The impact of exposure time on biophysical parameters of the wound environment and patient comfort during dressing changes: a descriptive study.

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Letter of Authenticity

I certify that this thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text.

I give consent to this copy of my thesis, when deposited in the Department library, being available for loan and photocopying.

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Abstract

Wound healing is a complex milieu that affects millions of people around the world every day. Practice based concerns have been described anecdotally by nurses in acute care facilities where wounds requiring an assessment by health care professionals have been left without their primary dressings for a considerable length of time. A number of studies have demonstrated that the temperature, transepidermal water loss (TEWL) and pH of a wound's microenvironment influence wound healing; however, there is limited research on the effect of the dressing changes on these parameters as well as the risk of contamination of the wound through prolonged exposure.

The impact of prolonged exposure throughout delays in a dressing change on these biophysical wound bed parameters and the possible contamination of the wound during the wound dressing procedure; and the affect delays have on patient pain, comfort and activities of daily living, were investigated through a descriptive correlational study.

Demographics and participant questionnaire data were analysed using descriptive statistics and frequency distributions. Patterns of distribution of the wound temperature, TEWL and pH data were reviewed before being further analysed along with the bacterial and patient questionnaire data using Generalised Estimating Equations regression models. A GEE linear regression model was used for normally distributed data; and GEE logistic regression models for data which were not normally distributed, using the Statistical Analysis System (SAS) 9.3.

The results identified that the participants' wounds were hypothermic as well as alkaline at dressing removal and throughout the period of exposure. The mean wound temperature increased throughout the total duration of the down time which was contrary to expectation,

although despite this all wounds remained hypothermic. The pH became more alkaline with the chance of having a pH of >8.5, 12% higher than having a pH of <8.5.

There was no relationship between the size of the wound and any of the wound bed parameters; however, there was a relationship between the type of wound, the temperature and pH. No associations could be made in regards to the participant's body temperature and wound temperature.

In addition to the investigation into the wound bed parameters, agar plates placed in proximity to the exposed wounds grew pathogens which could potentially contaminate the wound.

The third issue investigated was the affect wound dressing changes on the participant's pain, comfort and activities of daily living, an important aspect of the holistic approach to patient care. Participants were noted to be unable to perform some activities of daily living; including hygiene, toileting, nutrition and positioning during the wound down time. Analgesia was offered haphazardly despite the majority of patients having a pain score pre dressing removal that would indicate analgesia was required and an associated increase in their pain score during the dressing procedure.

The impact of delayed wound dressing changes on the patient's activities of daily living and pain are important in the delivery of patient centred care; however the major findings of the study relate to the poor state of the wounds immediately following removal of the dressing. Hypothermic, alkaline wound beds are not conducive to healing and warrant further investigation.

Glossary of terms

Acidic - A value between 0 and 7 (the logarithmic concentration of hydrogen ions in a substance).[1,2]

Acticoat™ - An antimicrobial silver impregnated dressing.[3]

Acute wound – A wound that follow the wound healing response and are 'healed' within a specific time frame.[4,5]

Agar - Gelatinous material used in Petri dishes for the growth of bacteria and fungi.[6]

Alkaline - pH between 7 and 14 (the logarithmic concentration of hydrogen ions in a substance).[1,2]

Ambient temperature (AT) – Environmental temperature surrounding an object.[7]

Anastomosis - Surgical connection between two structures.[8]

***Aspergillus Fumigatus* -** Opportunistic fungus.[9,10]

Aural temperature - Measurement of the infrared heat generated by both the eardrum and its surrounding tissue.[11,12]

Basal metabolic rate (BMR) - Rate at which the body uses energy to perform essential activities.[13]

Binary - Used in statistics where variables can only take on two possible values.[14]

Body mass index (BMI) - An estimate of body fat.[7]

Body temperature - Part of a homeostatic mechanism that maintains the body at optimum operating temperature .[15]

Brown adipose tissue (BAT) - Tissue is made up of many small lipid droplets and a wealth of mitochondria that is used to burn energy, Adipose tissue sits between the outer layer of the skin and the inner layer of muscle.[16]

Chronic wound – A wound with delayed healing as the wound does not progress through the acute wound healing phases in a timely manner.[4,5]

Cidex® ortho-phthalaldehyde (OPA) - A chemical disinfectant.[17]

Circadian rhythm - Regulates the body's biological functions and roughly follows a 24-hour cycle.[18-21]

Collagen - A protein that provides the skin with strength.[22]

Colonisation - The presence of bacteria in the wound.[23]

Colony forming unit (CFU) - A measure of the number of colonies of bacteria present in a sample, with a colony being a group of the same organism growing.[24]

Combine dressing – highly absorbent secondary dressing.

Conduction - Heat transferred through touching another object i.e. an electric blanket.[25-27]

Consultant - Medical officer who has undertaken specialist training following completion of their residency year.[28]

Contamination - Introduction of microbes (to the wound) that may lead to possible invasion by potential pathogens.[23]

Convection - Heat transferred through the movement of air or water over the skin such as having a bath or sitting in and air conditioned room.[25-27]

Cytokines – Protein that initiates vasodilation of the blood vessels surrounding a wound.[4,29]

Deep vein thrombosis (DVT) – Blood clot that forms in the veins of the leg and may impact on wound healing due to vascular integrity.[30]

Dermacheck - Software used with the Multi skin Centre MC750.[31]

Down time - The time between dressing removal and dressing reapplication.

Endogenous – When something originates from within the body.[4]

Epithelialisation - Involves the formation of new epidermal cells by mitosis and cell migration.[32,33]

Erythema - Redness of the skin.[34]

Evaporation - The outward heat transfer through water loss such as via perspiration.[25-27]

Exogenous – Something that originates from outside of the body.[4]

Exposure - The time between dressing removal and dressing reapplication.

Fibroblast - Cells which promote tissue growth through production of collagen.[22]

Fluke© 971 - A temperature and humidity meter.[35]

General Estimating Equations (GEE) - An analysis model utilised for analysing repeated measures data for both within and between participants.[14]

Glass electrode - A pH measuring probe connected to an electronic meter to measure and display the pH reading.[36]

Granulocytes – White blood cells also known as polymorphonuclear leukocytes that help fight infection.[22]

Graphic pain scale (GRS) – A visual analogue pain scale where descriptors are placed at intervals along the length of the line.[37]

Histamine - A protein that initiates vasodilation of the blood vessels surrounding a wound.[4,29]

Histiocytes – Cells which promote tissue growth through production of collagen.[22]

Humidity - The amount of water vapour present in the air.[38]

Hydrocolloid dressing – A flat occlusive adhesive dressing.[39]

Hydrofibre dressing – A highly absorbent wound dressing that converts to a gel.[40]

Hydrogel dressing - A 70-90% water based dressing product.[39]

Hypothermic wound - Where the temperature drops below the required temperature for normal wound healing - 36°C.[41]

Infection - The presence of at least *one* of the following: 1. Purulent drainage, with or without laboratory confirmation, from the wound; 2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the wound; 3. At least one of the following signs or

symptoms of infection: increased pain or tenderness, localized swelling, redness, or heat from the wound.[34]

Keratin - A protein within keratinocytes, cells mainly filled with a protein called keratin that resists changes in temperature, pH and enzymatic digestion.[22]

Lactate - The product formed when lactic acid disassociates in water and has been known to accelerate collagen deposition.

Langerhans cells - Found in the stratum germinativum which is important in the immune function of the skin as they recognise foreign invaders.[22]

Leukocytes - Inflammatory cells that defend the body against infections.[29]

Logarithmic scale – A scale that describes outcome variables which are not normally distributed nor have a normally distributed logarithmic function. I.e. a pH of 4 is ten times different to a pH of 5; however, this is tenfold to 6. A pH of 4 is 100 times different to a pH of 6.[1,2]

Macrophages - Inflammatory cells that defend the body against infections.[29]

Mast cells – A leukocyte found in the skin that participates in the early recognition of pathogens.[42]

MC750 - The platform which the pH and TEWL probes used to feed the data into the software program Derma Check.[43]

Microorganisms – Include bacteria, fungus or virus that are unable to be seen without the aid of a microscope that may be pathogenic or non-pathogenic.[44]

Mitotic activity – The degree of cell division and commencement of re epithelialisation.[45]

Mixed non-pathogens - Numerous types of skin flora found on the skins surface.[46]

Monocytes - Inflammatory cells that defend the body against infections.[29]

Myofibroblasts – Fibroblasts cell that assist in the wound healing process by aiding tissue repair.[47]

Neutrophils - Inflammatory cells that defend the body against infections.[29]

Non-pressure ulcer – An ulcer that presents from a non-pressure related aetiology.

Nosocomial infection – An infection contracted whilst an inpatient of a hospital.[48]

nu-beca© - A multi-function infrared thermometer.[49]

Open wound – A wound that is healing by secondary intention.[50]

Oxygen tension – The percentage of oxygen molecules present in the local blood supply.[51]

Parietal mass – A tumour located in the parietal lobe of the brain.

Partial thickness - The depth of a wound that has not penetrated through to the dermal layer.[52]

Petri dishes – The container used to hold agar.

Phagocytosis - The engulfing of a pathogen by a phagocyte.[44]

Planimetry – The measurement whereby the wound edges are traced to determine the wound size.[53]

Plasma cells – The white blood cells that secrete antibodies that aid healing.[54]

Polymorphonuclear leukocytes (PMN) - White blood cells that help fight infection.[22]

Polymyalgia rheumatic – An arthritic disorder.[55]

Post auricular – The region located behind the ear.

Pressure ulcer – An ulcer that develops due to a reduction in blood flow following prolonged pressure to the skin and underlying tissues which can cause the tissues to die.[56,57]

Primary dressing - The dressing applied directly to the wound bed to assist with wound healing.

Primary intention – Wound healing where approximation of the wound edges is able to be achieved using sutures.[58]

Radiation - The heat transfer through infrared rays with no contact such as from the sun.[25-27]

Registrar - A specialist medical trainee following completion of both internship and resident medical officer training.[28]

Relative humidity (RH) - The actual ratio of water vapour in the air at a given temperature and expressed as a percentage. Air with a RH of 50% contains half of the water it can contain at that temperature.[38]

Resident medical officer (RMO) – A medical officer who is undertaking additional training following completion of the intern year.[28]

Secondary intention – Wound healing in which an open wound heals over a period of time with the utilisation of dressings.[58]

Semi-critical site – The level of disinfection required for an instrument used on intact mucous membranes or non- intact skin.[59]

Skin temperature - The temperature of the skin.[15]

Strike through – Wound exudate that has been unable to be retained by the dressing and is visible as a patch of wetness on the outside of the dressing.

Temporal – The side of the head next to the eyes.[60]

Temporary dressing – An alternative cover placed over an open wound for a short period of time.[61]

Tertiary intention – Wound healing whereby dressings are initially utilised and once a wound is clean and viable it is then closed with sutures or grafting.[58]

Thermoregulation – The homeostatic control of a person's body temperature.[62]

T-lymphocytes - Inflammatory cells that defend the body against infections.[29]

Transepidermal water loss (TEWL) – Used to measure the amount of moisture evaporating from the epidermis, also used in the conduct of wound research.[63]

Traumatic wound – When tissue damage has been caused by some form of trauma.[64]

Tulle Gras™ – A cotton dressing that has been saturated with soft paraffin to reduce the risk of adherence to the wound bed.[65]

Vacuum assisted closure (VAC) - A negative pressure wound therapy that aids in the drawing of fluid from the wound bed in wounds healing by secondary intention to promote formulation of granulation tissue, removal of infectious wastes and drawing the wound edges together. [66]

Verbal rating scale (VRS) – A pain scale where descriptors are placed at intervals along the length of the line.[37]

Visitrak™ – A standardised wound measurement system using planimetry.[67]

Visitrak Digital – A portable tablet that provides an accurate area measurement by converting a line tracing into a true area measurement.[68]

Visitrak Grid - The tracing film used with the Visitrak Digital.[69]

Visual Analogue Scale (VAS) – A pain scale described as a straight line at which the end anchors are labelled as the extreme boundaries of the phenomena being studied i.e. no pain and extreme pain.[37]

White adipose tissue (WAT) - Adipose tissue which comprises 20-25% of the body weight in humans, with white adipose tissue storing energy in the form of fat.[16]

Wound - Where the function of the skin is impaired, following damage subsequent to an injury or underlying disease process.[70,71]

Wound assessment – The process of examining key wound parameters to be reviewed on a regular basis.[72]

Wound breakdown – A wound that dehisces or bursts open**.**

Wound microenvironment – The condition of the wound environment and cellular interfaces indicative of wound healing.[73]

Zinc dressing – A topical application of Zinc within a bandage to assist with superficial wounds that require occlusion.[65]

Chapter One - Introduction

Context of the study

Wound healing is a complex milieu that affects millions of people around the world every day; however, the exact numbers of people impacted cannot be accurately determined. Wounds result in considerable cost to the person, health care providers and the economy.[5] Addressing situations where there is an impact on the wound healing process is one way of reducing the costs to all involved. Practice based concerns have been described anecdotally for many years by nurses in acute care facilities. The major concern centres on the request from health care professionals for a wound dressing to be removed to allow an assessment of the wound to be performed. This involves the application of a temporary cover being placed on the wound and in many cases the wound being left without its primary dressing in situ for a number of hours.

To confirm the significance of this practice a descriptive study was previously conducted to ascertain the length of time for which wounds were being left exposed. Over a ten week period 227 wound dressings were observed with the average duration of time the wound was without its primary dressing found to be 104 minutes.[61] The study revealed that prolonged exposure impacted on the patients' comfort and activities of daily living in addition to health care professionals being unable to provide the required care in a timely fashion with a potential detrimental effect on the wound microenvironment.

The wound's microenvironment is an important consideration in the wound healing process as each wound will respond to injury based on its own distinct characteristics and key attributes. Understanding the normal skin structure and how endogenous and exogenous factors may influence the thermoregulatory and protective properties of the skin is an important factor as these can also impact on the sequence of events that occurs when the skin is wounded.

Ensuring an optimal environment for the wounded skin to heal also requires the application of a temporary dressing that will reduce contamination during the wound assessment process, which is vital to decrease the risk of infection.

In addition the impact of the wound dressing changes on patient pain, comfort and activities of daily living, are an important aspect of the holistic approach to patient care that needs to be considered.

Purpose of the study

The clinical wound bed parameters (temperature, TEWL and pH) have been defined as parameters within the wounds' microenvironment important to wound healing with these measurements needing to remain within an optimal range to aid wound healing. The impact of the wound assessment and the duration of the time the wounds are without their primary dressings on these biophysical wound bed parameters is the focal point of the study.

The purpose of the study was to investigate three issues. The first was to identify changes in temperature, Trans Epidermal Water Loss (TEWL) and pH of wounds left

exposed for assessment throughout the time the wound was without its primary dressing. The second issue was to identify any possible contamination of the wound during the wound dressing procedure through the use of air settle plates; and the third issue was to investigate the affect wound dressing changes had on the participant's pain, comfort and activities of daily living, an important aspect of the holistic approach to patient care.

Significance of the study

There are a number of studies which have demonstrated that changes in the parameters of the wounds microenvironment such as temperature, TEWL and pH have an impact on wound healing. However, there is limited research on the effect of the down time during dressing changes on these parameters as well as the risk of contamination of the wound through prolonged exposure. In addition the time taken to redress a wound (down time) and its impact on patient comfort and their ability to perform ADLs has not been previously investigated.

Assumptions

It was assumed that the results from each case in the sample would be representative of the population with similar wound characteristics; and although a local practice was being investigated it was assumed that these were comparable to practices occurring in other institutions.

It was also presumed that the tools utilised for the research would be practical to use and accurately measure the parameters in actual practice and that environmental factors

that may have impacted on the parameters such as the participant's body temperature and the clothing the participants were wearing were similar. There was also an implicit expectation that participants would accurately and honestly give feedback in the patient questionnaire.

Chapter Two - Literature review

Introduction

The skin protects and maintains the body's internal haemostatic environment from the external environment and possible mechanical, physical and chemical injury.[22] The makeup of the skin, its functions and the sequence of events which occur when it is wounded are important; as well as the three main modes of wound healing; primary, secondary and tertiary. Although wound healing should follow a normal sequence of events in response to injury, this can be interrupted by underlying co-morbidities as well as wound aetiology. Each wound has its own distinct characteristics and key attributes which affect wound healing.

There are a range of wound bed parameters that have been identified as important to wound healing and keeping these measurements within an optimal range may aid wound healing. The impact of the wound dressing change during assessment processes on these biophysical wound bed parameters has been the focal point of this study. The affect that wound dressing changes may have on participant comfort is also an important consideration.

Literature search

Two search strategies were undertaken with logic grids developed for each search. The search strategies sought to find studies published in the English language and initial identification of optimal search terms were undertaken in PubMed due to the large coverage of major biomedical journals.

Using all identified key words searches were constructed using either Medical Subject Headings (MeSH (mh)) or titles and abstracts (tiab). Syntax appropriate to the database being searched were used to find variants of each word; i.e. *. Boolean operators, were used to combine all terms in the columns with an 'OR', each of these columns were then combined with the Boolean 'AND' to gain the most precise literature in relation to the search. Search strategies were performed within PubMed and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) which also covers English language nursing journals and other nursing publications.

The initial strategy considered literature that described the normal skin anatomy, as well as the functions of the skin and associated areas that impact on these functions (Table 1).

Table 1 Logic grid 1

Skin	**Functions**
skin[mh] OR dermis[tiab] OR dermal[tiab] OR epiderm*[tiab] OR cutaneous[tiab]	Temperature[tw] OR biological clock*[mh] OR biological clock*[tiab] OR circadian rhythm[mh] OR circadian rhythm[tiab] OR body temperature[mh] OR body temperature[tiab] OR environment controlled[tiab] OR moisture[tiab] OR TEWL[tiab] OR water loss insensible[tw] OR hydration[tiab] OR acidi*[tiab] OR alkalin*[tiab] OR ph[tiab] OR bacteria*[mh] OR contaminat*[tiab] OR coloniz*[tiab] OR colonis*[tiab]

The subsequent search strategy added search terms related to skin injury, healing and factors that may impact on healing (Table 2). The logic grid assisted with defining the concepts to be searched and revealed the number of areas to be investigated and the complexity of the literature search.

A search of the databases was conducted; using all terms identified in each of the columns 'skin injury, healing and factors'; and the additional terms and spellings related to epithelialisation. The search was not date limited to enable the identification of any seminal papers.

Table 2 Logic Grid 2

Skin injury	Healing	Factors
burns[mh] OR burns[tiab] OR lacerations[mh] OR laceration*[tiab] OR vascular system injuries[mh] OR skin ulcer[mh] OR skin breakdown[tiab] OR skin[mh] OR dermis[tiab] OR dermal[tiab] OR epiderm*[tiab] OR cutaneous[tiab] OR sores[tiab]	Wound healing[mh:noexp] OR healing[tiab] OR Wound infection[mh] OR wound infection[tiab]	Temperature[tw] OR biological clock*[mh] OR biological clock*[tiab] OR circadian rhythm[mh] OR circadian rhythm[tiab] OR body temperature[mh] OR body temperature[tiab] OR environment controlled[tiab] OR hypotherm*[mh] OR hypotherm*[tiab] OR moisture[tiab] OR TEWL[tiab] OR water loss insensible[tw] OR hydration[tiab] OR acidi*[tiab] OR alkalin*[tiab] OR ph[tiab] OR bacteria*[mh] OR contaminat*[tiab] OR air pollut*[mh] OR surgical drape*[tiab] OR coloniz*[tiab] OR colonis*[tiab] OR pain[mh] OR pain[tiab] OR comfort[tiab] OR pain measurement[mh] OR pain measurement[tiab] OR VAS[tiab] OR visual analogue[tiab]
re-epithelialization[mh] OR re-epithelialization[tiab] OR reepithelialization[tiab] OR re-epithelialisation[tiab] OR reepithelialisation[tiab]		

All studies identified were assessed for relevance to the search based on the information provided in the title, abstract and MeSH descriptor terms. A total of 2,621 articles were retrieved in relation to normal skin anatomy and functions of the skin with

full text retrieved for 151 papers which appeared to be relevant to the study. A further 173 articles were found following the second search using the search terms related to skin injury, healing and factors that may impact on healing.

Before detailing the importance of the biophysical parameters on wound healing a description of what constitutes a wound and the normal wound healing response is described.

Skin structure

The skin is continually exposed to the elements of an ever changing environment and maintaining its integrity is paramount to it being able to carry out its major functions of protection, thermoregulation, sensation, metabolism and communication.[22] The skin varies in thickness at different parts of the body from 0.5mm to 6mm and is made up of the epidermis and the dermis.[74]

Epidermis

The outermost layer of the skin is called the epidermis and is composed of five layers, the stratum corneum, stratum lucidum, stratum granulosum, stratum spinosum and stratum germinativum or basale (Figure 1).

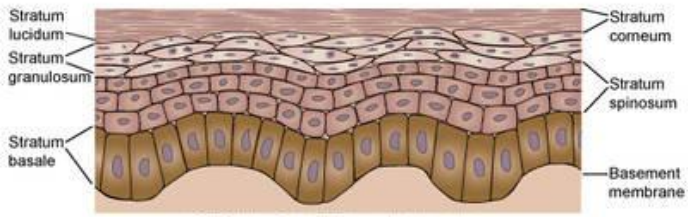

Figure 1 Section of the Epidermis[75]

The stratum corneum is the outer layer of the skin and contains keratinocytes, cells mainly filled with a protein called keratin. One of the capacities of keratin is it resists changes in temperature, pH and enzymatic digestion.[22] The stratum corneum also has a high lipid content that serves as a barrier, slowing the water loss from the subcutaneous spaces simply by the nature of its makeup as the cells are arranged like bricks and mortar.[76] Following injury to the skin there is a marked reduction in the water holding lipid content resulting in a decreased control on thermoregulation. This top layer of skin is constantly shed or abraded with daily mechanical or chemical trauma; such as hand washing and this assists with the release of pathogenic microorganisms which may otherwise become trapped in the skin.[22]

The stratum germinativum or basale is the basal layer or inner most layer and consists of a single layer of cells which continually regenerate. These cells are actively undergoing mitosis and leave the basal layer and begin an upward migration through the stratum spinosum, granulosum and lucidum to the outer stratum corneum layer, a process which can take two to three weeks.[22,74] This migration is stimulated by growth factors (epidermal growth factor and transforming growth factor-alpha), hormones (oestrogen, progesterone and epinephrine) and Vitamin A.[22] Another cell found in the stratum germinativum are Langerhans' cells which are important in the immune function of the skin as they recognise foreign invaders.[22]

Dermis

Within the dermis of the skin are cells called fibroblasts that synthesise and secrete the proteins collagen and elastin. Collagen provides the skin with strength; and elastin

provides it with elasticity.[22] The dermis also contains the cutaneous blood vessels and capillaries that provide oxygen and nutrients to the epidermis, required for the continual regeneration of cells and maintenance of the anatomical structure of the skin (Figure 2).[22,74]

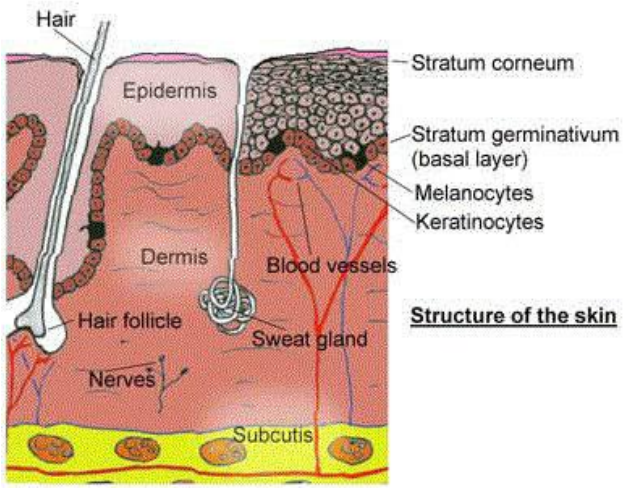

Figure 2 Structure of the skin[77]

Functions of the skin

Skin integrity is vital to maintain the functions of thermoregulation and protection and as depicted in Figure 3 there are many factors that can impact on its ability to provide those functions adequately. The skin also provides metabolic, sensory and communicative functions; however, the thermoregulatory and protective functions will primarily be discussed in detail within the context of this thesis; as well as some consideration of the sensory impact of a wound.

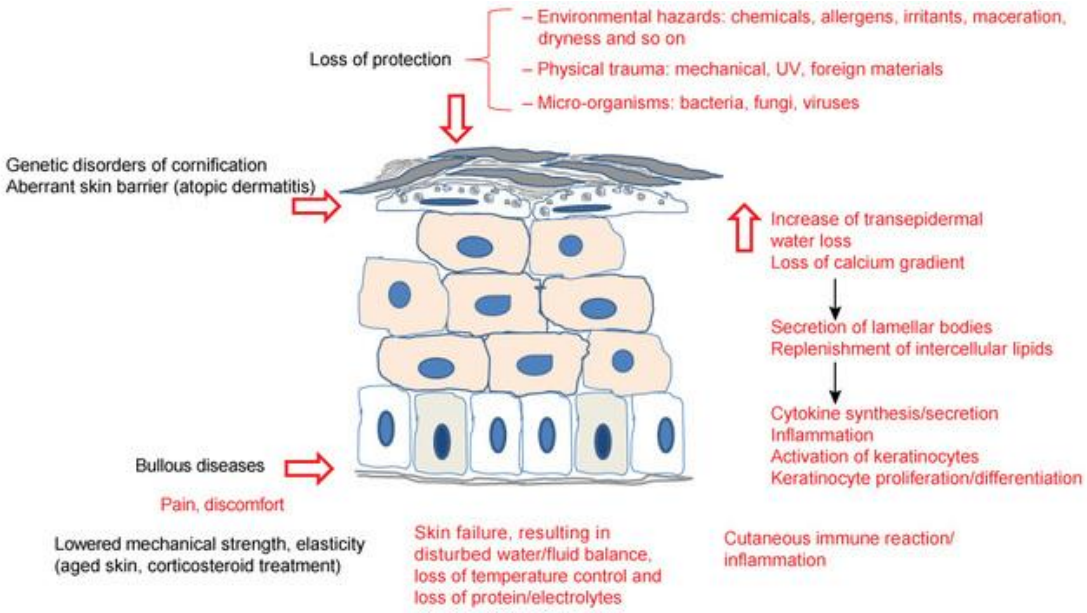

Figure 3 The functions of the skin[78] Reproduced with permission

Thermoregulation

The skin is unique and varies according to endogenous factors such as age, gender, ethnicity, metabolic rate, fever, activity and anatomical region of the body.[21,79,80] Body temperature is maintained by the skin operating as a communication wall between the internal and external environments. Blood vessels will dilate allowing more blood flow to the skin with a subsequent increase in skin temperature with the aim to decrease body heat; alternatively the blood vessels will constrict and move the blood away from the skin to reduce heat loss to underlying body organs. Normal body temperature is relatively constant between 36.2ºC and 37.0ºC dependent on the site it is measured, with hypothermia typically described as a core temperature of less than 36ºC.[21,80-82] In contrast, skin temperature is usually lower than the body temperature and may fluctuate substantially.[83]

The factors already described may impact on the transfer of heat affecting the body and skin temperatures, which in turn initiates the body's temperature regulation mechanisms through convection, conduction, radiation and evaporation (Figure 4).[25,26]

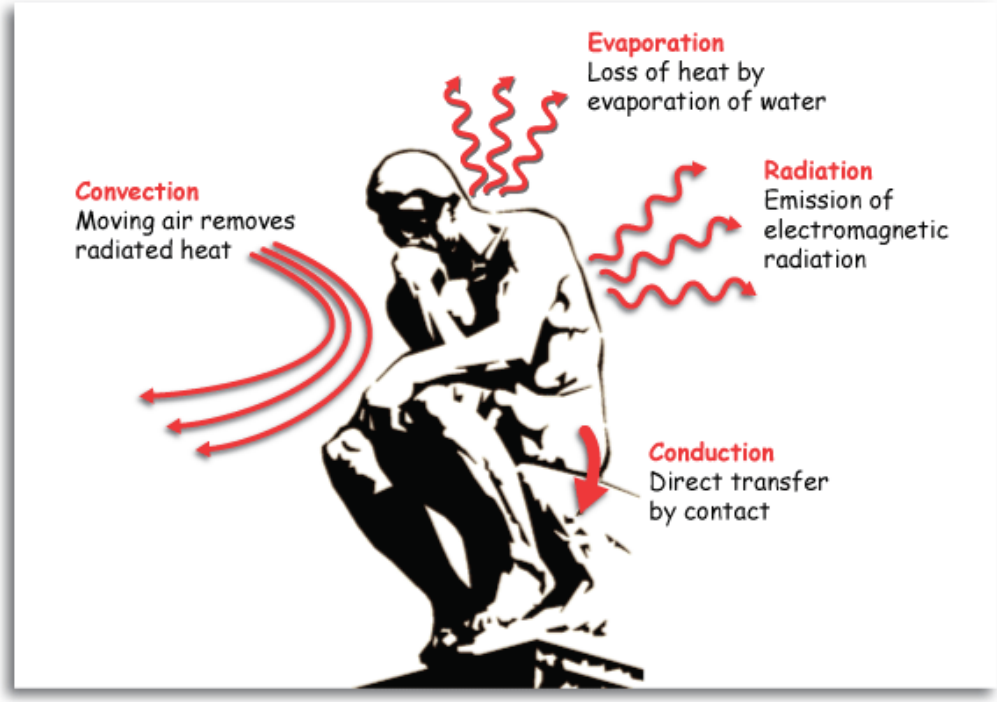

Figure 4 Heat transfer mechanisms[84] Reproduced with permission

The body and skin temperatures are altered by each of these mechanisms in different ways. Conduction is heat transfer through touching another object such as an electric blanket and radiation is heat transfer through infrared rays with no contact, such as from the sun. Convection is heat transfer through the movement of air or water over the skin, such as having a bath or sitting in and air conditioned room; and evaporation is the outward heat transfer through water loss via perspiration.[25-27] Heat transfer in a cool environment for a person at rest is primarily through radiation and convection (75%) with the remainder through evaporation (25%).[85]

In addition to the endogenous factors described, exogenous factors such as ambient temperature (AT), relative humidity (RH) and lighting can influence body and skin temperatures as well.[27,86] The following sections describe the vast number of endogenous/exogenous factors that may impact on the efficiency or effectiveness of each of the heat transfer mechanisms.

Age

Since the time of Hippocrates it has been believed that the older you are, the more hypothermic you become:

> Growing bodies have the most innate heat; they therefore require the most food, for otherwise their bodies are wasted. In old persons the heat is feeble, and therefore they require little fuel, as it were, to the flame, for it would be extinguished by much. On this account, also, fevers in old persons are not equally acute, because their bodies are cold.[87]

Contemporary studies further support Hippocrates' works and state that as a person ages there is a decrease in the number and organisation of small blood vessels which control thermoregulation (significantly more so in the areas exposed to the sun) and the water content of the skin reduces from 20% in young adults, to 10% in the elderly.[76,88-91] Consequently both of these alterations affect the efficiency of an older person's thermoregulation. Lu and Dai (2009) however, dispute the suggestion that 'older is colder' as it is not necessarily true for all older adults and this is supported by a number of other studies.[7,92-94] Hence, there is conflicting evidence on whether older people necessarily have lower temperatures than younger people.

Gender

Lu and Dai (2009), despite having found no connection between temperature and age, did support the view that gender plays a part in the temperature variation of older adults, over both winter and summer with women having a higher temperature than males.[7] However, this is refuted by some researchers,[80,95] and yet supported by others.[96] Although the literature is inconclusive on whether gender plays a defining role in thermoregulatory control there are a number of studies that report thermoregulatory responses are impacted on by specific gender differences.

Women generally have altered thermoregulation in response to hormonal changes associated with ovulation and the use of hormonal medications.[21,27,97] Oestrogen is one of the controlling mechanisms that determines the level of white adipose tissue (WAT) in humans and women also have higher levels of WAT.[16] There is little difference in thermoregulation due to sweat responses between genders, however, the sweat response in males occurs faster and with more intensity than those compared to females.[98,99]

Ethnicity

The issue of race can be a potential variable which should be accounted for when reviewing body temperature. Gillum (1992) found temperatures in children aged 12-17 years were higher in Caucasians compared to dark-skinned people;[100] whereas McGann (1993) found no difference in temperature between races in males, but a higher temperature in dark-skinned females compared to Caucasian women.[95,100] A more recent study by Smith (2003) found that dark-skinned people had significantly higher temperature readings, however, the heterogeneity of the sample needs to be

acknowledged when reviewing any conclusions (Caucasian participants, 85%, compared to dark-skinned participants, 15%).[101]

Zhu (1999) states that darker skinned people have higher skin temperatures due to higher pigmentation levels,[102] which is due to the prevalence of brown adipose tissue (BAT) cells, that contain a higher number of mitochondria which aid in the production of energy and therefore heat production.[16,103] This is supported by Rising (1995) who found temperatures in Pima Indians in comparison to Caucasians was attributed to increased body fat and weight (i.e. WAT tends to store energy in the form of fat rather than use it).[16,27,104] The literature appears to support the fact that ethnicity plays a defining role in thermoregulatory control.

Anatomical position

Variations in surface temperature have been researched since the 1950s with a number of studies reporting a principal pattern to the distribution.[86,102,105] Wyllie and Sutherland (1991) and Kelly (2006) reported that there is up to a five degree difference in the surface temperature of the human body with the trunk being warmer than the limbs.[21,86] In addition to this the temperature on opposite limbs of the body can also differ to each other (Figure 5).

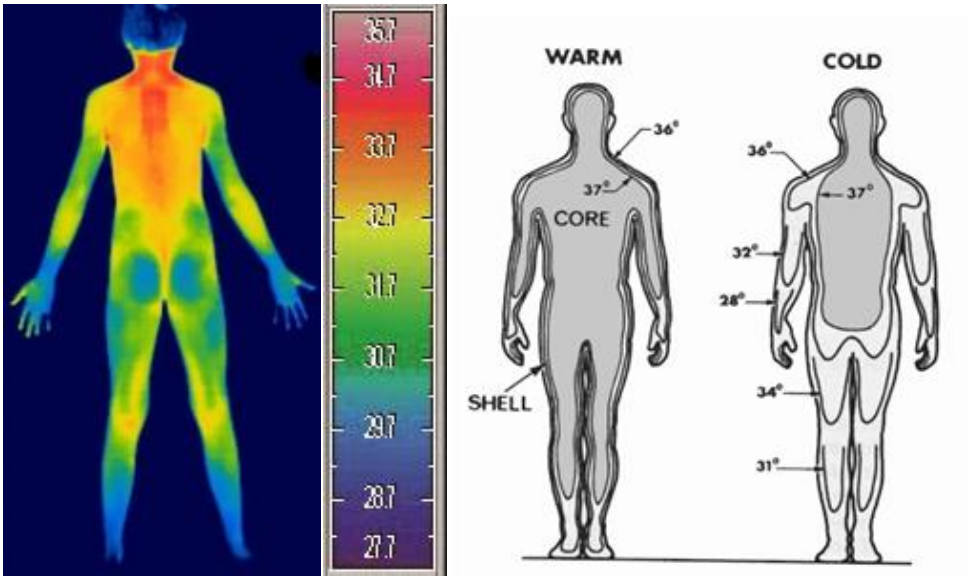

Figure 5 Anatomical variation in surface temperature[106,107]

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This was confirmed by Zhu (1999) and Wu (2007) who stated that the density of capillaries and thickness of the skin can also play a part in the skin temperature at different locations or the site of measurement;[21,83,102] however, Uematsu (1985) states the difference between sides is minimal and therefore more likely to be indicative of a disease process on one side.[108] Hence, the skin temperature of a person can vary and is dependent on the site in which it is taken, and the trunk usually presents as being warmer than the limbs. This is verified by Olesen (1982) who found the mean skin temperature can vary between 31.6°C at an ambient temperature of 23°C to 35.4°C at an ambient temperature of 34°C, with the trunk warmer and the limbs cooler.[109]

Circadian Rhythm

Humans have a 'biological clock' commonly known as a circadian rhythm which regulates the body's biological functions.[18-21] The circadian rhythm responds to changes

to light and darkness in the environment and roughly follows a 24-hour cycle. Subsequently a person's body temperature is usually lowest during sleep and highest in the day time (Figure 6).[19,20] It has also been found the less light there is, the sleepier the person becomes, which then decreases a person's blood temperature.[19,20] The body's temperature can be affected when physical, mental and behavioural changes disturb this sleep-wake cycle. For example, changes in schedules such as with shift workers and flight travel will impact on the circadian rhythm which will take some time to readjust, with each person reacting differently to these changes.[27]

The type of clothing the person is wearing can also influence their circadian rhythm, as the more clothing being worn contributes to a higher temperature due to less heat transfer from loss of convection.[27]

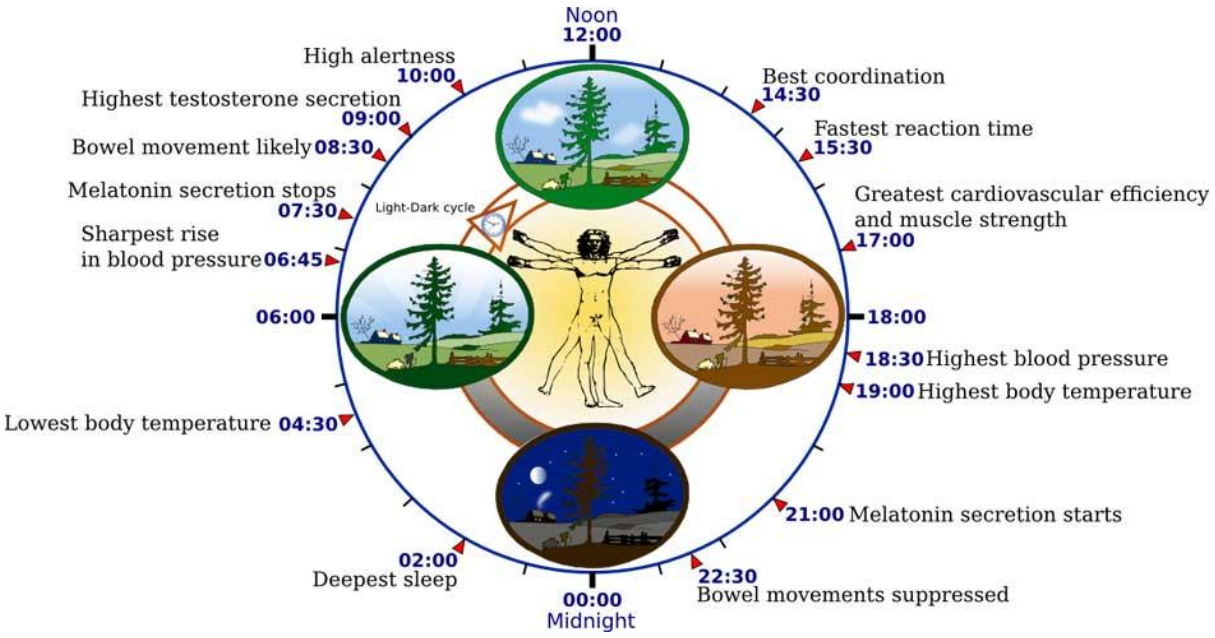

Figure 6 Circadian rhythm[110] Reproduced with permission

Another factor influencing thermoregulation is the basal metabolic rate (BMR). The BMR is the rate at which the body uses energy to perform essential activities and can be affected by a person's activities and current state of health.[13] Simple changes to normal activities such as a patient fasting for many hours can influence the thermoregulatory biological clock, as the heat energy which comes from metabolism of digestion is depleted and hence the body temperature decreases.[27,111,112] It is well documented that as a person ages their BMR decreases and that stress can increase metabolic rates.[13] In addition, those with a lower BMR are found to have a higher body mass index (BMI) which in turn influences the thermoregulatory processes.[113]

An elevated body temperature is known as having a fever or pyrexia. More often than not fevers are associated with pathological processes such as inflammatory diseases or infection.[13,27] Muscle activity through exercise or shivering produces heat and makes the body warmer with strenuous exercise being noted as having the potential to increase a person's body temperature to as high as 40°C.[13] The body sweats in reaction to excessive heat production and heat loss occurs through convection and perspiration to cool the body down.[13] Despite these processes it is noted that peoples' temperatures still fluctuate with the circadian rhythm, however, the 24 hour curve will occur at a higher level.[27]

Ambient temperature and humidity

A number of authors have affirmed that environmental conditions including the AT and RH are important for patient comfort and can influence a person's body temperature.[13,86,114-116] Lu (2009) found a significant relationship between ambient

temperature and oral temperatures especially in those people aged ≥85 years.[7] When the ambient temperature is higher than the body temperature then heat is transferred into the body through radiation, conduction and convection, hence the body's temperature regulation mechanisms are initiated causing the body to perspire and evaporative cooling to take place. People who are obese tend to sweat for longer periods of time in an attempt to regulate their body temperature; hence the TEWL increases as the BMI increases.[76] As the environmental temperature raises the evaporative heat loss becomes higher.[85]

If the ambient temperature is cooler than body temperature, heat is transferred out of the body through radiation, conduction and convection; hence the body's temperature regulation mechanisms are initiated causing the body to shiver increasing the metabolic rate and heating the body. [111,112] Patients complaining of feeling cold or shivering may be hypothermic with a body temperature of less than 36°C.[13]

The ambient temperature of facilities varies between departments, dependent on its function (i.e. within acute care facilities, conditions in the peri-operative area are commonly described in the literature as having a 'typically low' ambient temperature).[117]

Relative humidity (RH) is the most commonly used measure of humidity and is defined as the moisture holding content of the air, with capacity depending on the temperature.[38] The higher the ambient temperature the more capacity it has for holding moisture. As the air temperature varies, there is a change in the water evaporation and air saturation, which in turn leads to a change in air humidity. If the air temperature

drops and the water content remains constant the RH rises and alternatively the higher the temperature the lower the RH.[38] The impact of the RH on the moisture content of the skin has been examined in an animal model which showed a 31% reduction in TEWL when there was exposure to dry air or a lower RH.[76]

Thermoregulation of body temperature may be impacted upon by a number of endogenous factors such as age, gender, ethnicity, metabolic rate and fever, as well as diurnal differences and the anatomical region of the body. In addition the ambient temperature and RH may be contributing factors to thermoregulation changes. Optimal performance of the function of the skin in heat and moisture transfer is reliant on its integrity. The protective function of the skin also depends on undamaged skin to defend the body from invasion of bacteria.

Protection

The skin functions as a barrier protecting the internal organs from exposure to the outside environment, whilst maintaining a homeostatic internal environment. The stratum corneum is an effective barrier as the dead skin cells which are continually shed remove the potentially pathogenic micro-organisms or bacteria on a regular basis.[22,74] The keratinocytes within the stratum corneum resist changes in the pH of the skin, an important factor against the aqueous and chemical assaults it must deal with on a daily basis.[22,74] When the skin surface is occluded a more alkaline pH results due to an increase in the RH and subsequent production of carbon dioxide.[76]

Healthy pH of the surface skin has been reported in the literature as ranging anywhere between 4.0 and 6.5, however, more recent literature defines a pH as being acidic and

between 5.5 and 5.9.[76,118-120] The pH scale is a logarithmic scale that measures the acidity of a substance. A pH of 6.0 is ten times more acidic than a pH of 7.0, and a pH of 5.0 is 100 times more acidic than a pH of 7.0.[36] Hence even relatively small differences in the pH of the skin can impact on its effective function.

As with the body's temperature there have been diurnal differences reported in skin pH.[1,120] In a study by Ehlers (2001) an acidic pH was found on the forearms of participants between 2-4pm (pH 5.44) which became more acidic around 8pm (pH 4.87), however the clinical relevance is not known.[1]

In addition to pH, the skin also provides protection by serving as a barrier and limiting TEWL by ensuring the skin remains intact and well hydrated.[120] An increase in TEWL values indicate impaired barrier function which has been associated with an increase in pH.[120,121] The normal skin range of TEWL is reported to be anywhere from 2 $gm/m^2/hr$ to 20 $gm/m^2/hr$; which is equivalent to less than 40ml/hr.[122-124]. Other values have been adapted from the values described above and are reported as Units with 0-4 interpreted as a very healthy barrier, 5-9 as a healthy barrier, 10-12 as a normal barrier, 13-16 as a strained barrier, and 17-20 as indicating critical condition.[31,125]

As with thermoregulation, the skin pH and TEWL are affected by endogenous factors including the person's age, gender, ethnicity and region. Exogenous factors such as detergents and soaps will impact on both the skin pH and the TEWL as following injury to the skin there is a marked reduction in the water holding lipid content resulting in a decreased control on thermoregulation (Figure 7).

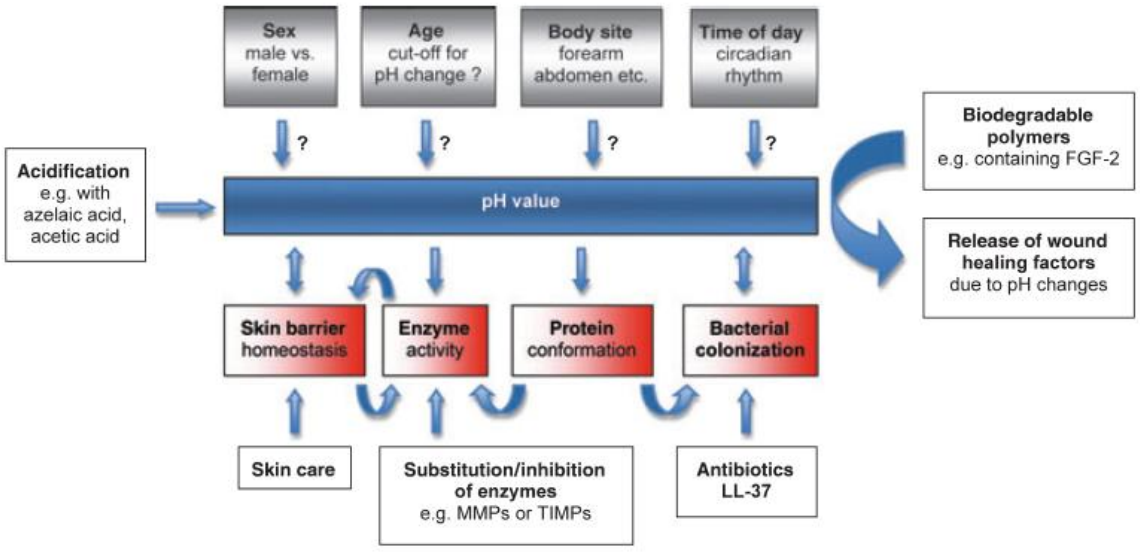

Figure 7 Determining factors of skin pH[126] Reproduced with permission

Age

As people age hormonal changes and disease processes become more abundant.[127] Dao (2007) reports that there are significant changes in the cerumide levels of females as they age, which can alter the skin pH and ultimately increase the potential for infection.[127] Wilhelm (1991) reports a significantly higher pH in only the ankle and forehead of older people, however, the TEWL was significantly lower in the older person in most anatomical areas studied except for the post auricular region and the palm of the hand.[121] The normal aging process may account for many of the altered levels found and any subsequent disruption to the effective function of the skin.[123]

Gender

There are a number of studies with different viewpoints on whether gender impacts on the skin's pH and TEWL. Wilhelm (1991) reports no differences in skin pH between

males and females,[121] whereas Ehlers (2001) stated men have a more alkaline pH than females[1] and other researchers state females have a higher or more alkaline pH than their male counterparts.[128-131]

Both Marples (1982) and Dao (2007) suggest that biochemical processes may lead to a gender related difference in skin pH.[127,132] Males are thought to perspire more than females and sweat ranges from a pH of 5 to 6, with the skin becoming more acidic upon evaporation.[127,129] In addition people who are obese tend to sweat for longer periods of time in an attempt to regulate their body temperature, which in turn increases their skin pH to become more alkaline.[76]

The impact hormones have on thermoregulation has already been discussed, but may also contribute to the more alkaline pH than those reported for males due to a decrease in the thickness of the skin in females.[127,133]

There are a number of studies that support a more alkaline skin pH in females in comparison to males, with some of these being due to natural phenomenon (hormonal) and others unnatural (use of cosmetics).

There are a number of studies which have reviewed the skin TEWL for any associated gender differences, with conflicting results. Wilhelm *et al* (1991) stated there is no difference between genders, which is supported by Jacobi (2005).[121,129] However, Agner *et al* (1991) and Reed *et al* (1993) state subtle differences in the skin TEWL can be attributed to the female menstrual cycle.[134,135]

Ethnicity

There have been minimal studies on ethnicity and skin pH; however the most recent studies state the pH of dark skinned people is lower than for Caucasians.[121,136,137] Warrier *et al* (1996) also describe an association between the number of sweat glands in dark skinned people compared to Caucasians and, as discussed above, sweat ranges from a pH of 5 to 6, with the skin becoming more acidic upon evaporation.[127,129]

The literature has reported no difference when comparisons have been investigated with a number of different races and TEWL.[138-141]

Anatomical position

The literature supports the view that there are minimal anatomical variations in the skin pH. However, Wilhelm *et al* (1991) reported anatomical differences of 100 fold in sebum levels with low levels reported in the limbs and high levels in the forehead and auricular region.[121] The sebaceous glands secrete sebum is a lipid rich oily substance onto the skin providing an acidic coating with a pH of between 4 to 6.8 (mean 5.5).[121] This slightly acidic and natural antibacterial substance retards the growth of micro-organisms and promotes epithelial growth.[22,130,142]

Skin pH has, however, been reported as being alkaline in areas where parts of the skin are in contact with each other (i.e. the armpit),[127] and in another study by Ehlers (2001) it was also found the skin near the wrist had an alkaline pH, however, this was attributed to being close to the hands and undergoing regular hand washing.[1]

The TEWL demonstrates similar patterns to pH with Wilhelm *et al* (1991) reporting the highest values were recorded on the palm of the hand and ankle in younger people due to the supply of eccrine sweat glands in this area; and the forehead and post auricular area in older people.[121] Pinnagoda *et al* (1990) states that the anatomic site does demonstrate a specific pattern, with the following distribution from highest to lowest values: palm, sole, forehead, post auricular skin, nail and dorsum of hand; forearm, upper arm, thigh, chest, abdomen and back.[123]

Circadian rhythm

As with the body's temperature there have been diurnal differences reported in skin pH and TEWL.[1,120] A circadian rhythm was reported for TEWL with the highest water loss noted later in the day at approximately 8pm in both the forehead and forearm.[120] In a study by Ehlers (2001) an acidic pH was found on the forearms of participants between 2 and 4pm (pH 5.44) which became more acidic around 8pm (pH 4.87), however, the clinical relevance is unknown.[1]

Personal products

A number of factors may impact on the skin's moisture barrier including; conditions such as atopic dermatitis;[76] and skin care products such as cosmetics and cleansing

products (including water). Each of these may alter the normal TEWL, as well as altering the skin pH, making it more alkaline.[119,143]

Summary

As described above the protection of the skin may be impacted upon by a number of endogenous factors such as age, gender, ethnicity, metabolic rate and fever, as well as diurnal differences and the anatomical region of the body. In addition the impact of skin conditions and personal products may be contributing factors to changes in the pH and barrier function.

The protective and thermoregulatory features of the skin against endogenous and exogenous assaults has been established, hence the inability of the body to maintain a haemostatic environment when there is a disruption to the normal anatomical structure of the skin due to disease or injury, is an important consideration when managing the wound healing response.

Wounds

Wound healing is a complex milieu that affects millions of people around the world every day.[144] A new wound would initially be classified as 'acute' and depending on the depth or size of the wound, an acute wound will be repaired in a variety of ways. Wounds which are uncomplicated or simple and that can be closed with sutures, tape or staples are stated to heal by primary intention; whereas wounds that require dressings as they are unable to be closed, heal by secondary intention.[145] Occasionally tertiary healing may take place, which is when both of the above methods occur; initially the

wound is treated with dressings (secondary intention) until such time as that it can be closed (primary intention).[145]

Wounds that do not progress through the acute wound healing phases in a timely manner are termed 'chronic' wounds. Reports indicate that 433,000 Australians, 6.5 million Americans, and between 3.55 and 4.5 per 1000 people in countries such as the United Kingdom and India suffer from chronic wounds.[5,144,146] The burden of chronic wounds is an ever growing issue due to the aging population and increasing associated co-morbidities and health care costs.[5,144,146] In order to address these issues it is important to investigate the normal wound healing response, wound aetiology and understand the factors that may impact on the wound healing process.[147]

Wound Healing Response

The literature describes wound healing as a 'complex and dynamic process' with three or four distinct phases involving a methodical series of events, where specialised cells move into the wound site, which results in the restoration of the skin anatomically and functionally.[29]

The initial response to injury resulting in a wound is that it bleeds. Damaged blood vessels release a chemical response alerting platelets to proceed to the injured area.[30] The primary goal of platelets is to prevent haemorrhage by adhering to collagenous fibres of the damaged connective tissue forming a clot, which acts as a patch until the coagulation system enhances the strength of the initial plug (Figure 8 - Picture a).[30] In addition to this system being enacted, other vasoactive substances (histamine and cytokines) are released to vasodilate the blood vessels surrounding the wound. This

allows the inflammatory cells (T lymphocytes, leukocytes, neutrophil granulocytes, and monocytes or macrophages) to reach the wound to cleanse and defend it against infections.[29,30]

Neutrophils are central to the cleansing of the wound and resistance to infection as they facilitate phagocytosis of bacteria. The macrophages migrate into the wounded area with neutrophils and assist not only with wound debridement, but they also play a key role in wound healing with the secretion of growth factors.[30] An increased temperature assists the neutrophils to remain bactericidal against bacteria such as *staphylococcus*.[148]

The second phase of wound healing involves the formation of granulation tissue to fill the wound and resurface the defect (Figure 8 - Picture b). This tissue growth involves the production of collagen assisted by a complex series of events involving leukocytes, histiocytes, plasma cells, mast cells, and in particular fibroblasts.[30]

Fibroblasts are termed resting cells and reside in the dermal tissue until phagocytosis by the macrophages produces amino acids which then stimulate the fibroblasts into action. The main function of fibroblasts is the synthesis of collagen, with the optimum condition for production being in a slightly acidic environment.[22] Blood and lymph vessels regenerate in pre-existing vessels at the edges of the wound (Figure 8 - Picture b).[30]

The wound begins to contract with the edges of the wound migrating inwards and decreasing the surface area of the wound (Figure 8 - Picture c). This occurs with maturation of collagenous fibres being influenced by the myofibroblasts.[30] The granulation tissue strengthens and commences remodelling to form scar tissue. The

final phase in wound healing is the epithelialisation process, which begins mainly at the edges of the wound and involves the formation of new epidermal cells by mitosis and cell migration (Figure 8 - Picture d).[30]

During maturation epidermal cells normally migrate towards the surface of the skin. However, in the wound healing process regenerative cell replacement proceeds sideways, with cell movement in the direction of the adjacent wound edges.[30]

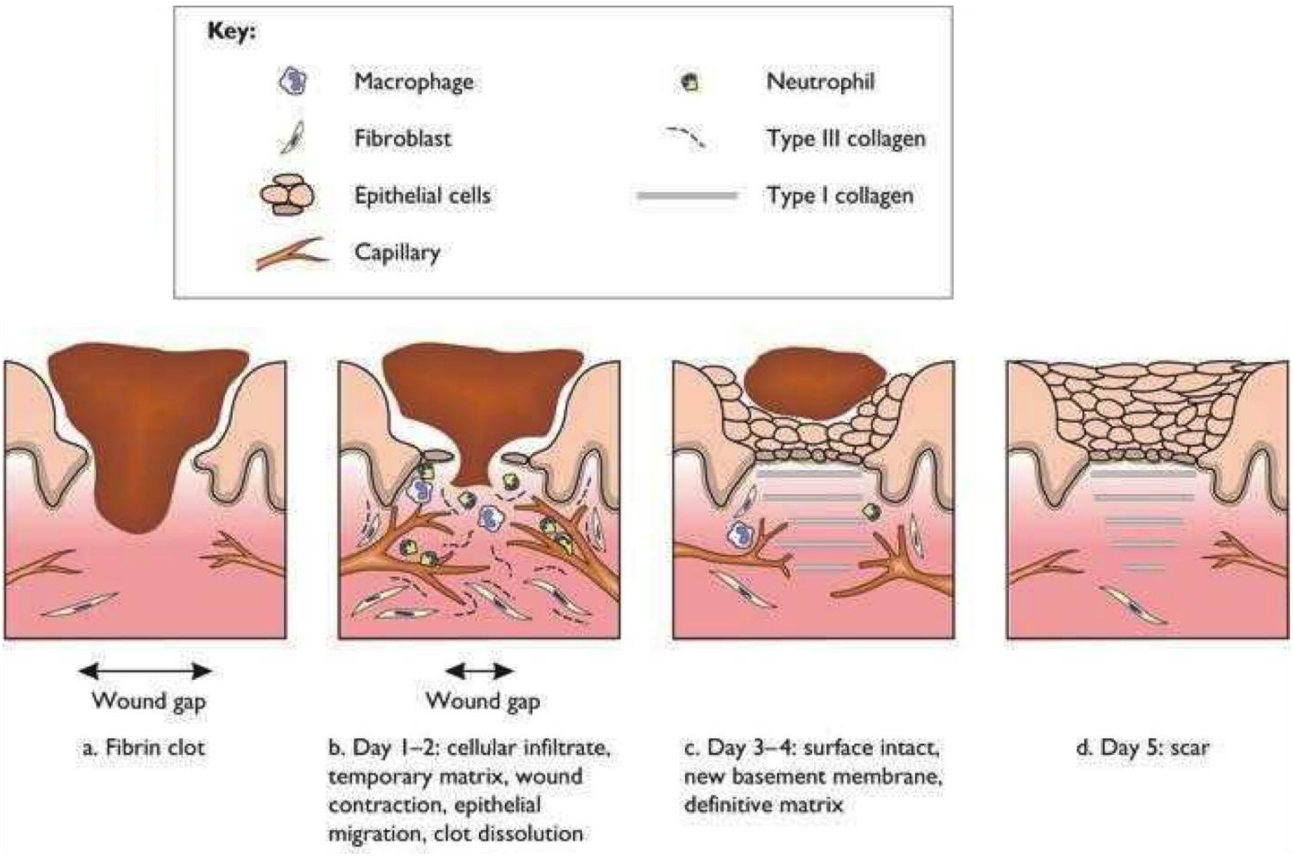

Figure 8 Pictorial representation of wound healing[149] Reproduced with permission

Acute wounds follow the wound healing response and 'heal' within a specific time frame; whereas wounds that do not progress through the acute wound healing phases in a timely manner are termed chronic wounds.[4,5] Wound aetiology needs to be investigated for all wounds that fail to heal.

Wound Aetiology

Before commencing any treatment of a wound and to enable the appropriate management to be commenced, it is important to identify the underlying cause and consider any factors which may impede healing.[88]

The major causes of acute wounds are some form of injury (e.g. burns, trauma or lacerations) and these wounds usually heal by either primary intention or require skin grafting. A chronic wound, however, usually heals by secondary intention and includes pressure ulcers or non-pressure ulcers of arterial, venous, or vasculitic aetiology, as well as acute wounds of other aetiologies that have become chronic as they have remained unhealed for a longer than normal time period.[4,5]

A large number of chronic wounds are preventable and it is important that a full holistic assessment of the patient occurs when establishing the aetiology of the wound as there are usually endogenous or exogenous patient factors which have a had a part to play in the formation of the wound. If these factors are not taken into consideration the wound may not progress from one wound healing phase to another and will then become chronic.[4,5]

Some of the endogenous factors previously described as impacting on the protective and thermoregulatory functions of the skin are important considerations during wound healing. For example, patients diagnosed with diabetes tend to have a poor inflammatory response which may lead to a higher rate of infection; increasing age is well-documented, but still controversial phenomenon; and nutritional status have all been demonstrated to have an effect on wound healing.[88] It has also been suggested that a lower body temperature will increase the risk of surgical site infections and decrease wound healing.[41,150] Exogenous factors which hinder wound healing are mechanical stressors such as unrelieved pressure, friction and shear, steroid medications, stress and environmental temperature.[13,74,86,114-116,127]

Wound healing can be affected by the patients underlying co-morbidities, such as diabetes, circulatory problems, anaemia and the patient's immune status.[88] Many of these co-morbidities will influence the biophysical parameters of a wound.

Once the integrity of the skin has been interrupted the protective and thermoregulatory functions are able to be affected by any exogenous factors to which the patient is exposed. The importance of the temperature, pH and TEWL has been described with changes to these physiological variables within the wound environment being influenced by blood flow, local metabolism and other endogenous/exogenous factors which may ultimately impact on the healing process.[151] Limiting exposure of the wounded skin is vitally important to ensure that the above functions of the skin are maximised.

Wound bed parameters

The wound bed parameters temperature, pH and TEWL are important parameters that assist in the wound healing process. The significance of each parameter and any factors that may influence or alter a parameter outside of the suggested norm will be discussed below.

Wound Temperature and TEWL

There are numerous studies which have reported the benefits of a warm moist environment, including accelerated healing time.[33,152-156] The literature derived mainly from animal research deems a temperature above 33°C to be critical for epithelialisation of a wound[41,157-159] and promotes warm moist wounds to allow newly formed skin cells to move freely across the wound bed.[4]

To ensure that wound temperature is maintained at optimum levels, additional heat loss should be avoided wherever possible. Local cooling of the wound will ultimately affect cellular growth, movement and phagocytosis. If cellular activity and phagocytosis are halted there may be an increase in wound infections ultimately leading to delays in wound healing.[45,82,142,157] Cells and enzymes also function optimally in a moist environment at normal body temperature; hence a loss of skin integrity or development of a wound enables TEWL via evaporation and convection, which in turn cools the tissue temperature.[85] The normal skin range of TEWL is reported to be anywhere from 2 $gm/m^2/hr$ to 20 $gm/m^2/hr$; which is equivalent to less than 40ml/hr.[122-124] The

prevention of evaporative moisture loss through the application of a dressing will aid in reducing this cooling.[153,157]

There are many factors which may play a part in maintaining a constant temperature and appropriate moisture levels, some of which can be controlled by clinicians and others that cannot. The size of the wound, where it is located on the body, the temperature and humidity of the environment and the patient's body temperature may all play an important part in the regulation of wound temperature and TEWL and ultimately impact on the wound healing process.

Wound surface area

Wounds with a greater surface area may lead to a decrease in both body, and wound temperature as the skins thermoregulatory properties are severely impacted and heat production cannot be maintained.[82,160] The surface area of a wound is determined by the length, width and depth of a wound and losses of greater than 300ml/hr have been reported in patients that have been burnt, compared to the normal TEWL which is less than 40ml/hr. The surface area of the wound is proportional to a decrease in wound temperature as the larger the surface area the more evaporative water loss and radiant heat loss will occur as evident in patients with burns and the assessment used for fluid resuscitation.[122,161]

Wound location

McGuiness *et al* (2004) postulate wound location could account for the wound temperatures that were lower than the critical 33ºC in their study as a high percentage

of wounds included in their study were located on patient limbs.[82] This is consistent with the previously discussed anatomical patterns of distribution,[86,102,105] however, no temperatures were taken adjacent to the wound or on the opposite limb to establish if this was in fact the case.[82] Pinnagoda *et al* (1990) clearly states that different anatomical sites have associated TEWL variants, hence wounds can be hypothesised to follow this same pattern of distribution.[123] All wounds are different and those which are located on a similar part of the body do not always possess identical healing activity and usually have rather different outcomes.[79]

Ambient temperature and humidity

Heat loss causing tissue dehydration and cell death can be decreased by maintaining high room temperatures and covering the wounds with dressing products to reduce heat loss.[153,162,163] The energy required by a person to maintain their temperature in a room which is too warm or too cool, or to regain 'normal' temperature after the hypothermia of surgery for example, increases the risk of inadequate perfusion to the healing wound.[122,164] Wyllie (1991) describes taking wound and skin temperature measurements once burn wounds were covered with polyvinyl chloride (PVC) film (Cling film) to avoid alterations in temperature due to evaporative cooling, however, there is no evidence provided to indicate how the author came to that conclusion.[86]

Body temperature

A number of studies have alluded to the fact that body temperature may influence the wound bed temperature, with further studies required to support or refute this suggestion.[82] A study by Allen (1997) reported that the temperature of surface and

peripheral wounds varies depending on the patient's perfusion, and are always lower than body temperature ranging from 29ºC in highly vasoconstricted patients to 39ºC in febrile vasodilated patients.[165] There are minimal studies in humans regarding disruptions to the body temperature and its influence on wound temperature, however, wound healing research has been conducted in mice and zebrafish that has documented disruptions to the circadian clock can impact on the wound repair process.[166,167]

Ensuring the regulation of wound temperature and TEWL is maintained whilst taking into consideration the above factors is an important part of the wound dressing procedure and may ultimately impact on the wound healing process.

Wound surface pH

It has been established that intact skin releases sebum, which provides an acidic coating with a pH anywhere between 4 and 6.5 and that this slightly acidic and natural antibacterial substance provides protective properties which retards the growth of micro-organisms and promotes epithelial growth.[22,142,168]

When the skin is wounded and initially debrided, the pH increases and the wound tends to be neutral or somewhat alkaline with wound surface pH reported as ranging from 5.8 to 6.6.[157] Gethin (2007) further delineates between acute and chronic wounds stating that chronic wounds have a pH of 7.15 to 8.9.[2] As wound epithelialisation is associated with a decrease in pH towards an acidic level, anything that can decrease the surface pH of a chronic wound and make it relatively more acidic is beneficial to wound healing.[2,52,157,168,169]

When tissues become hypoxic there are lower levels of adenosine triphosphate (ATP), which is necessary for cellular metabolism. If hypoxia is prolonged or severe, cells begin to produce lactic acid and as this increases the cellular pH becomes more acidic.[170,171] These findings are consistent with an acidotic, anaerobic environment and confirmed in a study by Trengove (1996) where lactate levels were significantly increased in the wound and serum samples collected.[172,173] During the first week of the skin being injured the wound repair process is subject to lower levels of oxygen and higher levels of carbon dioxide at a time when oxygen availability is paramount to determining the rate and quality of repair.[29] Leveen (1973) found a decrease in pH by at least 0.6 units may increase the amount of oxygen released by almost 50%.[174]

The bactericidal mechanisms of leukocytes and important bactericidal mechanisms in neutrophils are also dependent on adequate oxygenation.[165] Fibroblasts which are important for wound contraction are also reported to migrate faster and better in a mildly acidic environment[142] and increasing levels of lactate having been reported to indirectly stimulate collagen synthesis.[151]

The wound bed parameters need to be maintained at a level that will allow for effective wound healing. Table 3 demonstrates the range of values reported in the literature for each of the wound bed parameters. There are many factors that may influence or alter these wound bed parameters and typically these are controlled through the use of a wound dressing.

Parameter	Temperature	pH	TEWL
Body	36.2 - 37°C		
Skin	depends on anatomical location	4.0-6.5	2 gm/m^2/hr to 20 gm/m^2/hr; = 40ml/hr
Wound	>36°C	5.8-6.6 (acute) 7.15-8.9 (chronic)	> 2 gm/m^2/hr to 20 gm/m^2/hr; >40ml/hr

Table 3 Suggested ranges of skin and wound parameters

Wound Dressings

There are a plethora of wound dressing products available to choose from and the most appropriate product is determined by the wounds characteristics.[175] The type of wound dressing product chosen then determines the frequency of the wound dressing change and how often the wound will be assessed.[171] Advancements in contemporary wound dressing products have resulted in products which actively contribute to the wound healing process as many are designed to maintain wound bed parameters and assist in providing an optimum healing environment.[175]

Dressing materials that maintain a wound at or near body temperature are associated with significantly higher mitotic activity, with the number of dividing cells increased

by 108%,[45] therefore an optimal environment will accelerate healing and promote tissue growth.[153] In a study by McGuiness *et al* (2004) the surface temperatures were measured from the outside of the dressing applied to the wound, both pre and post the dressing change. No significant effect on the surface temperature of the dressing was found, with a number of different dressing products utilised.[82]

There are a number of wound dressing products which are described throughout the literature as having the ability to decrease the wound surface pH, with a mild antibacterial effect as acidic values are reached; these include Allevyn foam,[176] hydrocolloids,[142,177] and Cardesorb.[2] Thomas (1990) established that wound dressing will contribute to the loss of carbon dioxide from the wound and an elevated pH, whereas occlusive dressings prevent the loss of carbon dioxide preventing the wound from becoming more alkaline.[4,178] Gethin and Cowman (2006) reported a decrease in wound size as the wound became more acidic following the application of honey which had a pH of 3.5 units.[179]

The type of dressing chosen by the practitioner to dress the wound can influence the wound bed parameters thermoregulatory and protective functions normally provided by the skin. Each wound dressing also has its own criteria that best supports its use including the frequency of the dressing change (Table 4).

Table 4 List of contemporary wound dressing products and factors that impact on choice[39]

Dressing	Frequency	Parameter	Abilities	Secondary dressing
Low adherent	As required	TEWL	Allow exudate to pass through reduces adherence	Yes
Semipermeable	Several days	TEWL Temperature	Impermeable to fluids and bacteria, permeable to air and water vapour - has specified MVTR Unable to cope with large amounts of exudate	No
Hydrocolloid	Several days	pH TEWL Temperature	Impermeable to air and water vapour Reduce wound pain, rehydrate eschar	Yes
Hydrofibre	Several days	TEWL	Copes with large amounts of exudate	Yes
Hydrogels	Several days	TEWL	Transmit moisture vapour and oxygen - rehydration properties, permeable to bacteria and fluid Unable to cope with large amounts of exudate	Yes
Alginates	Daily	TEWL	Useful in cavities Copes with large amounts of exudate	Yes
Foam	2-3 days	pH TEWL Temperature	Transmit moisture vapour and oxygen and provide thermal insulation Copes with large amounts of exudate	Yes
Antimicrobial dressings	3 days	pH	Decrease the microbial load Reduce local infection	Yes
VAC	3 days	TEWL	Copes with large amounts of exudate	Yes

Wound dressing change

There are many factors which may play a part in maintaining a constant temperature, TEWL and pH throughout the wound dressing change, some of which can be controlled by the clinicians. The frequency of the dressing change, the cleansing solution used, the length of time the wound is exposed to the environment, and the temporary dressing cover applied whilst the wound is awaiting assessment are four such areas that can be controlled and may impact on these wound bed parameters.

Frequency of dressing change

The frequency of a dressing change is an important factor in the maintenance of the wounds biophysical parameters as a temperature decrease of 2ºC is sufficient to affect biological processes.[41,56,88] Invitro studies have concluded that 33ºC is the critical level at which neutrophil, fibroblast and epithelial cell activity decreases.[82] It has been reported by Hermans (1995) that following removal of a dressing for wound cleansing and assessment that leukocytes only regain their normal mitotic activity after four hours,[142] with another paper reporting that a temperature drop during a simple dressing change can take up to four hours to return to normal.[45]

The temperature recovery time reported above is similar to that reported by McGuiness, Vella and Harrison (2004) where it is stated that the average recovery time of wound temperature following a wound dressing change was only 23 minutes, however, the maximum time recorded was over three hours.[82] The average dressing change in their study took eleven minutes which would imply that there was no delay in redressing the

wound i.e. the dressing was removed from the wound, the wound cleaned and then the wound redressed.

However, in contrast a study by Page (2003) found the average length of time it took to complete a wound dressing change was 103 minutes.[61] There were significant delays in many of the wound dressing changes, as the wound dressings were removed to allow an assessment of the wound by health professionals and then redressed following that review.[61] The combination of the frequency of dressing changes and the time taken to redress the wound could delay wound healing.[61,81]

Cleansing solution

The use of warmed saline to cleanse the wound during the wound dressing change procedure has been reported to decrease the drop in wound temperature experienced during the wound dressing change, however, it did not totally diminish a reduction in wound temperature.[81,82,180]

Wound Exposure

Currently the impact on the temperature and TEWL of wounds being exposed during the wound dressing change for lengthy periods remains unclear. The impact of wound exposure to the environment originally investigated by Winter (1963) found that wounds on young domestic pigs healed faster when covered with plastic film, as compared to air-exposed wounds.[45,142,181]

This is reinforced by Herman's (1995) who states the number of Polymorphonuclear leukocytes (PMNS) one of the most important defences against infection is decreased

in the presence of a scab compared to a wound that is covered with an occlusive dressing. Hence, providing an environment conducive to these cells surviving is of major importance.[142]

It is also thought that wound dressings may reduce local cooling of the wound by preventing moisture and heat loss.[157] This claim is supported by Caldwell, Wallace and Cone (1994) who randomised participants with burns to receive application of dressings or no dressing, in an environment where they were subjected to a range of ambient temperatures with and without electromagnetic heat adjustment.[160] Using external heating and dressings decreased the heat loss from the wound, with a mean fall in body temperature of 0.5°C, therefore helping to maintain the participant's body temperature.[160,182] Another study by Shiozaki (1995) investigated the relationship between mean change in body temperature and the time taken to complete the dressing change and found no correlation.[182]

More recent research has demonstrated that local warming also increases wound healing with a faster reduction in the mean surface area.[82] An increase in wound temperature to 40ºC has been demonstrated to increase the phagocytosis and oxygen consumption of leukocytes. As these are immune cells this increases the ability of the cells to rid the wound of possible infectious agents.[81] McGuiness *et al* (2004) state that it would be fair to assume that warming wounds would result in increases in the blood flow, oxygen tension, collagen deposition and immune cell function which would lead to an improvement in wound healing.[82]

Wounds which are exposed to extreme heats greater than 42°C however, also have decreased cellular activity.[51,56,183] Therefore, wound healing is delayed when temperatures decrease below the body temperature of 36ºC or above 42ºC.[56,82]

Exposure of a wound to air for prolonged periods of time will also jeopardise the protective properties of the wound bed as it becomes more alkaline.[142] Gethin (2007) reports that pH readings have been recorded in previous studies to determine the wound surface pH. However, this was done as the dressing was removed and Gethin states that any prolonged exposure of the wound to the atmosphere could nullify results due to the loss of carbon dioxide which may influence the temperature, TEWL and pH of the wound bed.[2]

Temporary dressings

Limiting exposure of the wound bed during the wound assessment process is vitally important to ensure that the thermal, hydrating and protective properties are maximised. The wound should be covered with an appropriate temporary dressing. In the study by Page (2003) the temporary dressings applied to wounds included: cotton sterile towels, plastic wrap, gauze, the original primary dressing (removed and replaced) and in some cases no dressing at all.[61]

The frequency of wound dressing changes and the length of time it takes to complete the wound dressing change may result in a substantial drop in wound temperature, such as the 0.5°C mean fall reported by Shiozaki (1995) on patients with burn injuries. The fall in body temperature and varying times to thermal recovery may ultimately delay

wound healing.[82] MacLellan (2000) states that 'the wound should therefore be insulated and not left exposed to the environment for longer than necessary'.[88]

Prolonged dressing changes expose the wound to environmental conditions, enabling changes to the wound bed parameters and the subsequent risk of introduction of pathogens.

Microbiology

In addition to keeping the wound warm and moist, dressings provide a physical barrier to microorganisms which are imperative to reduce the risk of wound contamination.[184,185] Any delay in dressing a wound could enable the introduction of microbes to the wound. This in turn may lead to colonisation and possible invasion by potential pathogens, however, the abundance and diversity of microorganisms in any wound will be influenced by factors such as wound type, depth, location, and the level of tissue perfusion as previously discussed.[23]

A wound covered with dry gauze or a material towel may also disperse millions of airborne bacteria when removed from a wound, whereas occlusive dressings have been shown to minimise such bacterial 'spray' into the environment therefore lowering the risk of cross contamination.[142] In addition microorganisms pass easily through moist gauze dressings, whereas occlusive dressings can create a bacterial barrier, thus protecting a wound left with no dressing or wrapped in cotton sterile towels.[32,61,142,155,186,187]

Whatever dressing covering is applied, whether for a couple of days or a couple of minutes it should be an effective barrier to secondary contamination from pathogenic organisms from the patient's environment.[184,185] If a dressing has evidence of 'strike through' the chances of secondary contamination are greatly increased as a wet-path is established to the wound surface. [184,185] Organisms, such as *pseudomonas pyocyanea* and *bacillus proteas* are motile and able to pass through a thickness of material with strike through in a matter of hours,[185] however, increased levels of wound exudate may promote bacterial wound colonisation, but there is little evidence to demonstrate that this increases the risk of infection.[188]

A wound with no dressing or an ineffective dressing in situ for prolonged periods of time may be at increased risk of contamination and should be dressed appropriately.[32-34,45,58,142,170,185,189-195] The literature suggests that a wound dressing change should take the least amount of time possible to minimise changes to the local wound environment.[189,190]

This raises the question as to how long can a wound be left exposed during dressing changes. Harding (2000) stated that the most obvious response was 'that a wound should be left exposed for the minimum amount of time necessary for appropriate interventions to be carried out'.[189] Harding (2000) also stated that although studies investigating cell culture and animal studies; as well as the much quoted work of Lock (1979) may provide useful indicators as to the length of time a wound can be exposed, it may not necessarily equate to the clinical situation.[189]

Lengthy waits for dressing changes is a common scenario reported by both Page (2003) and McNicol (n.d.) that can negatively affect the wound care experience for patients.[61,81] As previously discussed the functions of the skin are compromised as it is wounded allowing inconsistent regulation of the patient's biochemical wound environment by both exogenous and endogenous factors. In addition to this, the negative impact on the patient themselves is an important issue to be considered.

The patient experience

Wound dressing changes impact on the patient in a number of ways. In particular there is an increasing amount of literature in relation to pain before, during and after wound dressing changes.[184,186,187] A wound dressing change can be painful as nerve endings that are intact but exposed in partial-thickness wounds are sensitive to pain and some literature states the greater the surface area of the wound, the more painful it is.[196,197] That, coupled with the fact that wounds are being left exposed for up to 103 minutes as previously described, may impact even more so on their pain levels.[63] Ensuring the nerve endings are covered with a dressing will assist in reducing the levels of pain experienced by a person.[196,198,199]

In addition to the pain, the impact of the wound dressing change on the patient's ability to perform activities of daily living has been described by Solowiej[200] and is supported by anecdotal reports from Page, as impeding the ability of the patient to toilet, bathe and eat.[61] The ability to go to the toilet as required, eat a meal when it arrives and shower when it suits are daily activities as important to a person as a healing wound and there is a call for them to be further investigated.

Conclusion

Optimal healing requires favourable local conditions of the biophysical wound parameters of moisture, temperature, bacterial contamination and pH.[157] In addition the impact of the wound dressing change on patient pain, comfort and activities of daily living are a part of the holistic approach to patient care.

Wound care practices can and must be optimised. Wound care has been revolutionised in the last couple of decades, with the change from outdated 'wet-dry dressing technique' to the moist wound concept of healing. Clinicians must understand the process of wound repair and adhere to the evidence based principles of wound management to ensure wound healing is optimised.[88]

In 1974 Hunt stated

> …only a few years prior, the idea that physiological processes were important in repair on an hour-by-hour, or minute-by-minute basis was almost unthinkable.[201]

However, a review of more contemporary literature has demonstrated it is imperative that something as simple as the time taken to undertake a dressing change could be quite detrimental to the wounds environment and its ability to maintain an optimal state to facilitate wound healing.

The prevalence and incidence of chronic wounds warrants the investigation of how prolonged exposure of wounds impacts on the wound parameters as well as patient comfort.

Chapter Three - Methods

Introduction

The plan was to investigate the effect of prolonged wound exposure on the wound bed parameter values. In addition, these values were explored for any relationships. In order for these goals to be achieved a descriptive correlational study was undertaken. The research question and aims of the study directed the data to be collected ensuring the use of reliable and valid measures, whilst enabling a robust analysis of the data to be performed. A key part of the study was ensuring that ethical issues were maintained and that the data collection process was followed exactly for each case.

Research question (s)

There are a number of studies which have demonstrated that changes in the parameters of the wounds microenvironment, such as temperature, TEWL and pH have an impact on wound healing.[33,34,45,56,57,142,145,153,170,190,192,202-204] However, there is limited research on the effect of the down time (time between dressing removal and dressing reapplication) during dressing changes on these parameters as well as the risk of contamination of the wound through prolonged exposure.[33,34,45,58,142,170,185,189-195] In addition anecdotal reports from discussions at international conferences would suggest that the time taken to redress a wound or 'down time' is not routinely considered in current clinical practice, which the literature supports as patient comfort is indicated to be a low priority when wounds are being redressed.[58,153,170,196,205]

The overarching research question ‘Are local wound conditions and patient comfort affected by the down time taken in association with a wound dressing change?’ was investigated and further explored through the specific aims of the study, which included:

- How do the wound bed conditions of pH, temperature, TEWL and bacterial levels change during the down time of dressing changes?
- Are there any patterns of change associated with each of the wound bed conditions and the length of down time?
- Is there a relationship between the patterns of change and the type or size of the wound?
- Is the participant’s body temperature a confounding variable in relation to any changes in wound temperature because of dressing down time?
- Does the type of temporary dressing applied during the down time impact on the wound bed conditions of pH, temperature, TEWL and bacterial levels?
- What is the impact on participant’s comfort is during a wound dressing change with extended down time?

Research Design

Descriptive Correlation Design

The literature reviewed in the previous chapter clearly demonstrated that there are gaps in relation to the aims of the study. The most appropriate design for this study was a descriptive, correlational design with the aim to explore and explain what happens to the temperature, pH and TEWL of each participant's wound microenvironment during the down time of the wound dressing procedure. In addition the participant's pain and comfort; and any potential contamination during the down time of the wound dressing change were investigated.

The progression of research in the study moved from purely descriptive to explanatory and finishes by indicating how the outcomes can be used to inform practice. The appropriate design was therefore dictated by this progression and consequently the nature of the observations meant the participants were not randomised.

A correlational study was appropriate because relationships were proposed between two or more variables where the data was assembled to look for relationships.[206] The preceding research in this area had been purely descriptive, however, within this study the researcher sought to identify a relationship between time and temperature, pH and TEWL. In addition, it aimed to identify if there were there any differences in the previous associations in relation to the aetiology of the wound or the size of the wound? Hence the study was conducted using a combined descriptive, correlational design.

Setting

The setting chosen included all non-critical care wards and outpatient areas of a large tertiary hospital in South Australia. The study was not restricted to areas of the hospital that would predominantly have patients admitted or seen with open wounds, as it is well known that many patients within public health systems are often placed as 'outliers' (in other departments' wards) due to issues such as lack of bed availability.[207]

The setting was a 600 bed organisation stratified into six distinct services: Surgical Specialties, Orthopaedic and Trauma Service, Cancer Centre, Internal Medicine Service, Cardiovascular Service and Emergency and Diagnostics. A total of 22 wards, two outpatient areas and two ambulatory care units within these services were available for recruitment. Staff attending to patient wound care within these services were predominantly nursing staff, however, medical and allied health staff do occasionally attend to wound care at times as well. The hospital has approximately 1,000 nursing staff at any time and the average length of stay per patient is six days.[208]

Participants

Population

The population included any patient admitted to non-critical care units of the setting with an open wound. Due to the nature of the research, the population could not be determined without the assistance of the staff to identify those patients with an open wound. Following this the number of wounds the patient had, the size of the wound and the state of the microenvironment had to be ascertained before the patient could be

asked if they would consent to be involved in the study. In addition, data could only be collected on one participant at any one time, as there was only one set of data collection tools due to the cost of the instruments; hence randomisation of participants was not practical or feasible.

Sample

Purposive sampling was utilised to draw a sample from the target population. In quantitative studies purposive sampling may result in biases, however, if the sample is representative of the topic being investigated it remains valid for the population being studied and can still provide reliable and robust data.[209,210]

The sample in this case pertained to a specific group of participants who had open wounds. This sampling process ensured the researcher could strategically draw a representative sample from the population who met the inclusion criteria. This in turn facilitated a stronger position upon which to draw conclusions from the sample findings and then generalise these findings to the wider population.[206,211,212]

Participants were selected from the total population who had their wound dressing removed for an assessment process. Staff working in the study setting usually identified potential participants for the study. One of the issues with this was the reliance on staff in the research setting advising of possible participants and when the dressing would be being assessed.

Determination of sample size

The size of the sample was determined by a power analysis with the assistance of a statistician and using data from a previous study which reviewed wound temperatures where a mean decrease of 2.7°C occurred during the dressing change and used the differences in means to determine the sample size required.[82] Power analysis assists the researcher to determine how large a difference in means is likely to be observed.[211] If a large difference in means is encountered a smaller sample is able to ensure that differences will be uncovered through data collection.[211] The aim of the study was to see what was happening in clinical practice. The statistician predicted a significant amount of data collection due to the complexity of the method, the number of variables being investigated and the multiple measurements being collected, hence a small number of participants were deemed appropriate. A sample size of 12 was determined to have 90% power to detect a difference in means of 2.7°C, assuming a standard deviation of 2.53°C. This determination was made based on the use of a paired t-test with a 0.05 two-tailed significance level.

Additional relationships between the temperature, pH and TEWL; the size of the participants wound; wound type (pressure ulcer, non-pressure ulcer, wound breakdown or traumatic wound) and the 'temporary dressing' applied during the assessment process were also collected to allow further analysis. The power analysis determined the sample size by detecting a difference in means using only the temperature parameter as there were no additional studies with pH and TEWL data.

Study population

Inclusion criteria

Participants were included in the study if they:

- Had no more than three open wounds (pressure ulcer, non-pressure ulcer, wound breakdown or traumatic wound), between $2cm^2$ and $60cm^2$ in surface area, requiring a dressing change by nursing or medical staff
- Had a wound for which the dressing was removed and was not redressed immediately, thus a period of down time was anticipated e.g. due to assessment by health care team
- Gave informed consent to participate in the study

Exclusion criteria

Participants were excluded from the study if they:

- Did not give consent to participate in the study
- Were unable to give informed consent
- Were non-English speaking
- Had more than three wounds
- Were already involved in other studies

- Had a wound where the centre was unable to be identified for the probe to be placed
- Had a wound which was smaller than $2cm^2$ or larger than $60cm^2$ in surface area
- Had a wound which was clinically infected
- Had a wound which was not a pressure ulcer, non-pressure ulcer, wound breakdown or traumatic wound (i.e. burn)

If the participant or guardian was unable to give informed consent, the subject was excluded from participating in the study, as ethically a researcher is bound to explain all aspects of the research including anonymity, expectations and right to withdraw. In addition participants were excluded if they were non-English speaking, due to costs associated with interpretation.

The initial inclusion criteria stated that participants should only have one wound. The definition of a wound is one where the function of the skin is impaired, following damage subsequent to an injury or underlying disease process.[70,71] However, this was adjusted after a number of weeks as it was discovered that many potential participants had secondary and subsequent wounds; such as a skin tear or a donor site taken ready to repair the primary wound. Hence, the inclusion criteria were modified to state that the participants could have no more than three wounds. None of the participants used in the study had more than one open wound that met the inclusion criteria. If the participant was already involved in other studies they were also excluded, in case the research studies were unintentionally at cross purposes to each other as well as exhausting to the participant. Additional exclusion criteria included participants admitted to critical care

areas, as it was deemed consent was unlikely to be obtained and the research may trigger further stress for the participants and families.

To ensure accuracy with repeated probe placement throughout the measurement period it was necessary to determine the centre of the wound. The size of the open wound was also specified, as there would be inherent difficulties obtaining an accurate measurement from the centre of wounds that were smaller than $2cm^2$. Wounds which were greater than $60cm^2$ would possibly have required additional measurements than just at the centre of the wound as wound temperatures can depend on the anatomical position of the wound and any impeding inflammation or vascular insufficiency.[21,83,102]

If the participant's wounds had a clinical infection they were also excluded as this may well have an impact on the temperature of the wound and/or the body temperature of the participant and could therefore bias the outcomes. Clinical infection was defined as the presence of at least *one* of the following:

> 1. Purulent drainage, with or without laboratory confirmation, from the wound; 2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the wound; 3. At least one of the following signs or symptoms of infection: increased pain or tenderness, localized swelling, redness, or heat from the wound.[34]

In addition it was determined that if the participant had a nosocomial infection and was isolated they would also be excluded. The data collection process required a large amount of equipment, both handheld and electronic which was required to be as close to the participant as possible for the data process to occur. The hospital's policy with regard to isolated patients is to minimise the amount of equipment entering rooms.[213,214]

The additional cleaning requirements made the cleansing operation too difficult and risk of transference of any microorganisms too great.

Recruitment strategies

At the commencement of the data collection period all non-critical care wards and outpatient areas within the setting were visited by the researcher to inform the health care teams about the research. Subsequent to this the researcher visited these areas to review the total population and identify any possible participants who could be included.

Participant's medical records were then reviewed to confirm if each did have an open wound and met the inclusion criteria. If the participant met the inclusion criteria the nurse caring for them advised them of the study and ascertained their readiness to be involved. The researcher then organised a convenient time to discuss the study at more length with the participant. At the initial contact the purpose of the research was explained to the participant and a written information sheet provided. At this time written consent was requested once the participant understood the purpose of the research and had verbally agreed to be involved. Once consent had been freely given, the participant was assigned a code number to ensure anonymity of data collected.

Staff were requested to notify the researcher when a participant's wound was going to be reviewed by the health care team and the dressing removed. As a reminder an A4 sheet was placed in the front of the participants patient care record stating that the participant was included in the study and to notify the researcher (Appendix 1).

Recruitment was an on-going process throughout the data collection period. To assist in the identification of new participants, a daily report which listed new patients admitted to the organisation on the previous day was obtained. The setting also had two wound specialists; a wound care nurse and a vascular care nurse. As a backup to the recruitment process both of these nurses were contacted and asked to notify the researcher of any suitable participants which they came across in their daily visits.

Data could only be collected on one participant per day due to instrument calibration and reprocessing requirements. Each day the researcher identified if there were any participants scheduled to have their wound dressing changed for review by the health care team. If a wound dressing change was going to be conducted the staff member allocated to that participant was approached by the researcher and asked what time the wound dressing change was going to commence. This allowed the researcher to set up the equipment well in advance of the commencement time and to limit any impact on the dressing procedure or delay the staff member who needed to remove the dressing.

If on any given day there was more than one participant who had consented to participate in the study having their dressing removed for assessment by a health care worker there was a number of criteria which determined which was included. The participant to be included was initially selected by the time their dressing was removed, the participant whose dressing was coming down first was chosen. This also allowed for any unforeseen issues with the participant chosen (i.e. dressing removal too painful and they decided to withdraw from the study) and would allow the researcher time to utilise the alternative participant before their dressing was removed and still be able to complete data collection that day.

If no new participants were identified as having dressing removal for assessment on any one day the researcher visited the wards, firstly where participants had previously consented to the study and secondly where it was known that there was a medical round that day, to ascertain if any wound dressing changes were in fact being taken down for assessment that day.

Ethical issues

Ethical approval was initially obtained from the Human Research Ethics Committee of the Royal Adelaide Hospital on the 13th July, 2005, Protocol number 050420a (Version 2) with subsequent approval Version 3 due to changes in inclusion criteria gained on 24 January, 2007. Approval to conduct the study in the various service units was obtained from each Director of the Unit, as well as the Nursing Director of the Service. Information sessions were then undertaken at ward level with the nursing staff prior to any data collection. All participants who fitted the inclusion criteria were advised of the study by the nurse. The nature and the purpose of the research were then carefully and fully explained to each participant verbally by the researcher and a written information sheet provided (Appendix 2).

The participant was informed that they would not directly benefit from taking part in the trial and that, while information gained during the study may be published, they would remain anonymous and any personal results would remain confidential. The participant was also informed that they could withdraw from the study at any stage and that this would not affect their medical care, then or in the future. They were given the opportunity to discuss taking part in the investigation with a family member or friend.

The name and contact number of the researcher was provided in case the participants had any questions. The participants were asked to sign a consent form prior to being entered into the study (Appendix 3).

Once the participant consented to participate in the study they were not formally enrolled in the study until a dressing change was being performed for assessment purposes. Data were only collected when a dressing episode involved assessment and prolonged 'down time' and data collection only occurred on one occasion for each participant.

All data will remain confidential and participant privacy maintained. Each participant was allocated a number to de-identify the data. The consent forms and any other identifying material were scanned and will be kept in a password protected file on a secure server for at least fifteen years.

Protocol

Keeping the conditions of the study constant and establishing specific sampling criteria are important in controlling for any bias.[206] The different types of controls exercised within this study and referred to in the following text include the inclusion and exclusion criteria, the specified data collection format to be followed and the calibration of instruments used.

Data specific to each dressing episode were obtained including:

- Reason for dressing change

- Time the wound was exposed (the time the dressing was removed from the participants wound until the wound was recovered with a dressing)

- Temporary covering applied to the wound whilst awaiting assessment by the health care team

- The type of dressing reapplied to the participants wound (Appendix 4)

Demographic data were also collected by the researcher for each participant including; i.e. age, gender, identification number, and co-morbidities (Appendix 5).

Procedure

Once the participant was identified as requiring wound assessment by the health care team the following procedure was followed for all wound dressings identified and taken down for assessment. This description of the procedure demonstrates the 'control' applied by the researcher to minimise bias during the data collection.

1. The ambient temperature and humidity of the room were recorded as well as the body temperature of the participant.

2. An agar plate was opened immediately the wound dressing was removed and the time noted. A piece of Velcro was adhered to a small piece of hydrocolloid and to the agar plate allowing the agar plate to be adhered to the participants skin, close to the wound without risk of the plate tipping or harm to the participants skin. Wounds in areas where the hydrocolloid was unable to be

applied (i.e. head/face) involved the agar plate being positioned as close as possible to the wound.

3. The stop watch was started immediately the dressing was removed.

4. Using a non-invasive technique, the measuring probes were applied to the surface of the wound for the minimal amount of time possible to allow for a clinical reading to be obtained. The following order of probe placement was followed for the duration of the recordings:

    a. TEWL

    b. pH

    c. Temperature

To ensure the data were recorded accurately this order of data collection was chosen as both the pH and temperature measurements were obtained within a few seconds of applying the probe to the wound but had to be individually recorded on paper following the collection of all the data. The TEWL had a response time of 30 seconds; however this result was automatically recorded on a computer.

These three measurements were then taken at five minute intervals (from commencement of the temperature measurement) for the first thirty minutes and then fifteen minutely until the staff commenced reapplication of the primary wound dressing.

5. A photo was taken of the participant's wound and a wound tracing completed during the course of the data collection.

6. Once the dressing was reapplied, the time was noted and the stopwatch stopped. The agar plate was sealed, the ambient temperature and humidity were recorded and the participant's body temperature was taken.

7. Once the participants wound had been covered the participant questionnaire was completed (Appendix 6).

During the course of the assessment, any temporary covering applied to the wound was documented.

A clinical assessment of the wound including size, depth, erythema (degree of redness of the skin), discharge (the amount and type i.e. serous), and colour (pink, red yellow, green, black) was noted and documented on the study settings standard wound monitoring assessment form (Appendix 7*).* The photo of each participant's wound was taken to assist the researcher in identifying which wound 'belonged' to which participant at the end of the data collection process and for discussion purposes within the thesis.

Follow up

1. A request form was completed and the agar plate was sent to the laboratory

2. Visitrak™ was used to determine the surface area of the wound from the wound tracing

3. All equipment was cleaned or reprocessed as per infection control guidelines

4. Data were entered into Statistical Package for the Social Sciences (SPSS)

The following flowchart (Figure 9 Data collection flowchart) details the data collection procedure followed, as discussed above, for each wound dressing changes that was assessed.

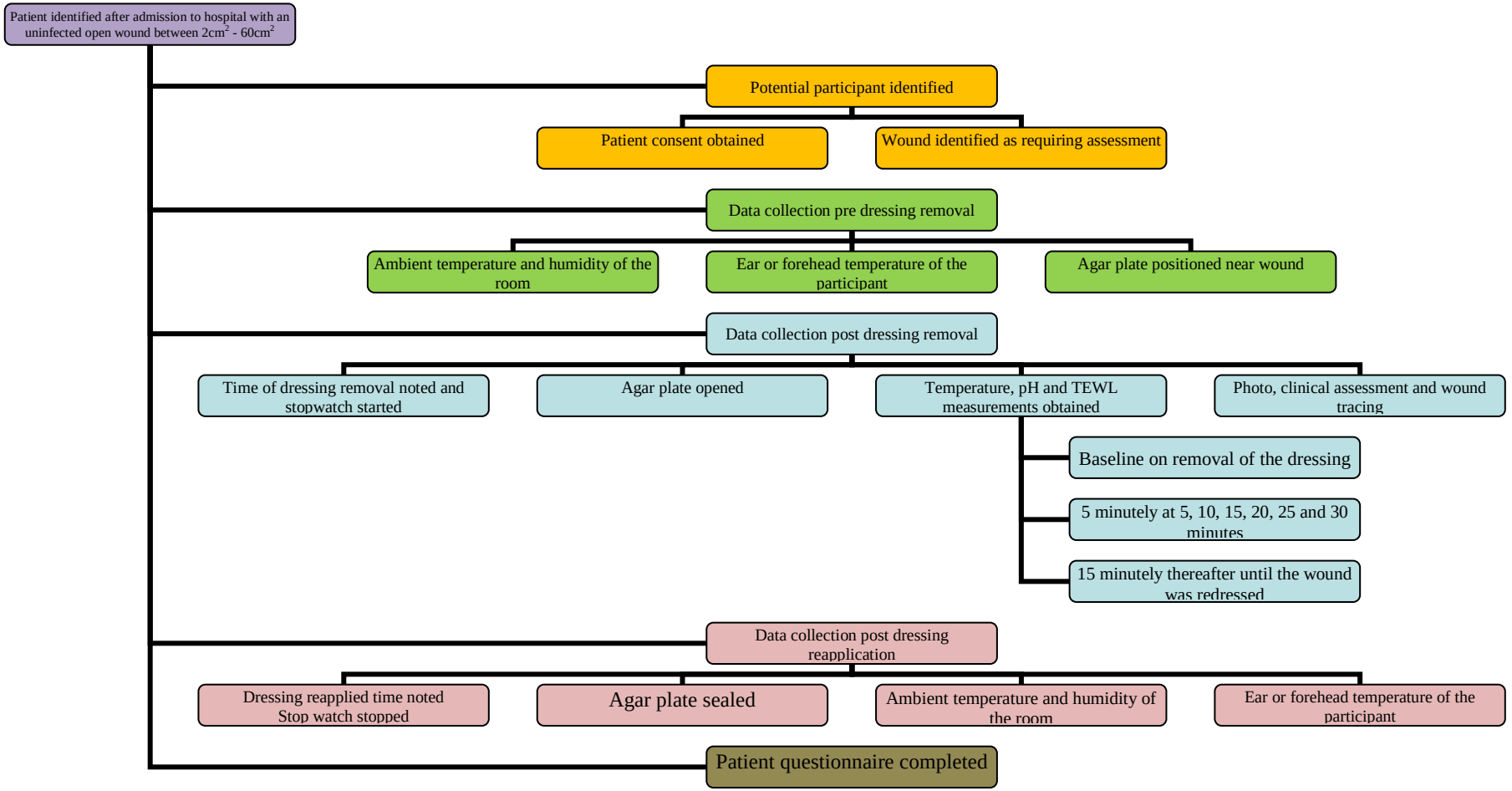

Figure 9 Data collection flowchart

Validity

Addressing issues which may compromise the internal or external validity of a study is a process usually more applicable to experimental studies, however, should be considered for all studies as this will only increase the soundness and robustness of the study.[211] Multiple instruments were used within this study and ensuring each instrument accurately measures what it is supposed to measure is discussed within the 'instrument section' of this chapter. [211]

Reliability

Researcher inaccuracy may contribute to whether random errors occur during data collection. Random errors could include inaccurate measurements which impact on the results.[206] This was made less likely with only one data collector.[215] The flowchart described previously was used to ensure maximum reliability of the data collected via the instruments.[215,216] However, the researcher's judgement on when to start and stop the timer could have been a source of researcher error, and this could have impacted on the time between measurements and the overall length of time that data collection took and be a possible threat to the reliability of the study.

The reliability of an instrument is the extent to which it yields the same results on repeated measures.[215,217] To ensure stability of an individual instrument, similar results need to be obtained on repeated administration of the instrument.[215,217] All of the instruments (except the questionnaire) used had been assessed for reliability prior to the instruments being purchased. The reliability of each instrument is discussed in more detail in the following text.

Instruments

The validity, reliability and reprocessing requirements, of each instrument will be considered in the discussion on the use of each instrument. No foreseeable risks to participants were identified in regard to data collection, however, the expertise of infection control staff was sought to review the information in relation to the reprocessing and cleansing of each of the instruments for multi participant use. In addition the calibration and electrical testing of the tools was conducted by the biomedical engineering department of the hospital prior to the commencement of the study. The instruments are discussed in order of their use.

Wound surface area

Instrument selection

To gain an accurate picture of the wound, the actual wound size or surface area needed to be determined along with the photo and textual description of the wound. There were a number of methods available to determine the surface area of a wound. Feinstein's (1983) framework[53] was used to guide instrument selection. The method chosen was the use of digital planimetry. The framework included reviewing the validity and reliability of the instrument being used, as well as considering the clinical environment it was being used in and the practical aspects of tracking the measurements. Digital planimetry was chosen based on the validity of the instrument to measure what it is intended to measure, the accuracy of the measurement obtained and the usability or practicality of the instrument. In addition to these three criteria, digital planimetry has been found to be reliable, consistent and able to be reproduced by multiple clinicians.[31218-220] A simple demonstration is

provided in the next section where the differences obtained between simple measurements, grid counting (mechanical planimetry) and digital planimetry are shown utilising an online application developed by Smith and Nephew.[218]

Reliability

The researcher completed the demonstration exercise using the online application to illustrate the precision of the alternative methods for measuring surface area. Figure 10 to Figure 12 demonstrates the use of simple measurements (Figure 10) and grid counting (Figure 11) in comparison to digital planimetry (Figure 12). The simple measurement requires the clinician to measure the width and length of a wound at its widest parts utilising the face of an imaginary clock to guide the measurement. The length is measured using the head as a reference point of 12 o'clock and the feet are 6 o'clock; with the width measured from 3o'clock to 9 o'clock.[221,222] In this example the measurement the researcher calculated was 6.1cm x 17.0cm which gives a surface area of 103.7cm^2 (Figure 10).

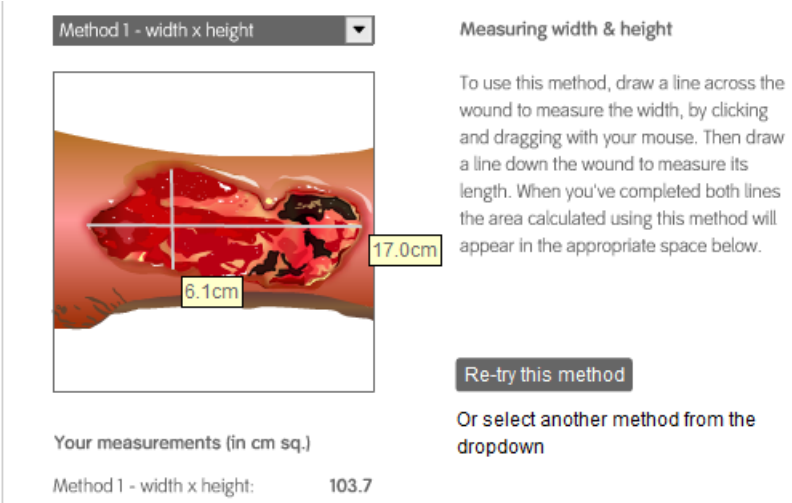

Figure 10 Simple measurement of a wound[68]

Grid square measurements require the clinician to trace the wound and then count the number of full squares on the grid and to add the partial squares to obtain a total number of squares.[69,222] In this example the measurement the researcher calculated was approximately 23 squares giving a surface area of 115cm^2 (Figure 11).

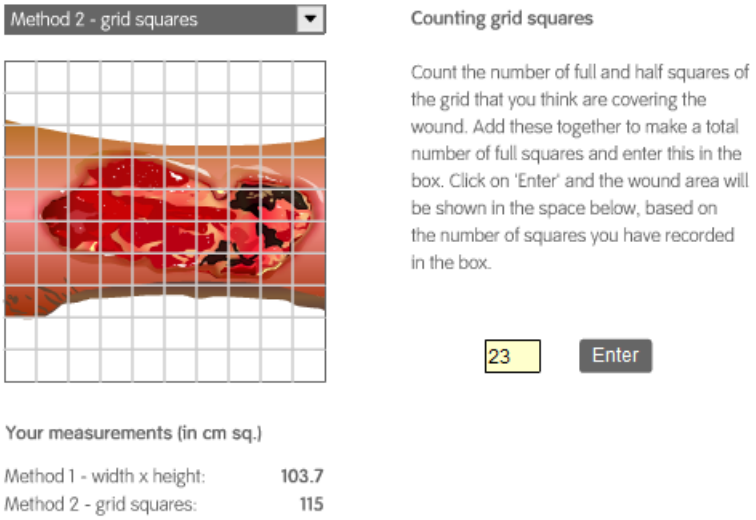

Figure 11 Grid square measurement of a wound[68]

Digital planimetry requires the clinician to precisely trace the margin of the wound and then retrace it onto an instrument (in this case the 'Visitrak Digital'), which calculates the measurement.[67,222] In this example the researcher calculated the surface area measurement as 116.7cm^2 (Figure 12).

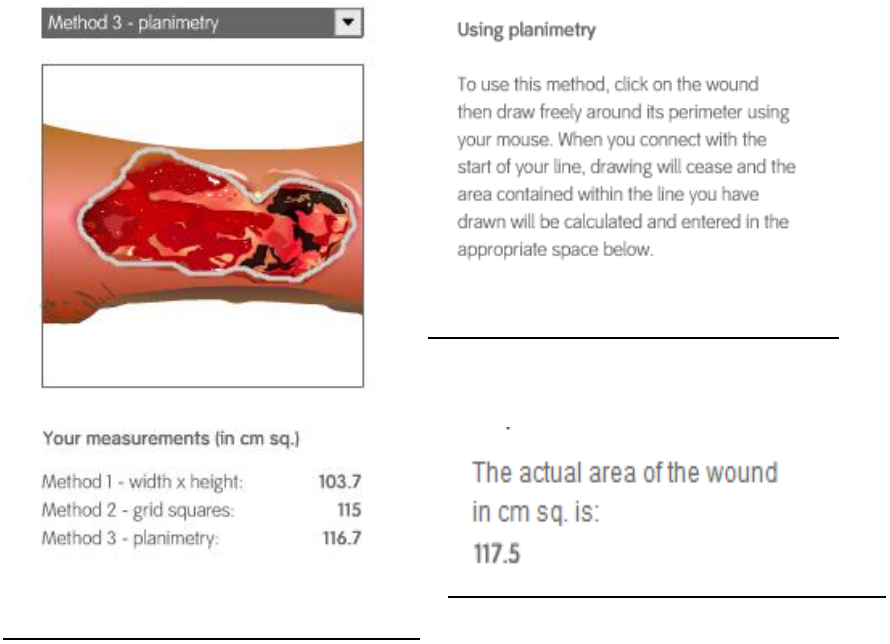

Figure 12 Digital planimetry measurement of a wound[68]

These three methods demonstrate the different wound surface area measurements obtainable (range of 103.7-116.7cm^2) by one researcher and the reliability of the digital planimetry method, where the measurement as determined by Smith and Nephew was 117.5cm^2.[68] Digital planimetry provides the most accurate wound surface area measurement, with simple measurement and grid counting providing measurements with differences of -13.8cm^2 and -2.5cm^2 respectively. [68,218-220]

Hence, the surface areas of the wounds for the research study were completed using digital planimetry and in this case using the Visitrak™ system. The Visitrak™, comprised of the 'Visitrak Digital' and 'Grid' provide a standardised approach to wound measurement (Figure 13).

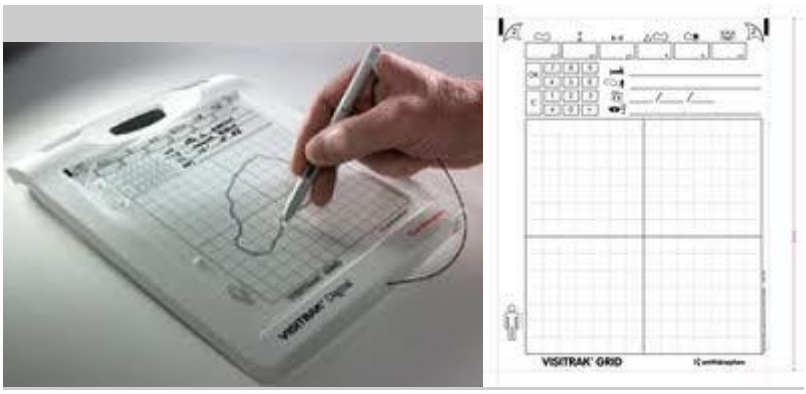

Figure 13 Visitrak Digital, Visitrak Grid and Visitrak Depth[68]

The 'Visitrak Digital' is a portable tablet, and as demonstrated above provides an accurate area measurement by converting a line tracing into a true area measurement. The wound is traced onto a 'Visitrak Grid' a film which has been specially designed with two separate layers to minimise the risk of cross-contamination and secondary infection.[68] There are three layers in the 'Visitrak Grid'. The first layer is removed to allow the 'Visitrak Grid' to be placed on the participants wound without causing any contamination. Once the tracing is drawn, the second layer is then removed to allow the third clean layer to be stored in the participant's records. The film is easy to draw on with a permanent marker and the wound can be seen through the film due to its transparency.

Once the wound edges are traced onto the 'Visitrak Grid' it is then placed onto the 'Visitrak Digital' and the margin retraced. When the tracing is completed the 'Visitrak Digital' makes a beep to alert the user that the tracing is complete. The immediate default result is overall wound area, calculated from the tracing provided (Figure 14). Functions are also available to calculate the percentages of different types of wound bed tissue (e.g. necrotic).

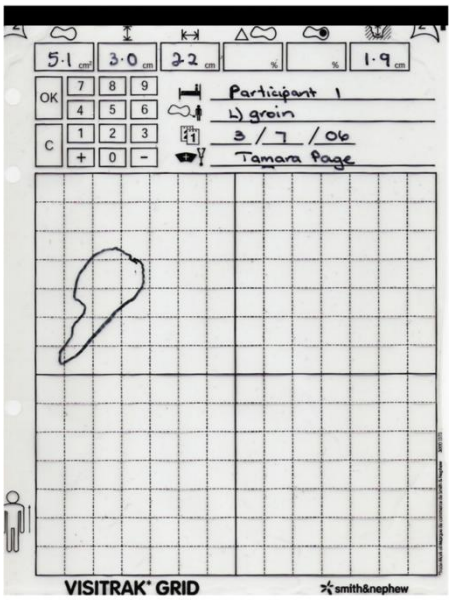

Figure 14 Example of a Visitrak Grid and results obtained for participant 1

Once the results were calculated, they were transcribed onto the participants 'Visitrak Grid' in the specified boxes at the top of the grid; Box 1 - surface area; Box 2 - length; Box 3 - width.

Reprocessing

The 'Visitrak Digital' did not come into contact with the participant and as the Visitrak Grid' has the two separate layers to reduce the risk of cross-contamination and secondary infection, the 'Visitrak Digital' was cleansed as per the hospital settings approved detergent.[59,223,224]

Environmental temperature and humidity

Instrument selection

External factors which needed to be considered during the research included the environmental temperature and humidity. These were measured to determine that the environmental conditions were consistent throughout the hospital and therefore did not bias the results in any way. The Fluke© 971 (temperature and humidity meter - Figure 15) was already used within the hospital setting and was able to provide both the temperature and the humidity simultaneously.

Reliability

The Fluke© 971 had a temperature accuracy of ±0.5°C at 0 to 45°C, with the humidity accuracy ±2.5% at 10 to 90% Relative Humidity (RH) at 23°C.[35] To gain a reliable or correct reading it was necessary to allow the appropriate response time. For a temperature reading, 500 milliseconds were required, whereas 60 seconds was required for the humidity reading.[35]

Reprocessing

The Fluke© 971 did not come into contact with the participant and was cleansed as per the hospital settings approved detergent.[59,223,224]

Figure 15 Fluke© 971

Participant body temperature

Instrument selection

The participant's body temperature was integral to establishing what if any relationship it may have had on the participant's wound temperature. Infra-red aural thermometers have become very popular in recent years due to the obvious advantages of performing quick, simple non-invasive measurements, however, recent publications have proposed that temporal scanners are more accurate than aural thermometers.[11,12] The participant's body temperature was measured using the nu-beca© RT 123 Multi-function Infrared Thermometer. The nu-beca© measured the participant's temperature by determining the infrared heat generated by both the eardrum and its surrounding tissue (aural) or the forehead skin surface over the temporal artery (temporal). In regard to the differences of temporal and aural accuracy, the nu-beca© has the advantage of taking both aural and temporal measurements with the user manual stating that the range of temperature considered 'normal' was the same for both methods (Figure 16).[49] This provided for a more

comprehensive assessment of body temperature, with both options also being available for participants where one temperature site was unobtainable.

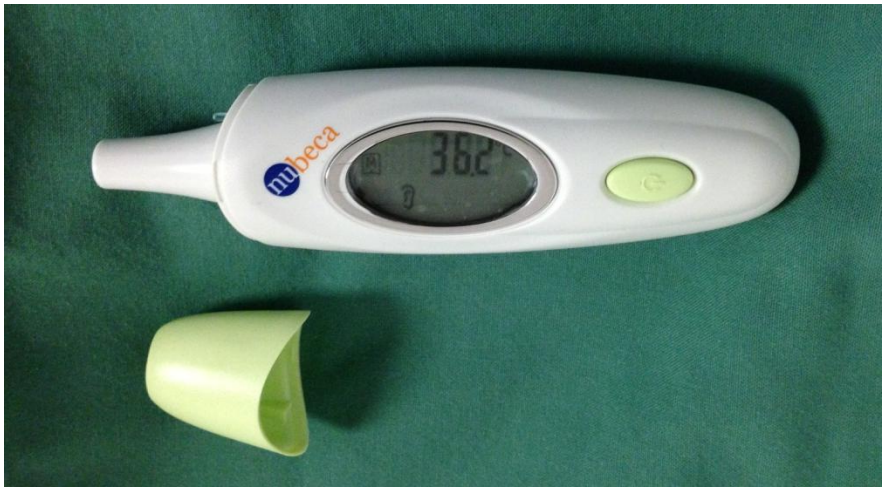

Figure 16 nu-beca© RT 123 Multi-function Infrared Thermometer.

Reliability

The nu-beca© thermometer has an accuracy range of ±0.2ºC for the temperature range 36.0ºC to 39.0ºC and ±0.3ºC outside of this temperature range.[49] Consistency of technique was maintained by ensuring the same procedure was followed when taking the participant temperature. Aural measurement accuracy relies on the thermometer being able to clearly view the tympanic membrane and not the inner walls of the ear drum.[11,12] This is achieved by the user pulling gently up and backwards on the pinna when taking the measurement.[11,12]

The temporal scanner relies on the user tracing across the forehead in a reasonably straight line and not down towards the participant's ears, whilst keeping the cover flat against the skin.[11,12] If the participant is sweating profusely the reading cannot be determined and

needs to be taken in the alternative position, behind the ear, where the temporal artery is close to the skin.[11,12] No specific time is required for a reading to be taken, but the thermometer does not display the participant's temperature until it has been established.[49]

Both methods need to be performed accurately and as all participants in the study were able to have their temperature measured aurally this was also the preferred route, as the site where most participants are accustomed to having their temperature measured.

Reprocessing

Single use probe covers were used for aural temperature readings and disposed of once the reading was obtained; the body of the thermometer was then wiped down using the hospitals approved detergent.[59,223,224]

Wound bed bacterial loads

Instrument selection

Wounds left without an appropriate covering may become contaminated. Contamination in the time taken to dress the wound, may lead to wound colonisation and therefore increase the risk of infection. The potential contamination (which is the abnormal presence, in a tissue or a sample, of microbes derived from the external environment, but without evidence of infection) was described using the agar settling plate counts.[64,225]

Wound swabs were initially going to be used to identify what bacteria may settle onto the wound bed whilst a wound did not have a dressing in place, however, in discussions with experts from the State Pathology Service it was established that this method would not

provide accurate contamination information specific to the episode of exposure (Winter 2006, pers.comm., 18 October). The time required for growth of an organism would not occur in the time the wound was exposed and the pre-existing wound flora would be all that was collected.

The use of agar plates to collect whatever organisms settled on the plate from the air during the time the wound was uncovered was considered to be a more suitable method of data collection. Agar in Petri dishes is the medium used in the growth of bacteria and fungi.[6] Blood agar was the medium considered as the most appropriate to gain useful microbiological data.

Blood agar contains a nutrient culture medium which is supplemented with sheep's blood and is the most appropriate medium used for the growth of certain strains of bacteria.[6] The types of bacteria usually found in air samples are grown extremely well on blood agar and this was the determining factor in the choice of agar plate.[6]

Reliability

The blood agar plates have a limited shelf life and are kept in a biomedical fridge at 2-8°C to prevent drying out and exposure to bacterial contaminants. They needed to be collected from the State Pathology Service prior to use. The State Pathology Service completed the biochemistry on the agar plates, with some qualitative and semi-quantitative data obtained, including the types of microbes and the number of colony forming units (CFU) (Figure 17). The plates are incubated aerobically at 35°C for four days before counting the number of colonies.[226,227] The colonies are expressed as number of CFU per hour; the number of

colonies counted is then averaged by the specified time period (i.e. for a three hour exposure the number of colonies counted is divided by three).

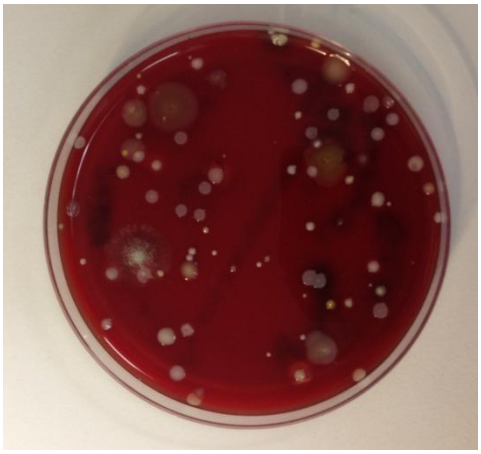

Figure 17 Growth on blood agar plate from participant 3

Timer

Instrument selection

The specified time intervals described in the data collection procedure for each of the probe placements were accurately determined with the use of the stopwatch function on a mobile phone (iPhone 4). These choice of interval times were guided by a previous study reviewing wound temperatures using five minutely intervals, and indicated that if the intervals were decreased any further the chances of recruiting participants was likely to become more difficult.[82]

Reliability

The mobile phone requires an operating temperature between 0-35°C and RH 5-95% to function reliably and has an inbuilt stopwatch function.[228]

Reprocessing

The phone did not come into contact with the participant and was cleansed as per the hospital settings approved detergent.[59,223,224]

Wound bed temperature

Instrument selection

Measuring the temperature of a wound has been an evolving science, with conventional methods deemed unsuccessful due to difficulty with placement of the probe, inadequate connection between the wound bed and the probe and also the time it takes for the sensor to reach a constant temperature.[229] With this in mind infrared thermography has been shown to provide reliable results which are fast and easy to measure.[230] Hence, wound bed temperature was measured using the DermaTemp™ which measures the temperature through the wound surface infrared thermography.

Reliability

Temperature measurements can be taken without actual contact of the probe being made with the wound, however, it is recommended that contact with the measurement site is attained for absolute accuracy.[229] The DermaTemp™ has a temperature range of 18 to 43°C, with a clinical accuracy of ±0.1°C and a response time of 0.1 seconds.[229] It automatically recalibrates each time the button is depressed.[229] Wound temperature measurements were taken at specified intervals.

Reprocessing

The DermaTemp™ has disposable sheaths available for measurements on moist skin.[230] This allowed for complete encasement of the instrument, which also protected against the risk of cross contamination (Figure 18). In line with the standard operating procedures the DermaTemp can be gas or plasma sterilised, or wiped down with any hospital approved disinfectant or bleach.[59] As a new disposable sheath was used for each participant, the DermaTemp™ was wiped down upon removal of the sheath with the hospitals approved detergent.[59,224]

Figure 18 DermaTemp™ being used and encased with a disposable sheath

CK© Electronic MC 750

The CK© Electronic MC 750 was the platform which the pH and TEWL probes used to feed the data into the software program Derma Check. This software was suitable for Windows XP and was installed onto a Compaq Presario laptop. The MC 750 device was then connected to the laptop via the universal serial bus (USB) cable.

The software allowed for multiple pieces of information to be collected including: participant, analysis, measurements, images, results and programs (Figure 19). Not all of

these programs were utilised for the study and only the programs actually used will be discussed. Participant's demographic data had to be input before data collection could occur. Once the participant had been selected, the measurement program was clicked on and a drop down box allowed the user to open the appropriate measuring image (Figure 19).

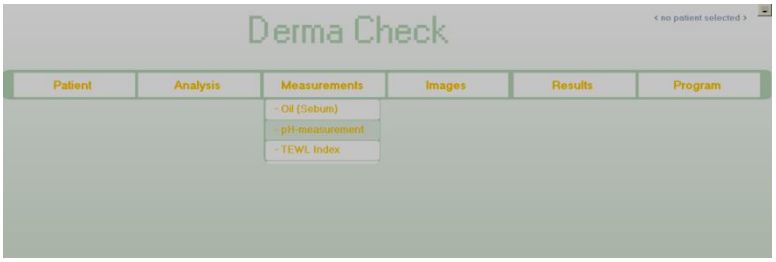

Figure 19 Derma Check measurements tab

Wound bed pH measurement

Instrument selection

The decision of which pH probe to utilise for the study, was based on discussions with company representatives and the application and reprocessing requirements. A typical pH probe measures the alkalinity or acidity of a substance.[36] A pH measurement requires both a measuring probe (a glass electrode) and an electronic meter to measure and display the pH reading. The combination pH electrode and a glass electrode with a flat bottom was determined to be the most suitable for pH measurements on participant wounds.[36] The glass electrode houses both a reference electrode and a pH sensitive glass electrode (the active measurement). The bottom of the probe needs to remain moist and be well protected during both measurement taking and storage as the membrane is very sensitive and this

will ensure that the results and calibration values remain correct. [31,36] The level of the electrolyte in the outer area of the probe needed to be monitored to ensure the level did not get too low and therefore enable inaccurate readings.[31,36]

Reliability

The wound bed pH probe was attached to the CK© Electronic MC 750. The measurement range was pH 0 to pH 14 with an accuracy of ±0.1, in room conditions of 20°C and 40-60RH.[31]

The supplied pH probe was calibrated when delivered and the company suggested recalibration every four weeks.[31] The accuracy of the pH probe could be checked easily at any time by measuring the pH of the buffer solution supplied, with the values of 4.0 or 7.0 being accepted with a 0.1 deviation.[31] A new buffer solution was required to be opened at each calibration as contact with air and handling of the solutions led to a loss of the buffer features.[31]

The pH measurement had to be taken with the probe-head pointing downwards and being held vertically to ensure the filling solution covered the membrane for an accurate measurement. [31] The pH probe needed to be kept moist both during use and in between measurements being taken and was therefore placed in distilled water. The excess water was shaken off before taking a measurement from the participant's wound (Figure 20).

Figure 20 CK© Electronic MC 750 platform and pH probe

To take the measurement the USB cable was connected to the laptop, the Derma Check program opened and the appropriate tab identified (Figure 19). The measurement was immediately displayed by pressing the button located on the side of the probe. The measurement result was displayed up to two decimal points and as a blue column (Figure 21), with a measuring value displayed above the box. Each of the measurements taken was displayed next to each other with the average pH measurement displayed at the far right with a green box (Figure 21).[31]

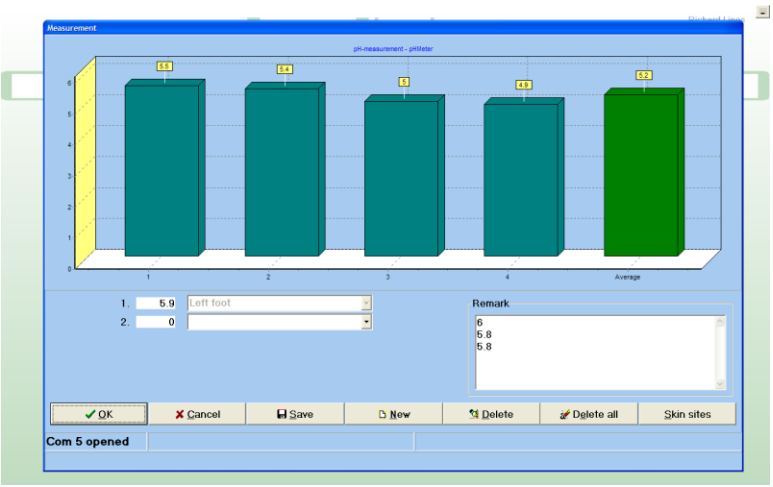

Figure 21 The pH measurement displayed with values from 0 (acidic) to 12 (alkaline)

After performing and storing the measurements, the results could be viewed in the results program and this could be printed out. This program was very useful as it automatically recorded the data into the program and kept it all together in a complete file. However, the pH program saved only the average pH each time and therefore each measurement was recorded in the remarks box prior to saving as displayed in (Figure 21).

Reprocessing

Following completion of the measurements on a participant, the probe was reprocessed. The instrument was classified as entering a semi-critical site according to Spaulding's classification system as its intended use involved contact with non-intact skin.[231] In the study setting high level disinfection is required for endoscopes and probes, however, high level disinfection is the minimum requirement for items classified as semi-critical which are unable to be sterilised.[17,59] Disinfection eliminates many or all pathogenic micro-

organisms with the exception of bacterial endospores unless there is prolonged disinfection.[17,231]

The solution recommended from the company for reprocessing was unavailable in South Australia and after much discussion with the company and the infection control unit of the setting, Cidex OPA® (ortho-phthalaldehyde) was determined to be satisfactory as it was used in the study setting to reprocess a wide range of medical devices and it also met the Australian Standard AS/NZS 4187:2003 *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment and maintenance of associated environments in health care facilities.*[232]

Reprocessing of instruments using Cidex OPA® requires the person reprocessing to have undergone training in its use and testing procedures.[17] The specific requirements and reprocessing procedure are detailed in Appendix 8. Following reprocessing the pH probe was stored in a bottle of potassium chloride (KCL) solution between data collection of participants as recommended.[31]

Wound bed Trans Epidermal Water Loss

Instrument selection

The TEWL measurement is the amount of water evaporating from the skin to the external atmosphere.[63] There are two basic methods for measuring TEWL, the closed method and the open method.[233] The closed method involves placing a sensor over the wound forming a housing effect and causing an increase in the RH inside the chamber (consistent with the

TEWL measurement value).[63] The microprocessor requires some recovery time to ensure it has returned to its pre-condition before starting a new measurement.[233]

The open chamber method requires the probe to be placed on the area being measured and water evaporates through the probes hollow cylinder and a microprocessor.[43] The open method has been acknowledged worldwide as the 'gold standard' for many years as it maintains the natural evaporation without having any influence on the area being measured with the sensors being protected from air flow by an open 'housing'.[234] This has been stated as ensuring less biased and more accurate readings, however, Imhof and Kramer (2007) state that the measurements from an open chamber are more vulnerable to air flow despite the housing, however, the difference in TEWL results are negligible.[233]

Due to the measurements being taken on the participants at five minute intervals it was decided to obtain an instrument which would measure the TEWL using the open method due to the issue described in the literature in relation to the microprocessor of a closed housing needing some recovery time before additional measurements could be taken (Figure 22).[233]

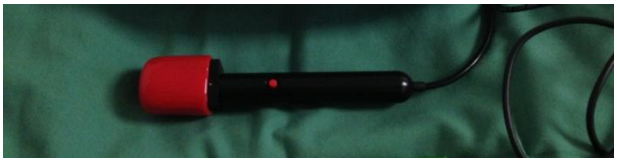

Figure 22 CK© Electronic MC 750 TEWL probe

The normal skin range of TEWL is reported to be anywhere from 2 gm/m^2/hr to 20 gm/m^2/hr; which is equivalent to less than 40ml/hr.[122-124]. The CK© Electronic MC 750 adapted the values above and measures TEWL in Units; with 0-4 interpreted as a very

healthy barrier, 5-9 as a healthy barrier, 10-12 as a normal barrier, 13-16 as a strained barrier, and 17-20 as indicating critical condition.[31,125] As the CK© Electronic MC 750 was being used to take measurements on wounds with damage to both epidermis and/or dermis higher values were expected to be recorded.

The TEWL of the wound was measured once the TEWL probe was attached to the CK© Electronic MC 750. The maximum value able to be recorded by the CK© Electronic MC 750 was 20 Units. Once the appropriate tab was open in Derma Check the measurement could be taken. The measurement was immediately displayed as a blue column (Figure 23), with a measuring value displayed above the box. Each of the measurements taken was displayed next to each other. After performing and storing the measurements, the results could be viewed in the results program and this could be printed out. This program was very useful as it automatically recorded the data into the program and kept it all together in a complete file.

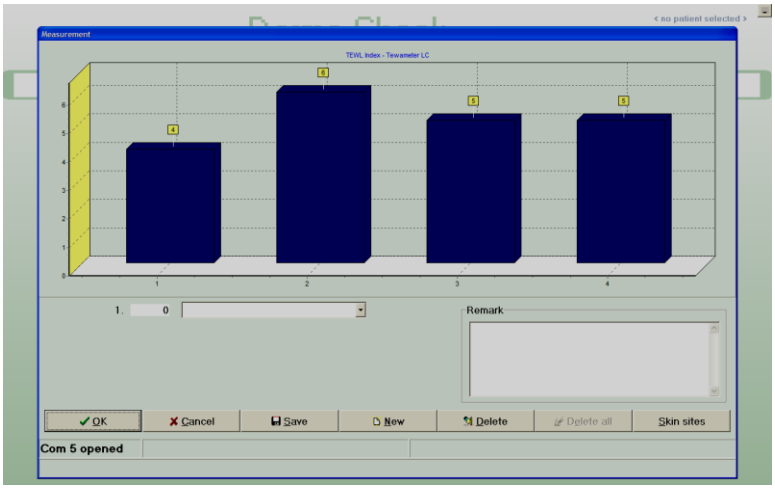

Figure 23 The Transepidermal water loss index value was displayed from 1 (healthy) to 20 (critical).

Reliability

The TEWL based on the 'open chamber' method required a measuring time of 30 seconds and the probe had to sit flat on the wound with a constant but low pressure to gain an accurate reading.[31] All calibration data were contained inside the probe to minimise the influence of air turbulence on the result.[31] The TEWL probe required an operating temperature of 20° C and 40-60 % RH.[31]

Reprocessing

The cleaning requirements of this instrument were difficult as the microprocessor is unable to be wet.[31] To minimise the risk of contamination between participants, a piece of Hydrocolloid™ (1mm thick) was attached to the probe to sit between the microprocessor and the wound bed. A hole measuring the same size as the opening in the probe head was fashioned into the Hydrocolloid which allowed the air to move through the probe head enabling the measurement to be taken accurately but also to allow the probe to be cleaned with detergent and alcohol following the completion of the measurements with the hospital settings approved detergent.[59,223,224]

Participant comfort

In addition to the quantitative data being collected by the instruments on the wounds, qualitative data were collected using a questionnaire. The researcher provided the participant with the questionnaire regarding their pain and comfort during the wound dressing change. This was done following the wound dressing change, however, the nature of the data collection measurements being taken may have impacted on the degree of

comfort reported during the time the participant was waiting for their wound to be assessed. The length of time the wound was exposed may also have impacted on the participant and how they were interpreting their comfort, the longer they were confined to their bed unable to perform activities of daily living could have impacted on their mental performance and created errors reducing the reliability of the data.

Existing questionnaires

A search of the literature for a pain questionnaire was conducted and an existing questionnaire was found that had been developed by Hollinworth a prominent nurse researcher from the United Kingdom.[235] This document was reviewed to determine its suitability for use. The pain questions in Hollinworth were specific to wound dressings; how did the wound dressing change impact on the pain before, during and after the wound dressing? However, questions in relation to the impact of the wound dressing procedure on the activities of daily living were not addressed in the Hollinworth tool and therefore these were added to the questionnaire.

The researcher's knowledge of wound dressing changes informed the development of the participant questionnaire tool. The appropriateness of the questionnaire used for data collection could have a profound effect on the findings of a study.[211] For the data collection tool to be valid it needed to measure the variable/concept which was being examined in the research.[236] There were different types of validity which needed to be considered. Face validity evaluated the ability of the questionnaire to measure the concept/variable, the clarity of the content and its readability. Content validity defines how

representative the data collection tool is in obtaining accurate data which the researcher wishes to measure.[211,212,216,236]

Peers in the clinical area evaluated the face validity of the questionnaire and the questionnaire was piloted on five participants representative of the types of participants expected to be included in the main study. There were some minor word changes made to enhance both the face and content validity of the tool and as the changes required were minor, the questionnaire was not re-piloted and the researcher proceeded with administration of the questionnaire to the full sample of respondents.

Instrument selection

An important aspect of the participant questionnaire was the scale chosen to assess pain intensity. Uni-dimensional scales have been described as useful for measuring a variety of subjective phenomena including pain and there are a variety of different formats which the scale can take.[237]

The Visual Analogue Scale (VAS) is described as a straight line at which the end anchors are labelled, as the extreme boundaries of the phenomena being studied (i.e. no pain and extreme pain). The most common length of a VAS is 100mm, and with the line in a horizontal direction in preference to vertical as a more uniform distribution of scores is found.[37] The Graphic or Verbal Rating Scale (GRS or VRS) is where descriptors are placed at intervals along the length of the line, and the Numeric Rating Scale (NRS) is where the line is calibrated with a number of graduations to determine trends in subjective phenomena such as pain.[37]

Reliability

To improve the reliability of the scales there are common formats suggested as being crucial to decreasing errors in use recommends right angle 'stops' at each end of the VAS are critical to limiting marks beyond the end of the line in preference to arrows.[238] There are no specific recommendations regarding the placement of the descriptors along the line, however the reliability of the scale may be affected.[37] Huskisson (1983) states that the descriptive anchor phrases (i.e. no pain and the most extreme pain) should be placed beyond the right angle stop, not underneath or above the stop.[237,239] In addition to this there are the added complexities of paper based versus mechanical slide ruler and computerised versions of the scales which studies have not compared to date.

The pain intensity scale used in the questionnaire was the NRS-11 (on a scale of 0-10, with 0 being no pain and 10 being the most extreme pain) as it was easy to administer, simply constructed and the inclusion of numbered calibrations may assist individuals who have difficulty conceptualising the tool to accurately use it.[198,199] Wewer's (1990) article supports 21 distinct graduations on the tool, however, a total number of ten graduations were chosen in deference as Hjermstad *et al* (2011) stated there is minimal gain in precision with more than nine options in the scale.[37,237] This was also preferable as it is the format currently used within the study setting and likely to have been used before by the participants.

The test-retest reliability of the NRS was determined to be 0.67-0.96 and the criterion validity when correlated with the VAS was 0.79 to 0.95.[240]

Due to the complex nature of the total data collection process a practice run on a 'simulated wound' was undertaken to ensure the method to be followed as well as familiarity with the instruments and recording of data was clear to the researcher to minimise reliability error.

Data Analysis

Using SPSS, a number of databases were initially developed to allow data to be entered immediately after each participant data collection episode. All data were entered into the database to allow for an overarching analysis. The TEWL data collected via the CK© Electronic MC 750 were unable to be exported from the Derma Check program into SPSS as one complete file for further analysis. The data were required to be manually entered into SPSS for further analysis. The data entry was checked with a second person reading out the parameters from the data collection sheets as the researcher confirmed the correct entry in SPSS.

The data were then able to be stratified according to a number of variables such as wound surface area, wound aetiology and the type of temporary dressing coverings used. For example participant 1 was included in the analysis stratification as depicted in Figure 24 dependent on their matching criterion.

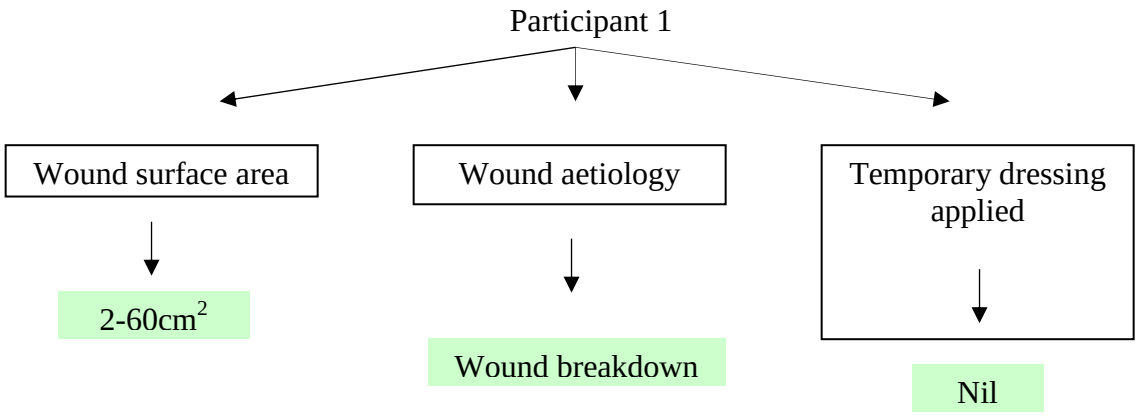

Figure 24 Participant 1 - data stratification

Descriptive statistics were used to investigate data collected in relation to participant demographics (such as, age, gender and wound aetiology) and the effect of down time on participant comfort. Frequency distributions were used to organise the data and show how data is distributed amongst the different variables. This shows how frequently particular events occurred. Standard deviations and the range of data were calculated to show the distribution of data.

As there was repeated data it was able to be analysed for each participant in addition to analysis between participants. Analysis of repeated data from a participant on more than one occasion creates a third layer of analysis that would make the results difficult to interpret, with some ambiguity as to the relevance due to the number of extraneous factors needing to be taken into account during the data collection process.

A more in depth analysis of the repeated measures was conducted with the assistance of a statistician and the statistical analysis package SAS 9.3 was used. Descriptive statistics were used to summarise data collected in relation to participant demographics, with histograms used to visually portray the distribution of outcome variables. Data resulting

from longitudinal studies where series of data is collected over periods of time, as in this study, are examined for correlation.[241]

Generalised Estimating Equations (GEE) were used to analyse this correlated data. Outcome variables that are normally distributed can be modelled and analysed using a 'linear' GEE.[14] There are two models used in a GEE analysis; 'model a' initially determines any statistical significance between time and the predictor variables (i.e. type or size of wound) on the outcome variables (temperature, TEWL and pH). If the interaction was not statistically significant then 'model b' was utilised to determine if there were any associations between time and the outcome variable.

Outcome variables which are not normally distributed nor have a normally distributed logarithmic function require a 'logistic' GEE model.[14] A GEE 'logistic' regression analysis is conducted the same as described for a 'linear' GEE model; however a logistic regression requires a binary outcome for the analysis to be performed. To determine the binary variable the outcome variables had to be converted into a binary variable and hence the median score of the outcome variable was used. A P value of <0.05 was considered to be statistically significant.

The State Pathology service undertook the cultures of the agar plates to determine the number and type of colonisations via way of a simple quantitative analysis of presence.[6]

Conclusion

The success of a descriptive correlation study is dependent on the validity and reliability of the instruments used during the data collection process to ensure a robust analysis of data

is able to be performed. Generalised Estimating Equations was used to analyse data that was both normally and not normally distributed and in an effort to answer whether local wound conditions and participant comfort are affected by the down time in association with a wound dressing change. The outcomes for the participants in the study will define the success of the methodology used to answer whether local wound conditions and participant comfort are affected by the down time in association with a wound dressing change.

Chapter Four - Results

Introduction

A total of twelve participants from the twenty prospective participants consented to be included in the study. The other eight participants initially recruited were excluded after consent was obtained as the inclusion criteria (prolonged down time) were not achieved. The twelve remaining participants had data collected for the duration of the time their primary dressing was not in situ.

Data were collected according to the methods with the aim to identify if local wound conditions and participant comfort were affected by the down time in association with a wound dressing change. The participant demographics and wound characteristics provide a background for each of the participants; then associations between the wound bed parameters of temperature, TEWL, and pH are identified. The final results presented relate to the participant questionnaire and finally the microbiology data.

The results address whether local wound conditions and patient comfort are affected by the down time taken in association with a wound dressing change; including how the wound bed conditions of pH, temperature, Transepidermal Water Loss (TEWL) and bacterial levels changed during the down time. In addition any patterns of change associated with the type of temporary dressing applied during the time the wound was without its primary dressing is explored. Other results look at relationships between the patterns of change and the type or size of the wound, the impact of the participant's body temperature and the impact on participant comfort during a wound dressing change with extended down time.

Study setting

The included participants were located in three areas of the study setting. Eleven participants' were from the inpatient setting and one patient from the outpatient setting. Table 5 details the pre and post ambient temperatures (AT) and relative humidity (RH) of each areas environment and the different times of day that the wound dressing assessments were conducted.

Table 5 AT and RH pre and post the wound dressing procedure

Participant	AT pre	AT post post	change	RH pre	RH post post	change	Area	Time
1	21.9	22.4	0.5	39.6	43	3.4	Area 1	0730
2	20.3	20	-0.3	41.2	43.3	2.1	Area 1	0815
3	24.8	23.6	-1.2	43.3	45.5	2.2	Area 2	1218
4	22.6	24.3	1.7	52.1	40.5	-11.6	Area 1	0750
5	23.7	24.6	0.9	62.7	56.4	-6.3	Area 1	0730
6	24.3	26.4	2.1	30.8	26.7	-4.1	Area 3	0923
7	21.6	24	2.4	46	38.9	-7.1	Area 1	0625
8	21.6	23.7	2.1	40.4	36.5	-3.9	Area 1	0643
9	22.8	24.6	1.8	34.9	30.6	-4.3	Area 1	0640
10	24.9	25	0.1	30.6	31.5	0.9	Area 1	0930
11	23.5	24.4	0.9	47.7	42	-5.7	Area 1	0630
12	23.5	24.5	1	28.6	28.4	-0.2	Area 1	0705

Participant demographics

The participants' demographics and associated wound description are detailed in Table 6.

Table 6 Participant demographics

Participant	Age	Gender	Wound size (cm^2)	Wound type	Wound location
1	71	M	4.1	Wound breakdown	Groin
2	49	M	4.1	Non-pressure ulcer	Lower Leg
3	62	F	26.1	Wound breakdown	Abdomen
4	52	F	16.3	Trauma	Heel
5	45	M	16.9	Pressure ulcer	Lower Leg
6	41	F	57.2	Non-pressure ulcer	Lower Leg
7	52	F	13.5	Wound breakdown	Abdomen
8	42	M	34.2	Non-pressure ulcer	Lower Leg
9	65	F	12.7	Wound breakdown	Abdomen
10	77	F	2.0	Wound breakdown	Hip
11	77	M	27.4	Non-pressure ulcer	Lower Leg
12	21	M	28.8	Non-pressure ulcer	Lower Leg

The participant's ages ranged from 21 to 77 years with a mean age of 54.5 years across both genders, with the age range fairly evenly distributed as demonstrated in Figure 25. The study had an equal number of male (6) and female participants (6), all Caucasian. The female participants in this sample were older (mean age 58.2) than the male participants (mean age 50.2).

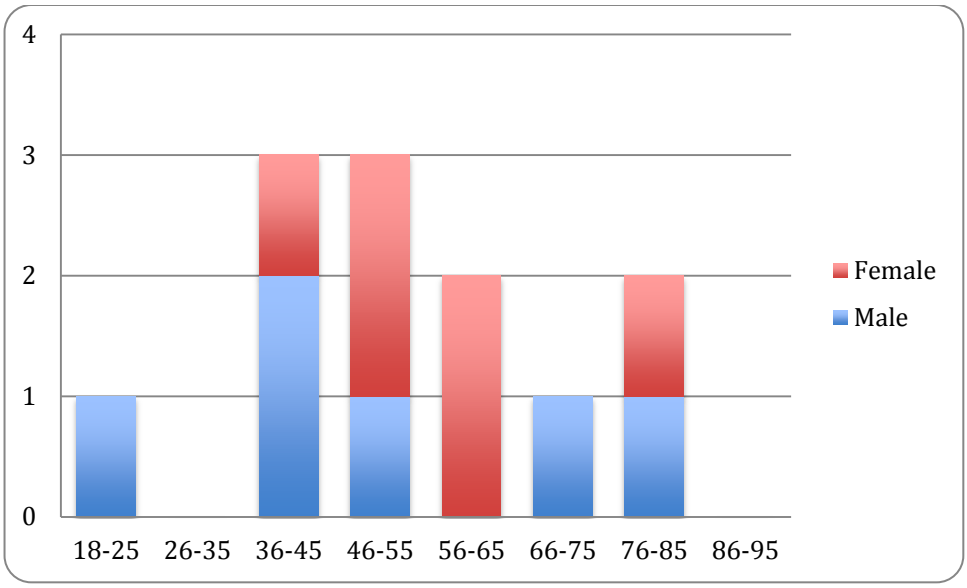

Figure 25 Age distribution of participants

The wounds were in varied anatomical locations with six participants having wounds located on the lower legs, three on the abdomen, one on the hip, one on the heel and one in the groin (Figure 26).

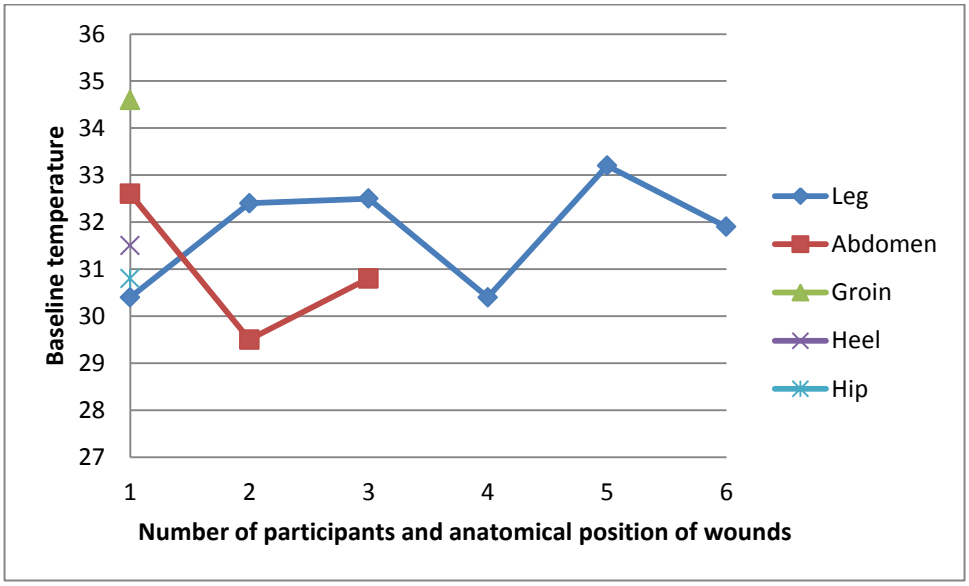

Figure 26 Baseline temperature by anatomical location and type of wound

Participant co-morbidities

Table 7 identifies co-morbidities that the participants presented with on admission.

Table 7 Participant co-morbidities

Participant	Co-morbidities
1	Peripheral vascular disease (PVD)
2	Quadriplegia
3	Endometrial carcinoma, Hypertension (HT), Gastro Oesophageal Reflux Disease (GORD)
4	Nil
5	Nil
6	Cervical cancer, Acute renal impairment, Deep Vein Thrombosis (DVT), Depression
7	Breast cancer
8	Asthma, Depression, GORD, Pulmonary embolism (PE)
9	Parietal mass, HT, GORD, Ischaemic heart Disease (IHD)
10	Total Hip Replacement (THR), Depression, Chronic Obstructive Airway Disease (COAD), Polymyalgia Rheumatica
11	Parkinson's Disease, Depression, Dementia
12	Nil

Of the twelve participants, three had no co-morbidities. Of the remaining nine participants a number of co-morbidities were documented which may impact on the wound healing process; namely circulatory disease, respiratory disease and oncologic related disease.

Participant wound characteristics

Surface area of the wound

To gain an accurate picture of the wound, the actual wound size or surface area needed to be determined (Table 8).

Table 8 Wound size as determined by the 'Visitrak Grid'™

Participant	Width (cm)	Length (cm)	'Visitrak Grid™' Surface area (cm^2)
1	3.0	2.2	4.1
2	2.2	3.0	4.1
3	11.3	3.5	26.1
4	6.9	3.5	16.3
5	5.5	4.0	16.9
6	8.8	8.9	57.2
7	13.0	1.8	13.5
8	7.2	6.1	34.2
9	4.5	4.0	12.7
10	2.9	1.0	2.0
11	6	5.7	27.4
12	6.5	6.0	28.8

The twelve participants had wounds of varying surface areas ranging from $2cm^2$ to $57.2cm^2$, with the mean size $20.3cm^2$ (Figure 27).

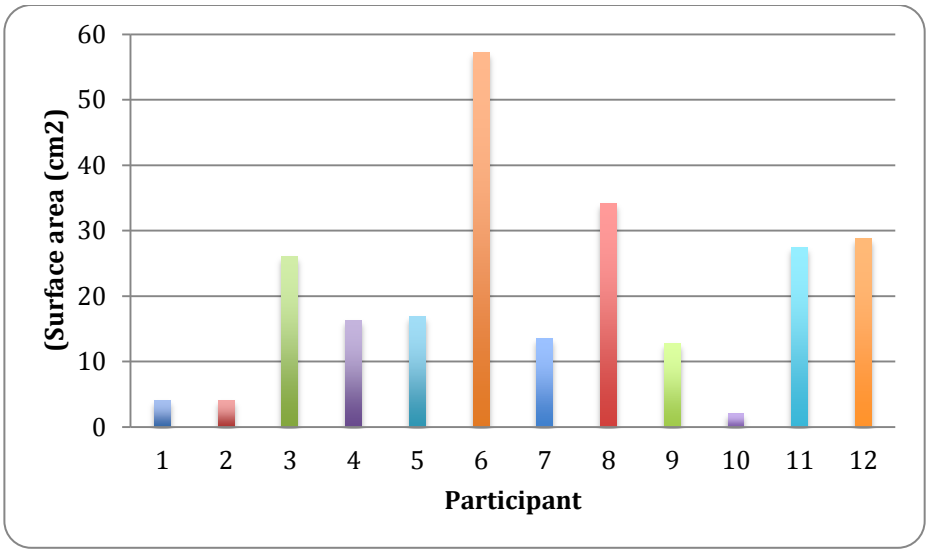

Figure 27 Wound size as determined by the Visitrak Grid™ (cm^2)

Wound type

The participants presented with four types of wounds with the majority being wound breakdown (5), and non-pressure ulcers (5); in addition one participant had a pressure ulcer, and another a traumatic wound (Figure 28).

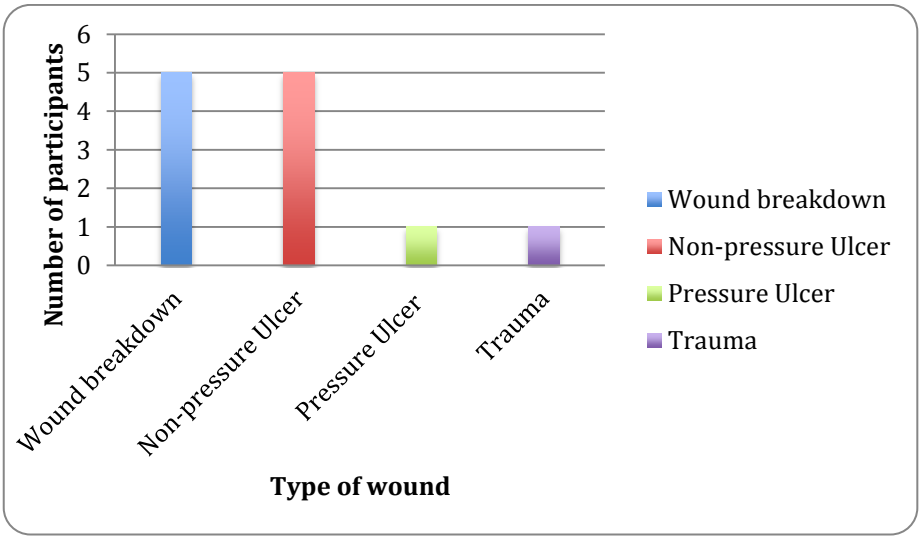

Figure 28 Wound type

Wound dressing in situ prior to assessment

The twelve participants' wounds were dressed with a number of wound care products with the main dressing product being Vacuum Assisted Closure (VAC) (Participants 3-5, 8-11), and others including Hydrogel (Participant 2), Hydrofibre (Participant 1), Hydrogel and Acticoat™ dressing (Participant 7), Tulle Gras™ (Participant 12), and Zinc (Participant 6) (Figure 29). Participants 1 and 6 (Hydrofibre and Zinc dressing) were the only participants to record temperatures above the critical 33°C temperature range required for mitotic activity to occur for the majority of the time that the wound was without its primary dressing. Three other wounds (Participants 3, 4 and 11) recorded one or two measurements above the 33°C and in the first 15 minutes of data collection.

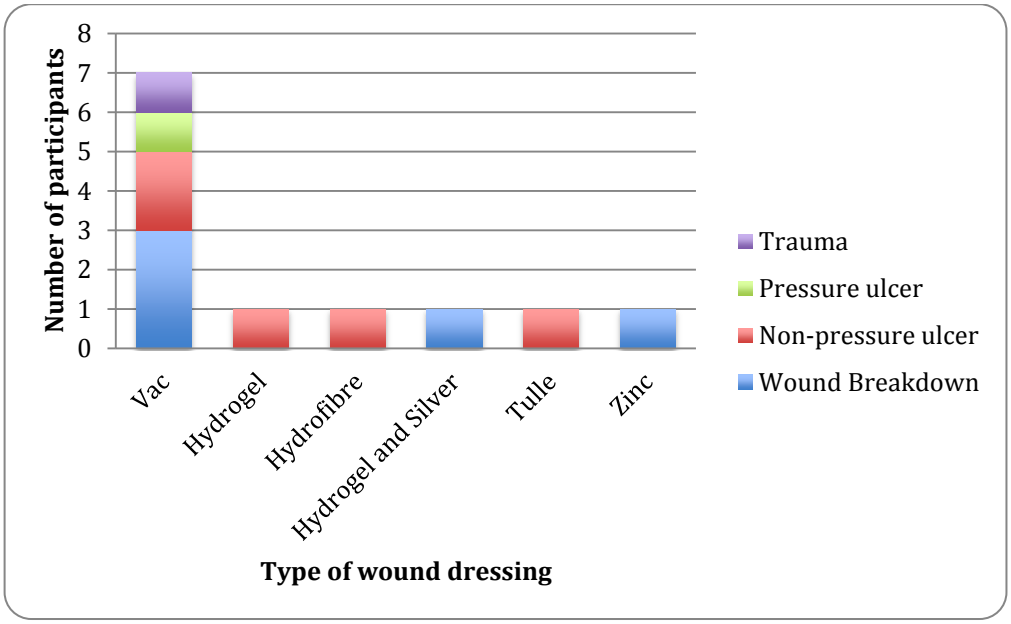

Figure 29 Type of dressing in situ for wound type

Temporary dressing cover applied to wounds

Wound care requires regular monitoring through assessment requiring the primary dressing to be removed and a temporary dressing covering was usually applied providing some protection to the wound whilst making it easy to be reviewed by the medical staff. The temporary coverings included a cotton sterile towel (Participants1-2 and 6-12), cotton sterile towel and Tulle Gras™ (Participants 4-5) nothing was used to cover Participants 3 wound at all (Figure 30).

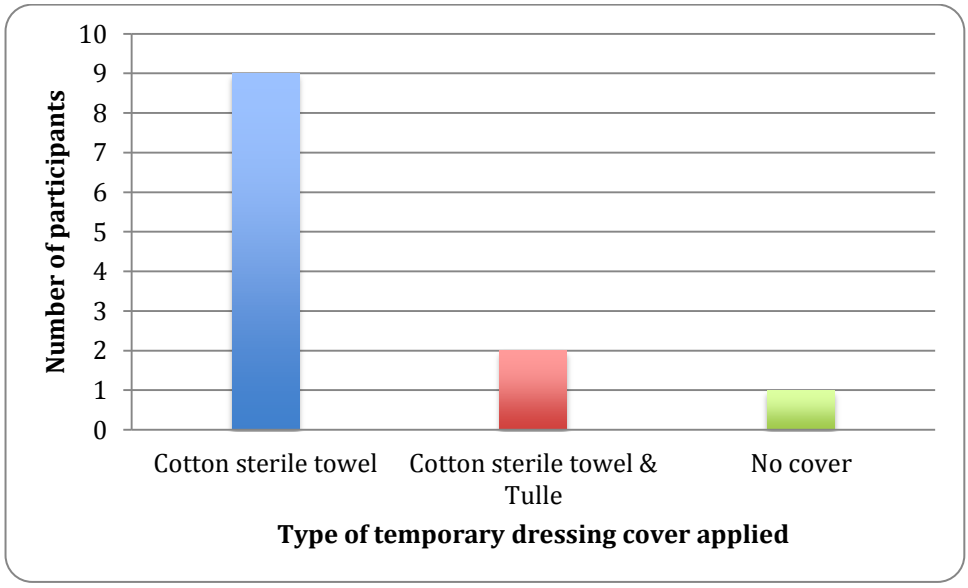

Figure 30 Type of temporary dressing cover applied

Length of wound exposure

Throughout the study the time in minutes that the wound was 'exposed' (without its primary dressing) were recorded. This was established from the time the primary dressing was removed from the participants wound and the temporary cover applied to the time the primary dressing was reapplied to the wound. The time in minutes was then described as

the 'down time' or time, and it ranged from 22 to 209 minutes, with the mean exposure time being 123 minutes (SD 63) (Table 9).

Table 9 Length of wound exposure

Participant	Time (minutes)
1	167
2	85
3	22
4	198
5	105
6	209
7	173
8	157
9	138
10	30
11	60
12	135

Wound bed parameters

In the following section the individual results for wound temperature, TEWL and pH are provided. These results are based on measurements taken from the time of the primary dressing removal to dressing reapplication. For the first half an hour the measurements were collected every five minutes and after 30 minutes they were collected every fifteen minutes until the wound was redressed. The minimum number of measurements taken on any one participant was five, (20 minute duration), with the most measurements being seventeen (209 minute duration). A total of 145 measurements were collected from the

twelve participants collectively. The data included all 12 participants up until the twenty minute time period and after that the number of participants remaining reduced as the primary dressings were reapplied. The time periods where the number of participants decreased are shown in Figure 31.

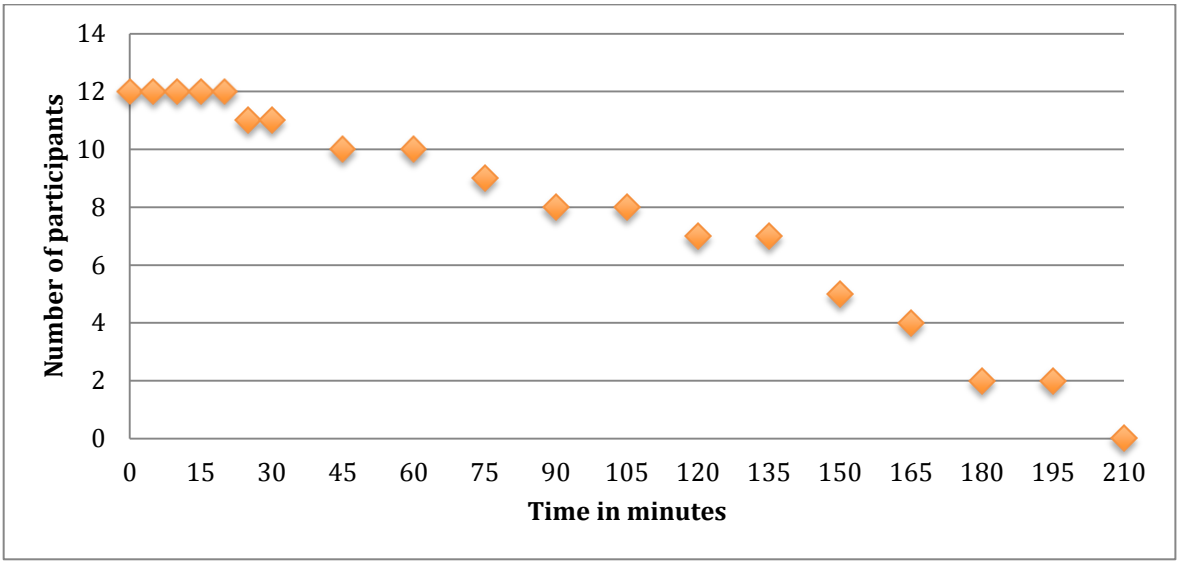

Figure 31 The time periods where the number of participants decreased

The data associated with the wound bed parameters temperature, TEWL and pH will be highlighted with results from baseline measurement for the length of exposure provided. The wound parameter data found at the 20 minute mark will be provided, however no further comparisons will be detailed due to the number of participants decreasing following this time period.

Wound bed temperature

Wound bed temperature during the dressing down time

The temperature for each of the participant's wounds for the length of exposure at each of the designated time periods is shown in Figure 32. The minimum temperature recorded throughout the time the wounds were without their primary dressing was 27.2°C for Participant 7 and the maximum was 36.0°C for Participant 1.

As the total data collection time (in minutes) varied for every participant the wound temperatures can only be compared at the same time points (in minutes). The baseline temperature was taken within the first 60 seconds post the primary wound dressing being removed. Of the twelve participants, ten had a wound temperature below the 33°C deemed critical for epithelialisation for the majority of the time the wound was exposed, depicted in the blue coloured area in Figure 32. All wound dressings bar one were removed at the patient's bedside; Participant 6 had their dressing removed in the shower under running water to assist with the removal of the dressing; however, the researcher was able to locate the equipment within reach of the shower to obtain the temperature reading.

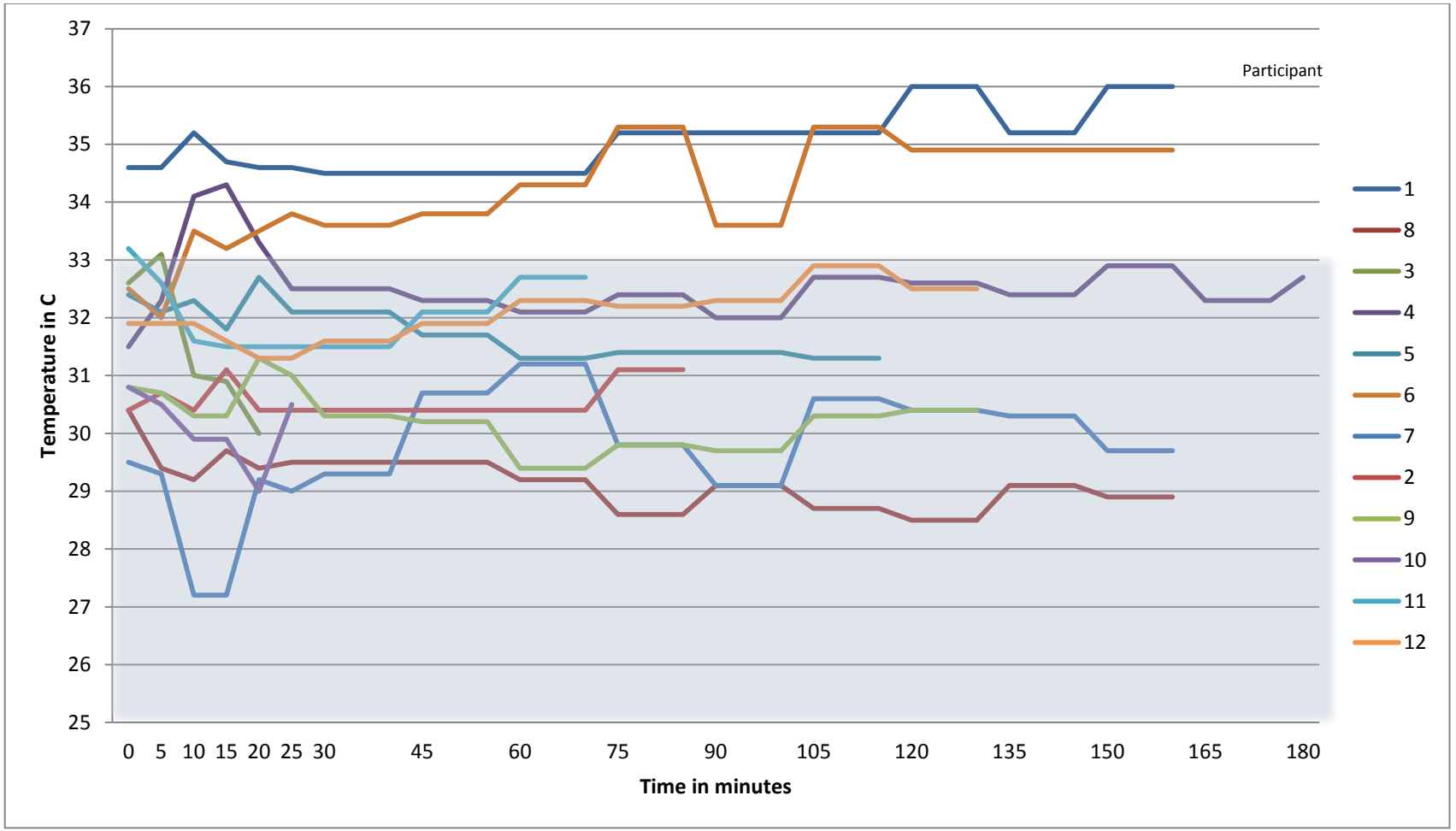

Figure 32 Participants' wound temperatures throughout the data collection process

Patterns of change in temperature for the length of exposure

The overall mean temperature for the duration of all 145 measurements was 31.69 (SD 1.93) The changes in temperature were small; however the results are clinically important as the wounds remain well below the critical 33°C required for mitotic activity to occur to assist in the healing process.

Table 10 illustrates the increases and decreases in wound temperature for individual participants. The boxes indicate the change in temperature from the previous reading with green indicating an increase in temperature, red a decrease and white no change. All numbers are expressed in degrees Celsius.

Table 10 Positive and negative changes in wound temperature during the dressing down time

		Time in minutes from baseline of 0																	
*P	Baseline Temp	0	5	10	15	20	25	30	45	60	75	90	105	120	135	150	165	180	*O/A
1	34.6	0	0	.6	.5	.1	0	.1	0	0	.7	0	0	.8	.8	.8			1.4
2	30.4	0	.3	.3	.7	.7	0	0	0	0	.7								.7
3	32.6	0	.5	2.1	.1	.9													2.6
4	31.5	0	.8	1.8	.2	1.0	.8	0	.2	.2	.3	.4	.7	.1	.2	.5	.6	.4	1.2
5	32.4	0	.3	.2	.5	.9	.1	.5	.4	.4	.1	0	.1						.8
6	32.5	0	.5	1.5	.3	.3	.3	.2	.2	.5	1.0	1.7	1.7	.4	0	0			2.4
7	29.5	0	.2	2.1	0	2.0	.2	.3	1.4	.5	1.4	.7	1.5	.2	.1	.6			.2
8	30.4	0	1.0	.2	.5	.3	.1	0	0	.3	.6	.5	.4	.2	.6	.2			.5
9	30.8	0	.1	.4	0	1.0	.3	.7	.1	.8	.4	.1	.6	.1					.4
10	30.8	0	.3	.6	0	.9	1.5												.3
11	33.2	0	.6	1.0	.1	0	0	0	.6	.6									.5
12	31.9	0	0	0	.3	.3	0	.3	.3	.4	.1	.1	.6	.4					.6

*P = Participant *O/A=overall change in temperature from baseline to completion

Participants 1, 2, 4, 6, 7 and 12 all had wounds that were warmer at the completion of the data collection in relation to the baseline temperature taken on removal of the dressing. Participants 3, 5, 8-11 all had wounds that were cooler at the completion of the data collection.

The mean temperature at baseline was 31.72°C which decreased to 31.35°C within the first twenty minutes post primary dressing removal (Figure 33). Within the first twenty minutes there appeared to be no consistent increase or decrease in temperature with all but one participant's wound temperature fluctuating.

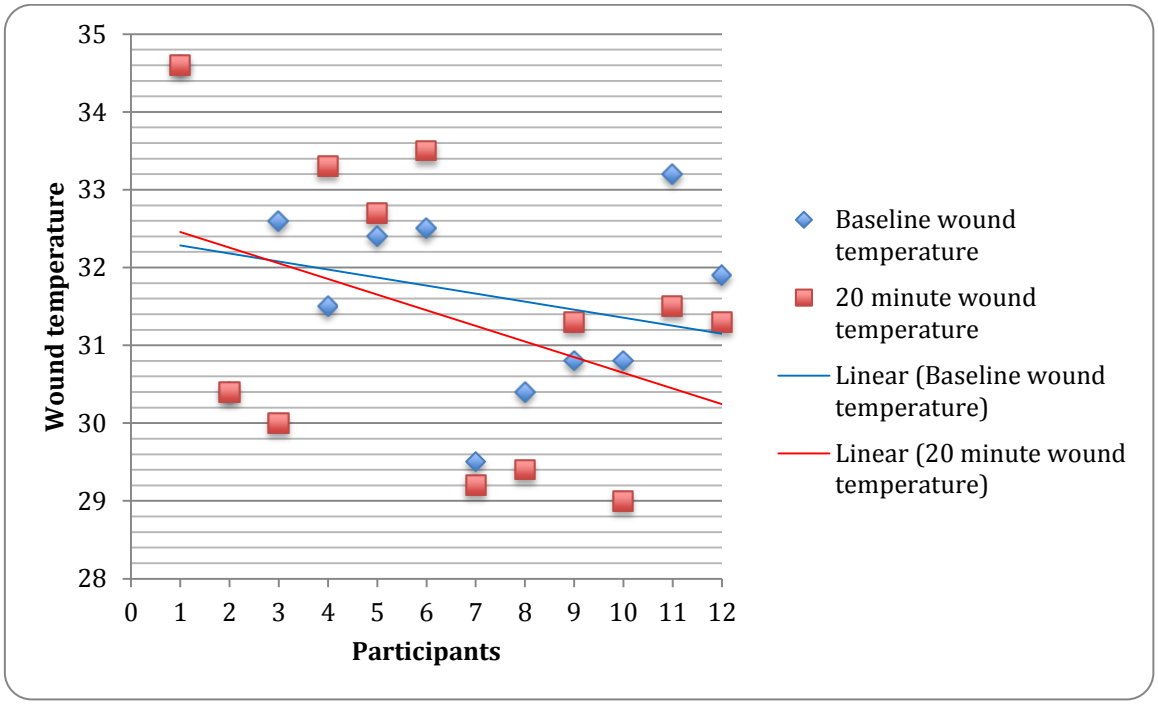

Figure 33 Wound temperature at baseline and 20 minutes post dressing removal

A histogram of all the temperature measurements (n=145) was plotted and noted to be normally distributed; hence analysis was performed using the GEE 'linear' regression model. There was no significant association found between the temperature of wound and

wound exposure in the first 20 minutes of exposure (linear Generalized Estimating Equations model accounting for repeated measures over time: P value=0.311).

In addition to the overarching question of identifying changes in wound temperature and any patterns associated with the length of time the wounds were without their primary dressing, it was also queried as to whether there were any relationships between the wound bed temperature and the type and/or size of the wound, body temperature and the temporary dressing applied. Table 11 provides an overview of the analysis undertaken, which is then elaborated on in the following text. A P value of <0.05 was considered to be statistically significant.

Table 11 GEE regression results for interactions between time and a range of variables for the dependent variable, temperature.

Dependent variable	Interaction variable	P value
Wound Temperature	Time*Size of the wound	0.934
Wound Temperature	Time*Type of the wound	0.003
Wound Temperature	Time*Body temperature	0.973
Wound Temperature	Time*Type of temporary dressing	<0.0001

Relationship between the participant's wound temperature and the size of the wound

The interaction between time (in minutes) and the size of the wound, for wound temperature, was not statistically significant (P value=0.934). Therefore the association between wound temperature and time (in minutes) was not dependent on the size of the wound.

Relationship between the participant's wound temperature and the type of the wound

The interaction between time (in minutes) and type of wound, for the wound temperature, was statistically significant (P value=0.003). Therefore an association between wound temperature and time (in minutes) was related to the type of wound (Figure 34). The wound temperature for the participant with a pressure ulcer decreased over time, whereas the wound temperature for the participants with a wound breakdown, a traumatic wound and a non-pressure ulcer increased over time. However these results need to be viewed with caution due to the small number of participants.

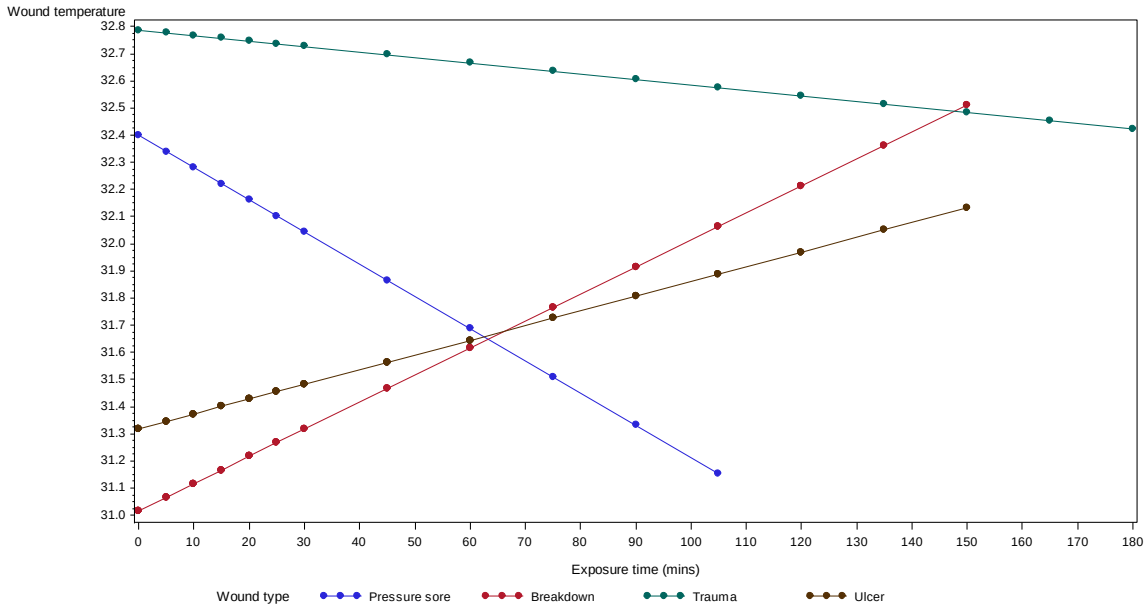

Figure 34 Relationship between the average wound temperature at each time point and the type of the wound

Relationship between the participant's wound temperature and their body temperature

All 12 participants had their body temperature recorded aurally prior to the wound being assessed. The lowest body temperature recorded was 34.6°C and the highest temperature was 37.0°C (Figure 35).

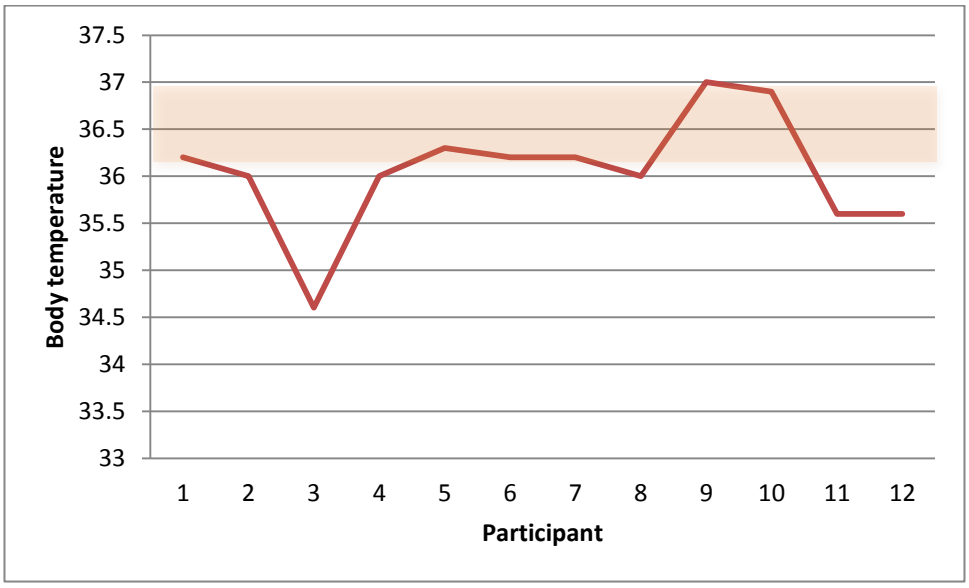

Figure 35 Participants body temperature

The existing literature supports normothermia as between 36.2 and 37°C, dependent on what site the temperature is taken from (depicted in the shaded area in Figure 35).[80] The interaction between time (in minutes) and the participant's body temperature, for wound temperature, was not statistically significant (P value=0.973). Therefore the association between wound temperature and time (in minutes) was not related to the participant's body temperature.

Relationship between the participant's wound temperature and the type of temporary dressing applied

The interaction between time (in minutes) and the type of temporary dressing applied to the wound, for wound temperature, was statistically significant (P value <0.0001). Therefore the association between wound temperature and time (in minutes) is related to the type of temporary dressing applied to the wound. Figure 36 displays the associations between time and temperature for the different temporary dressings applied.

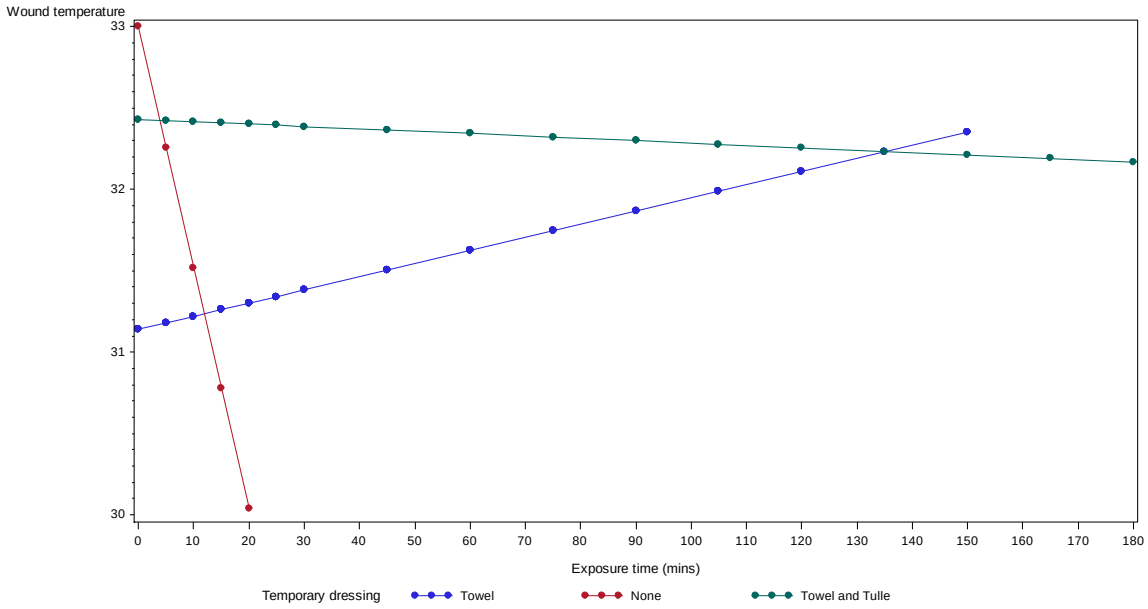

Figure 36 Predicted values between temperature, time and temporary dressing applications

The difference in wound temperature changes between a towel dressing and the towel and Tulle Gras™ dressing was not statistically significant. However, for each one minute increase in exposure time the temperature of the wound with no dressing dropped 0.148 degrees C (P value<0.0001).

The change in temperature per one minute increase in exposure time for cotton sterile towel is significantly higher (and positive) compared with the change in temperature of no dressing (mean difference in slope=0.156, P value<0.0001). The change in temperature per one minute increase in exposure time for Tulle Gras™ dressing is significantly higher (but still negative) compared with no dressing (mean difference in slope=0.147, P value<0.0001). In a logistic regression analysis the slope is the change in the average value of y, from one unit of change in x.

In Summary

The following summarises the results for the 12 participants in relation to the temperature of the wound bed:

- 83% (n=10) had a wound temperature less than 33°C at baseline
- 100% had a wound temperature less than 36°C
- After 20 minutes only two participants were able to maintain wound temperatures above 33°C and only one of these was able to achieve a temperature of 36°C at only two time points
- 50% (n=6) of the participants' wounds were warmer at the end of the data collection period and 50% (n=6) were cooler, with a very slight mean temerature increase of 0.24°C
- 91% (n=11) of the wound temperatures fluctuated throughout the time they were without their primary dressing
- The fluctuation was largely within the first twenty minutes and then plateaued
- The mean wound temperature decreased by 0.37°C at the 20 minute mark

- There was no association between the wound temperature over time and the size of the wound
- There was an association between the wound temperature over time and the type of wound
- There was no association between the wound temperature over time and the body temperature of the participant
- There was an association between the wound temperature over time and the type of temporary wound dressing applied

Despite the literature suggesting associations between body temperature and age, gender, ambient temperature and relative humidity an analysis of the data from this study found no such associations.

Transepidermal Water Loss (TEWL)

Wound bed TEWL during the dressing down time

The measurement of the TEWL for each of the participant's wounds for the length of exposure at each of the designated time points is shown in Figure 37. The minimum TEWL recorded was six units for Participant 3 with all participants recording a near/or maximum TEWL between 17 and 20 units at one time point, with 20 units being the maximum units able to be recorded.

As the data collection time (in minutes) was different for every participant the wound TEWL can only be compared at the same time (in minutes). The baseline TEWL was taken within the first 30 seconds post the primary wound dressing being removed. Only

four of the baseline measurements were less than 20 units and the mean TEWL at baseline was 19.25 units (Figure 37).

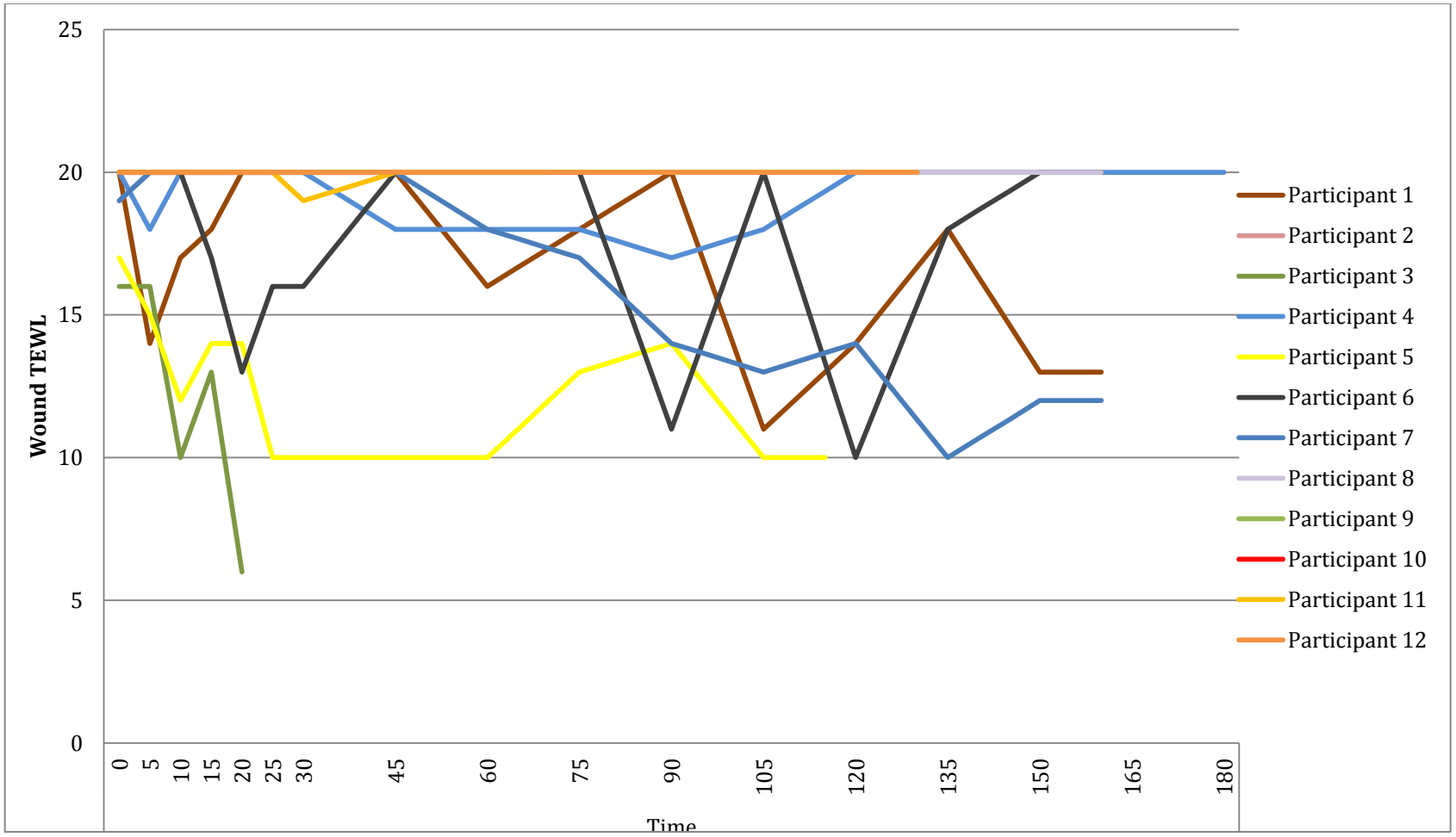

Figure 37 Graphical representation of all participants' wound TEWL

Patterns of change in TEWL for the length of exposure

The overall mean TEWL for the duration of all 145 measurements was 18.15 (SD 3.21). Table 12 illustrates the increases and decreases in TEWL for individual participants. The boxes indicate the change in TEWL from the previous reading with green indicating an increase in TEWL, red a decrease and white no change. The numbers are expressed in whole numbers with 0 units being no moisture loss and 20 units being the maximum measurable moisture loss for the device being used.

Table 12 Positive and negative changes in wound TEWL during the dressing down time

		Time in minutes from baseline of 0																	
*P	TEWL	0	5	10	15	20	25	30	45	60	75	90	105	120	135	150	165	180	*O/A
1	20	0	6	3	1	2	0	0	0	4	2	2	9	3	4	5			7
2	19	0	1	0	0	0	0	0	0	0	0								1
3	16	0	0	6	3	7													10
4	20	0	2	2	0	0	0	0	2	0	0	1	1	2	0	0	0	0	0
5	17	0	2	3	2	0	4	0	0	0	3	1	4						7
6	20	0	0	0	3	4	3	0	4	0	0	9	9	10	8	2			0
7	19	0	1	0	0	0	0	0	0	2	1	3	1	1	4	2			7
8	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			0
9	20	0	0	0	0	0	0	0	0	0	0	0	0	0					0
10	20	0	0	0	0	0	0												0
11	20	0	0	0	0	0	0	1	1	0									0
12	20	0	0	0	0	0	0	0	0	0	0	0	0	0					0

*P = Participant *O/A=overall change in TEWL from baseline to completion

Participants 1, 3, 5 and 7 all had wounds with a reduced rate of moisture loss at the completion of the data collection period demonstrated by the decrease in wound TEWL, with participant 2 having an increase in moisture loss demonstrated by an increase in wound TEWL. All other participants' moisture loss was at the same rate at both the commencement and completion of data collection; with participants 8-10 and 12 maintaining a constant maximum rate of moisture loss (20 units) from the wound throughout the wound down time; but participants 4, 6 and 11 demonstrated fluctuations in moisture loss throughout the data collection process.

The mean TEWL at baseline was 19.25 (SD 3.21) which reduced to 17.75 units within the first 20 minutes post dressing removal (Figure 38).

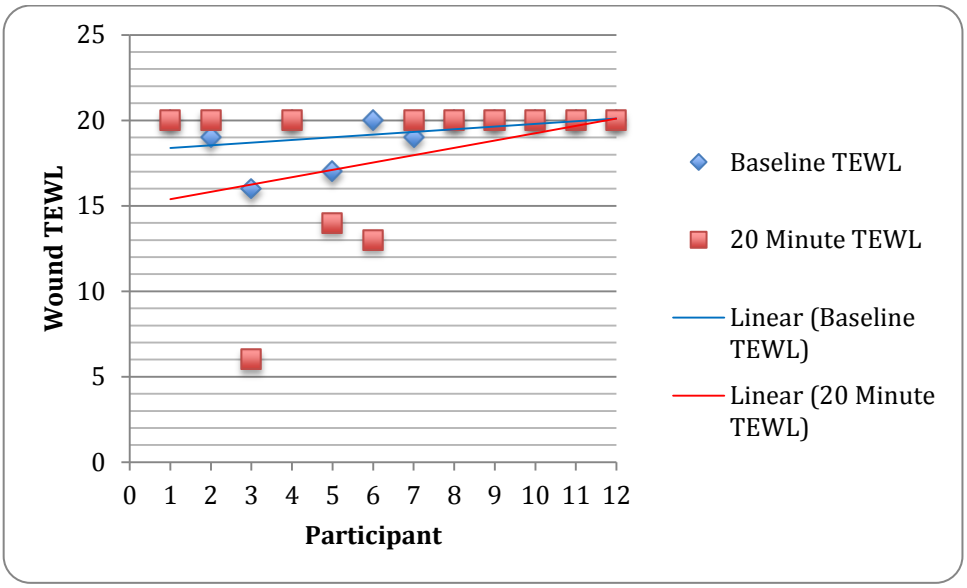

Figure 38 Wound TEWL at 20 minutes

A histogram of all the TEWL measurements (n=145) were plotted and noted to be left skewed, hence the TEWL was analysed using the GEE logistic regression model. As

logistic regression only allows for a binary outcome to conduct the analysis the TEWL data was converted into binary variables. The median result was used to determine the two binary values as the majority of the TEWL data was spread between a TEWL of 20 (1) and a TEWL of <20 (0). There was no significant association found between TEWL of wound and wound exposure time in the first 20 minutes of exposure (logistic Generalized Estimating Equations model accounting for repeated measures over time: P value=0.642).

In addition to the overarching question of identifying changes in wound TEWL and any patterns associated with the length of time the wounds were without their primary dressing, it was also queried as to whether there were any relationships between the wound bed TEWL and the type and/or size of the wound and the temporary dressing applied.

Table 13 provides an overview of the analysis undertaken, which is then elaborated on in the following text. A P value of <0.05 was considered to be statistically significant.

Table 13 GEE regression results for interactions between time and a range of variables for the dependent variable, TEWL

Dependent variable	Interaction variable	P value
Wound TEWL	Time*Size of the wound	0.216
Wound TEWL	Time*Type of the wound	UTA
Wound TEWL	Time*Type of temporary dressing	UTA

Relationship between the participant's wound TEWL and the size of the wound

The interaction between time (in minutes) and the size of the wound, for wound TEWL, was not statistically significant (P value=0.216).

Relationship between the participant's wound TEWL and the type of the wound

In the regression model with TEWL versus wound type and time (in minutes), none of the participants with pressure ulcers had a TEWL=20. This meant there was a zero cell in the contingency table of TEWL versus wound type; hence the GEE logistic regression model did not converge and an analysis was unable to be performed.

Relationship between the participant's wound TEWL and the type of temporary dressing applied

For the regression model with TEWL versus type of temporary dressing and time (in minutes), to converge all three temporary dressing categories required at least one TEWL reading equal to 20. The participant with no temporary dressing applied did not have any readings with a TEWL=20. This meant there was a zero cell in the contingency table of TEWL versus type of temporary dressing applied; hence the GEE logistic regression did not converge and an analysis was unable to be performed.

In Summary

The wound assessment process for the 12 participants included in the study impacted on the wound TEWL in the following way:

- All wounds had a measurable TEWL at all data collection time points, hence maintaining a moisture loss

- 67% of participants' wounds had maximum TEWL of 20 units at dressing removal
- 33% of participants' wounds had a constant maximum (20 units) moisture loss throughout the downtime of the wound
- 33% of participants' wounds had a decreased rate of moisture loss throughout the downtime of the wound
- the mean wound TEWL decreased by 1.5 units at the 20 minute mark
- there was no association between the wound TEWL and the size of the wound

Despite the literature suggesting associations between wound TEWL and age, gender, ambient temperature and relative humidity an analysis of the data from this study found no such associations.

pH

Wound bed pH during the dressing down time

The measurement of the pH for each of the participant's wounds for the length of exposure at each of the designated time periods is shown in Figure 39. The most acidic pH recorded was 6.71 for Participant 6 and the most alkaline was 9.3 for Participant 2.

As the data collection (in minutes) was different for every participant the wound surface pH can only be compared at the same time (in minutes) not just pre and post the wound dressing procedure. The baseline pH was taken within the first 60 seconds post the primary wound dressing being removed.

Figure 39 also demonstrates the appropriate range of wound pH (5.8 to 6.6), which retards the growth of micro-organisms and promotes epithelial growth. 100% of the

baseline pH measurements were alkaline. All twelve participants had a wound pH greater than the recommended pH for healing for the time the wound was exposed with the mean wound pH 8.25 (SD 0.66).

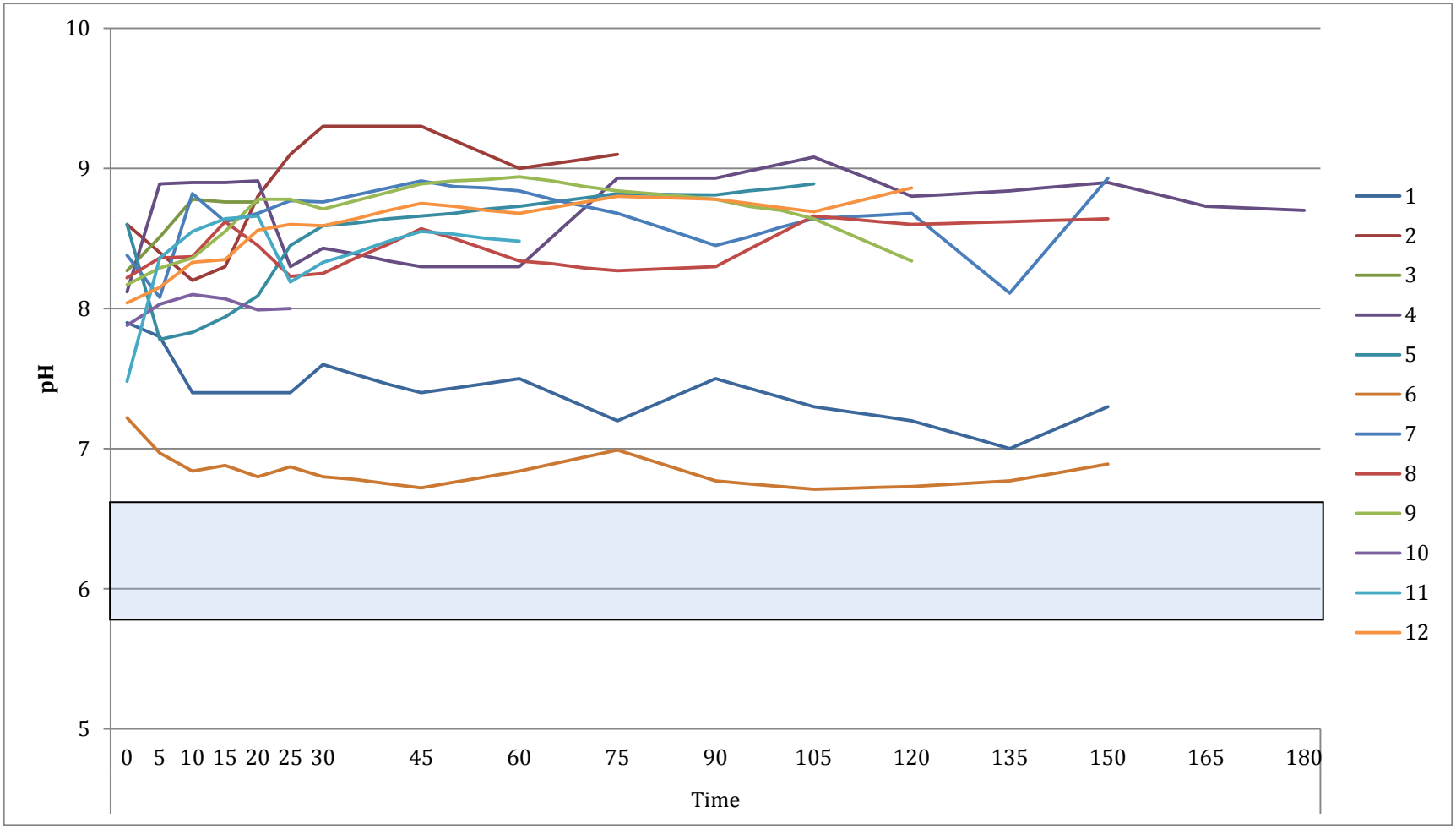

Figure 39 Graphical representation of all participants' wound surface pH

Patterns of change in pH for the length of exposure

The overall mean pH for the duration of all 145 measurements was 8.25 (SD 0.66). Table 14 illustrates the increases and decreases in pH for individual participants. The boxes indicate the change in pH from the previous reading with red indicating an increase in pH to a more alkaline environment, green a decrease in pH to a more acidic environment and white no change. The numbers are expressed as per the change in pH value.

Table 14 Positive and negative changes in wound surface pH during the dressing down time

		Time in minutes from baseline of 0																	
*P	pH	0	5	10	15	20	25	30	45	60	75	90	105	120	135	150	165	180	*O/A
1	7.9	0	.1	.4	0	0	0	.2	.2	.1	.3	.3	.2	.1	.2	.3			.6
2	8.6	0	.2	.2	.1	.5	.3	.2	0	.3	.1								.5
3	8.27	0	.24	.27	.02	0													.49
4	8.12	0	.77	.01	0	.01	.61	.13	.13	0	.63	0	.15	.28	.04	.06	.17	.03	.58
5	8.6	0	.82	.05	.11	.15	.36	.14	.07	.07	.09	.01	.08						.29
6	7.22	0	.25	.13	.04	.08	.07	.07	.08	.12	.15	.22	.06	.02	.04	.12			.33
7	8.38	0	.3	.74	.2	.06	.09	.01	.15	.07	.16	.23	.19	.04	.57	.82			.55
8	8.22	0	.14	.01	.25	.17	.22	.02	.32	.23	.07	.03	.36	.06	.02	.02			.42
9	8.17	0	.12	.07	.19	.23	0	.07	.18	.05	.1	.06	.14	.3					.17
10	7.88	0	.15	.07	.03	.08	.01												.12
11	7.48	0	.88	.19	.09	.02	.47	.14	.22	.07									1.0
12	8.04	0	.11	.18	.02	.21	.04	.01	.16	.07	.12	.02	.09	.17					.82

*P = Participant *O/A=overall change in pH from baseline to completion

All of the initial measurements were above 7.0 where the pH is alkaline and 83% of participant's wounds became more alkaline throughout the wound downtime. Participant 1

and 6 wounds had a slightly more acidic environment at the completion of the data collection period.

The mean pH at baseline was 8.07 which increased to 8.32 within the first 20-minute time period post primary dressing removal (Figure 40). Within the first 20 minutes three of the participant's pH became more acidic, with the remaining participants pH becoming more alkaline.

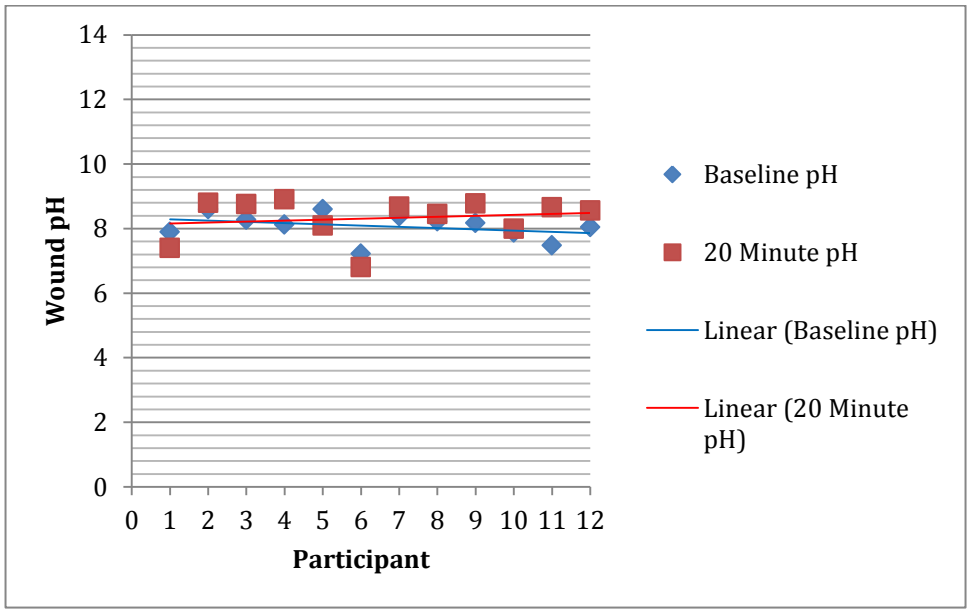

Figure 40 Wound surface pH at 20 minutes

A histogram of all the pH measurements (n=145) were plotted and noted to be left skewed. Hence the pH was analysed using the GEE logistic regression model with pH as the outcome variable and time (in minutes) as the predictor. As logistic regression only allows for a binary outcome the pH had to be converted into a binary variable. To determine the binary variable the median pH was used, hence a pH of >8.5 versus a pH of <=8.5. A P value of <0.05 was considered to be statistically significant. There was a significant

association found between pH of wound and wound exposure in the first 20 minutes of exposure (logistic Generalized Estimating Equations model accounting for repeated measures over time: P value=0.0079). For every increase of one minute in wound exposure time, the odds of having a pH>8.5 is12% greater (Odds ratio=1.12, 95% Confidence Interval: 1.03, 1.21).

In addition to the overarching question of identifying changes in wound pH and any patterns associated with the length of time the wounds were without their primary dressing, it was also queried as to whether there were any relationships between the wound bed pH and the type and/or size of the wound and the temporary dressing applied.

Table 15 provides an overview of the analysis undertaken which is further elaborated on in the following text.

Table 15 GEE regression results for main effects and interactions between pH, time and a range of variables

Dependent variable	Interaction/predictor variable	P value
Wound surface pH	Time*Size of the wound	0.633
Wound surface pH	Time* Type of the wound	<0.0001
Wound surface pH	Time*Type of temporary dressing	Did not converge

Relationship between the participant's wound surface pH and the size of the wound

The interaction between time (in minutes) and the size of the wound, for the wound surface pH, was not statistically significant (P value=0.633).

Relationship between the participant's wound surface pH and the type of the wound

The interaction between time (in minutes) and the type of wound for the wound surface pH, was statistically significant (P value<0.0001). Therefore the association between pH and time (in minutes) is related to the type of wound (Figure 41). During the time the wound was without its primary dressing the wound surface pH of the trauma and pressure wounds became more alkaline, whilst the non-pressure ulcers and the wound break downs became more acidic.

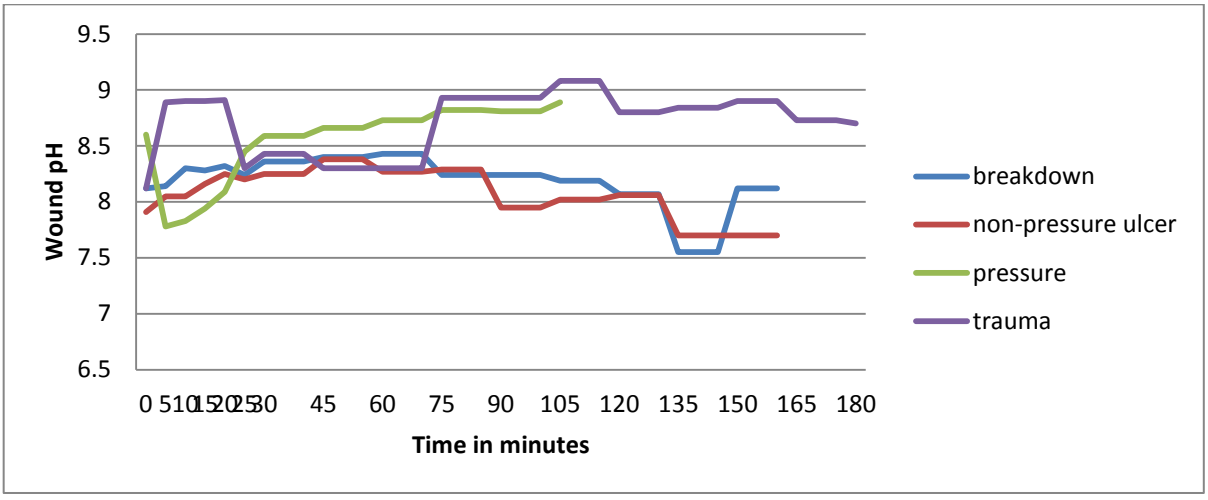

Figure 41 The average pH of each wound type from baseline to final measurement

Relationship between the participant's wound surface pH and the type of temporary dressing applied

A logistic GEE model including the interaction between time of wound exposure and type of temporary dressing and outcome: wound pH did not converge. However, a logistic GEE model with no interaction term found that a participant with no temporary dressing applied had 3.5 times greater chance of having a pH greater than 8.5 (the median) than a participant with a cotton sterile towel and Tulle Gras™ temporary dressing applied, after adjusting for time (in minutes) (Odds Ratio=3.5, 95% Confidence Interval: 2.3, 5.3, P value<0.0001). These results again need to be viewed with caution as there was only one participant who had no temporary dressing cover applied to their wound.

In Summary

The wound assessment process for the 12 participants included in the study impacted on the wound pH in the following way:

- 100% of participants' wounds maintained a pH greater than that recommended for healing at all time points
- 100% of participants' wounds had a baseline pH that was alkaline
- 83% of participants' wounds pH became more alkaline the longer they were exposed without their primary dressing
- there was no association between the wound pH and the size of the wound
- there was an association between the wound pH and the type of wound
- there was a high probability that the participants' wound pH would become more alakline the longer it was left uncovered without a temporary dressing

Despite the literature suggesting associations between wound pH and age, gender, ambient temperature and relative humidity an analysis of the data from this study found no such associations.

Are local wound conditions and patient comfort affected by the downtime taken in association with a wound dressing change? It is clear that certain aspects of the wound bed parameters of temperature, TEWL and pH are impacted upon by the downtime of a wound for assessment. To establish the impact on the patient, a questionnaire was conducted during the data collection period.

Impact of the wound assessment procedure on the patient

The participant questionnaire was conducted to gain the participant's perspective on the wound assessment process and the impact on activities of daily living and pain associated with the dressing procedure.

Wound assessment is a critical component for effective wound care. The issue around this process is the timing and duration of the assessment whilst the participant is a patient in an acute hospital or attending the outpatient department.

One of the twelve participants was unable to complete the questionnaire due to difficulty expressing themselves due to an existing co-morbidity. The following results relate to the eleven remaining participants that completed the questionnaire.

Timing of the dressing removal

Question 1 of the questionnaire asked the participant if they were informed of when the dressing would be removed. Six of the participants were not informed of when the dressing would be removed (Figure 42).

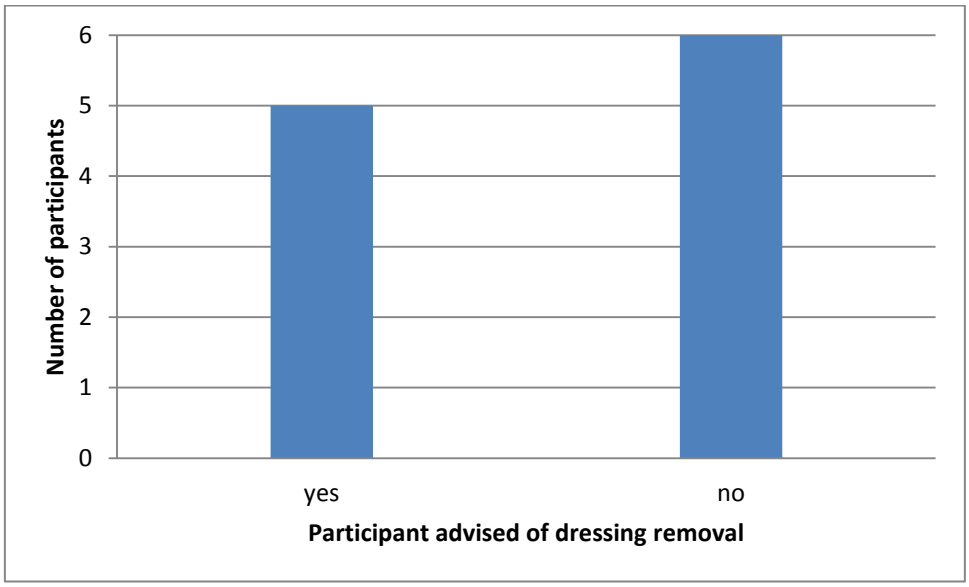

Figure 42 Participant advised of dressing removal time

Question 2 was to establish if there was any communication to the participant regarding the length of time they were required to wait for their wound to be assessed. Only two participants were informed that there was a delay in the wound assessment process with the majority remaining uninformed as to when their wound would be reviewed (Figure 43).

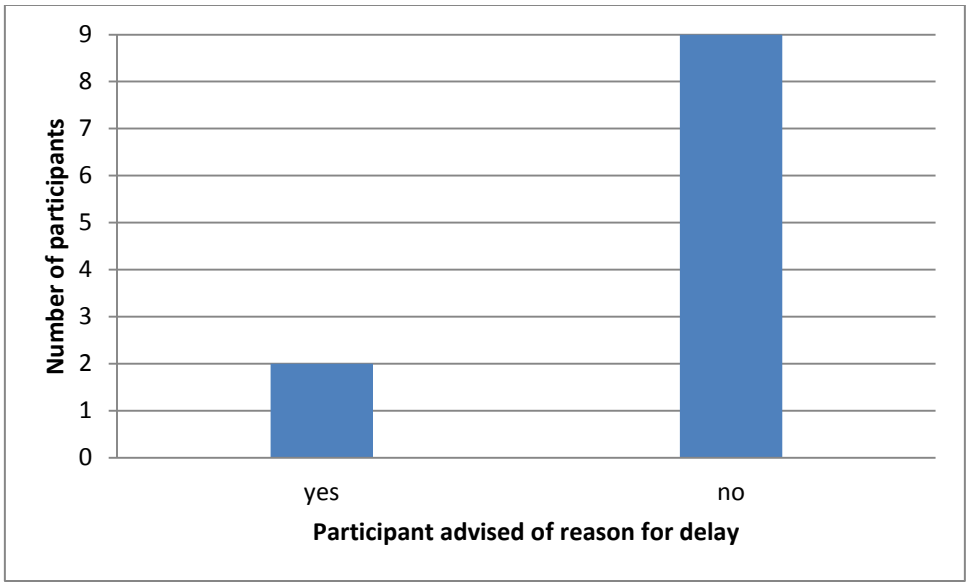

Figure 43 Reason for delay in wound dressing assessment provided to participant

Impact on activities of daily living

Participant comfort throughout the wound assessment process is often the least considered aspect and question three asked the participant to identify if the wound assessment process had impacted on any of their activities of daily living (ADL). Participants identified the following aspects to have been unable to be completed or hampered by the fact that the primary wound dressing was not in place (Table 16).

Table 16 Impact of the wound dressing procedure on ADLs

Participant (n=11)	1	2	3	4	5	6	7	8	9	10	12	% impact
Hygiene		X					X				X	27
Nutrition								X	X	X		27
Toilet	X			X		X	X				X	46
Visit												0
Positioning						X				X		18
Other	X											9
No impact			X		X							18

Two of the participants stated there was no impact on their ADLs (18%), however, the other nine participants gave varying results of how the wound dressing procedure impacted on one or more ADL. Toileting was the most common ADL impacted upon by the delay in the wound dressing change (46%); whereas visiting hours were not seen to be affected at all (0%).

Analgesia

Analgesia should be offered prior to having a procedure which could potentially be painful[170,235] and question four asked the participant if they had had any analgesia offered. Of the eleven participants, the question was not applicable for one participant as they had a continuous infusion of analgesic being administered. Of the remaining ten participants, seven stated they had not been offered analgesia (Figure 44). Of the three participants who

were offered analgesia, all three participants stated that it was effective. Two of the seven participants that were not offered analgesia prior to the wound dressing commencing requested analgesia during the procedure and also stated that it was effective.

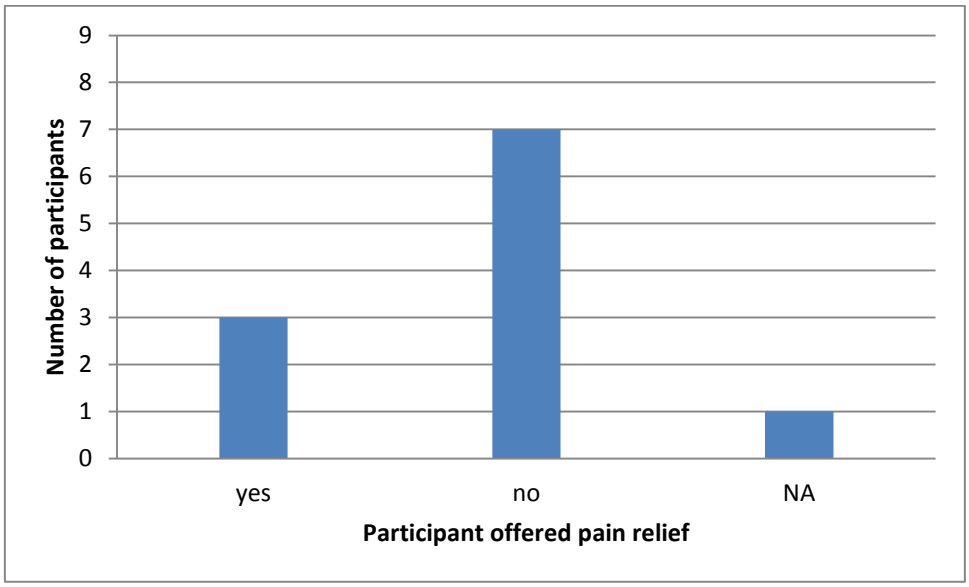

Figure 44 Percentage of participants offered pain relief prior to the dressing change

Pain scores

The pain scores of participants were assessed pre dressing removal, during dressing removal, during the dressing procedure and immediately post the dressing procedure, using a visual analogue scale (VAS).

The participant's VAS was measured on a 0-10 scale, with zero being no pain and ten being the worst pain the participant could imagine. The VAS scores at all four times of the dressing procedure were:

- pre removal - ranged from 0 to 7 with a mean of 2.42
- during removal - ranged from 0 to 9 with a mean of 4.33
- during the dressing procedure - ranged from 0 to 9 with a mean of 3.58
- post the dressing procedure - ranged from 0 to 9 with a mean of 3.42

The difference between each participants VAS score during the dressing change and VAS score prior to their dressing change was calculated. A positive number meant that the pain score had increased because of the dressing change. The histogram showed a normal distribution of the differences in VAS scores, therefore allowing a linear regression to be performed. Although the scatter plot (Figure 45) shows a positive linear relationship between the difference in VAS scores and time (in minutes), there was not enough power (n=11) to detect a significant association between the two variables (P value = 0.36).

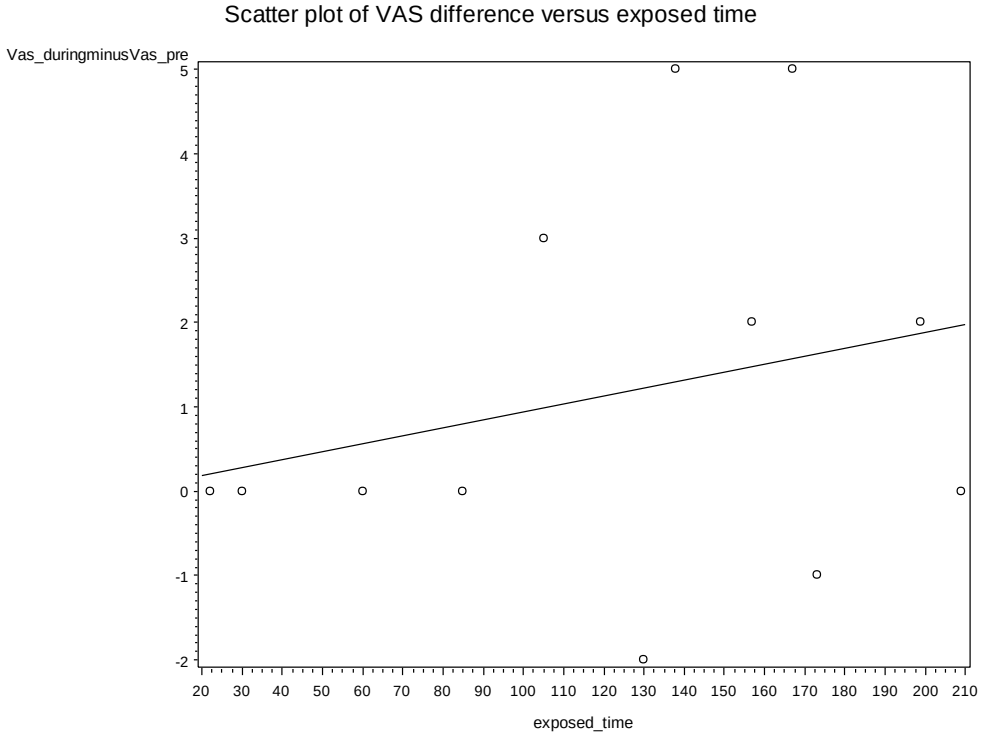

Figure 45 VAS difference in relation to wound exposure time

Other comments

The questionnaire had additional space for any other comments surrounding the wound assessment procedure to be recorded by the participants, however, none were documented.

In summary

The results of the participant's questionnaire clearly show that the communication regarding the wound assessment process is lacking. The dressing procedure and the delay caused by the exposure time impacted on the patients performing ADLs; in particular attending to toileting needs.

Analgesia was only offered in 30% of cases with some participants requesting analgesia after the procedure had commenced.

It should be noted that of the 11 participants 27% had minimal pain associated with the procedure at all with the only increased in pain evident on wound dressing removal. Another 27% of participants had pain prior to the dressing procedure commencing and this was exacerbated during the dressing removal however this reverted to the pre dressing removal VAS score despite being exposed. The other 46% (n=5) had an increased level of pain for the length of time the wound was exposed. There was no association found between the differences in the mean pain scores from pre dressing compared to the mean pain scores during the dressing change in relation to length of time the dressing change took. However the participants still had pain and others had increased pain for the period of time the wound was exposed. Hence the length of wound exposure may have impacted on the time the participant had to endure the pain.

The results regarding the research question around the wound bed parameters and the patient questionnaire have been provided. The final results to be presented are in regards to the possibility of wound contamination during the wound assessment procedure.

Wound contamination during the wound assessment procedure

To identify as accurately as possible potential contamination of the wound while the primary dressing was not in place agar plates were situated within close proximity to the wound. The agar plates were sent for analysis to the state pathology service and two types of bacteria were reported: *Aspergillus fumigatus* and mixed non-pathogens. Colony forming units (CFU) are a group of the same organism growing together and this is then termed an individual colony. CFU is used as a measure of the number of colonies present in the sample and the unit of measurement in this study is colonies per cm^2.

Data were only available for eleven participants as one sample went missing following delivery to the laboratory. Three participants (27%) had *Aspergillus fumigatus* detected in their agar plate during the time their wound was exposed and ten participants (91%) had mixed non-pathogens detected (Table 17).

Table 17 Detection of *Aspergillus fumigatus* and mixed non-pathogen *c*ontamination of participant's agar plate

Participant	Mixed non-pathogen (CFU)	*Aspergillus Fumigatus* (CFU)	Exposure Time
1	95	00	167
2	2	0	85
3	10	0	22
5	45	0	105
6	22	1	209
7	22	0	173
8	31	0	157
9	18	0	138
10	0	5	30
11	10	1	60
12	23	0	130

Aspergillus fumigatus

The maximum number of CFU of *Aspergillus fumigatus* recorded was 5. The data for *Aspergillus fumigatus* were placed in a scatter plot and using logistic regression no significant association was found between number of *Aspergillus fumigatus* (in CFU) and

time (in minutes) (P value=0.574) (Figure 46). However, there is possibly not enough power (n=11) to show a statistically significant association.

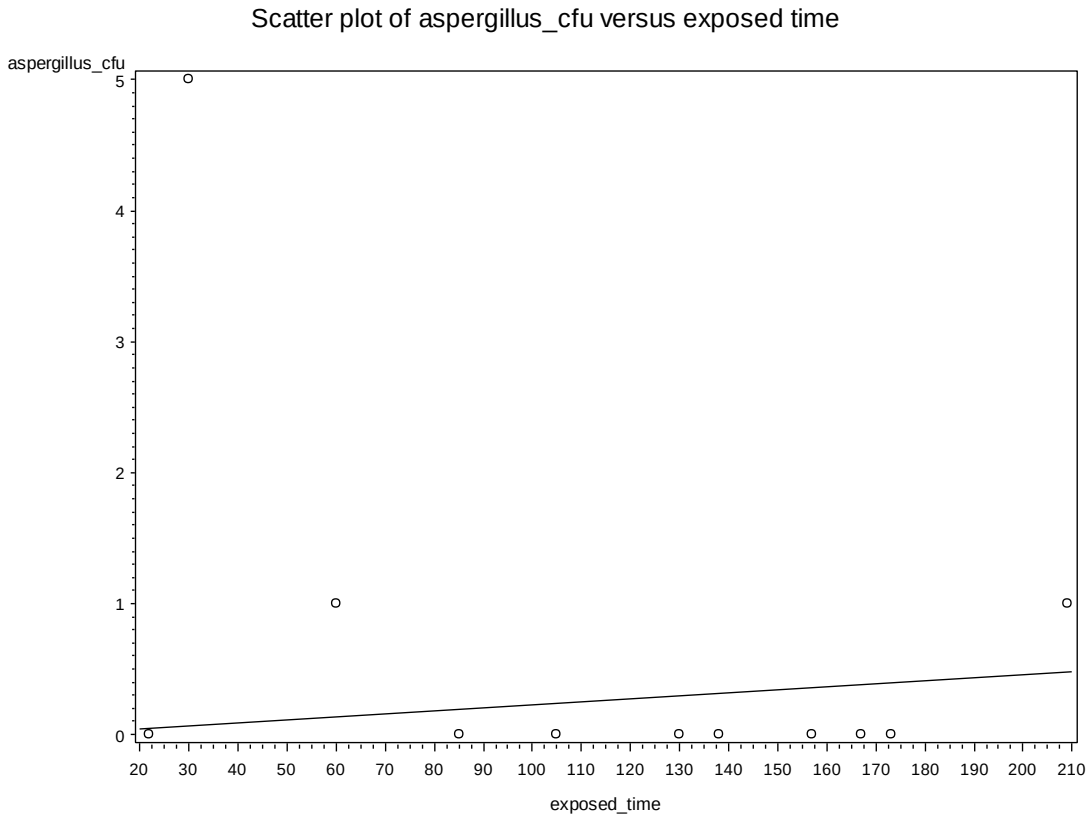

Figure 46 Scatter plot of *Aspergillus fumigatus* CFU in relation to exposure time (mins)

Mixed non-pathogens

The maximum number of CFU of non-mixed pathogens recorded was 95 CFU.

The CFU for mixed non-pathogens were placed in a scatter plot and using logistic regression no significant association was found between number of mixed non-pathogens and time (in minutes) (P value=0.326) (Figure 47). A possible positive linear relationship

demonstrated the greater the time (in minutes) the more CFU were grown. However, there is possibly not enough power (n=11) to show a statistically significant association.

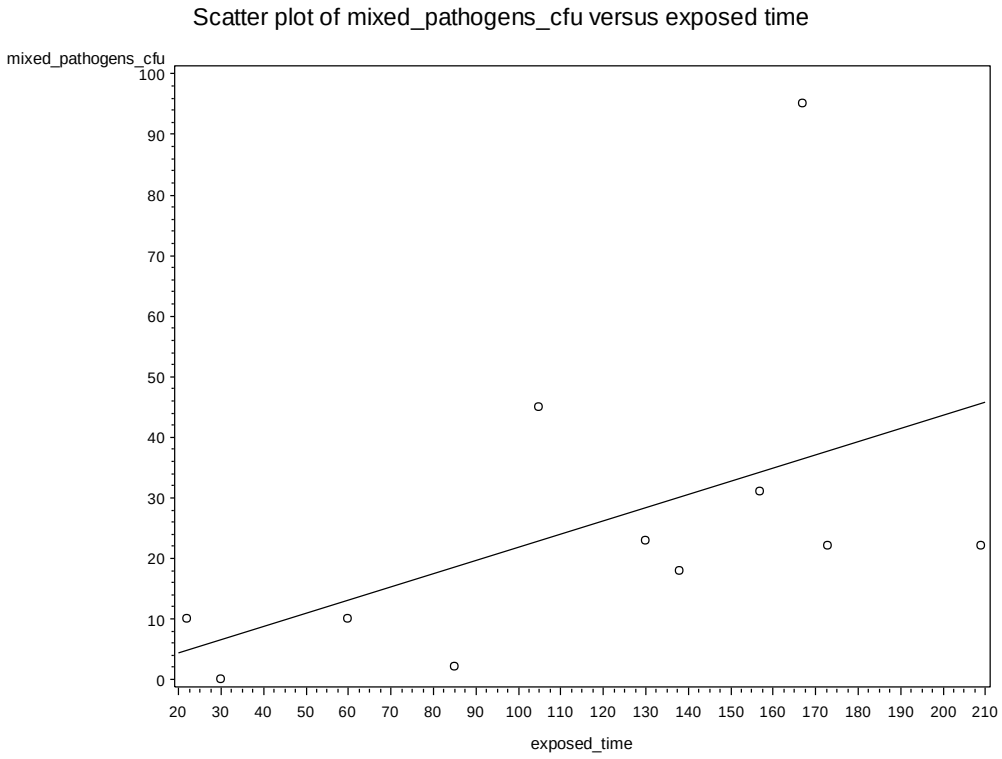

Figure 47 Scatter plot of mixed non-pathogens (CFU) in relation to exposure time (mins)

In summary

The results from the agar plates show three participants (27%) had *Aspergillus fumigatus* detected and ten participants (91%) had mixed non-pathogens detected during the time their wound was exposed.

The maximum number of CFU of *Aspergillus fumigatus* recorded was 5 CFU with no statistical significance found in relation to the time the wound was without its primary dressing. The maximum number of CFU of non-mixed pathogens recorded was 95 CFU. A possible positive linear relationship demonstrated the greater the time (in minutes) the more CFU were grown. However, there is possibly not enough power (n=11) to show a statistically significant association.

Conclusion

Analysis of the twelve participant data on the impact of the wound assessment process on the wound bed parameters; temperature, TEWL and pH demonstrated; all wounds were hypothermic at baseline (below 36°C) with ten of the 12 wounds below the critical temperature of 33°C deemed necessary for epithelial growth and this continued throughout the time the wounds were without their primary dressings. In addition to the hypothermia all wounds had maximum TEWL measurements at baseline indicating either a strained barrier or critical moisture loss, with 67% continuing to have critical moisture loss and the other 33% having a reduced moisture loss. All of the wounds were alkaline at baseline (above 7.0) with 83% increasing in alkalinity throughout the time the wounds were without their primary dressings, in addition all wounds were more alkaline than that required for optimum wound healing.

The impact of the wound assessment procedure on the patient showed that patients were unable to attend to their nutritional, toileting and hygiene needs; in addition the offering and administration of adequate analgesia was not conducted as per best practice. The

environmental assessment found a number of organisms present in the environment that could have contaminated the wounds throughout the wound assessment procedure.

Further discussion will be detailed in relation to the research questions and aims of the study, in line with best practice surrounding wound dressing changes and associated participant comfort. Implications for practice and recommendations are proposed; as well as any additional research which may assist to further expand the research already conducted.

Chapter Five – Discussion

Introduction

The findings both support and refute aspects of the overarching research proposition that local wound conditions and patient comfort are adversely affected by the down time taken in association with a wound dressing change. Additional findings are compared with the evidence available in the literature; however, due to the small number of participant's these need to be viewed with caution.

How the wound bed conditions of pH, temperature, transepidermal water loss (TEWL) and bacterial levels changed during the down time of dressing changes and any patterns of change will be discussed. Any relationships between the patterns of change and the type or size of the wound, whether the participant's body temperature was a confounding variable in relation to any changes in wound temperature and the impact on the wound bed conditions from the type of temporary dressing applied during the down time are also highlighted. Finally reflection on the importance of participant comfort during the wound dressing change with extended down time is considered.

Wound bed parameters

There are numerous studies which have reported the benefits of a warm moist environment, including accelerated healing time.[33,152-156] The literature deems a temperature above 33°C to be critical for epithelialisation of a wound[41,157-159] and promotes warm, moist wounds to allow newly formed skin cells to move freely across the wound bed.[4, 40,157-159] Wound epithelialisation is also associated with a decrease in pH towards an

acidic level, hence anything that can decrease the wound surface pH to an acidic level of 5.8 to 6.6 is beneficial to wound healing.[2,52,157,168,169]

Maintaining these wound bed parameters at a constant level and providing an optimal environment are important whilst the dressing is intact, throughout the wound being assessed and the dressing changed. Any impact on these parameters needs to be minimised throughout this process.

The study was based on the assumption that these wound bed parameters would deteriorate upon removal of the primary dressing and continue to deteriorate the longer the wound was without its primary dressing. What was not anticipated were the sub-optimal levels of the wound bed parameters at the time when the dressings were initially removed.

The question regarding patterns of change of the wound microenvironment and length of exposure cannot be completely answered. There appeared to be no consistent change throughout the down time of the dressing procedure in relation to wound temperature and TEWL; however there was a statistically significant change in wound pH. A number of other associations with each of these parameters will also be discussed under the following headings.

Wound bed temperature

On removal of the wound dressing the data demonstrates that ten of the participants' wounds had a temperature which was clinically lower than the stated 33°C said to be critical for wound epithelialisation to occur.[41,157-159] The wound temperatures were measured within sixty seconds of the dressing being removed with a mean wound

temperature of 31.7°C (27.2°C to 36°C) demonstrating they were already cool before their primary dressing was removed. Participant 6 had their dressing removed in the shower under running water to assist with the removal of the dressing. Curiously this patients wound was above 33°C after the ten minute data collection period and got warmer as the data collection continued. This may suggest it was above 33°C prior to removal and then cooled with the shower water but recovered as the vascularity may have been sufficient to regain any temperature loss. Throughout the time the wounds were without their primary dressing 50% of the participants had wounds that demonstrated a slight increase in wound temperature and the other 50% had wounds that demonstrated a decrease in wound temperature. Although there was a statistically significant overall mean increase in wound temperature, the difference was not clinically significant. More importantly it should be noted that the majority of wounds remained hypothermic for the duration of exposure.

The literature states that wound temperatures post dressing changes can take anywhere between 23 minutes to three hours to return to pre dressing temperatures and regain mitotic activity.[45] If the pre dressing temperatures are already below the temperature required for mitotic activity, not only is reducing the exposure time important to minimise this impact, but also addressing the baseline temperatures to a level consistent with wound healing must be considered.

Wounds will be warmed through endogenous means by the heat supplied from adjacent tissues which is dependent on the vascular supply to the region. There will also be exogenous factors that impact on heat loss through convection, conduction, radiation and evaporation from the wound including the temporary dressing in place, patient movement,

numbers of bed covers and the ambient temperature of the room. The heat produced by the body should ideally equal the loss of heat from the wound to maintain equilibrium; however this was not the case as all but two wounds were unable to maintain a temperature above the critical level of 33^0C.

Relationship between the participant's wound temperature and their type of dressing product

The dressing of choice for each wound is aligned with the functionality of the wound dressing, the manufacturer's recommendations as well as the clinical situation. The types of dressing product the participant's wounds are dressed with may play a role in maintaining the wound bed temperature depending on the thermal properties of the dressing.

Ideally wound dressings should assist in maintaining an appropriate and consistent wound temperature without interruption from frequent dressing changes, with the aim being for the wound to regain its initial temperature following reapplication of the dressing to allow any associated mitotic activity to continue.[41,56,82,88,142] Despite this, no matter which dressing was used for the 12 participants in the study the wounds remained hypothermic (<36°C) and the majority of products were unable to maintain the minimum wound temperature (<33°C) required for epithelialisation to occur. The two participants that had wounds above 33°C at baseline had been dressed with a hydrofibre dressing (Participant 1) and a VAC dressing (Participant 11). However, because of the small sample size it was not possible to determine if there was a statistically significant association between the type of primary dressing and differences in baseline temperature.

Relationship between the participant's wound temperature and their type of wound

The type of wound may be an important factor in the temperature of the wound as an association was found between wound temperature and the pressure ulcer (Participant 5), where the wound temperature decreased over time. This was in contrast to participants with a wound breakdown, a traumatic wound and a non-pressure ulcer where the wound temperature increased over time. As there was only one participant with a traumatic wound and one with a pressure wound, the results need to be viewed with caution.

Relationship between the participant's wound temperature and the type of temporary dressing applied

It is intuitive to assume that in the absence of a cover, the thermoregulatory properties of a wound will be negatively impacted upon in contrast to those which were covered with cotton sterile towels alone or with Tulle Gras™ and a cotton sterile towel. Although only one participant (Participant 3) had a wound not covered with a temporary dressing, this participant also had the shortest duration of time without its primary dressing. The association between temperature loss over time and the absence of a temporary cover was statistically significant. In considering the clinical significance of this result although most of the wounds were hypothermic, not having a temporary cover was additionally detrimental.

Other factors

The wound temperature was not dependent on the participant's body temperature or age, with the youngest participant having the lowest body temperature and one of the oldest participants having the highest body temperature.

Despite the literature suggesting associations between wound temperature and body temperature, age, gender, ambient temperature and relative humidity an analysis of the data from this study found no such associations.

Wound bed TEWL associations during the down time of dressing changes

On removal of the wound dressing the data demonstrates that eight of the wounds had a maximum TEWL of 20 units (mean 19.25) indicating a significant moisture loss.[31,125] However, the TEWL measures the rate of loss from the wound bed, which is dependent on the ability of the body to maintain a moist environment through the optimal function of cells and enzymes to ensure a moist environment at normal body temperature. The wounds all continued to have moisture loss, however the relevance of this is difficult to ascertain. The importance of TEWL is concerned with two related but different consequences. The ideal wound environment is moist and therefore conducive to healing. If the wound is too moist there is the risk of maceration, or too dry there is a risk of desiccation. The other consequence of TEWL relates to cooling.

A loss of skin integrity enables TEWL via evaporation and convection, which in turn cools the tissue temperature[85] and the prevention of evaporative moisture loss through the timely application of a dressing will aid in reducing this cooling.[153,157]

If the TEWL measurement is the loss of moisture through the epidermis to the external atmosphere, then it is natural to assume that the TEWL would be increased due to damage to the epidermal and dermal layers. It should also be considered that a desiccated wound is likely to have a low rate of TEWL. This is clinically important for a number of reasons. As

previously discussed the number of Polymorphonuclear leukocytes (PMNS) are one of the most important defences against infection and these decrease in the presence of a scab compared to a wound that is covered with an occlusive dressing and wounds heal faster when covered with plastic film, as compared to air-exposed wounds.[45,142,181]

There was no statistically significant change in TEWL during dressing down time with eight of the wounds remaining at their baseline moisture level (with some fluctuations throughout) with a third of those having a constant maximum (20 units) moisture loss throughout the downtime of the wound. The remaining four demonstrated a decreased moisture level, but again with some small fluctuations throughout the down time. It is notable that Participant 3, who had no covering placed on their wound, had the largest decrease in wound TEWL. This may indicate that the wound was drying out which would support the researcher's proposition and the literature that a temporary wound covering is required. The longer the wound is left exposed, the drier it is likely to become due to both evaporative and convection processes, ultimately leading to a lower TEWL reading.[157]

Throughout the wound dressing down time 33% of wounds demonstrated a reduction in moisture loss whilst exposed however apart from Participant 3 all continued to have significant moisture loss with a TEWL range between 10 and 20. This implies that the covered wounds were being protected from desiccation to some degree.

Despite the literature suggesting associations between wound TEWL and gender, size of the wound, ambient temperature and relative humidity an analysis of the data from this study found no such associations.

Wound bed pH associations during the down time of dressing changes

On removal of the wound dressing the data conclusively demonstrates that 100% of the wounds had a baseline pH that was alkaline, with 83% of participants' wounds pH becoming more alkaline the longer they were exposed without their primary dressing. The changes in pH range from 0.01 to 1.12 and although the pH changes appear to be small; a change of 1.12 corresponds to a change of more than 11 times the previous reading; as a pH of 6.0 is ten times more acidic than a pH of 7.0, and a pH of 5.0 is 100 times more acidic than a pH of 7.0.[36]

The clinical importance of this change in pH relates to the availability of oxygen as it is required for collagen synthesis and epithelialisation. Leveen (1973) found a decrease in pH by at least 0.6 units may increase the amount of oxygen released by almost 50%.[174] The resultant average 0.4 increase in pH for the participants in this study would indicate the potential for a decrease in the amount of oxygen available to the cells during the wound down time.[174] If hypoxia is prolonged or severe, the cells then produce lactic acid, which in turn increases the cellular pH.[170,171] Hence, establishing factors that impact on the wound pH is vital to ensuring an optimal wound bed.

The results from the study found the wound surface pH was not dependent on the wound size, participant's body temperature, age, gender, ambient temperature, RH or the type of temporary dressing applied. However, the type of wound and the length of exposure did impact on the wound surface pH. However the results need to be viewed with caution due to the small number of participants'.

Relationship between the participant's wound surface pH and the length of time the wound was exposed

The longer a participant's wound was exposed the greater chance there was of having a pH of >8.5 compared to having a pH <8.5. This result confirms suggestions that a wound exposed to air for prolonged periods of time will become more alkaline.[2,142] This was reaffirmed with the finding that Participant 3 who had no temporary dressing in place, had a 3.5 times increased risk of having a pH of >8.5 compared to participants in the study with a cotton sterile towel ±Tulle Gras™ applied. As there was only one participant with a wound left uncovered, the results need to be viewed with caution.

Relationship between the participant's wound surface pH and the type of wound

As described in the literature review a healing wound is more likely to have an acidic pH compared to a newly formed wound, when the skin is wounded and initially debrided, the pH increases and the wound tends to be neutral or somewhat alkaline.[157] Participant 6 had a wound with a pH that was fairly neutral throughout the down time (lowest pH), this wound had progressed further through the wound healing phases than the other wounds, evidenced by the pink epithelialising tissue present, whereas the majority of other wounds had red granulating tissue.[147]

Although only a relatively small sample the results indicate that there were differences in the pH of the types of wounds. All four wound types; trauma (Participant 4), pressure ulcer (Participant 5), non-pressure ulcer (2, 6, 8, 11 & 12) and wound breakdowns (Participants 1, 3, 7, 9 & 10) were alkaline at baseline. Although some wound types became more alkali and some more acidic throughout the length of exposure they all stayed within the alkali

range. Hence further evaluation needs to be undertaken to determine if a specific wound type is likely to become more alkaline than another, as this could alter the picture in relation to the impact of exposure.

Temporary dressing cover

Cotton sterile towels were applied in eleven cases as a temporary cover and in one case nothing at all. Two of the eleven cases with the cotton sterile towel also had Tulle Gras™ additionally applied directly to the wounds.

Although Participant 3 was the only participant that did not have their wound covered, this participant also had corresponding changes in their wound parameter values that supports the proposition that a temporary wound covering is required: the largest decrease in TEWL; a more alkaline pH that could have reduced the oxygen availability to the wound; and the second highest number of CFU per minute. Although this was only one data set the results indicate that leaving the wounds exposed to the environment is unacceptable practice.

The application of a temporary dressing such as a cotton sterile towel has the potential to protect the wound from pathogens and keep it warm as natural convection is minimised, however, it will not stop the evaporative process.[25-27] It has also been found that absorbent dressings only stay sterile and impervious to bacteria until such time that a wet-path has occurred, usually within a matter of hours; and once strike through has occurred the chances of contamination greatly increase.[185] During the time that the participant is waiting for the wound to be assessed the cotton sterile towel moves with the patient as they move

around the bed and may come unwrapped. The cotton sterile towel is also unwrapped by the medical team to review the wound.

Combining Tulle Gras™ with a cotton sterile towel to cover the wound did not demonstrate any differences in the wound parameters as the wounds remained cool, continued to lose moisture and became more alkaline throughout the down time. The use of Tulle Gras™ may eliminate the issue regarding trauma to the wound surface as it is a non-adherent dressing product.[65]

In identifying how to address this issue, taking heed of what is being utilised in the United Kingdom (UK), the application of plastic wrap to the wound may be useful. Pain relief should be provided to the patient and administered when the nurse has prioritised the wound dressing to be removed. Once the wound dressing has been removed the plastic wrap could then cover the wound, which has the benefit of allowing assessment of the wound at a pre-scheduled time, but if subsequently waylaid there would possibly be less impact on the patient.[242]

Coles *et al* (1991) state that plastic wrap maintains temperature and pH of the wound, prevents moisture loss as well as protecting it from contamination. This also ensures the raw nerve endings in the wound would not remain exposed and hence pain would possibly be less.[196-199] A plastic wrap cover is more secure than a cotton towel which will allow the patient greater mobility

Impact on the patient awaiting wound dressing assessment

The dressings removed in preparation for a wound assessment left the participants in this study without their primary dressings from 22-229 minutes impeding their ability to toilet, bathe and eat; issues which have also been discussed in other studies.[61,200] One reason for removing a dressing prior to the medical team arriving is that the most painful aspect of the dressing procedure is often the actual removal of the wound dressing.[184,186,187] Ensuring the patients dressing is removed in a controlled manner at a pace that is acceptable to them, with prior administration of analgesia is an important consideration.

Pain and analgesia

It should be standard practice for analgesia to be offered to patients prior to conducting an intervention that may be painful.[196] This was not regular practice in this study with 50% of the participants having analgesia administered just prior to the dressing being removed or during the actual dressing removal. Even though the other participants did not request analgesia all bar one of the participant's pain scores increased. Despite pain consensus documents having been developed to guide practice and improve patient outcomes,[243] participants regularly 'put up' with pain and nurses should be acting as an advocate for the participants.

Pain scores

Painful wounds and the wound dressing procedure may not only delay wound healing, but will also impact on the patient experience and ability to attend to activities of daily

living.[200] Nerve endings that are exposed in partial-thickness wounds are sensitive and therefore more likely to result in pain.[196,198,199]

In this study the participant's pain scores were relatively low with the means at all periods of assessment below four. However, it is still important to note that the participant's wounds were most painful during dressing removal, settling slightly during the wound cleansing process and then reducing slightly after being redressed. There was a positive linear relationship between higher pain scores and the length of time the wound was exposed, however, there was not enough power to detect a statistically significant association. The post dressing VAS score did not return immediately to the pre dressing removal VAS score and the patients were not reviewed post the dressing application to determine how long their pain levels took to return to pre dressing levels. Despite this it logical to suggest that minimising exposure time should increase patient comfort and reduce pain.

Activities of daily living

The wound assessments by medical staff were routinely being performed during the morning. Patients would normally tend to their personal hygiene in the morning and due to the wound dressings being down, the patients were unable to do this. Patient centred care is gaining considerable attention at present and addressing patient concerns and ensuring they are involved in their care is a necessary aspect in all organisations. What is valued by the patient must be respected by the health professional and assisting the patient to feel fresh and clean is something that is regularly overlooked.[273,274]

Toileting of the participants during the down time was the area of ADLs most impacted upon. Some participants had to use bedpans and others mobilised to the bathroom without an intact primary dressing. This increases the potential of trauma to the wound from the temporary cover and increases the risk of contamination. As identified in other studies It was also quite awkward for some participants to access the toilet at all due to the location of the wound.[61,200]

The majority of the wound dressings were removed around breakfast time and although some participants still managed to eat others were unable to due to the location of the wound. Adequate nutrition is an important part of wound healing and ensuring patients have timely access to food is an important aspect of their wound management.[61,200] The down time imposed on some participants meant that they ate it late or in some cases missed breakfast altogether.

Most of the wounds in this study were located in areas of the body that did not require alternative positioning; however, two participants did require positioning that was uncomfortable during the time their dressing was not in place. Their discomfort was quite obvious to the researcher from both the comments made and the need for regular repositioning of one participant from side to side during the three hours their wound was down. The second participant ceased the data collection procedure as they said 'they had had enough of everything'. This second participant already had a wound breakdown and was one of the older participants. A stage one pressure ulcer can take as little as two hours to form and in someone who is at risk, this occurrence is of concern.

Patient centred care can be promoted in this particular instance with co-ordination surrounding the dressing removal time being discussed with the patients.[273,274] In addition keeping the patient informed of what is happening regarding their care when there are delays is also important as 82% of the participants were not told why their wound had not been reviewed. This was evident through comments made by the participants during the dressing down time: 'You will be waiting a while … XXX is never on time'; 'What is going on, this is ridiculous'; 'can I roll back over yet?'; and one participant even voiced concerned for the researcher; 'This is so unfair for you'. These comments highlight how communicating on a regular basis with patients is a must, to alleviate any undue stress and anxiety, which has also been shown to impact on wound healing.[244,245]

Microbiology

The results from the agar plates show that the risk of contamination to the participants' wounds was very high with all participants agar plates detecting organisms (*Aspergillus fumigatus* and mixed non-pathogens*).* Although there was no statistically significant increase in the number of CFU grown for *Aspergillus fumigatus* over time, there was a positive linear relationship demonstrated for the growth of mixed non-pathogens; the greater the time (in minutes) the more CFU were grown.

The impact of exposure on wound contamination and bacterial load

All of the participants' wounds were alkaline, hence the micro environment was less favourable to wound healing and the wounds at increased risk of colonisation and possible infection. As previously stated two types of pathogens were reported from the eleven agar

plates that collected air samples during the time the wounds were without their primary dressing (22-209 minutes): *Aspergillus fumigatus (*27% of participants) and mixed non-pathogens (91% of participants).

Aspergillus fumigatus

*Aspergillu*s is an opportunistic fungus recognised as typically causing pulmonary disease; however, it has been found to contribute to wound infections, with a study by Stone *et al* (1979) undertaken in a single burns unit demonstrating 18 cases of *Aspergillus* infections over a fifteen year period. Although these numbers are small there were high mortality rates (72%), with the only means of total eradication of the pathogen found to be excision of the infected site.[9,10] A number of earlier papers state the risk of *Aspergillus* infections as an increasing problem particularly for immunocompromised patients.[9,10,246,247]

Mixed non-pathogens

The other results reported from the settle plates were mixed non-pathogens. Many microorganisms that reside on the skin are non-pathogenic meaning they do not cause disease; however, there are some bacteria that if able to break through the bodies normal defence mechanisms may become pathogenic.[23] Although not statistically significant, a positive linear relationship was found in the number of CFU increasing the longer the agar plate was exposed. The increasing numbers of non-pathogens increases the risk of pathogenesis especially with a loss in the first line of defence associated with a wound or a person who is immunocompromised. This is 'especially important if wounds are at any time exposed to the flow of air',[10 (p767)] as the larger the exposed area the greater the risk of contamination.[248]

The agar plate contamination does not state that the participants wound will become contaminated; however the participant's wounds in this study were left without their primary dressing for up to 209 minutes and their predisposition to contamination from pathogens may be increased dependent on their body defences to combat any invasion.

Summary

There were a number of research questions that have been discussed in this chapter with reference made to factors that did and did not impact on the wound bed parameters. Ultimately maintaining a warm, moist, acidic wound provides the best outcome in regards to wound healing. This study has detailed a number of areas of concern in regards to the time period that participants' wounds are being left without their primary dressings. What has been an unexpected but clinically significant result is that for most wounds in this study the wound bed parameters were already at inappropriate levels immediately after the primary dressing was removed. In addition to these concerns is the impact of the current practice on the patient's pain and their ability to attend to their activities of daily living.

Study Limitations

There are a number of factors that need to be recognised as possibly limiting the applicability and reliability of the results.

A power analysis using data from a previous study which reviewed wound temperatures during the dressing change was used to determine the sample size required.[82] A sample size of 12 was determined to have 90% power to detect a difference in means of 2.7°C, assuming a standard deviation of 2.53°C. The power analysis was not conducted using the

other wound bed parameters as there were no additional studies reporting pH and TEWL data. The small numbers of participants therefore require some of the results to be viewed with due caution. The variables with multiple measures such as temperature had sufficient power; however where the data were stratified for wound types, type of temporary dressing and size of the wound this was not the case. Thus results relating to these parameters must be considered with caution and further research is required to investigate any possible relationships.

Despite noting that accurate wound assessment could be further enhanced by measuring the depth of the wound this was not accounted for and may have impacted on the results in regards to wound size.

The temperature, pH and TEWL measurements were taken immediately the primary dressing was removed and measures were complete within 60 seconds. However, the impact of the data collection every five minutes for the first half an hour and then 15 minutely thereafter may have impacted on the results obtained due to the inability of keeping the wound enclosed in the temporary cover whilst the measurements were taken.

The TEWL measurement also needs to be taken in context. It is a measure of the rate of moisture loss not an absolute measure of the hydrated state of the wound. Moisture is lost through evaporation but this research was not able to take into account the wounds ability to rehydrate. A dry dessicated wound may result in a very low TEWL and a very moist wound may result in a very high TEWL. Both may be disadvantageous as wounds that are too moist may become macerated.[76]

The complexity of the situation should also be considered. There were a considerable number of variables outside of the control of the researcher including wound aetiology, size, location, as well as types of dressings applied prior to and during exposure time. Added to this was the complexity of different durations of wound exposure and of the data collection of multiple variables. This complexity means the results should be interpreted with caution. However, the purpose of the study was to investigate what was actually happening in practice and therefore a deliberately pragmatic approach was taken.

Reliability of the measures

The reliability of the measures depends on the accuracy of the tools being used and the processes that were undertaken. Although all steps were taken to take measures as quickly as possible, the temporary dressing that covered the wounds needed to be removed for the measures to take place. Each time data were required to be collected the wounds were therefore exposed to the local environment which may have impacted on the wound parameter readings.

Whenever data is collected there is the suggestion that the mere presence of the researcher will be impacted on by the 'Hawthorn' effect. One particular example was in regards to analgesia administration. The researcher was asking the participant about their pain score and if they had been offered pain relief. In some cases the nurse was prompted to ask the patient if they required pain relief.

Study Logistics

There were a number of logistical and technical issues that occurred throughout the study. In most cases these were a cause of frustration rather than an impact on the accuracy of the

data collection. The discussion is provided to assist others who would undertake a similar study.

There was some difficulty in sourcing measuring instruments. A lease had been negotiated for the wound parameter (temperature, pH and TEWL) measuring tool, (the cost of purchasing it outright was prohibitive) however, the week before data collection was due to commence, the company informed the researcher that they in fact did not lease to Australia. This resulted in delays until a new tool was sourced.

There were also issues in relation to the pragmatics of collecting data in the field where the researcher is reliant on others such as clinicians whose primary objectives are to care for their patient and not the research being conducted. The recruitment process using purposive sampling was hindered by staff not always providing complete or correct information. At times the incompleteness of patient's medical records made it difficult to discern whether the patients wound met the inclusion criteria. Staff occasionally did not advise the researcher that the wound dressing was being removed, or notification occurred after it had been removed, hence one of the dangers with purposive sampling.[210]

Recruitment was hampered by the necessity of only being able to collect data on one participant per day due to the time involved in the data collection, the cost and availability of equipment.

The data collection process was undertaken by one researcher. They were required to manually record the temperature measurements and to note other incongruous occurrences as they occurred. It would have been beneficial to have had two researchers present to assist with the data collection process.

The data collection process was made more difficult in a ward environment with limited space, darkened rooms with multiple types of data being collected in short time periods.

Recommendations for practice

The recommendations for practice are based on consideration of three main issues arising from the results. The first is the suboptimal condition of the wound at baseline, the second is the deteriorating condition of the wound with exposure and finally the negative impact on the patient in regards to their ADL and pain/comfort.

There is cause for concern as, the wounds in this study were found to be hypothermic and alkali on removal of the primary dressing. In contemporary wound management the choice of dressing is primarily dictated by the need to maintain an appropriate moisture level. Although different primary dressings will have diverse thermoregulatory qualities these are often secondary concerns.

While it may not be possible to use an alternate primary dressing there are options with regard to the secondary dressing used. For example the addition of a simple combine dressing held in place by a crepe bandage may assist in keeping the wound surface temperature at an appropriate level. Where possible the patient should have their bedclothes in place, although it is recognised that additional weight on the wound may cause pain or discomfort. These recommendations would not necessarily address the baseline alkalinity. There are dressings that by their nature promote a more acidic environment; however, they must also have the appropriate moisture management qualities.

The next issue to consider is the use of a temporary cover. Clinicians should plan for dressings to be removed so that the timing and duration results in the minimum amount of exposure; however there is always the potential for delay in assessment. Covering the wound with a temporary dressing is always necessary. Ideally the covering needs to provide a reasonable seal and have some thermal qualities while still being able to be removed quickly to examine the wound bed without discomfort to the patient. There are some options that could assist with this, such as only removing the secondary dressing and leaving the primary dressing in situ until the medical team arrive to review the wound. This may allow for a more accurate assessment of the wound bed parameters and the ability of the primary dressing to maintain thermoregulation, minimal moisture loss and decrease the alkalinity of the wound bed. However, the complexity of wound care and the abundance of product combinations and applications may not facilitate this. This does not address the patient impact either in regards to approrpiate analgesia and ability to attend to ADLs.

Alternatively other organisations have progressed to routinely plastic wraps to wounds once the primary dressing has been removed for assessment. This type of treatment is also recommended for patients who have received burns to reduce the risk of wound contamination prior to receiving medical care.[249] Concerns regarding the sterility of plastic wrap use has been researched be Heinle and Clopton (2001) with 39% of samples showing no bacterial growth and 81% of samples growing three or fewer colonies of typical flora normally found on the human skin.[249] Additional research has been conducted more recently by Liao *et al* (2014) with no clinically significant micro-organism growth found on the samples tested; reaffirming the potential for infection as extremely low.[250]

Another concern expressed regarding the use of plastic wrap is its potential toxicity due to the use of certain plasticisers; however a patient's exposure to the plastic wrap from a wound dressing is only for a brief period of time, lasting a few hours at most, so the risk would be minimal.[249]

The final major issue that needs to be considered is the time and timing of the dressing removal and assessment. Wounds need to be assessed to ensure achievement of identified outcomes; whether it is healing or maintenance care; and ensuring appropriate wound management continues; such as, appropriate dressing choice.[4,72] Wound care requires regular monitoring through dressing assessment and the only way to undertake this is for the dressing to be removed.[34] The issue around this process is the timing and duration of the assessment when the patient is an inpatient or attends the outpatient department.

It was noted that at the commencement of the data collection that in one area wound dressings were routinely removed at approximately 0715 to ensure wounds were ready to be assessed by the time the medical team reviewed the patient on the ward round. This timing of the dressing removal changed to 0600 during the course of the study. The rationale provided by the nursing staff was to minimise the 'rushed' workload following handover. This decision did not appear to take into account the impact on the patient or the patients wound. Waking the patient very early in the morning may not only impact on the patient's circadian rhythm,[19,20] but can also increase the patient's stress level. The decision would also increase the exposure time with subsequent impact on the wound microenvironment.[45,76,97,102,142,169,176,181,189,192] In addition this situation illustrates a lack of involvement of the patient in decisions about their care,[251]

No doubt the timing of the wound assessment can be a complex affair. Medical staff will have only certain times of the day that they are available to review wounds. They will be committed to operating lists and outpatient clinics. The nursing staff will be providing care that is not directly related to wounds. A recent study recommended that medical ward rounds should be conducted reasonably early in the morning to plan the necessary care for the day.[252] This timing however should take into account the activities of daily living to reduce the impact of the wound assessment process on the patient being able to eat, toilet and bathe, whilst at the same time accounting for procedures within the environment that they are having the wound assessment undertaken.

Consideration should be given to rostering, workflow and staff allocation. If wounds do need to be assessed on morning ward rounds then the use of staff should be managed to insure the least disruption to activities of daily living. Patient allocation to nursing staff could allow dressing activities to be staggered or shared between the nursing staff rostered on for the shift may again reduce the time of exposure, or alternatively having additional nursing resources available to assist with the wound dressing rounds.

The majority of the participants had their wound assessed by the Resident Medical Officer (RMO) or Registrar who were usually located within the organisation, with only two participants having their wound reviewed by a Consultant who is generally not located within the organisation on a daily basis. With an exposure time ranging from 22-209 minutes, and having already established that participant wounds are hypothermic, losing moisture and becoming alkaline the longer they are without their primary dressing. Communication and forward planning between medical and nursing staff is critical. Importantly any unexpected delays need to be conveyed as early as possible.

The timing of analgesia also needs to be accounted for prior to the wound assessment process, with analgesia being offered 30 minutes prior to the dressing removal ensuring staff adhere to evidence based guidelines related to analgesia administration. If the initial offer was declined ensuring repeated offers are also made as required throughout the procedure.

There should also be consideration of how often wounds need to be seen 'in the flesh'. An ongoing issue for wound management is accurate and detailed documentation of the wound.[253] Advances in clinical photography could assist here. There is an abundance of literature on the use of wound surface photography; however, this has its own challenges which may lead to misinterpretation of the condition of the wound.[253-255] Patients are required to consent to photography, and a number of factors that can impact on the quality and consistency of the image including the distance, background, lighting, focus and exposure.[253,255] Despite this there is considerable potential in using photography to reduce the number of times the wound needs to be observed and subsequently the duration of exposure without a primary dressing.

The planning of care including administering pain relief, ensuring medical officers attend in a timely fashion to assess the wound and the nurse removing the primary dressing to cause the least disruption to the patient will always be difficult. To reduce the amount of time that wounds are exposed this challenge needs to be accepted.

Recommendations for research

Wound care research is complex and there are many factors that need to be considered when conducting research in this area. The following recommendations are provided in

relation to increasing the robustness of the current research and further research that would be appropriate for this area of practice.

Although a power analysis was conducted to determine the sample size in relation to changes in temperature there are many aspects of this study that would require a larger sample size to investigate wound exposure time in a more complete fashion. The rationale for including all wounds that met the inclusion criteria was to investigate current clinical practice, rather than laboratory studies. No two wounds are identical and the noted differences between aetiologies unexpected. The participants were stratified in relation to wound type and position, co-morbidities, and dressing type and the impact of these variables particularly on the baseline measures needs to be further investigated.

In particular chronic wounds tend to have poorer wound bed quality to begin with. A larger sample of acute wounds may allow a clearer understanding of how exposure impacts on the wounds with better baseline measurements.

The measurement of wound parameters also needs to be considered. The measurements taken for this study relied on the primary dressing (for baseline measures) and then the temporary dressing (for subsequent measures) being removed. It would be ideal if the wound bed parameters could be measured with the dressings in situ. The instruments that were available to the researcher did not allow this as they needed to be removed between measures.

Given the difficulties of measuring the wound bed parameters and sample size there should be further investigation into alternate primary, secondary and temporary dressings to achieve and maintain an optimal wound bed environment. At present the focus is on

maintaining the appropriate moisture balance but further research should consider products that also will impact on temperature and pH.

The use of digital photography in wound care assessment and documentation should be investigated to compare the use of photography or video in the conduct of wound assessment on wound healing.

Ultimately research into the development of wound dressings that maintain or promote temperatures, moisture and acidity at a level conducive to wound healing is required. If primary dressings are unable to provide an environment that is thermally and pH appropriate we should consider what we can do to alter this.

Chapter Six - Conclusion

The purpose of this study was to determine the impact on patients and their wounds when primary dressings are removed to allow an assessment of the wound to occur. In particular the impact of exposure time on the wound bed parameters of temperature, TEWL and pH were investigated. The assumption was that over time the wound bed parameters would deteriorate to the point where healing was significantly hampered.

A major and somewhat unexpected finding of the study was that the wound bed environments were below optimal as soon as the primary dressing was removed. The findings demonstrated that most wounds were hypothermic, with 83% of cases below the 33°C deemed necessary for epithelialisation. In addition all wounds were alkaline, where an acidic environment is ideal for wound healing

The next area of concern was the change in wound parameters over time. There were fluctuations both positive and negative in mean wound temperature at the 20 minute mark but this was not statistically significant. The mean temperature at the time the wounds were redressed was slightly elevated, which was contrary to expectation. This increase in temperature was only small and the majority of wounds remained below the 33˚C mark. Importantly the pH did become more alkaline at both the 20 minute mark and throughout the total duration of the wound.

Most participants' wounds were covered with a temporary dressing of either a cotton sterile towel and/or Tulle Gras™ during the down time. One participant's wound was not covered with a temporary dressing and they had a marked decrease in temperature. In addition the wound became more alkaline to a level that could have reduced the oxygen

availability and the risk of an increased pH was 3.5 times more compared to that of the wounds covered with either a cotton sterile towel and/or Tulle Gras™. The microbiology for this participant also reported the second highest level of potential pathogens per minute.

Patient centred care should be a priority, however participants were noted to be unable to perform activities of daily living during the wound down time, including hygiene, toileting, nutrition and positioning. Analgesia was also poorly offered despite the majority of patients having a pain score that warranted analgesia pre dressing removal and an associated increase in that score during the dressing procedure.

In conclusion this study has confirmed leaving wounds without their primary dressing is problematic. The microenvironment of the wound bed continues to deteriorate and this has obvious implications in relation to delayed healing. Importantly the patient is comprimised in terms of activities of daily living and comfort. As a result there is a clear need to more effectively coordinate and plan care, working as a interdisciplinary team and consider the patients needs. The aim should be to minimise the amount of time the wound is left without it's primary dressing. In addition the results indicate there is a strong possibility that the condition of the wound bed may be sub optimal even when the primary dressing is intact. A larger study is required to confirm this finding.

The bottom line is the current practice of wound exposure should not be occurring, and industry could take into consideration the use of invitro studies to support the next generation of wound care to maximise wound healing potential. The wound care industry has gone a long way in investigating the application of moist wound dressings and

products that may assist the pH of the wound, however to date the application of dressings to improve wound temperature has not been investigated sufficiently.

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Appendix 1 Staff reminder sheets re recruitment of participants

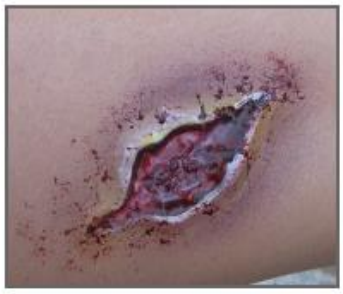
Wound study

Approved by the research and Ethics Committee

Funding by RAH and IMVS and SAWMA.

Does your patient have an open wound?

Are they interested in participating in a research study?



Please call Tammy Page

On

8313 1225

University of Adelaide

Wound study

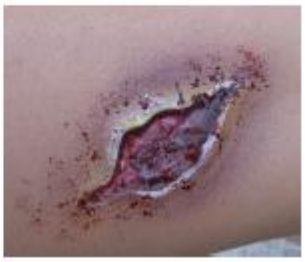
Approved by the Royal Adelaide Hospital
Research and Ethics Committee No: 050420a
Funding by RAH and IMVS and SAWMA.

Mr/s _____ has agreed to participate in a research study.

If you are planning to remove their dressing for it to be assessed by medical staff

please advise Tammy Page as soon as possible

0408812307



Appendix 2 Participant information sheet

My name is Tammy Page and I am a Registered Nurse and a lecturer at the University of Adelaide. I am currently conducting a study as a part of my PhD. The study is to identify firstly how the temperature, moisture, bacterial and acidity or alkalinity levels of wounds are affected by wound dressing changes; and secondly how the dressing procedure impacts on your comfort, including pain levels. This is a research project and you do not have to be involved. If you do not wish to participate, your medical and nursing care will not be affected in any way. If you agree to participate observation of ***one*** wound dressing change will involve taking measurements of your wound every 5 minutes for the first 30 minutes and then every 15 minutes for the duration of the dressing procedure. The measurements are taken by gently touching the wound bed with a probe. There may be some discomfort felt if your wound is particularly painful. The probes are sterilised between participants as per infection control requirements.

A small plastic plate with gel in it will also be placed close to your wound to detect the amount of bacteria which collects in the time taken to complete the dressing procedure. If necessary the plate may need to be secured near to the wound using a small piece of adhesive tape and a Velcro dot to decrease the risk of the plate tipping and without harming your skin. Following the procedure the researcher will ask questions to ascertain levels of pain and comfort. This study may not benefit the participants agreeing to be involved but will play a large part for future patients.

Participant information will be confidential and anonymity is assured. You are free to withdraw from the study at any time, without any prejudice to your care. Your time and participation would be highly appreciated. If you agree to participate, a consent form is

required to be signed. If you have any questions then please contact me on 0408812307. Alternatively you may contact my supervisors Dr Judy Magarey on 8313 6055, or Dr Rick Wiechula on 8313 4878.

If you wish to discuss aspects of the study with someone not directly involved, you may also contact the Chairman, Research Ethics Committee, Royal Adelaide Hospital, on 8222 4139.

Thank you for taking the time to read this.

Tammy Page

Appendix 3 Participant consent form

ROYAL ADELAIDE HOSPITAL

CONSENT FORM

PROTOCOL NAME: Clinical measurements during wound dressing changes.

INVESTIGATORS: Tammy Page

1. The nature and purpose of the research project has been explained to me. I understand it, and agree to take part.
2. I understand that I may not directly benefit from taking part in the trial.
3. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
4. I understand that I can withdraw from the study at any stage and that this will not affect my medical care, now or in the future.
5. I have the opportunity to discuss taking part in this investigation with a family member or friend.

Name of participant: _____

Signed: _____

Dated: _____

I certify that I have explained the study to the participant/volunteer and consider that he/she understands what is involved.

Signed: _____

Appendix 4 Data collection of dressing episode data

Time	**Date**	**TEWL** **1-20**	**pH** **0-14**	**Wound** **Temperature** **°C**

Appendix 5 Demographic data collection tool

Measurements pre and post dressing change

Date	
ID Number	
Age	
Gender	
Co-Morbidities	
Ambient Temperature ▫C	
Pre dressing change	
Post dressing change	
Relative Humidity	
Pre dressing change	
Post dressing change	
Core Temperature ▫C	
Pre dressing change	
Post dressing change	
Agar plate opened (Time)	
Agar plate closed (Time)	
Removal of primary dressing (Time)	
Start	
Finish	
Reapplication of primary dressing (Time)	
Start	
Finish	
Reason for dressing change	
1. Scheduled	
2. Assessment by Reg/Res	
3. Assessment by consultant	
4. Assessment by allied health	
5. Other	
Type of dressing applied	
1. VAC	
2. Hydrogel	
3. Hydrocolloid	
4. Foam	
5. Tulle	
6. Calcium Alginate	
7. Other	
If dressing changed for assessment purposes, what was the wound covered with?	
1. Sterile plastic wrap	
2. Material sterile towel	
3. Wet gauze	
4. Paper sterile towel	
5. Other	
6. None	

Appendix 6 Participant Questionnaire

Participant Comfort Survey

1. Were you informed of the time your wound dressing procedure would be taking place

   Yes □ No □

2. If there was a delay in your wound being redressed, were you informed of the reason?

   Yes □ No □ Reason _____

3. Did the wound dressing procedure impacted on the following activities?

   Nutrition/Hydration □ Toileting □ Hygiene □ Visiting □ Positioning □

   Other □

4. Were you offered pain relief prior to the wound dressing procedure commencing?

   Yes □ No □

5. Did you take the pain relief?

   Yes □ No □

6. Was the pain relief given prior to the dressing change adequate?

   Yes □ No □ N/A □

7. Indicate your pain score on a scale of 0 to 10 with 0 being no pain and 10 being the worst pain you can imagine.

Prior to dressing procedure ☺_____😐_____☹

0 1 2 3 4 5 6 7 8 9 10

Dressing removal ☺_____😐_____☹

0 1 2 3 4 5 6 7 8 9 10

During dressing procedure ☺_____😐_____☹

0 1 2 3 4 5 6 7 8 9 10

Immediately following the dressing procedure

☺_____😐_____☹

0 1 2 3 4 5 6 7 8 9 10

8. Was there anything else about the wound dressing procedure which you wish to comment on?

_____

_____

_____

Appendix 7 Wound monitoring medical record

Patient Name: ____________________ UR Number: ________

LEGEND

Wound / pressure ulcer

1. *Discolouration of intact skin, persistent redness (non blanchable), which in darker skin may appear with persistent red, blue or purple hues.*
2. *Partial thickness skin loss or damage involving the epidermis / dermis. The ulcer is superficial and presents as an abrasion, blister or shallow crater.*
3. *Full thickness involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, the underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.*
4. *Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures (for example, tendon, or joint capsule). Undermining and sinus tracts may also be associated with Stage 4 pressure ulcers.*

Exudate Odour

N = Nil
S = Slight
M = Malodourous / offensive

Pain Score (0 to 10)

0 = No pain 10 = Worst pain imaginable

Dressings

Primary:
A = Alginate
AC = Activated Charcoal
Ag = Silver containing
C = Combine
CI = Cadexomer Iodine
FM = Foam
G = Gauze
H = Hydrogel
HA = Hydroactive
HC = Hydrocolloid
NA = Non adherent
P = Powder
PG = Paraffin gauze
S = Silicone
VAC – Vacuum assisted closure

O = Other.......................................(state)

Secondary / Tertiary:
CR = Crepe bandage
CP = Compression bandage
ET = Elastic tubular bandage
N = Net
FX = Fixation
Ta = Tape
T = Transparent film

WOUND MONITORING

Wound Site Number ( )

Section	Item															
	Date															
	Time															
	Initials															
Wound / Pressure ulcer *refer Legend*	erythema 1															
	partial thickness 2	✓														
	full thickness 3															
	necrotic 4															
	other															
Clinical Appearance %	% pink – epithelialisation	50%														
	% red – granulation															
	– hyper-granulation															
	% green – infection	50%														
	% yellow – slough															
	% black – necrotic															
	other															
Surrounding Skin	healthy / intact															
	fragile	✓														
	dry / scaling															
	erythematous															
	dermatitic															
	bruised															
	blistered															
	cellulitic															
	macerated															
	oedematous															
Exudate Amount	none															
	small amount															
	moderate amount	✓														
	large amount															
	wound drain / site (Y or N)															
Exudate Type	serous															
	haemoserous															
	purulent	✓														
	other .... (type)															
	odour *refer legend*															
Pain *refer legend*	analgesia required (Y or N)	Y														
	pain score (0 - 10)	5														
Dressing *refer legend*	primary dressing	PG														
	secondary dressing	NA & C														
	tertiary dressing	Ta														
	wound appliance/bag (Y or N)	N														
Dressing Frequency	Daily	✓														
	BD															
	TDS															
	QID															
	4/24															
	Intact Until															

Weekly Wound Measurement

Date	Date ....
length (cm)	length (cm)
width (cm)	width (cm)
depth (cm)	depth (cm)
photos (date) ..../........./......... (see D 98.0)	photos (date) ..../........./......... (see D 98.0)
tracing (date) ..../........./.........	tracing (date) ..../........./.........
Date	Date ....
length (cm)	length (cm)
width (cm)	width (cm)
depth (cm)	depth (cm)
photos (date) ..../........./......... (see D 98.0)	photos (date) ..../........./......... (see D 98.0)
tracing (date) ..../........./.........	tracing (date) ..../........./.........
Date	Date ....
length (cm)	length (cm)
width (cm)	width (cm)
depth (cm)	depth (cm)
photos (date) ..../........./......... (see D 98.0)	photos (date) ..../........./......... (see D 98.0)
tracing (date) ..../........./.........	tracing (date) ..../........./.........

Appendix 8 Cidex OPA® Education

Cidex OPA® [17]

1. Health effects of contact with Cidex OPA®
    - Inhalation - Mild irritation of the nose, throat & respiratory system, chest discomfort, dyspnoea and exacerbation of asthma / bronchitis
    - Skin - Staining and mild irritation after prolonged exposure
    - Eye - Stinging, excess tearing and redness
2. Personal Protective Equipment (PPE)
    - Gloves must be worn if hands are likely to come in contact with body fluids or chemicals
        - Different types available
        – Latex – single glove (change after 10 minutes) or double glove
        – Nitrile rubber
        – Butyl rubber
        – Do not use polyvinyl gloves
    - Gowns must be worn to protect clothing and skin when there is a risk of splashing of blood or body fluids and chemicals
        - Gowns / aprons should be fluid resistant / impermeable
    - Facemasks must be worn when there is the possibility of splashing or splattering of body fluids or where transmission of airborne microorganisms may occur
        - Respirators are not required for chemical fumes under normal use
        - Face masks should be:
            – Fluid repellent

- Cover both the nose and mouth when worn
- Remove by touching the ties only
- Single use

3. Quality control – record keeping
    - AS/NZS 4187 - ‘Quality control is fundamental to the delivery of safe and effective clinical services’
    - Clear and detailed documentation must be kept showing compliance with all aspects of the cleaning and disinfection process
    - Traceability – to ensure that a record exists so that appropriate retrospective linkage analysis (look back) can be performed
    - Records to be kept as per AS/NZS 4187 related to endoscope / probe reprocessing:
        - Date of procedure / reprocessing
        - Participant name / Medical Record Number / Date Of Birth
        - Instrument and serial number
        - Name of person who manually cleaned, rinsed, disinfected (+ soak time) and final rinsed (x3) the instruments
        - Minimum effective concentration (MEC) test result - the result obtain when inserting a test strip into Cidex OPA® solution to determine that it is still the required concentration to achieve high level disinfection

- Records to be kept as per AS/NZS 4187 related to endoscope / probe reprocessing:
    - Batch no. of the Cidex OPA®
    - Date Cidex OPA® was decanted into tank and top up dates
- Additional records to be kept as decided by the Cidex OPA® working party:
    - Temperature of the ambient air or Cidex OPA® solution (each day Cidex OPA® is used)
    - Positive/negative – 3 strip quality control test each time a new bottle of test strips is opened
    - Lot number – test strips and Cidex OPA® solution
    - Expiry date for opened Cidex OPA® bottle

4. Reprocessing areas should have
    - Designated clean and dirty areas with separate benches and sinks – large enough to hold equipment
    - Items should go in a one way direction i.e. from dirty to clean and not the opposite way
    - Surfaces should be impervious to solutions
    - Reprocessing area dedicated for that purpose only
5. Chemical disinfection process

- Turn on the GUS® ventilated soak station which protects staff from toxic vapours

- Ensure soaking containers are labelled and filled with appropriate solution

- Check solution for precipitation

- Conduct test strip analysis of the Cidex OPA® solution

  - Take test strip and immerse it for one second in the Cidex OPA® solution and then wait 90 seconds before reading the result and ensuring that it passes (Pass=purple Fail=blue or mottled blue/purple).

  - Once satisfactory result obtained the disinfection process can continue

- Clean the probe - Organic material which is not removed by cleaning before disinfection can bind and inactivate many chemical disinfectants.

- Immerse probe completely - all surface areas (internal and external) of the equipment must make contact with the disinfectant.

- Time the soaking time with a timer – 10 minutes

- Equipment must be rinsed thoroughly with water - sterile or filtered water is used for rinsing if the instrument is for use in a sterile cavity, immunocompromised participants or for invasive procedures i.e. ERCP or bronchoscopies.

  - Rinse three times in a large volume of fresh water for at least one minute each time

- Failure to rinse equipment properly can result in residues of Cidex OPA® being left on the equipment – this may cause chemical burns, irritation of mucous membranes, staining of the skin / mucous membranes and allergic reactions

- Dry using a lint free cloth and alcohol

- Equipment should be immediately re-used or stored in a manner which minimises contamination

Appendix 9 Regression data

THE IMPACT OF EXPOSURE TIME ON WOUND MICROENVIRONMENTS AND PATIENT COMFORT DURING DRESSING CHANGES

Researcher: Tamara Page
Statistician: Suzanne Edwards

Date: 23/09/2013

The statistical software used was SAS 9.3 (SAS Institute Inc., Cary, NC, USA).

The aim was to firstly show how the down time of a dressing change affects the pH, temperature and Trans Epidermal Water Loss (TEWL) of the wound. pH, temperature and TEWL measurements were taken at between 5 and 17 time points for each patient during the period when the wound was exposed.

Table 1 gives frequency tables of relevant categorical variables. Table 2 gives descriptive statistics of relevant continuous and discrete variables. Table 3 gives descriptive statistics of all the pH, temperature and TEWL measurements (not by patient).

Because repeated measurements were taken over a period of time on each patient, the measurements will be correlated and Generalized Estimating Equations (GEEs) models were used to take this correlation into account.

Histograms in Figure 1 show that the outcome variable Temperature is approximately normally distributed and that the outcome variables pH and TEWL are left skewed (because they are left skewed, a logarithmic transform won't help in obtaining a normally distributed variable). Tables 4 and 5 give frequency tables of derived dichotomous pH and TEWL variables (cut-off taken to be the median of each continuous variable). This was done so that logistic GEEs could be modelled for the 2 non-normal outcome variables: pH and TEWL.

Table 6 shows results from a linear GEE model with wound temperature as the outcome, time (in minutes) as the predictor and various wound and patient characteristics as the confounder, taking repeated measures of temperature into account. Models (a) include the interaction term between time (in minutes) and the confounder, and Models (b) have only the main effects: time (in minutes) and

confounder. If the interaction is significant (P value<0.05) then Model (b) is not shown as it is not relevant. If the interaction is not significant, then Model (b) is the model that is relevant.

An example of interpretation is: Table 6: Model 3a: The interaction term time (in minutes)*type of wound is significant (P value=0.0025). Therefore the association between wound temperature and time depends on the type of wound.

Table 7 shows results from a logistic GEE model with the wound pH or wound TEWL as the outcome, time (in minutes) as the predictor and various wound and patient characteristics as the confounders, taking repeated measures of wound pH or TEWL into account. Once again, Model (a) includes the interaction term and Model (b) includes only main effects.

An example of interpretation is: Table 7: Model 3(b). As the interaction term is not significant (P value=0.6326) then Model 3(b) is the relevant model. There is a statistically significant association between pH and time (in minutes), controlling for size of wound (P value = 0.0465). For every minute increase in time, the odds of having a pH greater than 8.5 (the median) are 1.01 times greater than the odds of having a pH less than or equal to 8.5, after adjusting for size of wound (odds ratio=1.0117; 95% CI=1.0002,1.0234).

Figure 2 shows histograms of the 2 bacteria outcome variables. As they are not normally distributed, logistic regression was used instead of linear regression. Table 8 shows frequency tables of the dichotomized bacteria variables and Figures 4 and 5 give logistic regression results. Even though scatter plots of the 2 bacteria variables against wound exposure time show a possible positive linear relationship, there was possibly not enough power (n=12) to show this in logistic regression results: there were no significant associations found (P value=0.4164 for mixed pathogens and P value=0.6781 for aspergillus).

The difference between VAS score during dressing change and VAS score prior to dressing change was calculated for each patient so that a positive number meant that the pain score had increased because of the dressing change. Figure 6 shows a histogram of the VAS difference which is approximately normally distributed. Therefore a linear regression was performed with wound exposure time as the predictor. However, although the scatter plot in Figure 7 shows a possible positive linear relationship between difference in VAS score and wound exposure time, there was possibly not enough power to detect a statistically significant association between the two (P value=0.4047).

Table 1. Frequency tables of relevant categorical variables

Gender	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
F	6	50.00	6	50.00
M	6	50.00	12	100.00

type_of_wound	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
Pressure sore	1	8.33	1	8.33
breakdown	5	41.67	6	50.00
trauma	1	8.33	7	58.33
ulcer	5	41.67	12	100.00

reason_change	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
2	10	83.33	10	83.33
3	1	8.33	11	91.67
6	1	8.33	12	100.00

type_applied	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
1	7	58.33	7	58.33
2	1	8.33	8	66.67
5	1	8.33	9	75.00
7	1	8.33	10	83.33
8	1	8.33	11	91.67
9	1	8.33	12	100.00

temp_dress	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
2	9	75.00	9	75.00
6	1	8.33	10	83.33
8	2	16.67	12	100.00

Q1	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
0	1	8.33	1	8.33
No	6	50.00	7	58.33
Yes	1	8.33	8	66.67
yes	4	33.33	12	100.00

Q2	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	1	8.33	1	8.33
No	9	75.00	10	83.33
Yes	2	16.67	12	100.00

Q3	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	1	8.33	1	8.33
Hygiene	1	8.33	2	16.67
NA	2	16.67	4	33.33
Nutrition/Hydration/Positioning	1	8.33	5	41.67
Nutrition/hydration	2	16.67	7	58.33
Toileting	1	8.33	8	66.67
Toileting/Hygeine	2	16.67	10	83.33
Toileting/Other	1	8.33	11	91.67
Toileting/Positioning	1	8.33	12	100.00

Q4	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
0	1	8.33	1	8.33
NA	1	8.33	2	16.67
No	7	58.33	9	75.00
Yes	3	25.00	12	100.00

Q5	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
0	1	8.33	1	8.33
NA	6	50.00	7	58.33
No	1	8.33	8	66.67
Yes	4	33.33	12	100.00

Q6	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
0	1	8.33	1	8.33
NA	6	50.00	7	58.33
Yes	5	41.67	12	100.00

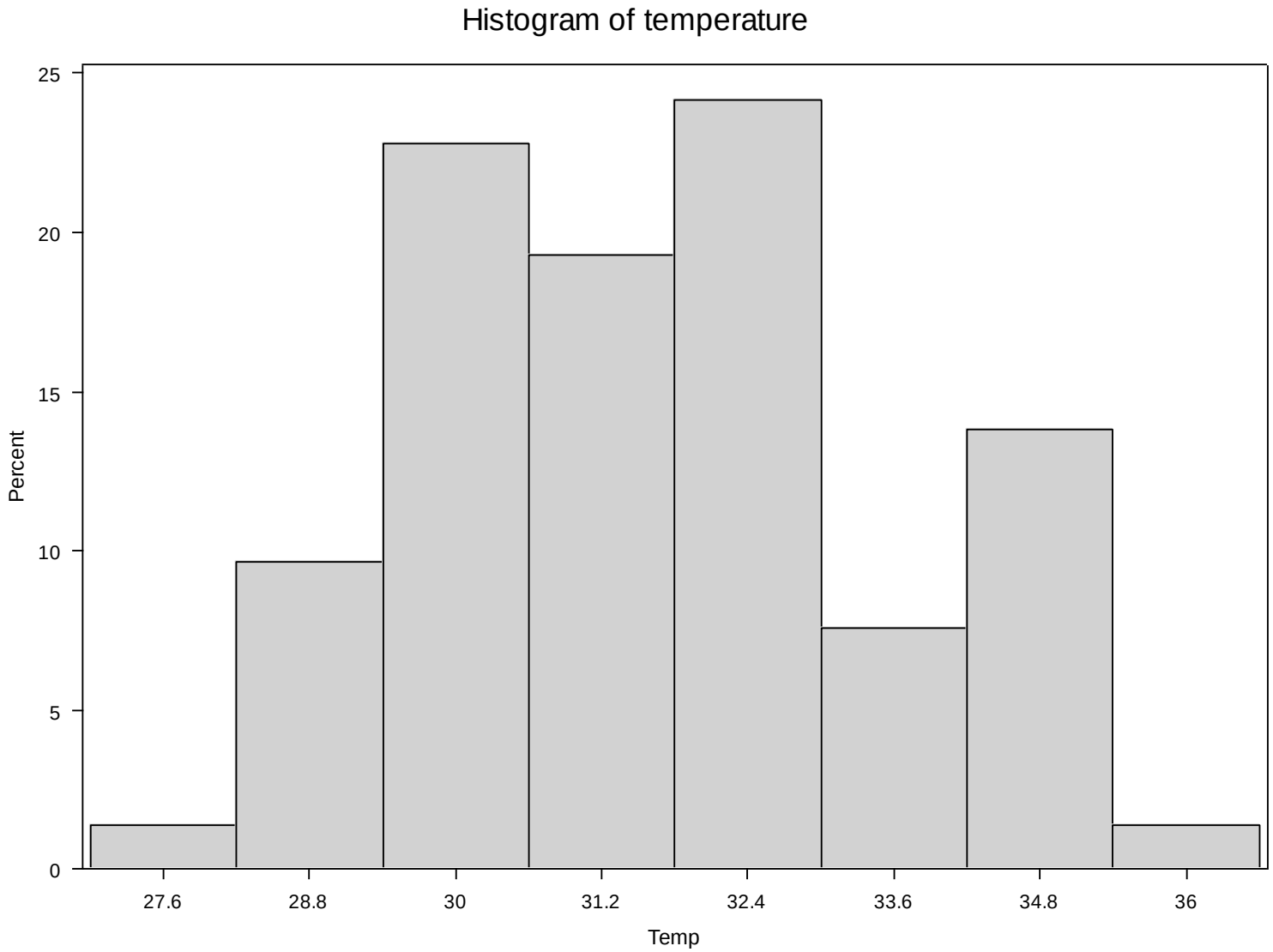
Table 2. Descriptive statistics of relevant continuous and discrete variables

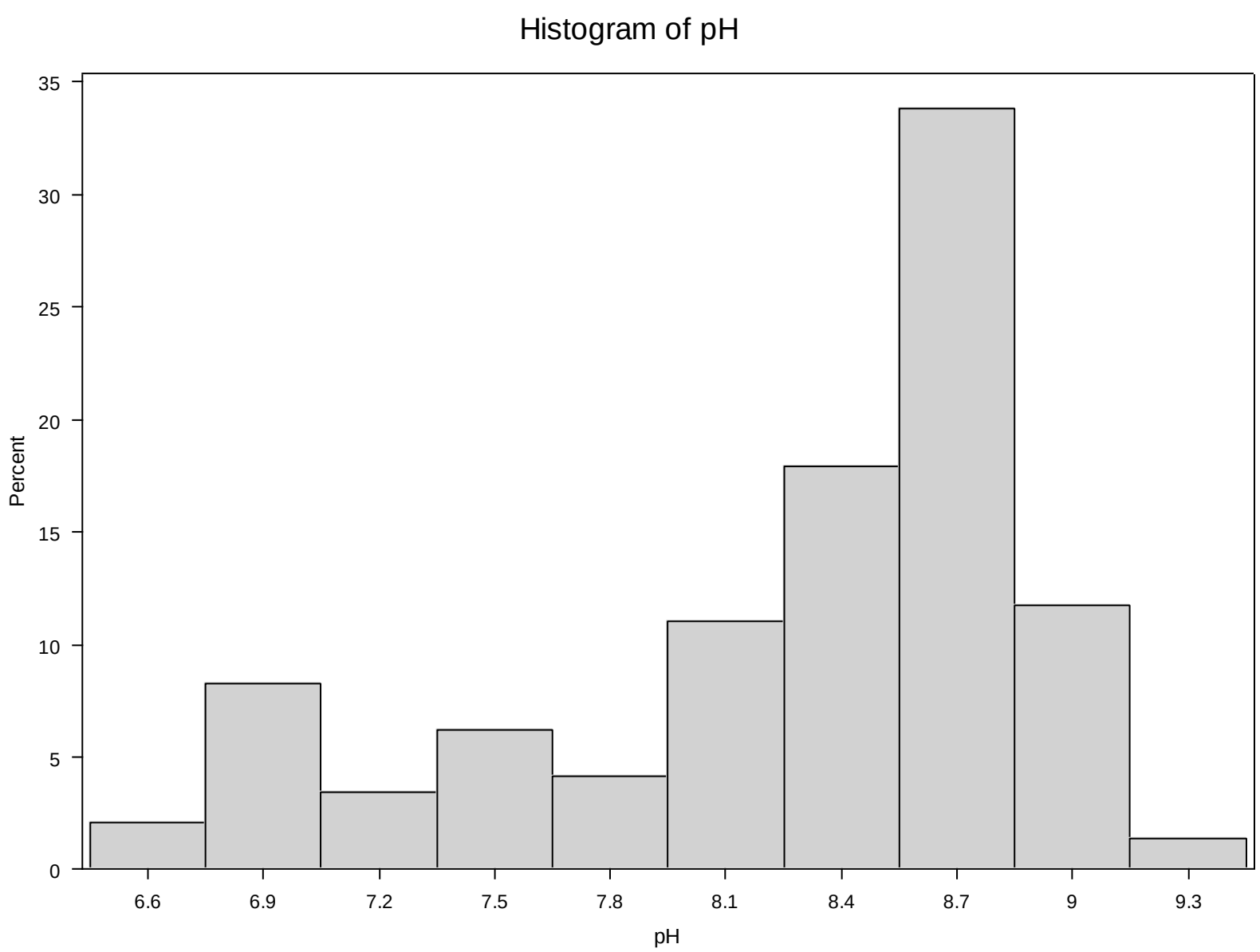
Variable	*Mean*	*Median*	*Std Dev*	*Minimum*	*Maximum*	*N*
Age	54.50	52.00	16.64	21.00	77.00	12
size_of_wound	20.36	16.60	15.58	2.00	57.20	12
exposed_time	118.83	126.00	63.30	12.00	209.00	12
Vas_pre	2.42	1.50	2.84	0.00	7.00	12
Vas_removal	4.33	5.00	3.26	0.00	9.00	12
Vas_during	3.58	3.50	3.40	0.00	9.00	12
vas_post	3.42	3.50	3.20	0.00	9.00	12
mixed_pathogens_cfu	25.27	22.00	26.48	0.00	95.00	11
aspergillus_cfu	0.64	0.00	1.50	0.00	5.00	11

Table 3. Descriptive statistics of pH, temp and TEWL

Variable	*Mean*	*Median*	*Minimum*	*Maximum*	*Std Dev*	*N*
pH	8.25	8.45	6.71	9.30	0.66	145
Temp	31.69	31.50	27.20	36.00	1.93	145
TEWL	18.15	20.00	6.00	20.00	3.21	145

Figure 1. Histograms of outcome variables




Histogram of pH
Percent
35
30
25
20
15
10
5
0
6.6
6.9
7.2
7.5
7.8
8.1
8.4
8.7
9
9.3
pH

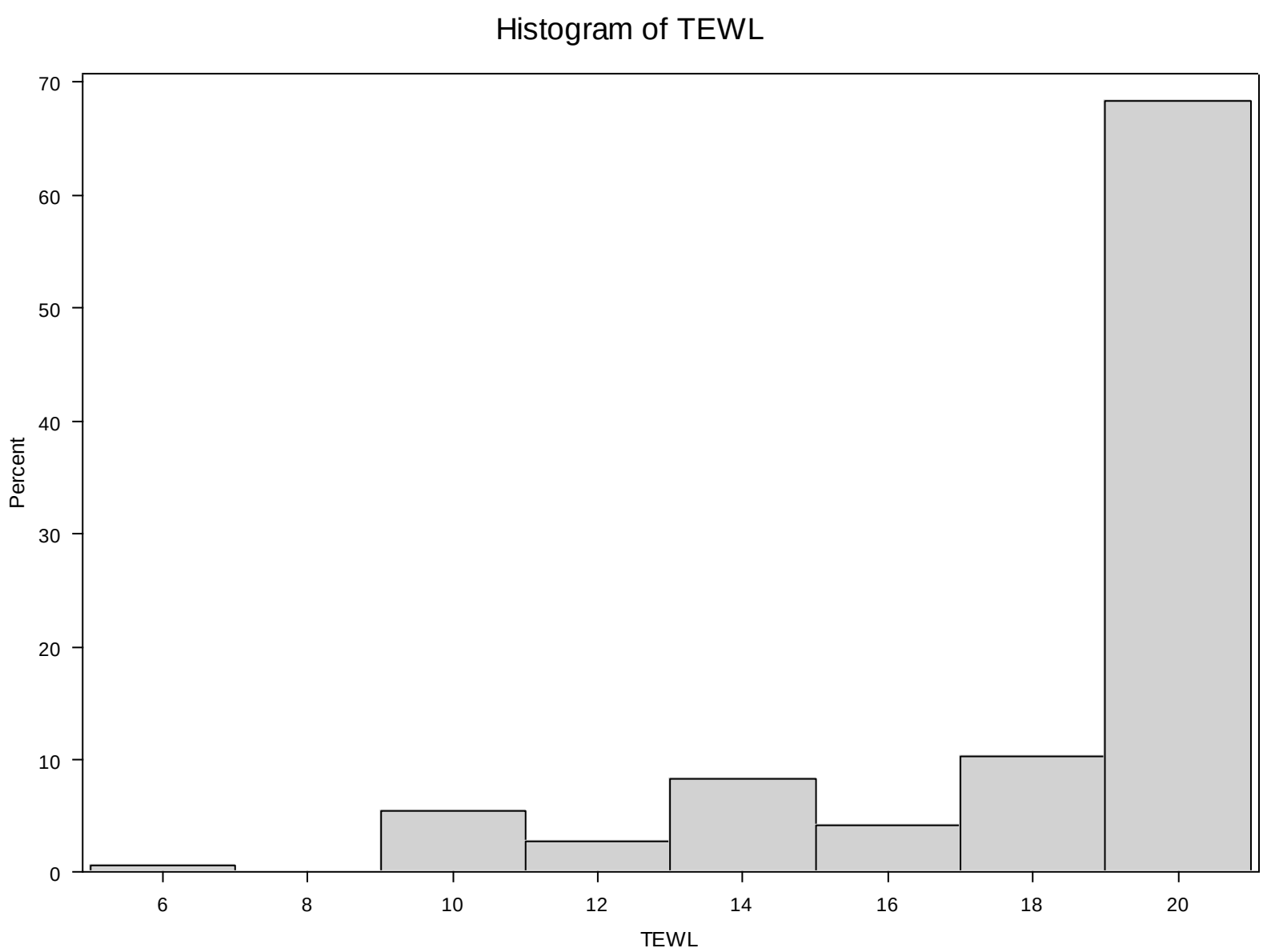

Histogram of TEWL
Percent
0
10
20
30
40
50
60
70
6
8
10
12
14
16
18
20
TEWL

Table 4. Frequency table of TEWL(binary)

TEWLB	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
<20	49	33.79	49	33.79
20	96	66.21	145	100.00

Table 5. Frequency table of pH (binary)

pHB	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
<=8.5	76	52.41	76	52.41
>8.5	69	47.59	145	100.00

Table 6. Generalized Estimating Equations Model (linear regression): results for temperature

Model Number	*Outcome Variable*	*Predictor Variable*	*Estimate*	*Lower 95% CL*	*Upper 95% CL*	*Comparison P value*	*Global P value*
1	temp	Time_mins	0.0060	-0.0027	0.0147	0.1750	0.1750
2a	temp	Time_mins	0.0061	-0.0086	0.0208	0.4171	0.4171
2a	temp	Time_mins*size_of_wound	.	.	.	.	0.9341
2a	temp	size_of_wound	.	.	.	.	0.4519
2b	temp	Time_mins	0.0055	-0.0027	0.0138	0.1887	0.1887
2b	temp	size_of_wound	0.0182	-0.0581	0.0944	0.6404	0.6404

Model Number	*Outcome Variable*	*Predictor Variable*	*Estimate*	*Lower 95% CL*	*Upper 95% CL*	*Comparison P value*	*Global P value*
3a	temp	Time_mins	0.0004	-0.0061	0.0068	0.9096	0.9096
3a	temp	Time_mins*type_of_wound	.	.	.	.	0.0025
3a	temp	type_of_wound	.	.	.	.	0.0064
4a	temp	Time_mins	-0.0105	-0.9778	0.9568	0.9830	0.9830
4a	temp	Time_mins*core_temp_mean	.	.	.	.	0.9726
4a	temp	core_temp_mean	.	.	.	.	0.0700
4b	temp	Time_mins	0.0064	-0.0021	0.0150	0.1383	0.1383
4b	temp	core_temp_mean	-0.5992	-1.5070	0.3085	0.1957	0.1957
5a	temp	Age	.	.	.	.	0.8838
5a	temp	Time_mins	-0.0087	-0.0519	0.0345	0.6919	0.6919
5a	temp	Time_mins*Age	.	.	.	.	0.4821
5b	temp	Age	0.0150	-0.0486	0.0786	0.6448	0.6448
5b	temp	Time_mins	0.0066	-0.0022	0.0153	0.1412	0.1412
6a	temp	Gender	.	.	.	.	0.4394
6a	temp	Time_mins	0.0058	-0.0047	0.0163	0.2809	0.2809
6a	temp	Time_mins*Gender	.	.	.	.	0.5777
6b	temp	Female vs Male	-0.3441	-2.5698	1.8815	0.7618	.
6b	temp	Gender	.	.	.	.	0.7618
6b	Temp	Time_mins	0.0063	-0.0031	0.0157	0.1894	0.1894
7a	Temp	Time_mins	-0.0443	-0.0788	-0.0098	0.0118	0.0118
7a	Temp	Time_mins*exposed_time	.	.	.	.	0.0124

Model Number	*Outcome Variable*	*Predictor Variable*	*Estimate*	*Lower 95% CL*	*Upper 95% CL*	*Comparison P value*	*Global P value*
7a	Temp	exposed_time	.	.	.	.	0.4080
8a	Temp	Ambient_temp_mean	.	.	.	.	0.4142
8a	Temp	Time_mins	-0.0911	-0.3448	0.1626	0.4815	0.4815
8a	Temp	Time_mins*Ambient_temp_mean	.	.	.	.	0.4454
8b	Temp	Ambient_temp_mean	0.3322	-0.4096	1.0741	0.3801	0.3801
8b	Temp	Time_mins	0.0061	-0.0021	0.0144	0.1459	0.1459
9a	temp	RH_mean	.	.	.	.	0.2076
9a	Temp	Time_mins	0.0391	0.0061	0.0720	0.0201	0.0201
9a	Temp	Time_mins*RH_mean	.	.	.	.	0.0256
10a	Temp	Time_mins	0.0075	0.0055	0.0095	<.0001	<.0001
10a	temp	Time_mins*type_applied	.	.	.	.	0.0134
10a	temp	type_applied	.	.	.	.	<.0001
11a	temp	Time_mins	-0.0471	-0.0513	-0.0429	<.0001	<.0001
11a	temp	Time_mins*temp_dress	.	.	.	.	<.0001
11a	temp	temp_dress	.	.	.	.	<.0001

Table 7. Generalized Estimating Equations Model (logistic regression): results for wound pH and TEWL

Model Number	*Outcome Variable*	*Predictor Variable*	*Estimate*	*Lower 95% CL*	*Upper 95% CL*	*Comparison P value*	*Global P value*
1	pHB	Exp(Time_mins)	1.0106	1.0003	1.0209	_	.
1	pHB	Time_mins	.	.	.	0.0438	0.0438
2	TEWLB	Exp(Time_mins)	0.9943	0.9840	1.0048	_	.
2	TEWLB	Time_mins	.	.	.	0.2861	0.2861
3a	phB	Exp(Time_mins)	1.0154	0.9908	1.0407	_	.
3a	pHB	Time_mins	.	.	.	0.2209	0.2209
3a	pHB	Time_mins*size_of_wound	.	.	.	.	0.6326
3a	pHB	size_of_wound	.	.	.	.	0.4298
3b	phB	Exp(Time_mins)	1.0117	1.0002	1.0234	_	.
3b	phB	Exp(size_of_wound)	0.9732	0.9140	1.0361	_	.
3b	pHB	Time_mins	.	.	.	0.0465	0.0465
3b	pHB	size_of_wound	.	.	.	0.3950	0.3950
4a	TEWLB	Exp(Time_mins)	0.9863	0.9693	1.0036	_	.
4a	TEWLB	Time_mins	.	.	.	0.1199	0.1199
4a	TEWLB	Time_mins*size_of_wound	.	.	.	.	0.2156
4a	TEWLB	size_of_wound	.	.	.	.	0.3774
4b	TEWLB	Exp(Time_mins)	0.9942	0.9837	1.0048	_	.
4b	TEWLB	Exp(size_of_wound)	1.0054	0.9666	1.0457	_	.
4b	TEWLB	Time_mins	.	.	.	0.2829	0.2829

Model Number	*Outcome Variable*	*Predictor Variable*	*Estimate*	*Lower 95% CL*	*Upper 95% CL*	*Comparison P value*	*Global P value*
4b	TEWLB	size_of_wound	.	.	.	0.7889	0.7889
5a	phB	Exp(Time_mins)	1.0285	1.0231	1.0340	_	.
5a	pHB	Time_mins	.	.	.	<.0001	<.0001
5a	pHB	Time_mins*type_of_wound	.	.	.	.	<.0001
5a	pHB	type_of_wound	.	.	.	.	0.0008
6a	phB	Exp(Time_mins)	1.3811	0.3573	5.3393	_	.
6a	pHB	Time_mins	.	.	.	0.6397	0.6397
6a	pHB	Time_mins*core_temp_mean	.	.	.	.	0.6513
6a	pHB	core_temp_mean	.	.	.	.	0.2913
6b	phB	Exp(Time_mins)	1.0114	1.0013	1.0217	_	.
6b	phB	Exp(core_temp_mean)	0.4446	0.0918	2.1540	_	.
6b	pHB	Time_mins	.	.	.	0.0272	0.0272
6b	pHB	core_temp_mean	.	.	.	0.3140	0.3140
7a	TEWLB	Exp(Time_mins)	2.4008	0.7247	7.9540	_	.
7a	TEWLB	Time_mins	.	.	.	0.1518	0.1518
7a	TEWLB	Time_mins*core_temp_mean	.	.	.	.	0.1489
7a	TEWLB	core_temp_mean	.	.	.	.	0.0026
7b	TEWLB	Exp(Time_mins)	0.9928	0.9829	1.0029	_	.
7b	TEWLB	Exp(core_temp_mean)	3.5544	0.7726	16.3517	_	.
7b	TEWLB	Time_mins	.	.	.	0.1625	0.1625
7b	TEWLB	core_temp_mean	.	.	.	0.1034	0.1034

Model Number	*Outcome Variable*	*Predictor Variable*	*Estimate*	*Lower 95% CL*	*Upper 95% CL*	*Comparison P value*	*Global P value*
8a	pHB	Age	.	.	.	.	0.7847
8a	pHB	Exp(Time_mins)	1.0414	0.9821	1.1042	_	.
8a	pHB	Time_mins	.	.	.	0.1748	0.1748
8a	pHB	Time_mins*Age	.	.	.	.	0.2579
8b	pHB	Age	.	.	.	0.4134	0.4134
8b	phB	Exp(Age)	0.9817	0.9393	1.0261	_	.
8b	phB	Exp(Time_mins)	1.0100	0.9998	1.0203	_	.
8b	pHB	Time_mins	.	.	.	0.0544	0.0544
9a	TEWLB	Age	.	.	.	.	0.6449
9a	TEWLB	Exp(Time_mins)	1.0234	0.9969	1.0505	_	.
9a	TEWLB	Time_mins	.	.	.	0.0838	0.0838
9a	TEWLB	Time_mins*Age	.	.	.	.	0.0333
10a	phB	Exp(Time_mins)	1.0109	0.9996	1.0223	_	.
10a	pHB	Gender	.	.	.	.	0.4853
10a	pHB	Time_mins	.	.	.	0.0590	0.0590
10a	pHB	Time_mins*Gender	.	.	.	.	0.6542
10b	phB	Exp(Female vs Male)	1.2029	0.2658	5.4440	_	.
10b	phB	Exp(Time_mins)	1.0104	1.0000	1.0210	_	.
	pHB	Female vs Male	.	.	.	0.8105	.
10b	pHB	Gender	.	.	.	.	0.8105
10b	pHB	Time_mins	.	.	.	0.0494	0.0494

Model Number	*Outcome Variable*	*Predictor Variable*	*Estimate*	*Lower 95% CL*	*Upper 95% CL*	*Comparison P value*	*Global P value*
11a	TEWLB	Exp(Time_mins)	0.9946	0.9844	1.0048	_	.
11a	TEWLB	Gender	.	.	.	.	0.8489
11a	TEWLB	Time_mins	.	.	.	0.2962	0.2962
11a	TEWLB	Time_mins*Gender	.	.	.	.	0.9691
11b	TEWLB	Exp(Female vs Male)	0.8122	0.1536	4.2940	_	.
11b	TEWLB	Exp(Time_mins)	0.9945	0.9840	1.0051	_	.
	TEWLB	Female vs Male	.	.	.	0.8065	.
11b	TEWLB	Gender	.	.	.	.	0.8065
11b	TEWLB	Time_mins	.	.	.	0.3084	0.3084
12a	phB	Exp(Time_mins)	1.0546	1.0039	1.1079	_	.
12a	pHB	Time_mins	.	.	.	0.0344	0.0344
12a	pHB	Time_mins*exposed_time	.	.	.	.	0.1116
12a	pHB	exposed_time	.	.	.	.	0.8605
12b	phB	Exp(Time_mins)	1.0141	1.0061	1.0221	_	.
12b	phB	Exp(exposed time)	0.9921	0.9782	1.0062	.	.
12b	pHB	Time_mins	.	.	.	0.0005	0.0005
12b	pHB	exposed_time	.	.	.	.	0.2701
13a	TEWLB	Exp(Time_mins)	1.0178	0.9698	1.0681	_	.
13a	TEWLB	Time_mins	.	.	.	0.4735	0.4735
13a	TEWLB	Time_mins*exposed_time	.	.	.	.	0.3745
13a	TEWLB	exposed_time	.	.	.	.	0.7677

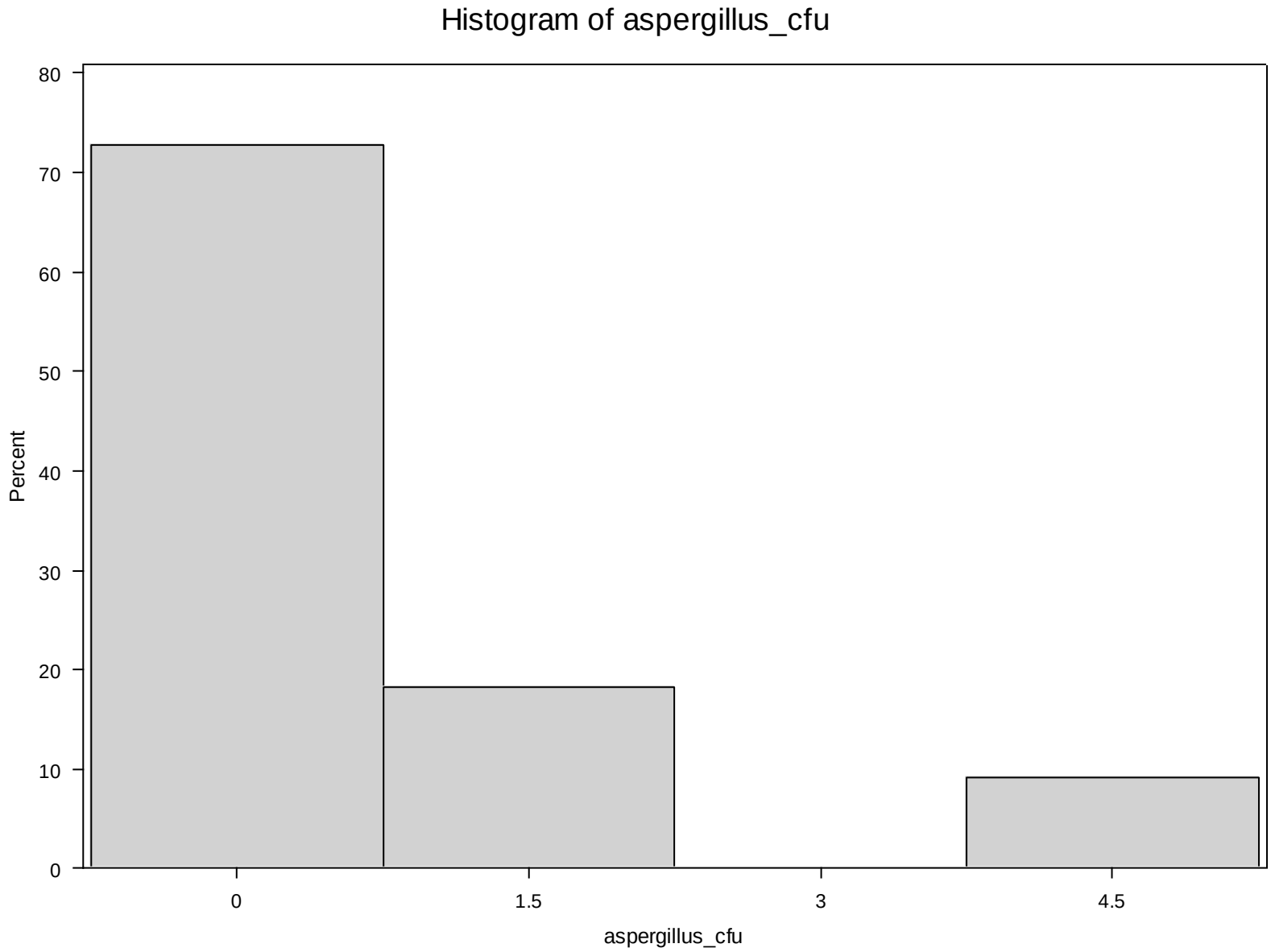
Model Number	*Outcome Variable*	*Predictor Variable*	*Estimate*	*Lower 95% CL*	*Upper 95% CL*	*Comparison P value*	*Global P value*
13b	TEWLB	Exp(Time_mins)	0.9951	0.9859	1.0044	_	.
13b	TEWLB	Exp(exposed time)	0.9981	0.9842	1.0122	.	.
13b	TEWLB	Time_mins	.	.	.	0.2963	0.2963
13b	TEWLB	exposed_time	.	.	.	.	0.7920
14a	pHB	Ambient_temp_mean	.	.	.	.	0.1301
14a	phB	Exp(Time_mins)	1.0292	0.7675	1.3802	_	.
14a	pHB	Time_mins	.	.	.	0.8476	0.8476
14a	pHB	Time_mins*Ambient_temp_mean	.	.	.	.	0.9028
14b	pHB	Ambient_temp_mean	.	.	.	0.4296	0.4296
14b	phB	Exp(Ambient_temp_mean	0.7817	0.4243	1.4402	_	.
14b	phB	Exp(Time_mins)	1.0106	1.0005	1.0209	_	.
14b	pHB	Time_mins	.	.	.	0.0406	0.0406
15a	TEWLB	Ambient_temp_mean	.	.	.	.	0.0930
15a	TEWLB	Exp(Time_mins)	0.9055	0.7604	1.0782	_	.
15a	TEWLB	Time_mins	.	.	.	0.2650	0.2650
15a	TEWLB	Time_mins*Ambient_temp_mean	.	.	.	.	0.2872
15b	TEWLB	Ambient_temp_mean	.	.	.	0.3981	0.3981
15b	TEWLB	Exp(Ambient_temp_mean	0.8233	0.5245	1.2924	_	.
15b	TEWLB	Exp(Time_mins)	0.9941	0.9840	1.0044	_	.
15b	TEWLB	Time_mins	.	.	.	0.2613	0.2613
16a	phB	Exp(Time_mins)	0.9881	0.9314	1.0484	_	.

Model Number	*Outcome Variable*	*Predictor Variable*	*Estimate*	*Lower 95% CL*	*Upper 95% CL*	*Comparison P value*	*Global P value*
16a	pHB	RH_mean	.	.	.	.	0.4827
16a	pHB	Time_mins	.	.	.	0.6928	0.6928
16a	pHB	Time_mins*RH_mean	.	.	.	.	0.4454
16b	phB	Exp(RH_mean)	1.0484	0.9701	1.1330	_	.
16b	phB	Exp(Time_mins)	1.0110	1.0012	1.0209	_	.
16b	pHB	RH_mean	.	.	.	0.2328	0.2328
16b	pHB	Time_mins	.	.	.	0.0276	0.0276
17a	TEWLB	Exp(Time_mins)	0.9660	0.9326	1.0007	_	.
17a	TEWLB	RH_mean	.	.	.	.	0.0405
17a	TEWLB	Time_mins	.	.	.	0.0548	0.0548
17a	TEWLB	Time_mins*RH_mean	.	.	.	.	0.1629
17b	TEWLB	Exp(RH_mean)	0.8821	0.7773	1.0011	_	.
17b	TEWLB	Exp(Time_mins)	0.9931	0.9806	1.0058	_	.
17b	TEWLB	RH_mean	.	.	.	0.0520	0.0520
17b	TEWLB	Time_mins	.	.	.	0.2870	0.2870
18	phB	2 vs 6	.	.	.	<.0001	.
18	phB	2 vs 8	.	.	.	0.0561	.
18	phB	6 vs 8	.	.	.	<.0001	.
18	phB	Exp(2 vs 6)	0.1127	0.0490	0.2593	_	.
18	phB	Exp(2 vs 8)	0.3925	0.1503	1.0246	_	.
18	phB	Exp(6 vs 8)	3.4813	2.2733	5.3313	_	.

Model Number	*Outcome Variable*	*Predictor Variable*	*Estimate*	*Lower 95% CL*	*Upper 95% CL*	*Comparison P value*	*Global P value*
18	phB	Exp(Time_mins)	1.0116	1.0014	1.0219	_	.
18	pHB	Time_mins	.	.	.	0.0258	0.0258
18	pHB	temp_dress	.	.	.	.	<.0001

Model with TEWL versus type of wound does not converge due to 4 categories
Models with TEWL and pH versus type of dressing applied do not converge due to 6 categories
Model with TEWL versus type of temporary dressing applied does not converge due to 3 categories

Figure 2. Histograms of bacteria variables



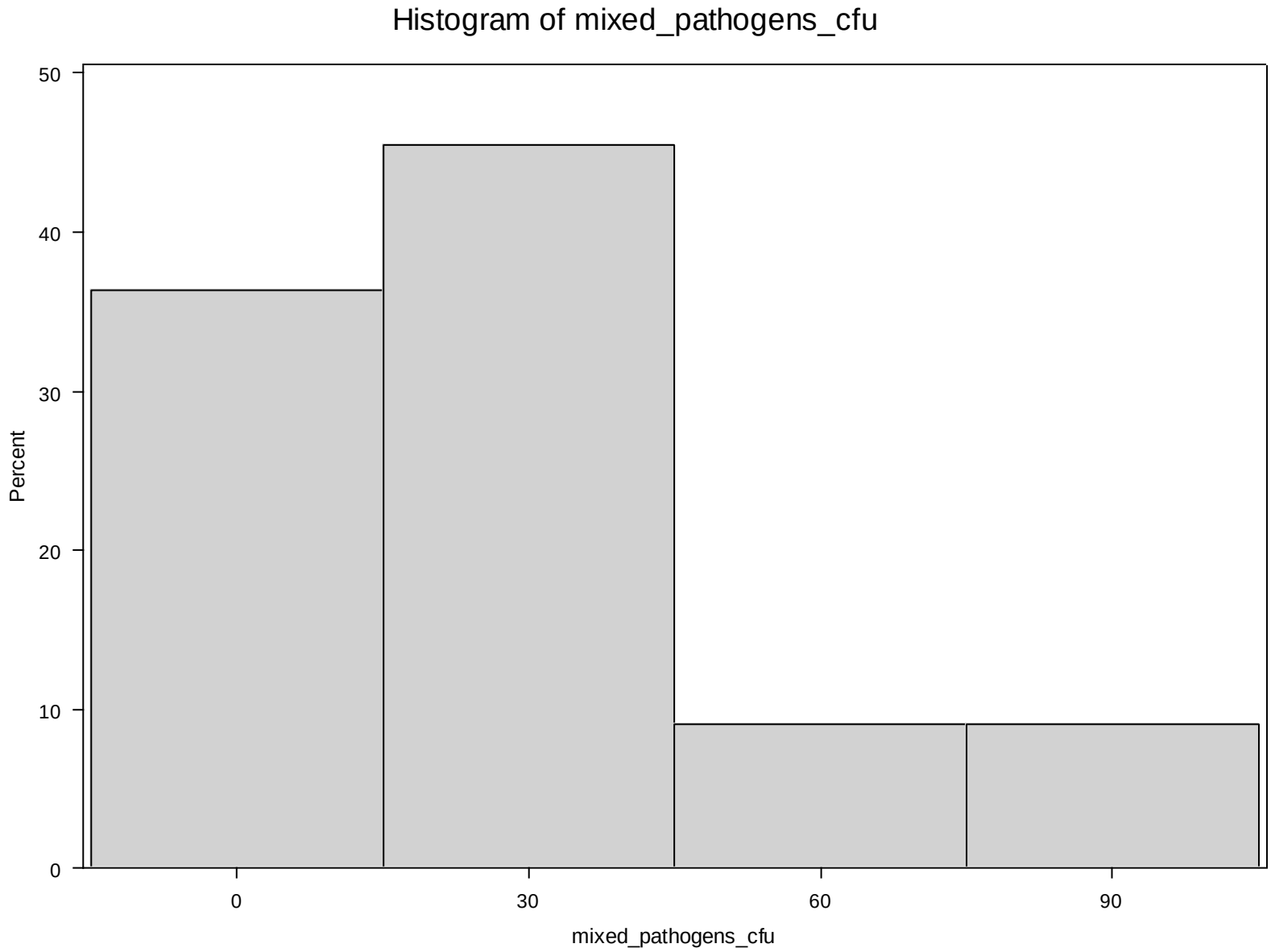
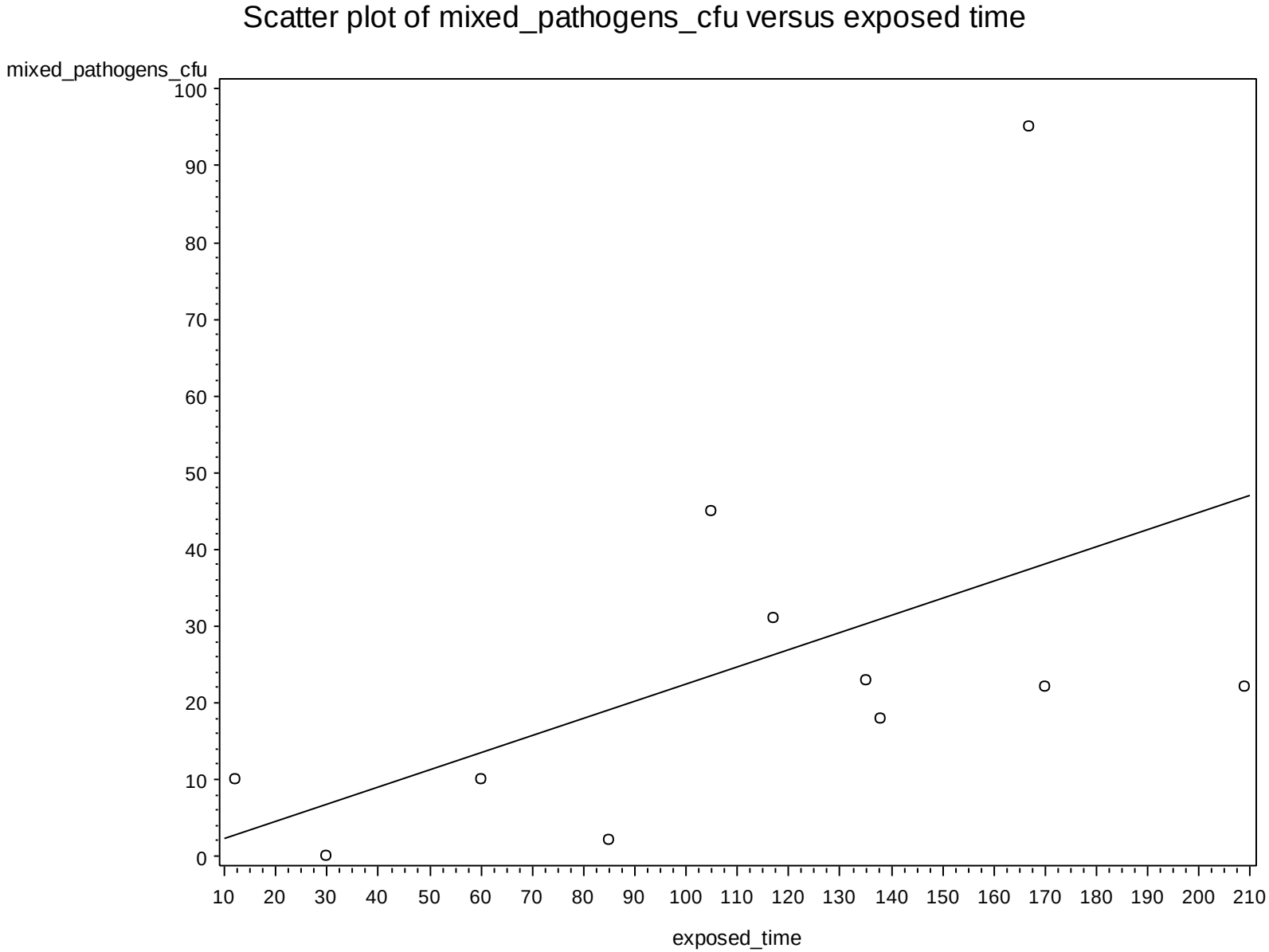

Histogram of mixed_pathogens_cfu
Percent
50
40
30
20
10
0
0
30
60
90
mixed_pathogens_cfu

Figure 3. Scatter plots of bacteria variables



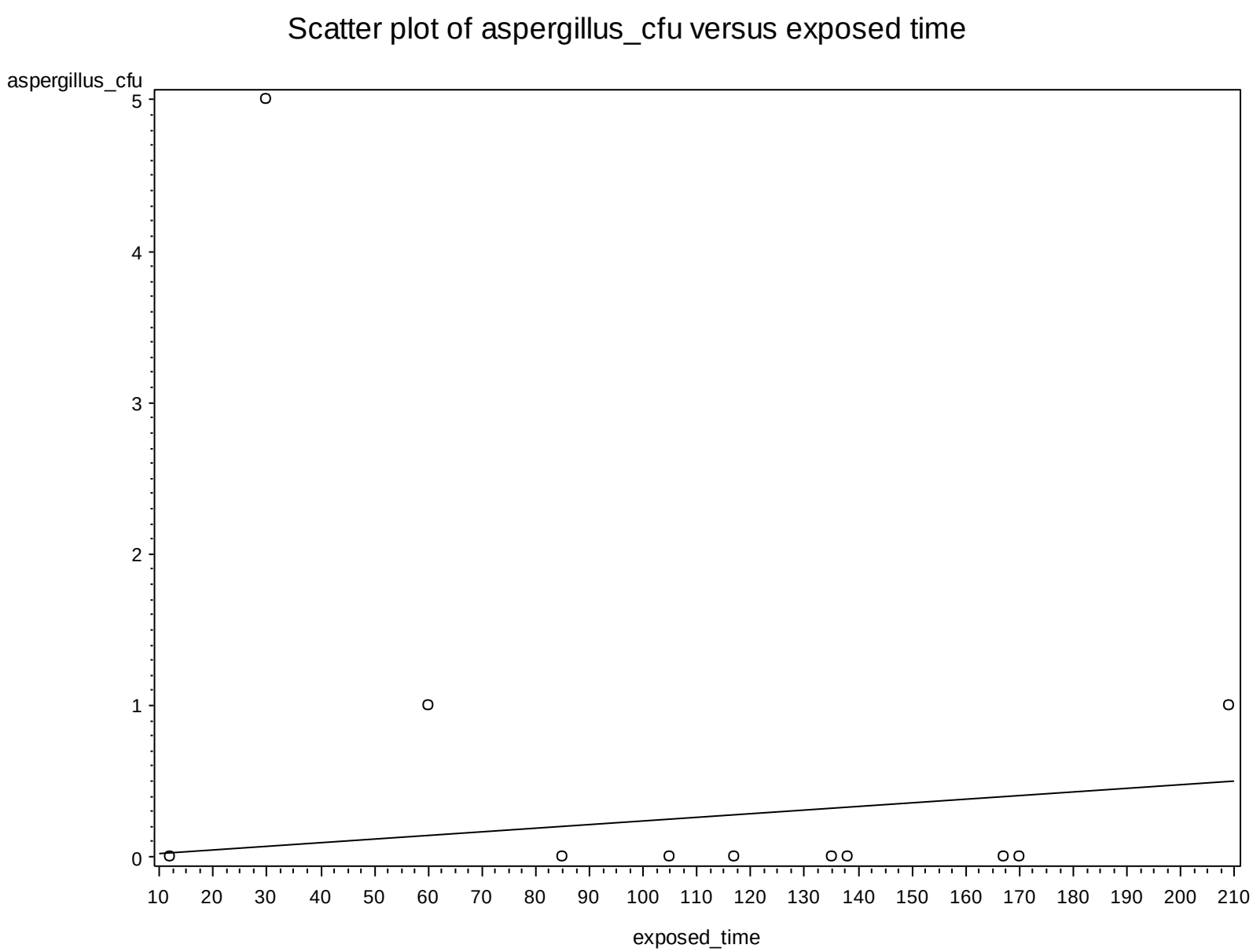

Scatter plot of aspergillus_cfu versus exposed time
aspergillus_cfu
5
4
3
2
1
0
10
20
30
40
50
60
70
80
90
100
110
120
130
140
150
160
170
180
190
200
210
exposed_time

Table 8. Frequency tables of 2 bacteria variables (binary)

mixed_pathogens_cfuB	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
Count<=22	7	63.64	7	63.64
Count>22	4	36.36	11	100.00

Frequency Missing = 1

aspergillus_cfuB	*Frequency*	*Percent*	*Cumulative Frequency*	*Cumulative Percent*
Count=0	8	72.73	8	72.73
Count>0	3	27.27	11	100.00

Frequency Missing = 1

Figure 4. Logistic regression of mixed_pathogens_cfu (binary) versus exposed time

Model Information	
Data Set	WORK.WOUNDX
Distribution	Binomial
Link Function	Logit
Dependent Variable	mixed_pathogens_cfuB

Model Information	
Number of Observations Read	12
Number of Observations Used	11
Number of Events	4
Number of Trials	11
Missing Values	1

Response Profile		
Ordered Value	mixed_pathogens_cfuB	Total Frequency
1	Count>22	4
2	Count<=22	7

PROC GENMOD is modeling the probability that mixed_pathogens_cfuB='Count>22'.

Algorithm converged.

Wald Statistics For Type 3 Analysis			
Source	DF	Chi-Square	Pr > ChiSq
exposed_time	1	0.66	0.4164

Contrast Estimate Results										
	Mean			L'Beta						
Label	Mean Estimate	Confidence Limits		L'Beta Estimate	Standard Error	Alpha	Confidence Limits		Chi-Square	Pr > ChiSq
exposed_time	0.5024	0.4966	0.5082	0.0096	0.0118	0.05	-0.0135	0.0327	0.66	0.4164
Exp(exposed_time)				1.0096	0.0119	0.05	0.9866	1.0332		

Figure 5. Logistic regression of aspergillus_cfu (binary) versus exposed time

Model Information	
Data Set	WORK.WOUNDX
Distribution	Binomial
Link Function	Logit
Dependent Variable	aspergillus_cfuB

Number of Observations Read	12
Number of Observations Used	11
Number of Events	3
Number of Trials	11
Missing Values	1

Response Profile

Ordered Value	*aspergillus_cfuB*	*Total Frequency*
1	Count>0	3
2	Count=0	8

PROC GENMOD is modeling the probability that aspergillus_cfuB='Count>0'.

Algorithm converged.

Wald Statistics For Type 3 Analysis

Source	*DF*	*Chi-Square*	*Pr > ChiSq*
exposed_time	1	0.17	0.6781

Contrast Estimate Results

	Mean			*L'Beta*					
Label	*Mean Estimate*	*Confidence Limits*		*L'Beta Estimate*	*Standard Error*	*Alpha*	*Confidence Limits*		*Chi-Square*	*Pr > ChiSq*
exposed_time	0.4988	0.4930	0.5045	-0.0049	0.0117	0.05	-0.0279	0.0181	0.17	0.6781
Exp(exposed_time)				0.9951	0.0117	0.05	0.9725	1.0183		

There are not enough observations to perform logistic regression on bacteria variables versus type of temporary dressing

Figure 6. Histogram of VAS difference

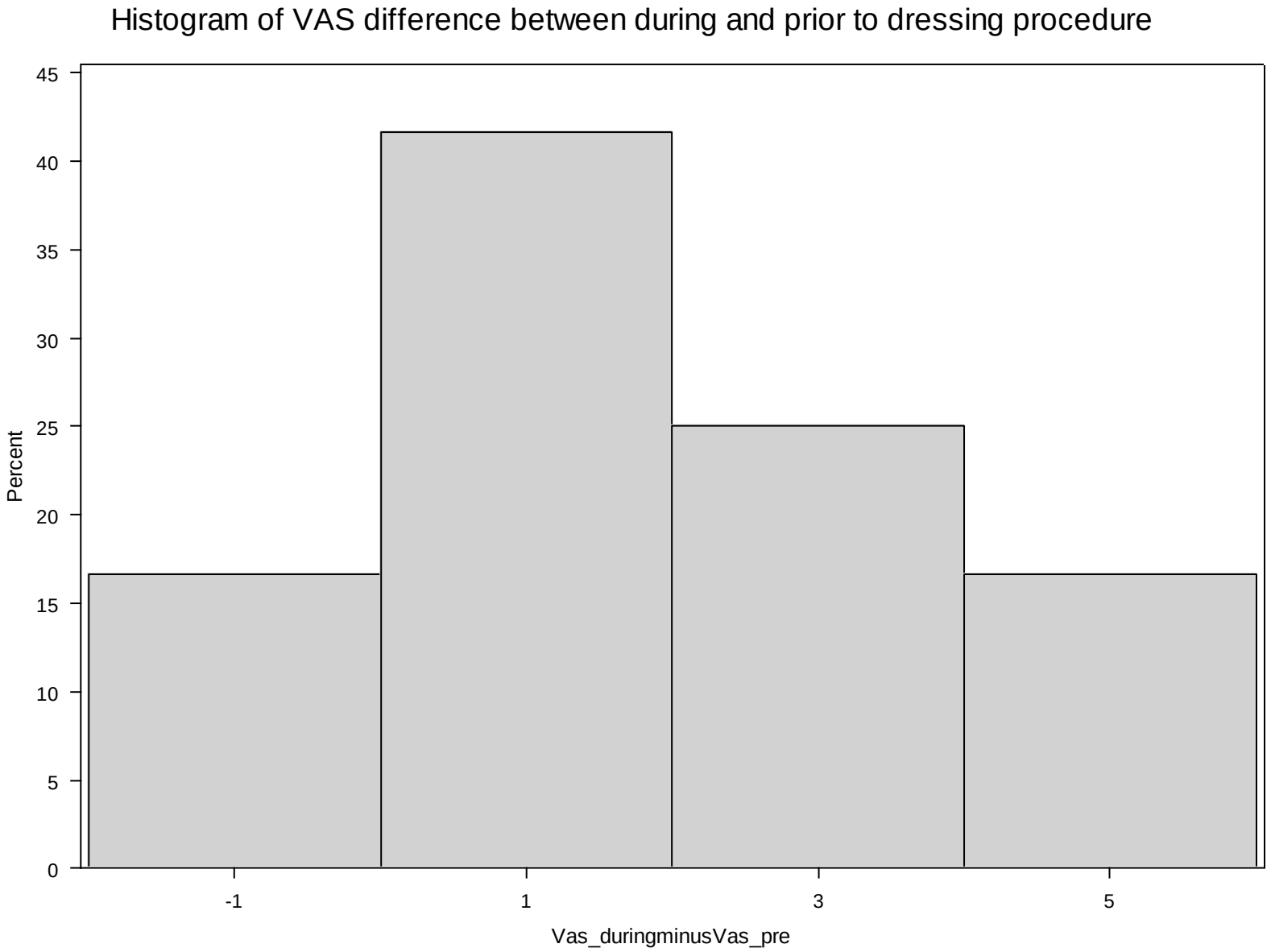


Figure 7. Scatter plot

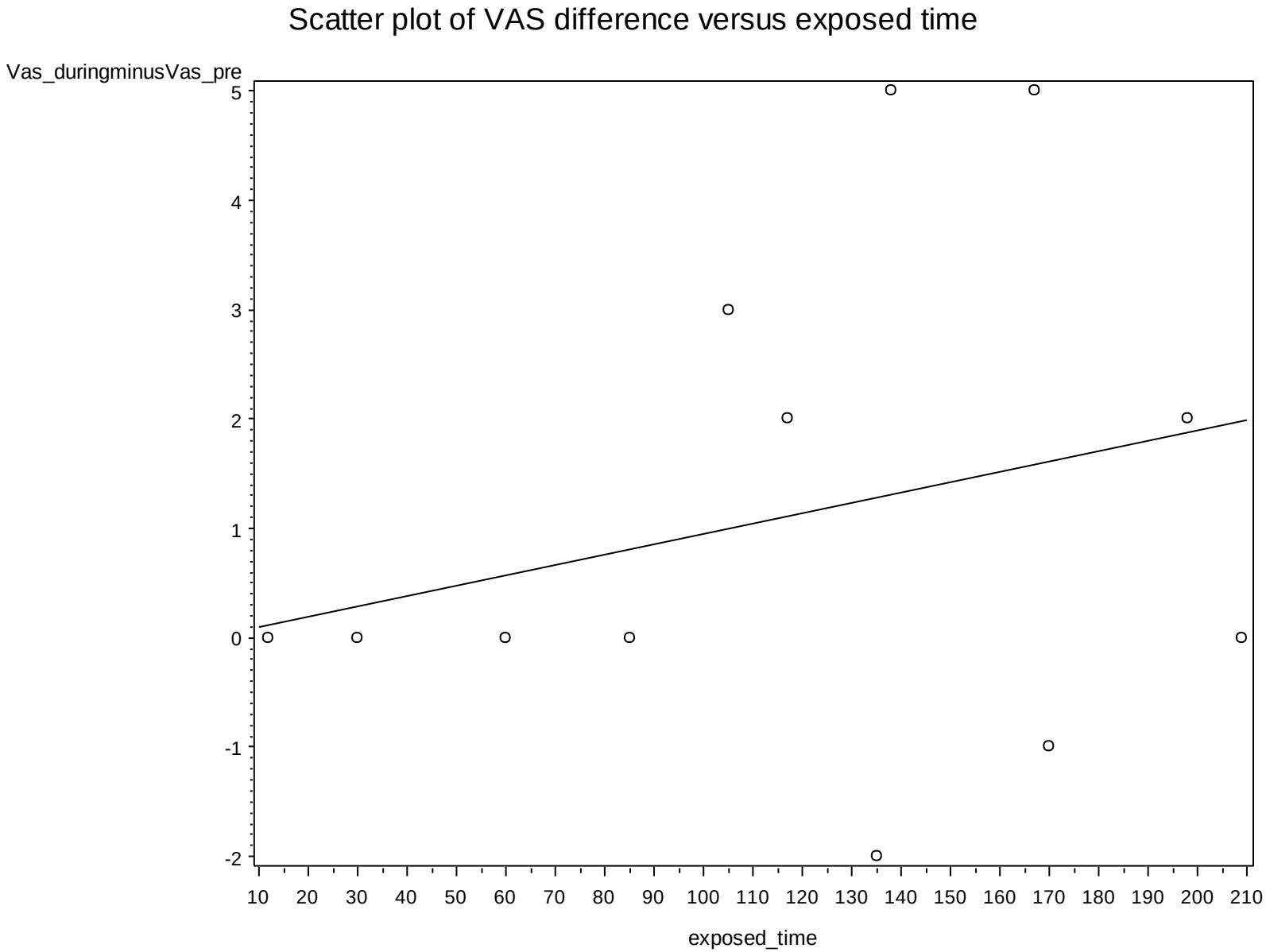


Figure 8. Linear regression of difference between VAS score during and prior dressing procedure, versus time of exposure

Model Information	
Data Set	WORK.WOUNDX
Distribution	Normal
Link Function	Identity
Dependent Variable	Vas_duringminusVas_pre

Number of Observations Read	12
Number of Observations Used	12

Algorithm converged.

Wald Statistics For Type 3 Analysis			
Source	*DF*	*Chi-Square*	*Pr > ChiSq*
exposed_time	1	0.69	0.4047

Contrast Estimate Results

	Mean			*L'Beta*					
Label	*Mean Estimate*	*Confidence Limits*		*L'Beta Estimate*	*Standard Error*	*Alpha*	*Confidence Limits*		*Chi-Square*	*Pr > ChiSq*
exposed_time	0.0083	-0.0112	0.0279	0.0083	0.0100	0.05	-0.0112	0.0279	0.69	0.4047
Exp(exposed_time)				1.0083	0.0101	0.05	0.9888	1.0283		