# Abstract

PURPOSE: This study sought to test the hypothesis that temperature differentials detected by thermal imaging of ICU patient sacral and remote skin areas could delineate patients with significant vascular disease presumably at greater risk for pressure ulcer development.

DESIGN: Convenience sample of intensive care unit (ICU) patients in a hospital setting.

SUBJECTS: Subjects evaluated were 100 patients (58 men, 42 women) with ages of 70.4 ± 14.4 and 74.0 ± 14.5 years respectively, who were admitted to an ICU.

METHODS: A commercially available thermal imaging system was used to obtain simultaneous standard photographic and infrared thermal images (11 x 14 inches) that included the patient's buttocks and remote areas after the patient was off-loaded for about four minutes. Images were processed to determine the temperature difference between the sacral region, deemed to be at-risk, and a remote region, deemed to be at minimal risk. Prior measurements of healthy subjects showed that sacral skin was on average 0.75°C less than a remote skin site (ΔT = -0.75°C). For the present analysis, a threshold ΔTTH of twice that amount (ΔT = -1.5°C) or more was considered to put a patient at greater than normal risk based on the hypothesis that low sacral temperatures were associated with lowered blood perfusion issues of various clinical conditions. The vascular status of patients who equaled or exceeded this threshold was compared to the other patients.

RESULTS: Thirty-two patients exceeded ΔTTH with an average ΔT of -1.92 ± 0.62°C. In six patients ΔT was greater than +1.5°C with average of +1.98 ± 0.49°C. The remaining 63 patients had an average ΔT of 0.13 ± 0.58°C. Chi-square analysis of the proportions of patients exceeding or not exceeding thresholds in relation to their known vascular disease status revealed no significant difference between these subgroups.

CONCLUSIONS: Although infrared thermal screening may provide visually impressive and potentially useful images in some cases, the use of temperature differentials to detect patients at particularly high risk related to vascular status is not supported by the
present results.
August 24, 2017

Mikel Gray, PhD, FNP, PNP, CUNP, CCCN, FAANP, FAAN
Editor – in – Chief

Dear Dr. Gray,

On behalf of my co-authors and myself, I am pleased to submit the manuscript entitled “Sacral Skin Temperature Assessed by Thermal Imaging: Role of Patient Vascular Attributes” for consideration as a contribution to the Journal of Wound, Ostomy, and Continence Nursing. In addition to the text, the manuscript consists of two figures and one table.

All authors have approved the manuscript and agree with its submission to the Journal of Wound, Ostomy, and Continence Nursing.

We confirm that this original manuscript has not been published elsewhere and is not under consideration by another journal and that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

Furthermore, we confirm that any aspect of the work covered in this manuscript that involved human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

Respectfully submitted,

Harvey N. Mayrovitz, PhD
Professor of Physiology
College of Medical Sciences
Nova Southeastern University
Sacral Skin Temperature Assessed by Thermal Imaging: Role of Patient Vascular Attributes

Harvey N. Mayrovitz, PhD, College of Medical Sciences, Nova Southeastern University, Fort Lauderdale, Florida
Paige E. Spagna, BS, College of Medical Sciences, Nova Southeastern University, Fort Lauderdale, Florida
Martha C. Taylor, BSN, RN, CWON, Holy Cross Hospital, Fort Lauderdale, Florida

Corresponding Author
Harvey N. Mayrovitz, PhD
College of Medical Sciences
Nova Southeastern University
3200 S. University Drive
Ft. Lauderdale Florida 33328
mayrovit@nova.edu
Phone: 954-262-1313
Fax: 954-262-1802
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ABSTRACT

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RESULTS: Thirty-two patients exceeded ΔT\textsubscript{TH} with an average ΔT of -1.92 ± 0.62°C. In six patients ΔT was greater than +1.5°C with average of +1.98 ± 0.49°C. The remaining 63 patients had an average ΔT of 0.13 ± 0.58°C. Chi-square analysis of the proportions of patients exceeding or not exceeding thresholds in relation to their known vascular disease status revealed no significant difference between these subgroups.

CONCLUSIONS: Although infrared thermal screening may provide visually impressive and potentially useful images in some cases, the use of temperature differentials to detect patients at particularly high risk related to vascular status is not supported by the present results.

KEY WORDS: sacrum, thermal imaging, pressure ulcer, vascular status, skin breakdown
INTRODUCTION

Hospital-acquired pressure injuries (HAPI) are a common and substantial burden on the health care system, with more than 2.5 million patients in acute-care hospitals treated in the United States annually.¹ Managing pressure ulcers (PU) is estimated to cost the US health system from $9.1 billion to $11.6 billion per year.² Beginning in 2008, the Centers for Medicare and Medicaid Services (CMS) ruled to discontinue hospital reimbursement for costs incurred by hospital-acquired conditions including acquired stage III or stage IV PU. According to CMS, the price of managing a single full-thickness HAPI in acute care (as a secondary diagnosis) costs an additional $43,180.00 per hospital stay.³ A primary concern to health-care providers is the significant health-related costs incurred by those patients suffering from HAPIs. The consequences of HAPIs on a patient’s quality of life may include unnecessary pain, costly treatment, increased length of hospital stays, greater comorbidity risk, burden to family, and mortality. It is estimated that each year, up to 60,000 Americans will die prematurely of PU-related complications.⁴ The current National Pressure Ulcer Advisory Panel (NPUAP) staging system delineates a Stage I pressure injury as a pressure-related area of intact, discolored skin, with localized non-blanchable erythema.⁵ Stage I PU are considered reversible, in that no irreparable tissue damage has occurred. A variant type of pressure injury, referred to by the NPUAP⁵ guidelines as a Deep Tissue Injury (DTI), presents as a “purple or maroon localized area of discolored intact skin or blood-filled blisters, due to damage of underlying soft tissue from pressure and/or shear.” DTIs are wounds of unknown depth, which range in severity depending on the extent of underlying tissue damage and/or necrosis. Thus, in the case of a DTI, variations in pain and temperature may proceed any visually detectable changes in skin color.⁵
The conflicting nature, given the staging criteria, for distinguishing between these two injuries is based solely on observable and palpable characteristics of the skin and is not reflective of the distinctive etiologies of these injuries. In the case of a DTI, the outward pattern of necrosis that ensues underneath an area of intact skin has been speculated to progress as rapidly as 48-hours from injury to initial appearance and within 7 to 10 days for further deterioration into a necrotic, full-thickness Stage III/IV HAPI, regardless of interventions.\textsuperscript{6,7} Drawing from observations taken from forensic science, Farid\textsuperscript{8} reported a 7 to 14 day timespan between when the initial tissue injury is thought to occur, and the first clinically observable signs of the injury as it progresses toward necrosis.

It has been stated that more than 100 physiological (intrinsic) and non-physiological (extrinsic) risk factors place adults at greater risk for developing PU.\textsuperscript{9} Malnutrition, hypotension, incontinence, cerebrovascular disease, diabetes and fractures were all associated with the PU presence among national inpatient populations.\textsuperscript{10} Thus, it is not surprising that patients admitted to intensive care units (ICUs) are the hospital population most critically at risk for developing HAPIs. A retrospective study by Kirkland-Kyhn et al.\textsuperscript{11} done on a population of ICU patients who developed a sacral DTI that evolved into a stage 3, stage 4 or unstageable HAPI, found that the odds of developing a DTI increased by about 7.5\% for each mmHg decrease in diastolic blood pressure, placing those with poor blood perfusion among those at greatest risk for developing one of these injuries.\textsuperscript{11} This finding seems to indicate greater vulnerability for tissue breakdown, particularly in critically ill patients, as hemodynamic status is progressively impaired. A review by Berlowitz and Brienza\textsuperscript{12} suggests that most HAPIs, even those that appear superficial enough to be pressure-induced, developed as a result of a precursory DTI.
While HAPs are a known concern for hospitalized patients with vascular disease\textsuperscript{13}, it is unknown if all such patients are similarly at risk. To date, there is no noninvasive method in which patients entering ICU can be expediently and efficiently screened to determine which patients with vascular disease are most likely to suffer a DTI. Measuring skin temperature is one potential strategy that may allow healthcare providers the ability to prospectively determine if an area of intact discoloration will eventually progress into necrosis. A study by Farid et al.,\textsuperscript{14} utilized thermography to discern between cool and warm surface temperatures of pressure-related areas of intact and discolored skin (suspected areas of DTI). Results found that by day 7 areas at the discolored site had cooler temperatures and were 31.8 times more likely to progress to necrosis than adjacent warm regions’.\textsuperscript{14} Thermography is a noninvasive and objective technique to index or estimate local hemodynamic status based on skin temperature differentials between and among different sites. An underlying assumption is that tissue regions with blood flow deficits will render skin temperatures less than those in regions not so affected. We hypothesized that such temperature differentials are more pronounced in persons with cardiovascular disease and conditions in which localized perfusion pressures are diminished due to regional vascular deficits or systemic hypotension. Our specific hypothesis is that patients with such conditions have a lower relative sacral skin temperature that can be detected via a rapidly obtained thermal image. Our goal was to test this hypothesis by examining temperature differentials between this common pressure ulcer prone region (sacrum) and a remote skin site in ICU patients using a commercial thermal imaging system.
METHODS

Patients

Buttocks and lower back areas of 100 ICU patients (58 male, 42 female) were imaged to obtain simultaneous infrared thermal and standard photographic images using a commercially available, FDA approved imaging system (Scout SCA100, Wound Vision LLC, Indianapolis, Indiana). This study was approved by the Western Institutional Review Board (WIRB 1163595). Requirements for participation were that subjects be at least 18 years of age and have been admitted to one of the following hospital intensive care units: the ICU, Cardiovascular Intermediate Care Unit (Cardiovascular- ICU step down unit), or the Neuro-Surgical/ Critical Care- ICU. Subjects deemed eligible to participate had to be willing and able to comply with being positioned in a lateral recombinant position for a period of about four-minutes, which was the necessary time required to stabilize the exposed skin to ambient temperature. Patients who had not been admitted to one of the named Intensive Care Units were excluded from participating in the study. Patients who could not tolerate being repositioned (either due to an unwillingness to cooperate, pain or deemed too physiologically unstable, as determined by their attending RN) were excluded from participating. Additionally, those unable to tolerate the required four-minute period subsequent to repositioning were excluded from the study. Patients with preexisting sacral ulcers were not eligible to participate in the study. Age (mean ± SD) of male and female participating patients were 70.4 ± 14.4 and 74.0 ± 14.5 years respectively, with an average hospital stay of 11.9 ± 11.3 days with the day of imaging being on their 5.4 ± 6.9 hospital-day. The overall Braden score was 16.5 ± 4.0 with 38 of the 100 patients having known diabetes. Of the 100 patients, 74 had atherosclerotic coronary
artery disease, 42 had either acute or chronic renal dysfunction, and 15 had peripheral arterial disease. A total of 14 patients went on to develop a sacral ulcer.

*Image Capture Procedure*

Prior to imaging, patients were re-positioned to a lateral recumbent position necessary to completely expose the sacral and lower back areas. All clothing or sacral dressings were removed from the patients' backsides allowing the areas to acclimate to the room air for about four minutes. This time window was chosen as a compromise to minimize the discomfort to the patient and yet have as much time as possible to allow for any recovery due to the prior lying time.

The ambient room temperature was measured using a handheld digital thermometer and values were recorded just prior to each subject being imaged. Overall room temperature was fairly constant at 22.2 ± 0.6°C. The handheld imaging device was positioned 18" away from the patient's sacral skin surface. Positioning was aided by a device feature that provided a visual image of an overlapping laser target on the skin indicating the proper imaging distance. Nothing was in contact with the subject's skin during the time the image was captured, unless a pair of gloved hands was needed to assist with positioning and exposure of the site. The captured image for analysis consisted of a standard digital photo of an 11 x 14-inch (28 x 35.5 cm) area together with a long-wave infrared thermal image of the same area. The thermal image provided a real-time temperature mapping of the area. Both images were uploaded and stored to a designated computer linked to the imaging device hardware and software. Images were stored in the system software using randomly generated subject numbers unrelated to any of
the patients’ identifying information. Pertinent patient medical history and follow-up information was obtained using the hospital’s electronic medical records (EMR) system.

**Image Analysis Initial Procedures**

All images were analyzed by a co-investigator that was not present or involved during the image acquisition phase. Further, the image analysis was done prior to any knowledge of the medical condition or past history of the patient. The analysis procedure was standardized as illustrated in figure 1 and described as follows. Starting with the standard digital image (figure 1A), a reference point was marked at or near the sacral end of the intergluteal cleft and a reference grid was superimposed over the image (figure 1B) to define absolute distances as needed. A remote skin site was then selected as a control temperature site (figure 1C). This site was always selected to be proximal to the target sacral region of interest with an average distance from the sacral reference point to the center of the control region of 17.9 ± 3.0 cm. Switching to the thermal image (figure 1D), a one cm² circular control area was placed at the previously selected remote point. The average temperature within this control area is subsequently compared to the average temperature in a target area, which is shown inscribed in the sacral region (figure 1F). Temperature differentials are expressed as $\Delta T = \text{sacral temperature} - \text{control temperature}$. The system software calculates the average temperatures within the target sacral area and the control area. Examples of patients with different temperature profiles are illustrated in figure 2 in which example thermal images and corresponding digital photos are shown for patients in whom the sacral target temperatures differed from the control by -1.5°C, +1.5°C and 0°C.
At-Risk Assessment and Analysis

Prior measurements of sacral skin temperatures of healthy subjects showed that sacral skin temperature is on average 0.75°C less than a remote skin site ($\Delta T = -0.75^\circ C$). For the purpose of the present analysis a $\Delta T$ of twice that amount ($\Delta T = -1.5^\circ C$) or more was considered to place a patient at greater risk based on the hypothesis that reduced relative sacral temperatures of this amount were associated with lowered blood perfusion issues of various clinical conditions. Comparisons of sacral to control area temperature differentials were used to categorize patients as either higher risk if $\Delta T \geq -1.5^\circ C$ or lower risk if $\Delta T$ was otherwise. Three broad categories of clinical classification were used to assess if temperature differentials were significantly associated with conditions likely to reduce blood perfusion. One was classified as a prior diagnosis of cardiovascular disease (CVD). For the present purpose, the presence of CVD was assigned to any patient with a diagnosis of coronary artery disease, peripheral arterial disease or atherosclerotic heart disease. There were 74 patients in this grouping. The other classification was for patients who at any time during their hospital stay there was recorded a mean arterial blood pressure (MBP) that was less than 60 mmHg (MBP<60 mmHg). There were 58 patients in this grouping. A third grouping was composed of patients that had both CAD and a MBP <60 mmHg (CVD + MBP). There were 43 patients in this grouping. The potential consequence of vascular status and temperature differentials was examined by considering the number of patients within each group who had $\Delta T \leq -1.5$ compared to those with $\Delta T >-1.5$ using a Chi Square analysis. In this analysis, the significance level taken to reject the null hypothesis of equality was taken as 0.05.
RESULTS

*Temperature Differentials*

A Total of 32 patients had sacral to control area temperature differentials that were equal to or exceeded the -1.5°C threshold with an average sacral to control area temperature differential of -1.92 ± 0.62°C (Range: -1.5°C to -3.9°C). Contrastingly 6 patients had a temperature differential that was greater or equal to +1.5°C with an average differential of +1.98 ± 0.49°C (Range: 1.5°C to 2.7°C). The remaining 63 patients had an average temperature differential of 0.13 ± 0.58°C (Range: -0.90°C – 1.3°C).

*Group conditions compared with temperature differentials*

*Table 1* shows the number of patients with and without the specified condition (CVD or MBP or both) and the number of patients within each group that exceed the low temperature threshold (ΔT ≤ -1.5°C) or whose temperature differential is greater (ΔT > -1.5°C). The chi-squared analysis values and the associated p-values (table 1) indicate no statistically significant discrimination attributable to temperature differentials are detected for any of the three groupings.
A primary aim of this study was to test the hypothesis that patients with vascular impairments would have a lower sacral temperature relative to a remote skin that was at a much lesser risk for breakdown. The longer-term goal was to capitalize on such findings if present and utilize such temperature differentials as a way to aid in stratifying breakdown risk aided by the use of thermographic images. Based on the results of the chi-square analysis the main findings of this study do not support the primary hypothesis. This means that patients with or without underlying vascular disease or low perfusion pressures may present with lowered relative sacral temperatures suggesting that such temperature gradients in and of themselves do not provide a general stratification procedure at this time, at least as represented by the ICU patients of the present study.

It is our belief that the absence of a clear separation is in part related to the specifics of any underlying vascular deficit. For example, a patient with documented peripheral arterial disease may or may not have their sacral area experience a blood flow deficit subsequent to reduced perfusion pressure dependent on the location and extent of the vascular lesions. Along the same lines, patients with documented coronary artery disease may or may not have perfusion deficits in the sacral region herein examined that would give rise to the hypothesized temperature reductions. This suggests that a clearer separation may be achievable if more specific and detailed vascular data were available than was available in the present study. Attempts to use temperature differentials to anticipate the course of patients with DTIs as an ancillary investigation was also not successful. Of the 16 patients with documented DTI, seven had documented sacral ulcers, but only two of these ulcers had prior sacral to control area
temperature differences \( \leq -1.5^\circ C \). Moreover, of the 14 patients with documented ulcers, five were observed to have prior temperature differentials that were \( \leq -1.5^\circ C \).

The four-minute window was the maximum time many of the subjects could tolerate lying on their side. While this is a limitation, it is also represents a very realistic clinical consideration when evaluating the true utility of devices in the acute care setting. In order for such devices to be clinically useful, a patients’ level of comfort and threshold for tolerating any extra measures that may be required for imaging, must be taken into serious consideration. Thus, although we would have liked to allow a greater time for acclimation to ambient temperature, the methodology that was used is reflective of the acute setting in which the device would theoretically be employed.

Although the hypothesis of the present study is not supported by the current experimental data, the present findings do not rule out the use of thermographic imaging as a possible useful assessment tool in other settings. Thermal imaging has shown some potential to predict time-to-healing based on wound bed temperature\(^{18}\), as a way to improve pressure ulcer detection\(^{19}\) and has been evaluated as a way to predict outcomes of patients with discolored skin in nursing facilities\(^{20}\). As we learn more about the confounding factors that impact the development and progression of DTIs towards skin breakdown we will be better positioned to apply thermography and other detection tools to better detect and circumvent these injuries, especially early on in the process, while they may still be reversible.
KEY POINTS

1. It was hypothesized that low sacral temperatures would most likely be observed in patients with vascular deficits, and that if detected, would identify patients at greatest risk of suffering a Hospital-acquired pressure injury.

2. The hypothesis was tested by thermal imaging of buttocks and remote areas of 100 ICU patients, yielding a range of easily obtainable temperature differentials between sacrum and remote skin areas.

3. The ability of these differentials to distinguish between patients with or without vascular deficits as a measure of increased breakdown was inconclusive.

4. While results did not demonstrate a statistically significant reduced skin temperature, thermographic imaging may have other uses as a potentially useful screening device to measure a patient’s sacral region upon admission and throughout their hospital stay.
REFERENCES


$\Delta T \leq -1.5^\circ C \quad \Delta T > -1.5^\circ C \quad \text{Total Patients} \quad \text{Chi-square} \quad \text{p-value}$

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| Group CVD & MBP |        |        |        |        |        |        |
| Both conditions | 15   | 28 | 43 | 1.268 | 0.260 |
| Neither condition | 14  | 43 | 57 |        |        |

Table 1. **Group conditions compared with temperature differentials**

Numeric entries are the number of patients with the specified condition and differential temperature range between target sacral area and control area. Chi-squared values and associated p-values indicate no statistically significant discrimination attributable to temperature differentials are detected.
FIGURE LEGENDS

Figure 1. Image Analysis Preliminary Procedures

Figure A through C show sample digital images and D through F thermal images. A. Starting with the standard digital image, a reference point is marked at or near the sacral end of the intergluteal cleft. B. A reference grid is superimposed to define absolute distances as needed. C. A remote skin site is selected as a control temperature site. D. On the thermal image, a one cm$^2$ circular control area is placed for subsequent comparison to the sacral target area. E. The control area shown without superimposed grid. F. Target area inscribed within the sacral region on the thermal image. The system software calculates the average temperatures within the target sacral area and the control area. In this example, the average temperature in the target area was 1.3°C greater than in the control area. The imbedded text in B, C and D is internal location information and not relevant to the illustrative material shown in the figures.

Figure 2. Example Images

Top row shows thermal images and bottom row shows corresponding digital photo of same area. In each case the superimposed text on the thermal images shows the distance from the control area to the sacral target (L) and the temperature difference (DT) between these areas. A) target area 1.5°C less than control, B) target area 1.5°C greater than control, C) target area temperature the same as the control.
A. Sacral reference marked
B. Superimposed grid
C. Remote control point
F. Sacral target area inscribed
E. Thermal with no grid
D. Thermal with control area