Title:

An overview of temperature monitoring devices for early detection of diabetic foot disorders

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An overview of temperature monitoring devices for early detection of diabetic foot disorders

Diabetic foot complications are associated with substantial costs and loss of quality of life. This article gives an overview of available and emerging devices for the monitoring of foot temperature as a means of early detection of foot disorders in diabetes. The aim is to describe the technologies and to summarize experiences from experimental use. Studies show that regular monitoring of foot temperature may limit the incidence of disabling conditions such as foot ulcers and lower limb amputations. Infrared thermometry and liquid crystal thermography were identified as the leading technologies in use today. Both technologies are feasible for temperature monitoring of the feet and could be used as a complement to current practices for foot examinations in diabetes.

Keywords: diagnosis • neuropathic diabetic foot • prevention • thermography • ulceration

Diabetic foot disease includes peripheral arterial disease, neuropathy and infection which, in presence of a triggering factor, may lead to ulceration and subsequent amputation. Osteoarthropathy and Charcot foot disease are also complications resulting from the neuropathic risk factors. These complications are extremely painful and disabling, and are a major economic burden for society. Expressed in disability adjusted life years (DALYs), diabetes mellitus accounts for 3% of all disability in high-income countries [101], which is mainly owing to diabetic foot disease, and consequent lower limb amputations.

The aims of this article were to find relevant inventions for the monitoring of foot temperature as a means of early detection of foot disorders in diabetes and to describe available technologies in this area, focusing on thermographic as well as thermometry devices. The article also summarizes the results from various experimental uses of the technologies.

Foot ulcers & temperature monitoring

The International Diabetes Federation (IDF) has estimated the World diabetes prevalence at 6% in the adult population (aged 20–79 years). Consequently, there are currently approximately 30 million people with diabetes in the EU-27 countries [102,103]. The annual incidence of foot ulceration among people with diabetes is approximately 2% and approximately 15% of these will lead to a lower-limb amputation [1,2]. This would imply that 600,000 diabetic foot ulcers occur each year in the EU-27 countries, of which 90,000 will require an amputation.

In many cases, development and deterioration of diabetic foot disorders can be avoided or substantially delayed with adequate treatment provided at an early stage. Risk assessment of diabetic patients and determination of foot status are therefore performed routinely in many countries. However, the incidence of serious complications could be further reduced according to diabetes experts [3–5].

Studies show that there is a relationship between increased temperature and foot complications in diabetes [6–8]. Increased temperature may be present up to a week before a foot ulcer occurs [8,9]. In this early stage of the disease, patients seldom feel pain because of neuropathic sensory loss, which indicates that increased temperature can be a useful predictive sign of foot ulceration and sub-clinical inflammation of the feet.

However, in order to define ‘increased temperature,’ a standardized reference temperature is required that can be employed for a specific risk category of patients. Foot temperatures vary

between patients, and depending on ambient tempera-ture and level of activity. The most frequently used reference is therefore a corresponding area on the contra lateral foot. Temperatures of corresponding areas of the right and left foot do not usually differ of more than 1°C and a temperature difference of more than 2.2°C (4°F) is considered abnormal [10–12]. Also, in conditions that lead to higher or lower foot temperatures, such as
arteriovenous shunts and atherosclerosis, the tempera-ture change is often evenly distributed between the feet [13]. Consequently, there seems to be a rationale for determining foot temperatures in diabetic patients.

The current healthcare practice for temperature assessment is manual palpation of foot temperature. However, the increase in temperature is usually too subtle to be detected manually [14]. Instrumental measurements are seldom performed. Mapping of
the foot temperature with a thermometer is rather time consuming and the invention of a thermographic instrument for temperature imaging of the entire foot has therefore been an attractive option.

Temperature difference between corresponding sites of the left and right foot is an early warning sign of foot disease in diabetes [10] but although assessment of foot temperature is recommended in guidelines for determin-ation of foot status [15,104], regular monitoring of foot temperature has not, so far, been integrated into standard diabetes care. The time aspect might have been a contributing factor that has slowed down adoption of the method but today new technologies are under way to facilitate and speed up the process.

The subject of foot temperature assessment in diabetes has been investigated by several authors and in a review by Bharara *et al.* conducted in 2006, here four feasible techniques were identified,
three of which have now been developed into commercial products by different inventors [16].

Methods & material

In order to find relevant inventions for monitoring of foot temperature, searches have been carried out using FreePatentsOnline (Jan 1990–Oct 2009) [105]. The search strategy was to find patents or patent applications with different combinations of the following sets of keywords in the title or abstract: diabetes, diabetic, plantar, foot/feet, temperature, thermographic, thermochromic, thermal imaging, and sensor/s. In order to find not-patented inventions, the internet (Google) was searched using the same search terms.

In total, 15 unique inventions were found in the review, 13 from FreePatentsOnline and two from the internet (Table 1). Experimental use and marketing of these inventions were traced via the Medline database and searches of the internet using keywords in the retrieved documents and names of inventors and/or organizations behind the inventions. The first 50 pages of each Internet search were examined. Personal communication with inventors or vendors has also been used in some cases. Knowledge regarding thermo-graphic methods has been compiled specifically
and articles that generally describe foot complications in diabetes have been studied to obtain background understanding of the problem.

Results

The literature review identified three technologies for temperature measurement that are available as commercial products intended for the diagnosis of foot problems, two of which have had an experimental clinical application. The technologies are scanning with infrared-thermometer, liquid crystal thermography (LCT) and temperature sensors integrated into a weighing scale. There is also an option to use traditional IR camera systems to assess foot temperature [8,16]. However, neither of the technologies has been adopted in standard healthcare, as judged from the studied literature.

Scanning of foot temperature with IR-thermometer

Several studies have shown that temperature is an important parameter in the assessment of the diabetic foot but few have investigated what could be gained in fewer complications and better health. However, three randomized trials (Lavery *et al.*, 2004 and 2007, and Armstrong *et al.*, 2007) all indicate that, at home, monitoring of foot temperature would significantly limit the rates of re-ulceration in diabetes [3,9,17]. The instrument used in the trials was the TempTouch® Dermal Thermometer, which is an IR-thermometer for selfinspection of the feet [3,17,201]. Foot temperature should be measured daily on six foot sites and recorded in a logbook. In case of a temperature difference of more than 2. 2oC between corresponding sites of the right and left foot, the users are advised to decrease their activity level and contact the diabetes nurse immediately.

The two trials from 2007 were physician-blinded, randomized and controlled. Subjects with diabetes and high risk for ulceration were assigned to either standard therapy or IR thermometry in addition to standard therapy. In both trials, patients in the standard therapy groups were significantly more likely to develop ulcers within the study time (15–18 months) than patients in the intervention group [3,17]. Study results indicate a more than 60% reduction in foot ulceration.

Liquid crystal thermography

The ideal instrument for temperature scanning should preferably produce temperature readings of the entire foot in one measurement procedure. Several different inventions have been presented, such as arrays of IR-thermosensors, IR camera systems, shoes that measure temperature, and LCT, but none has so far been diffused into widespread practice. The technology that seems to be in the most advanced stage is LCT but the literature review found only two commercial products within this field of innovations, the SpectraSole Pro 1000 [18], which has been available for some time and the more recent TempStat™ [19].

As early as 1983, Dribbon reported from clinical applications of liquid crystals and he later developed an LCT insole for assessment of diabetic feet, which was patented 1997 [20,202]. The invention has not been applied in healthcare but had an impact on later developments in the field.

Similar inventions have been developed independently by three different research teams. In Sweden, the small enterprise SpectraSole AB was founded on an LCT invention in 2004

(SpectraSole Pro 1000) and a similar invention was developed by Kantro *et al.* a couple of years later (TempStat™, Visual Footcare Technologies, NY, USA) [203,204]. Both these inventions are comprised of LCT indicator plates on which the patient places his/her feet for a minute in standing or sitting position to obtain the thermal images.

The LCT technology gives information regarding the warmth distribution of the foot through a colored foot imprint on a plate comprised by layers of encapsulated thermochromic liquid crystals. Warmth is transferred from the foot and accumulated in the plate, which gives rise to a spectrum of colors depending on the temperature. The image remains for a few minutes and then slowly fades away. The colors of the image can be compared with a template from which corresponding temperatures can be read. There is also an option for digital storage of images but currently no digital registration of the measured temperatures.

SpectraSole Pro 1000 is developed for preventive diagnostics and for the purpose of following the healing of foot complications. The target users are professionals in multidisciplinary diabetes teams. Results from a feasibility study of this instrument show that it is easy to use and that it gives additional information that could lead to more patients getting an adequate off loading and assessment of their feet [18]. The instrument is intended to be used together with standard inspections of the feet. The invention has so far had a limited experimental use in diabetes units in a handful of countries.

TempStat™ is intended for personal homecare in combination with regular standard examinations in professional care. Visual signs of the onset of complications can be detected both via temperature images and a magnification mirror integrated in the instrument.
No clinical studies were found in the literature but a patient survey by Frykberg *et al.*, (2009) has been conducted to obtain an estimate of the ability of TempStat™ to assist in self-examinations of the feet [19]. Results show that the instrument clearly visualizes hot spots and that the readings have good correlation with point measurements with IR thermometer.

There is also a third invention in this field, which so far is not available on the market [205]. However, several publications where found that used this LCT-system for assessment of diabetic feet. The prototype has been used in clinical experiments but not primarily with the purpose of prevention of diabetic foot complications. The prototype has been used for studies of temperature normalization of diabetic feet after cold and warm immersion [21,22].

Temperature sensing weighing scale

The Thermoscale® was invented in Taiwan and a patent application was filed in the USA in 2006. It is currently available as a personal selfcare device. It can be described as a body weighing scale with integrated temperature sensing thermistors, two under each foot. The scale also has a body fat measurement function [106].

Health economic aspects

This article identified a limited number of health economic evaluations of scanning and/or thermographic methods. The TempTouch® Dermal Thermometer is the only instrument that has been subject to any kind of evaluation with the purpose of informing healthcare decision makers regarding adoption of the technology. Parrella *et al.* at The National Horizon Scanning Unit, Adelaide Health Technology Assessment, Australia, made an assessment in 2005 based on Lavery *et al.* (2004) and local cost calculations of foot complications [17,23]. They recommended TempTouch® for home monitoring of diabetic patients, especially in rural settings, and claimed that this could reduce the number of amputations. TempTouch® has been evaluated further by the Anthem Blue Cross in California. However, in a policy statement revised in August 2008 it was declared that the use of TempTouch® Dermal Thermometer was to be considered investigational.

Lavery *et al.* (2007) concluded that temperature monitoring could most probably reduce the incidence of foot complications but an interpretation of the results may also be that this requires time and healthcare resources [3]. In the intervention group there was almost twice the number of diabetes nurse visits compared with the control group. The number of drop outs because of time and healthcare resource restraints was three-times higher. However, the additional foot inspections and healthcare contacts probably will lead to savings on severe cases of ulceration and hospitalization.

Expert commentary

Temperature differences between corresponding sites of the right and left foot indicates inflammatory processes. Studies demonstrate that an increased temperature may be detected at a stage where a potential diabetic foot complication is still reversible [8,9]. Consequently, monitoring of foot temperature could be used for preventive purposes. However, this requires that patients could get adequate treatment immediately after diagnosis and that treatment guidelines are implemented properly.

Studies of at-home monitoring of foot temperature show that the incidence of foot ulcers in a risk group may be reduced by more than 60% [3,9,17]. However, this requires a relatively large effort by patients, which can be hard to maintain in an everyday situation. Some sort of healthcare initiative might therefore be needed to support this.

Patient responsibility is also a factor that determines the course of the disease. Intensive treatment must be applied at a stage when the patients' perceptions of the indicated complication are usually vague. Insufficient understanding of the disease and low adherence to treatment is a well recognized problem in diabetes care and patient education and selfcare must therefore be prioritized [24,25].

The LCT technology offers rapid temperature imaging but the thermographs must be interpreted in consideration of findings from the standard foot status examination. However, an advantage with the technology is that it clearly visualizes problem areas and it has been suggested that this could lead to a higher compliance with therapeutic advice in diabetes foot care [18].

The temperature sensing weighing scale is a technology with development potential [106]. The concept of measuring body weight and foot temperature simultaneously can easily make the

procedure into a daily routine, and thereby lead to better compliance with selfcare advice. However, to get a useful assessment of foot temperature, the number of sensors would preferably be increased to cover all areas of the sole that are prone to ulceration. This implies that the two sensors per foot should be increased to a minimum of six sensors and that the positions of the sensors are made adjustable according to foot size.

Based on the studied literature, a conclusion was drawn that regular temperature monitoring of diabetic feet has a potential to reduce the incidence of foot ulcers, assuming that diagnosed foot complications are followed up and treated adequately.

Infrared thermometry and LCT may be used either for athomecare or for screening in hospital-scheduled diabetes care. Both technologies are easy to use but each has its own disadvantages. The IR method is relatively time consuming, while LCT is quick but can be more difficult to interpret. A useful combination of the two technologies may be to use LCT to get a first indication, after which suspected hot spots are measured with an IR-thermometer to determine the actual temperature increase.

Temperature monitoring could be a complementary therapy in the prevention of major foot complications but cannot replace any of the current steps in modern diabetes care. Adoption of temperature monitoring in standard care may lead to a more frequent referral of patients from primary care to specialists as further imaging studies will be needed to determine the cause of an increased temperature. Early diagnosis and early treatment is crucial for the healing of diabetic foot lesions, and resources for early interventions must therefore be available to take care of a higher number of suspected foot complications.

Five-year view

The prevalence and incidence of diabetes have increased dramatically over the past decade and forecasts do not indicate a declining trend. Huang *et al.* (2009) estimate that the number of people with diagnosed and undiagnosed diabetes will increase from 23.7 to 44.1 million between 2009 and 2034. The related Medicare costs are expected to double during that time [26].

Development of technologies to mitigate the consequences of the disease will therefore be of continued interest to healthcare as well as industry.

Most of the inventions identified in this article are still under development, which indicates that within the next 5 years the market will see several competing technologies suitable for temperature assessment of the feet. In addition to the technologies presented here, devices may be based on traditional IR camera systems. Presumably, some devices will give digital presentations of thermographic images in one measurement procedure. They will probably have image-storage options and software for diagnostic guidance. However, there is also a future for cheaper, uncomplicated devices intended for at homecare. The selfcare alternative will be even more important as public healthcare budgets probably cannot match the increasing costs of the technologic development and higher healthcare need owing to demographic factors.

The temperature sensing weighing scale may be introduced as a convenient selfcare device but the current design, with only two sensors per foot, has to be improved. At this point the LCT inventions seem to have the highest potential in the prospect of developing a feasible instrument for professional use but this is dependent on how the healthcare market develops, and the possibility for industry players to get a return on their investments.

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The author has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Key issues

- Increased temperature may be detected as an early warning for foot complications in diabetes. This occurs at a reversible stage of the disease.
- At home monitoring of foot temperature may reduce the incidence of foot ulcers by more than 60%.
- There are currently three types of devices available for monitoring of foot temperature: a specially designed infrared thermometer, the Liquid Crystal Thermography (LCT) indicator plates and a body weighing scale with built-in thermistors.
- The technologies may be used either for at-homecare or for screening in hospital scheduled diabetes care.
- Scanning of foot temperature with an infrared thermometer is relatively time consuming, while the LCT technology offers rapid temperature imaging. However, the thermographs may sometimes be difficult to interpret.
- The temperature-sensing weighing scale has a potential of making foot temperature monitoring into a daily routine but must be developed further.
- Temperature monitoring could be a complement in the prevention of major foot complications but cannot replace any of the current steps in diabetes care.
- Adoption of temperature monitoring in standard care may lead to a more frequent referral of patients from primary care to specialists but prevention of serious foot complication has a potential to save costs owing to avoided amputations and in-hospital care.
- Early diagnosis and early treatment is crucial for the healing of diabetic foot lesions. The healthcare system must therefore be prepared to take care of a higher number of suspected foot complications.

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** of considerable interest

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Table 1 (page 713-714)

Inventions for temperature assessment of diabetic foot disease, their origin, technology base and applications.

Product/ Company/ Inventor/ year of latest document	Identification number / patent/ application/ grant	Country	Name/description	Technology	Stage of innovation diffusion*	Ref.
OxyBand Technologies, Inc./ Postel, 2010	US20100041998A1, WO/2010/021932A3	USA	Method for detecting and/or monitoring a wound using infrared thermal imaging.	Three-dimensional infrared thermal imaging. Data processing and digital presentation of images.	Innovation in development. Patent application filed 2008.	[206]
ShoePod Diabetic™ / Zephyr Technology Inc./ Russell, 2009	WO/2009/005373A1	New Zealand	Footwear for prevention of foot ulceration.	Shoe/insole. Smart fabric technology. Pressure and temperature sensor arrays. Chip thermistors.	The invention has been commercially available. No recent marketing found.	[207]
SpectraSole Pro 1000 / SpectraSole AB / Carlsson et al., 2009	US20090219972, WO/2007/114768A1	Sweden	Device and method for measuring temperature over an area.	Imaging device. Liquid crystal thermography. Thermal images on indicator plates.	Commercially available product. European CE Mark approval. Limited use in a handful of countries.	[203]
TempTablet / 2009	No patent found.	USA		Sensor arrays. Temperature profiles of the feet. Storage of data for comparisons. Alarm function.	No recent marketing found.	[107]
Korosensor.com Inc./ Schoess, 2008	Grant 1R43DK083782-01	USA	Diabetic foot imaging scanner.	Clinical signs of skin breakdown. Infrared imaging.	R&D phase. [108]	
Cobb, 2008	Application filed, UK 0802913.4	UK	Apparatus and method for real-time full field thermal imaging of the sole of the foot.	Imaging device. Liquid crystal thermography. Real-time imaging.	Precursor used in clinical research [21, 22]. Clinical evaluation of current prototype under consideration.	[205]
TempStat™ / Visual Footcare Technologies / Kantro et al., 2008	US20080214962A1, WO/2008/073430A2	USA	System and method for monitoring plantar temperature of the foot.	Imaging device. Liquid crystal thermography. Thermal images on indicator plates.	Marketing clearance in the US (510k) June 2008. A coding request in May 2009 was denied. [109, 110]	[204]
Shoureshi & Albert, 2008	US20080109183, WO/2008/058051A2	USA	Smart insole for the diabetic patients.	Shoe/insole. Non-specified temperature sensors	No application/use found.	[208]
Thermoscale® / Tsai et al., 2006	US 20060030783A1	Taiwan	Weight and body fat measurement device with temperature measuring capability.	Body weighing scale with integrated temperature sensing thermistors, two under each foot. (Body fat measured using bio impedance.)	Commercially available product. [106]	[209]

Lavery et al., 2004	US/6767330B2	USA	Foot temperature and health monitoring system.	Apparatus for monitoring of the plantar foot temperatures and other parameters. Infrared sensor arrays.	Temperature assessment applications not found.	[211]
Truong, 2001	US6195921	USA	Virtual intelligence shoe with a podiatric analysis system.	Shoe/insole. Sensors for measuring pressure shear stress and shoe temperature.	Temperature assessment applications not found.	[212]
TempTouch® (FootScan) / Constantinides, 2000	US/6090050	USA	Thermometric apparatus and method. (Invention developed and tested in collaboration with Lavery et al.)	Infrared thermometer connected to a controller with alarm function. The thermometer is designed to facilitate self examination of the feet.	The thermometer (without the controller) is a commercially available product. Marketing clearance in the US (510k) and European CE Mark approval.	[201]
Brown, 1999	US5929332	USA	Sensor shoe for monitoring the condition of a foot.	Shoe/insole. Non-specified sensors for chafing of the skin, temperature and moisture.	Temperature assessment applications not found.	[213]
Harrison, 1998	EP0885587A1	UK	Thermal imaging method and apparatus.	Assessment of blood flow using temperature data. Infrared sensors to measure temperature in a number of points during recovery after cold immersion	Not applied for temperature assessment of the feet.	[214]
Dribbon, 1997	US5678566	USA	Method and apparatus of thermographic evaluation of the plantar surface of feet.	Shoe/insole. Liquid crystal thermography.	No application/use found.	[202]
Parotec / Paromed Medizintechnik / Leyerer et al., 1997	US5642096	Germany	Device for prevention of ulcers in the feet of diabetes patients.	Shoe/insole. Hydrocell pressure and temperature sensors. Alarm function.	Used for plantar pressure assessments [27]. Recent temperature assessment applications not found.	[215]

* As assessed from Internet searches and, in some cases, personal communications with inventors and vendors (Nov. - Dec. 2009)