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A Multimodality Imaging and Software System for Combining an Anatomical and Physiological Assessment of Skin and Underlying Tissue Conditions

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ABSTRACT

OBJECTIVE: The timely and accurate assessment of skin and underlying tissue is crucial for making informed decisions relating to wound development and existing wounds. The study objective was to determine within- and between-reader agreement of Scout Visual-to-Thermal Overlay (WoundVision LLC, Indianapolis, Indiana) placement (moving the wound edge trace from the visual image onto the wound edge signature of the infrared image). **MATERIALS AND METHODS:** For establishing within- and between-reader agreement of the Scout Visual-to-Thermal Overlay feature, 5 different readers overlaid a wound edge trace from the visual image and placed it onto the congruent thermal representation of the wound on a thermal image 3 independent times. Forty different wound image pairs were evaluated by each reader. All readers were trained by the same trainer on the operation of the Scout prior to using the software features. The Scout Visual-to-Thermal Overlay feature allows clinicians to use an anatomical measurement of the wound on the visual image (area and perimeter) to extract a congruent physiological measurement of the wound on the thermal image (thermal intensity variation data) by taking the wound edge trace from the visual image and overlaying it onto the corresponding thermal signature of the same wound edge. **RESULTS:** The results are very similar both within- and between-readers. The coefficient of variation (CV) for the mean PV both within- and between-readers averages less than 1%, 0.89 and 0.77 respectively. When converted into degrees Celsius across all 5 readers and all 3 wound replicates, the average temperature differential is 0.28° C (Table 2). The largest difference observed was 0.63° C and the smallest difference observed was 0.04° C.

CONCLUSIONS: The Scout software's Visual-to-Thermal Overlay procedure, as implemented in this study, is very precise. This study demonstrates that the thermal signature of wounds may be delineated repeatedly by the same operator and reproducibly by different operators. Thus, clinicians can integrate a criterion standard visual (anatomical) assessment with a congruent physiological assessment to provide them with knowledge relating to the presence or absence of blood flow, perfusion, and metabolic activity in the wound, periwound, and wound site. **KEYWORDS:** wound assessment of underlying tissue

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INTRODUCTION

The timely and accurate assessment of skin and underlying tissue is crucial for making informed decisions relating to wound development and existing wounds. Unfortunately, many drawbacks and limitations are associated with the current, clinically accepted methods for assessment. Current criterion standard methods combine a visual assessment of the intact skin at risk or the wound site (wound bed and periwound) with the patient's history and physical. Nothing can replace a comprehensive patient history and physical examination. However, in order for clinicians to keep pace with the growing burden of wounds, they must adopt new and innovative technologies and techniques to overcome the limitations of the current visual assessment standard. Unfortunately, the visual assessment is mostly limited to what clinicians are able to see and do.¹ This approach puts clinicians in a difficult situation because many of the early signs and symptoms associated with wound development and healing present with characteristics that are (a) not

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visually identifiable until manifestation has occurred or (*b*) difficult to assess with techniques that are largely subjective in nature. Based on new advances, clinicians have the opportunity to take part in a paradigm shift from reactive visual assessment techniques of the past to pursue more proactive visual assessment techniques afforded to them by modern-day technologies.

This study aims to demonstrate the importance of and limitations to the visual assessment, as well as an emerging technology that can be harnessed to minimize these limitations. In doing so, the assessment of the characteristics relating to wound development and healing is better understood by separating the characteristics into 2 categories: anatomical and physiological. In regard to wound care, the word *assessment* can be easily interchanged with the word *measurement* because when assessing a wound characteristic clinicians are measuring that characteristic. Fundamentally speaking, by assessing, a clinician is ultimately measuring the presence or absence of a characteristic and/or that characteristic's change over time.

Anatomical assessment is best described as a visual measurement of the structural existence and proportion of features and configurations associated with the disease or injury, that is, the assessment of a gross anatomy topographic characteristic, such as discoloration, which is visible to the naked eye.

Physiological assessment is best described as a nonvisual measurement of the functional change and development of processes and mechanisms associated with the disease or injury, that is, the assessment of a thermodynamic characteristic, such as temperature, which is not visible to the naked eye.

ANATOMICAL ASSESSMENT

Anatomical assessment is limited to what the clinician can see in the visible spectrum. Basically, this means clinical recognition, and measurement is possible with the naked eye. The visible characteristics include wound size, wound edge definition, tissue type, exudate type and amount, discoloration, and undermining/tunneling. Methods for identification and measurement of these characteristics can be subjective, but more importantly, they are often a reflection of what has already happened. This can leave clinicians with little or no room for early intervention. Another perspective is to consider it as a measure of the effect from a prior event (cause and effect). An example of this is the ability to identify and measure discoloration/erythema as it relates to suspected deep tissue injury (sDTI) of intact skin and/or the periwound tissue relating to an existing wound, especially in individuals with darkly pigmented skin.² Because evolution of sDTI may be rapid, and the damage to underlying tissues can manifest before discoloration becomes visually recognizable (topographically present), the identification and measurement of the structural existence and proportion

of deep tissue injury via anatomical assessment are impossible. It is imperative that preclinical changes such as these are recognized, and pressure is relieved before progressing to further damage.¹

PHYSIOLOGICAL ASSESSMENT

Physiological assessment is limited to what the clinician can touch, smell, or hear (from the patient) and is not recognizable in the visible spectrum; in other words, this means clinical recognition and measurement are not possible with the naked eye. These characteristics include temperature, texture, blanchable/ nonblanchable erythema, moisture, odor, edema, and pain. All of these characteristics can serve as valuable preclinical indicators for the development of nondesirable outcomes before they manifest further (ie, microperfusion, circulatory impairment, infection, or ischemia). Unfortunately, the methods for identification and measurement are not only subjective, but inherent difficulties remain in the clinician's ability to initially identify these characteristics, making it somewhat of a guessing game. An example of 1 such limitation is the evaluation of temperature (inflammation or lack thereof) by the method of manual palpation. This method has been shown to be a nonobjective means of temperature assessment, even in controlled environments.³ This method also presents concerns related to cross-contamination from continuous contact between a clinician's hand and a patient's body surface, particularly if the clinician was not wearing gloves.

Although the above examples of anatomical and physiological assessment highlight the limitations of current techniques, all of the methods remain important and serve a purpose. Until easier, more objective methods are developed, clinicians must continue to utilize those techniques to the best of their ability. In the interim, it is important that clinicians continue to look for new ways to overcome these shortcomings and embrace new tools and technologies.

A NEW TOOL FOR ANATOMICAL AND PHYSIOLOGICAL ASSESSMENT

It has been shown that anatomical structural imaging (anatomical) combined with analytic software tools can help to decrease the subjectivity and limitations of the anatomical assessment. One such method is an improvement in the way wound size is measured. A study by Langemo et al⁴ stated that a desirable wound measurement technique must be not only accurate, safe, and easy to use, but also valid, reliable, and sensitive enough to document change over time.

That study was based on the US FDA–cleared Scout device (WoundVision LLC, Indianapolis, Indiana), which met all of the desirable characteristics previously described. Study results showed that the Scout device could emulate the length \times width (L \times W)

measurement with an equal amount of undesired variability (44%). However, the advantage of the Scout device was its ability to measure the perimeter of an open wound with very limited variability (5%).⁴ The Scout device's precision and accuracy relating to anatomical imaging set the stage for this study, which combines a congruent, functional imaging (physiological) modality with long-wave infrared thermography. This allows clinicians to combine an anatomical and physiological imaging tool into their current assessment practices that can help to strengthen and empower them with knowledge that is objective, quantitative, and otherwise unattainable by current clinical standards.

This study evaluates 3 aspects of the Scout device's reliability: homogeneity, intrarater reliability, and interrater reliability in an effort to confirm the device's ability to provide clinicians with consistent preclinical and physiologic information that can be incorporated into the current assessment practices.

BACKGROUND INFORMATION

The Scout device, previously known as the Wound Measurement and Monitoring System, is a combination digital camera and long-wave infrared camera. The clinician simultaneously captures a visual and infrared image that can be uploaded and stored with a patient's electronic medical record, where body surface size and thermal intensity data can be measured and recorded. The digital camera captures the visible light wavelengths from the electromagnetic spectrum, which are visible to the human eye. The infrared camera captures the long-wave infrared radiation emitted by the human body from the electromagnetic spectrum (7–14 μ m), which is not visible to the human eye.

The Scout's digital camera is indicated for the use of capturing visual images to measure the diameter, surface area, and perimeter of a part of the body or 2 body surfaces (depth can be acquired manually by the clinician and recorded in the software to calculate to volumetric measurements). The long-wave infrared camera is indicated for capturing thermal images to aid in the measurement of thermal intensity data of a part of the body or 2 body surfaces. Both components of the Scout are noncontact with respect to the patient and provide an adjunctive tool to help a trained and qualified healthcare professional measure and record external wound and body surface data. The Scout is considered safe to use (for both patient and user) for capturing both visual and thermal images.

Institutional review board approval was obtained for this study, and it was conducted in compliance with the protocol, good clinical practices, and all applicable regulatory requirements. All investigators were trained on the protocol and the proper use of the device and software. There was no anticipated benefit to the study subjects who participated in this study. However, the images collected and results may lead to the improved care in the future.

Regulatory Bench Testing: Interdevice and Intradevice Reliability

At the request of the US FDA, a number of bench tests were required in order to fulfill the Scout device's 510(k) approval. These tests focused on the consistency and sensitivity of the thermographic temperature data provided to clinicians. The bench tests that were performed are described below.

Bench Test 1: Accuracy of Thermal Image Data Utilizing Scout at Varied Angles

Thermographic images were acquired at multiple angle variances while focused on a calibrated blackbody target. Baseline temperature of the blackbody target was captured at an X, Y coordinate of 0,0 degrees. After a baseline was determined, temperature measurements were then captured at 8 different angle variances of +30,0; +45,0; -30,0; -45,0 degrees; and 0,+30; 0,+45; 0,-30; 0,-45 degrees. The temperature measurements of the multiple angle variances were then compared with baseline to formulate a temperature differential.

There was a minor variation in the thermographic data measured. The average temperature differential across 3 devices at all angles was 0.15° C. The largest average variation was seen at angles of 0,+30 degrees and 0,-30 degrees, which resulted in a 0.22° C temperature variation. Because users are instructed to acquire images approximately 90 degrees perpendicular to the body's surface, the data of this bench test suggest that the variation of the angle in which users capture data do not affect the sensitivity of the device's thermographic data.

Bench Test 2: Accuracy of Thermal Image Data for Different Infrared Cameras

Three different sample devices acquired 1 thermographic image every 60 seconds for at least the first 15 minutes, and then images can be captured every 5 minutes. Images were captured for a 45-minute period. This process was repeated 3 times with the blackbody box set to 3 different temperatures (26° C, 32° C, and 38° C) to show that the trend pattern occurs similarly across multiple recorded target temperatures. Minimum, maximum, and mean thermal intensity values were recorded and then plotted to change over time.

The results showed reliability of the Scout to record similar trends between devices. However, because of environmental influences, such as room temperature and internal temperature of the device, it was shown that the device cannot accurately capture absolute temperature. The outcome of this test confirms need for the use of relative temperature.

Bench Test 3: Validation of the Scout Device's Conversion of Pixel Value to Celsius

The Scout device can capture up to 254 unique temperature values, also called pixel values (PVs). To avoid confusing clinicians with PV units, it was important to use a more familiar temperature unit. Thus, it was determined converting PV to Celsius would be more appropriate.

To validate the accuracy of the Scout's conversion of PV into Celsius within a 22° C to 42° C range, a calibrated blackbody box was set to 7 different temperatures within the 20° C window. The Scout measured these different temperatures in PV, converted them to Celsius, and showed a difference in PV between each degree Celsius of 12.7 (+/-2 pixels or +/-0.16° C) throughout the temperature range. Calibrated into a 22° C to 42° C range, the Scout is sensitive to changes in temperature down to 0.08° C.

Bench Test 4: Effect of Room Temperature on the Scout Device's Thermal Image Data

To determine how environmental temperature affects Scout temperature measurement of a calibrated and unchanging target, the Scout was used in multiple environments. Temperature measurement was affected by environmental temperature when the image was captured and the amount of the effect could not be conclusively confirmed from the data collected. The outcome of this test confirms need for the use of relative temperature.

EXAMPLE OF A VISUAL-TO-THERMAL OVERLAY

Bench Test 5: Accuracy of Thermal Image Data Utilizing Scout at Varied Distances

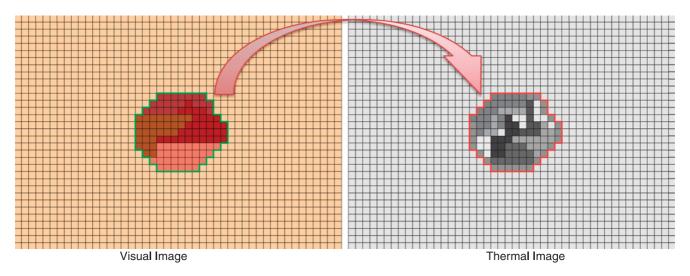
To determine how distance affects the temperature measurement of a calibrated and unchanging target, a distance test was performed to capture temperature at the suggested distance of 18 inches as well as 12 and 24 inches. The temperature variation was not greater than a $+/-0.5^{\circ}$ C per 6 inches of distance change. Furthermore, the largest variation recorded during the test was $+0.24^{\circ}$ C.

DESIGN

A prospective design was used to retrospectively analyze 40 visual and infrared image pairs of 22 independent wounds. Some of the 40 visual and infrared image pairs were the same wound measured on the same subject at different time points and different stages of healing. Thus, the data set included 22 independent wounds. Because the visual and infrared image pairs of "replicate wounds" were taken at different stages of healing, they were deemed independent wounds.

Study Objectives

The study objective was to determine within- and betweenreader agreement of Scout Visual-to-Thermal Overlay placement (moving the wound edge trace from the visual image onto the wound edge signature of the infrared image).



Overlaying the wound edge trace from the visual image onto the thermal image, the Scout provides a congruent anatomical and physiological measurement of a defined area. By accomplishing this, clinicians have the ability to obtain a measurement of size and temperature that allows them to compare future data with past data.

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Figure 1.

Methods

For establishing within- and between-reader agreement of the Scout Visual-to-Thermal Overlay feature, 5 different readers (2 Scout software experts and 3 wound care experts) overlaid a wound edge trace from the visual image and placed it onto the congruent thermal representation of the wound on a thermal image 3 independent

Figure 2.

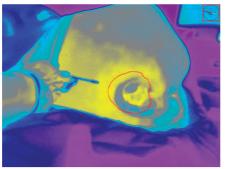
OVERLAYING THE WOUND EDGE TRACE FROM THE VISUAL IMAGE ONTO THE THERMAL IMAGE, THE SCOUT PROVIDES A CONGRUENT PHYSIOLOGICAL MEASUREMENT



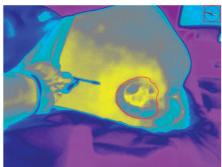
on the visual image, readers click the Overlay button to superimpose the trace onto the thermal image



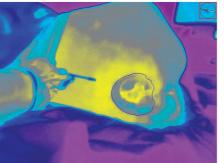
Step 1: After a wound edge trace has been completed Step 2: The Overlay of the wound edge trace is placed in the center of the GSV thermal image.



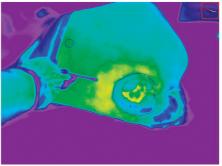
Step 3: Readers can toggle to the Color Filter to provide a clearer distinction of the wound edge's signature.



Step 4: The reader drags the Overlay onto the thermal signature of the wound edge.



Step 5: Once satisfied with the position of the Overlay, the reader double-clicks the mouse to place the Overlay. Once the Overlay is placed, the wound edge trace will turn from red to blue and the thermal intensity data can be extracted.



Step 6: Although not used in this study, the next logical step in the Scout software process would be to select a control area (small circle proximal to wound). This allows for a relative temperature visualization and data extraction

times (see an illustrative example of a Visual-to-Thermal Overlay in Figure 1). Forty different wound image pairs were evaluated by each reader. Some of the 40 wounds were the same wound measured on the same subject at different time points and different stages of healing. Thus, the data set included 22 completely independent wounds. Because the "replicate images" were taken at different stages of healing, however, they were considered independent wounds. The wounds were evaluated in a random order both for each user and for each of the 3 measurements. The step-bystep method for the Visual-to-Thermal Overlay is shown in Figure 2.

Measurements

All readers were trained by the same trainer on the operation of the Scout prior to using the software features. The Scout Visual-to-Thermal Overlay feature is designed to allow clinicians to use an anatomical measurement of the wound on the visual image (area and perimeter) to extract a congruent physiological measurement of the wound on the thermal image (thermal intensity variation data). This is done by taking the wound edge trace from the visual image and overlaying it onto the corresponding thermal signature of the same wound edge. In order to limit the introduction of variability, all 3 readers overlaid the same wound edge trace. This wound edge trace was completed by 1 expert Scout software user.

Once an overlay is placed, the software calculates the thermal intensity mean, maximum, and minimum values, as well as the total differential (difference between maximum and minimum values). Thermal intensity is calculated in the form of a PV from a gray-scale value (GSV) index, which has a range of 1 to 254. The GSV is a measurement index of thermal intensity, which quantifies and visualizes the temperature differences of the body surface. Darker colors reveal a decrease in the passage of thermal intensity through the tissue (cooler), and lighter colors reveal an increase in the passage of thermal intensity through the tissue (warmer). Each PV represents a percentage of a relative degree in Celsius. A PV of 1 is the coolest, and a PV of 254 is the warmest. The Scout device's thermographic imager is calibrated to identify temperature (thermal intensity) within a calibrated range of 22° C to 42° C. This captures both extremes of the human body's temperature spectrum. The PV is to be interpreted as a relative temperature index, and it cannot be used as a substitute or comparison to a systemic, absolute measure of temperature.

In GSV, a PV of 1 is totally black, a PV of 127/128 is a standard gray (halfway between total black and total white), and a PV of 254 is totally white. Because it is difficult for the human eye to distinguish between 254 shades of gray, the Scout software allows users to apply a color filter to the GSV thermal image. Readers had the ability to use this option for easier discernment of the wound's thermal signature (changing the filter does not alter the raw PV data).

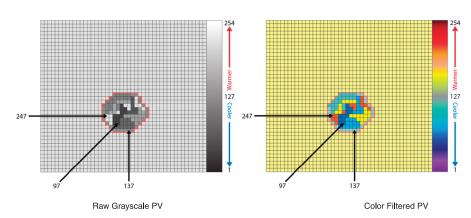
When calculating the thermal intensity data of the overlay, every single pixel and its respective PVs are factored into the equation. The illustrative example below (Figure 3) highlights 3 of the 113 pixels and their respective PVs from within the overlay. All of the pixels and their PVs within the overlay are factored into calculating the end points described in the following section.

End Points

The primary end points are (1) mean temperature (the average of all PVs within the overlay), (2) minimum temperature (the lowest PV within the overlay), (3) maximum temperature (the highest PV within the overlay), and (4) temperature differential (the difference in PV between the high and the low PVs within the

Figure 3.

THIS ILLUSTRATION SHOWS A THERMAL IMAGE IN RAW GRAY-SCALE PIXEL VALUE (LEFT) AND COLOR-FILTERED PIXEL VALUE (RIGHT)



overlay). These calculations are provided in both PV and Celsius (there are 12.7 pixels per 1° C).

Data Analysis

Data were handled according to WoundVision, LLC, data management procedures. The statistical analyses were focused on describing the observed within- and between-reader variability for the identification of the Visual-to-Thermal Overlay. Descriptive statistics for all of the outcome measures were completed. In addition, an analysis for the data set of 40 wounds and for the subset of the 22 independent wounds was completed. Analyses were also completed for subgroups of the expert readers and nonexpert readers.

RESULTS

The results are very similar both within and between readers. The coefficient of variation (CV) for the mean PV both withinand between-readers averages less than 1%, 0.89 and 0.77 respectively (Figures 3 and 4). When examined individually, the minimum within-reader %CV was wound 10, which had a %CV of 0.11. The maximum within-reader %CV was wound 17, which had a %CV of 2.00. For between-reader, the minimum %CV was wound 10, which had a %CV of 0.08. The maximum between-reader %CV was wound 36, which had a %CV of 3.00.

Across all readers and all 40 wounds, the within-reader mean temperature was less than 1 PV (or 0.08° C), and %CV was less than 1.0. Similarly, the maximum temperature was less than 1 PV (or 0.08° C), and the %CV was less than 2% (Table 1).

When converted into degrees Celsius across all 5 readers and all 3 wound replicates, the average temperature differential

Table 1.

WITHIN-READER MEAN AVERAGE OVERLAY FOR ALL READERS AND ALL 40 WOUNDS

	Mean PV	Mean PV %CV	Max PV	Max PV %CV
Reader 1	106.27	.64	129.68	1.53
Reader 2	106.28	.78	129.53	1.64
Reader 3	106.23	.64	129.73	1.44
Reader 4	106.90	.98	130.98	1.58
Reader 5	106.62	.74	129.87	1.39

When converted into degrees Celsius, across all 5 readers and all 3 wound replicates, the average temperature differential is 0.28° C (Table 2). The largest difference observed was 0.63° C, and the smallest difference observed was 0.04° C.

was 0.28° C (Table 2). The largest difference observed was 0.63° C, and the smallest difference observed was 0.04° C (Figure 5).

SUMMARY

The Scout software's Visual-to-Thermal Overlay procedure, as implemented in this study, is very precise. All reader measurements were similar and are reproducible both within- and betweenreaders with a CV well below 5%.

The within- and between-reader precisions of mean temperature measurements are also very similar, reflected by an average %CV of 0.89% and 0.77%, respectively. The maximum temperature average had a within-reader CV of 1.68% and betweenreader CV of 1.52%. The minimum temperature average had a within-reader CV of 0.52% and a between-reader CV of 0.35%. The temperature differential had a within-reader CV of 5.67% and a between-reader CV of 5.88%.

Figure 4.

WITHIN-READER PERCENT COEFFICIENT OF VARIATION (CV) FOR MEAN TEMPERATURE AVERAGED ACROSS ALL 5 READERS

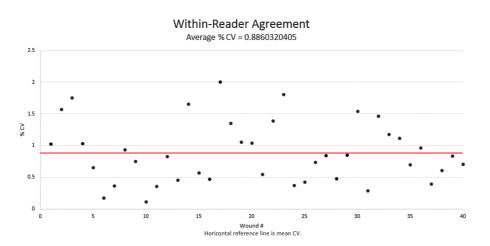


Table 2.

MEAN MINIMUM, MEAN MAXIMUM, AND MEAN TEMPERATURE DIFFERENCE FOR ALL 5 READERS AND ALL 3 WOUND REPLICATES IN DEGREES CELSIUS

No. of Wounds	No. of Reader Observations	Mean Minimum Temperature	Mean Maximum Temperature	Mean Difference Temperature
40	600	30.28° C	30.57° C	0.28° C

No wound measurement varied from minimal to maximum measurements by more than 0.63° C, with the smallest difference observed being only 0.04° C between the maximum and minimum measurements across all 5 readers, all 3 replicates. Across all readers and all wounds, the largest average temperature difference was 0.28° C.

This study demonstrates that the thermal signature of wounds may be delineated repeatedly by the same operator and reproducibly by different operators. Thus, clinicians can integrate a criterion standard visual (anatomical) assessment with a congruent physiological assessment to provide them with knowledge relating to the presence or absence of blood flow, perfusion, and metabolic activity in the wound, periwound, and wound site.

CONCLUSIONS

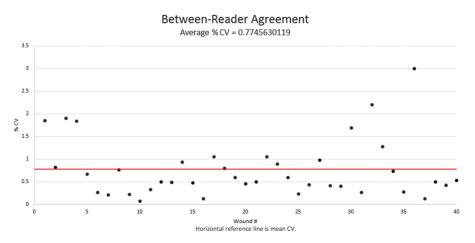
Temperature is an important, albeit underappreciated, characteristic in the assessment of wound development and wound evaluation over time. This underappreciation can be largely attributed to a clinician's inability to identify temperature with ease, accuracy, and precision. This study shows how these limiting factors have been overcome and allows for clinicians to harness these data in a way never before possible. The ability to harness temperature data as they relate to the physiology of skin and underlying tissue may offer healthcare providers a valuable tool for identifying preclinical changes associated with wound development and wound healing.

For example, using temperature to assess pressure ulcer development begins with the identification of sDTI, which results from the combination of pressure, shear, and frictional forces leading to tissue damage.⁵ These forces cause soft-tissue distortion that leads to reduction of blood flow to an area (ischemia, cell distortion, impaired lymphatic drainage, impaired interstitial fluid flow, and reperfusion injury).^{6–8} These pathophysiological changes lead to changes (increase or decrease) in the temperature of the affected tissue, which causes changes of the body surface (skin) temperature. Previous studies suggest that temperature measurement can assist in the detection of underlying skin necrosis and as an objective, noninvasive, and quantitative means of early DTI diagnosis.^{6,9}

In regard to temperature and pressure ulcer evaluation, all wound healing is dependent on vascularization. This translates to perfusion, which, in turn, translates to metabolic activity, ultimately increasing temperature.^{10,11} This increase in temperature is manifested in the form of inflammation or, in some cases, infection, which can be a barrier to healing. Conversely, without vascularization, there is no perfusion or metabolic activity. This ultimately results in a decrease in temperature. This decrease in temperature is manifested in the form of indequate tissue

Figure 5.

BETWEEN-READER PERCENT COEFFICIENT OF VARIATION (CV) FOR MEAN TEMPERATURE AVERAGED ACROSS ALL 5 READERS



perfusion or, in some cases, ischemia, which can also be a barrier to healing, as well as tissue necrosis. $^{10}\,$

The Scout software's ability to provide accurate and reliable quantitative measurements of size (and qualitative documentation) through anatomical structural imaging (visual image) is the foundation for obtaining a congruent measurement of temperature through physiologic functional imaging (long-wave infrared thermography). Clinicians now have the option to rely on more than just paper rulers and their naked eye with technologies such as the Scout device. By combining the repeatability and reproducibility of the Scout's visual and thermal software measurements, clinicians can combine clinical judgment with quantitative and objective documentation.

The Scout software application could potentially benefit the telemedicine approach to wound care. With the number of individuals 65 years or older continuing to increase, providers will need to "think outside the box" for ways to approach wound care. The ability for clinicians to remotely evaluate skin and wounds using the Scout's visual and thermal images has been proven to provide accurate and repeatable measurements of size and temperature. These quantitative and objective data are also combined with qualitative documentation of skin and wound appearance. The ability for 1 wound care expert to oversee operations at 1 or more facilities could increase not only the efficiency, but also the scope and effectiveness of care that providers can offer.

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