed International, 2014). According to the manufacturers, the pressure mat had a total area and a sensing area of 68.5cm x 68.5cm and 50.8cm x 50.8cm, respectively (Sumed International, 2014). The sensing area is defined as the area of the pressure mat that is fitted with sensors, and has the ability to record, save and transmit IP values onto a handheld support surface or a computer fitted with the Xsensor software. This pressure mat is fitted with 10,000 sensing points.

Manufacturer's specification also indicated that the pressure mat had an accuracy rate of ±10% of the calibrated values, sampling frame rate of 15.8 per second, and a spatial resolution of 0.51cm. This high spatial resolution was useful for this intervention study because it enabled for peak pressure index (PPI) for the head to be calculated because more sensors are packed within a small area, compared to the pressure mat used to conduct the baseline study. As indicated in the baseline study (section 4.7), PPI for the head could not be calculated because the number of sensors activated by the head was less than the 3x3 data matrix required. This could be attributed to the wider spatial resolution of that pressure mat (Gyi et al., 1998). Apart from the differences in the physical characteristics of the pressure mat that was used to conduct this intervention study, it has similar performance, electrical and piezoelectric properties to the one used in the baseline study. These properties have been discussed in chapter three section 3.10.1.

6.10.5 Procedure for pressure mapping

The recruitment strategy used for this intervention study was similar to the one used in the baseline study. Volunteers who were willing to participate in this study were asked to contact the researcher through email and telephone. The volunteers who expressed an interest in participating in the study were then sent the participants' information sheet (appendix 11) through an email. The participant information sheet contained thorough information about the intervention study. It was made clear in the information sheet that potential volunteers can get in touch with the researcher to ask questions and seek for clarifications where necessary. Appointments were made with volunteers who agreed to participate in the study. On the mutually convenient date, the opportunity was provided for each volunteer to ask questions and responses provided, after which each volunteer was screened to ensure that he/she met the inclusion criteria of the study. Those who did were requested to sign a consent form (appendix 12). Records of these are kept in a locked cabinet, and can only be accessed by the researcher and members of the research supervisory team.

The Xsensor mat was placed in the middle of the imaging table and securely fixed to the surface. The mat was then connected via the sensor connecting packs to the Xsensor handheld display system. Volunteers were asked to gently lie on the pressure mat in a position similar to the one used for the baseline study. The room temperature was 17 ˚C, similar to that of the baseline study. The volunteers were then asked to lie very still. The volunteer was informed and pressure mapping was started. During pressure mapping, the researcher observed directly the volunteer to ensure that there was no movement. Also, access to the imaging room was restricted to ensure volunteers' privacy, and also to avoid any distraction. Pressure measurements were taken for two minutes (after six minutes settling time) at one frame per second on the X-ray table without the intervention. This served as the control. The handheld Xsensor device was programmed to automatically start acquiring pressure data after the six minutes settling time, and stop collecting data after the two minutes pressure measurement time.

After this, the volunteer was helped off the X-ray table, the thin silicone gel surface over placed under the pressure mat for the second part of data collection. The interface pressure data was saved onto an in-built memory card. At the end of data collection each volunteer was helped off the X-ray table and that concludes the data collection for that volunteer. After each volunteer, the researcher removed the silicone gel surface overlay, taped the pressure mat back onto the X-ray table, and checked to ensure that the mat was correctly positioned, crease free, and then gets ready for the next volunteer. To ensure high levels of infection control and hygiene, the pressure mat was cleaned in between volunteers using wet wipes as recommended by the manufacturer. To preserve and maintain the Xsensor in good working condition, at the end of each day, the Xsensor was packed into its case as per the manufacturer's instructions, and kept safely at the imaging lab.

6.10.6 Proposed statistical tests

The statistical procedure that was used in this intervention study is summarised in figure 6.6.

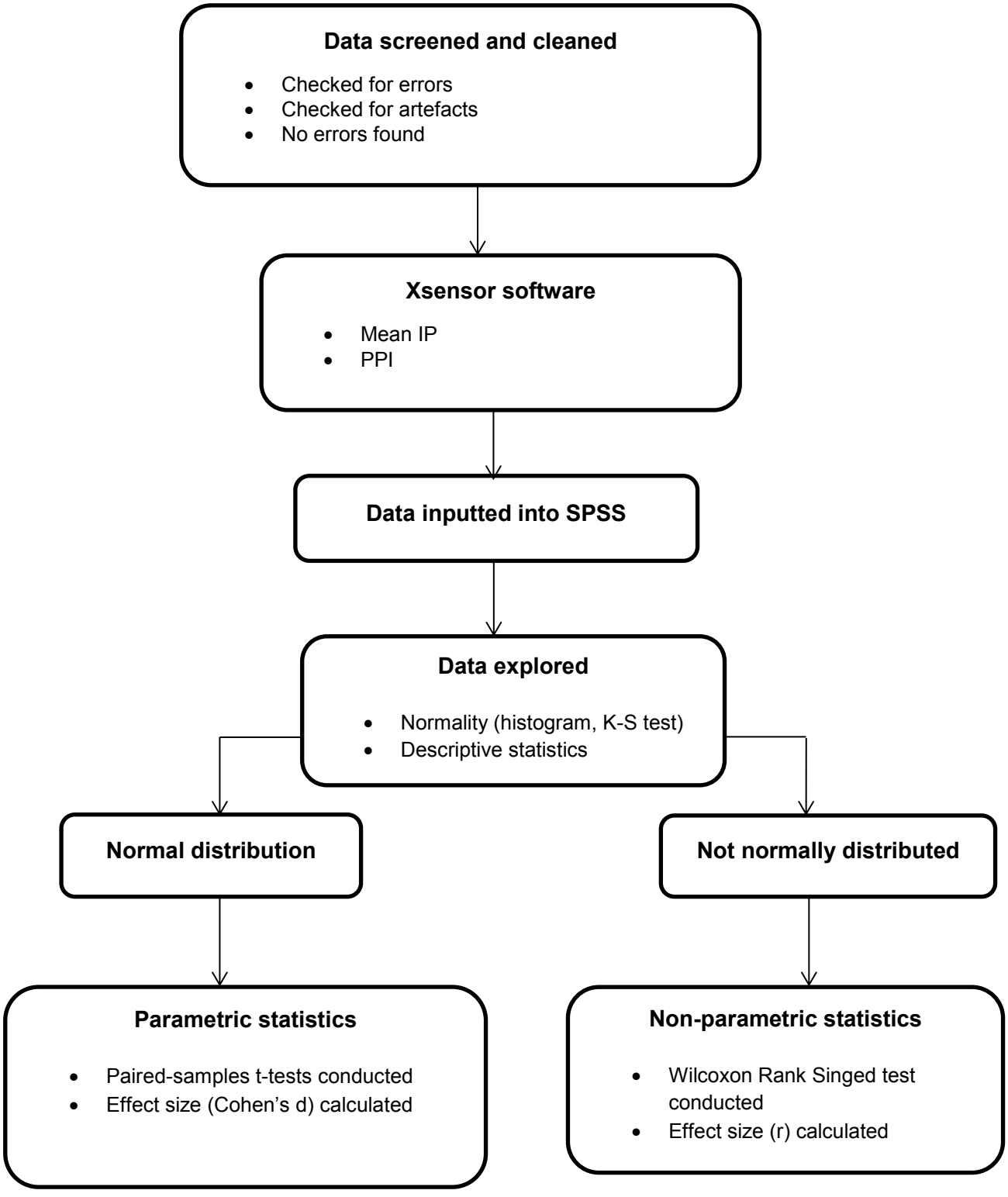


Figure 6.6: The statistical procedure used in the intervention study

The pressure mapping data for all the volunteers was screened to eliminate errors. This was essential because frames affected by errors such as artefacts would produce wrong results and would have invalidated the findings. The Xsensor X3 medical software version six was used to calculate the mean and PPI values of the head on the radiotherapy table with and without the gel surface overlay. The mean IP was achieved by merging all the frames and then the mean was calculated. The PPI was calculated per the procedure outlined in chapter three section 3.15.1. The values from the Xsensor X3 medical software were imputed into SPSS version 22 (IBM Corp, Armonk, NY) for analysis. Prior to statistical analysis, descriptive statistics were used to describe the sample and IP data. Frequencies (percentages) were used to describe the gender of the volunteers whereas mean, standard deviation, minimum, and maximum were used to describe volunteers' age, BMI, mean IP and PPI. Also, normal distribution of the data was assessed visually and objectively using the frequency distribution (histogram) and Kolmogorov-Smirnov (K-S) tests, respectively. See chapter three section 3.15.2 for justification of K-S tests.

To test the hypotheses and make definitive conclusions, inferential statistics were conducted. As indicated in figure 6.6, because the data was normally distributed, parametric paired-samples t-tests were used to compare the means of the mean IP and mean PPI for head on the radiotherapy table with and without the thin gel surface overlay. As the results indicated statistically significant differences between the two means, post-hoc Cohen's *d* was calculated to assess the magnitude of the difference between the two means. Cohen's *d* was calculated using the formula below:

$$d = \frac{M1 - M2}{SDpooled}, \text{ where } SDpooled = \sqrt{\frac{[(N1-1)SD1^2 + (N2-1)SD2^2]}{(N1+N2-2)}}, \text{ (Field, 2013)}$$

M1 = mean IP for the head on the radiotherapy table without the gel surface overlay

M2 = mean IP for the head on the radiotherapy table with the gel surface overlay

N1=N2 = sample size = 20

SD1 = SD of mean IP for the head on the radiotherapy table without the gel surface overlay

SD2 = SD of mean IP for the head on the radiotherapy table with the gel surface overlay

Cohen's classification of effect sizes for paired-samples t-tests (0.1 – small, 0.5 – medium, and 0.8 – large) was used to interpret the effect size results (Cohen, 1988).

6.11 Results of the intervention study

The sample comprised 14 males (70%) and six females (30%), with an age range of 25 to 53 years (mean=34.35, SD=7.03) and body mass Index (BMI) range of 20.8 to 34.6 (mean= 27.1, SD=4.9). Results from normality tests indicated normal distribution of the data because all the four variables (mean IP for head on the radiotherapy table with and without the gel surface overlay, and the mean PPI for head on the radiotherapy table with and without the gel surface overlay) have non-significant p-values ($p>0.05$). Consequently, parametric paired samples t-tests were conducted.

The results of the paired-samples t-test indicated that there was a statistically significant difference between the mean IP for the head on the radiotherapy table without the gel surface overlay (Mean=83.88, SD=8.15), and the radiotherapy table with the gel surface overlay (Mean=62.36, SD=6.06), $t(19)=14.47$, $p\leq0.001$. The mean IP difference was 21.52 with a 95% confidence interval ranging from 18.41 to 24.63, and a large effect size, $d = 2.99$. This large difference resulted in a 25.7% reduction in mean IP for the head.

The results of the paired-samples t-test indicated that there was a statistically significant difference between the mean PPI for the head on the radiotherapy table without the gel surface overlay (Mean=205.05, SD=28.23), and the radiotherapy table with the gel surface overlay (Mean=159.76, SD=26.80), $t(19)=5.50$, $p\leq0.001$. The mean PPI difference was 45.29 with a 95% confidence interval ranging from 28.07 to 62.51, and a large effect size, $d = 1.65$. This large difference resulted in a 22.1% reduction in mean PPI for the head.

6.12 Discussion of the results of the intervention study

As hypothesised, the results of the intervention study of this thesis indicated that the use of the thin silicone gel surface overlay resulted in a lower mean interface pressure for the head (62.36±6.06 mmHg) compared to the mean interface pressure for the head without the intervention (83.88±8.15 mmHg). This reduction resulted in a statistically significant difference between the two conditions, $p \leq 0.001$. Similarly, the mean peak pressure index (PPI) recorded for the head reduced from 205.05±28.23 mmHg when the volunteers laid on the X-ray table without the gel intervention to 159.76±26.80 mmHg when the gel intervention was applied ($p \leq 0.001$). The findings of this intervention study can be compared to previous studies which also proved that the use of gel surface overlay significantly reduces interface pressure (Miller et al., 2015, Groah et al., 2015, Walsh et al., 2012, Chaiken, 2012, Brienza et al., 2010, Dunlop, 1998, Nixon et al., 1998, Conine et al., 1994). It must be stated though that some of these studies were conducted on surfaces and on subjects that are different from the conditons and subjects of this thesis. However, all of these studies agree with the results of the intervention study in this thesis that gel surface overlays have a positive impact in reducing interface pressure.

The findings of this intervention study could have a major impact in reducing pressure ulcer risk for the head in patients accessing prolonged radiography imaging and radiotherapy planning and treatment procedures where the head needs to be immobilised. As indicated in chapter five section 5.5 of this thesis, high interface pressure could increase pressure ulcer risks in patients undergoing prolonged radiography and radiotherapy procedures of the head because of specific intrinsic and health characteristics of the patients who usually access these procedures, and also because of the conditions under which these prolonged procedures are performed. The specific characteristics of prolonged interventional radiography procedures (e.g. cervical vertebroplasty) and radiotherapy treatment procedures such as cranial stereotactic radiotherapy that are likely to expose patients to Medical Device Related (MDR) pressure ulcers were discussed in phase one of this thesis. It was also been discussed in phase one of this thesis that patients who are likely to access these procedures are usually older, of poorer health, and mostly suffering from chronic diseases such as cancer (Liao et al., 2013). Their advanced age comes

with a marked reduction in the collagen and elastin content in their skin which makes them highly prone to experiencing skin injuries (Livarinen et al., 2013). One factor which is likely to increase this risk is the application of immobilisation during these procedures. The findings of the intervention study could therefore be of significant clinical importance in reducing the risk of pressure ulcers during prolonged radiography and radiotherapy planning and treatment procedures.

Extrapolating the findings of this intervention study into clinical practice would mean that patients undergoing prolonged radiography and radiotherapy procedures might be provided with a thin silicone gel surface overlay at the head. The application of the gel could result in a significant reduction in the interface pressure for the head by approximately 25%. However, to ensure that the gel intervention does not interfere with the imaging or therapy procedure, they need to be tested to fulfil the specific conditions within these specialised settings. For example, any gel intervention that would be applied in diagnostic radiography should be assessed with image quality and dosimetry in mind. This is essential because any intervention that produces artefacts will degrade the diagnostic quality of any radiographic images which might result in poor or wrong diagnosis (Whitley et al., 2005); equally an increase in radiation dose from the intervention would increase risk from radiation. As in other cases, this risk should be mitigated against benefit; the benefit in this situation surrounds minimising the risk of developing a pressure ulcer.

To successfully apply gel intervention in radiotherapy treatment procedures, they ought to be applied during radiotherapy planning. This is crucial because the radiotherapy planning parameters must be the same as that for treatment (Barrett et al., 2009). Prior to radiotherapy treatment procedures, patients have to undergo a planning scan in a computerised tomography (CT) or a positron emission tomography-computerised tomography (PET-CT) machine. It is therefore important that if a gel intervention is to be used during treatment, it has to be applied during the course of the planning so as to ensure reproducibility of patient position as well as the position of the target tumour, internal organs and structures. This will help to ensure that the target tumour is not missed during treatment whilst healthy tissue is spared thereby improving the accuracy of the treatment (Barrett et al., 2009).

7 Chapter Seven – Summary and overall conclusion

7.1 Chapter overview

This chapter contains the overall conclusion of the thesis. It begins with a summary of the thesis. Under this section, a brief summary of the literature on pressure ulcers is provided. The specific type of pressure ulcers that are likely to occur within radiography and radiotherapy settings are also presented briefly. Also, the lack of detailed radiographic studies or literature on pressure ulcers has been discussed in brief to remind the reader of the rationale for the thesis. The method and results of the two components of the thesis (i.e. baseline and intervention study) will be summarised. In addition, the clinical implications and significance of the findings of this thesis will be presented in brief. This chapter also include limitations of this thesis as well as recommendations for future work. The chapter also contains information on the novelty of this thesis, and a conclusion statement.

7.2 Thesis summary

The primary aim of this PhD thesis was to investigate the interface pressure (IP) risk of healthy volunteers on modern medical imaging and radiotherapy tables. Using the findings of this thesis, inferences were made about patients. This was to critically assess if patients accessing radiography and radiotherapy planning and treatment procedures could be exposed to high interface pressures, which could lead to developing Medical Device Related (MDR) pressure ulcers. The secondary aim was to critically assess the volunteers' perception of pain and comfort whilst lying on the radiography and radiotherapy surfaces. To achieve these aims, the thesis was conducted in two phases. Phase one involved an empirical study that critically evaluated and analysed the IP risk of healthy volunteers on modern radiography and radiotherapy surfaces. As stated earlier, this was to assess if patients accessing radiography and radiotherapy planning and treatment procedures would be exposed to the risk of developing MDR pressure ulcers due to IPs above a critical threshold. MDR pressure ulcers, defined as localised injury to the skin or underlying tissue as a result of sustained pressure from a medical device, form a huge proportion of all pressure ulcer cases.

Pressure ulcers are a common problem in health and social care, and presents significant threat to patients. As indicated in this thesis, the prevalence of pressure ulcers is widespread worldwide, affecting millions of people and costing billions to treat. In addition, pressure ulcers put an enormous strain on healthcare authorities by causing delays in patient discharge. Also, pressure ulcers reduce the quality of life of patients due to the gargantuan negative physical and psychological impact that pressure ulcers have on patients. In radiography and radiotherapy settings, it was shown that patients are likely to be exposed to conditions which could result in MDR pressure ulcers. This is due to the conditions under which radiography and radiotherapy planning and treatment procedures are conducted. For example, in Ghana and Portugal, conventional imaging procedures are conducted on hard carbon fibre X-ray tables with no mattress. Similarly, because of the need to minimise patient movement and ensure reproducibility of patient position during radiotherapy planning and treatment procedures, patients are positioned on hard carbon fibre surfaces with no mattress. These conditions could increase the interface pressure between the patient and the surface. High interface pressure – the pressure between body and contact surfaces – plays a crucial role in skin damage which could lead to developing pressure ulcers.

Currently, there is only one study that investigated IP risk on radiography tables (Justham et al., 1996). However, this study was conducted over two decades ago and had many limitations within its method. This means there is a gap in the literature to fill. Consequently, the first phase of this thesis, which involved an empirical baseline study with reliable scientific method, was conducted to critically assess the IP risk of the whole body, head, sacrum and heels of 42 healthy volunteers on three different radiography and radiotherapy surfaces. The experiment was conducted using the latest Xsensor pressure mapping equipment/technology. In addition, a 5-point Likert scale questionnaire was used to evaluate the volunteers' perception of pain and comfort whilst lying on the surfaces.

Results from phase one of thesis indicated that the healthy volunteers experienced high IP for the head on the X-ray table with no mattress (75.85±6.89 mmHg). This confirmed the assertion that high interface pressure risks do exist on imaging/therapy tables with no mattress. Also, the results indicated that most of the volunteers found lying on the X-ray table with no mattress was the least comfortable of the three surfaces, with over 70% indicating that lying on the X-ray table with no mattress for 26 minutes was very uncomfortable. Volunteers also experienced the most pain on the X-ray table with no mattress, with over 81.3% of the pain occurring at the head.

The clinical implications of these findings on patients accessing prolonged interventional radiography procedures and radiotherapy planning and treatment procedures are twofold. First, they are likely to experience high interface pressure (IP) risks for the head on the X-ray table with no mattress which could cause tissue damage and lead to Medical Device Related (MDR) pressure ulcers. This is because the high IP would be sustained for the entire period of these prolonged procedures. Second, the conditions under which prolonged interventional and radiotherapy planning and treatment procedures are conducted, and the particular characteristics among patients likely to access these procedures could further increase the risk of developing pressure ulcers. For example some intervention radiography procedures take hours to complete and patients are required to lie still during the course of the procedure. In view of the fact that some of these procedures are conducted on X-ray tables with no mattress, patients undergoing interventional radiography procedures would be required to lie still on hard carbon fibre surface without any form of cushioning. This could induce skin tissue ischaemia which might lead to MDR pressure ulcers.

The finding that there was high interface pressure risks for the head on the X-ray table with no mattress could also have clinical implications for patients undergoing radiotherapy planning. Radiotherapy planning is an essential procedure that is conducted prior to the patient receiving radiotherapy treatment to delineate a tumour. Recent advancements in radiotherapy, such as cranial stereotactic radiotherapy (SRT), demand even more precise tumour delineation with the main aim of sparing of healthy organs from high radiation doses. This is essential in cranial SRT to avoid exposing very sensitive brain structures such as the optic nerve to higher than

necessary radiation doses. The need for precise tumour delineation and target definition has led to the introduction of PET/CT and SPECT/CT in radiotherapy planning. Irrespective of the enormous benefits of PECT/CT and SPECT/CT in radiotherapy planning, they could induce MDR pressure ulcers among patients. This is because these procedures take long time to complete, and they are conducted on hard carbon fibre surfaces.

In addition, the introduction of new radiotherapy techniques, such as cranial SRT, has increased radiotherapy treatment times significantly. Similar to radiotherapy planning, radiotherapy treatment procedures require patients to lie still. To enforce this, patients are immobilised. In the instance of cranial SRT, the immobilisation is strict because patients are fitted with personalised thermoplastic masks. The application of the masks could increase the interface pressure further between the patient's head and the radiotherapy table. Confounding this is the fact that most patients who undergo radiotherapy planning and treatment procedures are older and of poorer health. Also, a huge number of these patients have fragile skin which is susceptible to injury due to the poor collagen and elastin content in the skin.

The results of the first phase of this thesis confirmed the assertion that high interface pressure risks do exists for the head on radiography tables with no mattress and also radiotherapy tables. This could induce skin tissue injury which could lead to MDR pressure ulcers among patients accessing prolonged radiography and radiotherapy planning and treatment procedures.

To minimise the high IP risks identified for head on the X-ray table with no mattress, phase two of this thesis was conducted. This involved an intervention study with the sole aim of minimising the high IP risk identified for head in the baseline study by using a thin gel surface overlay. The intervention study concluded that the use of thin silicone gel surface overlay resulted in a reduction of the IP for the head by approximately 25%. This reduction in IP is very significant. The clinical implication of this is that if the thin silicone gel overlay is applied in clinical practice, it could protect the head of patients undergoing prolonged radiography and radiotherapy planning and treatment procedures form skin injury. This would reduce their risk of developing MDR pressure ulcers.

7.3 Limitations

Whilst this thesis makes a significant contribution to understanding interface pressure risks on modern medical imaging and radiotherapy surfaces, and how they might contribute to the induction of MDR pressure ulcers among patients accessing prolonged radiography and radiotherapy planning and treatment procedures, it has limitations.

First, the two empirical studies contained in this thesis involved only healthy able-bodied volunteers under the age of 60 years. Therefore, the findings of this thesis must be applied with caution into clinical practice. This is important because most of the patients who are likely to undergo prolonged radiography and radiotherapy planning and treatment procedures are elderly, and have significantly different body and health characteristics from healthy volunteers.

Second, the questionnaire used to assess the volunteers' perception of comfort and pain whilst lying on the medical imaging and radiotherapy surfaces is not a standardised scale, hence may not be reliable in other research settings. Nevertheless, there was no validated scale that could be applied to achieve the aims of this thesis; hence the need to create a new comfort and pain assessment questionnaire.

7.4 Recommendations for future work

1. This study should be replicated in an at risk patient population such as elderly patients suffering from cancer to investigate the interface pressure risks on medical imaging and radiotherapy surfaces.
2. A prospective study should be conducted on patients who will undergo prolonged radiography, radiotherapy planning or treatment procedures to evaluate if they go on to develop MDR pressure ulcers from these procedures.

7.5 Thesis novelty

No study has investigated interface pressure risks on modern medical imaging and radiotherapy surfaces using up to date pressure mapping technology. Consequently there is no up to date knowledge on the relationship between interface pressures on these surfaces and the possibility of developing MDR pressure ulcers among patients accessing prolonged radiography and radiotherapy planning and treatment procedures. This thesis adds new knowledge to academic/clinical literature because it shows that inferences can be made that patients accessing prolonged radiography and radiotherapy planning and treatment procedures could be exposed to high interface pressure risks for head when the head is in direct contact with the imaging/therapy table. This finding creates the need for raising awareness of the risk of MDR pressure ulcers on imaging/therapy tables. This finding could have an important impact on clinical practice in Ghana and Portugal where prolonged radiography procedures such as cervical vertebroplasty are conducted on X-ray tables with no mattress. In the UK where radiography procedures are conducted on surface overlays such as mattress, the findings of this thesis support the use of mattresses. This is because the intervention study of this thesis has shown that the use of a thin silicone gel surface overlay can reduce interface pressure risks for the head.

This thesis has also shown in its method a unique and novel technique of assessing the quality assurance (QA) of the Xsensor pressure mapping equipment. In the method of phase one of the thesis, a novel technique was developed which established that there was a pressure gradient between the left and right sides of the Xsensor pressure mat. This finding could have important implications for research because previous studies that have used the Xsensor pressure mapping made no mention of the existence of pressure gradient within the Xsensor. Previous studies have simply relied on the manufacturer providing evidence that the pressure mapping system works correctly. This thesis has proposed a simple yet scientifically reliable experiment which allowed the researcher an opportunity to quality test the Xsensor pressure mapping equipment prior to and after use. Researchers using the Xsensor in future would therefore benefit from this novel method to assess the QA of their pressure mat. It is essential that the pressure mat is assessed to rule out the existence of a pressure gradient. This is important because the presence of a

pressure gradient would invalidate the recorded interface pressure values, unless the gradient factor is factored into the calculation. It must be stated this was not part of the aims of the thesis.

7.6 Concluding statement

High interface pressure risks do exist for the head on medical imaging and radiotherapy surfaces with no mattress. This could induce skin injuries at the head in patients accessing prolonged radiography and radiotherapy planning and treatment procedures, which might lead to MDR pressure ulcers. This is because of the long duration of these procedures, and the conditions under which they are conducted. These risks could have very severe negative impact among elderly and patients of poor health such as those suffering from cancer and chronic spinal and neurological diseases due to the low collagen and elastin content in the skin of these patient populations. Therefore the presence of high interface pressure risks will significantly increase the risk of developing MDR pressure ulcers among these patients. The use of surface overlays such as thin silicone gel intervention for the head could have a positive impact in reducing the high interface pressure risk by a fourth. As a result, the risk of developing MDR pressure ulcers due to high interface pressure at the head would be significantly reduced.

7.7 Summary of conclusions

The findings of this thesis have shown that;

1. There was high interface pressure risk for the head on X-ray table with no mattress. This could significantly increase the risk of Medical Device Related (MDR) pressure ulcers among patients accessing prolonged interventional radiotherapy and radiotherapy planning and treatment procedures.
2. There was lack of comfort from lying on X-ray table with no mattress.
3. Lying on X-ray table with no mattress can cause pain at the head.
4. The use of thin silicone gel surface overlay reduced interface pressure risk for the head by approximately 25%.

7.8 Recommendations for radiography and radiotherapy practice

1. Where applicable, surface overlays should be used for the head on patients accessing radiography and radiotherapy planning and treatment procedures to reduce the risk of MDR pressure ulcers for the head.
2. There is the need to create awareness of the risk of MDR pressure ulcers for the head within radiography and radiotherapy.
3. There is the need to provide training on pressure ulcers risk assessment for radiographers and radiotherapy workers.
4. There is the need to incorporate the promotion and warning of the risks of MDR pressure ulcers and how it can be alleviated into radiographic and therapeutic curriculum.

Appendix 1 – Ethical approval letter for baseline study

Research, Innovation and Academic Engagement Ethical Approval Panel

College of Health & Social Care AD 101
Allerton Building University of Salford
M6 6PU
T +44(0)161 295 7016
r.shuttleworth@salford.ac.uk
www.salford.ac.uk/

14 May 2014

Dear Seth,

RE: ETHICS APPLICATION HSCR14/23 – An investigation into whether lying on couches associated with medical imaging increases the risk of developing pressure ulcers in healthy volunteers

Based on the information you provided, I am pleased to inform you that application HSCR14/23 has been approved.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible.

Yours sincerely,

Rachel Shuttleworth

Rachel Shuttleworth
College Support Officer (R&I)

Appendix 2 – Poster for baseline study

VOLUNTEERS NEEDED

Title of the project: An investigation into interface pressure (IP) risk of healthy volunteers on modern medical imaging and radiotherapy tables.

Are you 18 years plus, student or staff of the University of Salford, not pregnant, and you do not have any condition that prevents you from lying still on your back for 26 minutes, then you're invited to participate in the above study.

Please contact the researcher if you are interested to participate in the study.

Thank you.

Name of the Researcher: Seth Kwadjo Angmorterh

Email: S.Angmorterh@salford.edu.ac.uk **Telephone:** +44 (0) 161 295 2492

Appendix 3 – Participant information sheet for baseline study

Title of study

An investigation into interface pressure (IP) risk of healthy volunteers on modern medical imaging and radiotherapy tables.

Invitation paragraph

I would like to invite you to participate in this study. Before you decide you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully, this will take about 10 minutes. Take time to decide whether or not to take part.

Purpose of the study

This study will investigate the interface pressures exhibited on healthy volunteers whilst lying on three medical imaging/therapy examination tables. I am undertaking this research as part of my PhD. Also this is an important research for patient benefit.

Why have I been invited to participate?

You have been invited to participate in this study because you are a student and/or staff of the University of Salford, healthy, 18 years plus, not pregnant, and do not have any condition that prevents you from lying still for 26 minutes.

What is the purpose of this study?

Research has shown that sustained interface pressure for long periods could induce skin tissue injury. This increases the risk of developing pressure ulcers. Because of this patients should be repositioned at least every 15 minutes when seated and

every two hours when lying, to relieve pressure between the body and the surface of contact. However this is not done during prolonged radiography and radiotherapy procedures because patient movement during image acquisition and therapy planning and treatment could adversely affect image quality and the ability to make a diagnosis. In radiotherapy, patient movement could lead to exposing heathy tissues to harmful doses of radiation. The lack of movement during prolonged medical imaging and radiotherapy planning and treatment procedures will increase the length of time the interface pressure between the patient and the X-ray table is sustained, potentially increasing the risk of developing pressure ulcers. This study is therefore investigating the interface pressure (IP) risk of healthy volunteers on modern medical imaging and radiotherapy tables.

Are there other volunteers?

Yes. The study involves 49 volunteers.

What are the possible disadvantages and risks of taking part?

There is no risk to your participation in this study. However volunteers will be advised that they could have some discomfort following lying down for 26 minutes. To minimise these effects data collection has been spread over a period. If they have back pain, which they are unable to manage then they should contact their General Practitioner or other Healthcare Professional.

Do I have to take part?

It is up to you to decide. Your participation in this study is voluntary and you are free to withdraw from the study at any time.

What will I be required to do if I decide to take part?

A mutually convenient time will be agreed with you to read the participant information sheet. At that meeting you can ask for further clarification if you deem necessary. If you agree to participate, an appointment will be made for you to come into the medical imaging facility in the Mary Seacole building you to sign the consent form and for data collection. During data collection, you will be asked to change into a clean leggings and a t-shirt, then your weight and height will be recorded to calculate

your Body-Mass Index (BMI). After that you will be asked to lie still on a pressure mat placed on an X-ray table for 26 minutes, six minutes settling time, and 20 minutes for pressure mapping. After that you'll be asked to complete a questionnaire investigating the level of comfort and pain whilst lying on the surface.

Will my taking part be confidential?

Yes. Data from the study will be anonymised by assigning codes to the volunteers, and the master list will be stored on a password protected computer connected to a university network drive which is backed up, and this can only be accessed by the researcher and his supervisors. If you choose to withdraw you can request for your data to be removed from the study.

What will happen if I don't carry on with the study?

If you withdraw from the study all the information and data collected from you will be destroyed and your name removed from all the study files.

How will the data be used?

Data collected will be used to calculate the mean interface pressure, peak interface pressure, peak pressure index (PPI) in mmHg of the whole body and the three jeopardy areas (head, sacrum, and heels). This numbers will be analysed to see if they present a risk and could induce pressure ulcers development, especially in at-risk population.

What will happen to the results of the research study?

This research will be written into a PhD thesis which will be made available at the University of Salford Library and its online thesis repository. Also, findings of the study will be disseminated to the clinical/research community via conference / publication. Volunteers will not be identified in the any report/publication unless you have given your consent.

Are there any X-rays involved in the study?

No.

Are there any ionisation radiations involved in the study?

No

Who has reviewed the study?

This study has been reviewed and approved by University of Salford School of Healthcare College of Health and Social Care research ethics committee to protect your safety and rights as well as that of the researcher.

Contact details of the researcher

Seth Kwadjo Angmorterh
School of Health Sciences
L608, Allerton building
University of Salford
M54WT
Telephone: 07930472138
Email: S.Angmorterh@edu.salford.ac.uk
Telephone: 07930472138

Thank you.

Contact details of Supervisor

Prof. Peter Hogg
Professor of Radiography
School of Health Sciences
L608, Allerton building
University of Salford
M54WT
Email: P.Hogg@salford.ac.uk
Telephone: +44(0)1612952492

Appendix 4 – Participant consent form for baseline study

Title of Project: An investigation into interface pressure (IP) risk of healthy volunteers on modern medical imaging and radiotherapy tables.

Ethics Ref No: HSCR14/23

Name of Researcher: Seth Kwadjo Angmorterh

(*Circle as appropriate)*

➢ I confirm that I have read and understood the information sheet for the above study (version 2, 30/04/14) and what my contribution will be.	**Yes**	**No**
➢ I have been given the opportunity to ask questions (face to face, via telephone and e-mail)	**Yes**	**No**
➢ I agree to have my pressure measurement taken	**Yes**	**No**
➢ I understand that my participation is voluntary and that I can withdraw from the research at any time **without giving any reason**	**Yes**	**No**
➢ I understand how the researcher will use my responses, who will see them and how the data will be stored.	**Yes**	**No**
➢ **I agree to take part in the above study**	**Yes**	**No**

Name of volunteer …… Signature…… Date ……
Name of researcher …… Signature…….…… Date ……...

Appendix 5 – Risk assessment form for baseline study

All student projects must include a risk assessment. If this summary assessment of the risk proves insignificant: i.e. answer no to all questions, no further action is necessary. However, if you identify risks you must identify the precautions you will put in place to control these.

Please answer the following questions.

1. What is the title of the project?

An investigation into interface pressure (IP) risk of healthy volunteers on modern medical imaging and radiotherapy tables.

2. Is the project purely literature based? YES/NO

If YES, please go to the bottom of the assessment and sign where indicated. If NO, complete question 3 and then list your proposed controls.

3. Identifying the Risks

Hazards	**Risks**	**If yes, consider what precautions will be taken to minimise risk and discuss with your Supervisor**
Use of ionising or non ionising radiation	Exposure to radiation **NO**	Obtain copy of existing risk assessment from place of research and attach a copy to this risk assessment summary.
Use of hazardous substances	Exposure to harmful substances **NO**	Obtain copy of existing risk assessment from place of research and attach a copy to this risk assessment summary.
Use of face-to-face interviews Interviewees could be upset by interview and become aggressive or violent toward researcher	Interviewing; **NO** Own classmates=Low risk **NO** Other University students=Medium risk **NO** Non-University personnel=High	NB. Greater precautions are required for medium & high risk activities Consider: How will contact with volunteers be made - i.e. do not give out personal mobile no., home number or home email, etc. Location of interviews – to be held in a safe environment, e.g University building, workplace What support will be available, i.e. will anyone else be available to assist if you call for help,

	risk **NO**	etc. e.g. colleague knows where interview to take place and telephoned when completed and safe- what action to take after certain time if not phoned How to deal with aggressive/violent behaviour, what precautions will be taken to prevent this from happening?
Use of face-to-face interviews Volunteers or interviewees could become upset by interview and suffer psychological effects	**NO**	Consider: What initial and subsequent support will be made available for volunteers or interviewees? What to do if researcher uncovers information regarding an illegal act? What/who will be used to counsel distressed volunteers/ interviewees, what precautions will be taken to prevent this from happening?
Sensitive data	Exposure to data or information which may cause upset or distress to Researcher **NO**	Consider: What initial and subsequent support will be available to the researcher
Physical activity	Exposure to levels of excerption unsuitable for a individuals level of fitness **NO**	Consider: Health Questionnaire/ Medical declaration form / GP clearance. Trained First aid personnel/ Equipment.
Equipment	Exposure to faulty unfamiliar equipment. **NO**	Consider: Equipment is regularly checked and maintained as manufactures instructions. Operators receive adequate training in use of. Volunteers receive induction training prior to use.
Sensitive issues i.e. Gender / Cultural e.g. when observing or dealing with undressed members of the	Exposure to vulnerable situations/ sensitive issues that may cause distress to interviewer or interviewee	Consider: Use of chaperones/ Translators. What initial and subsequent support will be made available for volunteers or interviewees?

opposite sex Children	**NO**	Adhere; to local guidelines and take advice from research supervisor
Manual Handling Activities	Exposure to a activity that could result in injury **NO**	Adapt the task to reduce or eliminate risk from manual handling activities. Ensure that volunteers understand and are capable of the manual handling task beforehand. Perform health questionnaire to determine volunteer fitness prior to recruitment

If you have answered yes to any of the hazards in question 3, please list the proposed precautions below:

Not applicable

Signature of student: Seth Kwadjo Angmorterh Date: 15th February, 2014

Name of Supervisor: Prof. Peter Hogg Date: 15th February, 2014

Appendix 6 – UoS medical imaging facility risk assessment form

Local rules for Radiation Safety

Covering use of the CT scanner and fixed X-ray Units

The University of Salford

Directorate of Radiography

LOCAL RULES AGREED by RPA – Christie Medical Physics & Engineering			
Name	Dr Chrysoula Theodorakou	Signature	C. Theodorakou
Date	18 October 2013		
Review Date	RPS	RPA	Comments

1. INTRODUCTION

These local rules have been drawn up in accordance with Regulation 17 of the Ionising Radiations Regulations, 1999. They cover all work with X-ray equipment within the above University Department. These local rules are applicable to all who enter the controlled areas within the department.

Every member of staff and student must read these Local Rules and sign a statement that they have read them and understood the requirements of the Rules. A copy must be readily available to all staff working in the Controlled areas covered by these Rules.

2. RESPONSIBILITIES

The following have responsibilities under the requirements of the Ionising Radiations Regulations, 1999.

2.1. Employer

The University of Salford

It is the overall responsibility of the employer to ensure compliance with the requirements of the Regulations.

2.2. Radiation Protection Adviser (RPA)

Christie Medical Physics and Engineering, The Christie NHS Foundation Trust, Wilmslow Road, Withington, Manchester M20 4BX.

Your 'contact person' within the department will be:

Dr Chrysoula Theodorakou — Tel: 0161 446 3539
E-mail: christie.theodorakou@christie.nhs.uk

It is the responsibility of the RPA to provide expert advice to allow the employer to ensure that work is conducted in accordance with the Regulations.

2.3. Radiation Protection Supervisors (RPS)

Andrew Tootell — Telephone: 0161 295 6414
E-mail: a.k.tootell@salford.ac.uk

It is the responsibility of the RPS to ensure that the local rules and any other appropriate radiation protection measures are observed. He/she should be informed and his/her advice sought whenever a matter concerning radiation protection arises.

2.4. All Employees and Students

Employees must take reasonable care to ensure their own and their colleagues' safety and they must co-operate with all instructions from their employer e.g. local rules and Directorate procedures.

They must use any relevant protective devices which have been provided by the employer with care and must report any defects. They must not intentionally or recklessly misuse or interfere with radiation equipment or protective equipment.

If a member of staff or student becomes pregnant, then she should inform the RPS and the head of the practice in writing as soon as possible.

3. DESIGNATED AREAS

3.1. Description

CONTROLLED:- **All X-ray rooms within the Practice.**

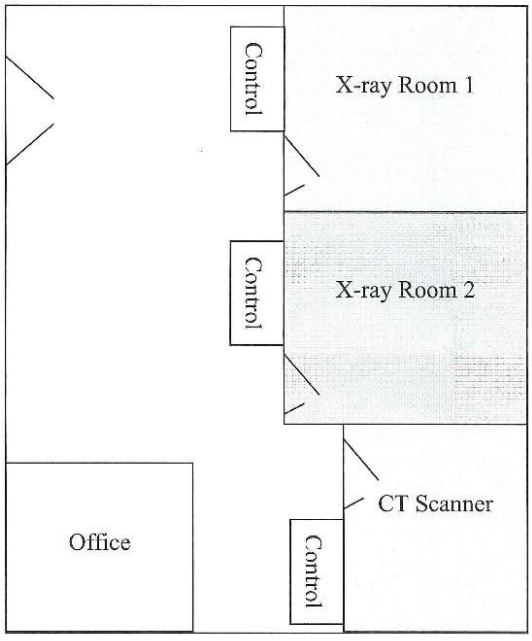
Both the CT scanner room and the X-ray rooms are designated as controlled areas. This does not incorporate the control areas. The controlled areas are shown shaded in the diagram of the departmental layout which follows.

SUPERVISED:- **None**

3.2. Warning Signs

The following signs are attached to all entrances to controlled areas to demarcate them and to restrict entry to those who have permission. This includes the doors of all X-ray rooms.

3.3. Plans showing area designation – controlled areas shaded



4. ENTERING AND WORKING IN CONTROLLED AREAS

1. Directorate staff and students are not classified workers. They may enter and work in the controlled areas provided that they follow the key work instructions contained in these local rules in which case personal monitoring is not required.

2. Ancillary staff (e.g. cleaners, clerical staff) and visitors without radiation protection training (e.g. workmen etc) must have permission from a member of the Department Staff before entering a controlled area when the room is in use (indicated by the warning light being on). The member of staff giving permission must ensure that it is safe for them to enter and that they have the required supervision whilst in the controlled area. When the room is not in use (warning light off), they may enter but must not attempt to use the X-ray equipment in any way.

3. Visitors to the department who normally work with ionising radiation and have received radiation protection training appropriate to their intended work. They include service engineers and medical physics staff.

   - Service engineers must report to an authorised person, e.g. RPS or radiology manager, before commencing work within the department.
   - It is the responsibility of service engineers' employers to ensure that suitable and sufficient risk assessments have been completed, that they are adequately trained in general radiation protection measures and that they are provided with local rules and facilities for monitoring their exposure to ionising radiation. It is the responsibility of the individual service engineers to co-operate with the RPS and take all the protective measures necessary to ensure that they do not place themselves or others at risk.
   - An authorised person must complete Part 1 of the handover document before commencement of work, temporarily handing over control of the area to the service engineer, who will then be acting under their employer's local rules.
   - At the completion of the visit, the service engineer should make a detailed report to the RPS or Directorate Technician regarding any alterations to the equipment, especially in those areas which would affect its radiation output or general radiation protection. It is then the responsibility of the authorised person receiving the equipment back from the service engineer to ensure that Part 2 of the handover document is completed before retaking control of the area. Any relevant QA tests should be performed by the department before returning the equipment to clinical use.
   - If the service engineer is not aware of their employer's risk assessment and systems of work, they must comply with the department local rules and not carry out any work that is not covered by the department's risk assessment. To this end they must be made aware of the sections of the local rules that will be applicable to their intended work within the department.
   - If the service engineer is a classified radiation worker and they work under the department local rules they will be an Outside Worker. It is their responsibility to give their radiation passbook to the RPS. After consultation with the RPA, the RPS should enter an estimate of the dose received during their work on the site.
   - The majority of the work undertaken by medical physics staff will be performed under the department local rules. Where this is not the case, CMPE will take control of the area, using the handover document in the manner described above, and work under their own local rules.

5. KEY WORK INSTRUCTIONS

1. No one should remain within the controlled area during X-ray exposure.

2. The operator must ensure that everyone has left the controlled area before initiating the exposure.

3. The X-ray room should not be entered when the red warning light outside the door indicates an X-ray exposure is taking place.

4. The entry doors into a controlled area must always be closed during an X- ray exposure. The primary beam should not be directed at the entry doors unless unavoidable.

5. The operator should normally remain at the control desk during exposure. During CT warm up the operator must lock the CT room door and place a notice on it indicating "CT warm up in progress" before leaving the control desk.

6. If controlled areas are to be left unsupervised by trained member of the Directorate staff in the immediate vicinity, the person who was in charge of the last examination must ensure that the X-ray equipment is left disabled.

7. Undergraduate students should be supervised by an appropriately trained member of Directorate staff.

6. CONTINGENCY PLAN

1. If any unit fails to terminate the production of x-rays at the end of the set time, it must immediately be isolated from the mains supply, using the emergency stop button if available. The unit should be taken out of use and a signed and dated 'do not use' warning sign attached to the control desk. The RPS or Directorate manager must be informed. The unit should not be used again until the incident has been investigated and the cause rectified.

2. If someone inadvertently remains within the room during exposure, the exposure should immediately be halted and the person removed from the controlled area before the exposure is restarted. The RPS and the Directorate manager must be informed. They must ensure that an investigation is carried out in conjunction with the RPA as required by the Regulations.

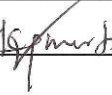
3. If an employee suspects that they have received an overexposure of radiation, then the RPS and the Directorate manager must be informed. They must ensure that an investigation is carried out in conjunction with the RPA as required by the Regulations.

University of Salford
MANCHESTER

University of Salford

Local Rules for Radiography

I confirm that I have read and understood the requirements of the local rules

Name	Signature	Designation (eg level 4 student, clinical tutor etc)	Date
SETH KWADJO ANGMORTERH		PhD STUDENT	23/01/2014

Appendix 7 – Certificates for participating in baseline study

Appendix 8 – Results of pilot study presented at the ECR Conference

EPOS™ Electronic Presentation Online System

ESR European Society of Radiology

Radiological perspective of the formation of pressure ulcers - A comparison of pressure and experience on two imaging surfaces.

Poster No.: C-1282
Congress: ECR 2015
Type: Scientific Exhibit
Authors: C. Everton[1], S. Bird[1], W. Brito[2], P. Collé[3], P. A. Franco[4], S. Lutjeber[3], K. Nodeland[5], S. Rième[2], S. Angmorterh[1], M. Siddika[6], A. England[7], K. Szczepura[1], P. Hogg[1]; [1]Salford/UK, [2]Lausanne/CH, [3]Groningen/NL, [4]Lisbon/PT, [5]Oslo/NO, [6]Oldham/UK, [7]Manchester/UK
Keywords: Soft tissues / Skin, Conventional radiography, Treatment effects, Biological effects
DOI: 10.1594/ecr2015/C-1282

Aims and objectives

Many medical imaging procedures, especially interventional, can take up to 20 minutes or more (1). Patients are required to lie completely still during image acquisition, any movement could render resultant images diagnostically unacceptable. Whitley et al (2) argued that movement during x-ray procedures is a major contributor to loss of diagnostic value, leading to repeat examinations, and can increase the prospect of the patient having a negative experience.

Studies have shown that sustained interface pressure, for more than 20 minutes, can cause tissue breakdown (5). This could heighten the probability of developing Pressure Ulcers (PUs) (3). PUs are a high cost problem for health care providers across Europe. The number of patients afflicted reaching over 18% (4).

In the radiographical context the interface pressure between the patient and the imaging surface is maintained for prolonged periods of time. A search of the available literature reveals that there are currently no studies which investigate the relationship between radiological surfaces and interface pressure, or how this could affect the formation of PUs in at risk patients.

The patient experience in the clinical setting is of paramount importance, and is an area where very little research has been undertaken. A number of studies and reviews recommend that further work should be done in this area to explore personal opinions (6)

Using healthy participants, this experimental study will therefore:

- Identify and compare the interface pressure on two imaging surfaces
- Identify and compare the average and peak interface pressures of three areas of interest (head, sacrum and heels) on the two imaging surfaces
- Compare the level of comfort experienced on the two imaging surfaces
- Explore the level of pain experienced on the two imaging surfaces

Hypothesis

- The average interface pressure will be higher on the imaging surface without the mattress
- The areas of interest (head, sacrum, heels) will have a higher interface pressure on the imaging surface without the mattress
- The overall comfort will be higher on the mattress surface

- The participants will experience higher pain when the interface pressure is higher in the three areas of interest

Methods and materials

Ethical Approval

This study was approved by the ethics committee of the College of Health and Social Care of the University of Salford, Manchester, UK.

Study Design and Setting

This study used pressure mapping equipment and software to measure interface pressures of 38 healthy participants whilst lying still on two medical imaging surfaces. The experiment was conducted in the medical imaging laboratory of the Escola Superior de Tecnologia da Saúde de Lisboa in Portugal during the Erasmus OPTIMAX 2014 Summer School.

Sample

A convenience sample of 38 healthy participants aged 19-51 was taken from a population of 65. These participants were from different countries in the European Union, with different academic backgrounds, attending the OPTIMAX summer school.

Inclusion criteria

Healthy adults, 18 years or older were recruited to the study and therefore the findings of the study can be generalised to an adult population. Gelis et al (7) stated that adult populations constitute the majority of all PU cases and recommended that studies into measuring interface pressures should be targeted at this population group, so that the findings will be beneficial for clinical practice.

Exclusion criteria

Participants with a height of 177 cm or more were excluded from the study, due to the limitations of the pressure mat equipment.

Participants with any health condition, such as back pain, that would prevent them from lying still for 20 minutes were excluded from the study. This was to ensure that participants could lie still during the acquisition of the interface pressure, as excessive movement

would render the data unusable in the study (8). Participants who could not participate on the grounds of religious beliefs were also excluded.

Surfaces

Two imaging surfaces were used for the study.

- Norland XR-36 bone density scanner with a mattress
- Siemens MULTIX Pro x-ray table without a mattress

Measurement tools

Pressure Mat - This study used the XSENSOR PX100:48.144.02 pressure mat from Sumed International. Various clinical studies (9) and academic studies (10) used the XSENSOR to perform pressure mapping on humans. Fader et al (11) stated that XSENSOR appears to be the gold standard technology for pressure mapping. The mat was calibrated to manufacturers' specification. Manufacturer calibration and quality control data, confirm a high level of precision and reliability (12).

The pressure mat has an accuracy rate of ±10 percent of the calibrated values (9). The pressure mat was linked to XSENSOR X3 Medical v5.0 software, which according to Trewartha and Stiller (10) has excellent calibration stability leading to consistent data collection with high reliability, high accuracy and low creep, (defined as the increase in pressure with constant force).

Questionnaire - A 5-point Likert scale questionnaire was designed to assess participants' level of comfort and pain. The Likert scale is the most widely used format for designing a questionnaire (14) suggested that scales ranging from 5-101 response categories show little difference in validity and reliability. Open-ended questions were also asked in order to explore the experience of the participants, providing responses in their own terms (15).

Pilot

A pilot study was performed with a participant representative of the target population to assess the validity and reliability of the equipment and method.

Data Collection

Pressure - The pressure mat equipment was securely fixed onto the imaging surface to ensure that it remained in place during data acquisition. The pressure mat was not removed or repositioned until the full sample had been acquired. Some artefacts in the data were noted and recorded for further evaluation.

Participants signed up at a mutually convenient time to participate in the study and were asked to change into a pair of leggings and two t-shirts to standardise clothing as per Fader et al (11). Participants were then positioned supine in the centre of the mat with their hands pronated.

A settling time of 6 minutes was used in this study, to reduce measurement error as recomended by Stinson et al (5) in a similar study which found that pressure values change significantly over the first 6 minutes.

Comfort and Pain - Following pressure data acquisition participants were asked to complete a questionnaire. In a cross-national setting, there is the potential for reliability error due to differences in knowledge, perceptions and familiarity with research instruments (16). Therefore two questions consisted of numerical descriptions with verbal anchors on a 5 point Likert scale, and the participants were escorted whilst completing the questionnaire by a member of the research team to assist with definitions and clarity.

Data Analysis

From the data acquired for each participant on both of the surfaces, the average pressure and the peak pressure in mmHg for the whole body and the areas of interest (head, sacrum & heel) were calculated. When taking the average readings, of the sacrum, the lower limit of the pressure was set to 32mmHg, as this represents the value from which the pressure may influence the formation of PUs (17). Objective data analysis was achieved by selecting and averaging 30 frames per person on both surfaces in order to ensure the reliability of results in the presence of any data artefacts previously noted. The peak pressure measurements, of the sacrum, were collected by selecting an area of 3x3 cells with the highest pressure value in the centre (Fig 1), in order to calculate the mean peak value (18). SPSS version 22 was used to assess normal distribution of data using histograms and Shapiro-Wilk tests. In the second phase, the average pressures of both the mattress and the x-ray table were compared using a paired t-test. Measures of the average and peak pressures were taken at the triple jeopardy areas and a comparison between the three individual areas on both surfaces were made using a paired t-test. Finally, a qualitative analysis was made in order to verify the relationship between the pain experience in the triple jeopardy areas during the experiment and the average pressure obtained in those areas. A Wilcoxon test was used to compare the level of pain in each of the triple jeopardy areas and the overall comfort of the participants.

Images for this section:

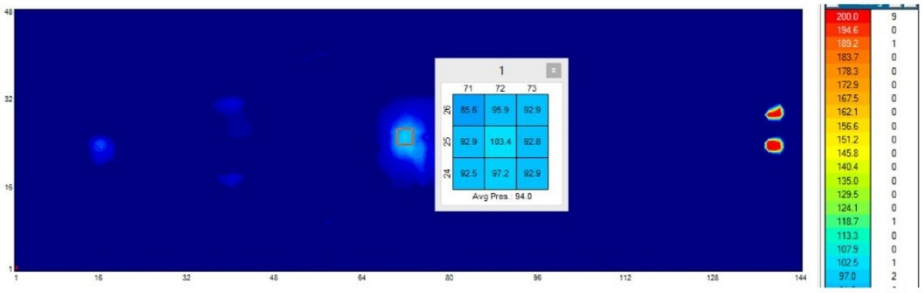


Fig. 1: Image depicting aquisition of mean peak value for the sacrum.

Results

Pressure -

The data sample of 30 healthy participants was analysed. The sample included 24 females (80%) and 6 males (20%) with an age range from 19 to 51 (mean=25.77; SD=7.72) and a BMI range from 18.7 to 33.6 (mean 24.12; SD=3.29). The average pressure of both surfaces is presented in Figure 2.

The results indicate a significant difference ($P<0.001$) in average IP between the different imaging surfaces showing a higher average pressure on the x-ray table with a mean difference of 11.95mmHg (Fig 2).

In the measurements of average and peak pressures of the triple jeopardy areas (Fig 2) the pressure reduction was found to be statistically significant in all three areas for the different surfaces ($P<0.001$). In both the peak (Fig 4) and average pressure (Fig 3) measurements, it was found that the pressure was higher on the x-ray table than on the density scanner with a mattress. For peak pressure the mean differences achieved for each area were 96.06mmHg (head), 117.61mmHg (sacrum) and 85.30mmHg (heels) and the differences obtained for the average pressures were 53.19mmHg, 19.18mmHg and 38.11mmHg respectively. There was no correlation between BMI and average pressure ($r2 =0.029$).

Comfort and Pain -

The comfort levels between the mattress and the x-ray table varied, 50% of the participants found the surface with a mattress was comfortable or very comfortable, compared to the x-ray table where only 23% found the table comfortable or very comfortable. 10% of participants described the x-ray table as very uncomfortable, whereas none of the participants scored the mattress as very uncomfortable.

There is a significant difference in the pain experienced in the sacrum and head ($P<0.001$) between the two surfaces. The participants experienced more pain in the head when lying on the x-ray table compared to the other areas of interest. For the other jeopardy areas the pain experienced was also higher for the hard surface.

Images for this section:

Total Average Pressure	43.04 ± 3.75	31.09 ± 2.34	<0.0001
Peak pressure measurements			
Peak Head	255.77 ± 1.18	159.72 ± 45.88	<0.0001
Peak Sacrum[a]	215.26 ± 54.6	97.65 ± 36.14	<0.0001
Peak Heels	246.87 ± 32.51	161.56 ± 63.02	<0.001
Average Pressure measurements			
Average Head	107.11 ± 19.29	53.92± 14.42	<0.0001
Average Sacrum	68.01 ± 10.09	48.83± 5.25	<0.0001
Average Heels	96.48 ± 26.28	58.36 ± 19.54	<0.0001

Fig. 2: Table showing total average bodu presure, and peak and average presure for head, sacrum and heels in mmGh.

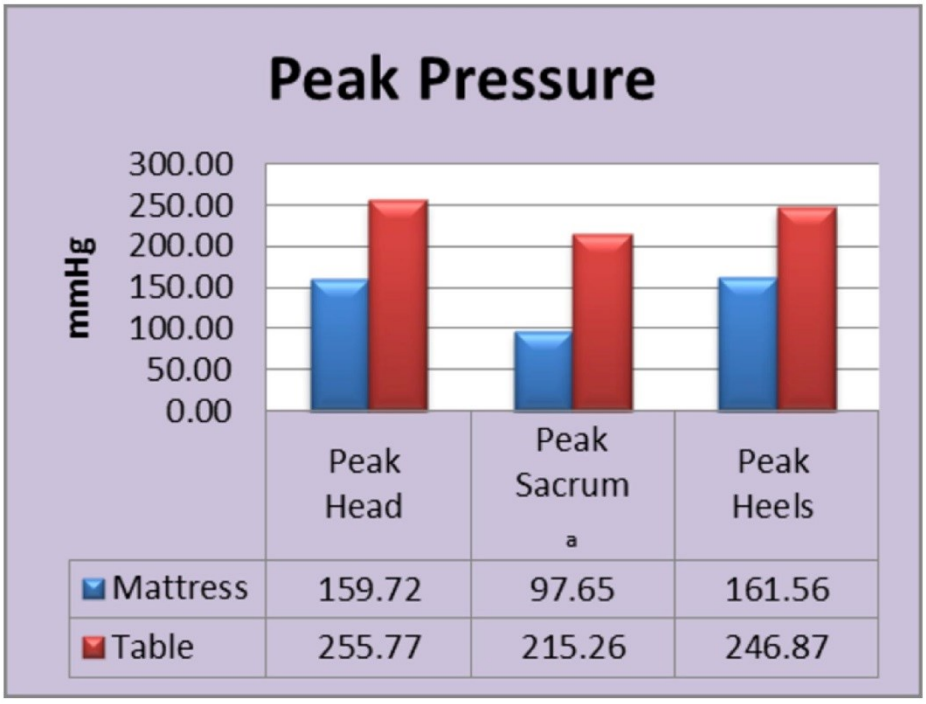


Fig. 4: Graph comparing peak pressure in mmHg for each of the jeopardy areas for both the mattress and the x-ray table. Inc standard deviation. a Mean peak of the 3x3 area.

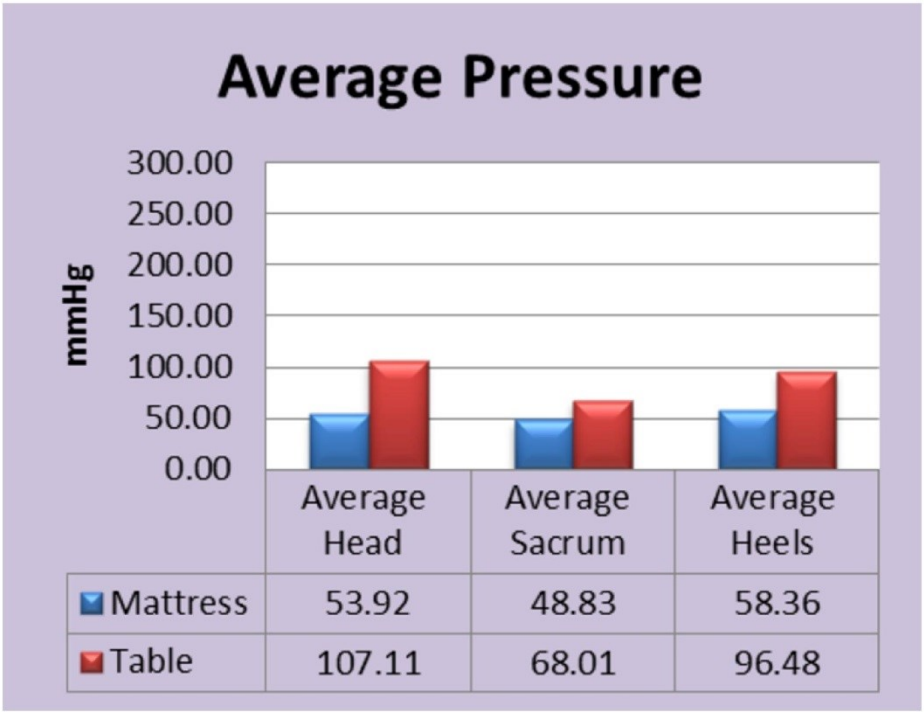


Fig. 3: Graph comparing average pressure in mmHg for each of the jeopardy areas for both the mattress and the x-ray table. Inc standard deviation.

Conclusion

The results obtained confirm that the average IP for whole body and average IP of the triple jeopardy areas were higher on the hard surface. All of the IP values recorded for the mattress surface showed an improvement when compared to the hard surface (Fig 5 & Fig 6).

It is therfore suggested that the inclusion of radiolucent mattresses could reduce average pressure on the jeopardy areas to below the accepted PU formation benchmark of 90mmHg. Bony prominences may need a thicker or higher specification mattress (5).

The mattress surface provides a more even distribution of pressure in the jeopardy regions; this is comparable to a previous study that found greater distribution to reduce the incidence of PUs (19). Although more work would need to be done as most jeopardy area values recorded from both surfaces still exceed the standard for a hospital mattress (60mmHg).

The open-ended questions revealed themes of movement and loss of sensation, a number of the participants highlighted that they had ´twitched´ or were ´shocked´, suggesting that they had could moved during the 20 minutes. This could have a negative impact on image quality, suggesting the need for further work on the impact of movement on image acquisition and dose. More participants had a sensation of 'numbness' on the mattress surface, this is an issue that needs further work as loss of sensation is another risk factor for the formation of PUs (20, Cochrane review).

The participants found the mattress surface to be overall more comfortable (P=0.015) and less painful in the head and sacrum, this is comparable with the findings of King & Bridges (5).

A mattress surface reduces both average and peak interface pressures on the whole body and the three jeopardy areas. Therefore it can be assumed that the use of a mattress will reduce the probability of developing pressure ulcers.

There is a significant difference in pain and comfort assessment between the two surfaces, which also supports the findings in favour of using radiolucent mattresses or supports (pillows, props, foam pads) where possible.

Limitations

This study included only healthy participants; it is recommended that further work be undertaken with samples including at risk patients.

Acknowledgements

The authors would like to thank, Erasmus for funding, The Nuffield Foundation, and Sumed International. Thanks are also extended to all participants who gave their time.

Images for this section:

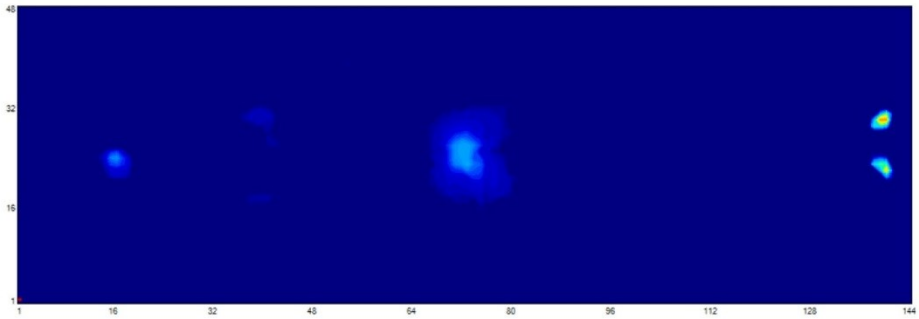


Fig. 5: Image representing total pressures exherted on the pressure mat during a 20 minitue session on the Norland XR-36 bone density scanner with a mattress.

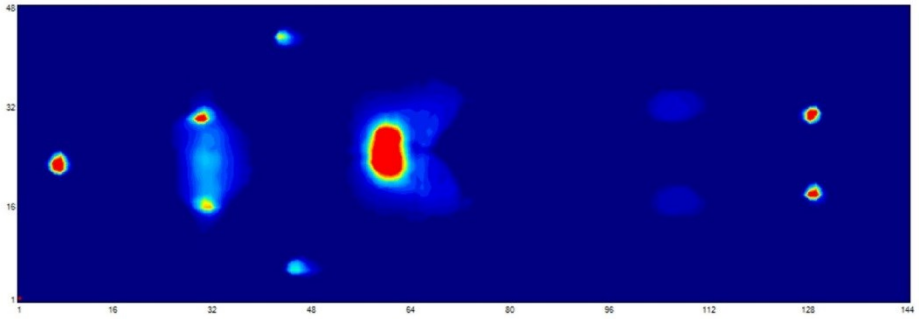


Fig. 6: Image representing total pressures exherted on the pressure mat during a 20 minitue session on the Siemens MULTIX Pro x-ray table without a mattress.

Personal information

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Appendix 9 – Questionnaire for baseline study

Participant's demographic data
Name…….. ID……
Age …… Gender ……..
Height (cm) ……. Weight (kg) ……..
Medical Imaging surface …….. Date ……..

Please tick the appropriate box

1. On a scale of 1 to 5, how comfortable were you lying on the medical imaging/radiotherapy surface?

1= very uncomfortable

2= uncomfortable

3= passable

4= comfortable

5= very comfortable

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

2a. Did you experience any pain whilst lying on the medical imaging/radiotherapy surface?

Yes ☐ No ☐

If yes, please answer questions **2b**, and **3**. If **No**, go to question **4**.

2b. If yes where did you experienced the pain?

……..

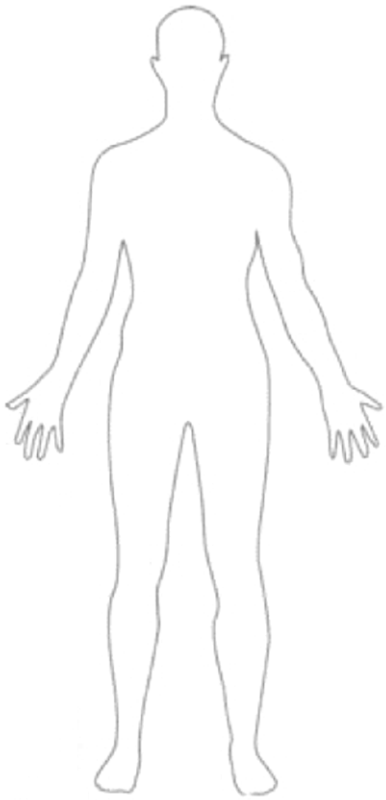
3. Using the diagram below please grade the pain on a scale of 1 to 5
1= hardly any pain

2= slight pain

3= moderate pain

4= a lot of pain

5= extreme pain



4. Anything other comments?

.....

.....

……

……

……

Thank you very much.

Appendix 10 – Ethical approval letter for intervention study

University of Salford MANCHESTER

Research, Innovation and Academic Engagement Ethical Approval Panel

Research Centres Support Team
G0.3 Joule House
University of Salford
M5 4WT

T +44(0)161 295 2280

www.salford.ac.uk/

11 January 2016

Dear Seth,

RE: ETHICS APPLICATION HSCR 15-141 – An experimental study using surface overlay interventions to reduce interface pressure (IP) risks of healthy volunteers on modern medical imaging tables in radiography

Based on the information you provided, I am pleased to inform you that application HSCR15-141 has been approved.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible by contacting Health-ResearchEthics@salford.ac.uk

Yours sincerely,

Sue McAndrew
Chair of the Research Ethics Panel

Appendix 11 – Poster for intervention study

VOLUNTEERS NEEDED

Title of the project: An experimental study using surface overlay interventions to reduce interface pressure (IP) risks of healthy volunteers on modern medical imaging and radiotherapy tables.

Are you 18 years plus, student or staff of the University of Salford, not pregnant, and you do not have any condition that prevents you from lying still on your back for 10 minutes, then you're invited to participate in the above study.

Please contact the researcher if you are interested to participate in the study.

Thank you.

Name of the Researcher: Seth Kwadjo Angmorterh
Email: S.Angmorterh@salford.edu.ac.uk **Telephone:** +44 (0) 161 295 2492

Appendix 12 – Participant information sheet for intervention study

Title of study

An experimental study using surface overlay interventions to reduce interface pressure (IP) risks of healthy volunteers on modern medical imaging and radiotherapy tables.

Invitation paragraph

I would like to invite you to participate in this study. Before you decide you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully, this will take about 10 minutes. Take time to decide whether or not to take part.

Purpose of the study

This is the second phase of a PhD research that is assessing interface pressure (IP) risk of healthy volunteers on modern medical imaging and radiotherapy surfaces. The purpose of this phase of the study is to minimise high IP risks identified for head on the X-ray table with no mattress. This will be achieved by using a gel, air, or foam-based surface overlay interventions. These interventions will be placed at the head, and the IP measured, using the Xsensor pressure mapping equipment, whilst volunteers lie still on the X-ray tables.

Why have I been invited to participate?

You have been invited to participate in this study because you are a student and/or staff of the University of Salford, healthy, 18 years plus, not pregnant, and do not have any condition that prevents you from lying still for eight minutes.

Are there other volunteers?

Yes. The study involves 20 volunteers.

What are the possible disadvantages and risks of taking part?

There is no risk to your participation in this study. It is not expected that lying still for eight minutes on an X-ray table will pose any risk to the volunteers.

Do I have to take part?

It is up to you to decide. Your participation in this study is voluntary and you are free to withdraw from the study at any time.

What will I be required to do if I decide to take part?

A mutually convenient time will be agreed with you to read the participants' information sheet. At that meeting you can ask for further clarification if you deem necessary. If you agree to participate, an appointment will be made for you to come into the imaging facility in the Mary Seacole building you to sign the consent form and for data collection. During data collection, you will be asked remove any pins in your hair, then your weight and height will be recorded to calculate your Body-Mass Index (BMI). After that you will be asked to lie still on a pressure mat placed on an X-ray table for eight minutes, six minutes settling time, and two minutes for pressure mapping of the head. After that, you'll be asked to lie on a gel, air, or foam-based surface overlay placed on the pressure mat on the X-ray table. The order of the interventions will be randomised. The pressure mapping will then be conducted. After that, you'll be asked to change into your clothing and that will be the end of your participation in the study.

Will my taking part be confidential?

Yes. Data from the study will be anonymised by assigning codes to the volunteers, and the master list will be stored on a password protected computer connected to a university network drive which is backed up, and this can only be accessed by the researcher and his supervisors. If you choose to withdraw from the study, you can request your data is removed from the study.

What will happen if I don't carry on with the study?

If you withdraw from the study you can request for all the information and data collected from you to be destroyed and your name removed from all the study files.

How will the data be used?

Data collected will be used to calculate the mean interface pressure and peak pressure index (PPI) in mmHg for head with and without the intervention. Depending on the normality of the data, the parametric paired sample test or its equivalent non-parametric Wilcoxon Rank test will be conducted on the data to compare the mean IP and the PPI on the two conditions.

What will happen to the results of the research study?

The findings of this study will for a chapter of the PhD thesis. It will also be disseminated to the clinical/research community via conference/publication. Volunteers will not be identified in the any report/publication unless you have given your consent.

Are there any X-rays involved in the study?

No.

Are there any ionisation radiations involved in the study?

No

Who has reviewed the study?

This study has been reviewed and approved by University of Salford School of Healthcare College of Health and Social Care research ethics committee to protect your safety and rights as well as that of the researcher.

Contact details of the researcher

Seth Kwadjo Angmorterh
School of Health Sciences
L711, Allerton building
University of Salford
M54WT
Telephone: 07930472138
Email: S.Angmorterh@edu.salford.ac.uk
Telephone: 07930472138

Contact details of Supervisor

Prof. Peter Hogg
Associate Head Research
School of Health Sciences
L608, Allerton building
University of Salford
M54WT
Email: P.Hogg@salford.ac.uk
Telephone: +44(0)1612952492

Thank you.

Appendix 13 – Consent form for intervention study

Title of Project: An experimental study using surface overlay interventions to reduce interface pressure (IP) risks of healthy volunteers on modern medical imaging and radiotherapy tables.

Ethics Ref No: HSC15-141 **Name of Researcher:** Seth Kwadjo Angmorterh

(*Circle as appropriate)*

➢ I confirm that I have read and understood the information sheet for the above study (version 1, 15/11/2015) and what my contribution will be.	**Yes**	**No**
➢ I have been given the opportunity to ask questions (face to face, via telephone and e-mail)	**Yes**	**No**
➢ I agree to have my pressure measurement taken	**Yes**	**No**
➢ I understand that my participation is voluntary and that I can withdraw from the research at any time without giving any reason	**Yes**	**No**
➢ I understand how the researcher will use my responses, who will see them and how the data will be stored.	**Yes**	**No**
➢ **I agree to take part in the above study**	**Yes**	**No**

Name of volunteer …….. Signature…… Date ……

Name of researcher…… Signature…… Date ……...

Appendix 14 – Risk assessment form for intervention study

All student projects must include a risk assessment. If this summary assessment of the risk proves insignificant: i.e. answer no to all questions, no further action is necessary. However, if you identify risks you must identify the precautions you will put in place to control these.

Please answer the following questions.

1. What is the title of the project?

An experimental study using surface overlay interventions to reduce interface pressure (IP) risks of healthy volunteers on modern medical imaging and radiotherapy tables.

2. Is the project purely literature based? NO

If YES, please go to the bottom of the assessment and sign where indicated. If NO, complete question 3 and then list your proposed controls.

3. Identifying the Risks

Hazards	**Risks**	**If yes, consider what precautions will be taken to minimise risk and discuss with your Supervisor**
Use of ionising or non ionising radiation	Exposure to radiation **NO**	Obtain copy of existing risk assessment from place of research and attach a copy to this risk assessment summary.
Use of hazardous substances	Exposure to harmful substances **NO**	Obtain copy of existing risk assessment from place of research and attach a copy to this risk assessment summary.
Use of face-to-face interviews Interviewees could be upset by interview and become aggressive or violent toward	Interviewing; **NO** Own classmates=Low risk **NO** Other University students=Medium risk **NO** Non-University	NB. Greater precautions are required for medium & high risk activities Consider: How will contact with volunteers be made - i.e. do not give out personal mobile no., home number or home email, etc. Location of interviews – to be held in a safe environment, e.g University building,

researcher	personnel=High risk **NO**	workplace What support will be available, i.e. will anyone else be available to assist if you call for help, etc. e.g. colleague knows where interview to take place and telephoned when completed and safe- what action to take after certain time if not phoned How to deal with aggressive/violent behaviour, what precautions will be taken to prevent this from happening?
Use of face-to-face interviews Volunteers or interviewees could become upset by interview and suffer psychological effects	**NO**	Consider: What initial and subsequent support will be made available for volunteers or interviewees? What to do if researcher uncovers information regarding an illegal act? What/who will be used to counsel distressed volunteers/ interviewees, what precautions will be taken to prevent this from happening?
Sensitive data	Exposure to data or information which may cause upset or distress to Researcher **NO**	Consider: What initial and subsequent support will be available to the researcher
Physical activity	Exposure to levels of excerption unsuitable for a individuals level of fitness **NO**	Consider: Health Questionnaire/ Medical declaration form / GP clearance. Trained First aid personnel/ Equipment.
Equipment	Exposure to faulty unfamiliar equipment. **NO**	Consider: Equipment is regularly checked and maintained as manufactures instructions. Operators receive adequate training in use of. Volunteers receive induction training prior to use.
Sensitive issues i.e. Gender / Cultural e.g. when observing or dealing with undressed	Exposure to vulnerable situations/ sensitive issues that may cause distress to interviewer or interviewee **NO**	Consider: Use of chaperones/ Translators. What initial and subsequent support will be made available for volunteers or interviewees?

members of the opposite sex Children		Adhere; to local guidelines and take advice from research supervisor
Manual Handling Activities	Exposure to a activity that could result in injury **NO**	Adapt the task to reduce or eliminate risk from manual handling activities. Ensure that volunteers understand and are capable of the manual handling task beforehand. Perform health questionnaire to determine volunteer fitness prior to recruitment

If you have answered yes to any of the hazards in question 3, please list the proposed precautions below:

Not applicable

Signature of student: Seth Kwadjo Angmorterh Date: 11th November, 2015

Name of Supervisor: Prof. Peter Hogg Date: 11th November, 2015

Appendix 15 – Volunteers' demographic data (baseline study)

No	Sex	Age	BMI
1	Female	55	23.9
2	Male	20	25.6
3	Male	26	25.4
4	Female	32	34.7
5	Male	44	26.5
6	Female	57	24.2
7	Male	35	32.6
8	Female	37	36.7
9	Male	35	29.8
10	Female	38	29.3
11	Female	43	22.5
12	Male	51	23.2
13	Male	35	25.8
14	Female	31	31.1
15	Male	28	23.2
16	Female	38	24.8
17	Female	59	27.6
18	Female	41	22.4
19	Male	34	25.5
20	Male	26	23.8
12	Male	21	27.2
22	Female	49	23.9
23	Male	34	23.4
24	Male	29	23
25	Male	32	23.8
26	Male	27	20.1
27	Male	28	23.1
28	Female	25	20.4
29	Female	40	22

30	Male	37	26.7
31	Female	34	28
32	Male	31	21
33	Male	31	24.8
34	Female	52	19.2
35	Female	49	23.9
36	Male	36	27.6
37	Female	53	24.2
38	Female	19	19.5
39	Male	28	27.2
40	Male	40	22.8
41	Female	31	19.9
42	Female	26	19.4
43	Female	21	20.7
44	Female	25	29.9
45	Male	23	28.2
46	Female	22	24.1
47	Female	18	19.9
48	Female	27	21.0
49	Female	23	19.2

Appendix 16 – Volunteers' demographic data (intervention study)

No	Sex	Age	BMI
1	Male	37	21.8
2	Male	29	34.2
3	Male	29	28.3
4	Male	28	24.8
5	Male	34	20.8
6	Male	39	26.9
7	Male	47	25.1
8	Male	34	30.9
9	Female	33	21.3
10	Male	38	21.9
11	Female	25	33.2
12	Female	38	34.6
13	Male	53	28.3
14	Male	38	22.5
15	Male	37	30.6
16	Male	38	20.8
17	Female	28	21.5
18	Male	26	34.6
19	Female	26	29.9
20	Female	31	29.8

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