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ORIGINAL ARTICLE

# An explorative study on the validity of various definitions of a 2·2°C temperature threshold as warning signal for impending diabetic foot ulceration

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**Key words**
Diabetic foot; Home monitoring; Infrared thermometer; Prevention; Skin temperature

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## Abstract

Home monitoring of skin temperature is effective to prevent diabetic foot ulceration. We explored the validity of various definitions for the >2·2°C left-to-right threshold used as a warning signal for impending ulceration. Twenty patients with diabetes and peripheral neuropathy monitored their skin temperature with an infrared thermometer at the plantar hallux, metatarsal heads, midfoot and heel four times a day for 6 consecutive days. Environmental temperature and walking activity were monitored and associated with foot temperature. The average temperature difference between feet was 0·65°C. At single locations, a left-to-right temperature difference of >2·2°C was found 245 times (8·5% of measurements). Confirmation of these above-threshold readings on the following day was found seven times (0·3%). Corrected for individual left-to-right mean foot temperature differences, this reduced to four (0·2%). No ulcers developed in the week after monitoring. Left-to-right foot temperature differences were not significantly correlated with walking activity, environmental temperature or time of day. The >2·2°C left-to-right foot temperature threshold for impending ulceration is not valid as single measurement, but validity improves to acceptable levels when an above-threshold temperature difference is confirmed the following day and further improves with individual correction. The threshold is independent of time of day, environmental temperature and walking activity.

## Introduction

Diabetic foot ulcers are a major contributor to morbidity and mortality as well as increased health care costs (1,2). Due to diabetic peripheral neuropathy, patients often do not recognise that their feet are injured until an ulcer appears. Identifying a method to warn people with diabetes and peripheral neuropathy of an impending complication is therefore necessary as daily inspection alone does not suffice (3).

Inflammation and enzymatic autolysis are early signs of tissue breakdown; this causes skin temperature to increase,

### Key Messages

- twenty diabetic patients monitored their foot skin temperature with a handheld infrared thermometer to explore the validity of various definitions for the >2·2°C left-to-right foot temperature difference threshold used as warning signal for impending foot ulceration
- a left-to-right foot temperature difference >2·2°C was found in 8·5% of measurements, while no ulcers developed in the week after skin temperature monitoring; this reduced to 0·2% when confirmed the following day and individually corrected

- left-to-right foot temperature differences were not significantly correlated with walking activity, environmental temperature or time of day
- the >2·2°C left-to-right foot temperature threshold for impending ulceration is not valid as single measurement, but validity improves to acceptable levels after subsequent confirmation the following day and further improves with individual correction

leading to a local temperature difference between the affected and the unaffected limb (4,5). This physiological characteristic has prompted several trials using home monitoring of foot skin temperature as a potential warning method for early detection of impending diabetic foot ulceration (6–8). From these trials, there is evidence that supports home monitoring by means of a hand-held infrared skin thermometer as an effective strategy to prevent diabetic foot ulcers (6–8). The crucial temperature threshold in these studies was a >2·2°C difference between similar locations on both feet, serving as the warning signal for impending ulceration. Despite the importance and great clinical need of interventions to prevent diabetic foot ulceration and the positive results from these trials, there has been limited implementation of home monitoring of foot temperature in routine foot care of high-risk patients with diabetes (9).

Several factors might explain the lack of adoption of home monitoring, for example, absence of easy access to calibrated equipment, insufficient information on cost effectiveness or issues related to feasibility (9). Furthermore, patient values and preferences may also hinder implementation (9). A recent case series reported a sensitivity value of 76% and a specificity value of 40% of the 2·2°C temperature difference used to detect the early development of foot ulceration (10). These findings imply that high numbers of false negatives and, especially, false positives may be expected when home monitoring of foot temperature is implemented in daily practice. Such false test results may be of concern to patients and affect their confidence in the method (9). However, this study was performed in an outpatient clinic setting and does not reflect true home monitoring.

In one of the randomised controlled trials, the authors chose to use two above-threshold measurements on consecutive days as a warning signal, rather than the single threshold exceeding measurement used in the previous studies (8). This questions if time between measurements and repetition of measurements plays a role in adequately applying temperature measurements to warn for an impending ulcer as it allows for temporary fluctuations in foot skin temperature. However, changes in foot skin temperature over time have not been studied in people with diabetic neuropathy.

Foot skin temperature, when measured over time or monitored at home, may be affected by various factors. For example, it can be hypothesised that daily variations in foot temperature, environmental temperature and ambulant activity could influence outcomes. It is also unknown whether the foot temperature of the left and right foot, under normal, non-pathological, conditions, is always similar in people with diabetes and neuropathy. This is crucial as the temperature difference between the left foot and right foot is used as the threshold marker (6–8,11,12), and consistent or fluctuating between-foot temperature differences will affect this outcome. To improve diagnostic values of home monitoring of foot skin temperature by individuals with diabetes, more insight on factors influencing foot skin temperature is needed.

The aims of this study were to explore the validity of various definitions used for the >2·2°C left-to-right foot temperature difference used as a warning signal for impending ulceration and to investigate the associations of this difference with baseline foot skin temperature, walking activity, time of day and environmental temperature.

## Methods

A convenience sample of 20 patients with diabetes mellitus type 1 or 2 was included. Patients were eligible for this study if classified in risk group 1 or 2 using the International Working Group on the Diabetic Foot (IWGDF) risk classification system (13,14), that is, diagnosed with peripheral neuropathy with or without a foot deformity or peripheral artery disease, but without a history of foot ulceration or amputation. They also had to be able to use the temperature measurement equipment at home. Participants were included from the multidisciplinary foot clinic of Ziekenhuisgroep (Hospital Group) Twente, Almelo and Hengelo, the Netherlands. Prior to the study, participants were screened by a podiatrist. Neurological examination consisted of assessment with the Semmes-Weinstein monofilament and tuning fork (14). Loss of protective sensation was defined as two out of three incorrect answers after application of the monofilament or tuning fork, in line with current guidelines (14). Vascular examination was performed by palpating the dorsalis pedis and the posterior tibial arteries. Patients with a history of peripheral artery disease or absence of palpable pulses of Arteria tibialis posterior and Arteria dorsalis pedis of one foot were excluded.

Prior to the start of the study, informed consent was obtained from each participant. The Medical Ethical Committee Twente approved the study protocol (NL53105044.15), and the study was registered in the Dutch Trial Registry (www.trialregister.nl; NTR5209). The study was conducted in accordance with the principles of the Declaration of Helsinki.

### Foot temperature measurements

During the initial visit, participants were shown how to use the measurement equipment, while baseline foot temperatures were collected simultaneously. A handheld infrared thermometer (TempTouch; Diabetica Solutions Inc., San Antonio, TX) was used to measure the plantar foot skin temperature. Six plantar foot locations were measured: hallux; first, third and fifth metatarsal head; central midfoot; and heel (6–8,11,12). The participants measured foot skin temperature four times per day for 6 consecutive days: (i) just after waking up; (ii) between 11·00 and 13·00 hours; (iii) between 17·00 and 19·00 hours and (iv) just before going to bed. The foot skin temperature was measured immediately after the patient woke up or had taken off their shoes and socks. Participants recorded the results and the time of measurement in a diary. Participants were instructed to contact the researcher if they recorded a temperature difference

 

>2·2°C between identical locations on the left and right foot. The researcher would advise the participants to reduce their activities and contact the researcher again if the temperature difference persisted the next day. Participants were instructed to measure temperature at these six sites only and not to change or add measurements based on potential clinical presentations (e.g. redness).

### Activity monitoring

To monitor walking activity, a Stepwatch™ Step Activity Monitor (Orthocare Innovations LLC, Mountlake Terrace, WA) was used. The device was fitted just above the ankle. In addition, participants completed a description of their daily activities in their study diary.

### Environmental temperature

The environmental temperature was measured at each of the four time points per day in the same room where the skin temperature measurement took place using a standard thermometer (TFA Dostmann GmbH & Co, Wertheim-Reicholzheim, Germany). Environmental temperatures were recorded in the study diary.

### Data analysis

The left-to-right foot temperature difference was first calculated at an individual level (i.e. difference between warmer and colder foot), after which the mean difference across patients was calculated over these individual outcomes. The same method was used to calculate the mean left-to-right difference per location. These outcomes were calculated at baseline and for the entire study period.

An 'impending ulcer warning signal' was defined in three different ways as different definitions have been used in previous studies (6–8,10–12):

- Definition 1: Observing a >2·2°C difference at identical locations on the left and right foot at a single measurement
- Definition 2: Observing a >2·2°C difference at identical locations on the left and right foot during two subsequent measurements
- Definition 3: Observing a >2·2°C difference at identical locations on the left and right foot during one measurement and during the measurement at the same time the following day

False-positive outcomes (i.e. warning signal without subsequent development of a foot ulcer) and false-negative outcomes (i.e. no warning signal despite development of a foot ulcer) using each definition were counted.

Additionally, individualised thresholds were calculated using the baseline mean temperature difference between the left and right foot. Instead of the >2·2°C threshold, a threshold of [2·2°C – (baseline temperature difference)] was used for the colder foot and a threshold of [2·2°C + (baseline temperature difference)] for the warmer foot. The same three definitions for an impending ulcer warning signal were then applied using this individualised threshold, and false-positive and false-negative outcomes were again assessed.

The mean individual left-to-right temperature difference was used in the calculation of the Pearson correlation coefficient to investigate the association between foot skin temperature differences and walking activity, time of day and environmental temperature. The statistical analyses were carried out using the statistical package for the social sciences (SPSS, IBM Corporation, Armonk, NY).

## Results

Of the 20 patients included, 12 were female. The mean age was 73 years (range: 55–86; SD: 8 years). Of the patients, 18 were diagnosed with type 2 diabetes, and 14 were classified as IWGDF risk category 1 (i.e. six as risk category 2). The total number of temperature measurements performed was 2880, and there were no missing measurements.

None of the participants developed an ulcer during the study period, and neither was abundant callus, a blister or haemorrhage (known pre-signs of ulceration) present during or at the end of the study (14). Examination of the data from the diaries showed that the majority of participants had a daily routine for their temperature monitoring and fixed times for monitoring the temperature.

At baseline, the mean temperature difference between the left and the right foot was 0·65°C across patients, with the largest mean difference (1·2°C) found at the hallux (Table 1). The right foot was the warmer foot in 12 patients. During the 6-day follow up, the warmer foot was consistently warmer compared to the colder foot, with a mean difference of 0·67°C (Table 2). The largest mean temperature difference (0·9°C) was again found at the hallux (Table 2). Individual analysis per patient showed that 18 patients (90%) presented with a minimum temperature difference of >0·5°C between their feet.

As no ulcer developed in the week after the data collection, all measurements that resulted in a 'warning signal' were considered false positives, whereas we could not calculate false-negatives. When using definition 1, an 'impending ulcer warning signal' was recorded 245 times, 8·5% of measurements (Table 3). The warning signal was recorded 152 times (5·5%) using definition 2 and 7 times (0·3%) using definition 3 as a warning signal. At least one false-positive outcome was found during the 6-day measurement in 95% of the patients (definition 1). This percentage reduced when definitions 2 or 3 were used (Table 3). None of the participants reported a measured temperature difference of >2·2°C to the research team, despite their instructions to do so.

The baseline temperature difference between the left and right foot was used to calculate the individually corrected temperature difference threshold. After correction, the number of false-positive outcomes using definition 1 reduced from 245 to 140, and the number participants with at least one false-positive outcome during the study period reduced from 95% to 80% (Table 3). The reduction in false-positive outcomes after correction was even greater when using definitions 2 and 3, with the best outcomes obtained using definition 3: 0·2% ($n = 4$) false-positive outcomes and 20% of participants with at least one false positive outcomes (Table 3).

**Table 1** Baseline foot skin temperature*

| | | Warmer foot (°C) | Colder foot (°C) | *P*-value | Mean difference† |
|---|---|---|---|---|---|
| All locations | Mean (SD) | 29·9 (1·17) | 29·2 (0·92) | <0·001 | 0·65 (0·40) |
| | Range | 25·7–32·2 | 26·3–32·9 | | 0·40–0·90 |
| Hallux | Mean (SD) | 29·1 (3·02) | 27·8 (2·61) | <0·001 | 1·10 (0·62) |
| | Range | 24·0–34·0 | 23·1–32·9 | | 0·75–1·65 |
| MH1 | Mean (SD) | 29·6 (2·05) | 28·9 (2·06) | 0·001 | 0·60 (0·56) |
| | Range | 26·2–32·6 | 24·8–32·2 | | 0·49–0·91 |
| MH3 | Mean (SD) | 29·7 (2·12) | 29·3 (2·08) | 0·121 | 0·50 (0·52) |
| | Range | 26·2–33·2 | 25·8–32·0 | | 0·22–0·78 |
| MH5 | Mean (SD) | 29·4 (2·16) | 28·8 (2·07) | 0·007 | 0·55 (0·42) |
| | Range | 26·2–32·8 | 25·2–32·6 | | 0·28–0·92 |
| Midfoot | Mean (SD) | 30·8 (1·58) | 30·1 (1·58) | <0·001 | 0·45 (0·40) |
| | Range | 28·2–33·2 | 27·4–33·0 | | 0·19–0·91 |
| Heel | Mean (SD) | 30·0 (2·50) | 29·3 (2·26) | 0·013 | 0·70 (0·72) |
| | Range | 25·2–34·2 | 25·4–33·5 | | 0·57–1·07 |

MH, metatarsal head; SD, standard deviation.

*Values are mean (standard deviation) in °C or as indicated.

†At baseline, the left-to-right temperature difference was first calculated at an individual level (i.e. difference between warmer and older foot), after which the mean difference was calculated over these individual outcomes; the foot with a higher temperature was labelled 'warmer foot', and differences were calculated as 'warmer minus colder', hence always greater than zero. This calculation was performed per location and mean left-to-right difference.

**Table 2** Mean foot skin temperature during study period*

| | | Warmer foot (°C) | Colder foot (°C) | *P*-value | Mean difference† |
|---|---|---|---|---|---|
| All locations | Mean (SD) | 30·6 (1·17) | 29·9 (0·92) | <0·001 | 0·67 (0·54) |
| | Range | 28·3–33·2 | 27·2–33·0 | | (0·39–0·95) |
| Hallux | Mean (SD) | 29·8 (1·80) | 29·1 (2·06) | 0·001 | 0·90 (0·59) |
| | Range | 26·9–32·9 | 25·4–32·6 | | (0·55–1·25) |
| MH1 | Mean (SD) | 30·2 (1·52) | 29·6 (1·81) | 0·029 | 0·68 (0·54) |
| | Range | 28·1–33·0 | 26·6–32·7 | | (0·35–0·91) |
| MH3 | Mean (SD) | 30·3 (1·54) | 29·7 (1·77) | 0·001 | 0·55 (0·53) |
| | Range | 27·7–33·1 | 26·8–33·3 | | (0·27–0·83) |
| MH5 | Mean (SD) | 30·2 (1·54) | 30·0 (1·56) | 0·003 | 0·61 (0·46) |
| | Range | 27·6–33·1 | 26·3–33·2 | | (0·31–0·91) |
| Midfoot | Mean (SD) | 32·4 (1·36) | 31·1 (1·17) | 0·165 | 0·53 (0·42) |
| | Range | 29·3–34·6 | 29·4–34·5 | | (0·29–0·82) |
| Heel | Mean (SD) | 30·8 (1·50) | 29·9 (1·66) | 0·023 | 0·70 (0·74) |
| | Range | 27·7–33·9 | 26·9–33·2 | | (0·47–0·93) |

MH, metatarsal head; SD, standard deviation.

*Values are mean (standard deviation) in °C, or as indicated.

†The left-to-right temperature difference was first calculated at an individual level (i.e. difference between warmer and colder foot), after which the mean difference was calculated over these individual outcomes; the foot with a higher temperature was labelled 'warmer foot', and differences were calculated as 'warmer minus colder', hence always greater than zero. This calculation was performed per location and mean left-to-right difference.

The mean temperature difference between the left and the right foot was consistent during the day (ranging from 0·65°C to 0·69°C; Table 4). The correlation coefficient between time of day and the mean temperature difference was low ($r = 0{\cdot}015$, $P = 0{\cdot}885$). The mean number of steps taken per participant per day was 6524 (Table 4). The correlation coefficient between walking activity and the mean temperature difference between both feet was $r = 0{\cdot}001$ ($P = 0{\cdot}970$). In addition, a significant correlation was not found between the absolute foot skin temperature and walking activity ($r = 0{\cdot}001$, $P = 0{\cdot}988$). The correlation coefficient between the environmental temperature and skin temperature difference was $r = 0{\cdot}025$ ($P = 0{\cdot}751$), while a moderate and significant association existed between absolute skin temperature and environmental temperature ($r = 0{\cdot}515$, $P < 0{\cdot}001$).

## Discussion

Foot skin temperature measurements have been shown to be an effective home-monitoring tool for ulcer prevention in individuals with diabetes but are rarely used in daily clinical practice (9). We investigated the validity of the different definitions of the >2·2°C left-to-right foot temperature difference used as a warning threshold in previous studies. The results show that a single measurement of a temperature difference of >2·2°C often occurs without a foot complication occurring after such a temperature difference is measured. This means that a single measurement is not valid to use as a warning signal to prevent foot ulceration, and its use is therefore limited in clinical practice. Confirmation of an above-threshold recording the subsequent day greatly improves validity, and with an individualised

 

**Table 3** Number of false-positive outcomes during 6 measurement days*

| | Cases >2·2°C | Patients >2·2°C† | Cases >2·2°C, after correction | Patients >2·2°C, after correction† |
|---|---|---|---|---|
| Definition 1 | 8·5% (*n* = 245) | | 4·8% (*n* = 140) | |
| Mean (range) | 12 (1–59) | 95·0% (*n* = 19) | 7 (1–28) | 80·0% (*n* = 16) |
| Definition 2 | 5·5% (*n* = 152) | | 2·9% (*n* = 80) | |
| Mean (range) | 7·6 (1–29) | 70·0% (*n* = 14) | 4 (1–16) | 45·0% (*n* = 9) |
| Definition 3 | 0·3% (*n* = 7) | | 0·2% (*n* = 4) | |
| Mean (range) | 1 (1) | 35·0% (*n* = 7) | 1 (*n* = 1) | 20·0% (*n* = 4) |

*Data are numbers (%) or mean [standard deviation (SD)] per patient. Definition 1: Observing a >2·2°C difference at a single measurement. Definition 2: Observing a >2·2°C difference during two subsequent measurements. Definition 3: Observing a >2·2°C difference during one measurement and at the same time the next day.
†Patients with a minimum of 1 false-positive measurement during the week.

**Table 4** Mean temperature difference, activity and environmental temperature during the day

| | Total per day | Measurement 1: ±08·00 hours | Measurement 2: 11·00–13·00 hours | Measurement 3: 17·00–19·00 hours | Measurement 4: 22·00–00·00hours |
|---|---|---|---|---|---|
| Temperature difference between feet (°C) | 0·67 (0·54) | 0·67 (0·53) | 0·69 (0·63) | 0·65 (0·55) | 0·66 (0·49) |
| Range | 0·49–1·20 | 0·49–1·15 | 0·50–1·20 | 0·30–0·90 | 0·39–1·02 |
| CI | 0·50–0·85 | 0·52–0·75 | 0·51–0·82 | 0·32–0·80 | 0·48–0·81 |
| Walking activity (steps) | 6524 (1250) | 204 (68) | 2230 (1076) | 2724 (994) | 1370 (692) |
| Range | 2416–8260 | 62–224 | 560–4202 | 624–4582 | 508–2888 |
| CI | 4416–7790 | 126–220 | 460–3042 | 1930–3772 | 906–2524 |
| Ambient temperature (°C) | 22·8 (2·35) | 22·2 (2·10) | 23·6 (2·4) | 23·4 (2·4) | 22·8 (2·2) |
| Range | 18·0–31·2 | 18·3–27·6 | 18·7–29·2 | 18·7–31·2 | 18–29·3 |
| CI | 22·7–23·7 | 21·8–22·5 | 22·6–23·4 | 22·9–23·8 | 22·5–23·3 |

CI, confidence interval.
*Values are mean (standard deviation) in °C or as indicated.
†The left-to-right temperature difference was first calculated at an individual level (i.e. difference between warmer and colder foot), after which the mean difference was calculated over these individual outcomes.

correction of the threshold, a further improvement is achieved. These findings suggest that for valid home monitoring of skin temperature, a measured left-to-right foot temperature difference of >2·2°C should be confirmed the next day before action is undertaken, which should be preferably based on individualised baseline foot temperature differences.

The validity of the 2·2°C temperature threshold increased most with the use of a corrected threshold based on individual temperature differences at baseline. This highlights the importance of an individual approach in temperature measurement in a complex disease such as diabetes, where multiple factors interact. Our findings are in agreement with a recent study finding differences of >0·5°C in 50% of plantar sites measured in healthy feet (15). Therefore, the baseline temperature differences between the left and right foot need to be measured and taken into account for home monitoring of skin temperature, to optimise validity and reduce false-positive outcomes. Future research should focus on this aspect and use advanced technological devices or smart sensors to continuously monitor foot skin temperature to identify better methods to individualise the warning threshold.

The >2·2°C left-to-right foot temperature difference is not used only as a warning threshold for impeding foot ulceration. In clinical practice, the >2·2°C left-to-right foot temperature difference is an important factor for the diagnosis and treatment in people with acute Charcot neuro-osteoarthropathy (16). The validity of this threshold has not been investigated in this specific patient group. However, the results our study implicate that health care professionals should be cautious with the use of single temperature measurements for major clinical decisions because of variability present within patients and baseline temperature differences between feet.

Environmental factors influencing foot skin temperature differences have not been examined before. We investigated the role of walking activity, time of measurement and ambient temperature and found very low and non-significant correlations with mean skin temperature difference between both feet. Only absolute skin temperature was correlated with ambient temperature, but as this affects both feet, we found no impact on the left-to-right differences. This implies that these variables do not have to be controlled during home monitoring of foot skin temperature when the difference between the left and the right foot is used as warning threshold.

A limitation of the current study was the inclusion of a relatively small group of participants, with none being in the highest risk group for the development of foot ulceration (IWGDF 3 – history of a foot ulcer or amputation) or diagnosed with peripheral artery disease. We chose to exclude these individuals to create a more homogeneous group as existing evidence suggests that foot skin temperature may change at the location of a healed foot ulcer and is influenced by peripheral artery disease (11,17). However, the relatively small sample size limits the generalisability of results. In addition, participants were screened for the presence of peripheral neuropathy using simple diagnostic tools, not capturing the entire extent of neurological disease. The degree of peripheral neuropathy affects absolute

 

skin temperature (11) and might affect temperature difference between feet when different degrees of peripheral neuropathy are prevalent between feet, something that we could not assess. Another limitation was the short time period of this study, with measurements taking place over 1 week only. This precluded us from looking at false-negative outcomes because the chance of an ulcer developing in 1 week in this medium-to-high risk group is quite low. Studies over longer time periods are important for a more complete understanding of the validity of temperature thresholds in home monitoring. The current study was primarily set up to explore false-positive outcomes as predicted to be present from a previously published case series, and for this, a shorter time period sufficed (10). Finally, home monitoring of foot skin temperature meant that we could not control the setting, ensure time intervals or full standardisation of the measurement procedures. This is reflective of true home monitoring, but the time between activity and skin temperature monitoring was not fully standardised. However, examination of the data from the diaries showed that the majority of participants had a standardised routine for their temperature monitoring.

Surprisingly, none of the participants who measured a >2·2°C temperature difference between identical locations on the left and right foot contacted the research team, despite receiving clear instructions to do so. This highlights a potential practical issue when applying home monitoring in everyday clinical practices and stresses the need for adequate concordance between patients' and physicians' understanding of the instructions and adequate patient education when they are provided with home-monitoring tools. Furthermore, it stresses the importance of having low numbers of false-positive outcomes so that adherence to protocols remains sufficient. Alternatively, home-monitoring systems should preferably be technologically improved to automatically give warning signals directly to care providers (in addition to patients) when above-threshold temperature differences are measured.

## Conclusion

The >2·2°C left-to-right foot temperature difference threshold for impending ulceration is not valid for home monitoring to prevent foot ulceration when used as single measurement. The validity improves to acceptable levels with subsequent confirmation of an above-threshold recording the following day and further improves with individual correction. The threshold is independent of time of day, environmental temperature and walking activity. These findings may be used in the development of measurement protocols or smarter methods and technology for home monitoring of foot skin temperature in people with diabetes to prevent foot ulceration.

## References


1. Bakker K, Apelqvist J, Schaper NC. Practical guidelines on the management and prevention of the diabetic foot 2011. *Diabetes Metab Res Rev* 2012;**28**(Suppl. 1):225–31.
2. Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J. The global burden of diabetic foot disease. *Lancet* 2005;**366**:1719–24.
3. Reiber GE. The epidemiology of diabetic foot problems. *Diabet Med* 1995;**13**:6–11.
4. Stess RM, Sisney PC, Moss KN, Graff PM, Louie KS, Gooding GA, Grunfeld C. Use of liquid crystal thermography in the evaluation of the diabetic foot. *Diabetes Care* 1986;**9**:267.
5. Bharara M, Schoess J, Armstrong DG. Coming events cast their shadows before: detecting inflammation in the acute diabetic foot and the foot in remission. *Diabetes Metab Res Rev* 2012;**28**(Suppl 1):15–20.
6. Lavery LA, Higgins KR, Lanctot DR, Constantinides GP, Zamorano RG, Armstrong DG, Athanasiou KA, Agrawal CM. Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes Care* 2004;**27**:2642–7.
7. Armstrong DG, Holtz-Neiderer K, Wendel C, Mohler MJ, Kimbriel HR, Lavery LA. Skin temperature monitoring reduces the risk for diabetic foot ulceration in high risk patients. *Am J Med* 2007;**120**:1042–6.
8. Lavery LA, Higgins KR, Lanctot DR, Constantinides GP, Zamorano RG, Athanasiou KA, Armstrong DG, Agrawal CM. Preventing diabetic foot ulcer recurrence in high risk patients:use of temperature monitoring as a self-assessment tool. *Diabetes Care* 2007;**30**:14–20.
9. Van Netten JJ, Price PE, Lavery LA, Monteiro-Soares M, Rasmussen A, Jubiz Y, Bus SA. Prevention of foot ulcers in the at-risk patient with diabetes: a systematic review. *Diabetes Metab Res Rev* 2016;**32**(suppl 1):84–98.
10. Van Netten JJ, Prijs M, van Baal JG, Liu C, van der Heijden F, Bus SA. Diagnostic values for skin temperature assessment to detect diabetes-related foot complications. *Diabetes Technol Ther* 2014;**14**:11.
11. Armstrong DG, Lavery LA. Monitoring neuropathic ulcer healing with infrared dermal thermometry. *J Foot Ankle Surg* 1996;**35**:335.
12. Armstrong DG, Lavery LA, Liswood PJ, Todd WF, Tredwell JA. Infrared dermal thermometry for the high risk diabetic foot. *Phys Ther* 1997;**77**:169–75.
13. Bus SA, van Netten JJ, Lavery LA, Monteiro-Soares M, Rasmussen A, Jubiz Y, Price PE. IWGDF guidance on the prevention of foot ulcers in at-risk patients with diabetes. *Diabetes metabolism research and review* 2016;**32**(Suppl. 1):16–24.
14. Schaper NC, van Netten JJ, Apelqvist J, Lipsky BA, Bakker K. Prevention and management of foot problems in diabetes: a Summary Guidance for daily practice 2015, based on the IWGDF guidance documents. *Diabetes Metab Res Rev* 2016;**32**(Suppl. 1):7–15.
15. Macdonald A, Petrova N, Ainarkar S, Allen J, Plassmann P, Whittam A, Bevans J, Ring F, Kluwe B, Simpson R, Rogers L, Machin G, Edmonds M. Thermal symmetry of healthy feet: a precursor to a thermal study of diabetic feet prior to skin breakdown. *Physiol Meas* 2017;**38**:33–44.
16. Milne TA, Rogers JR, Kinnear EM, Martin HV, Lazzarini PA, Quinon TR, Boyle FM. Developing an evidence-based clinical pathway for the assessment, diagnosis and management of acute Charcot Neuro-Arthropathy: a systematic review. *J Foot Ankle Res* 2013;**6**:30.
17. Nagase T, Sanada H, Takehara K, Oe M, Iizaka S, Ohashi Y, Oba M, Kadowaki T, Nakagami G. Variations of plantar thermographic patterns in normal controls and non-ulcer diabetic patients: novel classification using angiosome concept. *J Plast Reconstr Aesthet Surg* 2011;**64**:860–6.


 