Pressure Ulcer Risk Assessment and Prevention System Design

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This dissertation is submitted for the degree of

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Copyright Information

Dedication

This thesis dedicates to my dad who passed away in 2010 ...

Declaration

I hereby declare that except where specific reference is made to the work of others, the contents of this thesis are original and have not been submitted in whole or in part for consideration for any other degree or qualification in this, or any other university. The work shown in this thesis is carried out by me with the guidance of Dr. Venketesh N. Dubey, Prof. Tamas Hickish and Prof. Jonathan Cole. This thesis contains nothing which is the outcome of work done in collaboration with others, except as specified in the text and Acknowledgements.

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Abstract

Pressure ulcer (PU, bedsore, ischemia, decubitus ulcer) has become a global healthcare problem. In United Kingdom 412,000 people develop pressure ulcer annually and it costs the National Health Service (NHS) £1.4-£2.1 billion pounds (4% of total NHS budget). Pressure ulcers are a combined result of multiple factors such as prolonged external load applied to the skin, reduced blood flow in tissues, the patient's physiological parameters (body mass index, age, mobility) and body support surface properties. The aetiology of pressure ulcer formation includes both mechanical and biological properties of skin and soft tissues.

In order to prevent PU formation in the human body, a new type of risk predicting tool is required where identification of PU risk is based on combined effect of patient's physiological parameters and support surface properties. Previous research suggests that interface pressure (IP) of 32 mmHg (4.2kPa) can cause PU but there is no strong evidence to show when that pressure is reached. Also IP varies from person to person due to their physiology. There are three risk assessment scales available to predict the occurrence of PU formation; however, none of these scales take interaction of body support surface material into account. Also they do not provide any information at which area a person is at risk of ulceration. In order to identify the harmful IP, biomechanical behaviour of skin and soft tissue is modelled and interaction of body support surface is studied. A mathematical model has been developed to characterise a new type of body support surface material (viscoelastic) and validated by conducting experiments. The relationship between patient's physiological parameters and surface material are identified along with risk assessment scales for pressure ulcer prediction by conducting experiments. External load at different bony areas are measured using eleven volunteers. By measuring the external load for eleven subjects (age =33$\pm$7) and (BMI =25.0$\pm$3.01 kg/m^2) at different bony areas, the relationship between IP with the total body weight and BMI was developed. A mathematical model is proposed to predict the risk of PU formation combining the Waterlow risk assessment scale and risk prediction algorithms on a user friendly interface.

The risk prediction system is shown to match with the actual risk of ulceration in human body. This new risk model combines patient's physiological parameters, support surface characteristics and existing risk assessment scale. To further visualise the performance of the risk model, a graphic user interface (GUI) is developed that can predict the onset of ulceration over time at different locations of human body.
Finally, the risk predicting tool is integrated with alternating (air) pressure (AP) mattress. The AP mattress is used to inflate or deflate the air cylinders at a fixed period of time. This features a new type of intervention system where risk identification and prevention take place at the same time. Also the system is fully patient oriented that consider patient's physiological parameters and the interface surface properties and no manual setting is required. By integrating the risk predicting tool with an AP mattress allows incorporation of prevention strategy thus enhancing the scope of this research. The developed new tool can be used as a stand-alone risk prediction system and can also be used as a combined prevention system by allowing inflate/deflate action of the air cylinders.

- Keywords:

Pressure Ulcer, Support surface, Viscoelastic material, Mathematical modelling,
BMI, Waterlow score, Relative Risk, Alternating pressure mattress

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List of Abbreviation

ADC Analogue to Digital Converter

AM Air filled Mattress

AP Alternating Pressure

BMI Body Mass Index

CLP Constant Low Pressure

cm Centimeter

CNC Carbon Nano Coil

DAQ Data Acquisition system

EPUAP European Pressure Ulcer Advisory Panel

EU European Union

FSR Force Sensitive Resistor

GPa Giga Pascal

GUI Graphical User Interface

Hz Hertz

IP Interface Pressure

Kg Kilogram

kPa Kilo Pascal

m	Meter
mm	millimeter
mmHg	Millimeter of Mercury
MPa	Mega Pascal
MS	Multiple Sclerosis
N	Newton
NHS	National Health Service
NPUAP	National Pressure Ulcer Advisory Panel
PCB	Printed Circuit Board
PDMS	Polydimethylsiloxane
PU	Pressure Ulcer
RFID	Radio Frequency Identification
SCI	Spinal Cord Injury
*TcPO*2	Transcutaneous Oxygen Tension
UK	United Kingdom
USA	United States of America
V	Voltage

Chapter 1

Introduction

This chapter explains the motivation behind the work. The objectives and the approaches of the research are covered and an outline that summarises the thesis is discussed with future research direction.

1.1 Motivation

The healthcare industry is facing a major challenge against pressure ulcer (PU) in hospitals. Due to this, a huge amount of money is spent within the industry each year. In the United Kingdom, research shows that each year approximately 412,000 people develop pressure ulcers in hospitals while they are lying on beds or sitting on chairs for longer periods (Bennett et al. 2004). A study conducted in hospitals in five European countries found a PU prevalence of 18.1% (Vanderwee et al. 2007). In 2009 PU prevalence of 6.3%-6.7% was found among 207 hospitals in USA (Gunningberg et al. 2012). A Swedish survey in 2011 showed PU prevalence of 14.5% for nursing home residents and 16.6% in hospitals. Also the survey showed a PU prevalence of 21.9% (recorded as highest) among elderly population (Gunningberg et al. 2013).

The costs of treating PU is also a significant concern for the healthcare industry. It costs approximately £1.4-£2.1 billion to the UK hospitals a year (nearly 4% of NHS budget) (Bennett et al. 2004; Hsia et al. 2009). The problem is not confined to the UK; for instance a study showed that 1% of Netherland's healthcare budget is spent to treat PU (Severens et al. 2002). In United Kingdom, it is estimated that the treatment cost for grade-1 to grade-4 is £1064 to £10551 (Bennett et al. 2004). The individual monthly cost incurred to treat pressure ulcers is $4,745 among Spinal Cord Injury (SCI) population in USA (Chan et al. 2013). This is not only a problem in the United Kingdom but also for the rest of the world.

In 2007, a research conducted by Wild Iris Medical Education showed 2.4 million cases in the United States alone.

People with mobility impairments, spinal cord injury (SCI), head trauma or multiple sclerosis (MS) are the main victim of pressure ulcer (Manohar and Bhatia 2008; Solis et al. 2012). Also, people in coma or people in long surgical procedure develop pressure ulcers due to restricted mobility (Graves et al. 2005*b*).

These figures indicate the significance of developing a pressure ulcer prevention system for healthcare industry. It is a serious problem in today's society. Patients in hospitals, nursing homes, on wheel chairs, patients with prosthetic limbs and even patients in home care are vulnerable to this problem. It has become very important now to find a way to predict the early formation of pressure ulcers in all patients of varying age, body weight, mobility and many other physiological parameters.

Pressure ulcers can occur at different locations of the human body. Mostly it occurs at the sacrum, heel and buttock area. Figure 1.1 shows the common pressure points in the human. Pressure ulcers also have huge impact on patient's quality of life.

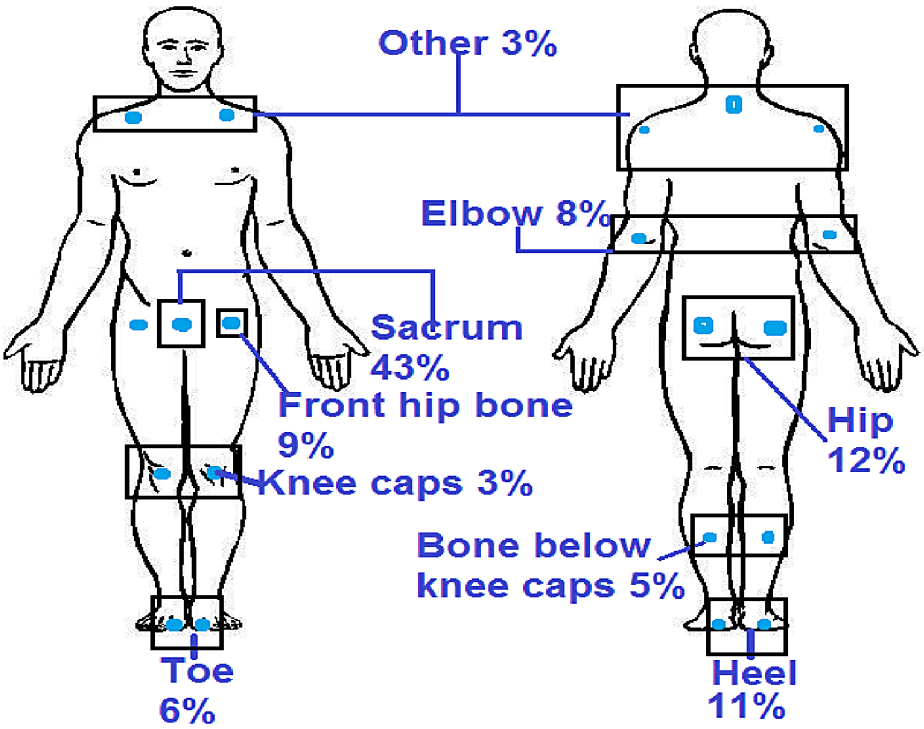

Fig. 1.1 Pressure ulcer occurrence rate in human body
(SYST'AM 2013)

Daily activities of a patient with PU become restricted (Stern et al. 2011). For instance those with SCI on a wheelchair; once they have a PU they have to lie down and sometimes are admitted to hospital, both of which curtail social activity and employment etc. Physiological health of a patient can be significantly affected by feelings of worry, anxiety, lack of self confidence and lack of self esteem. Sometimes it also lead to social isolation of the patients (Gorecki et al. 2010).

The key point is the identification of harmful interface pressure (IP) due to relevant PU factors such as body weight, age, mobility etc at skin and support surface level to prevent pressure ulcers in human body. To identify the risk of forming pressure ulcers, risk assessment scales are widely used, which collect systematic information of PU risk relating to the patient (Coleman et al. 2013). In order to prevent pressure ulcer formation, alternating pressure re-distributing mattresses and cushions are used and recommended to health-care industry (Bedo 2013). Support surface evaluation provides a general level of understanding e.g. incidence of pressure ulcer occurring (McInnes et al. 2012), quantification of interface pressure (Gil-Agudo et al. 2009; Miller et al. 2013; Moysidis et al. 2011), but analysis of interface pressure to identify the harmful interface pressure still remains complex and therefore it is not easy to choose one standard support surface that can reduce the chance of pressure ulcer formation (Oomens et al. 2010; Reenalda et al. 2009).

Pressure ulcer is a result of prolonged external load applied to skin and support surface due to not having any movement. Also a patient's physiological conditions influence pressure ulcer formation (Shilo and Gefen 2012). The assessment of the microcirculation has been proposed to be a better technique to investigate the mechanisms of pressure ulcer prevention (Liao et al. 2013). Studies of blood flow regulation are carried out in several clinical investigations (Allen 2007; Liao et al. 2013).

The goal of this project is to develop a fully automatic pressure ulcer identification and prevention system that can identify the harmful IP based on patient's physiological information. Also the system will set off an alarm to the care-giver under potential situation of developing pressure ulcers. These alarm conditions will be based upon physiological factors entered by the clinician to the system including age, body mass index (BMI), risk assessment scores. Figure 1.2 shows a person who has developed a pressure ulcer on his/her heel.

Fig. 1.2 A person with heel pressure ulcer
(NPUAP 2010)

1.2 Research Questions

In order to carry out the research, first the research questions are identified. In this section the research questions are provided.

1. What is the mechanism of PU formation in the human body?
2. What is the effect of external loading on the skin and how to characterise a body support surface material?
3. What are the patient's physiological parameters for PU formation and how are these parameters related to PU?
4. What is the role of current risk assessment scale for PU prevention?

1.3 Research Goals

Once the research questions are identified, the research goals are set and in this section the research goals are given. The main goal of this research is to design a new type of PU risk assessment and prevention system which will inform the care-giver about the patient's condition in real time. Also the system will prevent patients from developing ulcer at different parts of their bodies. The research goals are given below.

1. Modelling of the body support surface material mathematically and validate the model by conducting experiments.

2. Developing a mathematical model to identify the risk of PU formation at different areas of human body.

3. Comparing the results from the mathematical model with theoretical concept of PU formation.

4. Integration of the new risk model with an alternating pressure (AP) mattress so that AP mattress can be more patient oriented.

1.4 Approach

An extensive literature search was carried out to understand the subject area. The area of the search focused on the mechanics of pressure ulcer formation, biomechanics of human skin, economic factors of pressure ulcers, evaluation of body support surface, risk assessment scales for pressure ulcer prevention, technologies available to detect and prevent ulceration in human body. The aetiology of pressure ulcer was studied to develop PU model. Then a mathematical model of skin is developed to characterize the body deformation. Also well-known theoretical models (Maxwell, Kelvin-Voigt, Maxwell-Wiechert) were evaluated under a graphic user interface (GUI) to visualize the response of theoretical models. Different types of support surface material samples were modelled and experiments conducted to verify the simulation results. The material's response due to external loading was established and the developed support surface model was verified with experimental data.
The relationship between a person's physiological parameters (age, body mass index) with pressure ulcer formation was identified. Also the contribution of risk assessment scales for pressure ulcer formation was studied. Eleven volunteers with different age, sex and BMI were selected for external load measurement study at different bony areas. The purpose of the study was to establish a relationship between external load and a person's physiological parameters. Based on the experimental results it was possible to identify the maximum external load at one point by one person. On this basis, a new risk prediction mathematical algorithm has been developed by integrating a person's physiological parameters,
risk assessment score and body support surface material information. This new model shows the risk of pressure ulcer formation at bony areas of human body over a period of time.

To visualize the percentage of pressure ulcer risk, a GUI is developed in MATLAB and also the GUI was integrated with a commercial AP mattress system. The purpose of such integration was to make the AP mattress fully automatic so that the AP mattress can operate based on the risk predicted by the algorithm.

1.5 Outline

The elements of this research outlined in section 1.2 and 1.3 are given in the following chapters.

- Chapter 2 provides the extensive literature search on pressure ulcers. This contains a discussion of the aetiology of pressure ulcer formation, evaluation of body support surface, technology to identify and prevent ulceration. It also provides the treatment cost of pressure ulcer worldwide and how it is affecting patient's quality of life.
- Chapter 3 shows the mathematical modelling of body support surface material and development of graphic user interface (GUI) in MATLAB to visualize the model response under external loading.
- Chapter 4 shows the experimental validation of the developed model to characterize the body support surface material.
- Chapter 5 describes the mathematical algorithm to identify the risk of pressure ulcer formation in the human body.
- Chapter 6 shows the integration of the risk identification algorithm with AP mattress system. Also it shows the results obtained from the novel pressure ulcer prevention system and compares the results with existing data.
- Chapter 7 concludes the research based on the results and discusses the limitations of the research along with future directions.

1.6 Research Contribution

The following contributions have been made in this research:

1. Body support surface (viscoelastic mattress) modelling and validation of the model with experiment.

2. Implementation of harmful IP identification algorithm or relative risk algorithm for PU formation.

3. Validation of the risk identification algorithm with theoretical concept of PU formation.

4. Development of a person specific prevention system by combining IP risk algorithm with AP mattress actuation.

1.7 Publications From This Research

1. M.C. Mishu, J.W. Schroeder "Modelling of Pressure Ulcer (PU) Risk Identification System". Science and Information Conference, IEEE, July 2015, London.

2. M.C. Mishu, V.N. Dubey, T. Hickish and J. Cole, "A Review on Pressure Ulcer: Aetiology, Cost, Detection and Prevention Systems". International Journal of Engineering Sciences & Research Technologies, Vol:3 No:9, 2014.

3. M.C. Mishu, V.N. Dubey, T. Hickish and J. Cole, "Mathematical Modelling of Different Types of Body Support Surface for Pressure Ulcer Prevention". International Journal of Medical, Pharmaceutical Science and Engineering, Vol:8 No:5, pp.209-214, 2014.

1.8 Poster Conferences

1. Mishu, M.C., Dubey, V. N., Hickish, T. F., Cole, J. 2014. System Design for Pressure Ulcer (PU) Detection and Prevention. 6th DEC Research Conference, Bournemouth University, UK.

2. Mishu, M.C., Dubey, V. N., Hickish, T. F., Cole, J. 2013. Characterization of Soft Tissue and Body Support Surface: Towards Pressure Ulcer Prevention. 5th DEC Research Conference, Bournemouth University, UK.

3. Mishu, M.C., Dubey, V. N., Hickish, T. F., Cole, J. 2012. An Intelligent Bad Mattress System with Alarm for Long Term Bedridden Patient to Prevent Bedsore. 4th Annual Postgraduate Research Conference, Bournemouth University, UK.

4. Mishu, M.C., Dubey, V. N., Hickish, T. F., Cole, J. 2012. An Optical Fibre Based Intelligent Bedsore Identification and Alarm System Design, 4th DEC Research Conference, Bournemouth University, UK.

Chapter 2

Literature Review

The National Pressure Ulcer Advisory Panel *(NPUAP)*defines pressure ulcer as 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 and/or friction. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated"* (NPUAP 2007). Pressure ulcer also has various different names such as decubitus ulcers, ischemic ulcers, bedsores, and pressure sores. A pressure sore is an area of tissue damage appearing after a prolonged period of ischaemia in the tissue (Kosiak 1959). Persons with immobility and impairment are subjected to develop PU, e.g. elderly (because of skin conditions) residual limb amputees patients with hip fracture and SCI (because of long time bed-bound or chair-bound) (Byrne and Salzberg 1996; Lindgren et al. 2004; Maylor and Torrance 1999; Spittle et al. 2001; Torrance and Maylor 1999; Unosson et al. 1995).

2.1 Definition of Pressure Ulcer (PU)

Pressure ulcer is confined to a small area of tissue breakdown in skin (Bouten et al. 2003). It occurs in a situation when people are immobile and subjected to prolonged mechanical loads. Due to this loading, blood flow and the oxygen supply become insufficient to the soft tissues and that leads to tissue necrosis (Hsia et al. 2009; Manohar and Bhatia 2008; Solis et al. 2012). In early stages, it is known as pressure sore/ decubitus ulcer/ ischemic ulcer or bedsore, and later, it leads to ulceration. Current studies suggest a pressure higher than 32 mmHg applied to a skin at sacral area can be sufficient to cause PU if the patient is immobile for two hours (Bouten et al. 2003).

The interface pressure (IP) between the skin and the supporting surface (e.g. mattresses, chairs, cushions etc.) is an important parameter to consider. If the pressure value is higher than 32 mmHg, then it is considered as a risk of developing ischemia at sacrum. Study also shows that in terms of susceptibility to mechanical loading, muscle is more susceptible in comparison to skin (Daniel et al. 1981). According to the European Pressure Ulcer Advisory Panel (EPUAP) (Beeckman et al. 2007; EPUAP 2010; Lyder 2003), Pressure Ulcer can be classified in four different stages such as:

- Stage 1: Non-blanchable erythema refers the intact skin with non-blanchable redness of a localized area usually over a bony prominence. The reddened area remains red after the pressure is relieved. The area may be painful, firm and warmer as compared to adjacent tissue.

- Stage 2: Partial Thickness, in this stage a shallow open red pink ulcer is visible due to the partial thickness loss of the dermis. It can also be represented as an open serum-filled/sero-sanginous filled blister. A shiny/ dry shallow ulcer results without any slough or bruising.

- Stage 3: Full thickness skin Loss: In this stage pressure ulcer absorbs with full thickness skin loss and due to this the tissue necrosis results in a patient's body but not through bone tendon or joint capsule.

- Stage 4: Full thickness tissue loss:Full thickness tissue loss with exposed bone, tendon or muscle. Slough may be present. Often includes undermining and tunnelling. The depth of Stage 4 pressure ulcers varies by anatomical location. The bridge of the nose, ear and malleolus do not have tissue and these ulcers can be shallow. Stage 4 ulcers can extend into muscle and/or supporting structures (e.g. fascia, tendon or joint capsule) making osteomyelitis or osteitis likely to occur.

Figure 2.1 shows different stages of pressure ulcers in living tissues. The aetiology of pressure ulcer also depends on other measures such as properties of skin, patient's age, weight, blood flow in tissues etc.

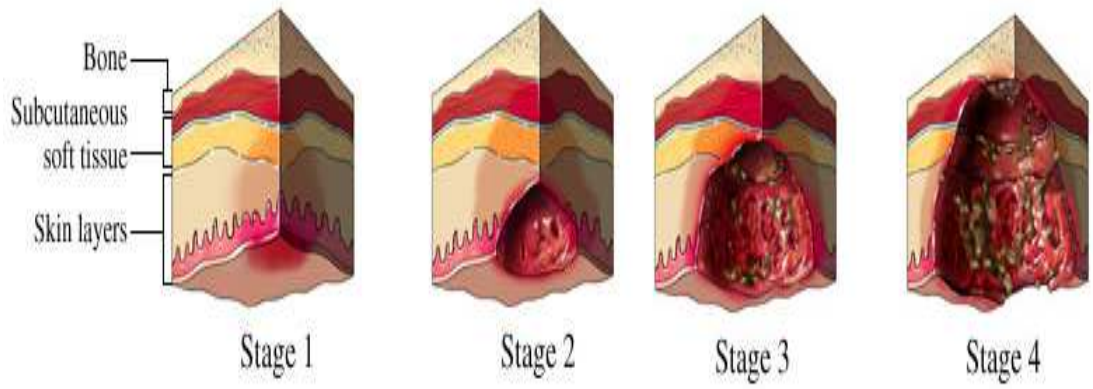

Fig. 2.1 Different stages of PU according to EPUAP
(Spacapsule 2001)

2.2 Biological Properties of Skin

The skin is the most outer cover in the human body. The skin offers strength and stiffness to oppose external mechanical loading. There are some other functions which are also provided by skin such as, insulation, sensation and temperature regulation. In order to perform these tasks, it is very important to have mechanical stability and mechanical flexibility of skin. There are different layers in skin including the epidermis and dermis and beneath them are subcutaneous fat, muscle and usually bone or internal organs. The epidermis is non-vascular and the main function of this type of layer is to protect the tissue (Liu and Yeung 2008). Dermis contains the blood vessels. These layers also contain 75% of the collagen. Collagen is the natural protein that constitutes most of the body's structural support. Collagen also gives strength and elastic properties to different organs and tissues (Elsner et al. 2001). For disease like pressure ulcers, the collective response of all the skin layers is important. Figure 2.2 shows the skin overview with different layers.

The subcutaneous fat encircles the body and gives curved shape. The subcutaneous layer does not haves major tensile strength and this layer is susceptible to mechanical forces (Shea 1975). The pressure distributing properties of muscle is good but studies have shown that the subcutaneous tissue and particularly the muscle is more susceptible to pressure induced injury in comparison to the epidermis (Daniel et al. 1981; Nola and Vistnes 1980). Tissue layers get compressed when the force is applied. This occurs due to the properties of the layers at different points. The subcutaneous fat becomes resistant to mechanical loads and it also becomes less susceptible to compression because of collagen content (Shea 1975).

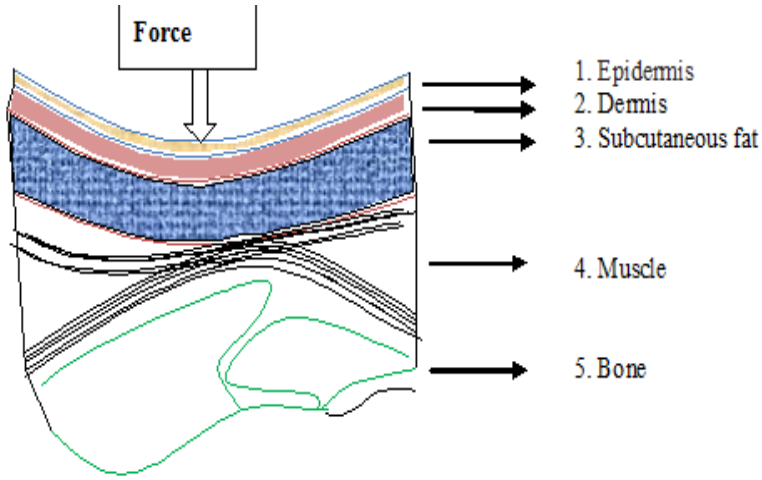

Fig. 2.2 Schematic of human skin
(Liu and Yeung 2008)

The collagen content of the dermis is decreased due to aging and elastic fibres become more structured therefore the resistivity due to mechanical loads decreased with age (Richey et al. 1988).

2.2.1 Blood Flow in Skin & Soft Tissue

Blood flow in skin depends on the relationship between blood vessel diameter and vascular resistance. Diameter of the blood vessels (arterioles) can change actively or passively. The change in diameter is because of smooth muscle (altering and contractile state) in the vascular wall (Jan et al. 2008; Popel and Johnson 2005). Due to these changes, resistance of the vascular segment varies in inverse proportion to the fourth power of vessel diameter. Therefore a very little increase in diameter could result a massive change in blood flow.
The factors responsible for the change of state in smooth muscles are: shear stress, metabolic stimuli, transmural pressure and neurogenic stimuli (JACOBITZ et al. 2011). If the pressure in a smooth muscle increases then the cutaneous arterioles become compressed and if the pressure decreases, the cutaneous arterioles become expanded. Arterial vessels react due to changes in shear stress and leads to an increase in skin blood flow (Holowatz et al. 2008). Therefore blood flow is considered as one of the biggest contributing factors to the formation of pressure ulcers. When blood flow is reduced, oxygen cannot get through the capillary bed and tissues. As a result, tissue and skin breaks down. Blood flow also has an effect on blood pressure.

If a person is in hypotensive (their blood pressure is below the normal range), blood flow decreases. This results in arterial blood not being transported quickly enough to the capillary bed in the tissue. Blood perfusion also decreases as external pressure increases in the body over a period of time. As soon as the external pressure exceeds arteriolar pressure, blood flow to that particular region stops. This is known as localized ischemia (Thomas 2010). After the ischemia, tissue necrosis (cell death) occurs. An important factor in the skin is the rate of blood flow in different areas of the body. For example, sacral blood flow is higher than over the Gluteus Maximus (Thomas 2010). This is important because when blood flow is decreased from an increase in external pressure there is more damage to the sacral; thus correlating to more incidences of pressure ulcers in the sacral region than the gluteus maximums (Thomas 2010).Tissue below the skin breaks down due to anoxia (the lack of oxygen) and lack of blood flow. Figure 2.3 shows an overall view on pressure ulcer development.

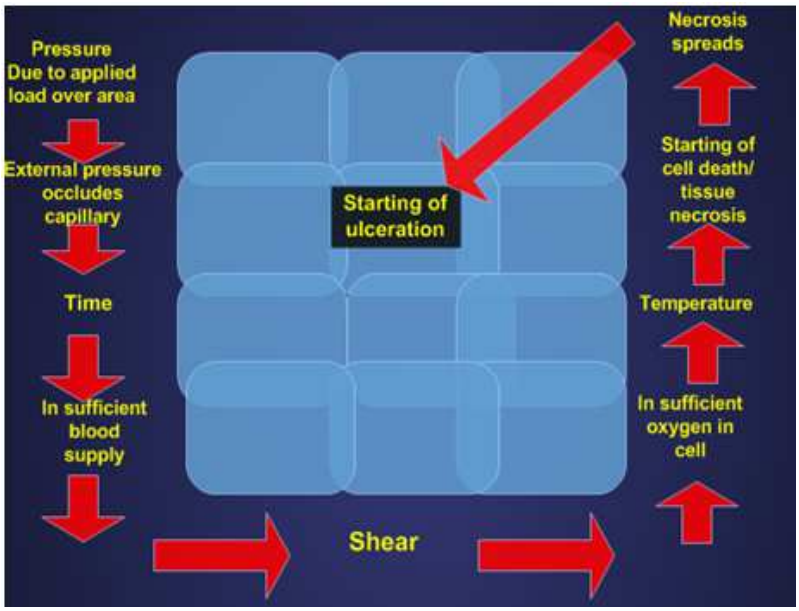

Fig. 2.3 Pressure Ulcer formation over time
(Keller et al. 2002)

2.2.2 Skin & Tissue Temperature

Temperature has been identified as a significant indicator/factor for ulcer formation by NPUAP. In order to identify the risk of ulceration, both (increased and decreased) temperatures are useful (NPUAP 2010).

Moreover, tissue breakdown can take place even if there is no changes in skin and tissue temperature (Baldwin 2001). Changes in skin and soft tissue temperatures have an effect on soft tissue damage. Skin temperature changes due to pressure at surface and skin level (normally known as interface pressure). An increase of 1°C results in a nearly 10% increase in soft tissue metabolic requirements. The relationship between change in skin temperature and perfusion has been found exponential in human body (Armstrong et al. 2007; Sprigle et al. 2001). The impact of temperature on soft tissue perfusion and tissue deformation has been analysed by Patel et al. 1999. It has been shown that skin is wrapped at the position of increased interface pressure and therefore temperature increases. They have also confirmed the hypothesis that tissue deforms less with temperature in the skin. Increasing the skin temperature has impacts on soft tissue stiffness. Change in the skin temperature is also a result of decreased tissue permeability for interstitial fluid so when the permeability decreases, less fluid is removed from interstitium and that causes less tissue deformation. Other studies have suggested that a skin temperature increase of ≈ 1.2°C over a 24-48 hours time period increased the risk of forming pressure ulcer (Gefen et al. 2005,Gefen 2011). If the temperature increase is still present even though patient has changed the body positions then it is more likely to be an intrinsic factor representing tissue inflammation and potential damage. When the skin temperature increases it interacts with sweat gland functions. When the body sweats it increases moisture on the damaged skin. When pressure is added to the body, skin tolerance decreases, increasing the patient's risk of forming a pressure ulcer.

2.2.3 Patient's Age

Age is considered as an important factor for PU formation in human body. As people get older their mobility decreases and they become weaker. Also age has effects on the skin properties, perfusion and other vascular diseases. These facts increase the chance of PU formation and also lowers the chance that a patient is able relieve the induced interface pressure in an area of concern. Patients aged over 65 are more susceptible to develop pressure ulcers and it has a great deal of correlation with the skin (Hopkins et al. 2006; Mathus-Vliegen 2004).

A total of 17560 patients in USA hospitals were examined for PU development and nearly 7% of the total population found with heel pressure ulcer (Whittington et al. 2000). Research has been conducted to see the effect of ageing on skin blood flow (Martin et al. 1995; Minson et al. 2002). They also have shown maximal cutaneous blood flow decreases linearly with age.

However, study has shown how to increase the blood flow during loading conditions (Minson et al. 2002). Another study has shown a load was applied to the forearm skin of younger (22-36 years) and older (60-71 years) volunteers (Hagisawa et al. 1991).
The load was removed after a period of time but it was found that the removal of the load was highly reduced in the older group. Capillary loops decrease with advancing age and lead to increased capillary distance (Li et al. 2006). They also have characterized the aged skin by a flat dermal-epidermal junction with the loss of capillary loops. A negative correlation has been shown between the density of capillary loops and age (Li et al. 2006).
The total vascular length increases with advancing age. Table 2.1 shows the relationship in more detail. The changes in skin function and structure mentioned above, along with risks that occur in overall health and functional capability can put elderly patient at a high risk for developing pressure ulcer.

Correlations between pressure ulcers and aging skin
The risk for blistering and skin tears increase because of flattening of the epidermal-dermal junction. Due to the flattening, the overall skin strength decreases.
Skin temperature decreases due to insufficient blood flow.
Body's natural insulation and padding decreases because of less subcutaneous tissue
Skin's incapability to absorb medication is a result of declining the reproduction of the outer most layer of epidermis.

Table 2.1 Correlations of age with Pressure Ulcer

2.2.4 Patient's Body Mass Index (BMI)

A patient's BMI is also significant. Malnourished patients with lower BMI, with less fat on their body and less cushioning between the bony surface and the skin are at very high risk for PU formation. Bedsores tend to already occur in areas where there is little tissue and fat between the bone and skin. A common expression used for a person who is very thin and does not weigh enough is "they are just skin and bone" which is nearly a direct correlation with the formation of pressure ulcers due to any underlying illness. On the other hand, patient's with high BMI known as obese are also at more risk of developing pressure ulcers (Levy et al. 2013; VanGilder et al. 2009). Because of obesity, a patient has several complications and co-morbidities. An obese patient does not have good mobility (e.g. rising from a bed or chair).

Lack of mobility leads to higher interface pressure at the skin and support surface level and that's why an obese patient is at risk of developing pressure ulcer.

2.2.5 Patient's Immobility & Repositioning

Patient's immobility is another important factor for pressure ulcer formation. The less mobile a person is, the more is the risk of a pressure ulcer. Mobility ranges from having problems with full range of motion to coma. Some patients simply can not move and rely completely on their healthcare professionals to try to relieve the pressure and restore the blood circulation (Hopkins et al. 2006; Mathus-Vliegen 2004; VanGilder et al. 2009).
The effects of immobility for PU formation have shown in several studies (Fisher et al. 2004, Papanikolaou et al. 2003, van Marum et al. 2000). These studies have revealed the odds ratio (OR) from 0.53-5.41 linked with immobility with PU formation. To improve the immobility, repositioning has been identified as a key prevention technique for PU. Repositioning includes moving a patient into a various position to relieve the harmful interface pressure from the parts of his/her body. But some of the positions have found not very helpful in terms of PU prevention e.g. 90°lateral position has been found not suitable compared to 30°lateral inclined position (Defloor 2000). A 90°position decreased the blood flow and transcutaneous oxygen tension (TcPO2) to anoxic levels and increased the interface pressure compared to 30°position. The timing of repositioning have been reported in two studies (Defloor et al. 2005 and Vanderwee et al. 2007). These studies have shown the effects of repositioning schedule on PU incidence. Four groups: two hourly, three hourly, four hourly and six hourly have considered for the repositioning schedule on a viscoelastic mattress and a standard foam mattress. Among all the groups, four hourly repositioning group on a viscoelastic mattress showed less PU incidence.

2.3 Mechanical Properties of Human Skin

Mechanical behaviour of human skin is classified as non-linear viscoelastic material (Ruvolo Jr et al. 2006; Zhang et al. 2008). Also it is considered as non-homogenous and anisotropic depending on prestress of skin. Non-linear and anistropic characteristics of human skin from a tensile test is described in (Ruvolo Jr et al. 2006). Epidermis is usually stiffer than dermis and because of this the mechanical property, epidermis is overlooked and only the mechanical characteristics of dermal collagen is considered (Ruvolo Jr et al. 2006).

These characteristics are established from a collagen test Delalleau et al. 2006. The role of stratum corneum is considered on the mechanical behaviour of the skin. Stratum corneum (outer layer of epidermis) consists of corneocytes. It usually protects the skin from mechanical stress (Agache et al. 1980).

2.3.1 Mechanical Characteristics of Dermis

To understand the mechanical characteristics of the human skin, it is important to know the correct mechanical properties of dermal section. Several studies have shown the mechanical behaviour of dermis (Gosline et al. 2002; Smith and Fazzalari 2009). There are two major components in dermal layer known as elastin and collagen. Also the ground substance is considered along with these two components to characterize the viscoelastic behaviour of human skin. Mechanical characteristics of dermal layers are described below.

2.3.1.1 Elastin

In a dermal layer, approximately 4% (fat-free) is elastin. Elastin fibres are surrounded by fibrillin micro-fibrils. Also the stiffness is less in elastin compare to collagen. It provides almost 100% reversible strain characteristic (Smith and Fazzalari 2009). The width of the elastin is 0.5-8μm. Elastin usually provide a linear elasticity and resilience in connective tissues (e.g. blood vessels) (Kielty et al. 2002). Its elastic modulus is reported as approximately 500 kPa (Gosline et al. 2002; Kielty et al. 2002). Mechanical properties of elastin is based on hydration. Usually elastic fibres need liquid to show the elasticity behaviour. If there is no exposure of swelling agent then the behaviour of elastin is solid (similar to glass) (Smith and Fazzalari 2009).

2.3.1.2 Collagen

Collagen fibres are considered as the most important element of dermis (77% fat-free). They establish an asymmetrical system of wavy coiled fibres which run almost parallel with the skin surface (Buehler 2006; Smith and Fazzalari 2009. Another study has shown that the fibres get separated from each other but held together by ground substance (Buehler 2006). The tensile strength of collagen is reported as 1500-3500kPa. The stiffness is very high in collagen and the Young's Modulus is 0.1GPa to 1GPa. The width of the collagen is usually 1-40μm (Kielty et al. 2002; Wenger et al. 2007.

2.3.1.3 Relationship of Stress-Strain

The stress-strain relationship of the skin is nonlinear even though elastin and collagen are linear elastic (Hussain et al. 2013; Karimi et al. 2014. The reason is the non-uniform structure of the skin. Figure 2.4 shows the relationship curve.

The curve is divided into three regions. In the first region the collagen fibres response is

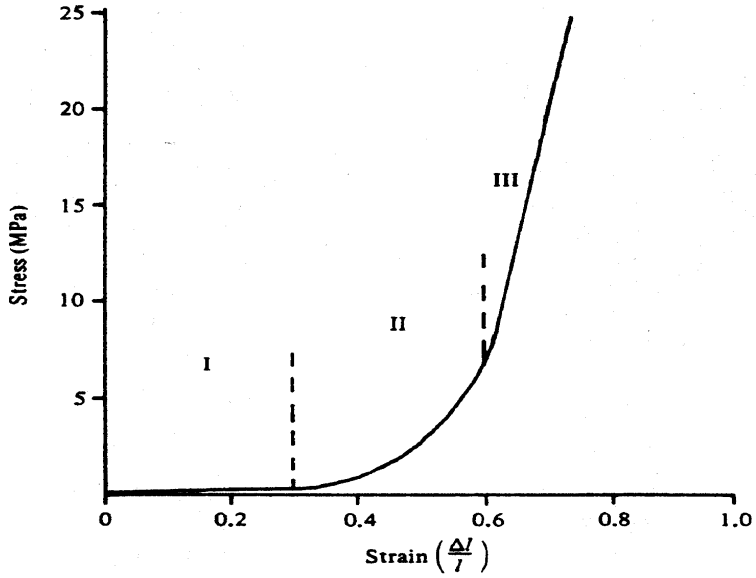

Fig. 2.4 Stress vs. Strain
(Maurel et al. 2014)

neglected and elastin is considered accountable for the elongating skin. The stress-strain relationship is linear at this stage with a Young's Modulus of 5kPa (Maurel et al. 2014). In the second region, because of higher stiffness, collagen fibres start straightening. All collagen fibres become straight in third region, elastic and cracked fibres occur (Maurel et al. 2014). Another research has shown the stress-strain relationship from experimental results conducted on the skin (Grant et al. 2012). They have shown that the elastin fibres have an effect on the stress-strain relationship.

2.3.1.4 Viscoelasticity of Skin

Viscoelastic behaviour of the human skin usually comes from the ground substance in dermal layer (Sakuma and Sango 2014). In figure 2.4 the first region shows elastic behaviour in the skin but second and third region show viscoelastic behaviour.

Research show that the viscous effects occur for a small period of time due to removal of stress from the skin (Karimi et al. 2014). If the load is applied to the skin, the deformation occurs and when the load is removed, the skin returns to its initial position, though not at once. This establishes that the human skin is not purely an elastic material. The skin gradually gets into its original position with respect to time. This type of mechanical behaviour is classified human skin as a viscoelastic material. Time dependant viscoelastic behaviour of dermis is related to viscous resistance fibres (Wenger et al. 2007). Another study has shown an induced stress, stiffness and relaxation with respect to time in dermis due to removal of ground substance (Crichton et al. 2011).

2.3.1.5 Prestress in Skin

If the thickness of the dermis can be measured during load applied and removal, the dermal layer can be found thicker (Buehler 2006). Therefore under normal situations, the human skin is subjected to pre-tension. The pre-tension of human skin is studied in (Flynn et al. 2011). In that study, wrinkles have appeared on the skin when the external load was applied. They have also established that the amount of the external load at which skin gets wrinkled is a measure for the pre-tension of the human skin. The experiment in that study was verified with a finite element model. Pre-tension was 24 kPa (direction along the fibres) and 9.3 kPa (direction across the fibres). However, a study have established that the elastic fibres are generally responsible for prestress of human skin (Smith and Fazzalari 2009).

2.3.2 Mechanical Experiments on Skin

A lot of experiments have been conducted to establish the mechanical behaviour of dermis. Mostly the experiments include tensile testing, indentation, suction testing and torsion testing of human skin. Other tests such as elastography, wave propagation and normal traction are also conducted. Skin layers are closely connected with each other. Therefore it is difficult to separate the mechanical behaviour of only dermal layer with epidermal and subcutaneous tissue layer.

2.3.2.1 Tensile Testing

Tensile testing has been used widely in the mechanical characterization of the human skin. The skin is loaded parallel with the surface during a tensile test and two modes used: uniaxial and biaxial. Usually two strips are attached to the skin and pulled apart. These strips have effects on the deformation of the skin due to its adhesive property.

An uniaxial test has been conducted on the human skin (calf area). A pair of strips (10×10 mm) were fixed to the skin at a distance of 5 mm then 12 N load was applied at a interval of 10 and 20 sec. Ultrasound technique was used to measure the deformation of 1.2 mm thick skin. During the test, a non-linear stress-strain graph was obtained. The Young's Modulus of 4 MPa was found from the test with strain of 0.32 (Manschot and Brakkee 1986). In order to obtain the skin deformation, the skin was mechanically separated from its surrounding area by a frame. To obtain the strain, markers were applied to the skin. Displacement of the strips and amount of force applied were used to solve a skin model (Lanir 1983). In that skin model, the structure of human skin is classified as the direction and distribution of collagen and elastin fibres.

2.3.2.2 Indentation Testing

Indentation test consists of a rigid indenter that is used to apply known load to the skin. a low-pressure indentometry on a 0.2 cm^2 forehead skin is used to observe the effect of the stratum corneum due to indentation (Dikstein and Hartzshtark 1983). They have shown that the stratum corneum does not provide any influence to the indentation. However, they have suggested that the condition of ground substance and elastin network has influence on the deformation of skin due to indentation. Another study has shown a use of an indenter to identify the mechanical characteristics of human skin and soft tissues (Bader and Bowker 1983). In that study, measurement of the tissue thickness was carried out. A constant load was applied for 120 sec then removed. The recovery of the soft tissue was observed. The experiment was conducted by varying the load and indenter diameter. Instant deformation, creep, and a long recovery was observed in the skin.

2.3.2.3 Skin Suction

Suction tests are normally carried out to identify the skin elevation. A probe with circular aperture is used for suction. The skin deformation is an output of optical system. Darmaflex and Optical Cutometer are the two commercially available system for suction testing. Two studies show the use of Dermaflex (Gniadecka and Serup 1995; Pedersen et al. 2003). In one of the studies the measuring probe was attached to the skin. The size of the aperture was 10 mm. The elevation measured was 1.8-4.0 mm (on different location of body) (Gniadecka and Serup 1995). Elasticity for different group of subjects were also measured during the test. This type of system only provides information about dermal properties.

On the other hand, Cutometer measures the mechanical characteristics of epidermal layer along with dermal layer. They have used Cutometer to establish the mechanical properties of human skin. A study have shown that a probe with 90 g of weight was used with variable apertures. Variable apertures provide deformation in deeper skin layer by the suction (Barel et al. 1995). They have shown the deformation vs. time and pressure vs. deformation graphs from a suction test.
Cutometer provides mechanical properties of epidermis and dermis but this type of system is very expensive and very sophisticated.

2.3.2.4 Skin Torsion

Another popular method is known as torsion. In this type of test, a mediator disc with a guard ring is attached to the skin. Mediator disc generates the torque. This type of method has very few advantages.

- Anisotropic effect of the skin is reduced
- Underlying soft tissues do not have any impact on measurements

The stiffness of the skin was studied in with an equipment and 28.6×10^{-3} Nm torque was applied for 2 min (Agache et al. 1980; Leveque et al. 1980). The diameter of the mediator disc was 25 mm and the guard ring diameter was 35 mm. They were attached to the forearm skin using adhesive. Then 12.6 kPa pressure was applied to the mediator disc to ensure the contact of skin constantly. The mathematical equation used to identify the Young's Modulus, E is given below (Agache et al. 1980).

$$E = \frac{M}{2 \times \Pi \times 0.4 \times e \times r_1 \times r_2 \times \theta} \tag{2.1}$$

where M is the torque applied in Nm, e is thickness of the skin, r_1 and r_2 are the radius of mediator disc and guard ring respectively and θ is the angle of rotation in radians. Young's Modulus for less than 30 years old group was calculated 4.2×10^5 Pa and 8.5×10^5 Pa for over 30 group. Using the same group, another test was carried out. They have established the effect of aging on mechanical properties of the skin (Escoffier et al. 1989). In that study, a 25 MHz ultrasound with 70 m resolution was used to measure the thickness of the skin. The diameter of the mediator disc was 18 mm and 24 mm for the guard ring. The torque was 2.3×10^{-3} and 10.1×10^{-3} Nm respectively. Time period was 60 sec. The instant skin deformation was described as U_e along with U_v (viscous).

Also a recovery U_r was found due to removal of torque (shown in figure 2.5). Mathematically the deformation was defined as:

$$U(t) = U_v \times (1 - e^{\frac{-t}{\tau}}) \tag{2.2}$$

where τ is relaxation time. Figure 2.5 shows the skin elasticity and recovery due to age. Results from that experiment strongly shows a linear relationship between skin elasticity

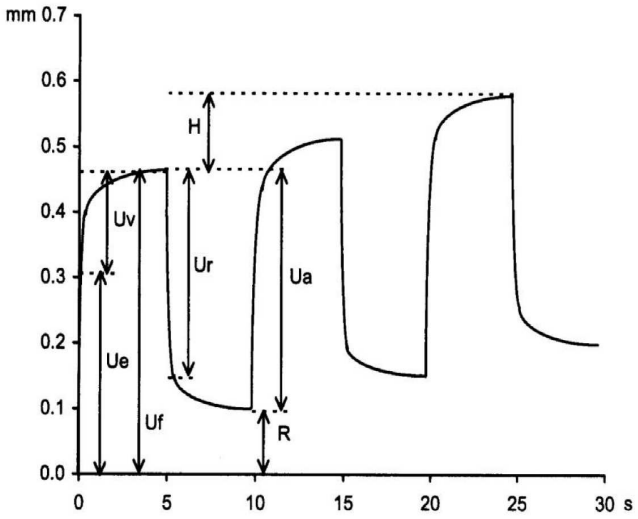

Fig. 2.5 Skin deformation curve
(Escoffier et al. 1989)

and recovery with age.

2.4 The Economic Impact of Pressure Ulcer

A report (Posnett and Franks 2008) showed that a hospital would require to spend £650,550 to £1,165,355 per year depending on its size (number of beds). If the prevention strategy in the care of patients is included then the cost will be increased to £2,739,380 (Posnett and Franks 2008). The standard cost per person for the different stages of pressure ulcer has been estimated at £1,076 for stage 1, £4,450 for stage 2, £7,393 for stage 3 and £10622 for stage 4 (Graves et al. 2005*b*; Posnett and Franks 2008). In UK, the number of people who develop PU annually has been estimated as 140,000 for stage 1, 170,000 for stage 2, 50,000 for stage 3 and 50,000 for stage 4 (Bennett et al. 2004). In EU total annual cost of pressure ulcers was estimated yearly at £154.5 million (stage 1), £756 million (stage 2), £393 million (stage 3) and £484 million (stage 4) (Graves et al. 2005*a*).

In Australia it was found by a research that a subject with pressure ulcer requires extra 4.31 days in hospital compared to other patients and the cost of this extra days were estimated as AU$ 28 million yearly (approximately £13.22 million) (Graves et al. 2005*a*).

In USA pressure ulcer cost the healthcare industry US$ 11 billion yearly (approximately £7.1 billion) with the average cost for each subject US$ 43,000 (approximately £27922). Also the length of stay in hospital is 3 times higher for the subject with pressure ulcer. Around 14.8% of total population in USA develop pressure ulcers in hospital whereas around 20% of people develop pressure ulcer in Europe (Lyder et al. 2002; Spilsbury et al. 2007). The number varies due to different risk assessment criteria for the patients. Figure 2.6 shows the population affected by pressure ulcer globally per year. Apart from the increased

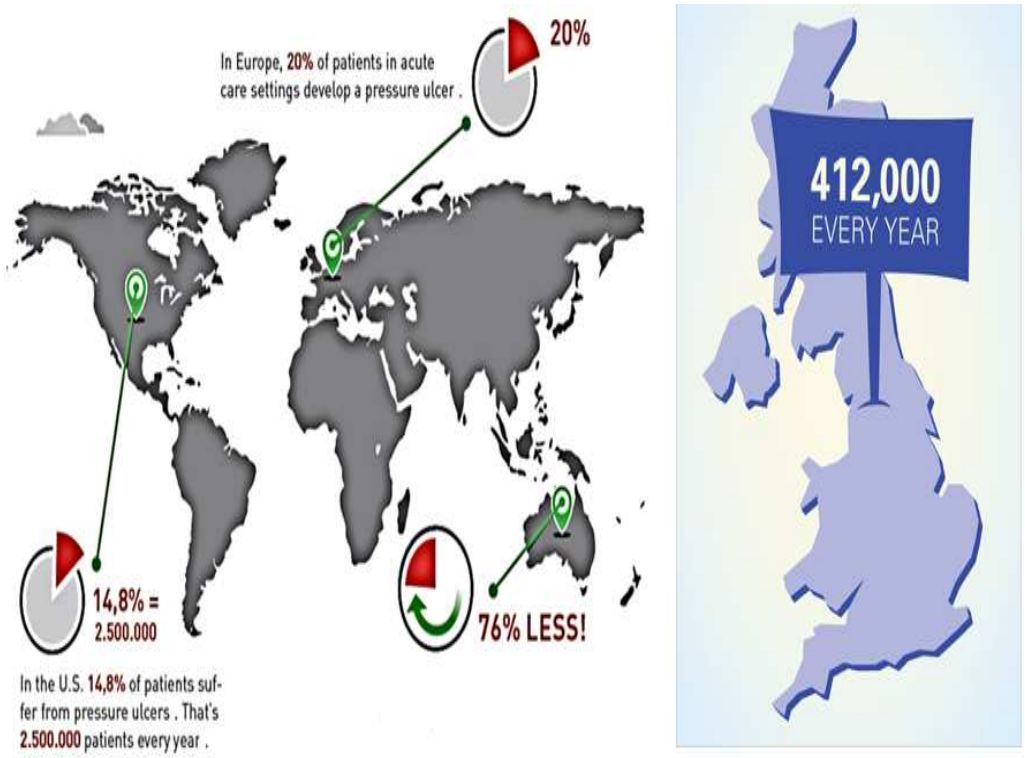

Fig. 2.6 Worldwide population affected by PU along with United Kingdom

morbidity and having patients at risk of hospital based infections from extended stays in wards, PU add a huge economic cost to society.

2.5 Technologies Available for PU Identification and Prevention

There are various technologies available to detect and prevent pressure ulcers. Several electronic systems are available to calculate pressure from patient's body and also several body support surface systems are available to prevent patients from developing ulcers. But these systems have some limitations. Available technologies for detection and prevention are discussed in section 2.5.1 and 2.5.2 along with their advantages and disadvantages. Also current and previous researches in this field are shown.

2.5.1 PU Identification Technology

There are a number of commercially available technologies exist to detect external pressure (due to load at different body parts) of human body while bed ridden such as flexiforce (by TEKSCAN), Xsensors. These technologies are capacitive, piezoresistive, load cell sensors, Carbon Nano coil (CNC), Metal strain gages (Holscher et al. 1994). But these technologies have some disadvantages, e.g. capacitive pressure sensors are susceptible to electrical interference due to its high impedance. Metal strain gauges needs supplementary configuration to identify force (Elfehri et al. 2011). Strain gages are also not suitable for mounting on the skin. However, piezoelectric materials are used very often for pressure sensing though the material is fragile and prone to breakage.

2.5.1.1 Capacitive pressure sensing

Capacitive sensors are used to measure the pressure on the human body. The change of capacitance occurs over a small distance of place due to a separation of two conductive plates (Yip et al. 2009). In general, to measure the shear component along with the normal forces, capacitive sensing technology is used. An example of capacitive pressure sensing established in Yip et al. 2009 is shown in figure 2.7.
When the pressure is applied, capacitance increases and thickness of the dielectric decreases. The amount of applied pressure can be extracted by sensing the capacitance. In figure 2.8, a schematic of capacitive sensor array is shown (Yip et al. 2009). The capacitors are arranged in 11 by 9 arrays. Each unit capacitance C_{xy} in row x and column y depends on the pressure applied there. The array is scanned in every 81 ms at a sampling frequency of 12 Hz. A 16-bit analogue-to-digital (A to D) converter is used to obtain results. The columns are multiplexed by using one 2:1 multiplexer per column.

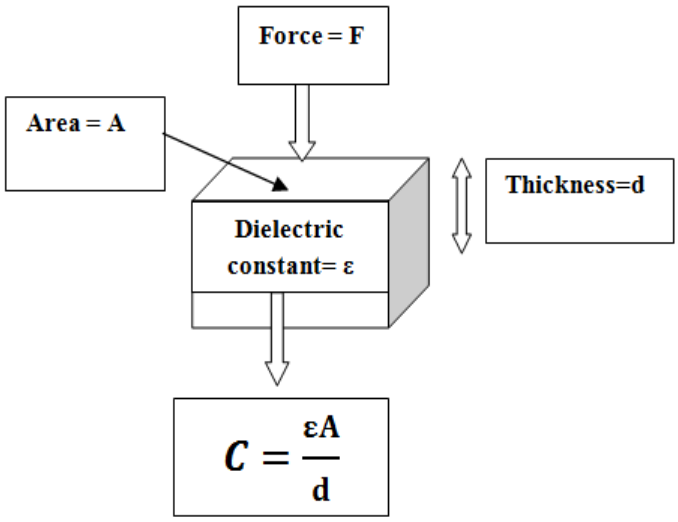

Fig. 2.7 Parallel plate capacitor model with variable capacitance due to modulation of the dielectric thickness by the applied pressure
(Yip et al. 2009)

An array of capacitive pressure sensors is located under the patient's bed. The sensing is done by an analogue device. A low power microcontroller controls the measurement sequence. The digitized data is then transmitted to a computer via a USB interface using a chip. A Graphic User Interface written in Visual Basic is used to plot the data in real time and post processing is done in MATLAB. In order to interface the electronics with the sensor sheet, a USB-powered printed circuit board (PCB) was designed and used. Though the hysteresis is recorded <10%, the limitation of this type of design includes sensor to sensor variations and drifting (Yip et al. 2009). Periodic re-calibration is required for individual sensor to overcome the drifting.
Moreover, the wearing is complex and the power consumption is high in this type of design. Also this research does not show individual pressure induced in tissue and support surface.
A design of a low cost and disposable mattress for non-invasive sleep and movement monitoring is discussed in Abraham et al. 2011. c-Paper, a non-woven material is used to design the pressure sensing array using capacitive principles. The conductivity of a single ply c-Paper area can be controlled by loading carbon fibres at different concentrations onto the base area. In order to design the top electrode, a width of 5 mm with a separation of 5 mm c-Paper strips is used for the sensor. The bottom column is same as the top (Abraham et al. 2011).

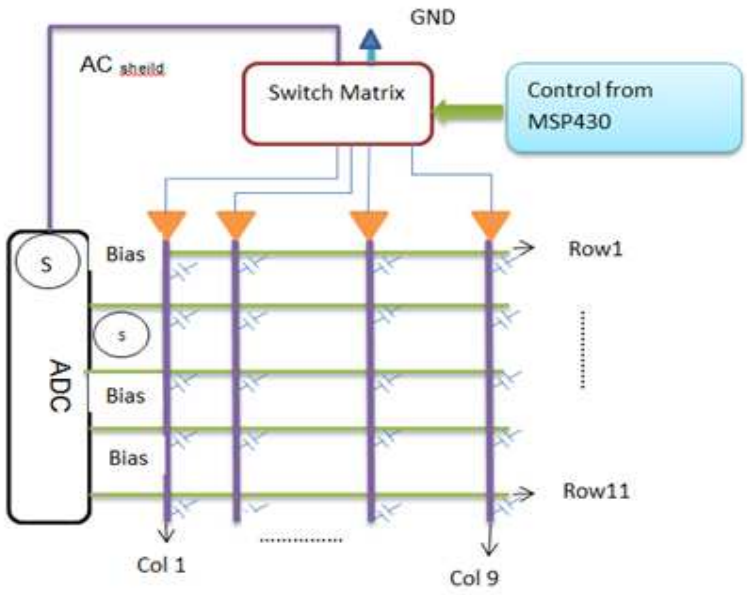

Fig. 2.8 Capacitive sensor array
(Yip et al. 2009)

When the pressure is applied, the dielectric material separates the capacitor plates and the capacitances change due to the displacement of electrodes. The data processing and results are obtained using LABVIEW (shown in figure 2.9). This type of prototype includes a large scale fabrication process and it is not suitable for the Shear force calculations. Disadvantages found with capacitive pressure sensing technologies are given below:

- The capacitance changes nonlinearly with diaphragm displacement.
- Sometimes capacitance is too large for the fractional change but absolute change is too small and that indicates a caution in designing the circuit.
- The impedance at the output is very large and that can cause interference to the circuit.

2.5.1.2 Piezoresistive Pressure Sensors

Piezoresistive technologies are often used to measure the pressure level on the human body (Hsu et al. 2008). If the pressure is applied to a surface it produces a deformation in the material. A wireless battery less piezoresistive pressure sensing system is shown here. A sensing system adjusts with Radio Frequency Identification (RFID) operation principle.

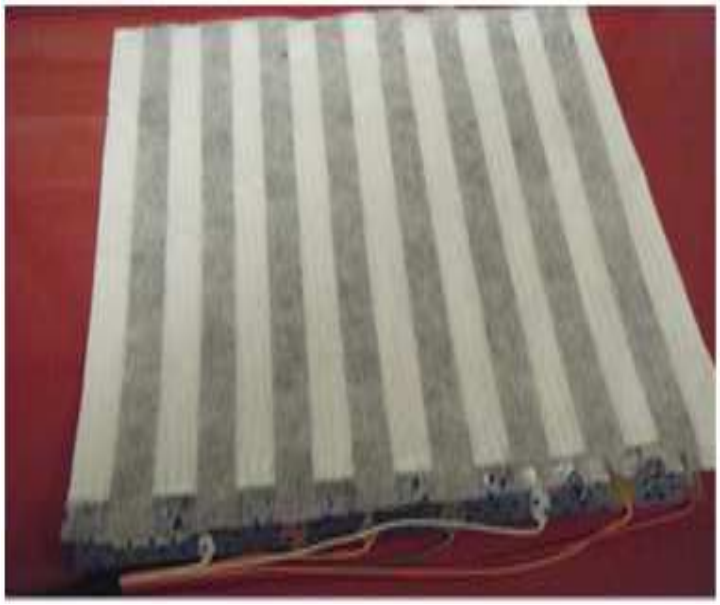

Fig. 2.9 8×8 matrix pressure mat tile with each element 5 mm wide and 15 cm long (Abraham et al. 2011)

The system comprised with force sensing resistors, transponder devices, and a monitoring reader system. The force sensing resistors are designed into an array format to measure the pressure distribution across an aperture. In order to signal multiplexing, a switching unit was also included and resistors were connected to that switching unit. The pressure information in the format of resistance values was fed into the transponder device to be converted into frequency shift information (Hsu et al. 2008). A pressure measurement system and mechanical design of the Polydimethylsiloxane (PDMS) was also included in that design. Figure 2.10 shows the architecture of a piezoresistive pressure sensing technology. When a force is applied directly on top of the sensing area of the force sensing resistor, the force will be converted into pressure that is defined by the buffer PDMS structure. This type of design has many advantages such as low cost, high mechanical stiffness, high sensitivity, and small in size.

2.5.1.3 Strain Gauge Sensors

Stain gauge technology is not suitable in some instances as the sensors need to be mounted on the patient's skin (Zhu et al. 2011). Strain gauges are mostly structured into load cells. A load cell is a mechanical support for a system with strain gages connected to its internal surface. It measures the strain and therefore the force applied to the structure.

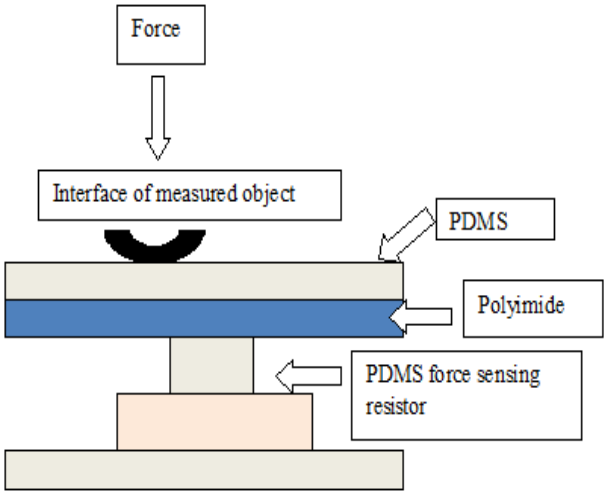

Fig. 2.10 Piezoresistive pressure sensing technology
(Hsu et al. 2008)

As load cells are constructed with strain gauges, care must be taken not to break the connection between the gage and strained surface. Disadvantages:

- Small variation in resistance when a force is applied to the interface surface.
- Sensitive to temperature (Resistance changes with temperature)
- Long wiring makes the overall system complex.
- Compared to piezoresistive sensors strain gages have lower sensitivity.

2.5.2 Technologies Available for Preventing PU

Various technologies are available to prevent pressure ulcers by distributing the force exerted on specific problem areas, or supportive surfaces that move the patients after a set period of time. These solutions do not come with feedback system for each patient's specific contributing physiological factors, such a pressure exerted or moisture content of the sample area, age, BMI etc. However another disadvantage is that these methods are meant purely for prevention based on time rather than prevention based on of physiological factors. Although these prevention technologies provide improvements for the existing treatment of pressure ulcers, none have been accepted as a standard of care.

2.5.2.1 Static & Dynamic Support Surface

Static body support surfaces are mainly low tech constant low pressure (CLP) systems (Bansal et al. 2005). These are classified as foam, air, gel, water mattresses. Furthermore, foam mattresses are classified into two categories such as cold foam mattress (memory less) and viscoelastic foam mattress (also known as memory foam mattresses).
Cold foam (also known as conventional foam) mattresses are made of polyether foam (Fenner Sr 1991; van Leen et al. 2011). This is elastic foam consisting of many very small closed air cells. After compression it recovers very quickly to its original shape. The foam shows "no memory" behaviour. In early days, cold foam mattresses were used to prevent the pressure sores (van Leen et al. 2011). Viscoelastic foam mattresses (memory foam mattresses) are also made from polyurethane, but they are generally less springy and maintain a sense longer, "remembering" the shape of patient's body. This type of mattresses has been used in many pressure ulcer prevention researches (McInnes et al. 2011; Swanson 1997). The advantages of using such kind of mattresses are:

- Strongly reduces the pressure by increasing the contact area between the body and the foam.
- Improves blood circulation by increasing the release of pressure.
- Increases the comfort and stability of the patient.

Viscoelastic foam is characterised by its slow recovery after compression. If a weighted object (e.g. human body) is placed on viscoelastic foam, the foam gradually conforms to the shape of the object, and after the weight is separated, the foam slowly returns to its initial shape. Viscoelastic foams are also known as "slow recovery" foams (Nixon et al. 1998). However, there are some other characteristics which include viscoelastic foam's ability to dampen vibration as well as absorb shock. In fact, certain viscoelastic foam mattresses are able to take up to 90% of impact (De Laat et al. 2006; Vanderwee et al. 2007). A unique physical characteristic of viscoelastic foam has led to its popularity in healthcare industries. Because of its conforming feature, viscoelastic foams are very well known for support surfaces. People with impaired mobility, limited to wheelchairs or hospital beds can be benefited by using this type of mattresses. Viscoelastic foam mattresses have the capacity to redistribute the surface pressure which is induced due to external loads. Since these types of mattresses can generate the shape of the human body, they can distribute pressure over the whole surface very efficiently. Pressure-mapping equipment is used to analyse the level of weight distribution.

Some viscoelastic foam manufacturers perform these tests as an indication of how well the foam might act to reduce pressure. So this type of mattress is very useful to prevent pressure sores. A comparison between a conventional foam and viscoelastic foam is studied where it was shown that viscoelastic foams are more suitable for reducing pressures (Fontaine et al. 1998). Figure 2.11 shows a viscoelastic foam mattress.

Air filled mattress (AM) is also a useful mattress for preventing pressure sores (Colin et al.

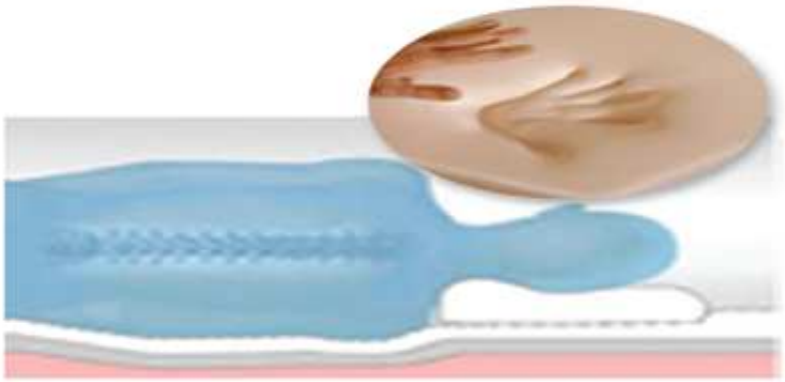

Fig. 2.11 Memory Foam
(Nixon et al. 1998)

2012). This type of mattress has a series of bladders filled with air. Air filled mattress is a dynamic support surface system. These bladders are usually divided into 6 different zones, to distribute the pressure. Each zone can be programmed individually. A interval of 3-5 min is created to make automatic adjustments to air volumes (Colin et al. 2012). Air-filled mattresses are usually bulky and only used in a critical care setting. Air is pumped into the mattress, which then supports the patients with minimal pressure. Figure 2.12 shows an air filled mattress system used to treat ulceration in the human body.

Dynamic mattress features a temperature control system that can be used to prevent the early onset of pressure ulcers. The two chambers of the mattress can be pressurized at independent times to shift the weight distribution.

Each chamber can either be filled with gasses or liquids, which allow airflow between the patient and the surface of the pad to cool the skin and remove moisture (Butler 2010). But, this method of preventing pressure ulcers is bulky, non-portable, and expensive. It also only applies to bed-ridden patients and does not factor in the difference between these patients (Figure 2.13).

Fig. 2.12 Air filled mattress to assist wound healing and treat pressure ulcers for very high risk users

(Colin et al. 2012; healthcarematters 2010)

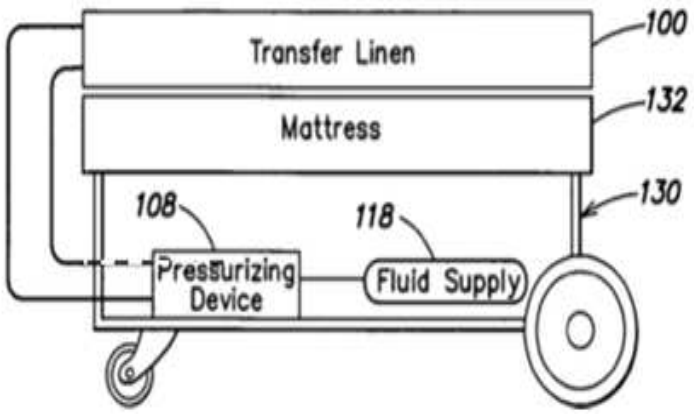

Fig. 2.13 Dynamic Support Surface System

(Butler 2010)

2.5.2.2 Commercially Available Systems

ROHO 3 is a very popular air filled mattress used widely to treat PU. This type of support surface system (healthcarematters 2010) is a constant low pressure (CLP) device in which the patient can be comfortable so that the weight is distributed over a greater surface area. The degree of patient immersion is controlled by the volume of air introduced into the air cells with a hand pump. The unique design of each individual air cell allows for maximum skin contact and pressure area relief. It is used for patients with spinal injuries and unstable hip fractures. It is also used in ward and operating theatre situations and also comes with a waterproof therapeutic cover if patient incontinence becomes an issue. This mattress is most popular for superficial pressure ulcer healing (Figure 2.14).

The comfort-air mattress overlay system includes low pressure support for the sacrum and

Fig. 2.14 ROHO 3, Air filled mattress
(Pegasushealthcare 2011)

heels area (Pegasushealthcare 2011). The amount of patient immersion for the sacrum area is controlled by the volume of air introduced into the ROHO air section with a hand pump. It features the benefit of even pressure distribution, increases air flotation, the foam cells are self-adjusting with minimum shear and friction, the Dartex waterproof two ways stretch clinical cover also reduces shear forces. Figure 2.15 shows a comfort mattress.

2.6 Risk Assessment Scales for PU

There are three risk assessment scales currently used by the healthcare professionals which to predict the PU risk type (e.g. low risk/ at risk/ high risk/ very high risk); Norton, Braden and Waterlow scales.

Fig. 2.15 Comfort-air mattress, Air filled mattress
(Pegasushealthcare 2011)

These scales are used prior to subjects admission into hospital (Bolton 2007; Papanikolaou et al. 2007). But none of these scales can be used in real time (e.g. when subject is bed bound or chair bound for a long time). Three risk assessment scales are summarizes in Table 2.2. These scales are also shown in Appendix 2 with associated risk parameters.

2.6.1 Braden Scale

The Braden scale was introduced in 1987 (Bergstrom et al. 1987). This scale was the outcome of a review on aetiological factors of pressure ulcer formation . The Braden scale has six subscales and each subscale has 3-4 criteria. Subscales include mobility, sensory perception, moisture, nutrition, friction and shear. The scale provides a minimum score of 6 to a maximum of 23. The lower the score, the higher the chance of the subject developing a pressure ulcer. The cut-off point for pressure ulcer formation was 16 (Bergstrom et al. 1987). Initially skin condition was recorded and then nurses rate the patients using the scale at a weekly basis. Validation and reliability of this scale was reported in Bergstrom et al. 1987; Demuth 1987. Like the Norton scale, Braden scale was also used on patients prior to their admission to the hospital. Also this scale has limitations and therefore the validity and reliability was criticised (Bland and Altman 1986). However, other studies have shown Braden scale is more accurate than Norton (Dealey 1989; Lincoln et al. 1986). The reason to consider Braden as more accurate was its sensory perception and nutrition as Norton does not cover these parameters. But later the results were not very favourable. Also a study showed that 40% of pressure ulcer incidence was found among 60 patients. The cut-off score 16 was found 83% sensitive and 64% specific.

Scale	Criteria of assessment	Scoring method and risk type
Braden	Sensory perception Moisture, Activity Mobility, Friction, Nutrition	Additive Total score <=9: severe risk Total score 12-13: high risk Total score 13-14: moderate risk Total score 15-18: mild risk
Norton	Physical & mental conditions, activity, mobility, incontinence	Additive >18: Low risk 18-14: Medium risk 14-10: High risk <10: Very high risk
Waterlow	Previous history of PU Age,sex,BMI, incontinence, mobility, tissue malnutritions, neurological factors, skin type, medication, surgery history	Additive <=9: low risk 10+: at risk 15+: high risk 20+ very high risk

(Bolton 2007; Papanikolaou et al. 2007; Waterlow 1984)

Table 2.2 Risk assessment scale for PU

61% of score was found positive and 85% of score was found negative for predictive values (Bergstrom et al. 1987). The limitation was found in the statistical method used for calculations. But other studies (Lyder et al. 1999; VandenBosch et al. 1996) show the cut-off was changed to 18 for elderly subject. But this scale does not consider subjects physiological information, tissue malnutrition (organ failure, smoking), neurological deficits (diabetes, multiple sclerosis).

2.6.2 Norton Scale

Norton scale was the first risk assessment scale for pressure ulcer, developed in 1963. The scale was developed during a study of geriatric nursing problems to assess a patient's risk of PU in the context of their physical and mental state in a straight forward way (POST 1963). This scale has mainly five criteria: physical condition, activity, mobility, incontinence and consciousness. Each criterion is scored from 1 to 4. 20 is the highest score and a patient with maximum score of 20 is considered to be physically and mentally stable with complete mobility. and so at very low risk of PU. A minimum score of 5 indicates the patient is at high risk of developing pressure ulcer due to bad physical and mental condition along with immobility and incontinence.

A survey of 250 patients showed a linear relationship between the scores and incidence of pressure ulcer (POST 1963). The survey was conducted on patients prior to their admission to the hospital. According to this scale, if a patient scores <14 then he/she is at risk of developing pressure ulcer and very high if the score is <12. Given this strong evidence the scale was recommended by the clinician (Torrance 1983).
But the Norton scale has some limitations. A study suggests some patients with very high score (not at risk) developed pressure ulcer whereas some patient with less score (at high risk) did not develop any pressure ulcer (Lincoln et al. 1986).
Despite, Norton scale was considered most predominant tool at ward level during 1980 (Dealey 1989). The validation of Norton scale was done in many occasion by different people (Berglund and Nordström 1995; HAMILTON 1992; Hibbs 1987; Lincoln et al. 1986; Torrance 1983). A review on the validity and reliability of this scale (Pancorbo-Hidalgo et al. 2006) shows some serious limitations on assessing the risk of pressure ulcer development. The scale was found unable to predict the accurate risk among the patients.

2.6.3 Waterlow Scale

The Waterlow scale was developed in a UK hospital by J. Waterlow (Balzer et al. 2007; Pancorbo-Hidalgo et al. 2006; Wai-Han et al. 1997; Waterlow 1984). This scale is considered as more comprehensive compared to other two assessment scales. A Waterlow scale includes subject's physiological factors such as age, BMI, and sex along with tissue health, skin type, and subjects neurological deficits. The scoring for this scale is from 1-8 for different factors. Finally scores are added and based on the score, risk is predicted. A score of 10 to 14 indicates at risk, 15-19 as high risk and above 19 is very high risk. Although 10 indicates at risk but a survey showed patient with score <12 did not develop pressure ulcer. The scoring values vary from factors to factors. The subject's gender scores 1 for female and 2 for male, whereas neurological deficits are scored as 4-6. 17.1% of prevalence was shown in a study (Waterlow 1988). The study also showed a group patients at risk did not develop any pressure ulcer. The accuracy of this assessment tool was score 98%-100% (Dealey 1989). However the reliability of Waterlow scale has been criticised highly later (Millward 1990; Richardson 1990). But despite this, the Waterlow tool has been adopted throughout the country for assessing the risk of pressure ulcer development.
Among all these three scales, Waterlow scale is more subject information oriented because it takes subjects physical parameters such as Body mass Index (BMI), age into consideration along with tissue factors, neurological deficits and skin conditions.

2.7 Summary

Pressure ulcer is the result of subject's physiological parameters and body support surface interaction. Although there are several technologies available to detect pressure ulcer, none has been adopted as a standard detecting procedure for healthcare. This is equally true for prevention techniques.

Risk assessment scales are used as a pre-admission tool to assess the risk of pressure ulcer formation but currently there is no integrated risk assessment tool with prevention systems. Also, the current alternating pressure (AP) mattress systems do not support patient specific requirements, in terms of age, BMI etc. So there is a gap between detection and prevention techniques. An integration of detection system together with prevention system would be a significant advance for healthcare industries. A proposed block diagram integrating the above ideas is shown in figure 2.16. The block diagram shows the underlying concepts of both identification and prevention systems.

The model includes Waterlow score to characterise the physiological parameters of subject's risk factor combined with interfacial pressure at the support surface. Implementation of such a model would allow risk identification and prevention at the same time.

Moreover, the risk assessment will be subject-specific and can be dynamically monitored and controlled. The currently existing systems do not consider the effect of surface material but they directly measure the applied pressure and are considerably expensive and cumbersome to use. In the proposed architecture the ulceration detection and prevention would be automatic based on mattress properties.

By integrating support surface characteristics with human risk factors will provide patient specific care for automatic PU risk identification. The interface pressure calculations is based on, material's Young's modulus and viscosity of the mattress or support surface. This, combined with subject's physiological parameters using Waterlow score, will provide actual risk factor. This will allow identifying harmful interface pressure for individuals and the risk of ulceration in real time. Based on the pressure level (detected by the threshold interface pressure) the AP mattress (prevention system) will inflate or deflate. This will relieve harmful pressure at the skin surface and subject will have continuous blood flow. The aim of this review was to identify the requirements of an ideal PU system and propose some new design ideas that can comprehensively integrate all the missing links.

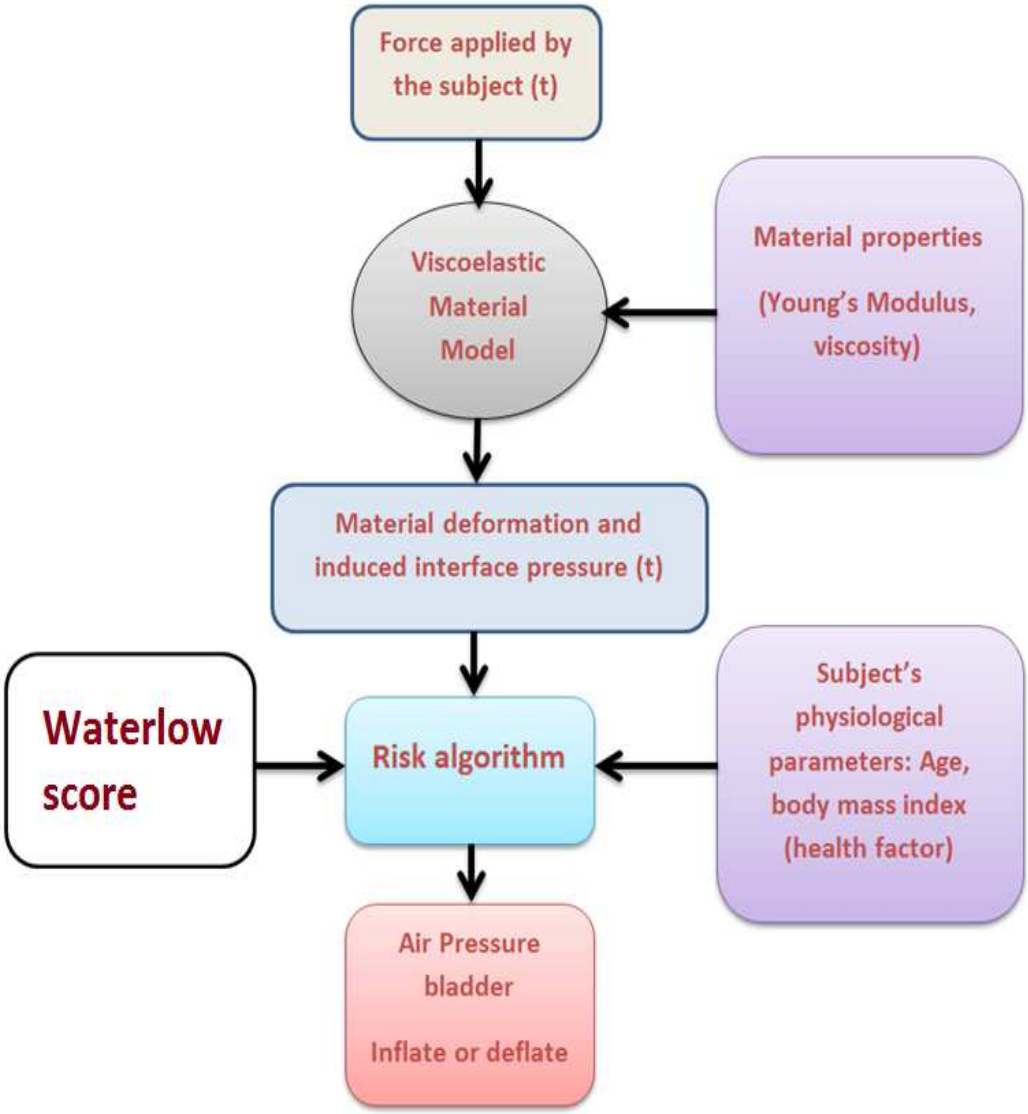

Fig. 2.16 A proposed PU detection and prevention model

Chapter 3

Mathematical Modelling of Body Support Surface Material

Body support surface (viscoelastic foam) has a significant role in preventing ulceration so their characteristics under loadings are important. There are several types of support surfaces available commercially though no single one is the standard for pressure ulcer prevention. In order to begin the modelling of body support surface for this research, first the response of different types of theoretical surface models were observed by implementing the models in MATLAB. Once all the models are implemented, a graphic user interface (GUI) is written so that the performance of each model can be observed during external loading. Based on the response from the different surface models, a new type of body support surface material is characterize mathematically. This characterization is based on the performance of theoretical support surface models. In this chapter a body support surface material modelling and simulation are shown along with the model's parameter estimation.

3.1 Modelling and Implementation of Body Support Surfaces

In order to understand the characteristics of various models under loading conditions, it is important to know the basics of stress, strain, elasticity and viscoelasticity. Therefore these basics are described here to understand the mechanics of support surface due to external loading. Three different types of surface models (Maxwell, Kelvin-Voigt and Maxwell Wiechert) are considered to characterize the new surface model for pressure ulcer prevention. These models represent solid, semi-solid and soft materials (viscoelastic/memory foam).

Emphasis is given on soft material's response due to external loading as this type of surface is widely used as body support surface.

3.1.1 Stress & Strain

Stress

When external load is applied to the materials, they are being restrained next to rigid body movement and pressure builds up inside the material because of the induced load whose intensity is known as stress, measured in Pascal (Pa) (Juvinall and Marshek 2006). Stress generally has two components i.e. a normal stress (perpendicular to the area) and shearing stress (acts plane of the area). σ and τ are used often to denote normal stress and shear stress respectively. In order to show the direction of the plane subscript x,y,z are used. For example, in a Euclidean space a normal stresses are described as σ_x,σ_y, and σ_z. For tension, normal stresses are positive and for compression it is negative.

Strain

When external load is applied, the material starts deforming with displacement known as strain (Juvinall and Marshek 2006). Strain does not have any units or dimensions. The strain has two components: unit elongation and shearing strain. Unit elongation means a one directional change of two points in the material and denotes as ε_i. Shearing strains are defined as γ_i and γ_j. A comparison between stress and strain is given in the figure below.

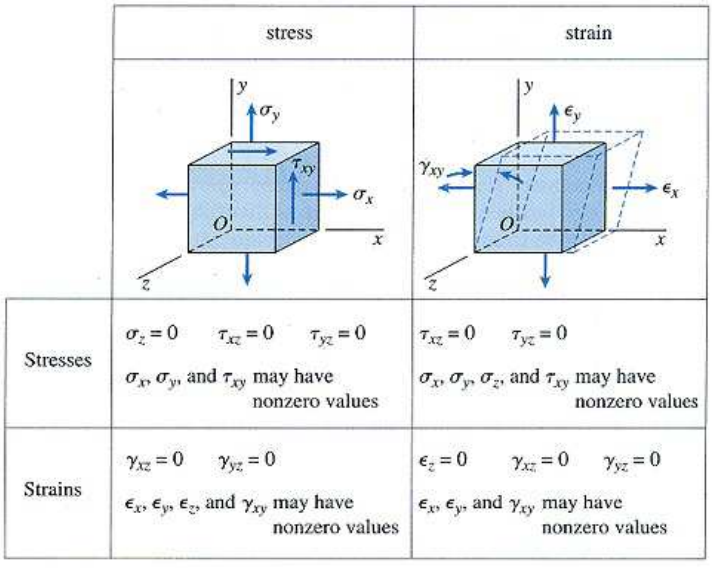

Fig. 3.1 Difference between stress and strain definition (Juvinall and Marshek 2006)

3.1.2 Elasticity & Viscoelasticity

Elasticity

Elasticity, the disappearance of deformation on force removal, is seen in all materials to an extent. An object is said to be perfectly elastic when it resumes its initial form completely after the removal of all external forces. Often when modeling elastic bodies it will be assumed that the matter of the body is homogeneous. This means that when taking a very small element of the body the same specific physical properties as the entire body will apply. Another assumption that is often made is the assumption that the body is isotropic. This means that the elastic properties are the same in all directions. Even though many structural materials do not satisfy these assumptions, experience has shown that the solutions of the theory of elasticity using these assumptions give very good results for these materials. When the elastic properties however are not the same in all directions, and also cannot be assumed to be the same, the condition of anistropy must be considered.

Viscoelasticity

Viscoelastic material has a special type of behaviour which is a combination of viscous and elastic responses (Roylance 2001). There are many theoretical models available to describe viscoelasticity (Christensen 2012; Ortega et al. 2013). These models usually consist of various spring and dashpot combinations, with the spring representing the elastic response and the dashpot the viscous response. Viscous response means, when load is applied to the material, it deforms gradually with respect to time and when load is removed, it starts coming back to its original shape. On the other hand, elastic response is quite rapid during loading and unloading situations. Theoretically, viscoelastic materials have a tendency to start deforming gradually when load is applied to the surface and when load is removed, it starts getting back to its original position (Aou et al. 2015; Gnanasundaram et al. 2013; Men et al. 2013).

The simulation of a viscoelastic model is validated with experimental results and shown in chapter 4. Subsection 3.1.4 to 3.1.6 explains the modelling and implementation of these theoretical models and subsection 3.1.7 explains the developed new surface model.

3.1.3 Young's Modulus

Young's Modulus also known as Modulus of Elasticity was named after Thomas Young (Agache et al. 1980). Sometimes, it is known as tensile modulus or elastic modulus. Young's Modulus is a measurement of the stiffness of an elastic material. It is a ratio of stress in an axis to the strain in another axis. The SI unit of Young's modulus is Pascal (Pa).

Young's Modulus may have different values in anisotropic materials due to its different directions of applied load with respect to the structure of the materials. The value usually represents the rigidness of the material e.g. if the material has a high Young's Modulus then it is considered as very rigid or vice versa.

3.1.4 Maxwell Model

In the Maxwell model a spring and dashpot is placed in series (Figure 3.2). Stress in the Maxwell model is same for both spring and dashpot. The deformation of this type of model can be obtained by dividing the total strain into one for the spring and one for the dashpot. Following mathematical equations describe the deformation in the Maxwell model.

$$\varepsilon_1(t) = \frac{1}{E}\sigma(t) \tag{3.1}$$

$$\varepsilon_2(t) = \frac{1}{\eta}\frac{d\varepsilon}{dt} \tag{3.2}$$

Equation 3.1 describes the deformation in the spring and equation 3.2 describes for the dashpot part. The total deformation of the model is described by equation 3.3.

$$\varepsilon(t) = \varepsilon_1(t) + \varepsilon_2(t) \tag{3.3}$$

Where $\varepsilon(t)$ is total deformation, $\varepsilon_1(t)$ is deformation due to spring, $\varepsilon_2(t)$ is deformation due to dashpot, E is the material's Young's Modulus, η is viscosity of material, t is time of loading. When initial stress (σ_0) is applied to the model it starts deforming. Also when the Maxwell model is subjected to a stress, the spring starts stretching instantly and dashpot takes time to react. So initial deformation of the material is

$$\varepsilon(0) = \frac{\sigma_0}{E} \tag{3.4}$$

Due to initial deformation, the total deformation of Maxwell model can be described as

$$\varepsilon(t) = \sigma_0(\frac{1}{\eta}t + \frac{1}{E}) \tag{3.5}$$

When the load is removed, the spring again reacts instantly. Hence there is an instant elastic recovery (due to spring).

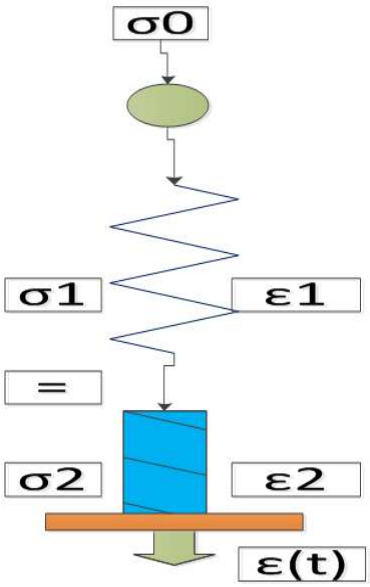

Fig. 3.2 Maxwell Model (Spring and dashpot in series)

The full deformation and recovery behaviour is shown in figure 3.3 (Obtained using the developed simulation model for material characterization).

Although Maxwell model shows linear deformation, but it does not provide any viscous recovery when the external load is removed. The response from this type of model is simply elastic due to its physical combination. The numbers on the plot (Figure 3.3) show the following conditions:

1. The external load transmits to Maxwell model due to spring.
2. Linear deformation due to spring.
3. When the load is removed, the spring gets back to its previous position very rapidly.

This model can be a good representation of semi-solid material but it can not be used as soft material.

3.1.5 Kelvin-Voigt Model

The Kelvin-Voigt model consists a spring and a dashpot in parallel (shown in figure 3.4). In this type of model, deformation in spring and dashpot are same but stress is different. Also this type of model establishes better deformation results compared to the Maxwell model.

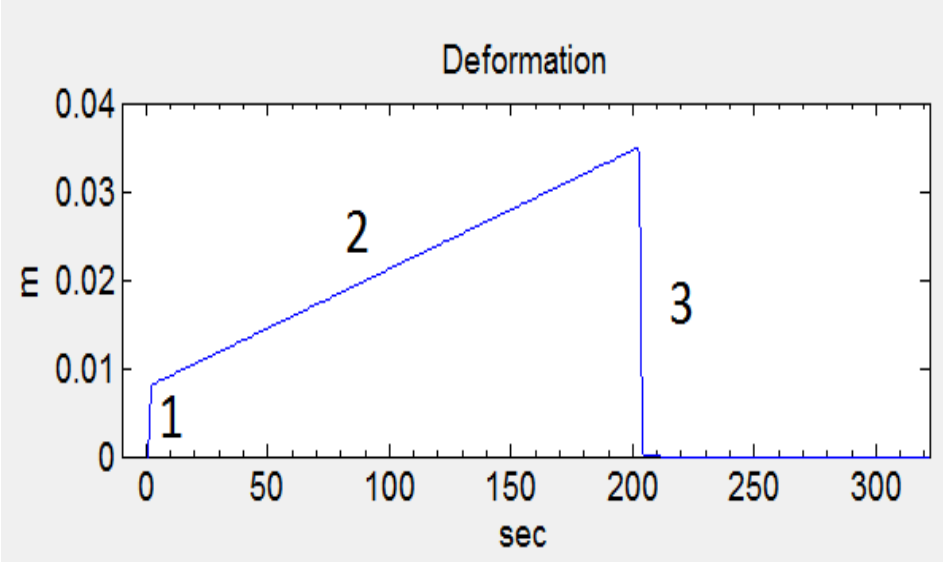

Fig. 3.3 Deformation and relaxation behaviour in Maxwell model

Mathematical equations which describe relaxation and deformation of the Kelvin-Voigt model are given below.

$$\sigma(t) = E\varepsilon(t) + \eta\frac{d\varepsilon}{dt} \tag{3.6}$$

$$\varepsilon(t) = \frac{\sigma_0}{E} - \frac{\eta}{E}\frac{d\varepsilon}{dt} \tag{3.7}$$

Where $\sigma(t)$ is relaxation of stress, $\varepsilon(t)$ is deformation of material, E is Young's modulus, η is viscosity (constant for soft foam), σ_0 is initial stress applied to the model and t is time.

In figure 3.4 a Kelvin-Voigt model is shown. When initial stress, σ_0 is applied to the model, spring will stretch due to its elastic nature, but is held back by the dashpot. Since the spring does not change length, the stress is initially taken up by the dashpot. The deformation thus starts with an initial slope $\frac{\sigma_0}{\eta}$. Deformation then occurs and so some of the stress is transferred from the dashpot to the spring. The slope of the deformation curve becomes $\frac{\sigma_2}{\eta}$ where σ_2 is the stress in the dashpot. In the limit when $\sigma_2 = 0$, the spring takes all the stress and maximum deformation becomes $\frac{\sigma_0}{E}$. By solving the first order non-homogeneous differential equation 3.5 with an initial condition $\varepsilon(0) = 0$ provides the following equation for deformation of Kelvin-Voigt model.

$$\varepsilon(t) = \frac{\sigma_0}{E}(1 - e^{\frac{-E}{\eta}t}) \tag{3.8}$$

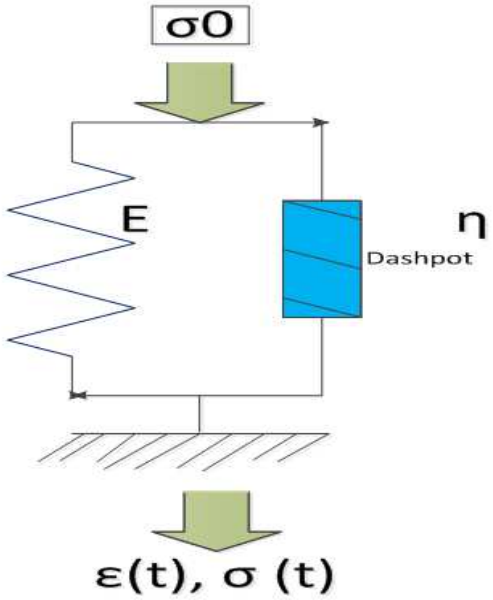

Fig. 3.4 Kelvin-Voigt model (spring and dashpot in parallel)

Thus deformation function becomes,

$$\delta(t) = \frac{1}{E}(1 - e^{\frac{t}{t_R}}) \tag{3.9}$$

The variable t_R, is called retardation time of the material. It is a measure of the time taken for the deformation to occur. If the retardation time is shorter, deformation occurs more rapidly. When the initial stress is removed in Kelvin model, spring respond instantly but dashpot holds it back. The spring however eventually pulls the dashpot back to its original zero position in a given time and thus full recovery occurs. Deformation and relaxation response of the Kelvin-Voigt is shown in figure 3.5.

The numbers on the plot (Figure 3.5) show the following conditions:

1. Due to the external load, the material starts deforming gradually with respect to time. This behaviour is known as Creep. Because of the parallel combination of the spring and the dashpot, the material shows the creep behaviour.

2. When the external load is removed, the spring and dashpot gets back to its previous position gradually w.r.t time. This is known as the relaxation behaviour of soft material.

The Kelvin-Voigt Model is ideal to optimize the deformation behaviour but it does not provide a total viscous relaxation. This type of model returns elastic retardation when the initial stress is removed.

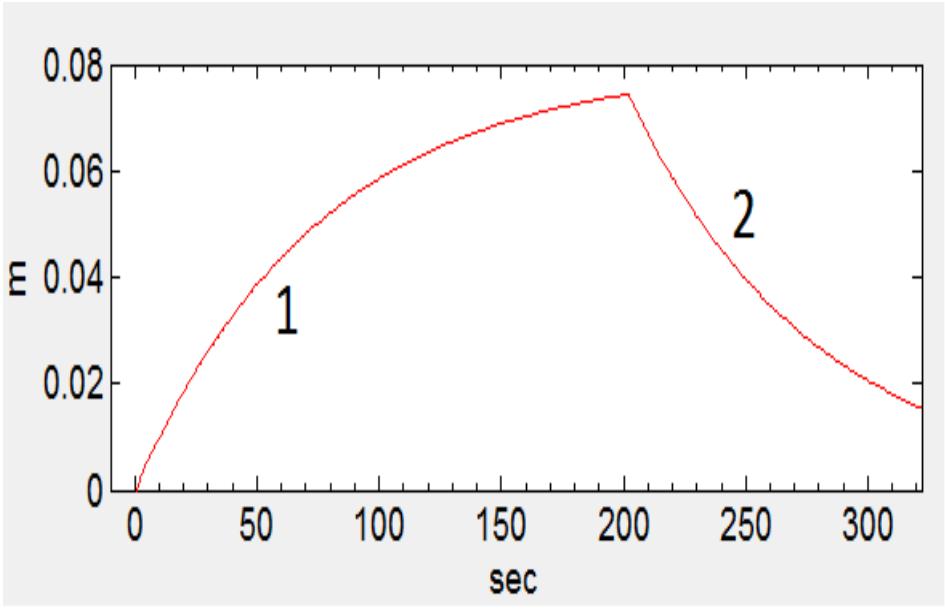

Fig. 3.5 Deformation and relaxation in Kelvin-Voigt model (obtained using developed simulation model)

3.1.6 Maxwell-Wiechert Model

Maxwell model and Kelvin-Voigt model does not provide full viscoelastic behaviour. In Maxwell model, the deformation takes place linearly and in Kelvin-Voigt model, although the deformation is nonlinear but the recovery or relaxation of stress is not viscous. Hence, Maxwell-Wiechert model is considered where three single Maxwell block is connected in parallel to a single spring. This model is also known as generalized Maxwell model (Figure 3.6). The Maxwell-Wiechert model consists of three different Maxwell units in parallel. In order to observe soft material behaviour, material parameter is set same for all three blocks. By simulating this model, deformation and relaxation behaviour of soft material is obtained. Mathematical equation which describes viscous characteristics of this model are given below.

$$\varepsilon(t) = \frac{\sigma_0}{E} + \frac{\sigma_0}{\eta}t + \frac{\sigma_0}{\eta}t + \frac{\sigma_0}{\eta}t + \frac{\sigma_0}{E}(1 - e^{\frac{E}{\eta}}t) \tag{3.10}$$

$\varepsilon(t)$ is deformation of material, σ_0 is initial stress applied to the material, E is Young's modulus of the material, η is the viscosity and t is time. In order to obtain relaxation behaviour following equation is used.

$$\sigma(t) = \sigma_1(t) + \sigma_2(t) + \sigma_3(t) \tag{3.11}$$

where $\sigma_1(t) = \sigma_0.e^{\frac{t}{t_1}}$, $\sigma_2(t) = \sigma_0.e^{\frac{t}{t_2}}$ and $\sigma_3(t) = \sigma_0.e^{\frac{t}{t_3}}$.

The numbers on the plot (Figure 3.7) show the following conditions:

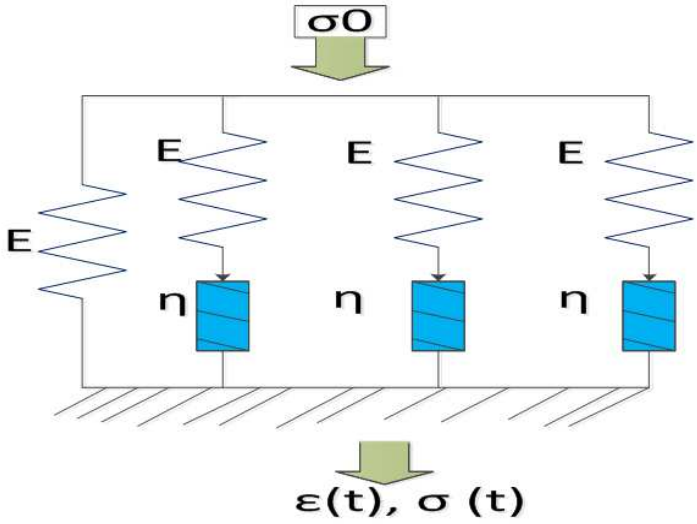

Fig. 3.6 Maxwell-Wiechert model

1. The loading starts as the external load applied.
2. The Creep occurs due to the external loading.
3. The load starts to saturate. In this stage, the pressure is induced at the interface of the skin and support surface.
4. Due to removal of the load, recovery stage occurs. Here only the viscous recovery occurs and no elastic recovery.

The deformation and the relaxation of the soft material are explained with this model. In the Maxwell-Wiechert model, the deformation behaviour is viscoelastic but relaxation behaviour obtained from this model does not show a complete relaxation of stress and also it does not fully relaxed though the initial stress is removed completely. Figure 3.7 shows the deformation and relaxation of stress by Maxwell-Wiechert model. As discussed earlier, viscoelastic material has a tendency to distribute stress gradually into the material and also it has a tendency to relax the stress over a period of time (when initial loading is removed). Based on the simulation results, it is clear that the Maxwell model does not establish viscoelastic behaviour of the material. This model provides only elastic response of the material as it is connected series with a dashpot.

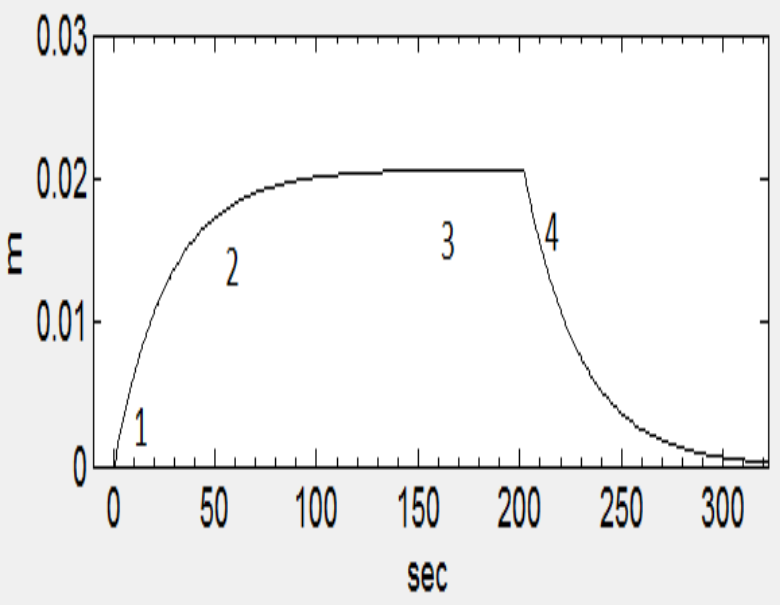

Fig. 3.7 Deformation of soft material with Maxwell-Wiechert model

The Kelvin-Voigt model provides a viscoelastic deformation due to initial stress applied but when the initial stress is removed it starts relaxing rapidly. It does not show the steady state of the material. Same type of behaviour is observed when the Maxwell-Wiechert model is simulated. Therefore based on three theoretical models and their mathematical equations, a new model is developed to characterize soft material more accurately. By developing such model ensures material's viscoelastic behaviour. Also the deformation and relaxation obtained by this model are purely viscoelastic. In a comparison with three theoretical models, this new model provides complete viscoelastic behaviour of soft material.

3.2 A New Support Surface Model

The output response of three theoretical models were shown in figures (3.3, 3.5 and 3.7) and none of the model showed complete viscoelastic behaviour due to external load as could be representative in pressure ulcer formation point of view. So an enhanced support surface model (viscoelastic) was developed which may ensure material's viscoelastic behaviour in pressure sore formation. Also the deformation and relaxation obtained by this enhanced model are purely viscoelastic. Figure 3.8 shows the developed model to characterize soft material's viscoelastic behaviour. The model is mathematically described by following equation and shown in figure 3.8.

$$\varepsilon(t) = \frac{\sigma_0}{E} + \sum_{n=0}^{3} \frac{\sigma_n}{\eta} t + \frac{\sigma_0}{E}(1 - e^{\frac{E}{\eta}t}) + \frac{\sigma_0}{E} - \frac{\eta}{E}\frac{d\varepsilon}{dt} \tag{3.12}$$

The new surface material was modelled by combining the Maxwell-Wiechert block and

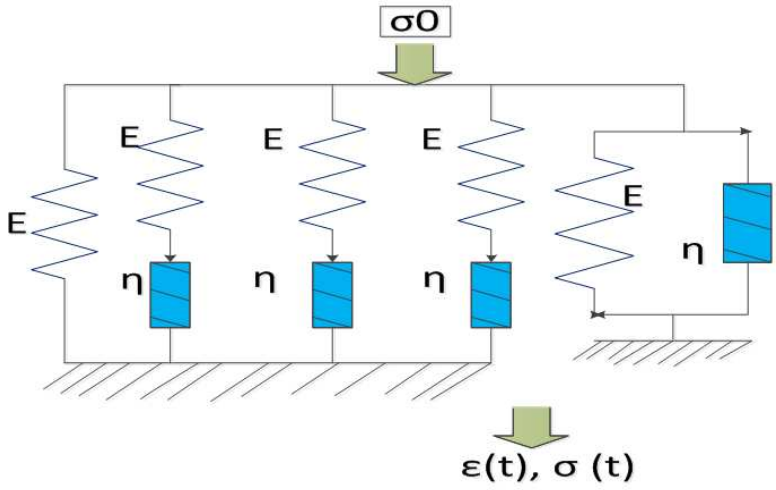

Fig. 3.8 Developed new model to characterize viscoelastic support surface material

the Kelvin-Voigt block. In order to validate this model, experiments were conducted and discussed simulation results are obtained to show good viscoelastic deformation and relaxation behaviour both. Figure 3.9 shows a deformation graph from the new support surface model. The numbers on the plot (Figure 3.9) show the following conditions:

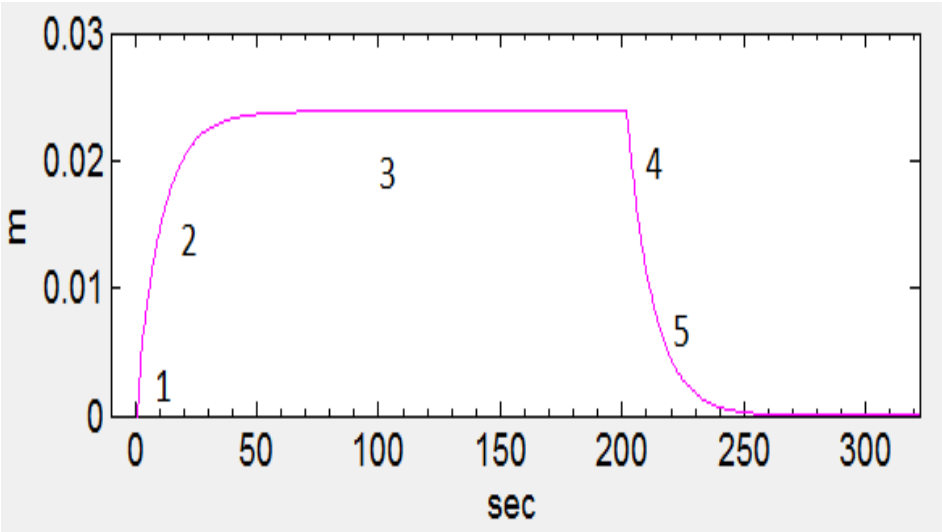

Fig. 3.9 Deformation in new surface model (obtained using the developed GUI)

1. The loading starts as the external load applied.
2. The Creep occurs due to the external loading.
3. The load starts to saturate.
4. Due to removal of the load, first elastic recovery occurs in the spring.
5. Then the viscous recovery occurs. Thus it represents the viscoelastic material.

The deformation graph shows a pure viscoelastic behaviour (non-linear deformation and relaxation of stress in spring and dashpot upon load removal). This type of response is important in a viscoelastic material. Also for pressure ulcer prevention, the support surface has to be soft and viscoelastic. Because only viscoelastic material can distribute the external load gradually and this helps the person lying on the surface.

3.2.1 Parameter Estimation for Developed New Model

In order to begin simulation of soft material model, first material parameters are estimated. These estimations are done by conducting a literature search and values are taken from previous research on viscoelastic materials (Rodriguez et al. 2014)(Müller et al. 2013). However, these values are also confirmed later by conducting experiments. Finally simulation results are shown using estimated values in section 3.3. Young's Modulus ranges between 0.025-0.0360 MPa is used as estimated E.

3.2.2 Simulation of New Model Using MATLAB

In this section the complete simulation of body support surface model along with three theoretical models is shown. In order to begin simulation of soft material model, equations describe in section 3.1 for all the models are programmed in MATLAB. Then an estimated value for Young's modulus is used as input along with initial stress. Based on input, the models provide deformation and relaxation as output. Then to visualize all models together, a graphic user interface was created in MATLAB. This user interface acts as simulation software where input can be manually entered and deformation graph can be visualized. Figure 3.10 shows a screenshot of the developed simulation software. Figure 3.10 provides a complete simulation using developed software for viscoelastic models. All three theoretical models including new developed models are simulated using estimated Young's Modulus values. Also an initial stress is passed to each model individually to obtain deformation graphs. Figure 3.10 also shows different deformation graphs for different viscoelastic models.

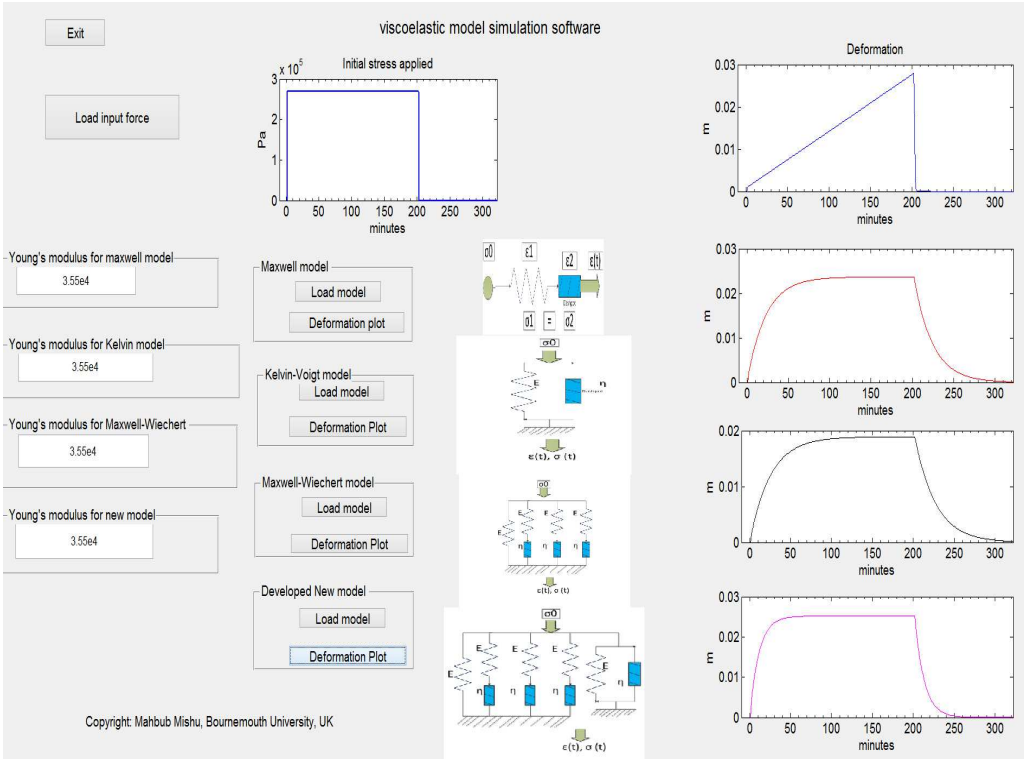

Fig. 3.10 Developed viscoelastic simulation software to obtain deformation of soft material

3.3 Summary

In this chapter, modelling of different types of viscoelastic material is shown (used as body support surface). The Maxwell & Kelvin Models, explain the basic characteristics of viscoelastic behaviour. The Maxwell model, for example, has a linear deformation behaviour and does not show any viscous tendency of deformation. The Kelvin-Voigt model, on the other hand is good for soft material and explains the retarded elasticity behaviour. However, The Maxwell-Wiechert model provides an understanding of soft material viscous response but not complete viscoelastic. The developed new model of support surface material provides the closest match compared to three theoretical models. The validation of developed new model is done by testing different types of viscoelastic material under loading conditions (experimentally) and shown in next chapter. These types of modelling and developments have significant importance for characterising support surface material for pressure ulcer prevention. To prevent ulceration in human body, selection of support surface material is important. To cover a wide range of materials a graphic user interface is developed where material's characteristics/response under loading can be seen and support surface could be designed.

Chapter 4

Experimental Validation of Body Support Surface Model

Experiments were conducted to identify material characteristics under external loading. In this chapter, the experimental procedure and validation of developed support surface model are shown. In order to conduct experiments, a mechanical indenter is used to apply the load more accurately. A circular wooden disc is placed at the top of the device so that load can be placed. In order to get accurate data from the sensor, area of the indenter was chosen same as the area of the sensor. During the experiments, FSR (Force sensing resistor) is used to measure force. Later on, based on the material's area, pressure was calculated. Figure 4.1 shows the experimental setup for different types of materials.

Fig. 4.1 Experimental setup used for validation of developed support surface model

Experimental setup is shown above with a digital height gauge. Digital height gauge is used to measure the change in length of the indenter due to applied load. This change in length is used later to find out Young's modulus of material experimentally. Load is applied at the top of the indenter (wooden disc) and the height gauge measures the length change. Initial length of the indenter is measured as 0.3 m (without any material). Also the area of the indenter remains same as area of the sensor. FSR area is measured as 0.00000631 m^2 (6.31 mm^2). The weight of indenter is also measured and then it is added with the applied load.

4.1 Hardware Specification for Viscoelastic Material Characterization

Force sensor (Piezo resistive) from Tekscan is used for measuring transmitting the force. Specification of the sensor is given in Table 4.1 below. Also, an electronic circuit interface

Thickness in mm	Sensing area in mm^2	Sensing capability in N	Supply voltage in V
0.208	6.31	400	9

Table 4.1 Sensor system specifications

with MATLAB in real time is developed to visualize the force data. The electronic circuit used during the experiments is shown in figure 4.2. Using the circuit shown in figure 4.2, change in force is measured in different types of viscoelastic materials. In order to communicate with PC, data acquisition software is written. Also the ATMEGA-32 microcontroller is programmed in such a way so that it can collect force data in real time.

4.2 Viscoelastic Material Selection

Various types of viscous foam blocks are used with different thicknesses (0.015 m, 0.02 m, 0.025 m, 0.035 m, 0.04 m, 0.05 m, 0.055 m, 0.065 m and 0.07 m). Usually viscous materials are soft and widely used as body support surface. This type of material has a tendency of relaxation over the period of time. When load is applied to this type of material, it starts deforming and the deformation depends on material's thickness.

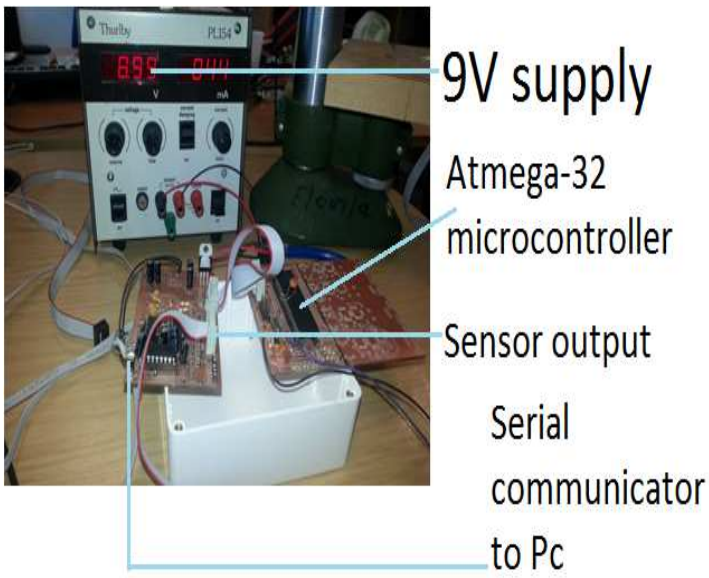

Fig. 4.2 Hardware used for support surface characterization

However, when the load is removed, material starts coming back to its initial position (known as relaxation behaviour). Both loading and relaxation occur with respect to time. Details of different types of viscoelastic materials are provided in Appendix A1.

4.2.1 Young's Modulus of Viscoelastic Material Identification During Experiment

Young's modulus also known as elasticity modulus is a material property. In order to identify Young's modulus of different types of viscoelastic material, the following equation is used.

$$E = \frac{F \times H_0}{A \times \Delta H} \tag{4.1}$$

Where E is the Young's modulus, A is the area where load is applied, F is the applied load, H_0 is the initial length of the indenter (without any load applied) and ΔH is the difference of length (due to applied load).

Based on above equation E value is identified for all different materials. For viscoelastic material, it is important to know E value accurately otherwise if E value is not accurate then creep and relaxation behaviour of a viscoelastic material will be different and actual deformation will not be measured. Table shows Young's modulus value for all the different viscoelastic materials (used in the experiment) are given below:

Material model	E (experimental) in MPa	E (supplier) in MPa
VC60135	0.0365	0.03-0.038
VL75075	0.058	0.05-0.06
VASCO40	3.17	2.1-3.2
VASCO50	2.55	2-2.8
VASCO60	1.61	0.98-1.7

Table 4.2 Young's Modulus of different types of material

4.2.2 Material's Response Due to External Loading

Experiments were conducted in the mechanical workshop where a height gauge meter (digital) is used to identify material's Young's Modulus. Besides, each material is placed to the indenter base and then load is applied. When load is applied to the material, real time data are collected by the data acquisition software. In this section, response of different types of the viscoelastic materials are shown under external loading conditions.

- VC60135

During the experimental setup, the sensor was placed underneath the material and, it was found that force does not transmit to the sensor instantly due to the viscoelastic property of the materials. Also it was found that the load becomes constant after a period of time. The amount of load applied to the material was found different from the force transmitted to the sensor. When the external load was applied to the wooden disc (Figure 4.1), the indenter starts deforming the viscoelastic material and the sensor reads the deformation values. But due to the thickness of the material and sensor characteristics, the load transmitted to the material is different from the load applied to it.
The variation of applied force and transmitted force is described by the term called Transmissibility Factor. Transmissibility Factor is defined as the change of percentage in transmitted load to the sensor. It is characterized by the following equation 5.2 below.

$$\zeta = \frac{F_t}{F_a} \tag{4.2}$$

Where ζ is the transmissibility factor of the surface material and F_a is the total force placed on the top of the indenter and F_t is the transmitted force to the sensor.
Transmissibility factor is considered as an important parameter for materials. In a real life scenario, when someone is lying or sitting on a surface then the actual force applied by the person would not be the same at the sensor placed underneath the surface.

This difference will occur due to transmissibility. Especially for Pressure ulcer research, it is important to know the material's transmissibility factor. If the factor is known then it can be simply multiplied with actual force and then transmitted force can be obtained. For example, a load of 4.5N is applied to the material but due to thickness of the material, the load transmits to the sensor is 0.69 N. So only 15.3% of applied is transmitted. So the transmissibility factor of the material is 0.153. It has been found from all other experiments, that change in thickness and change in load have an impact on transmissibility. This is why transmissibility values are considered for individual material. Also it has been found that if the material is not very thick then after some variation in loading, the transmissibility reaches 100% but same loading gives different transmissibility when thickness is changed. Finally, after conducting experiments, the transmissibility factor is identified experimentally for all the different types of materials with different thicknesses.

First, the load was varying from 4.5 N to 21.26 N for VC60135 and the thickness remains same. After this experiment, transmissibility is calculated for different thickness of the material. In figure 4.3, transmissibility is found proportional with the load. Also, it depends on the thickness of the material. When the thickness starts increasing then transmissibility of the material starts decreasing. Next, the thickness of the material is varying and the

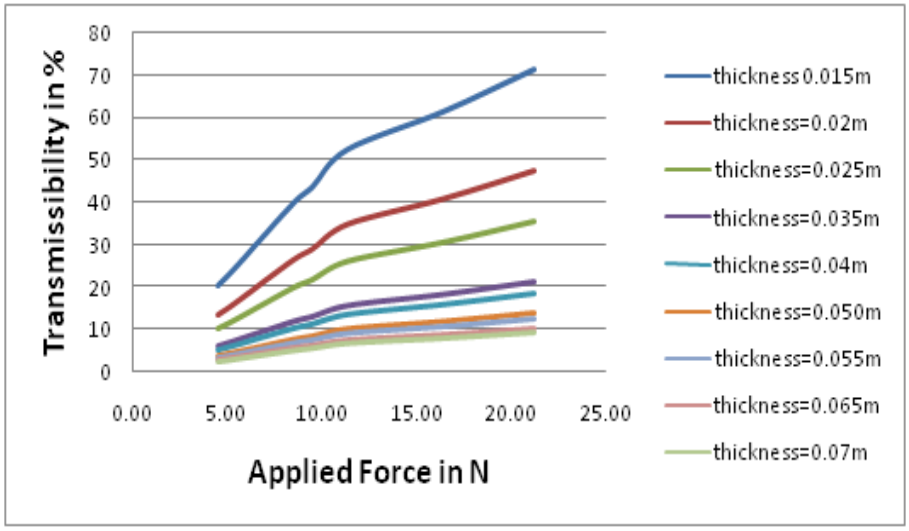

Fig. 4.3 Applied Load vs. Transmissibility (VC60135)

transmissibility was measured. In this stage the applied load remains same. Figure 4.4 shows the change of transmissibility due to thickness. When the applied load was 21.26 N, maximum transmission (72%) occurs for 0.02 m thickness but for same amount of load, transmissibility becomes 9.41% when thickness increases from 0. 02 to 0.07 m.

Figure 4.5 shows applied force vs. transmissibility for all five different materials. Thickness

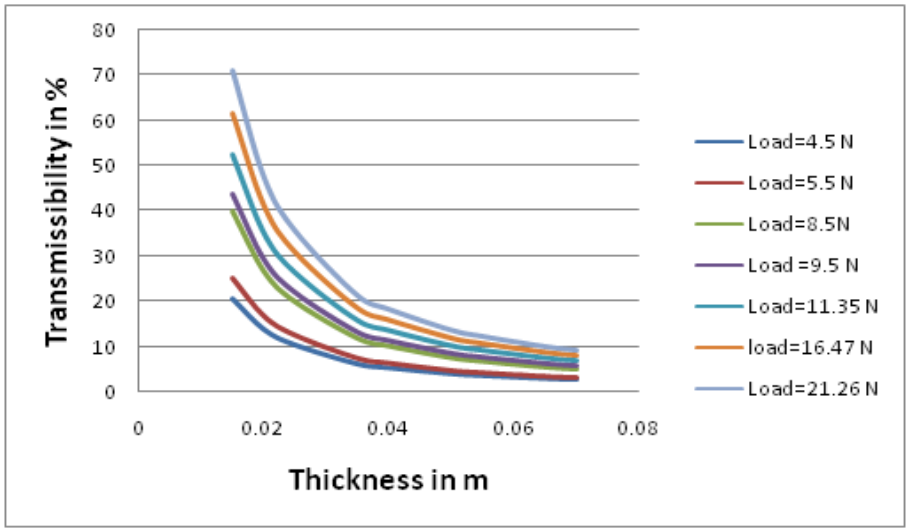

Fig. 4.4 Change of transmissibility due to thickness (VC60135)

of all the materials remain same (0.015 m) and load varied from 4.5-21.26 N. Now due to load variation from a very small amount to a higher amount, material's transmissibility changes significantly e.g. VASCO40, VASCO50 and VASCO60 materials transmit 100% of applied load when 21.26 N applied. In order to observe the transmissibility at higher thickness for different materials, thickness vs. transmissibility is plotted.

Figure 4.6 shows thickness vs. transmissibility graph.

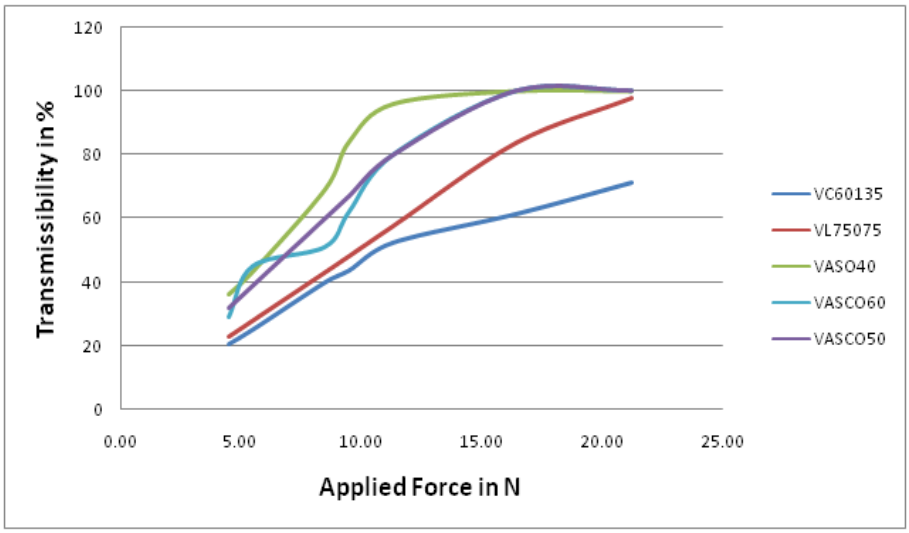

Fig. 4.5 Applied force vs. Transmissibility (for five materials)

Here, thickness of all five materials varies from 0.015 m to 0.07 m and the applied load is 4.5 N. For VC60135 material, maximum transmissibility is found 20.5% at 0.015 m thickness and minimum transmissibility (2.69%) occurs at 0.07 m thickness. VASCO40, VASCO50 and VASCO60 provide higher transmissibility compare to VC60135 and VL75075. This is identified by comparing experimental data. As discussed earlier, even at a higher load, these materials provide high transmissibility (almost 100%). Figure 4.7 shows the transmissibility

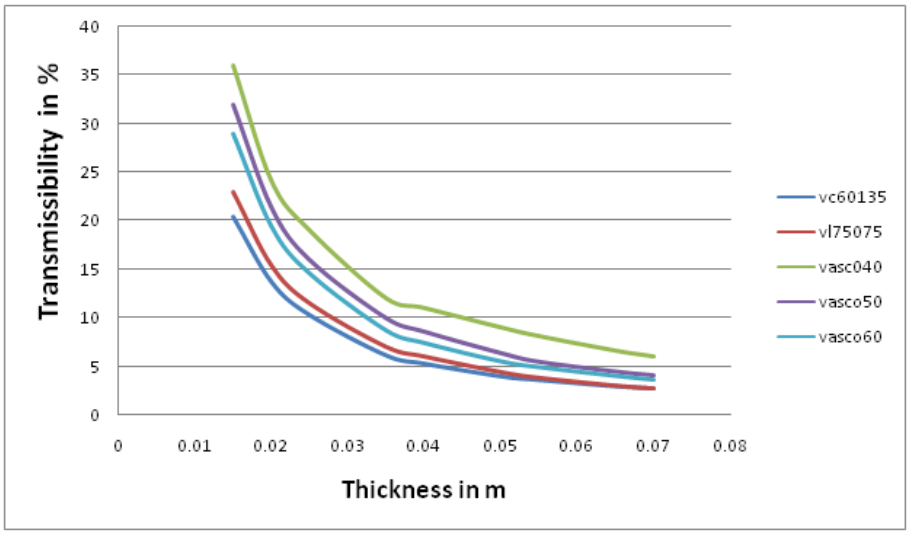

Fig. 4.6 Thickness vs. Transmissibility (for five materials at 4.5 N).

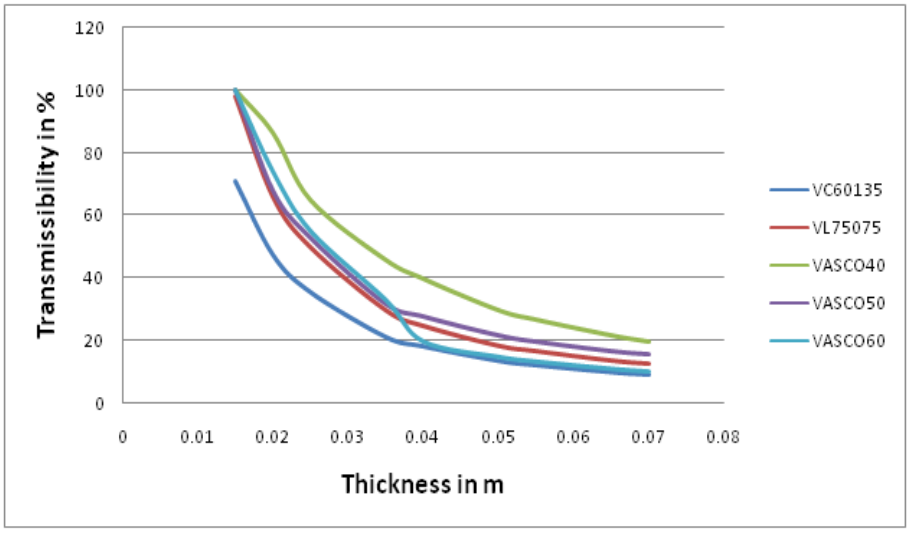

Fig. 4.7 Thickness vs. Transmissibility (for five materials at 21.26 N)

factor for all five materials at a load of 16.35 N. After conducting experiments for individual materials, a comparison is done between all the materials.

Also applied force vs. transmissibility, thickness vs. transmissibility graphs are plotted to show different transmissibility factor for different materials. Figure 4.5 and 4.6 show the comparison between all different types of viscoelastic materials. When applied load increases to 4.5 N to 21.26 N transmissibility for VL75075, VASCO40, VASCO50 and VASCO60 become 100%. But for VC60135 it is 71.2% which is 30% less compare to other four materials. In this stage, transmissibility factor is considered as an important factor because it can provide information about the load applied and load transmitted (when the sensor is placed underneath the surface). But this factor becomes less important when the sensor is placed at the top of the surface. To identify the behaviour of viscoelastic material, the sensor is placed at the bottom of the surface and then load was applied to the material (Figure 4.1).

4.3 Validation of Developed Support Surface Model

In order to validate simulation results (discussed in chapter 3), experimental force data is converted to stress by simply dividing force data over area. In chapter 3, the simulation of a viscoelastic model is shown using an initial stress data as an input to the viscoelastic model. Also due to input, model generates deformation graph and induced stress. Now in this section, behaviour of experimental stress data is shown. Stress was calculated by measuring experimental force data divided by contact area. During experiment, force is measured for different materials. These forces are transmitted forces to materials. The contact area is measured as 0.00000631 m^2 (6.31 mm^2). Figure 4.8 shows experimental stress data for VC60135 material (thickness=0.035 m, Applied load= 21.68 N). A small fluctuation is seen in the stress data and this is due to a noise from the circuit. This fluctuation is negligible.

From figure 4.8, the load increases from 0 to 3.5 MPa during loading from experimental data and then deformation due to this stress was calculated by using following equation.

$$\varepsilon(t) = \frac{\sigma(t)}{E} \tag{4.3}$$

Where $\varepsilon(t)$ is the deformation with respect to time, $\sigma(t)$ is stress in time and E is the Young's modulus of the material. Figure 4.9 shows the experimental deformation graph below This deformation exactly matches with simulation results shown in Chapter 3. However, the relaxation behaviour was not obtained due to the limitation of experimental setup. The experimental setup is designed in such a way that load can be applied in a control way but when the load is removed, sensor values become zero thus there is a drop in force value.

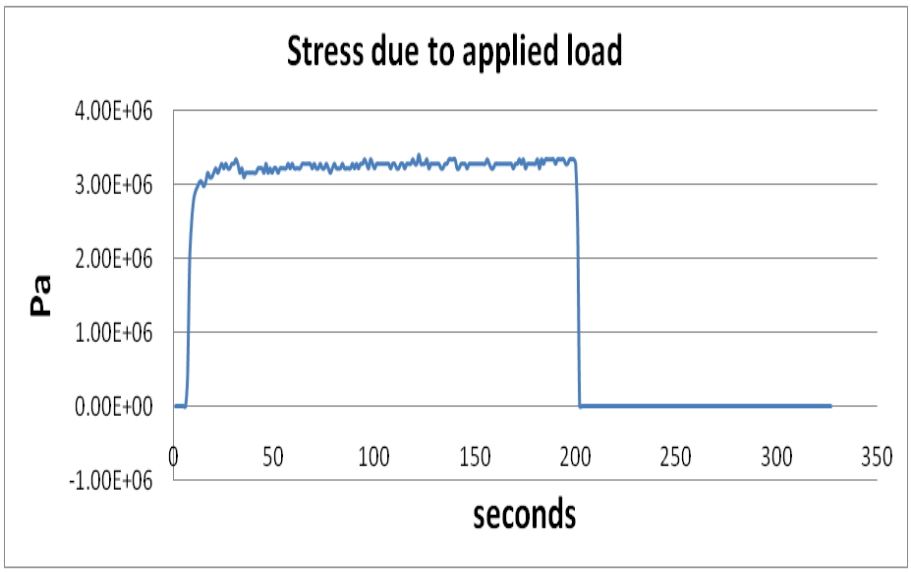

Fig. 4.8 Induced stress in viscoelastic material due to applied external load

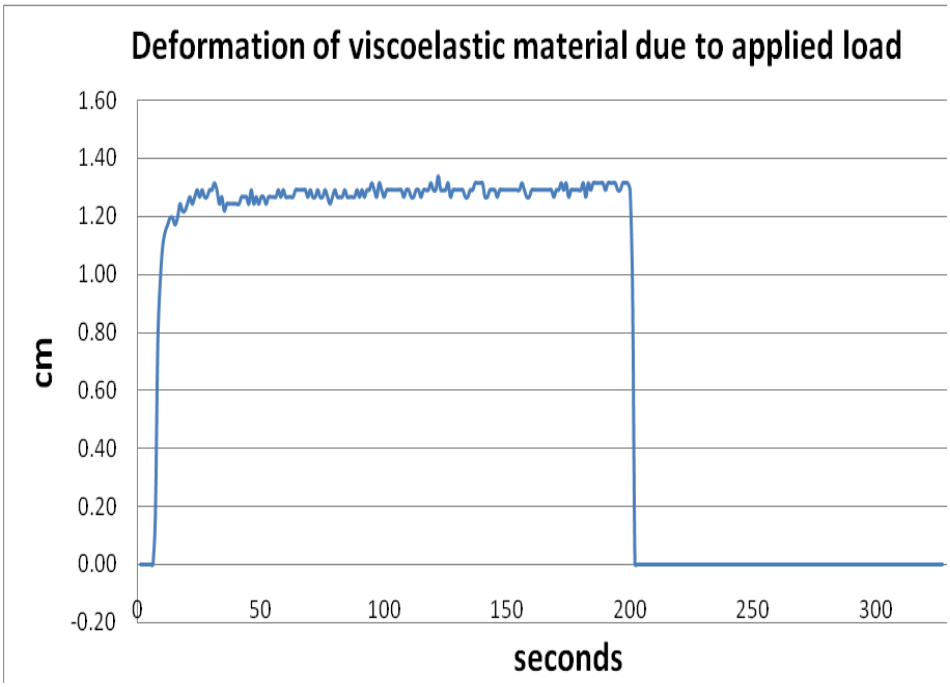

Fig. 4.9 Deformation in viscoelastic material due to applied external load

Figure 4.10 shows the deformation obtained from new developed model along with material's deformation during experiment. Figure 4.10 shows two results together and it shows how

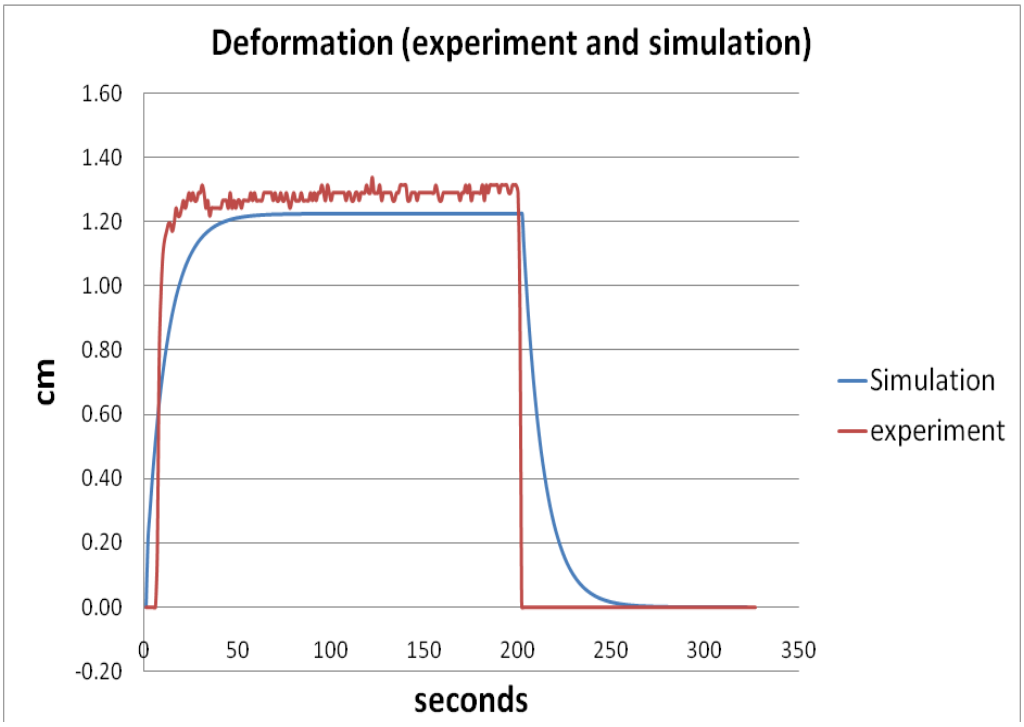

Fig. 4.10 Deformation of viscoelastic material during experiment and simulation

the experimental data matches with simulation results.

Equation 3.11 was shown in Chapter 3, and that equation was simulated to show viscoelastic behaviour of material. Here, experiments are conducted to verify the equation and above figures show that it matches with results obtained in Chapter 3. However, the relaxation behaviour is not fully achieved through experiment due to the limitation of the setup. The developed model has been verified and the equation can be used to describe a viscoelastic material. In order to visualize the viscoelastic creep, the experimental and simulation results are plotted for 100 sec simulation. Figure 4.11 shows both results. Relaxation behaviour was not obtained during experiments because force sensor system due to load removal, output of sensor becomes zero as there is no contact between the indenter tip and sensor. That's why we have only shown the deformation during loading. This is the limitation of the current experiments.

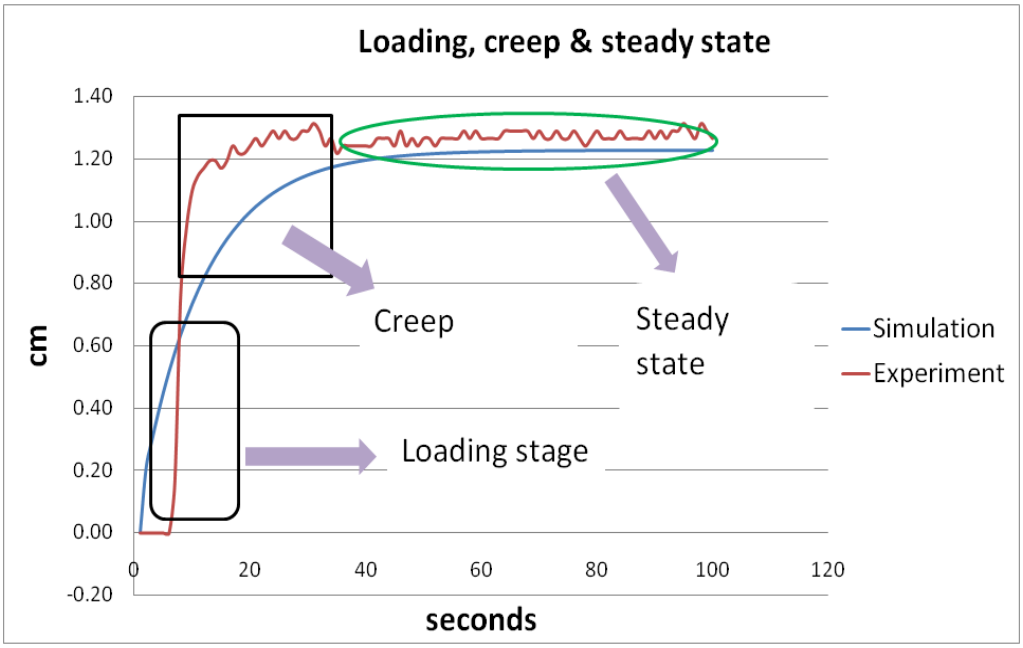

Fig. 4.11 Creep in viscoelastic material due to external loading along with steady state

4.4 Summary

In this chapter the validation of new body support surface is shown with experimental results. In order to validate the developed model, different types of viscoelastic materials are collected and then the characteristics of these materials due to external are observed. Also material parameter such as Young's modulus is identified during the experiment and then it was compared with the estimated values.

During the experiment, the force sensor was placed underneath the material. The force sensor only read the force value when there is a contact between the indenter tip and sensor. If there is no contact then the sensor will not read any value. Thus the relaxation behaviour was not possible to achieve during the experiment.

Also it was found that the amount of load applied to the material does not transmit to the sensor fully. This happens because of the viscoelastic nature of the material. The load starts transmitting gradually rather than at once and after a period of time the transmitted load induced into the material completely (creep state) and no further load transmits to the sensor is possible (due to material's thickness and no contact between the sensor and indenter tip). Therefore the transmissibility factor was also identified when the load was applied to the material. After calculating the transmissibility factors for all the materials once material is identified and this material is later used as a support surface material.

Chapter 5

Modelling of PU Risk Prediction System

Human skin deformation occurs due to external loading. As a result, blood flow in soft tissue becomes low and also the oxygenation decreases. Tissue under continuous loading results in tissue necrosis and leads to pressure ulcer (PU), also known as bedsore, decubitus ulcer, and ischemia. The amount of external load applied to the body support surface is associated with a subject's BMI. Therefore interface pressure (IP) at the skin and the surface is the result of a subject's physical and support surface properties. Interface pressure increases, the blood flow decreases and a subject starts developing stage-1 pressure ulcer. Previous research suggests that interface pressure of 32 mmHg (4.26 kPa) can cause PU, but there is no strong evidence to show at what time that pressure is reached and duration it needs to be sustained. Also interface pressure changes from subject to subject due to their body compositions. Three risk assessment scales are available to predict overall risk of PU formation. But none of these scales take interaction of body support surface materials into account. Also these do not provide any information at which area a subject is at risk of PU formation. In this chapter a study is presented where external load at different bony areas are measured using eleven volunteers. By measuring the external load for eleven subjects (age =33$\pm$7) and (BMI =25.0$\pm$3.01 kg/m^2) at different bony areas, the relationship of the total body weight was identified. The details of subject's physiological information along with load measurement are given in Table 5.1. During the experiments, participants were asked to lie down on a viscoelastic mattress (flat posture). Also they were asked not to move for the time of the experiment. Figure 5.1 and 5.2 show the measured external load data (at sacrum and heel) for two subjects.

ID	Age	Weight in Kg	Height in m	BMI in kg/m^2
A1	26	76.4	1.7	26.44
A2	28	75	1.62	28.58
A3	30	70	1.78	22.03
A4	31	75.8	1.74	25.04
A5	31	83	1.79	25.90
A6	33	74.4	1.73	24.86
A7	35	70.2	1.7	24.29
A8	35	73	1.73	24.39
A9	36	55.7	1.54	23.49
A10	40	76	1.7	26.30
A11	40	66	1.61	25.46

Table 5.1 Subject's physiological information

The external load at sacrum was measured and shown in figure 5.1. The load was measured for two subjects (A5 & A6) with body weight of 83.00 kg and 74.40 kg respectively. During the experiment, external load at sacrum for A5 was 13% of the total body weight and for A6 the external load was 9.6% of the body weight. Figure 5.2 shows the external load at heel for two subjects (A5 & A9). For A5 and A9 the external load at heel were 6.5% and 6.4% of the total body weight. The load was measured at different bony areas for 11 subjects and the relationship with total body weight was established and given in Table 5.2. These information were used to develop the risk prediction system later. A mathematical model and a graphic user interface (GUI) are proposed to predict the risk of PU formation combining the Waterlow risk assessment scales for bony areas.

5.1 Real Time Risk Predicting Algorithm

Pressure ulcer is the result of subject's physiological properties and those of the support surface material. In this section, a risk prediction system is developed. For this, relationship between subject's ages and BMI with interface pressure are considered (Brienza et al. 2001; Kottner et al. 2011). Based on the relationships, a mathematical model is developed where a subject's information can be entered as input information and the system will predict percentage of risk at different bony areas. The main objective of developing such a system is to predict the risk of forming stage-1 pressure ulcer and by knowing the risk, a subject can be saved from developing PU. To develop the mathematical model, relative risk predication algorithm is considered (Goede et al. 2003; Spitz et al. 2007).

Fig. 5.1 External load at sacrum

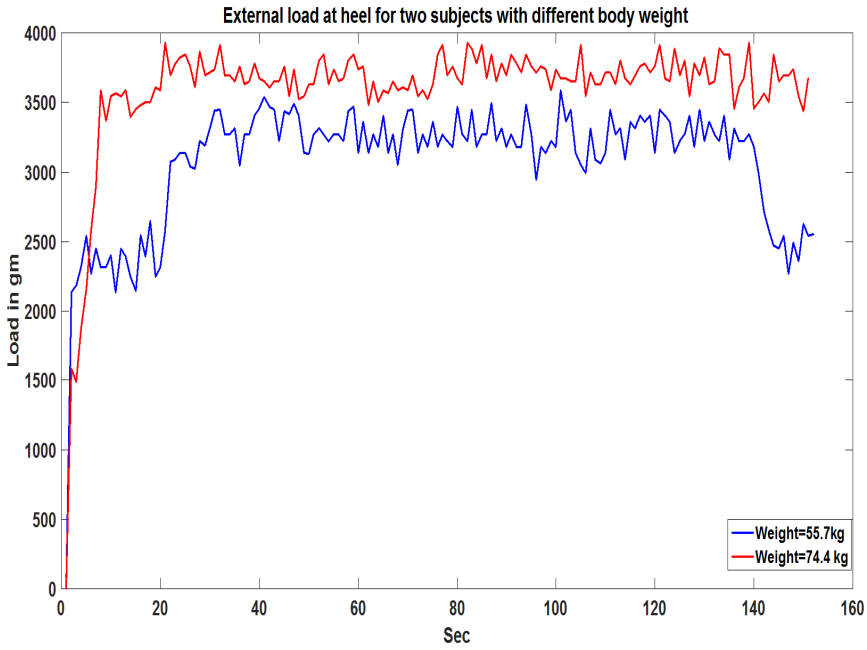

Fig. 5.2 External load at heel

Area	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	A11
% of total weight at right heel	6.2	5.8	6.3	5.7	6.5	6.1	6.4	6.2	6.4	6.3	6.0
% of total weight at left heel	5.8	6.5	6.7	6.1	6.7	6.6	6.4	6.0	6.4	5.8	6.4
% of total weight at right elbow	3.6	2.8	3.5	2.7	2.8	2.7	3.2	3.2	3.5	3.4	3.4
% of total weight at left elbow	3.2	2.9	3.2	2.7	3.0	3.0	3.0	3.0	3.65	3.2	3.4
% of total weight at sacrum	10	10.2	9.8	9.8	13	9.6	10.2	9.8	10.1	9.9	9.7

Table 5.2 External load data (measured at five bony areas for 11 subjects)

Location	% of total weight
Right heel	6.17
Left heel	6.30
Right elbow	3.17
Left elbow	3.11
Sacrum	10.20

Table 5.3 Relationship of bony areas with percentage of total body weight at different bony areas

Also to predict risk at any bony prominence, percentage of the total weight data (shown in table 5.3) is used. The algorithm is modified as per the relationship between ages, BMI with interface pressure and it provides the risk of PU at bony areas. Figure 5.3 shows the flow chart for risk prediction model.

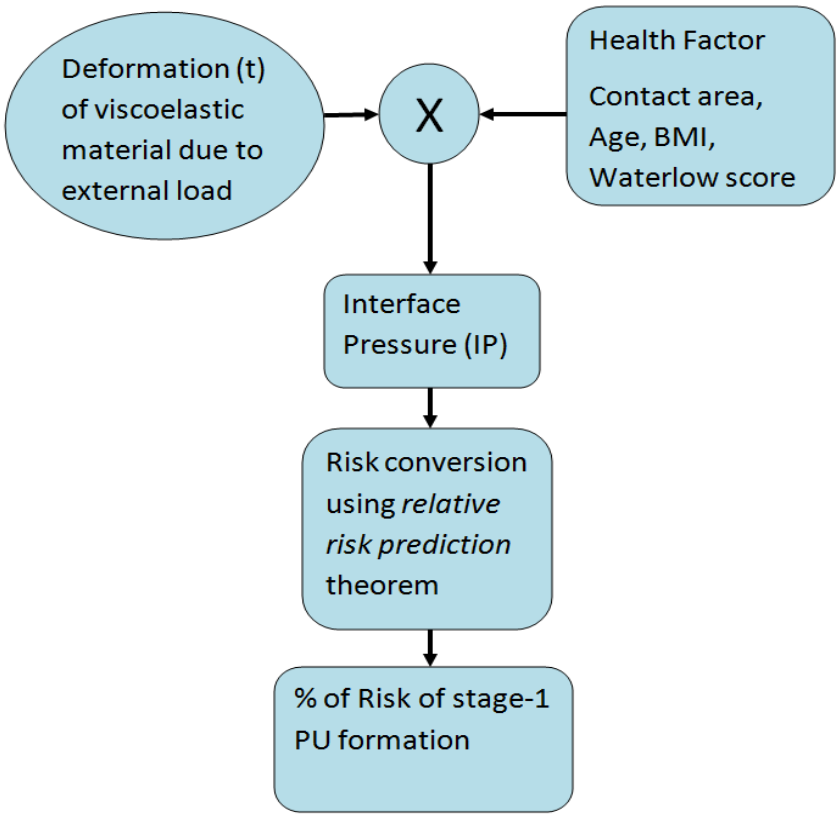

Fig. 5.3 Development chart for PU risk prediction system

5.1.1 Relative Risk Prediction Theorem

Relative risk prediction algorithm has been used in biomedical research to measure the risk of various diseases (Goede et al. 2003; MAGEE et al. 2007; McCloskey et al. 2009; Spitz et al. 2007). This type of algorithm consists of multiple parameters and it provides the odds of risk. Each parameter is converted into a associated risk score and finally the risk is calculated. It uses a general linear modelling system.

Previously it was used to identify the risk of lung cancer development and dermal wound exposure among two groups of patients (Assmann et al. 2002; Rocke et al. 1993).

$$O_R = C_1 \times (\frac{P_1}{max(P_1)}) + C_0 \times (\frac{P_0}{max(P_0)}) \tag{5.1}$$

$$R_R = \frac{O_R}{(1-P_0) + (P_0 \times O_R)} \tag{5.2}$$

Where P_0 and P_1 are the incidence of the outcome of the non-exposed and exposed group respectively; O_R is the odd ratio; C_0 and C_1 is model coefficient and R_R is the relative risk. To calculate the risk of PU formation, PU risk factors (physiological and support surface properties)are considered. Then the relative risk prediction algorithm is used and thus PU risk prediction model is developed(shown in next section)

5.1.2 Mathematical Implementation of PU Risk Algorithm

The following equations are developed to predict the risk of PU formation.

$$R_f = \varepsilon(t) \times H_f \tag{5.3}$$

Where R_f is the risk factor of PU for any individual, $\varepsilon(t)$ is the strain. H_f describes the health factors (age, BMI, and Waterlow score).

$$H_f = [a \times (\frac{r_a}{max(r_a)}) + b \times (\frac{r_b}{max(r_b)}) + c \times (\frac{r_w}{max(r_w)})] \tag{5.4}$$

where a<1,b<1 and c<1 and r_a, r_b and r_w is the converted values of age, BMI and Waterlow score (shown in Table 5.4,5.5 and 5.6).

To obtain the deformation of viscoelastic material $\varepsilon(t)$, the material model (developed in Chapter 3) is used (Figure 3.8). Previous research shows a pressure higher than 32 mmHg can cause pressure ulcer but it does not provide the time when subject will reach that value. Also other studies suggest 32 mmHg pressure is not the only threshold for ulceration. The pressure value can vary from subject to subject as per physical parameters (Body mass index). Therefore, by using this model (equation 5.3 and equation 5.4), it is possible to predict the risk for different individuals. Another reason to developing such a model is, currently there is no prediction system available which predict the risk of ulceration in the human body based on subject's physical information and surface material's property at the same time.

5.1.3 Conversion of Physiological Parameters into risk values

5.1.3.1 Age

In order to achieve the risk of pressure ulcer, the age of a subject is converted into risk score. This is done based on age vs. pressure ulcer formation risk (Chai and Bader 2013). Also the three risk assessment scales are used to identify how age is contributing towards formation of stage-1 PU. Once the relationship is established then the age values are converted into risk scores. Also, it has been shown that elderly subjects are more likely to form PU due to their skin type and tissue health (Chai and Bader 2013). Therefore, the score is high for 61-80 years and higher for >81 years. Conversion of age into risk is shown in Table 5.4.

Age	Risk scores
<21	0
21-40	1
41-60	2
61-80	3
>81	4

Table 5.4 Conversion of age into risk scores

5.1.3.2 Body Mass Index

The body mass index has a major role for PU formation (VanGilder et al. 2009). People with BMI below (<20 kg/m^2) in average are considered as malnourished because they are thin and these people are prone to develop PU (Due to lack of cushioning in subcutaneous tissue). Also people with BMI (>30 kg/m^2) have a higher incidence of PU (bodyweight, perfusion etc). Research shows that people with average (20.1-24.9 kg/m^2) and above average (25.0-29.9 kg/m^2) BMI are less likely to develop PU compare to other two groups (Stinson et al. 2003; VanGilder et al. 2009). A malnourished subject has higher chance to develop ulcer in bony prominence (heel and sacrum) because there is not enough soft tissue to support that area (Sopher et al. 2010). If the bony area is under continuous loading and the subject is immobile then blood flow in that area will decrease significantly. As a result stage-1 ulcer will develop. For an obese subject the scenario is different. An immobile obese people develop stage-1 PU under continuous external loading. Due to no movement, soft tissues do not get enough oxygenation and as a result it causes cell death and gradually leads to form stage-1 pressure ulcer. Obese subjects are likely to develop ulcer in the buttock area (Sopher et al. 2010).

By studying the experimental results from previous research (Berlowitz et al. 2001), the relationship of PU formation with body mass index is developed and then each group is converted into risk scores (shown in Table 5.5).

BMI type	Risk score
Average (20-24.9)	1
Above average (25.0-29.1)	2
Obese >30	3
Below average <20	4

Table 5.5 Conversion of BMI into risk scores

5.1.3.3 Risk Assessment Parameters

The parameters a, b, c are used to decide the importance of ulceration risk. Here, a+b+c=1 and a<1, b<1 and c<1. E.g. for a 25 years of old subject with below average (<20 kg/m^2) BMI and low risk Waterlow score:

$$a=0.2$$
$$b=0.6$$
$$c=0.2$$

here b is high priority as the subject has a below average (<20 kg/m^2) BMI.
But for the 84 years old subject with an average BMI (20.1-24.9 kg/m^2) and very high Waterlow score:

$$a = 0.33$$
$$b = 0.33$$
$$c = 0.34$$

Values for a, b, c are set to the system. So based on the subject's physiological properties, the system will decide the values for a,b,c. These values are shown in table 5.6.

5.2 Graphic User Interface (GUI) Development for Risk Prediction

A graphical user interface (GUI) is developed in MATLAB. The objective of developing such GUI is to visualize the PU risk along with interface pressure and surface deformation more interactively. Waterlow scoring system is also incorporated with the GUI so that components of the risk types can be seen separately.

	Physiological Parameters	Risk values of physiological Parameters	value
a	age	0	0.10
		1	0.20
		2	0.25
		3	0.30
		4	0.33
b	BMI	1	0.10
		2	0.25
		3	0.30
		4	0.33
c	Waterlow	Low risk	0.10
		At risk	0.20
		High risk	0.25
		Very high risk	0.34

Table 5.6 values for a,b,c

Figure 5.4 shows the developed GUI for risk prediction model. In order to obtain the PU risk for any individual using the GUI, following steps need to be completed.

- Step 1: On the right hand side, the Waterlow scale is provided and user needs to complete the Waterlow score first. Once Waterlow is completed, the system will generate the score along with risk type (shown in figure 5.2).

- Step 2: The user needs to insert subjects physiological parameters (age, weight and height) and based on that subject's body mass index (BMI) will be calculated by the system.

- Step 3: Young's Modulus of the viscoelastic support surface needs to be set.

- Step 4: Sensor contact area needs to be set

- Step 5: After completing step 1-4, a user needs to select the area to get the risk of PU. Then the graphs appear. The Top left graph is the deformation of viscoelastic material. Top right one is the interface pressure graph due to deformation of the material. Bottom left one is the pressure distribution image at the skin and material level and finally the bottom right graph is the percentage of PU formation risk.

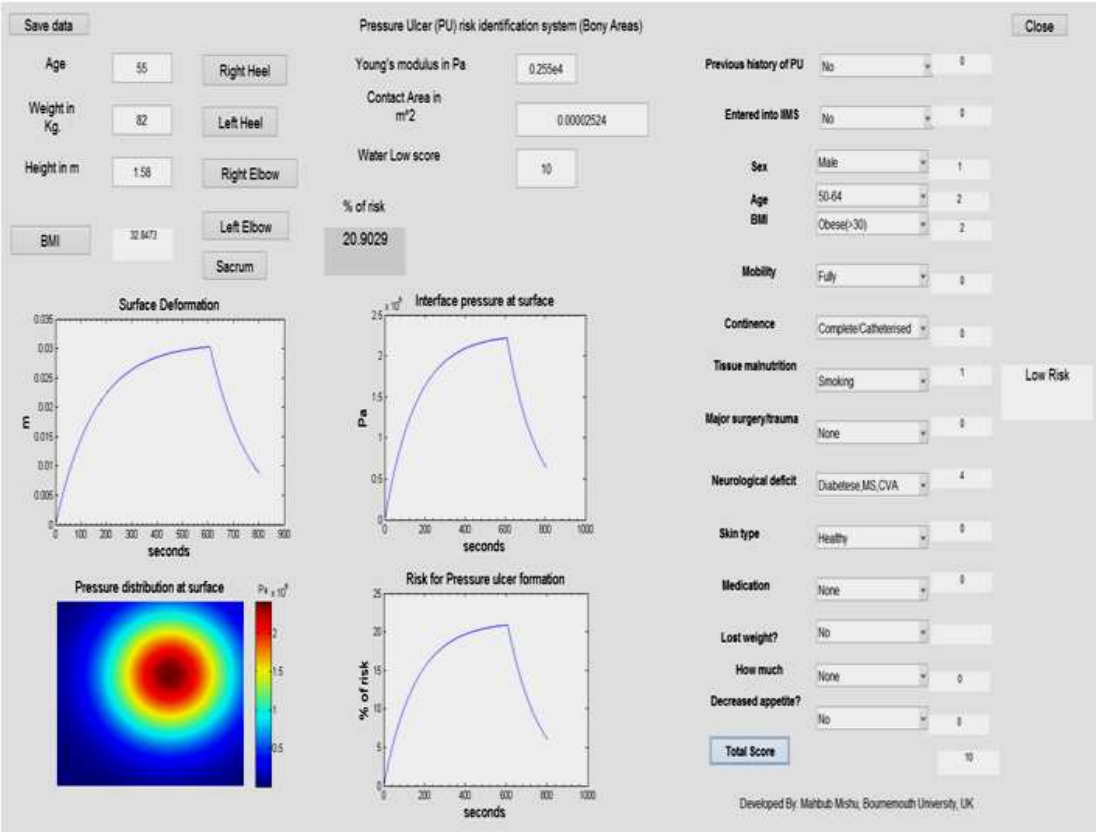

Fig. 5.4 Graphic user interface *(GUI)* for PU risk prediction

5.3 Results

Here the results of PU risk for different individuals using the GUI are shown in this section. In order to generate the risk at different bony areas, four types of BMIs (below average, average, above average and obese) are considered along with different age groups.
Theoretically, it has been established that people with high BMI and below average BMI are at more risk for ulceration compare to people with an average and above average BMI. Also elderly people are at more risk compared to younger age people due to skin and tissue conditions. Prediction of the PU risk formation percentage for different combination of physiological parameter is done by using the developed GUI. The results are given in figure 5.5 and 5.6 respectively.

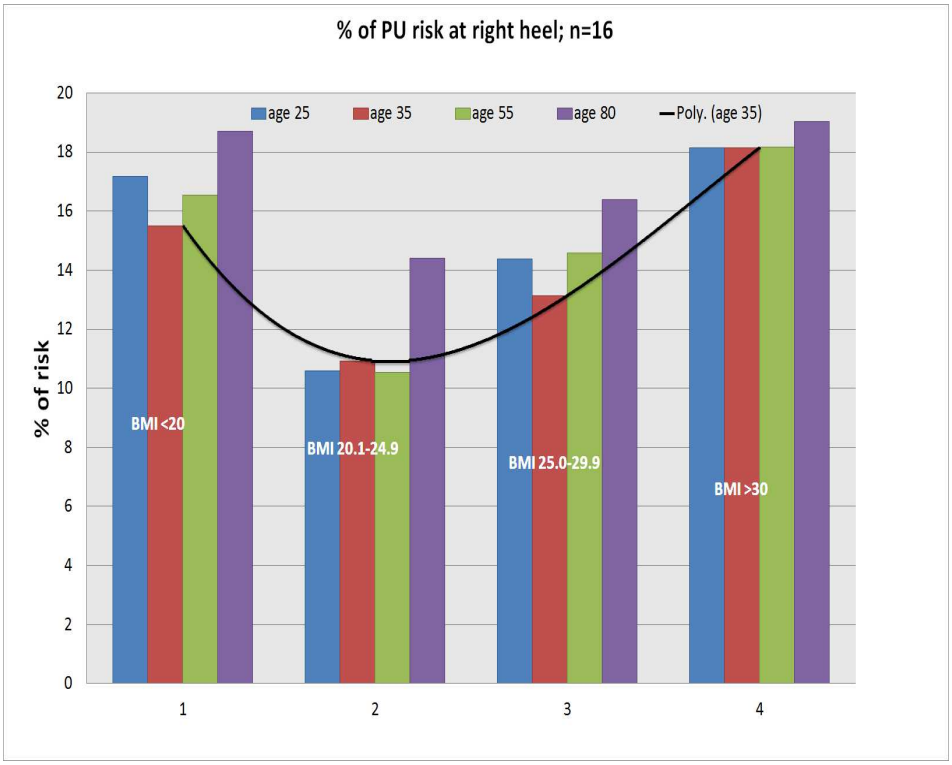

Fig. 5.5 Percentage of PU risk at the right heel after 600 sec (using GUI),n is the number of different combination of physiological parameters

Here the percentage of risk at the right heel and the sacrum area are shown. The results shown in Figure 5.5 and 5.6 matches closely with the theoretical results (people with below average BMI and obese BMI are at more risk compared to average and above average BMI)(Berlowitz et al. 2001). The percentage of PU risk at bony areas (heel, elbow and sacrum) are given in Table 5.7.

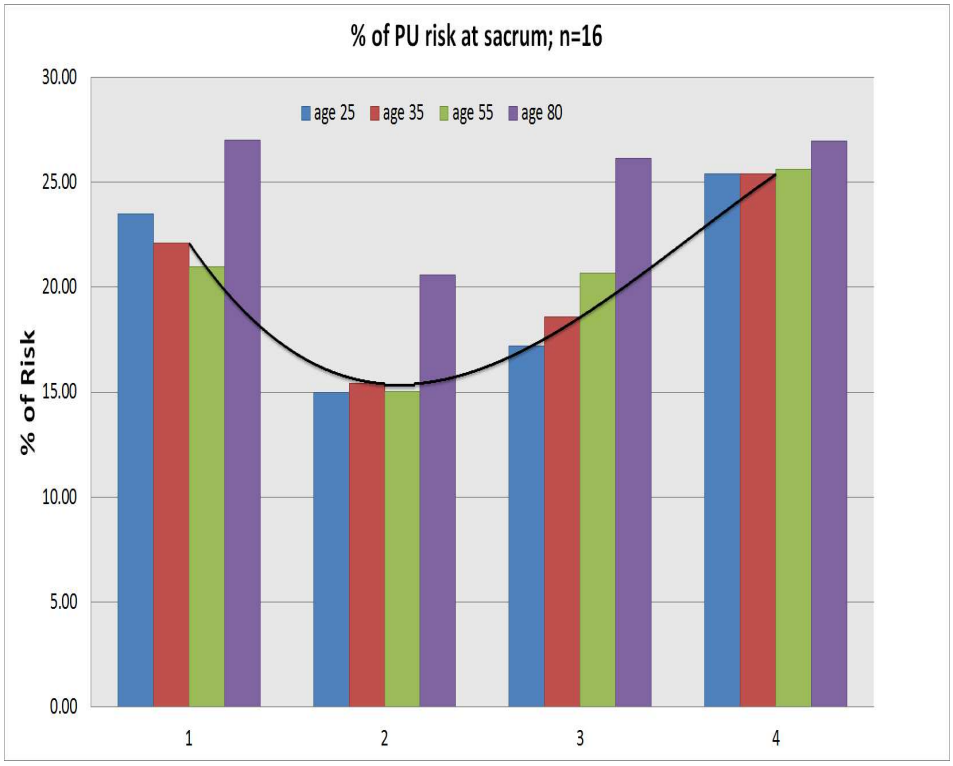

Fig. 5.6 Percentage of PU risk at the sacrum after 600 sec (using GUI),n is the number of different combination of physiological parameters

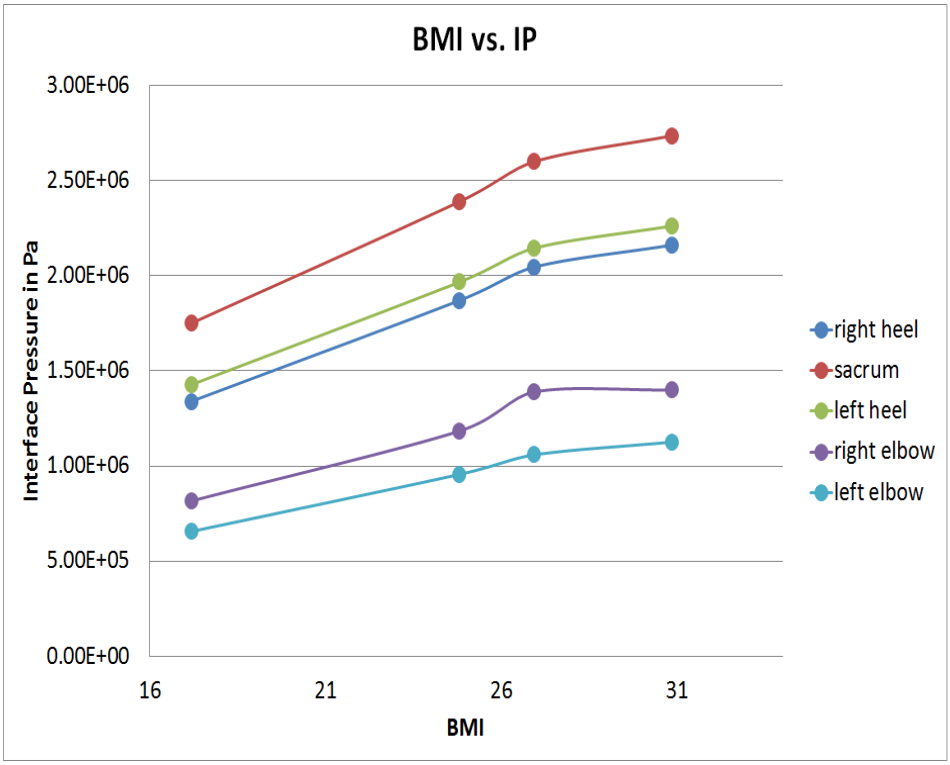

Fig. 5.7 Interface pressure due to different BMI

The interface pressure (IP) values at the support surface are given in Table 5.8. Table 5.7 and 5.8 shows the results of PU risk at different locations in the human body. In Table 5.7, the percentage of risk is shown and the risk values show that people with below average and obese BMI have a higher risk compared to people with average and above average BMI. Also PU risk is higher for at 80 years old compared to 25 years old. Interface pressure (IP) is a result of skin and contact area on the surface. Table 5.8 shows the IP in different areas. The relationship between external load at one point with the total body weight is identified from the experiments. These relationships are used to characterize different bony locations of the human body. Based on these relationships, the prediction model can predict the surface deformation and the IP. Figure 5.7 shows the change in interface pressure due to different BMI.

5.4 Summary

The development of the risk predicting system for PU is done by considering a subject's physiological parameters and body support surface property. The mathematical model is developed by converting physiological parameters into risk values.

Age	BMI	% of Risk at right heel	% of risk at left heel	% of risk at right elbow	% of risk at left elbow	% of risk at sacrum
25	17.18	17.17	17.82	7.84	7.71	23.50
	24.81	10.6	11.00	4.91	4.80	15.00
	26.93	14.38	14.86	6.73	6.59	17.19
	30.86	18.14	18.71	8.55	8.37	25.38
35	18.52	15.5	16.15	7.01	6.86	22.12
	24.06	10.93	11.30	5.08	4.97	15.40
	27.69	13.14	13.63	6.10	5.95	18.57
	34.17	18.15	18.71	8.55	8.37	25.38
55	18.21	16.53	15.26	6.45	6.30	20.99
	21.26	10.54	11.00	4.77	4.67	15.05
	27.23	14.59	14.14	6.72	6.58	20.65
	30.36	18.17	18.80	8.44	8.26	25.61
80	19	18.7	19.06	8.32	8.13	27.00
	21.3	14.4	13.03	6.48	6.34	20.60
	26.3	16.39	15.12	8.40	8.22	26.12
	30.06	19.02	19.76	8.74	8.54	26.97

Table 5.7 Percentage of PU formation risk at different bony areas after 600 sec, n=16

Age	BMI	IP right heel in MPa	IP left heel in MPa	IP right elbow in MPa	IP left elbow in MPa	IP sacrum in MPa
25	17.18	1.34	1.43	0.81	0.66	1.75
	24.81	1.87	1.97	1.18	0.96	2.39
	26.93	2.05	2.14	1.39	1.06	2.60
	30.86	2.16	2.26	1.40	1.13	2.74
35	18.52	1.58	1.67	0.95	0.79	2.04
	24.06	1.93	2.03	1.25	1.00	2.46
	27.69	1.87	1.97	1.18	0.96	2.39
	34.17	2.16	2.26	1.39	1.13	2.74
55	18.21	1.34	1.43	0.82	0.66	1.75
	21.26	1.58	1.67	0.97	0.79	2.04
	27.23	1.81	1.91	1.14	0.93	2.32
	30.36	1.93	2.03	1.22	0.99	2.46
80	19	1.37	1.46	0.83	0.67	1.79
	21.3	1.52	1.61	0.94	0.75	1.97
	26.3	1.69	1.79	1.06	0.85	2.18
	30.06	1.75	1.85	1.10	0.88	2.25

Table 5.8 Interface Pressure (IP) at support surface

Also, the Waterlow scale is incorporated in the GUI. This type of model will enhance the scope of pressure ulcer prevention research in the future. The developed model can be considered as a simulation toolbox where inputs are the subject's age, weight and height along with material information. The GUI will show PU risk at bony areas. The external load at different bony areas are identified by measuring for eleven different subjects.
Experiments are conducted with subjects to identify parameters of risk. Conducting experiments using subjects to identify pressure ulcer formation could be a challenging task. Sometimes it takes long time and it is also difficult to manage subjects for studies. Therefore, a toolbox is developed in MATLAB which can be used for a risk prediction system of pressure ulcer. The current model allows the user to observe the interface pressure and surface deformation due to external load. Body support surface has a significant role in pressure ulcer formation in human body. The model allows a user to set the material property (Young's Modulus) along with a subject's physiological parameters. Previous research in this field used measurement of perfusion, interface pressure and other parameters but the research did not include subjects physiological parameters with surface properties to predict risk of PU formation as it was presented in our model.

Chapter 6

Integration of AP Mattress System with PU Risk Predicting System

6.1 Alternating Pressure (AP) Mattress System

Alternating Pressure (AP) mattress usually has a number of air cylinders which periodically inflate or deflate and so vary the pressure inside them. This alters continuously the pressure on a patient's skin and improves blood flow and tissue perfusion. Various types of AP mattress systems are available commercially (described in Chapter 2) but the key question still remains how can we prevent ulceration in human body?. In an AP mattress system, inflation or deflation of a cylinder depends on factors such as pressure rate, cycle time, cylinder structure (in series or parallel). Figure 6.1 shows the response of different types of the AP systems. AP mattress systems are widely used to prevent ulceration in human body. Despite this people are still developing pressure ulcers. A conventional AP mattress system works periodically, i.e a care giver sets the pressure range and time cycle for inflation or deflation of cylinders and the cylinders act on the set parameters but because human body compositions are different to each other, the pressure ranges and time cycles are not suitable for everyone. Also other factors such as surface material's behaviour have a key role for ulceration. Current AP mattress system does not consider the material's response when a subject is lying or seating for a long time. These systems are also not considered as fully automatic or intelligent systems as manual setting is required. To develop an automated pressure ulcer prevention system first the AP mattress system needs to be integrated with the risk predicting model. By integrating the AP system with risk predicting model will provide more accurate prevention (more subject specific) of ulceration.

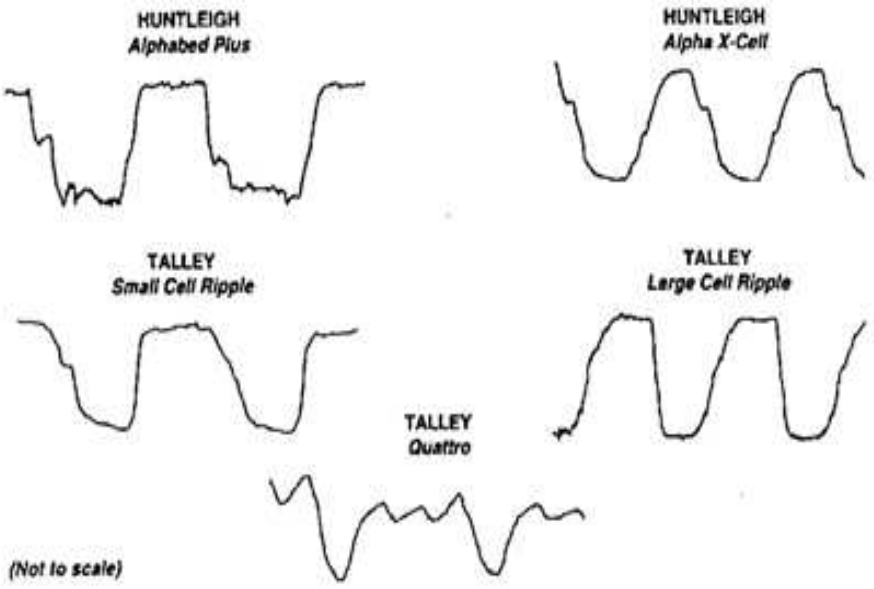

Fig. 6.1 Different types of AP mattress systems
(MDA 1993)

The developed risk predicting model (discussed in Chapter 5) predicts the risk of ulceration at five different bony locations in the human body considering subject's physiological parameters and surface material's response. If this model is integrated with an AP mattress system then the working principles of air cylinders in an AP mattress system can be controlled automatically (a care giver's input will not be required) and the complete system will provide a robust prevention that is based on multi factors. By developing such a combined automatic pressure ulcer prevention system can answer the key question.

6.2 AP mattress System with PU Risk Predicting Model

In order to the integrate the risk model with an AP system, an existing alternating mattress system was obtained from Salisbury Hospital, UK (Figure 6.2). The mattress system has 20 cylinders where air can be pumped in and pumped out (inflate/deflate).
However, the current system can only control four cylinders (highlighted in figure 6.2) and rest of the mattress is connected to a conventional air pump (at a constant pressure). Also, inflate and deflate occurs for a given period of time set manually. In a previous research the Salisbury Hospital developed this mattress system only to improve the blood flow in the sacrum area by cyclic loading. No information was included regarding subject's physiological aspects and surface material's response.

The GUI for the existing AP mattress system was written in LABVIEW. The schematic of the AP mattress system is given in Appendix C. After observing the conventional system's performance, a simulation model of the cylinder's response was developed in MATLAB.

Fig. 6.2 AP mattress obtained from Salisbury Hospital, UK

6.2.1 Simulation of Air Cylinders Under External Loading

The simulation model was developed in such a way that the inflate or deflate of a cylinder will depend on the surface load not on any timer block (e.g. when the the maximum applied load is transmitted to the force sensor which is attached to the viscoelastic material, load becomes constant after a period and at that point the cylinder starts changing its internal pressure). This provides a better understanding of cylinder's response due to external loading. In order to develop the simulation model, a pulse train is assumed as an external load. The pulse train was then applied to the enhanced viscoelastic model (discussed in Chapter 3). Mathematical equation used to develop the cylinder's response is shown below.

$$f(t) = \frac{F}{T} + \sum_{n=1}^{n=t} [\frac{2}{n \times \pi} \times sin(\frac{n \times \pi}{T}) cos(\frac{2 \times n \times \pi}{T})] \tag{6.1}$$

$$IP(t) = \frac{f(t)}{A} \times \varepsilon(t) \tag{6.2}$$

In equation 6.1 $f(t)$ creates a simple pulse train that was assumed as the external applied load to the surface area and F is the amount of load applied in N. T is the time period for each pulse and n was the total number of pulse.

Once the pulse train (external load) is generated it is then associated with the enhanced material model (described in Chapter 3). When the load is applied viscoelastic material starts deforming due to induced interface pressure. Thus equation 6.2 shows the interface pressure (IP) induced in the material with respect to time. Then the following algorithm is developed to control the cylinder's action (inflate/deflate) due to external load. Developed simulation model was shown in figure 6.3. The purpose of developing such a simple simulation was to understand the response of air cylinder with respect to external load not the time of load application.

```
f(t)=int;
IP(t)=int;
c(t)=int [n*n];
for i=1:T
   case 1
        numel(IP(t)) = = f(t)
                c(t)=f(t)
  case 2
        numel(IP(t)) >= numel(f(t))
             update.c(t)=c(t)-c(t-1)
                  c(t)=update.c(t)
   case 3
         numel(IP(t)) <=numel(f(t))
            update.c(t)=c(t) +c(t-1)
                  c(t)= update.c(t)
   case end
end
```

In figure 6.3 four pulse train (external load) with different pulse width was generated and then it was applied to the viscoelastic material. The aim was to establish the concept of cylinder's inner pressure change due to different load settings not at a constant time. The viscoelastic material showed creep and relaxation behaviour due to external load and thus IP was induced in the material. Due to this IP, the air cylinder responds. The cylinder was inflated at the beginning and when the IP starts increasing cylinder starts deflating the inner pressure. Due to this, a movement is felt in the mattress area. Cylinder deflates its pressure until the force becomes steady. When the IP started relaxing, the cylinder again inflated its pressure.

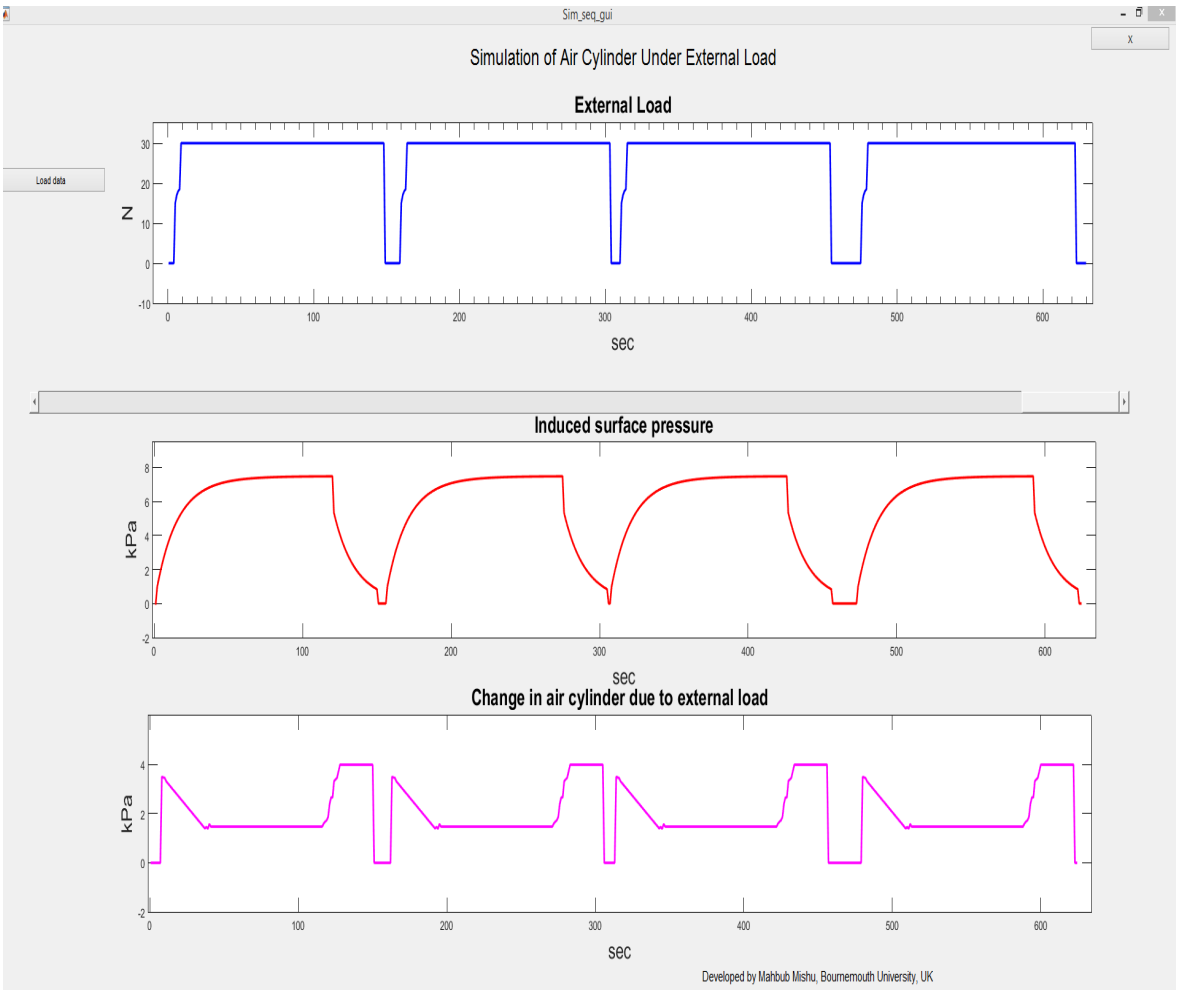

Fig. 6.3 Simulation of an air cylinder under external loading

So due to the induced IP in the viscoelastic material, the cylinder inflates or deflates. This type of simulation shows that there is no need for a set timer for the air cylinder. If the set time was used then cylinder will only inflate or deflate at a fixed interval and that was not going to be helpful for a subject at all. Also this type of development shows the automation of an AP mattress system for PU prevention research.

6.2.2 Integration of AP Mattress with PU Risk Model

In this section the integration of AP mattress system with PU risk model is discussed. In order to integrate two systems, first the orientation of the air cylinders are changed. Previously the four cylinders were placed in the middle (Figure 6.2) but in this research, the air cylinders are placed at different locations (mostly targeting the bony areas). By changing the orientation of the cylinders now it is possible to inflate/deflate four cylinders at four different loading. For example, If someone develops a significant risk at the sacrum area then only two cylinders in the middle will inflate or deflate based on external loads and risk factors. On the other hand, if heel is at risk then only that particular cylinder will response under external loading at heel area.
Next, The PU risk model is integrated with the AP mattress system. This is done by connecting the current data acquisition system LABJACK DAQ for the AP system with the force sensor system.
The force sensor measures the external load when a subject is lying on the viscoelastic surface. Now based on the external load and viscoelastic material's properties, the interface pressure (IP) induced at the skin and surface interaction point. Then the risk model calculates the risk at the bony areas considering physiological and surface parameters. The IP starts building at the interaction point and after a period, the IP becomes constant. If IP becomes constant that means the IP needs to be relieved otherwise blood flow in soft tissue will be reduced. The output of that constant IP then passed to the LABJACK DAQ system and then based on the constant IP the air cylinder starts responding (inflate or deflate). Figure 6.4 shows a complete block diagrams of the integrated system for automatic PU prevention. There are nine steps need to be completed for the automatic PU prevention system. These steps are discussed below.

- 1. A viscoelastic surface is placed at the top of the cylinders and a subject is lying on the surface. The FSRs are placed at the top of the viscoelastic surface. When a subject is lying on the surface the FSRs measure external load applied to the surface and pass it to ATMEGA-32 micro-controller.

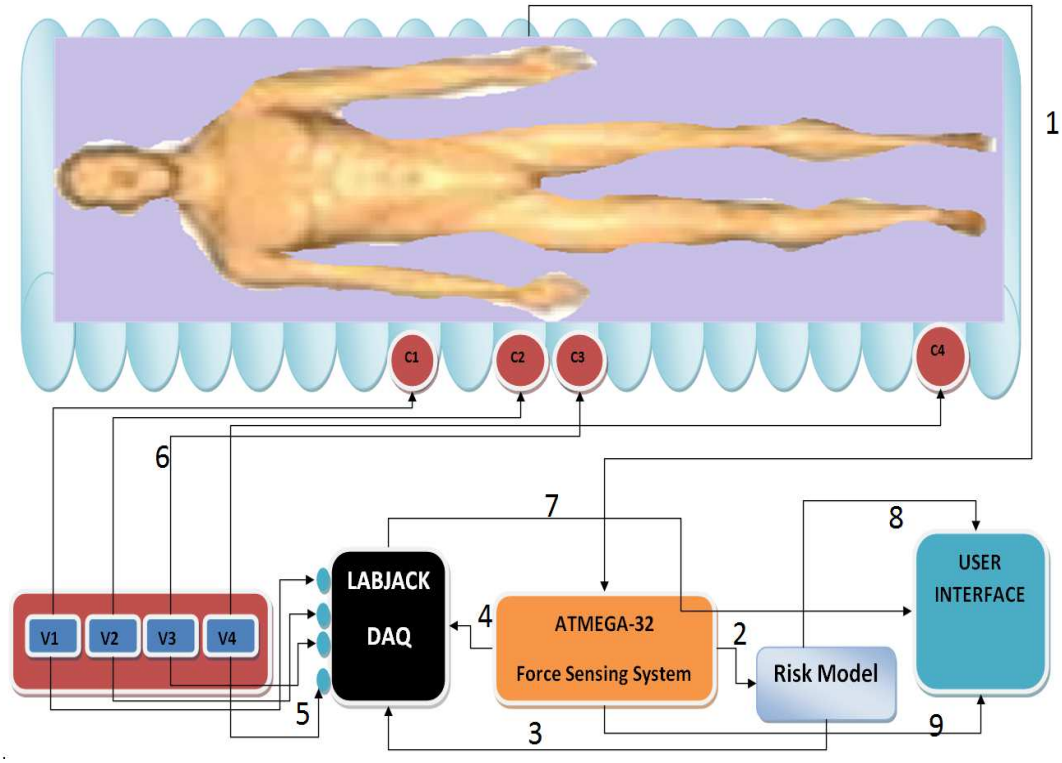

Fig. 6.4 Block diagram of developed automated PU prevention system

- 2. The micro-controller then passes the induced IP to the PU risk model.
- 3. The PU risk model calculates the risk at different bony areas based on subject's physiological parameters and material's properties and risk values are passed to LABJACK DAQ.
- 4. Then the IP at the material and skin interaction point is passed to LABJACK DAQ.
- 5-6. Based on these IP and risk value, the pressure valves v1-v4 operate (inflate or deflate).
- 7. LABJACK DAQ finally passes the pressure valves status to the GUI.
- 8. Risk model output is passed to the GUI.
- 9. ATMEGA-32 passes the IP to the GUI.

A graphic user interface (GUI) is developed to visualize the performance of the integrated system in MATLAB (shown in figure 6.5 and 6.6.

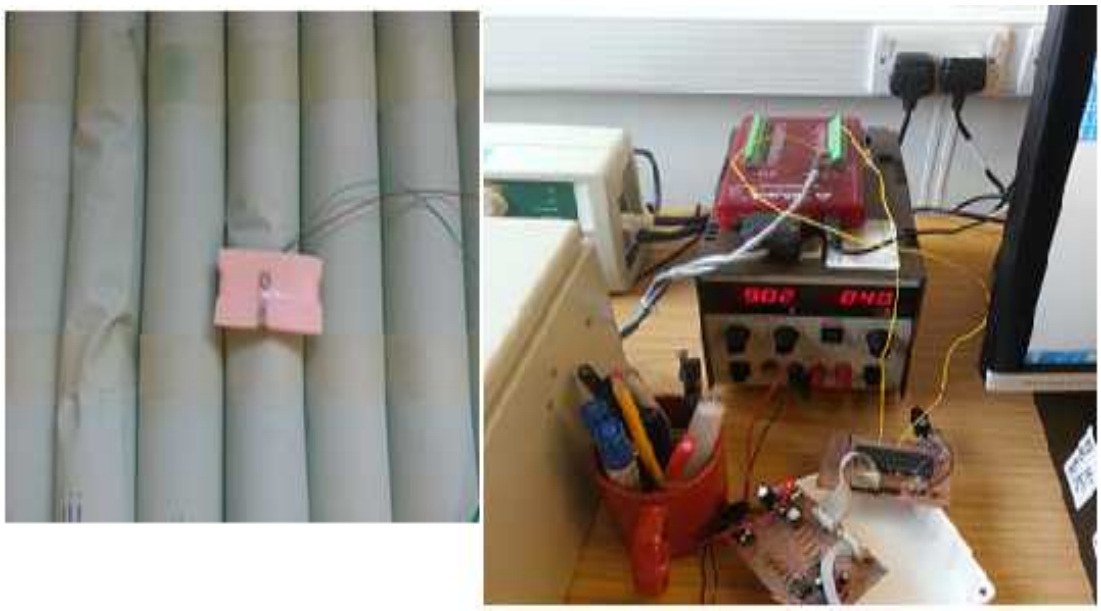

Fig. 6.5 Integration of AP mattress system with Force sensing system and viscoelastic material

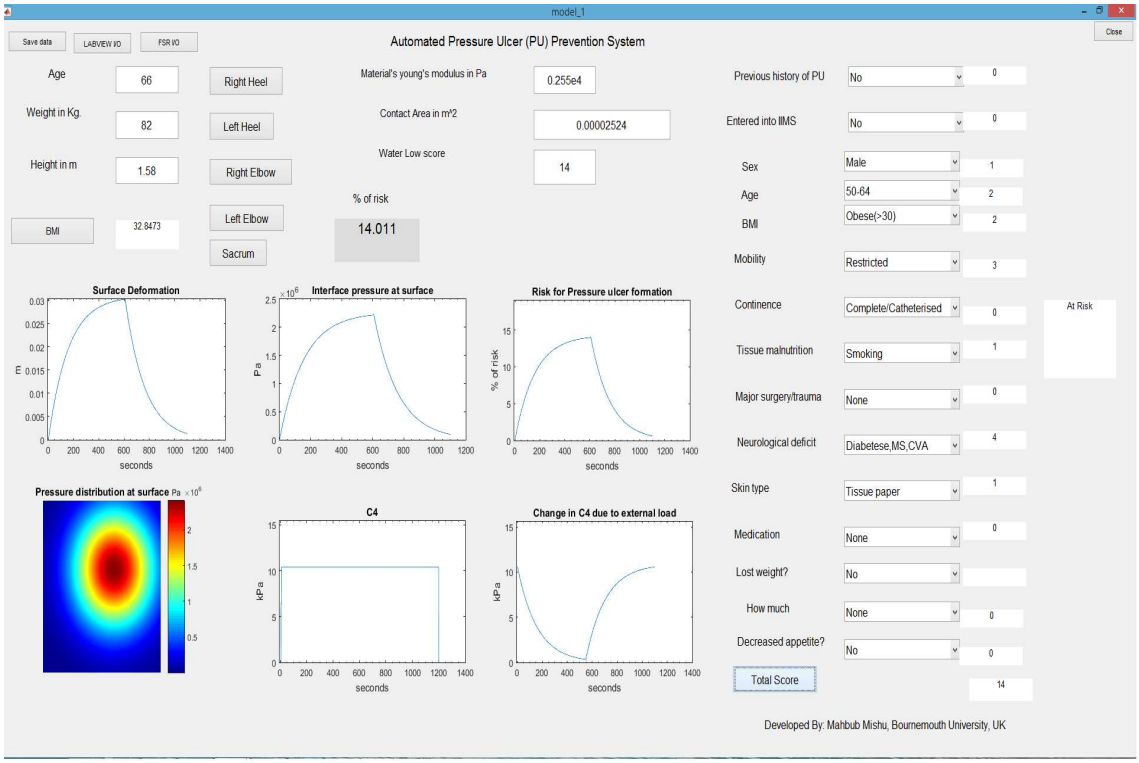

Fig. 6.6 GUI with the automatic prevention system

To start with first the LABVIEW I/O is activated and by doing so, the cylinders (C1-C4) are inflated. Once this is done, the next task is to activate the force sensor system.
Four Flexiforce sensors are combined together to make the sensor array (shown in figure 6.7). The sensor array is then placed on the viscoelastic material. Then four subjects with

Fig. 6.7 Force sensor array to measure external load at bony areas

different physiology (i.e. different age body mass index) were asked to lie down in a flat posture on the mattress. They were also asked to pretend to be immobile. When a subject is on the mattress, the force sensor starts collecting the force at different bony areas and the IP induced at the skin and surface interface are continuously recorded. Based on the IP at the interface, the cylinders start deflating. The cylinders starts inflating again when the IP is completely relieved from the skin and surface interface. Thus a movement is felt at the interface point due to cylinder's inflate and deflate behaviour. Figure 6.8 shows measuring external load at heel area of a subject.

The objective of integrating AP system with the risk model is to prevent ulceration in the human body. Also this type of development ensures the automatic activation of cylinders based on induced IP, material properties and other risk parameters. The integrated system can prevent ulceration at five different bony areas at the same time.

Fig. 6.8 Measuring external load at the heel

6.3 Results from the Integrated System

In this section results are shown from the integrated PU prevention system. The main objective was to create movement in the surface and skin interface area so that the subject laying on the mattress does not have limited blood flow at any point due to immobility. By using the integrated system, it has been possible to achieved automatic cylinder response due to external load behaviour. Four subjects were chosen to with different age and BMI. External load was measured and the response of the 4 air cylinders at five different bony areas are observed. When the subjects were laying on the mattress system, different inflating and deflating times of cylinders are found. This explains that the system works based on interface pressure which operates automatically relieving time of the care giver. Figure 6.9-6.12 shows the different inflate/deflate characteristics of air cylinders for two subjects at heel and sacrum due to induced IP. Figure 6.9 & 6.10 show the response of the cylinders due to external load and induced IP at the heel and sacrum for a 32 years old obese (30.86 kg/m^2) and a 61 years old malnutrant (19.82 kg/m^2) subject. During the experiment it was found that the cylinder started inflating at 551 sec for 32 years old subject and at 380 sec for 61 years old subject.

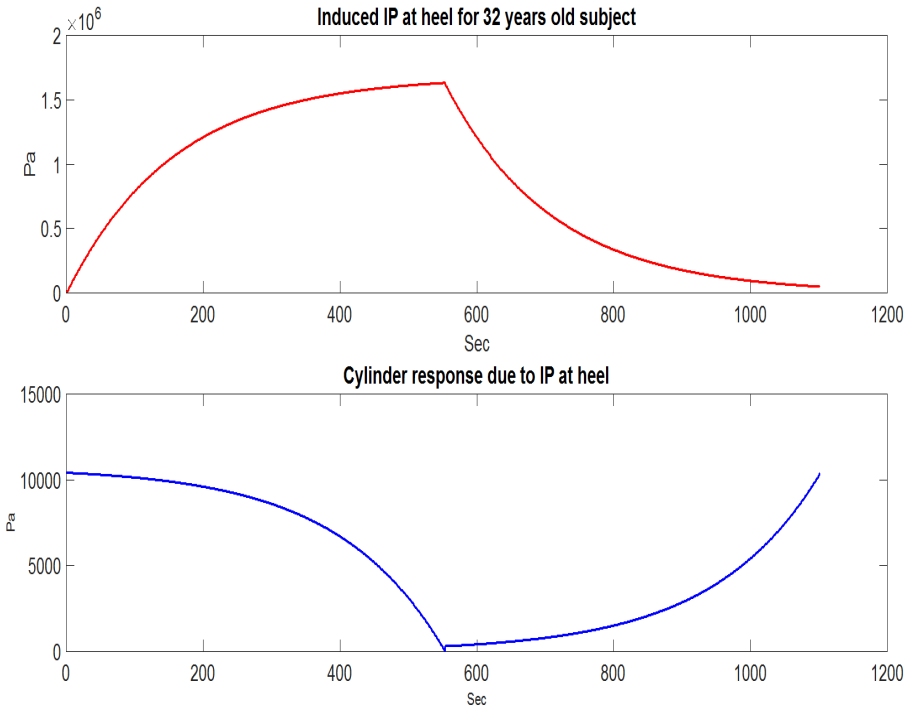

Fig. 6.9 Cylinder response at heel due to IP for 32 years old subject

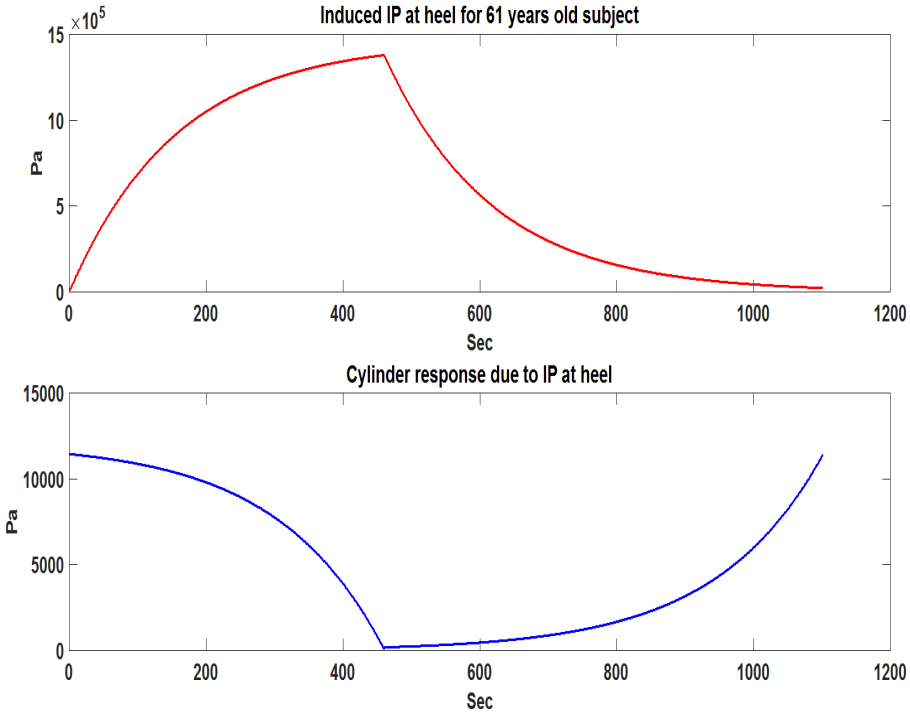

Fig. 6.10 Cylinder response at heel due to IP for 61 years old subject

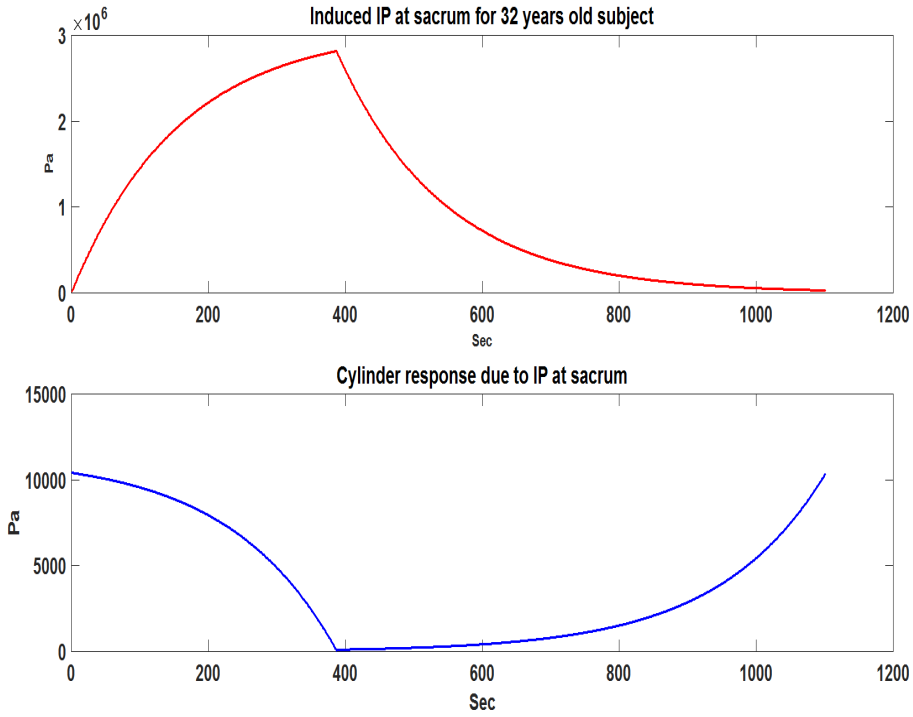

Fig. 6.11 Cylinder response at sacrum due to IP for 32 years old subject

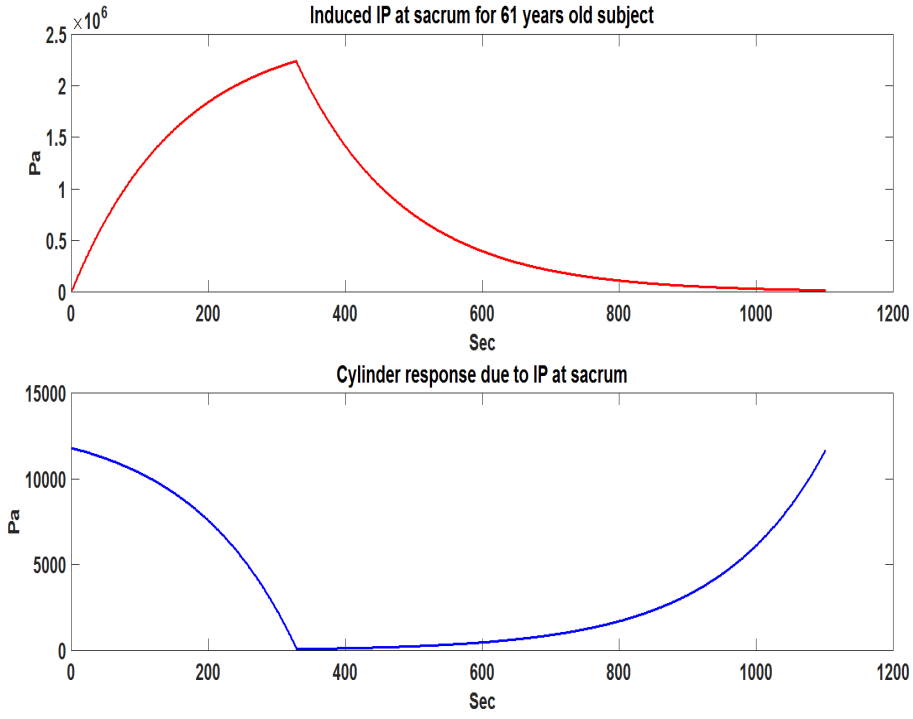

Fig. 6.12 Cylinder response at sacrum due to IP for 61 years old subject

The risk was calculated by the GUI was 15.01 % and 24.96 % respectively. Cylinder's actuating time was quicker for the 61 years old subject compared to 32 years due to his age. It was also found that the response of the cylinder depends on the induced IP and other parameters (subject's physiology and surface material properties). So when the maximum IP is induced at the surface after a period of time, then the cylinder starts deflating. By doing so it ensures the movement within the surface area due to deflating, the induced IP starts relaxing in the viscoelastic material. Once the IP is completely relieved at the interface of skin and surface point then cylinder starts inflating again so the movement in the surface area remains enforced all the time. Actuating time at sacrum was also obtained for different subjects (Figure 6.11 & 6.12). The cylinder actuating time at sacrum was found faster (463 sec for 32 years old subject and 310 sec for 61 years old subject) than the actuating time for heel. There are strong evidences which show the sacrum has the highest percentage rate for PU formation compared to other bony areas. Integrated prevention system shows that the % of PU risk is higher at the sacrum and therefore the actuating time is faster than any other bony areas.

This automatic PU prevention system ensures that the cylinder behaviour is subject specific. Therefore the time for inflating or deflating the cylinders are different. The associated risk for PU formation at any part of the human body also decreases when the interface pressure is relieved. Figure 6.13 shows heel and sacrum risk graphs for different subjects. Risks at heel and sacrum are shown in Table 6.1 for four subjects with different physiology.

Location	Age	BMI in	Risk	Actuating time
	yrs	kg/m^2	in %	in *sec*
Heel	32	30.86	15.01	551
	61	19.82	24.96	380
	28	22.56	3.4	880
	32	26.84	4.8	865
Sacrum	32	30.86	24.06	463
	61	19.16	32.48	310
	28	22.56	4	825
	32	26.84	5.8	818

Table 6.1 Results from the Integrated PU Prevention System

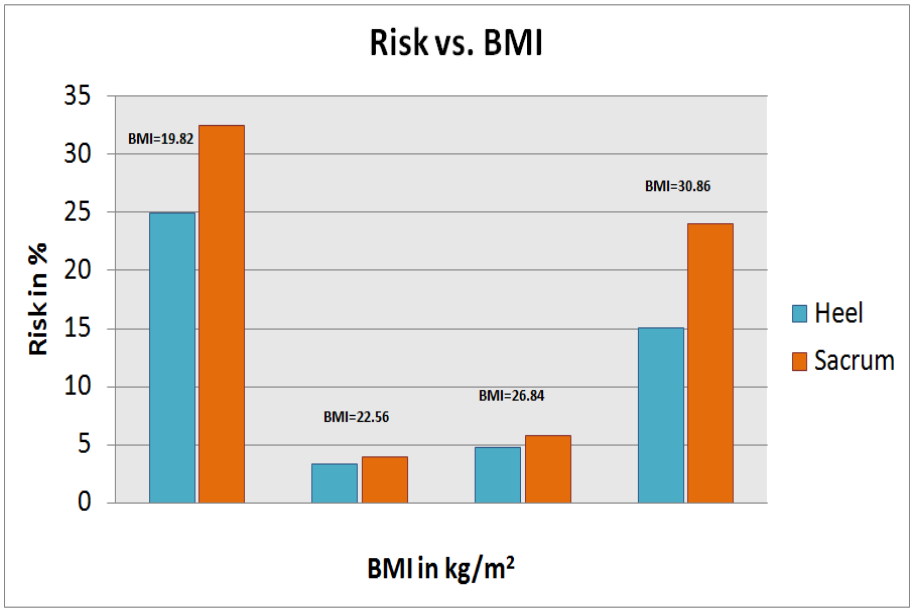

Fig. 6.13 Risk of PU formation at heel & sacrum for individuals

6.4 Summary

In this chapter the integration of AP mattress system with the PU risk predicting model is discussed. AP mattress systems are useful for PU prevention but existing systems can not prevent PU automatically. The identification systems can only identify but can not prevent the patient. So a combination of both identification and prevention has enhanced the scope of PU prevention research significantly. The integrated system shows that it can identify the risk and induced IP based on subject's physiological parameters and support surface material's property. The system relives the IP at the skin surface interface point and thus it prevents the subject from developing stage-1 PU. The main objective of developing the integrated system was to prevent ulceration automatically based on subject's requirements. This type of system does not required any manual settings for prevention. The results shown in this chapter explains the automation of the system and also shows it is subject specific. This system can work in a dynamic environment and it can prevent possible PU formation independently. The associated risk due to IP is reduced by this system when pressure is relieved at the surface area. Using this type of integrated system will allow a subject to have normal blood flow in soft tissues all the time. If the AP cylinders respond due to IP then each time the IP is induced at risk level, it will be relieved by inflating the AP cylinders. This will result a movement in the skin and surface interface point and therefore the blood flow will remain normal and thus preventing PU.

Chapter 7

Conclusion

7.1 General Discussion

Pressure ulcers are very painful for patients, and affect their quality of life. They also are very costly to society. A lot of systems are available to detect the pressure level and prevent the ulceration but there is no system which can predict the harmful pressure and relieve that pressure at the same time. Also current detection and prevention systems are very expensive and do not provide a solution to the subject. The risk assessment scales are used in hospitals prior to admission of subjects. These scales provide risk type and based on that health care professionals take actions (rotate subject manually at a fixed time interval) to prevent ulceration in subject's body. Also, these scales cannot tell us at what pressure level or at what time a subject could start developing ulceration in his/her body.

Support surface materials play a key role in pressure ulcer formation but currently none of the commercial systems consider the effect of surface material in pressure ulcer formation. Therefore in this research, the impact of body support surface material is studied and a mathematical model is established for the support surface material. The model represents a viscoelastic material and by simulation the response of the material is observed. Also the model is validated by conducting experiments and then both results (simulation and experimental) are compared with each other. During the experiment five different viscoelastic material's behaviour and their characteristics are identified under various loading conditions. The simulation model provides viscoelastic result such as creep and relaxation with experimental data. This indicates the model and the governing equation are viscoelastic and viscoelastic material can be described by the model. The objective of conducting experiment was to know material characteristics to be used in simulation.

So far material behaviour and characteristics are analysed (through experiment and simulation). The real time data acquisition software which collects data from the micro-controller and passes to PC validates simulation results with experiments.

There are many risk assessment scales available. These scales predicts an overall risk for a subject prior to hospital admission. These scales can not provide any useful information in real time. Also these scales do not tell us when a subject could start ulceration. Ulceration can occur at different location in the human body and by using these scales it is not possible currently to identify the risk at different locations in the subject's body. Moreover, these scales have different parameters and some of the scales are not very much subject specific. Therefore in this thesis, a new type of risk identification system has been developed where an existing risk assessment scale is associated with the new system. This new risk identification system is more subject oriented and also it considers the impact of support surface material. The developed system can predict risk in real time and also at different bony areas.

To prevent ulceration, alternating pressure mattress (AP) systems are used often but AP mattress systems are unable to identify the harmful pressure for the subject. These systems can only inflate or deflate the bladders at a certain pressure level set by the care giver manually. Therefore these are not automatic and also not subject specific (not considering any physiological parameters). The subject's movement is controlled by inflating or deflating cylinders at certain pressure and time interval but that interval may not be suitable for a particular subject. Because there is strong evidence that shows subject's physiological parameters have significant impact for pressure ulcer formation and without considering these parameters it would not be possible to identify the real-time risk level for any individual. Therefore it is very important to consider these parameters while identifying the harmful pressure level and preventing ulceration. An automatic prevention system for PU is developed in this research and this is achieved by integrating an individualised risk identification paradigm with a prevention system. Once the model is used as a identification tool it can predict possible time of ulceration for any individual. The output from the identification model is used as an input to the prevention system and thus inflate or deflate the bladders in a controlled manner. By doing so, the system is fully subject specific and operating in a dynamic environment independently.

7.2 Limitations

A major challenge was to identify the correct mathematical model to represent support surface material. There are many material models are available but to choose one particular model that can accurately represent the support surface material was critical. However, this limitation was overcome by studying the characteristics of material's behaviour under external loading conditions. Then a new type of surface model is developed.

The developed mathematical model was validated with the experimental results and while conducting experiments, there were few challenges such as material sample collection, experimental environment etc. During the experiment, the force sensor calibration was done but the noise from the sensor circuit could not be filtered. Therefore a small fluctuation in the experimental force data exists.

Next challenge was how to develop a risk model that took subject's physiological information and material properties together. This was challenging because human body compositions are different from one to other and often it is not easy to derive an equation that predicts the risk of ulceration. So to overcome this issue, the relationships between physiological parameters and load was studied. But still it was not clear that how etiological factors are related to each other and how they are contributing towards ulceration. Relationship between some basic factors such as age, BMI were identified but factors such as blood perfusion, tissue physiology were not identified that could have improved the model.
Theoretically the relationship of blood flow and ulceration is understood but it was not validated experimentally. Blood flow monitoring systems are very difficult to configure individually and such systems are expensive as well. So the blood flow measurement was not included in this research. Factors such as oxygenation, arterial and capillary functions were not included while developing the risk identification model.

The most significant challenging part was integrating the AP mattress system with the risk model. The AP mattress system was a custom made system (developed by Salisbury Hospital, UK) to improve the blood flow in sacrum area for subjects. The risk prediction system developed in this research was to identify the risk based on subject's physiological and support surface material's properties. The aim was to integrate both the systems so that the prevention of PU formation can be undertaken by the system automatically.

Also the GUI to read data from the integrated system was developed and existing LABVIEW GUI was ruled out. The communication between two microcontroller and AP system was not very powerful and this is one of the limitations of this research.

7.3 Future Work

In future all the cylinders of the AP mattress system could be integrated with the risk model. Then the system will be able to prevent ulceration at any location in the human body (not only in bony areas but also in soft muscle). At present the AP mattress system along with the pressure sensor circuit is large in size. In future the size of the pressure sensor system will be minimized. The developed Automatic PU prevention system needs support from LABVIEW to start the pressure cylinders but in future this could be operated by a stand alone software. The pressure sensor part (LABVIEW) could be developed in MATLAB by using simulink toolbox. Currently the GUI for the integrated system run only on PC platform but in future an application could be developed that can run in tablets and mobile phone. Also wireless transmission of data will be done.

The future of pressure ulcer prevention research requires more parameter integration to the main system. The parameters such as oxygenation, perfusion etc, if these parameters are included then the system will be more robust and it will predict the harmful IP more accurately. Also the prevention would be based on accurate prediction.

Soft tissue behaviour due to viscoelastic material and external load will be very interesting to explore in the future. Based on the tissue behaviour, 3D modelling of pressure ulcer formation would be developed. The 3D images will explain the tissue characteristics in real detail. This will also show the interface pressure image for soft tissue and material separately. By doing such analyses this will enhance the knowledge of pressure ulcer locations on human body.

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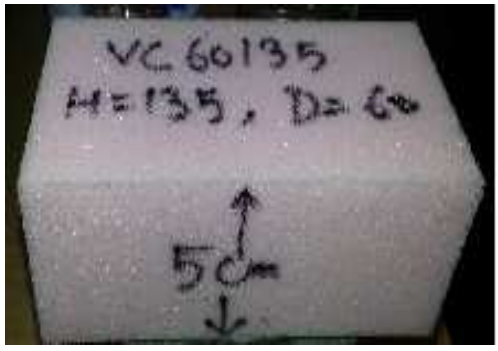
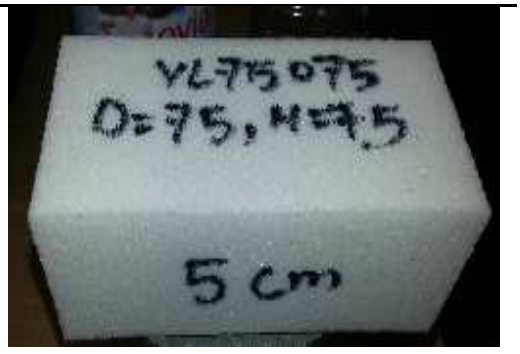
Appendix A

Viscoelastic Materials

A.1 Material Details

All five viscous materials which are used for experiments are given below. The table shows material with 0.05 m thickness but these materials are also tested with different thicknesses.

Material	Image
VC60135	
VL75075	

VASC60	
VASCO50	
VASCO40	

Table A.1 Viscoelastic material used for validating the support surface model

A.2 Experimental Data for Five Materials

- *VC60135*

Thickness m	Load applied N	Load Transmitted in N	Transmissibility %
0.015	4.50	0.93	20.5
0.02	4.50	0.62	13.74
0.025	4.50	0.46	10.31
0.035	4.50	0.28	6.12

0.04	4.50	0.24	5.26
0.05	4.50	0.18	3.95
0.055	4.50	0.16	3.56
0.065	4.50	0.13	2.92
0.07	4.50	0.12	2.69
0.015	5.50	1.38	25.1
0.02	5.50	0.93	16.82
0.025	5.50	0.69	12.62
0.035	5.50	0.42	7.57
0.04	5.50	0.36	6.51
0.05	5.50	0.27	4.88
0.055	5.50	0.24	4.39
0.065	5.50	0.2	3.6
0.07	5.50	0.18	3.31
0.015	8.50	3.39	39.88
0.02	8.50	2.27	26.72
0.025	8.50	1.7	20.04
0.035	8.50	1.02	12.02
0.04	8.50	0.88	10.34
0.05	8.50	0.66	7.76
0.055	8.50	0.6	6.98
0.065	8.50	0.49	5.72
0.07	8.50	0.45	5.26
0.015	9.50	4.14	43.62
0.02	9.50	2.78	29.23
0.025	9.50	2.08	21.93
0.035	9.50	1.25	13.16
0.04	9.50	1.08	11.32
0.05	9.50	0.81	8.5
0.055	9.50	0.73	7.65
0.065	9.50	0.6	6.27
0.07	9.50	0.55	5.77
0.015	11.45	5.95	52.41
0.02	11.45	4	35.11
0.025	11.45	3	26.33
0.035	11.45	1.8	15.8
0.04	11.45	1.55	13.59
0.05	11.45	1.16	10.2

0.055	11.45	1.05	9.18
0.065	11.45	0.86	7.53
0.07	11.45	0.79	6.93
0.015	16.35	10.1	61.37
0.02	16.35	6.78	41.12
0.025	16.35	5.08	30.84
0.035	16.35	3.05	18.5
0.04	16.35	2.62	15.91
0.05	16.35	1.96	11.93
0.055	16.35	1.77	10.74
0.065	16.35	1.45	8.81
0.07	16.35	1.34	8.11
0.015	21.26	15.13	71.2
0.02	21.26	10.14	47.7
0.025	21.26	7.61	35.78
0.035	21.26	4.57	21.47
0.04	21.26	3.93	18.46
0.05	21.26	2.95	13.85
0.055	21.26	2.65	12.47
0.065	21.26	2.18	10.23
0.07	21.26	2	9.41

Table A.2 Load transmission to VC60153 (various thickness)

- *VL75075*

Thickness m	Load applied N	Load Transmitted in N	Transmissibility %
0.015	4.50	1.03	23
0.02	4.50	0.69	15.4
0.025	4.50	0.52	11.5
0.035	4.50	0.32	7
0.04	4.50	0.27	6
0.05	4.50	0.2	4.4
0.055	4.50	0.17	3.8
0.065	4.50	0.14	3
0.07	4.50	0.12	2.7
0.015	5.50	1.55	28.06

0.02	5.50	1.03	18.8
0.025	5.50	0.77	14
0.035	5.50	0.5	9
0.04	5.50	0.41	7.5
0.05	5.50	0.3	5.6
0.055	5.50	0.28	5
0.065	5.50	0.22	4
0.07	5.50	0.2	3.6
0.015	8.50	3.66	43.2
0.02	8.50	2.45	29
0.025	8.50	1.87	22
0.035	8.50	1.1	13.2
0.04	8.50	0.96	11.3
0.05	8.50	0.73	8.5
0.055	8.50	0.64	7.5
0.065	8.50	0.51	6
0.07	8.50	0.47	5.5
0.015	9.50	4.6	48.3
0.02	9.50	3.06	32.3
0.025	9.50	2.3	24.2
0.035	9.50	1.38	14.5
0.04	9.50	1.19	12.5
0.05	9.50	0.9	9.4
0.055	9.50	0.8	8.4
0.065	9.50	0.67	7
0.07	9.50	0.62	6.5
0.015	11.45	6.6	58
0.02	11.45	4.43	39
0.025	11.45	3.3	29
0.035	11.45	1.93	17
0.04	11.45	1.65	14.5
0.05	11.45	1.25	11
0.055	11.45	1.13	10
0.065	11.45	0.93	8.2
0.07	11.45	0.85	7.5
0.015	16.35	14	84
0.02	16.35	9.26	56.2

0.025	16.35	6.92	42
0.035	16.35	4.11	25
0.04	16.35	3.63	22
0.05	16.35	2.72	16.5
0.055	16.35	2.4	14.5
0.065	16.35	1.98	12
0.07	16.35	1.81	11
0.015	21.26	20.83	98
0.02	21.26	14.03	66
0.025	21.26	10.63	50
0.035	21.26	6.34	30
0.04	21.26	5.32	25
0.05	21.26	4	18.7
0.055	21.26	3.6	17
0.065	21.26	2.98	14
0.07	21.26	2.76	13

Table A.3 Load transmission to VL75075 (various thickness)

- *VASCO40*

Thickness m	Load applied N	Load Transmitted in N	Transmissibility %
0.015	4.50	1.62	36
0.02	4.50	1.08	24.1
0.025	4.50	0.86	19
0.035	4.50	0.54	12
0.04	4.50	0.5	11
0.05	4.50	0.4	9
0.055	4.50	0.37	8.1
0.065	4.50	0.3	6.6
0.07	4.50	0.27	6
0.015	5.50	2.38	43.2
0.02	5.50	1.6	29
0.025	5.50	1.21	22
0.035	5.50	0.77	14
0.04	5.50	0.66	12
0.05	5.50	0.5	9
0.055	5.50	0.45	8.1

0.065	5.50	0.36	6.6
0.07	5.50	0.33	6
0.015	8.50	5.87	69
0.02	8.50	4	47
0.025	8.50	3	35.2
0.035	8.50	1.19	21.1
0.04	8.50	1.62	19
0.05	8.50	1.28	15
0.055	8.50	1.15	13.5
0.065	8.50	0.94	11
0.07	8.50	0.85	10
0.015	9.50	8	84
0.02	9.50	5.42	57
0.025	9.50	4.1	43
0.035	9.50	2.47	26
0.04	9.50	2.12	23
0.05	9.50	1.71	18
0.055	9.50	1.54	16.2
0.065	9.50	1.24	13
0.07	9.50	0.94	10
0.015	11.45	10.92	96
0.02	11.45	7.4	65
0.025	11.45	5.58	49
0.035	11.45	3.41	30
0.04	11.45	2.96	26
0.05	11.45	2.28	20
0.055	11.45	2.04	18
0.065	11.45	1.71	15
0.07	11.45	1.58	13.8
0.015	16.35	16.47	100
0.02	16.35	11.03	67
0.025	16.35	8.4	51
0.035	16.35	5.11	31
0.04	16.35	4.45	27
0.05	16.35	3.46	21
0.055	16.35	3.13	19
0.065	16.35	2.64	16

0.07	16.35	2.42	14.7
0.015	21.26	21.26	100
0.02	21.26	18.37	86.4
0.025	21.26	13.82	65
0.035	21.26	9.78	46
0.04	21.26	85	40
0.05	21.26	6.34	30
0.055	21.26	5.74	27
0.065	21.26	4.68	22
0.07	21.26	4.25	20

Table A.4 Load transmission to VASCO40 (various thickness)

- *VASCO50*

Thickness m	Load applied N	Load Transmitted in N	Transmissibility %
0.015	4.50	1.44	32
0.02	4.50	0.96	21.4
0.025	4.50	0.73	16
0.035	4.50	0.45	10
0.04	4.50	0.38	8.6
0.05	4.50	0.29	6.4
0.055	4.50	0.25	5.5
0.065	4.50	0.2	4.5
0.07	4.50	0.18	4.1
0.015	5.50	2.15	39
0.02	5.50	1.49	27
0.025	5.50	1.1	20
0.035	5.50	0.66	12
0.04	5.50	0.55	10
0.05	5.50	0.42	7.5
0.055	5.50	0.37	6.7
0.065	5.50	0.3	5.5
0.07	5.50	0.26	5
0.015	8.50	5.1	60
0.02	8.50	3.4	40
0.025	8.50	2.56	30

0.035	8.50	1.53	18
0.04	8.50	1.3	15.4
0.05	8.50	1.02	12
0.055	8.50	0.94	11
0.065	8.50	0.77	9
0.07	8.50	0.7	8.2
0.015	9.50	6.36	67
0.02	9.50	4.23	45
0.025	9.50	3.23	34
0.035	9.50	1.9	20
0.04	9.50	1.62	17
0.05	9.50	1.24	13
0.055	9.50	1.14	12
0.065	9.50	0.95	10
0.07	9.50	0.87	9.2
0.015	11.45	9.1	80
0.02	11.45	6.15	54
0.025	11.45	4.55	40
0.035	11.45	2.73	24
0.04	11.45	2.28	20
0.05	11.45	1.71	15
0.055	11.45	1.54	13.5
0.065	11.45	1.25	11
0.07	11.45	1.13	10
0.015	16.35	16.47	100
0.02	16.35	10.87	66
0.025	16.35	8.24	50
0.035	16.35	4.94	30
0.04	16.35	4.12	25
0.05	16.35	3.13	19
0.055	16.35	2.8	17
0.065	16.35	2.31	14
0.07	16.35	1.13	10
0.015	21.26	21.26	100
0.02	21.26	14.46	68
0.025	21.26	11.27	53
0.035	21.26	6.8	32

0.04	21.26	6	28
0.05	21.26	4.68	22
0.055	21.26	4.25	20
0.065	21.26	3.61	17
0.07	21.26	3.4	16

Table A.5 Load transmission to VASCO50 (various thickness)

- *VASCO60*

Thickness m	Load applied N	Load Transmitted in N	Transmissibility %
0.015	4.50	1.31	29
0.02	4.50	0.88	19.43
0.025	4.50	0.66	14.58
0.035	4.50	0.33	8.7
0.04	4.50	0.33	7.4
0.05	4.50	0.25	5.5
0.055	4.50	0.22	4.9
0.065	4.50	0.18	4
0.07	4.50	0.16	3.6
0.015	5.50	2.48	45
0.02	5.50	1.66	30.1
0.025	5.50	1.24	22.5
0.035	5.50	0.74	13.5
0.04	5.50	0.64	11.6
0.05	5.50	0.48	8.7
0.055	5.50	0.43	7.8
0.065	5.50	0.35	6.4
0.07	5.50	0.32	5.8
0.015	8.50	4.34	51
0.02	8.50	2.9	34.1
0.025	8.50	2.12	25
0.035	8.50	1.28	15
0.04	8.50	1.1	13
0.05	8.50	0.83	9.75
0.055	8.50	0.75	8.8
0.065	8.50	0.61	7.2
0.07	8.50	0.56	6.6

0.015	9.50	5.9	62
0.02	9.50	3.94	41.5
0.025	9.50	2.95	31
0.035	9.50	1.77	18.6
0.04	9.50	1.5	16
0.05	9.50	1.14	12
0.055	9.50	1.02	10.8
0.065	9.50	0.83	8.8
0.07	9.50	0.76	8
0.015	11.45	9.1	80
0.02	11.45	6.15	54
0.025	11.45	4.58	40
0.035	11.45	2.75	24
0.04	11.45	2.36	20.6
0.05	11.45	1.77	15.45
0.055	11.45	1.6	14
0.065	11.45	1.3	11.4
0.07	11.45	1.2	10.5
0.015	16.35	16.47	100
0.02	16.35	11.2	68
0.025	16.35	8.34	51
0.035	16.35	4.9	30
0.04	16.35	4.21	25.8
0.05	16.35	3.16	19.35
0.055	16.35	2.85	17.4
0.065	16.35	2.32	14.2
0.07	16.35	2.13	13
0.015	21.26	21.26	100
0.02	21.26	15.73	74
0.025	21.26	11.7	55
0.035	21.26	7.02	33
0.04	21.26	4.19	19.7
0.05	21.26	3.15	14.8
0.055	21.26	2.83	13.3
0.065	21.26	2.34	11
0.07	21.26	2.15	10.1

Table A.6 Load transmission to VASCO60 (various thickness)

Appendix B

Risk Assessment Scales

B.1 Norton Scale

Norton Scale for PU Risk Assessment		
Criterion	Score	
Physical condition	4=Good	
	3=Fair	
	2=Poor	
	1=Very bad	
Mental Condition	4=Alert	
	3=Apathetic	
	2=Confuse	
	1=Stupor	
Activity	4=Ambulant	
	3=Walk with help	
	2=Chair bound	
	1=Bed bound	
Mobility	4=Full	
	3=Slightly	
	2=Very limited	
	1=Immobile	
Incontinent	4=Not	
	3=Occasionaly	
	2=Usually	
	1=Doubly	

*Source: Doreen Norton, Rhoda McLarenand and A N Exton-Smith, An Investigation of Geriatric Nursing Problems in Hospital, © National Corporation for the Care of Old People (now Centre for Policy on Ageing), London, 1962. Table B.1 Norton Scale

B.2 Braden Scale

Risk Factor	Description				Score
SENSORY PERCEPTION Ability to respond meaningfully to pressure-related discomfort	1. COMPLETELY LIMITED Unresponsive (does not moan, flinch, or grasp) to painful stimuli,due to diminished level of consciousness or sedation, OR limited ability to feel pain over most of body surface.	2. VERY LIMITED Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness, OR has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.	3. SLIGHTLY LIMITED Responds to verbal commands but cannot always communicate discomfort or need to be turned, OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	4. NO IMPAIRMENT Responds to verbal commands.Has no sensory deficit which would limit ability to feel or voice pain or discomfort.	
MOISTURE Degree to which skin is exposed to moisture	1.CONSTANTLY MOIST Skin is kept moist almost constantly by perspiration,urine, etc. Dampness is detected every time patient is moved or turned	2. OFTEN MOIST Skin is often but not always moist. Linen must be changed at least once a shift.	3. OCCASIONALLY MOIST Skin is occasionally moist, requiring an extra linen change approximately once a day.	4. RARELY MOIST Skin is usually dry; linen only requires changing at routine intervals.	
ACTIVITY Degree of physical activity	1. BEDFAST Confined to bed.	2. CHAIRFAST Ability to walk severely limited or nonexistent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	3. WALKS OCCASIONALLY Walks occasionally during day,but for very short distances, with or without assistance. Spends majority of each shift in bed or chair	4. WALKS FREQUENTLY Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours.	

MOBILITY Ability to change and control body position	1. COMPLETELY IMMOBILE Does not make even slight changes in body or extremity position without assistance.	2.VERY LIMITED Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently	3. SLIGHTLY LIMITED Makes frequent though slight changes in body or extremity position independently.	4. NO LIMITATIONS Makes major and frequent changes in position without assistance.	
NUTRITION Usual food intake pattern NPO: Nothing by mouth. IV: Intravenously. TPN: Total parenteral nutrition.	1. VERY POOR Never eats a complete meal. Rarely eats more than 1/3 of any food offered. Eats 2 servings or less of protein supplement, OR is NPO and/or maintained on clear liquids or IV for more than 5 days.	2. PROBABLY INADEQUATE Rarely eats a complete meal and generally eats only about ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement OR receives less than optimum amount of liquid diet or tube feeding.	3. ADEQUATE Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products) each day. Occasionally refuses a meal, but will usually take a supplement if offered, OR is on a tube feeding or TPN regimen, which probably meet most of nutritional needs.	4. EXCELLENT – Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.	

FRICTION AND SHEAR	1. PROBLEM Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures,or agitation leads to almost constant friction.	2.POTENTIAL PROBLEM Moves feebly or requires minimum assistance. During a move, skin probably slides to some extent against sheets, chair, restraints, or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	3. NO APPARENT PROBLEM Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair at all times.		
Total Score	Score <9 Severe RiskScore 10-12 High Risk Score: 13-14 Moderate Score 15-18 Mild				

Table B.2 Braden Scale

B.3 Waterlow Scale

Waterlow Risk Assessment Scale		
Sex		
Male	1	
Female	2	
Age		
14 – 49	1	
50 – 64	2	
65 – 74	3	
75 – 80	4	
81+	5	
Build/Weight for Height (BMI= Kg/m^2)		
Average – BMI 20-24.9	0	
Above average – BMI 25-29.9	1	
Obese – BMI >30	2	
Below average – BMI <20	3	
Continence		
Complete/catheterised	0	
Incontinent urine	1	
Incontinent faeces	2	
Doubly incontinent (urine & faeces)	3	
Skin Type – Visual Risks Area		
Healthy	0	
Tissue paper (thin/fragile)	1	
Dry (appears flaky)	1	
Oedematous (puffy)	1	
Clammy (moist to touch)/pyrexia	1	
Discoloured (bruising/mottled)	2	
Broken (established ulcer)	3	
Mobility		
Fully mobile	0	
Restless/fidgety	1	
Apathetic (sedated/depressed/reluctant to move)	2	
Restricted (restricted by severe pain or disease)	3	
Bedbound (unconscious/unable to change position/traction)	4	
Chair bound (unable to leave chair without assistance)	5	
Nutritional Element		
Unplanned weight loss in past 3-6 months		
<5% Score 0, 5-10% Score 1, >10% Score 2	0-2	
BMI >20 Score 0, BMI 18.5-20 Score 1, BMI <18.5 Score 2	0-2	
Patient/ client acutely ill or no nutritional intake >5 days	2	

Special Risks – Tissue Malnutrition		
Multiple organ failure/terminal cachexia	8	
Single organ failure e.g. cardiac, renal, respiratory	5	
Peripheral vascular disease	5	
Anaemia = Hb<8	2	
Smoking	1	
Special Risks – Neurological Deficit		
Diabetes/MS/CVA/motor/sensory/paraplegiaMax 6	4-6	
Special Risks – Surgery/Trauma		
On table >6 hours	8	
Orthopaedic/ below waist/spinal (up to 48 *hours* post op)	5	
On table >2 hours(up to 48 *hours* post op)	5	
Special Risks – Medication		
Cytotoxic, anti-inflammatory, long term/high dose steroid Max 4	4	
Total Score		

Table B.3 Waterlow score card

Appendix C

Modified LABVIEW Diagram for Integrated system

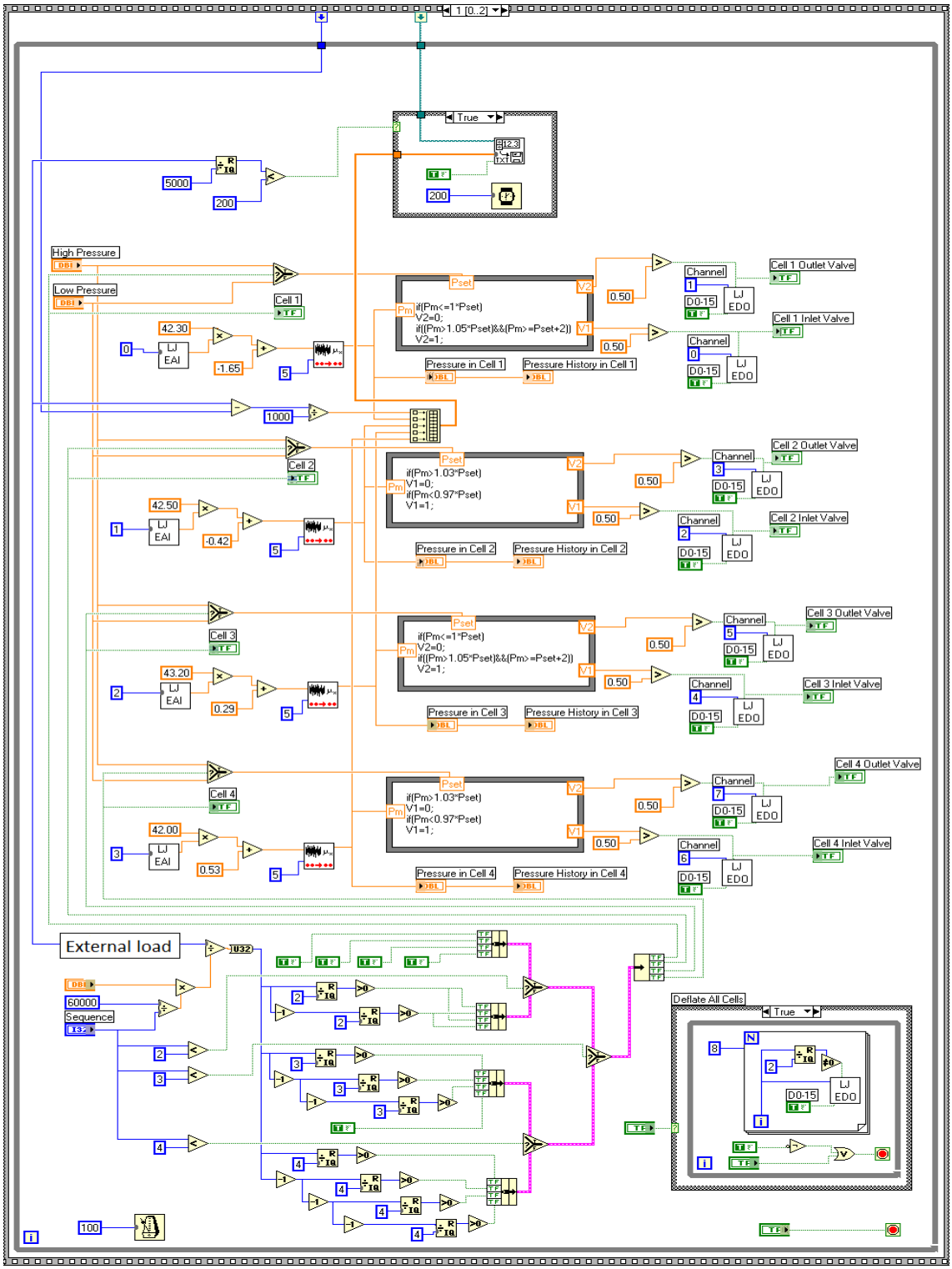


Fig. C.1 Modified LABVIEW diagram

Appendix D

Summary of Studied Papers

In order to complete the analysis on Prevalence, cost, aetiology, prevention techniques and risk factors of PU, Hawker's assessment tool was used. The tool provided the information on studies more accurately. In this method, each paper was scored between <10 (very poor)-40 (good). The assessment criteria of Hawker's tool is shown in table D1.

Criteia	Good (4)	Fair (3)	Poor (2)	Very Poor (1)
Abstract and title	Structured abstract with full information and clear title	Abstract with most of the information	Inadequate abstract	No abstract
Introduction and aims	Full but concise background to discussion/study containing up-to date literature review and highlighting gaps in knowledge. Clear statement of aim and objectives including research questions	Some background and literature review. Research questions outlined.	Some background but no aim/objectives/questions, OR Aims/objectives but inadequate background	No mention of aims/objectives No background or literature review
Method and data	Method is appropriate and described clearly. Clear details of the data collection and recording	Method appropriate, description could be better. Data described.	Questionable whether method is appropriate Method described inadequately. Little description of data	No mention of method, AND/OR Method inappropriate, AND/OR No details of data
Sampling of information	Details (age/gender/race/context) of who was studied and how they were recruited. Why this group was targeted. The sample size was justified for the study. Response rates shown and explained	Sample size justified. Most information given, but some missing	Sampling mentioned but few descriptive details	No details of sample
Data analysis	Clear description of how analysis was done.Qualitative studies: Description of how themes derived/respondent validation ortriangulation.Quantitative studies: Reasons for tests selected hypothesis driven/ numbers addup/statistical significance discussed	Descriptive discussion of analysis	Minimal details about analysis	No discussion of analysis

Ethics	Where necessary issues of confidentiality, sensitivity, and consent were addressed	Lip service was paid to above	Brief mention of issues	No mention of issues
Results	Findings explicit, easy to understand, and in logical progression. Tables, if present, are explained in text. Results relate directly to aims. Sufficient data are presented to support findings.	Findings mentioned but more explanation could be given. Data presented relate directly to results.	Findings presented haphazardly, not explained, and do not progress logically from results	Findings not mentioned or do not relate to aims
Repeatability	Context and setting of the study is described sufficiently to allow comparison with other contexts and settings	Some context and setting described, but more needed to replicate or compare the study with others.	Minimal description of context/setting	No description of context/setting
Usefulness	Contributes something new and/or different in terms of understanding/insight or perspective. Suggests ideas for further research, Suggests implications for policy and/or practice	Two of the above (state what is missing in comments).	Only one of the above	None of the above
Total				

Table D.1 Hawker's Assessment Tool

Evaluation of PU prevalence studies					
Study	**Settings**	**Number of participant, n**	**Findings**	**Comment**	**Score**
Vanderwee et al. 2007	Repositioning of patients after 2 *hours* in lateral position and 4 *hours* supine position	235	18.8% developed PU	Statisical analysis	30
Gunningberg et al. 2012	Medical and surgical units in the 207 hospitals in USA	16427	6.3%-6.7% developed PU	Benchmarking standard procedures	28
Gunningbergetal. 2013	A survey of 35058 person in the hospitals and nursing homes Sweden	35058	16.6% in hospitals and 14.5% in nursing homes developed PU	Statisical analysis	30
Evaluation of treating cost for PU					
Study	**Settings**	**Number of participant, n**	**Findings**	**Comment**	**Score**
Bennett et al. 2004	Survey	not reported	£1064 for grade-1 £3948 for grade-2 £6350 for grade-3 £7750 for grade-4	Statistical analysis	26
Severens et al.2002	A survey for Netherland healthcare industry	not reported	$362 *million* to a high estimate of $2.8 *billion*	Statistical analysis	27
Chan et al.2013	A cost analysis was conducted on community dwelling SCI individuals experiencing a PU	14	Monthly $4748 for individual	Statistical analysis	30

Graves et al. 2005a	Cross sectional, observational	2000	PU resulted in a median excess length of stay of 4.31 days	Regressional analysis	30
Graves et al. 2005b	Observational	not reported	95,695 cases of pressure ulcer have found with a median of 398,432 bed days lost, the median opportunity costs of AU$285	Statistical analysis	24
Posnett and Franks 2008	A review on PU cost among UK hospital patients	not reported	1. 55% of patients had had leg ulcer for longer than a year and cost to the *NHS* is 168–198*million* per year. 2. 64,000 individuals with active foot ulceration at any time and 2,600 amputations annually in patients with a foot ulcer. The cost to the *NHS* is 300*million* per year.	Not reported	20
Lyder et al. 2002	A survey for Centers for Medicare and Medicaid Services and state agencies	260	The average monthly cost of PU prevention resident was $519.73 (plus a one time cost of $277 for mattress and chair overlays).	Retrospective	30
Spilsbury et al. 2007	Qualitative semi-structured interviews	23 hospital inpatients with a pressure ulcer at various anatomical sites.		Statistical analysis	20

PU Aetieology					
Study	**Settings**	**Number of participant, n**	**Findings**	**Comment**	**Score**
Bouten et al. 2003	Review	N/A	Relationships between (1) Mechanical loading at skin, (2) Local internal mechanical state within the soft tissue layers, (3) Pathophysiological response to loading.	Hierarchical research approach to obtain improved insights into the basic pathways whereby mechanical loading leads to soft tissue breakdown	28
Danielet al. 1981	Review and experimental	N/A	Muscle damage occurred at high pressure-short duration (500 *mmHg*, 4 *hours*),	N/A	28
Beeckmanet al. 2007	Inter-observer reliability of the European Pressure Ulcer Advisory Panel (EPUAP) pressure ulcer classification system	1452 nurses from 5 European countries with 20 photographs as normal skin, blanchable erythema, pressure ulcers.	(1) Pressure ulcers were classified erroneously and only a minority of the nurses reached a substantial level of agreement. (2) Non-blanchable erythema was assessed incorrect as blanchable erythema.	EPUAP classification system was found to be low.	25

Liu and Yeung 2008	Study on the preconditioning effects and stress relaxation behaviour of fresh swine skin	N/A	Strain and time independency appears at different strain levels. The skin tissue has stress relaxation characteristics at strain of 15% and below.	Quasi-viscoelastic modelling	29
Elsner et al. 2001	Book	N/A	Characteristics of different skin components have shown	N/A	20
Shea 1975	Review	N/A	Classification of PU grades	N/A	28
Nola and Vistnes 1980	Experimental evaluation of skin	N/A	Various pressure values under different environment	An experimental model developed to characterize dorsal skin	30
Richey et al.1988	Review on aging and skin	N/A	Wrinkling and loss of elasticity, dyspigmentation,vascular ectasias,	Focuses on the intrinsic changes behind geriatric skin problems	30
Jan et al. 2008	wavelet analysis of skin blood flow *(SBF)* oscillations	10	(1) Alternating pressure stimulated an increase in sacral of soft tissues as compared with constant loading. (2) Frequency range during alternating pressure were observed compared with *SBF* prior to loading.	(1) A laser Doppler flowmeter have used (2) Wavelet-based spectrum analysis of *SBF* oscillations have used to assess underlying physiologic mechanisms	30
Popel and Johnson 2005	Review on microcirculation	N/A	Explanation of microcirculation	How microcirculation effects tissue damage	26
JACOBITZ et al. 2011	Computational modelling of rat muscle	N/A	The arterial pressure is varied from 40 to 140 *mmHg* and the venual pressure remains constant at 20 *mmHg*	The microcirculation in rat's muscle and is investigated	27

Holowatz et al. 2008	Review on microcirculation	N/A	Explanation of microcirculation	How microcirculation effects tissue damage	30
Thomas 2010	Review on intrinsic PU factors	N/A	N/A	Summarized the effects of PU intrinsic factors on patients	20
Baldwin 2001	Experimental results of sacrum pressure and temperature	38	(1) Subjects who moved (n = 24) had a statistically significant difference between pre-pressure and post-pressure temperature. (2) Post-pressure transcutaneous carbon dioxide *(TcPCO2)* mean levels were lower at all time-points and transcutaneous oxygen (TcPO2) mean levels were higher at most time-points in subjects who moved.	Pre-pressure and temperature readings have taken on the sacrum.	23
Armstrong et al. 2007	Temperature monitoring for diabetes patient	225	(1) 8.4% of the sample ulcerated over the study period. (2) Subjects had a temperature difference	Self-monitoring reduces the risk of PU.	30
Sprigle et al. 2001	A study in a acute hospital	65	15% of the erythematic sites were the same temperature as the surrounding tissue, 23% of the erythematic sites were cooler than the control sites, and 63% were warmer.	Increased and decreased temperature differences may be suitable to predict a Stage-1 PU	34

Gefen et al. 2005	A study to measure shear Moduli in vivo	N/A	(1) Shear Moduli of muscle tissue in rats were measured after applying 35 *KPa* or 70 *KPa* for 1/4–2 *hour* and evaluated tissue viability in matched groups. (2) Significant stiffening tissue was found in muscles subjected to 35 *KPa* for 30 *min* or over, and in muscles subjected to 70 *KPa* for 15 *min* or over. 3. cell death in rat muscle within 15 *min*.	Thresholds from animal models may allow to predict the muscle regions susceptible to PU.	32
Gefen 2011	A study on microclimate factors	N/A	The modeling showed factors decrease the tolerance of skin to PU and increase in the skin temperature	A computational modelling has shown for analyzing the effects of the microclimate on skin tolerance to PU	29
Hopkins et al. 2006	A pilot study	Not reported	(1) PU generates pain and a restricted life. (2) Patients found that the PU restricted their activities and had an impact on their families.	Mainly describes the quality of life for a patient with PU.	25
Mathus-Vliegen 2004	A study on physiological factors	300	(1) Describes the ageing effects on skin. (2) Showed that over 65 has significant risk of PU. (3) Higher and malnutrant subjects are also develop PU quickly than other BMI combination	Showed relationship between age and PU along with BMI.	35

Minson et al. 2002	A study on ageing and blood flow	20	(1) Two microdialysis fibers were placed in the forearm skin. (2) The response was significantly lower in the older subjects	Age related changes cause PU due to mechanical loading on the skin	35
Hagisawa et al. 1991	A study to evaluate the response of skin blood flow in younger and older subjects	10	(1) Ischaemia was generated with external loads of 22.3 *N* and 44.5 *N* applied to the skin for 3 *min.* (3) The perfusion in the older group following loading with 44.5 *N* was significantly reduced compared to the younger group	Hyperaemia in the older skin was reduced compared with the younger skin.	35
Li et al. 2006	A study to investigate the changes of the microvasculature with age	50	The density of capillary loops in the eldest group decreased by about 40-70% compared with the youngest group whereas the vascular length increased by 35-156%	Blood flow and redness of the skin increases with the age of the subject	35
Levy et al. 2013	A FE model that explains the effects of external load on the soft muscle	N/A	Theoretical modelling was done to show the muscle characteristics due to external loading	FE analysis	30
VanGilder et al. 2009	A survey to establish the relationship between BMI and PU	1200	1. Malnutrant and very high BMI subjects have 45% higher chance to develop PU compared to other BMI	Statistical analysis	35
Ruvolo Jret al. 2006	A study on the viscoelastic response of the skin	28	(1) Measures the deformation time. (2) Measures the strain rate	Mathematical modelling	35

Zhang et al. 2008	A study to characterize the viscoelastic mechanical properties of skin	38	(1) Stress vs. Strain relationship	FE analysis	35
PU Identification and prevention technology					
Study	**Settings**	**Number of participant, n**	**Findings**	**Comment**	**Score**
Yip et al. 2009	A pressure monitoring device to prevent PU consists of 99 capacitive pressure sensors on a 17cm by 22cm sheet flexible in two dimensions	N/A	Cycling tests have performed for 2 *hours*. The measured pressure had and shown good repeatability.Sensor drift was also measured by applying 50 *mmHg* of pressure over.	Limitations with this type of the system include sensor-to-sensor variation and baseline drift	30
Abraham et al. 2011	Development and implementation of a low-cost and disposable pressure sensor mat	N/A	Mattress consists of a 3mm by 5mm array. Pressure measurement resolution of 0.1 PSI	The sensors are disposable and therefore it is ideal to use in physiological monitoring.	25
Hsu et al. 2008	A wireless batteryless piezoresistive pressure sensing system	N/A	The Pressure range is 0 to 10 *psi* while the modulated frequency shift was 7.35 *kHz*-8.55 *kHz*	A pressure sensor array has designed to detect high pressure for long-term bedridden patient	25
Zhu et al. 2011	Design of a pocket spring mattress system	N/A	A soft pocket spring mattress provides lowest pressure in the sacrum, and a medium elastic spring mattress provides lowest pressure in the shoulder.	The study explored pressure distribution of sacrum and shoulder zones of pocket spring mattress. Test results showed that material type and sleeping postures have influences on body pressure distribution	34
Fenner Sr 1991	Patent	N/A	Described the design of a PU prevention mattress	Used for clinical purposes in USA	26

van Leen et al. 2011	A study to investigate the PU incidence on different types of support surface	83	17.1% of the sample developed PU on a cold foam mattress and 4.8% developed PU on a static air mattress.	cold foam mattress seems to have higher risk for PU than a normal foam mattress with a static air overlay. The results show a very clear relationship between the mattress and PU risk	32
McInnes et al.2011	Cochrane review and meta analysis	16285	RR 0.40, 95% CI 0.21–0.74	Foam mattress reduce the incidence of PU in people at risk.Alternating pressure mattress on the operating table compared to standard care reduce postoperative PU incidence	35
Swanson 1997	Patent	N/A	N/A	Design of a viscoelastic mattress system for PU prevention	22
De Laat et al. 2006	A study in a 900 bed hospital in Netherlands.	755	Prevention decreased from 19 to 4% after 4 months and to 6% after 11 months.	Difference between before and after the policy implementation of the care behaviour of nurses and the patients with PU.	30
Vanderwee et al. 2007	A study conducted on support surface material's behaviour due to repositioning of patients.	235	patients were repositioned in every 2 and 4 *hours* but despite, 16.4% developed PU	Repositioning on a alternating pressure mattress does not necessarily lead to fewer pressure ulcer and can not be considered as an effective prevention regime.	29

Fontaine et al. 1998	A study to compare the pressure and shear on 3 different support surface	11	Pressure on the fluid overlay was 23.7 *mmHg* and 36.7 *mmHg* at the air-filled overlay Both fluid overlay and air-filled mattress showed pressure data at the sacrum. Shear force readings were 79.3 *g* and 257.82 *g*	Reduction in shear force explained the healing observed in patients with the PU but needs more randomize trial to validate this.	35
Colinet al. 2012	A review of the literature Biomed, PubMed and Cochrane Library databases from 2000 through 2010.	N/A	N/A	Various types of body support surface material's behaviour have evaluated	20
Nixon et al. 1998	A clinical trial with post-operative patients on a viscoleastic surface	446	5% of the sample developed PU after 3 hours at the heel area	Statistical analysis	25
Butler 2010	Patent	N/A	N/A	A dynamic prevention system for PU	20
PU Risk Factor					
Study	**Settings**	**Number of participant, n**	**Findings**	**Comment**	**Score**
Bolton2007	A review on risk assessment scales for PU	N/A	Describes three major scales and their suitability	A collection of huge data of reliability and validity of the scales	30
Papanikolaou et al. 2007	Methodological review	N/A	Explained the three scales and their sub-scales	Summarized the results in a meta analysis table	30
Bergstromet al. 1987	A study to validate the Braden scale	843	within 48-72 hours of admission	Statistical	35

Demuth 1987	Clinical trial to validate the Braden scale	256	Patient at risk did not develop any PU within 72 hours	Describes Braden tool not suitable as it does not consider the physiological components directly	35
Bland and Altman 1986	A clinical trial to predict the reliability of Norton scales	445	Patients were found with PU and the correlation between risk factors and risk score was established	Suggested the Norton scale as a good assessment tool.	35
Dealey 1989	A comparison between Norton and Waterlow scale	N/A	N/A	Waterlow score has found more accurate due to its risk components	30
Lincoln et al. 1986	A study to predict the reliability of Norton scale among the elderly people in the acute care	155	More accurate for elderly	The scale provides good results and reliability over Braden scale	30

Table D.2 Summary of selected studied papers