

**UNIVERSITY OF SOUTHAMPTON**

**FACULTY OF HEALTH SCIENCES**

**Are strategies, including mechanical and traditional repositioning,  
effective for pressure ulcer prevention?**

by

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## **ABSTRACT**

FACULTY OF HEALTH SCIENCES

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### **ARE STRATEGIES, INCLUDING MECHANICAL AND TRADITIONAL REPOSITIONING, EFFECTIVE FOR PRESSURE ULCER PREVENTION?**

By Margriet Johanna Susanna Woodhouse

Pressure ulcers represent a debilitating condition for patients and present a significant challenge for healthcare professionals. To determine the risk of pressure ulcer development, patients are typically assessed with pressure ulcer risk assessment scales. Bedbound patients deemed at risk of pressure ulcers may receive a range of interventions, including regular repositioning by nursing staff. However, this is resource intensive and could be augmented by mechanical lateral rotation systems, although there is a paucity of research examining these systems.

Several experimental studies were conducted, utilising physical output parameters and comfort assessments to examine the efficacy and acceptability of two lateral rotation systems, when compared to traditional repositioning, in cohorts of healthy participants. In addition, a study sought to determine the inter-practitioner variability of traditional repositioning. An integrative review of pressure ulcer risk assessments scales was further undertaken, to update and extend previous reviews.

A number of differences were observed in the physical and comfort data, some of which were device dependent. A trend towards fewer instances of compromised tissue viability was observed during traditional repositioning, although some participants preferred turning by means of a lateral rotation system. Considerable variation was noted in the repositioning technique employed by practitioners, even after written guidance, and offloading of vulnerable areas was not always achieved. Ninety-four risk assessment scales were identified, but only 15% of these scales were assessed for inter-rater reliability. The methodological quality of such studies was often poor.

Lateral rotation systems may provide an adjunct to repositioning by traditional methods, but the design is important, both in terms of efficacy and acceptability. Practitioners should be provided with practical training, focusing on the procedural aspects of repositioning. Further high-quality primary research is required to evaluate existing risk assessment scales.



# Table of Contents

<b>Table of Contents .....</b>	<b>i</b>
<b>List of Tables .....</b>	<b>vii</b>
<b>List of Figures .....</b>	<b>xi</b>
<b>DECLARATION OF AUTHORSHIP.....</b>	<b>xvii</b>
<b>Acknowledgements.....</b>	<b>xix</b>
<b>Abbreviations .....</b>	<b>xxi</b>
<b>Chapter 1: Skin and Soft Tissue Anatomy and Physiology .....</b>	<b>1</b>
1.1 Skin .....	1
1.1.1 Epidermis.....	2
1.1.2 Dermis .....	4
1.2 Subcutaneous Tissue .....	5
1.3 Muscle .....	6
1.4 Microcirculation.....	6
1.4.1 Cellular Respiration and Oxygen and Carbon Dioxide Transport.....	8
1.5 Age-Related Changes in Skin and Soft Tissue .....	11
1.6 Skin and Soft Tissue Response to Loading .....	12
1.7 Summary .....	13
<b>Chapter 2: Introduction, Epidemiology, Aetiology, Classification and Risk</b>	<b>15</b>
2.1 The Burden of Pressure Ulcers .....	15
2.2 Prevalence and Incidence .....	16
2.3 Aetiology.....	19
2.4 Pressure Ulcer Classification .....	22
2.4.1 Pathophysiological Basis of Pressure Ulcer Categories.....	23
2.4.2 Reliability of the NPUAP, EPUAP and PPPIA Classification System ...	
.....	26
2.5 Risk Factors .....	29
2.5.1 Extrinsic Risk Factors .....	30
2.5.2 Intrinsic Risk Factors.....	33
2.6 Risk Assessment Scales .....	34

2.6.1	Systematic Reviews of Effectiveness, Validity and Reliability of RASs	39
2.7	Summary	40
<b>Chapter 3:</b>	<b>Integrative Review of Risk Assessment Scales</b>	<b>41</b>
3.1	Methods	41
3.1.1	Review Methodology and Scope	41
3.1.2	Eligibility Criteria	42
3.1.3	Search Strategy	44
3.1.4	Data Extraction	45
3.1.5	Quality Appraisal	45
3.1.6	Data Analysis and Synthesis	46
3.2	Search Results	48
3.3	The Characteristics of Risk Assessment Scales	50
3.3.1	Scale Derivation	66
3.3.2	Contemporary Scale Development	68
3.3.3	Scale Composition	70
3.3.4	Content Validation	71
3.4	The Reliability of Risk Assessment Scales	74
3.4.1	Quality Appraisal	81
3.4.2	Inter-rater Reliability Results	83
3.5	Discussion	85
3.6	Summary	87
<b>Chapter 4:</b>	<b>Pressure Ulcer Prevention</b>	<b>89</b>
4.1	Magnitude and Duration of Loading	89
4.2	Pressure Redistributing Support Surfaces	92
4.3	Repositioning	96
4.3.1	Frequency	96
4.3.2	Technique: 30° Side-lying Position	99
4.4	Lateral Rotation	104
4.5	Summary	107
4.6	Aim and Objectives	108
4.7	Measurement Techniques to Assess Tissue Viability	110

4.7.1	Transcutaneous Gas Tension Measurement .....	111
4.7.2	Interface Pressure Measurement.....	113
4.8	Comfort Assessment .....	115
<b>Chapter 5:</b>	<b>Evaluation of a Prototype Support Surface Incorporating a Lateral Rotation Function .....</b>	<b>117</b>
5.1	Materials and Methods .....	118
5.1.1	Prototype Support Surface Description and Settings .....	118
5.1.2	Transcutaneous Gas Tension Measurements .....	119
5.1.3	Interface Pressure Measurements .....	120
5.1.4	Comfort Assessment.....	121
5.1.5	Study Protocol .....	122
5.1.6	Data Collection Process.....	122
5.1.7	Data Processing and Analysis .....	125
5.2	Results .....	128
5.2.1	Participant Characteristics .....	128
5.2.2	Transcutaneous Gas Tensions Responses over the Entire Data Collection Period of a Single Session .....	128
5.2.3	Transcutaneous Gas Tension Responses Associated with Specific Turn Positions.....	131
5.2.4	Interface Pressures.....	134
5.2.5	Comfort Assessment.....	135
5.3	Discussion.....	138
5.4	Summary, Conclusion and Future Work .....	139
<b>Chapter 6:</b>	<b>Comparison of the Lateral Rotation Function of a Prototype Support Surface to Conventional Repositioning .....</b>	<b>141</b>
6.1	Materials and Methods .....	142
6.1.1	Prototype Support Surface.....	142
6.1.2	Manual Repositioning Technique .....	142
6.1.3	Transcutaneous Gas Tension Measurement .....	143
6.1.4	Interface Pressure Measurements .....	143
6.1.5	Inclinometer Measurements.....	144
6.1.6	Comfort Assessment.....	144
6.1.7	Study Protocol and Data Collection Process.....	144

6.1.8	Data Processing and Analysis.....	147
6.2	Results.....	149
6.2.1	Participants .....	149
6.2.2	Turn Angle Measurements.....	150
6.2.3	Transcutaneous Gas Tension Categories during LPR Turning and Manual Repositioning.....	152
6.2.4	Oxygen Debt and Carbon Dioxide Accumulation Associated with LPR Turning and Manual Repositioning.....	158
6.2.5	Position-specific Oxygen Debt and Carbon Dioxide Accumulation Associated with LPR Turning and Manual Repositioning .....	160
6.2.6	Interface Pressures .....	164
6.2.7	Comfort Assessment.....	167
6.2.8	Bilateral Sacral Gas Tensions and Interface Pressures .....	171
6.3	Discussion .....	174
6.4	Summary, Conclusion and Future Work .....	176

**Chapter 7: Comparison of a Lateral Rotation Platform to Conventional Repositioning..... 177**

7.1	Materials and Methods.....	177
7.1.1	Lateral Rotation Platform.....	177
7.1.2	Manual Repositioning Technique .....	179
7.1.3	Instruments .....	179
7.1.4	Study Protocol, Data Collection Process and Data Analysis .....	179
7.2	Results.....	182
7.2.1	Participants .....	182
7.2.2	Turn Angle Measurements .....	183
7.2.3	Transcutaneous Gas Tension Categories during LRP Turning and Manual Repositioning.....	185
7.2.4	Total Sacral Oxygen Debt and BMI .....	189
7.2.5	Position-Specific Oxygen Debt and Carbon Dioxide Accumulation Associated with LRP Turning and Manual Repositioning .....	190
7.2.6	Interface Pressures .....	194
7.2.7	Comfort Assessment.....	195
7.3	Discussion .....	199

7.4	Summary, Conclusion and Future Work .....	200
<b>Chapter 8:</b>	<b>The Variability and Effectiveness of Repositioning for Pressure Ulcer Prevention.....</b>	<b>203</b>
8.1	Materials and Methods .....	204
8.1.1	Survey .....	204
8.1.2	Inclinometer Measurements.....	204
8.1.3	Assessors Data Collection Instrument .....	204
8.1.4	Interface Pressure Measurements .....	205
8.1.5	Written Guidance on Repositioning.....	205
8.1.6	Study Protocol and Data Collection Process.....	205
8.1.7	Data Processing and Analysis .....	207
8.2	Results .....	209
8.2.1	Participants .....	209
8.2.2	Intraclass Correlation Coefficients of Turn Angles .....	210
8.2.3	Turn Angle Measurements.....	210
8.2.4	Agreement and Inter-rater Reliability of the Physical Assessment Results.....	211
8.2.5	Physical Assessment Results .....	213
8.2.6	Interface Pressures.....	218
8.3	Discussion .....	218
8.4	Summary, Conclusion and Future Work .....	219
<b>Chapter 9:</b>	<b>Discussion.....</b>	<b>221</b>
9.1	Evaluation of a Prototype Support Surface Incorporating a Lateral Rotation Function.....	222
9.2	Are Lateral Rotation Systems an Effective and Acceptable Alternative to Manual Repositioning? .....	224
9.3	Does the Repositioning Technique Vary Between Practitioners? .....	232
9.4	Integrative Review of Risk Assessment Scales .....	236
9.5	Summary .....	239
9.5.1	Recommendations for Clinical Practice.....	239
9.5.2	Recommendations for Designers of Lateral Rotation Systems .....	240
9.5.3	Future Work .....	240

<b>Appendices .....</b>	<b>243</b>
<b>Appendix A      RAS Review Search Strategy .....</b>	<b>245</b>
<b>Appendix B      QAREL Checklist.....</b>	<b>247</b>
<b>Appendix C      QAREL Assessments .....</b>	<b>249</b>
<b>Appendix D      Lateral Rotation Search Strategy.....</b>	<b>251</b>
<b>Appendix E      Prototype Support Surface Incorporating a Lateral Rotation                         Function Comfort Assessment.....</b>	<b>253</b>
<b>Appendix F      Evaluation of a Prototype Support Surface Incorporating a                         Lateral Rotation Function Participant Information Sheet.....</b>	<b>255</b>
<b>Appendix G      Prototype Lateral Rotation System and Manual Repositioning                         Comfort Assessment.....</b>	<b>259</b>
<b>Appendix H      Comparison of the Lateral Rotation Function of a Prototype                         Support Surface to Conventional Repositioning Participant Information                         Sheet .....</b>	<b>261</b>
<b>Appendix I      Comparison of a Lateral Rotation Platform to Conventional                         Repositioning Participant Information Sheet .....</b>	<b>265</b>
<b>Appendix J      Lateral Rotation Platform and Manual Repositioning Comfort                         Assessment .....</b>	<b>269</b>
<b>Appendix K      Reliability of Repositioning Participant Survey .....</b>	<b>271</b>
<b>Appendix L      The Reliability of Repositioning for Pressure Ulcer Prevention                         Participant Information Sheet.....</b>	<b>273</b>
<b>Appendix M      Publications and Conference Presentations .....</b>	<b>275</b>
<b>References .....</b>	<b>277</b>

# List of Tables

Table 1-1: Approximate partial pressures of oxygen and carbon dioxide at different sites .....	9
Table 2-1: Summary of pressure ulcer prevalence and incidence studies.....	18
Table 2-2: NPUAP, EPUAP and PPPIA PU classification system. ....	23
Table 2-3: Studies examining the inter- and intra-rater reliability of the NPUAP, EPUAP and PPPIA PU classification system. ....	27
Table 2-4: Extrinsic and intrinsic risk factors.....	30
Table 2-5: Scoring system developed by Norton and colleagues .....	35
Table 2-6: Key features of RASs commonly used in the UK.....	35
Table 2-7: Risk factors contained in a selection of commonly used RASs.....	36
Table 2-8: Sensitivity, specificity, predictive value, and likelihood ratio formulae.....	37
Table 2-9: Summary of a selection of systematic reviews which have investigated the predictive validity of RASs.....	39
Table 3-1: Summary of the key characteristics of the RASs identified by the search strategy. ....	51
Table 3-2: Summary of studies reporting on the inter-rater reliability of RAS. ....	75
Table 4-1: Summary of a selection of studies which have employed physical measurement techniques to evaluate the performance of support surfaces/ or positioning strategies .....	110
Table 5-1: Participant demographics.....	128
Table 5-2: Gas tension response at the sacrum over the entire data collection period of each test condition. ....	129
Table 5-3: Gas tension response at the shoulder over the entire data collection period of each test condition .....	129

Table 5-4: Percentage of participants within the TcPO <sub>2</sub> categories defined by Bogie and colleagues, per prescribed setting, position, and measurement site..131	
Table 5-5: Percentage of all participants within the TcPCO <sub>2</sub> categories defined by Bogie and colleagues per prescribed setting, position, and measurement site.....133	
Table 5-6: Summary of the median and range of the initial and end peak interface pressures that were associated with each of the test conditions. .... 134	
Table 5-7: Comfort assessment results for CLP and ALP sessions.....136	
Table 6-1: Participant demographics. ....149	
Table 6-2: Summary of the median and range of turn angle measurements in the three body locations during the tilt positions of the LPR turning and manual repositioning protocols.....150	
Table 6-3: Categorical responses of gas tensions at the sacrum during each turn position of the LPR turning and manual repositioning sessions.....153	
Table 6-4: Categorical responses of gas tensions at the shoulder during each turn position of the LPR turning and manual repositioning sessions.....154	
Table 6-5: Summary of the categorical responses from all participants, separated by site, protocol and position .....155	
Table 6-6: Summary of the median and interquartile range of the peak interface pressures during the initial supine, right and left tilt positions of the LPR and manual repositioning sessions.....165	
Table 6-7: Comfort assessment results for the LPR and manual repositioning protocols.....168	
Table 6-8: Categorical responses of gas tensions at the left and right sacral area, shown per position of the LPR turn cycle.....171	
Table 6-9: Peak body and sacral interface pressures of all participants, separated by turn cycle position.....174	
Table 7-1: Demographic details of participants.....182	

Table 7-2: Summary of the median and range of turn angle measurements in the three body locations during the tilt positions of the LRP turning and manual repositioning protocols. ....	183
Table 7-3: Categorical responses of gas tensions at the sacrum during each turn position of the LRP turning and manual repositioning sessions.....	186
Table 7-4: Categorical responses of gas tensions at the shoulder during each turn position of the LRP turning and manual repositioning sessions.....	188
Table 7-5: Summary of the median and interquartile range of the peak interface pressures during the initial supine, right tilt, left tilt and final supine positions of the LRP turning and manual repositioning sessions.....	194
Table 7-6: Comfort assessment results for the LRP and manual repositioning protocols.. ..	196
Table 8-1: Participant characteristics.....	209
Table 8-2: ICCs and 95% CIs associated with the pre- and post-test turn angle measurements obtained from the sternum, pelvis, and ankles.....	210
Table 8-3: Cross-tabulation of assessors A and B pre- and post-test physical assessment results .....	212
Table 8-4: Cross-tabulation of pre- and post-test physical assessment results .....	217
Table 8-5: Summary of the median and range of peak interface pressures during the pre- and post-test conditions .....	218
Table 9-1: Summary of studies which have investigated the effect of variation in the internal air cell pressure. ....	223
Table 9-2: Summary of the key features of the prototype support surface incorporating a lateral rotation function and the lateral rotation platform. ....	231
Table A-1: Full search strategy for each database. ....	245
Table B-1: The QAREL checklist.....	247
Table C-1: QAREL assessment results for the individual inter-rater reliability studies....	
.....	249

Table A-1: Search terms, limiters and results of the search strategy. ..... 251

# List of Figures

Figure 1-1: Cross-section of the skin and subcutaneous tissue.....	1
Figure 1-2: Sensory receptors in the skin.....	5
Figure 1-3: Schematic of tissue fluid filtration and reabsorption.....	7
Figure 1-4: Simplified model of cellular respiration.....	8
Figure 1-5: Oxyhaemoglobin dissociation curve.....	10
Figure 1-6: Stresses generated within skin and soft tissues overlying a bony prominence upon application of a perpendicular force.....	12
Figure 2-1: Simplified model of an 80kg male seated on a foam cushion, demonstrating differential responses of soft tissue layers.....	26
Figure 2-2: The effect of extrinsic factors on skin .....	32
Figure 2-3: Characteristics of the ideal RAS.....	38
Figure 3-1: Applied five-stage framework for integrative reviews.....	42
Figure 3-2: Flow diagram of the search and selection process.....	49
Figure 3-3: Primary development method of RASs published from 1962-2016.....	69
Figure 3-4: The frequency of inclusion of the 10 NPUAP, EPUAP and PPPIA risk factor domains within RASs .....	72
Figure 4-1: Pressure ulcer risk curves.....	90
Figure 4-2: Conceptual basis for intervention strategies.....	91
Figure 4-3: Selection of the parameters of active pressure redistribution surfaces.....	93
Figure 4-4: The relationship between internal pressures in the alternating pressure segment of the mattress and BMI for four HOB angles .....	94
Figure 4-5: The 30° side-lying position .....	99
Figure 4-6: The Freedom Bed .....	105

Figure 4-7: Schematic of prototype automated inclining beds developed by Yi and colleagues .....	106
Figure 4-8: Flow diagram of the studies contained in this thesis.....	109
Figure 4-9: Schematic of the 3 distinct gas tension responses .....	113
Figure 5-1: Schematic of the prototype LPR device.....	118
Figure 5-2: Mattress with LPR function activated.....	119
Figure 5-3: Configuration of pressure sensors.....	121
Figure 5-4: Schematic of study protocol over the two test sessions.....	122
Figure 5-5: Data collection process for both sessions.....	124
Figure 5-6: Typical transcutaneous oxygen and carbon dioxide tensions at the shoulder and sacrum.....	126
Figure 5-7: Transcutaneous gas tensions exhibited by participant F, during the CLP and ALP test conditions.....	130
Figure 5-8: Boxplot of the initial and end sacral interface pressures obtained during each measurement session.....	135
Figure 6-1: Example of manual repositioning to a right tilt position .....	143
Figure 6-2: Data collection process for the bilateral sacrum session. ....	145
Figure 6-3: Data collection process for the LPR and manual repositioning sessions. 146	
Figure 6-4: Schematic of oxygen debt and carbon dioxide accumulation over the data collection period. ....	148
Figure 6-5: Boxplot showing the turn angles obtained during the right tilt position of the LPR turning and manual repositioning protocols. ....	151
Figure 6-6: Boxplot showing the turn angles obtained during the left tilt position of the LPR turning and manual repositioning protocols. ....	151
Figure 6-7: Gas tension results from participant A during the LPR session .....	156
Figure 6-8: Gas tension results from participant B during the LPR session .....	156

Figure 6-9: Gas tension results from participant E during the LPR session .....	157
Figure 6-10: Total oxygen debt at the sacrum and shoulder, measured over the entire turn cycle of the LPR and manual repositioning sessions. ....	159
Figure 6-11: Total carbon dioxide accumulation at the sacrum and shoulder, measured over the entire turn cycle of the LPR and manual repositioning sessions. ....	159
Figure 6-12: Linear model of total sacral oxygen debt and carbon dioxide accumulation, observed during LPR turning.....	160
Figure 6-13: Oxygen debt at the sacrum during LPR turning and manual repositioning, separated by position. ....	161
Figure 6-14: Carbon dioxide accumulation at the sacrum during LPR turning and manual repositioning, separated by position. ....	161
Figure 6-15: Oxygen debt at the shoulder during LPR turning and manual repositioning, separated by position. ....	163
Figure 6-16: Carbon dioxide accumulation at the shoulder during LPR turning and manual repositioning, separated by position. ....	163
Figure 6-17: Sacral and shoulder peak interface pressures and oxygen debt during the right and left tilt positions of the LPR and manual repositioning sessions .....	166
Figure 6-18: Comparison of perceived safety during the turned positions of the LPR and manual repositioning protocols.....	170
Figure 6-19: Transcutaneous gas tensions from participant E, measured during the bilateral sacrum session.....	172
Figure 6-20: Oxygen debt at the right and left sacral regions, separated by position.	173
Figure 6-21: Carbon dioxide accumulation at the left and right sacral regions, separated by position. ....	173
Figure 7-1: Schematic of the ToTo™ turn mechanism and turn cycle. ....	178
Figure 7-2: LRP induced turn with the castellated foam mattress in situ.....	178

Figure 7-3: Data collection process for the LRP and manual repositioning sessions.	181
Figure 7-4: Boxplot showing the turn angles obtained during the right tilt position of the LRP turning and manual repositioning protocols.	184
Figure 7-5: Boxplot showing the turn angles obtained during the left tilt position of the LRP turning and manual repositioning protocols.	184
Figure 7-6: Linear model of BMI and total sacral oxygen debt associated with the LRP protocol.	189
Figure 7-7: Linear model of BMI and total sacral oxygen debt associated with the manual repositioning protocol.	189
Figure 7-8: Oxygen debt at the sacrum during LRP turning and manual repositioning, separated by position.	191
Figure 7-9: Carbon dioxide accumulation at the sacrum during LRP turning and manual repositioning, separated by position.	191
Figure 7-10: Oxygen debt at the shoulder during LRP turning and manual repositioning, separated by position.	193
Figure 7-11: Carbon dioxide accumulation at the shoulder during LRP turning and manual repositioning, separated by position.	193
Figure 7-12: Scatter plot of the peak interface pressure and oxygen debt recorded at the shoulder, during the left tilt position of the LRP turning and manual repositioning sessions.	195
Figure 7-13: Comparison of perceived safety during the right tilt position of the LRP and manual repositioning protocols.	198
Figure 7-14: Comparison of perceived safety during the left tilt position of the LRP and manual repositioning protocols.	198
Figure 8-1: Data collection process.	207
Figure 8-2: Boxplot showing the pre- and post-test turn angles at each of the sites.	211
Figure 8-3: Differences in the pre-test repositioning technique of participants.	215
Figure 8-4: Differences in the post-test repositioning technique of participants.	216

Figure 9-1: Boxplot illustrating the turn angles obtained during the left tilt position of the prototype support surface, lateral rotation platform and manual repositioning protocols .....	225
Figure 9-2: Sacral oxygen debt across the positions of the prototype support surface, lateral rotation platform and manual repositioning protocols.....	227
Figure 9-3: Sacral carbon dioxide accumulation across the positions of the prototype support surface, lateral rotation platform and manual repositioning protocols. ....	227
Figure 9-4: Comparison of perceived overall comfort during the right tilt position of the prototype support surface, lateral rotation platform and manual repositioning protocols .....	230
Figure 9-5: Comparison of perceived safety during the right tilt position of the prototype support surface, lateral rotation platform and manual repositioning protocols. ....	230
Figure 9-6: Variation in the 30° side-lying position.....	234
Figure D-1: Lateral rotation search and selection process.....	252



# DECLARATION OF AUTHORSHIP

I, Margriet Johanna Susanna Woodhouse declare that this thesis entitled 'Are strategies, including mechanical and traditional repositioning, effective for pressure ulcer prevention?' and the work presented in it are my own and has been generated by me as the result of my own original research.

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
5. I have acknowledged all main sources of help;
6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
7. Parts of this work have been published as:

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## Abbreviations

AfC	Agenda for Change
ALP	Alternating low pressure
APAM	Alternating pressure air mattress
ATP	Adenosine triphosphate
BMI	Body mass index
CENTRAL	The Cochrane Central Register of Controlled Trials (database)
CI	Confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature (database)
CLP	Continuous low pressure
CLRT	Continuous lateral rotation therapy
CMS	Centers for Medicare & Medicaid Services
CT	Computed tomography
CULP	Continuous ultra low pressure
CVA	Cerebrovascular accident
EN	Enrolled nurse
EPUAP	European Pressure Ulcer Advisory Panel
HOB	Head of bed
HRV	Heart rate variability
ICC	Intraclass correlation coefficient
ICU	Intensive care unit
IP	Interface pressure
IP <sub>opt</sub>	Optimum internal air pressure

K	Cohen's Kappa
LDF	Laser Doppler Flowmetry
LPN	Licensed practical nurse
LPR	Lateral pressure redistribution
LRP	Lateral rotation platform
MeSH	Medical Subject Headings
MRI	Magnetic resonance imaging
NA	Nursing assistant
NHS	National Health Service
NMF	Natural Moisturising Factor
NPUAP	National Pressure Ulcer Advisory Panel
$p_o$	Proportion of agreement
PPG	Photoplethysmography
PPPIA	Pan Pacific Pressure Injury Alliance
PU	Pressure ulcer
PURAS	Pressure ulcer risk assessment scale
PVD	Peripheral vascular disease
QAREL	Quality Appraisal of Reliability Studies (checklist)
RAS	Risk assessment scale
RCT	Randomised control trial
RN	Registered nurse
ROC	Receiver operator characteristic (curves)
SCI	Spinal cord injury
SD	Standard deviation

SEM	Standard error of measurement
SICU	Surgical intensive care unit
SvO <sub>2</sub>	Mixed venous oxygen saturation
TcPCO <sub>2</sub>	Transcutaneous carbon dioxide tension
TcPO <sub>2</sub>	Transcutaneous oxygen tension
WoS	Web of Science (database)



# Chapter 1: Skin and Soft Tissue Anatomy and Physiology

This chapter aims to consider the structure and function of the skin and the underlying soft tissues. Additionally, the microcirculation, fundamental in maintaining the viability of these tissues, will be considered and age-associated changes discussed. Finally, consideration will be given to the skin and soft tissues response to loading. Discussion of these topics serves as a prelude to subsequent chapters, which will focus on pressure ulcers, a type of skin and soft tissue impairment resulting from mechanical loading.

## 1.1 Skin

The skin (Figure 1-1) is the largest organ of the human body, which measures approximately  $1.8\text{m}^2$ , and accounts for 16% of the total body weight (Gawkrodger 2008). Its purpose is multifactorial, and can be broadly classified into protective, thermoregulatory, sensory, biochemical and psychosocial functions.

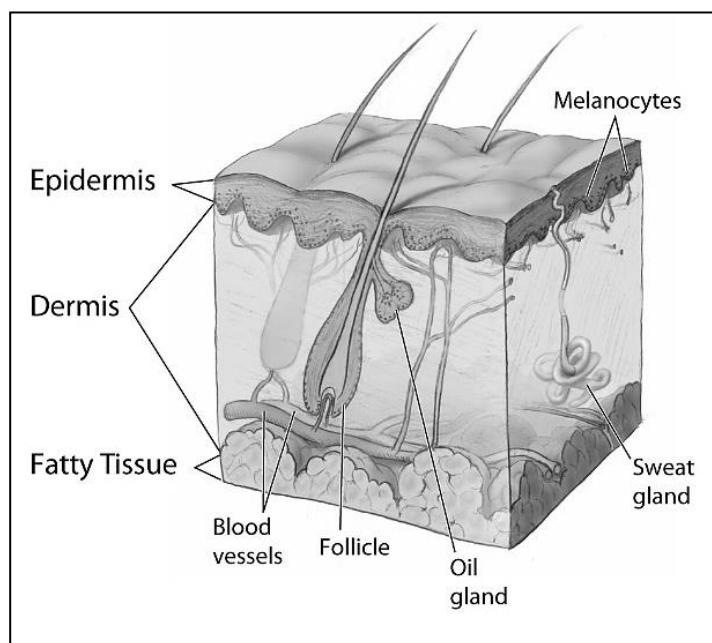


Figure 1-1: Cross-section of the skin and subcutaneous tissue (National Cancer Institute 2010, copyright free).

## Skin and Soft Tissues

Intact skin provides a barrier to the outside environment, protecting from noxious external stimuli and mechanical damage and, in so doing, maintains internal systems and prevents excessive fluid loss. Additionally, its acidic surface, with an estimated 'natural' pH value of 4.7 (Lambers et al. 2006), inhibits colonisation of potentially harmful microorganisms. Dendritic Langerhans cells, found in the epidermis, and dermal macrophages further provide immunological protection.

Thermoregulation in part occurs through cutaneous thermoreceptors. Warmth and cold receptors in the skin transmit impulses to the hypothalamus, which induces cutaneous vasoconstriction or vasodilation, as appropriate. Vasodilation causes heat loss from the surface by radiation, and sweat released from eccrine glands evaporates, thereby cooling the surface of the skin. Conversely, vasoconstriction enables heat conservation by reducing surface cooling. In addition to thermoreceptors, other sensory receptors located in the skin function as mechanoreceptors and nociceptors. The former detect touch, pressure and vibration, while the latter are free nerve endings, which respond to painful stimuli from mechanical, thermal or chemical tissue damage.

Several biochemical reactions take place in the skin. As an example, vitamin D synthesis relies on activation of a precursor molecule, cholecalciferol, when skin is exposed to ultraviolet B light. The metabolism of androgen, a subclass of steroid hormones, further occurs in the skin (Hughes 2003).

In terms of its psychosocial function, the skin functions as an organ of expression, and as Penzer (2010) states, adornment or display, or lack thereof, may serve as an indicator of religion or culture. As the interface to the external environment, skin may reveal underlying pathologies, and irregularities in the form of dermatological conditions (Bowe et al. 2011; Khoury et al. 2014), or chronic wounds (Persoon et al. 2004; Spilsbury et al. 2007), may adversely affect psychological well-being.

### 1.1.1 Epidermis

The epidermis forms the avascular outer layer of the skin and consists of stratified squamous epithelium. Its thickness is site dependent but varies from 0.05mm at the eyelids, to as much as 1.5mm at the soles of the feet (Bensouilah & Buck 2006). The total epidermal turnover rate, which represents the sum of cell proliferation, epidermal transit time and the shedding of corneocytes, termed desquamation, is approximately 39 days in healthy skin (Weinstein et al. 1984). Four or five distinct cell layers are found

in the epidermis; the Stratum Basale, Stratum Spinosum, Stratum Granulosum, Stratum Lucidum and Stratum Corneum.

The Stratum Basale consists of a single row of columnar keratinocytes and forms the innermost layer of the epidermis. Structural proteins contained within the cytoplasm of these keratinocytes, tonofilaments, attach to desmosomes that function as inter-cellular rivets, binding adjacent cells together. Similarly, hemidesmosomes attach to tonofilaments and anchor keratinocytes in the basal stratum to the dermo-epidermal junction, otherwise known as the basement membrane. The corrugated shape of this membrane promotes adhesion between the epidermal and dermal layers and increases the surface area for oxygen and nutrient delivery to the epidermis, and waste product removal via the dermis. Mitotic activity occurs in the Stratum Basale, and daughter keratinocytes migrate upwards towards the outer layer of the epidermis, where eventual desquamation occurs. Other cells contained in the basal layer are pigment producing melanocytes and touch-sensitive Merkel cells, which contact sensory receptors via the terminal Merkel discs (Penzer 2010).

Within the Stratum Spinosum 8 to 10 layers of keratinocytes, which assume a polyhedral shape as a result of desmosomal connections, are tightly packed together thus contributing to the tensile strength and flexibility of the skin. These connections are continuously broken and reformed as cells migrate through this layer. A scattering of Langerhans cells is found in this stratum, as well as melanocytic projections.

Keratinocyte apoptosis takes place in the adjacent Stratum Granulosum and the 3 to 5 rows of keratinocytes that are present in this layer flatten. Tonofilaments are converted into keratin, a tough, pliable protein. Additionally, exocytosis of lipid vesicles occurs, filling the intercellular spaces in this, and subsequent strata, thereby creating a hydrophobic barrier.

The Stratum Lucidum is present only in 'thick' skin areas, namely the palmar surface of the hands and soles of the feet. Consisting of 3 to 5 rows of translucent keratinocytes, it serves to reduce friction between the subjacent and the most superficial layer of the epidermis.

Corneocytes form the fibrous keratinised remains of keratinocytes in the Stratum Corneum, held in place by corneodesmosomes and intercellular lipids. The thickness of the Stratum Corneum is site-dependent, but consists of approximately 10 to 30 rows of corneocytes. Compounds including amino acids, lactate and urea, collectively known as Natural Moisturising Factor (NMF), are present within corneocytes and serve to

## Skin and Soft Tissues

draw atmospheric water into these cells, thereby maintaining elasticity and enabling optimum barrier function (Fore-Pfliger 2004; Fowler 2012). Adequate hydration is further necessary for corneodesmolytic processes and subsequent desquamation to occur which, if inhibited, lead to xerosis (Harding et al. 2000).

### 1.1.2 Dermis

The dermis lies beneath the basement membrane and can be divided into two strata; the superficial papillary dermis and deep reticular dermis, although the boundary between these layers is poorly defined. Dermal thickness varies from 0.6mm to 3mm depending on anatomical site (Gawkrodger 2008), about 20% of which represents the papillary dermis (Tortora & Derrickson 2009).

The main structural components of the dermis are collagen, elastin and proteoglycans. Collagen type I and III are the primary collagen fibres in the dermis, which cross-link to form a network that serves to provide tensile strength and stiffness (Schultz et al. 2005), capable of withstanding relatively high loads. In the papillary dermis, these fibres are relatively thin and haphazardly arranged, while coarser bundles run parallel to the skin surface in the reticular dermis. Elastin fibres, which provide elasticity, are scarcer but similar to collagen the density varies and coarser fibres are found in the reticular dermis. Collagen and elastin fibres are suspended in an amorphous gel formed by the hydrophilic proteoglycans, which are important in maintaining the high dermal water content. The resulting 'ground substance' of the dermis provides lubrication thus enabling a degree of movement of dermal fibres, offers a medium for the diffusion of nutrients and hormones, and withstands external compression forces by virtue of its viscoelastic properties.

Fibroblasts are found extensively throughout the dermis and synthesise collagen, elastin and proteoglycans. These cells further release cytokines and growth factors which are required for both normal skin maintenance, and wound healing (Wong et al. 2007). In addition to macrophages and several other immune cells, mast cells are also present in the dermis, sited in the vicinity of blood vessels, an abundance of which is found in the dermis. Arborising vessels from the subcutaneous tissue extend upwards into the dermis and form the deep cutaneous plexus, where they branch upwards again to form the superficial subpapillary plexus. Capillary loops branch off this plexus and extend into the dermal papillae beneath the basement membrane, which intertwine with the rete pegs of the epidermis.

Sensory receptors are present throughout the dermis, as is illustrated in Figure 1-2. Other structures contained in the dermis are lymphatic capillaries, hair follicles and connected sebaceous glands, as well as sweat glands.

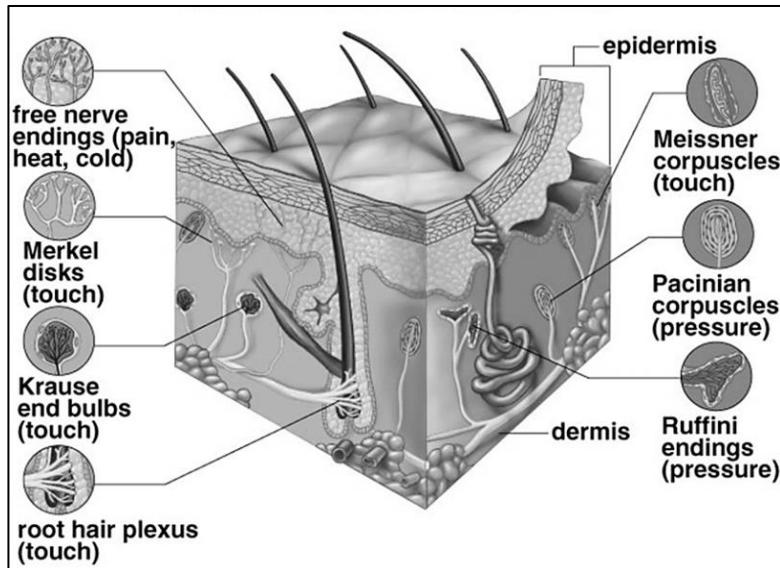


Figure 1-2: Sensory receptors in the skin (Constantin et al. 2006, reproduced with permission from the rights holder, McGraw-Hill).

## 1.2 Subcutaneous Tissue

Subcutaneous tissue lies beneath the dermis and is anchored by collagen fibres that extend from the reticular layer of the dermis. This loose connective tissue is mostly comprised of adipocytes. Vacuoles within adipocytes store triglycerides and cell size and, eventually cell count, increase if nutritional intake exceeds metabolic demand (Albright & Stern 1998). Conversely, lipolysis of triglycerides occurs if demand exceeds intake. In addition to this energy reserve function, the subcutaneous tissue also provides insulation thus reducing cutaneous heat loss, and cushioning thereby protecting underlying structures. The subcutaneous vascular plexus runs parallel to the skin and lymphatic vessels and nerves contained within the subcutaneous tissue run perpendicular, towards the skin. A proportion of pacinian corpuscles, a type of mechanoreceptor that is responsive to pressure (Figure 1-2), terminate in the subcutaneous tissue.

### **1.3 Muscle**

Beneath the subcutaneous tissue lies skeletal muscle, encapsulated by a band of irregular connective tissue, the fascia, which serves to bind muscle fibres together and reduce friction thereby enabling muscle movement. Skeletal muscle is composed of elongated muscle cells known as fibres, groups of which respond to nerve impulses to produce voluntary body movements and serve to stabilise body positions. Additionally, muscle contraction has a role in thermogenesis. Since contraction requires a substantial amount of energy in the form of adenosine triphosphate (ATP), a dense capillary network is found throughout muscle tissue to supply oxygen and glucose, and remove waste products. An increase in muscle size occurs as a result of hypertrophy of existing fibres rather than an increase in fibre numbers due to cellular division, a mechanism which is inherently limited. Therefore, if muscle damage occurs full regeneration may not be possible.

### **1.4 Microcirculation**

The skin and soft tissue microcirculation facilitates the exchange of nutrients and waste products. Oxygenated blood is transported by arteries which branch into arterioles and metarterioles before arriving at the capillaries, where cellular exchange occurs through thin-walled vessels, consisting of a single layer of endothelial cells. Following this, capillary vessels drain into venules and finally veins, which carry deoxygenated blood back to the systemic circulation where gaseous exchange occurs and the cycle recommences. However, blood flow to the capillary bed is not constant and at any given time approximately 75% of capillaries are bypassed (Tortora & Derrickson 2011), and flows continues through anastomotic 'preferential' vessels. This mechanism is controlled by both contraction and relaxation of metarterioles, and precapillary sphincters, in response to nervous regulation and vasoactive chemicals and hormones. The cyclical opening and closing of flow into capillaries, termed vasomotion, is proportional to the metabolic need of the surrounding tissues, ensuring that supply meets but does not exceed tissue requirements. Hyperaemia may occur with increasing tissue demands, such as in muscle during exercise, or when there is a lack of oxygen and accumulation of waste products, termed active and reactive hyperaemia respectively (Bliss 1998).

Excess interstitial fluid accumulates as a result of normal vascular microcirculation. High hydrostatic pressure in the arteriolar end of capillaries exceeds plasma osmotic pressure created by large proteins, such as albumin. As interstitial fluid exerts little if any opposing force, fluid filtration occurs. This is offset by the lower hydrostatic pressure at the venule end of the capillary, where plasma osmotic pressure exceeds capillary hydrostatic pressure and reabsorption occurs. Nonetheless, under normal physiological conditions approximately 10% of the interstitial fluid created as a result of capillary hydrostatic pressure is not reabsorbed and instead enters the lymphatic capillaries (Hall 2011). This process is depicted in Figure 1-3.

Lymphatic capillaries lie in close proximity to vascular capillaries. These blind ended capillaries consist of one-way valves as a result of overlapping endothelial cells that are fixed to surrounding connective tissue by anchoring filaments. As interstitial pressure rises the anchoring filaments open the spaces between the endothelial cells, and the subsequent rise in capillary volume closes these spaces thereby preventing backflow. This not only ensures that excess fluid, but also larger particles unable to be reabsorbed by the vascular microcirculation, such as proteins, are drained from the interstitial space. The resulting lymph fluid is transported into larger lymphatic vessels towards lymph nodes followed by lymph trunks, prior to returning to the venous circulation via lymphatic ducts (Tortora & Derrickson 2011).

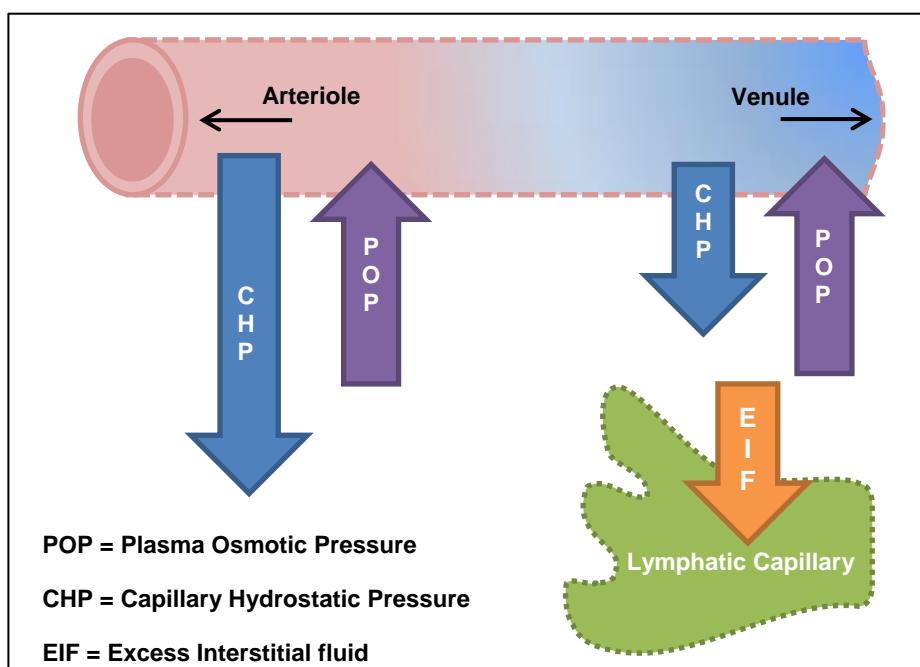


Figure 1-3: Schematic of tissue fluid filtration and reabsorption (figure adapted by author from Tortora & Derrickson 2011).

#### 1.4.1 Cellular Respiration and Oxygen and Carbon Dioxide Transport

Cellular respiration comprises of several metabolic pathways that facilitate the production of ATP, required to provide energy for intracellular reactions. During aerobic respiration oxygen is utilised and carbon dioxide generated, as is illustrated in Figure 1-4. Anaerobic respiration, although the predominant mechanism in certain tissues such as the epidermis (Ronquist et al. 2003), is generally insufficient to meet the metabolic demands and therefore delays but does not prevent cellular injury (Schober & Schwarte 2012). Consequently, a near constant supply of oxygen and removal of carbon dioxide is required, which occurs as a result of the differing partial pressures between sites and their immediate surrounding areas.

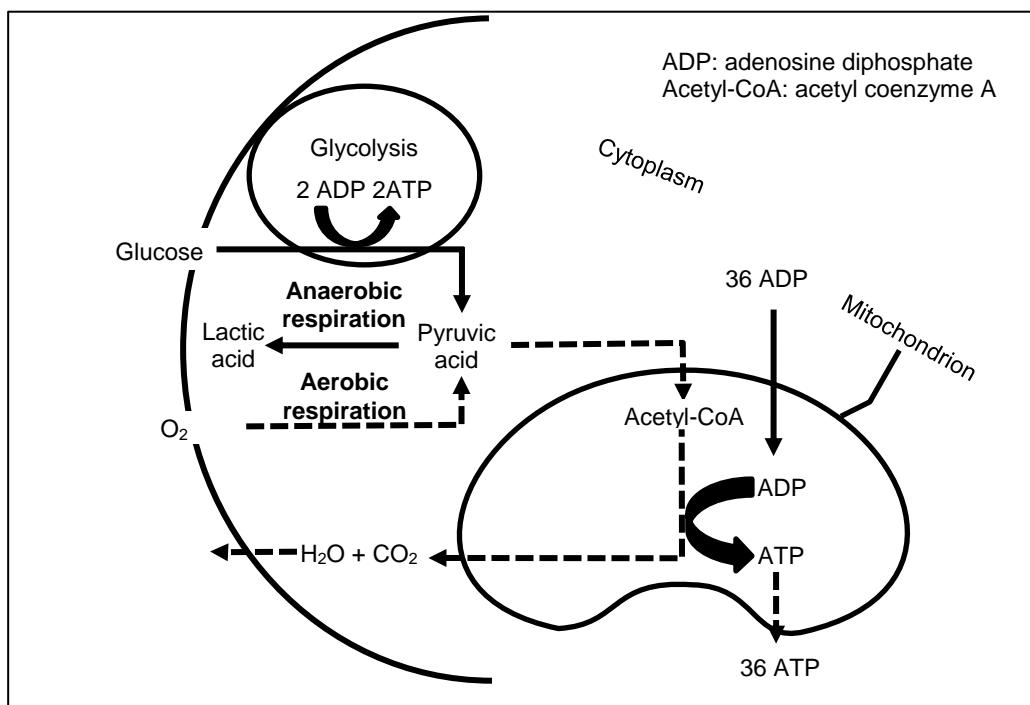


Figure 1-4: Simplified model of cellular respiration (figure adapted by author from Hall 2011). Glycolysis produces 2 ATP, and results in the synthesis of pyruvic acid. In the presence of oxygen pyruvic acid forms the substrate for the first of two metabolic pathways generating 36 ATP, while converting to lactic acid under anaerobic conditions.

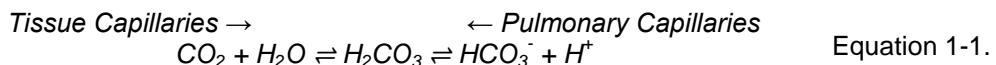
Oxygen utilised for cell metabolism depletes intracellular oxygen levels and thus encourages diffusion from the interstitial fluid into these tissues. The resulting decline in the partial pressure of oxygen within the interstitial fluid ensures the diffusion of oxygen from the peripheral capillaries. Similarly, intracellular carbon dioxide generated from aerobic metabolism diffuses into the interstitial fluid, where the partial pressure of this gas is lower, and subsequently diffuses into the peripheral capillaries. The approximate partial pressures of oxygen and carbon dioxide at various sites are contained in Table

1-1. The decline of oxygen in blood leaving the pulmonary capillaries and arriving at the peripheral capillaries results from the venous admixture of blood, where blood shunted past the alveoli to supply the deep tissue of the lungs, combines with blood from pulmonary capillaries in the pulmonary veins (Hall 2011).

Table 1-1: Approximate partial pressures of oxygen and carbon dioxide at different sites (table adapted by author from Wywialowski 1999, with permission from the rights holder, Elsevier, data from Wywialowski 1999; Hall 2011). The capillary partial pressures proximal to the arterioles are denoted in red, and partial pressures proximal to venules in blue.

Gas	Atmosphere (sea level)	Alveoli	Pulmonary capillaries	Peripheral capillaries	Interstitial fluid	Intracellular (peripheral)
PO <sub>2</sub>	160mmHg	104mmHg	40 - 104 mmHg	95 - 40 mmHg	40mmHg	23mmHg
PCO <sub>2</sub>	0.3mmHg	40mmHg	45 - 40 mmHg	40 - 45 mmHg	45mmHg	46mmHg

Within the capillaries erythrocytes facilitate the transport of oxygen and, to a lesser extent, carbon dioxide. Haemoglobin molecules contained within erythrocytes, consisting of four amino acid chains and associated haem groups, bind with oxygen to produce oxyhaemoglobin or, in the case of carbon dioxide, carbaminohaemoglobin. Most of the circulatory oxygen is bound to haemoglobin, while the remainder travels dissolved in plasma water. In contrast, only a small percentage of the carbon dioxide that diffuses into the capillaries travels bound to haemoglobin. The majority reacts with water to form carbonic acid (H<sub>2</sub>CO<sub>3</sub>), a reaction which is catalysed by carbonic anhydrase contained in erythrocytes. In turn, carbonic acid swiftly dissociates into a bicarbonate ion (HCO<sub>3</sub><sup>-</sup>) and a hydrogen ion (H<sup>+</sup>). The former transfers to plasma and circulates in this form, while the latter binds with haemoglobin, thus buffering blood and maintaining a normal pH of 7.35-7.45. A reversal of this process occurs at the pulmonary capillaries, thereby enabling the diffusion and subsequent expiration of carbon dioxide. The above is summarised in Equation 1-1. The final remaining proportion of carbon dioxide dissolves directly in blood plasma.



The ability of haemoglobin to bind oxygen where high partial pressures exist and release this where low partial pressures are present can be graphically represented in the oxyhaemoglobin dissociation curve, shown in Figure 1-5<sup>1</sup>. This illustrates that at

<sup>1</sup> This image was published in Arterial Blood Gases Made Easy, Hennessey and Japp, page 11, Copyright Churchill Livingstone Elsevier (2007).

## Skin and Soft Tissues

high partial pressures of oxygen, such as found in the pulmonary capillaries, haemoglobin reaches a saturation of approximately 97%, whereas in areas with low partial pressures, such as blood returning to the venous circulation via the peripheral capillaries, haemoglobin saturation is approximately 72%. Overall, Figure 1-5 indicates that at higher partial pressures, increased haemoglobin saturation occurs. However, this relationship is not linear. The sigmoidal shape of the oxyhaemoglobin dissociation curve may be attributed to the fact that once oxygen binds to haemoglobin, allosteric activation increases its affinity for oxygen. The flat part of the curve reflects near maximal binding capacity, where higher partial pressures of oxygen have relatively little effect on haemoglobin saturation.

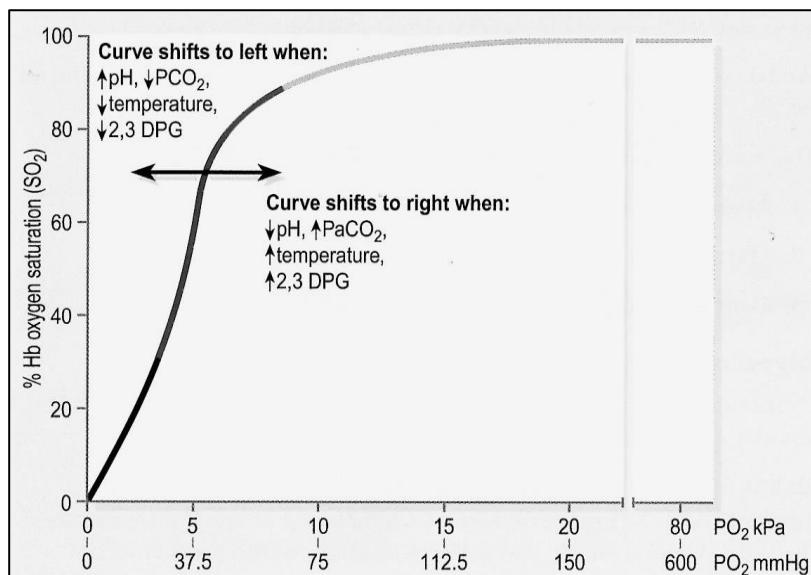


Figure 1-5: Oxyhaemoglobin dissociation curve (Hennessey & Japp 2007, reproduced with permission from the rights holder, Elsevier).

Several factors affect oxyhaemoglobin saturation. One of these is a decrease in pH, which may result from an accumulation of carbon dioxide. This causes a reduced affinity for oxygen, thus increasing oxygen release, denoted by a rightward shift of the oxyhaemoglobin dissociation curve. An increase in metabolic demand and the associated increase in temperature further result in reduced oxygen affinity, as do increasing levels of 2, 3-diphosphoglycerate (2, 3 DPG) due to hypoxia. All of the above factors may also increase haemoglobin's affinity for oxygen when reversed, such as an increase in pH, and are denoted by a leftward shift of the oxyhaemoglobin dissociation curve. The preceding mechanisms, combined with heart rate and vasomotion, ensure that oxygen transport and release is optimised in response to systemic or local tissue demands.

## 1.5 Age-Related Changes in Skin and Soft Tissue

Ageing results in numerous changes within skin and soft tissues. Epidermal transit time, which represents the time required for cells to migrate from the Stratum Basale to the Stratum Corneum, has been found to lengthen by 50% (Grove & Kligman 1983). Furthermore, the overall thickness of the epidermis declines and a reduction of intercellular lipids, NMF, Langerhans cells and melanocytes occurs (Farage et al. 2007). Early histological observations have further revealed a flattening of the epidermal rete pegs, and a thickening and shrinking of dermal elastin fibres in aged skin specimens (Montagna & Carlisle 1979). More recently, modern imaging techniques have shown a thinned and disarrayed dermal collagen network in older skin when compared to younger skin (Koehler et al. 2008). Ageing further alters the proteoglycan content thereby reducing the ability to retain water and decreasing dermal thickness (Naylor et al. 2011). The combined effect of these changes may be readily noticeable externally, such as the development of dry or loose skin with advancing age. However, some of the above changes are less discernible, but nonetheless contribute to an overall reduced ability to withstand external stimuli and mechanical damage.

These events may be exacerbated by the significant increase in tactile thresholds found in studies involving elderly subjects (Wickremaratchi & Llewelyn 2006). This decrease in sensory perception results in an impaired response to mechanical stimuli, which may be due to a reduction in Pacinian and Meissner corpuscles and Merkel discs (Figure 1-2). Ageing further affects the microcirculation in a number of ways. Next to a reduction in both the diameter and number of lymphatic capillaries, vascular capillary loops in the papillary dermis also become sparser and, in the remaining vessels, vasomotion is impaired (Ryan 2004). Underneath the skin, the density of subcutaneous tissue alters with advancing age. Where in middle age this has a tendency to increase, in old age there is a general decline, in part resulting from fat redistribution from these tissues to sites surrounding organs, termed visceral fat, as well as an impaired lipogenesis and lipolysis function (Tchkonia et al. 2010). A loss of both muscle mass and strength, sarcopenia, also occurs with ageing and is believed to be multifactorial in origin (Morley et al. 2001).

In addition to these largely intrinsic ageing processes, age-associated morbidities such as peripheral vascular disease, or treatments, such as corticosteroids, may also have deleterious effects on the skin and soft tissues. Moreover, the functional decline which may accompany advancing age can result in skin and soft tissue changes, as

## Skin and Soft Tissues

illustrated by incontinence, which may affect the barrier function of the superficial skin, and may further precipitate deeper tissue damage. Combined the changes outlined above not only increase the risk of skin and soft tissue damage, but also contribute to a protracted healing process when skin integrity is lost.

### 1.6 Skin and Soft Tissue Response to Loading

Gravitational forces acting downwards and opposing forces exerted by the supporting surface expose localised skin and soft tissue areas, depending on body position, to several potentially damaging forces (Gibson et al. 2006). The effect these forces exert on skin and soft tissues is referred to as stress, and is defined as the force over the area on which it acts (Hampton et al. 2005). A load applied perpendicularly to the skin and soft tissues overlying a bony prominence results not only in a direct compression stress, but also a tensile stress reflecting the subsequent stretching of the tissues, and a shear stress as a result of tissue distortion (Takahashi et al. 2010). These stresses are illustrated in the schematic contained in Figure 1-6. However, while the skin and soft tissues are presented as a homogenous mass in this figure, these stresses vary between individual tissue layers due to the specific mechanical properties of tissues (Oomens et al. 2010).

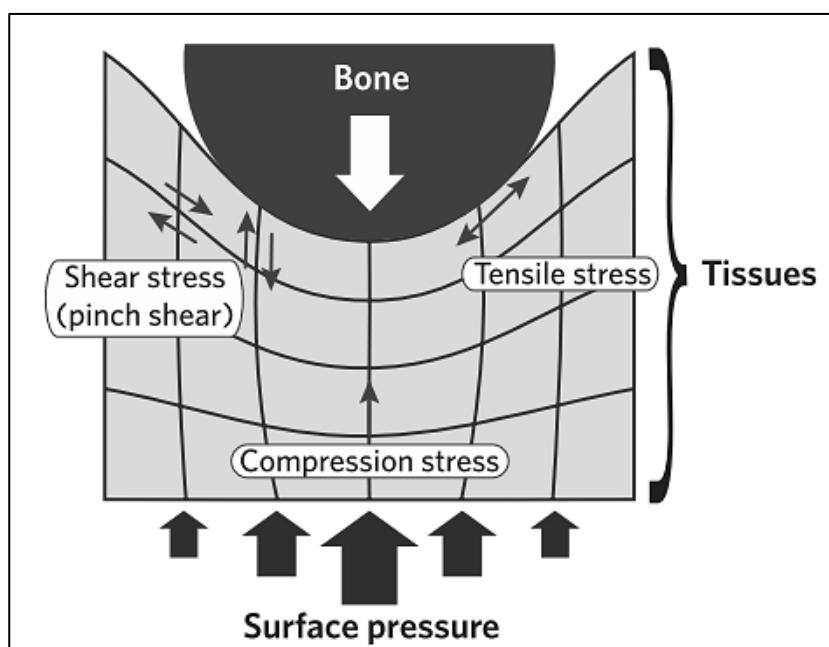


Figure 1-6: Stresses generated within skin and soft tissues overlying a bony prominence upon application of a perpendicular force (Reger et al. 2010, reproduced with permission from the rights holder).

Additionally, the mechanical properties of identical tissues may vary depending on the location of these tissues. Sanders et al. (1995) suggest that prediction of the typical force applied to individual tissue layers may be made based on morphological and biochemical features of these tissues. Animal studies have revealed that collagen fibres in skin subjected primarily to tensional loading, such as the dorsum, are larger in diameter than those primarily subjected to compression, such as plantar surfaces (Sanders et al. 1995). In contrast, post-mortem examination of human skin obtained from the plantar and posterior aspect of the heel, sacrum, and gluteal sites found thickened collagen fibres, as well as an increased epidermal thickness at the heel sites (Arao et al. 2013). In terms of collagen fibre architecture, longitudinal and cross-sectional directions were noted at the sacrum and gluteal site, however, an additional oblique direction was observed at the heel sites, which, the authors suggest, has resulted from repeated exposure to compression and shear forces at these sites. This evolvement provides some protection for the skin and soft tissues and external loads applied up to a threshold point result in full recovery of the skin and soft tissues upon load removal, nonetheless, when this threshold is exceeded irreversible tissue damage occurs (Hagisawa & Shimada 2005). The magnitude and duration of loading are critical factors in determining tissue recovery or damage, as is discussed in Section 4.1.

In addition to the tissue changes associated with age, other conditions may contribute to an impaired ability to withstand mechanical loading, such as spinal cord injury (SCI). Wu and Bogie (2013) investigated the gluteal muscle of ten SCI individuals, by means of computed tomography (CT) with contrast agent, and compared this to ten able-bodied volunteers. Findings indicate that muscle volume in the able-bodied group nearly doubled that observed in the SCI group, and a decreased muscle quality, represented by low-density muscle and intramuscular fat infiltration, was noted in the latter group. The authors add that adipose tissue lacks the viscoelasticity of muscle tissue and perfusion is impaired in this tissue, thus resulting in an altered tissue response to loading.

## 1.7 Summary

This chapter has detailed the normal anatomy and physiology of the skin and soft tissues, as well as age-related changes to these tissues. The skin and soft tissue response to loading has also been considered, and as outlined in this chapter, sustained loading over a threshold point may result in tissue damage. The following chapter will focus on this type of tissue damage, referred to as a pressure ulcer, and

## Skin and Soft Tissues

will give consideration to the prevalence and incidence, aetiology, and classification of these ulcers. Additionally, risk factors that may predispose an individual to pressure ulcer development are reviewed and research pertaining to risk assessment scales, which aim to identify those at risk of pressure ulcers, is presented.

## **Chapter 2: Introduction, Epidemiology, Aetiology, Classification and Risk**

*A pressure ulcer is a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear (NPUAP, EPUAP and PPPIA 2014b, p12).*

The present chapter considers the impact of pressure ulcers on individuals and healthcare providers. In addition, wider issues such as the prevalence and incidence of pressure ulcers, their aetiology and classification are discussed. Finally, risk factors that may render individuals susceptible to pressure ulcer development and formalised risk assessment scales which are derived from these risk factors are described.

### **2.1 The Burden of Pressure Ulcers**

Pressure ulcers (PUs) lead to a significant decline in the quality of life of those affected. Pain, physical restrictions and social isolation are some of the recurring themes identified in the systematic review by Gorecki et al. (2009). Landi et al. (2007) further report an increased mortality in community-based individuals suffering from PUs, despite adjusting for confounding variables such as age, physical ability and cognitive impairment. The effect on spouses caring for a partner with a PU was explored in Baharestani's (1994) phenomenological study, and social isolation and emotional distress are raised as some of the issues facing these caregivers. The burden on the National Health Service (NHS) is also significant; in a recent estimate the mean treatment cost in institutional settings, where care of these ulcers was not the sole reason for admittance, were £1,214 for a category I PU, rising to £14,108 for a category IV ulcer (Dealey et al. 2012b). Costs incurred from PU care are believed to represent up to 4% of the NHS budget (Posnett & Franks 2007).

In addition to suffering and associated costs, the development of care-acquired PUs has long been a contentious issue, as these are perceived to be indicative of the quality of nursing care. Nightingale (1859) asserted that the incidence of PUs is generally a reflection of the care provided, rather than a result of underlying disease, and this view persists to the current day (Newton 2010; Still et al. 2013). The US Centers for Medicare & Medicaid Services (CMS) ceased reimbursements for nosocomial PUs in 2009, recognising these as one of the conditions that may be

## Introduction, Epidemiology, Aetiology, Classification and Risk

reasonably preventable if guidelines are implemented (Stokowski 2010). Beyond immediate repercussions, litigation for care-acquired PUs is likely to increase since CMS policy reinforces the belief that such injuries are avoidable. McKeeney (2002) cites several PU litigation cases in the UK, with damages awarded ranging from £7,000-£32,000. However, as noted by the author the full extent of litigation is unknown as cases may be settled locally, and the details kept confidential.

While it may be argued that not all PUs are avoidable (Levine et al. 2009), findings from an expert consensus panel indicate that participants believed that the majority of ulcers can be prevented (Black et al. 2011). Prevention relies on accurate risk assessment and the implementation of appropriate intervention strategies, but while these areas have been the subject of continued research over recent decades, the prevalence and incidence of PUs remains unacceptably high.

## 2.2 Prevalence and Incidence

The prevalence and incidence of pressure ulcers in various settings has been examined in a recent monograph published by the NPUAP (Pieper 2012b). In this, Goldberg (2012) found a prevalence in general acute care of up to 33.3% internationally, while in the UK the prevalence was reported to be as high as 27.8%. The highest general acute care incidence was found in the UK, at 18.7%, with a reported incidence of up to 14% in all other countries under survey (Goldberg 2012). In particular inpatient care settings, such as critical care, higher values were observed. Cuddigan (2012) found a worldwide critical care prevalence ranging from 25.1-45.5%, and an incidence of 3.3-53.4%, although figures pertaining to the UK are absent. By contrast, fewer studies examined community prevalence and incidence, which may be partly due to a more fragmented care provision. Nevertheless, the prevalence among nursing home and long-term care residents was reported to range from 1.9-47.6%, while the incidence varied from 4.1-47% (Pieper 2012a). Investigating care delivered at home, Garcia (2012) reported a global prevalence and incidence of 2.9-19.1% and 4.5-6.3%, respectively, although of the 14 studies identified, none presented data relating to the UK.

From the above, it is apparent that although figures vary, PUs are common throughout most healthcare settings. Differing patient groups and care settings may contribute to the observed variation, and local prevention procedures and study methodological differences may account for the intra-group variation. Furthermore, patient

homogeneity cannot be assumed, even when identical care settings are compared.

Table 2-1 summarises a selection of individual epidemiological studies, from a variety of settings in the UK, or Europe where UK data were unavailable. With regards to methodology, this table demonstrates the variation in study design, as well as PU categorisation.

With reference to the studies presented in Table 2-1, it is interesting to note that the majority of identified lesions were classified as category I or II PUs, in both acute and community settings. Vanderwee et al. (2007a) report that in the former location these accounted for 68.2% of all PUs, while in the latter setting McDermott-Scales et al. (2009) found that these comprised 67% of the PUs identified. Indeed, when re-examining the NPUAP monograph (Pieper 2012b), it is apparent many studies included category I and II PUs. Since category I PUs may be considered reversible (Section 2.4.1), and can be particularly difficult to distinguish from other types of skin lesions (Section 2.4.2), whether these PUs should be included in incidence and prevalence reports is open to debate.

## Introduction, Epidemiology, Aetiology, Classification and Risk

Table 2-1: Summary of pressure ulcer prevalence and incidence studies.

Authors	Setting	Subjects	Study design	Prevalence	Incidence	Categories Included †
Kottner et al. (2010)	Acute & community, Germany	2008: 3,754 patients from 19 hospitals; 3,345 residents from 37 nursing homes. 2009: 2,930 patients from 15 hospitals; 5,521 residents from 76 nursing homes.	Cross-sectional study x2	2008: 6.4% in hospitals 5.1% in nursing homes 2009: 7.1% in hospitals 4.3% in nursing homes	-	I-IV & Deep Tissue Injury
McDermott-Scales et al. (2009)	Community, Ireland	80 community sites; district nursing teams, GP practices, mental health, learning disability, nursing home, addiction and prison services. 1,853 patients attended to by nurses on study day, total population of area 133,562.	Cross-sectional study	0.057%	-	I-IV
Nixon et al. (2007)	Acute, UK	97 surgical patients, aged $\geq 55$ , expected hospital stay $\geq 5$ days.	Prospective cohort study	-	15.5%	Adapted, Category 0-5
Raghavan et al. (2003)	Community, UK	427 community based spinal cord injury patients, under the care of a spinal injuries unit.	Postal survey	23.2%	-	I-IV
Schuurman et al. (2009)	Acute, The Netherlands	204 elective cardiothoracic patients with an intensive care unit (ICU) stay $> 48$ hours.	Prospective cohort study	-	Developed in ICU=53.4% Developed in ward=8.3%	I-IV
Stevenson et al. (2013)	Community, UK	Site 1 ††: All patients aged $\geq 18$ on community nursing caseload, residing in residential or nursing homes, or inpatients in community rehabilitation or palliative care units. Total population of area aged $\geq 18$ : 240,038.	Cross-sectional study	0.077%	-	I-IV & Unstageable
Vanderwee et al. (2007a)	Acute, Belgium, Italy, Portugal, UK and Sweden	5,947 inpatients aged $> 18$ , from 25 university and general hospitals.	Cross-sectional study	Overall: 18.1%, Belgium: 21.1%, Italy: 8.3%, Portugal: 12.5%, Sweden: 23%, UK: 21.9%	-	I-IV

† NPUAP, EPUAP and PPPIA (2014b). †† Site 2 omitted; only patients on the caseload known to have a PU were assessed.

## 2.3 Aetiology

PU development has traditionally been attributed to localised tissue ischaemia (Lowthian 2005). Early investigations conducted on a murine animal model suggested that vascular obstruction due to compression caused a diminished oxygenation and nutritive supply to local cells thus leading to cell damage (Husain 1953). Kosiak (1961), following load application to rat and dog specimens, also concluded that ischaemia formed one of the primary factors leading to PUs and, in a similar manner, attributed this to an impaired oxygen and nutrient delivery. However, more recently Hotter et al. (2004) have proposed that tissue damage may not result from hypoxia per se, but rather that impaired oxygenation combined with an excess of carbon dioxide, termed hypercapnia, forms the cause of cell apoptosis. The authors induced unilateral renal ischaemia in rats for thirty minutes while monitoring intrarenal pH and computed corresponding pCO<sub>2</sub> values. These were reproduced in vitro and, to simulate early ischaemia, groups of cultures were exposed to gas atmospheres of 0.5% O<sub>2</sub> and 18% CO<sub>2</sub>, or 0.5% O<sub>2</sub> and 30% CO<sub>2</sub>; the latter selected to reflect prolonged ischaemia. Additionally, a control group was exposed to 5% CO<sub>2</sub> in air, a solely hypoxic group to 0.5% O<sub>2</sub> and 5% CO<sub>2</sub>, and two solely hypercapnic groups, both exposed to 20% O<sub>2</sub> and either 18% or 30% CO<sub>2</sub> mixtures. Following a seven-hour exposure and subsequent return to normal culture conditions, examination of these cultures indicated that, compared to the control group, significant apoptotic activity was limited to the two groups exposed to hypoxia with concomitant hypercapnia.

The latter conditions occur when an impaired blood flow decreases carbon dioxide clearance from tissues (Johnson & Weil 1991), thereby causing an increased oxygen release from haemoglobin (Figure 1-5), and producing additional carbon dioxide (Tonnessen 1997). However, as oxygen availability is finite when a diminished blood flow occurs, this accounts for only small increases in carbon dioxide and the majority of the excess carbon dioxide observed in ischaemic conditions is thought to derive from lactic acid (Figure 1-4), generated as a result of anaerobic respiration (Johnson & Weil 1991). When this dissociates hydrogen ions accumulate and, since intracellular bicarbonate levels are largely equal to blood plasma levels, intracellular hydrogen leads to the release of previously buffered carbon dioxide (Tonnessen 1997), as is demonstrated in Equation 1-1. Since carbon dioxide readily diffuses into the extracellular space, localised tissue acidosis may occur (Tonnessen 1997). Accordingly, Husain and Kosiak's view that impaired oxygen and nutrient delivery

## Introduction, Epidemiology, Aetiology, Classification and Risk

forms the primary cause of PUs appears inadequate as the only mechanism. Nevertheless, as proposed by Tonnessen (1997), and supported by the findings of Hotter et al. (2004), under normoxic conditions cells may tolerate extreme carbon dioxide induced acidosis, whereas equivalent concentrations of carbon dioxide in the absence of oxygen may prove harmful. Moreover, neither hypoxia nor hypercapnia may be solely responsible for skin and soft tissue damage. Tonnessen (1997) suggests that tissue acidosis below a threshold may serve to protect cells by reducing the activity of enzymes involved in the generation of damaging substances. The author adds that when blood flow is resumed a rapid change in intracellular pH and increase in metabolic activity occurs, which may lead to the formation of free radicals. Oxygen-derived free radicals, collectively known as reactive oxygen species, are unstable and highly reactive as a result of unpaired electrons (Taylor & James 2005). The upregulation of these reactive oxygen species following ischaemic episodes may cause tissue damage by initiating an inflammatory cascade, resulting in microvascular dysfunction and cell apoptosis (Taylor & James 2005).

The role of ischaemia-reperfusion injury in the aetiology of PUs has been investigated by Peirce et al. (2000). Ischaemic episodes, of variable duration, were created over the dorsal skin of rats by periodic magnetic-induced deformation by means of an implanted steel plate. The resultant pressure, equivalent to 50mmHg (6.7kPa), was selected to reflect a clinically relevant pressure. In the first of a series of experiments, a progressive decrease in skin blood flow and transcutaneous oxygen tension ( $T_cPO_2$ ) was observed as the frequency of the load/ unloading cycle increased. Furthermore, larger necrotic areas were noted at the treatment sites, and an increase in leucocyte count at the perimeter of the site was observed. When the total duration of ischaemia was held constant but cycle duration between groups varied, shorter periods of ischaemia with an increased number of reperfusion events resulted in larger necrotic areas than longer periods of ischaemia with fewer reperfusion events ( $p=0.05$ ). The authors report similar findings following comparison of a single ischaemic episode to five separate ischaemic events of an equivalent total time. Tsuji et al. (2005) also applied a single ischaemic insult to the dorsal skin of mice by means of a skin fold chamber, incorporating a pressure tip, and compared this to four successive cycles of ischaemia of an overall equal duration. Microscopic images were recorded at baseline and 35 hours thereafter and functional capillary density, defined as the total length of capillaries exhibiting red cell flow, was compared to establish the nature of the microcirculatory injury. In accordance with the results reported by Peirce et al. (2000), the microcirculatory injury in the cyclic ischaemia group was found to be significantly

higher than that observed in the group subjected to a single ischaemic event ( $p<0.01$ ). Combined, these results indicate that reperfusion may result in greater tissue damage than that which occurs as a result of prolonged ischaemia alone.

While the preceding mechanisms focus exclusively on the sequelae of vascular microcirculatory impairment, Krouskop et al. (1978) suggest that lymphatic impairment also forms a major contributing factor to the aetiology of PUs. This hypothesis was derived from the observation that applied pressures of sufficient intensity to collapse the local vascular microcirculation may be sustained for extended periods without apparent tissue damage. Consequently, it is proposed that direct occlusion of lymphatic vessels, or impairment of lymphatic contractility as a result of hypoxia, leads to the accumulation of toxic metabolites in the interstitial space, which exacerbate PU formation. Reddy et al. (1981) further examined interstitial fluid flow as a factor in the aetiology of PUs. In previous experiments conducted on the skin and subcutaneous tissues of pigs, load application led to a continued increase in indentation depth as a result of the gradual flow of interstitial fluid and ground substance in spaces away from the site of compression. This led to the proposal that once sufficient fluid and ground substance have been forced out of an area, subsequent load removal results in a diminished interstitial fluid pressure which, in turn, causes capillary rupture, oedema and lymphatic vessel damage.

More direct mechanisms of cell destruction have also been proposed. Breuls et al. (2003) utilised an indenter to apply compressive strains to engineered skeletal muscle tissue and observed an immediate cell death of 8.2% at a 30% strain, and 13.6% at a 50% strain, as a result of direct rupture of cell membranes. Nevertheless, the majority of cellular damage occurred following a one to four hour compression period, and the higher strain regime resulted in a more rapid and extensive cell death. While the authors acknowledge that the nature of the *in vitro* tissues and thus the degree of cell deformation may differ from that occurring *in vivo*, these results nonetheless suggest the potential role of sustained cell deformation in the aetiology of PUs. Gawlitta et al. (2007) further exposed engineered skeletal muscle to up to 40% compression under normoxic and solely hypoxic conditions and, like Breuls and colleagues, found that compression led to immediate cell death, which increased over time. However, hypoxia, with or without compression, was noted to have a minimal additional effect on cell death over a 22-hour period.

## Introduction, Epidemiology, Aetiology, Classification and Risk

To distinguish between the different factors leading to tissue damage Stekelenburg et al. (2007) used the tibialis anterior muscle of a rat model to examine the effects of ischaemia alone, using an above knee tourniquet, and cell deformation with concomitant ischaemia resulting from uniaxial compression with an indenter. Reversible tissue changes were identified following a two-hour period of ischaemia, while irreversible tissue damage occurred as a result of the compressive loading regime. Thus it may be concluded that cellular damage resulting from sustained cell deformation is independent from the effects of ischaemia.

The preceding theories focus on different units of the soft tissues, namely the microvasculature, extracellular environment and cells. Nevertheless, as Bader and Oomens (2006) suggest, each mechanism will have a role in the aetiology of PUs, although their relative contribution will vary depending on the nature and timing of the mechanical insult, and inherent characteristics of the individual.

## 2.4 Pressure Ulcer Classification

PU classification systems provide a standardised approach to describe ulcer severity, proposed to be useful not only for clinical practice, but also for audit and research purposes (Nixon et al. 2006). Such systems categorise PUs based on the anatomic depth of tissue damage, assessed by visual inspection or palpation, with higher categories generally denoting more extensive tissue damage (Dealey & Lindholm 2006). Shea (1975) is often credited with developing the first PU classification system, however, descriptions of PU appearance and anticipated depth have been previously reported in the nineteenth century (Black & Langemo 2012).

A consensus conference held in 1992 identified thirteen classification systems used within the UK and, following a review of the limitations of these, a new classification system was developed (Reid & Morison 1994). In 1999 the EPUAP largely adopted the four stage system devised by its American counterpart (Defloor & Schoonhoven 2004), although two additional categories were recommended for use in the US only (EPUAP & NPUAP 2009). Clark (2005) suggests that the additional categories have resulted from the environment in which US practitioners operate, where litigation and financial incentives drive classification. This has also become visible in the UK (Newton 2010), which may provide an explanation for the Tissue Viability Society's recommendation to adopt the unstageable category in the UK (Dealey et al. 2012a). Indeed, the most recent guidelines recommend that the full six category classification system is adopted

internationally (NPUAP, EPUAP and PPPIA 2014b). These categories, and their descriptors are contained Table 2-2.

Table 2-2: NPUAP, EPUAP and PPPIA (2014b) PU classification system.

Category	Description
Category I	<i>Non-blanchable erythema of intact skin.</i> Oedema, heat, induration or pain may be present. May be difficult to detect in individuals with darker skin tones.
Category II	<i>Partial thickness skin loss or blister.</i> Presents as a shallow ulcer, or serous/ serosanguineous blister, without slough or bruising.
Category III	<i>Full-thickness skin loss.</i> Subcutaneous tissue may be visible but muscle or bone is not visible or directly palpable.
Category IV	<i>Full-thickness tissue loss.</i> Bone, muscle or tendon is visible or directly palpable. Often includes undermining and tunneling.
Unstageable	<i>Full-thickness skin or tissue loss.</i> Slough or eschar obscures the base of the wound and therefore the depth of the wound cannot be determined, however, the ulcer will be $\geq$ Category III.
Suspected Deep Tissue Injury (SDTI)	<i>Depth unknown.</i> Presents as a purple or maroon area of discoloured intact skin or a sanguineous blister. Evolution may rapidly expose additional tissue layers.

#### 2.4.1 Pathophysiological Basis of Pressure Ulcer Categories

Reactive hyperaemia (Section 1.4) following a period of sustained pressure represents a normal physiological response to circulatory occlusion (Günnewicht & Dunford 2004). It is designed to remove potentially damaging metabolites and provide an influx of oxygen and other nutrients (Hampton & Collins 2005). This may be visible outwardly as a localised erythematous area of skin, which resolves if pressure to the area is relieved, with exact resolution time suggested to be proportional to the duration of vessel occlusion (Collier 1999; Manorama et al. 2010). Temporary application of light pressure to the area results in a characteristic blanching of skin, reflecting the occlusion and subsequent refill of capillaries, thereby demonstrating the patency of the microvasculature. As such, blanching erythema is considered a precursor to the development of a category I PU, where microcirculatory changes have occurred (Dealey & Lindholm 2006). A number of studies have observed individuals with an impaired hyperaemic response to single or successive load application (Bader 1990; Neander & Birkenfeld 1990; Wong 2011), which may predispose such individuals to PU development.

Non-blanching erythema forms the defining characteristic of category I PUs. Prolonged occlusion leads to micro-thrombi formation in the capillaries due to platelet and erythrocyte aggregation (Bethell 2003), and pro-inflammatory cytokine release from

## Introduction, Epidemiology, Aetiology, Classification and Risk

dead cells results in persistent vasodilation and an increased capillary permeability with associated oedema (Bliss 1998). The presence of a category I PU has been found to be an independent risk factor of more extensive PU development (Nixon et al. 2007). However, in the majority of cases, this condition is resolved and can therefore not be considered indicative of irreversible damage (Nixon et al. 2007).

Blister formation, as a result of the separation of the epidermal and dermal skin layers, or ulcers presenting with partial loss of the dermis are defined as category II PUs.

However, some researchers question the validity of this category (Berlowitz & Brienza 2007; Lahmann & Kottner 2011). As an example, a secondary data analysis of a prevalence study indicated that while immobility, as measured by the Braden mobility subscale, led to the development of deeper ulcers, the 'friction and shear' subscale score represented the strongest predictor for category II ulcers (Lahmann & Kottner 2011). Accordingly, the authors conclude that friction rather than pressure is the primary factor causing the latter ulcers. Nevertheless, Lahman and Kottner concede that the subscale items in question are not direct measures of these mechanical forces, and it may be argued that causation cannot be established from this association.

In order to determine the clinical course of category I PUs, the prevalence study by Halfens et al. (2001) monitored the progress of such ulcers by reassessments for up to a week in acute hospitals, and over a two-week period in long-term care hospitals.

They found that a deterioration occurred in 14% of patients presenting with a category I PU, most of which were identified as category II PUs, although the exact distribution of these categories is not reported. This strongly suggests that pressure, as opposed to friction (Lahmann & Kottner 2011) is the main cause of deterioration to category II PUs. Further support for this is provided by the findings of Witkowski and Parish (1982).

Following histopathological examination of ulcers the authors concluded that while skin subjected to friction led to intraepidermal blisters, subepidermal blisters occurred in lesions classified as PUs. However, this does not alter the fact that many of the lesions identified in clinical practice as category II PUs may well result from friction as opposed to pressure, and the question as to whether category II ulcers should be included in the classification system will likely continue to be a matter of debate.

The 'top to bottom' and 'bottom to top' theories of PU pathogenesis have also led to much debate in the literature. Shea (1975) proposed that PUs develop in an orderly evolutionary fashion commencing at the skin. Progression to the deeper tissues was suggested to arise in the absence of intervention, a view which represents the top to

bottom theory. However, numerous studies employing a variety of techniques indicate that PUs may develop in deeper soft tissues and subsequently progress towards the surface of the skin, referred to as the bottom to top theory. Husain (1953) reported that localised pressure to rat limbs resulted in a more pronounced vessel obliteration within muscle than that noted in the immediate subcutaneous and skin layers. The observed post-load increase in vessel number and diameter was also more pronounced in muscle tissue. Nola and Vistnes (1980), following identical loading regimes to the skin overlying both the trochanter and biceps femoris muscle of rats, found a consistent occurrence of PUs in the former location, and no visible skin damage in the latter location. However, microscopic examination revealed various degrees of necrosis to the biceps femoris muscle in spite of the fact that the overlying skin remained intact. Furthermore, in an experimental study conducted on pigs, the internal pressures of loaded tissues were found to be three to five times greater than pressures measured at the skin-surface interface (Le et al. 1984). More recently, finite element analysis has made it possible to model the mechanical properties of loaded tissues (Bader & Oomens 2006), and such models add further support to the bottom to top theory of PU evolution. This is demonstrated in Figure 2-1, which shows that the highest stress occurs within muscle tissue adjacent to a bony prominence.

Kottner et al. (2009a) contend that the bottom to top theory accurately reflects the evolution of all true PUs, namely those caused by pressure or shear. However, as Halfens et al. (2001) argue, this theory is unable to explain the lesion progression observed in their study. Equally, the SDTI category appears incompatible with the top to bottom theory. Whatever their exact evolution, it is apparent that the traditional top to bottom theory cannot be considered the only mechanism of PU development, and that both this theory and the bottom to top theory likely reflect valid means of PU pathogenesis. As such, the 2009 NPUAP and EPUAP guidelines suggested abandoning the terms stage and grade and replacing these with the term category, in an attempt to avoid hierarchical inferences.

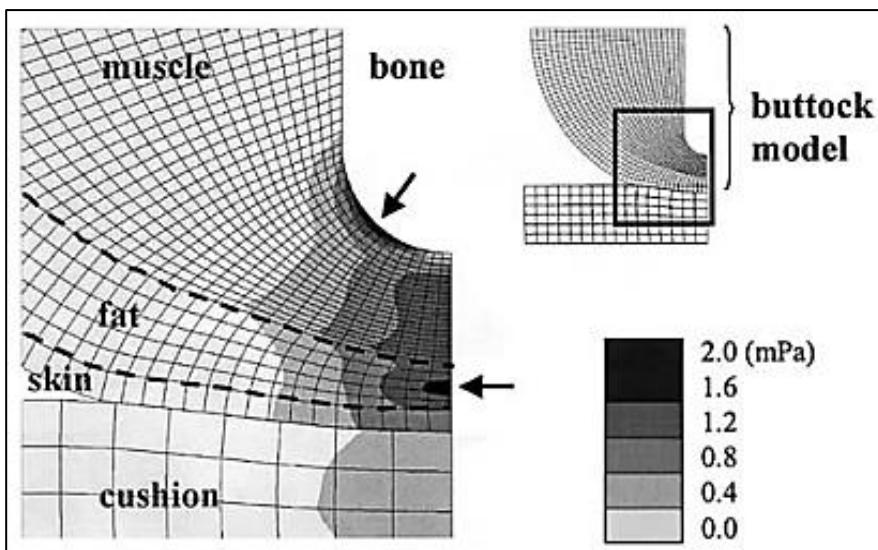


Figure 2-1: Simplified model of an 80kg male seated on a foam cushion, demonstrating differential responses of soft tissue layers. Legend values indicate Von Mises stresses, representing distortional energy. Arrows indicate areas of high stress (Bouten et al. 2003, reproduced with permission from the rights holder, Elsevier).

#### 2.4.2 Reliability of the NPUAP, EPUAP and PPPIA Classification System

Numerous researchers have investigated the inter-rater reliability of PU classification systems. The systematic review of all classification systems by Kottner et al. (2009d), identified 47 such studies and, following quality assessment, 24 of these were considered of suitable quality for inclusion. Nonetheless, the authors concluded that due to the heterogeneity of studies a meaningful comparison was impossible and suggest that further high-quality research, comparing two or more classification systems, is still required. Comparison of several classification systems is undoubtedly a prerequisite if recommendations regarding the seemingly superior system are to be made. However, as the NPUAP, EPUAP and PPPIA classification system (Table 2-2) is the most widely adopted in Europe, research pertaining to this is presented in Table 2-3.

## Introduction, Epidemiology, Aetiology, Classification and Risk

Table 2-3: Studies examining the inter- and intra-rater reliability of the NPUAP, EPUAP and PPPIA PU classification system.

Authors	Sample	Method	Categories	Cohen's Kappa ( $\kappa$ ) †
Beeckman et al. (2007)	1,452 European nurses employed in hospitals, nursing homes, home care and education settings.	<b>Inter-rater reliability</b> , 20 photographs shown and each assessment compared against expert opinion.	Normal skin, blanching erythema, category I-IV, moisture lesion, combined (pressure and moisture) lesion	Overall: 0.33 Hospital: 0.35 Nursing home: 0.31 Home care: 0.36 Education: 0.30
Beeckman et al. (2008)	426 hospital, nursing home and home care nurses and final-year nursing students	<b>Inter-rater reliability</b> 20 photographs shown at pre-test, 40 each post-test, each assessment compared against expert opinion. Participants randomised to experimental group (EG) received 1-hour e-learning, or control group (CG) received 1-hour lecture, content of both comparable. Pre-test, instruction and 1st post-test executed consecutively on inception day, 2 <sup>nd</sup> and 3 <sup>rd</sup> post-test at monthly intervals. 43.2% lost to follow-up between 1 <sup>st</sup> and 3 <sup>rd</sup> post-test.	Normal skin, blanching erythema, category I-IV, moisture lesion, combined lesion	Pre-test: EG: CG: 1 <sup>st</sup> post-test: 0.24 0.24 2 <sup>nd</sup> post-test: 0.65 0.63 3 <sup>rd</sup> post-test: 0.53 0.56
Defloor and Schoonhoven (2004)	44 experts: 7 researchers, 20 staff nurses involved in pressure ulcer policy and 17 pressure ulcer nurses	<b>Inter-rater reliability</b> , 56 photographs selected and classified by 9 EPUAP trustees, which formed the gold standard. Expert assessments compared to the gold standard. Provision made to facilitate assessment of photos with visible erythema.	Normal skin, blanching erythema, category I-IV, moisture lesion	Researchers: 0.64 Staff Nurses: 0.75 Pressure ulcer nurses: 0.75
Defloor et al. (2006), Phase I	473 nurses attending a wound care conference	<b>Inter- &amp; intra-rater reliability</b> , 56 photographs including 9 duplicates. Provision made to facilitate assessment of photos with visible erythema. Assessments compared against expert opinion or, for intra-rater reliability, previous assessment by the same nurse.	Normal skin, blanching erythema, category I-IV, moisture lesion and 'unsure' option	Inter-rater reliability: 0.50 Intra-rater reliability: 0.38
Defloor et al. (2006), Phase II	86 hospital nurses	<b>Inter- &amp; intra-rater reliability</b> , 56 photographs, shown in altered sequence, one month apart. Provision made to facilitate assessment of photos with visible erythema. Assessments compared against expert opinion or, for intra-rater reliability, previous assessment by the same nurse.	Normal skin, blanching erythema, category I-IV, moisture lesion and 'unsure' option	Inception inter-rater reliability: 0.51 At follow-up: 0.55 Intra-rater reliability: 0.52
Sterner et al. (2011)	2 nurses on duty at time of assessment.	<b>Inter-rater reliability</b> , written instructions and classification card provided. Sacral area of patients aged $\geq 65$ admitted with hip fracture assessed by 2 assessors with finger-press test on arrival at ward/ theatre. Repeated daily postoperatively. Assessments performed simultaneously but assessors blinded to other assessor's findings. Not blinded to previous assessment findings.	Blanching erythema/ category I	Day 1 (n=75): 0.44 Day 2 (n=75): 0.50 Day 3 (n=75): 0.23 Day 4 (n=65): 0.22 Day 5 (n=50): 0.20

† Landis and Koch's (1977) interpretation of  $\kappa$ : <0.00=poor, 0.00-0.20=slight, 0.21-0.40=fair, 0.41-0.60=moderate, 0.61-0.80=substantial, 0.81-1.00=almost perfect

## Introduction, Epidemiology, Aetiology, Classification and Risk

It is evident that all but one of the studies presented in Table 2-3 used photographs to examine inter- and intra-rater reliability. As suggested by Kottner et al. (2009d), these provide a limited view and lack a patient history and, as such, may prove more difficult to classify when compared to a bed-side assessment. However, in addition to the convenience of this method, consistency is ensured and it could be argued that, since all raters encounter this difficulty, the results remain representative of reliability. Nevertheless, utilising photographs, carefully selected to represent the various pressure ulcer categories, may not be comparable to the wounds practitioners encounter in clinical practice.

Overall, Table 2-3 indicates that inter-rater reliability is suboptimal when the assessment of general nurses, whatever their clinical setting, is compared to the assessment of subject experts. Equally, the reported intra-rater reliability appears low. As an example, differentiating between blanching erythema and category I PUs appears to be problematic (Defloor et al. 2006; Beeckman et al. 2007; Beeckman et al. 2008; Sterner et al. 2011), as does distinguishing moisture lesions from PUs (Defloor & Schoonhoven 2004; Defloor et al. 2006; Beeckman et al. 2007; Beeckman et al. 2008). Indeed, Defloor et al. (2006) report that the images of moisture lesions were misclassified in 44.3% of cases.

Houwing et al. (2007) contend that the distinction PUs and moisture lesions is not justified and could adversely affect implementation of PU prevention strategies. Their study compared the clinical diagnosis of buttock and sacral skin lesions in incontinent bedbound patients (n=14) to a histopathological examination of skin adjacent to these lesions. A chronic irritation pattern was observed in 8 lesions clinically diagnosed as moisture lesions, and an ischaemic pattern was identified in a PU, a combined lesion, and 4 moisture lesions. Since the clinical diagnosis of most lesions was associated with an appropriate pattern, namely lesions resulting from pressure with an ischaemic pattern (100%), and lesions due to moisture with a chronic irritation pattern (62%), the authors' interpretation of these findings is questionable. Moreover, given that PUs are perceived as a quality of care indicator (Section 2.1), whose treatment typically involve costly interventions (Figure 3.2), which may not be required for lesions solely originating from moisture, the view that differentiating is unnecessary appears overly simplistic.

Nevertheless, the previously presented studies (Table 2-3) indicate that distinguishing PUs from moisture lesions, or identifying the category of the former, is challenging. While the paper by Beeckman et al. (2008) demonstrates that training improves classification reliability, the selected follow-up period was limited and, as the authors acknowledge, repetition of this approach is recommended. Extended operational descriptors could provide a means to increase reliability (Beeckman et al. 2007), but may also lead to a classification system which is cumbersome and thus impracticable. Moreover, accurate classification relies not only on an unambiguous classification system, but also on a thorough anatomical knowledge of the skin and soft tissues, which nurses may lack (Sharp 2004; Black et al. 2010).

## 2.5 Risk Factors

In contrast to causal factors, which are defined experimentally and are known to affect an outcome of interest (Brotman et al. 2005), risk factors are determined statistically and are associated with the outcome they precede (Kraemer et al. 2001). When altered, causal risk factors influence the probability of the outcome (Kraemer et al. 2001) and are called independent when statistical association is retained when other established risk factors are included in the model (Brotman et al. 2005).

It is apparent from the NPUAP, EPUAP and PPPIA definition (Chapter 2) that pressure, or pressure in combination with shear, forms the cause of PUs. However, these parameters are difficult to measure in clinical practice and their effects on tissue are highly dependent on individual tolerance thresholds, which in turn are affected by a range of intermediate variables (Defloor 1999). A plethora of research has attempted to ascertain the intermediate variables which may predispose to PU development. Indeed, a recent systematic review by Coleman et al. (2013) identified 365 papers on the topic, which provides an explanation for the large number of reported independent risk factors.

Such risk factors need not be causal, as is illustrated when considering a selection of the reported risk factors, such as the presence of a Do Not Resuscitate order, identified by Reed et al. (2003). This risk factor cannot be considered causal, serving instead as a noncausal, or proxy, risk factor that is likely to reflect the poorer health status and prognosis of such individuals. Similarly, the category I PU risk factor reported by Nixon et al. (2007), does not reflect risk factors contributing to these ulcers, but rather indicates that those factors that precipitated the initial PU are likely to cause further

## Introduction, Epidemiology, Aetiology, Classification and Risk

damage. As Coleman et al. (2013) suggest, interpretation is required to determine risk factors that have both statistical association and clinical relevance. However, it may be argued that even when these criteria are fulfilled predicting risk is challenging as this results from a complex interaction of factors which, when combined, increase the overall probability of PU development (Coleman et al. 2013).

Risk factors are typically classified as extrinsic, denoting factors that directly affect the outer surface of skin, or intrinsic, indicating factors that influence skin and soft tissue architecture and thus influence an individual's tolerance to mechanical loading (Bergstrom et al. 1987). A selection of some of the most commonly cited extrinsic and intrinsic factors is shown in Table 2-4.

Table 2-4: Extrinsic and intrinsic risk factors (Dealey 2012; Carville 2013).

Extrinsic Risk Factors	Intrinsic Risk Factors
Shear	Immobility/ inactivity
Friction	Sensory deficits
Moisture	Peripheral vascular disease
	Malnutrition and dehydration
	Advancing age

### 2.5.1 Extrinsic Risk Factors

In contrast to pressure, which represents a force perpendicular to an area of skin (Section 1.6), shear results from a force applied parallel to the skin surface (Reger et al. 2010). In bedbound patients, shear occurs when backrest elevation encourages downward movement of the skeleton and soft tissues, while the epidermis remains fixed to its original position (Nixon 2001). Inappropriate seating is further frequently attributed to shear forces (Ousey 2005; Dealey 2012). However, findings from the study by Kobara et al. (2008) suggest that shear may even result from adopting a comfortable seating posture where seating provision is adequate.

In terms of physiological effects, shear may cause tissue distortion and capillary occlusion, which can occur between all tissue layers, although the bone-muscle interface is particularly susceptible to damage as a result of exposure to this force (Reger et al. 2010).

Several experimental studies have demonstrated the combined effects of pressure and shear, including Goossens et al. (1994). This study measured skin oxygen tensions at the sacrum of ten healthy volunteers in order to examine the mean pressure necessary to reduce oxygen tension levels to 10mmHg (1.3kPa), defined by the authors as the threshold at which ischaemia occurs. Mean threshold values of 87mmHg (11.6kPa)

were reported. However, when pressure was combined with a 23mmHg (3.1kPa) shear stress, representative of values estimated in volunteers lying on a hospital bed, a reduced mean pressure of 65mmHg (8.7kPa) induced ischaemia. No significant correlations between the pressure required to reach the threshold level and blood pressure, sacral skin thickness, body fat percentage or basal oxygen tension levels were observed. Manorama et al. (2010), using a repeated measures design, further investigated the effects of pressure in the absence or presence of shear at the forearm of fifteen healthy volunteers using transcutaneous oxygen measurements and blood perfusion, assessed with Laser Doppler Flowmetry (LDF). Unlike the previous study, pressure and shear application were not standardised. However, the authors also noted that pressure in combination with shear caused an additional reduction in  $TcPO_2$  levels and blood perfusion, although these differences were not statistically significant in this small cohort study.

Another extrinsic risk factor is friction, defined as the resistance to parallel movement at the shared boundary of two surfaces, as expressed by the coefficient of friction (NPUAP 2007). It is inevitable that friction is required to keep the base of an object stationary and thus induce shear forces. In the context of PU literature, friction may also refer to the motion of two surfaces repeatedly moving against each other (Günnewicht & Dunford 2004; Dealey 2012), as might occur in those with tremors or due to inappropriate patient repositioning (Hanson et al. 2010). The skin damage that occurs as a result of this is typically superficial in nature and is not synonymous to damage resulting from pressure or shear (Defloor et al. 2005b).

Following a series of experiments using healthy and paraplegic swine, Dinsdale (1974) concluded that friction plays a role in the pathogenesis of PUs. Indeed, ulcers occurred at lower pressures when both friction and pressure were applied, in comparison to pressure alone. In paraplegic swine pressure combined with friction increased the susceptibility to PUs at applied pressures up to 500mmHg (66.7kPa). A further experiment designed to ascertain skin and subcutaneous blood flow in healthy swine reported no significant differences between the two loading regimes and, as a result, the author concluded that ischaemia is not a significant factor in ulcers produced by friction. However, Antokal et al. (2012) have observed that the methods described did not provide a clear distinction as to whether this friction caused superficial damage or induced shear. Nevertheless, they hypothesize that since ulcer incidence increased when friction was present, the induced friction created shear.

## Introduction, Epidemiology, Aetiology, Classification and Risk

Skin moisture may typically occur as a result of perspiration or incontinence. Studies measuring the effects of moisture indicate that dry skin exhibits a lower friction coefficient when compared to wet skin (Sivamani et al. 2006). Therefore, saturated skin, by virtue of an increased friction coefficient, may also increase the potential of shear forces. However, an increased PU risk as a result of moisture may not solely result from an increased risk of shear. Mayrovitz and Sims (2001) investigated the effects of prolonged exposure to both water and synthetic urine at the volar forearm of healthy volunteers, which were subsequently subjected to a 60mmHg (8kPa) load for five minutes. Compared to control sites, a greater decrease in immediate post-load perfusion was noted in sites exposed to synthetic urine and water ( $p=0.01$ ), with the greatest decrease observed at the synthetic urine site. These results suggest that in addition to an increased likelihood of shear, moisture may also intrinsically affect the skin response to loading.

From the preceding it may be concluded that when pressure, shear, friction and moisture act in tandem there is an enhanced risk of pressure damage. An ulcer intended to illustrate the combined effects of these extrinsic factors is shown in Figure 2-2, although it is acknowledged that such distinctions are challenging (Section 2.4.2).

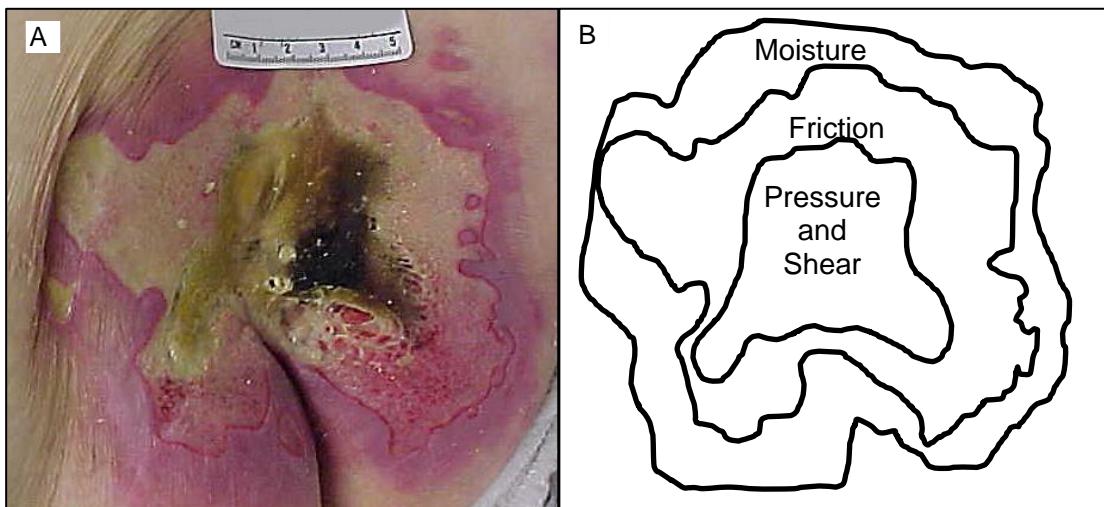


Figure 2-2: The effect of extrinsic factors on skin. A: sacral wound, reproduced with permission from the rights holder, Medscape Drugs & Diseases (<http://emedicine.medscape.com/>), 2016, available at: <http://emedicine.medscape.com/article/194018-overview>. B: physical factors suggested to have contributed to the development of this wound.

## 2.5.2 Intrinsic Risk Factors

Impaired mobility or activity descriptors are directly related to the primary cause of PU development, namely, sustained pressure, and as illustrated in Table 2-4 (Section 2.5), are frequently cited as intrinsic risk factors to PU development. While related, the activity variable classifies patients as, for example, bedbound, chairbound or walking with limitations, whereas mobility variables usually categorise movement frequency or magnitude (Coleman et al. 2013). Indeed, one or more mobility or activity variables were included in 36 of the risk factor studies identified by Coleman et al. (2013), and were reported to be an independent risk factor in 80.5% of these. However, where variables spanning both domains were selected for inclusion in multivariable modelling, mobility alone emerged as predictive in the majority of studies (Coleman et al. 2013).

Factors affecting oxygen and nutrient delivery to local tissues, collectively termed perfusion variables, may result in a decreased ability to tolerate external loads (Nixon 2004). Coleman et al. (2013) identified 27 studies that included a variety of variables affecting perfusion, including vascular disease, diabetes, and oedema, which emerged as predictive in 70.4% of these studies. Nonetheless, differences were observed within the perfusion domain. While diabetes and vascular disease were identified as independent risk factors in several high and medium quality studies, oedema was found to be significant in only one study (25%), which was deemed to be of low methodological quality. In contrast, low haemoglobin levels were found to be independently associated with PU incidence in 6 out of the 11 relevant studies. When low albumin levels were included, these emerged as predictive in 63.6% of studies, while lymphopenia was found to be predictive by both of the studies including this variable. However, the association with other haematological variables was found to be more tenuous.

Although sensory perception is a frequently quoted intrinsic risk factor, as is demonstrated in Table 2-4, Coleman et al. (2013) report that this factor was found to be significant in only 2 out of the 9 relevant studies. This may be explained by the close association of sensory perception and mobility. While impaired sensation may lead to reduced impetus, or indeed be accompanied by an inability to alter position, the result of this may be outwardly observed as a reduction in, or absence of, movement. Consequently, when both factors are included in the multivariable model, as appears to be the case in all of the studies identified by Coleman and colleagues, independence of one of these variables, most frequently sensory impairment, is lost.

## Introduction, Epidemiology, Aetiology, Classification and Risk

In terms of nutrition, Coleman et al. (2013) identified a range of variables included by researchers such as PU risk assessment nutrition subscales, body mass index (BMI), food intake, malnourishment, and weight. Yet, of these, food intake was the only variable frequently identified as an independent risk factor, which occurred in 57.1% studies considering this factor. Furthermore, when modelled with other risk assessment subscales, the nutrition subscale was found to be independently predictive by only 1 of the 14 studies considering this variable, and this study was deemed to be of low methodological quality.

Finally, as discussed in Section 1.5 numerous skin and soft tissue changes occur as a result of ageing, some of which directly impact the likelihood of PU development, and as such advancing age has been proposed as another intrinsic risk factor (Ousey 2005; Carville 2013). Nevertheless, this was found to be an independent risk factor in just 12 out of the 32 studies with homogeneous study populations, reviewed by Coleman et al. (2013). However, this proportion was found to increase significantly to 86% of studies if heterogeneous populations were included.

## 2.6 Risk Assessment Scales

Risk assessment scales (RASs) are defined by Torra I Bou et al (2006) as tools that establish a point scale based on a group of parameters, which are regarded as risk factors for PU development. They are intended to identify those patients most at risk of PU development thereby enabling the targeted implementation of prevention strategies, designed to reduce the incidence of PUs (McGough 1999). Their accuracy is critical since preventative strategies are both labour and resource intensive. From a nursing perspective, RASs are suggested to act as an 'aide memoire', providing a framework for intervention, and facilitating the expeditious documentation of PU risk (Nixon 2001; Günnewicht & Dunford 2004). The use of such scales, in conjunction with clinical judgment, is recommended by guidelines and best practice statements (Wounds UK 2012; National Institute for Health and Care Excellence 2014).

The first published scale, devised by Norton et al. (1962), is shown in Table 2-5. This so-called Norton Scale was first used in series of studies conducted in elderly wards. The authors reported a near linear relationship between the initial score and pressure ulcer incidence, with a 50% incidence in patients with scores less than 12, a 32% incidence among those with scores between 12-14, and a 5% incidence in those where the initial score fell within the 18-20 range.

## Introduction, Epidemiology, Aetiology, Classification and Risk

Table 2-5: Scoring system developed by Norton et al. (1962), reproduced with permission from the rights holder, Centre for Policy on Ageing (formerly NCCOP), London, UK. Scores allocated to each category are totalled, and an overall score of  $\leq 14$  indicates an individual at risk, or if  $< 12$ , at very high risk.

Physical Condition		Mental Condition		Activity		Mobility		Incontinent	
Good	4	Alert	4	Ambulant	4	Full	4	Not	4
Fair	3	Apathetic	3	Walk/ help	3	Slightly limited	3	Occasional	3
Poor	2	Confused	2	Chairbound	2	Very limited	2	Usually/ Urine	2
Very bad	1	Stupor	1	Bed	1	Immobile	1	Doubly	1

Although created for research purposes, the authors concluded that their 'patient assessment form' proved a simple and reliable means of evaluating an individual's likelihood of PU development, and its use was favoured by nurses. While undoubtedly innovative for its time, a multitude of new scales have since been developed. The main features of a selection of such scales, frequently used in a variety of UK healthcare settings, are shown in Table 2-6.

Table 2-6: Key features of RASs commonly used in the UK.

Author	Scale	Setting	Origin of risk factors	'At risk' score
Norton et al. (1962)	Norton	Elderly Care	Clinical experience	Low
Waterlow (1985)	Waterlow	Generic	Literature review, clinical experience	High
Bergstrom et al. (1987)	Braden	Generic	Research derived conceptual schema, clinical experience	Low
Cubbin & Jackson (1991)	Cubbin & Jackson	Intensive Care	Adaptation of existing scale, clinical experience	Low
Milward et al. (1993)	Walsall	Community	Adaptation of existing scales, clinical experience	High

The above table demonstrates that many scales are adaptations of existing scales and, as McGough (1999) adds, are largely constructed using risk factors that are perceived to be clinically important, as opposed to criteria that are research derived. The subsequent adaptation of such scales when designing new scales further perpetuates this situation. Nevertheless, the three variables that consistently emerge in scales, namely moisture, food intake and mobility, at 95%, 84% and 79% respectively (McGough 1999), have all been recently identified as independent risk factors (Coleman et al. 2013). Table 2-7 compares the risk factors that are contained in the previously presented RASs.

Maylor (2006) suggests that the adaptation of existing scales stems from an anxiety that key risk factors for specific areas of practice have not been considered in the original scale and, as a result, patient harm may occur. However, although this may appear intuitively correct, this can result in a scale 'cluttered' with spurious risk factors,

## Introduction, Epidemiology, Aetiology, Classification and Risk

while a simple RAS incorporating few but valid risk factors may be more appropriate. The author recommends that scale adaptations, or the creation of new scales to suit the care setting, is undertaken in a systematic manner and supported by statistics, a view which is supported by Cullum et al. (1995). Papanikolaou et al. (2007) add that the equal weighting of risk factors, common to many scales, fails to consider that certain risk factors may be more important, thus leading to an incorrect total score. They also recommend that statistical methods should be employed to create robust RASs, and that such scales should incorporate weighted risk factors.

Table 2-7: Risk factors contained in a selection of commonly used RASs.

Item	Norton (1962)	Waterlow (1985)	Braden (Bergstrom et al. 1987)	Cubbin & Jackson (1991)	Walsall (Milward et al. 1993)
Activity	✓		✓		
Age		✓		✓	
Carer input					✓
Consciousness	✓			✓	✓
Friction and shear			✓		
Gender		✓			
Haemodynamic status				✓	
Hygiene				✓	
Medication		✓			
Mobility	✓	✓	✓	✓	✓
Moisture/ incontinence	✓	✓	✓	✓	✓
Nutritional status/ food intake		✓	✓	✓	
Organ failure					
Pain					✓
Physical condition	✓				✓
Respiration				✓	
Sensory perception		✓	✓		
Skin condition		✓		✓	✓
Smoking		✓			
Surgery		✓			
Weight		✓		✓	

Scale construction utilising statistical methods has occurred. Schoonhoven et al. (2006) developed their prePURSE Scale following data collection from 1229 inpatients as part of a larger prospective cohort study. The authors utilised univariate regression analysis to determine potential risk factors and created a final prediction rule using multivariate regression modelling, with risk factors weighted in accordance with the regression coefficient. Nevertheless, the authors concluded that up to 30% of patients may still be misclassified as false negatives, and while altering the threshold score may reduce this value, the number of false positive predictions would rise and a balance between

optimum prediction and cost effectiveness is required (Schoonhoven et al. 2005). Thus it is has been suggested that PU risk may be best assessed by means of a traditional RAS, augmented by skin inspection and clinical judgment (Schoonhoven et al. 2005).

Numerous studies have examined the predictive validity of traditional RASs, using the sensitivity and specificity criteria shown in Table 2-8. The reported sensitivity varies widely, ranging from 0-92%, 73-100%, and 27-100% for the Norton, Waterlow and Braden Scales, respectively (Torra i Bou et al. 2006). Equally, the specificity of these scales, presented in identical order, has been found to range from 3-94%, 10-44% and 19-95% (Torra i Bou et al. 2006). This large variation in reported sensitivity and specificity may be attributed to the differing patient groups and settings in which these studies were conducted, and methodological differences, such as length of observation (Deeks & Dealey 1996). Defloor and Grypdonck (2004) further add that prevention strategies influence sensitivity and specificity, by decreasing the former and increasing the latter, and recommend that preventative measures are considered when RASs are evaluated.

Table 2-8: Sensitivity, specificity, predictive value, and likelihood ratio formulae (adapted from Thompson & Van den Breul 2012, with permission from the rights holder).

<b>RAS designates person as at risk</b>	<b>Subsequent pressure ulcer development</b>		<b>Pressure ulcers remain absent</b>
	<b>A</b> (True positives)	<b>B</b> (False positives)	
<b>RAS designates person as not at risk</b>	<b>C</b> (False negatives)	<b>D</b> (True negatives)	
<i>Sensitivity = A / A+C Specificity= D / B+D</i>			
<i>Positive predictive value= A / A+B</i>			
<i>Positive likelihood ratio= (A / A+C) / (B / B+D)</i>			
<i>Negative predictive value= D / C+D</i>			
<i>Negative likelihood ratio= (C / A+C) / (D / B+D)</i>			

It has been proposed that cut-off scores, the point at which risk is considered to occur, should be set locally to improve the performance of RASs (Bergstrom et al. 1987; Smith et al. 1995; Papanikolaou et al. 2007). Receiver operator characteristic (ROC) curves, which plot the sensitivity and specificity of particular score values (Lange & Weinstock 2006), could enable the selection of optimum cut-off scores for specific practice areas. However, as stated by Defloor and Grypdonck (2004), it would be unethical to withhold preventative strategies from patients enrolled in a study, designed to determine the sensitivity and specificity values from which setting specific cut-off

## Introduction, Epidemiology, Aetiology, Classification and Risk

scores may be derived. When this cut-off score subsequently guides the allocation of preventative measures in a new patient group, the group receiving prevention would differ from the original group, thus altering the sensitivity and specificity values and resulting in a cut-off score which is no longer accurate. Therefore, altering cut-off scores may not improve the predictive ability of RAS.

Authors such as Waterlow and Norton contend that their scales were never intended to function as accurate predictors of risk, and should be viewed as supportive indicators of risk, to be used in conjunction with clinical judgment (Waterlow 1997), a view which is echoed by current guidelines (National Institute for Health and Care Excellence 2014; NPUAP, EPUAP and PPPIA 2014b). However, it has been suggested that RASs are highly valued in practice and are perceived as objective measures of risk (McGough 1999), which may provide support if litigation should arise following PU development (Waterlow 1991; Hampton & Collins 2005; Papanikolaou et al. 2007). Accordingly, nurses may not routinely depend on their clinical judgment. Nevertheless, a study conducted in long-term care settings found that nurses generated their own hypothesis of PU risk and altered the Waterlow score to suit their views, leading the author to question the utility of RASs (Baxter 2008). However, this finding may be setting specific and since national guidelines recommend their use, the reliance on RASs will likely continue, as will the search for the ideal scale, the characteristics of which are summarised in Figure 2-3.

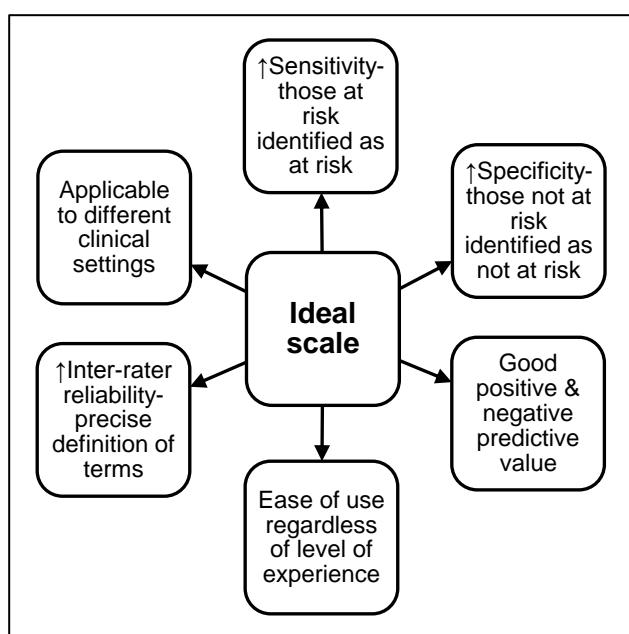


Figure 2-3: Characteristics of the ideal RAS (Torra i Bou et al. 2006).

### 2.6.1 Systematic Reviews of Effectiveness, Validity and Reliability of RASs

A number of systematic reviews have examined the clinical effectiveness of RASs in reducing the incidence of PUs (Cullum et al. 1995; McGough 1999; Pancorbo-Hidalgo et al. 2006; Moore & Cowman 2008; Moore & Cowman 2014). The most recent of these considered randomised control trials (RCTs) and cluster-RCTs and identified two eligible studies (Moore & Cowman 2014). The first of these comprised a cluster randomised study, which investigated the impact of the Braden Scale and training, clinical judgment and training, or clinical judgment alone on PU incidence. No statistically significant difference between groups was observed, although the authors add that the study had a number of methodological limitations. The second study, a RCT which compared screening by means of the Waterlow Scale, Ramstadius Tool, or clinical judgment, also found no significant differences between the different screening methods, and the reviewers judged this study to be at low risk of bias. Overall, systematic reviews have indicated that there is little research supporting the clinical effectiveness of RASs (Cullum et al. 1995; McGough 1999; Pancorbo-Hidalgo et al. 2006; Moore & Cowman 2008; Moore & Cowman 2014).

Numerous systematic reviews have also investigated the validity of RASs. However, some of these reviews are dated (Cullum et al. 1995; McGough 1999; Pancorbo-Hidalgo et al. 2006), or had other limitations as indicated in the Table 2-9.

Table 2-9: Summary of a selection of systematic reviews which have investigated the predictive validity of RASs.

Author	Inclusion period	Eligible study designs	No Studies included	Comments
Cullum et al. (1995)	1962-1994	Not specified	15	Few details regarding methodology, but states that inclusion assessment, quality assessment, and data extraction was performed by a single reviewer
McGough (1999)	1966-1997	Prospective cohort studies, randomised controlled trials	16	Single reviewer
Pancorbo-Hidalgo et al. (2006)	1966-2003	Prospective cohort studies, controlled trials	31	Limited search terms
Šáteková and Žiaková (2014)	2003-2013	Systematic reviews, meta-analysis, RCTs, cohort studies, case-control studies	15	Limited search terms and inclusion period, few details regarding methodology
Wilchesky and Lungu (2015)	1985-2013	Design not specified, empirical studies eligible if they contained information required to assess validity	9	Systematic review and meta-analysis, exclusively focused on use of the Braden Scale in long-term care, few methodological details

## Introduction, Epidemiology, Aetiology, Classification and Risk

Edwards (1996) argues that reliability is an essential component of validity. However, comparatively few systematic reviews have examined the reliability of RASs. While McGough (1999) and Pancorbo-Hidalgo et al. (2006), present some data pertaining to the inter-rater reliability of scales, this was not a primary outcome of either of these reviews. By contrast, Kottner and Dassen (2008a) and Kottner et al. (2009b) focused on the reliability of RASs, but both reports were restricted to the review of a single scale, the Braden and Waterlow Scales, respectively. More recently, a comprehensive review by Kottner et al. (2013) sought to determine which RASs exist and the reliability, validity, and clinical effectiveness of them, but this focused exclusively on paediatric RASs.

## 2.7 Summary

This chapter has established that PUs represent a debilitating condition for patients and a significant challenge for healthcare professionals. Furthermore, although significant advances have been made in recent decades in understanding the aetiology and risk factors for PUs, data from prevalence and incidence studies indicate that such lesions remain relatively common across most healthcare settings. Risk assessment scales aim to identify those at most at risk PU development, thus enabling the targeted use of prevention strategies and ultimately reducing the incidence of PUs. However, while it may be concluded that the topic of the clinical effectiveness of these scales has benefitted from recent and rigorous review, a comprehensive review is indicated to examine the characteristics of RASs designed for an adult population, and the reported reliability and validity of these scales. This review is presented in Chapter 3.

## Chapter 3: Integrative Review of Risk Assessment Scales

Despite their well-reported limitations (Defloor & Grypdonck 2004; Papanikolaou et al. 2007), RASs continue to form an integral part of pressure ulcer prevention in the clinical setting. The characteristics which the ideal scale should possess, including predictive validity and inter-rater reliability, have been presented previously (Figure 2-3), as have a series of systematic reviews which aimed to consider these aspects (Table 2-9). However, several of these reviews are dated, have apparent methodological limitations and most have focused on the assessment of one particular psychometric property. Therefore, the present review was conducted to provide an up-to-date and comprehensive portrayal of the topic. In particular, it sought to address the following research questions:

- I. What are the characteristics of RASs designed for use by healthcare professionals, to determine PU risk in an adult population?
- II. What is the reported inter-rater reliability of these scales?
- III. What is the reported predictive validity of these scales?

### 3.1 Methods

#### 3.1.1 Review Methodology and Scope

An integrative methodology was adopted for the present review. Integrative reviews aim to consolidate findings from diverse sources, as guided by the research questions, to facilitate a comprehensive understanding of a phenomenon (Kirkevold 1997; Crossetti 2012). Such reviews may typically incorporate several related research questions (Soares et al. 2014), and contribute to knowledge building by considering the depth and breadth of research, in a manner distinct from other review methods, which have been criticised for overemphasizing hierarchies of evidence (Kirkevold 1997; Whittemore & Knafl 2005). Nevertheless, methodological rigour is required (Whittemore 2005; Crossetti 2012) and a five-stage framework incorporating problem formulation, data collection/ literature search, data evaluation, analysis and interpretation, and data presentation has been proposed (Cooper 1989). More recently, Whittemore and Knafl (2005) have expanded Cooper's framework, and their modified framework has been

## Integrative Review of Risk Assessment Scales

used to guide and structure the present review. Figure 3-1 illustrates the stages of this framework, mapped against the corresponding sections of this chapter.

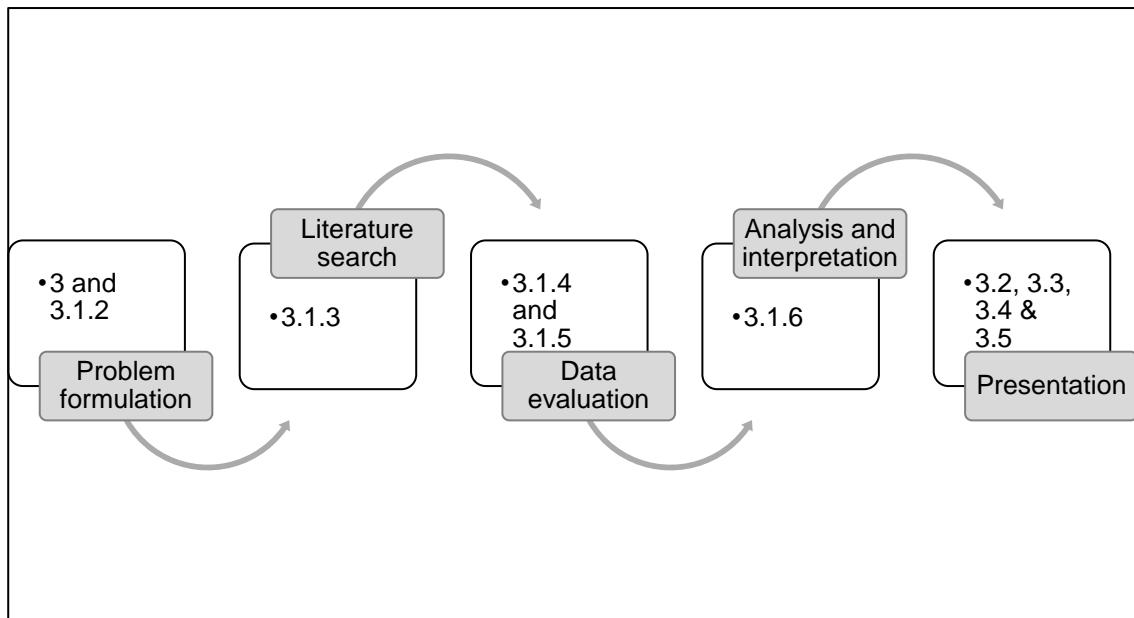


Figure 3-1: Five-stage framework for integrative reviews (Whittemore & Knafl 2005), and the sections of this chapter that pertain to each of these stages.

While the review encompassed three research questions, as previously specified, the methods and results that follow relate to the characteristics of RAS and their reported inter-rater reliability. Consideration of the predictive validity of RASs is outside the scope of this chapter, since this formed the focus of a second PhD candidate from Maastricht University.

### 3.1.2 Eligibility Criteria

In accordance with the purpose of this review, broad eligibility criteria were specified. Studies conducted in every healthcare setting were considered potentially eligible for inclusion, and no restrictions were placed on the date of publication. However, for practical reasons grey literature, namely theses, commercial literature or other unpublished reports, was excluded, as were papers written in a language other than English, German or Dutch. Other general exclusion criteria, derived from the research questions, were papers reporting on software-generated PU risk assessments, RASs designed for patients to self-assess their risk of PUs or constructed to assess the care provided by the institution, or scales indicated for use in a paediatric population.

To determine the characteristics of RASs, all sources introducing or describing a standardised scale were eligible. No distinction was made between RASs created within the context of research, or those derived from clinical practice, since widespread clinical adoption of several scales fitting the former category has occurred (Gosnell 1989). Modifications of previously published scales were considered eligible for inclusion if risk factors were added or removed, items were re-weighted or operational definitions were modified, since any of these may result in a substantively different RAS. By contrast, sources describing a previously published RAS, modified solely by means of a revised cut-off score were excluded.

As noted by Cooper (1989), eligibility criteria may evolve when a review progresses as unforeseen operations of a construct are identified, and in the present review a further three exclusion criteria applicable to sources describing a RAS emerged. The first of these related to studies that evaluated the predictive validity of assessment tools which were devised for use in a context other than PU risk assessment (Vandenbroele et al. 1994; Balzer et al. 2007; Mertens et al. 2008; Tannen et al. 2010; Yatabe et al. 2013). Such tools were not considered PURASs and therefore these studies were excluded from this review. Papers were further excluded when they described a new or revised RAS but the authors concluded that the resultant scales did not substantially improve on existing RASs (Goldstone & Goldstone 1982; Watkinson 1996; Tourtual et al. 1997; Compton et al. 2008), or when regression analysis was utilised to derive a PU prediction model but an accompanying weighting scheme for risk factors was not presented (Batson et al. 1993; Kim & Lang 2006; Hatanaka et al. 2008; Cowan et al. 2012; DeJong et al. 2014; Lee et al. 2014; Nakamura et al. 2015). In either circumstance, the adoption of these scales by healthcare professionals may be deemed unlikely.

With regards to inter-rater reliability, prospective and cross-sectional studies presenting primary data on the reliability of any scale meeting the previously specified inclusion criteria were potentially eligible for inclusion, with no raters or rater-pairings excluded. However, as noted in recent guidelines for reliability studies, the quality of reporting is often poor when inter-rater reliability does not form the primary objective but is instead utilised as a quality control measure for the main study (Kottner et al. 2011). Accordingly, only papers which specified that scale inter-rater reliability was a primary study outcome were included in the present review. Furthermore, while reports of item-level reliability can be useful in identifying particular areas of concern with a given scale (Kottner & Dassen 2008a), the purpose was to examine the reliability of all scales and

## Integrative Review of Risk Assessment Scales

as such the overall scale scores formed the parameter of interest and studies which focused exclusively on subscale reliability were excluded. Similarly, studies that categorised the overall scores into risk categories for the analysis of reliability were excluded since this would impede between-scale comparisons.

### 3.1.3 Search Strategy

A comprehensive search was performed across the PubMed, EBSCO Cumulative Index to Nursing and Allied Health Literature (CINAHL), Ovid Embase, Web of Science (WoS) and the Cochrane Central Register of Controlled Trials (CENTRAL) databases, with each of these searched from inception to April 2016. The search terms were devised in consultation with a specialist librarian and comprised the keywords pressure ulcer, pressure sore, decubitus, bedsore, pressure damage, pressure injury, combined using the OR Boolean operator, and, where relevant, included word variations. Subsequently, the search terms risk assessment, risk factor, risk scale, benefits and risk, safety management, risk calculator and risk prediction, or word variations of these, were combined and both search strings were joined using the AND operator. Appendix A shows the full search strategy relating to each of the databases.

The title and abstracts of retrieved records were independently screened by two reviewers, the author and a second PhD candidate from Maastricht University. Potentially relevant sources were retrieved in full and independently assessed for eligibility by both reviewers, as were records which contained insufficient information in the title and abstract. Disagreement at either the screening or full-text assessment stage was resolved by involving a third reviewer, a senior nurse researcher from the University of Southampton, as an arbiter. Citation searching was performed by the author in the resulting sample of eligible papers, to find literature not identified by the database searches, with the reference lists of sources retrieved in this manner further scanned for relevant papers.

Where multiple sources describing an identical RAS were identified by the above approaches, the seminal source was retained and subsequent iterations were excluded, except where these seminal reports were unpublished, published in a language excluded from this review (Section 3.1.2), or a more comprehensive description of the RASs was provided in a subsequent source.

### 3.1.4 Data Extraction

Data from sources that fulfilled all the eligibility criteria were summarised by means of structured data extraction tables. This process was undertaken by a single reviewer, namely the author, with a second reviewer, a senior nurse researcher, checking a random sample for accuracy (10% of entries in the respective tables).

The following data were collected from all sources:

- Author(s);
- Year of publication;
- RAS name;
- Country;
- Care setting and speciality.

Additionally, for sources pertaining to the characteristics of RASs, the following data were collected:

- Method of development;
- Scale items and weighting;
- Direction of scoring;
- Proposed cut-off score.

For papers reporting on the inter-reliability of scales, data extraction further included:

- Study methodology;
- Rater details;
- Participant details;
- Results.

### 3.1.5 Quality Appraisal

Evans (2007) suggests that quality appraisal may not be a prerequisite of all integrative reviews, with its utility dependent on the nature of the review, while Whittemore and Knafl (2005) add that the process of quality appraisal in integrative reviews can be complex as a result of the diversity of sources. For the present review, the quality appraisal approaches were tailored to the research questions, as identified in the introduction of this chapter. The first of these questions focused on the characteristics of all identified RASs which represented the broadest sampling frame of the literature considered in this review, with many of the sources non-empirical in nature and, as such, quality appraisal of these sources was not undertaken.

## Integrative Review of Risk Assessment Scales

Comparatively, papers examining the inter-rater reliability of RASs were less diverse, and a quality appraisal tool designed specifically for reliability studies was used to evaluate the presence of bias related to study methodology. This tool, the Quality Appraisal of Reliability Studies (QAREL) checklist, consists of 11 items covering 7 domains namely, the spectrum of subjects, the spectrum of examiners, examiner blinding, the order effects of examination, the time interval between repeated measurements, test application and interpretation, and statistical analysis (Lucas et al. 2013). It is recommended that the checklist is piloted to clarify the interpretation of the items (Lucas et al. 2013) and therefore the author and a second reviewer independently appraised two studies which had been selected for inclusion, using the checklist and accompanying instructions (Lucas et al. 2010). The results were compared, and differences in interpretation were resolved by discussion. The item concerning the order in which raters examine subjects was deemed to be of particular relevance to studies examining the intra-rater reliability of RASs, which were outside the scope of the present review, and as such this item was excluded. The resulting 10-item checklist is detailed in Appendix B. Quality appraisal of all the remaining reliability studies was undertaken by the author.

Where a number of studies with varying methods were reported in a single paper, one QAREL assessment was performed, and the item assessment that is presented reflects the least favourable rating assigned across the individual studies.

### **3.1.6 Data Analysis and Synthesis**

Narrative synthesis was utilised to summarise the results (Whittemore 2005; Popay et al. 2006), with tabulation of the salient data extracted from the identified sources. Scales and their key characteristics have been presented chronologically by date of publication, while the table summarising the inter-rater reliability studies has been grouped according to scale.

Content analysis, as detailed by de Vet et al. (2011), was performed. This involved mapping the items contained in RASs to the risk factor domains recognized as relevant, or potentially relevant, to PU risk in recent guidelines (NPUAP, EPUAP and PPPIA 2014a). When an item was mapped to a risk factor domain, such as for example a scale item labelled 'food intake' to the 'poor nutritional status' risk factor domain, that domain was considered to be present in the scale, regardless of whether the item was deemed to be a comprehensive representation of the domain in question. In addition to the aggregated results of this analysis, indicating the frequency the various domains

are represented in RASs, the content validity of individual RASs, defined as the percentage of the ten domains which are covered by a scale, was also examined.

The QAREL assessment results were classified using the criteria employed by Manchikanti et al. (2013), where methodological quality is deemed high, moderate or poor when affirmative responses are assigned to  $\geq 67\%$ , between 50-66%, or  $< 50\%$  of the QAREL items, respectively.

It has been suggested that instruments used to guide clinical decision making should exhibit a greater reliability than that which is required for instruments utilised in the course of research (Streiner et al. 2015). Indeed, in an inter-rater reliability study of the Braden Scale, Kottner and Dassen (2008b) demonstrated that clinically relevant differences in scores ( $> 3$  points) occurred when intraclass correlation coefficients (ICC) values were  $< 0.90$ . Accordingly, in the present review ICCs of  $\geq 0.90$  were regarded as the minimum acceptable values for reliability estimates, as recommended by the guidelines surrounding reporting of reliability studies (Kottner et al. 2011).

Measures of agreement have also been presented, in cases where reliability statistics were not reported, or when papers reported both reliability and agreement parameters. Agreement refers to measurement error and is considered a characteristic of the instrument, while reliability provides an indication of an instrument's ability to discriminate between participants and is highly dependent on the population examined (de Vet et al. 2006; Streiner & Norman 2006). The latter parameter represents the ratio of participant variability over the total observed variation resulting from participant variability and measurement error (de Vet et al. 2006; Bartlett & Frost 2008). Thus, while related, measures of agreement such as percentage agreement and the standard error of measurement (SEM), are not synonymous to reliability parameters, although they do provide context for reliability estimates (de Vet et al. 2006; Lucas et al. 2010; Kottner & Streiner 2011).

## 3.2 Search Results

The database searches yielded 14869 records, 9508 of which remained after the removal of duplicates. Of these, 8989 records were excluded following screening of title and abstracts, as they did not meet the inclusion criteria. The remaining 519 articles were selected for full-text eligibility assessment. However, one article proved to be irretrievable. Therefore, 518 papers were retrieved and reviewed in full and of these, 86 were found to be eligible for inclusion. Citation searching within these papers identified a further 31 potential sources, 19 of which were selected for inclusion following full-text assessment. In total, 105 of the identified sources fulfilled the inclusion criteria and were included in this review. Some of these addressed both research questions and consequently the number of sources describing a RAS, describing a RAS and reporting its inter-rater reliability, or solely reporting the inter-rater reliability of a RAS were 81, 10 and 14, respectively. This search and selection process is depicted in Figure 3-2.

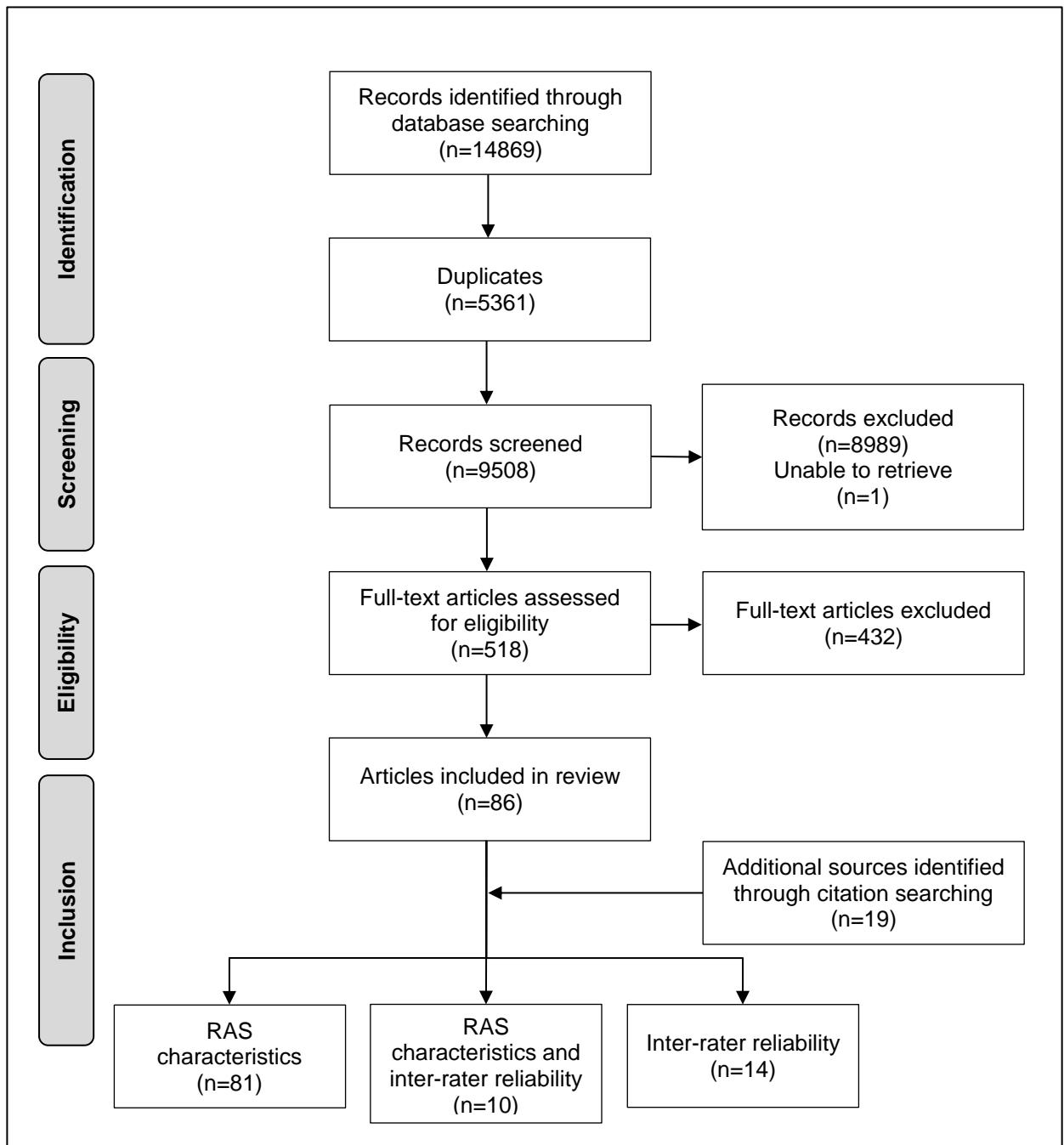


Figure 3-2: Flow diagram of the search and selection process. Adapted from the PRISMA diagram (Moher et al. 2009).

### 3.3 The Characteristics of Risk Assessment Scales

The search strategy identified 94 RASs which were described in 91 sources (Figure 3-2). The key characteristics of these scales have been summarised in Table 3-1. It is apparent from this table that most scales, namely 73%, were devised for use with either generic or specific inpatient populations. By contrast, only 13% of scales targeted patients in community settings, while 11% of scales were intended for use across acute and community settings, with the target population not specified in the remaining 3%.

Of the RASs targeting specific inpatient populations, scales for use with intensive or critical care patients were most frequently observed, with 18 of such scales identified (Table 3-1). These ranged from relatively minor adaptations of scales originally devised for generic inpatient populations, such as those presented by Weststrate and Bruining (1996) and Compton et al. (2008), both modifications of the Waterlow Scale (Waterlow 1987), to scales specifically created for intensive or critical care patients, including the S.S. (Suriadi et al. 2008) and the SPURA (Slowikowski & Funk 2010) Scales. Of note are the RASs devised by Prölß and colleagues (1996), who present a tool for use at intensive care admission, designated the DRS I Scale, and the more elaborate DRS II Scale, intended for the subsequent monitoring of these patients. Other inpatient populations frequently considered were surgical and elderly care patients, which formed the target population of 7 and 6 RASs, respectively (Table 3-1). With regards to surgical patients, it is interesting to note that the majority of these scales are relatively recent additions to the literature (Price et al. 2005; Munro 2010; Nicoladis et al. 2011; Gao et al. 2015; Scott 2015; Munro in Putnam 2016), and that risk factors specific to the intraoperative period regularly feature in such scales (Price et al. 2005; Nicoladis et al. 2011; Gao et al. 2015; Munro in Putnam 2016).

High acuity populations, such as emergency department attendees, were the target population of two scales, with the need for rapid completion of assessments cited as the motivation for adopting these scales in both instances (McClemont et al. 1992; Faulkner et al. 2015). Other less frequently observed hospitalised target groups include oncology and SCI patients, each considered by two scales, as a result of the continued research efforts of specific investigators (Salzberg et al. 1996; Salzberg et al. 1999; Fromantin et al. 2011), and neurology patients which form the population of interest in Johnson's (1994) Pressure Sore Risk Assessment Chart, an adaptation of the Waterlow Scale (Waterlow 1987) borne out of a perceived clinical need (Table 3-1).

## Integrative Review of Risk Assessment Scales

Table 3-1: Summary of the key characteristics of the RASs identified by the search strategy.

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ‡‡
Norton et al. (1962), UK	Patient Assessment Form- 'Norton Scale'	Elderly care inpatients	Scale devised for research purposes, items derived from clinical experience	5	Physical condition, Mental condition, Activity, Mobility, Incontinence	≤14
Redfern (in Isler 1972), US	Hackensack Hospital Decubitus Evaluation Form	Generic inpatients	Adapted from an unpublished scale	7	General condition, Activity, Incontinence, Medical evaluation, Mental state, Mobility, Proposed surgery	≥8
Williams (1972), US	Dichotomous Rating Scale	Generic inpatients	Items derived from clinical experience and literature review, revised following clinical feedback and pilot testing, further evaluation in a subsequent study utilising stepwise regression	20	Sex, Ethnicity, Level of consciousness, Moves self, Dryness of skin, Body weight, Oedema, Sensation, General circulation, Genitourinary infection, Incontinent of urine, Incontinent of faeces, Routine skin care, Padding devices, Treatment with corticosteroids, Treatment with vitamins, Infection other than genitourinary, Calories per day, Temperature, Skin breakdown	Not specified
Gosnell (1973), US	Assessment Tool- 'Gosnell Scale'	Extended care facility residents	Items derived from previous research, including findings of Norton et al. (1962), scale evaluated in prospective study	5	Mental status, Continence, Mobility, Activity, Nutrition	Not specified
Lowthian (1977), UK	Bedsore Liability Score (BLS)	Elderly care inpatients	Scale adapted from the Norton Scale and the Rating Scale by Williams (1972)	Not specified	Among others: Consciousness, Mobility, Activity, Incontinence, Pyrexia, Frequency of movement	≥6
Stamper (1978), US	Skin Condition of Patients Encountered (S.C.O.P.E.)	Not specified	Items derived from literature review	4	Age, Body structure, Control of Function, Degree of integrity	≥7
Goldstone and Roberts (1980), UK	Revised Norton Score	Orthopaedic ward	Devised from the Norton Scale, items selected following discriminant function analysis of data pertaining to orthopaedic patients	2	Activity, Mobility	≤3
Kerr et al. (1981), US	Pressure Assessment Scale	Not specified	Not specified but scale similar to the Norton Scale, presented with extended operational definitions	5	Physical condition, Mental condition, Activity, Mobility, Continence	Not specified

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ††
Andersen et al. (1982), Denmark	Risk Assessment Score	Generic inpatients	Items derived from clinical experience	8	Unconsciousness, Dehydration, Paralysis, Age $\geq 70$ , Restricted mobility, Incontinence, Pronounced emaciation, Redness over bony prominences	$\geq 2$
Arnell (1983), UK	Assessment of Decubitus Ulcer Potential	Generic inpatients	Development method not specified but scale similar to the Knoll Scale, published in 1986	7	Mental status, Incontinence, Activity, Mobility, Nutrition, Skin appearance, Skin sensation	$\geq 12$
Shannon (1984), US	Determining Patients at Risk for Pressure Sores Chart- 'Shannon Scale'	Not specified	Development method not specified but certain items identical to the Gosnell Scale	8	Mental status, Continence, Mobility, Activity, Nutrition, Circulation, Temperature, Medications	$\leq 16$
Waterlow (1985), UK	Pressure Sore Risk Assessment- 'Waterlow Scale'	Generic- acute and community	Items derived from literature review and clinical experience	7	Build/ weight for height, Visual skin type risk areas, Continence, Mobility, Sex/ Age, Appetite, Special risks (Poor nutrition, Sensory deprivation, High dose anti-inflammatory drugs or steroids in use, Smoking, Orthopaedic surgery/ fracture below waist)	$\geq 10$
Abruzzese (1986), US	Assessment of Decubitus Ulcer Potential- 'Knoll Scale'	Generic inpatients	Review of the scales devised by Norton, Gosnell and Williams and other risk factor literature, subsequent year-long clinical audit to determine key items, scale refined following clinical input, including feedback from subject experts	8	General state of health, Mental status, Activity, Mobility, Incontinence, Oral nutrition intake, Oral fluid intake, Predisposing diseases	$> 12$
Lincoln et al. (1986), US	Norton Scale (Modified)	Generic inpatients	Norton Scale modified by means of extended operational definitions following an inter-rater reliability study	5	General condition, Mental status, Activity, Mobility, Incontinence	$\leq 14$
Pajk et al. (1986), US	Risk Factor Assessment Tool	Generic inpatients	Risk factors derived from Norton and Gosnell Scales, with items selected for inclusion if they were significantly associated with skin breakdown in a cross-sectional audit	5	Mental status, Continence, Mobility, Activity, Nutrition	$\leq 15$
Pritchard (1986), UK	Douglas Pressure Sore Risk Calculator	Medical ward	Derived from the Norton Scale with additional items selection guided by clinical experience and further refinement following pilot testing	7	Nutritional state/ haemoglobin, Activity, Incontinence, Pain, Skin state, Mental State, Special risk factors (Steroid therapy, Diabetes, Cytotoxic therapy, Dyspnoea)	$\leq 18$

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ‡‡
Bergstrom et al. (1987), US	Braden Scale for Predicting Pressure Sore Risk	Generic- acute and community	Items selected from research derived conceptual schema, with content validity ascertained by expert opinion	6	Sensory perception, Activity, Mobility, Moisture, Nutrition, Friction and shear	≤16
Ek (1987), Sweden	Modified Norton Scale	Medical ward	Most items derived from Norton Scale, unclear how additional variables were selected, subsequently evaluated in a prospective study by means of regression analysis	8	Mental state, Activity, Mobility, Social activity, Food and fluid intake, Incontinence, Body temperature, General physical condition	<25
Ek and Bjurulf (1987), Sweden	Modified Norton Scale	Nursing home residents and elderly care rehabilitation wards	Scale further revised following findings reported by Ek (1987)	7	Mental condition, Activity, Mobility, Food intake, Fluid intake, Incontinence, General physical condition	Not specified
Lowthian (1987), UK	Pressure Sore Prediction Score (PSPS)	Generic inpatients	Adapted from the Bedsore Liability Scale and refined following a number of pilot studies	6	Sitting up, Unconscious, Poor general condition, Incontinent, Lifts up, Gets up and walks	≥6
Waterlow (1987), UK	Waterlow Risk Assessment Card- 'Waterlow Scale'	Generic- acute and community	Not specified but minor revisions to the Pressure Sore Risk Assessment previously presented by the author (Waterlow 1985)	10	Build/ weight for height, Risk areas visual skin type, Sex/ age, Continence, Mobility, Appetite, Neurological deficit, Major surgery/ trauma, Medication, Tissue malnutrition (Terminal cachexia, Cardiac failure, Peripheral Vascular Disease (PWD), Anaemia, Smoking)	>10
Stotts (1988), US	Modified Norton Scale	Surgical patients	Norton Scale revised through extended operational definitions, utilising Gosnell's work (1973) and other literature	5	Physical condition, Mental status, Activity, Mobility, Incontinence	≤14
Towey and Erland (1988), US	Modified Knoll Scale	Long-term care facility residents	Knoll Scale revised following prospective study of elderly patients, with an improved internal consistency reported following the deletion of 3 of the original items	5	General state of health, Mental status, Activity, Mobility, Incontinence	Not specified
Gosnell (1989), US	Gosnell Pressure Sore Risk Assessment Instrument	Generic- acute and community	Gosnell Scale (1973) revised following further research, literature review, and pilot tests, changes include extended operational definitions and reversal of the direction of scoring	5	Mental status, Continence, Mobility, Activity, Nutrition	Not specified

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	Nº Scale items †	Items	Cut-off score ††
Dreßler (1990), Germany	Extended Norton Scale	Generic inpatients	Revision of the Norton Scale, additional items derived from clinical experience	9	Physical condition, Mental status, Activity, Mobility, Incontinence, Concordance, Age, Skin condition, Additional disease	≤25
Cubbin and Jackson (1991), UK	Cubbin & Jackson Pressure Area Risk Calculator	Intensive care	Review of several existing scales, scoring and items largely based on the Norton Scale, with additional ICU factors derived from clinical experience and further refinements made following pilot testing	10	Age, Weight, General skin condition, Mental condition, Mobility, Haemodynamic status, Respiration, Nutrition, Incontinence, Hygiene	≤24
Aronovitch et al. (1992), US	Adapted Knoll Assessment Tool	Generic inpatients	Knoll Scale revised following review of the findings reported by Towey and Erland (1988) as well as other literature, several items relabelled and extended operational definitions specified	8	General health status, Mental status, Activity, Mobility, Incontinence, Nutritional intake, Fluid intake, Predisposing diseases	≥12
Clark and Farrar (1992), UK	Nursing Practice Research Unit (NPRU) Pressure Sore Risk Calculator	Generic inpatients	Development method not specified	6	<i>Mobility while in Bed</i> - Cannot raise arms, Cannot move legs over side of bed to allow standing, When supine cannot bend knees, Cannot sit up from a supine position, From supine cannot turn to a lateral position, From lateral cannot move to a supine/ prone position	≥18
McClemont et al. (1992), UK	Andersen Pressure Risk Screening System (Modified Andersen Score)	High acuity patients (i.e. emergency department)	Adapted from the Risk Assessment Score by Andersen et al. (1982), further details not provided	10	Not conscious, Ortho Trauma/ Surgery (major), Rehydration necessary, Tetraplegia/ Paralysis, Having difficulty to or won't move, Limb mobility restricted, Incontinent, Nutritionally deficient/ Emaciated, Coloured red over bony prominences, Seventy years or more	≥2
West et al. (1992), UK	Pressure Sore Assessment Tool	Elderly care inpatients	Adapted from the Norton and Waterlow (1985) Scales, with item selection based on clinical experience	8	Build/ Weight, Skin type, Sex/ Age, Continence, Mobility, Appetite, Medication, Special risks (Cardiac failure, PVD, Anaemia, Smoking, Diabetes, Multiple Sclerosis, Cerebrovascular Accident (CVA), Paraplegic, Amputee)	>10
Williams, (1992), UK	Medley Score	Generic inpatients	Derived from the (unpublished) Medley Score, refinements made following pilot testing	9	Activity, Mobility, Skin condition, Predisposing disease, Level of consciousness, Nutritional status, Incontinence-bladder, Incontinence- bowel, Pain	≥10

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ‡‡
Milward et al. (1993), UK	Walsall Community Risk Score Calculator	Community nursing patients	Items derived from Medley Score and the Douglas Risk Calculator, selection based on clinical experience, further refinements made following pilot testing and feedback from an external subject expert	9	Predisposing disease, Level of consciousness, Mobility/ ambulation, Skin condition, Nutritional status, Pain, Bladder incontinence, Bowel incontinence, Care at home	≥12
Sparks (1993), US	Sparks Custer Assessment of Pressure Ulcer Risk (SCAPUR)	Nursing home residents	11 potential items derived from previous research, item presence among nursing home residents ascertained by two expert practitioners in a cross-sectional study, with findings supporting inclusion of 7 items	7	Activity status, Incontinence, Mechanical factors, Mobility status, Musculoskeletal status, Nutritional status, Self-care ability	Not specified
Birtwistle, (1994), UK	Birty's Pressure Area Risk Assessment Tool	Intensive care	Items derived from literature review and clinical experience	8	Age, Weight & Nutritional status, Conscious level, Underlying problems (Smoker, Diabetic, Hyperglycaemia, Fractures, Skin damage, System failure, Pain), Skin condition, Mobility, Continenence, Additional problems (Inotropic support, Steroid therapy, Orthopaedic surgery, Vascular disease)	Not applicable
Johnson (1994), UK	Pressure Sore Risk Assessment Chart (Modified Waterlow Scale)	Neurological inpatients	Adapted from the Waterlow Scale (1987), revisions suggested by expert clinicians and further minor refinements made following pilot testing	10	Sex/ Age, Dietary intake, Continenence, Skin over pressure points, Mobility, Nutritional status, Cardiovascular, Neurological deficit, Medication, Surgery	>10
Bale et al. (1995), UK	Risk Assessment Score (Modified Norton Scale)	Hospice patients	Adapted from the Norton Scale with the additional risk factors derived from clinical experience	6	General physical condition, Mobility, Nutritional status, Pain, Continenence, Special risk factors (Diabetes, Vascular/ arterial disease, Drug therapy, Psychological state, Lymphoedema/ ascites, Fungating wound, Paraplegia)	≥11
Gill (1995), UK	Coppull Pressure Sore Risk Assessment Tool	Community nursing patients	Review of existing scales with the Waterlow Scale (1987) strongly influencing the items selected	7	Pain, Nutritional status, Build and weight, Continenence, Skin Type, Mobility, Contributing factors	Not specified
Jiricka et al. (1995), US	Decubitus Ulcer Potential Analyzer (DUPA)	Intensive care	Adapted from the Norton, Gosnell and Braden Scales	7	Mental status/ Sensory perception, Nutrition, Mobility, Activity, Moisture, Friction and shear, Circulation	Not specified

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	Nº Scale items †	Items	Cut-off score ††
Lowery, (1995), UK	Sunderland Pressure Sore Risk Calculator	Intensive care	Adapted from the Cubbin & Jackson Risk Calculator following literature review and pilot testing	9	Medical condition, Weight, General skin condition, Mental condition, Body temperature, Nutrition, Respiration, Haemodynamic status, Incontinence	<28
Healey (1996), UK	Waterlow/ York Scale	Generic- acute and community	Adapted from the Waterlow Scale (1987) following pilot testing	Not specified	Not specified	≥15
McCormack (1996), UK	Stratheden Pressure Sore Risk Scale	Elderly care inpatients	Items derived from existing scales and clinical experience	7	Build/ weight for height, Continenence, Skin state, Mobility, Nutritional intake, Physical state, Mental awareness	≥8
Prölß et al. (1996), Germany	Decubitus Risk Score I (DRS I)	Intensive care	Based on the Extended Norton Scale (Dreßler 1990), with additional risk factors derived from literature review and clinical experience, final item selection and item weighting determined by regression analysis of data from a prospective cohort study. DRS I has been designed for completion at intensive care admission.	5	Skin moisture, Weight, Age, Serum lactate, Catecholamines	≤7
Prölß et al. (1996), Germany	Decubitus Risk Score II (DRS II)	Intensive care	Method of development identical to DRS I. DRS II has been designed for the continual monitoring of intensive care patients.	9	<i>Physiological biochemical variables</i> - Skin state Albumin, $\text{SvO}_2$ (mixed venous oxygen saturation), Lactate, Dopamine, Epinephrine/ Norepinephrine <i>Individual variables</i> - Weight, Age <i>Kinetic variable</i> - Degree of immobility due to disease	≤20
Salzberg et al. (1996), US	Pressure Ulcer Risk Assessment Scale for the Spinal Cord Injured (SCIPUS)	SCI patients	Regression analyses of retrospective data; final item selection if risk factors were cited in the literature, were biologically plausible, proved to be statistically associated with PU development and if addition improved the predictivity of the scale	15	Level of activity, Mobility, Complete SCI, Urinary incontinence or constantly moist, Autonomic dysreflexia or severe spasticity, Age, Tobacco use/ smoking, Pulmonary disease, Cardiac disease or abnormal electrocardiogram, Diabetes or glucose $\geq 110$ mg/ dL, Renal disease, Impaired cognitive function, In a nursing home or hospital, Serum albumin $< 3.4$ gm/ dL or Total protein $< 6.4$ g/ dL, Haematocrit $< 36\%$	≥3

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ‡‡
Weststrate and Bruining (1996), The Netherlands	Adapted Waterlow Pressure Sore Risk Scale	Intensive care	Adapted from the Waterlow Scale (1987)	10	Build/ weight for height, Skin type visual risk areas, Continence, Mobility, Sex/ Age, Appetite, Tissue Malnutrition, Neurological deficit, Major surgery/ trauma, Medication	Not specified
Watkinson (1997), UK	Watkinson Scale	Generic inpatients	Items derived from existing scales, selection guided by clinical experience and further refinements made following pilot testing	7	Urinary incontinence, Faecal incontinence, Skin state, Dietary intake, Activity, Pain, Special risk factors (Smoking, Anaemia, Chest infection, Steroid therapy, Dyspnoea, Neurological deficit, Cardiac failure, PVD, Diabetes)	≥10
Schue and Langemo (1998), US	Modified Braden Scale	Rehabilitation unit	Adapted from the Braden Scale after regression analysis of retrospective data, with backward elimination of non-significant subscales	3	Moisture, Nutrition, Friction and shear	≤8
Chaloner and Franks (1999), UK	Walsall Community Risk Score Calculator (Revised)	Community nursing patients	Revision of the Walsall Calculator (Milward et al. 1993) following multiple regression analysis of retrospective data (cross-sectional study design), leading to the removal of 2 risk factors and item re-weighting, new weighting in accordance with the regression coefficient	7	Level of consciousness, Mobility/ ambulation, Skin condition, Nutritional status, Bladder incontinence, Bowel incontinence, Carer input	≥10
Cook et al. (1999), UK	Adapted Waterlow Pressure Ulcer Risk Assessment Scale	Elderly care inpatients	Adapted from the Waterlow Scale (1987) following pilot testing	10	Build/ weight for height, Continence, Skin Type, Mobility, Sex/ Age , Appetite , Neurological deficit/ general medical condition, Major surgery/ trauma, Medication, Special risks (Terminal cachexia, Cardiac failure, PVD, Anaemia, Smoking)	>10
Jackson (1999), UK	Revised Jackson/ Cubbin Pressure Area Risk Calculator	Intensive care	Revision of Cubbin & Jackson Calculator (1991) following feedback from clinicians	15	Age, Weight/ Tissue Viability, Past medical history, General skin condition, Mental condition, Mobility, Haemodynamics, Respiration, Oxygen requirements, Nutrition, Incontinence, Hygiene, Surgery/ scan last 48 hours, Blood products required, Hypothermia	≤29

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ‡‡
Salzberg et al. (1999), US	Acute Version of the Spinal Cord Injury Pressure Ulcer Scale (SCIPUS-A)	SCI patients, immediate post-SCI hospitalisation	Regression analyses of retrospective data, with item selection guided by the previously utilised criteria (Salzberg et al. 1996), and item weighting derived from the regression coefficient	8	Extent of paralysis, Level of activity, Mobility, Urine incontinence, Moisture, Pulmonary disease, Serum creatinine >1.0, Albumin <3.4 or decrease from admission by >0.2 g/dL	≥13
Chaplin (2000), UK	Hunters Hill Marie Curie Centre Pressure Sore Risk Assessment Tool	Hospice patients	Items derived from existing scales, with selection guided by clinical experience and scale refinement following pilot testing	7	Sensation, Mobility, Moisture, Activity in bed, Nutrition/weight change, Skin condition, Friction/ shear	≥12
Halfens et al. (2000), The Netherlands	Modified Braden-4-factor model	Generic inpatients	Examination of the items contained in the Braden Scale and additional items identified from a literature review, and from practicing nurses/ subject experts, with the final 4-factor model derived following stepwise regression analysis of data from a prospective study	4	Sensory perception, Friction and shear, Age, Moisture	Not specified
Moore and Pitman (2000), Ireland	Maelor Score	Generic inpatients	Adapted from the Medley Score (Williams 1992)	9	Ambulation, Mobility, Skin condition in pressure areas, Predisposing disease, Level of consciousness, Nutritional status, Incontinence- bladder, Incontinence- bowel, Pain	≥10
Van Marum et al. (2000), The Netherlands	CBO (Centraal Begeleidingsorgaan voor de Intercollegiale Toetsing) Score	Generic- acute and community	Few details provided on the development method but the score originates from a hospital setting and was subsequently recommended by a national quality assurance body	10	Mental status, Mobility, Nutritional status, Nutritional intake, Incontinence, Age, Temperature, Medication, Diabetes Mellitus, Neurology	Not specified
Lindgren et al. (2002), Sweden	Risk Assessment Pressure Sore (RAPS) Scale	Generic inpatients	Items largely derived from the Norton, Modified Norton (Ek & Bjurulf 1987) and Braden Scales with additional factors identified from a literature review and scale refinement after examination of the item-item and item-total correlation observed in data from a prospective study	10	General physical condition, Activity, Mobility, Moisture, Food intake, Fluid Intake, Sensory Perception, Friction and shear, Body temperature, Serum albumin level	Not specified

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ‡‡
McErlean et al. (2002), Australia	Pressure Risk Assessment Screen	Generic inpatients	Items derived from relevant guidelines and other literature, with the Ramstadius Tool (Webster et al. 2011) influencing the format adopted	4	Difficulty in changing own position in bed/ chair, Prolonged exposure to friction on pressure points, Existing PUs or redness of pressure points, Prolonged exposure to moisture on pressure points	Not applicable
Perneger et al. (2002), Switzerland	Fragnment Score	Generic inpatients	Examination of the Norton and Braden Scale items as well as 2 other variables, item selection determined by stepwise regression analysis following a prospective study, with suggested item weightings derived from the regression coefficient	4	Age group, Mobility, Mental status, Friction/ shear	Not specified
Henoch and Gustafsson (2003), Sweden	Hospice Pressure Ulcer Risk Assessment Scale (HoRT)	Hospice patients	Items derived from the Modified Norton (Ek & Bjurulf 1987), Braden, Waterlow (1985; 1987) and RAPS Scales, with the association between items and PUs examined in a prospective study, 9 RASs subsequently constructed and tested for the ability to detect between-group differences after which the HoRT emerged as superior in terms of statistical significance and predictivity	3	Physical activity, Mobility, Age	≤8
Lewin et al. (2003), Australia	Silver Chain Pressure Ulcer Risk Assessment Tool	Community nursing patients	Adapted from the Braden Scale	7	Sensory perception, Activity, Mobility, Moisture, Nutrition, Friction and shear, Carer support score	Not specified
Gledhill and Hampton (2005), UK	Hampton-Gledhill 2-stage Pressure Risk-Assessment System	Generic- acute and community	Items derived from clinical experience	2	Skin condition, Independent whole position movement during the past 2 hours	Not applicable
Kwong et al. (2005), China	Modified Braden Scale	Generic inpatients	Braden Scale modified by the addition of 2 research-derived items and evaluated using descriptive analysis following a prospective study, leading to the exclusion of 1 original Braden Scale item	7	Sensory perception, Skin moisture, Mobility, Activity, Friction and shear, Skin type, Build for height	16

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ††
Ongoma et al. (2005), South Africa	ICU Risk Assessment Scale	Intensive care	Derived from the Sunderland Pressure Sore Risk Calculator(Lowery 1995), presented with minor changes to the operational definitions	9	Medical condition, Weight, Skin condition, Mental condition, Temperature, Nutrition, Respiration, Haemodynamic status, Incontinence	<35
Ongoma et al. (2005), South Africa	Not specified- 'Control Scale'	Intensive care	Adapted from the Norton and Waterlow (version not specified) scales, with item selection guided by clinical experience	7	Physical, Mental, Activity, Mobility, Incontinence, Skin Type, Other risks (Nutritional deficiencies, Neurological deficit, Poor circulation, Poor hydration, Infection, Anaemia, On hard surface >2hrs, Medication, Age 65+)	≤20
Price et al. (2005), US	Preoperative Risk Assessment	Surgical patients- preoperative and intraoperative period	Items derived from literature review and the tool incorporates the Braden Scale, no weighting scheme presented for the non-Braden items	23	<i>Preoperative risk-</i> Age, Comorbidities, Preoperative haematocrit/ haemoglobin, Preoperative albumin, Preoperative Braden Scale (6 items) <i>Intraoperative risk-</i> Surgical time, Surgical position, Type of surgery, Patient's temperature, Use of bypass, Hypotensive episodes, Use of warming device, Type of padding, Positioning devices, Operative support surface, Anaesthetic agent, Type of skin preparation, Skin exposure to moisture	Not specified
Waterlow (2005), UK	Revised Waterlow Scale	Generic-acute and community	Revisions following research surrounding the original Waterlow Scale (1985; 1987)	10	Build/ weight for height, Skin type visual risk areas, Sex/age, Malnutrition Screening Tool, Continence, Mobility, Tissue malnutrition, Neurological deficit, Major surgery or Trauma, Medication	>10
Lepistö et al.(2006), Finland	Not specified	Long-term care facility residents	Items derived following a review of existing scales and other research, refinements made following feedback from expert clinicians	18	<i>Patient risk factors-</i> Activity, Mobility in bed, Mental status, Nutrition, Urinary incontinence, Faecal incontinence, Sensory perception, Skin condition <i>Devices and methods used in patient care-</i> Technical devices, Bed type, Mattress, Mattress overlay, Seating cushions, Care methods <i>Organisational factors-</i> Number of staff members, Educational background of staff, Maximum number of beds, Beds in use	Not specified

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ‡‡
Schoonhoven et al. (2006), The Netherlands	Pressure Ulcer Risk Score Evaluation (prePURSE) Scale	Generic inpatients	Items derived from literature review and included in a multiple regression model if they were significantly associated with PUs in a prospective study and were frequently observed/ easy to obtain in clinical practice, with item weighting in accordance with the regression coefficient	5	Age, Weight at admission, Abnormal appearance of skin, Friction/ Shear, Surgery in coming week	≥20
Compton et al. (2008), Germany	Modified Waterlow at the Charité Benjamin Franklin	Intensive care	Adapted from the Waterlow Scale (1987), with additional items derived from clinical experience	10	Build/ weight for height, Visual skin type risk areas, Continence, Mobility, Sex/ Age, Appetite, Poor Nutrition, Special risks (Terminal cachexia, Cardiac failure, PVD, Anaemia, Smoking), Neurological disease, Substantial surgery/ trauma, Medication	≥30
Nonnemacher et al. (2008), Germany	Essener Dekubitus-Score	Generic inpatients	Potential items derived from existing scales and guidelines and evaluated in a prospective study using multiple regression analysis, with item weighting proportional to the regression coefficient	12	Limited mobility/ activity, Presence of a malignant tumour, Presence of pain, Insufficient hydration, Insufficient nutrition, Application of drugs with a strong sedative effect, Inhibited sense of pain, Arterial obstructive disease of abdominal and pelvic arteries, Skin problems in areas at risk for PUs, Previous occurrence of a PU, General skin problems, Friction/ shearing forces	>6
Suriadi et al. (2008), Indonesia	Suriadi and Sanada (S.S.) Scale	Intensive care	Items derived from a previous prospective cohort study, with the most significant predictors incorporated in the new scale and item weighting determined by the regression coefficients	3	Interface pressure, Body temperature, Cigarette smoking	≥4
Kim et al. (2009), Korea	Song and Choi Scale	Generic inpatients	Adapted from the Braden Scale but further details not provided, scale was not developed by authors	8	Sensory perception, Activity, Mobility, Moisture, Nutrition, Body temperature, Amount of medication, Friction and shear	≤21

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ††
Brindle (2010), US	High-risk ICU Tool	Intensive care	Item selection guided by research and clinical experience, tool designed as an adjunct to the Braden Scale to identify patients at 'highest risk' for subsequent inclusion in an intervention bundle	19	Surgical procedure >8hrs, Cardiac arrest during this admission, Vasopressors >48hrs, Shock/ Systemic Inflammatory Response Syndrome/ Multiple Organ Dysfunction Syndrome, Weeping oedema, Traction, Morbid obesity, Age >65, Diabetes, Bed rest, Liver failure, Malnutrition, Sedation/ paralytics >48hrs, Mechanical ventilation >48hrs, Quadriplegia/ SCI, Nitric Oxide ventilation, Restraints, Drive lines, Past history of PUs	≥5, or presence of any of the first 4 items †††
Munro (2010), US	Munro Pressure Ulcer Risk Assessment Scale for Perioperative Patients	Surgical patients- preoperative period	Items derived from literature review and expert clinical opinion, elicited via Delphi technique	8	Comorbidities, Nutritional state, BMI or weight, Age, Body temperature, Preoperative mobility/ activity, Physical status/ American Society of Anaesthesiologists pre-anaesthesia evaluation score, Friction and shear during transfers	Not specified
Slowikowski and Funk (2010), US	SICU Pressure Ulcer Risk Assessment (SPURA) Scale	Surgical intensive care	Items identified from a literature review and reviewed by clinical experts, with items that were significantly associated with PUs in a 2-phase cross-sectional study examined by means of stepwise regression analysis, resulting in an 8-item scale which includes all the Braden subscales	8	Sensory perception, Activity, Mobility, Moisture, Nutrition, Friction and shear, Diabetes mellitus, Age ≥70 years	Not specified
Fromantin et al. (2011), France	Curie Scale	Oncology inpatients	Scale developed by a multidisciplinary team of clinicians, no further details provided	6	Mobility, Incontinence, Nutrition, Patient participation, Moisture/ shearing, Markers of tissue and cellular damage (among others: Anaemia, Neutropenia, Diabetes, High C-reactive protein)	>3
Fromantin et al. (2011), France	Pressure Ulcer Scale in Oncology (PUSO)	Oncology inpatients	Retrospective data from prevalence surveys was utilised to examine the Curie Scale, with 3 of the original scale items found to be predictive of PUs following regression analysis which led to the development of the PUSO scale	3	Mobility, Incontinence, Moisture/ shearing	≥1
Jackson (2011), US	Skin Scoring Tool	Generic inpatients	Items selected by clinical experts	6	Sensorium, Mobility, Continence, Skin, Activity, Nutrition	≥10

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ‡‡
Nicolades et al. (2011), US	Pressure Ulcer Risk Evaluation (PURE) Scale	Surgical patients- preoperative and intraoperative period	Incorporates 2 items from the Braden Scale, other items derived from clinical experience	15	<i>Preoperative risk</i> - Age, Activity, Malnutrition, Skin assessment, Previous history of ulcers, Diabetes, Haematocrit, Cardiovascular surgery <i>Intraoperative risk</i> - Anaesthesia risk score, Use of warming blanket under patient, Use of extracorporeal circulation, Hypotensive episodes, Operating room time, Surgical position, Hypothermic episodes	Not specified
Page et al. (2011), Australia	The Northern Hospital Pressure Ulcer Prevention Plan (TNH-PUPP)	Generic inpatients	Items derived from a literature review, with items significantly associated with PUs in a retrospective dataset (prevalence surveys) examined by means of regression analysis and item weighting broadly congruent with the regression coefficient	6	Aged ≥65 years, Admission to ICU during current admission, Reduced sensation, Cognitive impairment, Requires assistance to move in bed, Presence of PU	≥2
Webster et al. (2011), Australia	Ramstadius Pressure Screening and Intervention Tool	Generic inpatients	Development method not specified, tool not developed by authors	2	<i>Skin integrity</i> - Is there evidence of pressure damage/ skin breakdown? <i>Mobility assessment</i> - Does this person regularly reposition themselves without assistance every few minutes?	Not applicable
Kumar et al. (2012), India	Risk Assessment Tool	Generic inpatients	Items derived from literature review, authors' clinical experience, and input from clinical experts, with the identified items compared to the Norton, Braden and RAPS Scales to derive a draft scale, which was refined following review by clinical experts and pilot testing	15	Age, Gender, General physical condition, Level of consciousness, Skin type, Physique, Activity, Mobility, Food intake pattern, Haemoglobin, Moisture, Body temperature, Sensory perception, Friction & shear, Basic nursing care	>35
Ahtiala et al. (2014), Finland	Modified Jackson/ Cubbin Risk Scale (mJ/C)	Intensive care	Adapted from the Revised Jackson/ Cubbin Pressure Area Risk Calculator (1999)	15	Age, Weight/ tissue viability, Past medical history, General skin condition, Mental alertness, Mobility, Haemodynamics, Respiratory support required, Oxygen requirements, Nutrition, Incontinence, Hygiene, Surgery/ CT/ Magnetic Resonance Imaging (MRI)/ Hyperbaric Oxygen Therapy last 48 hours, Required blood product in last 24 hours, Hypothermia (≤ 35°C or under)	≤29

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ‡‡
Gonzalez-Ruiz et al. (2014), Spain	Norton Scale modified by INSALUD (Norton-MI)	Generic inpatients	Adapted from the Norton Scale by INSALUD (Spanish National Institute for Health Care) in 1996, by means of extended operational definitions	5	General condition, Mental status, Activity, Mobility, Incontinence	≤15
Soppi et al. (2014), Finland	Shape Risk Scale (SRS)	Generic- acute and community	Items derived in part from the Braden Scale, with other items identified from literature review and scale refinement following pilot testing	5	Body shape, BMI, Physical activity and mobility, Consciousness and sensory perception, Body temperature	≥7
Coleman et al. (2015), UK	Risk Assessment Framework (PURPOSE-T)	Generic- acute and community	Items derived from a systematic review and subsequent consensus study with clinical and academic subject experts, which included input from patients/ carers of patients at risk of PUs, scale amended following focus groups and 'think out loud' interviews with clinicians, and field testing with inpatients and community nursing patients	10	Screening- Mobility, Skin status Full assessment- Independent movement, Sensory perception, Skin assessment, Previous history of PUs, Perfusion, Nutrition, Moisture, Diabetes	Not applicable
Faulkner et al. (2015), UK	Exeter Pressure Risk Assessment Tool (EPRAT)	Emergency department	Items derived from clinical experience	9	History of/ existing pressure damage, Unable/ unlikely to reposition independently, PVD/ diabetes/ peripheral sensory impairment, Terminal illness/ acutely unwell (Early Warning Score>3), Significant cognitive impairment, Any organ failure or impaired function, Incontinence/ oedema/ excess moisture, Visually obese or underweight, History of ongoing weight loss/ reduced intake	≥2, or presence of any of the first 3 items
Gao et al. (2015), China	3S Intraoperative Risk Assessment Scale of Pressure Sores	Surgical patients- intraoperative period	Items derived from literature review, scale refined following feedback from expert clinicians	9	Preoperative risk- Skin condition, Limb exercise, Body height/weight ratio, Skin under stress Intraoperative risk- Blood loss, Operating time, Intraoperative stress, Intraoperative body temperature, Operative position	Not specified
Kumari et al. (2015), India	Norton Plus Scale	Generic inpatients	Adapted from the Norton Scale but no further details provided, revised scale does not appear to have been developed by the authors	Not specified	Among others: Physical condition, Mental condition, Activity, Mobility, Incontinence, Diabetes, Hypertension, Fever, Low haematocrit, Low haemoglobin and albumin, Changes in mental status, Concurrent use of ≥5 medications	≤15

## Integrative Review of Risk Assessment Scales

Author and country of origin	RAS name	Target population	Development method	No Scale items †	Items	Cut-off score ††
Richardson and Barrow (2015), UK	Critical Care Pressure Ulcer Assessment Tool Made Easy (CALCULATE)	Critical care	Literature review to identify potentially relevant RASs or risk factors, with content validity of potential items assessed by expert clinicians	7	Too unstable to turn, Impaired circulation, Dialysis, Mechanical ventilation, Long surgery (in last 24 hours), Low protein (low protein and serum albumin and/ or poor nutritional state), Faecal incontinence	≥4, or presence of the first item †††
Richardson and Straughan (2015), UK	Revised CALCULATE (Critical Care Assessment Tool Made Easy)	Critical care	CALCULATE revised following a clinical pilot	8	Too unstable to turn, Impaired circulation, Dialysis, Mechanical ventilation, Immobility (secondary to neuromuscular disease, sedation/ paralysis or limb weakness), Long surgery/ cardiac arrest, Low protein (low protein and serum albumin and/ or poor nutritional state), Faecal incontinence	≥4, or presence of the first item †††
Scott (2015), US	Scott Triggers Tool	Surgical patients	Items derived from previous research by the author, with an additional item added following review of the literature	4	Age ≥62, American Society of Anaesthesiology Score ≥3, Serum albumin <3.5 g/dL, Estimated surgery time >180mins	≥2 ▲
Fulbrook and Anderson (2016), Australia ▲▲	COMHON Index	Intensive care	Development method not specified but scale was not developed by the authors ▲▲	5	Level of consciousness (Richmond Agitation Sedation Scale Score), Mobility, Haemodynamics Oxygenation, Nutrition	≥10
Munro (in Putnam 2016), US	The Munro Risk Pressure Ulcer Risk Assessment Scale	Surgical patients- preoperative, intraoperative and postoperative period	Adapted from Munro (2010), further details absent	15	<i>Preoperative risk-</i> Mobility, Nutritional Status, Body weight, Weight loss, Age, Comorbidities <i>Intraoperative risk-</i> Physical Status, Anaesthesia, Body temperature, Hypotension, Skin moisture, Patient positioning, Support devices <i>Postoperative risk-</i> Duration of perioperative care, Blood loss in postoperative phase of care	Not specified

† The number of items recorded reflect the subscale headings as presented by the author, in spite of the fact that such subscales sometimes contain multiple risk factors, such as the 'Sex/ Age' subscale in the Waterlow Scale (Waterlow 1985). †† The cut-off score generally indicates the threshold at which the authors suggest PU risk first occurs, unless a 'low risk' threshold is given, as for example by Milward et al. (1993) and McCormack (1996), in which case the cut-off score that is presented indicates moderate or medium risk. ††† The cut-off score indicates patients deemed to be at very high risk. ▲ The cut-off score indicates patients deemed to be at high risk. ▲▲ Developed in Spain by Cobos Vargas et al. (2011).

## Integrative Review of Risk Assessment Scales

Of the RASs focused on primary care settings, nursing home, long-term, or extended care facility residents most frequently formed the population of interest (Table 3-1), with 5 such scales identified (Gosnell 1973; Ek & Bjurulf 1987; Towey & Erland 1988; Sparks 1993; Lepistö et al. 2006), and all of these were devised in the context of research. Conversely, the 4 scales designed for use with community nursing patients tended to originate from clinical practice (Milward et al. 1993; Gill 1995; Chaloner & Franks 1999; Lewin et al. 2003). However, this distinction is somewhat ambiguous as is demonstrated by the Walsall Community Risk Score Calculator (Milward et al. 1993), the development of which was clinician-led initially, but a revised version of the scale was subsequently published, which was informed by the findings of a cross-sectional study (Chaloner & Franks 1999). Hospice patients comprised the final community-based group (Table 3-1), with these patients forming the population of interest in 3 of the identified RASs (Bale et al. 1995; Chaplin 2000; Henoch & Gustafsson 2003).

Next to the variation in their target population, RASs were further found to differ in terms of the target raters. Specifically, two scales were identified which were devised for use by auxiliary nursing staff, namely the S.C.O.P.E tool (Stamper 1978) and the Hampton-Gledhill 2-stage Pressure Risk-Assessment System (Gledhill & Hampton 2005). As illustrated in Table 3-1, these scales incorporate relatively few items and when PU risk is identified, as a result of a cut-off score or particular dichotomous responses, liaison with a registered practitioner is advocated by both scales.

### 3.3.1 Scale Derivation

The origin of a given RAS was frequently not explicitly stated, a situation which was particularly evident in publications describing scales which were not devised by the authors. When the development methods were apparent, numerous strategies were typically employed to develop a RAS. Of these, adaptations of previously devised scales formed the most common approach to RAS development, as is evident from Table 3-1. Indeed, 69% of scales were reported to be modified versions of other scales, although the degree of this alteration varied significantly, from revisions to the operational definitions of a pre-existing scale, such as the Modified Norton Scale presented in Stotts (1988), to a review of 21 scales which informed the content of a new scale, as is reported by Lepistö et al. (2006). Furthermore, it is likely that most new RASs are influenced to some extent by existing scales, irrespective of whether this is made explicit in publications, since it may be assumed that scale creators are familiar with the content and format of previous scales. To illustrate, the 'Mental status'

subscale of the CBO Score described by Van Marum et al. (2000) bears a remarkable resemblance to the 'Mental condition' subscale included in the Norton Scale (Norton et al. 1962), in spite of the difference in the direction of scoring adopted by these scales.

Where authors specified that a scale was derived from one or several other scales, the Norton Scale was most frequently cited, followed by the Braden, Waterlow (1985; 1987) and Gosnell Scales, which were cited as forming the foundation of 24, 19, 15 and 8 RASs, respectively. Often scales which had been devised in this manner were subsequently re-modified. As an example, the Cubbin & Jackson Pressure Area Risk Calculator (Cubbin & Jackson 1991) was derived from several scales including the Norton Scale and, following national and international adoption, a revised version was presented by one of the scale's original creators (Jackson 1999), which was subsequently modified by Finnish researchers (Ahtiala et al. 2014). When examining Table 3-1, another fourth-generation modification can also be observed, namely the ICU Risk Assessment Scale presented in Ongoma et al. (2005). This scale was adapted from the Sunderland Pressure Sore Risk Calculator (Lowery 1995), which was derived from the Cubbin & Jackson Risk Calculator (Cubbin & Jackson 1991), which in turn was informed by the Norton Scale (Norton et al. 1962), as previously highlighted.

Next to adaptations of existing scales, clinical experience was utilised to guide item selection for RAS development, a process which contributed to the development of 35% of scales (Table 3-1), with some scale creators utilising formal consensus methods to elicit this input (Munro 2010; Coleman et al. 2015). Equally, a review of the PU risk factor literature was often used to inform the content of a scale and this method was observed in 32% of scales (Table 3-1). Nevertheless, such reviews were found to lie on a spectrum, from brief narrative reviews, as employed by Birtwistle (1994), to a research-derived conceptual model constructed by Bergstrom et al. (1987), and a systematic review conducted by Coleman et al. (2015).

Other forms of research were also conducted, and such studies directed the construction of 31% of scales, with almost half of these studies (45%) utilising regression analysis (Table 3-1). It is interesting to note that some researchers used parameters of internal consistency, namely inter-item and item-total correlations or Cronbach's alpha, to evaluate their scale (Aronovitch et al. 1992; Halfens et al. 2000; Kumar et al. 2012), or as an item reduction method (Towey & Erland 1988; Lindgren et al. 2002). While appropriate for reflective models, where items represent the consequences of a construct, such measures are considered irrelevant for formative

## Integrative Review of Risk Assessment Scales

models where items determine the construct, as is the case with RASs, since the expectation of item correlation is unfounded (Kottner & Streiner 2010; de Vet et al. 2011; Streiner et al. 2015).

Finally, once an initial scale had been developed by one or more of the above methods, evaluation of the scale through pilot testing was sometimes described, and this invariably led to scale refinements, a process which contributed to the development of 17% of scales (Table 3-1). Examples of this are a 4-week pilot of the Medley Score in an acute medical ward, leading to the inclusion of an additional item and extended operational definitions (Williams 1992), and a pilot of the Shape Risk Scale involving 280 patients which led to item re-weighting (Soppi et al. 2014).

### 3.3.2 Contemporary Scale Development

Several authors have proposed that RASs should be developed by statistical methods, with prognostic models derived from regression analysis deemed to represent the most valid way of RAS development (Cullum et al. 1995; Nixon & McGough 2001; Wang et al. 2015). To examine whether this recommendation has influenced contemporary scale development, the primary development method of every scale was examined. This was classified as utilising traditional methods, namely clinical experience, adaptations of existing scales and literature reviews, or research methods. The latter category was further divided into scales created by regression analysis and other research methods, which included diverse approaches such as audits (Abruzzese 1986; Pajk et al. 1986) and a descriptive analysis of data from a prospective study (Kwong et al. 2005). In contrast to the previous analysis (Section 3.3.1), where the systematic review by Coleman et al. (2015) contributed to both the literature review and research derived scales percentages, for the present analysis this was classified as constituting research methods. The result of this analysis is shown in Figure 3-3.

It is evident from this figure that traditional methods remain the most common approach to RAS development, with 79% (15/19) of scales that were published between 2011-2016 utilising this approach. Indeed, across all time periods, the number of RASs developed by traditional methods exceeds research based scales (Figure 3-3). Nevertheless, scales created by means of regression analysis have appeared in the literature in recent decades, and in the most recent data (2011-2016) these account for half of the research derived scales. However, the methods employed to create these prognostic models were found to differ, with most researchers conducting cross-sectional surveys or retrospective chart reviews (Salzberg et al. 1996; Schue &

Langemo 1998; Chaloner & Franks 1999; Salzberg et al. 1999; Slowikowski & Funk 2010; Fromantin et al. 2011; Page et al. 2011), while others conducted a prospective cohort study (Prölß et al. 1996; Halfens et al. 2000; Perneger et al. 2002; Schoonhoven et al. 2006; Nonnemacher et al. 2008; Suriadi et al. 2008). While both retrospective and prospective data can be utilised for the development of prognostic models, the latter is preferred, since this enables optimal measurement of predictors and outcomes (Moons et al. 2009; Han et al. 2016).

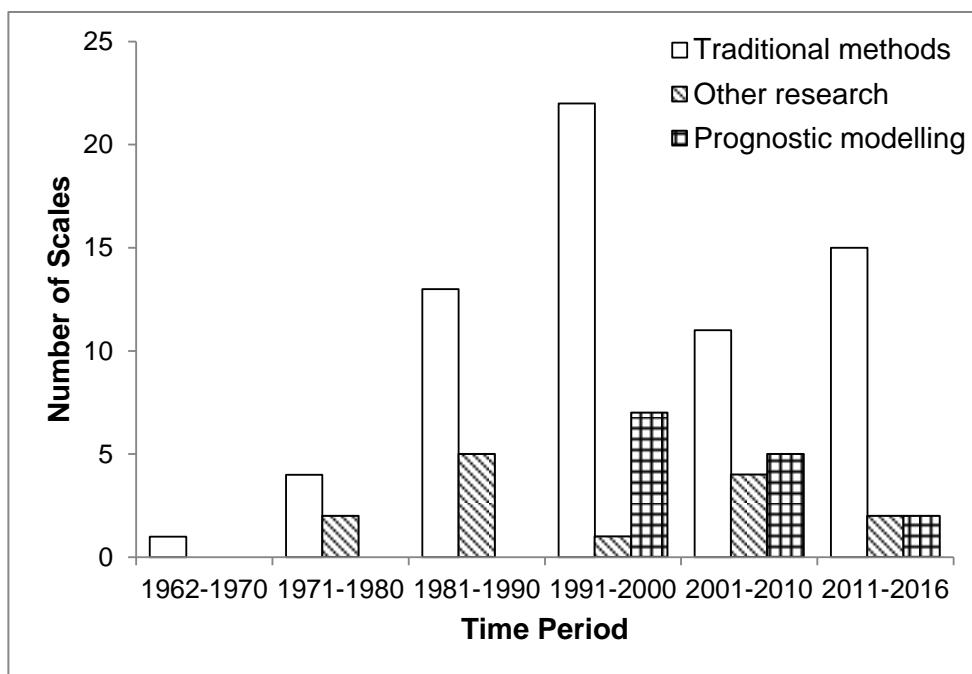


Figure 3-3: Primary development method of RASs published from 1962-2016.

It is further generally accepted that  $\geq 10$  events per variable are required to reduce the risk of overfitting of a model, where too many factors, including erroneous variables, are retained in the final model (Peduzzi et al. 1996; Moons et al. 2009; Han et al. 2016). However, this requirement was unmet by a substantial number of models, with 38% (5/13) publications describing an insufficient number of events (Prölß et al. 1996; Schue & Langemo 1998; Halfens et al. 2000; Fromantin et al. 2011; Page et al. 2011).

Consideration of both optimal study design and the requisite events per variable, revealed only 4 scales which met both requirements, namely the Fragment Score (Perneger et al. 2002), the prePURSE Scale (Schoonhoven et al. 2006), the Essener Dekubitus-Score (Nonnemacher et al. 2008), and the S.S. Scale (Suriadi et al. 2008).

### 3.3.3 Scale Composition

The number of items contained in RASs ranged from 2 items, observed in 3 scales including the Ramstadius Pressure Screening and Intervention Tool (Webster et al. 2011), to 23 items, incorporated in the Preoperative Risk Assessment (Price et al. 2005), with a median of 7 items evident (Table 3-1). However, these numbers reflect the item headings that were adopted by authors and a number of scales contained composite items, such as the 'special risk factors' in the Douglas Pressure Sore Risk Calculator (Pritchard 1986), which comprises 4 risk factors (Table 3-1). Indeed, some scales were found to incorporate other assessment tools, or the outcomes of such tools. Examples of this include the Malnutrition Screening Tool contained in the Revised Waterlow Scale (Waterlow 2005), the American Society of Anaesthesiologists Score in the PURE Scale (Nicoladis et al. 2011), and the Early Warning Score included in the Exeter Pressure Risk Assessment Tool (Faulkner et al. 2015).

The majority of scales adopted an ordinal scoring system, resulting in subscales where item scoring is proportionate to the perceived severity of a given attribute. As illustrated in Table 2-5, this system was used by the first published RAS, the Norton Scale (Norton et al. 1962), and many of the subsequently developed scales, including the Gosnell Scale (Gosnell 1973), Braden Scale (Bergstrom et al. 1987), and COMHON Index (Fulbrook & Anderson 2016) use an identical format. Other scales consist exclusively of dichotomously scored items, which are typically only scored when a particular risk factor applies, with the Scott Trigger Tool (Scott 2015) providing an example of this format. The remaining scales tend to incorporate both forms of scoring and such scales largely consist of ordinal subscales, with dichotomous level scoring assigned to composite items. Examples of this are the Waterlow and Revised Waterlow Scales (Waterlow 1985; 1987; 2005).

A small number of scales have adopted a non-numbered scoring system (Table 3-1). In particular, Birty's Pressure Area Risk Assessment Tool (Birtwistle 1994) and the PURPOSE-T (Coleman et al. 2015) both utilise an ordinal colour-coded system to stratify PU risk. By contrast, the Pressure Risk Assessment Screen (McErlean et al. 2002), the Hampton-Gledhill 2-stage Pressure Risk-Assessment System (Gledhill & Hampton 2005) and the Ramstadius Pressure Screening and Intervention Tool (Webster et al. 2011) all use a dichotomous 'yes' or 'no' response format, with the authors of the latter two tools specifying which of these responses are deemed to represent risk.

When a numbered scoring system was used and had been presented by authors, the direction of scoring was most frequently a high score indicating high risk, which was evident in 52 scales (63%), with the remaining 31 scales (37%) adopting a system where a low score represented a high level of risk.

The method used to determine the weighting of items was often not specified, unless a RAS had been constructed by regression analysis, in which case individual item weightings were commonly derived from the regression coefficients (Prölß et al. 1996; Chaloner & Franks 1999; Salzberg et al. 1999; Perneger et al. 2002; Schoonhoven et al. 2006; Nonnemacher et al. 2008; Suriadi et al. 2008; Page et al. 2011), as indicated in Table 3-1. Similarly, the rationale for the selected cut-off score was frequently not articulated, although there were exceptions to this, such as Kim et al. (2009), who constructed ROC curves to determine optimal cut-off scores. By contrast, Chaplin (2000) describes comparing practitioners clinical judgment of risk to the accompanying numerical score to identify threshold levels.

### 3.3.4 Content Validation

The aggregated result of the content analysis of RASs is shown in Figure 3-4. It is evident from this figure that all 10 of the risk factor domains which were identified in recent guidelines (NPUAP, EPUAP and PPPIA 2014a) were observed in scales. Nevertheless, considerable variation was noted, with mobility and activity measures present in 96% scales and haematological measures found in 17% of scales (Figure 3-4). However, there may be some justification for this difference since the former measures are considered key risk factors, while the latter are deemed potential risk factors (NPUAP, EPUAP and PPPIA 2014a). Nevertheless, a clear trend in terms of the importance assigned to the risk factor domains by the guidelines, and the frequency in which these domains were observed in RASs was not evident. As an example, measures of skin status, which includes existing and previous PUs, are recognised as another key risk factor domain but this domain was found to be present in just over half of scales (Figure 3-4). By contrast, general and mental health status measures are considered potential risk factors and yet these were identified in 77% of scales (Figure 3-4). Although it should be noted that compared to other domains, this particular domain encompasses a wide range of risk factors from broad indicators of health status, to medication, chronic wounds, illness severity scores, and mental status measures (NPUAP, EPUAP and PPPIA 2014a).

## Integrative Review of Risk Assessment Scales

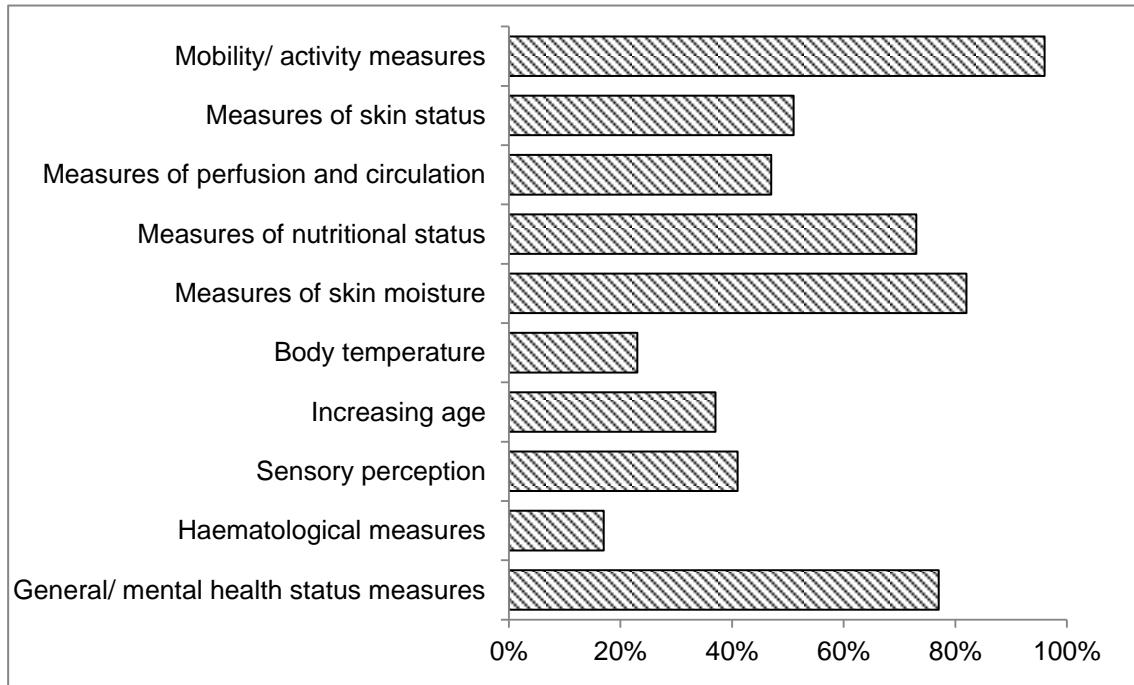


Figure 3-4: The frequency of inclusion of the 10 NPUAP, EPUAP and PPPIA (2014a) risk factor domains within RASs. Based on 93 scales as the items contained in Waterlow/ York Scale (Healey 1996) were not specified, as indicated in Table 3-1.

Overall, the results of the content analysis provide a measure of quantitative support for the items contained in the identified scales (Table 3-1). However, this does not infer that item redundancy, indicating the presence of items which are not relevant risk factors, was not observed. Although difficult to quantify, since certain RASs contained composite items (Section 3.3.3) and therefore the recorded number of items was not an accurate reflection of the risk factors a scale encompassed, a number of items which may not be relevant indicators of PU risk were noted. In particular, sex and pain were two recurrent items not covered by the risk factors domains, found to be present in 10 (Williams 1972; Waterlow 1985; Waterlow 1987; West et al. 1992; Johnson 1994; Weststrate & Bruining 1996; Cook et al. 1999; Waterlow 2005; Compton et al. 2008; Kumar et al. 2012) and 9 (Pritchard 1986; Williams 1992; Milward et al. 1993; Birtwistle 1994; Bale et al. 1995; Gill 1995; Watkinson 1997; Moore & Pitman 2000; Nonnemacher et al. 2008) RASs, respectively. When considering individual scales, the scale constructed by Lepistö et al. (2006) appeared to contain the highest number of potentially redundant items, particularly those items listed under organisational factors (Table 3-1). However, it should be recognised that such factors could plausibly contribute to PU risk, but are not part of the NPUAP, EPUAP and PPPIA (2014a) domains, since these focus on patient-specific characteristics. Equally, although

current research is inconclusive, items such as pain may well emerge as independent risk factors in future research.

The content validity of individual RASs ranged from 10-100%. Both the Revised Norton Scale (Goldstone & Roberts 1980) and the NPRU Pressure Sore Risk Calculator (Clark & Farrar 1992) exclusively consisted of mobility and activity items (Table 3-1), resulting in a content validity of 10%. By contrast, the Preoperative Risk Assessment constructed by Price et al. (2005) contained items spanning all domains and thus its content validity was 100%, although as previously noted (Section 3.3.3), this scale comprises a substantial number of items. Similarly, Birty's Pressure Area Risk Assessment Tool (Birtwistle 1994) and the Risk Assessment Tool presented by Kumar et al. (2012) achieved a relatively high content validity of 90%. However, both contained a significant number of items when composite items were considered (Table 3-1). A good balance with regards to the number of scale items and the resulting content validity was observed in the Risk Assessment Score constructed by Andersen et al. (1982). This tool consists of 8 items, including items fitting the two key risk factor domains (mobility/ activity measures and measures of skin status), and its content validity of 70% was above the sample median of 60%.

### **3.4 The Reliability of Risk Assessment Scales**

A total of 24 inter-rater reliability papers were identified (Figure 3-2), which examined 14 different RASs, as is indicated in Table 3-2. Of these RASs, research surrounding the Braden Scale was most frequently observed, with 11 studies reporting on its inter-rater reliability. The Norton and Waterlow Scales were also regularly examined, with 4 studies reporting on the former and 7 on the latter, if all versions published by the original author are combined (Waterlow 1985; 1987; 2005). The remaining studies typically investigated the reliability of a newly presented scale (Johnson 1994; McCormack 1996; Watkinson 1997; Cook et al. 1999; Lindgren et al. 2002; Cobos Vargas et al. 2011; Kumar et al. 2012) or a recent translation of an existing scale (Fossum et al. 2012; Gunes & Efteli 2015).

Considerable participant heterogeneity was observed across studies (Table 3-2), from 9 elderly care ward patients who participated in one of the studies reported by Watkinson (1996), to 496 critical care patients drawn from 2 hospitals, which formed the sample of participants in the study conducted by Cobos Vargas et al. (2011). Similarly, the number and type of raters varied, with Bergstrom et al. (1987) reporting a study which compared the assessments conducted by a small number of nursing assistants (NAs) and licensed practical nurses (LPNs), while the raters employed by Kumar et al. (2012) exclusively consisted of investigators, although the sample of 2 raters was equally small. A larger rater sample was utilised by Kelly (2005), who compared the Waterlow (1987) scores obtained by 3 nurse specialists to the scores assigned by 110 qualified nurses attending a PU study day. The latter study was further unique in terms of its methodology, with assessments performed by means of a fictitious patient case study. Other methodological approaches included the use of prevalence surveys to establish the inter-rater rater reliability of a RAS (Kottner & Dassen 2008b; Kottner et al. 2008; Kottner et al. 2009c), which conducted subsequent post-survey assessments to determine the reliability between raters (Kottner et al. 2009c), or rater pairs (Kottner & Dassen 2008b; Kottner et al. 2008). Also of note are the studies by Rogenski and Kurcgant (2012) and Delparte et al. (2015), both of which specified the use of a prospective design, where the assessments performed by study collaborators were compared to that of general nursing staff, with the latter assessments extracted from the patient records.

## Integrative Review of Risk Assessment Scales

Table 3-2: Summary of studies reporting on the inter-rater reliability of RAS.

Author and country	RAS name	Method	Raters	Participants	Results†	QAREL rating
Dealey (1989), UK	Norton Scale	Independent assessments performed with both the Waterlow and Norton Scales	2 or 3 student nurses, at the same stage of training, allocated to 4 wards, exact number not specified	Inpatients from 4 wards, n=20	$p_0 \pm 1 = 0.60$	Poor
Fulbrook and Anderson (2016), Australia	Norton Scale	Sequential (non-random) independent assessments performed with the COMHON Index, Braden, Norton and Waterlow Scales	ICU nurses, with 4-8 years ICU experience, n=5	Postoperative cardiac and general ICU patients, mean age 63.1 (SD 17.2), n=26	ICC(2,1)=0.77 (95% CI 0.65-0.88), SEM 1.34	Moderate
Lincoln et al. (1986), US	Norton Scale	Independent weekly assessments conducted by 2 pairs of investigators over a 4-week period	Nurse investigators, number not specified but implies n=4	Medical-surgical patients, aged >65, free from PUs at admission, n=73	Week 1- $p_0=0.23$ , $p_0 \pm 1=0.58$ Week 2- $p_0=0.46$ , $p_0 \pm 1=0.64$ Week 3- $p_0=0.70$ , $p_0 \pm 1=0.80$ Week 3- $p_0=0.10$ , $p_0 \pm 1=0.70$	Poor
Wang et al. (2015), China	Norton Scale	Sequential (non-random) independent assessments performed with the Braden, Norton and Waterlow Scales	Chief nurses from a number of departments, with a mean work experience of 22.2 years (SD 2.4), n=6	Neurosurgery, ICU, orthopaedic, neurology, respiratory medicine, spinal surgery and cardiothoracic surgery patients, mean age 58.7 (SD 11.2), free from PUs, n=23	ICC(2)=0.92 (95% CI 0.86-0.96)	Poor
Watkinson (1996), UK	Douglas Scale	2 studies reported, study 1 examined inter-rater reliability of the Douglas, Braden and Waterlow Scales, study 2 compared the reliability of a trial scale †† to the Braden Scale	Study 1- Registered nurses (RNs), n=9, enrolled nurses (ENs), n=2, student nurses, n=2	Study 1- Elderly care ward patients, aged 70-100, n=9	Study 1- $p_0=0.11$ , $p_0 \pm 1=0.22$	Poor
Watkinson (1996), UK	Waterlow Scale (1985)	2 studies reported, study 1 examined inter-rater reliability of the Douglas, Braden and Waterlow Scales, study 2 compared the reliability of a trial scale †† to the Braden Scale	Study 1- RNs, n=9, ENs, n=2, student nurses, n=2	Study 1- Elderly care ward patients, aged 70-100, n=9	Study 1- $p_0=0.00$ , $p_0 \pm 1=0.11$	Poor

## Integrative Review of Risk Assessment Scales

Author and country	RAS name	Method	Raters	Participants	Results†	QAREL rating
Dealey (1989), UK	Waterlow Scale (1987)	Independent assessments performed with both the Waterlow and Norton Scales	2 or 3 student nurses, at the same stage of training, allocated to 4 wards, exact number not specified	Inpatients from 4 wards, n=20	$p_0=0.70$	Poor
Edwards (1995), UK	Waterlow Scale (1987)	Assessments conducted concurrently and independently	1 nurse researcher and a research assistant	Community patients with and without PUs, mean age 83.9 (SD 6.17), n=40	$p_0=0.25$ , $p_0\pm 1=0.50$	Poor
Kelly (2005), UK	Waterlow Scale (1987)	Assessment by tissue viability nurse specialists, deemed to represent the gold standard, compared to the independently completed assessments of qualified nurses	Tissue viability nurse specialists, n=3, and qualified nurses attending a PU prevention and management study day, n=110	1 patient case study	$p_0=0.12$ , $p_0\pm 1=0.23\ddagger\ddagger$	Moderate
Kottner and Dassen (2010), Germany	Waterlow Scale (1987)	Sequential (non-random) independent assessments performed with the Braden and Waterlow Scales	ICU nurses, ICU 1, n=22, ICU 2, n=31	ICU patients, mean age ICU 1 69.7 (SD 8.3), n=21, mean age ICU 2 67.2 (SD 11.3), n=24	ICU 1- ICC(1,1)=0.36 (95% CI 0.09-0.63), SEM 5.63 ICU 2- ICC(1,1)=0.51 (95% CI 0.27-0.72), SEM 4.78	High
Fulbrook and Anderson (2016), Australia	Revised Waterlow Scale (Waterlow 2005)	Sequential (non-random) independent assessments performed with the COMHON Index, Braden, Norton and Waterlow Scales	ICU nurses, with 4-8 years ICU experience, n=5	Postoperative cardiac and general ICU patients, mean age 63.1 (SD 17.2), n=26	ICC(2,1)=0.47 (95% CI 0.22-0.69), SEM 3.83	Moderate
Wang et al. (2015), China	Revised Waterlow Scale (Waterlow 2005)	Sequential (non-random) independent assessments performed with the Braden, Norton and Waterlow Scales	Chief nurses from a number of departments, with a mean work experience of 22.2 years (SD 2.4), n=6	Neurosurgery, ICU, orthopaedic, neurology, respiratory medicine, spinal surgery and cardiothoracic surgery patients, mean age 58.7 (SD 11.2), free from PUs, n=23	ICC(2)=0.97 (95% CI 0.94-0.98)	Poor

## Integrative Review of Risk Assessment Scales

Author and country	RAS name	Method	Raters	Participants	Results†	QAREL rating
Johnson (1994), UK	Pressure Sore Risk Assessment Chart (Modified Waterlow Scale)	Assessments of clinical experts compared to the independently completed assessments of ward nurses	Senior nurses with neuroscience training and experience, n=2, and neuromedical and neurosurgical ward nurses, n=8	Neuromedical and neurosurgical patients, varying in PU risk, n=8	$p_o=0.80$ , $p_o \pm 1=0.90$	Poor
Cook et al. (1999), UK	Adapted Waterlow Pressure Ulcer Risk Assessment Scale	Daily independent assessments of participants from 2 wards performed by nurse pairs, over a 7-day period	RNs, n=26, and final-year nursing students, n=2	Medically stable patients from a stroke rehabilitation unit (ward 1), n=9, and acute medical/ rehabilitation ward (ward 2), n=6	<i>Ward 1-</i> mean $p_o=0.56$ , Kendall's tau coefficient=0.36 <i>Ward 2-</i> mean $p_o=0.73$ , Kendall's tau coefficient=0.50	Poor
Bergstrom et al. (1987), US	Braden Scale	3 studies reported, independent assessments performed in all studies, study 1 compared concurrently completed assessments with participants rated over 1-7 weeks, studies 2 and 3 adopted a cross-sectional design, comparing assessments conducted by day and evening shift staff	<i>Study 1-</i> RN, n=1, and graduate student, n=1 <i>Study 2-</i> licensed practical nurses (LPNs) and nursing assistants (NAs), number not specified <i>Study 3-</i> LPN, n=2, and NAs, n=2	<i>Study 1-</i> skilled nursing facility residents, mean age 75 (SD 20), free from PUs at admittance, n=20 <i>Study 2-</i> institutionalised elderly, mean age 79 (SD 12.2), n=54 <i>Study 3-</i> skilled nursing facility residents in a stable condition, n=50	<i>Study 1-</i> $p_o=0.88$ , $p_o \pm 1=1.00$ , $r=0.99$ <i>Study 2-</i> ranging from $p_o=0.11$ for the day and evening NA to 0.19 for the day and evening LPNs, correlation ranging from $r=0.83$ for day LPN and NA, to $r=0.87$ for the day and evening NAs <i>Study 3-</i> ranging from $p_o=0.12$ for the day and evening LPNs to 0.46 for the evening LPN and NA, correlation ranging from $r=0.84$ for the day and evening NA to $r=0.94$ for day LPN and NA	Poor
Fulbrook and Anderson (2016), Australia	Braden Scale	Sequential (non-random) independent assessments performed with the COMHON Index, Braden, Norton and Waterlow Scales	ICU nurses, with 4-8 years ICU experience, n=5	Postoperative cardiac and general ICU patients, mean age 63.1 (SD 17.2), n=26	$ICC(2,1)=0.66$ (95% CI 0.50-0.80), SEM 1.83	Moderate
Halfens et al. (2000), The Netherlands	Braden Scale	Independent assessments performed with the Braden and the Extended Braden Scale ††	Ward nurses, n=22 ††	Patients from among others surgical, neurology, orthopaedic and internal medicine wards of 3 hospitals, free from PUs at admission, n=55 ††	$\kappa=0.86$	Poor

## Integrative Review of Risk Assessment Scales

Author and country	RAS name	Method	Raters	Participants	Results†	QAREL rating
Kottner and Dassen (2008b), Germany	Braden Scale	Paired assessments conducted as part of a prevalence survey, second assessment performed by a single nurse or nurse pair, with the pairs treated as one rater for the purposes of analysis and with a maximum timeframe of 3 days between assessments	8 pairs of nursing home ward nurses for the initial assessment, 8 nurses/ pairs of nurses for the second assessment, exact number not specified, work experience ranging from 0.5-30 years	Residents from 8 units of 2 nursing homes, mean age 85.6 (SD 10.5), n=152	<i>Unit 1- p<sub>o</sub> 0.00, ICC(2,1)=0.92 (95% CI 0.76-0.98)</i> <i>Unit 2- p<sub>o</sub>=0.14, ICC(2,1)=0.84 (95% CI 0.66-0.93)</i> <i>Unit 3- p<sub>o</sub>=0.27, ICC (2,1)=0.94 (95% CI 0.84-0.98)</i> <i>Unit 4- p<sub>o</sub>=0.25, ICC(2,1)=0.93 (95% CI 0.84-0.97)</i> <i>Unit 5- p<sub>o</sub>=0.18, ICC(2,1)=0.89 (95% CI 0.73-0.96)</i> <i>Unit 6- p<sub>o</sub>=0.33, ICC(2,1)=0.95 (95% CI 0.87-0.98)</i> <i>Unit 7- p<sub>o</sub>=0.15, ICC(2,1)=0.73 (95% CI 0.26-0.91)</i> <i>Unit 8- p<sub>o</sub>=0.16, ICC(2,1)=0.92 (95% CI 0.81-0.97)</i>	Moderate
Kottner et al. (2008), Germany	Braden Scale	Paired assessments conducted as part of a prevalence survey, with a second assessment performed by a separate nurse pair with a maximum timeframe of 4 days between assessments	Trained nurses with $\geq$ 5 years professional experience, n=6	Residents from 2 nursing home units, mean age 87.4 (SD 7.7), unit 1 n=32, unit 2 n=18	<i>Unit 1- p<sub>o</sub>=0.30, p<sub>o</sub><math>\pm</math>1=0.40, ICC(2,1)=0.91 (95% CI 0.82-0.96)</i> <i>Unit 2- p<sub>o</sub>=0.18, p<sub>o</sub><math>\pm</math>1=0.41, ICC(2,1)=0.88 (95% CI 0.61-0.96)</i>	Poor
Kottner et al. (2009c), The Netherlands	Braden Scale	Assessments conducted as part of prevalence surveys in 2007 and 2008, with a second independent assessment performed by nurse specialists with a maximum time frame of 3 days between assessments	Trained nurses and nurses qualified in wound management, numbers not specified	2007- Home care clients, mean age 77.8 (SD 11.8), n=352 2008- Home care clients, mean age 77.4 (SD 13.4), n=339	<i>2007- p<sub>o</sub>=0.66, ICC(1,1)=0.90 (95% CI 0.88-0.92), SEM 1.00</i> <i>2008- p<sub>o</sub>=0.63, ICC(1,1)=0.88 (95% CI 0.85-0.91), SEM 0.98</i>	Poor
Kottner and Dassen (2010), Germany	Braden Scale	Sequential (non-random) independent assessments performed with the Braden and Waterlow Scales	ICU nurses, ICU 1, n=22, ICU 2, n=31	ICU patients, mean age ICU 1 69.7 (SD 8.3), n=21, mean age ICU 2 67.2 (SD 11.3), n=24	<i>ICU 1- ICC(1,1)=0.72 (95% CI 0.52-0.87), SEM 1.67</i> <i>ICU 2- ICC(1,1)=0.84 (95% CI 0.72-0.92), SEM 1.64</i>	High

## Integrative Review of Risk Assessment Scales

Author and country	RAS name	Method	Raters	Participants	Results†	QAREL rating
Rogenski and Kurcgant (2012), Brazil	Braden Scale	Prospective study comparing assessments performed by collaborators, deemed to represent the gold standard, to the nursing assessments recorded in the patient records	Trained collaborators, n=6, and nursing staff, number not specified	Clinical surgery, internal medicine, intensive and semi-intensive care patients, with and without PUs, mean age 56.6 (SD 19.2), n=87	ICC=0.95	Poor
Wang et al. (2015), China	Braden Scale	Sequential (non-random) independent assessments performed with the Braden, Norton and Waterlow Scales	Chief nurses from a number of departments, with a mean work experience of 22.2 years (SD 2.4), n=6	Neurosurgery, ICU, orthopaedic, neurology, respiratory medicine, spinal surgery and cardiothoracic surgery patients, mean age 58.7 (SD 11.2), free from PUs, n=23	ICC(2)=0.96 (95% CI 0.92-0.98)	Poor
Watkinson (1996), UK	Braden Scale	2 studies reported, study 1 examined inter-rater reliability of the Douglas, Braden and Waterlow Scales, study 2 compared the reliability of a trial scale †† to the Braden Scale	Study 1- RNs, n=9, ENs, n=2, student nurses, n=2 Study 2- RNs, n=11, ENs, n=1, student nurses, n=4	Study 1- Elderly care ward patients, aged 70-100, n=9 Study 2- Elderly care ward patients, aged 62-98, n=36	Study 1- $p_o=0.00$ , $p_o \pm 1=0.11$ Study 2- $p_o=0.10$ , $p_o \pm 1=0.40$	Poor
Watkinson (1997), UK	Braden Scale	Paired assessments performed with the Braden and Watkinson Scales by nurses working the morning and successive afternoon shift	RNs, n=10, ENs, n=1	Elderly care ward patients, aged 63-99, n=92	$p_o=0.43$ , $p_o \pm 1=0.69$	Poor
McCormack (1996), UK	Stratheden Pressure Sore Risk Assessment Scale	Assessments conducted on the same day and performed independently	Trained nurses from 3 long-stay wards, number not specified	Long-stay ward patients, aged 64-94, n=63	$p_o \pm 1=0.97 \dagger \ddagger$ , $\kappa=0.87$	Poor
Delparte et al. (2015), Canada	SCIPUS	Prospective study comparing the assessments recorded in the patient records to the independent assessment of a second nurse	Nurse and inpatient nurses, numbers not specified	SCI inpatients, n=150	$p_o=0.29$ , ICC(3)=0.91	Poor

## Integrative Review of Risk Assessment Scales

Author and country	RAS name	Method	Raters	Participants	Results†	QAREL rating
Watkinson (1997), UK	Watkinson Scale	Paired assessments performed with the Braden and Watkinson Scales by nurses working the morning and successive afternoon shift	RNs, n=10, ENs, n=1	Elderly care ward patients, aged 63-99, n=92	$p_o=0.41$ , $p_o \pm 1=0.56$	Poor
Lindgren et al. (2002), Sweden	RAPS Scale	Paired assessments conducted concurrently and independently	RNs, n=20	Patients from 10 wards, n=116	mean $p_o=0.70$ , ICC=0.83	High
Fossum et al. (2012), Norway	RAPS Scale (Norwegian-language version)	Paired assessments conducted independently	RN's, n=10	Nursing home residents, mean age 86.2 (SD 7.3), n=26	ICC(3)=0.95 (95% CI 0.89-0.98)	High
Gunes and Efteli (2015), Turkey	RAPS Scale (Turkish-language version)	Assessments conducted concurrently and independently	ICU nurses, n=3	ICU patients, n=30	ICC=0.92 (95% CI 0.82-0.96)	High
Kumar et al. (2012), India	Risk Assessment Tool	Assessments completed independently but further methodological details not provided	Investigators, n=2	Patients with an anticipated hospital stay >6 days, from medical, surgical and orthopaedic wards and special units (ICU, neurosurgery), number unclear	$p_o=0.82$ , $r=0.92$ ▲	Poor
Cobos Vargas et al. (2011), Spain	COMHON Index	Methodological details not provided	Trained observers, n=5	Critical care patients in two hospitals, n=496	$\kappa=0.89$ (95% CI 0.83-0.94) and $\kappa=0.93$ (95% CI 0.88-0.98)	Poor
Fulbrook and Anderson (2016), Australia	COMHON Index	Sequential (non-random) independent assessments performed with the COMHON Index, Braden, Norton and Waterlow Scales	ICU nurses, with 4-8 years ICU experience, n=5	Postoperative cardiac and general ICU patients, mean age 63.1 (SD 17.2), n=26	ICC(2,1)=0.90 (95% CI 0.83-0.95), SEM 1.32	Moderate

† ICC(1,1): one-way random effects model ICC- single measures, ICC(2): two-way random effects model ICC, ICC(2,1): two-way random effects model ICC- single measures, ICC(3): two-way fixed effects model ICC,  $p_o$ : proportion of exact agreement,  $p_o \pm 1$ : proportion of agreement with 1 point difference in either direction,  $r$ : Pearson's product-moment correlation coefficient. † The results pertaining to the new RAS have been omitted since the author concluded that this scale did not represent a substantial improvement on pre-existing scales (Section 3.1.2). †† The reported figure was recalculated. ▲ Unclear, referred to by authors as the 'correlation coefficient'.

### 3.4.1 Quality Appraisal

The global QAREL ratings for the reliability studies are shown in Table 3-2, while the detailed quality assessment results have been included in Appendix C. As indicated in Table 3-2, the majority of studies, namely 71% (17), were deemed to be of poor methodological quality, while just 13% (3) and 17% (4) of studies were classified as moderate and high quality, respectively. Nevertheless, all but one study used a representative sample of subjects, that is, participants who would typically be the subject of a RAS assessment in clinical practice. The study by Kelly (2005) formed an exception to this, since a written case study, however realistic, cannot be deemed comparable to a patient assessment, as is acknowledged by the author. In terms of the representativeness of raters, approximately half of the studies were considered to have selected raters who would typically perform a RAS assessment in practice (46%). However, some studies compared the assessments conducted by nurse specialists, senior nurses or trained research collaborators to general nursing staff (Johnson 1994; Kelly 2005; Kottner et al. 2009c; Rogenski & Kurcgant 2012). While such comparisons may be useful in identifying the concordance between what are arguably gold standard raters and general nurse raters, the former group do not commonly perform risk assessments in clinical practice and as such the raters in these studies were not deemed to be representative. Equally, studies in which the rater sample exclusively consisted of researchers were not considered to be representative (Lincoln et al. 1986; Edwards 1995; Cobos Vargas et al. 2011; Kumar et al. 2012). It is interesting to note that while papers frequently contained some reference to the participant inclusion criteria and characteristics, such as age and medical conditions, reporting of rater details was often sparse, with little reference to the selection process, clinical experience and training, or even the number of raters that participated in a study (Lincoln et al. 1986; Dealey 1989; McCormack 1996; Kottner et al. 2009c; Delparte et al. 2015).

Most studies explicitly stated that raters were blinded to the assessments of other raters, although there were exceptions such as Watkinson (1997), who described a process to discourage raters from accessing previous assessments, although it did not appear impossible to do so. Rater blinding to their own previous assessments was frequently not applicable since the RAS of interest was newly developed or introduced to a clinical area. Nevertheless, in instances where this item could potentially be relevant, this information was generally not provided except in the paper by Kottner and

## Integrative Review of Risk Assessment Scales

Dassen (2008b), which specified that the Braden Scale was already in use, but assessments were conducted independently from the nursing documentation. In all other items pertaining to blinding (Items 5, 6 and 7, Appendix B) the study by Kelly (2005) had a distinct advantage, as the use of a case study enabled control over information provision, with omission of details that could influence assessments, a situation which is difficult to emulate in studies conducted in clinical practice.

Considering pressure ulcer risk may change over a relatively short time period, depending on the stability of the population that is assessed, it is noteworthy that the time interval between assessments was frequently not made explicit (Dealey 1989; Johnson 1994; Halfens et al. 2000; Cobos Vargas et al. 2011; Kumar et al. 2012; Rogenski & Kurcgant 2012; Delparte et al. 2015; Wang et al. 2015; Fulbrook & Anderson 2016). Other studies specified the time interval but the period between assessments, which could extend to 3 (Kottner & Dassen 2008b; Kottner et al. 2009c), 4 (Kottner et al. 2008), or 7 days (Cook et al. 1999) was deemed too long, even for relatively stable populations (Table 3-2). In the remaining studies, the time between assessments was considered appropriate, or the authors specified that raters completed assessments simultaneously (Edwards 1995; Lindgren et al. 2002; Gunes & Efteli 2015). With regards to assessment conduct (Item 9, Appendix B), more than half of papers (54%) made reference to RAS training procedures and as such the assessments were deemed to have been performed correctly. Rogenski and Kurcgant (2012) formed an exception to this, as the authors describe adjustments to subscales by the research team prior to data collection thus affecting the applicability of these results to the nursing assessments obtained from the patient records.

Information surrounding statistical measures was limited at times, as is illustrated by Kumar et al. (2012), who report the use of a 'correlation coefficient'. Similarly, where ICCs were computed the model was not always provided (Lindgren et al. 2002; Rogenski & Kurcgant 2012; Gunes & Efteli 2015), thus limiting the interpretation of these results (Shrout & Fleiss 1979; Weir 2005). In terms of the appropriateness of the statistical measures utilised, 29% of studies did not provide estimates of reliability, solely reporting percentage agreement instead (Lincoln et al. 1986; Dealey 1989; Johnson 1994; Edwards 1995; Watkinson 1996; Watkinson 1997; Kelly 2005). Finally, correlations coefficients, which appeared to be utilised in 3 studies (Bergstrom et al. 1987; Cook et al. 1999; Kumar et al. 2012), do not account for systematic biases between raters and therefore present a liberal estimate of reliability (Streiner 1993; Cicchetti 1994), and as such their use was deemed inappropriate (Lucas et al. 2010).

### 3.4.2 Inter-rater Reliability Results

The results of the individual studies have been summarised in Table 3-2. With regards to the Norton Scale, ICCs ranged from 0.77 in a moderate quality study of ICU patients (Fulbrook & Anderson 2016), to 0.92 in a poor quality study involving inpatients from 7 different departments (Wang et al. 2015), while percentage agreement varied from 10-70% in a study of medical-surgical patients (Lincoln et al. 1986). When permitting score differences of 1 point, student nurses achieved 60% agreement in the scores assigned to inpatients from a variety of wards (Dealey 1989), whereas a maximum of 80% agreement between paired investigators was observed in the previous study of medical-surgical patients (Lincoln et al. 1986). Nevertheless, the methodological quality of both these papers was considered to be poor (Table 3-2).

When compared to the Norton Scale, the reported reliability of the Waterlow Scale (Waterlow 1987) was considerably lower, with a high-quality ICU study, conducted by Kottner and Dassen (2010), indicating that close to two-thirds (64%) of the observed differences in scores could be attributable to measurement error, as opposed to genuine differences between participants (ICC 0.36, Table 3-2). The accompanying SEM of 5.63 further indicates that the observed scores for a given participant lie within an approximate but substantial range of 20 points in 95% cases, as compared to other scales such as the Braden Scale, which exhibited a SEM of 1.67 under identical circumstances (Kottner & Dassen 2010). However, it should be acknowledged that the latter scale has a smaller range of possible scores. In their study of ICU patients, Fulbrook and Anderson (2016) observed an equally low ICC of 0.47 for the latest version of the Waterlow Scale (Waterlow 2005), but this was in contrast to the findings of Wang et al. (2015) who report an ICC of 0.97, following a study of patients from a range of departments including neurology, spinal surgery and the ICU (Table 3-2). While these results should be interpreted with caution since the methodology of the latter study was considered to be at high risk of bias, this finding may be due to the greater heterogeneity of participants.

In a similar manner to that observed with the Waterlow Scale, the inter-rater reliability of the Braden Scale, when utilised in an ICU sample, was found to be less than the acceptable level (Section 3.1.6), by both of the studies that were conducted in this setting. Fulbrook and Anderson (2016) report an ICC of 0.66, while ICCs of 0.72 and 0.84 were observed in the two ICUs sampled by Kottner and Dassen (2010). By contrast, a moderate quality study which applied the Braden Scale to residents from 8

## Integrative Review of Risk Assessment Scales

units of two nursing homes, found ICCs greater than  $\geq 0.90$  in 63% (5/8) of cases (Kottner & Dassen 2008b). Indeed, in the 4 remaining studies presenting ICCs for the Braden Scale (Table 3-2), ICCs consistently met or exceeded the recommended threshold (Kottner et al. 2008; Kottner et al. 2009c; Rogenski & Kurcgant 2012; Wang et al. 2015), although all these studies received a poor quality rating. As is evident from Table 3-2, a number of papers also assessed the percentage agreement associated with the Braden Scale, with figures of exact agreement varying from 0% (Watkinson 1996; Kottner & Dassen 2008b), to 66% (Kottner et al. 2009c).

It is interesting to note that two high-quality studies examining the inter-rater reliability of the Norwegian (Fossum et al. 2012) and Turkish (Gunes & Efteli 2015) language versions of the RAPS Scale report relatively high ICCs of 0.95 and 0.92, respectively. This is in spite of the fact that the latter study was conducted in an ICU setting. Nevertheless, few details, specific to the participants of the reliability study, are provided and it is possible that the sample variability was greater in this study, as compared to the other studies which have examined ICU patients (Kottner & Dassen 2010; Fulbrook & Anderson 2016). The reliability estimate of the final study which considered the RAPS scale was somewhat less, and at 0.83, fell short of the acceptable standard (Lindgren et al. 2002).

### 3.5 Discussion

This review aimed to examine the characteristics of RASs used in an adult population, as well as the inter-rater reliability of such scales. A total of 94 scales were identified, designed for use across a range of clinical settings, with more than two-thirds (69%) of these RASs derived from pre-existing scales (Section 3.3.1). Other scale construction methods that were regularly observed were the selection of items based on clinical experience, literature reviews and primary research. A typical scale contained 7 items, including mobility and activity, skin moisture, general/ mental health status and nutritional status measures (Section 3.3.4), a finding which is broadly congruent with a previous systematic review (McGough 1999). Most scales used an ordinal scoring system where higher scores represented increasing PU risk (Section 3.3.3).

When scale development was examined over time, relatively few scales were found to be derived from modern methods, and traditional methods continue to be favoured (Figure 3-3). Studies that had utilised regression analysis to develop a RAS were often found to have limitations, namely the use of a retrospective dataset or an insufficient number of events. Indeed, only 4 scales were deemed to have been created by means of robust methods (Section 3.3.2). It may be hypothesised that traditional development methods, such as adapting existing scales, remain common because RASs fulfil a clinical need and practitioners are unfamiliar with, or sceptical of, more complex methods, with Wyatt and Altman (1995) noting a similar situation regarding the adoption of prognostic models in the field of medicine. Furthermore, it should be acknowledged that perspectives as to the ideal instrument development method differ and statistical methods, if utilised correctly, may not be the only valid means of RAS development. Psychometricians suggest that methods such as adopting items from previous scales are a valid instrument development technique, although they generally discourage the creation of new scales when existing instruments are available (Streiner 1993; de Vet et al. 2011; Streiner et al. 2015).

In terms of inter-rater reliability, only 15% (14/94) of scales have been the subject of reliability investigations. When such studies were conducted, they were often found to be at high risk of methodological bias, with the majority of these studies receiving a poor QAREL rating (Section 3.4.1, Table 3-2). Nevertheless, of the studies reviewed, one moderate quality study conducted with a nursing home sample (Kottner & Dassen 2008b) suggests that the Braden Scale may have an acceptable inter-rater reliability in this setting, while language adaptations of the RAPS Scale exhibited acceptable

## Integrative Review of Risk Assessment Scales

reliability in two high-quality studies involving ICU patients (Gunes & Efteli 2015), and nursing home residents (Fossum et al. 2012). Finally, a moderate quality study investigating, among other RASs, the COMHON Index in an ICU sample (Fulbrook & Anderson 2016) also reported an ICC meeting the threshold value (0.90).

Overall, there is a limited body of research suggesting that 3 of the identified RASs may have an acceptable inter-rater reliability. However, it should be noted that reliability is not an immutable scale property, but rather an estimated parameter which is context specific (Bartlett & Frost 2008; Streiner & Kottner 2014). Furthermore, paradoxically, reports of low inter-rater reliability may not preclude the clinical use of a given scale. Floor and ceiling effects are said to occur when a considerable proportion of participants receive a score near the lower or upper bounds of a scale, respectively, thus making it difficult to distinguish between participants (de Vet et al. 2011). Within the present review, it was observed that many authors expressed concern with the inability of a particular scale to discriminate between patients in their clinical setting, which provided the impetus for the development of a new scale, or the modification of an existing scale (e.g. Lowery 1995; Richardson & Barrow 2015). Similarly, a tool designed as an adjunct to the Braden Scale was identified (Brindle 2010), to further identify ICU patients deemed to be at high risk (Table 3-1). However, it is questionable whether these approaches, essentially designed to address apparent floor and ceiling effects, are warranted. It is known that certain patient populations, such as ICU patients, are generally at risk of PU development (Fulbrook & Anderson 2016). Therefore, adapting existing scales, or developing new scales, to re-stratify risk in these patient groups appears unnecessary, since a scale which identifies the majority of these patients as being at risk is arguably fulfilling its purpose, irrespective of the fact that such homogeneous populations may result in relatively low estimates of inter-rater reliability (Section 3.1.6).

Furthermore, although reliability is often deemed a prerequisite of predictive validity (Section 2.6.1), content validity may be argued to be the primary requirement, since a scale which lacks this would not be utilised in clinical practice (Terwee et al. 2007), and the results of the content analysis (Section 3.3.4) confirm that the majority of RASs, at least to some extent, meet this requirement. Nevertheless, it is important to note that the PU risk factor domains that were utilised to perform the content analysis (NPUAP, EPUAP and PPPIA 2014a) were derived from a systematic review of risk factors (Coleman et al. 2013) and examination of this revealed that a number of authors included RAS subscales in their model. This limitation stems from the fact that the

development of certain widely adopted scales has preceded research investigating PU risk factors.

A multitude of scales are now available, with reports of new scales continuing to appear in the literature in recent years (Table 3-1, Figure 3-3). It is further likely that many more locally developed or adapted scales exist in clinical practice. While this indicates that they remain popular, the value of such tools in improving patient outcomes remains uncertain (Section 2.6.1). They offer a structured assessment framework, thus providing a minimum auditable standard (NPUAP, EPUAP and PPPIA 2014a), but their use does not necessarily prompt the provision of preventative care, as concluded by a qualitative study eliciting nurses' views of risk assessment and prevention (Johansen et al. 2014).

### 3.6 Summary

The present review has identified 94 RASs, used to determine PU risk in an adult population. In terms of the characteristics of these scales, most had been derived from pre-existing scales, and a median of 7 items were contained in these scales, with items surrounding mobility and activity most frequently included. Scoring was usually ordinal and in most scales higher scores were indicative of an increased risk of PU development. Scales constructed with the aid of modern development methods, namely regression analysis, were infrequently observed and when such studies were conducted they were often limited by the use of a retrospective dataset or an insufficient number of events.

The inter-rater reliability of RASs varied considerably, although most of the inter-rater reliability studies that were identified were at high risk of bias. Only 3 scales exhibited an acceptable inter-rater reliability, in 4 moderate and high-quality studies conducted in nursing home and ICU settings.

Overall, this review has concluded that the use of RASs remains commonplace, with scales for many different care settings identified in the literature. Although there is a growing body of research suggesting that the use of a RAS does not necessarily lead to the provision of preventative care, this has traditionally been their intended purpose. Once PU risk has been identified, a range of preventative strategies may be implemented for patients that are bedbound, including pressure redistributing support surfaces and repositioning. These strategies will be considered in the following chapter.



## Chapter 4: Pressure Ulcer Prevention

The maintenance of skin integrity is central to nursing practice, with the need to prevent harm reflected in a number of nursing models, including Henderson's model of nursing, and Roper, Logan and Tierney's activities of daily living model of nursing (Aggleton & Chalmers 2000). Moreover, PU prevention was identified as one of the High Impact Actions for Nursing and Midwifery (NHS Institute for Innovation and Improvement 2009), and prevention benchmarks are outlined in the Department of Health's Essence of Care (2010), which emphasise the importance of pressure redistributing support surfaces and repositioning. While patients deemed at risk of PU development may receive a range of preventative strategies including nutritional support and skin care regimen, arguably the most consistently implemented interventions in bedbound patients are the provision of pressure redistributing support surfaces and repositioning regimes and these will form the focus of the present chapter. Since both techniques aim to limit the magnitude and/ or duration of loading, research pertaining to these parameters will be presented. Additionally, consideration will be given to assessment methods that may be utilised to determine the effectiveness and acceptability of support surfaces and repositioning.

### 4.1 Magnitude and Duration of Loading

A number of researchers have endeavoured to quantify the relationship between the magnitude and duration of loading, with the aim of establishing threshold values for each, above which PUs are likely to develop. Hussain (1953) exposed the limbs of rats to circumferential pressures ranging from 100mmHg - 600mmHg (13.3kPa - 80kPa) and found that changes in all soft tissue layers first occurred after exposure to a 100mmHg (13.3kPa) load, maintained for a two-hour period. While the same pressure applied over a six-hour period led to more severe changes, exposure to an increased pressure of 600mmHg (80kPa) maintained over an identical time period did not produce significant additional damage. Consequently, Hussain concluded that the duration of pressure is of greater significance than the magnitude of pressure. By contrast, Kosiak (1959), using a canine model, identified an inverse relationship between the magnitude and duration of loading, which followed a hyperbolic curve. Loading of the trochanter and ischial tuberosity resulted in pressure damage when high pressures were applied for short time periods, and when low pressures were maintained for prolonged periods. A later study conducted on rat specimens (Kosiak

## Pressure Ulcer Prevention

1961), revealed that moderate leg muscle damage occurred following a 70mmHg (9.3kPa) load applied for a two hour period, which appears largely congruent with Hussain's findings. Nevertheless, some variability in the degree of muscle damage is reported, and pressures in excess of 70mmHg (9.3kPa) did not consistently produce comparable or more extensive muscle damage when the duration of loading was held constant or reduced. In a porcine model, Daniel et al. (1981) observed full-thickness ulcers at the greater femoral trochanter following an eleven hour 600mmHg (80kPa) loading regime, and a 200mmHg (26.7kPa) regime, applied for a sixteen-hour period. While the exact magnitude and duration required for pressure damage varied from the thresholds previously identified by Kosiak (1959), the pressure-time curve presented by Daniel and colleagues further demonstrated the inverse relationship of the magnitude and duration parameters. Figure 4-1 illustrates the threshold values identified by a number of authors. The apparent variation of reported threshold values may be attributed to the differing experimental conditions, animal models, loading methods and tissue sites exposed to loading (Stekelenburg et al. 2005).

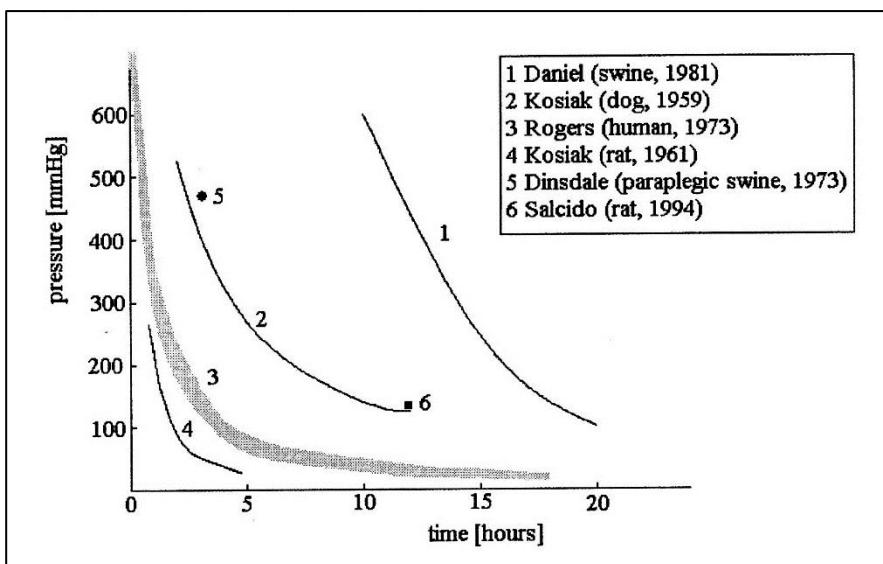


Figure 4-1: Pressure ulcer risk curves. Time/ pressure combinations above the curve result in tissue breakdown (Stekelenburg et al. 2005, reproduced with permission from the rights holder).

As is illustrated in the above figure, human threshold values have also been proposed. Reswick and Rogers (1976) constructed their pressure-time curve from interface pressures measured in patients with discernible skin changes following a known duration of exposure, and experiments conducted on healthy volunteers. The resultant curve was suggested to provide a guideline for the maximum sustainable magnitude and duration of loading of tissue over bony prominences (Reswick & Rogers 1976).

However, as Gefen (2009) suggests, this curve cannot be accurate at extremes of the timescale, since loads of sufficiently high magnitude may cause instantaneous tissue damage and loads of a very low magnitude may not cause damage even when the suggested maximum duration is exceeded. Indeed, Linder-Ganz et al. (2006) utilised a murine model to extend the seminal work of authors such as Hussain and Kosiak. They identified a sigmoidal curve, where for short or prolonged periods of exposure ( $1 < \text{ } \geq 2$  hours) the magnitude of pressure represented the factor governing muscle damage, while for intermediate periods (1-2 hours) time was found to be the critical factor. However, as the authors note, these data cannot be extrapolated to human tissue.

It is apparent that threshold levels, suitable for clinical use, have not yet been fully elucidated. Moreover, it may be argued that definitive thresholds are unlikely to be established since a wide variety of factors may contribute to an individual's PU susceptibility (Section 2.5). Nevertheless, the magnitude and time parameters provide a conceptual basis for prevention strategies, as shown in Figure 4-2. Reducing the magnitude or duration of pressure on tissues inevitably reduces the risk of PU development.

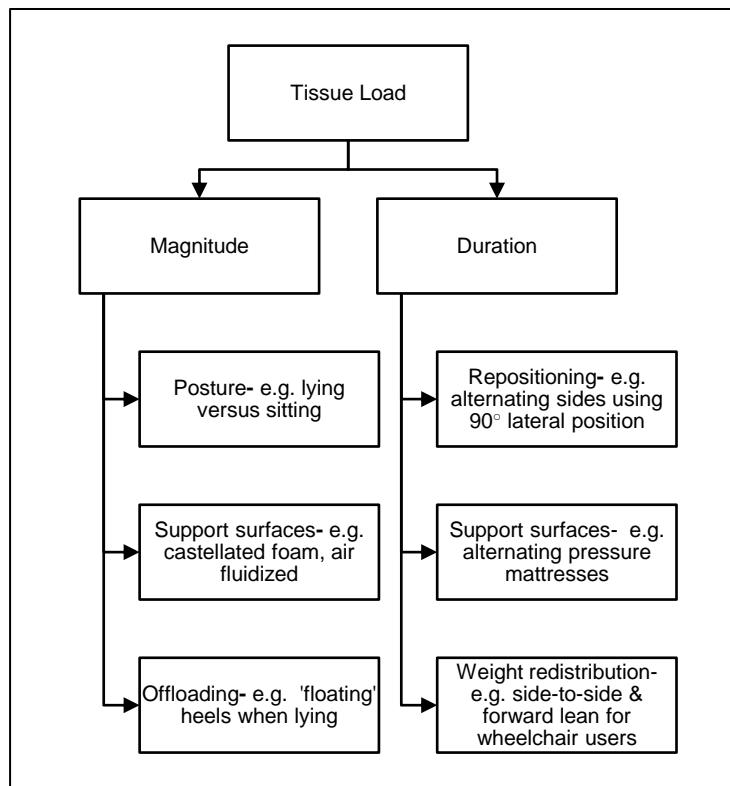


Figure 4-2: Conceptual basis for intervention (prevention and treatment) strategies (figure adapted by author from Takahashi et al. 2010; Sprigle & Sonenblum 2011).

## 4.2 Pressure Redistributing Support Surfaces

Support surfaces are defined as specialised devices, which include mattresses, overlays and seat cushions, that are designed for the management of tissue loads by means of pressure redistribution (NPUAP 2007). The annual NHS spend on the purchase or rental of such products was recently estimated to be in excess of £100 million, while equipment cost for an average 500-bed hospital amounts to as much as £250,000 per annum (Clancy 2013). Although several historical classifications exist (Clark 2011), the terms reactive and active support surfaces are currently favoured to categorise the different modes of operation of these devices (NPUAP 2007).

The common feature of reactive support surfaces is their ability to enable immersion and envelopment (Takahashi et al. 2010), thereby increasing the contact area and resulting in a reduced magnitude of pressure. Thus reactive support surfaces respond to an applied load (Sprigle & Sonnenblum 2011), and may be comprised of foam, or consist of columns or compartments filled with air or gel (Takahashi et al. 2010). Air fluidised mattresses are also classified as reactive support surfaces and operate through beads contained within the mattress through which pressurised air is forced, thus giving the surface its fluid-like properties (Ovens 2012). Other support surfaces in this category are low air loss systems, which incorporate air flow features that enable skin microclimate management (NPUAP 2007).

Contrary to reactive support surfaces, active support surfaces offer the capacity to change their load distribution properties independent of load application (NPUAP 2007). Support surfaces in this category are referred to as alternating pressure air mattresses (APAMs) (Takahashi et al. 2010), and are characterised by the cyclical inflation and deflation of air cells, enabling temporal load distribution (Rithalia & Kenney 2000), as indicated in Figure 4-2. Air cell configuration, which refers to individual cell dimensions aligned across the support surface, the ratio at which the cells inflate, and the total cycle period, vary between the different APAMs (Phillips et al. 2012). Furthermore, cycle frequency while generally sequential, may be interspersed with static intervals and the rate of change, defined as the speed of air transfer during inflation and deflation, differs between APAMs (Phillips et al. 2012). Cycle amplitude, which represents the range between the highest and lowest support pressures generated during the inflation and deflation cycle, further varies widely between alternating air mattresses (Phillips et al. 2012). Figure 4-3 illustrates some of the above parameters of alternating air mattresses.

While the peak internal air pressure of cells is usually factory set, and largely dictated by the internal pump, newer systems can incorporate pressure sensors that allow a degree of air pressure regulation, in response to subject morphology and position (Rithalia & Kenney 2000; Fletcher 2006). These sensors have been incorporated to enable decreased contact pressures. They also reduce the likelihood of 'bottoming out', a term used to describe localised immersion into a mattress to such an extent that parts of the body are in direct contact with the bed frame (Rithalia & Kenney 2000).

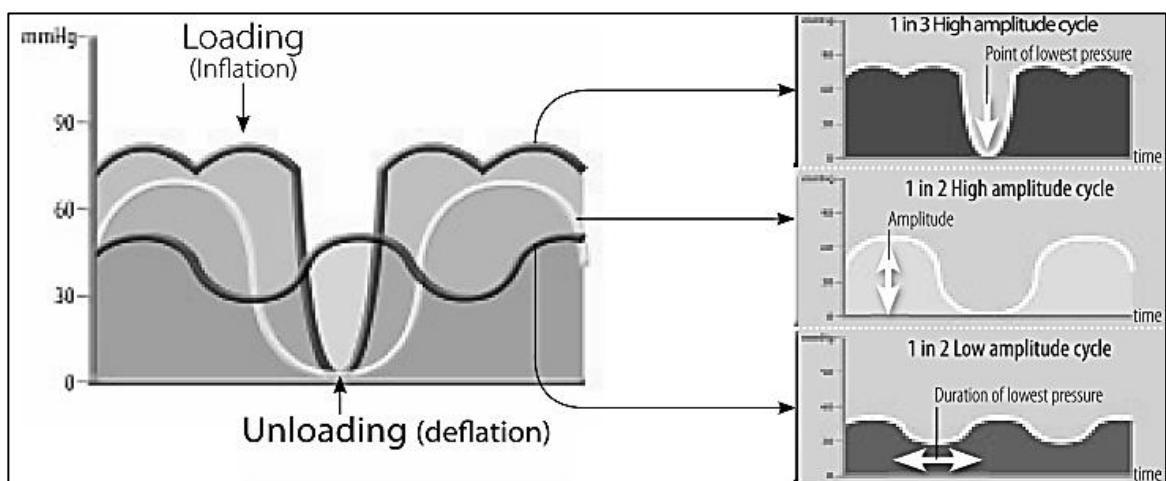


Figure 4-3: Selection of the parameters of active pressure redistribution surfaces: cell configuration, cycle duration, rate of change and amplitude (Phillips et al. 2012, reproduced with permission from the rights holder).

The performance of an in-built pressure sensor has been investigated by Chai and Bader (2013), using a prototype mattress incorporating continuous low-pressure zones to support the lower limbs and upper torso, and alternating pressure cells in the sacral region. Healthy volunteers, placed supine on the mattress, were exposed to a range of head of bed (HOB) elevation angles, while internal cell air pressures were monitored. To assess the effect of the in-built pressure sensor on the maintenance of tissue viability, transcutaneous gas tensions were continuously monitored at both the sacrum and a control site, namely the scapula. In addition, interface pressure measurements were obtained at the start and end of each test period. The maximum internal cell air pressures at the sacrum were found to be sensitive to participants' BMI, as is illustrated in Figure 4-4, and the corresponding linear models for each of the HOB angles were statistically significant at the 1% level. In most test conditions,  $TcPO_2$  levels remained similar to those measured at the control site, or fluctuated at non-injurious levels. However, in a few subjects exposed to a HOB elevation  $\geq 45^\circ$ , compromised tissue viability was observed at the sacrum, even at interface pressures which rarely

## Pressure Ulcer Prevention

exceeded 60mmHg. The authors conclude that intelligent support surfaces, sensitive to subject morphology, may offer a means to prevent PUs in bedbound patients.

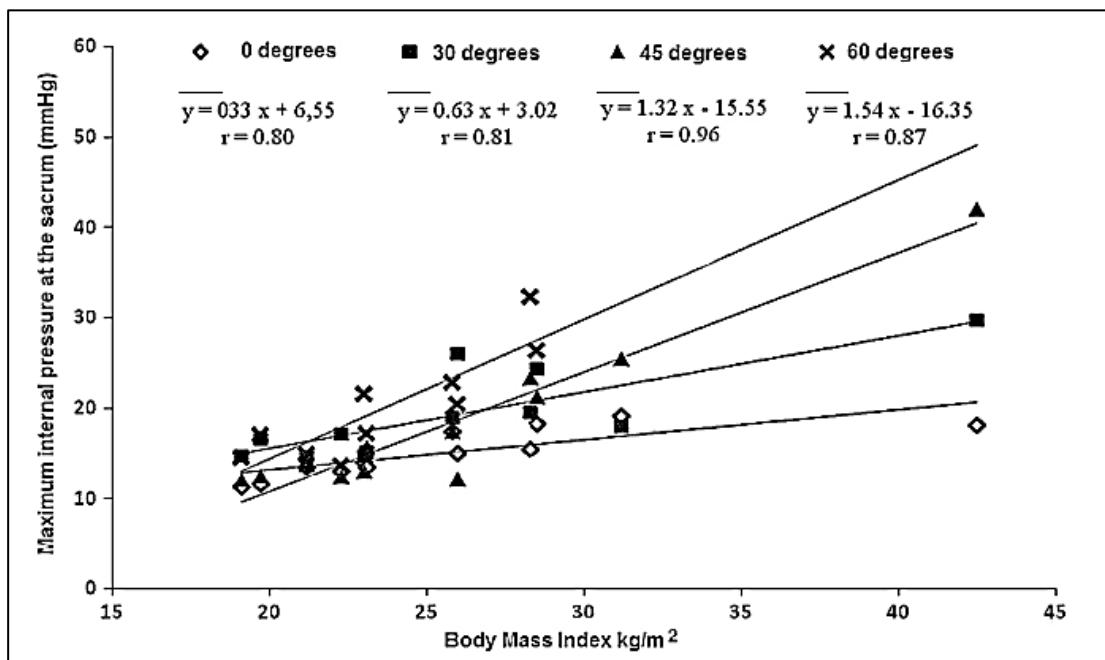


Figure 4-4: The relationship between internal pressures in the alternating pressure segment of the mattress and BMI for four HOB angles. Statistical analysis of each linear model is also indicated (Chai & Bader 2013, reproduced with permission from the rights holder, Elsevier).

Other studies, utilising similar robust parameters reflecting tissue viability, have examined the efficacy of specific pressure redistributing support surfaces (Colin et al. 1995; Rithalia & Gonsalkorale 2000; Rithalia 2004). Equally, clinical outcome measures have been used to evaluate these systems, and while high-quality RCTs are uncommon (Clancy 2013), several reviews of such studies have been undertaken.

In particular, Cullum et al. (1995) identified 30 RCTs, sixteen of which enrolled patients deemed at high risk of PUs, without pre-existing damage. Of these, two RCTs considered active support surfaces, and both reported that the use of an APAM led to a reduction in the incidence of PUs. Of the six trials that considered reactive support surfaces, five noted a decreased incidence of PUs when these mattresses were compared against standard hospital mattress (Cullum et al. 1995). The authors conclude that both active and reactive support surfaces yield an improved performance in terms of PU prevention, when compared to standard hospital mattresses. They further recommend that foam based support surfaces should be provided for those at risk of PUs, while alternating pressure, low air loss, or air fluidised devices should be reserved for high-risk patients. The review by Vanderwee et al. (2008) considered both

RCTs and experimental studies, which investigated APAMs and overlays in the context of PU prevention. Assessment of the 35 studies identified revealed that APAMs appear to be more effective than standard hospital mattresses. More recently, both RCTs and quasi-randomised studies examining support surfaces as a preventative measure were considered by McInnes et al. (2011). Fifty-three studies were selected for inclusion, although the methodological quality of many of these was deemed to be poor. Nevertheless, review of these studies indicated that both active and reactive support surfaces consistently outperformed standard hospital mattresses, which supports the conclusions of the previous reviews (Cullum et al. 1995; Vanderwee et al. 2008). However, the later review suggested that the relative merits of reactive and active support surfaces remained unclear, since most studies were unable to demonstrate a significant difference between treatment groups. The authors conclude that further research comparing alternating air mattresses to powered reactive support surfaces, such as air fluidised, is indicated, as is research comparing alternating air mattresses to high specification foam mattresses. These recommendations remain unchanged in the latest update of this review, which considered 6 additional studies (McInnes et al. 2015).

It is interesting to note that until recently, both UK and international guidelines followed the findings of Cullum et al. (1995), stating that high specification foam mattresses should be provided to those at risk of PU development, and APAMs to those at higher risk (National Institute for Health and Care Excellence 2005; EPUAP & NPUAP 2009). While these recommendations are still incorporated in the current international guidelines (NPUAP, EPUAP and PPPIA 2014b), UK specific guidelines no longer distinguish between high and higher risk, and recommend the use of high specification foam mattresses for all those considered at risk of PUs (National Institute for Health and Care Excellence 2014). Moreover, as has been previously recognised by the European and US organisations, perceived risk level cannot solely guide equipment selection and consideration should be given to factors such as patient comfort, mobility and care setting (EPUAP & NPUAP 2009).

## 4.3 Repositioning

The aim of repositioning is to limit the duration of pressure to any given site thereby enabling recovery of previously loaded tissues (Figure 4-2). In a seminal study, Exton-Smith and Sherwin (1961) utilised an automated device to record spontaneous movements in fifty elderly patients for up to ten consecutive nights and noted that the majority of PUs developed in patients that made twenty or less positional changes. Consequently, they suggested that regular repositioning should be undertaken in all patients unable to move independently. While the role of repositioning in PU prevention had long since been recognised (Trumble 1930; Hgisawa & Ferguson-Pell 2008), and indeed was routinely implemented in certain specialities, in elderly care PU prevention at the time appears to have centered on the application of topical preparations (Norton et al. 1962). Currently, repositioning forms an integral part of prevention strategies, which is incorporated in various prevention guidelines (NPUAP, EPUAP and PPPIA 2014b). These recommend that repositioning is undertaken irrespective of the use of pressure redistributing support surfaces, although the use of the latter can influence the required frequency of repositioning (NPUAP, EPUAP and PPPIA 2014b). Nevertheless, data from the inpatient prevalence study by Vanderwee et al. (2007a), shown in Table 2-1, indicates that patients considered at risk of PU development, defined by a Braden Scale score <17, frequently do not receive regular repositioning. In spite of the fact that 95.1% of UK patients deemed at risk of PUs were provided with pressure redistributing mattresses, a regular repositioning regime was implemented for only 44% of these patients (Vanderwee et al. 2007a). This strategy may be a direct result of an unsubstantiated belief that the provision of support surfaces obviates the need for repositioning, and the pressures associated with a limited workforce.

### 4.3.1 Frequency

Traditionally, two-hourly repositioning has been advocated, although the exact rationale supporting this practice is unclear (Hgisawa & Ferguson-Pell 2008). Nonetheless, when repositioning regimes are instigated for bedbound patients, two-hourly repositioning remains common practice. Vanderwee et al. (2007a) report that this frequency was adopted for 55.5% of at-risk patients receiving repositioning in the UK, while the remainder were repositioned either three-hourly (20.9%), or four-hourly (23.6%). It should be noted, however, that this data was not derived from direct observation, and may not accurately reflect actual repositioning frequency. Indeed, Bates-Jensen et al. (2003) compared the care provision recorded in the medical notes

of nursing home residents with data from wireless movement monitors and found that while two-hourly repositioning was frequently documented, the movement data did not reflect this. Conversely, a cross-sectional study in a nursing home setting compared nursing records to patient examinations and concluded that repositioning was implemented more often than was evident from the patient records, with this intervention documented in just 22% of the instances identified by patient examination (Hansen & Fossum 2016). Utilising an observational prospective study design, Latimer et al. (2015) conducted half-hourly semi-structured observations of hospitalised patients over a 24-hour period, with findings suggesting that patient movement occurred on average once every 1.7 hours. However, the authors note that as age increased the frequency of repositioning decreased and the positions adopted were frequently such that they were deemed to increase the risk of PUs. With reference to the latter, a HOB elevation of 1-90° was found to be the most commonly adopted position, with patients spending an average of 40% of their time in this position across the 24-hour period (Latimer et al. 2015). This is in spite of the fact that, to minimise the effects of pressure and shear, a HOB elevation of >30° is generally discouraged (NPUAP, EPUAP and PPPIA 2014b).

Defloor et al. (2005a) considered various repositioning regimes, implemented in conjunction with, or in the absence of support surfaces. Nursing home residents assessed as at risk of PUs received two or three-hourly repositioning on a standard mattress, four or six-hourly repositioning on a viscoelastic mattress, or standard care over a four week period. While the standard care group were provided with a variety of pressure redistributing devices, as deemed appropriate by nursing staff, a repositioning regime was not implemented. The repositioning regime in all experimental groups consisted of the semi-Fowler position alternated with the 30° side-lying position. Analysis revealed that the incidence of category I PUs did not significantly vary between groups. However, a significant reduction the incidence of category II-IV PUs was observed ( $p<0.01$ ), with a 3% incidence noted in the four hourly repositioning and viscoelastic mattress group, compared to a range of 15.9-24.1% observed in all other groups. Nevertheless, a viscoelastic mattress combined with a six-hourly turning regime did not result in a significant reduction in incidence when compared to the standard-care group, suggesting that while support surfaces may prolong the required interval, they do not provide a substitute for repositioning. Vanderwee et al. (2007b) further conducted a study among nursing home residents with non-blanchable erythema (category I PUs) at study inception. Similar to Defloor et al. (2005a), repositioning consisted of the semi-Fowler position and the 30° side-lying position, with

## Pressure Ulcer Prevention

the control group alternating between these positions on a four-hourly basis, while participants in the experimental group were positioned for four hours in the semi-Fowler position, and two hours in the 30° side-lying position. No statistically significant differences in the incidence of category II-IV PUs were observed between the groups, with an incidence of 21.2% in the control group, versus an incidence of 16.4% in the experimental group.

In a hospital-based study, Rich et al. (2011) examined the incidence of category II-IV PUs among elderly bedbound hip fracture patients. The authors found that frequent repositioning, defined as 12 or more turns per hospital day, did not result in fewer PUs the subsequent day as compared to those receiving less frequent repositioning, with values of 12% and 10%, respectively. However, since there may be a delay of several days between causation and the external appearance of category II-IV PUs (Vanderwee et al. 2007b), the selected follow-up period is deemed inadequate.

Contrasting findings are reported by Still et al. (2013). They investigated PU prevalence in a surgical intensive care unit (SICU) following the introduction of a turn team, which repositioned all haemodynamically stable patients 2-hourly over the 24-hour period, and reported a statistically significant reduction in PUs post-intervention ( $p<0.01$ ). It should be noted that training in PU risk assessment and prevention was delivered to all SICU staff before study implementation, which may have influenced the observed prevalence, although a pressure redistributing support surface protocol was in situ prior to the intervention, and remained unchanged throughout the study period (Still et al. 2013).

A variety of turning regimes was examined in a nursing home population in an RCT by Bergstrom et al. (2013), with participants allocated to a two, three, or four-hourly repositioning schedule, each combined with a high-density foam mattress. Blinded assessors subsequently performed weekly skin checks over a period of three weeks. PU incidence was not found to differ significantly between groups, with mean incidence values ranging from 0.6-2.5%. Manzano et al. (2014) further compared two and four hourly repositioning in ventilated ICU patients nursed on an APAM and, similarly, did not identify statistically significant difference between groups in the incidence of category  $\geq$  II PUs. It is interesting to note that more frequent repositioning was associated with a significant increase in overall device-related adverse events ( $p<0.02$ ), such as endotracheal tube obstruction and accidental extubation (Manzano et al. 2014).

#### 4.3.2      Technique: 30° Side-lying Position

The preferred repositioning technique has changed over the years, from the traditional 90° lateral position, to the 30° side-lying position, as shown in Figure 4-5. Guidelines recommend that this is performed in an alternating sequence starting with a left or right 30° tilt, moving to a horizontal position, followed by a tilt to the contralateral side, after which the cycle is repeated (NPUAP, EPUAP and PPPIA 2014b).



Figure 4-5: The 30° side-lying position (Moore et al. 2011, reproduced with permission from the rights holder, Blackwell Publishing).

Both the 90° lateral position and the 30° side-lying position enable tissue recovery by limiting the duration of pressure to any given tissue site. However, compared to former, the 30° side-lying position may further be proposed to reduce the magnitude of pressures, since a larger surface area is in contact with the support surface during the tilted position. Data supporting this is reported by Defloor (2000), who observed a significant reduction in the maximum interface pressures obtained when healthy volunteers were lying on a standard hospital mattress in the 30° position, in comparison to the 90° lateral position ( $p<0.01$ ).

The use of pillows in the 30° side-lying position ensures that bony prominences are offloaded, with pressures redistributed to other areas such as the gluteal muscles. Notwithstanding the apparent susceptibility of muscle tissue to pressure-induced

## Pressure Ulcer Prevention

damage, as discussed in Section 2.4.1, in a lying position pressure over bony prominences beneath the gluteal muscles are minimised, resulting in a uniform distribution of stresses within the tissues. Accordingly, there is a clear theoretical basis to support the use of the 30° tilt. In addition, numerous studies have been undertaken to verify its validity using both physical measurements, typically conducted on healthy volunteers, and clinical RCTs.

In a seminal study, Seiler et al. (1986) observed a reduced incidence of PUs after the introduction of the 30° side-lying position in clinical settings and thus hypothesized that tissue viability over bony prominences in this position would more closely resemble the unloaded state. Accordingly, TcPO<sub>2</sub> values were recorded at the sacrum and trochanter of healthy volunteers, lying alternately in supine, 30° side-lying, and 90° lateral positions. Results indicate that compared to unloaded values, the mean sacral TcPO<sub>2</sub> values decreased significantly while in the supine position ( $p<0.05$ ), while remaining similar in the 30° side-lying position. At the trochanter, oxygen tensions remained unaffected during the 30° side-lying position. However, a significant decrease was observed when participants were placed in the 90° lateral position ( $p<0.01$ ). In a comparable study, Colin et al. (1996) recruited healthy participants and measured both TcPO<sub>2</sub> and TcPCO<sub>2</sub> (transcutaneous carbon dioxide tension) at different areas of the trochanter. Repositioning in the 90° position led to a marked decrease of trochanter TcPO<sub>2</sub> values, with an associated increase in TcPCO<sub>2</sub>, which had not stabilised at the end of the measurement period. These values were largely restored to basal levels during subsequent repositioning to the 30° side-lying position.

More recently, Peterson et al. (2010) have questioned the use of repositioning as an intervention to prevent PU development. They studied the effect of the 30° side-lying position on interface pressures in healthy adults positioned on a low air loss mattress. Repositioning took the form of pillow or wedge support and the effect of 30° HOB elevation was also investigated. The 'at risk area' was defined as an area with an interface pressure greater than 32mmHg. Their results suggest that turning with the aid of pillows did not increase the risk area, unless the HOB was elevated. Yet, repositioning did not relieve pressures to these risk areas either; specific sites exhibited high interface pressures throughout the supine, lateral left and lateral right positions, leading the authors to conclude that turning by experienced ICU nurses does not reliably offload areas at risk of PU development.

Nevertheless, the appropriateness of the risk parameter utilised in this study is questionable. Derived from the work of Landis (1930), this often cited parameter of capillary-closing pressure was obtained from a single capillary loop adjacent to the cuticle edge and as such its applicability to pressure induced ischaemia is limited. Additionally, typical interface pressure readings contained in the paper demonstrate that the magnitude of pressure to the skin adjacent to the areas considered at risk shifts between positions, suggesting that repositioning does afford some measure of pressure redistribution. Furthermore, the specific risk sites, although described by the authors as peri-sacral, appear to be exclusively situated in the gluteal region, while the sacral and immediate peri-sacral areas exhibit low pressures on all images.

A subsequent study by Peterson and colleagues (2013) examined repositioning in bedbound intensive or intermediate care patients at risk of PUs, as defined by a Braden Scale score of <18. While the repositioning technique was not standardised, the description of the observed procedure suggests that nursing staff employed the 30° side-lying position. The results were broadly congruent with previous findings (Peterson et al. 2010), with certain areas of skin deemed continuously at risk. Nevertheless, the mean at risk area was smaller among those patients that were observed in all three positions (supine, left, and right) and, at an altered interface pressure threshold of 50mmHg, a smaller proportion of these patients exhibited persistent at risk areas (23%), when compared to patients not observed in all positions (43%). Thus, the authors suggest that if performed correctly, repositioning may reduce the risk of PU development.

Following a pilot study, Källman et al. (2015) investigated the effects of different lying positions on interface pressures, skin temperature and tissue blood flow, assessed by means of photoplethysmography (PPG) and LDF, in a nursing home cohort. This involved the supine position, the 30° supine tilt position, created by the placement of triangle-shaped wedges underneath the mattress, the 30° side-lying position and the 90° lateral position, with measurements obtained at the sacral area for the former two positions and the trochanter for the latter two positions. The authors reported that both variants of the 30° position exhibited the lowest interface pressures, and tissue perfusion was significantly greater during the 30° supine tilt position ( $p<0.01$ ), when compared to all other positions. However, variation in measurement sites precludes direct comparison between the two 30° positions. Similarly, Yoshikawa et al. (2015) evaluated the interface pressures in elderly patients adopting various postures including the supine, 30° side-lying, and 90° lateral positions, and found that sacral

## Pressure Ulcer Prevention

pressures were considerably lower in the 30° position when compared to the supine position ( $p<0.01$ ). Furthermore, the mean peak pressure index at the greater trochanter in the 30° side-lying position with the hip joints aligned, the 30° position with the hip joints misaligned, and 90° lateral position differed significantly, with observed values of 15, 39 and 92mmHg, respectively (all  $p<0.01$ ).

In a clinical RCT, Young (2004) compared the 30° side-lying position to the standard 90° position. Elderly patients in an acute care hospital, assessed at risk of PU development by means of the Waterlow Scale and without PUs at study inception, were examined over a period of one night. The frequency of repositioning was not controlled, but results infer a similar range of two to three hours for both groups. No difference in PU occurrence was observed between groups ( $p>0.05$ ). However, as acknowledged by the author, the sample was small and follow-up period limited. The site of PUs in the group subjected to the 30° side-lying position is of interest; one participant developed non-blanching erythema at the sacrum, while two other participants developed non-blanching erythema at both the trochanter and heel sites. While not explicit, the paper suggests that repositioning took place in an alternating sequence, without a supine period between the 30° positions. Therefore, the location of the PUs incurred seems counterintuitive, since it could be assumed that the sacral and heel sites were offloaded for the duration of the protocol, while pressure at the trochanter may have been anticipated to be minimal. These results could be attributed to nurses' unfamiliarity with the experimental position, as the 90° lateral position was standard practice, or the fact that the 30° side-lying position proved difficult to maintain, as was recorded in 26% of this group. A similar trend was observed by Vanderwee et al. (2007b), with 34% of patients self-adjusting their position from the 30° side-lying position to a supine position. While it may be argued that those patients most in need of repositioning would usually be unable to make major postural changes, results of both these studies indicate that comfort may be a critical determinant in maintaining the 30° side-lying position.

More recently, Moore et al. (2011) conducted a RCT which compared the 30° side-lying position to the 90° lateral position in elderly hospitalised patients, initially free of PUs. Repositioning in both groups was performed nightly over a four week period, with care provision reverting to standard planned care at other times. Pressure redistributing mattresses were in place for 86% of the participants in the control group and 96% of the experimental group, and seating support surfaces were prescribed for >97% of participants in both groups. Results indicated that 3% of participants in the

experimental group developed a PU, compared to an 11% incidence in the control group, the difference being statistically significant ( $p<0.05$ ). However, the prescribed repositioning frequency, namely three-hourly in the experimental group and six-hourly in the control group, confound these results. The authors further examined these data and suggested that, despite the increased frequency, the 30° side-lying positioning is less time consuming, requiring a mean nightly nurse time of 18.5 minutes, compared to 24.5 minutes in the control group (Moore et al. 2013). While repositioning of participants using the 90° lateral position typically required two nurses, approximately 50% of participants were able to be repositioned by a single nurse when the 30° side-lying position was utilised. The associated cost savings in terms of nursing time were estimated to amount to €46 per patient over the study period (Moore et al. 2013).

By contrast, Marsden et al. (2015), performed a secondary analysis of data presented by Vanderwee et al. (2007b) and found that an increased frequency of repositioning, namely alternating two and four-hourly repositioning versus four-hourly repositioning, was not cost effective at a threshold of £20,000 per quality adjusted life years. However, as acknowledged by the authors the interventions under consideration differed from those of Moore et al. (2013), minimising the relevance of direct comparison.

A recent systematic review of PU prevention considered the effect of different repositioning techniques, repositioning frequency, and associated costs (Gillespie et al. 2014). Several studies met the inclusion criteria (Young 2004; Defloor et al. 2005a; Moore et al. 2011; Moore et al. 2013), and a review of these led to the conclusion that there is a paucity of robust research supporting the use of the 30° side-lying position, the optimal frequency, and its cost effectiveness. Nevertheless, the authors reaffirm that a sound theoretical rationale underlies the use of this intervention (Gillespie et al. 2014).

#### 4.4 Lateral Rotation

*[The lateral tilting bed] appears to be helpful in the prevention of pressure sores. More extensive trials, however, are being conducted to prove its value (Norton et al. 1962, p231).*

The implementation of regular repositioning regimes appears challenging in hospital settings (Section 4.3.1). Moreover, it may not be practically possible for staff in primary care settings to regularly reposition those at risk of PU development. Lateral rotation systems incorporate an automated rotation function which moves on a longitudinal axis (NPUAP 2007), and may therefore provide an alternative to manual repositioning. Such systems may further offer an additional advantage over manual repositioning. Krapfl and Gray (2008) debate the apparent paradox of repositioning, which although considered a necessary measure to prevent irreversible damage, may further compromise tissues as a result of ischaemia-reperfusion injury (Section 2.3). In the context of vascular surgery, the role of gradual reperfusion has been investigated in both animal models (Unal et al. 2001; Beyersdorf 2009) and clinical studies (Beyersdorf 2009), with encouraging results. Accordingly, the relatively minor weight shifts and gradual reperfusion, which may be anticipated to occur as a result of a lateral rotation feature, could prove preferable to the abrupt reperfusion that occurs when tissues are subjected to manual offloading. However, a distinction between support surfaces that incorporate lateral rotation for the purpose of PU prevention, and continuous lateral rotation therapy (CLRT) systems should be made, since turn angles of the latter typically range from 25-62° (Goldhill et al. 2007), which may induce shear forces (NPUAP, EPUAP and PPPIA 2014b). Such systems are largely confined to intensive care units and are primarily employed as a prophylactic, or treatment strategy for respiratory complications (Goldhill et al. 2007). Treatment with these systems may also be referred to as Kinetic Therapy™, when prescribed turn angles are  $\geq 40^\circ$  (Goldhill et al. 2007).

Despite their intended purpose, evidence regarding the efficacy of lateral rotation devices in PU prevention is primarily anecdotal in nature. A literature search, the full details of which are shown in Appendix D, yielded only four studies which considered such systems. The first of these, conducted by Melland et al. (1999), evaluated the Freedom Bed™ (ProBed, Abbotsford, Canada) in 24 adults with degenerative disease, residing at home or in a long-term care facility. The lateral rotation system consisted of three longitudinal sections with the central section forming 50% of the surface area

(Figure 4-6), and had a rotation range of 1° - 30°. The accompanying mattress consisted of three connected segments, constructed from high-performance foam.



Figure 4-6: The Freedom Bed (ProBed Medical Technologies Inc., 2016, reproduced with permission from the rights holder).

An initial questionnaire focused on comfort, sleep patterns and caregiver assistance with turning. Additionally, participants' risk of PU development was assessed using the Braden Scale, and a skin inspection was performed twice over a four week period. While one participant had PUs at study inception, no new PUs developed during the trial period. A statistically significant difference ( $p<0.01$ ) was observed between the number of participants that required assistance turning in their own bed versus the Freedom Bed. For those that still required assistance while lying on the lateral rotation system, this consisted mainly of repositioning of the arms and shoulders. The authors further report that self-reported sleep quality was poorer on participants' own bed ( $p<0.05$ ), and perceived comfort improved on the lateral rotation bed, although the latter was not statistically significant.

Futamura et al. (2008) also evaluated the comfort of lateral rotation, using the NEO® air-cell mattress (Cape Co., Japan). Ten bedbound female participants with impaired verbal communication were exposed to nightly repositioning using the lateral rotation system for a one-week period. This was compared to a control period of equal duration, the latter involving manual repositioning by nurses, although the repositioning technique and frequency is not reported. The prescribed turn angle during the lateral rotation phase was 10°, maintained for a two-hour period. Comfort was ascertained by means of the high-frequency component of heart rate variability (HRV), which has been utilised in a number of studies for the analysis of mental stress (Futamura et al. 2008). HRV measurements were obtained during sleeping hours of the final two nights of the control and experimental periods. In half of the participants, no significant difference in

## Pressure Ulcer Prevention

the high-frequency component of HRV was observed between the repositioning regimes. Three participants exhibited significant increases in the high-frequency component during the lateral rotation phase ( $p<0.05$ ), which may indicate an increased comfort. In the remaining two participants, significant decreases in the high-frequency component were observed during lateral rotation ( $p<0.05$ ). The authors suggest that this may result from morphology, as recorded BMI values of these participants were low ( $\leq 17$ ). Throughout the study period, all participants remained free of pressure ulcers.

In contrast to the previous authors, Yi et al. (2009) recruited healthy volunteers to examine the effect of three prototype lateral rotation systems, illustrated in Figure 4-7, on pressure redistribution. Comparison of baseline peak interface pressures to turn angles of 10°, 15° and 20°, respectively, revealed that bed 2 was associated with the greatest reduction in interface pressure, with differences statistically significant at the 5% level. This reduction increased as the turn angle increased. However, as acknowledged by the authors, comfort and stability are sacrificed when larger turn angles are utilised. Their results further indicate that turning in either direction did not significantly increase peak pressures measured at the contralateral (loaded) site, as might be predicted.

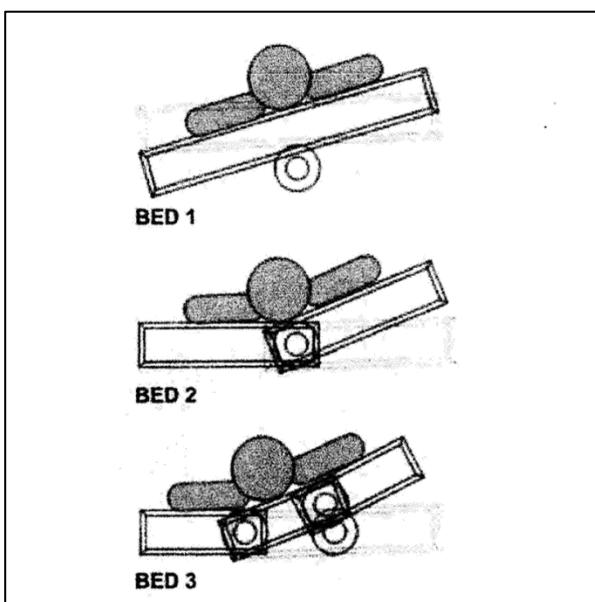


Figure 4-7: Schematic of prototype automated inclining beds developed by Yi and colleagues, 1-axis tilting (bed 1), 1-axis and 2-segment tilting (bed 2), and 2-axis and 3-segment tilting (bed 3). Yi et al. (2009), reproduced with permission from the rights holder.

The lateral turning device developed by Do et al. (2016) consisted of two lateral tilting components, continuously turning at a constant speed to reach a right turn angle up to 45° within a prescribed time period. The device was fitted with a standard mattress and evaluated in cohort of 24 healthy volunteers in four consecutive sessions, where the device remained at a 0° angle, and 15°, 30° and 45° angles were each induced, with maximum elevation occurring at 15 minutes, after which participants were returned to a supine position over an equal time period. In accordance with the results of Yi et al. (2009), an inverse relationship between turn angles and peak interface pressures was observed. When compared to the supine position, the peak pressures associated with the various turn angles were significantly lower ( $p<0.05$ ) at the majority of body sites, including the scapulae, sacrum and heels. However, at the right trochanter, peak pressures progressively increased, reaching a mean of 36mmHg at a 45° tilt. Furthermore, participants reported increasing discomfort at higher turn angles, with comfort ratings significantly lower as compared to the supine position ( $p<0.05$ ). This was equally evident when comfort ratings associated with the 30° and 45° turning protocols were compared to the ratings of the 15° and 30° protocols, respectively (both  $p<0.05$ ).

## 4.5 Summary

This chapter has considered the role of pressure redistributing support surfaces and repositioning in PU prevention. With reference to the former, many types of support surfaces exist, which can be broadly classified into reactive and active surfaces. Nevertheless, the research that has been reviewed in this chapter indicates that the relative merit of these surfaces remains unclear, although both have been shown to outperform standard hospital mattresses. With respect to repositioning, a recent systematic review has concluded that further research is required to determine the optimal technique and frequency of repositioning, while acknowledging that there is a sound theoretical basis to support the use of this intervention.

However, the implementation of regular repositioning regimes may not feasible in all care settings, and in these cases automated devices, termed lateral rotation systems, may provide a potential solution. Yet there is a paucity of research examining such systems, with only four studies identified, none of which directly compared repositioning by traditional methods to turning by means of automated methods. Accordingly, this thesis sought to examine the performance of two lateral rotation systems and compare this to manual repositioning. In addition, a preliminary study

investigated the different support surface features of a lateral rotation system, and a study was conducted to examine the variability and effectiveness of manual repositioning, since variation and/ or a lack of effectiveness could support the adoption of lateral rotation systems in clinical practice.

## 4.6 Aim and Objectives

The literature presented in Section 4.4 suggests that lateral rotation might be an effective alternative to manual repositioning. Nevertheless, it is apparent that the design of the turn mechanism affects the efficacy of such systems and it may equally be assumed that the particular support surface characteristics will influence tissue response. Comfort is of further concern since no matter how effective a system may be in preventing PUs, it will not prove to be an acceptable alternative to current practice if end-users feel uncomfortable or unstable. Therefore, the aim of this thesis was to examine the performance of two lateral rotation systems, and to compare this to repositioning by traditional nursing procedures.

The objectives were as follows:

- To evaluate the efficacy and acceptability of different support surface features of a prototype support surface which incorporates a lateral rotation function (Chapter 5);
- To evaluate the efficacy of the lateral rotation function of a prototype support surface (Chapter 5 and 6), and a lateral rotation platform (Chapter 7), as determined by objective techniques to assess tissue viability;
- To compare the efficacy of these systems to current repositioning practice, using the 30° side-lying position (Chapter 6 and 7);
- To evaluate perceived comfort and safety associated with the lateral rotation systems, and repositioning by means of the 30° side-lying position (Chapter 6 and 7);
- To evaluate the inter-practitioner variability and effectiveness of manual repositioning, using several assessment methods, including a number of the previously utilised techniques (Chapter 8).

Figure 4-8 further illustrates the experimental work presented in this thesis, the chapters that pertain to each of the studies, and the relationship between these studies.

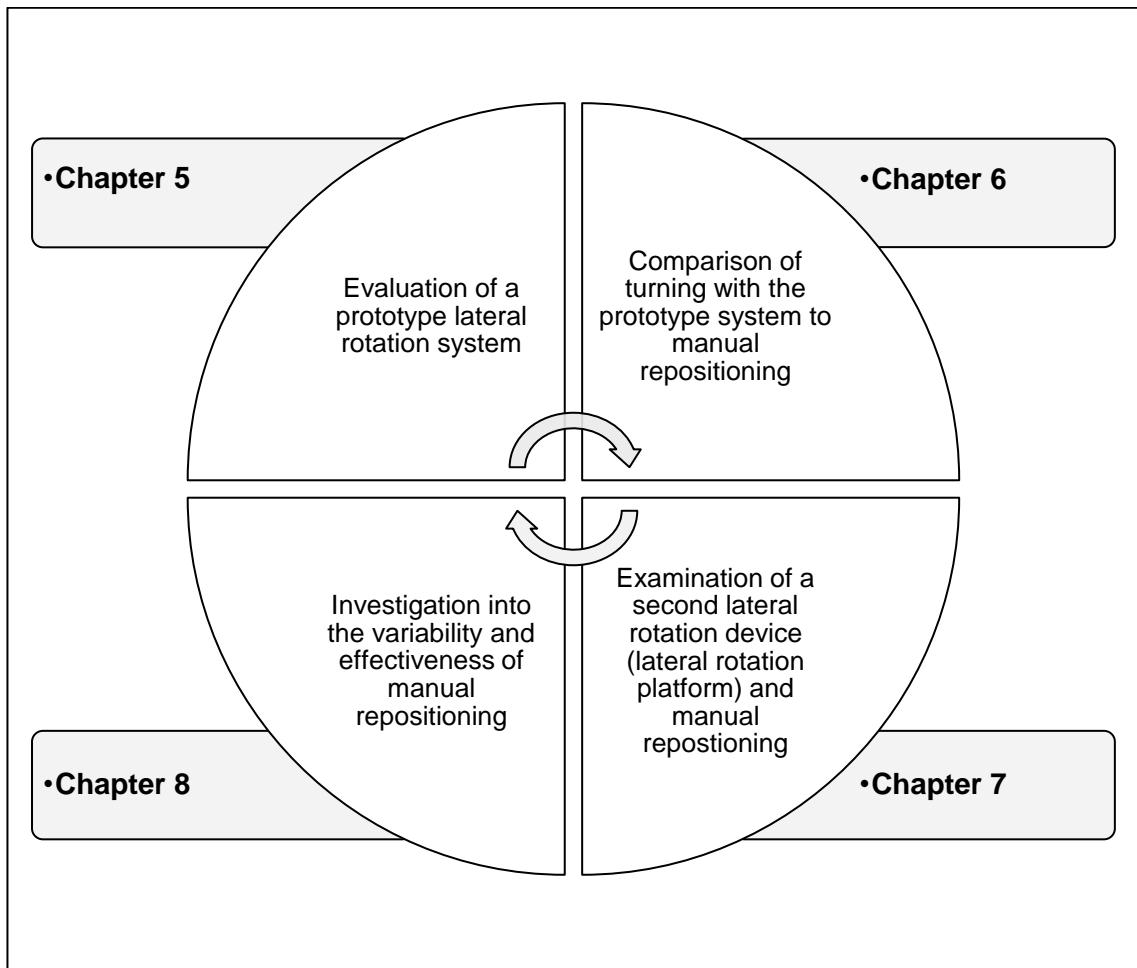


Figure 4-8: Flow diagram of the studies contained in this thesis and the relationship between these studies.

In the sections that follow (4.7 and 4.8) a number of methods previously utilised to evaluate the effectiveness and acceptability of support surfaces and repositioning are critiqued, with the aim of providing an overview of the techniques that have been employed in several of the studies described in this thesis. Where relevant, potential approaches to interpreting the results of such methods are also evaluated.

## 4.7 Measurement Techniques to Assess Tissue Viability

A range of non-invasive methods have been used to determine the status of soft tissues, when loaded on support surfaces, including transcutaneous gas tension measurements, LDF, PPG and interface pressure measurements and, as illustrated in Table 4-1, a combination of these methods is often used.

Table 4-1: Summary of a selection of studies which have employed physical measurement techniques to evaluate the performance of support surfaces/ or positioning strategies.

Study	Aim		Sample		Method			TcPO <sub>2</sub> / TcPCO <sub>2</sub> Measurement Site							
	Support surface evaluation	Positioning evaluation	Healthy volunteers	'at risk' volunteers	Sample	Interface Pressure	TcPO <sub>2</sub>	TcPCO <sub>2</sub>	Laser Doppler Flowmetry	Photoplethysmography	Sacrum	Trochanter	Ischial tuberosity	Heel	Scapula
Chai and Bader (2013)	✓		✓		12	✓	✓	✓			✓			✓	
Colin et al. (1996)		✓			20		✓	✓					✓		
Defloor (2000)	✓	✓	✓		62	✓									N/A
Källman et al. (2015)		✓		✓	25	✓			✓	✓					N/A
Rithalia and Gonsalkorale (2000)	✓		✓		11	✓	✓	✓			✓				
Rithalia (2004)	✓		✓		10	✓	✓	✓	✓	✓		✓			
Wong (2011)	✓		✓		9		✓				✓	✓		✓	
Yi et al. (2009)	✓	✓			20	✓									N/A

LDF provides a measure of tissue perfusion, generated as a result of a laser light source and the Doppler shift induced by moving erythrocytes in the blood (Rajan et al. 2009). Skin blood flow is assessed at an approximate depth of 1-2mm, and the output signal, referred to as flux, is expressed in arbitrary units (Belcaro & Nicolaides 2006). However, LDF is sensitive to artefact noise, which can occur as a result of subject movement and produce erroneously high readings (Rajan et al. 2009; Worsley & Voegeli 2013). Therefore, this technique must be considered unsuitable for the evaluation of lateral rotation systems and manual repositioning. In a similar manner,

PPG provides an indirect measure of blood flow in arbitrary units. Accordingly, the other techniques, i.e. transcutaneous gas tensions and interface pressure measurements, are considered more appropriate for assessing tissue viability and these will provide the focus of this section.

#### **4.7.1 Transcutaneous Gas Tension Measurement**

Transcutaneous gas monitoring was originally developed to monitor neonates who were at risk of respiratory complications (Takiwaki 2006; Eberhard 2007). However, it has been established that the association between arterial and transcutaneous oxygen values is weaker in adults (Takiwaki 2006) due, in part, to the thicker stratum corneum of adult skin (Abu-Own et al. 1993). By contrast, transcutaneous carbon dioxide has a closer correlation to arterial carbon dioxide, since this gas more readily diffuses through the skin (Rithalia 1991). Nevertheless, a correction factor is required to adjust for the additional carbon dioxide measured as a result of normal metabolic activity, occurring between the capillaries and the electrode at the skin surface, and the increased carbon dioxide production resulting from the heated state of the tissue (Nickelsen 2006). Indeed, heating up to 43-44° is necessary to 'arterialise' capillaries, so that transcutaneous oxygen values may be obtained. In addition to inducing vasodilation and thereby increasing blood flow, this increases oxygen unloading as a result of a rightward shift of the oxyhaemoglobin dissociation curve (Figure 1-5) (Rich 2001). The liquefaction of the lipid structures in the Stratum Corneum further increases oxygen diffusion (Rich 2001).

Bromley (2008) contends that transcutaneous gas tension values should be seen as physiological entities in their own right, rather than an inaccurate reflection of arterial blood gas values. The successful use of transcutaneous oximetry as a tool for the prediction of healing complications in adults with chronic wounds (Fife et al. 2009), and in predicting post-amputation healing (Wyss et al. 1988), demonstrates the merit of this argument. In this context, the method is used as an indicator of local tissue perfusion, derived from systemic values but affected by the measurement technique and, more importantly, the extent of vessel occlusion. The value obtained in these applications is thus representative of the degree of ischaemia. Tentative  $TcPO_2$  threshold values, below which healing complications are likely to occur, have been established for both chronic wounds and lower limb amputations, at values of 20mmHg (Arsenault et al. 2011) and 40mmHg (Arsenault et al. 2012), respectively. Yet, as Jakobsen and Christensen (1987) contend, there is a fundamental difference between the oxygen

## Pressure Ulcer Prevention

required to facilitate wound healing, and that needed for the survival of intact tissue.

Nevertheless, several authors have suggested threshold values for intact tissues.

Bogie et al. (1995) utilised transcutaneous gas tensions to monitor changes in tissue response at the ischial tuberosity in subjects that had recently sustained a SCI, and obtained these measurements on a minimum of two occasions. Transcutaneous oxygen values of 30mmHg, representing an approximate 60% reduction from baseline, were defined as the upper threshold values below which tissue viability risk occurs.

Threshold values of <10mmHg were further defined as low TcPO<sub>2</sub> levels, while TcPCO<sub>2</sub> levels of 36-44mmHg were defined as normal, with values >44mmHg representing high TcPCO<sub>2</sub> levels. Analysis of these tissue responses as a percentage of assessment time revealed that tissue viability status at the ischial tuberosity improved over time in subjects with higher spinal cord lesions, while a progressive deterioration was noted among those with lower lesions. The 60% parameter utilised in this study was subsequently corroborated by the findings of Knight et al. (2001). They combined transcutaneous gas tension measurements with analysis of biochemical markers, namely sweat metabolites, both obtained at the sacrum of healthy volunteers, after exposure to loads ranging from 40-120mmHg (5.3-16 kPa). A statistically significant increase in lactate and urea was observed when TcPO<sub>2</sub> levels fell below 60% of unloaded values ( $p<0.01$ ). Furthermore, below this threshold level, 90% of subjects exhibited TcPCO<sub>2</sub> levels in excess of 50mmHg for a significant proportion of the loading period, further indicating tissue ischaemia (Section 1.4.1 and 2.3).

In addition to threshold values, other parameters have been employed to establish the effect of repositioning and support surfaces on transcutaneous gas tensions. In their comparative analysis of two alternating pressure mattresses, Rithalia and Gonsalkorale (2000) utilised oxygen debt and carbon dioxide surplus, as compared to unloaded baseline values. The distinct loading responses such as those observed by Chai and Bader (2013), illustrated in Figure 4-9, further provide a means of classifying transcutaneous gas tension data.

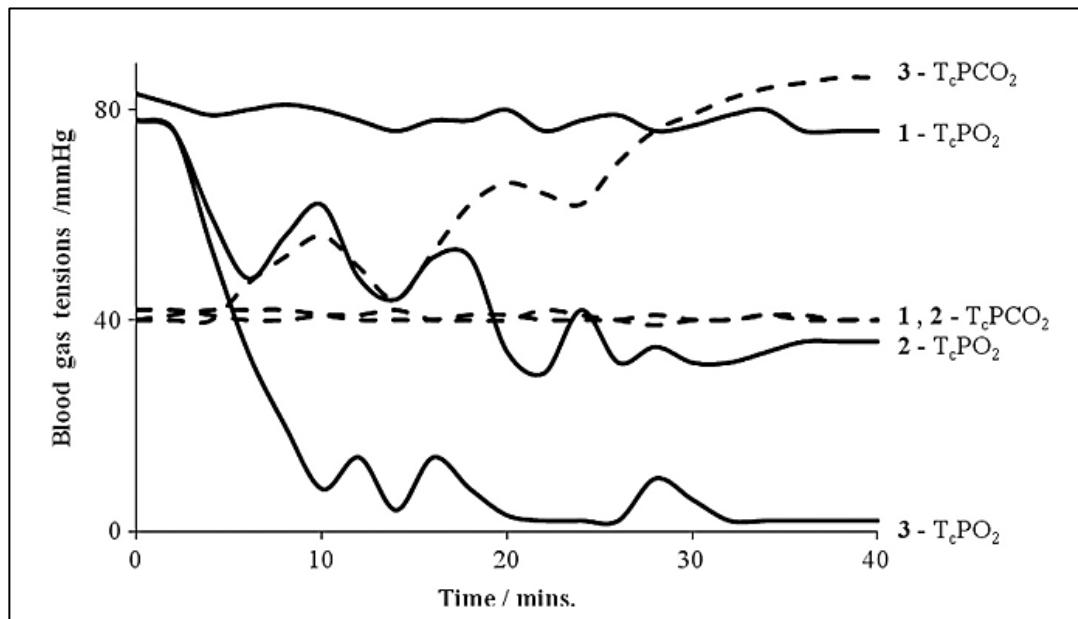


Figure 4-9: Schematic of the 3 distinct gas tension responses: response 1 shows little variation in  $T_cPO_2/T_cPCO_2$  values compared to baseline; response 2 indicates a reduction in  $T_cPO_2$  compared to baseline, with stable  $T_cPCO_2$  values; response 3 shows a reduction in  $T_cPO_2$  compared to baseline, and is associated with an increase in  $T_cPCO_2$ , above normal physiological values (Chai & Bader 2013, reproduced with permission from the rights holder, Elsevier).

#### 4.7.2 Interface Pressure Measurement

Interface pressure measurement have been utilised in clinical settings, typically in seating clinics, where they may provide feedback to aid patient education and assist clinicians with support surface selection (Crawford et al. 2005; Swain 2005). Equally, these systems have been employed by researchers (Table 4-1) and commercial manufacturers to assess the efficacy of support surfaces or positioning.

However, interface pressure measurements have several limitations, including:

- Uncertainty surrounding acceptable pressure values (Sections 4.1 and 4.3.2);
- Measurements are obtained at the skin-support surface interface, and as such, these values do not reflect the pressures in the deeper tissues, which may be significantly higher (Section 2.4.1);
- Measurements are subject to a degree of variability. Even when repeated readings are obtained from a particular anatomical site of a given individual, results may vary due to minor postural changes (Swain & Bader 2002).

## Pressure Ulcer Prevention

Despite these limitations, when utilised as an adjunct to other measures of tissue viability, interface pressure measurements may provide a measure of relative changes induced by positioning strategies or support surfaces.

A range of sensors have been developed including electronic, pneumatic and electro-pneumatic (Gyi et al. 1998). Electronic sensors measure the electronic signal proportional to the applied pressure and provide real-time display, thereby enabling temporal data acquisition. Such sensors are typically embedded within large array systems. However, they may be inflexible affecting the accuracy of the values obtained (Swain & Bader 2002). Pneumatic sensors consist of an air cell connected to air reservoir (Gyi et al. 1998). On inflation the sudden increase in air volume, which occurs when internal air cell pressure exceeds the externally applied pressure, causes an abrupt reduction in the rate of pressure increase, which is recorded as the interface pressure (Gyi et al. 1998). Electro-pneumatic sensors are equipped with metallic elements on the opposing inner surfaces of the air cell, which following inflation and subsequent deflation make contact, thereby providing the interface pressure values (Abu-Own et al. 1993).

Ferguson-Pell and Cardi (1993) compared the performance of three pressure mapping systems, namely the Tekscan system (Tekscan Inc., South Boston, USA) incorporating 2064 sensors, the Force Sensing Array (FSA) system (VISTAMED, Winnipeg, Canada) consisting of 225 sensors, and the Talley Pressure Monitor 3 (TPM3, Talley Medical, Romsey, UK), which contains up to 96 sensors. The former two systems incorporate electronic sensors whereas the latter is based on pneumatic sensors. Following both laboratory tests and a focus group meeting the authors report that the TPM3 proved to be the most accurate, stable and reproducible device, although it was limited in terms of ease of use, speed and data presentation. Gyi et al. (1998) further conducted experimental work using the TPM3 and found that partial sensor coverage affects the accuracy of the readings obtained and the lack of real-time display was considered a limitation of the system.

In terms of data analysis, a range of parameters have been utilised by researchers including minimum, maximum and average pressures, while others have opted to present data as the time for which interface pressures are above or below certain pressure thresholds (Swain & Bader 2002).

## 4.8 Comfort Assessment

The concept of comfort has been explored by numerous nursing theorists, and many consider the promotion of comfort an integral component of nursing care (Malinowski & Stamler 2002; Tutton & Seers 2003; Lin 2010). Indeed, a taxonomic structure of comfort was devised by Kolcaba (1992), to operationalise this in its application to holistic nursing practice and research, which presents comfort as a multidimensional personal experience, with differing degrees of intensity. It follows that the measurement of comfort is inherently subjective. Nevertheless, focusing on the physical comfort domain, several studies in the field of ergonomics have identified an association between perceived comfort and objective measurement techniques, such as interface pressures (de Looze et al. 2003).

In nursing research, the radiation therapy comfort questionnaire has been utilised to examine the effect of guided imagery during radiotherapy treatment, with the results suggesting that comfort has both trait and state characteristics, and that instruments such as these can detect temporal differences between groups (Kolcaba & Steiner 2000). A range of comfort questionnaires have since been developed, including tools to investigate the effects of complementary therapies in diverse populations (Dowd et al. 2006; Kolcaba et al. 2006; Apostolo & Kolcaba 2009), and an instrument designed to assess the utility of preoperative warming interventions (Wagner et al. 2006).

In the context of PU prevention, several studies have provided an indirect indication that aspects of comfort are pertinent to the implementation of PU prevention strategies, such as repositioning (Section 4.3.2). Furthermore, when considering PU treatment, direct indications of this are also evident in the literature. For example, following qualitative interviews with inpatients presenting with a PU, Spilsbury et al. (2007) reported that they raised concerns about the comfort and safety of pressure redistributing equipment. In a prior phenomenological study conducted in hospital, home care and nursing home settings, several participants described discomfort associated with equipment, while another participant reported that the 30° side-lying position had felt unsafe (Hopkins et al. 2006). More recently, semi-structured interviews with hospital and community-based patients with a PU revealed that mattresses were sometimes perceived as uncomfortable, while issues surrounding comfort and stability were associated with the use of pressure redistributing cushions (Gorecki et al. 2012).

Several studies have evaluated the perceived comfort of specific support surfaces. As an example, Grindley and Acres (1996) assessed patient comfort and quality of sleep

## Pressure Ulcer Prevention

with two APAMs in a hospice setting. A previously published quality of sleep questionnaire was adapted by including a question examining comfort. Largely consistent with the format of the original survey, this question consisted of a 7-point bipolar (Likert) item. A large-scale RCT examining APAMs and alternating pressure overlays by Nixon et al. (2006) also considered mattress comfort by means of a patient acceptability questionnaire, although specific details were not reported. More recently, Rafter (2011) conducted a small evaluation audit of two mattresses and elicited patients' perception of comfort, with a single unipolar adjectival-format question presented in the results. Examining various wheelchair cushions in able-bodied subjects Goncalves et al. (2015) further utilised 10-point visual analogue scales to determine perceived comfort, stability and posture.

As indicated in Section 4.4, studies evaluating lateral rotation devices have equally utilised assessment instruments to determine participant comfort. The first of these incorporated a 5-point Likert item to rate comfort (Melland et al. 1999), while the second was adapted from the quality of sleep questionnaire in a manner identical to that described by Grindley and Acres (Do et al. 2016).

It is evident from the above that in terms of PU prevention, comfort has been assessed using a variety of instruments, developed by the investigators or adapted from questionnaires that were originally designed for use in a different context. Indeed, a literature review which aimed to identify suitable measures for assessing physical comfort related to postures or surfaces concluded that there are few standardised tools, with only two such instruments identified, designed to assess wheelchair seating discomfort and comfort related to wearable devices (Pearson 2009).

## Chapter 5: Evaluation of a Prototype Support Surface Incorporating a Lateral Rotation Function

Support surfaces incorporating automated lateral rotation features may provide an alternative to manual repositioning, as is discussed in Section 4.4. However, relatively few studies have examined the efficacy and acceptability of these devices. While Melland et al. (1999), Futamura et al. (2008) and Do et al. (2016) all considered comfort, the study by Yi et al. (2009) focused exclusively on the efficacy of lateral rotation devices, using the measurement of interface pressure as their single objective parameter. Therefore, the present study aimed to examine the performance of a prototype support surface incorporating a lateral rotation function, and to interrogate whether its specific features affected tissue response and perceived comfort.

It has been recently demonstrated by Chai and Bader (2013) that adjustment of internal cell air pressures, according to BMI and individual morphology, can influence tissue viability (Figure 4-4). The support surface utilised in their study contained an integral pressure sensor. In the present study, the optimum internal air pressure was computed and adjusted manually. To further explore the effects of varying the internal air pressure on tissue viability, participants were exposed to a range of air cell pressures.

A number of specific research questions were identified, namely:

- I. Is lateral pressure redistribution (LPR) turning effective at maintaining tissue viability, as measured by transcutaneous gas tensions and interface pressures in healthy participants?
- II. Are the continuous low pressure (CLP) and alternating low pressure (ALP) settings equally effective at maintaining tissue viability at the sacrum of healthy participants?
- III. Does variation of internal air pressure in the support surface affect tissue viability measures in healthy participants?
- IV. What is participants' perceived comfort of the support surface and LPR function, and are there differences in perceived comfort between CLP and ALP settings?

## 5.1 Materials and Methods

### 5.1.1 Prototype Support Surface Description and Settings

The support surface utilised in this study represented a prototype mattress (model P500 MRS INT'L mattress, Hill-Rom, Montpellier, France), which incorporates a variety of functions. The sacral segment consists of eight rows of air cells which can operate in either a CLP mode or an ALP mode with a 1 in 4 cycle, lasting approximately 10 minutes. In the latter case, 2 rows of cells are deflated for a period of 90 seconds, followed by an equilibrium period of 60 seconds, after which adjacent cells are deflated. The head, back and leg segments consist of cells which permanently operate at CLP mode, while the heel segment is permanently maintained at a continuous ultra low pressure (CULP), of 7.5mmHg (1 kPa). The lateral rotation function, referred to as lateral pressure redistribution (LPR™), is created by longitudinal air bellows incorporated in the base of the mattress, as is illustrated in Figure 5-1. Figure 5-2 illustrates the mattress with the LPR function activated. The LPR function is software controlled, and the turn cycle can be set from a minimum of three minutes to a maximum of four hours. The software further enables some degree of variation in the turn angles, and cell internal air pressure.

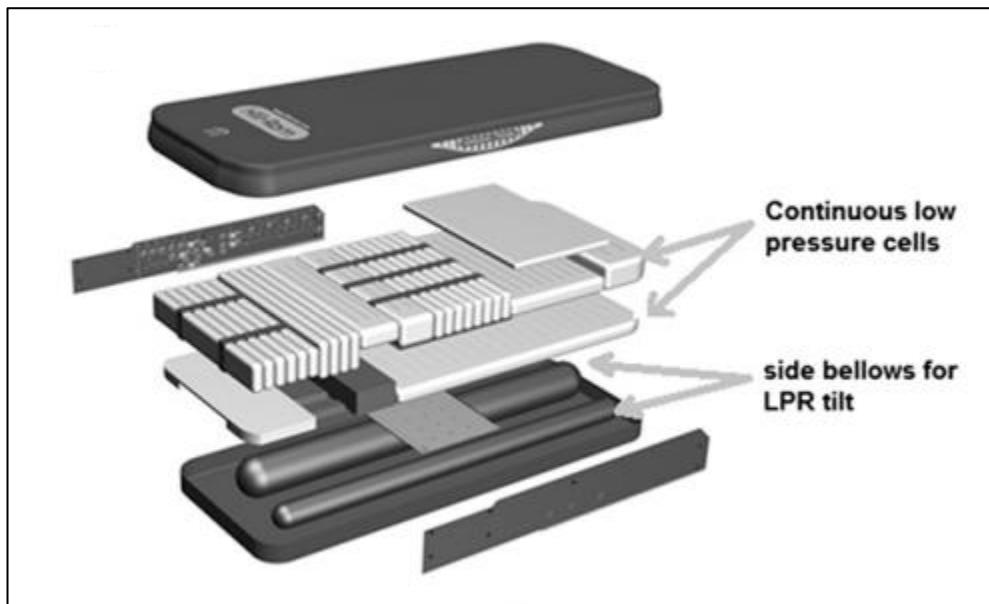


Figure 5-1: Schematic of the prototype LPR device, with air bellows to provide tilt (Woodhouse et al. 2015, reproduced with permission from the rights holder, Elsevier).



Figure 5-2: Mattress with LPR function activated.

A 3-minute turn cycle, prescribed at the maximum turn angle, was selected for the present study. The optimum internal air pressure ( $IP_{opt}$ ), as defined by Chai and Bader (2013), was ascertained for each participant using the formula derived from a supine position, where the Head of Bed (HOB) angle was prescribed at  $0^\circ$ . This formula is shown in Equation 5-1.

$$IP_{opt} (\text{mmHg}) = BMI \times 0.033 + 6.55 \quad \text{Equation 5-1.}$$

### 5.1.2 Transcutaneous Gas Tension Measurements

Transcutaneous gas tensions were recorded using either a TCM3 or a TCM4 monitor, each with combined E5280 oxygen ( $TcPO_2$ ) and carbon dioxide ( $TcPCO_2$ ) electrodes (all Radiometer, Denmark). Prior to every data collection session, both electrodes were re-membraned and calibrated using a calibration gas consisting of 20.9%  $O_2$  and 5%  $CO_2$  for the TCM3, and 20.9%  $O_2$  and 7.5%  $CO_2$  for the TCM4, as per the manufacturer's recommendation. Both electrodes were heated to  $43.5^\circ\text{C}$  during data collection periods, a temperature which will ensure maximum vasodilation of vessels in the skin tissues (Knight et al. 2001). Gas tension data was logged using LabVIEW

## Evaluation of a Prototype Support Surface

software (2012, version 12, National Instruments, Austin, US), with a data acquisition rate of 0.33Hz. Turn events were flagged on LabVIEW by means of a trigger.

Sacral pressure ulcers are relatively common in bedbound individuals (Vanderwee et al. 2007a) and, as previously discussed, the prototype mattress incorporates two therapeutic modes, namely ALP and CLP, for this location. To ascertain the effects of these functions on sacral tissue response an electrode was applied to this site using fixation rings (Radiometer, Denmark). The second electrode was applied to the right scapula, which was selected as the control site.

### **5.1.3 Interface Pressure Measurements**

Interface pressure measurements were obtained using a 96 cell pressure mapping system (TPM3, Talley Medical, Romsey, UK), which has previously been reported to produce robust and accurate readings (Ferguson-Pell & Cardi 1993). Seventy-two of the cells were incorporated in a flexible sheet and positioned in an area covering the length of the mattress. This area consisted of 6 columns of 12 sensors, each cell spaced approximately 50mm apart horizontally, and 120mm vertically.

Two separate 12 cell arrays, where sensors were spaced 30mm apart horizontally and vertically, were employed to increase spatial resolution at the test locations under the sacrum and right scapula. Participants were carefully positioned on these arrays. The configuration of the pressure cells is shown in Figure 5-3.



Figure 5-3: Configuration of pressure sensors.

#### 5.1.4 Comfort Assessment

Participants were asked to rate their comfort while lying on the support surface, using a custom-made assessment form, which had been formulated in consultation with the mattress' manufacturer. It included a range of questions designed to ascertain overall comfort while lying on the mattress, firmness of the mattress and its ability to provide support, with each item assessed using a 7-point scale. Individual items followed a Likert-format, with bipolar end-points including 'extremely satisfied' and 'extremely dissatisfied', as well as 'extremely comfortable' and 'extremely uncomfortable', with a central 'neutral' anchor, as recommended by Pearson (2009). Congruent with Pearson's recommendations regarding the evaluation of physical comfort associated with support surfaces, feedback was further sought on perceived comfort at specific body sites.

The assessment consisted of two identical parts, the first to be administered by the researcher while the LPR function was inactive (i.e. when the mattress was in the supine position) and the second while the LPR was activated. The complete assessment is detailed in Appendix E.

### 5.1.5 Study Protocol

The study was comprised of two identical sessions in terms of measurement techniques, and sequence of measurements. The internal cell pressure of the mattress was adjusted to the value equivalent to the individual  $IP_{opt}$  (Equation 5-1) for the duration of the first data collection session, with the therapeutic mode of the mattress' sacral section initially set to CLP, and altered to ALP during the latter half of the session. In the second session, the sacral section was set to the ALP mode and was adjusted to 5mmHg (0.67kPa) above the individual  $IP_{opt}$  setting during the first half, and to 5mmHg (0.67kPa) below the  $IP_{opt}$  during the latter half of the session. Figure 5-4 depicts this study protocol. Data collection sessions took place approximately 7 days apart.

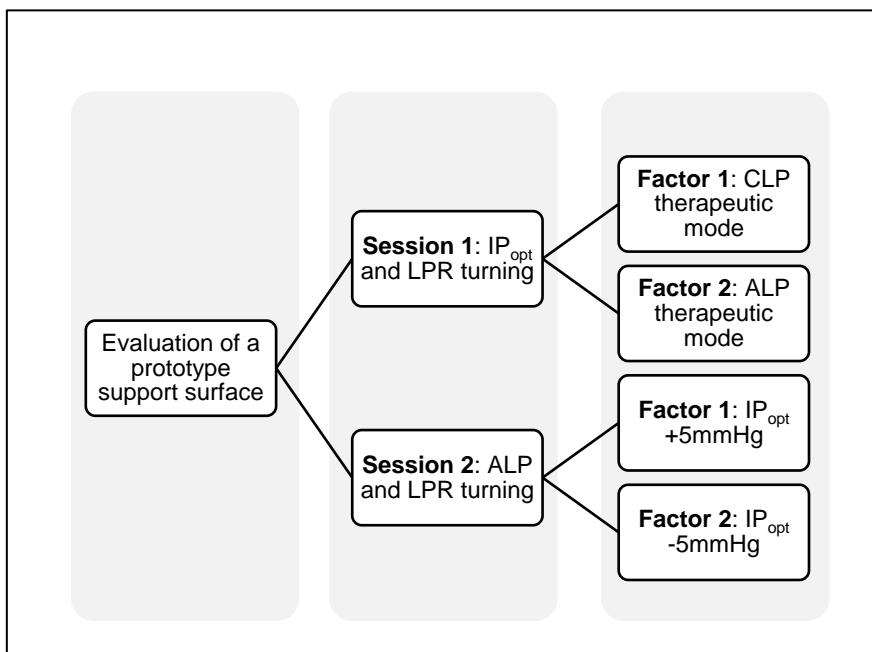


Figure 5-4: Schematic of study protocol over the two test sessions.

### 5.1.6 Data Collection Process

The study was approved by the local Faculty ethics committee of the University of Southampton (FoHS-ETHICS-978). Participant recruitment was conducted by means of poster advertisements and word of mouth. The participant inclusion criteria were as follows:

- Healthy volunteers;

- Aged  $\geq 18$  years.

As detailed in the participant information sheet (Appendix F), potential subjects were excluded if they met any of the following criteria, which could potentially affect the physiological responses:

- Current participation in another study;
- Medical history of any dermatological condition, including pressure ulcers;
- History of diseases of the skin, nervous system and musculoskeletal system, or diabetes.

Additionally, participants were excluded if they experienced pain or discomfort directly before participation (Appendix F), since turning by means of the LPR system could exacerbate this.

Following written consent, participants' height and weight were recorded, and their  $IP_{opt}$  was calculated. The gas tension electrodes were then applied, and participants were asked to lie in a prone position on the support surface, while gas tensions equilibrated, typically over a 20 minute period. After this acclimatisation period, participants were carefully positioned in a supine position and the first interface pressure measurements were recorded. Each interface pressure consisted of three cycles of data recorded over the 96 cells. LPR turning was then enabled, at the maximum turn angle. Gas tension measurements were recorded continuously for two complete turn cycles (right tilt, supine, left tilt, supine and repeated), with each position change flagged using the trigger. Following the second turn cycle, a further set of interface pressures were recorded. The mattress was then adjusted and the above process was repeated for the second half of the data collection session. All data were stored on the internal network server.

Figure 5-5 depicts the data collection process for both sessions. The comfort assessment was administered during the first session only. As previously described, questions designed to be answered while the LPR was inactive were asked while the participant was in a supine position during the turn cycle (Section 5.1.4).

## Evaluation of a Prototype Support Surface

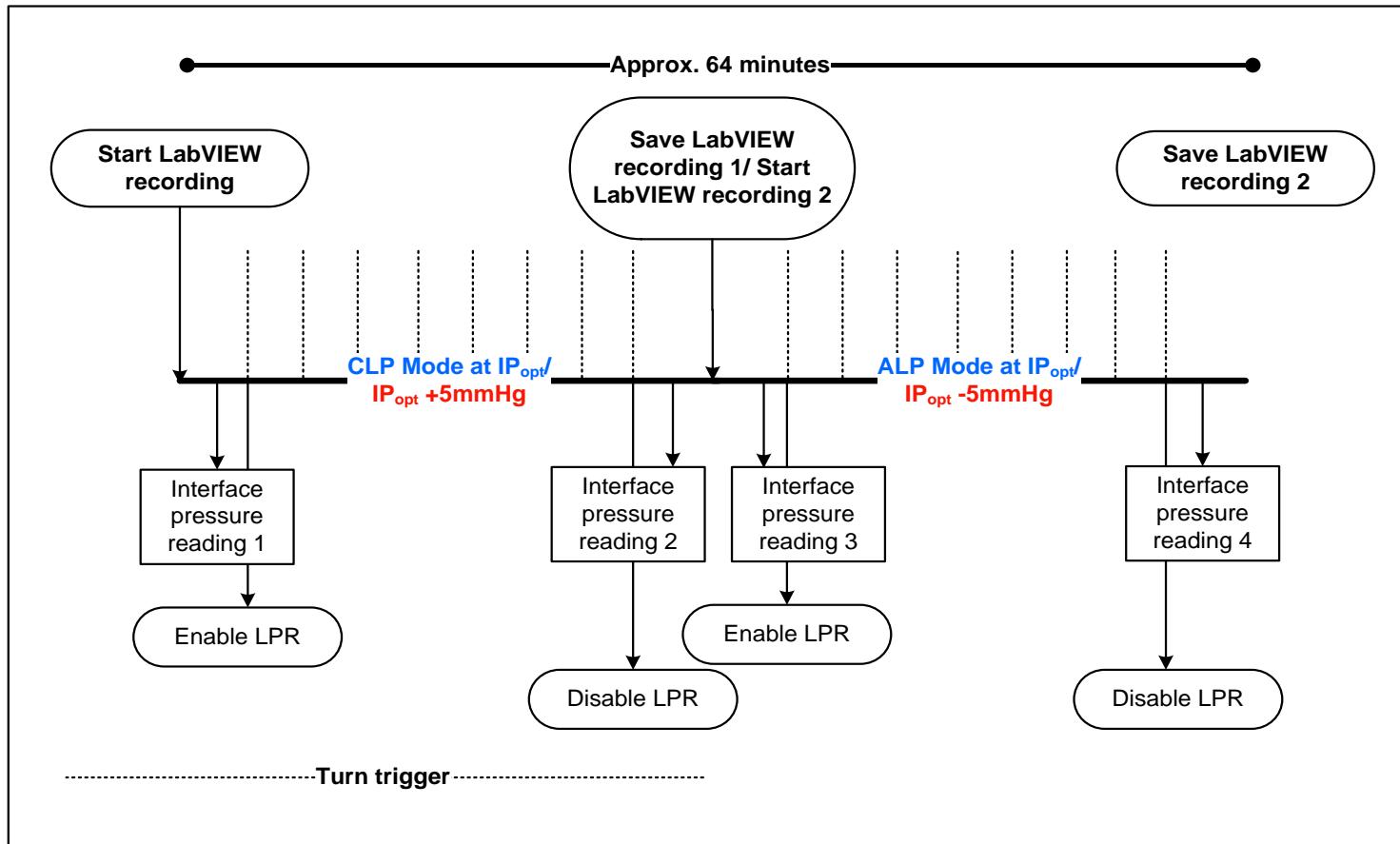


Figure 5-5: Data collection process for both sessions. Sessions were identical in the sequence of measurements; however mattress settings varied between sessions, these are denoted by the blue font for the first session, while the second session is shown in red.

### 5.1.7 Data Processing and Analysis

Data processing of transcutaneous gas tensions and interface pressures were performed using Matlab (MathWorks, USA) and exported to Microsoft Excel (Microsoft Office Professional Plus 2010, USA). Preliminary statistical analysis of all data was performed using Microsoft Excel, while significance testing was performed with IBM SPSS Statistics (version 22, USA). Prior to significance testing continuous data, namely interface pressures for the present study, were assessed for normality by visual inspection of histograms and Normal Q-Q plots, and by means of the Shapiro-Wilk test, and the statistical test was selected accordingly. The significance value for all statistical tests was set to  $p \leq 0.05$ .

Where a non-parametric test was indicated to examine the differences between sessions, the Wilcoxon matched-pairs signed-ranks test was used (Pett 1997). If this test revealed a statistically significant difference, the distribution of these differences were visually assessed for symmetry to ensure the test assumptions were met (Daniel 1990; Pett 1997; Altman 1999). Where the assumption of symmetry was violated, the data were re-examined using the sign test (Pett 1997; Altman 1999). The Friedman test was utilised when more than two conditions were examined (Daniel 1990; Pett 1997).

Transcutaneous gas tension data were classified using the parameters recently described by Chai and Bader (2013), which are illustrated Figure 4-9. To review briefly these categories are;

- Category 1 response, which signifies minimal changes in both  $TcPO_2$  and  $TcPCO_2$ ;
- Category 2 response, which indicates a decreased  $TcPO_2$  with a minimal change in  $TcPCO_2$ ;
- Category 3 response, which indicates a decreased  $TcPO_2$  with an associated increase in  $TcPCO_2$ .

Data were classified over the entire 32-minute duration of a prescribed mattress setting (CLP at  $IP_{opt}$ , ALP at  $IP_{opt}$ ,  $IP_{opt} + 5\text{mmHg}$ ,  $IP_{opt} - 5\text{mmHg}$ ). This duration was selected as participants sometimes exhibited a decrease in oxygen tension with, or without, an associated increase in carbon dioxide tension during a specific position (3-minute turn cycle), both of which would show a recovery towards baseline readings during the subsequent position. However, this recovery could take several minutes to occur and, as a result, the latter position would be classified using the same response that was

## Evaluation of a Prototype Support Surface

utilised for the previous position, since this would be most accurate for the majority of the 3-minute period. Thus, the data would not reflect the observed recovery response. Therefore, no attempt was made to separate the data by position for the analysis of the Chai and Bader (2013) responses in the present study. The responses relate to the data across the entire collection period of each test condition, with the category selected reflecting the most severe response, irrespective of which position this occurred in, or the length of time this was maintained.

Figure 5-6 shows a typical temporal response of gas tensions recorded at both the sacrum and the right shoulder. In this example, a category 1 response is exhibited at the sacrum throughout the first session. By contrast, a category 2 response was observed at the shoulder.

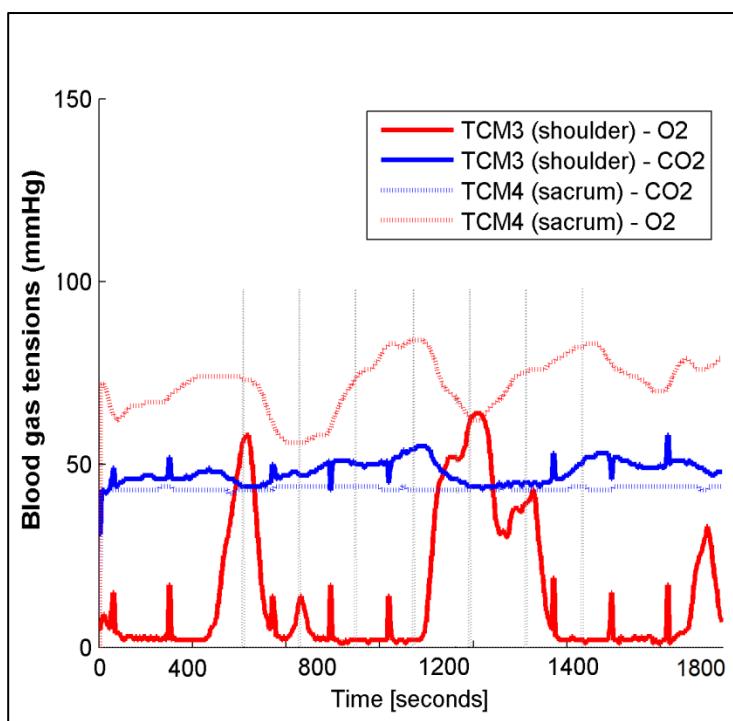


Figure 5-6: Typical transcutaneous oxygen and carbon dioxide tensions at the shoulder and sacrum, obtained from participant A during session 1, with the mattress set to CLP mode. The grey vertical lines denote position changes, recorded using the trigger.

The turn specific gas tension results that were associated with each prescribed mattress setting were further classified using the earlier criteria defined by Bogie et al. (1995), previously described in Section 4.7.1, namely:

- Low TcPO<sub>2</sub>, where TcPO<sub>2</sub> was <10mmHg (1.3kPa);

- Intermediate TcPO<sub>2</sub>, where TcPO<sub>2</sub> was between 10mmHg and 30mmHg (1.3-4kPa);
- High TcPO<sub>2</sub>, where TcPO<sub>2</sub> was >30mmHg (4kPa);
- Low TcPCO<sub>2</sub>, where TcPCO<sub>2</sub> was <36mmHg (4.8kPa);
- Normal TcPCO<sub>2</sub>, where TcPCO<sub>2</sub> was between 36mmHg and 44mmHg (4.8kPa-5.9kPa);
- High TcCO<sub>2</sub>, where TcPCO<sub>2</sub> was >44mmHg (5.9kPa).

The category selected in present study denotes the most prevalent category that was observed over each 3-minute position. On the infrequent occasions where an equal period of time was spent in more than one category, the most severe category was selected.

The peak pressure parameter, utilised in a recent study (Chai & Bader 2013) was selected to analyse interface pressures. This consisted of the highest value of any one cell, over the 3 cycles which comprised a single interface pressure reading. Data were screened in Microsoft Excel and the highest value of the 72 cell body segment, and 12-cell sacral and shoulder arrays, were selected as the peak pressures, after removal of any extreme outliers which resulted from a device error, i.e. crinkling under the lying participant, resulting in high individual cell values.

## 5.2 Results

### 5.2.1 Participant Characteristics

Ten able-bodied participants (6 male, 4 females, with an age range 23-65 years) were recruited and completed both sessions. The demographics of these participants, including the computed  $IP_{opt}$ , are summarised in Table 5-1.

Table 5-1: Participant demographics.

Participant	Sex	Age	Height (m)	Weight (kg)	BMI (kg/m <sup>2</sup> )	$IP_{opt}$ (mmHg)
A	Male	27	1.75	86	28.1	15.8
B	Male	59	1.92	93	25.2	14.9
C	Male	65	1.68	81	28.7	16.0
D	Male	32	1.91	78	21.4	13.6
E	Male	29	1.75	71	23.2	14.2
F	Male	23	1.83	69	20.6	13.3
G	Female	42	1.65	90	33.1	17.5
H	Female	25	1.58	86	34.4	17.9
I	Female	26	1.68	66	23.4	14.3
J	Female	50	1.62	75	28.6	16.0

### 5.2.2 Transcutaneous Gas Tensions Responses over the Entire Data Collection Period of a Single Session

Tables 5-2 and 5-3 indicate gas tension responses over the entire data collection period of each test condition at the sacrum and shoulder, respectively. With reference to the response at the sacrum, most participants exhibited only small changes from baseline  $TcPO_2$  and  $TcPCO_2$  values throughout each of the test conditions (Table 5-2). However, two participants, namely participants D and F, with a BMI (kg/m<sup>2</sup>) of 21.4 and 20.6 respectively, demonstrated a reduction in  $TcPO_2$  levels at the sacrum across most test conditions, i.e. a category 2 response.

Of the various test conditions, the ALP therapeutic mode combined with an internal cell pressure of 5mmHg below  $IP_{opt}$  appeared to produce the most stable  $TcPO_2$ /  $TcPCO_2$  values, i.e. a category 1 response for all participants. Nevertheless, when the Friedman test was utilised to compare the responses of the ALP, ALP+5mmHg and ALP -5mmHg test conditions, these differences were not found to be significant ( $p>0.05$ ). Equally,

comparison of the CLP and ALP test conditions using the Wilcoxon signed-ranks test did not produce statistically significant results.

Table 5-2: Gas tension response at the sacrum over the entire data collection period of each test condition, classified using the criteria defined by Chai and Bader (2013).

Participant	CLP	ALP	ALP +5mmHg	ALP -5mmHg
A	Category 1	Category 1	Category 1	Category 1
B	Category 1	Category 1	Category 1	Category 1
C	Category 1	Category 1	Category 2	Category 1
D	Category 2	Category 2	Category 2	Category 1
E	Category 1	Category 1	Category 1	Category 1
F	Category 2	Category 2	Category 2	Category 1
G	Category 2	Category 1	Category 1	Category 1
H	Category 1	Category 1	Category 1	Category 1
I	Category 1	Category 1	Category 1	Category 1
J	Category 1	Category 1	Category 1	Category 1

Table 5-3: Gas tension response at the shoulder over the entire data collection period of each test condition, classified using the criteria defined by Chai and Bader (2013).

Participant	CLP	ALP	ALP +5mmHg	ALP -5mmHg
A	Category 2	Category 2	Category 3	Category 3
B	Category 2	Category 2	Category 1	Category 2
C	Category 1	Category 2	Category 1	Category 1
D	Category 3	Category 3	Category 2	Category 1
E	Category 1	Category 1	Category 1	Category 1
F	Category 3	Category 3	Category 3	Category 1
G	Category 1	Category 2	Category 2	Category 2
H	Category 1	Category 1	Category 1	†
I	Category 3	Category 3	Category 2	Category 3
J	Category 1	Category 2	Category 1	Category 1

† Excluded from statistical analysis, due to a recording error of shoulder TcPCO<sub>2</sub> data.

## Evaluation of a Prototype Support Surface

In contrast to the sacral responses, shoulder responses across all test conditions frequently exhibited a reduction in TcPO<sub>2</sub> from baseline values, associated with either an absence (category 2), or presence (category 3), of increases in TcPCO<sub>2</sub> values. Moreover, while absolute TcPO<sub>2</sub> and TcPCO<sub>2</sub> values varied between test conditions, when a category 2 or 3 was noted across multiple test conditions for a specific participant, these responses often occurred during identical positions in the turn cycle, as is illustrated in Figure 5-7.

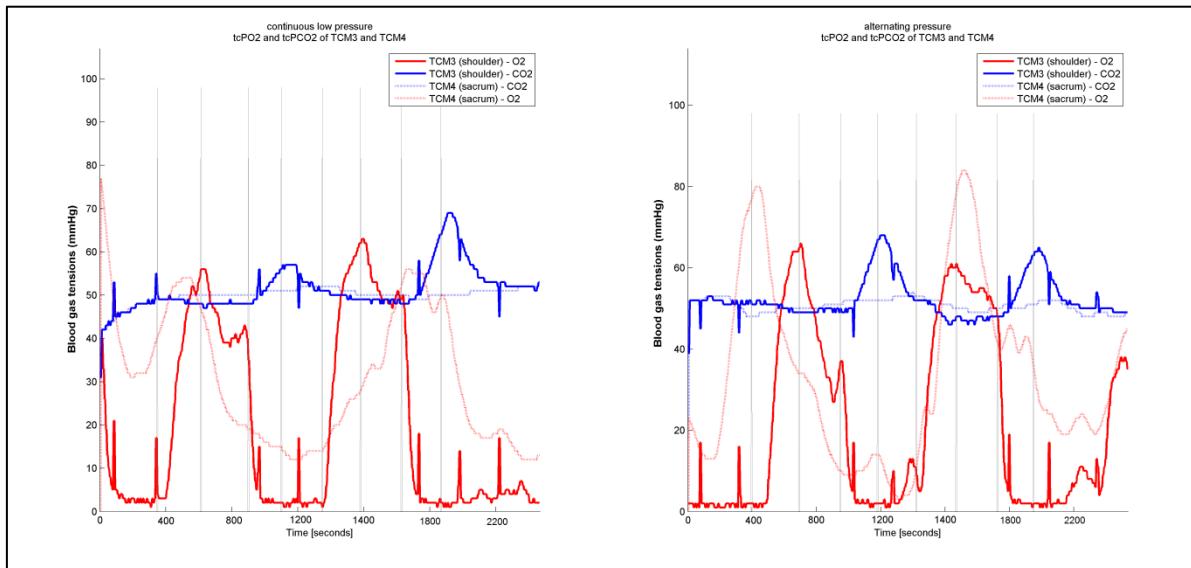


Figure 5-7: Transcutaneous gas tensions exhibited by participant F, during the CLP (left) and ALP (right) test conditions. With reference to the shoulder TcPO<sub>2</sub> and TcPCO<sub>2</sub> values (solid line); declining oxygen levels are observed during the first supine period following LPR activation, which decrease further during the subsequent left tilt position, leading to increasing TcPCO<sub>2</sub> values. A recovery response occurs during the right tilt position marking the start of the second turn cycle, however subsequent positions mirror those observed in the first turn cycle. This characteristic response pattern occurs during both the CLP and ALP test conditions.

Indeed, when the Wilcoxon signed-ranks and Friedman tests were employed to compare the differences in the observed responses between the CLP and ALP sessions, and the ALP, ALP +5mmHg, and ALP -5mmHg sessions, these differences were not found to be statistically significant ( $p>0.05$ ). However, a statistically significant difference was observed when the responses at the sacrum during the ALP session were compared to those observed at the shoulder ( $p<0.01$ ). Nevertheless, comparison of the sacral and shoulder responses across all other test conditions did not yield significant results ( $p>0.05$ ).

### 5.2.3 Transcutaneous Gas Tension Responses Associated with Specific Turn Positions

The turn specific transcutaneous gas tensions were analysed using the criteria defined by Bogie et al. (1995), as detailed in Section 5.1.7. The proportion of participants within each of the  $TcPO_2$  bands per test condition, position and measurement site, are summarised in Table 5-4, while the  $TcPCO_2$  data are presented in Table 5-5.

Table 5-4: Percentage of all participants within the  $TcPO_2$  categories defined by Bogie et al. (1995), per prescribed setting, position, and measurement site. Since each of the four prescribed settings were recorded over two turn cycles, the data pertaining to each position have been pooled.

Mattress Mode	Position	Sacrum			Shoulder		
		High $TcPO_2$	Intermediate $TcPO_2$	Low $TcPO_2$	High $TcPO_2$	Intermediate $TcPO_2$	Low $TcPO_2$
CLP at $IP_{opt}$	Right tilt	95%	5%	-	90%	-	10%
	Supine 1	95%	5%	-	55%	10%	35%
	Left tilt †	90%	5%	5%	65%	-	35%
	Supine 2	90%	10%	-	80%	5%	15%
ALP at $IP_{opt}$	Right tilt	90%	5%	5%	75%	10%	15%
	Supine 1	85%	10%	5%	65%	-	35%
	Left tilt †	80%	10%	10%	70%	-	30%
	Supine 2	80%	10%	10%	80%	-	20%
ALP at $IP_{opt} + 5mmHg$	Right tilt	80%	10%	10%	85%	-	15%
	Supine 1	80%	15%	5%	85%	-	15%
	Left tilt †	85%	10%	5%	85%	-	15%
	Supine 2	75%	15%	10%	80%	-	20%
ALP at $IP_{opt} - 5mmHg$	Right tilt	100%	-	-	90%	-	10%
	Supine 1	100%	-	-	90%	-	10%
	Left tilt †	100%	-	-	80%	-	20%
	Supine 2	100%	-	-	85%	-	15%

† The gas tension electrode was situated at the right shoulder.

It is evident from Table 5-4 that  $TcPO_2$  levels at the sacrum were generally high, with the mattress mode (CLP/ ALP) appearing to produce little variation in  $TcPO_2$  values. Subsequent comparison of the individual sacral responses, associated with each position of the CLP and ALP settings, did not produce statistically significant differences in any of the positions of the two turn cycles (all  $p>0.05$ ). Similarly, Friedman tests indicated that the difference in sacral  $TcPO_2$  values across the ALP at  $IP_{opt}$  and  $IP_{opt} \pm 5mmHg$  settings did not differ significantly ( $p>0.05$ ). Nevertheless, it is evident from Table 5-4 that the highest sacral  $TcPO_2$  values were observed during the

## Evaluation of a Prototype Support Surface

ALP at  $IP_{opt} - 5\text{mmHg}$  setting, which is consistent with the previous results (Section 5.2.2).

At the shoulder,  $TcPO_2$  levels were generally lower, with greater percentages of  $TcPO_2$  values classified as low across all test conditions, and fewer  $TcPO_2$  results classified as intermediate, when compared to the sacrum. This is consistent with the findings in Table 5-3, where a greater number of category 2 and 3 responses are observed at the shoulder. Nevertheless, when the inter-session differences across each position of the CLP cycle were compared to the corresponding results of the ALP cycle using Wilcoxon signed-ranks tests, no statistically significant differences were observed. Friedman tests further indicated that variation in the internal cell air pressure (ALP at  $IP_{opt}$ ,  $IP_{opt} \pm 5\text{mmHg}$ ) did not result in significant differences in the  $TcPO_2$  categories during any of the positions across the test conditions.

It is interesting to note that  $TcPO_2$  levels at the sacrum demonstrate little variation during the turned positions, when compared to the supine positions (Table 5-4). Indeed, Friedman tests of the individual turn cycles associated with the CLP, ALP and ALP at  $IP_{opt} \pm 5\text{mmHg}$  sessions, indicated that the  $TcPO_2$  categories did not differ significantly between the positions, at either the sacrum, or the shoulder ( $p > 0.05$ ). With respect to the former, these results indicate that LPR turning feature did not appear to facilitate the recovery of  $TcPO_2$  values. However, it is possible that this finding is due to the relatively small proportion of participants that exhibited intermediate or low  $TcPO_2$  values at the sacrum.

Similarly, Table 5-5 illustrates that position-specific differences in  $TcPCO_2$  categories at both sites were minimal. Accordingly, Friedman tests examining  $TcPCO_2$  categories across the positions of each of the turn cycles associated with the different test conditions produced no significant results at the sacrum or the shoulder ( $p > 0.05$ ). Wilcoxon signed-ranks and Friedman tests of the position-specific differences between the CLP and ALP modes, and across the across the ALP at  $IP_{opt}$  and  $IP_{opt} \pm 5\text{mmHg}$  sessions, identified no significant differences in  $TcPCO_2$  categories at either of the measurement sites ( $p > 0.05$ ).

It is evident from Table 5-5 that a substantial percentage of participants exhibited  $TcPCO_2$  values which were classified as high at both the sacrum and the shoulder. This is in spite of the fact that previous results demonstrate that a category 3 infrequently

occurred (Table 5-2 and 5-3), and that the corresponding  $TcPO_2$  values, which were categorised as low, were relatively infrequent (Table 5-4). However, close examination of the data revealed that certain participants had baseline  $TcPCO_2$  levels which were close to, or in excess of, the criteria defined as high by Bogie et al. (1995). To illustrate, during the ALP at  $IP_{opt}$  -5mmHg test condition high  $TcPO_2$  levels were observed among all participants, yet a high  $TcPCO_2$  was observed among 20-30% of participants. These results can be attributed to participant A, B and H, who exhibited basal  $TcPCO_2$  levels of 44mmHg, 49mmHg and 43mmHg respectively, and in each instance  $TcPCO_2$  values fluctuated close to these baseline values for the duration of the session.

Table 5-5: Percentage of all participants within the  $TcPCO_2$  categories defined by Bogie et al. (1995), per prescribed setting, position, and measurement site. Since each of the four prescribed settings were recorded over two turn cycles, the data pertaining to each position have been pooled.

Mattress Mode	Position	Sacrum			Shoulder		
		Low $TcPCO_2$	Normal $TcPCO_2$	High $TcPCO_2$	Low $TcPCO_2$	Normal $TcPCO_2$	High $TcPCO_2$
CLP at $IP_{opt}$	Right tilt	-	45%	55%	-	45%	55%
	Supine 1	-	35%	65%	-	35%	45%
	Left tilt †	-	40%	60%	-	40%	60%
	Supine 2	-	40%	60%	-	40%	60%
ALP at $IP_{opt}$	Right tilt	-	50%	50%	10%	45%	45%
	Supine 1	-	55%	45%	10%	30%	60%
	Left tilt †	-	50%	50%	5%	40%	55%
	Supine 2	-	55%	45%	5%	45%	50%
ALP at $IP_{opt}$ +5mmHg	Right tilt	20%	45%	35%	-	55%	45%
	Supine 1	15%	45%	40%	-	55%	45%
	Left tilt †	25%	35%	40%	-	60%	40%
	Supine 2	20%	35%	45%	-	60%	40%
ALP at $IP_{opt}$ -5mmHg	Right tilt	30%	45%	25%	6% ††	61% ††	33% ††
	Supine 1	30%	40%	30%	-	67% ††	33% ††
	Left tilt †	30%	45%	25%	6% ††	56% ††	39% ††
	Supine 2	30%	50%	20%	6% ††	50% ††	44% ††

† The gas tension electrode was situated at the right shoulder. †† Based on 9 participants, participant H was excluded from analysis due to a recording error of shoulder  $TcPCO_2$  data.

### 5.2.4 Interface Pressures

The median and range of peak interface pressures that were measured at the start and end of every session are shown in Table 5-6. It is evident from this table that sacral interface pressures were generally greater than the corresponding interface pressures observed at the body and shoulder. Indeed, when the initial and end interface pressures across the three sites of each session were compared with Friedman tests, these differences were found to be significant in all test conditions ( $p<0.01$ ). Post hoc analysis revealed that the differences between the shoulder and sacral interface pressures were significant in every condition ( $p<0.01$ ), while the differences between the shoulder and body pressures were significant during the three ALP test conditions, both during the initial and end measurements of these sessions ( $p<0.01$ ).

Table 5-6: Summary of the median and range of the initial and end peak interface pressures (IPs) that were associated with each of the test conditions (mmHg).

		CLP	ALP at $IP_{opt}$	ALP at $IP_{opt} + 5\text{mmHg}$	ALP at $IP_{opt} - 5\text{mmHg}$
<b>Peak body IP †</b>	Initial	47 (37-71)	48 (40-86)	53 (34-78)	56 (32-109)
	End	44 (34-74)	49 (39-114)	49 (38-78)	54 (39-90)
<b>Peak sacral IP ‡‡</b>	Initial	69 (39-111)	66 (39-93)	59 (36-112)	80 (47-128)
	End	59 (42-95)	67 (32-102)	58 (36-93)	66 (46-121)
<b>Peak shoulder IP ‡‡</b>	Initial	29 (15-97)	27 (21-51)	30 (21-43)	31 (21-33)
	End	28 (19-50)	27 (20-48)	29 (21-41)	30 (23-48)

† Recorded over 72 sensors. ‡‡ Recorded over a 12-sensor array.

Further examination indicates that the median peak pressures at each of the measurement sites varied little between conditions. Accordingly, comparison of the differences in peak pressures between the CLP and ALP test conditions using Wilcoxon signed-ranks tests, and comparison of the ALP at  $IP_{opt}$  and ALP at  $IP_{opt} \pm 5\text{mmHg}$  sessions with Friedman tests indicated that the inter-session differences were not significant at any of the measurement sites (all  $p>0.05$ ). Nevertheless, when the median and range of peak sacral pressures are compared between sessions, it is apparent that these were generally greater during the ALP at  $IP_{opt} - 5\text{mmHg}$  session, both during the initial and end measurements. This is further illustrated Figure 5-8.

This finding appears to contradict the trend towards higher sacral oxygen tensions and lower carbon dioxide tensions during this condition (ALP at  $IP_{opt} - 5\text{mmHg}$ ). This strongly suggests that higher interface pressures are not necessarily associated with compromised gas tensions and vice versa.

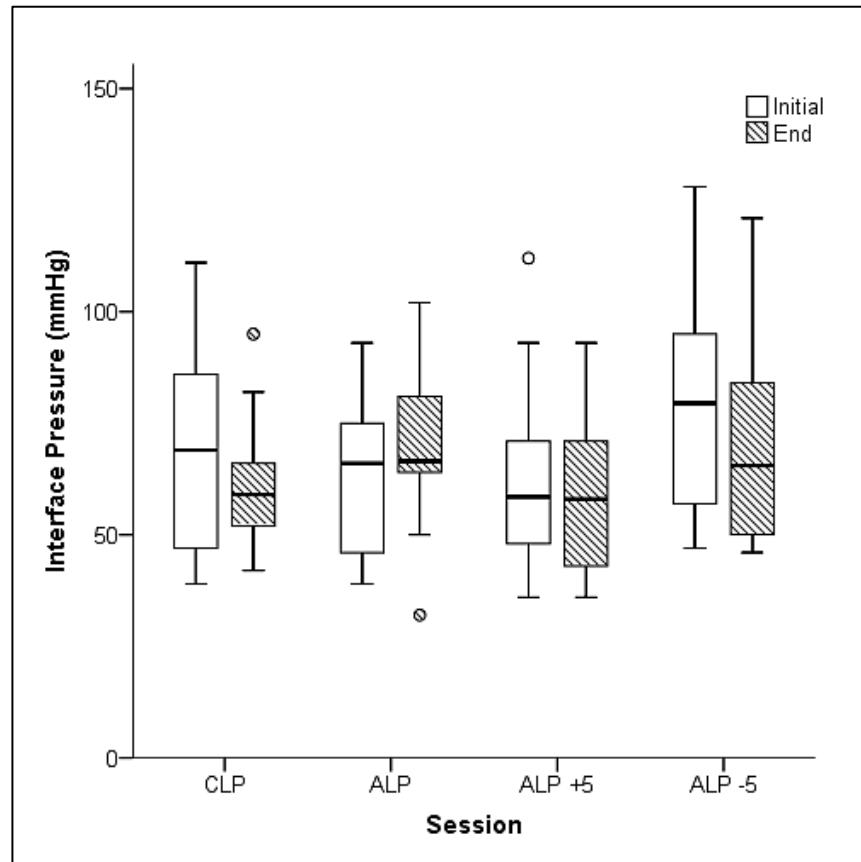


Figure 5-8: Boxplot of the initial and end sacral interface pressures obtained during each measurement session.

### 5.2.5 Comfort Assessment

Table 5-7 shows the results from questions 3, 5, 6, 10, 12 and 13 (Appendix E) for both CLP and ALP sessions. These results indicate that overall perceived comfort was high while LPR turning was inactive (question 3, Appendix E). Additionally, participants were generally satisfied with the mattress' ability to provide support (question 5, Appendix E), during both the CLP and ALP sessions, although ratings associated with ALP were slightly lower. Perceived comfort and support often decreased when the LPR feature was activated (question 10 and 12, Appendix E), with this trend particularly noticeable with the CLP sessions. Furthermore, when compared to the corresponding supine phase, a trend towards a decreased perception of stability is evident while the LPR feature was active (question 6 and 13, Appendix E), during both the CLP and ALP sessions.

## Evaluation of a Prototype Support Surface

Table 5-7: Comfort assessment results for CLP and ALP sessions, while the LPR feature was inactive and active. Ratings are expressed in percentages and have been aggregated for simplicity.

Session	LPR Feature	Rating	Comfort	Support	Stability
CLP	Inactive	Extremely satisfied/ Very satisfied	67%	100%	100%
		Somewhat satisfied/ Neutral/ Somewhat dissatisfied	33%	-	-
		Very dissatisfied/ Extremely dissatisfied	-	-	-
ALP	Inactive	Extremely satisfied/ Very satisfied	86%	71%	71%
		Somewhat satisfied/ Neutral/ Somewhat dissatisfied	14%	29%	29%
		Very dissatisfied/ Extremely dissatisfied	-	-	-
CLP	Active	Extremely satisfied/ Very satisfied	20%	60%	-
		Somewhat satisfied/ Neutral/ Somewhat dissatisfied	80%	40%	40%
		Very dissatisfied/ Extremely dissatisfied	-	-	60%
ALP	Active	Extremely satisfied/ Very satisfied	60%	80%	-
		Somewhat satisfied/ Neutral/ Somewhat dissatisfied	40%	20%	80%
		Very dissatisfied/ Extremely dissatisfied	-	-	20%

Feedback regarding the firmness of the mattress indicated that participants were generally content, with responses ranging from 'somewhat soft' to 'somewhat firm'. Combined responses while the LPR feature was active and inactive, during both CLP and ALP modes, revealed that in 55% (11/20) of cases, the participants felt that the mattress firmness was 'just right' (questions 4 and 11, Appendix E). Responses indicating that the mattress was 'somewhat soft' were exclusively found during the ALP session, with this response observed during both active and inactive LPR periods.

Question 7 and 14, detailed in Appendix E, examined the comfort with respect to various body sites. However, examination of this data revealed few trends across the test conditions (CLP/ ALP, LPR active/ inactive), or body sites, with the majority of ratings ranging from 'very comfortable' to 'neutral'. Nevertheless, 'extremely comfortable' ratings were more frequently observed during the inactive LPR phases (CLP and ALP), as compared to the corresponding active phases, and perceived comfort was greatest at the legs and feet. At this site, the number of 'extremely comfortable' and 'very comfortable' responses ranged from 62-75%, over the four test conditions. Examination of the comfort ratings associated with the left and right shoulder, and left and right buttocks, revealed that 68% of participants assigned identical ratings to these respective sites, throughout each of the test conditions. Similarly, comfort scores associated with the upper, middle and lower back were found to vary little in a given phase (CLP/ ALP, LPR active/ inactive).

### 5.3 Discussion

This study was designed to examine the efficacy and acceptability of a prototype support surface which incorporated a lateral rotation feature, across a range of different therapeutic modes and internal air pressures. The test protocol and the objective measures of tissue viability that were utilised in this study generally proved appropriate in enabling comparisons between the features of the prototype support surface.

Transcutaneous gas tension data revealed that participants frequently exhibited a similar response pattern, across all modes and internal air pressures. Indeed, no statistically significant differences in gas tensions were observed at the sacrum or shoulder when the results at each of the respective sites were compared over the CLP, ALP and ALP at  $IP_{opt} \pm 5\text{mmHg}$  sessions, with sacral oxygen tensions generally high across all test conditions. Comparison of the peak interface pressures associated with each of the sessions did not reveal any statistically significant differences across sessions, although a trend towards higher peak pressures was observed during the ALP at  $IP_{opt} - 5\text{mmHg}$  session (Table 5-6 and Figure 5-8). Variation of the internal air pressure in the support surface did not appear to have a pronounced effect on the selected measures of tissue viability, despite the fact that the  $\pm 5\text{mmHg}$  parameters resulted in changes which represented a 28-38% increase or reduction from the  $IP_{opt}$  values.

Overall, these findings suggest that the LPR feature was effective at maintaining tissue viability at the sacrum in the majority of participants. However, in a number of cases, participants exhibited a marked reduction in  $TcPO_2$  levels, with or without an associated increase in  $TcPCO_2$ . In these cases, the LPR turn positions did not evoke a recovery to basal gas tensions (Tables 5-4 and 5-5). As the objective of conventional repositioning is to enable the recovery of previously loaded tissues, this finding suggests that turning by means of the LPR function may not be as effective as manual repositioning, although the short duration of the turn cycle could have affected these results.

The comfort assessment was found to be a useful adjunct to assess the acceptability of the prototype device, which is a vital consideration if such a system is to be successfully employed in the clinical setting with patients. The present results indicate that the support surface was generally deemed comfortable and supportive during both the CLP and ALP sessions. Nevertheless, during the ALP sessions a number of participants indicated that the mattress was 'somewhat soft'. This may be due to the

cyclical cell deflation at the sacral region, resulting in a perception of sinking into the mattress, often termed 'bottoming out', as was observed in a RCT investigating replacement APAMs versus overlay APAMs (Nixon et al. 2006).

A reduction in both the comfort and support ratings was observed when the LPR feature was active and a number of participants reported feeling unstable during the turn phases of both the CLP and ALP sessions. However, the statistical significance of these results could not be determined, as the point at which the comfort assessment was administered was not standardised and therefore individual responses could relate to different therapeutic modes and positions of the turn cycle. Participant feedback further indicated that certain questions were ambiguous in nature, particularly questions 6 and 13 (Appendix E), which assessed the ability of the mattress to prevent participants from feeling tilted or rotated.

## 5.4 Summary, Conclusion and Future Work

The present study established that:

- The objective measures of tissue viability were effective in enabling comparisons between the features of a prototype support surface;
- The comfort assessment proved successful in identifying differences between the settings of the prototype support surface, however, some of the items contained in this assessment needed to be rephrased to improve clarity;
- The sacral physiological response exhibited by participants was often similar across the various mattress modes and internal cell settings, although a trend towards higher  $TcPO_2$  levels was observed during the ALP at  $IP_{opt} -5mmHg$  session, while peak sacral pressures were generally higher during this session;
- A small number of participants experienced compromised gas tension throughout the majority of sessions, which did not appear to recover following LPR-induced turning;
- The comfort and support ratings declined during the LPR turn phases.

When considering the research questions of this study (Chapter 5), it can be concluded that LPR turning was effective at maintaining tissue viability for the majority of participants. The CLP and ALP settings were further found to be equally effective in maintaining tissue viability at the sacrum of participants. Variation in the internal air pressure did not have a marked effect on the selected measures of tissue viability, although higher  $TcPO_2$  levels were observed during the ALP at  $IP_{opt} -5mmHg$  session,

## Evaluation of a Prototype Support Surface

which was associated higher peak sacral pressures. The comfort ratings indicated that participants were generally comfortable on the support surface, but comfort and stability ratings declined when the LPR function was activated. Differences in comfort scores were observed between the ALP and CLP settings, although the statistical significance of these results could not be ascertained.

To further examine the prototype support surface, a subsequent study was conducted, which has been presented in Chapter 6. This extended the present work by comparing turning by means of the prototype support surface to manual repositioning, as undertaken in clinical practice, using the 30° side-lying position (Section 4.3.2). To more closely reflect clinical practice, the turn interval was further extended in this study, and the apparent limitations of the comfort assessment were addressed.

## **Chapter 6: Comparison of the Lateral Rotation Function of a Prototype Support Surface to Conventional Repositioning**

The efficacy and acceptability of a prototype support surface incorporating an automated lateral rotation function has been examined in a previous study, as discussed in Chapter 5. Although the results of this study indicated that the prototype device was effective at maintaining tissue viability at the sacrum and was generally perceived to be comfortable, a comparison with manual repositioning as undertaken in clinical practice was not performed. Indeed, there is a paucity of research comparing turning by means of lateral rotation to conventional repositioning, despite the fact that such devices have been available for many decades (Norton et al. 1962). While Melland and colleagues (1999) assessed comfort and dependence on caregivers to aid with repositioning at study inception, prospective data pertaining to conventional repositioning was not collected. In contrast, a more recent study incorporated a control period during which time participants received standard repositioning, however, the technique and frequency of this intervention were not reported (Futamura et al. 2008).

Therefore, the present study was designed to compare turning by means of an automated lateral rotation system to manual repositioning using the 30° side-lying position, as recommended in current guidelines (NPUAP, EPUAP and PPPIA 2014b). Additionally, it examined the ability of the automated system to partially offload the sacrum, an area at high risk of PU development in bedbound patients (Vanderwee et al. 2007a).

Specific research questions were defined as follows:

- I. Are the turning processes provided by the LPR function of the prototype system, and repositioning by means of the 30° side-lying position, equally effective at maintaining tissue viability, as reflected in both physiological and biomechanical factors recorded in healthy participants?
- II. Does perceived comfort of participants differ between turning using the prototype system and manual repositioning?
- III. Is the LPR feature able to partially offload the sacrum of participants?

## 6.1 Materials and Methods

### 6.1.1 Prototype Support Surface

The support surface utilised in this study was a prototype mattress (model P500 MRS INT'L mattress, Hill-Rom, Montpellier, France), which has previously been described in Section 5.1.1. The ALP therapeutic mode was utilised for all data collection sessions. The  $IP_{opt}$  was ascertained for each participant (Equation 5-1), and the internal pressure of the mattress was adjusted accordingly, using the system software. During the LPR turning protocols, the maximum turn angles permitted by the software were prescribed.

A major change from the prescribed protocol in Chapter 5 involved the turn frequency, which was extended from 3 to 15 minutes, the latter period more closely resembling clinical practice. The revised turn frequency was such that the total data collection period did not exceed 120 minutes, a period considered appropriate for individual participants. Furthermore, Kim and colleagues (2012) have recently suggested that a continuous 10-minute period of loading may provide a reliable indication of tissue health, as measured by transcutaneous oxygen tensions ( $TcPO_2$ ) and interface pressures. Accordingly, in the present study, it may be anticipated that a 15-minute cycle time provides sufficient time for tissue gas tension responses, resulting from positional changes, to fully develop.

### 6.1.2 Manual Repositioning Technique

During the manual repositioning protocol, participants were repositioned using the 30° side-lying position (Section 4.3.2). Postures were maintained with pillow support at the level of the thoracic and lumbar spine, to achieve an approximate 30° elevation angle at the pelvis (Wilson 2008; Moore & Cowman 2012). The sacral area was carefully palpated, to check offloading of this area (Preston 1988). Pillows were further placed lengthways under the legs, with the heels 'floating', as recommended in current guidelines (NPUAP, EPUAP and PPPIA 2014a). Figure 6-1 demonstrates that the resulting position was similar to that previously depicted in Figure 4-5. Prior to commencing data collection, advice was sought from clinical experts, to ensure that the manner of repositioning was comparable to repositioning in clinical practice. A timer was utilised to measure 15-minute periods, after which pillows were positioned or removed, as appropriate.



Figure 6-1: Example of manual repositioning to a right tilt position, with the individual supported by pillows.

### 6.1.3 Transcutaneous Gas Tension Measurement

Transcutaneous gas tensions were recorded at the sacrum and right shoulder for both the LPR and manual repositioning sessions. Electrode temperature, preparation and transcutaneous gas tension data logging were identical to that described in Section 5.1.2.

To ascertain the ability of the LPR function to partially offload the sacrum of individual participants, a third data collection session was performed, during which the two electrodes were positioned at the level of the sacrum, approximately 15mm away from the medial line. This was designated the bilateral sacrum session.

### 6.1.4 Interface Pressure Measurements

Interface pressures were measured using the Talley Pressure Monitor (TPM3, Talley Medical, Romsey, UK), using the pressure sensor configuration previously described in Section 5.1.3. During the manual repositioning protocol, the 12 sensor array associated with the shoulder region was placed over the pillows during the right tilt position, to ensure direct contact with participants' body. This sensor array was omitted during the

## Comparison of Lateral Rotation to Conventional Repositioning

third data collection session of the present study, and thus a total of 84 pressure sensors were utilised.

### **6.1.5 Inclinometer Measurements**

In order to ascertain the magnitude of turning that was associated with the different turning processes, inclinometer measurements were obtained using a handheld device (SOAR, Digital Levelmeter 1700). The device measured the angle rotation from the horizontal, with a resolution of 0.5°. These measurements were taken by situating the device centrally over the supine body, and were recorded at the sternum, pelvic and ankle levels. Measurements were obtained during both the right tilt and left tilt positions of the LPR and manual repositioning protocols.

### **6.1.6 Comfort Assessment**

The comfort assessment was simplified from the earlier study to improve the clarity of questions, and the response format was altered to a 5-point scale, since few respondents in the previous study had utilised descriptors at the extreme ends of the scale (Chapter 5). Furthermore, as the previous results indicated that there was little variation between the ratings assigned to the left and right shoulder, the left and right buttock, or the upper, middle and lower back, the present study assessed comfort at four sites only, namely the shoulder, back, buttocks and legs and feet. The resulting assessment, detailed in Appendix G, was performed during the first tilted position and the subsequent supine period of both the LPR and manual repositioning sessions.

### **6.1.7 Study Protocol and Data Collection Process**

Ethics approval had previously been granted (FoHS-ETHICS-978). Participants that consented to take part were asked to participate in the LPR turning and manual repositioning sessions, or the LPR, manual repositioning and bilateral sacrum sessions, with every data collection session separated by an approximate 7-day period. The participant recruitment strategy and the inclusion and exclusion criteria were identical to those presented in Section 5.1.6. The full participant information sheet for the present study is included in Appendix H.

Participant preparation was identical to the process described in Section 5.1.6. Once gas tensions stabilised, typically over a period of 20 minutes, participants were again carefully positioned in a supine position on the prototype mattress which, for all data

## Comparison of Lateral Rotation to Conventional Repositioning

collection sessions, was set to the ALP therapeutic mode. The first of three interface pressure measurements, each consisting of 3 cycles of data, was then recorded. Subsequently, LPR turning or manual repositioning commenced and each phase was flagged using the trigger. Transcutaneous gas tensions were recorded for one complete turn cycle (right tilt, supine, left tilt and supine). Two cycles of interface pressures were repeated after five minutes in each distinct phase, namely the right tilt and the left tilt. This test process is depicted in Figure 6-3.

Similarly, data collection in the bilateral sacrum session comprised both physiological and biomechanical measurements. However, inclinometer measurements were omitted and the comfort assessment was not administered, since data pertaining to both these instruments had previously been collected during the LPR turning session. Additionally, the initial period during which the first interface pressure was measured, was extended to 15 minutes, measured by means of a timer, and the LPR function was enabled following this. Thus the sequence of the positions assessed during this protocol was supine, right tilt, supine, left tilt, and a final supine position, as is shown in Figure 6-2.

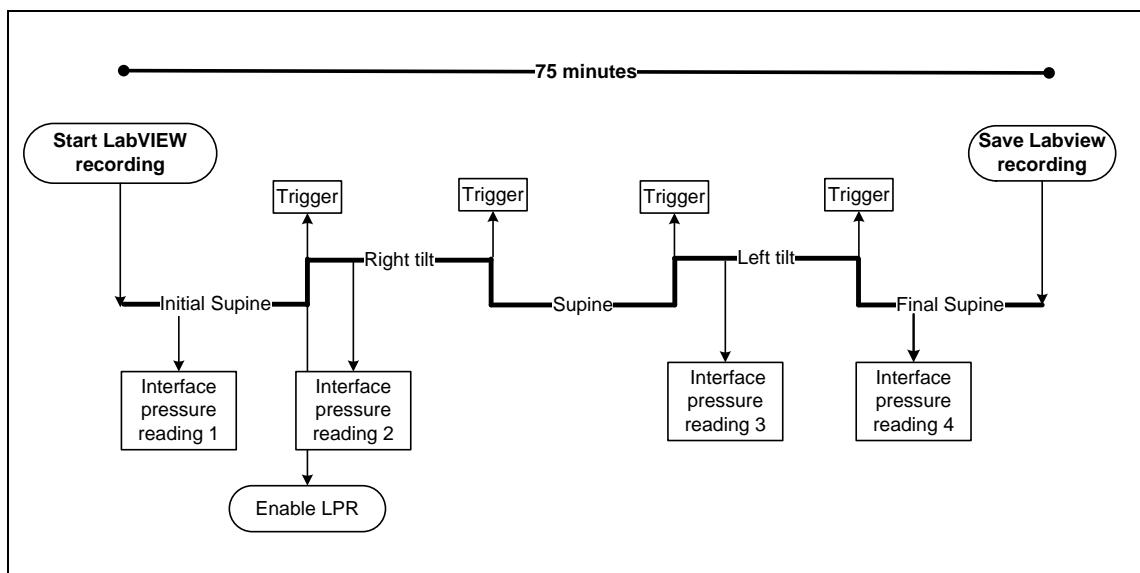


Figure 6-2: Data collection process for the bilateral sacrum session.

## Comparison of Lateral Rotation to Conventional Repositioning

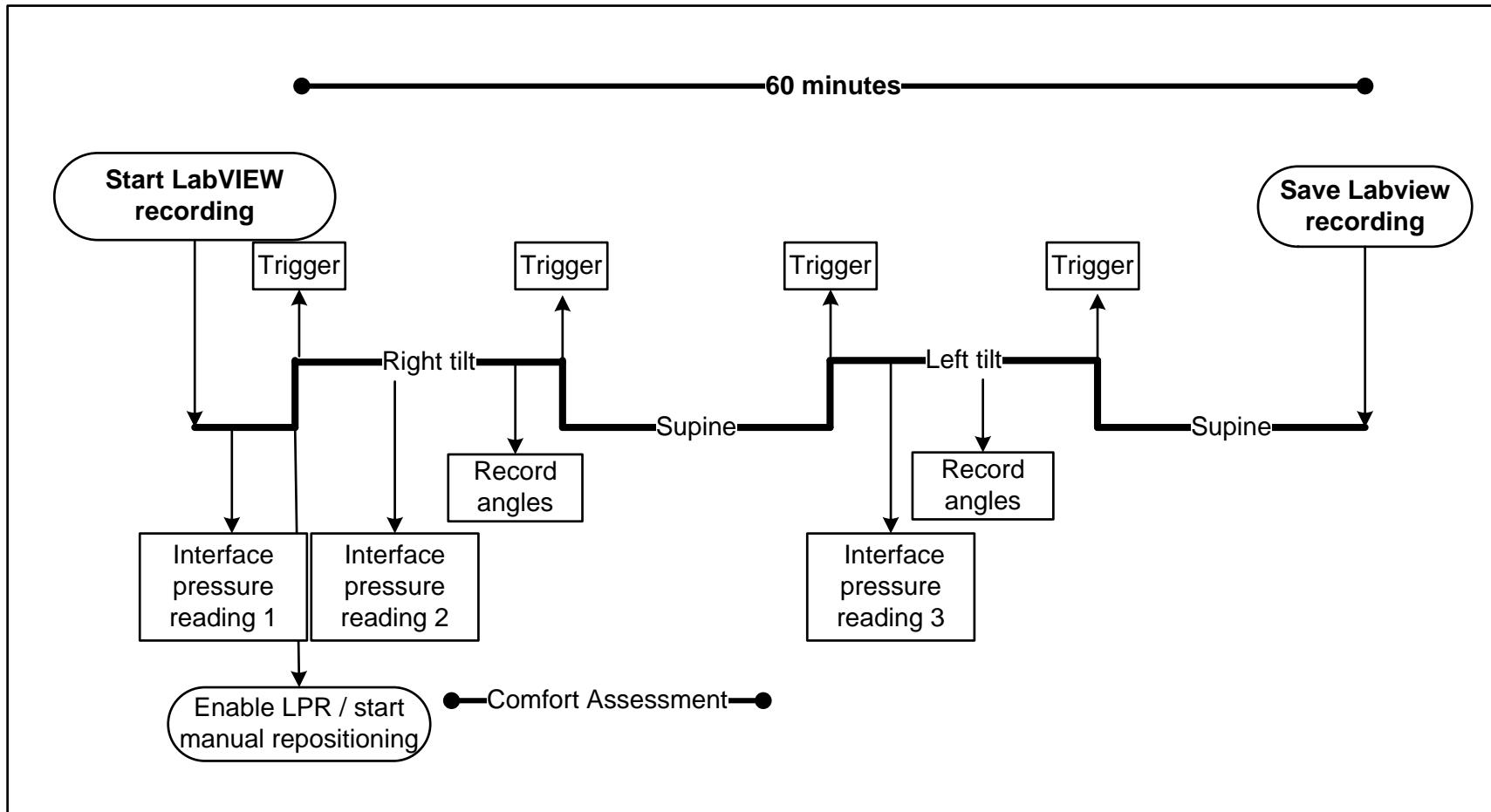


Figure 6-3: Data collection process for the LPR and manual repositioning sessions.

### 6.1.8 Data Processing and Analysis

Transcutaneous gas tension and interface pressure data were processed in the manner described in Section 5.1.7. Inclinometer data was collected using Microsoft Excel (Microsoft Office Professional Plus 2010, USA). The manner in which preliminary statistical analysis and significance testing was undertaken was further identical to that detailed in Section 5.1.7.

For the present study peak pressures, described previously in Section 5.1.7, were again utilised to analyse interface pressures, while the Chai and Bader (2013) responses were used to categorise the transcutaneous gas tension data pertaining to each position of every protocol. The categories presented in this chapter indicate the category that was most prevalent over the 15-minute period. In addition, transcutaneous gas tensions were assessed using parameters defined as oxygen debt and carbon dioxide accumulation, in a similar manner to those described by Rithalia and Gonsalkorale (2000). These parameters are illustrated in Figure 6-4. To facilitate comparison between protocols the resulting values were subsequently normalised to baseline levels, and thus the final values were derived using the equations shown in Equation 6-1 and 6-2. The relationship between these two variables was further examined by means of (bivariate) linear regression, following visual inspection of the scatter plots, to confirm linearity, and confirmation of normality and homoscedasticity of residuals (Rovay et al. 2014).

$$\text{Total oxygen debt} = \int_0^{t1} \frac{(TcPO_2 t - TcPO_2 \text{ baseline})}{TcPO_2 \text{ baseline}} \quad t1 = \text{Period of each position}$$

Equation 6-1

$$\text{Total carbon dioxide accumulation} = \int_0^{t1} \frac{(TcPCO_2 t - TcPCO_2 \text{ baseline})}{TcPCO_2 \text{ baseline}} \quad t1 = \text{Period of each position}$$

Equation 6-2

## Comparison of Lateral Rotation to Conventional Repositioning

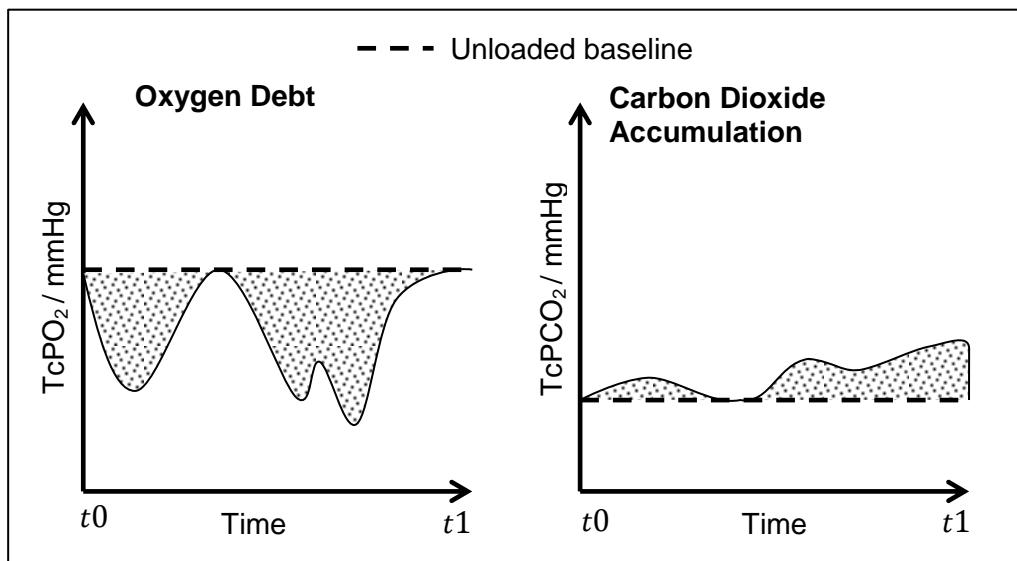


Figure 6-4: Schematic of oxygen debt and carbon dioxide accumulation over the data collection period. The shaded areas represent the parameters of interest, namely the residual  $TcPO_2$ /  $TcPCO_2$  values, above or below the initial unloaded basal value.

## 6.2 Results

### 6.2.1 Participants

Ten participants were recruited, and each completed the LPR turning and manual repositioning sessions. Of these 7 were male and 3 female, with ages ranging from 23-66 years. Four of these participants also consented to take part in the subsequent bilateral sacrum session. Their demographic details are summarised in table 6-1.

Table 6-1: Participant demographics.

Participants	Sex	Age	Height (m)	Weight (kg)	BMI (kg/m <sup>2</sup> )	IP <sub>opt</sub> †† (mmHg)
A †	Male	60	1.92	93	25.2	14.9
B †	Male	27	1.75	86	28.1	15.8
C	Female	25	1.58	86	34.4	17.9
D	Male	23	1.83	69	20.6	13.3
E †	Male	33	1.91	78	21.4	13.6
F	Female	33	1.71	64	21.9	13.8
G †	Male	66	1.68	81	28.7	16.0
H	Male	52	1.71	82	28.0	15.8
I	Male	25	1.87	90	25.7	15.0
J	Female	62	1.51	57	25.0	14.8

† Indicates participants that completed the bilateral sacrum session. †† Based on Chai and Bader (2013).

## Comparison of Lateral Rotation to Conventional Repositioning

### 6.2.2 Turn Angle Measurements

The median and range of turn angles for the LPR and manual repositioning sessions are detailed in Table 6-2, with Figures 6-5 and 6-6 further illustrating the distribution of data. When data from all sites are examined, it can be observed that turn angles progressively reduced from sternum to ankles, during both the right and left tilt of the LPR and manual repositioning sessions. Comparison of the median turn angles associated with each of the LPR turn positions reveals a trend of greater angles associated with the right tilt position. By contrast, turn angles associated with the manual right and left tilt positions appear to be more consistent across the two positions.

Table 6-2: Summary of the median and range of turn angle measurements (degrees) in the three body locations during the right tilt and left tilt positions of the LPR turning and manual repositioning protocols.

		<b>Sternum</b>	<b>Pelvis</b>	<b>Ankles</b>
<b>LPR Turning</b>	Right tilt	23.3 (15.5-30.0)	17.3 (9.5-24.5)	8.8 (5.0-16.0)
	Left tilt	16.5 (11.0-28.5)	11.8 (7.5-19.5)	8.0 (1.0-13.0)
<b>Manual Repositioning</b>	Right tilt	30.3 (19.5-40.5)	23.0 (14.5-31.5)	3.8 (0.5-17.0)
	Left tilt	30.3 (22.0-42.0)	28.3 (12.5-31.5)	2.3 (0.5-7.5)

At the sternum and pelvis, turn angles were generally greater during the manual repositioning session, with median differences of 7.0° (right tilt) and 13.8° (left tilt), and 5.7° (right tilt) and 16.5° (left tilt), at the respective sites. In contrast, at the ankles turn angles were greater during LPR turning with a median difference of 5.0° during the right tilt and 5.7° during the left tilt position.

The turn angles obtained from the three sites during the tilted positions were compared using the Wilcoxon signed-ranks test. This revealed that the differences between the protocols were not statistically significant at any of the sites during the right tilt position. However, examination of the turn angles associated with the left tilt position revealed that manual repositioning yielded values that differed significantly from those observed during LPR turning, at each of the three sites ( $p<0.05$  in all cases).

## Comparison of Lateral Rotation to Conventional Repositioning

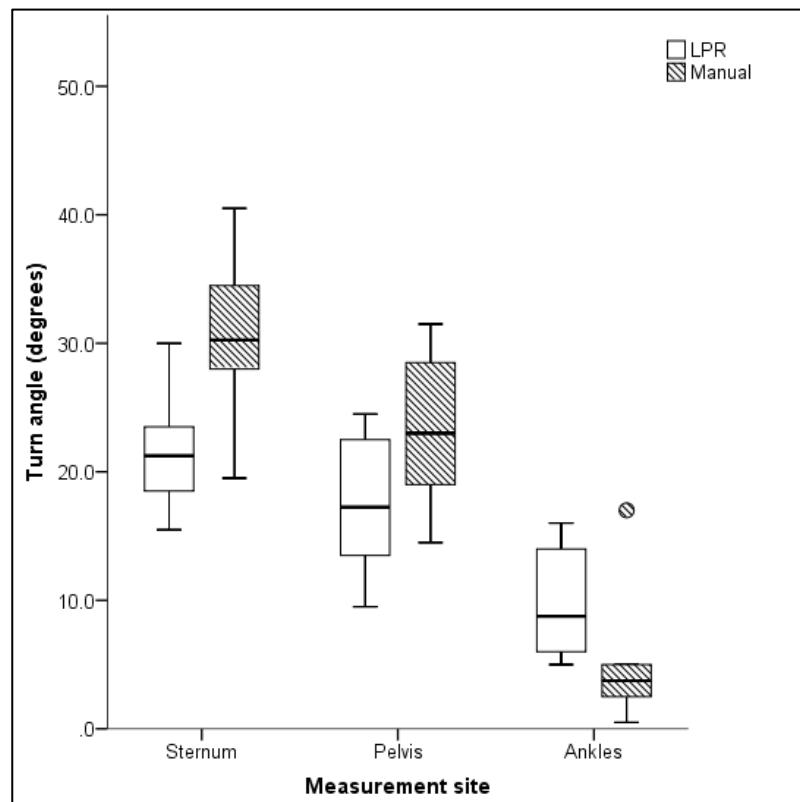


Figure 6-5: Boxplot showing the turn angles obtained during the right tilt position of the LPR turning and manual repositioning protocols.

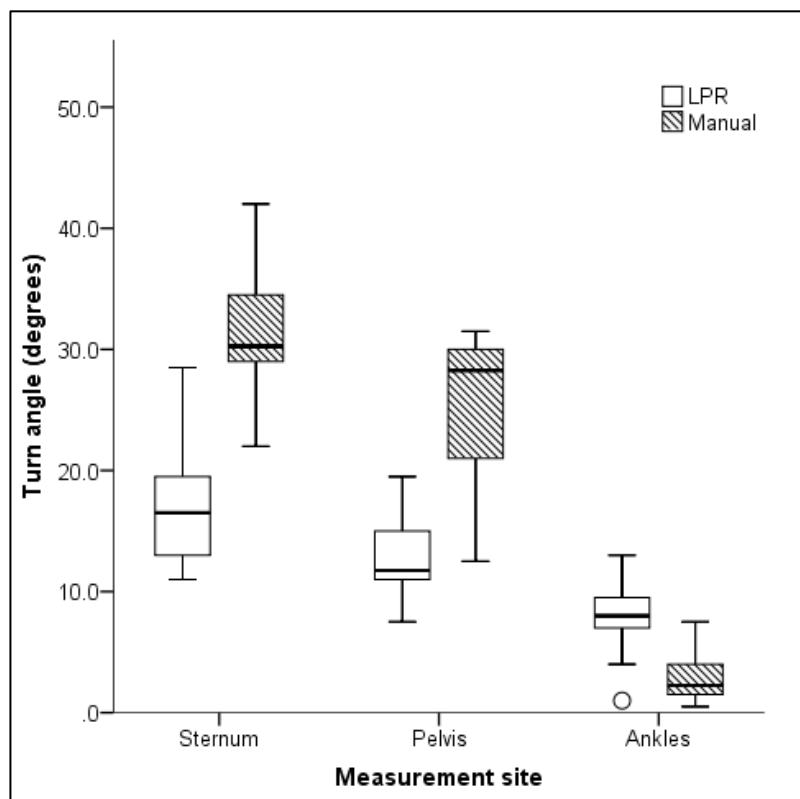


Figure 6-6: Boxplot showing the turn angles obtained during the left tilt position of the LPR turning and manual repositioning protocols.

### **6.2.3 Transcutaneous Gas Tension Categories during LPR Turning and Manual Repositioning**

The transcutaneous gas tension categorical responses at the sacrum and shoulder, as defined by Chai and Bader (2013), are shown in Table 6-3 and 6-4, respectively. As indicated in Table 6-3 the changes in  $TcPO_2$  and  $TcPCO_2$  were generally minimal, with 5 participants exhibiting a category 1 response throughout the turn cycles of both the LPR turning and manual repositioning sessions. However, this was not the case at the shoulder, where only one 1 participant consistently exhibited a category 1 response throughout both protocols, namely participant C (Table 6-4).

It is evident from Tables 6-3 and 6-4 that the category for any given position of the LPR turning protocol was generally consistent with that observed in the identical position of the manual repositioning protocol. Indeed, at the sacrum, an identical category was observed in 60% of cases, and, at the shoulder, this occurred in 55% of cases.

Accordingly, the Wilcoxon signed-ranks test revealed no significant differences at either the sacrum or the shoulder, when the categories associated with each position of the LPR and manual repositioning sessions were compared. Moreover, of the remaining cases, the responses differed by more than one category (category 1 to category 3 and vice versa) in only 10% and 20% of cases for the sacrum and shoulder, respectively.

Comparison of Lateral Rotation to Conventional Repositioning

Table 6-3: Categorical responses of gas tensions at the sacrum during each turn position of the LPR turning and manual repositioning sessions.

Participant	Right tilt		Supine		Left tilt		Final Supine	
	LPR	Manual	LPR	Manual	LPR	Manual	LPR	Manual
A	Category 2	Category 1	Category 2	Category 1	Category 2	Category 1	Category 2	Category 1
B	Category 1	Category 2	Category 1	Category 2	Category 1	Category 2	Category 1	Category 2
C	Category 1	Category 1						
D	Category 3	Category 1	Category 3	Category 1	Category 3	Category 1	Category 3	Category 1
E	Category 3	Category 2	Category 2	Category 1	Category 3	Category 2	Category 2	Category 2
F	Category 1	Category 1						
G	Category 1	Category 1						
H	Category 1	Category 1	Category 2	Category 1	Category 1	Category 1	Category 1	Category 1
I	Category 1	Category 1						
J	Category 1	Category 1						

## Comparison of Lateral Rotation to Conventional Repositioning

Table 6-4: Categorical responses of gas tensions at the shoulder during each turn position of the LPR turning and manual repositioning sessions.

	Right tilt		Supine		Left tilt		Final Supine	
Participant	LPR	Manual	LPR	Manual	LPR	Manual	LPR	Manual
A	Category 1	Category 1	Category 1	Category 2	Category 3	Category 3	Category 1	Category 3
B	Category 3	Category 1	Category 3	Category 3	Category 3	Category 1	Category 3	Category 3
C	Category 1	Category 1						
D	Category 1	Category 1	Category 3	Category 3	Category 1	Category 2	Category 3	Category 2
E	Category 2	Category 1	Category 1	Category 1	Category 3	Category 3	Category 1	Category 3
F	Category 1	Category 3	Category 1	Category 3				
G	Category 2	Category 1	Category 2	Category 1	Category 2	Category 1	Category 2	Category 1
H	Category 1	Category 3	Category 1	Category 1				
I	Category 1	Category 1	Category 1	Category 1	Category 2	Category 2	Category 1	Category 3
J	Category 1	Category 1	Category 1	Category 2	Category 2	Category 2	Category 1	Category 2

The Friedman test was utilised to determine if the response categories differed significantly between the turn positions of a given session (LPR and manual repositioning). It revealed that during LPR turning, the categories did not significantly differ across turn positions, at either the sacrum or shoulder ( $p>0.05$ ). In a similar manner, the stability of sacral responses across the turn positions of the manual repositioning session did not produce any statistically significant differences ( $p>0.05$ ). However, at the shoulder, the Friedman test results indicated that there was a significant difference in the response categories observed across the turn positions of the manual repositioning protocol ( $p<0.01$ ). However, when pairwise comparisons with a Bonferroni correction for multiple comparisons were performed, the revised alpha level of 0.008 meant that the results were not statistically significant.

A summary of the responses for both protocols at each body site is presented in Table 6-5. It reveals a trend towards higher categories at the shoulder during manual repositioning, particularly during the left tilt and final supine positions, when compared to the initial right tilt position. A similar pattern emerges when shoulder responses associated with the LPR right and left tilt positions are examined. Indeed, on a few occasions a significant increase in  $TcPCO_2$ , with an accompanying reduction in  $TcPO_2$  (category 3), was observed during the left tilt position, which was associated with discomfort at the measurement site. When this occurred the shoulder was offloaded for a brief period, as is depicted in Figures 6-7 to 6-9. The need for such manoeuvres occurred exclusively during the LPR session.

Table 6-5: Summary of the categorical responses from all participants, separated by site, protocol and position (%).

Turn Mechanism	Category	Position			
		Right tilt	Supine	Left tilt	Final Supine
Sacrum	LPR	Cat. 1	70%	60%	70%
		Cat. 2	10%	30%	10%
		Cat. 3	20%	10%	20%
	Manual	Cat. 1	80%	90%	80%
		Cat. 2	20%	10%	20%
		Cat. 3	0%	0%	0%
Shoulder	LPR	Cat. 1	70%	70%	40%
		Cat. 2	20%	10%	30%
		Cat. 3	10%	20%	30%
	Manual	Cat. 1	100%	60%	30%
		Cat. 2	0%	20%	30%
		Cat. 3	0%	20%	40%
					50%

## Comparison of Lateral Rotation to Conventional Repositioning

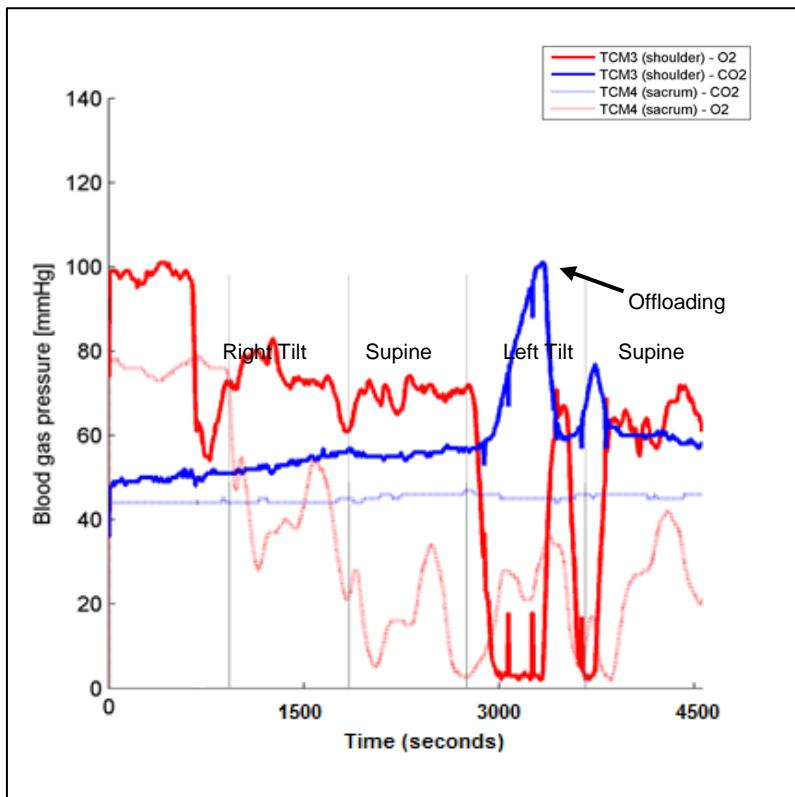


Figure 6-7: Gas tension results from participant A during the LPR session. The shoulder was temporarily offloaded (right arm raised and placed across the chest) during the left tilt position as a significant rise in TcPCO<sub>2</sub> occurred, which was associated with localised discomfort.

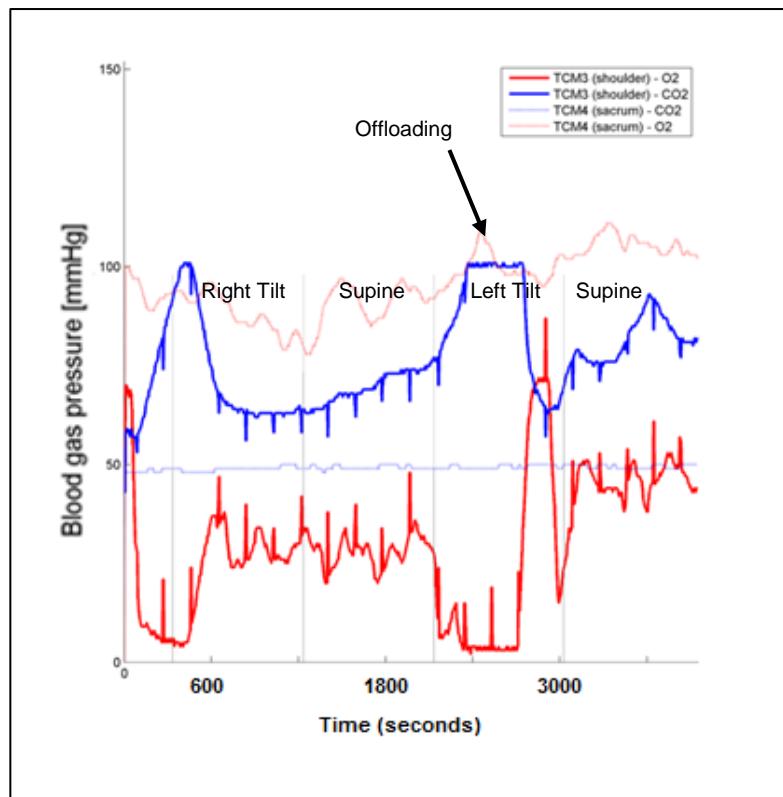


Figure 6-8: Gas tension results from participant B during the LPR session. The shoulder was temporarily offloaded (right arm raised and placed across the chest) during the left tilt position as a significant rise in TcPCO<sub>2</sub> occurred, which was associated with localised discomfort.

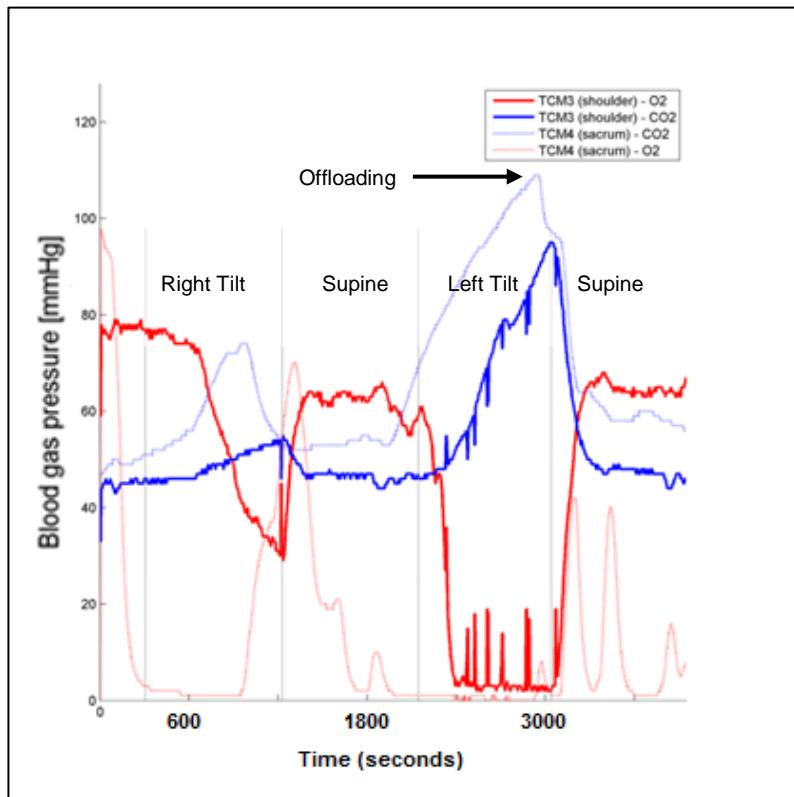


Figure 6-9: Gas tension results from participant E during the LPR session. Both the shoulder and sacrum were offloaded during the left tilt position, by means of a slight lateral tilt, until repositioning as a result of the LPR function occurred.

This trend towards higher categories during the latter stages of both the LPR and manual repositioning sessions may be attributed to the placement of the transcutaneous gas tension electrode at the right shoulder, an area which was directly loaded during the left tilt position.

With reference to the sacrum, during the turn positions of the manual repositioning protocol (right tilt, left tilt), the sacral area was assumed to be free from contact with the mattress and, as such, it was anticipated that this would result in sacral  $T_cPO_2$  values close to baseline, as typified by a category 1 response. However, for two participants (B and E) a category 2 response was observed during the majority of the monitoring period (Table 6-3), indicating that, for these participants, manual repositioning proved ineffective in totally removing contact at the sacrum. Similarly, during the LPR protocol participants A and D exhibited a category 2 and 3 response, respectively, for the duration of monitoring, indicating that the LPR turning function, designed to periodically redistribute support pressures, had a minimal effect on gas tensions. It is interesting to note that in participant E sacral responses did demonstrate a degree of variation within the LPR turn phases (Figure 6-9). However, in contrast to a turn induced recovery of

## Comparison of Lateral Rotation to Conventional Repositioning

gas tensions, category 3 responses were observed during both LPR turn positions, while category 2 responses were noted during the supine positions.

No clear trends are apparent when the demographic details of participants exhibiting category 2 or 3 responses at the sacrum during either turn session are examined (Table 6-1). Of these, participants D and E each had a low BMI ( $\text{kg}/\text{m}^2$ ), below the sample mean of 25.9, while the BMI of participants A and B was close to (A), or above (B) the sample mean. Nevertheless, category 3 responses were limited to those participants with a relatively low BMI.

Overall, when category 2 and 3 responses were observed at the sacrum, these did not appear to recover as a result of either the LPR function, or manual repositioning. However, the significance of this finding is limited by the small proportion of category 2 or 3 responses observed at the sacrum, with 60% participants exhibiting category 1 response throughout the majority of both protocols.

### **6.2.4 Oxygen Debt and Carbon Dioxide Accumulation Associated with LPR Turning and Manual Repositioning**

The oxygen debt and carbon dioxide accumulation parameters were ascertained for each participant, using Equations 6-1 and 6-2. The two parameters, measured over the entire duration of the turn cycle of both sessions, are shown in Figures 6-10 and 6-11. These figures reveal that the oxygen debt and carbon dioxide accumulation at the sacrum were relatively low during the manual repositioning session, when compared to the values observed at the shoulder, broadly supporting the previous findings (Tables 6-3 to 6-5). Comparison between the LPR and manual repositioning sessions demonstrates that oxygen debt at the sacrum was greater during LPR turning, with a corresponding elevation of carbon dioxide accumulation. Figures 6-10 and 6-11 further indicate that the magnitude of the difference between the sacral and shoulder sites, evident in both parameters during manual repositioning, are less pronounced when identical values associated with LPR turning are examined.

Nevertheless, when Wilcoxon signed-ranks tests were utilised to compare participants' total oxygen debt and carbon dioxide accumulation between the turning mechanisms, the differences were not statistically significant, at either the sacrum or the shoulder ( $p>0.05$  in all cases).

## Comparison of Lateral Rotation to Conventional Repositioning

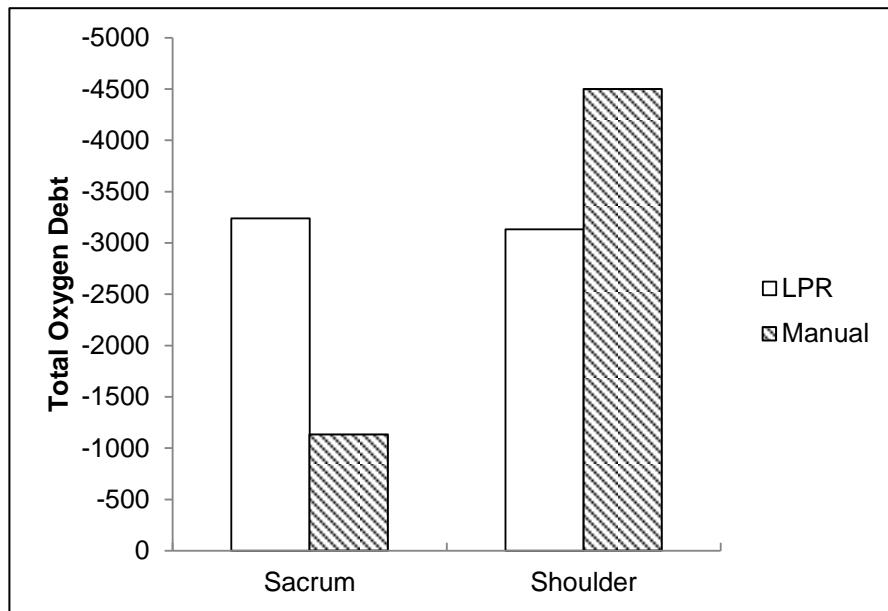


Figure 6-10: Total oxygen debt (all participants) at the sacrum and shoulder, measured over the entire turn cycle of the LPR and manual repositioning sessions.

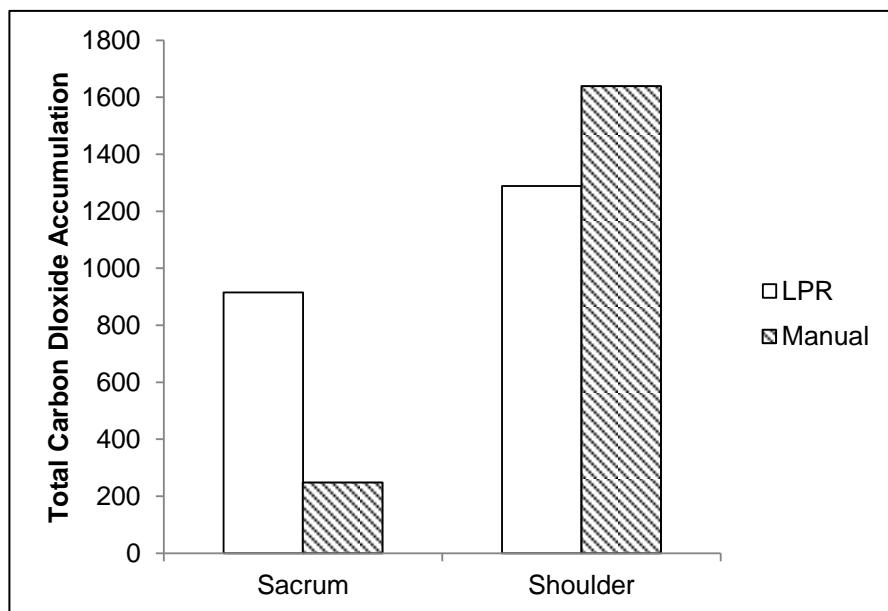


Figure 6-11: Total carbon dioxide accumulation (all participants) at the sacrum and shoulder, measured over the entire turn cycle of the LPR and manual repositioning sessions.

It has previously been established that ischaemic conditions are associated with increasing carbon dioxide levels (Section 2.3). To examine whether this causal relationship was apparent in the current data, linear regression models were applied to the total (entire turn cycle) oxygen debt and carbon dioxide accumulation that was associated with each turning mechanism and measurement site. This established that

## Comparison of Lateral Rotation to Conventional Repositioning

oxygen debt significantly ( $p<0.01$ ) predicted carbon dioxide accumulation at the sacrum during LPR turning (Figure 6-12), where oxygen debt accounted for 67% of the variability (adjusted  $R^2$ ). However, the three remaining linear models were found to be not statistically significant.

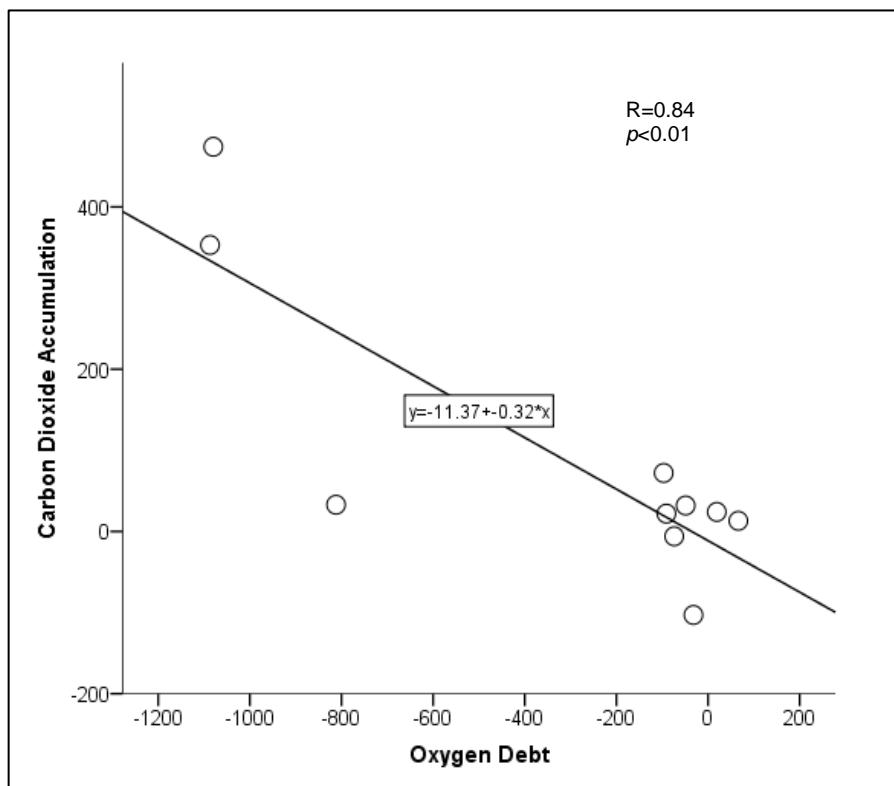


Figure 6-12: Linear model of total sacral oxygen debt and carbon dioxide accumulation, observed during LPR turning. This was found to be significant at the 1% level.

### 6.2.5 Position-specific Oxygen Debt and Carbon Dioxide Accumulation Associated with LPR Turning and Manual Repositioning

The sacral position-specific oxygen debt and carbon dioxide accumulation during both turning protocols are illustrated in Figure 6-13 and 6-14, while shoulder values are shown in Figure 6-15 and 6-16. Consistent with the previously reported results, Figure 6-13 demonstrates that oxygen debt at the sacrum was generally minimal and throughout the turn positions of either session the oxygen debt rarely exceeded 100 (21% of cases). Nevertheless, it is apparent that outlying values more frequently occurred during the LPR protocol, all of which can be attributed to participant A, D and E. By contrast, only participant B consistently experienced oxygen debt values in excess of 100 throughout the turn cycle of the manual repositioning session, as denoted by a response 2 in Table 6-3.

### Comparison of Lateral Rotation to Conventional Repositioning

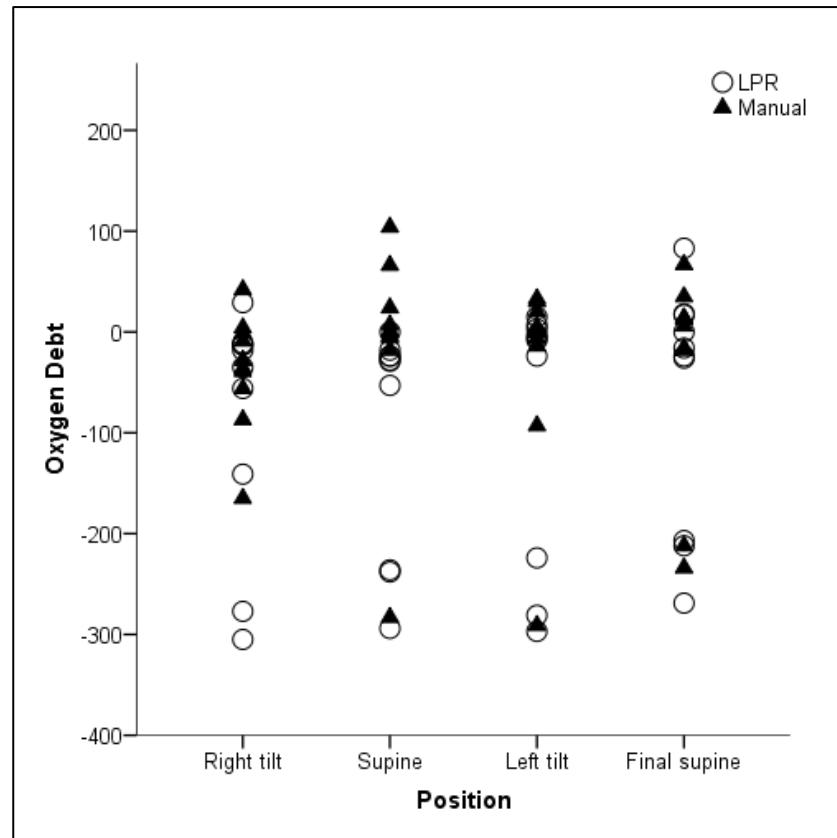


Figure 6-13: Oxygen debt at the sacrum during LPR turning and manual repositioning, separated by position.

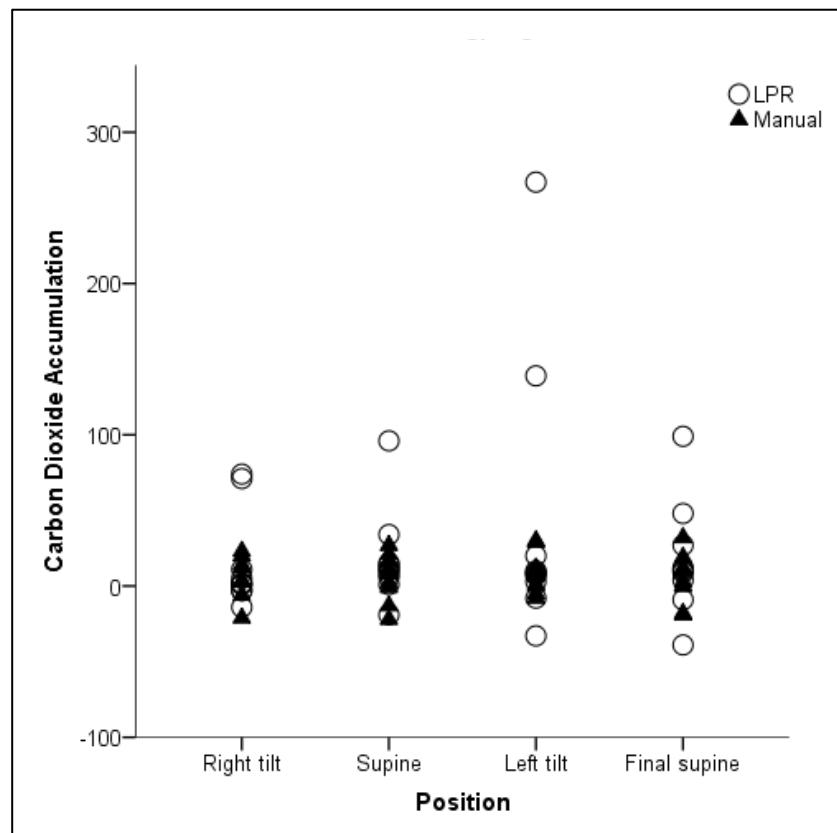


Figure 6-14: Carbon dioxide accumulation at the sacrum during LPR turning and manual repositioning, separated by position.

## Comparison of Lateral Rotation to Conventional Repositioning

The corresponding carbon dioxide accumulation, shown in Figure 6-14, indicates that most values clustered around zero throughout the positions, with only two participants regularly deviating from this, both during LPR turning. These participants, namely D and E, were classified as exhibiting a category 3 response in Table 6-3. Despite these apparent trends, Wilcoxon signed-ranks tests comparing the LPR turning and manual repositioning position-specific sacral values yielded no significant results, in either the oxygen debt, or the carbon dioxide accumulation parameters ( $p>0.05$ ).

Examination of participants' oxygen debt and carbon dioxide accumulation over a given protocol revealed that these tended to vary little between the turn positions. Indeed, group comparisons with Friedman tests did not produce significant results in either protocol ( $p>0.05$ ). Accordingly, the present results, like the previous categorical analysis, do not demonstrate recovering gas tensions at the sacrum during either of the tilt positions of the two protocols.

At the shoulder, oxygen debt and carbon dioxide accumulation during the right tilt position were minimal throughout both protocols for the majority of participants; however, Figure 6-15 and 6-16 demonstrate that during later positions these tended to increase, a pattern which was also evident in the previous categorical analysis (Section 6.2.3). Nevertheless, when comparisons of the positions specific values were made using Friedman tests, the results indicated that oxygen debt did not differ significantly between any of the LPR turning positions. In contrast, post hoc analysis of carbon dioxide accumulation revealed significant differences from the (first) supine position (median 46) to the left tilt position (median 53) ( $p<0.05$ ), although all other pairwise comparisons produced non-significant results. Significant differences between positions were also found during the manual repositioning protocol, in both oxygen debt and carbon dioxide accumulation. However, these occurred between different points of the turn cycle, namely from the right tilt to left tilt positions ( $p<0.01$  for both parameters), and the right tilt to final supine positions (oxygen debt  $p<0.05$ , carbon dioxide accumulation  $p<0.01$ ).

### Comparison of Lateral Rotation to Conventional Repositioning

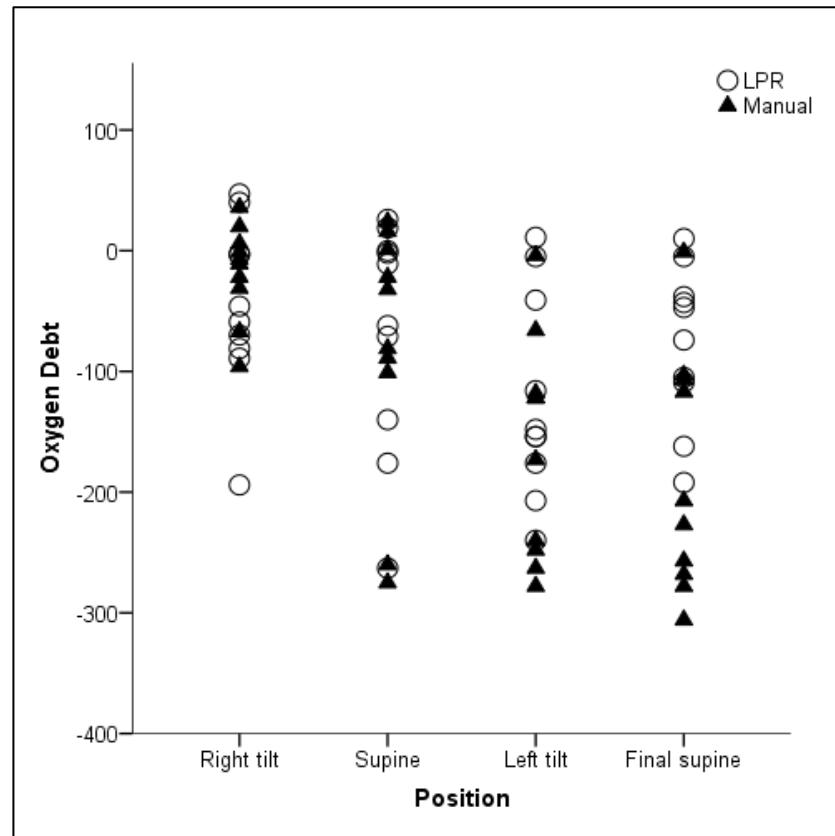


Figure 6-15: Oxygen debt at the shoulder during LPR turning and manual repositioning, separated by position.

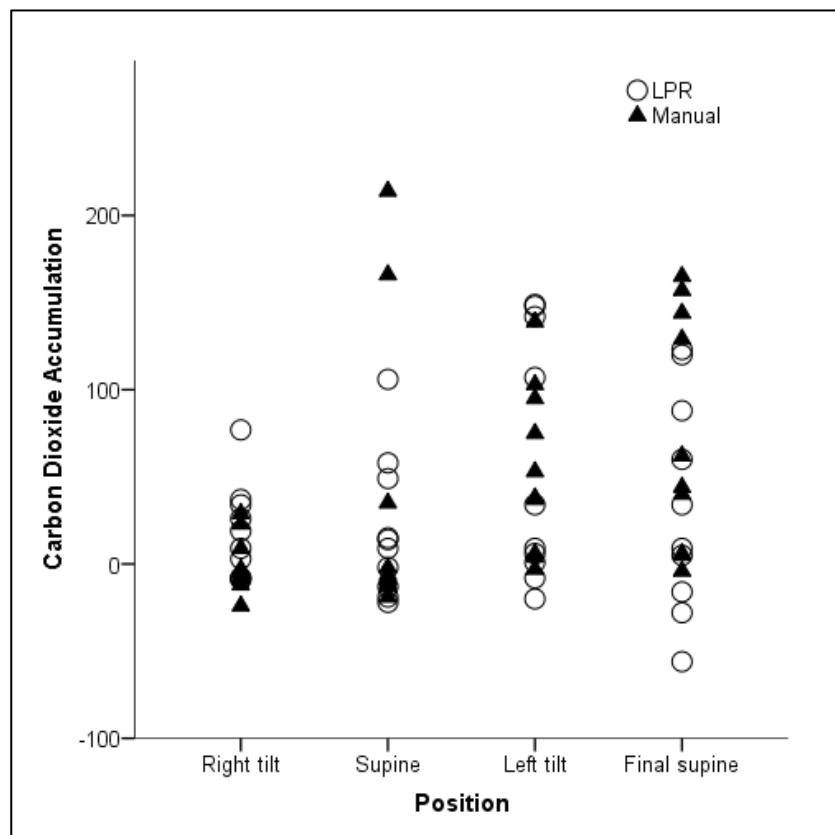


Figure 6-16: Carbon dioxide accumulation at the shoulder during LPR turning and manual repositioning, separated by position.

## Comparison of Lateral Rotation to Conventional Repositioning

Close examination of the individual values associated with the two final positions of the respective protocols demonstrated that during manual repositioning oxygen debt and carbon dioxide accumulation either varied little, or increased during the final supine position. In contrast, a decrease in both parameters was more frequently observed following the final position change during the LPR turning protocol. Indeed, Wilcoxon signed-ranks tests indicated that out of all the positions, oxygen debt during the final supine position produced the only significant difference between the protocols ( $p<0.05$ ).

Combined these results indicate that direct loading at the shoulder during the left tilt position affected oxygen debt and carbon dioxide accumulation, both during the LPR and manual repositioning protocols. However, the effects were more severe during the latter protocol. It may be hypothesised that this is due to higher contact pressures during manual repositioning, since a smaller surface area is in contact with the mattress during the turn positions of this protocol, when compared to LPR turning. Whether this resulted in significant differences in interface pressures between the protocols will be assessed in the following section.

### 6.2.6 Interface Pressures

A summary of the median and interquartile range of the peak interface pressures, associated with every measurement site and position, is presented in Table 6-6. It is evident that the median interface pressures during the LPR and manual repositioning protocols generally did not exceed 60mmHg. Nevertheless, there were some exceptions to this, which were more frequently associated with manual repositioning. It is interesting to note that while manual repositioning is designed to offload the sacral area, the manoeuvre did not result in lower interface pressures when compared with LPR turning. Indeed, the median and interquartile range of interface pressures at the sacral region were generally higher throughout the positions of the manual repositioning protocol, as compared to the LPR protocol. However, when the peak sacral pressures were compared using Wilcoxon signed-ranks tests or the sign test, where appropriate, no significant differences were found between LPR and manual repositioning ( $p>0.05$  in all cases). Equally, comparison of the differences at the body and shoulder sites did not produce statistically significant results between protocols ( $p>0.05$ ).

## Comparison of Lateral Rotation to Conventional Repositioning

Table 6-6: Summary of the median and interquartile range of the peak interface pressures (IPs) (mmHg) during the initial supine, right and left tilt positions of the LPR and manual repositioning sessions.

		<b>Initial supine †</b>	<b>Right tilt</b>	<b>Left tilt</b>
<b>Peak body IP ‡‡</b>	LPR	50 (45-64)	64 (48-68)	56 (38-69)
	Manual	68 (55-85)	56 (46-67)	42 (40-69)
<b>Peak sacral IP ‡‡‡</b>	LPR	56 (48-78)	50 (48-51)	52 (45-57)
	Manual	91 (61-109)	55 (53-64)	58 (47-64)
<b>Peak shoulder IP ‡‡‡</b>	LPR	45 (36-51)	51 (43-108)	51 (39-74)
	Manual	60 (46-102)	36 (30-51)	51 (41-53)

† The initial supine position refers to the supine position immediately prior to the commencement of the turn cycle (Figure 6-3). ‡‡ Recorded over 72 sensors. ‡‡‡ Recorded over a 12-sensor array.

In addition to the peak body interface pressure shown in the above table, peak pressures were collated for the left and right body sites. These values, associated with both turn positions and protocols, were compared using the Wilcoxon signed-ranks test and the inter- and intra-session differences were not found to be statistically significant ( $p>0.05$  in all cases). Friedman tests were utilised to determine the differences between the measurement sites for every position, and the site-specific differences between positions of a given protocol. While inter-site differences were not statistically significant ( $p>0.05$ ), the peak body pressures in the initial supine and left tilt positions ( $p<0.05$ ), and peak shoulder pressures in the initial supine and right tilt position ( $p<0.05$ ), both during manual repositioning, were significantly different. The latter finding may be due to the support provided by the pillow at this site, which was used to maintain the tilted position.

With reference to interface pressures at the shoulder during manual repositioning, the present results indicate that the left tilt position did not result in significantly greater peak pressures, when compared to the LPR feature. Accordingly, the trend towards a greater oxygen debt during the left tilt position of the manual repositioning session cannot be attributed to interface pressures. Indeed, when the peak interface pressures at the shoulder and sacrum during the tilted positions of each protocol were plotted against the corresponding oxygen debt, the relationship between the variables was found to be tenuous, as is illustrated in Figure 6-17.

## Comparison of Lateral Rotation to Conventional Repositioning

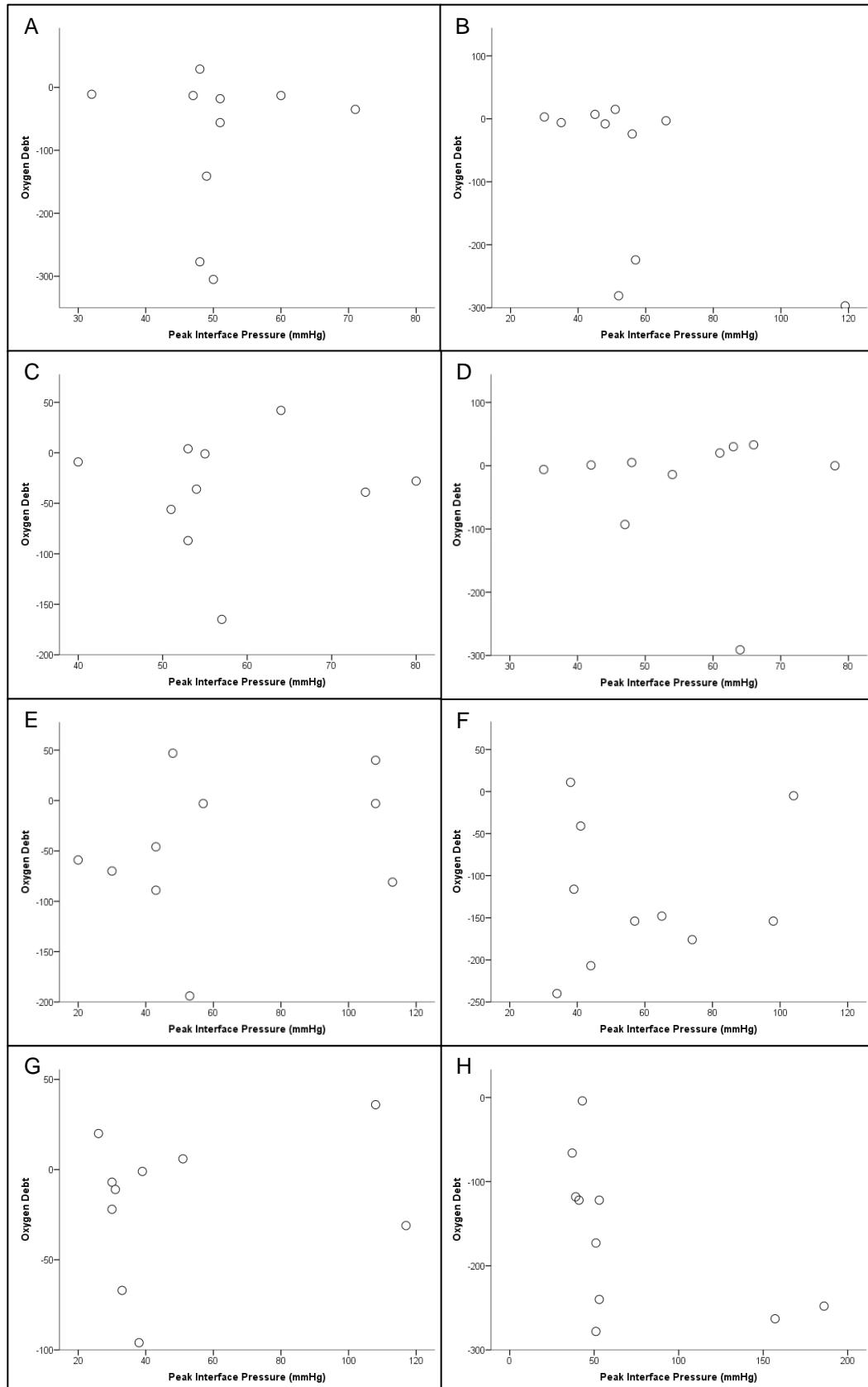


Figure 6-17: Sacral peak interface pressures and oxygen debt during the right (A) and left (B) tilt positions of the LPR session, and right (C) and left (D) tilt positions of the manual repositioning session. Peak interface pressures and oxygen debt at the shoulder during the right and left tilt positions of the LPR and manual repositioning sessions are shown in E, F, G and H, respectively.

### 6.2.7 Comfort Assessment

The comfort assessment results, presented in Table 6-7, demonstrate that during the supine position participants generally reported a high overall perceived comfort for both protocols (question 1, Appendix G), although ratings associated with manual repositioning were lower. However, comparison using the Wilcoxon signed-ranks test indicated that these observed differences in overall comfort were not statistically significant ( $p>0.05$ ).

When specific body sites are examined (question 3, Appendix G), a trend of increasing comfort scores at the lower half of the body is apparent during the supine position of the LPR turning protocol, although site comparisons using the Friedman test indicated that these differences were not statistically significant ( $p>0.05$ ). A similar trend is observed during the manual repositioning protocol, but lower perceived comfort at the legs and feet was reported. During the latter protocol, the Friedman test results suggested that comfort did differ significantly between body sites ( $p>0.05$ ), but this significance was lost when pairwise comparisons, with a Bonferroni correction for multiple comparisons (revised  $p=0.008$ ), were performed. Comparisons of perceived comfort at the specific regions with the Wilcoxon signed-ranks tests indicated that these did not significantly differ between the LPR turning and manual repositioning protocols, with the exception of the back, where comfort was rated lower during manual repositioning ( $p<0.05$ ).

Nevertheless, when supine comfort ratings at the specific body sites are compared between protocols, it is evident that the ratings during the manual repositioning are consistently lower. Since the mattress settings (ALP cycle,  $IP_{opt}$ ) were identical, this is an unexpected finding.

When examining perceived overall comfort associated with the turn positions (question 4, appendix G), a decrease is evident during both protocols, although overall comfort was rated higher during manual repositioning. However, analysis of the inter-session differences, that are evident from Table 6-7, did not yield statistically significant results (all  $p>0.05$ ). By contrast, the Wilcoxon signed-ranks test indicated that the intra-session difference in comfort was significant during the LPR protocol ( $p<0.01$ ), with overall comfort during the turn position rated lower than that of the supine position. However, the differences in the overall comfort scores during the supine and turn positions of the manual repositioning session were not statistically significant.

## Comparison of Lateral Rotation to Conventional Repositioning

Table 6-7: Comfort assessment results for the LPR and manual repositioning protocols. Ratings are expressed in percentages and have been aggregated for simplicity.

Protocol	Rating	Supine comfort-overall	Supine comfort-shoulders	Supine comfort- back	Supine comfort- buttocks	Supine comfort- legs & feet
LPR	Very comfortable/ Comfortable	100%	80%	90%	90%	100%
	Neutral	-	-	-	10%	-
	Uncomfortable/ Very uncomfortable	-	20%	10%	-	-
Manual	Very comfortable/ Comfortable	70%	60%	70%	80%	70%
	Neutral	30%	20%	20%	20%	20%
	Uncomfortable/ Very uncomfortable	-	20%	10%	-	10%
		Turn comfort- overall	Turn comfort-shoulders	Turn comfort- back	Turn comfort- buttocks	Turn comfort- legs & feet
LPR	Very comfortable/ Comfortable	20%	30%	70%	60%	-
	Neutral	60%	30%	10%	30%	80%
	Uncomfortable/ Very uncomfortable	20%	40%	20%	10%	20%
Manual	Very comfortable/ Comfortable	70%	30%	80%	90%	100%
	Neutral	10%	40%	10%	10%	-
	Uncomfortable/ Very uncomfortable	20%	30%	10%	-	-

With regards to the specific body sites while in a turned position (question 5, Appendix G), increased comfort ratings at the lower body are again observed in the manual repositioning protocol, such that the Friedman test indicated that comfort differed significantly between the shoulder region, and legs and feet ( $p<0.01$ ). However, this trend is not apparent during the turn phase of the LPR protocol. In addition, between protocol comparisons of the turn comfort ratings, associated with the specific sites, produced no significant results except at the legs and feet, where the differences were significant at the 5% level. Furthermore, intra-session comparisons of perceived comfort at the various sites demonstrated that comfort at the legs and feet increased in the turned phase of manual repositioning (Table 6-7), a difference which was found to be statistically significant ( $p<0.01$ ).

It may be hypothesised that this increased perception of comfort results from the pillow support provided at this region during the turned position. However, as illustrated in Table 6-7, reported comfort at the legs and feet varied between the two turning protocols when participants were in the supine position where the position of the legs and feet was identical, and therefore these results should be interpreted with caution.

Comfort ratings at the shoulder were relatively poor during the turned position of both protocols, and Wilcoxon signed-ranks tests indicated that these intra-session differences were significant during the LPR protocol ( $p<0.05$ ). This may, in part, be due to the higher turn angles at this region, when compared to the pelvis and ankles (Section 6.2.2).

The mattress firmness (question 2, Appendix G) was rated as optimal by 70% of participants during the LPR session, with the remaining 30% perceiving the mattress as 'somewhat firm'. Conversely, during the manual repositioning session 70% of participants found the mattress 'somewhat firm', and only 30% of participants reported mattress firmness was 'just right'. These differences were found to be statistically significant ( $p<0.05$ ).

The responses to perceived safety (question 6, Appendix G) are depicted in Figure 6-18. This illustrates that participants generally felt safer during the turn phase of the manual repositioning session, with 80% of participants reporting feeling 'safe' or 'very safe' during the latter protocol, while only 1 participant (10%) felt 'safe' during the turn phase of the LPR protocol. A Wilcoxon signed-ranks tests determined that this difference was statistically significant ( $p<0.01$ ).

## Comparison of Lateral Rotation to Conventional Repositioning

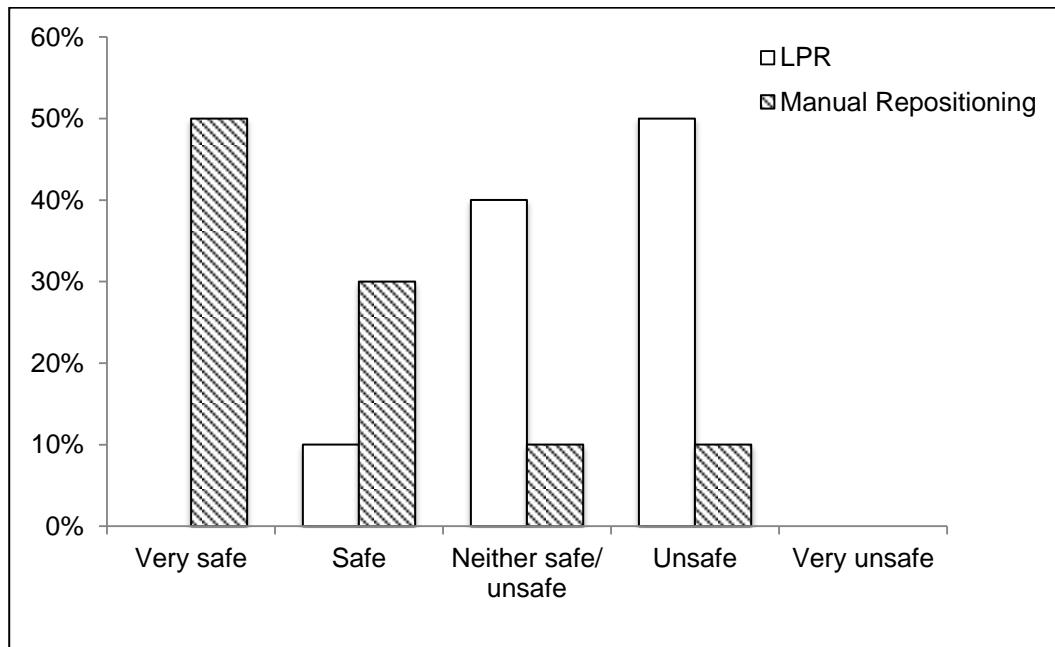


Figure 6-18: Comparison of perceived safety (Appendix G, question 6) during the turned positions of the LPR and manual repositioning protocols.

Overall, the comfort assessment results reveal a number of differences in the reported perception of comfort and safety for the two turning protocols. However, these regularly occurred when test conditions were identical, and therefore the implications of these findings remain unclear. Nevertheless, it is apparent that perceived comfort decreased during the turn position of both protocols and that there was a perception of reduced safety associated with LPR turning.

### 6.2.8 Bilateral Sacral Gas Tensions and Interface Pressures

The gas tensions at the left and right sacral areas were assessed in participants A, B, E and G (Table 6-1), for the duration of a LPR cycle. Data were classified using the Chai and Bader responses (2013), with the results presented in Table 6-8. This table reveals that in three of the participants, gas tensions remained relatively stable for the duration of the measurement period, although some minor variations in  $TcPO_2$  values are observed when the left and right sacral sites are compared. However, in participant E, distinctly different responses occurred at the respective sites. At the left site,  $TcPO_2$  values diminished shortly after loading and remained significantly lower than the basal value for the majority of the session, which led to an associated  $TcPCO_2$  accumulation (category 3 response) in the second supine and subsequent left tilt phases. By contrast, at the right sacrum, despite perturbations about the basal  $TcPO_2$  levels, each 15-minute phase yielded a category 1 response (Figure 6-19).

Table 6-8: Categorical responses of gas tensions at the left and right sacral area, shown per position of the LPR turn cycle.

Position	Sacral area	Participant			
		A	B	E	G
Initial Supine	Left	Category 1	Category 1	Category 2	Category 1
	Right	Category 1	Category 1	Category 1	Category 2
Right tilt	Left	Category 1	Category 1	Category 2	Category 2
	Right	Category 1	Category 1	Category 1	Category 2
Supine	Left	Category 1	Category 1	Category 3	Category 2
	Right	Category 1	Category 1	Category 1	Category 2
Left tilt	Left	Category 1	Category 1	Category 3	Category 2
	Right	Category 2	Category 1	Category 1	Category 2
Final Supine	Left	Category 1	Category 1	Category 2	Category 1
	Right	Category 1	Category 1	Category 1	Category 2

## Comparison of Lateral Rotation to Conventional Repositioning

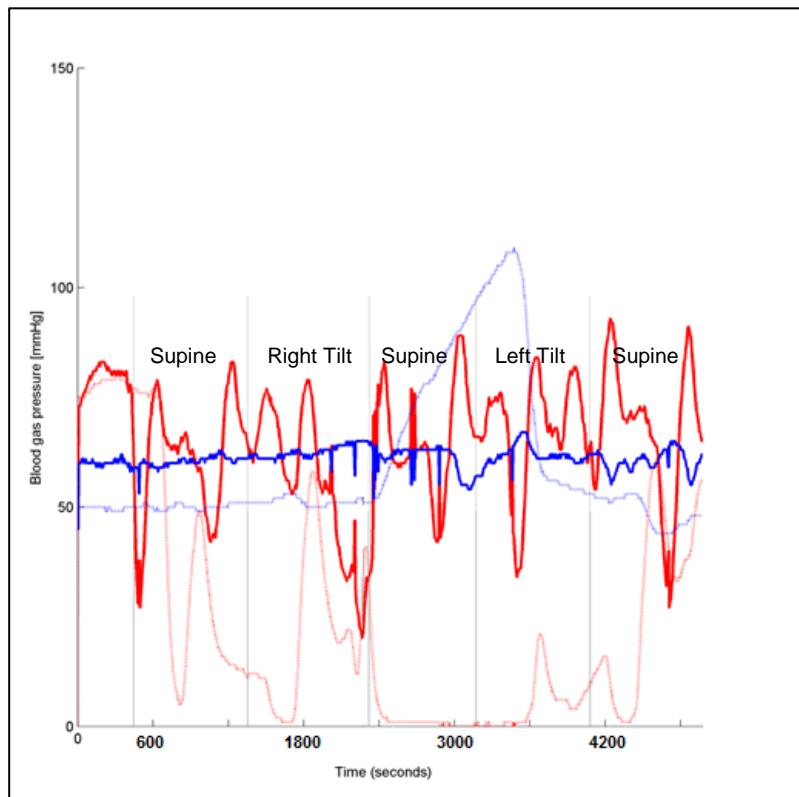


Figure 6-19: Transcutaneous gas tensions from participant E, measured during the bilateral sacrum session. The solid red ( $TcPO_2$ ) and blue ( $TcPCO_2$ ) lines represent the right sacral values, and the dashed lines the left sacral values.

Oxygen debt and carbon dioxide accumulation parameters were again computed for each participant, as shown in Figures 6-20 and 6-21. The oxygen debt showed little variation during the turned position when compared to the supine phases, at either of the sacral sites. Nonetheless, it is apparent that a greater variation occurred at the left sacrum, with extreme values corresponding to participants B and E. The latter participant also exhibited the most significant carbon dioxide accumulation at the left sacrum during the supine and left tilt positions (Figure 6-21), as reflected in a category 3 response (Table 6-8). It is interesting to note that, consistent with the present findings, more extreme responses were also observed in participant E during both the LPR and manual repositioning protocols, while participant B exhibited a category 1 response for the duration of the LPR protocol (Table 6-3).

### Comparison of Lateral Rotation to Conventional Repositioning

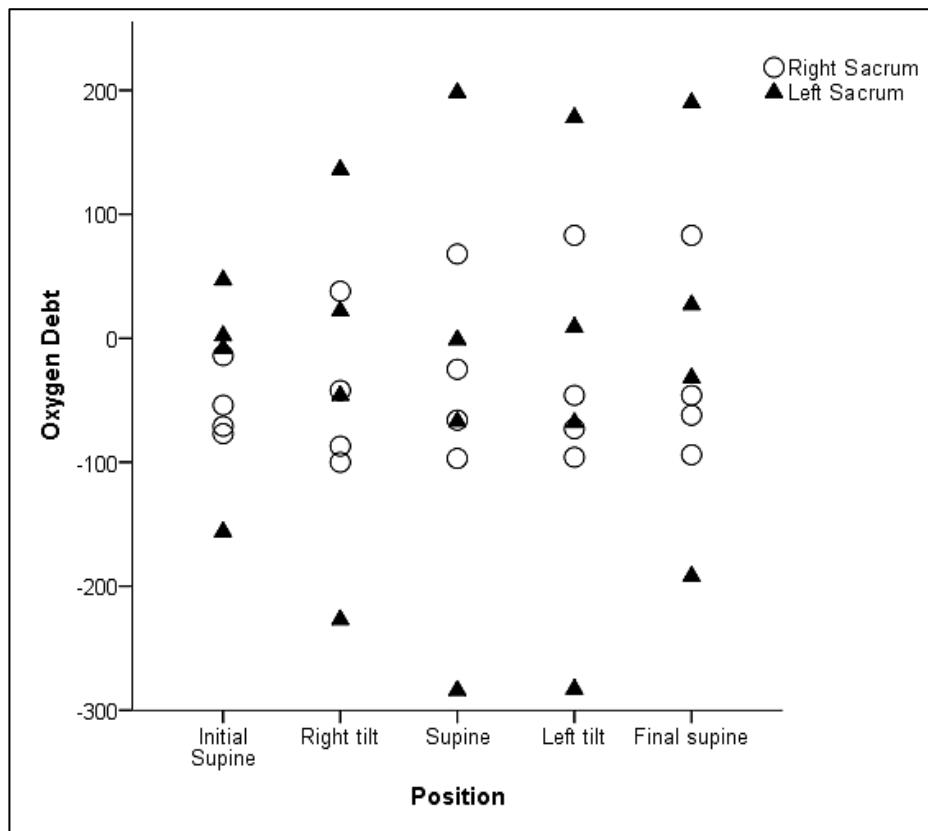


Figure 6-20: Oxygen debt at the right and left sacral regions, separated by position.

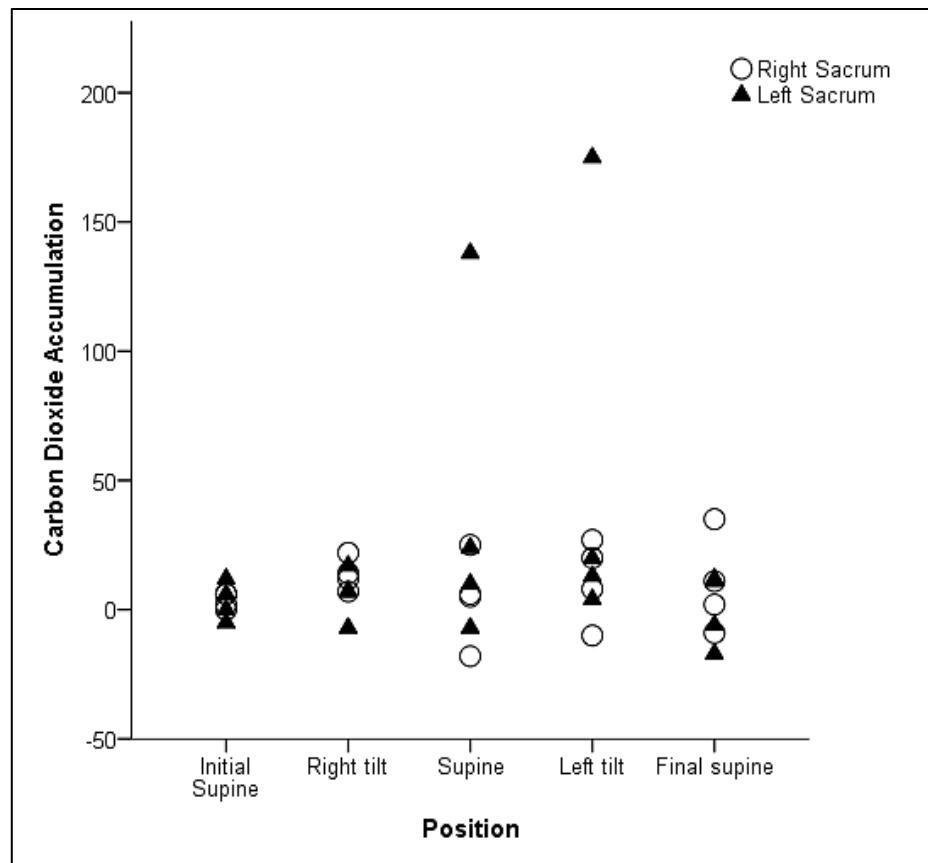


Figure 6-21: Carbon dioxide accumulation at the left and right sacral regions, separated by position.

## Comparison of Lateral Rotation to Conventional Repositioning

Examination of the carbon dioxide accumulation of the remaining participants demonstrated only small variations between the left and right sacral regions (Figure 6-21). Therefore, in the small number of participants considered here, it appears that the LPR function did not facilitate partial offloading of the sacral area, as assessed by gas tension levels. In addition, examination of the peak body and sacral interface pressures, presented in Table 6-9, revealed no apparent trends with respect to the turn cycle.

Table 6-9: Peak body and sacral interface pressures (IPs) of all participants (mmHg), separated by turn cycle position.

Position	Site	Participant			
		A	B	E	G
Initial supine	Peak Body IP †	42	40	38	75
	Peak Sacral IP ††	53	71	42	86
Right tilt	Peak Body IP †	51	52	45	80
	Peak Sacral IP ††	62	59	38	99
Left tilt	Peak Body IP †	49	38	49	63
	Peak Sacral IP ††	51	69	45	111
Final Supine	Peak Body IP †	56	67	48	97
	Peak Sacral IP ††	60	61	38	85

† Recorded over 72 sensors. †† Recorded over a 12-sensor array.

## 6.3 Discussion

The present study was designed to compare turning by means of an automated lateral rotation system with conventional manual repositioning, as reflected by physiological and biomechanical factors. The data demonstrated clear differences between the turn angles associated with the different turning protocols, with the values being statistically significant during the left turn position (Table 6-2). However, at the sacrum, these differences were not apparent in the physiological response associated with the LPR turning and manual repositioning protocols. In a similar manner, the peak interface pressures did not significantly differ between protocols (Table 6-6).

A relationship between the peak pressure and oxygen debt parameters was not identified, which is consistent with previous work comparing interface pressures to physiological measurements (Goossens & Rithalia 2008; Kim et al. 2012; Chai & Bader 2013).

## Comparison of Lateral Rotation to Conventional Repositioning

It has previously been reported that LPR turning did not have a marked effect on the recovery characteristics of tissues, in those cases where compromised gas tensions occurred (Chapter 5). These results are supported by the present findings which, during a 15-minute turn cycle, indicated that LPR turning did not facilitate partial offloading of the sacral area. Similarly, there was little recovery in the compromised gas tensions during the turn phases of the manual repositioning protocol, thus questioning the efficacy of this intervention. Nevertheless, examination of pooled oxygen debt and carbon dioxide accumulation at the sacrum (Figure 6-10 and 6-11), demonstrated that each parameter was lower during manual repositioning, when compared to the values associated with LPR turning. It is further possible that comparison of the results associated with the turn positions of both protocols may not have yielded statistically significant results in view of the small number of participants that experienced significant changes from basal values. In addition, although the turn cycle duration of 15-minutes was sufficient to ensure the stabilisation of gas tensions, it does not reflect clinical practice, where 2-hourly repositioning is commonly employed (Section 4.3.1).

The comfort assessment data revealed that comfort during the supine position was generally high during both protocols, although some variation was observed at the different body sites, and ratings during the LPR protocol were marginally higher. Comfort scores generally decreased during the turn phases of either protocol, when compared to the supine position and, with reference to the LPR session, this finding is consistent with previous results (Chapter 5). Equally, with reference to manual repositioning, this appears consistent with other research findings, which have reported an inability among participants to maintain the 30° side-lying position, which could result from discomfort associated with this position (Young 2004; Vanderwee et al. 2007b).

Turning during the LPR protocol was further found to be associated with a decreased perception of safety, when compared to manual repositioning, a difference which was found to be statistically significant. Yi and colleagues (2009) have previously asserted that lateral rotation systems with greater turn angles may lead to a reduced perception of comfort and stability. However, as previously indicated, greater turn angles were generally observed during manual repositioning in the current study. Accordingly, it may be argued that greater turn angles may not be the sole determinant of perceived comfort and safety, and that the nature of the turning mechanism may equally be of importance. It should be noted that the present study did not incorporate a period of familiarisation with the automated turning mechanism, and it is possible that if

## Comparison of Lateral Rotation to Conventional Repositioning

participants had been conditioned to repositioning by means of the LPR feature, the reported perception of comfort and safety might have improved. In addition, it is appreciated that despite the revisions to the comfort assessment, this remains a subjective assessment. Nevertheless, the trends highlighted in the current study are important considerations if lateral rotation devices are to be widely adopted in practice.

## 6.4 Summary, Conclusion and Future Work

The present study demonstrated that:

- Turn angles differed between the automated and manual repositioning protocols, and these differences reached statistical significance on a number of occasions;
- Differences were not apparent when the position-specific sacral gas tensions and peak interface pressures that were associated with the two turning mechanisms were compared;
- Turning by either method did not appear to facilitate recovery of compromised gas tensions;
- Comfort ratings declined during the turn positions of both protocols;
- Participants reported a decreased perception of safety during LPR-induced turns, and these were significantly lower than the ratings associated with manual repositioning.

With reference to the research questions that have previously been specified (Chapter 6), the findings from this study indicate that the turning processes of the LPR function and manual repositioning were equally effective in maintaining tissue viability, as reflected by transcutaneous gas tensions and interface pressures. Perceived comfort did not significantly differ between the turning methods, although turning by means of the LPR function did result in a reduced perception of safety. The LPR feature did not facilitate partial offloading of the sacral area.

The present work has identified a number of differences between turning by means of the LPR feature of the prototype device and manual repositioning, particularly in terms of turn angles and participants' perception of safety. Nevertheless, the results pertaining to the prototype support surface could be device specific. Accordingly, a subsequent study examined turning by means of a lateral rotation platform and compared this to manual repositioning. This study is detailed in Chapter 7.

## Chapter 7: Comparison of a Lateral Rotation Platform to Conventional Repositioning

The performance of a prototype lateral rotation system has been evaluated in Chapters 5 and 6, with the latter detailing a comparison with conventional nursing practice. To further determine the effect of different turning mechanisms, the present study compared the performance of a lateral rotation platform (LRP) to manual repositioning using the 30° side-lying position.

Specific research questions were defined as follows:

- I. Are the turning processes of the LRP and manual repositioning equally effective at maintaining tissue viability in a group of healthy participants, as reflected in both physiological and biomechanical factors?
- II. Does perceived comfort differ between turning by means of the LRP and manual repositioning?

### 7.1 Materials and Methods

#### 7.1.1 Lateral Rotation Platform

To induce automated turns the ToTo™ (Genie Care Ltd, Arundel, UK) system was utilised. This system uses longitudinal air bladders to induce a turn, to a 30° elevation, which are controlled via a pump unit. However, in contrast to the prototype device (Section 5.1.1), the air bladders in the present system are sandwiched between two platforms, as indicated in the schematic contained in Figure 7-1. These platforms feature a central spine with side-wing construction, and are arranged in 3 hinged sections to enable HOB and knee break elevation. The system is designed to be used in combination with a standard foam mattress or APAM, according to clinical judgment. Turn and dwell times can be adjusted using the pump unit, from a minimum of 10 minutes to a maximum of 2 hours.

A castellated foam mattress (Dyna-form Mercury™, Direct Healthcare Services Ltd, Caerphilly, UK) was used as the support surface for this study, as depicted in Figure 7-2. This mattress is marketed as a product for those at high risk of PU development, and was selected as it is frequently used with the LRP system in clinical practice.

## Comparison of a Lateral Rotation Platform to Conventional Repositioning

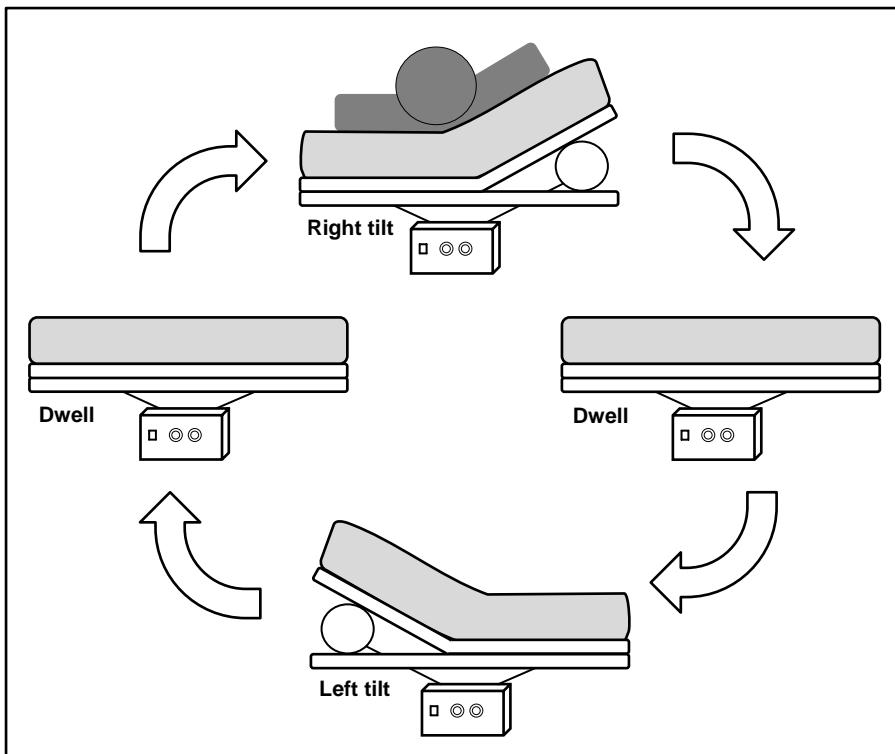


Figure 7-1: Schematic of the ToTo™ turn mechanism and turn cycle.



Figure 7-2: LRP induced turn with the castellated foam mattress in situ.

### **7.1.2 Manual Repositioning Technique**

The manual repositioning technique utilised in this study was identical to that described in Section 6.1.2, and as illustrated in Figure 6-1. To review briefly, pillow support was utilised during the turned positions, to achieve pelvic elevation and offloading of the sacral area, with pillows further placed lengthways under the legs to offload the heels.

### **7.1.3 Instruments**

In a similar manner to the protocols adopted in Chapters 5 and 6, transcutaneous gas tensions at both the sacrum and the right shoulder were monitored during the LRP and manual repositioning sessions. Electrode preparation and TCM data logging have previously been described in Section 6.1.2. Equally, the interface pressure measurement system and the configuration of the pressure sensor arrays are described in Section 6.1.3 and illustrated in Figure 5.3, respectively. A 12-sensor array was again positioned adjacent to the right shoulder and placed over the pillows during the right tilt position of the manual repositioning session, thereby ensuring that this was in direct contact with the body (Section 6.1.4). Inclinometer measurements were recorded at the sternal, pelvic and ankle levels during the right and left tilt positions for both protocols, in the manner described in Section 6.1.5.

### **7.1.4 Study Protocol, Data Collection Process and Data Analysis**

Ethics approval had previously been granted (FoHS-ETHICS-978). To extend the original data collection period, and reflect an altered means of achieving a lateral tilt using the LRP, an amendment was submitted March 2013 and approved April 2013. The inclusion and exclusion criteria remained identical to those listed in Section 5.1.6. The participant information sheet for the current study is presented in Appendix I. Participant recruitment was performed in the same manner as that described in Section 5.1.6.

The turn/ repositioning period was prescribed at 15 minutes, as this had previously been found to be an adequate length of time to enable stabilisation of gas tensions (Section 6.3). The castellated foam mattress was employed as the support surface for both test sessions. The LRP remained in situ during the manual repositioning sessions, although the pump unit was not activated, and a separate timer was used to measure the 15-minute position periods. Participant preparation and the sequence of measurements were similar to that described in Section 6.1.7. However, an additional

## Comparison of a Lateral Rotation Platform to Conventional Repositioning

set of interface pressure measurements was obtained in the final supine position of the present study. Furthermore, the comfort assessment was extended to include comfort questions during both turn (right tilt and left tilt) positions, as is detailed in Appendix J. These modifications are highlighted in the schematic of the complete test protocol, which is illustrated in Figure 7-3.

Data processing and analysis were identical to that described in Section 6.1.8, with the categorical responses defined by Chai and Bader (2013) and the oxygen debt and carbon dioxide accumulation parameters again utilised for analysis of transcutaneous gas tension data. The peak pressure parameter was further employed for the analysis of interface pressure data.

Comparison of a Lateral Rotation Platform to Conventional Repositioning

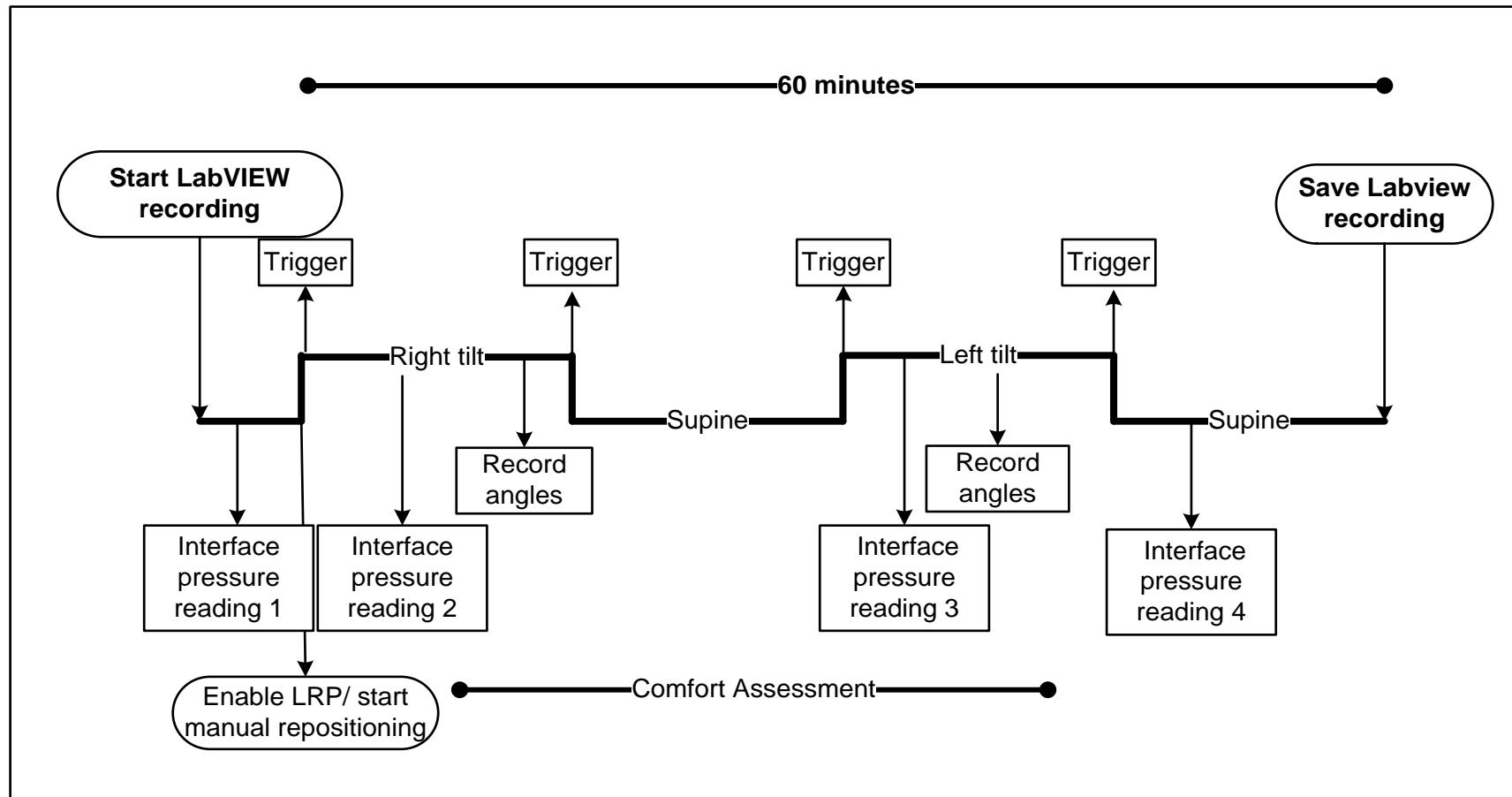


Figure 7-3: Data collection process for the LRP and manual repositioning sessions.

## 7.2 Results

### 7.2.1 Participants

Eleven participants, aged 23-60 years, with a BMI ( $\text{kg}/\text{m}^2$ ) ranging from 20.6-34.4, took part in both the LRP and manual repositioning sessions. The demographic details of these participants are shown in table 7-1.

Table 7-1: Demographic details of participants.

Participant	Sex	Age	Height (m)	Weight (kg)	BMI ( $\text{kg}/\text{m}^2$ )
A	Male	60	1.92	93	25.2
B	Male	28	1.75	86	28.1
C	Female	26	1.58	86	34.4
D	Male	23	1.83	69	20.6
E	Male	33	1.91	78	21.4
F	Female	54	1.76	73	23.6
G	Female	42	1.61	65	25.1
H	Male	52	1.71	82	27.9
I	Male	34	1.83	70	20.8
J	Female	32	1.42	48	23.8
K	Female	49	1.66	88	31.9

### 7.2.2 Turn Angle Measurements

The turn angles for each of the three body regions during the right and left tilt positions of the LRP and manual repositioning protocols are shown in Table 7-2. It is evident that the median turn angles associated with manual repositioning at the sternum and pelvis were significantly higher than the corresponding LRP turn angles. Indeed, when these differences were examined, using either the Wilcoxon signed-ranks test or the sign test, where appropriate, they were found to be statistically significant during both the right and left tilt positions ( $p<0.01$  in all cases). By contrast, at the ankles, greater turn angles were generally observed during LRP turning, a difference which was found to be statistically significant during the right tilt position only ( $p<0.05$ ).

Table 7-2: Summary of the median and range of turn angle measurements (degrees) in the three body locations during the right tilt and left tilt positions of the LRP turning and manual repositioning protocols.

		<b>Sternum</b>	<b>Pelvis</b>	<b>Ankles</b>
<b>LRP Turning</b>	Right tilt	10.5 (7.5-16.0)	8.0 (4.0-10.5)	7.0 (4.5-14.0)
	Left tilt	10.5 (4.0-16.0)	10.0 (5.0-14.5)	8.0 (6.0-14.0)
<b>Manual Repositioning</b>	Right tilt	32.0 (26.5-48.0)	25.0 (17.0-40.5)	1.0 (0.5-11.0)
	Left tilt	29.0 (18.5-42.0)	27.5 (19.0-36.0)	3.5 (0.5-21.0)

It is further apparent from the above table that while turn angles reduced from sternum to ankles during manual repositioning, as was observed in the previous study (Table 6-2), the LRP turn angles demonstrated minimal variation between the body locations.

These trends are clearly illustrated in Figures 7-4 and 7-5.

## Comparison of a Lateral Rotation Platform to Conventional Repositioning

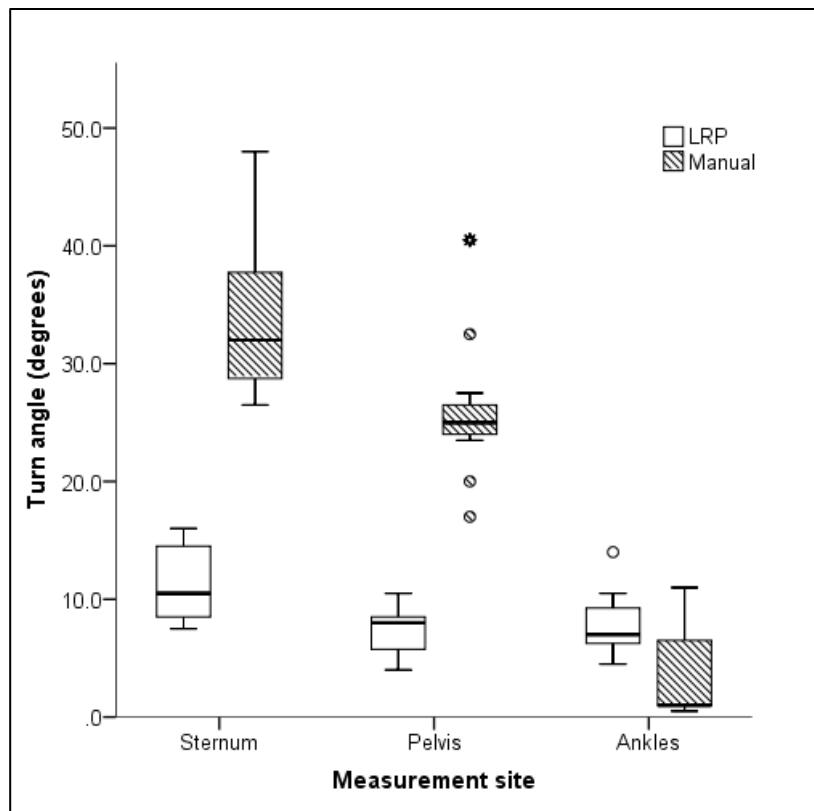


Figure 7-4: Boxplot showing the turn angles obtained during the right tilt position of the LRP turning and manual repositioning protocols.

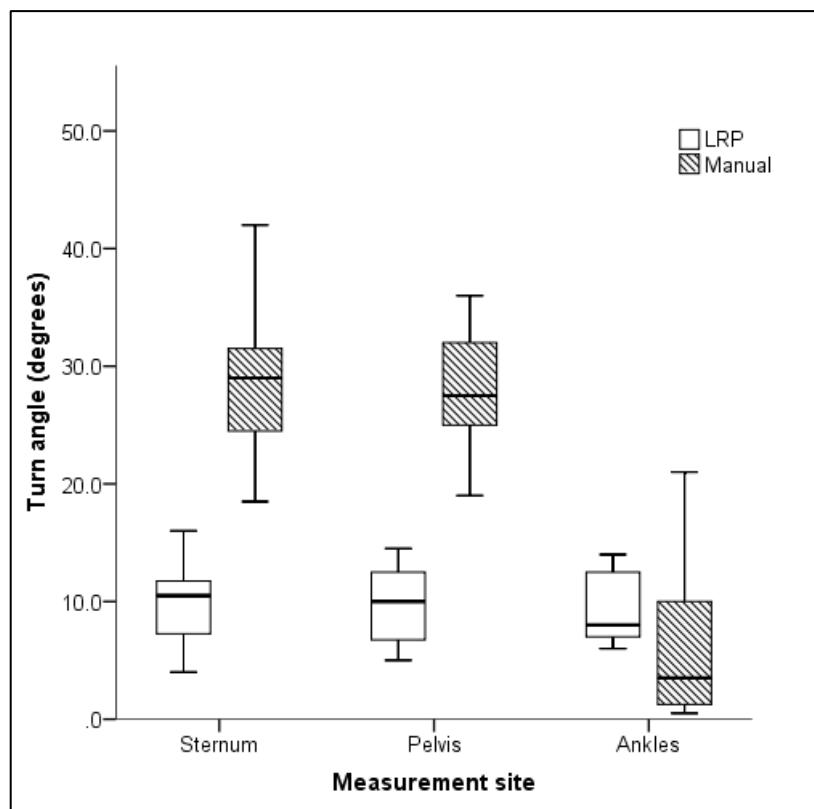


Figure 7-5: Boxplot showing the turn angles obtained during the left tilt position of the LRP turning and manual repositioning protocols.

### **7.2.3 Transcutaneous Gas Tension Categories during LRP Turning and Manual Repositioning**

The responses at the sacrum, using the categories defined by Chai and Bader (2013), are summarised in Table 7-3. It is evident that 8/11 (73%) of participants exhibited a category 1 response throughout the majority of positions of the LRP and manual repositioning protocols. The latter figure includes participant J, who exhibited a category 1 at both the sacrum and shoulder for the duration of both protocols, but is excluded from further analysis in this section due to a recording error of the TCM data during the manual repositioning session. By contrast, three of the participants exhibited category 2 and 3 responses at various phases of each of the two protocols, and it is interesting to note that each of these participants (D, E and I) had a considerably lower BMI ( $\text{kg}/\text{m}^2$ ) than the cohort mean of 25.7 (Table 7-1).

With respect to the turn positions of both LRP turning and manual repositioning, there were relatively few category 2 and 3 responses evident during the first supine position (15%), whereas these responses occurred in 45% and 30% of cases for the right tilt and left tilt positions, respectively, for both protocols. Nevertheless, a Friedman test indicated that the differences in responses across the turn positions of a given protocol did not differ significantly in either protocol ( $p>0.05$ ). Wilcoxon signed-ranks tests further determined that the position-specific responses did not differ significantly between the LRP and manual repositioning sessions ( $p>0.05$ ).

## Comparison of a Lateral Rotation Platform to Conventional Repositioning

Table 7-3: Categorical responses of gas tensions at the sacrum during each turn position of the LRP turning and manual repositioning sessions.

	Right tilt		Supine		Left tilt		Final Supine	
Participant	LRP	Manual	LRP	Manual	LRP	Manual	LRP	Manual
A	Category 1	Category 1	Category 2	Category 1	Category 1	Category 1	Category 1	Category 2
B	Category 1	Category 1						
C	Category 1	Category 1						
D	Category 3	Category 1	Category 1	Category 2	Category 3	Category 1	Category 3	Category 1
E	Category 3	Category 2	Category 2	Category 1	Category 3	Category 2	Category 3	Category 3
F	Category 2	Category 2	Category 1	Category 1	Category 1	Category 2	Category 1	Category 2
G	Category 1	Category 2	Category 1	Category 1	Category 2	Category 1	Category 1	Category 1
H	Category 2	Category 1	Category 1					
I	Category 2	Category 3	Category 1	Category 1	Category 1	Category 3	Category 1	Category 1
J	Category 1	†	Category 1	†	Category 1	†	Category 1	†
K	Category 1	Category 1						

† Excluded from statistical analysis, due to a recording error of TcPO<sub>2</sub> and TcPCO<sub>2</sub> data.

When examining the responses at the shoulder, shown in Table 7-4, a trend towards higher categories can be observed during the left tilt positions of both protocols. Indeed, in this position about 60% of cases corresponded to either a category 2 or 3 response. By contrast, these responses occurred in 10%, 10% and 20% of cases during the right tilt, supine and final supine positions, respectively. It is evident that gas tensions frequently returned to near basal values (category 1) during the final supine period of both test sessions. Nevertheless, a Friedman test indicated that the differences in the responses across the positions of the manual repositioning protocol were not statistically significant ( $p>0.05$ ). Similarly, once pairwise comparisons with a Bonferroni correction for multiple comparisons were performed (yielding a revised  $p=0.008$ ), the differences in responses across the LRP positions were not found to be significant.

Table 7-4 further reveals that the category exhibited during a given position of LRP turning was frequently identical to that observed during manual repositioning, with a disparity evident in only 28% of cases. Indeed, Wilcoxon signed-ranks tests determined that the differences between the protocols were not statistically significant for any of the turn positions ( $p>0.05$ ). When comparing Table 7-4 with Table 7-3, similarities are also observed between the shoulder and sacral responses, with category 3 responses again evident in participants D, E and I.

## Comparison of a Lateral Rotation Platform to Conventional Repositioning

Table 7-4: Categorical responses of gas tensions at the shoulder during each turn position of the LRP turning and manual repositioning sessions.

Participant	Right tilt		Supine		Left tilt		Final Supine	
	LRP	Manual	LRP	Manual	LRP	Manual	LRP	Manual
A	Category 1	Category 1	Category 1	Category 2	Category 1	Category 1	Category 1	Category 2
B	Category 1	Category 2	Category 1	Category 3				
C	Category 1	Category 1						
D	Category 1	Category 1	Category 1	Category 3	Category 3	Category 1	Category 1	Category 2
E	Category 1	Category 1	Category 1	Category 1	Category 2	Category 3	Category 1	Category 1
F	Category 1	Category 1	Category 1	Category 1	Category 2	Category 1	Category 1	Category 1
G	Category 1	Category 1	Category 1	Category 1	Category 2	Category 2	Category 1	Category 1
H	Category 2	Category 2	Category 1	Category 1	Category 2	Category 2	Category 2	Category 1
I	Category 1	Category 1	Category 1	Category 1	Category 2	Category 3	Category 1	Category 1
J	Category 1	†	Category 1	†	Category 1	†	Category 1	†
K	Category 1	Category 2	Category 1	Category 1				

† Excluded from statistical analysis, due to a recording error of TcPO<sub>2</sub> and TcPCO<sub>2</sub> data.

### 7.2.4 Total Sacral Oxygen Debt and BMI

To determine the extent to which BMI might predict the total oxygen debt (Equation 6-1), the pooled data of the four positions comprising the LRP and manual repositioning protocols were examined in by means of linear models, as illustrated in Figures 7-6 and 7-7, respectively. Both of these were found to be statistically significant at the 5% level. BMI accounted for 37% of the variability (adjusted  $R^2$ ) in the total oxygen debt observed during the LRP protocol (Figure 7-6), and 50% of the variability (adjusted  $R^2$ ) noted during the manual repositioning protocol (Figure 7-7).

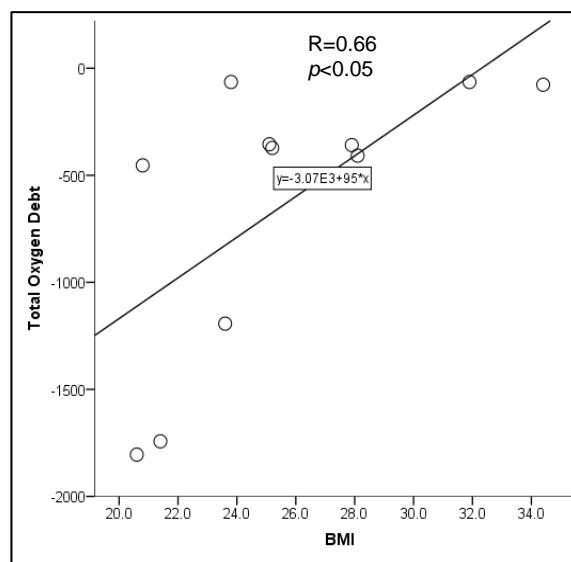


Figure 7-6: Linear model of BMI and total sacral oxygen debt associated with the LRP protocol ( $p < 0.05$ );  $n=11$ .

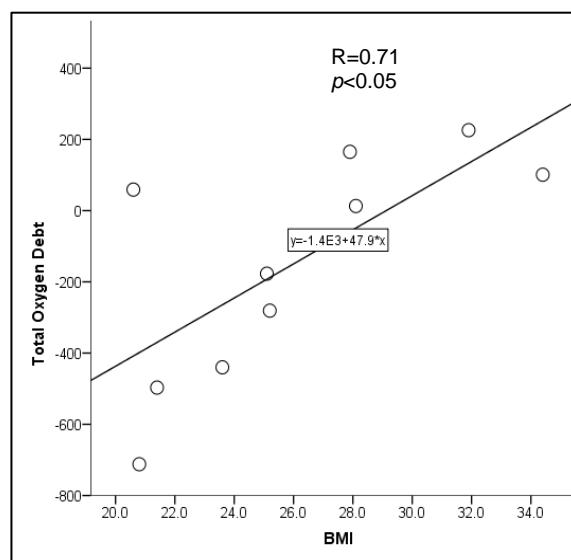


Figure 7-7: Linear model of BMI and total sacral oxygen debt associated with the manual repositioning protocol ( $p < 0.05$ );  $n=10$ .

### **7.2.5 Position-Specific Oxygen Debt and Carbon Dioxide Accumulation Associated with LRP Turning and Manual Repositioning**

The position-specific oxygen debt and carbon dioxide accumulation parameters at the sacrum, determined using Equations 6-1 and 6-2, are shown in Figures 7-8 and 7-9, respectively. With reference to oxygen debt (Figure 7-8), it is evident that the values associated with manual repositioning demonstrate considerably less variability, when compared to those associated with turning by means of the LRP. In particular, some of the oxygen debt values associated with the LRP protocol were three-fold higher than those observed during manual repositioning, specifically during the right and left tilt positions.

Nevertheless, a Friedman test determined that the position-specific differences observed during LRP turning did not reach statistical significance ( $p>0.05$ ). However, when inter-session differences were examined using Wilcoxon signed-ranks tests, the values associated with the right tilt, supine and left tilt positions were found to differ significantly between the two protocols (all  $p<0.05$ ), although the differences during the final supine position were not statistically significant ( $p>0.05$ ).

The corresponding carbon dioxide values, shown in Figure 7-9, generally clustered around zero during each of the protocols, with values in excess of 100 occurring in only 6% (5/84) of cases. The most severe carbon dioxide accumulation, observed during the final supine position of the LRP protocol, represent participants D and E, as denoted by category 3 responses in Table 7-3. Nevertheless, examination of the position-specific differences in carbon dioxide accumulation by means of the Friedman test did not reveal statistically significant differences between the positions of the LRP protocol ( $p>0.05$ ). Equally, position-specific differences were not found to be significant during the manual repositioning protocol ( $p>0.05$ ). Furthermore, comparisons of the differences in sacral carbon dioxide accumulation between the protocols, using the Wilcoxon signed-ranks or sign tests, did not yield statistically significant results in any of the positions (all  $p>0.05$ ).

### Comparison of Lateral Rotation to Conventional Repositioning

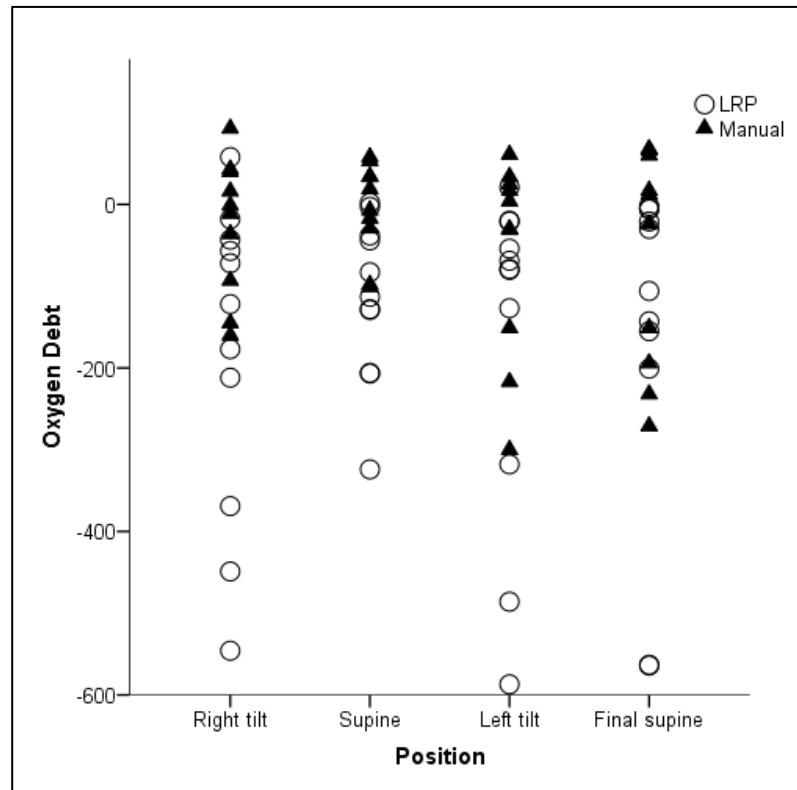


Figure 7-8: Oxygen debt at the sacrum during LRP turning and manual repositioning, separated by position.

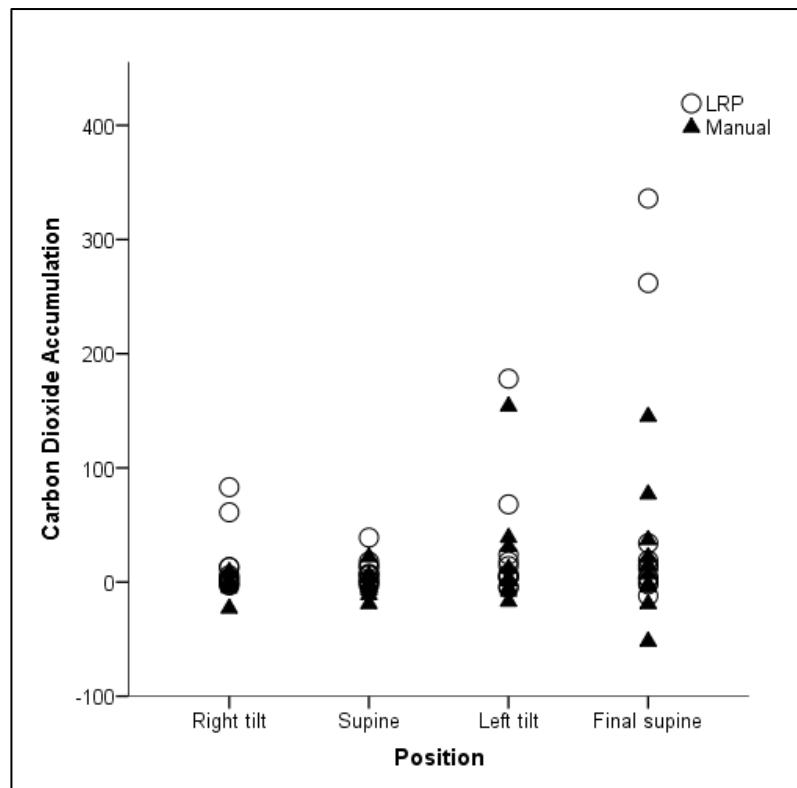


Figure 7-9: Carbon dioxide accumulation at the sacrum during LRP turning and manual repositioning, separated by position.

## Comparison of a Lateral Rotation Platform to Conventional Repositioning

The oxygen debt at the shoulder during the manual repositioning and LRP protocols is shown in Figure 7-10. A trend towards increasing oxygen debt is apparent during the left tilt positions of both protocols, which in a number of cases, was associated with high carbon dioxide accumulation values (Figure 7-11). Indeed, Friedman tests comparing the differences across the positions associated with the LRP protocol revealed significant differences across the turn positions, in both parameters. The oxygen debt during both the right tilt and supine positions were found to differ significantly from the values associated with the left tilt position ( $p=0.01$  and  $p<0.01$ , respectively). Equally, the carbon dioxide accumulation differed significantly between the right tilt and final supine positions of the LRP protocol ( $p<0.01$ ), with Figure 7-11 indicating that carbon dioxide accumulation decreased during the final supine position. By contrast, tests examining the differences across the positions of the manual repositioning protocol did not produce statistically significant results in either the oxygen debt, or carbon dioxide accumulation parameters (both  $p>0.05$ ). When the differences between each of the positions of the two protocols were compared using Wilcoxon signed-ranks tests, no statistically significant results were identified in any of the positions ( $p>0.05$ ).

### Comparison of Lateral Rotation to Conventional Repositioning

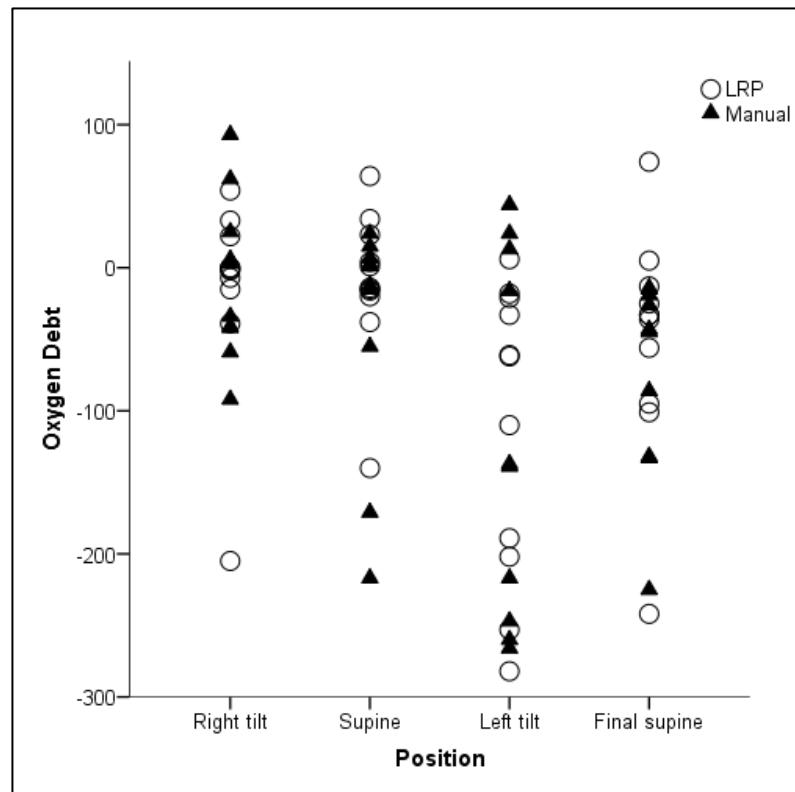


Figure 7-10: Oxygen debt at the shoulder during LRP turning and manual repositioning, separated by position.

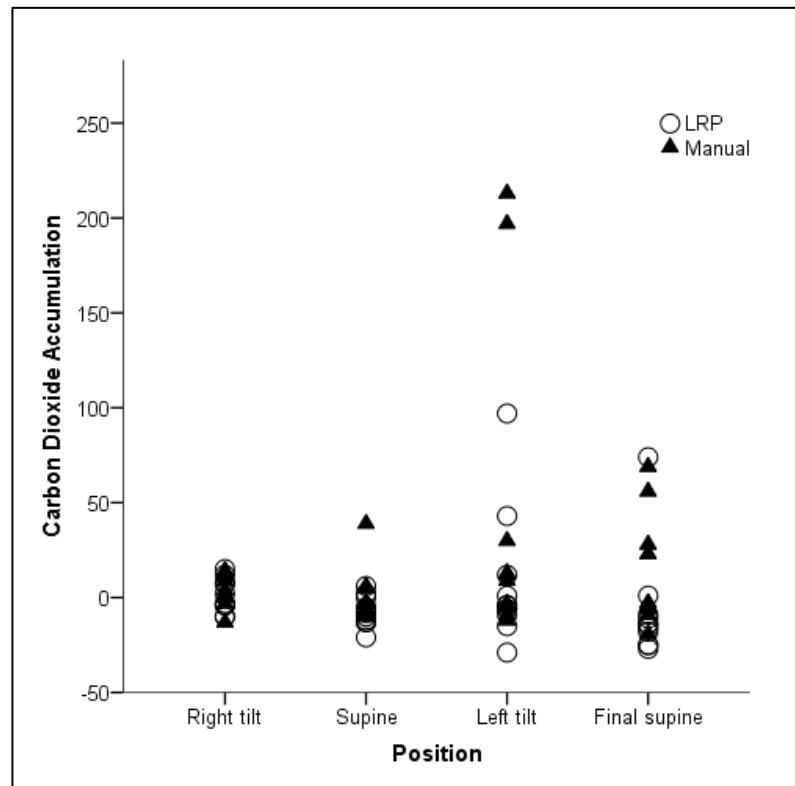


Figure 7-11: Carbon dioxide accumulation at the shoulder during LRP turning and manual repositioning, separated by position.

### 7.2.6 Interface Pressures

The median and interquartile ranges of the peak interface pressures observed at the body, sacral and shoulder regions are summarised in Table 7-5. The results reveal that, in the majority of cases, there were minimal differences in the median peak pressures between protocols, at each of the respective sites. However, it is evident that the median peak pressures at the body were greater during the final supine position of the manual repositioning protocol, a difference which was found to be statistically significant ( $p<0.05$ ). In a similar manner, the median peak pressure at the shoulder associated with the left tilt position of the manual repositioning protocol was greater than the corresponding LRP pressure, and a Wilcoxon signed-ranks test revealed that this difference was statistically significant ( $p<0.01$ ).

Table 7-5: Summary of the median and interquartile range of the peak interface pressures (IPs) (mmHg) during the initial supine, right tilt, left tilt and final supine positions of the LRP turning and manual repositioning sessions.

		Initial supine †	Right tilt	Left tilt	Final Supine
<b>Peak body IP ††</b>	LRP	62 (53-90)	81 (64-89)	74 (63-83)	56 (46-68)
	Manual	56 (53-62)	57 (51-62)	60 (55-86)	85 (59-118)
<b>Peak sacral IP †††</b>	LRP	58 (50-81)	59 (54-66)	61 (48-83)	59 (51-74)
	Manual	52 (47-65)	70 (53-81)	59 (43-69)	60 (74-95)
<b>Peak shoulder IP †††</b>	LRP	46 (42-56)	53 (45-64)	47 (45-64)	58 (50-73)
	Manual	46 (44-62)	51 (39-100)	95 (65-136)	82 (65-103)

† The initial supine position refers to the supine position immediately prior to the commencement of the turn cycle (Figure 7-3). †† Recorded over 72 sensors. ††† Recorded over 12-sensor arrays.

Close examination of the data during individual positions of the turn cycle, reveals no consistent trends of higher pressures corresponding to a particular position, as evidenced by differences which were not statistically significant at the body or sacrum, in either of the two protocols ( $p>0.05$ ). In a similar manner, Friedman tests indicated that the differences in peak pressures at the shoulder were not significant during the LRP protocol ( $p>0.05$ ). However, statistically significant differences were identified during the manual repositioning protocol, with post hoc analysis indicating that these corresponded to the initial and final supine position, the initial supine and left tilt position and between the right and left tilt positions (in all cases  $p\leq0.05$ ).

## Comparison of Lateral Rotation to Conventional Repositioning

Examination of the peak pressures and position-specific oxygen debt at the sacrum and the shoulder did not demonstrate any obvious relationship between these variables, as is demonstrated in the example contained in Figure 7-12.

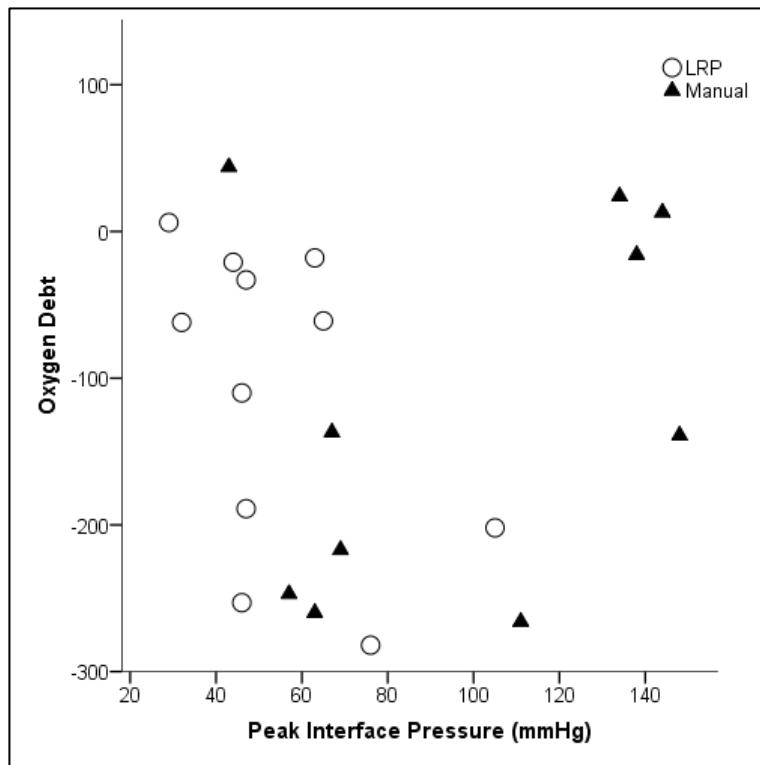


Figure 7-12: Scatter plot of the peak interface pressure and oxygen debt recorded at the shoulder, during the left tilt position of the LRP turning and manual repositioning sessions.

### 7.2.7 Comfort Assessment

The results of the comfort assessment are shown in Table 7-6. This indicates that perceived overall comfort while in a supine position (question 1, Appendix J) was generally high, during both LRP turning and manual repositioning protocols. In addition, the overall comfort was rated high during the turn positions of the LRP protocol (questions 4 and 7, Appendix J) and a Friedman test did not identify significant differences in comfort ratings assigned to the supine, right tilt and left tilt positions ( $p>0.05$ ). However, when comparing the overall comfort ratings associated with the supine, right and left tilt positions of the manual repositioning protocol (questions 1, 4 and 7, Appendix J), it is evident that overall comfort decreased during both of these turn positions (Table 7-6).

## Comparison of a Lateral Rotation Platform to Conventional Repositioning

Table 7-6: Comfort assessment results for the LRP and manual repositioning protocols. Ratings are expressed in percentages and have been aggregated for simplicity.

Protocol	Rating	Supine comfort-overall	Supine comfort-shoulders	Supine comfort-back	Supine comfort-buttocks	Supine comfort-legs & feet
LRP	Very comfortable/Comfortable	91%	82%	82%	64%	91%
	Neutral	9%	9%	18%	27%	9%
	Uncomfortable/Very uncomfortable	-	9%	-	9	-
	Very comfortable/Comfortable	91%	91%	64%	82%	91%
Manual	Neutral	9%	9%	27%	9%	-
	Uncomfortable/Very uncomfortable	-	-	9%	9%	9%
Protocol	Rating-Right tilt	Turn comfort-overall	Turn comfort-shoulders	Turn comfort-back	Turn comfort-buttocks	Turn comfort-legs & feet
LRP	Very comfortable/Comfortable	91%	82%	82%	82%	100%
	Neutral	9%	9%	9%	18%	-
	Uncomfortable/Very uncomfortable	-	9%	9%	-	-
	Very comfortable/Comfortable	55%	55%	64%	73%	91%
Manual	Neutral	27%	27%	18%	-	9%
	Uncomfortable/Very uncomfortable	18%	18%	18%	27%	-
Protocol	Rating-Left tilt	Turn comfort-overall	Turn comfort-shoulders	Turn comfort-back	Turn comfort-buttocks	Turn comfort-legs & feet
LRP	Very comfortable/Comfortable	91%	91%	73%	64%	100%
	Neutral	-	-	27%	27%	-
	Uncomfortable/Very uncomfortable	9%	9%	-	9%	-
	Very comfortable/Comfortable	36%	27%	55%	45%	73%
Manual	Neutral	27%	45%	27%	27%	27%
	Uncomfortable/Very uncomfortable	36%	27%	18%	27%	-

## Comparison of Lateral Rotation to Conventional Repositioning

Nevertheless, when a Friedman test was employed to compare these differences, pairwise comparisons with a revised alpha level ( $p=0.02$ ) yielded non-significant results ( $p>0.05$ ). By contrast, comparison of the inter-session differences revealed that the overall comfort ratings significantly differed between the LRP turning and manual repositioning sessions, during both the right and left tilt positions ( $p<0.05$ ), the latter of which was determined following re-examination using the sign test (Section 5.1.7).

When examining the specific body regions during the supine and turned positions of the LRP protocol (questions 3, 5 and 8, Appendix J), Table 7-6 demonstrates that the comfort ratings varied little, and Friedman tests found that the differences between the ratings associated with the various regions were not statistically significant in any of the positions. Similarly, the comfort ratings associated with the body regions during the supine position of the manual repositioning protocol (question 3, Appendix J) were not found to differ significantly ( $p>0.05$ ), while the differences observed during the right tilt position (question 5, Appendix J) lost statistical significance following pairwise comparisons. However, during the left tilt position of the manual repositioning session (question 8, Appendix J), the Friedman test indicated that the comfort ratings associated with the shoulders and legs and feet differed significantly ( $p<0.05$ ). Equally, when the ratings assigned to a particular body region were compared across the three positions of a given protocol, the shoulder ratings yielded a significant result during the manual repositioning session, from the supine to the left tilt position ( $p<0.05$ ), although all other differences were not significant in either protocol (all  $p>0.05$ ). Inter-session comparisons further indicated that of all the positions and body regions, the comfort ratings at the shoulder during the left tilt position (question 8, Appendix J) formed the only statistically significant difference between protocols ( $p<0.05$ , sign test), which may be due the placement of the gas tension electrode at the right shoulder. Nevertheless, similar to the overall comfort associated with the turned positions (questions 4 and 7, Appendix J), examination of comfort ratings at the various body regions during LRP turning and manual repositioning reveals a trend towards lower scores during the latter protocol (Table 7-6).

The firmness of the mattress was frequently rated as optimal (question 2, Appendix J), with the firmness rated 'just right' in 45% and 55% of cases during the LRP and manual repositioning protocols, respectively. The remaining participants generally perceived the mattress as 'somewhat firm', which formed 45% of the responses in the LRP protocol and 36% in the manual repositioning protocol, and one participant (9%) rated the mattress as 'somewhat soft' during both protocols.

## Comparison of a Lateral Rotation Platform to Conventional Repositioning

Perceived safety during the turn positions (questions 6 and 9, Appendix J) was generally rated high, as is illustrated in Figures 7-13 and 7-14. Nevertheless, marginally higher ratings were observed during turning by means of the LRP, although these differences did not reach statistical significance in either turn position ( $p>0.05$ ).

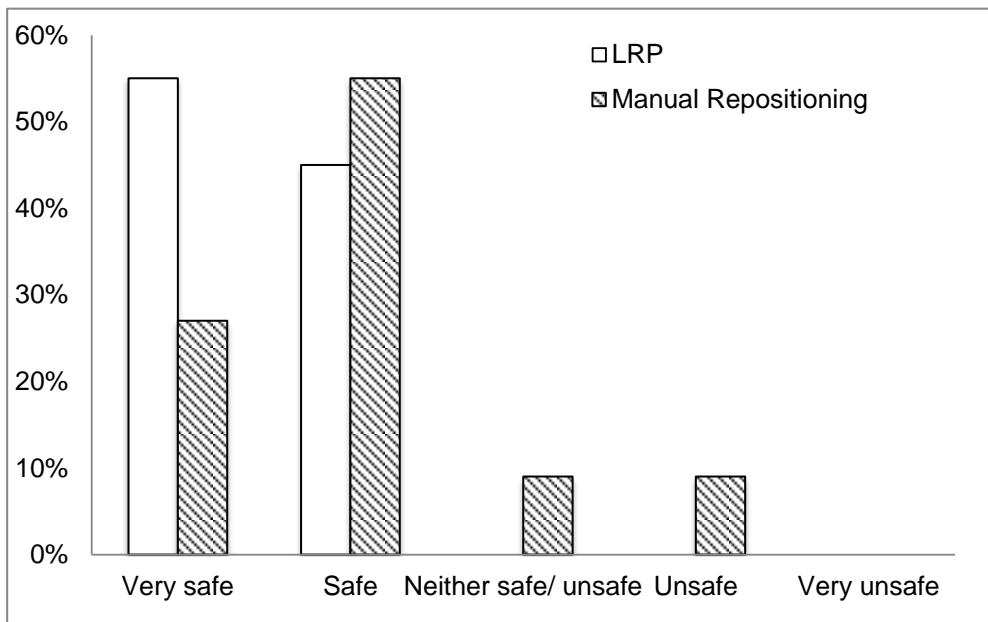


Figure 7-13: Comparison of perceived safety (question 6, Appendix J) during the right tilt position of the LRP and manual repositioning protocols.

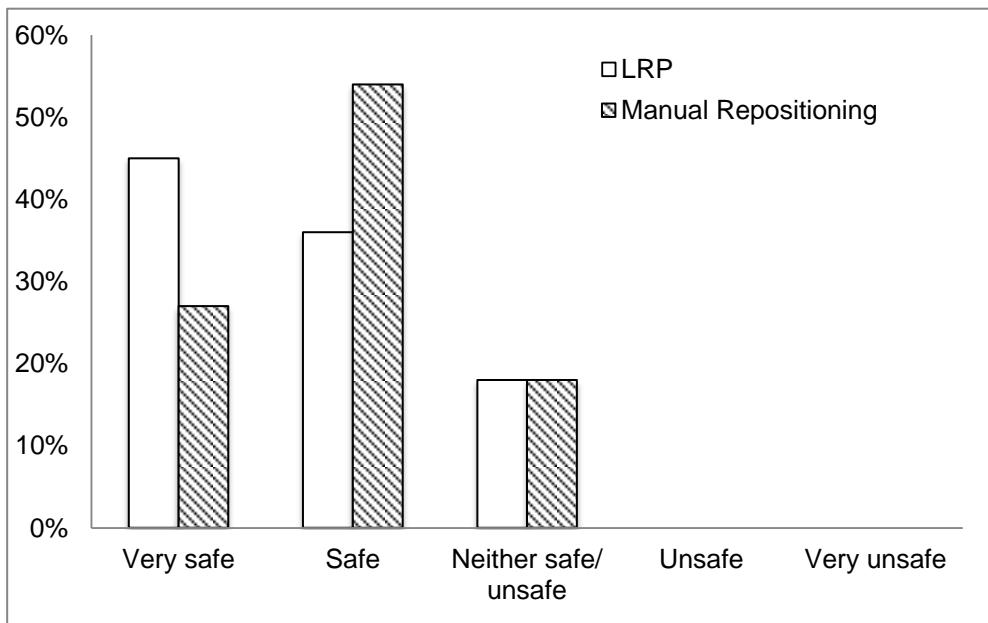


Figure 7-14: Comparison of perceived safety (question 9, Appendix J) during the left tilt position of the LRP and manual repositioning protocols.

### 7.3 Discussion

This chapter has described a study designed to examine the performance of a lateral rotation platform when compared to manual repositioning. The sternal and pelvic turn angles associated with the former were found to be significantly lower than those observed during manual repositioning (Figure 7-4 and 7-5), with these differences being statistically significant during both turn phases. By contrast, the turn angles obtained during the manual repositioning protocol were found to be comparable to those reported previously (Figures 6-5 and 6-6). Despite the difference in the magnitude of turn angles, categorical analysis of the sacral gas tension data did not identify significant differences between protocols in any of the positions, supporting previous findings (Section 6.2.3). Additionally, comparison of the sacral peak interface pressures did not identify significant differences between turning by means of LRP and manual repositioning (Section 7.2.6). However, when the oxygen debt parameter was considered, there was a statistically significant difference between the LRP and manual repositioning protocols, observed in three out of the four positions (Section 7.2.5). By contrast, no significant differences between protocols were found in the carbon dioxide accumulation parameter (Section 7.2.5).

A trend towards lower transcutaneous oxygen values, at times with an accompanying increase in carbon dioxide values, has previously been observed among participants with a low BMI (Section 5.2.2 and 6.2.3), with the present findings corroborating these results (Section 7.2.3). Indeed, when linear models were applied to the total oxygen debt associated with the LRP and manual repositioning sessions, BMI accounted for 37% and 50% of the variability in oxygen debt during LRP turning and manual repositioning, respectively, with both models significant at the 5% level (Figures 7-6 and 7-7). Several researchers have identified BMI as an independent risk factor for PU development and although the precise role of this, and other metabolic and nutrition-related variables remains unclear, it is acknowledged that such factors may be important (Coleman et al. 2013).

Comfort ratings associated with the turn positions of the LRP and manual repositioning protocols indicated that perceived comfort was lower during manual repositioning, with the inter-session differences in overall comfort statistically significant during both turn positions (Section 7.2.7). In addition, comfort ratings at the various body regions were consistently lower during the manual repositioning protocol, although these differences were frequently not statistically significant. The perceived safety ratings during the turn

## Comparison of a Lateral Rotation Platform to Conventional Repositioning

positions were further found to be marginally lower during the manual repositioning session. These findings are in contrast to the study described in Chapter 6, where comfort and safety ratings associated with the turn positions were higher during manual repositioning. It has previously been suggested that the nature of the turning mechanism may be an important determinant of perceived comfort and safety (Section 6.3). The results presented in this chapter support this assertion, since turning by means of an automated method was preferred to manual repositioning, and participant feedback indicated that LRP-induced turns were imperceptible at times. This could explain the system's adoption into clinical practice, where it is generally well accepted by both patients and clinicians. However, in terms of efficacy, the present results have identified some statistically significant differences in the physiological factors associated with the LRP and manual repositioning, which suggest that the former may not facilitate tissue recovery at the sacrum. Yet, on closer examination of the manual repositioning results, turned positions were not always associated with unequivocal signs of tissue recovery, a finding which was consistent with previously reported results (Section 6.2.5).

## 7.4 Summary, Conclusion and Future Work

The key findings of the current study were as follows:

- Turning by means of the lateral rotation platform resulted in statistically significant lower turn angles, as compared to manual repositioning, at two of the three sites examined;
- Categorical analysis of sacral gas tensions did not yield significant differences between the two turning mechanisms;
- Differences were observed in the oxygen debt parameter, which was significantly higher during the majority of the LRP turn positions;
- Manual repositioning did not consistently facilitate the recovery of previously loaded tissues;
- Sacral peak interface pressures did not significantly differ between the two protocols;
- The overall turn comfort ratings were lower during manual repositioning and these differences were significant in both turn positions;
- Perceived safety ratings were lower during the turn positions of the manual repositioning protocol.

## Comparison of Lateral Rotation to Conventional Repositioning

When examining the research questions for this study (Chapter 7), it can be concluded that the LRP and manual repositioning turning processes were not equally effective at maintaining tissue viability, with a higher oxygen debt associated with the former turning method, although peak sacral pressures did not differ between these methods. Conversely, lower comfort and safety ratings were associated with manual repositioning.

While the above results have identified a number of differences between the turning processes, it is interesting to note that manual repositioning did not always result in full tissue recovery, as indicated by gas tensions and interface pressures. A number of studies have utilised physical measurement techniques to examine the ability of manual repositioning, and in particular the 30° side-lying position, to reliably offload those areas at high risk of PU formation (Section 4.3.2). However, some of the present findings do not support assertions from these previous studies. Indeed, despite the care taken in repositioning participants, the absence of contact between the sacrum and support surface could not be guaranteed. This calls into question the efficacy of the intervention, particularly when employed by different nurses, an area which has not been examined to date. Therefore, a study was designed to examine the ability of manual repositioning to offload vulnerable areas, and the variability of this intervention when employed by different practitioners. This study is detailed in Chapter 8.



## Chapter 8: The Variability and Effectiveness of Repositioning for Pressure Ulcer Prevention

Repositioning forms a central tenet of PU prevention, which is advocated in current guidelines (National Institute for Health and Care Excellence 2014; NPUAP, EPUAP and PPPIA 2014b). These guidelines recommend the use of the 30° side-lying position for bed-bound individuals and this strategy has been examined in the studies presented in Chapters 6 and 7. However, despite research supporting the use of the 30° side-lying position (Section 4.3.2), the present results have indicated that this manoeuvre may not be efficacious, with little variation in terms of peak interface pressures and sacral gas tensions between the supine and tilted positions of the manual repositioning turn cycle (Sections 6.2.3, 6.2.4, 6.2.5, 7.2.3, 7.2.5 and 7.2.6).

Nevertheless, the generalisability of these findings may be limited since the intervention was administered by a single clinician in both studies. Indeed, while Moore and colleagues (2011) describe a range of methods which were employed to educate staff on the use of the 30° side-lying position, the inter-practitioner variability of the intervention has not been examined to date. In addition, the extent to which the 30° side-lying position has been adopted in clinical practice remains unclear, and it is likely that certain clinicians continue to use the 90° lateral position for PU prevention.

Accordingly, this study was designed to examine the inter-practitioner variability of repositioning and its ability to offload those areas particularly susceptible to PU development. The specific research questions were as follows:

- I. Does the repositioning technique, undertaken for the purpose of PU prevention, vary between practitioners?
- II. Does repositioning reliably offload particular areas, as determined by physical inspection and interface pressures?
- III. Does written guidance influence the repositioning technique of practitioners?

## **8.1 Materials and Methods**

### **8.1.1 Survey**

A survey was utilised to collect descriptive data from participants prior to the commencement of every data collection session. This survey, included in Appendix K, contained questions detailing years of experience, Agenda for Change (AfC) band and job title, setting and speciality, the frequency in which participants undertook repositioning within their present role, and the extent of their training on pressure ulcer prevention.

### **8.1.2 Inclinometer Measurements**

Inclinometer measurements (SOAR, Digital Levelmeter 1700) were independently obtained by two assessors following each repositioning manoeuvre, namely the principal investigator, a registered nurse (assessor A), and a second assessor, a senior nurse researcher from the University of Southampton with expertise in the area of pressure ulcer prevention (assessor B). Turn angles were recorded at the sternal, pelvic and ankle levels in the manner previously described in Section 6.1.5. However, in contrast to previous studies, all measurements were obtained from a single healthy volunteer, namely a male post-graduate research student, hereafter referred to as the volunteer, while the participants, consisting of nursing and associate practitioners, performed all repositioning manoeuvres.

### **8.1.3 Assessors Data Collection Instrument**

A data collection sheet was completed by both assessors after every repositioning manoeuvre, to record the turn angles at the respective sites. Initially, assessors also determined whether the heels and sacrum were free from contact with the mattress and this was recorded on the data collection sheet. However, after completion of the first data collection session it became apparent that while the heels were free from contact with the mattress, complete offloading was not achieved, an issue which could also arise at the sacral area. Accordingly, the questions within the data collection sheet were revised to distinguish between the areas being free from contact with the support surface, and complete offloading.

Furthermore, assessment of both the lateral and medial malleoli was included resulting in the following assessment items:

- Are both heels free from contact with the mattress?
- Are both heels offloaded?
- Are the malleoli offloaded?
- Is the sacrum free from contact with the mattress?
- Is the sacrum offloaded?

#### **8.1.4 Interface Pressure Measurements**

The previously employed Talley Pressure Monitor (TPM3, Talley Medical, Romsey, UK) was used to obtain interface pressures, which were recorded following every episode of repositioning, in an equivalent manner to that described in Section 6.1.4. However, the shoulder array was omitted so as not to interfere with the position of the volunteer once the participant had completed the manoeuvre. Thus, the configuration of the pressure sensors consisted of 72 sensors covering the length of the mattress, with a separate 12-cell array utilised at the sacrum. Prior to every manoeuvre the position of the volunteer lying supine on the support surface was checked, to ensure that the sacral array was located underneath the sacrum.

#### **8.1.5 Written Guidance on Repositioning**

Following the first repositioning manoeuvre, participants were provided with an article describing the procedure of positioning using the 30° side-lying position (Wilson 2008). This publication, referred to as a technical guide, was selected as it most closely described the technique employed by the investigator in the previous studies comparing lateral rotation to manual repositioning, and its guidance was written in an accessible manner.

#### **8.1.6 Study Protocol and Data Collection Process**

Approval was granted by the Faculty ethics committee of the University of Southampton (FoHS-ETHICS-14219) in May 2015. Recruitment was undertaken via poster advertisements, and the study details were further disseminated by other researchers and academic tutors. As indicated in the participant information sheet, contained in Appendix L, the inclusion criteria were as follows:

- Registered nurse, healthcare support worker or student nurse;

## The Variability and Effectiveness of Repositioning

- Some clinical experience of repositioning for pressure ulcer prevention.

Potential participants were excluded if they demonstrated any of the following criteria:

- Musculoskeletal conditions, or any other condition which precluded safely performing the repositioning manoeuvres;
- Pain or discomfort directly before participation in the study, since this could impede their ability to perform the repositioning manoeuvres.

Written consent was obtained before data collection. Following this, participants were asked to complete the survey. Each was then invited to reposition the volunteer lying on the support surface to a left tilt position, using the technique they would routinely use in clinical practice for the purpose of pressure ulcer prevention. The Hill-Rom NP150 viscoelastic mattress (Hill-Rom, Ashby, UK) represented the support surface, which was placed on a profiling bed. A range of pillows were made available to participants, varying in firmness, to utilise as per their clinical judgment. No time restriction was placed on the manoeuvre and participants were instructed to alert the researcher once they felt the position of the volunteer was optimal.

Subsequently, participants were asked to read the guidance on repositioning (Wilson 2008) behind a screened area, while the assessors recorded the first set of interface pressures, consisting of three cycles of data over the 84 cells. Following this, photographs of the newly positioned volunteer were obtained by one of the assessors. The data collection sheets were then completed independently, with the assessors blinded to the results of the other assessor. The sequence in which these assessments were performed was randomised. Once this process was complete, the pillows were removed and the position of the volunteer was adjusted to ensure contact with the 12-cell array under the sacrum. Each participant was then invited to repeat the manoeuvre and data collection was repeated, with the sequence identical to the order determined at the commencement of the first set of assessments. This data collection process, depicted in Figure 8-1, took between 20 and 30 minutes to complete.

Interface pressure data and photographs were stored on the internal network server, while the survey and data collection sheets were stored in a locked filing cabinet, located in a restricted access office within the Skin Health research group.

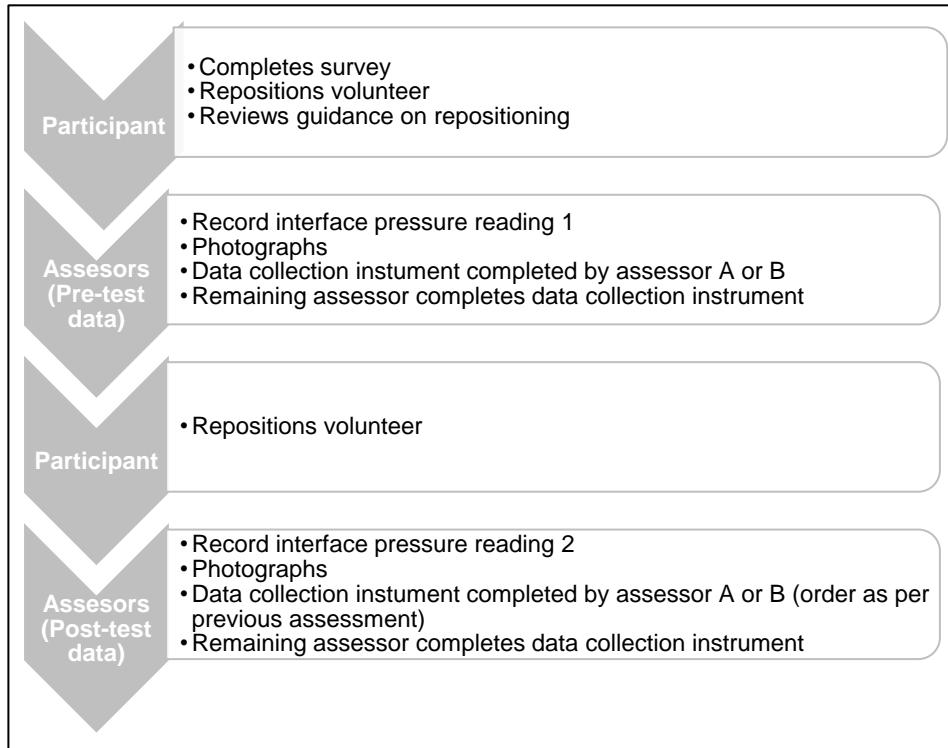


Figure 8-1: Data collection process.

### 8.1.7 Data Processing and Analysis

The survey results were entered into Microsoft Excel (Microsoft Office Professional Plus 2010, USA) and analysed using descriptive statistics. The interface pressures were processed using Matlab (MathWorks, USA) and exported to Microsoft Excel, where the peak pressure parameter was determined, as has previously been utilised (Section 5.1.7). Subsequently, pre-test (prior to written guidance), and post-test (after written guidance) conditions were described using descriptive statistics.

Inclinometer measurements were entered into IBM SPSS Statistics (version 22, USA), where the distribution was assessed for normality by inspection of the histograms, Normal Q-Q plots, and the Shapiro-Wilk test. Since these data were found to violate the assumption of normality, Wilcoxon matched-pairs signed-ranks tests or sign tests (Section 5.1.7) were utilised to assess statistical significance between the pre- and post-test data, with a prescribed significance value of  $p \leq 0.05$ . Variability between each of the measurement sites was further described by the coefficient of variation (CV), which represents the ratio of the mean divided by the standard deviation (SD), and is usually expressed as a percentage (Lexell & Downham 2005; Shoukri 2011).

## The Variability and Effectiveness of Repositioning

The inter-rater reliability of inclinometer measurements were determined by means of intraclass correlation coefficients (ICCs), which is presented with confidence intervals (CIs) (Kottner et al. 2011). Prior to the computation of ICCs, homogeneity of variances was confirmed by means of Levene's tests, to ensure the ICC requirements were met (Rovay et al. 2014). A two-way random effects model was selected, to assess the generalisability of the present results (Shrout & Fleiss 1979; Hallgren 2012). Since the objective was to determine the similarity of inclinometer measurements in absolute values, as opposed to the consistency of ratings in rank order, absolute agreement was selected and the reported ICCs pertain to single-measures (ICC(2,1), Shrout & Fleiss 1979), to enable generalisation of the measurements obtained by a single assessor (Hallgren 2012). ICC values were interpreted using the guidelines discussed by Cicchetti (1994), where values  $<0.40$ , between  $0.40-0.59$ ,  $0.60-0.74$  and  $\geq0.75$  are deemed poor, fair, good and excellent reliability, respectively.

To determine the agreement between assessors with respect to the physical assessment findings, overall percentage agreement has been reported, expressed as proportion of agreement ( $p_o$ ), and Cohen's Kappa coefficients ( $\kappa$ ) were computed, to provide a measure of chance-adjusted agreement (Pett 1997). The results of the latter were interpreted with the guidelines previously presented in Table 2-3 (Landis & Koch 1977), where the strength of agreement ranges from poor ( $\kappa<0.00$ ) to almost perfect ( $\kappa=0.81-1.00$ ). To determine whether the assessment findings significantly differed between assessors, the McNemar test for related samples was utilised (Pett 1997; Shoukri 2011), with differences of  $p\leq0.05$  accepted as statistically significant. Subsequently, participants pre-and post-test results, obtained by a single assessor, were compared with McNemar tests (Pett 1997).

## 8.2 Results

### 8.2.1 Participants

As indicated in Table 8-1, twelve participants were recruited, the majority of whom were registered nurses, with a median experience of 6 years (range 1-36 years) within a nursing/ auxiliary nursing role. Of the registered nurses, 64% were employed at AfC band 5, while band 6 and 7 nurses comprised 27% and 9% of the sample, respectively. Most participants worked in a secondary care setting, and 75% undertook repositioning for pressure ulcer prevention on at least a weekly basis. All participants had received training regarding pressure ulcer prevention within the last five years, and most participants reported that this training included instruction on repositioning (83%).

Table 8-1: Participant characteristics.

Participant	Experience (years)	AfC Band	Role	Setting	Speciality	Frequency of repositioning
A †	1	N/A	Student Nurse	Primary Care	Community Nursing	Daily
B †	4	5	Nurse	Secondary Care	Haematology	Not part of current role
C †	7	5	Senior Staff Nurse	Secondary Care	Oncology	Daily
D †	6	6	Nurse Practitioner	Secondary Care	Acute Oncology	Monthly
E †	6	5	Staff Nurse	Secondary Care	Paediatric Surgery	Yearly
F	5	5	Staff Nurse	Secondary Care	Emergency Medicine	Daily
G	11	7	Ward Manager	Secondary Care	Medicine for Older People	Daily
H	8	6	Clinical Practice Educator	Secondary Care	Acute Medical Unit	Weekly
I	36	6	Clinical Practice Educator	Secondary Care	Medicine for Older People	Weekly
J	6	5	Staff Nurse	Secondary Care	Acute Medical Unit	Daily
K	8	5	Staff Nurse	Primary Care	Hospice	Daily
L †	4	5	Community Staff Nurse	Primary Care	Community Nursing	Daily

† Indicates sessions for which interface pressure data are presented.

### 8.2.2 Intraclass Correlation Coefficients of Turn Angles

The pre- and post-test turn angle measurements from each of the assessors were collated, and ICCs computed. The results, as shown in Table 8-2, reveal that there was a high degree of reliability for all conditions, with ICC values that may be interpreted as excellent (i.e.  $\geq 0.75$ ). Nevertheless, it is evident that pelvic measurements resulted in lower ICCs, and it is interesting to note that these occurred during both pre- and post-test conditions. This may be due to the fact that this site was less accessible when compared to the other two sites, and greater effort was required to ensure the inclinometer device was located centrally. The results presented in the remainder of this chapter (Section 8.2.3) relate to the measurements obtained by the principal investigator, i.e. assessor A.

Table 8-2: ICCs and 95% CIs associated with the pre- and post-test turn angle measurements obtained from the sternum, pelvis, and ankles (all  $p < 0.01$ ).

		<b>Sternum</b>	<b>Pelvis</b>	<b>Ankles</b>
<b>Pre-Test</b>	<b>ICC</b>	<b>0.98</b>	<b>0.85</b>	<b>0.97</b>
	95% CI	0.92-0.99	0.59-0.96	0.89-0.99
<b>Post-test</b>	<b>ICC</b>	<b>0.93</b>	<b>0.76</b>	<b>0.93</b>
	95% CI	0.77-0.98	0.36-0.92	0.77-0.98

### 8.2.3 Turn Angle Measurements

Figure 8-2 illustrates the turn angles associated with the pre and post-test conditions. It is evident that the pre-test turn angles observed at the sternum and pelvis were of a similar magnitude, with CVs of 43% and 34%, respectively. By contrast, the pre-test turn angles at the ankles demonstrated a greater variability, as reflected by a CV of 82%. The observed post-test sternal and pelvic ranges were slightly lower (Figure 8-2), and were associated with a CV of 29% at the sternum, and 32% at the pelvis. Similar to the pre-test condition, variability was greatest at the ankles, resulting in a CV of 111%. Nevertheless, all but 2 values were below 30°, and removal of these outliers resulted in a CV comparable to that observed during the pre-test condition (81%).

It is interesting to note that, in contrast to the previous manual repositioning turn angles (Sections 6.2.2 and 7.2.2), the median sternal angles were lower than the associated pelvic angles during both test conditions, with medians of 28° (pre-test) and 24° (post-

test) for the former, and 38° (pre-test) and 30° (post-test) for the latter site. Indeed, in 3 of the pre-test cases the difference between these sites was  $\geq 14^\circ$ .

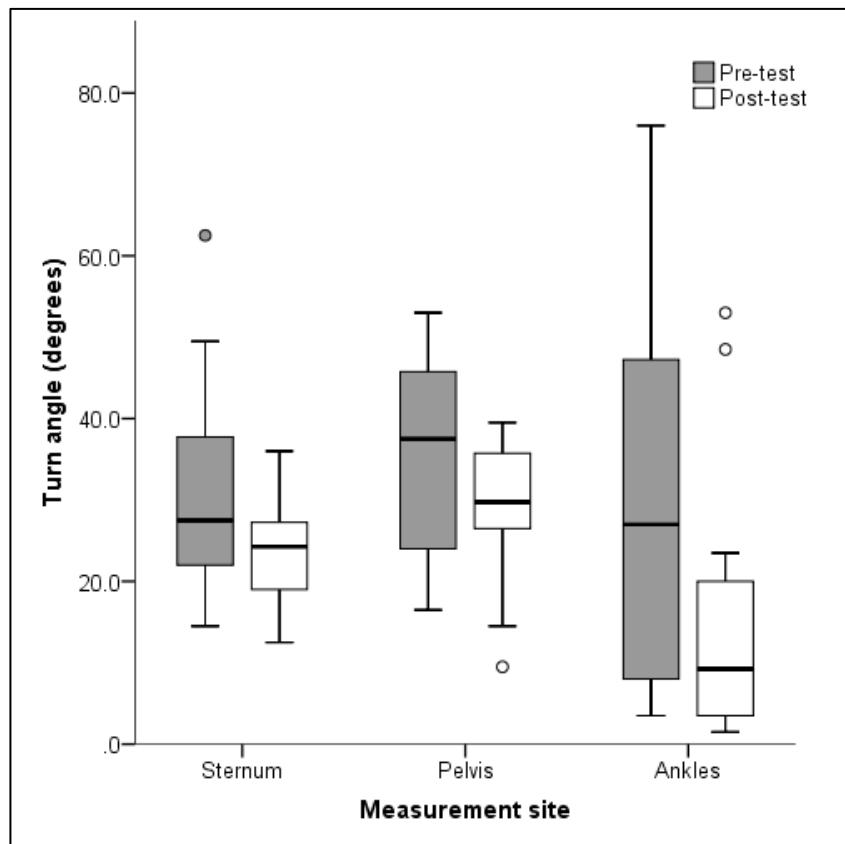


Figure 8-2: Boxplot showing the pre- and post-test turn angles at each of the sites.

Comparison between the pre- and post-test results illustrates that median post-test turn angles were lower at all sites and Wilcoxon signed-ranks tests determined that these differences were statistically significant at the sternum ( $p<0.05$ ) and ankles ( $p=0.05$ ), although re-examination of the pelvic angles by means of the sign test yielded non-significant results ( $p>0.05$ ).

#### 8.2.4 Agreement and Inter-rater Reliability of the Physical Assessment Results

A cross-tabulation of the results of assessors A and B, for each of the items contained in the data collection instrument (Section 8.1.3) is shown in Table 8-3. This table indicates that the pre-test percentage agreement ranged between 75-100% across the assessment items. In particular, the responses related to whether the heels were free of the mattress and the sacrum was offloaded yielded a 100% agreement (Table 8-3).

## The Variability and Effectiveness of Repositioning

Table 8-3: Cross-tabulation of assessors A and B pre- and post-test physical assessment results, presented with overall percentage agreement ( $p_0$ ) and Kappa ( $\kappa$ ). Identical positive results and negative results are highlighted in green and red, respectively.

Are both heels free from contact with the mattress?						
Pre-test $p_0=1.00, \kappa=1.00$		Assessor B		$p_0=0.67, \kappa=0.14$	Assessor B	
		Yes	No		Yes	No
Assessor A	Yes	5	-	5	Assessor A	Yes
	No	-	7	7		No
	Total	5	7	12		Total
Are both heels offloaded?						
Pre-test $p_0=0.82, \kappa=0.42$		Assessor B		$p_0=0.64, \kappa=0.21$	Assessor B	
		Yes	No		Yes	No
Assessor A	Yes	1	-	1	Assessor A	Yes
	No	2	8	10		No
	Total	3	8	11		Total
Are the malleoli offloaded?						
Pre-test $p_0=0.82, \kappa=0.00$		Assessor B		$p_0=0.82, \kappa=0.62$	Assessor B	
		Yes	No		Yes	No
Assessor A	Yes	-	2	2	Assessor A	Yes
	No	-	9	9		No
	Total	-	11	11		Total
Is the sacrum free from contact with the mattress?						
Pre-test $p_0=0.75, \kappa=0.31$		Assessor B		$p_0=0.50, \kappa=0.12$	Assessor B	
		Yes	No		Yes	No
Assessor A	Yes	8	3	11	Assessor A	Yes
	No	-	1	1		No
	Total	8	4	12		Total
Is the sacrum offloaded?						
Pre-test $p_0=1.00, \kappa=1.00$		Assessor B		$p_0=0.73, \kappa=0.23$	Assessor B	
		Yes	No		Yes	No
Assessor A	Yes	4	-	4	Assessor A	Yes
	No	-	7	7		No
	Total	4	7	11		Total

By contrast, the item ascertaining whether the sacrum was free from contact with the mattress received more variable responses, yielding a 75% agreement. When the pre- and post-test percentage agreements of each of the items are compared, it is notable that in the latter condition a reduction occurred in 4 out of the 5 assessment items. Indeed, the lowest post-test agreement observed related to whether the sacrum was free from contact with the mattress (50%).

The Kappa coefficients were found to vary significantly, from slight agreement as noted in the pre-test response with respect to offloading the malleoli ( $\kappa=0.00$ ), to almost perfect agreement in the pre-test response with respect to sacral offloading ( $\kappa=1.00$ ). With regards to the former, it should be noted that the accompanying percentage agreement was 82% (Table 8-3). This disparity is due to the fact that Kappa is affected by the prevalence of the attribute under consideration, and in cases where the majority of observed ratings lie within one category, estimates may be low (Sim & Wright 2005; Viera & Garrett 2005).

Close examination of Table 8-3 reveals that discordant responses frequently resulted from a positive ('yes') response from assessor A, and a negative ('no') response from assessor B (indicated in the off-diagonals), which occurred in 5/10 of the combined pre- and post-test items. By contrast, negative responses from assessor A with corresponding positive responses from assessor B occurred in 2/10 of the pre- and post-test assessment items. Nevertheless, when assessment findings were compared with McNemar tests, these differences were generally not statistically significant. However, the post-test assessment ascertaining whether the sacrum was free from contact with the mattress was found to differ significantly between assessors ( $p<0.05$ ), and Table 8-3 illustrates that positive responses were more often provided by assessor A. Accordingly, the assessment results presented in Section 8.2.5 relate to the findings of assessor B.

### **8.2.5 Physical Assessment Results**

The pre-test repositioning technique of participants was found to vary considerably, although none of the participants utilised the 90° lateral position and all employed pillow support at the level of the thoracic and lumbar spine, in a similar manner to that described in Section 6.1.2. Nonetheless, placement of the legs and feet was found to particularly differ among participants. To illustrate, Figure 8-3 shows the resulting posture following the repositioning manoeuvre administered by participants F, J, K and

## The Variability and Effectiveness of Repositioning

L, each of which were Staff Nurses who undertook repositioning on a daily basis within their clinical role (Table 8-1), and had received instruction on repositioning for pressure ulcer prevention in the last five years.

The pre-test assessment findings, detailed in Table 8-4, indicate that the heels were free from contact with the mattress in a minority of cases, namely 42% (5/12). Of these cases, pillow support did not facilitate offloading at the heels in 2 instances and thus complete offloading of the heel area was achieved by only 3 participants, while offloading of the malleoli was not observed in any of the 11 assessments. By contrast, the repositioning manoeuvre resulted in the sacrum being free from contact with the mattress in 67% (8/12) of instances, although this did not consistently ensure offloading of the area, which was deemed to be achieved in 4/11 assessments (36%).

Following guidance (Wilson 2008), participants most frequently altered the positioning of the legs and feet as is illustrated in the corresponding post-test images (Figure 8-4). The accompanying assessment results (Table 8-4) indicate that these changes resulted in an improvement regarding the number of cases where the heels were free from contact with the mattress, which was noted in 10/12 cases (83%). Nevertheless, complete offloading of the area still only occurred in 4/11 cases. Conversely, a deterioration was observed in both the items assessing the sacral area, as compared to the pre-test assessments, with the sacrum deemed free from contact with the mattress in 5/12 assessments (42%), and offloading achieved in 2/11 instances (18%).

The Variability and Effectiveness of Repositioning



Figure 8-3: Observed differences in the pre-test repositioning technique of participants. From left to right the images relate to participant F, J, K and L.

## The Variability and Effectiveness of Repositioning



Figure 8-4: Differences in the post-test repositioning technique of participants. From left to right the images relate to participant F, J, K and L.

Table 8-4: Cross-tabulation of pre- and post-test physical assessment results (assessor B). The parameters of interest, namely those instances where an improvement was noted are highlighted in green, while the instances where a deterioration occurred are highlighted in red.

Are both heels free from contact with the mattress?				
		Post-test		
		Yes	No	Total
Pre-test	Yes	5	-	5
	No	5	2	7
	<b>Total</b>	10	2	<b>12</b>
Are both heels offloaded?				
		Post-test		
		Yes	No	Total
Pre-test	Yes	2	1	3
	No	2	6	8
	<b>Total</b>	4	7	<b>11</b>
Are the malleoli offloaded?				
		Post-test		
		Yes	No	Total
Pre-test	Yes	-	-	-
	No	3	8	11
	<b>Total</b>	3	8	<b>11</b>
Is the sacrum free from contact with the mattress?				
		Post-test		
		Yes	No	Total
Pre-test	Yes	4	4	8
	No	1	3	4
	<b>Total</b>	5	7	<b>12</b>
Is the sacrum offloaded?				
		Post-test		
		Yes	No	Total
Pre-test	Yes	2	2	4
	No	-	7	7
	<b>Total</b>	2	9	<b>11</b>

It is evident from the above table that written guidance only marginally improved the assessment results concerning items related to the heels and malleoli. By contrast, at the sacrum, the post-test results indicate a deterioration. Nevertheless, comparison of the pre- and post-test results with McNemar tests did not identify statistically significant differences for any of the 5 assessment items (all  $p>0.05$ ).

### 8.2.6 Interface Pressures

Table 8-5 shows a summary of the median and peak interface pressures. This illustrates that the median post-test pressures were lower at both the body and sacral sites. With reference to the latter, these results appear to contradict the findings of the physical assessment, which suggest that offloading of the sacrum occurred less frequently during the post-test condition, although these differences were minimal.

Table 8-5: Summary of the median and range of peak interface pressures (IPs) (mmHg) during the pre- and post-test conditions (n=6, Table 8-1).

	Pre-test	Post-test
<b>Peak body IP †</b>	68 (50-158)	51 (43-80)
<b>Peak sacral IP ††</b>	60 (54-101)	48 (23-113)

† Recorded over 72 sensors. †† Recorded over a 12-sensor array.

## 8.3 Discussion

The variation in the repositioning technique between practitioners has been examined in the present study, with the results suggesting that there is considerable variation in the technique employed. In particular, the positioning of the legs and feet was found to differ, as is indicated by the turn angle at the ankles (Figure 8-2), the accompanying CV (Section 8.2.3), and the pre-test photographs (Figure 8-3). Nevertheless, all participants employed a variant of the 30° side-lying position as is recommended in current guidelines (NPUAP, EPUAP and PPPIA 2014b). However, physical assessment determined that offloading of areas vulnerable to PU development was frequently not achieved (Table 8-4), although this assessment was not as simple as may be anticipated, with some discord evident between assessors (Section 8.2.4). By contrast, the inclinometer measurements were associated with excellent inter-rater reliability (Section 8.2.2).

Following the provision of written guidance there was generally a reduced variation in repositioning, as indicated in Figure 8-2, with a reduced CV observed at the sternal and pelvic sites. Examination of the pre- and post-test turn angles found these differences to be statistically significant at the sternum and the ankle (Section 8.2.3). Additionally, comparison of the accompanying interface pressures associated with six participants

(Table 8-2) revealed a trend towards lower interface pressures following written guidance. Despite this, the physical assessment items did not demonstrate a substantial improvement, as compared to the pre-test results, and in certain assessment items a deterioration was observed (Table 8-4).

Overall, the findings of the present study suggest that repositioning practice is variable among practitioners and this intervention does not appear to consistently offload areas particularly susceptible to PU development. Since these results were obtained in optimal laboratory conditions, with adequate resources and no time restrictions on completing the manoeuvre, it may be argued that in clinical practice greater variation is likely to be observed. Equally, the assessments were conducted immediately after the intervention and it is possible that the observed positions may have been more stable than those which would have been observed if the assessments had been undertaken some time after the manoeuvre. Previous studies have identified difficulty in maintaining the 30° side-lying position, as well as issues surrounding perceived security (Sections 4.3.2 and 4.8), and similar issues may have emerged if the time-period following the manoeuvre and the assessment had been greater.

It should also be recognised that in practice positioning can be affected by a variety of patient-related factors, such as medical condition, patient preference, pain, and contractures, all of which may further contribute to a disparity and may ultimately impede the effectiveness of the intervention.

## 8.4 Summary, Conclusion and Future Work

The present study identified that:

- The turn angles obtained prior to written guidance varied considerably between practitioners;
- Offloading of areas susceptible to PU development was infrequent;
- Written guidance influenced the repositioning technique of practitioners resulting in statistically lower turn angles at two of the three sites but total offloading still remained infrequent;
- The inclinometer measurements that have been utilised in this study, and previous studies, exhibited excellent inter-rater reliability;
- Assessing clearance between the body and the support surface, or complete offloading, may prove difficult in practice.

## The Variability and Effectiveness of Repositioning

Accordingly, when examining the previously specified research questions (Chapter 8), it can be concluded that the repositioning technique varied between practitioners, and that this manoeuvre did not reliably offload areas susceptible to PU formation.

Nevertheless, written guidance was found to influence the repositioning technique employed by practitioners, although this did not result in a significant improvement in terms of offloading.

It has been suggested that greater variability could exist in clinical practice. To extend the present work a practice-based study of repositioning for the purpose of pressure ulcer prevention should be conducted.

## Chapter 9: Discussion

Pressure ulcers represent a debilitating condition for patients and present a significant challenge for healthcare professionals. Numerous strategies may be implemented to prevent PUs for those deemed at risk due to prolonged periods in bed, including regular repositioning, the use of pressure redistributing support surfaces and routine skin inspection. In addition to traditional methods, repositioning can be achieved by mechanical means in the form of lateral rotation systems, which can be integrated into a support surface, or offered as a system used in combination with a standard support surface.

A review of the literature established that there are few studies which have examined lateral rotation systems, despite the fact that such systems have been available for over five decades (Section 4.4). Moreover, none of the studies that were identified directly compared these interventions to current clinical practice involving the repositioning of bedbound patients using the 30° side-lying position. Accordingly, as outlined in the aim and objectives (Section 4.6), a series of studies were designed to examine efficacy and acceptability of two distinct lateral rotation systems, in comparison to repositioning as employed in clinical practice. Additionally, a study was conducted to evaluate the inter-practitioner variability of conventional repositioning, as no such research had been identified (Section 4.3.2). This study also investigated whether offloading of vulnerable areas occurred as a result of the intervention, and if the technique utilised by practitioners changed following the provision of written guidance. In addition to these experimental studies, an integrative review of risk assessment scales was conducted, to update and extend related work in this area (Section 2.6.1).

The present chapter reviews the key findings of these studies, and interprets these in the context of the existing body of knowledge. The findings will also be considered in terms of the implications for clinical practice, and future research avenues will be suggested to extend the work presented in this thesis.

## 9.1 Evaluation of a Prototype Support Surface Incorporating a Lateral Rotation Function

A study was undertaken to evaluate a prototype support surface which incorporates a lateral rotation feature (LPR). Specifically, this study sought to determine the effect of the LPR function on selected parameters of tissue viability and subjective perception of comfort. The effect of two therapeutic modes, namely the continuous and alternating low pressure profiles (CLP and ALP), was further evaluated, in conjunction with the effect of variation in internal air pressure. In defining the tissue response to loading, these studies adopt the criteria established by Chai and Bader (2013), discussed recently in the review paper by Mirtaheri and colleagues (2015). To reiterate, compromised tissue viability would be demonstrated by low transcutaneous oxygen values ( $TcPO_2$ ), in combination with elevated carbon dioxide values ( $TcPCO_2$ ). In addition to gas tensions, interface pressures were measured as this represents a standard technique utilised by commercial manufacturers, researchers and clinicians to evaluate the performance of a range of support surfaces (Section 4.7.2).

The results of the present study indicated that variation of the air pressure in the support surface within a 10mmHg range did not produce marked differences in transcutaneous gas tensions. Nonetheless, at the sacrum, compromised tissue viability occurred less frequently when the internal air pressures were set at 5mmHg below the previously defined optimum air pressure (Chai & Bader 2013) (Table 5-2, 5-4 and 5-5). Conversely, peak sacral interface pressures were generally greater when internal pressures were 5mmHg below the optimum air pressures (Table 5-6). These findings contrast with those reported by Mayrovitz and Sims (2002), who investigated skin blood flow at the heels of healthy participants using LDF with corresponding measurements of interface pressures. They found that while interface pressures were higher in the group exposed to a greater cycle amplitude, that is a greater range of internal air cell pressures during the inflation and deflation cycle (Section 4.2), the reduction in skin blood flow was less marked when compared to a group exposed to a lower cycle amplitude. By contrast, Rithalia (2004) examined two APAMs with integral pressure sensors, one generating relatively high internal air pressures and one with lower air pressures, and reported higher interface pressures at the heel of healthy participants in the latter system, consistent with the present results. However, peak perfusion, assessed by LDF at the contralateral heel, was significantly greater ( $p<0.01$ ) in the

APAM system with higher air pressures. A summary of the findings of the respective studies is contained in Table 9-1.

Table 9-1: Summary of studies which have investigated the effect of variation in the internal air cell pressure.

Author	Sample	Site	Measurement techniques	Internal air pressure †	Interface pressures †	Physiological response ††
Mayrovitz and Simms (2002)	20	Heels	IP and LDF	↑	↑	↑
Rithalia (2004)	10	Heels	IP and LDF	↓	↑	↓
Present study	10	Sacrum	IP and TcPO <sub>2</sub> /CO <sub>2</sub>	↓	↑	↑

† A relatively higher pressure (↑) or lower pressure (↓). †† A relative improvement (↑), or deterioration (↓), in the physiological response.

A possible interpretation of the results reported by both Mayrovitz and Sims (2002) and Rithalia (2004) is that higher internal air pressures are better able to facilitate complete offloading of specific areas during the deflation phase of APAM cycle, and thus result in increased skin blood flow levels. Nevertheless, this was not evident in the present study, where a higher internal air pressure (5mmHg above the optimal pressure) had minimal effect on gas tensions. Furthermore, when extending this proposition to the ALP and CLP modes, the latter may have been predicted to be associated with more cases of compromised tissue viability at the sacrum, but this was not evident in the results. It is relevant to note that the present findings support clinical trial findings, which have failed to demonstrate significant differences between alternating air surfaces, and devices maintained at a constant low pressure (McInnes et al. 2015).

A major difference between the three studies were the measurement techniques (Table 9-1), which may offer an explanation for the inconsistency in the findings. While both measures reflect tissue perfusion, transcutaneous gas tensions provide a more direct indicator of tissue viability than LDF, which indicates local blood flow using a parameter with arbitrary units. There were also differences in the anatomical sites under investigation (Table 9-1), with previous research suggesting that loading regimes may not affect the sacrum and heels in an identical manner (Ek et al. 1987; Wong 2011). What is evident, from each of the studies, however, is that interface pressures do not unequivocally predict the physiological response of loaded soft tissues, as recognised by a range of authors (Goossens & Rithalia 2008; Chai & Bader 2013; Bergstrand et al. 2014).

## Discussion

With regards to the LPR function, analysis of gas tensions at the sacrum revealed that tissue viability was generally maintained throughout the various phases of the turn cycle (Tables 5-2, 5-4 and 5-5). By contrast, more variable responses occurred at the shoulder (Tables 5-3, 5-4 and 5-5), which could be a direct result of the turning mechanism. Close examination of the data revealed, however, that some participants, particularly those with a low BMI, exhibited depressed oxygen levels at the sacrum in both CLP and ALP test conditions. These values were recorded following the onset of the test protocols and continued throughout the LPR turn phases. These participants also demonstrated a compromised tissue viability at the shoulder. This supports the hypothesis that certain individuals, healthy or otherwise, present with an increased susceptibility to PU development (Bergstrand et al. 2014). These overall findings suggest that turning by mechanical means may not be effective in facilitating a marked degree of recovery in previously loaded tissues. However, it should be recognised that the turn cycle was of short duration (3-minute per position), and differences between LPR induced turning and manual repositioning were not examined. Nevertheless, the objective parameters which were utilised in this study proved successful in answering a number of the research questions (I-III, Chapter 5) and the study procedures were tolerated well by the individual participants.

The comfort assessment further provided valuable insight into the perceived comfort of participants. In particular, it indicated that while the prototype support surface was generally deemed comfortable during the supine phases of the CLP and ALP protocols, comfort declined during the LPR turn phases (Table 5-7). Furthermore, a trend towards decreased stability was recorded during LPR turning. It must be recognised, however, that the time at which the assessment was administered was not standardised, and participants felt that certain questions were ambiguous in nature. As a consequence, in subsequent studies the timing of the assessment was standardised, and the content of the instrument was revised.

## **9.2 Are Lateral Rotation Systems an Effective and Acceptable Alternative to Manual Repositioning?**

Two studies were conducted to examine the efficacy and acceptability of the prototype support surface (LPR) and a lateral rotation platform (LRP), each of which was compared to manual repositioning. Turn positions were maintained for 15 minutes throughout the test sessions, a period which has been considered to be adequate to

provide an accurate indication of tissue viability or status (Kim et al. 2012). To evaluate the efficacy of the different turning methods, in addition to the parameters employed in Chapter 5 (Chai & Bader 2013), alternative parameters were estimated, which reflect oxygen debt and carbon dioxide accumulation (Equations 6-1 and 6-2), as previously described (Rithalia & Gonsalkorale 2000). An inclinometer was further used to assess the magnitude of turns associated with each of the repositioning methods, and these measurements were found to exhibit a high inter-rater reliability in a later study (Table 8-2).

With respect to the inclinometer measurements, there were clear differences between the turn angles of the respective lateral rotation systems, when compared to manual repositioning, and on a number of occasions these differences reached statistical significance (Figure 9-1). It is evident that for automated systems (LPR and LRP), the tilt angles were considerably lower at both the sternum and pelvis, when compared to the corresponding values of manual repositioning. Close examination of the data also reveals differences in the tilt angles at the sternum for the two automated systems (Figure 9-1).

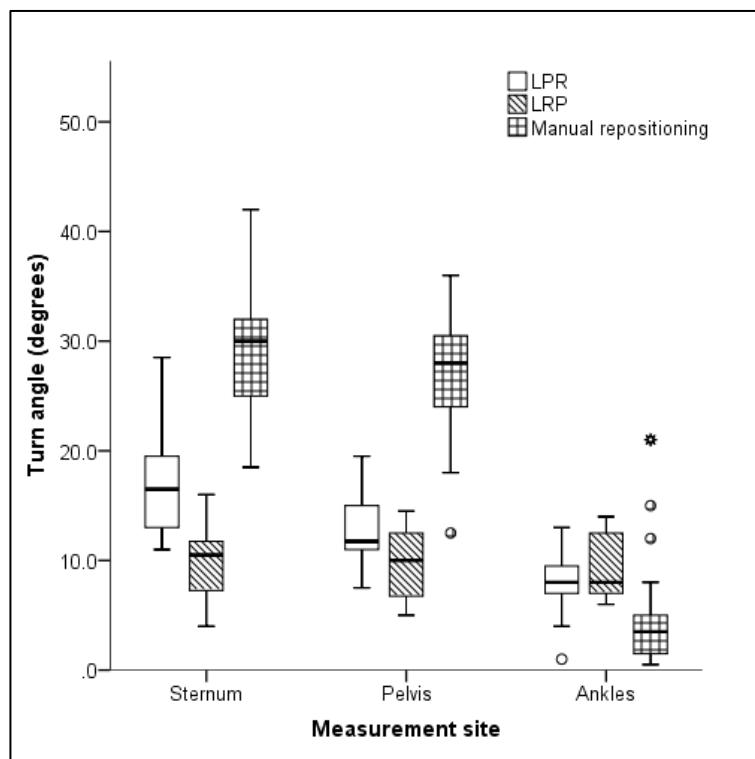


Figure 9-1: Boxplot illustrating the turn angles obtained during the left tilt position of the prototype support surface (LPR, n=10), lateral rotation platform (LRP, n=11) and manual repositioning protocols (n=21).

## Discussion

Such variation has been reported in previous studies of lateral rotation systems, with reported turn angles ranging from 10° (Futamura et al. 2008; Yi et al. 2009) to 45° (Do et al. 2016). However, these differences could be attributed to the turn angles prescribed by the various devices, as opposed to the degree of rotation measured on the participants. Thus direct comparisons with the present study are not appropriate. Indeed, the lateral rotation platform has been reported to provide a 30° turn (Section 7.1.1), which reflects the side-wing elevation, but the resulting degree of rotation of participants was found to be considerably lower (Figures 7-4, 7-5 and 9-1). In terms of optimal device or manual repositioning turn angles, a recent study utilised finite element modelling to determine internal soft tissue strains at the sacrum and found that the internal tissue strains were highest in the supine position, whereas a 20-30° tilt produced the lowest peak strains (Oomens et al. 2016).

With respect to gas tensions, analysis revealed that the categorical tissue response was often identical within individuals across the lateral rotation and manual repositioning sessions, at each of the measurement sites (Table 6-3, 6-4, 7-3 and 7-4), which is congruent with the findings of a previous study (Section 5.2.2, Figure 5-7). Accordingly, the differences between the turning methods were not found to be statistically significant in either study (Sections 6.2.3 and 7.2.3). Moreover, when the positions of a particular protocol were examined, the responses did not differ significantly across the turn cycle in any of the protocols (Sections 7.2.3 and 7.2.3), although a compromised tissue viability was evident at the loaded shoulder during the left-tilt position for all sessions (Table 6-4 and 6-4). Nevertheless, turning by means of the prototype support surface (LPR) resulted in a greater total oxygen debt and carbon dioxide accumulation at the sacrum (Figure 6-10 and 6-11). Equally, when the position-specific differences between the turning methods are examined, oxygen debt at the sacrum was generally lower during manual repositioning when compared to the corresponding lateral rotation values (Figure 6-13 and 7-8). This difference proved significant in the lateral rotation platform study, in three out of the four positions that were evaluated (Section 7.2.5). Sacral carbon dioxide accumulation demonstrated less variability and the differences between the turning methods were not found to be significant, but extreme outliers were more frequently observed when turning was achieved by either of the lateral rotation systems (Figure 6-14 and 7-9). A summary of these trends is clearly illustrated in Figures 9-2 and 9-3.

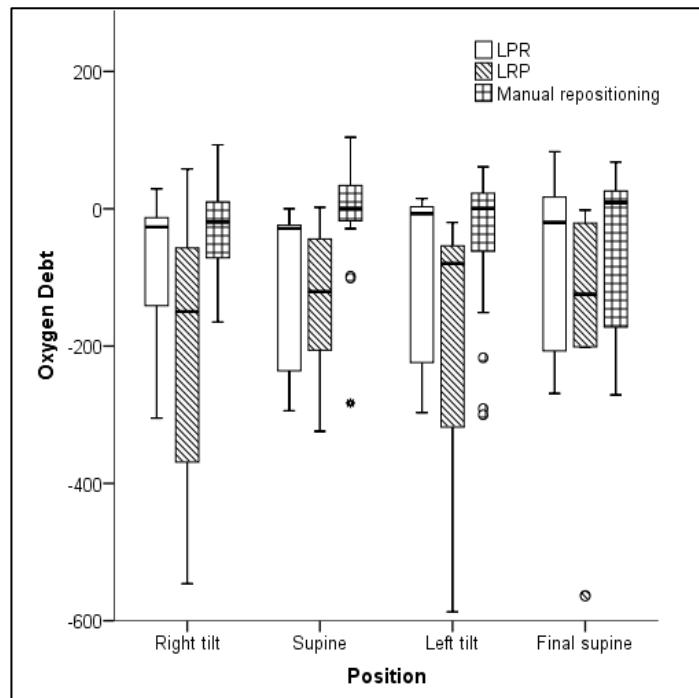


Figure 9-2: Sacral oxygen debt across the positions of the prototype support surface (LPR, n=10), lateral rotation platform (LRP, n=10) and manual repositioning protocols (n=20).

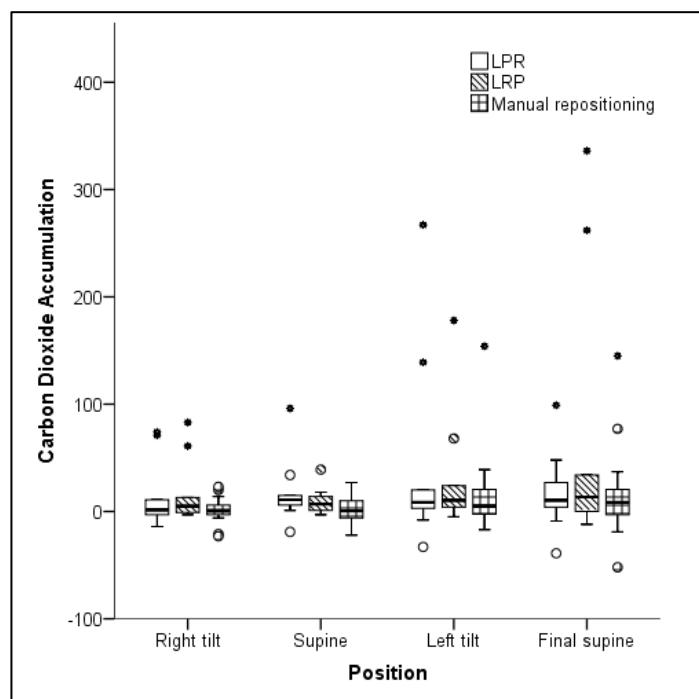


Figure 9-3: Sacral carbon dioxide accumulation across the positions of the prototype support surface (LPR, n=10), lateral rotation platform (LRP, n=10) and manual repositioning protocols (n=20).

## Discussion

It is interesting to note that manual repositioning did not appear to produce a lower oxygen debt during the right and left turn positions, when compared to the first supine position (Figure 9-2). Given that manual repositioning by means of the 30° side-lying position is designed to ensure that the sacrum is free from contact (Young 2004; Wilson 2008), which should lead to a lower oxygen debt, this is an unpredicted finding. It indicates that, despite careful positioning of participants, offloading of the sacral area was not achieved. Nevertheless, the current findings suggest that manual repositioning may be preferable to turns induced by a lateral rotation device.

A recent study by Källman et al. (2015), reported that the 30° supine tilt position, which most closely reflects a turn induced by a lateral rotation system, enabled a higher tissue perfusion than the 30° side-lying position. Accordingly, the authors suggested that the former was the most beneficial position. However, this study used different measurement techniques, at different sites, namely the trochanter and the sacrum. Therefore, a direct comparison between this and the present study is not appropriate. With respect to interface pressures, the authors report that these were similar between the two positions (Källman et al. 2015), although the previous limitation applies. Nevertheless, this is consistent with the present findings which did not identify a significant difference in the peak sacral pressures associated with turning by means of the lateral rotation systems, and manual repositioning (Section 6.2.6, Table 6-6, Section 7.2.6, and Table 7-5).

A statistically significant difference ( $p<0.01$ ) was identified at the shoulder during the left-tilt position of the manual repositioning session, as compared to the lateral rotation platform, with higher pressures observed during the latter session (Section 7.2.6, Table 7-5). However, this was not evident when turns induced by the prototype support surface were compared to manual repositioning (Section 6.2.6 and Table 6-6). Moreover, neither study, yielded a meaningful relationship between peak interface pressures and oxygen debt (Figures 6-17 and 7-12), a finding previously identified in an earlier study (Section 5.2.4).

The perceived overall comfort was high during the supine position for all test sessions (Table 6-7 and 7-6). However, consistent with the previous results (Table 5-7), comfort ratings declined during the turn positions that were induced by both the prototype support surface (Table 6-7) and manual repositioning sessions of both studies (Table 6-7 and 7-6). Indeed, differences in the overall comfort ratings for both repositioning

strategies were not significant (Section 6.2.7). By contrast, overall comfort was generally rated higher during turns induced by the lateral rotation platform, with statistically significant differences in both right and left tilt positions ( $p<0.05$ ) (Section 7.2.7). In a similar manner, perceived safety was rated higher during turning by means of the lateral rotation platform (Figures 7-13 and 7-14), although this difference was not statistically significant. Conversely, perceived safety was significantly lower during the turn position of the prototype support surface ( $p<0.01$ ) when compared to manual repositioning (Section 6.2.7 and Figure 6-18). These findings are demonstrated in Figures 9-4 and 9-5, which illustrate the overall comfort and safety ratings during the right tilt position, respectively. Close examination of the comfort ratings at specific body sites revealed some differences between the repositioning strategies, although they generally mirrored those of the overall ratings (Tables 6-7 and 7-6).

Nevertheless, differences in perceived comfort were sometimes observed when conditions were identical. As an example, overall comfort in the supine position of the manual repositioning session was somewhat lower compared to that observed during the corresponding position of the prototype support surface (Table 6-7). This demonstrates the inherent subjectivity of such ratings. In addition, the studies did not include a period to allow complete familiarisation with the different turning regimes, and the present findings may have altered if a conditioning period had been included.

Previous studies examining lateral rotation systems have suggested that comfort and stability are sacrificed when increased turn angles are employed (Yi et al. 2009; Do et al. 2016). However, the present findings do not support this assertion, since the turn angles observed during the manual repositioning sessions were higher than those associated with the corresponding lateral rotation system sessions, at two of the three measurement sites (Figure 9-1). This highlights the importance of the mechanism of the turn, which clearly varies with the three repositioning strategies under investigation (Figures 5-1, 5-2, 6-1 and 7-2).

## Discussion

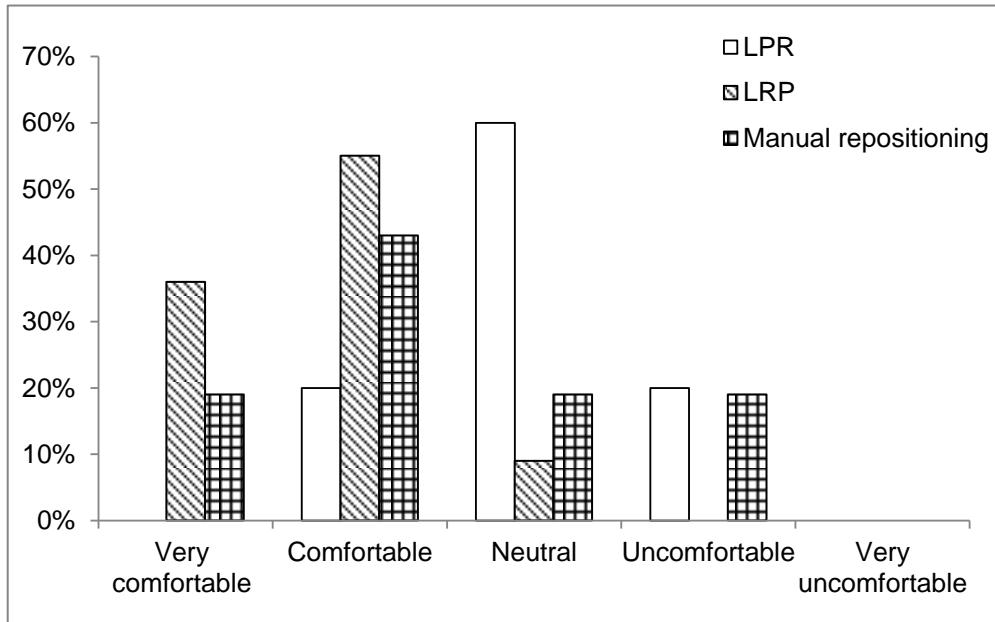


Figure 9-4: Comparison of perceived overall comfort (Appendix G and J, question 4) during the right tilt position of the prototype support surface (LPR, n=10), lateral rotation platform (LRP, n=11) and manual repositioning protocols (n=21).

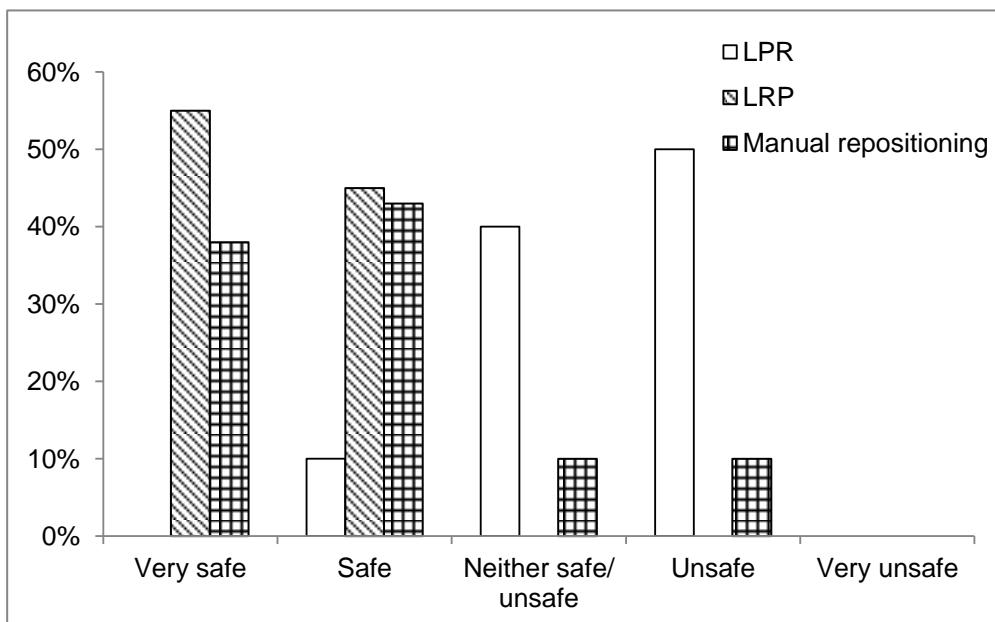


Figure 9-5: Comparison of perceived safety (Appendix G and J, question 6) during the right tilt position of the prototype support surface (LPR, n=10), lateral rotation platform (LRP, n=11) and manual repositioning protocols (n=21).

Overall, the methods adopted in the present studies proved effective in evaluating the efficacy and acceptability of the lateral rotation systems, and a number of differences between the systems were identified. These, and other criteria have been summarised in Table 9-2. It is evident that the prototype support surface performed better in terms of physiological response, but its perceived comfort was less than that of the lateral rotation platform (Table 9-2). Furthermore, while the prototype device incorporates a range of functions designed to maintain skin integrity, these features make the initial set-up and subsequent adjustment less intuitive and therefore it is deemed unsuitable for use in community settings. In addition, the relative unit cost is higher, which may preclude its widespread adoption in all but the most specialist units in acute settings. By contrast, the unit cost of the lateral rotation platform is lower, and its simple design facilitates its use in both acute and community settings. It should be noted, however, that in terms of physiological responses, both lateral rotation systems performed less well than manual repositioning by means on the 30° side-lying position (Figures 9.2 and 9.3).

Table 9-2: Summary of the key features of the prototype support surface incorporating a lateral rotation function and the lateral rotation platform.

Criteria	Prototype Support Surface with Lateral Rotation Function (LPR)	Lateral Rotation Platform (LRP)
Relative unit cost	High	Low
Incorporates a variety of functions aimed at the maintenance of tissue viability	✓	✗
Turn cycle time interval (minutes)	3-240	10-120
Ease of turn angle adjustment	Easy	More difficult
Physiological response †	↑	↓
Turn comfort/ safety †	↓	↑
Suitable for acute care settings	✓	✓
Suitable for community care settings	✗	✓

† Relatively better (↑), or poorer (↓).

Nevertheless, lateral rotation systems may provide a useful adjunct in situations where regular repositioning by traditional means is not feasible, for example, where there is limited nursing care or due to the frailty of the carer. Additionally, dependent on the mechanism, automated turning may be more acceptable to patients since several studies have reported that regular repositioning, particularly throughout the night,

## Discussion

causes sleep fragmentation and is perceived as disruptive by patients (Spilsbury et al. 2007; Gorecki et al. 2012). Indeed, several participants in the study examining the lateral rotation platform commented that they had not perceived the individual turns (Section 7.3). It should be recognised, however, that manual repositioning affords other benefits, including patient-clinician interaction, the opportunity to inspect areas vulnerable to pressure damage, and the provision of skin care. It should further be acknowledged that lateral rotation systems may not be appropriate for certain patient groups, including patients with severe contractures. Such considerations highlight the importance of a manual repositioning strategy in many situations.

While the present studies have examined lateral rotation systems and manual repositioning in cohorts of healthy participants, the physical and comfort trends that have emerged may reasonably be assumed to be applicable to patients at risk of PU development, although the findings may have been attenuated in the present cohorts. A standardised instrument to evaluate participants' experience of repositioning using either of the repositioning strategies was not identified. Therefore, the comfort assessment was developed, and while this incorporated reported concerns regarding patients' experiences of repositioning and pressure redistributing support surfaces, namely comfort and safety (Hopkins et al. 2006; Spilsbury et al. 2007; Gorecki et al. 2012), it may not consider all relevant aspects of physical comfort relating to repositioning by mechanical or traditional means.

### **9.3 Does the Repositioning Technique Vary Between Practitioners?**

A study was conducted to examine the inter-practitioner variability of manual repositioning. It additionally sought to determine if repositioning led to offloading of selected vulnerable areas and whether practitioners' technique altered following written guidance. Output parameters involved turn angles and interface pressures, and, additionally, physical assessments were undertaken by two assessors.

The results revealed a considerable variability in the technique employed. Although the median pelvic turn angle of 38° was of the same order as the recommended 30° tilt, angles measured at the ankle varied considerably over the range of 4-76° (Figure 8.2). This variation is further illustrated in Figure 8-3, with particular differences observed in the positioning of the legs and feet of the volunteer. These findings support the observations of Victor (2013), following a focus group with staff nurses employed in

elderly care. The author concluded that nurses were unaware of the technique required to achieve pressure relief at the sacrum and the heels when employing the 30° side-lying position.

When the literature surrounding the 30° side-lying position is examined considerable variation is equally evident, as is illustrated in Figure 9-6. These images reveal two distinct techniques associated with positioning of the legs and feet, namely:

- Positioning with the legs rotated outwards and placement of a pillow between the flexed knees (Figure 9-6, A, C and E);
- Positioning with a lesser degree of rotation of the legs, which are supported by lengthwise placed pillows (Figure 9-6, B and D).

Indeed, there appears to be a discrepancy between the technique shown in the guidelines (Figure 9-6, A), and the accompanying recommendations involving the process of offloading the heels (NPUAP, EPUAP and PPPIA 2014a), which might be difficult to achieve with the technique shown (Figure 9-6, A). It is interesting to note that in the present study some nurses made an attempt to address this by placing a pillow under the leg that would otherwise be in contact with the mattress (Figure 8-3, participant F and J).

All participants took care in performing the manoeuvre, often providing an explanation of the procedure to the volunteer. Subsequently, the volunteer would adopt a position that they deemed to be optimal for pressure relief, regardless of the time required to achieve this. Therefore, it is unlikely that the observed variation in repositioning is due to the simulated conditions involving an able-bodied volunteer. Indeed, it might be predicted that a greater variability would exist with patients and their inherent characteristics (Section 8.3). It would be interesting to examine this further by means of a practice-based observational study. While such studies have been conducted previously, they have largely focused on repositioning frequency (Chaboyer et al. 2013; Latimer et al. 2015), or physical parameters to assess the effect of repositioning (Peterson et al. 2013), as opposed to the reproducibility of the technique *per se*.

The physical assessment results reveal that offloading of vulnerable areas was frequently not achieved. However, comparison of the findings of two independent assessors suggests that this procedure may not be as simple as predicted, with a degree of measurement error evident (Table 8-3).

## Discussion

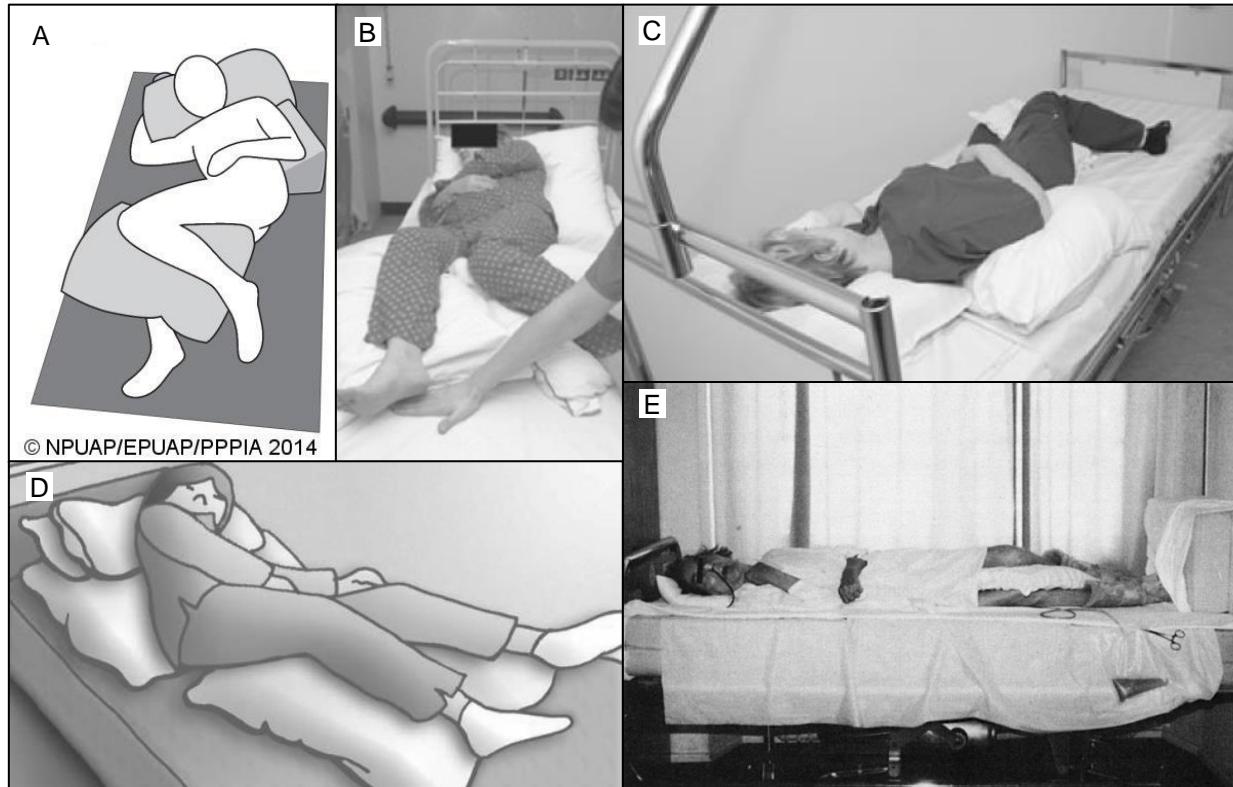


Figure 9-6: Variation in the 30° side-lying position. A: NPUAP, EPUAP and PPPIA (2014a), reproduced with permission from the rights holder (<http://internationalguideline.com/permissions>). B: Moore et al. (2011), reproduced with permission from the rights holder, Blackwell Publishing. C: Källman et al. (2013), reproduced with permission from the rights holder, Blackwell Publishing. D: Wilson (2008), reproduced with permission from the rights holder. E: Seiler et al. (1986), reproduced with permission from the rights holder, copyright © 1986 Karger Publishers, Basel, Switzerland.

This has practical implications, since assessing clearance between the body and the support surface has been advocated as a means to evaluate whether a patient has been positioned correctly (Seiler et al. 1986; Preston 1988; Defloor 2000; Moore & Van Etten 2014). These findings may also be partially attributed to the technique employed by practitioners, which, at times, made the assessment challenging due to pillow placement. An example of this is illustrated in Figure 8-4 (participant L), where the configuration of pillows hindered access to the sacral region. Nonetheless, the findings of both assessors indicate that sacral, heel, and malleoli offloading was variable (Table 8-3), which provides context to the reported observations that routine clinical repositioning does not relieve pressures at the sacrum of high-risk patients (Peterson et al. 2013).

The provision of written guidance was found to influence the technique utilised by practitioners, as evidenced by significantly lower turn angles and reduced variability at two of the three body sites (Figures 8-2 and 8-4, Section 8.2.3), and a trend towards lower interface pressures (Table 8-5). However, in terms of physical assessment, written guidance did not result in a significant improvement in offloading and, in some cases, appeared detrimental to several of the parameters (Table 8-4). A potential explanation for this unpredicted finding is that practitioners focused on emulating the position illustrated within the guidance, while overlooking the written instructions surrounding offloading. This is supported by previous research suggesting that nurses exhibit a preference for visual and kinaesthetic learning styles (Frankel 2009). Accordingly, the present findings imply that training specifically focused on the procedural aspects of patient positioning is required, as concluded by Victor (2013), and that such training may best be delivered by practical demonstrations including opportunities to practice this skill. This training should also accommodate potential variant positions, for instances where practitioners are faced with competing objectives, for example, HOB elevation necessitated by medical condition or therapy intervention, or where postural changes, including contractures, impede implementation of the optimum position (Pope 2007).

Nevertheless, to facilitate a change in practice, other strategies are required, as indicated by a RCT, which examined the effect of a training package related to the optimal positioning of patients in stroke rehabilitation (Jones et al. 2005). While training, including a practical ward-based element, was found to improve patient positioning in the intervention group ( $p<0.01$ ), post-training differences between the control and

## Discussion

intervention groups were less pronounced ( $p=0.06$ ), and there was no resulting improvement in the selected patient outcome measures at a six month follow-up (Jones et al. 2005). Therefore, to embed change into practice, training should form part of a multifaceted strategy, which could also include support and iteration from opinion leaders, audit and feedback, and reminder systems (le May 2007; Chaplin 2008; Gesme & Wiseman 2010).

## 9.4 Integrative Review of Risk Assessment Scales

A review of risk assessment scales (RASs) was undertaken, to examine their characteristics and determine the reported inter-rater reliability of these scales (Chapter 3). An integrative methodology was adopted, which facilitates the consolidation of diverse sources (Kirkevold 1997; Crossetti 2012).

Ninety-four scales were identified (Table 3-1), many of which were adapted from previously devised scales, with adaptations of the Norton Scale most frequently observed (Section 3.3.1). Other regularly observed scale development techniques included item selection based on clinical experience, and a review of the PU risk factor literature. Research methods were also utilised, which informed the development of 31% of scales. However, few researchers performed regression analysis to derive their scales, as has been recommended by Cullum et al. (1995) and Nixon and McGough (2001). Furthermore, most studies that had utilised this method were deemed to have limitations, namely the use of retrospective data and an insufficient number of events (Section 3.3.2). Nevertheless, regression analysis may not be the only valid technique of scale development (Streiner 1993; de Vet et al. 2011; Streiner et al. 2015). Furthermore, examinations of RASs that were developed in this manner have not demonstrated a significant improvement when compared to scales devised by traditional methods (Schoonhoven et al. 2005; Delparte et al. 2015), although external validation studies, as recommended by Altman et al. (2009), are scarce.

Validation studies of RASs such as the Norton, Waterlow and Braden Scales are more common, but the results of these studies reveal that certain scales consistently exhibit a suboptimal predictive validity (Pancorbo-Hidalgo et al. 2006). However, these parameters represent a surrogate for patient outcomes, with high predictive validity assumed to lead to an improved outcome (Schünemann et al. 2008). Nevertheless, these results are consistent with the findings from RCTs which indicate that RASs do not reduce PU incidence (Moore & Cowman 2014). Indeed, a qualitative study

involving Irish and Norwegian nurses revealed a disconnect between risk assessment, whether performed by a RAS or clinical judgment, care planning and care provision (Johansen et al. 2014). Accordingly, the value of RASs in PU prevention is debatable. However, the continuing development of new scales (Table 3-1, Figure 3-3) indicates that they fulfil a clinical need. Another less considered function of RASs is to demonstrate that the first step in PU prevention has been performed (Guy 2007). They provide a structured framework to document risk, which can be audited to ensure minimum standards of care are met (Department of Health 2010; NPUAP, EPUAP and PPPIA 2014b). However, if this is the motivation for their widespread adoption, then what is documented should be an accurate reflection of a patient's status (Black & Cheatle 2016). Accordingly, scales should exhibit low levels of measurement error. However, the present review has indicated that as much as 64% of the differences in observed scores of certain scales are due to measurement error (Section 3.4.2). Indeed, only 3 scales, namely the Braden Scale, COMHON index and RAPS Scale, met the specified threshold level of  $\geq 0.90$ , and thus exhibited a measurement error of  $\leq 10\%$ , in 4 high and moderate quality studies involving nursing home and ICU populations (Section 3.4.2).

Overall, the present review found that only 14 of the 94 scales have been examined for their inter-rater reliability (Section 3.4, Table 3-2). When these studies were conducted, they were often deemed to be at high risk of methodological bias, with rater representativeness, examiner blinding to PU status or other clinical information, and the time interval between assessments all representing particular areas of concern (Section 3.4.1, Table C-1). Nevertheless, it should be acknowledged that in the present work the quality assessments were performed by a single reviewer, although the checklist was piloted by two reviewers to agree on the interpretation of items (Section 3.1.5), as has been recommended (Lucas et al. 2013). A further limitation is that data extraction was performed by a single reviewer, but accuracy was checked by a second reviewer on a subsample of sources (Section 3.1.4).

In interpreting the results of the inter-rater reliability studies, it is interesting to note a recent study involving the Braden Scale, conducted by Choi and colleagues (2014). This compared the interpretation of item descriptors by expert nurses to ward nurses from a range of specialities and found a large variability in the interpretation of several of the scale items. Accordingly, the authors suggest that hospital training programs should provide operational definitions to enhance the consistency of assessments. While this appears reasonable, this would result in a locally defined scale, which may

## Discussion

be interpreted differently in another facility, although training in itself is a frequently advocated strategy to improve measurement error (Streiner et al. 2015). Another approach could be to devise simpler scales, which function as a checklist to determine the presence or absence of the most pertinent PU risk factors, as has been suggested by Kottner and Balzer (2010). These may further reduce variation arising from nurses adjusting scores to suit their perception of a patient's PU risk, as was reported by Baxter (2008). Alternatively, simple tools which incorporate both an assessment of relevant risk factors and a degree of clinical judgment could offer a solution. As an example, the PURPOSE-T devised by Coleman et al. (2015) has adopted a checklist format to document a patient's status and enables clinical judgment when risk factors, other than key risk factors, are present. This tool further utilises pathways based on the assessment findings, where interventions can be tailored to the particular risk profile (Coleman et al. 2015). This strategy may improve the planning and implementation of PU prevention, although further research is required to evaluate this.

## 9.5 Summary

The aim of this thesis was to examine the performance of two lateral rotation systems, and (Section 4.6). In addition, an integrative review of RAS was conducted. This work has added to existing research surrounding PU prevention in a number of ways, namely:

- This is the first time that a comprehensive analysis of the performance of mechanical turning systems has been performed, in the form of biomechanical and physiological parameters, on able-bodied volunteers;
- The objective outputs which were originally established to assess alternating and continuous low pressure support surfaces have proved successful in assessing different repositioning strategies;
- An objective evaluation of manual repositioning in two separate studies indicated that it is not totally effective in offloading vulnerable bony prominences and facilitating recovery from compromised tissue viability;
- Lateral rotation systems can provide an adjunct to repositioning by traditional methods but the mechanism of turning is important, as it clearly influences the efficacy of pressure relief and the acceptability in terms of comfort and safety;
- The variability of manual repositioning was highlighted among a group of nursing practitioners;
- An integrative review revealed a plethora of PURASs, many of which had not been evaluated in terms of ease of use, inter-rater reliability and measurement error, and predictive validity.

### 9.5.1 Recommendations for Clinical Practice

Several important implications for clinical practice have arisen from this work. In particular, it is recommended that:

- Repositioning strategies in both acute and community settings need to be based on a holistic assessment of patient factors and organisational constraints;
- Lateral rotation systems can be considered where the implementation of traditional repositioning is challenging, although consideration must be made to cost, design and clinical setting;
- Practitioners should be provided with practical training surrounding patient positioning for the purpose of PU prevention, which needs to be supported by

## Discussion

- other change management strategies, such as iteration from opinion leaders and other reminder systems;
- Guidelines should provide unambiguous instruction on the preferred 30° side-lying position technique;
- Simpler RASs that facilitate an accurate documentation of risk factors and incorporate an element of clinical judgment should be introduced.

### **9.5.2 Recommendations for Designers of Lateral Rotation Systems**

The present work has highlighted a number of issues that are relevant for designers of commercial lateral rotation systems, namely:

- Device turn angles are not required and should not aim to simulate the 30° angle that is recommended for manual repositioning;
- Multi-axis turning mechanisms may be more acceptable to end-users although these may adversely affect the efficacy in terms of tissue response;
- User perceptions of comfort and safety are paramount and must be assessed at all stages to ensure the successful adoption and utilisation of lateral rotation systems in clinical practice.

### **9.5.3 Future Work**

The present work could be extended by studies involving individuals at risk of PU development. Since a standardised instrument to evaluate the patient experience of turning by traditional and mechanical methods was not identified, a qualitative study is required to explore this aspect of repositioning. While a previous study has investigated the experience of repositioning by means of the 30° side-lying position in an elderly care population (Victor 2013), this did not specifically focus on comfort and different issues may emerge when turning is achieved by mechanical means. Crane et al. (2004) conducted semi-structured qualitative interviews to explore seating comfort in wheelchair users which informed the content of a seating assessment tool. A similar approach could be utilised to create a standardised instrument, suitable for assessing the relative comfort of different turning methods.

In addition, a practice-based study of positioning would be of interest. This research would involve an observation of patients, receiving care in both acute and community settings, which require repositioning for PU prevention. Participants would be observed over day and night periods, with the researcher recording both the technique and

frequency of repositioning by caregivers, and positional adjustments made by patients. Data would be collected on visually evident features, such as the use of pillows to support the legs and pressure relief in situ while seated. This could be augmented with the use of long-term monitoring of body pressures using a commercial system (e.g. ForeSite™, XSENSOR Technology Corporation, Canada). The study would further incorporate a skin inspection at inception and completion. This would add to existing research, which has solely focused on acute care settings, and primarily investigated the frequency of repositioning (Chaboyer et al. 2013; Latimer et al. 2015).

To further test the efficacy and acceptability of available lateral rotation systems, in a group of vulnerable community-based individuals, a prospective study should be conducted. This research would provide a controlled intervention over a 3-month period. Output parameters would include:

- Skin changes at areas susceptible to pressure;
- Sleep quality;
- Patient comfort, assessed with the newly developed instrument;
- Caregiver dependence.

The results of this would provide informed guidance surrounding the use of lateral rotation systems within community trusts.



## Appendices



## Appendix A RAS Review Search Strategy

Table A-1: Full search strategy for each database.

Database	Search terms
PubMed	MeSH † Pressure Ulcer OR pressure ulcer* (Title/ Abstract) OR pressure sore* (Title/ Abstract) OR decubitus (Title/ Abstract) OR bed sore* (Title/ Abstract) OR bedsore* (Title/ Abstract) OR pressure damage (Title/ Abstract) OR pressure injur* (Title/ Abstract) AND Mesh risk assessment OR Mesh risk factor OR MeSH risk management OR risk scale* (Title/ Abstract) OR risk (Title/ Abstract) OR scale* (Title/ Abstract) OR risk assessment scale (Title/ Abstract) OR risk assessment* (Title/ Abstract) OR risks and benefits (Title/ Abstract) OR benefits and risks (Title/ Abstract) OR benefit-risk (Title/ Abstract) OR risk-benefit (Title/ Abstract) OR safety management (Title/ Abstract) OR risk calculator (Title/ Abstract) OR risk predictability (Title/ Abstract) OR risk predictions (Title/ Abstract) OR risk predicting (Title/ Abstract) OR risk prediction (Title/ Abstract) OR risk predictions (Title/ Abstract) OR risk predictive (Title/ Abstract) OR risk predictive (Title/ Abstract) OR risk predictivity (Title/ Abstract) OR risk predictor* (Title/ Abstract)
EBSCO CINAHL	MeSH Pressure Ulcer OR pressure ulcer* (Title/ Abstract) OR pressure sore* (Title/ Abstract) OR decubitus (Title/ Abstract) OR bed sore* (Title/ Abstract) OR bedsore* (Title/ Abstract) OR pressure damage (Title/ Abstract) OR pressure injur* (Title/ Abstract) AND MeSH Risk Assessment OR MeSH Risk Factors OR MeSH Risk Management OR risk scale* (Title/ Abstract) OR risk (Title/ Abstract) OR scale* (Title/ Abstract) OR risk assessment scale (Title/ Abstract) OR risk assessment* (Title/ Abstract) OR risks and benefits (Title/ Abstract) OR benefits and risks (Title/ Abstract) OR benefit-risk (Title) OR risk-benefit (Abstract) OR safety management (Title/ Abstract) OR risk calculator (Title/ Abstract) OR risk predictability (Title/ Abstract) OR risk predicting (Title/ Abstract) OR risk prediction (Title/ Abstract) OR risk predictions (Title/ Abstract) OR risk predictive (Title/ Abstract) OR risk predictivity (Title/ Abstract) OR risk predictor* (Title/ Abstract)
Ovid Embase	(decubitus OR pressure ulcer* OR pressure sore* OR bed sore* OR bedsore* OR pressure damage* OR pressure injur*) mp (mp: Title/ Abstract/ Subject headings, Heading Word, Drug Trade Name/ Original Title/ Device Manufacturer/ Drug Manufacturer/ Device Trade Name/ Keyword) AND (risk benefit analysis OR risk assessment OR risk factor OR risk management OR risk assessment* OR risk factor* OR risk management* OR risks adj (adjacent to) benefits OR benefits adj risks OR benefit-risk OR risk-benefit OR safety management* OR risk calculator OR risk predict*) mp

## Appendix A

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Web of Science	Pressure ulcer* (Topic (Title/ Abstract/ Author Keyword/ Keywords Plus®)) OR pressure sore* (Topic) OR decubitus (Topic) OR bed sore* (Topic) OR bedsore* (Topic) OR pressure damage* (topic) OR pressure injur* (Topic) AND Risk scale* (Topic) OR risk (Topic) OR scale (Topic) risk assessment scale (Topic) risk assessment (Topic) risks and benefits (Topic) OR benefits and risks (Topic) OR benefit-risk (Topic) OR risk-benefit (Topic) OR risk factor (Topic) OR risk management (Topic) safety management (Topic) OR risk calculator (Topic) OR risk predictability (Topic) OR risk predicting (Topic) risk prediction (Topic) OR risk predictive (Topic) OR risk predictivity (Topic) OR risk predictor (Topic)
The Cochrane Central Register of Controlled Trials	("pressure ulcer" OR "pressure sore" OR decubitus OR "bed sore*" OR bedsore OR "pressure damage" OR "pressure injury") Title/ Abstract/ Keyword (Word variations searched) AND ("risk assessment" OR "risk factor" OR "risk management" OR "risks and benefits" OR "benefits and risks" OR benefit-risk OR risk-benefit OR "safety management" OR "risk calculator" OR "risk predict*") Title/ Abstract/ Keyword (Word variations searched)

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† MeSH: Medical Subject Headings

## Appendix B QAREL Checklist

Table B-1: The QAREL checklist (Adapted from Lucas et al. 2010).

Item	Yes	No	Unclear	N/A
1. Was the test evaluated in a representative sample of subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Was the test performed by a representative sample of raters?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Were raters blinded to the findings of other raters during the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were raters blinded to their own prior findings of the test under evaluation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5: Were raters blinded to the results of the accepted reference standard or disease status for the target disorder (or variable) being evaluated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6: Were raters blinded to clinical information that was not intended to be provided as part of the testing procedure or study design?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7: Were raters blinded to additional cues that were not part of the test?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Was the stability (or theoretical stability) of the variable being measured taken into account when determining the suitability of the time-interval between repeated measures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was the test applied correctly and interpreted appropriately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10. Were appropriate statistical measures of agreement used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
TOTAL				



## Appendix C QAREL Assessments

Table C-1: QAREL assessment results for the individual inter-rater reliability studies (Y: yes, N: no, U: unclear, N/A: not applicable).

	Bergstrom et al. (1987)	Cobos Vargas et al. (2011)	Cook et al. (1999)	Dealey (1989)	Delparte et al. (2015)	Edwards (1995)	Fossum et al. (2012)	Fullbrook and Anderson (2016)	Gunes and Eftel (2015)	Halfens et al. (2000)	Johnson (1994)	Kelly (2005)	Kottner and Dassen (2010)	Kottner et al. (2009c)	Kottner et al. (2008)	Kottner and Dassen (2008b)	Kumar et al. (2012)	Lincoln et al. (1986)	Lindgren et al. (2002)	McCormack (1996)	Rogenski and Kurcgtan (2012)	Wang et al. (2015)	Watkinson (1997)	Watkinson (1996)	
1. Representative sample?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
2. Representative raters	U	N	Y	Y	U	N	Y	Y	Y	Y	N	N	Y	N	N	N	N	N	Y	Y	Y	N	U	Y	Y
3. Blinding (other raters)	Y	U	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	U	Y	U
4. Blinding (own findings)?	U	N/A	N/A	U	N/A	N/A	N/A	U	N/A	U	U	N/A	N/A	N/A	U	Y	U	U	N/A	N/A	N/A	N/A	N/A	U	U
5. Blinding (reference / disease)?	N	U	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	U	N	N	N	N	N	N	N	N
6. Blinding (clinical information)?	N	U	N	N	N	N	N	N	N	N	N	Y	N	N	N	U	U	U	N	N	N	N	U	N	N
7. Blinding (additional cues)?	N	U	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	U	U	N	N	N	N	N	N	N
8. Appropriate time interval?	Y	U	N	U	U	Y	Y	U	Y	U	U	N/A	Y	N	N	N	U	Y	Y	Y	U	U	Y	Y	
9. Test appropriate?	U	Y	Y	U	Y	Y	Y	Y	Y	U	U	Y	Y	Y	Y	Y	U	U	Y	U	N	U	Y	U	
10. Appropriate statistics?	N	U	N	N	Y	N	Y	Y	Y	U	N	N	Y	Y	Y	Y	U	N	Y	U	Y	Y	N	N	
Percentage 'yes'	30%	22%	44%	30%	44%	44%	67%	50%	67%	30%	20%	63%	67%	44%	40%	50%	20%	30%	67%	44%	22%	33%	40%	30%	



## Appendix D Lateral Rotation Search Strategy

A literature search was performed using the Medline and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases, to identify studies that investigated lateral rotation systems. The initial search was performed in February 2013 and was subsequently updated in December 2014. Table D-1 shows the search terms used, and the resulting records in each of the databases.

Table D-1: Search terms, limiters and results of the search strategy.

Database	Search terms	Limiters	Records†
EBSCO Medline	MeSH†† Major Concept: Pressure Ulcer AND lateral rotation OR tilt* OR repositioning OR position* OR turning	English Language	427
EBSCO CINAHL	CINAHL Headings Major Concept: Pressure Ulcer AND lateral rotation OR tilt* OR repositioning OR position* OR turning	English Language	650

† Figures as of December 2014. †† MeSH: Medical Subject Headings

Primary research articles of any date, reporting on lateral rotation systems in the context of pressure ulcer prevention were eligible. For practical reasons, the search was limited to studies published in English. Reports focused on the effect of lateral rotation on pressure ulcer healing were excluded.

In addition to the database searches, citation searching was performed in the papers included. A Google Scholar email alert was further created at the time of the initial search using the terms 'pressure ulcers' and 'automated turning'. Figure D-1 illustrates the search and selection process described above.

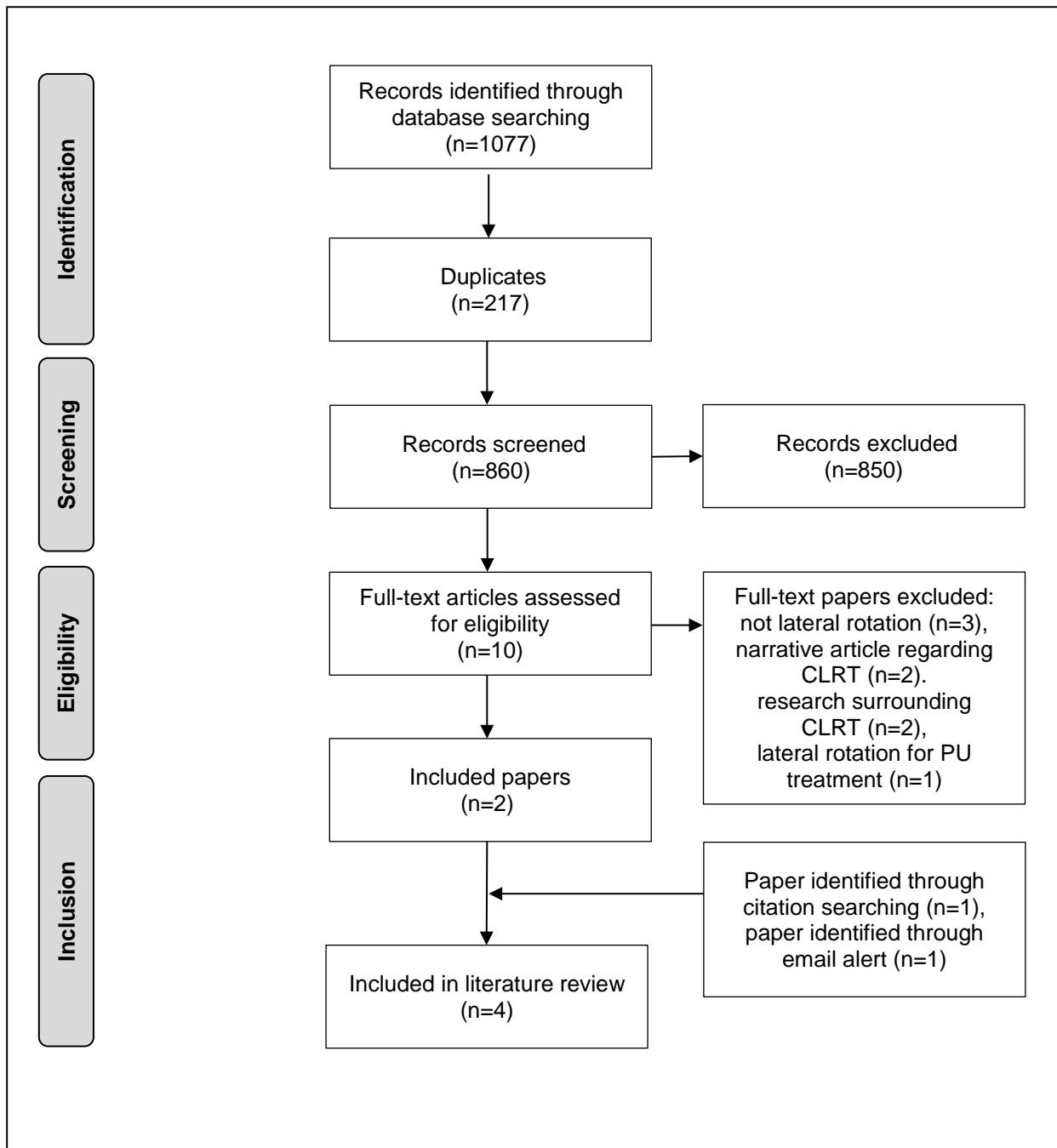


Figure D-1: Lateral rotation search and selection process. Adapted from the PRISMA diagram (Moher et al. 2009).

# Appendix E Prototype Support Surface

## Incorporating a Lateral Rotation Function

### Comfort Assessment

**LPR is NOT activated. Either ALP or CLP is activated**

Q1 Head Of Bed		0 °	SL	30°	45°	Q2 Therapy mode		ALP	CLP
Head of Bed		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Selected mode	<input type="checkbox"/>	<input type="checkbox"/>	
Q3 While lying on the surface, overall how comfortable are you on this mattress?						Q4 Thinking about your experiences lying down in bed, please rate the firmness of this mattress.			
Extremely Satisfied		<input type="checkbox"/>	Very Satisfied		<input type="checkbox"/>	Somewhat Satisfied		<input type="checkbox"/>	
Neutral		<input type="checkbox"/>	Somewhat Dissatisfied		<input type="checkbox"/>	Just Right		<input type="checkbox"/>	
Very Dissatisfied		<input type="checkbox"/>	Extremely Dissatisfied		<input type="checkbox"/>	Somewhat Soft		<input type="checkbox"/>	
Extremely Dissatisfied		<input type="checkbox"/>				Too Soft		<input type="checkbox"/>	
						Way Too Soft		<input type="checkbox"/>	
Q5 Thinking about your experiences lying down in bed, how satisfied are you with the ability of the mattress to SUPPORT you?						Q6 While lying in the CENTER of the surface how satisfied are you with the ability of the mattress to prevent you from feeling tilted or rotated to one side or the other?			
Extremely Satisfied		<input type="checkbox"/>	Very Satisfied		<input type="checkbox"/>	Somewhat Satisfied		<input type="checkbox"/>	
Neutral		<input type="checkbox"/>	Somewhat Dissatisfied		<input type="checkbox"/>	Just Right		<input type="checkbox"/>	
Very Dissatisfied		<input type="checkbox"/>	Extremely Dissatisfied		<input type="checkbox"/>	Somewhat Soft		<input type="checkbox"/>	
Extremely Dissatisfied		<input type="checkbox"/>				Too Soft		<input type="checkbox"/>	
						Way Too Soft		<input type="checkbox"/>	

**While lying on the surface, please rate your comfort level using the 7-point rating scale for each of the regions of your body.**

1: Extremely Comfortable	2: Very Comfortable	3: Somewhat Comfortable
4: Neutral	5: Somewhat Uncomfortable	6: Very Uncomfortable
7: Extremely Uncomfortable		

**Q7**

	1	2	3	4	5	6	7
Right Shoulder	<input type="checkbox"/>						
Left Shoulder	<input type="checkbox"/>						
Neck	<input type="checkbox"/>						
Upper Back	<input type="checkbox"/>						
Middle Back	<input type="checkbox"/>						
Lower Back	<input type="checkbox"/>						
Right Buttock	<input type="checkbox"/>						
Left Buttock	<input type="checkbox"/>						

## Appendix E

Legs	<input type="checkbox"/>						
Feet	<input type="checkbox"/>						

### LPR is activated. Either ALP or CLP is activated

Q8 Head Of Bed	0 °	SL	30°	45°	Q9 Therapy mode	ALP	CLP
Head of Bed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Selected mode	<input type="checkbox"/>	<input type="checkbox"/>

#### **Q10 While lying on the surface, overall how comfortable are you on this mattress?**

Extremely Satisfied  
Very Satisfied  
Somewhat Satisfied  
Neutral  
Somewhat Dissatisfied  
Very Dissatisfied  
Extremely Dissatisfied

Way Too Firm  
 Too Firm  
 Somewhat Firm  
 Just Right  
 Somewhat Soft  
 Too Soft  
 Way Too Soft

#### **Q12 Thinking about your experiences lying down in bed, how satisfied are you with the ability of the mattress to SUPPORT you?**

Extremely Satisfied  
Very Satisfied  
Somewhat Satisfied  
Neutral  
Somewhat Dissatisfied  
Very Dissatisfied  
Extremely Dissatisfied

Extremely Satisfied  
 Very Satisfied  
 Somewhat Satisfied  
 Neutral  
 Somewhat Dissatisfied  
 Very Dissatisfied  
 Extremely Dissatisfied

#### **Q13 While lying in the CENTER of the surface how satisfied are you with the ability of the mattress to prevent you from feeling tilted or rotated to one side or the other?**

**While lying on the surface, please rate your comfort level using the 7-point rating scale for each of the regions of your body.**

1: Extremely Comfortable  
4: Neutral  
7: Extremely Uncomfortable

2: Very Comfortable  
5: Somewhat Uncomfortable

3: Somewhat Comfortable  
6: Very Uncomfortable

#### Q14

	1	2	3	4	5	6	7
Right Shoulder	<input type="checkbox"/>						
Left Shoulder	<input type="checkbox"/>						
Neck	<input type="checkbox"/>						
Upper Back	<input type="checkbox"/>						
Middle Back	<input type="checkbox"/>						
Lower Back	<input type="checkbox"/>						
Right Buttock	<input type="checkbox"/>						
Left Buttock	<input type="checkbox"/>						
Legs	<input type="checkbox"/>						
Feet	<input type="checkbox"/>						

# Appendix F Evaluation of a Prototype Support Surface Incorporating a Lateral Rotation Function Participant Information Sheet

## **Title of Study:**

### **The performance characteristics of support surfaces**

Investigator Name: Dan L Bader BSc, MSc, PhD, DSc.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

## **What is the research about?**

Please take time to read the following information carefully and discuss it with others if you wish. Take time to decide whether or not you wish to take part.

## **What is the purpose of the research study?**

I am a Professor of Bioengineering and Tissue Health, who joined the Faculty of Health Sciences in January 2011. For many years in both Oxford and London, my research has focused on developing measurement techniques to assess support surfaces to minimise the risk of skin damage as a result of prolonged loading. This specific research is designed to assess the effectiveness of air support surfaces that can provide either low continuous pressure support or alternating pressure relief, with the potential of a small degree of lateral tilt. I will be supervising the work as part of a PhD programme of Ms Marjolein Woodhouse, who has a Postgraduate Diploma in Nursing from the University of Southampton.

Biophysical and biomechanical measurements of your skin will be recorded from skin areas for each of the two visits. Skin oxygen and carbon dioxide levels will be measured using a **transcutaneous gas monitor** and the pressure between the body and the support surface will be measured using an **interface pressure monitor**. Both measurements are completely painless and non-invasive.

If you decide to participate in each part of the study you will be required to attend the laboratory on two separate occasions. Each visit will last approximately 1.5 hours.

## **Physical Measurements**

### ***Transcutaneous gas monitor***

Small sensors will be attached with double-sided tape to two body sites. You are required to keep as still as possible during these measurements. The output of the sensors will be connected to a computer, which will record a constant trace of blood gases, namely oxygen and carbon dioxide, during the measurement period.

## Appendix F

### Interface pressure measurements

The measurements of interface pressures are recorded with a 96 array of thin air cells which are draped across the top of the mattress. The cells map the interface pressures between yourself and the surface of the mattress in a painless and harmless manner.

#### Why have I been chosen?

Both men and women over the age of 18 years are being invited to take part. However, there are certain conditions for which inclusion is contraindicated. These include:

- Current participation in another study
- Complaints of pain or discomfort directly before participation
- Medical history of any dermatological condition, including pressure ulcers
- History of disease associated with the skin, nervous system, musculoskeletal system or diabetes

#### Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. *If you decide to take part you are still free to withdraw at any time and without giving a reason.*

#### What will happen to me if I take part?

If you decide to take part you will be required to attend the Faculty Research facility at the South Academic Block at SGH on two separate occasions, separated by about one week. Thus the overall study will be about two weeks.

##### **Visit 1:**

On the day of the test, you will be shown the test methods which will be included in the study. At this point, if agreeable, you will be asked to sign the consent form. You will be asked to bring some loose fitting clothes, involving t-shirts and shorts/ tracksuit bottoms, and change into them.

After a short preparation period in which the transcutaneous sensors will be attached to your sacrum (lower back) and the back of your right shoulder, you will lie on your back on the air support surface. The physical measurements outlined above will be recorded for a period of 60 minutes. After this time you will be able to change and leave at your convenience.

The research team will make sure you are comfortable at all times and will never do anything you are not happy with. You will be able to stop the tests at any time.

##### **Visit 2:**

Following a gap of one week you will be asked to return for the second part of the study. You will be tested on the other prescribed settings of the air support surface, using an identical protocol as that described in Visit 1.

#### What are the risks involved in taking part?

The experienced research team will take great care to avoid any discomfort, embarrassment, or harm to your body.

**What are the possible benefits of taking part?**

Whilst there are no direct benefits to you from taking part, it is hoped that the information gained from this study will enable us to identify features of the support surface, which will ensure the maintenance of skin health.

**What happens if I change my mind?**

Volunteers take part only if they want to and you are free to drop out of the study at any time. Your future care or treatment will be just the same whether you choose to take part or not.

**What happens if something goes wrong?**

If you have any complaints or concerns during this study you should immediately inform the investigator. In the unlikely event that something goes wrong during the study indemnity insurance has been provided.

If you have a concern or a complaint about this study you should contact [REDACTED] [REDACTED] Research Governance Office, at the Faculty of Health Sciences (Address: University of Southampton, Building 67, Highfield, Southampton, SO17 1BJ; Tel: +44 (0)23 8059 5058; Email: [REDACTED]). If you remain unhappy and wish to complain formally Martina Prude can provide you with details of the University of Southampton Complaints Procedure.

**Will my taking part in this study be kept confidential?**

All data will be treated in compliance with the Data Protection Act and the University of Southampton policy for the storage of data. Your details will be coded and no identifiable personal information will be stored on computer.

**What will happen to the results of the research study?**

It is hoped that the results from this study will be published in suitable professional and scientific journals. It will not be possible to identify any individuals from any of the data presented. You will be asked whether you wish to be personally informed of the results of this study at the end.

**Contact for Further Information:**

Dan Bader PhD DSc

Faculty of Health Sciences

University of Southampton

[REDACTED]  
Email: [REDACTED]

***You will be given a copy of this information sheet and a signed consent form to keep.***

***Thank you for taking the time to read this information.***



# Appendix G Prototype Lateral Rotation System and Manual Repositioning Comfort Assessment

Participant Number:

**Protocol:**

*LPR*                    *Manual*

**Q1 While lying horizontally without being tilted, overall how comfortable are you?**

<i>Very Comfortable</i>	<input type="checkbox"/>	<i>Too Firm</i>	<input type="checkbox"/>
<i>Comfortable</i>	<input type="checkbox"/>	<i>Somewhat Firm</i>	<input type="checkbox"/>
<i>Neutral</i>	<input type="checkbox"/>	<i>Just Right</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>	<i>Somewhat Soft</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>	<i>Too Soft</i>	<input type="checkbox"/>

**Q2 Please rate the firmness of this mattress.**

<i>Very Comfortable</i>	<input type="checkbox"/>	<i>Too Firm</i>	<input type="checkbox"/>
<i>Comfortable</i>	<input type="checkbox"/>	<i>Somewhat Firm</i>	<input type="checkbox"/>
<i>Neutral</i>	<input type="checkbox"/>	<i>Just Right</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>	<i>Somewhat Soft</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>	<i>Too Soft</i>	<input type="checkbox"/>

**Q3 While lying horizontally without being tilted, please rate comfort levels for the following regions:**

<b>Shoulders</b>	<b>Back</b>		
<i>Very Comfortable</i>	<input type="checkbox"/>	<i>Very Comfortable</i>	<input type="checkbox"/>
<i>Comfortable</i>	<input type="checkbox"/>	<i>Comfortable</i>	<input type="checkbox"/>
<i>Neutral</i>	<input type="checkbox"/>	<i>Neutral</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>	<i>Uncomfortable</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>	<i>Very uncomfortable</i>	<input type="checkbox"/>
<b>Buttocks</b>	<b>Legs and feet</b>		
<i>Very Comfortable</i>	<input type="checkbox"/>	<i>Very Comfortable</i>	<input type="checkbox"/>
<i>Comfortable</i>	<input type="checkbox"/>	<i>Comfortable</i>	<input type="checkbox"/>
<i>Neutral</i>	<input type="checkbox"/>	<i>Neutral</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>	<i>Uncomfortable</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>	<i>Very uncomfortable</i>	<input type="checkbox"/>

**Q4 While being tilted/ repositioned with pillows, overall how comfortable are you?**

<i>Very Comfortable</i>	<input type="checkbox"/>
<i>Comfortable</i>	<input type="checkbox"/>
<i>Neutral</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>

**Q5 While being tilted/ repositioned with pillows, please rate comfort levels for the following regions:**

<b>Shoulders</b>	<b>Back</b>		
<i>Very Comfortable</i>	<input type="checkbox"/>	<i>Very Comfortable</i>	<input type="checkbox"/>
<i>Comfortable</i>	<input type="checkbox"/>	<i>Comfortable</i>	<input type="checkbox"/>
<i>Neutral</i>	<input type="checkbox"/>	<i>Neutral</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>	<i>Uncomfortable</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>	<i>Very uncomfortable</i>	<input type="checkbox"/>

## Appendix G

<b>Buttocks</b>		<b>Legs and feet</b>	
<i>Very Comfortable</i>	<input type="checkbox"/>	<i>Very Comfortable</i>	<input type="checkbox"/>
<i>Comfortable</i>	<input type="checkbox"/>	<i>Comfortable</i>	<input type="checkbox"/>
<i>Neutral</i>	<input type="checkbox"/>	<i>Neutral</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>	<i>Uncomfortable</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>	<i>Very uncomfortable</i>	<input type="checkbox"/>

**Q6 While lying in a tilted position, please rate how safe you feel:**

<i>Very Safe</i>	<input type="checkbox"/>
<i>Safe</i>	<input type="checkbox"/>
<i>Neither Safe/ Unsafe</i>	<input type="checkbox"/>
<i>Unsafe</i>	<input type="checkbox"/>
<i>Very Unsafe</i>	<input type="checkbox"/>

**NB.** Participants will be asked to rate the least comfortable side, in cases where the perceived comfort differs between the different sides of the body.

# Appendix H Comparison of the Lateral Rotation Function of a Prototype Support Surface to Conventional Repositioning Participant Information Sheet

## **Title of Study:**

### **The performance characteristics of support surfaces**

Investigator Name: Dan L Bader BSc, MSc, PhD, DSc.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

## **What is the research about?**

Please take time to read the following information carefully and discuss it with others if you wish. Take time to decide whether or not you wish to take part.

## **What is the purpose of the research study?**

I am a Professor of Bioengineering and Tissue Health, who joined the Faculty of Health Sciences in January 2011. For many years in both Oxford and London, my research has focused on developing measurement techniques to assess support surfaces to minimise the risk of skin damage as a result of prolonged loading. This specific research is designed to assess the effectiveness of air support surfaces that can provide either low continuous pressure support or alternating pressure relief, with the potential of a small degree of lateral tilt. I will be supervising the work as part of a PhD programme of Ms Marjolein Woodhouse, who has a Postgraduate Diploma in Nursing from the University of Southampton.

Biophysical and biomechanical measurements of your skin will be recorded from skin areas for each of the visits. Skin oxygen and carbon dioxide levels will be measured using a **transcutaneous gas monitor** and the pressure between the body and the support surface will be measured using an **interface pressure monitor**. Both measurements are completely painless and non-invasive.

If you decide to participate you can choose to take part in visit 1 and 2, or visit 1, 2 and 3. Each visit will last approximately 1.5 hours.

## **Physical Measurements**

### ***Transcutaneous gas monitor***

Small sensors will be attached with double-sided tape to two body sites. You are required to keep as still as possible during these measurements. The output of the sensors will be connected to a computer, which will record a constant trace of blood gases, namely oxygen and carbon dioxide, during the measurement period.

## Appendix H

### Interface pressure measurements

The measurements of interface pressures are recorded with a 96 array of thin air cells which are draped across the top of the mattress. The cells map the interface pressures between yourself and the surface of the mattress in a painless and harmless manner.

### Why have I been chosen?

Both men and women over the age of 18 years are being invited to take part. However, there are certain conditions for which inclusion is contraindicated. These include:

- Current participation in another study
- Complaints of pain or discomfort directly before participation
- Medical history of any dermatological condition, including pressure ulcers
- History of disease associated with the skin, nervous system, musculoskeletal system or diabetes.

### Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. ***If you decide to take part you are still free to withdraw at any time and without giving a reason.***

### What will happen to me if I take part?

If you decide to take part you will be required to attend the Faculty Research facility at the South Academic Block at SGH on either two or three separate occasions, separated by about one week. Thus the overall study will be either two or three weeks.

#### **Visit 1:**

On the day of the test, you will be shown the test methods which will be included in the study. At this point, if agreeable, you will be asked to sign the consent form. You will be asked to bring some loose fitting clothes, involving t-shirts and shorts/ tracksuit bottoms, and change into them.

After a short preparation period in which the transcutaneous sensors will be attached to your sacrum (lower back) and your right shoulder, you will lie on your back on the air support surface. The support surface will automatically reposition you every 15 minutes by inflating and deflating air bladders incorporated in the mattress. The physical measurements outlined above will be recorded for a period of 65 minutes. After this time you will be able to change and leave at your convenience.

The research team will make sure you are comfortable at all times and will never do anything you are not happy with. You will be able to stop the tests at any time.

#### **Visit 2:**

Following a gap of one week you will be asked to return for the second part of the study. The protocol is very similar to that described in Visit 1, but during visit 2 you will be repositioned with the aid of pillows.

#### **Visit 3:**

If you choose to take part in all of the sessions, you will be asked to return on the third week. During this visit you will be repositioned by the support surface in the same manner as visit 1, but both transcutaneous sensors will be attached to your sacrum.

**What are the risks involved in taking part?**

The experienced research team will take great care to avoid any discomfort, embarrassment, or harm to your body.

**What are the possible benefits of taking part?**

Whilst there are no direct benefits to you from taking part, it is hoped that the information gained from this study will enable us to identify features of the support surface, which will ensure the maintenance of skin health.

**What happens if I change my mind?**

Volunteers take part only if they want to and you are free to drop out of the study at any time. Your future care or treatment will be just the same whether you choose to take part or not.

**What happens if something goes wrong?**

If you have any complaints or concerns during this study you should immediately inform the investigator. In the unlikely event that something goes wrong during the study indemnity insurance has been provided.

If you have a concern or a complaint about this study you should contact [REDACTED] [REDACTED], Research Governance Office, at the Faculty of Health Sciences (Address: University of Southampton, Building 67, Highfield, Southampton, SO17 1BJ; Tel: +44 (0)23 8059 5058; Email: [REDACTED]). If you remain unhappy and wish to complain formally [REDACTED] can provide you with details of the University of Southampton Complaints Procedure.

**Will my taking part in this study be kept confidential?**

All data will be treated in compliance with the Data Protection Act and the University of Southampton policy for the storage of data. Your details will be coded and no identifiable personal information will be stored on computer.

**What will happen to the results of the research study?**

It is hoped that the results from this study will be published in suitable professional and scientific journals. It will not be possible to identify any individuals from any of the data presented. You will be asked whether you wish to be personally informed of the results of this study at the end.

**Contact for Further Information:**

Dan Bader PhD DSc  
Faculty of Health Sciences  
University of Southampton.

Email: [REDACTED]

***You will be given a copy of this information sheet and a signed consent form to keep.***

***Thank you for taking the time to read this information.***



# Appendix I Comparison of a Lateral Rotation Platform to Conventional Repositioning Participant Information Sheet

## **Title of Study:**

**The performance characteristics of support surfaces**

Investigator Name: Dan L Bader BSc, MSc, PhD, DSc.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

## **What is the research about?**

Please take time to read the following information carefully and discuss it with others if you wish. Take time to decide whether or not you wish to take part.

## **What is the purpose of the research study?**

I am a Professor of Bioengineering and Tissue Health, who joined the Faculty of Health Sciences in January 2011. For many years in both Oxford and London, my research has focused on developing measurement techniques to assess support surfaces to minimise the risk of skin damage as a result of prolonged loading. This specific research is designed to assess the effectiveness of a system placed under a standard mattress, which is designed to periodically alter your position to a slight side-lying position. This will be compared against the current nursing practice of manual repositioning. I will be supervising the work as part of a PhD programme of Marjolein Woodhouse, who has a Postgraduate Diploma in Nursing from the University of Southampton.

Biophysical and biomechanical measurements of your skin will be recorded from both skin areas for each of the visits. Skin oxygen and carbon dioxide levels will be measured using a transcutaneous gas monitor and the pressure between the body and mattress will be measured using an interface pressure monitor. Both measurements are completely painless and non-invasive.

If you decide to participate in each part of the study you will be required to attend the laboratory on two separate occasions. Each visit will last approximately 1.5 hours.

## **Physical Measurements**

### ***Transcutaneous gas monitor***

Small sensors will be attached with double-sided tape to two body sites (non-invasive). You are required to keep as still as possible during these measurements. The output of the sensors will be connected to a computer, which will record a constant trace of blood gases, namely oxygen and carbon dioxide, during the measurement period.

## Appendix I

### **Interface pressure measurements**

The measurements of interface pressures are recorded with a 96 array of thin air cells which are draped across the top of the mattress. The cells map the interface pressures between yourself and the surface of the mattress in a painless and harmless manner.

### **Why have I been chosen?**

Both men and women over the age of 18 years are being invited to take part. However, there are certain conditions for which inclusion is contraindicated. These include:

- Current participation in another study
- Complaints of pain or discomfort directly before participation
- Medical history of any dermatological condition, including pressure ulcers
- History of disease associated with the skin, nervous system, musculoskeletal system or diabetes.

### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. ***If you decide to take part you are still free to withdraw at any time and without giving a reason.***

### **What will happen to me if I take part?**

If you decide to take part you will be required to attend the Faculty Research facility at the South Academic Block at SGH on two separate occasions, separated by about one week. Thus the overall study will be about two weeks.

#### **Visit 1:**

On the day of the test, you will be shown the test methods which will be included in the study. At this point, if agreeable, you will be asked to sign the consent form. You will be asked to bring some loose fitting clothes, involving t-shirts and shorts/ tracksuit bottoms, and change into them. After a short preparation period in which the transcutaneous sensors will be attached to your sacrum (lower back) and your right shoulder, you will lie on your back on the mattress. You will be repositioned every 15 minutes by inflating and deflating air bladders that are incorporated in the system placed under the mattress. The physical measurements outlined above will be recorded for a period of 65 minutes. After this time you will be able to change and leave at your convenience.

The research team will make sure you are comfortable at all times and will never do anything you are not happy with. You will be able to stop the tests at any time.

#### **Visit 2:**

Following a gap of one week you will be asked to return for the second part of the study. The protocol is very similar to that described in Visit 1, but during visit 2 you will be repositioned every 15 minutes with the aid of pillows.

### **What are the risks involved in taking part?**

The experienced research team will take great care to avoid any discomfort, embarrassment, or harm to your body.

**What are the possible benefits of taking part?**

Whilst there are no direct benefits to you from taking part, it is hoped that the information gained from this study will enable us to identify features of repositioning, which will ensure the maintenance of skin health.

**What happens if I change my mind?**

Volunteers take part only if they want to and you are free to drop out of the study at any time. Your future care or treatment will be just the same whether you choose to take part or not.

**What happens if something goes wrong?**

If you have any complaints or concerns during this study you should immediately inform the investigator. In the unlikely event that something goes wrong during the study indemnity insurance has been provided.

If you have a concern or a complaint about this study you should contact [REDACTED] [REDACTED], Research Governance Office, at the Faculty of Health Sciences (Address: University of Southampton, Building 67, Highfield, Southampton, SO17 1BJ; Tel: +44 (0)23 8059 5058; Email: [REDACTED]). If you remain unhappy and wish to complain formally [REDACTED] can provide you with details of the University of Southampton Complaints Procedure.

**Will my taking part in this study be kept confidential?**

All data will be treated in compliance with the Data Protection Act and the University of Southampton policy for the storage of data. Your details will be coded and no identifiable personal information will be stored on computer.

**What will happen to the results of the research study?**

It is hoped that the results from this study will be published in suitable professional and scientific journals. It will not be possible to identify any individuals from any of the data presented. You will be asked whether you wish to be personally informed of the results of this study at the end.

**Contact for Further Information:**

Dan Bader PhD DSc

Faculty of Health Sciences

University of Southampton.

[REDACTED]  
Email: [REDACTED]

***You will be given a copy of this information sheet and a signed consent form to keep.***

***Thank you for taking the time to read this information.***





## Appendix J

<i>Neutral</i>	<input type="checkbox"/>	<i>Neutral</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>	<i>Uncomfortable</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>	<i>Very uncomfortable</i>	<input type="checkbox"/>

**Q6 Right tilt- while lying in a tilted position, please rate how safe you feel:**

<i>Very Safe</i>	<input type="checkbox"/>
<i>Safe</i>	<input type="checkbox"/>
<i>Neither Safe/ Unsafe</i>	<input type="checkbox"/>
<i>Unsafe</i>	<input type="checkbox"/>
<i>Very Unsafe</i>	<input type="checkbox"/>

**Q7 Left tilt- while being tilted/ repositioned with pillows, overall how comfortable are you?**

<i>Very Comfortable</i>	<input type="checkbox"/>
<i>Comfortable</i>	<input type="checkbox"/>
<i>Neutral</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>

**Q8 Left tilt- while being tilted/ repositioned with pillows, please rate comfort levels for the following regions:**

<u>Shoulders</u>	<u>Back</u>
<i>Very Comfortable</i>	<input type="checkbox"/>
<i>Comfortable</i>	<input type="checkbox"/>
<i>Neutral</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>
<u>Buttocks</u>	<u>Legs and feet</u>
<i>Very Comfortable</i>	<input type="checkbox"/>
<i>Comfortable</i>	<input type="checkbox"/>
<i>Neutral</i>	<input type="checkbox"/>
<i>Uncomfortable</i>	<input type="checkbox"/>
<i>Very uncomfortable</i>	<input type="checkbox"/>

**Q9 Left tilt- while lying in a tilted position, please rate how safe you feel:**

<i>Very Safe</i>	<input type="checkbox"/>
<i>Safe</i>	<input type="checkbox"/>
<i>Neither Safe/ Unsafe</i>	<input type="checkbox"/>
<i>Unsafe</i>	<input type="checkbox"/>
<i>Very Unsafe</i>	<input type="checkbox"/>

**NB. Participants will be asked to rate the least comfortable side, in cases where the perceived comfort differs between the different sides of the body.**

## **Appendix K Reliability of Repositioning Participant Survey**

1. How many years of nursing/ auxiliary nursing experience do you have, including any time where you were working as a healthcare support worker or student nurse?.....
2. What is your current Agenda for Change band and/ or job title (e.g. student nurse)?  
a. AfC Band (if applicable):..... b.. Job title:.....
3. In which setting do you currently work, or what was the setting of your current/ last placement (e.g. acute, community)?.....
4. In which speciality do you work, or in which speciality did you undertake your current/ last placement?.....
5. How often do you reposition patients for the purpose of pressure ulcer prevention in your current role or current/ last placement (e.g. daily, weekly, monthly, yearly or I do not reposition patients in my current role).....
6. Have you received classroom based or e-learning training on pressure ulcer prevention in the last 5 years?.....
7. Did this training include guidance on repositioning for pressure ulcer prevention? .....



# Appendix L The Reliability of Repositioning for Pressure Ulcer Prevention Participant Information Sheet

**Study Title:** The reliability of repositioning for pressure ulcer prevention

**Researcher:** Marjolein Woodhouse

**Ethics number:** 14219

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Ask the researcher if there is anything that is not clear or if you would like more information.

**Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to sign a consent form.**

## **What is the research about?**

I am a PhD candidate and work clinically as a nurse. My research is focussed on pressure ulcer prevention and my previous studies have examined the use of automated turning beds and compared this to manual repositioning. However, in these studies all the repositioning was carried out by me. Therefore, in the current study I would like to compare repositioning by different nurses to investigate whether repositioning is consistent between nurses, because if manual repositioning varies widely, this may affect the effectiveness of this intervention. The current study further aims to investigate whether the measurement techniques I have previously used are reproducible.

## **Why have I been chosen?**

Nurses, healthcare support workers, or student nurses are being invited to take part if they have experience of repositioning patients for the purpose of pressure ulcer prevention. However, there are some contraindications to participating in this study, these are:

- Musculoskeletal conditions, or any other condition which prevents you from safely performing repositioning;
- Pain or discomfort directly before participation in the study.

## **What will happen to me if I take part?**

If you decide to take part you will be invited to attend the lab at Clinical Academic Facility, located in the South Academic Block at Southampton General Hospital. When you arrive you can ask any further questions that you may have about the study and after this, if you decide to take part, you will be asked to sign a consent form. The researcher will then ask you some questions about your current role and training you may have received on pressure ulcer prevention. You will then be asked to reposition a healthy volunteer lying on a standard hospital bed, in the same way that you would reposition patients in practice to prevent pressure ulcers. After this you will be invited to wait in one of the screened areas in the lab, and asked to read some information on repositioning. In the meantime, two researchers will separately take some

## Appendix L

measurements from the volunteer lying on the bed. You will then be asked to reposition the volunteer again, after which the measurements will be repeated and the test procedure is complete. The total time required from you will not be longer than 30 minutes.

### **Are there any benefits in my taking part?**

Whilst there are no direct benefits to you from taking part, it is hoped that the information gained from this study will give some insight into the consistency of repositioning.

### **Are there any risks involved?**

Because this study involves repositioning, there is a small risk of injury as a result of manual handling. As such, people with a history of musculoskeletal conditions, or with pain or discomfort immediately before participation in the study will not be able to take part. If you experience any pain or discomfort during participation in the study you should alert the researcher immediately, at which time the test procedure will be stopped.

### **Will my participation be confidential?**

All data will be treated in compliance with the Data Protection Act and the University of Southampton policy for the storage of data. Your details will be coded and no identifiable personal information will be stored. Electronic data arising from this study will be stored on University's internal network server, with access restricted to members of the research team. All other data will be stored in a locked filing cabinet, located in a restricted access office within the research group.

### **What happens if I change my mind?**

Participation in this study is voluntary and you are free to withdraw at any time, without your legal rights being affected.

### **What happens if something goes wrong?**

If you have any complaints or concerns during this study you should immediately inform the researcher. In the unlikely event that something goes wrong during the study indemnity insurance has been provided.

If you have a concern or a complaint about this study you should contact [REDACTED] [REDACTED], Research Governance Office, at the Faculty of Health Sciences (Address: University of Southampton, Building 37/ 4055, Highfield, Southampton, SO17 1BJ; Tel: +44 (0)23 8059 5058; Email: [REDACTED]). If you remain unhappy and wish to complain formally [REDACTED] can provide you with details of the University of Southampton Complaints Procedure.

### **Where can I get more information?**

For further information please contact:

Marjolein Woodhouse  
Faculty of Health Sciences  
University of Southampton  
Email: [REDACTED]

## Appendix M Publications and Conference Presentations

### Publications

Woodhouse M, Worsley PR, Voegeli D, Schoonhoven L and Bader DL (2015) The physiological response of soft tissue to periodic repositioning as a strategy for pressure ulcer prevention. *Clinical Biomechanics* 30(2): 166-174.

### Conference Presentations

Woodhouse, M. 2015 *The efficacy and acceptability of a prototype dynamic support surface incorporating a lateral rotation feature*. Solent Conference: Demonstrating the Value of Research, Evaluation and Clinical Audit, 9 July, Hedge End.

Woodhouse, M. 2014 *The effect of lateral rotation and the 30°side-lying position on tissue viability*. Tissue Viability Society Conference, 1 April, Leeds.

Woodhouse, M. 2014 *The effect of lateral rotation and the 30°side-lying position on tissue viability*. Solent Research and Clinical Audit Conference, 13 March, Southampton.

### Awards

Solent Research and Clinical Audit Conference, Best Presentation, July 2015.

Tissue Viability Scholarship, February 2014.



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