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# Subepidermal Moisture Measures and Their Relationship to Early Identification of Pressure Injuries in both Dark and Light Skin Tones in the Acute Care Setting

Cecilia Zamarripa

# SUBEPIDERMAL MOISTURE MEASURES AND THEIR RELATIONSHIP TO EARLY IDENTIFICATION OF PRESSURE INJURIES IN BOTH DARK AND LIGHT SKIN TONES IN THE ACUTE CARE SETTING

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By

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# ABSTRACT

## SUBEPIDERMAL MOISTURE MEASURES AND THEIR RELATIONSHIP TO EARLY IDENTIFICATION OF PRESSURE INJURIES IN BOTH DARK AND LIGHT SKIN TONES IN THE ACUTE CARE SETTING

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***Background***: Pressure injuries are an important quality measure. Most are avoidable and can be prevented by implementing nursing care strategies early. Pressure injury prevention is significant to nursing practice. There is a gap in the ability to detect early skin damage through standard visual skin assessment in dark skin toned individuals. Subepidermal moisture (SEM) values have been shown to detect early tissue damage in people with dark skin, prior to it being detected through standard visual skin assessment. ***Objectives***: This study sought to explore the relationship between visual skin assessment and SEM as indicators of pressure injury and if threshold SEM values as potential predictors could determine stage 1 pressure injury and deep tissue pressure injury (DTPI) in adult individuals hospitalized in the acute care setting.

***Methods***: This non-experimental, repeated measures, descriptive design measured visual skin assessment and SEM and their relationship to early identification of pressure injuries in people with light and dark skin tones. Daily follow-up assessments and measurements included concurrent visual skin assessment and SEM measures, and up to six time points. Data was examined to understand the effectiveness of visual skin assessment and subepidermal moisture measures to detect early signs of a pressure injury. Demographic data on characteristics of the sample population was collected to examine any confounding variables.

***Results***: Twenty two of the 122 individuals that participated in the study developed a total of 25 pressure injuries. Only one of the 22 individuals that developed a pressure injury was dark skin toned. Mean SEM values varied at anatomical locations, with highest values at the sacrum (M = 40.3, SD = 9.0) and above the sacrum (M = 41.1, SD = 7.4). Days to initial discovery of pressure injury through visual skin assessment averaged 4.3 days.

***Discussion***: These findings suggest that early skin damage may be more difficult to detect through visual skin assessment in dark and light skin toned individuals and further exploration of SEM as a more reliable method to detect pressure injuries should be conducted.

***Key Words***: pressure injury * pressure ulcer * visual skin assessment * subepidermal moisture measures *

# DEDICATION

This dissertation is dedicated to my dear family and especially my husband Rick, who relentlessly pushed me to "finish the gosh darn thing already." There is a special place for you in my heart, and I truly appreciate your encouragement. To my adult children Anelise and Vicente: you are both very precious, always supportive, and encouraging. I hope that this day will encourage you both to seek opportunities for life-long learning. I would also like to say a special dedication to my parents Ricardo y Vicenta, who did not have the same educational opportunities but always offered life's wonderful wisdom to succeed. My parents recognized the struggles that I faced as a first-generation, college-bound Mexicana, and they proudly encouraged me every step of the way.

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# LIST OF ABBREVIATIONS

AHRQ- Agency for health Research and Quality

BWAT- Bates-Jensen Wound Assessment Tool

CMS- Centers for Medicare and Medicaid Services

DPM- Dermal Phase Meter

DPU- Dermal Phase Unit

DTPI- Deep Tissue Pressure Injury

HAPI- Hospital Acquired Pressure Injury

HAPU- Hospital Acquired Pressure Ulcer

NPIAP- National Pressure Injury Advisory Panel

NPUAP- National Pressure Ulcer Advisory Panel

POA- Present on Admission

SEM- Subepidermal Moisture

WOCN- Wound, Ostomy, Continence Nurse

WOCNCB- Wound, Ostomy, Continence Nurse Certification Board

# CHAPTER 1

# INTRODUCTION

## 1.0 Introduction

This chapter justifies the need for this study. The background section provides an overview of problems and issues associated with pressure injuries, including their detection. The problem statement, purpose of the study, and significance to the science of nursing are addressed. The research questions that guide this study as well as the assumptions and limitations, operational definitions, and the expected outcomes are included. Specific aims addressed pressure injury damage in people with darkly pigmented skin tones and the potential efficacy of a dermal phase meter to detect early pressure injury in people with dark and light skin tones. This chapter concludes with a discussion of the study's significance to the profession of nursing.

## 1.1 Background

A pressure injury, also known as a bedsore or decubitus ulcer, is defined by the National Pressure Injury Advisory Panel (NPIAP) as a "localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue" (Edsberg et al., 2016). In 2016, the NPIAP updated the definition of a stage I pressure injury, further describing this stage to assist in detecting tissue injury in persons with darker skin tones. Early detection is a key factor in preventing the serious consequences of pressure injuries. Poor early detection could lead to delayed early intervention and worsening of outcomes. At this time, further discussion of stage 1 stage pressure injury description in people with darkly pigmented skin focused on the difficulties and challenges associated with determining

a stage 1 pressure injury versus a deep tissue pressure injury (DTPI) (Edsberg et al., 2016). This present study is innovative as it is one of few studies known in the acute care hospital setting that will address health disparities related to pressure injury detection in people who have dark skin tones such as but not limited to Africans, African Americans, Afro-Carribeans, and Latinos.

There exists limited evidence about pressure injury prevalence and early identification and detection of pressure injuries in people with dark skin tones (Li et al., 2011; Lyder, 2009). Limited research in this area presents a major problem considering the number of people with dark skin tones that live in the United States (U.S.). Dark skin tones are common among minority Blacks and Hispanics. Minority population demographics are changing with Black minority population groups growing by 12 percent from 34.7 to 38.9 million in comparison to the total U.S. population growth of 9.7 percent from 281.4 to 308.7 million in 2010. The Black population in 2020 rose to 48.2 million in the U.S. (Commerce, 2021). Healthcare reporting about people of multiple races grew at a much faster pace than for the Black population alone. This is related to the revision to the Standards for the Classification of Federal Data on Race and Ethnicity mandating that race and ethnicity are distinct and separate concepts, thus presenting an opportunity for individuals to self-identify with more than one race combination (Bureau, 2010).

People of minority populations often have unmet healthcare needs that are related to predisposing (race and ethnicity) and enabling risk factors (income, care source, and healthcare insurance coverage), placing patients at a higher risk for delays in healthcare. Minorities are less likely to report unmet healthcare needs because of differences in health needs perception, previous negative care experiences, and perceived or real discrimination. Low literacy is another factor that contributes to underreporting of unmet healthcare needs (Shi et al., 2008).

Pressure injuries are known to occur in every healthcare setting, and people who develop pressure injuries require more financial and nursing care resources to treat them (Padula &

Delarmente, 2019; Youn et al., 2012). In most healthcare settings, quality of care is defined by pressure injury prevalence rates rather than incidence rates (Bergstrom & Horn, 2011). Prevalence is measured by dividing the number of patients with pressure injuries by the total number of patients included in the sample. Incidence is measured by dividing the number of patients with new pressure injury cases developed after admission by the total number of patients in the sample (Pieper, 2012b). In New York state nursing homes, pressure injury prevalence and incidence rates among people with dark skin were higher than those with light skin. Blacks may be more likely to have pressure injuries than whites as a result of residing in facilities with poorer care quality (Cai et al., 2010).

### 1.2 Statement of Problem

Knowing how to do an accurate visual skin assessment is a skill learned and practiced by nurses. Skin assessment includes a comprehensive skin health history and a subjective and objective visual assessment. In order to acquire the skills needed to detect skin changes or early signs of pressure injuries in people with dark skin tones, the clinician needs to learn to distinguish skin assessment differences between light and dark skin tones (Bates-Jensen et al., 2017). Skin changes and early signs of pressure injuries are often more difficult to detect in darker skin tones, delaying early detection and prompt intervention to treat and prevent worsening of pressure injuries (Bates-Jensen et al., 2017; Bergstrom & Horn, 2011; Garrigues & Cartwright, 2011).

The Agency for Healthcare Research and Quality (AHRQ) views pressure injuries as a quality indicator, and full thickness (stage 3 and stage 4) pressure injuries are considered “never events” or adverse events that should never occur (Bry et al., 2012). Early detection could reduce the frequency of pressure injuries progressing in severity during the early stages and therefore decrease the progression to a more severe stage 3 or 4 pressure injury. In addition to the enormous pain and suffering, the cost incurred from a single complex stage 4 pressure injury can reach in

excess of $70, 000 (Padula & Delarmente, 2019). The Center for Medicare and Medicaid Services (CMS) estimated that the cost of treating pressure injuries in the United States in 2007 was 11 billion dollars. Currently, over 2.5 million individuals in the United States develop a pressure injury in the acute care setting, with financial burden and annual costs ranging from 3.3 billion to 12 billion dollars (Padula & Delarmente, 2019; Van Den Bos et al., 2011). In October 2008, the CMS changed reimbursement for pressure injuries that were not present on admission (POA) or not documented as POA. Consequently, in these cases, the hospital does not receive the higher diagnosis related group (DRG) rate if a pressure injury was not POA or a pressure injury was not documented to be present when the patient was admitted. This has led hospitals to implement pressure injury prevention practices that include assessment of pressure injury risk and a comprehensive skin assessment as part of a quality pressure injury prevention plan of care. Utilizing a pressure injury risk assessment tool to assess a patient's level of pressure injury risk can help evaluate and identify patients at risk for pressure injuries so that interventions to prevent skin breakdown can be implemented. The Braden Scale for predicting pressure injuries is one such tool used to assess pressure injury risk (Braden, 2014).

Healthcare reform has increased the focus on pressure injuries, placing at the forefront, legislation with attention to their prevention. People affected by pressure injuries include the patient with a pressure injury, their family and caregivers, hospitals, long-term acute care (LTAC) facilities, skilled nursing facilities (SNF), the consumer, insurance companies, and government. The costs of hospitalizations to treat patients with pressure injuries are influenced by length of stay, readmissions, and morbidity and mortality rates related to sepsis and infection (Padula & Delarmente, 2019; Wassel et al., 2020).

Regardless of the fact that most pressure injuries are avoidable, their prevalence continues to vary. Benchmarking of patient safety indicators, including hospital acquired pressure injuries,

(HAPI), are measured annually, ranging overall from 3.5% to 29.5%% in acute care and long-term care settings (House et al., 2011). Facility acquired pressure injury incidence rates overall are reported to range between 2.8% and 9.0% and, pressure injury incidence tends to be higher in older populations (Song et al., 2019).

The Patient Protection Affordable Care Act (PPACA) provides an avenue for partnering to improve patient safety and promote quality. The section of the PPACA that affects work with pressure injury prevention, practice, and research is the section to improve and coordinate care for Medicare patients by partnering with CMS. The partnership focuses on decreasing nine preventable errors and complications. Pressure injuries are a preventable complication, and the initiative addresses reduction in healthcare costs to Medicare by about $50 billion and a significant amount to Medicaid (Schwartz, 2010).

In recent years, pressure injuries are receiving the attention of many public and private organizations such as CMS and their declaration of pressure injuries as a “never event.” In 2001, the term “never event” was first introduced by the National Quality Forum (NQF) in reference to serious, preventable, adverse events that should never occur (Bry et al., 2012).

Organizations are no longer being reimbursed for a hospital acquired pressure injury (HAPI) thus, documentation is required of all pressure injuries POA. The treatment of pressure injuries as the major focus in 1992, and the Agency for Healthcare Research and Quality (AHRQ), formerly the Agency for Health Care Policy and Research (AHCPR), published evidence-based guidelines for the prevention of pressure injuries. Since then, interest and research on pressure injury prevention has grown. Founded in 1968, the Wound, Ostomy, and Continence Nurses Society (WOCN), an association of healthcare professionals specializing in care of individuals with wounds, has focused on advancing the practice and guiding expert delivery of wound care, including prevention of pressure injuries. In addition, health disparities that

disproportionately affect vulnerable populations are targeted by the Department of Health and Human Services, with the National Institute of Health encouraging research that recommends interventions to eliminate health disparities (de Chesnay, 2012).

Using standard visual skin assessment methods, nurses often miss early signs of a pressure injury in individuals with dark skin (Bates-Jensen et al., 2009; Bates-Jensen et al., 2010). There is a vital need to develop valid and reliable skin assessment methods for individuals with dark skin to detect early tissue damage and prevent more severe pressure injuries. Findings in a pilot study with 11 African American nursing home patients suggested that SEM measured by a dermal phase meter may provide a more accurate method to detect stage 1 and stage 2 pressure injury damage than standard visual assessment (Bates-Jensen et al., 2007). Further research utilizing this technique is needed to determine its usefulness as an objective tool to detect early pressure injury damage in people with dark skin and in different settings including acute care settings.

It is well documented that pressure injuries have a negative impact on life, regardless of skin color (Li et al., 2020; Shiferaw et al., 2020; Van Den Bos et al., 2011) and that it is necessary to decrease their prevalence. Federal regulators and other interested parties are placing additional importance on pressure injury prevention (Squitieri et al., 2018).

Interventions to prevent pressure injuries should include assessing skin integrity to determine interventions required to prevent pressure injuries; however, studies have shown that the standard visual assessment used in practice is not sufficient to detect early development of pressure injuries in acute care hospitalized patients (Bates-Jensen et al., 2017; Moore et al., 2017). Those with darker skin tones are at an even greater risk to be missed for early pressure injury detection. It is important to reduce the time of detection so that pressure injury prevention care interventions can be implemented earlier. Therefore, it is imperative that other more effective

methods of early detection are developed. All persons deemed at risk for pressure injuries should have a pressure injury prevention plan implemented according to the identified risk factors. However, with the changing demographics of the U.S. population, specifically those with darker skin tones, it is imperative for healthcare personnel and organizations to take a close look at the individual needs of vulnerable populations and reduce health disparities.

### 1.3 Purpose of the Study

The purpose of this study was to examine the effectiveness of a hand-held device that measures SEM to detect early signs of pressure injuries in acute care hospitalized patients with dark and light skin. This method of detecting the onset of pressure injuries was compared to visual assessment, the current standard of detection. The overarching goal was to describe the relationship between SEM measures and standard visual skin assessment for detection of early skin damage that can lead to pressure injuries in people with dark skin and thus validate SEM's ability to detect early skin damage.

The overall goal of the proposed research study was to define the gap in ability to detect early skin damage regarding skin assessment and early pressure injury identification in people with darkly pigmented skin tones. Currently, the standard practice for detection of stage 1 pressure injuries and DTPI regardless of skin tones includes visual skin assessment, but this method used alone may not be effective in detecting early pressure injuries in people with dark skin tones. Too frequently, early detection of stage 1 pressure injuries and DTPI in individuals with dark skin tones is missed by visual skin assessment alone. It is, therefore, important that new techniques and procedures for early detection of stage 1 pressure injuries and DTPI in individuals with dark skin tones are developed and tested for effectiveness. In this study, a hand-held device that measures tissue edema, a potential early sign of skin damage and pressure injury development, was compared to the standard practice of visual skin inspection. Visual skin

assessment was done as part of the assessment regardless of whether the handheld device or standard procedures were used.

### 1.4 Specific Aims

The specific aims of the research study were to:

(a) Examine and compare the effectiveness of visual skin assessment and SEM measures as early indicators of stage 1 pressure injury and DTPI in people with dark skin tones.

(b) Explore the efficacy of visual skin assessment and SEM measures as indicators of stage 1 and deep tissue pressure injuries in individuals with dark and light skin tones.

(c) Identify threshold SEM values that can be used to predict stage 1 and/or DTPI in hospitalized individuals in acute care settings.

### 1.5 Research Questions and Hypotheses

This study asked the following research questions:

1. Is there a difference in time to detection of pressure injury between standard visual skin assessment and SEM in those patients that go on to develop a stage 1 pressure injury or deep tissue pressure injury in the acute care setting?

2. Are there any differences in time to detection of pressure injuries between standard visual skin assessment and SEM between those patients with light and dark skin tones?

3. Does SEM predict stage 1 pressure injuries or deep tissue pressure injury in patients hospitalized in an acute care setting?

The hypotheses for this study were as follows:

1. SEM will detect stage 1 pressure injury or deep tissue pressure injury sooner (fewer days) than visual skin assessment.

2. Light skin tone patients with stage 1 pressure injury or deep tissue pressure injury

will be detected sooner (in number of days) compared to dark skin tone patients in acute care hospitalized patients.

3. SEM values will predict stage 1 pressure injury and deep tissue injury in acute care hospitalized patients.

## 1.6 Definitions Operationalized

In quantitative studies, operational definitions are important to understand in the context of the study and to define variables as they are operationalized. Defining variables can be a difficult task and must specify the operations that must be performed by the researcher to measure. For the purposes of this research study, the following terms were operationally defined.

Pressure injury: The NPIAP defines a pressure injury as a "localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue" (National Pressure Ulcer Advisory, 2016).

### *1.6.1 Subepidermal Moisture Measure (SEM) (Quantification of Water Concentration)*

SEM is a biophysical measure used to quantify skin and water which indirectly represents the epidermal barrier function of skin (Bates-Jensen et al., 2010). In this study, SEM was measured by using a MoistureMeter D dermal phase meter (DPM) device made by Delfin Technologies and on loan from Dr. Barbara Bates-Jensen, UCLA School of Nursing. The DPM device measured the dielectric constant relation to the thickness of the stratum corneum, which, when dry, acts like a dielectric medium. When water is introduced to the tissue, the stratum corneum is then responsive to an electrical field. A probe that is manually placed on the skin uses

dielectric parameters to transmit electromagnetic waves. An interaction of induced electrical fields and water molecules in position close to the probe determines a depth of interaction that is dependent on size of the probe. SEM values are calculated and displayed in relative dielectric constant units quantifying water content in the measured tissue (Bates-Jensen et al., 2010). The impedance value of the skin is measured in dermal phase units (DPUs) and is an arbitrary unit relative value with higher readings indicative of higher SEM (Bates-Jensen et al., 2009). In previous studies, SEM values greater than 50 DPUs dermal phase units may include the likelihood of developing a pressure injury (Bates-Jensen BM, 2007; Bates-Jensen et al., 2010). DPU values were grouped from 0-999 DPUs for analyses. Groupings were selected based on the mean, median and 75$^{th}$ percentile SEM values. Groupings of SEM values were classified as values either below or equal versus greater than the selected values (Bates-Jensen et al., 2007).

### *1.6.2 Reactive Hyperemia*

Reactive hyperemia is the engorgement of blood flow to tissues in the body with increased perfusion that is a normal physiological response and may exist before a stage 1 pressure ulcer is reached.

### *1.6.3 Stage 1 Pressure Injury*

As defined by the NPIAP, a stage 1 pressure injury is "localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue". A stage I pressure injury may be difficult to detect in individuals with dark skin tones and may indicate at risk persons (National Pressure Ulcer Advisory, 2016).

### *1.6.4 Stage 2 Pressure Injury*

Stage 2 pressure injury is defined as partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissue is not visible. Granulation tissue, slough and eschar, are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel" (National Pressure Ulcer Advisory, 2016).

### *1.6.5 Deep Tissue Pressure Injury*

Deep tissue injury is defined as "intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood-filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface" (National Pressure Ulcer Advisory, 2016).

### *1.6.6 Unstageable Pressure Injury*

An unstageable pressure injury is defined as "Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on an ischemic limb or the heel(s) should not be softened or removed" (National Pressure Ulcer Advisory, 2016).

### *1.6.7 Pressure Injury Prevalence*

Pressure ulcer prevalence as used in this study "describes the number or percentage of people having a pressure ulcer while on your unit. It may reflect a single point in time, such as on

the first day of each month or it can also reflect a prolonged period of time, such as an entire hospital stay" (Pieper, 2012b).

### *1.6.8 Pressure Injury Incidence*

Describes the "number or percentage of people developing a new ulcer while in your facility or on your unit. Therefore, it only counts pressure ulcers developing after admission. Incidence rates provide the most direct evidence of the quality of your care" (Pieper, 2012b).

### *1.6.9 Visual Skin Assessment*

Although there is no diagnostic tool to aid in the determination of the numeric pressure injury classification, defining the level or depth of soft tissue damage for staging is determined by observed and subjective visual skin assessment. A standard visual skin assessment includes assessment of skin to the entire body, and the usual practice includes five elements: skin turgor, moisture, color, temperature, and integrity (Baranoski & Ayello, 2004). In this study, visual skin assessment was done by a registered nurse (RN) and included skin in the areas of the sacrum, left and right buttocks, and heels. The method for visual skin assessment included the use of one's eyes to visualize skin and conduct a subjective visual skin assessment and is the standard method to observe non-blanchable erythema. There is no institutional tool available or in use to visually assess skin.

## 1.7 Assumptions and Limitations

### *1.7.1 Assumptions*

Assumptions for this study are as follows:

1. Patients acutely admitted to a hospital may vary in health status.
2. Patients presented with varying skin tones.
3. Visual skin assessment is an augment to SEM readings.

4. Data was collected and recorded in a reliable and precise manner.

5. Most pressure injuries are an avoidable event.

6. If pressure injuries can be detected early by utilizing SEM during the non-visual stage, then interventions to prevent pressure injuries can be implemented earlier with potential for possibly decreasing severity of pressure injuries in dark and light skin.

7. Visual skin assessments done by RNs are reliable.

### *1.7.2 Limitations*

Limitations for this study are as follows:

1. The most common bony prominence anatomic sites of the body for pressure injury development were used for data collection including the sacrum, left and right buttocks, and heels. Therefore, the results were not generalizable to other bony prominent areas where pressure injuries may also develop such as the trochanters.

2. Subject groups in a correlational research design may be similar and pre-existing differences or other alternative differences may account for any outcome variable group differences with a limited generalizability.

3. Visual skin assessment relied on the subjective nature of inspecting skin and may be difficult to result in inherent reliability.

## 1.8 Significance of the Study

Pressure injuries are a serious health problem worldwide. Pressure injury development remains a significant health care problem, especially for at-risk patients. Pressure injuries threaten patient safety across all settings and are prevalent in long-term, acute care and home care settings (Agency For Healthcare & Quality, 2011; Beckrich & Aronovitch, 1999; Black et al., 2011; Bry et al., 2012). Pressure injuries affect millions of people annually leading to significant threats to

patient safety. Clearly not all pressure injuries are avoidable; however, most pressure injuries can be prevented with the proper pressure injury prevention plan (Black et al., 2011).

Pressure injury research has historically focused on prevention and treatment. Few studies (Bates-Jensen et al., 2009; Bates-Jensen et al., 2010; Baumgarten et al., 2004; Bennett, 1995) have focused on early identification of pressure injury among individuals with dark skin tones. Pressure injury prevention specific to people with dark skin tones is vitally important and significant to nursing practice.

In the acute care hospital setting, patients present with a diverse range of skin tones. Skin damage changes and early signs of pressure injuries are often more difficult to detect in darker skin tones, delaying early detection and prompt intervention to treat and prevent the worsening of pressure injuries (Cai et al., 2010; Gerardo et al., 2009; Li et al., 2011; Lyder, 2009). The clinician is often challenged to inspect and assess skin for early signs of pressure injury presented as non-blanchable erythema, the first warning sign that tissue death is imminent if pressure is not redistributed or removed from the area. RNs have a major responsibility to keep patients safe from harm and possess the knowledge and ability to decrease pressure injury rates. Currently, this is can be done simply by conducting a visual and pressure injury risk assessment to help identify those patients at risk for developing a pressure injury then implementing pressure injury prevention interventions immediately upon hospitalization.

There has been more attention to dark skin vulnerability related to pressure injury development due to the dependence on visual assessment, which, when used alone, is not adequate to detect stage 1 pressure injury in people with darkly pigmented skin. Failure to identify early signs of pressure injury may lead to advanced stages even before they are identified via visual assessment and may lead to worsened pressure injury or late identification and, thus, discovering a pressure injury after it has become a more severe stage 3 or 4 pressure injury (Clark,

2010).

It is posited that nurses require an augment to the standard visual skin assessment to identify early signs of pressure injuries in dark skin tones. It may be that SEM provides a more reliable method to detect stage 1 and DTPI pressure injury damage that is frequently missed even with expert visual skin assessments. This study explored the relationship between SEM and visual skin assessment as methods for earlier detection of pressure damage in people with dark skin tones.

There are many reasons this study is important. First and foremost is the need to identify pressure injuries early so they can be treated before they become worse and lead to further complications. Failure to detect early signs of pressure damage, especially in people with dark skin tones, could lead to a more severe pressure injury. Early detection would be an indicator that would trigger interventions to prevent further pressure damage, thus preventing worsening pressure injuries such as stage 3 or 4 pressure injuries. Severe pressure injuries ultimately lead to increased pain and suffering, prolonged hospitalizations, and increased costs, and may ultimately lead to sepsis and/or death (Padula & Delarmente, 2019; Polancich et al., 2020). Reliable and early detection of pressure injuries would help prevent a pressure injury from worsening and improve patient care outcomes through the implementation of pressure injury prevention interventions earlier.

The financial implications of pressure injuries are huge and, specifically, the money spent on healthcare due to the presence of pressure injuries also provides a very important reason for this study. The financial impact is related to an increased length of stay, direct patient care, physician charges, operating room charges if surgically debrided, cost for equipment such as specialty support surface rental or purchase, and cost for treatments. In a study exploring the cost of pressure injuries in medical patients versus surgical patients, the overall cost of pressure

injuries varied and reached between 2.2 and 3.6 billion dollars for hospital-acquired pressure injuries (Beckrich & Aronovitch, 1999).

This study also impacts awareness about health and disparities in healthcare, especially in people with darkly pigmented skin. Blacks have a higher risk than Whites for developing certain adverse events such as pressure injuries (Metersky et al., 2011). Fogerty et al. (Fogerty et al., 2008) identified advanced age and the African American race as risk factors for pressure injury diagnosis. Overall mortality of severe health conditions often related to pressure injuries is reported to be higher in Blacks than in any other race or ethnic group (Cunningham et al., 2017). In a report prepared by the AHRQ, it was reported that there are major gaps and inequities in the U.S. health system when providing healthcare to ethnic minorities in comparison to the majority White population. The report recognized disparity in healthcare quality and identified a need for improvement in implementing strategies to improve patient care safety and quality care (Agency for Health & Quality, 2011). Furthermore, there is also increasing evidence based that provider behaviors and practice patterns contribute to disparities in care.

The results of this proposed study could help provide evidence that will help detect pressure-induced tissue damage not usually detected by the current standard visual assessment method. This information is vital to allow early implementation of interventions to prevent pressure injuries. Results of the study may have a positive impact on clinical practice and may provide evidence to support SEM as a more accurate method to detect tissue damage in people with dark and light skin tones. Earlier detection will subsequently provide the evidence to implement appropriate pressure injury prevention interventions sooner. Pressure injury incidence and mortality could be positively impacted as a result of implementing pressure injury prevention early based on tissue damage detected by SEM.

## 1.9 Summary

The AHRQ views pressure injuries as a quality indicator, and full thickness (stage 3 and stage 4) pressure injuries are considered "never events." The importance of detecting and preventing pressure injuries cannot be underestimated. Practices focused on early identification of pressure injuries in people with dark skin tone could decrease pressure injury rates and decrease more severe pressure injury progression in people with dark skin. By detecting pressure injuries early, especially those that may progress in severity and those not visible through standard visual assessment, progression can be reduced when pressure injury prevention practices are implemented, resulting in decreased pressure injury occurrence (Bry et al., 2012).

SEM has been shown to assist in early detection and subsequent prevention of pressure injuries, especially in dark skin tones, through the early implementation of prevention strategies (Bates-Jensen, McCreath, & Pongquan, 2009). Moisture and tissue edema are detected through SEM measures, and then interventions can be implemented to prevent pressure injuries or decrease their chance of worsening to a more severe pressure injury stage. Results of several studies have focused on nursing home resident subjects with light and dark skin tones, as well as spinal cord (SCI) patients in the rehabilitation phase after their injury (Guihan et al., 2012). To date, there is no known U.S. study that has investigated the use of SEM as a biophysical measure to detect pressure injuries in the U.S. acute and intensive care medical surgical population.

# CHAPTER 2

# REVIEW OF THE LITERATURE

## 2.0 Introduction

In this chapter, a review of the literature relevant to research studies of skin assessment and pressure injury detection as it relates to darker and light skin tones are critically addressed. The background and historical evolution of pressure injuries, the theoretical framework that guided this study, and descriptions of pressure injuries and pressure injury stages and skin anatomy are presented. Gaps in the literature specific to mechanisms used to detect early signs of pressure injuries are also discussed.

## 2.1 Background and Historical Evolution of Pressure Injuries

Pressure injuries are sometimes referred to as decubitus ulcers or bedsores and have been documented to exist since the early 1300s. At that time, evidence of wound healing and bandaging was found in unearthed mummies. In Egypt, preparation of body parts had immense ritualistic meaning similar to Native Americans depicting the cultural symbolism found when wounds would be painted to provide wound healing as well as a symbol of life (Cohen, 1988). Throughout the ages, wounds have been described utilizing different methods considered healing gestures. As early as 2200 B.C., medical manuscripts called clay tablets described interventions to heal wounds with variations of recipe preparations mixed in collaboration with a priest or magician (Cohen, 1988). Wound care descriptions appeared in several procedural forms to treat amputations during the Civil War, prompting an effort to prevent sepsis and save lives. In the 19$^{th}$ century, Frenchman Jean-Martin Charcot studied “decubitus ulcers” as a disease relating the contributing factor to a central nervous system problem as opposed to a pressure related or localized injury etiology (Levine, 2005). Charcot was one of the earliest to offer insight into

lesions we now call pressure injuries. Three hundred years prior to that, Ambrose Pare recognized the significant role that nutrition and pressure relief had in the development of pressure ulcers. He described lesions related to inactivity as decubitus chronicus and lesions related to a neurological injury as decubitus acutus (Levine, 2005).

Physicians and nurses such as Florence Nightingale worked diligently to prevent infections and processes that contributed to inflammation, concurrently making discovery of principles we would identify today as pressure injury prevention. Nightingale's body of knowledge expanded nursing practice to promote the best environment possible and the best possible conditions to prevent disease and promote health. The evolution of medical and nursing care, especially during World War II, impacted the epidemiology of pressure injury prevention and treatment (Levine, 2008).

To date, pressure injuries have been studied both qualitatively and quantitatively, providing evidence that these conditions have a profound effect on quality of life, including physical, financial, and social status, as well as body image changes and feelings of loss of control. In 2000, the first known phenomenological study addressed the impact of pressure injuries on health-related quality of life. Several themes and subthemes emerged in this study of persons with SCI and pressure injuries. Major emerging themes relevant to quality of life include social isolation related to having a pressure injury, impact on body image, healing expectations, and questioning whether the wound would heal. Pressure injuries impacted these individuals psychosocially, physically, financially, emotionally, and spiritually. Little is known of the impact of pressure injuries on quality of life, but we do know that pressure injuries are a significant health burden with many people viewing and describing the ulcer as the worst thing that could happen (Langemo et al., 2008; Langemo, 2005).

## 2.2 Theoretical Framework

For this study, Braden and Bergstrom's (1987) conceptual schema was used as the guiding framework and organizational model. The overall framework identifies extrinsic and intrinsic factors as critical determinants that are causal factors influencing skin integrity. Pressure is the mechanical force that primarily causes pressure injuries. Tissue tolerance is exposure of the skin to prolonged and intense pressure leading to pressure injury development under any circumstance (Braden & Bergstrom, 1987).

A comparative clinical picture of pressure describes intensity over a long period of time to be more detrimental, causing tissue ischemia that results in damage in comparison to high pressure over a short period of time. External unrelieved pressure on blood vessels in underlying tissues over a long period of time limits adequate oxygen perfusion, closing capillary pressure, causing vessels to dilate and spilling interstitial fluid that cause edema. This process further explains tissue tolerating high-pressure amounts if relieved after a short period of time, thus allowing reperfusion of blood flow to blood vessels before they are damaged (Preston et al., 2008). Constant pressure time length resulting in tissue damage may vary and can be as short as one-hour in duration (Barbara et al., 2000).

Current knowledge describes both intrinsic and extrinsic factors as primary and critical determinants contributing to pressure injury development in conjunction with tissue tolerance. Within this conceptualization, the relationship between prolonged and intense pressure duration and decreased activity, decreased mobility, and sensory perception impairment factors may further lead to and increase likelihood of intense pressure. In this conceptualization, other conditions identified to contribute to pressure injury development are related to prolonged exposure to pressure and are identified as activity, sensory perception, and mobility.

The conceptual framework further identifies principal extrinsic and intrinsic factors contributing to pressure injury development. Extrinsic factors include moisture, friction, and shear. Intrinsic factors contributing to pressure and influencing skin integrity include age, nutrition, and arteriolar pressure (Braden & Bergstrom, 1987). Hypothetical factors identified as additional clinical determinants of pressure are alteration in interstitial fluid flow, physiologic effects of stress, skin temperature, and smoking.

Tissue tolerance from prolonged pressure to skin leads to eventual pressure injury development. The ability for tissue to tolerate pressure is further diminished from exposure to moisture, friction, and shear. Excessive moisture on the skin may be present as a result of exposure to perspiration, urine and/or feces, and wound or fistula drainage (Braden & Bergstrom, 1987). Moisture, an extrinsic factor, is known to be an active causative factor in the formation of pressure injuries. Moisture can lead to maceration and subsequently could contribute to pressure injury.

The differentiation between friction as a contributory force and/or shear to pressure injury formation has been explored. Friction is described as the mechanical force exerted when skin is dragged across a coarse surface such as bed linens. The more recent literature describes friction as static and dynamic. Static friction is "the force resisting the relative motion between two bodies when there is no sliding. Static friction is the force that prevents a person from sliding down the bed when the head of the bed is raised." Friction increases as moisture is increased (Brienza et al., 2015).

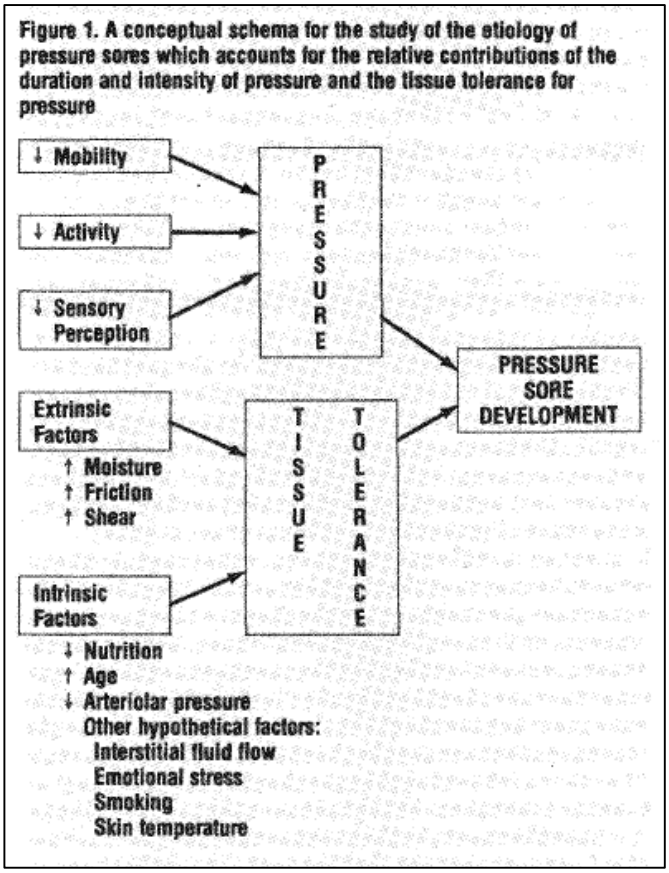
In 2005, the Shear Force Initiative (SFI) was created and met to understand the impact of shear on pressure injury formation. Research groups sought to explore the physiologic effects of shear force on deep tissue as well as seeking to design a process to disseminate shear education information. Shear is important to understand as a contributory factor to pressure injury formation. Shearing forces are produced when the force per unit exerted are parallel to the perpendicular

plane of interest and are a major contributory factor in the development of pressure injuries and other tissue injuries. (Perla, 2007).

The following intrinsic factors relative to age, nutrition, and arteriolar pressure also need to be considered. Intrinsic factors contributing to pressure and influencing skin integrity include age, nutrition, alteration in cellular respiration, physiologic effects of stress, and arteriolar pressure. Interstitial fluid flow is considered a hypothetical intrinsic factor affecting tissue tolerance that may contribute to pressure injury development. This is a significant factor supporting the conceptual framework to fit this study that investigated SEM as a predictor of pressure injuries. A diagram of the conceptual schema that was used in this study to explain the factors influencing pressure ulcer development is shown in Figure 1 (Braden & Bergstrom, 1987). The main focus of this study was on the extrinsic factor of moisture detection, which affects tissue tolerance.

**Figure 1**

*A Conceptual Schema*




*Note.* Permission to use was obtained from Dr. Nancy Bergstrom (Braden & Bergstrom, 1987).

## 2.3 Factors that Affect Development and Assessment of Pressure Injuries

The following factors affect pressure injury development and their assessment: Personal factors, nutritional factors, and physical factors.

Personal Factors: Race, Skin Tone, and Pressure Ulcer Assessment

Nutritional Factors: Serum Albumin and Pre-albumin

Physical Factors: Age, weight, disease, and co-morbidities

## 2.4 Review of Studies

This section of chapter 2 includes a review of studies related to pressure injury detection,

prevalence, and incidence in people with dark and light skin tones, feasibility of subepidermal moisture measures (SEM) to predict early pressure ulcers in persons with dark skin tones, and pertinent literature related to the Braden Scale pressure ulcer risk assessment. A discussion of spectroscopy as an alternative to detect blanch response in dark skin tones will be included.

A systematic review of the literature was conducted within a search period of January 2000 to December 2019. Database searches included CINAHL, ProQuest, PubMed, Cochrane Library, and Medline. Keywords used in the search were pressure ulcer, pressure injury, dark skin tones, ethnic disparities, pressure ulcer incidence, pressure injury incidence, pressure ulcer risk, pressure injury risk, pressure injury, bedsores, and decubitus. These terms were combined with keywords pressure ulcer, pressure injury, pressure ulcer prevention, disparities, darkly pigmented skin, skin assessment, and racial disparities.

### *2.4.1 Pressure Injury Risk, Prevalence and Incidence, and Disparity*

**Pressure Injury Risk.** Pressure injury risk is a quality-of-care concern and identifying those at risk is key to preventing pressure injuries and thus implementing interventions early. Although the literature notes that not all pressure injuries are avoidable, most pressure injuries can be prevented with the proper pressure injury prevention plan (Palese et al., 2020).

**Pressure Injury Prevalence and Incidence.** Pressure injury rates are utilized to measure quality of care and are generally determined to compare rates for quality improvement. Pressure injury prevalence and incidence are two types of measures utilized when monitoring pressure injury rates. Prevalence and incidence rates highlight how pressure injury prevention has improved over time and if pressure injury care has improved over time in response to care interventions.

Pressure injury prevalence describes the number of persons in a defined population with a pressure injury at a particular moment in time. Pressure injury incidence rates describe the number of new cases developing a pressure injury that was not present on admission. Although both types

of pressure injury rate measures are utilized for monitoring quality care, pressure injury incidence rates are best to determine quality of care evidence (National Pressure Ulcer Advisory, 2011).

In several studies, researchers have identified that people with dark skin tones have a higher incidence of more severe (stage 3 and stage 4) pressure injuries because those injuries are usually not identified early and progress to a more severe stage (Baumgarten et al., 2004; Lyder, 2009; Zanca, 2006). Two of those studies also confirm predictive validity in pressure injury risk. One prospective study examined the predicative validity of the Braden scale for predicting pressure injury risk. In this study of 74 patients ages 60 years and older, 32% of patients developed stage 1 and 2 pressure injuries with Black elders having a higher incidence rate of pressure injuries (21%) than Latino elders (11%). The pilot study results provided evidence of 34% pressure injury incidence rates among Blacks and Hispanics in the acute care setting (Lyder et al., 1999). A study conducted by Li, Yin, Cai, Temkin-Greener, & Mukamel (2011) revealed a disparity in nursing home resident pressure injury rates. Black residents' pressure injury rates were 16.8% (95% confidence interval [CI], 16.6%-17.0%) compared to White residents' rates, which were 11.4% (95% confidence interval CI, 11.3%-11.5%). Interestingly, in another study, nursing home resident pressure injury rates among Black residents decreased to 14.6% (95% CI, 14.4%-14.8%). Nevertheless, Black residents persistently showed higher pressure injury prevalence rates in comparison to White resident pressure injury rates, which were 9.6% (95% CI, 9.5%-9.7%) $p > .05$ for trend of disparities (Li et al., 2011).

**Pressure Injury Disparity.** In a prospective cohort study conducted by Baumgarten (2004), Black residents of a nursing home facility were found to have a higher risk of pressure injuries compared to White residents (Baumgarten et al., 2004). The analysis was based on either Black or White residents, excluding those that were neither Black nor White such as Hispanics or Asians. Of the 1938 nursing home residents included in this study, 301 were Black and 1,637 were

White. Nursing home resident overall pressure injury incidence rates were 38% per year, with Black residents' pressure injury rates higher (56%) in comparison to White residents' pressure injury rates (35%), $p < .001$. However, in a London study exploring the relevance of ethnicity in pressure injuries, no differences were found in pressure injury rates for Pakistani ethnic minorities in comparison to White residents. In this study, pressure injuries PO, hospital acquired pressure injuries (HAPI), and no or "un" hospital acquired pressure injury (UHAPI) rates were analyzed. Chi square analysis was used to determine if nominal variables were independent of each other. Within the two groups of Whites and Pakistanis, results were significant for the two major groups for POA ($p < .001$), and HAPU ($p = .037$), but not significant for no or "un" HAPI ($p = .11$). A t-test for independent groups analysis was done to determine differences between all ethnic groups with Whites between 2.6 and 41.7 times more likely to develop pressure ulcer POA (95%CI) although for HAPU, a 95% CI could not be assumed. An alpha level of 0.05 was used for all inferential tests. Ethnicity was self-reported, and Whites were the most common group in this study at 97.3% and was a limitation for this study. Pakistani ethnicity accounted for 1.7% and the remaining 1.6% were of six or more other ethnicities or ethnicity information was not provided. Further limitations include small numbers of ethnic groups and use of a hospital information support system database that relied on accuracy of documentation (Anthony et al., 2002).

One other longitudinal nursing home study examined a quality improvement educational intervention with three components to a computer-based interactive video to determine if educating nursing home staff about pressure injury risk would reduce the differential risks of black and white residents. One hundred and fifty-four staff members from one nursing home were included in the organizational change to improve skin by utilizing an educational program about skin care. Nurses and ancillary staff that included dietary staff, environmental services staff and administrators were included in the quality improvement process program. The results of the sub-

analysis showed that Black residents were more likely to have more severe (stage 3-4) pressure injuries and less likely to have a stage I pressure injury identified. Differences between White and Black residents and between groups were evaluated utilizing a z-test for proportions. During the baseline period, the rate of stage 1 through stage 4 pressure injury was 47% for Black residents and 28% for White residents ($z = 1.65$, $P < .098$). For stages 2 through 4 pressure injury, the rate of total emergent was 18% for White residents and 42% for Black residents ($z = 2.65$, $P < 0.008$). No statistical differences were detected between the two groups at baseline. When comparing with the intervention period, stage 1 through 4 pressure injury rates decreased significantly for both groups of residents ($z=2.85$). There was a difference only noted in detecting 7 of 22 (31.8%) stage 1 pressure injuries in White residents but none were detected in Black residents. The results of this study identified a component of the education intervention effectively reduced pressure injury prevalence for all residents and eliminated the racial disparity noted prior to the intervention period (Rosen et al., 2006).

## 2.5 Spectroscopy, Ultrasound, and Subepidermal Moisture Measures to Detect Pressure Injury Spectroscopy

A variety of methods to detect pressure injury damage have been studied including spectroscopy, subepidermal moisture (SEM), and ultrasound.

**Spectroscopy.** In one pilot study, Zanca (2006) (Zanca, 2006) measured tissue reflectance spectroscopy (TRS) was used to detect blanch response at sites at risk for pressure injury development in individuals with various levels of skin pigmentation. Through the use of TRS, detection of the blanch response is measured by the change in total hemoglobin (tHb) that occurs with pressure applied to the skin and can be detected regardless of skin color. Heel and sacral assessments in both light and dark-skinned healthy individuals were also included. A significant decrease in tHb, ($p < .001$) measured in both dark and light skinned subjects with good inter-rater

reliability at the heel (0.80) although not at the sacral area (0.32-0.69). The researchers also identified a reliable method of skin color response to evaluate skin color using a procedure called Munsell color tile matching and colorimetry. In this study, Munsell tiles were used for visual color matching and color identification. Munsell color values have been found to be a reliable method of skin description with good inter-rater reliability for colorimetry between 2 examiners (93% agreement, kappa 0.87-1.00) for this study (Zanca, 2006). The researcher concluded that blanch response in dark and light skin could be detected using portable spectroscopy. This method is different from SEM in that spectroscopy technique relies on light reflected from oxygenated and non-oxygenated red blood cells. The skin color contributions to the reflected light are subtracted out of the signal so they can be effectively ignored. This technique is designed to not be sensitive to pigmentation of skin (Zanca, 2006).

Another study explored temperature differences that were measured to evaluate if clinical temperature levels could be used to determine stage 1 pressure induced tissue damage. In this study, 65 outpatients and inpatients in a rehabilitation setting that presented with pressure induced erythema and exhibited a range of skin pigmentation were evaluated. Fifty-one subjects with light skin pigmentation and 14 dark skin pigmentation were included in this study. African, Haitian, and Hispanic descent subjects were typically characterized as having dark skin if their skin did not visibly blanch under finger pressure. There were four Hispanics and one Asian that were included in the Caucasian group. Skin temperatures were calculated for each test pair and skin temperature was measured by utilizing DermaTherm strips that are thermometers mounted on nonlatex-based paper. A repeated measures design was used to determine whether clinical temperature could be used to indicate tissue damage at sites determined to be at risk for pressure injury. Findings reported that both decreased and increased temperature differences could be used to indicate a stage 1 pressure injury or reactive hyperemia and areas of discoloration and regardless, if able to

be visually detected. For all pairs, the sites over erythemic sites were warmer (0.82□F) than the adjacent site with equally distributed (around zero) data range (-5□F to +5□F). Erythemic sites were warmer than the control sites for (62%) of the subjects, (23%) were cooler than the control sites and (15%) were the same temperature as surrounding tissue. When compared utilizing a 2-tailed paired comparison, temperatures between the control and erythemic sites were significantly different ($p < .0015$). Temperature differences may be a useful indicator of a potential problem such as inflammation or ischemia with reactive hyperemia. However, regardless of temperature differences, skin integrity problems could still exist (Sprigle et al., 2001).

**Ultrasound.** An observational prospective study by (Quintavalle et al., 2006) used high-resolution ultrasound to detect incipient pressure injuries prior to visual clinical signs. In the study, common pressure injury sites universally accepted as being at risk for pressure injury development were measured. Heel, sacrum, and ischial tuberosity anatomical sites that did not have visual evidence of skin breakdown, were scanned on healthy volunteers and long-term care facility residents determined to be at risk for pressure injury. If the images were found to be abnormal, the compared images were classified by depth of abnormal findings, further classified and subdivided by anatomical locations that showed evidence of subdermal, subdermal and dermal, or subdermal, dermal and subepidermal edema. In images for residents found to be at risk for pressure injury, weak reflective patterns indicated edema or increased fluid content in the tissue and demonstrated three phases of pressure injury development. Pressure injuries that developed in conjunction with edema were found at the subcutaneous level alone, where edema extended from the subcutaneous tissue into the dermis, and at the location where edema was noted from the subcutaneous tissue through the dermis with pooling of edema to the dermal/epidermal junction. Pressure injury risk assessment and high-resolution ultrasound images correlate with images where fluid or edema

were present. Image comparisons of healthy volunteers showed homogeneous patterns of ultrasound reflections with visualization of underlying tissues visible. Visible images differed in 55.3% of long-term-care residents at risk for pressure injury indicating that various levels of tissue were not visible due to presence of fluid and edema.

Normal patterns consistent with normal skin were demonstrated in the remaining 44.7%. Image patterns revealed abnormal ultrasound patterns with areas of weak reflection fluid content or tissue edema. Limitation for this study include absent statistical analysis of findings. The findings concluded that high resolution is an effective tool for the investigation of soft tissue and skin changes consistent with the documented pathogenesis of pressure ulcers (Quintavalle et al., 2006).

Matas (2001) conducted a similar study using spectroscopy including 10 healthy light skinned individuals and 10 dark skinned individuals. Since the blanch response is difficult to detect in dark skin because of the high melanin concentration in dark skin, spectroscopy was used to monitor blood volume changes noted in blanch response. For this study, spectroscopy was used as a technique similar one used in pulse oximetry to monitor a blanch response based on changes in blood volume. Each participant was tested to determine blanch response by attaching a probe to deliver and monitor blanch response. Spectra analysis was acquired throughout the blanching cycle with the two groups visibly and near infrared. Despite pigmentation differences, total hemoglobin at low and high pressures demonstrated a significant difference in total hemoglobin at pressures high and low capturing blood volumes between both groups with different pigmentation. In both spectra regions, dark skinned individuals had a significantly greater amount of melanin ($p < .01$) then light skinned subjects. This work is limited by the lack of elderly individuals as there are skin differences between skin of young, healthy individuals and the elderly (Matas et al., 2001).

**Subepidermal Moisture (SEM).** In a pilot study, Bates-Jensen et al. (2009) found that the higher SEM value, the greater likelihood of an early stage 1 or stage 2 pressure injury developing the next week following the value measurement in nursing home residents with dark skin tones. SEM was compared to visual assessment. In this descriptive, cohort study that recruited 66 participants from 4 nursing homes who were part of a larger RCT studying nutrition in nursing home residents, mean age was 84 years. Of the 66 consented, 56 subjects completed the study. Greater likelihood of non-blanchable erythema or stage 1 pressure ulcer and/or stage 2 pressure ulcer were predicted with a higher SEM reading (Odds Ratio 1.88 for every 100 DPUs increase in SEM, $p = .004$). Dark skin tones were 8.5, 13, and 10 times likely to develop a stage 2 pressure injury with SEM values greater than 50, 150, and 300 DPU's, respectively. In comparison, light skin tones were 7.2, 3.5, and 4.3 times likely to develop stage 2 pressure injury at 50, 150, and 300 DPUs respectively. Stage 1 pressure injury/erythema was more likely to be detected in persons with dark skin with an SEM of 50 DPUs (OR = 5.3, 95% CI, 1.87-15.11, $p < .001$). This study explored a more diverse age population with varying degrees of acute and critical care needs and co-morbidities.

Previous studies exploring SEM provided a strong foundation for the current study. Other measures of skin such utilizing surface electrical capacitance have also been studied as a method to examine relationships in SEM, stage 1 pressure injury, erythema prevalence, and to quantify wound healing in patients experiencing burns. Capacitance measurements have been used to measure the hydration state of the skin inexpensively, conveniently and non-invasively. In one study, the clinical utility of SEM was used to evaluate skin hydration as an epidermal barrier function providing an objective assessment. Goretsky et al., (1995) utilized SEM to monitor 5 patients split- thickness autograft healing in comparison to cultured skin substitute healing. Results

showed that as sites showed healing with epidermal maturity, there was a decrease in SEM values correlating with clinical observations. Bedside SEM measurements were taken at 7, 10, 12, 14, 21 and 28 days after grafting with SEM decreasing with time for all grafts. Cultured skin capacitance results were similar with values approaching (32+ or – 5 picofarads). Surface electrical capacitance can be used to measure and evaluate skin surface hydration and provide a reliable, convenient and accurate quantitative moisture assessment (Goretsky et al., 1995).

In a study exploring pressure injuries in spinal cord injury SCI patients, periwound tissue moisture content and edema were measured also utilizing a dermal phase meter in 16 SCI patients with chronic stage 3 or 4 pressure injuries located over the sacrum or ischium. Four standard periwound sites were measured at 12, 3, 6, and 9 o'clock as well as a control area measuring superior to the sacral pressure injury and on the contralateral uninvolved ischium if an ischial pressure injury were involved. Findings showed a greater amount of tissue water content around the pressure injury periwound skin in comparison to lower tissue water content in the control group. A Friedman nonparametric test compared paired groups and findings demonstrated increased water to tissue around pressure injuries in comparison to control sites ($p = .046$). Skin with increased moisture and water may potentially macerate the skin making a person more vulnerable to increased risk for pressure injury damage (Harrow & Mayrovitz, 2014).

## 2.6 Gaps in Literature/Summary

Visual inspection of skin is the usual standard for detecting pressure injuries. Dark skin tones are more difficult to detect early signs of pressure injuries therefore interventions to prevent pressure injuries in people with dark skin tones may be delayed resulting in higher prevalence or higher, more severe stage of pressure injury. Most studies related to early detection of pressure injury damage utilizing SEM have been done in the nursing homes and with patients with SCIs

(Bates-Jensen et al., 2007; Bates-Jensen et al., 2009; Bates-Jensen et al., 2008; Bates-Jensen et al., 2010; Guihan et al., 2012). Few studies have been conducted in acute care settings, therefore, there is a need to further investigate and address the concurrent use of visual skin assessment and SEM to identify early pressure injury damage in the acute care setting.

The use of technology to measure early detection pressure injury risk is an emerging science and has shown an association between higher levels of SEM and subsequent observation of a pressure injury visually detected. A recent study conducted in an acute care hospital in Ireland explored the relationship between nurses' visual skin assessment and SEM. Nurses' documented assessments data and SEM readings were collected in a medical surgical care setting. Anatomical locations studied included the heels and sacrum with 21 of the 47 patients included in this study developing a stage 1 pressure injury. Patients demonstrated higher SEM delta readings before the pressure injury was visibly observed on average 4 days sooner (O'Brien et al., 2018).

A recent multisite, longitudinal study was blinded in that generalists gathered SEM data and specialists gathered pressure injury absence or presence. Heels and sacrum SEM data was collected starting from admission to six days minimally up to 21 days or if patient was discharged or developed a pressure injury. "Sensitivity was 87.5% (95% CI: 74.8%-95.3%) and specificity was 32.9% (95% CI: 28.3%-37.8%). SEM changes were observed 4.7 (± 2.4 days) earlier than diagnosis of a pressure injury via skin and tissue assessment alone" (Okonkwo et al., 2020).

Existing research investigating SEM measures and early identification of pressure injuries in the acute care and intensive care unit (ICU) setting remains limited. The use of SEM in nursing home patients and in SCI patients have been shown to help in the early detection and prevention of pressure injuries and some of these studies were longitudinal studies conducted in an environment less acute than hospital and critical care unit with patients of varying health conditions and contextual factors. One was a 16-week study in Los Angeles nursing homes that explored the

relationship between SEM and concurrent visual skin assessments. Anatomical sites assessed in the trunk area included sacrum and trochanters. The 417 participants were multiethnic (29% African American, 12% Asian American, 38% Caucasian, and 21% Hispanic). Higher SEM levels correlated with skin damage and incidence of skin damage was 52% utilizing a dermal phase meter to obtain SEM readings. Findings demonstrated a potential for subepidermal moisture measures as a method to detect tissue damage (Bates-Jensen et al., 2017).

In 2015, an independent study by the Royal College of Surgeons in Ireland's School of Nursing was presented at the European Pressure Ulcer Advisory Panel meeting describing the Bruin SEM scanner detecting pressure injury damage more quickly than the gold visual assessment standard. The study results revealed that pressure injury detection within 1.1 days with SEM scanner gave nurses 3.9 day lead-time versus pressure injury detection of 5 days with the gold visual standard (O'Brien, 2015). A more recent multisite, blinded longitudinal study explored and evaluated sensitivity and specificity of SEM compared to clinical tissue and skin assessment and SEM changes timing in relation to pressure injury discovery. Specificity may have been confounded due to time intervals between the SEM biomarker, standard of care intervention for at risk patients and pressure injury discovery (Okonkwo et al., 2020).

In the U.S. acute and critical care population, there have been no known studies to date that have investigated the use of SEM that included the intensive care unit population. The use of a sound method to detect early pressure injury damage in dark skin tones needs to be further explored in the acute and critical care population, particularly in patients with dark skin.

## 2.7 Pressure Injury Descriptions and Staging

Pressure injury staging was originally developed in 1975 by Shea to describe and define the level of soft tissue damage based on pathology (Black et al., 2007). At that time, Shea described 4 levels of injury that he classified numerically and described according to soft tissue damage and

levels of extent of injury. Levels of injury identified were described as Grades I-IV and closed injury that is similarly linked to what is now described as a deep tissue pressure injury. Several years later in 1988, The International Association of Enterostomal Therapists (IAET), now known as the Wound, Ostomy, and Continence Nurses (WOCN) Society developed a classification system describing levels of skin injury. This was based on Shea's classification system (Black et al., 2007; Pieper, 2012b).

The staging system presently used in most acute care hospitals is the National Pressure Ulcer Advisory Panel (NPUAP) definitions. In 1989, the NPUAP developed a staging system based on the similar system developed by the IAET and Shea (Pieper, 2012a).

Pressure injuries are described according to the amount or degree of tissue loss. The NPIAP definition of pressure injury is widely accepted and describes four stages of pressure injuries to define levels of tissue involvement. Pressure injury stage descriptions rely on visual inspection and assessment of tissue damage or tissue loss (Black et al., 2007; Edsberg et al., 2016).

### *2.7.1 Skin Anatomy/Pressure Injury Stages*

The skin is the largest organ of the body, generally 2 mm thickness. It is responsible for thermoregulation and made of two distinct layers. The epidermis is the outermost layer of the skin consisting of five layers also called strata including corneum, lucidum, granulosum, spinosum and basale. General functions of the strata include pigmentation, synthesis of vitamin D and cytokines, and acts as a protective barrier. Melanocytes are part of the epidermal structure and produce the pigment melanin that is responsible for skin color. The junction between the epidermis and dermis separates the two layers and is referred to as the basement membrane zone (BMZ). The dermal layer is composed of collagen, nerve endings, blood vessels, sweat glands, hair follicles, and lymph vessels. Layers of tissue under the dermis are composed of subcutaneous

tissue or fat.

- Stage 1 pressure injury: “Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury” (Edsberg et al., 2016).

- Stage 2 pressure injury: “Partial-thickness skin loss with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel” (Edsberg et al., 2016).

- Stage 3 pressure injury: “Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage or bone is not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury” (Edsberg et al., 2016).

- Stage 4 pressure injury: “Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury” (Edsberg et al., 2016).

Further description of stage 4

- The depth of a stage 4 pressure injury varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Stage 4 ulcers can extend into muscle and/or supporting structures (for example, fascia, tendon, or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable (Edsberg et al., 2016).

- Unstageable pressure injury: "Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on an ischemic limb or the heel(s) should not be softened or removed" as eschar on the heels serves as "the body's natural (biological) cover" (Edsberg et al., 2016).

- Deep tissue pressure injury: "Intact or non-intact skin with localized area of persistent non- blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood-filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface" (Edsberg et al., 2016).

# CHAPTER 3

# METHODOLOGY AND RESEARCH DESIGN

## 3.0 Introduction

This chapter presents an overview of the methods that were used to conduct this study including study design, setting, sample population, estimation of sample size and recruitment procedures. In addition, instruments that were used for data collection, protocol for data collection, and ethical considerations are described.

Lastly, the planned statistical analysis is addressed as well as planned procedures for statistical analysis. All data were categorized into variables and entered into the IBM Statistical Package for the Social Sciences (SPSS) version 26 (Green & Salkind, 2016).

Planned statistical analysis included the following. A 2 (VSA versus SEM) x 2 (light skin tones versus dark skin tones) factorial design with average number of days to pressure injury development as the outcome variable were utilized to answer the research questions. A factorial design was an appropriate design for this study because two or more independent variables were manipulated simultaneously and allowed an analysis of the main effects of the independent variables and interaction effects as shown in Table 1. As shown in Table 1, there are four independent variables including visual skin assessment, SEM, and patients with light and dark skin tones. Average number of days to detection is the outcome variable with any interaction occurring between skin tones and detection techniques.

**Table 1.**

*Design*

| | Light Skin Tones | Dark Skin Tones |
|---|---|---|
| VSA | Average number of days to detection | Average number of days to detection |
| SEM | Average number of days to detection | Average number of days to detection |

## 3.1 Setting

The setting for this study was a major university medical center in Western Pennsylvania and one of the leading nonprofit health systems in the U. S. The medical center campus entails two hospital buildings with a maximum patient census of 750. Occupancy beds include 156 ICU beds, 587 medical surgical beds, and 20 rehabilitation care unit beds. Patient type specialties included critical care medicine, trauma services, adult medical-surgical, cardiothoracic surgery, heart and lung transplantation, neurosurgery and abdominal organ transplantation. Pressure injuries are prevalent across all care settings. The acute care setting benchmark pressure injury prevalence rates in 2014 measured at 12.2% as evidenced by the Hill Rom International Pressure Ulcer Prevalence Survey conducted at this facility in February 2014. Pressure injury incidence were measured to capture new cases appearing in the patient population. During calendar year 2019, stage 1 pressure injuries and DTPI's accounted for 46% of hospital acquired pressure injuries with majority of the DTPI's and all stages of hospital acquired pressure injuries discovered in the ICU population.

## 3.2 Sample Population

Participants included all consenting adult patients age 18 and over admitted to medical, surgical or intensive care units in the hospital. Patients on acute care medical surgical and critical care units with the highest quarterly NDNQI pressure injury prevalence rate and/or the highest-pressure ulcer incidence rates were targeted. Participants included medical- surgical and critical

care patients both with dark and light pigmented skin tones. Patients with dark skin tones as well as those with light skin tones were recruited. Patients who present with scabies, acinetobacter bacterial infection or those admitted for 24-hour observation were excluded from the study. Only those patients at higher risk for developing a pressure injury indicated by a score of 16 or less on the Braden Scale were included in this study (Kring, 2007).

### 3.3 Sample Size Estimation

Power is defined as the ability to reject the null hypotheses when it is false (Huck, 2008). A study with adequate power has a reduced risk for a Type II error or acceptance of a false null hypothesis (Huck). According to Cohen (1988), power is dependent on three factors: the reliability of the results, effect size, and the degree of statistical significance. A power analysis was done to determine the required number of participants needed to answer the research questions and test the hypotheses.

Previous research results from a similar study (Bates-Jensen et al., 2008) with a similar design was examined to determine approximate effect size (ES) for this factorial design. A moderate ES of .25 seemed appropriate. To test the first two hypotheses using analyses of variance techniques, a total sample size (N) of 128 or 32/group using a two-tailed test of significance set at $p < .05$ and power of .80 with a moderate ES of .25 (G*Power 3.1.3) were required.

An additional power analysis using G*Power (3 G*Power 3.1.3) was done to determine the number of participants needed to test hypothesis 3 using polytomous logistic regression with outcome variable groups of pressure injury stages of 0, 1, 2 and greater and SEM dermal phase units (0 - 80) as the predictor variable. The sample size for this analysis was 128 to achieve significance at $p < .05$ using a two-tailed test of significance and a power of .80. Another study similar in nature (Bates-Jensen et al., 2007) used a sample size that approximated the power analyses planned for this study. At the hospital setting facility, pressure injury prevalence data is

collected quarterly and incidence data that were considered a hospital acquired pressure injury were collected as they occurred. In 2019, between January 1 and December 31, pressure injury incidence rates for this study facility including stages 1 through 4, deep tissue pressure injury and unstageable in both intensive care units and non-intensive care units. There was a potential need to recruit additional participants that meet inclusion criteria because it was not expected that every person in this study would develop a pressure injury. Oversampling by approximately 20% or more was anticipated but not needed as most participants recruited met the inclusion criteria.

### 3.4 Recruitment Activities

Once Institutional Review Board (IRB) approvals were obtained from the appropriate institutions, recruitment activities began. Acute and intensive care hospitalized adult patients over the age of 18 who were admitted to any medical-surgical or intensive care unit were recruited for this study. The principal investigator (PI) networked with participating site hospital units' nurse managers, admission team nurses, staff registered nurses, and case managers to assist with recruitment efforts. Additionally, the hospital admission team registered nurse routinely generated a list of new patient admissions to all medical surgical and intensive care units. Arrangements were made so that the PI was notified of potential participants that met inclusion criteria by email, office voicemail, or word of mouth when the PI was present on the prospective units. The admission team RN or the intensive care unit clinician/charge nurse helped to identify potential participants for this study, Once identified, potential participants were approached by the PI to ascertain their willingness to participate in this study. The purpose of the study and expectations for participation were addressed. Time was allowed for any questions and answers. Potential participants were informed that they had the right to say no about participating in this research study and may stop participating or withdraw from the study at any time without penalty or change in standards of care. After all questions were answered, potential participants were asked to

voluntarily sign the consent form if they wished to participate.

## 3.5 Instruments for Data Collection

Several instruments were employed in this study to measure visual skin assessment, SEM, pressure injury risk, pressure injury staging, wound assessment, visual skin assessment and skin tones. These instruments included the Delphin Moisture Meter D dermal phase meter, the Braden Pressure Ulcer Risk Assessment Tool, NPIAP pressure ulcer staging definitions, the Bates Wound Assessment Tool (BWAT) and Munsell Color Matching Tiles. In addition, a demographic form was used to collect the participants' characteristics information. Specific laboratory values were collected from the electronic medical record for participants who agreed to participate. Data were entered into RedCap (Harris et al., 2009), then cleaned and checked for any inconsistencies. Once data entry was completed, this database was exported to Statistical Package for the Social Sciences (SPSS) Version 26 for statistical analysis (Green & Salkind, 2016).

### *3.5.1 Visual Skin Assessment (VSA)*

Although there is no diagnostic tool to aid in the determination of the numeric pressure ulcer classification, defining the level or depth of soft tissue damage for staging was determined by observed and subjective visual skin assessment. Standard visual skin assessment includes assessment of skin to the entire body and the usual practice includes five elements: skin turgor, moisture, color, temperature and integrity (Baranoski & Ayello, 2004). In this study, visual skin assessment was done by the registered nurse and documented in the patient's personal health record. The nurse assessed skin by direct independent visual skin assessments each day at the beginning of their morning work shift inclusive of five anatomical locations: sacrum, right and left buttocks (two), and heels (two). The method for visual skin assessment included the use of one's eyes to visualize skin and conduct a subjective visual skin assessment and is the standard method to observe non-blanchable erythema. There is no institutional tool available or in use to visually

assess skin. Once discovered, pressure injuries were staged using the NPIAP's stage definitions and evaluated using the Bates-Jensen Wound Assessment Tool (Black et al., 2007). Visual skin assessment was reported on the visual skin assessment form (Appendix A).

### *3.5.2 The Delphin Moisture Meter D Dermal Phase Meter (DPM)*

The Delphin Moisture Meter D dermal phase meter (DPM), serial number D3N0129 (Delfin Technologies, Finland), was used to obtain skin surface impedance measurements and determine water amounts of the skin measured as SEM. The DPM consists of a control unit, cable and measurement probe and measures the dielectric constant in relation to thickness of the stratum corneum. There are four corresponding wands each with varying probe diameters. The corresponding effective measurement depths are 0.5 mm, 1.5 mm, 2.5 mm and 5 mm with corresponding maximum probe diameters of 10, 20, 23, and 55 mm. The 20 mm and 23 mm corresponding probes diameter with 1.5 and 2.5 mm inner-outer conductor spacing were utilized for this study. The control unit "generates an ultra-high frequency electromagnetic (EM) wave of 300 MHz which is transmitted into a coaxial probe placed on the skin (outer diameter 20 or 23 mm). The measurement is thus a localized and noninvasive measure where the diameter of the probe defines the measurement area while the measurement depth is adjusted by changing the dimensions of the probe. If a wide separation of the electrodes is applied, the electric field extends deeper in tissue" (Nuutinen et al., 2004). DPM readings are immediately generated after eight seconds of light touch on the skin. Strong reliability has been described in relation to the instrument. A previous study showed a low (2.8%) coefficient of variation. Wand placement was an issue of variability because of the difficulty in identifying precise placement of the wand on the different anatomical locations consistently. The hand-held device used for this study was on loan from Dr. Barbara Bates-Jensen at the UCLA School of Nursing. Dr. Bates-Jensen has conducted several studies related to pressure injury prevention and care. Her previous work relevant to SEM

and utilization of the DPM included pilot testing of SEM in spinal cord injury patients and in a study testing preliminary threshold values to detect stage 1 pressure ulcer in nursing home residents (Bates-Jensen et al., 2007). SEM values were recorded on the SEM and Visual Skin Assessment Form and included data collected for each anatomical site (Appendix A). This form was developed by Dr. Barbara Bates-Jensen and was modified for this study. Permission to use was obtained.

### *3.5.3 The Braden Pressure Ulcer Risk Assessment Tool*

The Braden Pressure Ulcer Risk Assessment Tool (Appendix B) was used to assess the risk of developing a pressure injury. This tool, developed by Dr. Barbara Braden, is a summated rating scale and is composed of six subscales: sensory perception, moisture, activity, mobility, nutritional status, and friction/shear. The tool has been validated with inter-rater validity ranging from .83 to .99. The scale has been tested, validated, and shown to be equally reliable on black and white skin nor does this imply that visual skin assessment is reliable in darkly pigmented skin. This does not imply that visual skin assessment is reliable in darkly pigmented skin as this pertains to pressure injury risk only (Lyder et al., 1999). Operational definitions are provided for each subscale, and each subscale is rated from 1 (least favorable) to 3 or 4 (most favorable). A total score can range from 6 to 23. A score of equal to or less than 18 indicates risk for pressure injury development. A low numerical Braden score of 12 and below, indicates high risk for developing a pressure injury. Scores ranging from 13 to 14 indicate moderate risk, whereas scores ranging from 15 to18 indicate at risk for developing pressure injury. Scores ranging from 19 to 23 indicate low risk for developing a pressure injury. In older patients, cutoff scores of 17 or 18 have been shown to be predictors of subsequent pressure injury development (Bergstrom et al., 1998). The Braden Scale form (Appendix B), developed by Barbara Braden was used to record pressure injury risk assessment data (Braden, 2014). Permission to use this form was obtained for this study and

associated scholarly publications.

### *3.5.4 Pressure Injury Staging*

Pressure injury staging is another measure defined by the NPIAP and was utilized to identify pressure injury stages of all pressure related wounds. Pressure injury staging definitions were used during skin inspection and assessment to identify pressure injury (if present) and their stage. Staging definitions were refined by the NPIAP taskforce with input from an on-line evaluation of their face validity, accuracy clarity, succinctness, utility, and discrimination (Black et al., 2007). Pressure injury staging definitions have since been reviewed by a consensus conference. Pressure injury stages include stages 1through 4, with the additional definitions of unstageable, deep tissue pressure injury and mucosal pressure injury. The revised NPIAP pressure injury staging definitions were used to reference pressure injury definitions (Edsberg et al., 2016).

### *3.5.5 The Bates-Jensen Wound Assessment Tool*

The Bates-Jensen Wound Assessment Tool (Appendix C) was utilized to document wound characteristics with each visit by the PI. The BWAT is a wound assessment tool that is used in many care settings to objectively document wound characteristics and to help standardize wound assessment and documentation (Bates-Jensen et al., 2019). The Bates-Jensen Wound Assessment Tool, developed by Barbara Bates-Jensen, is intended to assess and monitor a wound's healing status as they relate to the definitions and methods of assessment described in the tool specific instructions. There are 13 scored description items thatinclude wound size, depth, appearance of wound edges, description of undermining if present, necrotic tissue type and amount if present, exudate type and amount, periwound skin color, peripheral skin tissue edema and induration, presence of granulation tissue, and epithelialization. The tool was used to assess and document wound descriptions if present during visual skin inspection. For this study and to ensure validity, the PI, who is a certified wound nurse and expert, conducted a skin assessment for pressure injury

and if present, pressure injury was assessed and documented in the BWAT. The anatomical site of the wound and the overall wound pattern/shape description was indicated but not scored. A total score of the numerical value ranging from 1 to 5 with 1 being the optimal attribute corresponds to the presence and amount of the descriptor scored. The 13 subscores were added to obtain a total score. For documentation and if present, the pressure injury wound was assessed for size dimensions written in centimeters, wound characteristics including type of tissue, type and amount of exudate if present. Revised in 2001, the BWAT was formerly known as the Pressure Sore Score Tool (PSST) was found to be a reliable and valid (Bates-Jensen et al., 2019; Harris et al., 2010; McCreath et al., 2016). The BWAT form was used to reference data related to pressure injury characteristics.

### *3.5.6 Munsell Color Tiles*

Different shades of dark of skin tones were assessed utilizing Munsell color tiles. Munsell Color Tile Color Notation System is a commercially available tool that was used to objectively and accurately define skin color when assessing skin tone in human subjects. This color code system has been used in previous studies to describe and classify skin color in human subjects (Bates-Jensen et al., 2010; Zanca, 2006). Color samples are based on hue quantifying the ruddiness of the complexion, value (2.5 to 8) to describe darkness or lightness of color and chroma (1 to 8). Colors are assigned alphanumeric designations to describe color quality, darkness or lightness of color, and saturation of color or vividness. The Munsell 5YR color chart was used with lower values (2.5 to 5.9) indicating darker skin and higher Munsell values (6 to 8) indicating light skin. The Munsell Skin Tone Assessment form was used to record these data (McCreath et al., 2016). (Appendix D).

### *3.5.7 Demographic Form*

A researcher generated demographic form (Appendix E) was used to describe the

population understudy. Permission was sought to access the medical record. Demographic and health characteristics were retrieved from each participants' electronic health record. Age, gender, race, and ethnicity were collected. In addition, specific health characteristics including obesity diagnosis and/or body mass index, diabetes, and presence of fecal and/or urinary incontinence were collected from the participant's medical record. The participant demographics were used to describe the population under study.

### *3.5.8 Laboratory Value Form*

A researcher-generated Laboratory Value was part of the demographic form (Appendix E) and was used to enter data on specific laboratory values as indicated in the patient's medical record. Laboratory values were collected one time in conjunction with demographic data collection or one time during the days of data collection if laboratory values were not initially available. Laboratory values included serum albumin and pre-albumin only if ordered by the provider and if available on the medical record. These data were only used to describe the sample. In addition, it may be that laboratory data are potential confounding variables in which case they were statistically controlled during analysis.

### *3.5.9 Screening Tool*

A researcher-generated Screening Tool (Appendix F) was used to document potential participants for the study. The screening tool was used to keep a log of subject name, date screened, yes/no selection box if subject meets eligibility criteria, reason for exclusion, consent date for eligible participants and subject study number.

## *3.6 Data Collection Procedures*

Once approvals from IRBs were obtained, recruitment activities began. Patients were screened for participation in this study. To obtain sufficient numbers to evaluate SEM on persons

with dark skin tones, attempt was made to oversample minority subjects although the number of minorities were not available as expected. Once the potential participant qualified to participate in the study, informed consent was obtained. Participant related study activity and data were collected by a wound, ostomy, continence (WOC) nurse who was also the PI for this research study. Prior to obtaining consent, the researcher explained the study procedure to the patient and answered all questions. Once written consent was obtained, data collection began, and patient demographic data and laboratory values were collected.

Permission to access the medical record was obtained through informed consent. Data collection was conducted in the privacy of the participant's assigned hospital unit room. Next, Munsell color tiles 5YR were used to determine skin tone and were categorized into light or dark skin tones. The participants forearm midway between the antecubital fossa area and the wrist was the point of location to assess skin and classify tone. Skin tones were categorized for analyses with light skin Munsell values (6-8); dark skin Munsell values (2.5 to 5.9).

Prior to visual skin assessment and SEM measurement, the participant was asked and assisted if needed to roll on his or her left side. The participant was then positioned on their side for two minutes for removal of linen or disposable under pads, non-surgical wound bandages, briefs, or undergarments, and in order to allow for reactive hyperemia to resolve. If skin was soiled from incontinence, sweat, or wound drainage, the skin was cleaned prior to visual assessment and SEM measurement. Presence of urinary and/or fecal incontinence were noted and recorded. A staff nurse first conducted a visual skin assessment during the first skin assessment of the morning and recorded the results. The researcher was blinded to the results of the visual skin assessment. The researcher independently conducted SEM measures. SEM measures were obtained and recorded for each site with wand (size S and M) and followed the same order of anatomical locations as was used for the visual skin assessment; the sacrum, buttocks and heels. SEM measure at the 12-o-

clock position above the sacrum were included at the wound edge if open wounds were present. Open wounds did not negate participation in this study as these participants potentially could have developed pressure injuries during this study.

A disinfectable single patient use plastic flexible template with anatomic placement identified to guide placement of the template on the participant's body was used to determine a more exact wand placement. The MoistureMeter D dermal phase meter small and medium wand size is capable of measuring depth to 2.5mm and were used to measure SEM. Both the small and medium wand were used one right after the other starting with the small wand to obtain two DPU readings at each anatomical site. Each reading is generated almost immediately after light skin touch for eight seconds. SEM measures were obtained with the DPM placed directly above each anatomical site with a cut-out opening to guide specific wand placement. There was no risk associated as the DPM wand rests on the skin since the wand requires only light touch for eight seconds. Once visual skin assessment and SEM measurements were completed, dressings, under pads, and briefs were replaced as needed. The wands were then cleaned between participants with a bleach antimicrobial wipe.

Data on presence or absence of pressure injury and stage of pressure injury if present were recorded. If a pressure injury was discovered, the NPIAP pressure injury staging definitions were used to stage pressure injuries and a wound care nurse consult was initiated (Edsberg et al., 2016). Each patient admitted to the hospital had a nurse assessment completed that included skin assessment. If a pressure injury was discovered, a wound care nurse consult was triggered through the initial pressure injury rule once documented by the nurse discovering the pressure injury.

Visual assessment data and SEM measures were collected then recorded. There was one data form completed per participant. Data were securely stored in the pressure injury study folder using the date and subject identification (ID) number as the file name in a locked file cabinet in the

PI's home office. Data was collected for each participant once daily for up to 6 days if participant continued to be hospitalized. The goal was to collect data points daily although was not always feasible because participants were often off the unit for a procedure, off the unit for a long surgery, were unable to be turned due to hemodynamic instability or declined for the day yet did not request to withdraw from the study.

Evidence from clinical studies about pressure injury development time is limited with one retrospective study suggesting that external pressures on or under a bony prominence may exceed diastolic pressures and may compromise tissues in patients undergoing surgical procedure. Time for pressure injury development may range, depending on length of time confined to a bed, anatomical differences and general health status (Nixon et al., 2000). Newly developed pressure injuries or worsening of existing pressure injuries found during the course of the study, were reported to the WOC Nurse for immediate referral and consultation. All data collected was documented in the appropriate data forms.

### 3.7 Planned Statistical Analysis

Descriptive statistic was performed on all demographic and major variables under study. In addition, descriptive statistics were used to describe the population under study in regard to health information collected. To describe the sample population, mean and standard deviations were calculated for each demographic and health characteristic. Descriptive statistics were employed to describe the overall sample as well as to describe groups, specifically, those with versus without a pressure injury and for dark and light skin. Histograms and graphs were generated to visualize data collected. A correlation matrix was generated to ascertain any demographic variables that may co-vary with variables that were collected in this study. If two variables co-vary, a measure of covariance was computed in which case, these variables were controlled statistically in the analysis data.

To test the first two hypotheses, a two-way analysis of variance (ANOVA) was planned to simultaneously analyze the effects of the independent variables on the dependent variable and ascertain interaction. The independent variables for this study were visual skin assessment and SEM measures (0 = VSA, 1 = SEM) and light/dark skin tones (0 = light, 1 = dark), along with dummy coding for the interaction in the ANOVA. In addition, polytomous logistic regression analysis was also planned to test the third hypothesis with SEM measures (0 to 80) as the predictor variable and pressure injury stages (o = no damage, 1 = erythema/stage 1, pressure injury, 2 = stage 2 pressure injury and/or deep tissue pressure injury as outcomes measures. The predictor variable, SEM, was based upon the existing evidence (Bates-Jensen et al., 2009). Polytomous logistic regression is a useful technique to simultaneously model predicted probabilities of multiple outcomes categories. It is for the most part assumption free and was used to predict categorical dependent variables and estimate relative risk. This approach estimates the probability that an event will occur.

The analysis as planned was not conducted due to several issues including but not limited to the few dark-skinned participants compared to the number of light skinned participants that participated in the study, the number of dark-skinned participants that developed a pressure injury and the total number of participants, both dark and light skinned, that developed pressure injuries. The analysis that was conducted is described in chapter 4.

## 3.8 Ethical Considerations

Human subjects involved in the research study were protected during data collection. People of dark skin tones likely include ethnic minorities including but not limited to Africans, African Americans, Latinos, Afro Caribbean, and other people with a dark or light skin tone. The involvement of human subjects in this research study was justified and the subjects were adequately protected for any risk related to skin assessment and SEM measurement. Women,

minority groups and their subpopulations were included in this research study as well as males to allow for analyses of gender and/or ethnic differences and identifying disparities in pressure injury prevention and early detection of pressure injury. The inclusion of both genders and minorities was planned in order to have a positive impact on reaching the scientific goals of this research. Adult participants age 18 and over were involved in daily visits for up to six days to conduct visual skin assessments and SEM measurement on six anatomical locations.

All participants voluntarily consented to participate in this study (Appendix G). To ensure that all documents related to human subjects were kept safe, private and secure, the project's IRB approved protocol was observed and practiced. Signed consent forms, data, and all documentation related to human subjects were stored in accordance with the IRB approved protocol and HIPAA compliance. Signed consent forms were stored separately from data. De-identified data stored on a computer with subject information were stored in a password protected and encrypted hard drive. Only members of the research team had access to the database. Data and all paper documents were stored in a locked cabinet in the researcher's locked home office. All data will be destroyed after 6 years of completing the study. Stored data will be destroyed, all hard copies will be shredded, and files will be deleted from electronic storage devices. Data confidentiality was maintained throughout the study by assigning the participants a unique ID number that was used on all paper and electronic documents.

## Appendix A

Visual Skin and SEM Form

**Assessment Week:** 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

**Date:** ____/____/____

**Day:** Mon Tues Wed Thurs Fri

**Existing PU location(s):**

**Existing PU size:**

**Photo Orientation direction:**

| | | | **0:** None<br>**1:** Blanchable<br>**2**: Non-blanchable<br>**3**: Dark skin tone, unable to determine | **0**: None<br>**1**: Slight, pink<br>**2**: Minimal, red<br>**3**: Moderate, bright red, distinct<br>**4**: Severe, dark red, purple, bruise | | **0**: None<br>**1**: Stage 1 (erythema, intact skin)<br>**2**: Stage 2 (partial thickness, blister)<br>**3**: Stage 3 (full thickness, no bone)<br>**4**: Stage 4 (full thickness, bone)<br>**5**: Unstageable (Mostly necrotic tiss.)<br>**6**: Deep tissue injury | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Location** | **Scar tissue? √** | **Erythema Present? √** | **Erythema Type** | **Erythema Severity** | **Photos taken? √** | **PU Stage** | **PU Size** Length X Width | **SEM Small Color:_____** | **SEM Medium Color:_____** |
| **Sacr/Coccyx** | | | | | | | | | |
| **R Buttock** | | | | | | | | | |
| **L Buttock** | | | | | | | | | |
| **R ischial** | | | | | | | | | |
| **L ischial** | | | | | | | | | |
| **R Heel** | | | | | | | | | |
| **L Heel** | | | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **R Forearm** | | | | | | | | | |
| **R trochanter (Wk 1, 8, 16)** | | | | | | | | | |
| **L trochanter (Wk 1, 8, 16)** | | | | | | | | | |
| **F ill in the Visual cells if the same person is also performing Visual Reliability this week.** | | | | | | | | | |

**Skin condition (Check all that apply:**

| **Trunk** | **Heel** | |
|---|---|---|
| ☐ | ☐ | Normal |
| ☐ | ☐ | Urinary incontinence |
| ☐ | ☐ | Fecal incontinence |
| ☐ | ☐ | Sweat |
| ☐ | ☐ | Ointment, powder |
| ☐ | ☐ | Dry skin |
| ☐ | ☐ | Edema |
| ☐ | ☐ | Hairy |
| ☐ | ☐ | Other (specify: _____) |

**Obese?**

0 ☐ No

1 ☐ Yes

***Enter 0s for all***

**Support surfaces**

0 ☐ No

1 ☐ Yes

☐ pillows ☐ heel protectors ☐ low air loss mattress ☐ wedge/folded blankets ☐ other

(specify other: _____)

**Patient infection? (indicate type)**

0 ☐ No

1 ☐ Yes (specify: _____)

**Comments:**

# Appendix B
## BRADEN PRESSURE ULCER RISK ASSESSMENT SCALE

| Patient's Name_____Evaluator's Name_____ | | | | Date of Assessment |
|---|---|---|---|---|
| **SENSORY PERCEPTION** ability to respond meaning-fully to pressure-related discomfort | **1. Completely Limited** Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of con-sciousness or sedation. OR limited ability to feel pain over most of body | **2. Very Limited** Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over 2 of body. | **3. Slightly Limited** Responds to verbal commands, but cannot always communicate discomfort or the need to be turned. OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities. | **4. No Impairment** Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.. |
| **MOISTURE** degree to which skin is exposed to moisture | **1. Constantly Moist** Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned. | **2. Very Moist** Skin is often, but not always moist. Linen must be changed at least once a shift. | **3. Occasionally Moist:** Skin is occasionally moist, requiring an extra linen change approximately once a day. | **4. Rarely Moist** Skin is usually dry, linen only requires changing at routine intervals. |
| **ACTIVITY** degree of physical activity | **1. Bedfast** Confined to bed. | **2. Chairfast** Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair. | **3. Walks Occasionally** Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair | **4. Walks Frequently** Walks outside room at least twice a day and inside room at least once every two hours during waking hours |
| **MOBILITY** ability to change and control body position | **1. Completely Immobile** Does not make even slight changes in body or extremity position without assistance | **2. Very Limited** Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently. | **3. Slightly Limited** Makes frequent though slight changes in body or extremity position independently. | **4. No Limitation** Makes major and frequent changes in position without assistance. |
| **NUTRITION** usual food intake pattern | **1. Very Poor** Never eats a complete meal. Rarely eats more than a of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IV=s for more than 5 days. | **2. Probably Inadequate** Rarely eats a complete meal and generally eats only about 2 of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement. OR receives less than optimum amount of liquid diet or tube feeding | **3. Adequate** Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products per day. Occasionally will refuse a meal, but will usually take a supplement when offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs | **4. Excellent** Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation. |
| **FRICTION & SHEAR** | **1. Problem** Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction | **2. Potential Problem** Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down. | **3. No Apparent Problem** Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair. | |
|  | | | | Total Score |

# Appendix C

BATES-JENSEN WOUND ASSESSMENT TOOL

## Instructions for use

General Guidelines:
Fill out the attached rating sheet to assess a wound's status after reading the definitions and methods of assessment described below. Evaluate once a week and whenever a change occurs in the wound. Rate according to each item by picking the response that best describes the wound and entering that score in the item score column for the appropriate date. When you have rated the wound on all items, determine the total score by adding together the 13-item scores. The HIGHER the total score, the more severe the wound status. Plot total score on the Wound Status Continuum to determine progress.

Specific Instructions:

1. **Size**: Use ruler to measure the longest and widest aspect of the wound surface incentimeters; multiply length x width.

2. **Depth**: Pick the depth, thickness, most appropriate to the wound using these additional descriptions:

| | |
|---|---|
| 1 = | tissues damaged but no break in skin surface. |
| 2 = | superficial, abrasion, blister or shallow crater. Even with, &/or elevated above skin surface (e.g., hyperplasia). |
| 3 = | deep crater with or without undermining of adjacent tissue. |
| 4 = | visualization of tissue layers not possible due to necrosis. |
| 5 = | supporting structures include tendon, joint capsule. |

3. **Edges**: Use this guide:

| | | |
|---|---|---|
| Indistinct, diffuse | = | unable to clearly distinguish wound outline. |
| Attached | = | even or flush with wound base, no sides or walls present; flat. |
| Not attached | = | sides or walls are present; floor or base of wound is deeper than edge. |
| Rolled under, thickened | = | soft to firm and flexible to touch. |
| Hyperkeratosis | = | callous-like tissue formation around wound & at edges. |
| Fibrotic, scarred | = | hard, rigid to touch. |

4. **Undermining**: Assess by inserting a cotton tipped applicator under the wound edge; advance it as far as it will go without using undue force; raise the tip of the applicator so it maybe seen or felt on the surface of the skin; mark the surface with a pen; measure the distance from the mark on the skin to the edge of the wound. Continue process around the wound. Then use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved.

5. **Necrotic Tissue Type**: Pick the type of necrotic tissue that is predominant in the wound according to color, consistency and adherence using this guide:

| | | |
|---|---|---|
| White/gray non-viable tissue | = | may appear prior to wound opening; skin surface is white or gray. |
| Non-adherent, yellow slough | = | thin, mucinous substance; scattered throughout wound bed; easily separated from wound tissue. |
| Loosely adherent, yellow slough | = | thick, stringy, clumps of debris; attached to wound tissue. |
| Adherent, soft, black eschar | = | soggy tissue; strongly attached to tissue in center or base of wound. |

| | | |
|---|---|---|
| Firmly adherent, hard/black eschar | = | firm, crusty tissue; strongly attached to wound base and edges (like a hard scab). |

6. **Necrotic Tissue Amount**: Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved.

7. **Exudate Type**: Some dressings interact with wound drainage to produce a gel or trap liquid. Before assessing exudate type, gently cleanse wound with normal saline or water. Pick the exudate type that is predominant in the wound according to color and consistency, using this guide:

| | | |
|---|---|---|
| Bloody | = | thin, bright red |
| Serosanguineous | = | thin, watery pale red to pink |
| Serous | = | thin, watery, clear |
| Purulent | = | thin or thick, opaque tan to yellow |
| Foul purulent | = | thick, opaque yellow to green with offensive odor |

8. **Exudate Amount**: Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to determine percent of dressing involved with exudate. Use this guide:

| | | |
|---|---|---|
| None | = | wound tissues dry. |
| Scant | = | wound tissues moist; no measurable exudate. |
| Small | = | wound tissues wet; moisture evenly distributed in wound; drainage involves ≤ 25% dressing. |
| Moderate | = | wound tissues saturated; drainage may or may not be evenly distributed in wound; drainage involves > 25% to < 75% dressing. |
| Large | = | wound tissues bathed in fluid; drainage freely expressed; may or may not be evenly distributed in wound; drainage involves > 75% of dressing. |

9. **Skin Color Surrounding Wound**: Assess tissues within 4cm of wound edge. Dark-skinned persons show the colors "bright red" and "dark red" as a deepening of normal ethnic skin color or a purple hue. As healing occurs in dark-skinned persons, the new skin is pink and may never darken.

10. **Peripheral Tissue Edema & Induration**: Assess tissues within 4cm of wound edge. Non- pitting edema appears as skin that is shiny and taut. Identify pitting edema by firmly pressing a finger down into the tissues and waiting for 5 seconds, on release of pressure, tissues fail to resume previous position and an indentation appears. Induration is abnormal firmness of tissues with margins. Assess by gently pinching the tissues. Induration results in an inability to pinch the tissues. Use a transparent metric measuring guide to determine how far edema or induration extends beyond wound.

11. **Granulation Tissue**: Granulation tissue is the growth of small blood vessels and connective tissue to fill in full thickness wounds. Tissue is healthy when bright, beefy red, shiny and granular with a velvety appearance. Poor vascular supply appears as pale pink or blanched to dull, dusky red color.

12. **Epithelialization**: Epithelialization is the process of epidermal resurfacing and appears as pink or red skin. In partial thickness wounds it can occur throughout the wound bed as well as from the wound edges. In full thickness wounds it occurs from the edges only. Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved and to measure the distance the epithelial tissue extends into the wound.

**BATES-JENSEN WOUND ASSESSMENT TOOL** (BWAT)

Complete the rating sheet to assess wound status. Evaluate each item by picking the response that best describes the wound and entering the score in the item score column for the appropriate date.

**Location**: Anatomic site. Circle, identify right **(R)** or left **(L)** and use **"X"** to mark site on body diagrams:

_____ Sacrum & coccyx _____ Lateral ankle
_____ Trochanter _____ Medial ankle
_____ Ischial tuberosity _____ Heel Other Site

**Shape:** Overall wound pattern; assess by observing perimeter and depth.

Circle and date appropriate description:

____ Irregular _____ Linear or elongated
_____ Round/oval _____ Bowl/boat
_____ Square/rectangle _____ Butterfly Other Shape

| Item | Assessment | Date Score | Date Score | Date Score |
|---|---|---|---|---|
| **1. Size** | 1 = Length x width <4 sq cm<br>2 = Length x width 4--<16 sq cm<br>3 = Length x width 16.1--<36 sq cm<br>4 = Length x width 36.1--<80 sq cm<br>5 = Length x width >80 sq cm | | | |
| **2. Depth** | 1 = Non-blanchable erythema on intact skin<br>2 = Partial thickness skin loss involving epidermis &/or dermis<br>3 = Full thickness skin loss involving damage or necrosis of subcutaneous tissue; may extend down to but not through underlying fascia; &/or mixed partial & full thickness &/or tissue layers obscured by granulation tissue<br>4 = Obscured by necrosis<br>5 = Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures | | | |
| **3. Edges** | 1 = Indistinct, diffuse, none clearly visible<br>2 = Distinct, outline clearly visible, attached, even with wound base<br>3 = Well-defined, not attached to wound base<br>4 = Well-defined, not attached to base, rolled under, thickened<br>5 = Well-defined, fibrotic, scarred or hyperkeratotic | | | |
| **4. Undermining** | 1 = None present<br>2 =Undermining < 2 cm in any area<br>3 = Undermining 2-4 cm involving < 50% wound margins<br>4 = Undermining 2-4 cm involving > 50% wound margins<br>5 = Undermining > 4 cm or Tunneling in any area | | | |
| **5. Necrotic Tissue Type** | 1 = None visible<br>2 = White/grey non-viable tissue &/or non-adherent yellow slough<br>3 = Loosely adherent yellow slough<br>4 = Adherent, soft, black eschar | | | |

| | |
|---|---|
| | 5 = Firmly adherent, hard, black eschar |
| **6. Necrotic Tissue Amount** | 1 = None visible 2 = < 25% of wound bed covered 3 = 25% to 50% of wound covered 4 = > 50% and < 75% of wound covered 5 = 75% to 100% of wound covered |
| **7. Exudate Type** | 1 = None<br>2 = Bloody<br>3 = Serosanguineous: thin, watery, pale red/pink<br>4 = Serous: thin, watery, clear<br>5 = Purulent: thin or thick, opaque, tan/yellow, with or without odor |
| **8. Exudate Amount** | 1 = None, dry wound<br>2 = Scant, wound moist but no observable exudate<br>3 = Small<br>4 = Moderate<br>5 = Large |
| **9. Skin Color Surrounding Wound** | 1 = Pink or normal for ethnic group<br>2 = Bright red &/or blanches to touch<br>3 = White or grey pallor or hypopigmented<br>4 = Dark red or purple &/or non-blanchable<br>5 = Black or hyperpigmented |
| **10. Peripheral Tissue Edema** | 1 = No swelling or edema<br>2 = Non-pitting edema extends <4 cm around wound<br>3 = Non-pitting edema extends >4 cm around wound<br>4 = Pitting edema extends < 4 cm around wound<br>5 = Crepitus and/or pitting edema extends >4 cm around wound |
| **11. Peripheral Tissue Induration** | 1 = None present<br>2 = Induration, < 2 cm around wound<br>3 = Induration 2-4 cm extending < 50% around wound<br>4 = Induration 2-4 cm extending > 50% around wound<br>5 = Induration > 4 cm in any area around wound |
| **12. Granulation Tissue** | 1 = Skin intact or partial thickness wound<br>2 = Bright, beefy red; 75% to 100% of wound filled &/or tissue overgrowth<br>3 = Bright, beefy red; < 75% & > 25% of wound filled<br>4 = Pink, &/or dull, dusky red &/or fills < 25% of wound<br>5 = No granulation tissue present |
| **13. Epithelization** | 1 = 100% wound covered, surface intact<br>2 = 75% to <100% wound covered &/or epithelial tissue extends >0.5cm into wound bed<br>3 = 50% to <75% wound covered &/or epithelial tissue extends to <0.5cm into wound bed<br>4 = 25% to < 50% wound covered 5 = < 25% wound covered |
| | TOTAL SCORE |
| | SIGNATURE |

## Appendix D

Munsell Skin Tone Assessment Form

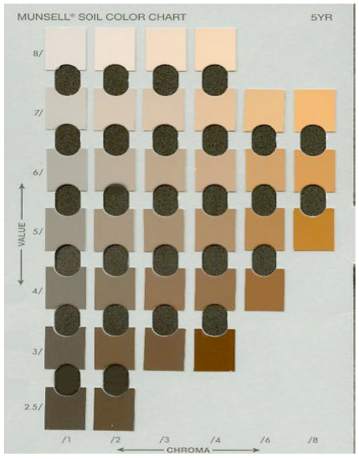
Participant ID: _____

Assessment Day: _____

Date: _____ / _____ / _____

| Munsell Site | Color Tile match |
|---|---|
| Right Forearm | |
| Left Forearm (if Right not available) | |

Skin Tone Assessment with Munsell color tiles 5YR



COMMENTS: _____

## Appendix E

Demographic and Laboratory Collection Form

### Subject Baseline Data

**Date** __ /__ / __

1. Hospital Admission Date __ __ / __ __ / __ __ __ __ Time : __ __ : __
2. Date of Birth: __ __ / __ __ / __ __ __ __ Age_____
3. Sex: ☐ Male ☐ Female

4. Race (check all that apply):
   - ☐ White or Caucasian
   - ☐ Black or African-American
   - ☐ Asian
   - ☐ American Indian or Alaska Native
   - ☐ Native Hawaiian or other Pacific Islander
   - ☐ Other (specify)_____

   Ethnicity: ☐ Hispanic ☐ Non-Hispanic

5. Body Measurements Height: ____ ft. ____ in Weight_____lb, BMI_____

6. Dialysis? ☐ Yes ☐ No

7. Incontinent? ☐ Yes ☐ No

   ↓

   If yes,

   | |
   |---|
   | Urine: ☐ Yes ☐ No |
   | Feces: ☐ Yes ☐ No |
   | Both: ☐ Yes ☐ No |

8. Braden Scale Score (Enter from Braden form filled after consent/randomization)

   Overall score: _____

9. Lab Results: Albumin___(_____)___Prealbumin___(_____)

10. Comorbidities:
    - ☐ Diabetes
    - ☐ Chronic heart failure
    - ☐ Hypertension
    - ☐ Transplant
    - ☐ Chronic obstructive pulmonary disease
    - ☐ Coronary artery disease
    - ☐ Chronic renal failure
    - ☐ Other (specify): _____

Research Staff signature(s): _____ Date: __ __ / __ __ / __

**Appendix F**

# Pre-Screening Log

PI: Cecilia Zamarripa

Study Title: Subepidermal Moisture Measures and Early Identification of Pressure Ulcers

| | * Subject | Date Screened | Met Eligibility Criteria | | Reason for Exclusion/Screen Failure | For Subjects Eligible and Signing Consent | |
|---|---|---|---|---|---|---|---|
| | | | | | | Date of Consent | Subject Study # |
| 1 | _____ | _____ | Y ☐ | N | | | |
| 2 | _____ | _____ | Y | N | | | |
| 3 | _____ | _____ | Y | N | | | |
| 4 | _____ | _____ | Y | N ☐ | | | |
| 5 | _____ | _____ | Y ☐ | N | | | |
| 6 | _____ | _____ | Y | N | | | |
| 7 | _____ | _____ | Y | N | | | |
| 8 | _____ | _____ | Y | N | | | |
| 9 | _____ | _____ | Y | N | | | |
| 10 | _____ | _____ | Y | N | | | |
| 11 | _____ | _____ | Y | N | | | |
| 12 | _____ | _____ | Y | N | | | |
| 13 | _____ | _____ | Y | N | | | |
| 14 | _____ | _____ | Y | N | | | |
| 15 | _____ | _____ | Y | N | | | ..... |

**Appendix G**

Consent Form

# DUQUESNE UNIVERSITY

600 FORBES AVENUE ♦ PITTSBURGH, PA 15282

## CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**TITLE:** Skin assessment and early identification of pressure ulcers in persons with dark skin tones.

**INVESTIGATOR:**
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Wound, Ostomy, Continence Nurse
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**ADVISOR:**
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Associate Professor
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**SOURCE OF SUPPORT:** This study is being performed as partial fulfillment of the requirements for the doctoral degree in Nursing at Duquesne University. This study is not grant supported.

**PURPOSE:** You are being asked to participate in this research study that seeks to investigate pressure ulcers (also known as bedsore or decubitus), the prevention of pressure ulcers, and evaluating for early detection of pressure ulcer in persons with dark and light skin tones. You will be asked to participate in a complete skin assessment to determine presence or absence of pressure ulcers and moisture on the skin. This means you will be asked to turn and reposition, move to a side lying position and/or stand with assistance in order to look at your skin and its condition. I will also use a hand-held wand and gently place it on top of your skin to measure skin moisture. I will return every day for 6 days or less if you are discharged before then and I will repeat the same measurements. These are the only requests that will be made of you. The skin assessment will be done in the privacy of your hospital room. In order to qualify for participation, you must be free of any infections such as scabies and/or bacteria called acinetobacter and you must be 18 years of age.



**PARTICIPANT PROCEDURES:** To participate in this study, you will be asked to turn to your side while in bed so your skin on 4 different places of your buttocks and then each heel can be inspected. You will receive help to turn if needed. Next, a small or medium size wand the size of a Sharpie type pen will be lightly touched on your skin to measure moisture. This skin inspection and moisture measure will be conducted so as not to interfere with your routine care and will be done every day for 6 days or until you are discharged and leave the hospital. You can ask for this inspection and assessment to be stopped if there is discomfort. These are the only requests that will be made of you.

**RISKS AND BENEFITS:** There are minimal risks associated with this participation but no greater than those encountered in everyday life. During the assessment, you may experience slight pain but no more than the usual for skin assessment if a pressure ulcer is present. Although there may not be any direct benefits for you participating in this study, this research study will help answer questions about how healthcare professionals assess skin of persons with dark skin tones more accurately and decrease pressure ulcers in persons with dark and light skin tones. Consequently, you will have the satisfaction of knowing that your participation may help others at risk for pressure ulcers. If

there are any pressure ulcers discovered upon assessment, you will be referred to a Wound, Ostomy, and Continence Nurse for consult.

**COMPENSATION:** There will be no compensation for participation in this study. Participation in the project will require no monetary cost to you. Upon your request, you may be provided with a verbal report of absence or presence of pressure ulcer. A summary of the study will be provided upon request.

**CONFIDENTIALITY:** Your name will never appear on any survey or research instruments. No identity will be made in the data analysis. All written materials and consent forms will be stored in a locked file in the researcher's home. The assessment data will only appear in statistical summaries. All materials will be destroyed at the completion of the research. The research study results may be presented at a professional meeting or written as a manuscript for publication in a professional journal. In no way will your name be identified.

**HIPAA AUTHORIZATION**: You understand that by participating in this study, you are giving us permission to use your personal health information in your medical record and information that can identify you. The health information procedures in this study are HIPAA compliant. Any health-protected information obtained will be stored by the researcher for five years after the completion of the study.



**RIGHT TO WITHDRAW:** You are under no obligation to participate in this study. You are free to withdraw your consent to participate at any time. Regardless of whether you should you decide to be in the study, decide that you do not want to be in the study or you withdraw from the study, there will be no effect on the care you receive while hospitalized.

**SUMMARY OF RESULTS:** A summary of the results of this research will be supplied to you, at no cost, upon request.

**VOLUNTARY CONSENT:** I have read the above statements and understand what is being requested of me. I also understand that my participation is voluntary and that I am free to withdraw my consent at any time, for any reason. On these terms, I certify that I am willing to participate in this research project.

I understand that should I have any further questions about my participation in this study, I may call Cecilia Zamarripa, the Principal Investigator 412 389-6132 or 412 647-7728. Should I have

questions regarding protection of human subject issues, I may call Dr. David Delmonico, Chair of the Duquesne University Institutional Review Board, at 412-396-4032.

| | |
|---|---|
| _____ | _____ |
| Participant's Signature | Date |
| _____ | _____ |
| Researcher's Signature | Date |

CHAPTERS 4 & 5

# MANUSCRIPT

## Subepidermal Moisture Measures and Their Relationship to Early Identification of Pressure in the Acute Care Setting

The authors listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any non-financial or financial interest in the subject matter or materials discussed in this manuscript

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Pittsburgh, PA 15281 Approval to conduct this study was obtained from the Institutional Review Board of the University of Pittsburgh and Duquesne University. Acknowledgements – A special thank you to Darina Protovnak for her masterful work and expertise with data management;and to Ashley Kunsa and Brad Coffield for their valuable insight and expertise in the review and editing of my manuscript.

Abstract

***Purpose***: This study aimed to explore a hand-held device that measures subepidermal moisture (SEM) to detect early signs of pressure injury compared to visual skin assessment in hospitalized patients with dark and light skin tones in an acute care setting.

***Design***: Non-experimental, repeated measures, descriptive design exploring SEM and its relationship to early identification of pressure injuries in people with light and dark skin tones.

***Subjects and Setting***: A convenience sample of patients with light and dark skin tones admitted to medical and surgical units or intensive care units in a Level 1 Trauma hospital facility were recruited. Those with highest risk for pressure injury, were admitted within 48 hours, age 18 and over, and had a Braden Pressure Ulcer Risk score of 16 or less were targeted.

***Methods***: Demographic, SEM measures, visual skin assessment, pressure injury risk assessment and if developed, pressure injury characteristics were collected within 48 hours of admission. Daily follow-up assessments included pressure injury risk assessment, concurrent visual skin assessment, and SEM measures at six anatomical sites for up to six non-consecutive days. Descriptive and correlational statistics were used to describe the sample. A Pearson correlation coefficient was computed to compare visual skin assessment and SEM measures.

***Results***: Twenty-two of 122 participants (mean age = 66.68 years; SD = 13.91) developed a total of 25 pressure injuries. Sixty-eight percent of participants that developed a pressure injury were in the high risk to very high-risk category as measured by the Braden Pressure Ulcer Risk Assessment Scale on day of discovery. Mean SEM values varied at anatomical locations with highest values at the sacrum (M = 40.3, SD = 9.0) and above the sacrum (M = 41.1, SD = 7.4). Number of days to discovery of pressure injuries through visual skin assessment averaged 4.3 days.

***Conclusions***: Information in regard to the use of a hand-held dermal phase meter that measures SEM in acute care settings was revealed. The clinical practicality and use of the visual skin assessment as the gold standard to detect pressure injury development was further established. The difficulty in assessing patients with dark skinned tones remains a challenge. Further research should focus on identifying newer technologies that identify SEM threshold values for the acute care population.

***Key Terms***: pressure injury/ulcer, dark skin tones, subepidermal moisture measures, pressure injury risk, and bedsores.

## Introduction

Pressure injuries are a serious health problem worldwide and their development remains a significant health care problem especially for patients at risk (Tubaishat et al., 2018). Pressure injuries threaten patient safety across all settings and are prevalent in long term, acute care, critical care, and home care settings, and thus, affect millions of people annually leading to significant threats to patient safety (Quality, 2014). Pressure injuries and their prevention remain a challenge especially in acute care populations where, assessing skin accurately is critical to their prevention (Palese et al., 2020; Solmos et al., 2021). Skin care is fundamental to the nursing standard of care and is a learned and practiced skill. Skin assessment is vital to pressure injury prevention and the current nursing standard of care to inspect and assess skin, skin condition, skin characteristics and pressure damaged skin is based on a subjective view using one's eyes as a tool (Moore et al., 2017). Pressure injury prevention is a high priority, and their eradication is a clinical challenge. Their detection at an early stage is equally important because early pressure injury intervention implementation can occur, thus allowing early viable tissue rescue, lessening mortality and morbidity (Bates-Jensen et al., 2017).

To add to skin assessment challenges, the skin of persons with dark skin tones may be difficult to visually assess then identify early pressure induced tissue injury that result in skin changes such as non-blanchable erythema difficult to detect (Bates-Jensen et al., 2017). Darkly pigmented skin can mask early visual detection of stage 1 pressure injury and erythema, thus more likely to go undetected and deteriorate to a more severe full thickness pressure injuries (Bates-Jensen et al., 2017; Bergstrom & Horn, 2011; Garrigues & Cartwright, 2011). Similarly, in a nursing home study, pressure injury rates in persons with Blacks were significantly higher than rates for Whites, (0.56 versus 0.35, respectively) with a higher rate associated with more activities of daily living and other characteristics associated with the nursing home population (Baumgarten

et al., 2004). Persons with dark skin are more vulnerable to pressure injury development due to the dependence on visual skin assessment, which, when used alone, may not be adequate to detect early signs of pressure injury such as a stage 1 pressure injury (Clark, 2010). Mortality related to pressure injuries is reported to be higher in Blacks than in any other race or ethnic group (National Pressure Injury Advisory Panel, 2019).

Adjunct technological tools are becoming more readily available, and the United States (US) Food and Drug Administration has recently approved tools to potentially assist the bedside caregiver to examine skin for clinical signs of pressure injury not yet visually detected (Gefen & Gershon, 2018). One of those tools that may help bridge that gap to identify early and non-visible signs of pressure injury is a dermal phase meter that detects and measures subepidermal moisture (SEM), water below the stratum corneum possibly indicating signs of pressure injury before visually detected (Bates-Jensen et al., 2010; Bates-Jensen et al., 2017).

SEM measures have been shown to assist in early detection of pressure injuries and tissue damage especially in dark skin tones by early implementation of prevention strategies in long term care facilities (Bates-Jensen et al., 2017). SEM measures include moisture and tissue edema and obtained via a dermal phase meter that measures extracellular water content called SEM and is a good indicator of tissue health status. SEM values increase when a localized inflammatory response is triggered at the subepidermal layers beneath the stratum corneum and when the first tissue cells die. Consequently, when SEM measures are elevated, nursing interventions can be implemented to prevent pressure injuries earlier or to decrease their chance of worsening to a more severe pressure injury stage in (Bates-Jensen et al., 2007; Bates-Jensen et al., 2009; Bates-Jensen et al., 2008; Bates-Jensen et al., 2017). Significant progress in pressure injury research has been conducted to better understand pressure injury risk, pressure injury etiology, and visual skin assessment as a tool to identify early signs of pressure injury (Gefen & Gershon, 2018). Results of

previous studies have focused on nursing home residents with light and dark skin tones and spinal cord injury patients in the rehabilitation centers (Guihan et al., 2012). Pressure injury research has historically focused on prevention and treatment (Ayello & Lyder, 2007) and pressure injury early detection studies (Bates-Jensen et al., 2007; Bates-Jensen et al., 2010; Clark, 2010) more focused on early identification of pressure injuries among individuals with dark skin tones. Until recently, few studies have investigated the use of SEM as a biophysical measure to detect pressure injuries in acute and intensive care medical surgical populations and several have begun to emerge in various care settings (Bates-Jensen et al., 2017; Gefen & Gershon, 2018; O'Brien et al., 2018; Okonkwo et al., 2020; Park et al., 2018; Smith, 2019).

Pressure injury prevention specific to people with dark skin tones is vitally important and significant to nursing practice. Registered nurses (RNs) have the responsibility to keep patients safe from harm and must possess the knowledge and ability to decrease pressure injury rates potentially by identifying early signs of pressure injuries. The standard visual skin assessment and Braden Pressure Ulcer Risk Assessment are routinely conducted by nurses and are subjective, dependent on one's ability to accurately determine observable skin and tissue damage. Other ways to identify early signs of pressure injury in conjunction with visual skin assessment must be identified and tested. It may be that a dermal phase meter that measures SEM is a more reliable method to detect stage 1 and deep tissue pressure injury (DTPI) damage that is frequently missed even with expert visual skin assessments. Therefore, the specific aims of this study were to: 1) examine and compare the effectiveness of visual skin assessment and SEM measures as early indicators of stage 1 pressure injury and DTPI in people with dark skin tones; 2) explore the efficacy of visual skin assessment and SEM measures as indicators of stage 1 and DTPI in individuals with dark and light skin tones and, 3) identify threshold SEM values that can be used to predict stage 1 and/or DTPI in the individual hospitalized in an acute care setting.

**Design**

For this study, we used a non-experimental, repeated measures design. Adult patients age 18 and over admitted to medical/surgical or intensive care units and at risk for developing a pressure injury indicated by a score of 16 or less on the Braden Pressure Ulcer Risk Assessment Scale (Braden, 2014) were included in the study, as were all races and ethnic backgrounds. Visual skin assessment and SEM values were measured daily and up to 6 data points if participants were available, to capture any potential change in adult patients with light and dark skin tones at risk for pressure injury and to determine if SEM measures were capable of detecting early signs of pressure injury prior to visual skin assessment. Approved by Duquesne University Institutional Review Board (IRB) on January 5, 2018 (#2017-11-16) and the University of Pittsburgh IRB on October 16, 2018, (#19090166), this study was conducted at a large, urban hospital facility, Level 1 Trauma Center in Western Pennsylvania. Patients on acute care medical/surgical and critical care units with the highest quarterly National Database Nursing Quality Indicators (NDNQI) pressure injury prevalence rate and/or the highest-pressure injury incidence rates were targeted. To obtain sufficient numbers to evaluate SEM on persons with dark skin tones, an attempt was made to oversample dark skinned participants. Potential participants who presented with scabies, an Acinetobacter bacterial infection, or were admitted for 24-hour observation were excluded from the study.

Based on the literature (Bates-Jensen et al., 2008) and pressure injury prevalence and incidence data routinely collected during 2019, a moderate effect size (ES) of .25 was deemed appropriate. The results of a power analysis indicated that a total sample size of 128 using a two-tailed test of significance set at $p < .05$ and power of .80 with a moderate effect size of .25 (G*Power 3.1.3) was required.

A non-probability purposive convenience sampling methodology was employed to best

target patients who were at risk for developing a pressure injury. If the potential participant was willing to participate in the study and met the inclusion criteria, voluntary informed consent was obtained.

## Instruments

### Electronic Medical Record (EMR)

Data were extracted from the EMR to qualify potential participants for this study. Demographic and medical information including age, weight, height, body mass index (BMI), ethnicity, pressure injury risk, and presence of incontinence were extracted to describe the sample and for study purposes.

### The Braden Pressure Ulcer Risk Assessment Tool

The Braden Pressure Ulcer Risk Assessment Scale (Adibelli & Korkmaz, 2019; Braden & Bergstrom, 1994) was initially used to qualify patients for the study and then, to assess participants' risk of developing a pressure injury each day they were in the study. The summated rating scale is composed of six subscales: sensory perception, moisture, activity, mobility, nutritional status, and friction/shear. The tool has been validated with inter-rater validity ranging from .83 to .99 (Braden & Bergstrom, 1994). The scale has been tested, validated, and shown to be equally reliable on black and white skin (Lyder et al., 1999). Operational definitions are provided for each subscale, and each subscale is rated from 1 (least favorable) to 3 or 4 (most favorable). Total scores can range from 6 to 23 with scores of 19 and above indicating no risk for pressure injury development (Braden & Bergstrom, 1994). Braden Pressure Ulcer Risk score cut off points has a range of specificity from 26% to 100% and a sensitivity range from 61% to 100% (Kring, 2007). A Braden Pressure Ulcer Risk score of 18 or less indicates risk for pressure injury development. In order to recruit participants with higher risk scores, participants were considered eligible for this study if the Braden Pressure Ulcer Risk Score was 16 or less indicating a higher

risk of pressure injury (Braden & Bergstrom, 1994; Kring, 2007). Categorically, a total Braden pressure injury risk score 9 or less indicates a very high PI risk, (10-12) high risk, (13-14) moderate risk, (15-18) mild risk, and (19-23) represents no PI risk.

**Visual Skin Assessment**

Traditionally, nurses assess skin by visually inspecting skin and assessing for early signs of pressure injury, which usually presents itself as non-blanchable erythema. Early detection of tissue damage is important as early interventions to prevent further tissue damage can prevent more severe pressure injuries. Visual skin assessment is the nursing standard of care to assess skin and includes skin assessment of the entire body, including assessment of skin turgor, moisture, color, temperature, integrity, and destruction of skin integrity if present (Clark, 2010; McCreath et al., 2016; O'Brien et al., 2018). Visual skin assessment is considered a diagnostic tool to aid in the determination of the pressure injury classification and to define the level or depth of soft tissue damage for staging determined by observation and subjective visual skin assessment. Numeric pressure injury classifications define the level or depth of soft tissue damage for staging and is determined by observed and subjective visual skin assessments. In this study, visual skin assessment was conducted by the RN assigned to care for that patient on the day of data collection and was documented on the patient's EMR, visual skin assessment and SEM study forms. Skin assessments were conducted in the morning of each day of study participation and included the following bony prominence anatomical locations: sacrum, above sacrum, right and left buttocks, and heels. For analyses, results of each visual skin assessment were recorded as categorical, pressure injury (yes) or pressure injury (no). In addition, if discovered, visible pressure injuries were also staged using the National Pressure Injury Advisory Panel (NPIAP) stage definitions and were evaluated using the Bates-Jensen Wound Assessment Tool (BWAT) (Black et al., 2007).

**The Delphin Moisture Meter D dermal phase meter (DPM)**

The Delphin Moisture Meter D dermal phase meter (DPM), serial number D3N0129 (Delfin Technologies, Finland), was used to obtain skin surface impedance measurements and determine water amounts of the skin measured as an SEM value. The DPM consists of a control unit, cable and measurement probe and measures tissue dielectric constant (TDC) in relation to thickness of the stratum corneum with the TDC proportional to the amount of water in tissue, which increases with edema and increased water content (Bates-Jensen et al., 2017). There are four corresponding wands each with varying probe diameters. The measurement depths are 0.5 mm, 1.5 mm, 2.5 mm and 5 mm corresponding to maximum probe diameters of 10 mm, 20 mm, 23 mm, and 55 mm. The 20 mm and 23 mm probes corresponding to diameter with 1.5 mm and 2.5 mm inner-outer conductor spacing were utilized for this study. The DPM is totally non-invasive and locally measures water content changes in skin and subcutaneous tissue (SEM) and is a value that increases ~~with~~ as water content increase. DPM SEM readings are immediately generated after 8 seconds of light touch on the skin. Strong reliability has been described in relation to the instrument and a previous study, revealed a low (2.8%) coefficient of variation. However, it was noted in a previous study, that wand placement was a limitation of the device related to variability because of the difficulty in identifying precise placement of the wand on different anatomical locations (Bates-Jensen et al., 2017).

SEM values are considered a localized and a noninvasive measure that may detect early pressure injury and are indicated in dermal phase units (dpu) to measure the TDC value of the skin ranging from 0 to 80; higher values indicate more edema present. The measurements are arbitrary units referred to as dermal phase meter units that range from 0 to 80. SEM data were collected once per day on six anatomical sites for up to six days, depending on participant availability and recorded on the SEM and visual skin assessment study forms. Pressure injury staging definitions, developed by the National Pressure Injury Advisory Panel (NPIAP), were used during skin

inspection and assessment to stage pressure injuries if present. Pressure injury stages include stages one through four with additional definitions of unstageable, DTPI and mucosal membrane pressure injury. Pressure injury staging face validity, accuracy, clarity, succinctness, utility and discrimination factors have been established (Black et al., 2007; Edsberg et al., 2016).

**Bates-Jensen Wound Assessment Tool**

The Bates-Jensen Wound Assessment Tool (BWAT), an objective measure used to assess wound healing, wound characteristics and help standardize wound assessment and documentation (Harris et al., 2010), was used when a pressure injury was discovered during visual skin assessment ~~w~~ith each visit. Scored description items include wound characteristics such as size, depth, appearance of wound edges, description of undermining if present, necrotic tissue type and amount if present, exudate type and amount, periwound skin color, peripheral skin tissue edema and induration, presence of granulation tissue, and epithelialization. For this study and to ensure validity, the principal investigator (PI), who is a wound care expert, conducted a skin assessment for pressure injury when discovered by the bedside RN, then documented according to the BWAT. If present, the pressure injury wound was assessed for size dimensions in centimeters, wound characteristics including type of tissue, type and amount of exudate if present. Revised in 2001, the BWAT, formerly known as the Pressure Sore Score Tool (PSST) was found to be a reliable and valid tool and was used to reference data related to pressure injury characteristics (Harris et al., 2010; McCreath et al., 2016)

**Skin Tone Assessment**

The Munsell Color Tile Color Notation System is a commercially available tool that was used in this study to objectively define skin color (dark/light) when assessing skin tones in human subjects and has been used in previous studies (Bates-Jensen et al., 2010; Zanca, 2006). Colors are assigned alphanumeric designations to describe color quality, darkness or lightness of color, and saturation

of color or vividness. Specifically, the Munsell 5YR color chart was used to ascertain dark or light skin tones (figure 3). Lower values (2.5 to 5.9) indicated darker skin tones and higher values (6 to 8) indicated light skin tones. The participants forearm midway between the antecubital fossa area and the wrist was the point of location used to assess skin tones, and the Munsell Skin Tone Assessment form was used to record data collected (McCreath et al., 2016).

**Study Procedures**

Prior to visual skin assessment and SEM measurements, the participants were placed on their left side for removal of linen or disposable under pads, non-surgical wound bandages, briefs, or undergarments, and to allow for reactive hyperemia to resolve. If skin was soiled from incontinence, sweat, or wound drainage, the skin was cleaned prior to assessments. Presence of urinary and/or fecal incontinence were noted and recorded. An RN first conducted a visual skin assessment using the first skin assessment of the morning and recorded the results in the EMR. The PI was blinded to the results of the RN's visual skin assessment and thus, independently collected and recorded SEM measures in the same order of anatomical locations as was used for visual skin assessment of the sacrum, buttocks, and heels. SEM measures at the 12 o'clock position above the sacrum were included at the wound edge for open wounds if present. SEM measures were obtained with the DPM placed directly above each anatomical site with a cut-out opening to guide specific wand placement. A medium size wand was used. Once visual skin assessment and SEM measurements were collected, dressings, under pads, and briefs were replaced as needed. The wands were then cleaned between participants with a bleach antimicrobial wipe. For our study, if a pressure injury was discovered, the revised NPIAP pressure injury staging definitions were used to reference pressure injury definitions (Edsberg et al., 2016). Data on presence or absence of pressure injury and stage of pressure injury, if present, were recorded. Discovery of a pressure injury also initiated a wound care nurse consult. Visual skin assessment and SEM measures were

collected once daily for up to six days while participants remained hospitalized. All data were securely stored in the study folder using the date and participant's identification number as the file name in a locked file cabinet in the PI's work office.

**Data Analysis**

All data collected were documented on the appropriate data forms and routinely transferred to REDCap (Research Electronic Data Capture) data management software program as required by the study site. REDCap is a secure, web-based software platform designed to support data capture for research studies and was used to detect and correct data quality issues (Harris et al., 2009). Once data collection ended and all data were transferred to REDCap, data were imported to IBM Statistical Package for the Social Sciences (SPSS) version 26 (Green & Salkind, 2016).

Descriptive statistics were conducted on all demographic, health information and major variables under study including SEM and visual skin assessment. To describe the sample, mean and standard deviations were calculated for each demographic and health characteristics of all participants. Braden Pressure Ulcer risk scores for those that did and did not develop a pressure injury were analyzed as categorical outcome variable frequencies. Pearson's product moment correlation coefficient (r) was used to ascertain any potential relationships between SEM values and the day the pressure injury was discovered through visual skin assessment. An independent *t* test was used to determine if there were any differences between the mean number of assessment hours in pressure injury group and group that did not develop a pressure injury. The comparison examined number of hours from admittance to either pressure injury discovery or until discharge in the no pressure injury group.

**Results**

Data were collected from March 13, 2019 to November 26, 2019. The study sample included 122 participants who qualified for this study. The follow-up time was conducted, and data were

collected daily with a target of three and up to six different days or until patients were discharged. In some cases, data collection days were not conducted in sequential days or for less than three days if a participant was not available for reasons such as procedures, in surgery, or hemodynamic instability. The majority of participants were Caucasian (n = 96, 79%); there were 16 (13%) Black participants and one (.01%) Indian-Native American. Ethnicity was reported as Non-Hispanic, Non-Latino for 113 participants, and 9 reported as unknown or did not disclose this information. Participants varied in age typical of an acute care facility from 24 to 95 years with a mean age of 66.68 years (SD = 13.91). The majority of participants were male. Pressure injuries occurred in 22 of the participants. There were no significant group differences on sex regarding those that developed a pressure injury and those that did not. The phi coefficient was computed to measure the strength of association between participant skin tone and pressure injury incidence, phi coefficient (-0.11) and, for association between participant gender and pressure injury incidence phi coefficient (0.009), to show that the relationships were very small and thus, not meaningfully different. The phi coefficient (r value =.289) indicated a weak positive relationship. Majority of participants with light skin tone accounted for 107 of the total population. Individuals with dark skin tones accounted for the remaining 15 participants; only one female participant with a dark skin tone developed a pressure injury. No male participants with dark skin tone developed a pressure injury. Seven light skin tone females and 14 light skin tone males accounted for participants that did develop a pressure injury. See Table 1 for more specific information related to demographics and participant characteristics.

BMI, a measure of body fat, was calculated from height and weight and classified into four groups including underweight, normal weight, obese and extremely obese. Participants' weight ranged from 39.8kg (87.74 pounds) to 245 kg (540.13 pounds). Differences in BMI means were similar for the pressure injury group (M = 31.4, SD = 14.92) and the no pressure injury group (M =

30.7, SD = 9.05). Fecal and urinary incontinence were present in both those that did and did not develop a pressure injury as shown in Table 1. However, fecal and urinary incontinence was more prevalent in those participants that developed a pressure injury.

A total of 25 pressure injuries developed in 22 participants with the left heel (n = 7, 31.8%) as the most common anatomical location, followed by left buttock (n = 5. 22.7%), right buttock (n = 5, 22.7%), sacrum (n = 4, 18.2%) and right heel (n = 1, 4.5%). As shown in Table 2, stage 1 pressure injury (59.1%; n = 13) accounted for most of the pressure injuries followed by stage 2 (31.8%; n = 7) and DTPI (9.1%; n = 2). RNs followed hospital protocol and assessed skin every 12 hours. In this study, RNs identified a pressure injury at varying data points/days in 22 of the 122 participants.

SEM measures differed across participants with both light and dark skin, both sex, those with or without incontinence, all levels of pressure injury risk, those with and without a pressure injury and all anatomical sites. Mean day of discovery across all anatomical locations on the average was on day 4. Average number of days for RNs to visually detect a pressure injury through visual skin assessment was 4.3 days (M = 4.3, SD = 1.91). SEM measures on day of pressure injury discovery were highest at the sacrum (M = 40.3, SD = 9.03) and above the sacrum (M = 41.1, SD = 7.48). For those without pressure injury, mean SEM measures ranged from 31.2 dpu (SD = 6.0 dpu) to 40.1 dpu (SD = 9.1 dpu). Mean SEM measures for those with pressure injury were slightly higher across all anatomical locations ranging from 32.7 dpu (SD = 6.6 dpu) to 41.5 dpu (SD = 7.9dpu). There were no differences in SEM scores between those who did or did not develop a pressure injury as shown in Table 2.

Participants with light and dark skin tones were equally at risk for pressure injury as measured by the Braden Pressure Ulcer Risk Assessment Scale. All 22 participants that developed a pressure injury were determined to be at risk for developing a pressure injury at every assessment

from day one of data collection. Those who developed a pressure injury were in the high risk to very high-risk category 68.2% of the time on day of discovery. Braden Pressure Ulcer Risk score in participants with a pressure injury ranged from 8 to 18 and in the no pressure injury group, pressure injury risk score ranged from 6 to 22 although three of these participants were not at risk for pressure injury. It is equally important to note that cut off points for determining significant risk of pressure injury vary in care settings. In this study, we used a score of 16 or less as a significant predictor of pressure injury risk. Although not significant, the mean Braden Pressure Ulcer Risk score for the pressure injury group (11.64) indicated a slightly higher risk for developing pressure injuries compared to the no pressure injury group with a mean score of 12.03

Pearson's r was computed to assess the relationship between nurses' visual skin assessment on day of discovery and subepidermal moisture measures at six anatomical locations. Pearson's r varied with all anatomical locations, with a positive correlation between the sacrum SEM ($r = .451$, $n = 22$, $P = 0.05$), directly above sacrum SEM ($r = .786$, $n = 22$, $p = 0.01$), left buttock SEM ($r = .445$, $n = 22$, $p = 0.05$), and right buttock SEM ($r = .477$, $n = 22$, $P = 0.05$).

An independent sample t test was conducted to evaluate whether there were any differences in time to discover a pressure injury through visual skin assessment in comparison to those that did not develop a pressure injury. Results of t test computed Mean time in hours to detect a pressure injury was ($M = 81.33$ hours, $SD = 46.37$) in comparison to mean number of hours from first to last assessment with no pressure injury development ($M = 89.81$, $SD = 56.90$). The mean difference between groups, 8.47, was not significant, $t$ (df 120) $= .652$, $p = .282$. Therefore, there were no significant mean group differences between the pressure injury group and the no pressure injury group, however, it did represent a small effect size, ($d = .15$).

**Discussion**

The sample population in this study consisted of 122 hospitalized patients in an acute care setting. Twenty-two of these participants developed a total of 25 pressure injuries discovered on an average of 4.3 days by visual skin assessment. Majority of pressure injuries detected were stage 1 pressure injuries and located primarily on heels of the participants. It may be that more pressure injuries developed on heels due to greater shear forces compared to sacrum and buttocks. At our facility, the highest incidence of pressure injuries was anatomically located on the sacrum and heel. Additionally, the heel anatomy consists of the largest of the tarsal bones and are well cushioned by a bursal sac and fat pad with a thickened skin covering compared to other anatomical structures assessed. Heel pressure injuries are a possible result of soft tissue sustained deformations causing tissue damage in areas that may be "motionless" in supine or lying still positions. The end result is tissue deformation from shear load that may be a direct cause of pressure injuries (Gefen, 2017). Participants who developed a pressure injury scored lower on the Braden Pressure Ulcer Risk Assessment indicating a higher risk for developing a pressure injury. Although not surprising, the majority of participants that did not develop a pressure injury were also at risk for developing a pressure injury with scores ranging from six (very high risk) to 22 (no risk) with a mean of 12.03.

In comparison to other studies, (Bates-Jensen et al., 2007; Bates-Jensen et al., 2009; Bates-Jensen BM, 2007; Bates-Jensen et al., 2010), most participants in this study were younger. This is most likely due to differences in data collection sites as a mean age of 66 in the acute care population is typically lower than a mean age of 84 found in a nursing home population. There were no mean differences on between groups on age, sex or BMI and no relationships were found between these variables and those that did or did not develop a pressure injury. In another study (Bates-Jensen et al., 2009), racial and ethnic minorities with dark skin tones were found to have a higher burden of pressure injury. Unfortunately, in this study, lack of variety in skin tones in this study did not allow for a more notable representation of dark-skinned participants to compare with

light skinned participants. Overall, few patients developed a pressure injury and only one of these participants had dark skinned tones.

In our study, participants with higher SEM measures differed across participants with both light and dark skin. Mean SEM values on day of discovery did not differ when compared to number of days for pressure injury discovery by visual skin assessment In contrast to other studies, SEM values were measured over several weeks or longer (Bates-Jensen et al., 2009; Bates-Jensen et al., 2008; Bates-Jensen et al., 2010), but in this study, SEM measures and visual skin assessment data were only collected up to six different sequential days. Consequently, the number of days of data collection may have been too brief for the dermal phase meter to capture edema changes associated with tissue damage. It may be that an extended period of time up to 21 days as used in nursing home studies (Bates-Jensen et al., 2010) could provide a more favorable situation for the feasibility of SEM damage detection compared to the much lower average length of stay in the acute care. In this study, participant's length of hospitalization days averaged 7.2 days.

SEM measure values were slightly higher in the pressure injury group compared to the no pressure injury group, but the differences were not significant in our study. Preliminary SEM threshold values were previously tested in pooled data in nursing homes over 20 weeks and were used to determine if an SEM measure could be an indicator of pressure injury. In this study, we were not able to identify a threshold value due to the high variability within the groups and their physiological differences. Nevertheless, the results of this study may help nurses and other healthcare professionals be more aware of skin color differences and the use of assessment tools to help identify early tissue damage.

The results of this study demonstrate feasibility of the methodology to support future studies aimed at mitigating pressure injuries, preventing pressure injury deterioration and implementing prevention interventions early once early signs of pressure injuries are identified. It

is also reasonable to suggest that this study provides further information related to a relationship between SEM and early identification of pressure injuries in the acute care population at risk for developing pressure injury. Unfortunately, we were not able to determine predictive validity of threshold SEM values but recommend that future studies further investigate in order to provide further insight. We were not able to clearly separate and analyze SEM differences and threshold values in those that did and did not develop a pressure injury.

Although only 22 of 122 participants developed a pressure injury, there remains a high incidence of pressure injury at the acute care facility where data were collected. Pressure injury prevention practices are taught and frequently reiterated as standard of nursing care, but other factors that may affect pressure injury development or inability to identify early signs of a pressure injury may prevail.

New studies related to early identification of pressure injuries in the acute care setting especially in people with dark skin tones are beginning to emerge and have shown that SEM measures aide in early detection and subsequent prevention of pressure injuries, especially in dark skin tones (O'Brien et al., 2018; Okonkwo et al., 2020; Park et al., 2018). In this study, the overall occurrence of PIs was only 22 and the number of dark-skinned participants was limited with only one dark skinned and 21 light skinned participants developing a pressure injury. The limited number of participants developing a pressure ulcer prevented us from meeting two of our specific aims. In a recent study, SEM measures identified pressure injuries four days sooner than through visual skin assessment (O'Brien et al., 2018). In our study, even though nurses were able to visually detect a pressure injury on average, day four, we were unable to determine a threshold value to compare and correlate visual skin assessment and SEM measurements. Regardless, visual skin assessment remains a valuable tool, and the RN’s ability to detect pressure injuries attests to the quality of nursing staff at this facility as well as the number of Wound Treatment Associates

and hospital Skin Representatives that undergo robust skin assessment and pressure injury prevention training.

Pressure injury prevention specific to people with dark skin tones is vitally important and significant to nursing practice. Assistance in identifying early signs of pressure injuries in dark skin tones, in addition to the standard visual skin assessment by nurses, can help identify and potentially benefit people with all skin tones. It may be that SEM provides a more reliable method to detect stage 1 and deep tissue pressure injury (DTPI) damage that is frequently missed even with expert visual skin assessments. Unfortunately, we were not able to make this conclusion due to limited sample size, lack of diverse skin tones and limited days for data collection. Further studies to explore the relationship between SEM and VSA as combined methods to detect pressure damage early in people with dark skin tones are needed to help narrow the gap in detecting pressure injuries in patients with dark skin tones.

Lastly, the Delphin dermal phase meter used to measure SEM in this study, was not designed for high volume use in health settings (Bates-Jensen et al., 2017). Recently, SEM and early pressure injury detection was studied utilizing a small handheld SEM scanner device and was tested for use in the European acute care environment with threshold SEM measurements described as delta readings. In one such study, participants were similar in relation to lack of dark skin tone participants in their sample, and no persons of color were noted to be participants in that study (O'Brien, 2015). Newer devices to measure SEM show greater promise for use of this technology in the acute care setting (O'Brien et al., 2018). One current example is the BBI SEM Scanner used to measure SEM. This newer technology for detecting SEM was approved for use in the U.S. in 2019 and was not available when we collected data for this study. Before then, investigators had conducted studies utilizing the Delphin M dermal phase meter technology that measured and quantified bioimpedance using SEM measures as a predictor of pressure injuries

(Bates-Jensen et al., 2007; Bates-Jensen et al., 2009; Bates-Jensen et al., 2008; Guihan et al., 2012). In a pilot study, investigators found that the higher SEM value, the greater the likelihood of an early stage 1 or 2 pressure injury developing the week following the value measurement in nursing home residents with dark skin tones (Bates-Jensen et al., 2009). Similar to our study, a dermal phase meter was utilized to measure SEM. Nursing home residents were followed weekly resulting in many more data points over a significantly longer period of time compared to our study and thus, created challenges for repeated measures analyses. The SEM measures ranged as a result of the number of days/data points and made repeated measures analysis more challenging. Consequently, we considered looking at number of daily assessments completed on each participant and to analyze utilizing chi square or Wilcoxon statistical tests but there were no differences between the groups. To show a relationship between sensitivity and specificity for every possible cutoff, the receiver operating characteristic (ROC) curve was proposed as a useful tool to predict the probability but was not useful in our study. The maximum SEM measure value used as a predictor variable and pressure injury as the outcome in logistic regression, yielded a ROC curve that failed to predict pressure injuries in this study.

**Strengths and Limitations**

Our study was able to provide insights about physiological characteristic differences in the ICU and non-ICU populations, thus, gaining information about determining number of days to assess SEM and visual skin assessment and could permit further investigation to explore possible confounding variables. There are a number of limitations to consider in our study. First, we were limited in the number of assessment days due to average length of stay in the acute care setting. A limited number of assessment days varied due to early discharge and did not allow for a sample size of patients with dark skin tone and a larger number of assessment days. For our study, wand placement posed a challenge depending on the availability of nursing staff to assist with turning

and positioning the participant for assessments. Regardless of utilizing a wipeable template for precision SEM measurements, wand placement was a limitation of the device related to variability because of the difficulty in identifying precise placement of the wand on different anatomical locations.

The total number of patients who developed a pressure injury was too small to analyze repeated measures data, and cell sizes were too small for analysis. Consequently, our options for statistical analysis and ability to generalize were limited. In addition, the need to develop determination of an SEM threshold value in this population to help predict pressure injury occurrence in all skin tones was impossible due to limited sample size and lack of differences in skin tones. Future studies will need to target a more diverse population regarding skin tones. The information gleaned from our limited sample size nevertheless provided us with valuable information that can be used in future studies in acute care settings. This study could be used to generalize concepts more widely based on a larger sample to help further investigate causal relationships. In addition, a more adequate representation of participants with dark skin could perpetuate different outcome disparities. The need for deliberate dark skin tone participant enrollment could impact a more adequate disparity outcome and is highly recommended for future studies.

**Conclusions**

Despite the fact that we were not able to examine all of our specific aims, information in regard to the use of a hand-held dermal phase meter that measures SEM in acute care settings was revealed. The clinical practicality and use of the visual skin assessment as the gold standard to detect pressure injury development was further established. The difficulty in assessing patients with dark skinned tones remains a challenge. Nurses and other healthcare professionals need to monitor and recognize pressure injury risk scores that indicate high risk for pressure injury development, thus

implementing pressure injury prevention interventions early. Future research should focus on identifying newer technologies that identify threshold SEM values for the acute care hospitalized population.

**Table 1**

*Characteristics of Acute Care Hospitalized Participants (N = 122)*

| | Total<br>Mean ± SD, (N) | PI Group<br>Mean ± SD, (n) | No PI Group<br>Mean ± SD, (n) |
|---|---|---|---|
| Age | 66.8 ± 13.91 (122) | 67.64 ± 14.15 (22) | 66.47 ± 13.92 (100) |
| Body Mass Index | 30.85 ± 10.28 (122) | 31.4 ± 14.90 (22) | 30.7 ± 9.05 (100) |
| | Total<br>n (%) | PI Group<br>n (%) | No PI Group<br>n (%) |
| Gender | | | |
| Female | 57 (46.7) | 8 (36.4) | 49 (49) |
| Male | 65 (53.2) | 14 (63.6) | 51 (51) |
| Race | | | |
| Caucasian | 96 (78.7) | 17 (77) | 79 (79) |
| Black | 16 (13.3) | 2 (9) | 14 (14) |
| Native American | 1 (.8) | 0 (0) | 1 (1) |
| Unknown or Not Reported | 9 (7.4) | 3 (13) | 6 (6) |
| Skin Tone | | | |
| Dark | 15 (12) | 1 (.45) | 14 (14) |
| Light | 107 (87.7) | 21 (95.5) | 86 (86) |
| Incontinence | | | |
| None | 59 (48) | 9 (41) | 50 (50) |
| Fecal | 8 (6) | 3 (13.6) | 5 (5) |
| Urinary only | 19 (15) | 4 (18) | 15 (15) |
| Fecal and Urinary | 36 (29.5) | 6 (27) | 30 (30) |

*Note.* PI = pressure injury; Skin tones were determined by utilizing the Munsell Color Tiles.

**Table 2**

*Subepidermal Moisture Measures in Participants with and without Pressure Injury*

| **Anatomical Site** | **PI observed** | **No PI observed** |
|---|---|---|
| | Mean SEM ± SD, (#) | Mean SEM ± SD, (#) |
| **Right heel** | 32.7 ± 6.68 (118) | 31.2 ± 6.05 (412) |
| **Left heel** | 33 ± 6.0 (112) | 31.7 ± 6.56 (402) |
| **Sacrum** | 41.4 ± 9.17 (116) | 39.7 ± 9.7 (415) |
| **Sacrum directly above** | 41.5 ± 7.97 (116) | 40.1 ± 9.15 (414) |
| **Left buttock** | 39.4 ± 7.47 (116) | 37.6 ± 6.49 (415) |
| **Right buttock** | 39.7 ± 6.79 (116) | 37.4 ± 6.54 (415) |

*Note.* SEM = subepidermal moisture measures and measured in dermal phase units (dpu).

# = total number of measurements collected per anatomical site, measured once per day for up to 6 days.

PI = pressure injuries; SEM = subepidermal moisture measures.

Manuscript References


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