Prevention and detection of diabetic foot complications in at-risk patients employing novel skin temperature monitoring techniques: a systematic review

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Key words

- Diabetic foot
- Infrared
- Skin temperature
- Thermal imaging
- Thermography

Article points

1. Diabetic foot complications (DFCs) are a common and devastating occurrence for individuals with diabetes;
2. Early detection of DFCs would enable the initiation of targeted interventions to reduce the risk of more serious complications arising;
3. Skin temperature monitoring could be utilised as an adjunctive diagnostic tool to track the trajectory of DFCs and implement early interventions.

Authors

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Diabetic foot complications (DFCs) incur considerable healthcare costs, societal costs and affect patients' quality of life. Such complications can be challenging to treat with conventional therapies, therefore, early detection and prevention is critical. Patients with a history of DFCs are at risk for recurrence of such complications. DFCs encompass ulcers, infection, calli, osteomyelitis and Charcot foot. However, such complications can go unnoticed by patients and caregivers due to diabetic neuropathy. Skin temperature monitoring has been shown to be effective in preventing and detecting DFCs in at-risk patients. Devices used for skin temperature monitoring include; thermographic cameras, liquid crystal thermography and infrared thermometers. The aim of this systematic review is to determine the clinical effectiveness of skin temperature monitoring in detecting DFCs in the at-risk patient with diabetes mellitus. A systematic search of relevant literature identified pertinent studies analysing the relationship between skin temperature and the detection and prevention of DFCS. Methodological quality of the nine included studies was carried out by two independent reviewers. Methodological information with skin temperature parameters were extracted from the studies along with a narrative analysis. Studies investigating the use of skin temperature monitoring devices by subjects in the home environment as part of self-care strategies in detecting and preventing DFCs showed promising results.

Diabetes mellitus is a chronic illness with a complex disease trajectory that affects all major body organs and systems. Diabetic foot complications (DFCs) are a manifestation of the microvascular complications of diabetes mellitus. A previous medical history of foot ulcers, foot infections or other DFCs increases the risk for developing future DFCs (van Netten et al, 2016). The term "at-risk" is used in this systematic review to refer to patients with a previous history of DFCs.

DFC is an umbrella term for pathological changes in the feet of people with diabetes mellitus namely; ulceration, infection, callus formation, Charcot foot and osteomyelitis. A systematic review of the global epidemiology of DFCs yielded prevalence rates of 6.3%. Males were found to have a prevalence of 4.5% compared with females (Zhang et al, 2017). The International Working Group on the Diabetic Foot (Lipsky et al, 2016) states that the worldwide prevalence of diabetes mellitus will rise to 600 million and 80% of the affected population will be from the poorer nations. Moreover, up to 28% of diabetic foot ulcers lead to a lower-limb amputation (Lipsky et al, 2016). Furthermore, individuals with diabetes are 10 to 20 times at risk of lower-limb amputation compared with the non-diabetic population (World Health Organization, [WHO], 2016). Additionally, 80% of amputations are preceded by a diabetic foot ulcer (Diabetes UK, 2016).

In one Irish study, a person with diabetes was 22.3 times more likely to undergo a non-traumatic lower-extremity amputation (LEA), than a person without

diabetes (Buckley et al, 2012). Additionally, the median hospital stay for patients undergoing diabetes-related LEA was 24 days, while a mortality rate of 6.4% was reported (Buckley et al, 2012). The Health Service Executive's (HSE) national clinical programme for diabetes has a major goal of saving the limbs of patients with diabetes and reducing the number of lower-limb amputations by 40% (HSE, 2016).

In tandem with the above, there is the associated costs of treating DFCs. Gillespie et al (2014), cite a cost analysis study in Ireland of managing a DFU over an 18-month period (inclusive of in-hospital and community care) as €18,753 compared with those without foot ulcers, €6,472. Likewise, in the US, the cost of treating diabetic foot complications was estimated between $9–$13bn (Raghav et al, 2018).

DFCs are a consequence of one of the microvascular pathologies of diabetes, namely peripheral neuropathy. Neuropathy, with reference to the foot in diabetes denotes autonomic, sensory and motor neuropathy. Each event alone or in combination give rise to DFCs. Alarmingly, it has been reported that 40% to 90% of people with diabetes with peripheral neuropathy are unaware they actually have it (Barshes et al, 2013). When the diabetic foot is exposed to trauma, injury, excess pressure or shear and friction injuries, very often no pain or inflammation is experienced, hence the natural protective mechanism is absent (Lavery and Armstrong, 2007).

Additionally, patients do not curtail physical activities while repetitive stress is placed on already damaged tissue in the foot (Sibbald et al, 2015). Such inflammatory symptoms may go unnoticed for a prolonged time, especially if present on the plantar surface of the foot until they suddenly become problematic (loss of function of the foot or severe infection leading to osteomyelitis).

Despite national screening strategies, patient education interventions, specialist footwear interventions (offloading boots, therapeutic shoes/ footwear) and specialist education for clinicians, compliance with prevention mechanisms remains a challenge in this patient population. The literature reports that barriers to patient adherence to foot care strategies are complex (Lavery and Armstrong, 2007). It is recognised that certain barriers are internal to patient beliefs and attitudes thereby affecting behaviours i.e. walking barefoot at home and not wearing offloading footwear at home or while on holiday (Roback, 2010). Other contextual barriers are limited access to healthcare services, poverty and low literacy levels.

Current screening practices for DFCs comprise of sensory nerve function tests using 10g monofilament test (cutaneous pressure perception testing), vibration perception testing and assessing for foot structure abnormalities (Charcot foot, Hallux Vagus) (HSE, 2016; National Institute for Health and Care Excellence [NICE], 2015). Additionally, Ankle Brachial Pressure Index (ABPI) tests assess vascular blood flow to the foot. Manual palpation is the conventional practice to assess for signs of soft tissue inflammation, the presence of calli and signs of breaks in skin integrity (Scottish Intercollegiate Guidelines Network [SIGN], 2010). However, such traditional methods of manual palpation and foot inspection even by the most experience experts have shortcomings due to subjectivity (Lavery and Armstrong, 2007).

There are limited quantitative and objective tests to predict and detect DFCs, apart from ABPI readings. However, ABPIs only provide values for the vascular status/ blood flow to the lower limbs and do not detect inflammation. Furthermore, the diagnostic accuracy of manual palpation and visual inspection of the diabetic foot is limited by subjectivity and lack of quantifiable data/measurements (Sibbald et al, 2015; Lepow et al, 2010). Manual palpation does not detect latent inflammation or subtle temperature changes in the diabetic foot in every instance (Roback, 2010). Thermoreceptors in the distal limbs (feet) are disrupted via degeneration of the sensory nerves, as a consequence of the pathological disease processes of diabetes mellitus (Lepow et al, 2010). Therefore, detection of impending inflammatory changes under thick callous skin is, therefore, difficult to detect by manual palpation.

In recent years, a growing body of work has investigated the feasibility of skin temperature monitoring devices for preventing and detecting DFCs (Bakker et al, 2015). Increases in temperature under a callus (latent inflammation) can be present up to 7 days prior to the development of an ulcer (Roback, 2010). It is not unreasonable then to re-evaluate the current practice of manual assessment of the DF and give due consideration to the feasibility of skin temperature monitoring as a diagnostic aid in the prevention and detection of DFCs.

Such quiescent inflammation can be detected by skin temperature monitoring devices. The temperature

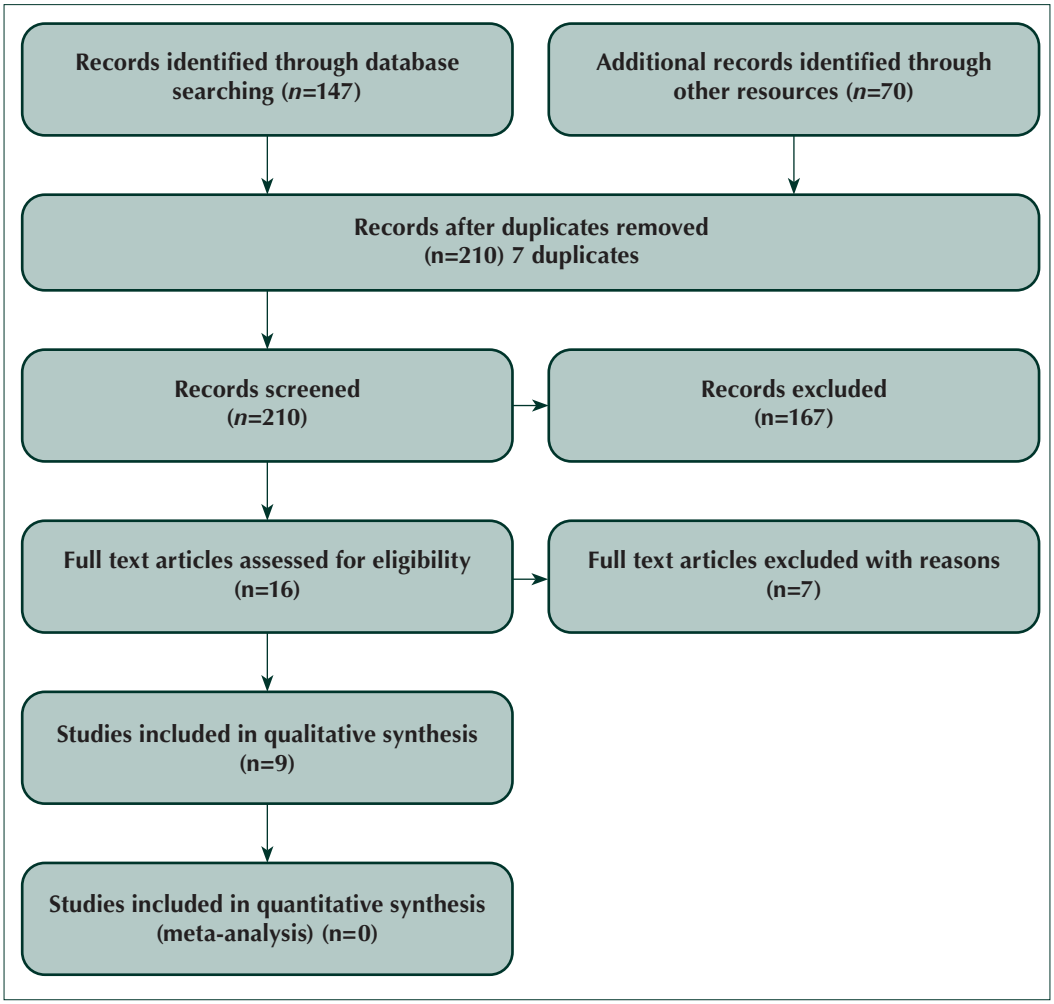

Figure 1. PRISMA 2009 f flow diagram.

reading can be compared with that of the contralateral limb and a significant differential between the readings is indicative of inflammation/infection or some other pathology (Howard, 2009). Currently, the standardised reference temperature is that of the opposite foot (Roback, 2010).

In states of health equilibrium, heat is emitted from the plantar surfaces of both feet in a symmetrical fashion (Ring, 2010). Thermal assessment technology incorporates thermography and infrared thermometry (Lepow et al, 2010). In short, thermographic devices are infrared cameras, that produce a full thermal image of the foot, using thermal patterns of heat distribution. Such thermal patterns can be analysed for regions of interest (ROI), namely inflammation and/or infection. Such thermographic devices have been used in specialised diabetic foot clinics (Lepow et al, 2010).

The aim of this SR is to investigate the effectiveness of skin temperature measurement technology as a diagnostic aid for preventing and detecting DFCs in the at-risk person with diabetes.

Methods

Search strategy

An electronic search of the following databases was carried out to source the relevant primary studies; Pubmed, Embase, CINHAL, Scopus, Medline, Google Scholar and the Cochrane database. To facilitate the search strategy, the topic was broken down into three aspects; "diabetic foot complications", "skin temperature" and "temperature measurement devices". A hand search of relevant journals was undertaken to source more papers. Technologies accepted and included for measuring skin temperature were "thermography", "thermometry" and "liquid crystal thermometry".

A PRISMA diagram (*Figure 1*) was used to

Table 1. Temperature monitoring devices.

Study	Temperature measurement Device
Thermographic Cameras	
Van Netten et al (2014)	FLIR SC305 Thermal Image Camera
Van Netten et al (2013)	FLIR SC305 Thermal Image Camera
Oe et al (2013)	Thermotracer TH7800N
Nishide et al (2009)	Thermotracer TH5108ME
Liquid Crystal Thermography	
Roback et al (2009)	SpectraSole Pro 1000 Liquid Crystal
Infrared Thermometry Devices	
Armstrong et al (2007)	TempTouch Xilas Medical
Lavery et al (2007)	TempTouch Xilas Medical
Skafjeld et al (2015)	TempTouch Xilas Medical
Armstrong et al (2006)	Thermo-Trace Deltatrak

maintain a record of all databases searched and to ensure the search strategy was reproducible.

Identification and article selection

The abstracts of selected papers were read and the content noted. A second reviewer also read the abstracts for relevant themes and content. Papers that satisfied the inclusion/exclusion criteria for the review were read over several times for content analysis by both reviewers. A consensus was then reached between the reviewers regarding what full text papers to include for this systematic review. Inclusion criteria for papers included in the review were diagnosis of diabetes mellitus (type 1 or 2), adults >18 years, any clinical setting, and be self-caring in the activities of living. Exclusion criteria were studies looking at non-diabetic foot disease, studies where subjects were fully dependent on others for their activities of daily living and critical limb ischaemia. Studies published from 2006 onwards were included. The review was limited to English language papers due time constraints and a lack of financial resources for a translation service.

Methodological quality

Assessment of the quality of primary studies determines if the findings of such studies are applicable to population of interest (Centre for Reviews and Dissemination [CRD] 2008). Considering the heterogeneity and variability of study designs sourced for this SR, all such studies were assessed for quality using the Evidence Based Information Librarianship (EBIL) critical appraisal checklist (Glynn, 2006). The cumulative score of each study was used to determine its validity. Each study was scored according to the presence/absence of pertinent items across four domains of the checklist, namely; population, data collection, study design and results. According to this checklist, a study is valid if it scores ≥75% in the overall validity criteria.

Data extraction & analysis

A data extraction tool was formulated based on general guidance from the Centre for Reviews and Dissemination (CRD, 2009). Here, the author extracted the pertinent data from the chosen papers. The second author independently checked the data extraction tool for accuracy. This was to ensure inter-rater agreement on the content of the data extracted. Relevant data extracted from the chosen primary studies included; author, journal, date of study, title, geographical location, aim of study, population, setting, intervention and results.

Results

Search strategy

A total of nine papers were included for this systematic review. Two were cross- sectional/observational studies (Nishide et al, 2009; and Oe et al, 2013), three comparative/experimental studies (Roback et al, 2009; van Netten et al, 2013; 2014), two randomised trials (Armstrong et al, 2006; Lavery et al, 2007) and two randomised controlled trials (Armstrong et al, 2007;

Skafjeld et al, 2015). The years of the studies ranged from 2006 to 2015.

Methodological quality

Two independent reviewers scored the studies for validity using the EBL checklist (*Table 2*). Out of a total of nine studies, four were assessed as valid according to the checklist (Armstrong et al, 2006; Armstrong et al, 2007; Lavery et al, 2007; Skafjeld et al, 2015). The remaining five studies scored 57.1%, 50%, 50%, 57.1% and 67.85%; van Netten et al (2014), van Netten et al (2013), Oe et al (2013), Roback et al (2009) and Nishide et al (2009), respectively.

Details of included studies

Specific details were extracted from the studies as relevant to the content of this SR and are presented in a table format (*Table 1*).

Geographical locations of studies

The studies took place across a range of geographical locations inclusive of; the Netherlands; the USA, Japan, Sweden and Norway.

Subject details

A total of 656 participants were included across the studies. The largest study population was 225 participants (Armstrong et al, 2007) while the smallest study population was 15 (van Netten et al, 2013). Participant age ranged from 18 years to 93 years, while the mean age across eight of the studies was 66.7 years. The characteristics of participants varied across the studies in terms of comorbidities. Not all studies gave data pertaining to comorbidities, but where given the data was extracted. Peripheral neuropathy was diagnosed in all intervention groups across the studies.

The duration of diabetes (either type 1 or type 2) across the studies (where such data was provided) ranged from 13.4 years (Lavery et al, 2007) to 22.4 years (Oe et al, 2013). Smoking was recorded as risk factor in two studies (Roback et al, 2009; Skafjeld et al, 2015). HbA_{1c}, ranged from 6.7% (Nishide et al, 2009) to 8.4 % (Oe et al, 2013) across the study groups. Body Mass Index (BMI, Kg/m^2) was given in two studies and ranged from 25 (Nishide et al, 2009) to 31.4 (Skafjeld et al, 2015).

Data pertaining to angiopathy, ABPI <0.9 were available for a total of 12 subjects; (Nishide et al, 2009; Oe et al, 2013). Other comorbidities across the studies were renal disease (nephropathy), heart disease, rheumatic disease, osteopathy, impaired vision (retinopathy), abnormal gait, Charcot foot, previous vascular surgery and previous foot surgery.

Study intervention; skin temperature monitoring devices used in studies

Temperature monitoring devices used in the studies were classified according to the principles of design, namely; thermographic cameras, liquid crystal thermography and infrared thermometers. Four studies used thermographic cameras (Nishide et al, 2009; Oe et al, 2013; van Netten et al, 2013; 2014). The SpectraSole Pro 1000 liquid crystal thermography was used in one study (Roback et al, 2009). Four studies used the Temp Touch digital infra-red thermometer (Xilas medical) (Armstrong et al, 2006; Armstrong et al, 2007; Lavery et al, 2007; Skafjeld et al, 2015).

Infrared Thermography

Thermographic cameras produced images of the dorsum and plantar surface of the foot. Such images showed heat distribution patterns. The studies by van Netten et al (2013 and 2014) necessitated the use of a colour image camera and thermal image camera. The thermal image camera is the focus of discussion here. The foot boundary and ROI (calli, ulcers etc.) were manually annotated via digital software and subsequently transferred to the thermal image where foot temperatures were calculated.

The Thermotracer TH7800N device obtained thermal images and automatically displayed morphological distribution of skin temperature on the surface of subjects' feet (Oe et al, 2013). Temperature readings were automatically displayed on screen.. No manual annotation of foot boundaries was required for this. Likewise, the device used in the study by Nishide et al (2009), the Thermotracer TH510 recorded thermal images and temperature readings of plantar foot surfaces.

Liquid Crystal Thermography (LCT)

For the LCT device (SpectraSole Pro 1000), subjects placed both feet on two rectangular plates made of thermochromic liquid crystals layers for one minute (Roback et al, 2009). These layers changed colour according to the heat distribution of the soles of the feet of subjects. Such colour patterns were compared to a template with temperature references and the

Table 2. Methodological quality assessment.

EBL Critical Appraisal Checklist		Yes	No	Unclear	N/A
Section A	Is the study population representative of all users, actual and eligible, who might be included in the study?				
	Are inclusion and exclusion criteria definitively outlined?				
	Is the sample size large enough for sufficiently precise estimates?				
	Is the response rate large enough for sufficiently precise estimates?				
	Is the choice of population bias-free?				
	If a comparative study: Were participants randomized into groups? Were the groups comparable at baseline? If groups were not comparable at baseline, was incomparability addressed by the authors in the analysis?				
	Was informed consent obtained?				
Section B	Are data collection methods clearly described?				
	If a face-to-face survey, were inter-observer and intra-observer bias reduced?				
	Is the data collection instrument validated?				
	If based on regularly collected statistics, are the statistics free from subjectivity?				
	Does the study measure the outcome at a time appropriate for capturing the intervention's effect?				
	Is the instrument included in the publication?				
	Are questions posed clearly enough to be able to elicit precise answers?				
	Were those involved in data collection not involved in delivering a service to the target population?				
Section C	Is the study type / methodology utilized appropriate?				
	Is there face validity?				
	Is the research methodology clearly stated at a level of detail that would allow its replication?				
	Was ethics approval obtained?				
	Are the outcomes clearly stated and discussed in relation to the data collection?				
Section D	Are all the results clearly outlined?				
	Are confounding variables accounted for?				
	Do the conclusions accurately reflect the analysis?				
	Is subset analysis a minor, rather than a major, focus of the article?				
	Are suggestions provided for further areas to research?				
	Is there external validity?				

Calculation for section validity: (Y+N+U=T) If Y/T <75% or if N+U/T > 25% then you can safely conclude that the section identifies significant omissions and that the study's validity is questionable. It is important to look at the overall validity as well as section validity.	**Calculation for overall validity: (Y+N+U=T)** If Y/T ≥75% or if N+U/T ≤ 25% then you can safely conclude that the study is valid.
Section A validity calculation: Y/T = **Secion B validity calculation, :Y/T=** **Section C validity calculation: Y/T =** **Section D validity calculation: Y/T =**	**Overall validity calculation: Y/T=**

temperature patterns of the plantar feet were noted and recorded.

Infrared thermometry

In the case of the infrared thermometers, the operator placed the tip of the device on the region/spot of the

foot to be measured. A temperature reading was then automatically displayed on the screen. Three studies investigated the feasibility of infrared thermometry by intervention groups the home environment; Armstrong et al (2007), Lavery et al (2007) and Skafjeld et al (2015). The intervention groups received instruction and training on how to operate the infrared thermometers from study co-ordinators. They were instructed to monitor the same six anatomical sites on each foot daily or twice daily. Temperature measurements were recorded in a log book and reviewed by the study co-ordinators during follow-ups. The same temperature measuring device was utilised in all three studies, namely the TempTouch Xilas Medical Infrared skin contact thermometer. Raw data for temperature recordings were not available for the studies.

Temperature measurements

Results for the study by van Netten et al (2014) showed a mean temperature difference of 2.65ºC between the affected foot compared to the contralateral foot (study group 1) requiring immediate treatment for diabetic foot complications (infection, ulcer, Charcot foot). This measurement was statistically significant, $P<0.001$, compared with results for groups 2 and 3 (non-immediate complications and no complications, respectively). The optimal measurement point to detect a diabetes related foot complication was 2.2ºC. Additionally, the optimal measurement point to determine urgent intervention for the same complication was 1.35ºC (van Netten et al, 2014).

In van Netten et al (2013) results for the diffuse DFC group showed a mean temperature difference in regions of interest (ROI) of >3ºC between the affected foot and the same site on the contralateral foot. In the study group with local signs of DFCs, temperature measurements at the ROI in the affected foot was >2ºC in contrast to the contralateral foot.

In Nishide et al (2009), latent inflammation in 10% of diabetic foot calli were identified by a mean temperature elevation measurement of 2.04ºC, $P=0.014$. The largest temperature increase was 2.8ºC. Conversely, 100% of the calli in the non-diabetic group had no signs of inflammation.

Similar findings were illustrated in temperature measurements as part of the SIDESTEP trial (Armstrong et al, 2006). In this study, the mean temperature difference between the affected foot (infected wound/ulcer) and the contralateral foot was 2.81ºF. The Fahrenheit unit of measurement used in this study made it difficult to convert to Celsius for comparison with results of the aforementioned studies.

Studies with no raw data temperature measurements

A feasibility study by Roback et al (2009) revealed temperature differences (data not given) between the affected foot and the contralateral foot in 31 out of 69 examinations. Six of these differences were undetected by a standard foot examination (manual palpation for inflammation, wounds and deformities. Heat specific distribution patterns were obtained with the device (SpectraSole Pro 1000, liquid crystal thermography). The researchers relied on visual estimates of heat distribution patterns from the soles of feet to determine ROI/inflammation. Oe et al (2013) used the Thermotracer TH7800N to measure temperature patterns in a study group with osteomyelitis of the foot compared with a study group with no osteomyelitis. The correlation between areas of increased temperature extending from the ulcerated region to the ankle and osteomyelitis was significant — $P=0.011$. Specific areas of original ulceration were detailed in the paper.

Lavery et al (2007) had three study groups; standard therapy group (STG), structured foot examination group (SFEG) and enhanced therapy group (ETG). The STG received standard foot examinations, an education programme on foot care practices/examination, and therapeutic footwear. In the SFEG, subjects received all of the above with the addition of a mirror to inspect the sole of the foot for abnormalities. All observations were recorded in a log book. The ETG were instructed in the use of the infrared thermometer (TempTouch Xilas) and to record temperature measurements in a log book on six anatomical sites in each foot. Results for the STG and the SFEG were similar for rates of ulceration; 29.3% ulcerated ($n=17$) and 30.4% ulcerated ($n=17$), respectively. Whereas, 8.5% of five subjects ($n=5$) in the ETG (temperature monitoring) ulcerated. Clinically significant difference outcomes for the ETG compared with the STG, $P=0.0059$. Clinically significant difference outcomes for temperature monitoring group compared with the structured foot examination group (use of a mirror for self-examination) was $P=0.0055$.

Results for the study by Skafjeld et al (2015) contrasted with the preceding two studies. In this

study, subjects were randomly allocated to either the standard therapy group (standard foot care practices) or the intervention group (temperature monitoring). The intervention group were instructed to measure the temperature on six anatomical points on each foot daily and input temperature measurements into a personalised log book. The standard therapy group also recorded daily foot inspection observations into a personalised log book. The incidence of foot ulcers in the control group was 50% (*n*=10). The incidence of foot ulcers for the intervention group (temperature monitoring group) was 39% (*n*=7). There was no difference in foot ulcer occurrence between the two study groups — *P*=0.407.

Primary outcomes

Reduction in the incidence of DFCs.

Three studies met the primary outcome of a reduction in the incidence of DFCs using skin temperature monitoring as a diagnostic tool, namely Armstrong et al (2006), Lavery et al (2007) and Skafjeld et al (2015). Raw values for temperature measurements were not given in these studies. A total of 58 (calculated from percentage data in studies) ulcers were recorded across the four control groups for the three studies combined. In the Lavery et al (2007) study, during the 15-month long study, there was only a minor difference between the standard therapy group (17 ulcers; 29.3%) and the structured examination group (17 ulcers; 30.4%). Additionally, the Kaplan-Meier survival analysis showed the mean time to develop ulcers was similar for the two groups, 378.5 days and 377.3 days, respectively.

A total of 17 ulcerations were reported across the three studies for the intervention groups combined. The incidence for each study intervention group was; Armstrong et al (2007); 4.7% (*n*=5), Lavery et al (2007); 8.5% (*n*=5) and Skafjeld et al (2015); 39% (*n*=10). The latter study being the only one where there was no significance between control and intervention groups (*P*=0.532). The first two studies demonstrated a reduction in the incidence of DFC with the use of home monitoring of foot temperatures.

In the temperature monitoring group in the Lavery et al (2007) study, if skin temperatures were >2.2ºC for more than 2 days, subjects reduced physical activity and contacted the study nurse. There was significant trend of prolonged time to develop an DFC in the temperature monitoring group, *P*=0.0107. Notably, subjects in the enhanced therapy group who recorded skin temperatures at least 50% of the time, were less likely to develop DFCs (*P*<0.001, Odds Ratio 50.0).

Interestingly, 52.5% of subjects in the enhanced therapy group contacted the study nurse once they temperature increases/foot problems, compared with 31% and 17% in the standard group (*P*=0.030) and structured examination group (*P*=0.026), respectively. All subjects in the study had a history of DFCs and were therefore deemed at high-risk for future complications. Since monitoring of foot skin temperatures was carried out in subjects' own homes, self-reported adherence to instructions as per the study nurse was important. Moreover, temperature monitoring was akin to a biofeedback mechanism where subjects would curtail activities when the temperature between both feet was 2.2ºC.

The authors reported that adherence to wearing therapeutic shoes was high in all groups. It is questionable, therefore, if the footcare practices by subjects across the three studies were influenced by being part of an experiment? Subjects were in contact with the study physician or nurse at intervals across the three studies. Regular contact with study staff may have influenced behaviours and foot care practices. Interestingly, adherence (self-reported) to therapeutic footwear was high across study groups in Lavery et al, (2007) and Skafjeld et al (2015). No information pertaining to footwear practices was available for Armstrong et al (2007). A larger sample size in the study by Skafjeld et al (2015), would be required to detect the true effect of an intervention.

Secondary outcomes

Detection of DFCs

Complications detected using temperature measuring devices were calli, ulcers, Charcot foot and osteomyelitis. In van Netten et al's (2013) study, Charcot foot and osteomyelitis (regions of interest, ROI), were diagnosed by X-rays and Magnetic Resonance Imaging (MRI). In the subjects with the most severe complications (Charcot foot, osteomyelitis and ulceration), detection was confirmed by a temperature difference of >3ºC between the affected foot and the contralateral foot. This temperature differential coincided with the diagnosis of Charcot foot and osteomyelitis by X-ray and MRI. Interestingly, there was a temperature difference of <1.5ºC between the ROI and mean temperature of the ipsilateral foot.

Therefore, a mean temperature difference of >3ºC between the affected foot and non-affected foot should be referred on for immediate intervention. Hence, the rationale for using the contralateral foot as a reference point.

In the follow up study by van Netten et al, (2014), a mean temperature difference between the affected foot and the contralateral foot of 2.65ºC indicated the need for immediate intervention. This was evident in group 1 subjects with significant temperature differences between the affected foot and the contralateral foot. This group required immediate treatment (hospitalisation). Such results correlated with results from X-rays and MRI scans as well as standard foot examination. Group 2 had complications requiring non-immediate treatment (wound care, sharp debridement and offloading).

In the study by Roback et al (2009), the SpectraSole device detected temperature increases in groups 3, 4 and 5 (several problem areas and one large problem area to severe problem areas, total of 27 problem spots). These findings coincided with findings from the standard foot examination. Temperature differences were recorded in 20 out of these 27 problem areas. Notably, seven temperature differences out of eight examinations were recorded for severe foot problems.

Oe et al (2013) also used MRI to diagnose osteomyelitis in subjects with diabetes. The study described numbers of DFCs as 20 occurrences. There were 20 DFCs, 10 of which were complicated by osteomyelitis. Increased temperature extended from the local peri-wound area up to the knee. These temperature increases coincided with the MRI results for osteomyelitis. In one case, the ulcer was located on the plantar surface of the fourth toe, but the temperature increase extended up to the ankle area. This was validated by MRI results showing the site of osteomyelitis and subsequent tissue inflammation extending out from the site. Conversely, two subjects with osteomyelitis showed no temperature increase in the foot. However, both subjects were diagnosed with angiopathy, thereby affecting temperature patterns (Oe et al, 2013).

Dermal thermometry was used to measure temperature recordings in subjects with moderate to severe DFCs in Armstrong et al (2006). Here temperature differentials between the affected limb and the contralateral limb were recorded. Interestingly skin temperature differentials for with moderate and severe DFCs were similar, 3.04ºF and 3.09ºF respectively.

Temperature to detect evolving DFCs was an outcome in the study by Roback et al (2009). Out of 42 foot examinations, in study groups 1 and 2 (no visible problem areas and one/few minor problem areas, respectively, using standard foot examinations) 11 (26%) were found to be at risk for DFCS according to temperature recordings (raw data not given). In Nishide et al (2009), subjects with asymptomatic calli on the plantar surfaces of feet were assessed for latent inflammation using temperature measurements. Here, five out of 50 calli (10%) in the diabetes mellitus group showed a mean temperature recording of 2.04ºC, with the greatest temperature recorded as 2.8ºC. Ultrasonography was used to validate the findings of latent inflammation under the calli. Latent inflammation, that is not visible under calli is a precursor to DFCs (Nishide et al, 2009). In the ROI with the greatest temperature reading (2.8ºC) data from ultrasonography results confirmed the extent of inflammation down to the deep muscle layer (Nishide et al, 2009).

Diagnostic values for urgency of treatment

In order to determine what temperature differential value should indicate urgent treatment for a DFC, the results of the six relevant studies were analysed. In van Netten et al (2014), a temperature differential of 2.65ºC between contralateral feet in group 1 (requiring immediate treatment) was the diagnostic value for urgency of treatment. In this study group, a diagnosis of osteopathy and Charcot foot was confirmed by X-ray and MRI. Additionally, a cut off value for the difference in mean temperature values between both feet was found to be 1.35ºC. This value was clinically significant compared with the values for the non-immediate treatment group and the no complications group, (P<0.001).

Furthermore, it was noted from raw data in the study that two patients with Charcot foot had temperature differences between contralateral foot of between 5.5ºC and 6.10ºC (van Netten et al, 2013). In two cases of osteomyelitis, the temperature differential was 3.0ºC and 3.7ºC. The condition known as Charcot Foot is often challenging to diagnose without X-ray or MRI. It is noteworthy that there is often no patient history of trauma or cuts to the foot in the case of Charcot foot.

Hence, it is difficult to diagnose during routine foot examinations and is often treated as a cellulitis if inflammation is evident (Rogers and Frykberg, 2013). Likewise, osteomyelitis is a severe DFC where there is direct spread of infection from the ulcer to the bone tissues. Moreover, this condition is also difficult to diagnose with subjective examination (Malhotra et al, 2014).

Discussion

The purpose of this SR was to systematically collect and analyse data pertaining to skin temperature monitoring technologies for the prevention of DFCs. It specifically explored the practical application of thermographic cameras, liquid crystal thermography and infrared thermometry devices as diagnostic tools in clinical practice. Each of the three technologies had advantages and disadvantages when compared.

Thermographic cameras (FLIR SC305 Thermal Image Cameras) required specialist skill and time resources to produce data. In such studies, researchers had to manually annotate the foot heat patterns obtained using digital software and transfer them to a computer to produce a thermal image (Netten et al, 2013; Netten et al, 2014). The subjective nature of such manual annotation is time consuming, requires specialist skills and may lead to misinterpreted results.

Likewise, LCT produces images that fade after several minutes thereby affecting the reliability of the study outcomes. Such thermographic cameras and LCT were found to be time consuming and required specialist expertise and digital equipment. This was highlighted in the pilot study by van Netten et al (2013), where areas of increased temperature (ROI) were manually drawn. Such annotations were transferred to a computer programme to produce the colour and thermal image of the foot. This was time consuming and had potential for errors in reading areas of increased temperature. However, this issue was rectified in the next study by van Netten et al (2014) where the boundaries of the feet were automatically annotated and transferred to the thermal image.

Temperature data collected by the SpectraSole Pro 1000 LCT instrument was considered to be diffuse and difficult to interpret. Moreover, the thermal images faded quickly and had to be compared against a template showing temperature readings. It may be inferred that reading of the template affected inter-rater reliability of the study. It was unclear if areas of increased temperature were manually recorded in a diagram or thermal images were stored digitally for later use (Roback et al, 2009).

Details of comorbidities varied between studies. Charcot foot and critical limb ischaemia were exclusion criterion in some studies, while other studies included such conditions. Similarly, osteomyelitis was an exclusion while in others it was included, pending on whether the outcomes of the study were detection or prevention.

In addition to the self-monitoring of foot temperatures by participants in homes, other routine aspects of footcare were carried out in the studies. It is questionable if a subject's behaviour was influenced by taking part in an experiment, i.e. did subjects adhere more to footcare practices than if they were not in a study?

Not all risk factors for DFCs were reported in all studies. Two studies reported subjects as smokers. Smoking is a well-known risk factor in lower limb complications for diabetic patients. The lack of information pertaining to such a factor could have caused bias in selection/ allocation of subjects to intervention groups or selection for studies. If more subjects in a control group were smokers than the intervention group, this could have influenced the development of DFCs.

Clinical markers such as HbA_{1c} and BMI are also risk factors for DFCs. Only four studies reported HbA1c, while three studies reported BMI as comorbidities. Similarly, vascular abnormalities, i.e.; peripheral vascular disease (PVD), peripheral arterial disease (PAD) varied across the studies. Where such data was given, 12 were recorded as having ABPIs ≤0.9. According to Jeffcoate et al (2016) there are a minimum set of core data that should be reported for studies pertaining to the prevention/detection of DFCs. As such these are; the person, limb, ulcer, age, sex, ethnicity, comorbidities, risk classification and sample size (Jeffcoate et al, 2016).

Studies also differed with reference to full foot imaging or temperature measurement of anatomical spots. Five studies used devices that produced thermal images of the entire plantar foot surface. However, expertise is required in reading the thermographic images and such devices were only used in outpatient hospital settings.

In contrast, handheld thermometry devices were deemed practical to use by subjects in their home

environment. However, subjects had to be independent with the ADL in order to operate the thermometers.

Four studies used devices that measured specific spots on the foot. Three of these studies were the home monitoring studies. These devices were deemed simple to use and gave immediate temperature measurements on a display screen. In the three self-monitoring studies, researchers relied on subjects adhering to specific instructions on how to record foot temperatures.

Resting of feet prior to temperature measurements varied between studies. In three studies, there was a rest interval of 3-5 minutes, rest time was not mentioned in one study (Roback et al, 2009), whereas two studies had bed rest of more than 15 minutes. In the three self/home monitoring studies foot rest instruction was not stated. A standardised time for resting feet prior to temperature monitoring would reduce the risk of error/bias in results. Additionally, falsely elevated temperature levels after periods of prolonged activity could result in unnecessary contact with clinicians for non-urgent referrals.

Foot temperature monitoring provides an objective measurement to complement the standard foot examination (Roback et al, 2009). It has the potential to increase patient self-care with objective feedback data. It has also been questioned if frequent skin temperature monitoring will result in more contacts with clinicians. Would this place extra strain on primary care resources? Conversely, early detection and prevention of DFCs would lead to reduced hospital admissions and a reduction in the need for costly dressings, anti-biotic therapy and procedures such as digit, foot or limb amputations. Temperature monitoring devices that use thermal imaging/scanning the entire plantar foot service are more suited to specialist clinician's practices. Thermal images and temperature readings of the entire foot can be stored digitally in a telemedicine system. It is suggested that severe foot complications could be promptly referred to tertiary centres for specialist vascular/orthopaedic intervention without delay.

The technology for temperature monitoring in the at-risk diabetic foot has much potential going forward. Temperature scanning devices could be incorporated into smartphones and the acquired images sent to health centres for storage and monitoring. However, all of the above requires motivation and skills on the part of patients. Such devices are not suitable for every patient, i.e., those with cognitive impairment, sight impairment or major foot structural abnormalities.

The findings in this SR show the relationship between increased skin foot temperature and latent skin inflammation. Additionally, it was found that daily skin temperature monitoring of feet prevented ulceration and infection from developing. Notably, there is no known absolute value for skin temperature change that is indicative of DFCs. Comparative temperature readings on other areas of the affected foot or those of the contralateral foot are indicative of infective/inflammatory processes under the skin. Such findings are consistent with those of Houghton et al (2013).

Thermographic cameras and LCT were found to be time consuming and required specialist expertise and further digital equipment. Moreover, such infrared thermometry technology could be incorporated into clients' mobile phones increasing the capacity for storage of foot temperature recordings, diurnal trends in temperature changes, analysis of foot temperature after activities. Such data could be sent remotely (via application programmes; APPs) to clients' healthcare providers thereby reducing the need to attend clinics unless deemed necessary according to temperature readings. Such a targeted intervention could have cost saving effects relative to the overall cost of treating DFCs, especially LEAs. This is reflected in the study by Armstrong et al. (2007) where increases in foot skin temperature were observed up to seven days prior to the development of a DFC.

Limitations

Due to the heterogeneity of the studies selected for this SR, it was not possible to carry out a meta-analysis of the findings. There was variability between studies pertaining to interventions and the clinical characteristics of the study populations.

Conclusion

This review systematically analysed 9 articles examining the clinical effectiveness of foot skin temperature monitoring for the prevention and detection of DFCs. The feasibility of self-monitoring of foot temperatures as part of everyday foot care has shown promising results in the early detection of DFCs. Skin temperature monitoring could be utilised as an adjunctive diagnostic tool to track the trajectory of DFCs and implement early interventions. ■

Conflict of interest

This systematic review did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

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