Is Thermal Imaging a Useful Predictor of the Healing Status of Diabetes-Related Foot Ulcers? A Pilot Study

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Abstract

Introduction: In clinical practice, both area and temperature of the ulcer have been shown to be effective in tracking the healing status of diabetes-related foot ulcer (DRFU). However, traditionally, the area of the DRFU is measured regardless of the temperature distribution. The current prospective, observational study used thermal imaging, as a more accurate tool, to measure both the area and the temperature of DRFU. We aimed to predict healing of DRFU using thermal imaging within the first 4 weeks of ulceration.

Method: A pilot study was conducted where thermal and color images of 26 neuropathic DRFUs (11 healing vs 15 nonhealing) from individuals with type 1 or 2 diabetes were taken at the initial clinic visit (baseline), at week 2, and at week 4. The thermal images were segmented into isothermal patches to identify the wound boundary and area corresponding to temperature distribution. Five parameters were obtained: temperature of the wound bed, area of the isothermal patch of the wound bed, area of isothermal patch of periwound, number of isolated isothermal patches of the wound region, and physical wound bed area from color image. The ulcers were also measured by experienced podiatrists over 4 consecutive weeks and used as the healing reference.

Results: For healing cases, the ratio of the area of the wound bed to its baseline measured using thermal images was found to be significantly lower at 2 weeks compared to nonhealing cases and this corresponded with a 50% reduction in area of DRFU at 4 weeks (group rank-based nonparametric analysis of variance $P = .036$). In comparison, neither the planimetric area measured using color images nor the temperature of the wound bed was associated with the healing.

Conclusion: This study of 26 patients demonstrates that change in the isothermal area of DRFU can predict the healing status at week 4. Thermal imaging of DRFUs has the advantage of incorporating both area and temperature allowing for early prediction of the healing of these ulcers. Further studies with greater sample sizes are required to test the significance of these results.

Keywords

thermal imaging, diabetes, diabetes-related foot ulcer, wound healing

It is estimated that 415 million people worldwide have diabetes, and the prevalence of diabetes-related foot ulcer (DRFU) is in the order of 4% to 10%.^{1,2} In the United States, DRFUs are the most common diabetes-related complication requiring hospitalization.³ The lifetime risk for developing these ulcers among people with diabetes is estimated to be 19% to 34%.⁴ While careful management can generally lead to healing of ulcers within 12 weeks, a significant number of the

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ulcers do not heal by 12 weeks, resulting into further complications, such as amputation.³

Chronic foot ulcers impose a substantial burden on people with diabetes and to the health care system with an associated care cost of up to \$13 billion a year.⁵ To prevent the complications of these ulcers such as amputation, a comprehensive management plan is required for which the clinicians need to identify nonhealing ulcers and to concentrate their efforts to prevent complications. A reported method to predict healing of DRFU is based on the comparison between the change in surface area of the ulcer in week 1 to week 4, with week 1 corresponding to the first visit of the person with diabetes to the clinic.⁶ If the rate of reduction in ulcer size within the first 4 weeks of ulceration is more than 50%, the ulcer is considered to be on a healing trajectory.⁶ The surface area of an ulcer is generally measured by planimetry technique using either acetate film, medical ruler, 2D color image analysis or the use of wound measurement software systems that incorporate 3D analysis. However, in some of these methods, the ulcers are often assumed to have a simple shape, and to overcome this, advanced measurement software systems have been introduced.⁷

With advancement of medical optics and technologies, the area and volume of DRFU can be simultaneously measured using wound measurement software systems that incorporate 3D analysis.⁸ In such systems, the 3D image is constructed using two laterally displaced 2D imaging systems known as stereo camera. However, a relatively high error can be observed for small and shallow ulcers.⁹

In recent years, thermal imaging^{10,11} has been investigated to predict the healing status of DFUs.¹² It has potential advantages of providing information about systemic or local thermal anomalies in the tissue such as ischemia, trauma and presence of inflammation by demonstrating temperature variations underlying the skin surface.¹³

Thermal imaging techniques compare the images of the two feet to obtain skin temperature and perform asymmetrical analysis by subtracting mean temperature of the nonulcerated foot from the corresponding value of the ulcerated one.¹⁴⁻¹⁶ Previous studies using this technique have empirically determined the difference between the two limbs of 2.2°C as sign of abnormality in skin circulation and haemodynamics.¹⁷⁻¹⁹ The limitations of such studies are that they used the contralateral foot as a reference for detection of ulcers in the ipsilateral foot. This method would fail if the contralateral foot also has ulcers or has the potential of ulceration or if it is affected by the same underlying disease process. Another limitation is that there are number of other reasons which may cause change in the temperature such as inflammation or ischemia, which are both commonly seen in diabetes. Therefore, using the contralateral foot in the method of analysis could potentially lead to erroneous results.

In this work, we have proposed a method to measure area of the ulcer using thermal camera and used the newly defined area to predict the healing of DRFUs. Our hypothesis is that

area of ulcers observed under thermal images is different to the area which can be seen by naked eye or under any other imaging devices. This is due to the difference between boundaries of ulcer obtained from temperature data (emitted infrared light) and the emitted visible light as captured by naked eye or other conventional imaging systems. Therefore, reduction in the area of the ulcer obtained using thermal images may show better association with healing status of DRFUs compared to the area measured by conventional techniques. Primary outcome measure of this study was the association between the ratio of the area of wound bed in week 2 to area of the same wound in week 1 (the baseline measure) and the healing status of the DRFU. The wound bed is defined as the region which includes the wound base. The periwound region is defined as the region surrounding and enclosing the wound bed.

This prospective observational study investigated whether changes in DRFU area, as determined by thermal imaging, can identify the chronic cases earlier than the current 4 weeks. For this purpose, it was investigated if the thermal image at baseline, compared to week two can predict the healing trajectory better than the area measured using traditional imaging methods. We also investigated other features of thermal images such as temperature of the wound bed and periwound to determine the association of these feature with the healing status of chronic DRFUs at the early stage of ulceration.

Methodology

Participant Recruitment

Inpatients and outpatients with both type-I and II diabetes aged 30 and over who attended Austin Health, Melbourne, Australia for the management of DRFU, were recruited in this prospective, longitudinal, observational study. Austin Health is a large tertiary hospital in Melbourne, affiliated with the University of Melbourne. This study was approved by the Austin Health Human Ethics Committee (Ref. No. LNR/15/Austin/51) and participants provided written consent.

In total, 26 patients with plantar neuropathic DRFU (11 healing and 15 nonhealing cases) were recruited into this study over a 12-month period. This study required the patients to attend the clinic for weekly follow-ups for a total of 4 weeks. The patients had their ulcer treated according to the Australian National Evidence Based Guidelines on Prevention, Identification and Management of Foot Complications in Diabetes.²⁰ All the ulcers received routine care by the podiatrists and endocrinologists during the study period including routine care for dressing, adequate offloading and use of antibiotics where necessary. Exclusion criteria for this study were ischemic and postamputation ulcers and the ulcers which were complicated by factors such as osteomyelitis and tissue infection. None of the wounds had tunneling or were undermined.

Table 1. Baseline Characteristics With Their Measured Values and Interquartile Range (IQR).

Baseline characteristic	Measure	IQR, 25th-75th percentiles
Median age	62 years	56-71 years
Ratio of type 1/type 2 diabetes	8/18	—
Median of duration of diabetes	20 years	14.5-25.5 years
Median HbA1c	7.9%	7.2-9%
BMI	28.6 kg/m ²	26.3-31.4 kg/m ²
Hemoglobin concentration	134 g/L	118-144 g/L

Three independent observers consisting of two podiatrists and one endocrinologist observed the ulcers. The ulcer was manually measured using a measuring scale by the podiatrist though the measurements obtained from the image analysis were instead used for the analysis. Healing status of the ulcers was determined based on 50% reduction in the ulcer area at 4 weeks and checked according to the podiatrists' report for complete epithelialization by week 12, which was considered as the label and reported in this study.

Baseline Characteristics

Eight clinical data parameters, that is, duration of diabetes, presence of diabetes microvascular and macrovascular complications, blood pressure, smoking, estimated glomerular filtration rate (eGFR), and body mass index (BMI) were recorded at baseline. Baseline blood tests were performed at the Austin Health Pathology Department.

85% of the study participants were males and 52% had peripheral vascular disease (PVD) defined based on ankle brachial index (ABI) <0.9 and/or angiographic evidence of lower limb arteries stenosis and/or total occlusion. Of the participants, 60% had diabetic retinopathy and 85% had hypertension defined by past history of hypertension, or use of antihypertensive or BP > 140/80, and 83% had dyslipidemia as defined by low HDL and/or high triglyceride, high LDL with or without statin therapy. A summary of the participants' baseline characteristics is provided in Table 1.

Data Collection

All the experiments were performed in the hospital with temperature regulated at 25°C. Sufficient resting time (minimum 15 minutes) was given prior to recording the data to stabilize blood circulation. All the ulcers were photographed using Fluke-TiR1 infrared thermo-imaging camera. This is a non-contact tool that detects the superficial temperature at every point on a target (here, diabetes-related foot ulcers) which can be used for the detection of tissue inflammation. The temperature measurement range of this camera is -20°C to 150°C and the temperature measurement accuracy is ±2°C or 2% (at 25°C, whichever is greater). Color images were

also collected using Nikon D90 DSLR camera for manual tracing of the DRFU contour and measurement of the ulcer area as the reference for comparison purpose. The area was also measured onsite in mm² by podiatrists using medical ruler and the greatest length times using the greatest width method. The area was measured over 4 consecutive weeks starting from the time of ulceration, after performing appropriate debridement if needed. Color and thermal images were collected in the first 2 weeks. Data collection was undertaken in a closed room with stable and regulated temperature. The emissivity parameter of thermal camera was set to 0.98, corresponding to the emissivity of clean human skin.²¹ Emissivity is a measure of surface radiation and absorption efficiency, which is required for characterization of human skin temperature using optical devices.²² Due to a large variation in pressure distribution across different part of the feet and in order to remove the confounding effect of such factor on the healing trajectory, only plantar ulcers were included in this study and the heel and dorsal DRFUs were excluded. To avoid any bias in the measurement of area, the ulcer area was measured from the RGB images using the advanced automated image processing methods.

Thermal Image Analysis

The thermal images for each patient were manually aligned to remove interexperimental rotation, translation, and skewness variability to ensure accurate comparison between these images. This was performed using a measuring ruler placed next to the ulcer and which was included in the picture and using the toes and heel edges as the reference points for image alignment. Only the edges of the feet were used as reference for alignment using custom-made supervised edge detection and alignment software based in MATLAB®, Mathworks, USA platform.

The temperature data (in degrees Celsius) was rounded to the first decimal point and isothermal maps were created from the aligned thermal images. The isothermal regions are the regions with the same temperature and these regions corresponding to the wound bed and periwound were identified using MATLAB. This created images as shown in the figure and boundaries of the patches were considered as the boundary of the wound bed and periwound. The wound bed was considered as the region over which the temperature was the same, while the region surrounding the wound bed having a different temperature was assumed to be the periwound region. The isothermal maps were further investigated to obtain the median temperature of the ulcer and periwound as well as the total number of independent isothermal patches.

Color Image Analysis

Color images corresponding to each patient were aligned to remove interexperimental rotation, scale and skewness variation. The toes and heel edges a measuring ruler placed next

Figure 1. Example of a healing ulcer. (a) Color image at baseline. (b) Isothermal image at baseline. (c) Color image of week 2. (d) Isothermal image of week 2.

to the ulcer and which was included in the picture were used as the reference points. DRFU contours were traced using the custom made supervised software in MATLAB. Total number of pixels enclosed by the wound bed contour was considered as the area of the ulcer.

Statistical Analysis

This study considered the use of reduction of the DRFU area from week 1 to week 4 by 50% obtained using color images as the gold standard for healing characterization. The primary aim of this study was to test if the change in the isothermal areas of DRFUs in the first 2 weeks corresponded to the healing as determined using 50% reduction in the DRFU area obtained from the color images. The study also investigated the association of the temperature of the wound bed, its periwound, and the number of isothermal patches with the healing characteristics.

Descriptive statistics, median and IQR of the patients' baseline characteristics and quantitative parameters defined above, were computed. Nonparametric Kruskal-Wallis test was performed to determine the association between the ratio of DRFU parameters obtained over the first and second weeks of ulceration (ratio of week 2 to week 1) with the healing status of the ulcer at week 4; more than 50% reduction in area at week 4 was considered as timely healing ulcer trajectory.⁶ All statistical analyses were performed in Minitab® v.17.1.0.

Results and Observations

Figure 1 demonstrates the color and isothermal image of the first and second week of a DRFU classified as healing ulcer, based on its area reducing to less than 50% at week 4. Figure 2

Figure 2. Example of a nonhealing ulcer. (a) Color image at baseline. (b) Isothermal image at baseline. (c) Color image of week 2. (d) Isothermal image of week 2.

demonstrates the color and isothermal image of a nonhealing DRFU, area of which did not reduce to less than 50% at week 4. Visual comparison of the color images of weeks 1 and 2 of a healing ulcer (Figures 1a and 1c) did not indicate reduction in the size of the ulcer. On the contrary, comparison of images of weeks 1 and 2 (Figures 2a and 2c), the nonhealing ulcer appears to be reducing in size.

Visual comparison of isothermal patches in Figures 1b and 1d shows that the size of the wound bed and periwound region reduced from week 1 to week 2. According to Figures 1d and 2d, the heat map across the plantar region for healing ulcer was more homogenous compared with nonhealing DRFU. It is also observed that the nonhealing ulcer had higher number of isolated isothermal patches and hot-spots, nonuniform tissue perfusion and increased inflammation around fifth metatarsal head. This indicates that the isothermal patches obtained from the thermal images in weeks one and two are useful in identifying nonhealing DRFU (or the ones with delayed healing).

Table 2 summarizes changes in DRFU parameters from baseline to week 2 as measured using thermal and color images. This table demonstrates the median and average rank values of healing compared to nonhealing ulcers based on their status at week 4. Compared to baselines, we observed a reduction in wound bed area at week 2 using thermal images which was found to be significantly associated with 50% reduction in size of the ulcers ($P = .036$). In contrast, there was no association between area using color images

Table 2. Kruskal-Wallis Test—Association Between Different DRFU Parameters and the Healing Status at week 4 (ie, more than 50% reduction in area) $n = 26$.

		Healing			Nonhealing			H	P value
Week 2/week 1 (ratio)		Median	Mean	SE	Median	Mean	SE		
Thermal	Wound bed area	0.31	5.67	3.82	1.312	10.72	5.40	4.42	.036
	Temperature of wound bed	0.986	0.962	0.034	0.990	0.994	0.015	0.57	.452
	Temperature of periwound	0.975	0.955	0.031	1.000	0.998	0.017	1.25	.264
	Periwound area	0.691	2.57	1.65	0.880	8.90	4.90	1.25	.264
	Total no. of isothermal patches	0.993	0.967	0.036	1.020	0.993	0.017	0.00	.979
Color	Wound bed area	1.193	1.165	0.112	1.093	1.184	0.205	0.49	.484

and change in ulcer area over this time ($P = .484$). Similarity to the examples provided in Figures 1 and 2, while color images of change in area of ulcer from baseline and week 2 are not associated with change in area observed at week 4, the thermal images were significantly associated with change in area at week 4.

Discussion

The most important finding of this prospective, observational study was that area of the DRFU obtained for thermal images is different to the area that is observable by eye or using color images and that the thermal images can be used to predict the healing of DRFU. We have shown the use of thermal imaging for assessment of chronic DRFUs. This study has demonstrated the change in the DRFU area from week 1 to week 2 of the wound bed obtained from the isothermal maps of the thermal images was suitable to predict the healing trajectory ($P = .036$). A similar area obtained from color images was unable to predict the healing trajectory ($P = .484$). We found that the median temperature of the DRFU in the first 2 weeks was not associated with the healing trajectory.

DRFUs present a major personal, economic cost and burden for people with diabetes as well as for their clinicians. These chronic DRFUs can lead to amputations; however, they can be prevented by early detection and appropriate treatment plan.²³ The treatment plans require estimating the healing trajectory, and whether with standard care alone the ulcer will heal over a 12-week period or whether there is a need to alter the treatment. Current practice is imprecise and requires monitoring the ulcer for over 4 weeks after first presentation before making a decision as to the healing status of the DRFU. Currently, there is an undesirable delay of up to 4 weeks in development of treatment plan and making decision on whether other therapies should be used. There is therefore a need for earlier identification of the healing status of these chronic ulcers.

Previous studies, using thermography of the foot, have demonstrated association of changes in foot temperature with risk of developing ulcers on the feet, neuropathic and

ischemic conditions^{24,25} and used the temperature for prediction of the healing trajectory of the ulcers.¹⁴ These studies have considered the absolute temperature of the foot as the variable and identified the association of the healing based on the difference of the median temperature of the contralateral and ipsilateral feet with differences higher than 2.2°C indicating a nonhealing or delayed healing ulcer. However, this approach makes several assumptions that may not always be valid. It assumes that the contralateral foot is not ulcerated or well perfused and the patient has no PVD, which however is often not valid. The other assumption of this approach is that the temperature distribution in the plantar section of the foot is homogenous; however, our study has shown that based on the patients' condition, the thermal map of the plantar section of the foot may not be homogenous (depending on the types of complications) and there are differences in the temperature distribution in wound bed, periwound, and the rest of the foot.

While earlier studies have considered the temperature of the foot as an indicator of the healing of the ulcer, our work has considered the thermal distribution of the foot. One advantage of the proposed method is that unlike other techniques, it does not rely on measurement of contralateral foot as a reference for prediction of the ulcer status on the ipsilateral foot. This will allow for independent analysis of each foot and the results will not be affected even if the contralateral foot has ulcers or potential of ulcers.

Our findings have shown that the proposed isothermal mapping technique can be used to indicate area of inflammation which is associated with the healing trajectory of the DRFUs. If the prognostic factors and patients' clinical information are taken into account, the proposed feature can be used to model the healing rate of DRFU at early stages and make appropriate management decisions.

We recognize the limitations of the current study. This study included only plantar neuropathic DRFUs to have a matched database according to the ulcer type and to limit the ascertainment bias as DRFUs are multifactorial the reported outcome may be valid only for these two types of ulcers. Another limitation is that patients with osteomyelitis and ulcer infection were not included in the current study due to

limited numbers and limit the risk of bias, although being important factors for prediction of the healing trajectory. This work studied only DRFUs with limited sample size, and the conclusions made may not be generalizable to all foot ulcers. This study focused only on one significant finding (ie, wound bed area) as 5 out of 6 measurements were not statistically significant. Also, the result of multiple comparison test and control for the familywise error rate has not been reported. This study was performed inside the temperature-controlled hospital rooms, and we did not investigate the effect of ambient conditions on the measurements.

Conclusion

In this prospective observational study, we explored for the first time the application of thermal imaging for assessing DRFUs, which may have delayed healing based on the measurement of the area of DRFU in weeks 1 and 2. The novelty of the method was in the method of segmentation of thermal images into isothermal patches, taking the area of the patch corresponding to wound bed and periwound as the area of the ulcer. We have found that, unlike conventional area measurement method, measurement of ulcer area using isothermal patches is more accurate for early healing prediction.

Further studies are required to confirm the current study findings because of the relatively small number of wounds (26) that were investigated. Future studies will also need to investigate thermal images for detection of the area of inflammation and ischemic region, which may not have any visual apparent sign and will use these images to predict the healing status of the ulcers. Furthermore, other studies investigating whether the changes in the isothermal area will be monitored and compared over a longer period of time (ie, 12 weeks), which could have application for early prediction of skin breakdowns of the ulcers and the risk of reulceration. Another limitation of this study is that we did not collect all the relevant information suggested by Jeffcoate et al,²⁶ which should be considered for future studies.

Abbreviations

ABI, ankle brachial index; BMI, body mass index; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; DRFU, diabetes-related foot ulcer; eGFR, estimated glomerular filtration rate; IQR, interquartile range; PVD, peripheral vascular disease.

Acknowledgments

This study was approved by the Austin Health Human Ethics Committee and participants provided written consent. The data have consent for publication. The deidentified datasets generated and/or analyzed during the current study are not publicly available as they remain property of the university and for preserving privacy of data for further investigation but are available from the corresponding author on reasonable request. We would like to acknowledge the assistance of the vascular unit at Austin Health.

Declaration of Conflicting Interests

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