Feasibility of a Thermographic Method for Early Detection of Foot Disorders in Diabetes

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Abstract

Background: Foot complications due to diabetes impose a major economic burden on society and loss of health-related quality of life for the patients. Early diagnosis and intensified preventive measures have proved useful to limit the incidence of foot ulcers and lower limb amputations in diabetes, and the development of new tools for early diagnosis has therefore become an attractive option. This article covers a feasibility study of the SpectraSole (Linköping, Sweden) Pro 1000 foot indicator, an innovation based on liquid crystal thermography. The technology identifies increases in temperature, a known indicator of inflammation.

Methods: Sixty-five patients with diagnosed diabetes were examined with the foot indicator immediately after their ordinary foot examinations according to current practice, and findings from the two investigations were compared.

Results: Sixty-nine examinations were performed. The foot indicator identified increased temperature in 31 cases, of which six had not been detected in the preceding ordinary examinations. The instrument was perceived as easy to use, and the thermographs could be used to visualize problem areas of the foot, which might contribute to better compliance with therapeutic advice.

Conclusions: The foot indicator detected a relatively high share of the different types of complications but not all. It can be used as a complement to current practices for foot examination. The instrument provides rapid imaging of the foot temperature, and the study indicates that it yields valuable diagnostic information in early stages of foot disease.

Introduction

Foot complications due to diabetes cause great suffering and are a major economic burden to the patients and society. Diabetes mellitus accounts for 3% of all disability in high-income countries,1 which to a great extent is due to foot disease caused by diabetes and consequent lower limb amputations. Many of the serious complications can, however, be avoided if adequate treatment is provided at an early stage. Determination of foot status is performed routinely in many countries, but the incidence of serious complications could be further reduced, according to diabetes experts, and it has been shown that many diabetes patients have inadequate off-loading of foot problems.2–4

In order to avoid serious complications, intensive treatment must be applied early. It is crucial to detect early warning signs, but symptoms are often vague, and diagnostic tests may be inconclusive. Further, it may be hard to motivate an active treatment of an indicated complication that the patients probably, at that stage, perceive as a minor problem. Low compliance to treatment is a well-recognized problem in diabetes care.5,6 Many minor problems therefore progress to limb-threatening conditions such as infected ulcers, gangrene, or Charcot foot. Hospitalization, antibiotics, amputations, and other surgery incur considerable expenses, whereas costs for diagnosis and prevention are relatively small.7,8 A reduction of hospital admissions through preventive care is thus likely to be a cost-effective strategy. Total costs of an average foot ulcer due to diabetes, from diagnosis to healing, has recently been estimated to be 10,091 EUR, and a case that requires a major amputation to be 25,222 EUR.7

Several studies have shown that there is a relation between increased temperature and foot complications in diabetes9–11 and that temperature increases may be detected at a reversible stage of the disease.11,12 At this stage, the patients seldom feel

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This feasibility study has also been reported at the International Conference on Advanced Technologies & Treatments for Diabetes, February 2009.
pain, and increased temperature may therefore be a useful predictive sign.

There are two commercial products available that are intended for diagnosis of increased temperature as an indicator of foot problems in diabetes. The technologies behind these products are scanning with an infrared thermometer and imaging with liquid crystal thermography. Neither of the technologies has been adopted in standard health care.

At-home monitoring of foot temperature with an infrared thermometer has been suggested as a method to avoid foot complications. Three studies have been performed to assess the benefits in terms of fewer complications and better health.2,12,13 Foot temperature was measured daily on six foot sites on both feet, and the users were advised to decrease their activity and contact the diabetes nurse immediately if the temperature differed more than 4°F between corresponding sites of the right and left foot. There are normal variations in foot temperatures between patients and according to ambient temperature, but temperatures of corresponding sites of the feet do usually not differ much, and temperatures of the contralateral foot can therefore be used as a reference.14–16 The method shows promising results, and the studies indicate that the incidence of foot ulceration in diabetes could be significantly decreased through daily self-inspections of the feet.

However, to map the temperature of the entire sole of the foot is a time-consuming process, and development of a feasible instrument for rapid temperature imaging of the feet has therefore been the object of several inventors. The SpectraSole (foot indicator) Pro 1000 is a Swedish invention based on liquid crystal thermography. This article reports on a feasibility study of the instrument in diabetes foot care. The aim of the study was to test the innovation in an authentic care situation and to assess the value of the instrument for early detection of subclinical foot disorders.

**Materials and Methods**

The setting for the study was Swedish health care, and the investigators were diabetes-specialized nurses and foot specialists in two participating care units: one highly specialized orthopedic unit and one primary care unit. The investigators have had long experience with diabetes foot care and are well acquainted with the specific problems of diagnosis and compliance in diabetes care.

The following questions were raised:

- Does the foot indicator give diagnostic information that would not be found in a standard examination?
- Does diagnostic information from the foot indicator lead to a more thorough examination of the patient, a different prescription, referral to a specialist, or earlier follow-up of the patient?
- Does the foot indicator facilitate communication between caregiver and patient?

The study was conducted in accordance with Good Clinical Practice and the Declaration of Helsinki. Approval has been granted by the Regional Ethics Committee of Linköping, Sweden.

**Description of the instrument**

The liquid crystal thermography instrument, SpectraSole Pro 1000, has had a limited use in diabetes units in a handful of countries. It is developed for preventive diagnostics and for the purpose of following healing of foot complications. The target users are professionals in multidisciplinary diabetes teams.

The foot indicator gives information about the warmth distribution of the feet. It consists of two rectangular plates, with encapsulated thermochromic liquid crystals, supported in a frame (Fig. 1). The plates are built up of layers of liquid crystals. Each layer change color within a determined temperature interval. The colors of the layers are visible as small hexagons at the plates, and the combination of different liquid crystals, sensitive to different temperatures, gives rise to temperature-specific patterns.

An examination with the foot indicator is relatively quick to perform. The patient places his or her feet on the indicator for 1 min, in a sitting or standing position. Warmth is transferred from the feet and accumulated in the plates, which gives rise to a spectrum of colors depending on the temperature. Comparison of the left and right thermal foot images reveals warm areas, which may indicate inflammation. The image remains for a few minutes and then slowly fades away. The colors on the plates can be compared to a template from which the temperatures can be read. Areas that show increased temperatures could be documented manually in a foot diagram, but there is also an option for digital storage of images.

**Description of the intervention**

The patients initially had their foot status determined in a standard examination, according to current Swedish guidelines. These guidelines recommend that feet of individuals with diabetes are inspected by professionals regularly at an interval determined by patients’ foot status and risk factors for foot disease. Diabetes patients should be assessed on the background of neuropathy, peripheral vascular disease, osteoarthropathy, and other risk factors, and the feet should be inspected for signs of deformities, inflammation, and wounds.

Upon completion of the ordinary foot examination, the findings were noted in a study protocol containing data on risk factors, clinical findings, and a foot diagram, where the investigator could fill in located problem areas. The patient was then examined with the SpectraSole Pro 1000, and the second part of the protocol was filled in. Temperature differences between corresponding areas of the left and right foot were marked in a foot diagram and it was noted if investigation with the foot indicator had led to a different prescription, referral, self-care advice, or earlier follow-up. Temperature differences were classified as (a) a moderate difference according to a visual estimate of the plates, (b) a difference that ought to be followed up (visual estimate), and (c) a difference that ought to be followed up (>1.5°C, measured by an infrared thermometer). The investigators were free to decide if they should check the indicated temperature difference with a thermometer or not.

The investigators were also asked to reflect on the usability of the instrument and the patients’ reactions.

**Inclusion of patients**

Diabetes patients coming for a scheduled or self-induced visit during spring 2008 were invited to take part in the study. Exclusion occurred only if the patient had had a major amputation or if examination with the foot indicator was not
physically possible. Sixty-nine examinations were performed in 65 patients, 22–93 years old (Table 1).

Patient characteristics varied regarding age, disease duration, and risk factors for foot complications. A selection of risk factors were noted in the study protocol, and most patients had two or three of these risk factors. Five patients had none, and 12 patients had five or more risk factors (Table 2).

Results

Findings from 69 SpectraSole examinations have been analyzed and compared to preceding standard examinations, according to guidelines for diabetes care. In order to objectively assess whether the foot indicator had detected temperature differences where no or minor problems were expected, the filled-in protocols were categorized into five groups based on documentation of problem areas and foot status after the standard examination (Table 3).

The SpectraSole Pro 1000 indicated temperature differences between the right and left foot in 31 cases, 21 in primary care and 10 in specialized care (Table 3). Six of these temperature differences had not been detected in the preceding ordinary examinations: five in primary care and one in specialized care. The six patients received necessary changes in prescriptions and/or augmented self-care advice, and in a follow-up examination the patients had no or only moderate temperature differences between the feet.

![FIG. 1. The foot indicator SpectraSole Pro 1000. Examination of the feet at a routine visit for determination of foot status. Reprinted with permission from SpectraSole AB. Color images available online at www.liebertonline.com/dia.](image)

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<th>Demographic</th>
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<td>Duration of diabetes (years)</td>
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<td>Median</td>
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<td>Impaired vision</td>
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<td>Rheumatic disease</td>
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<td>Other important disease</td>
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Table 1. Patient Demographics

Table 2. Risk Factors Documented in the Study Protocol
Among the 42 examinations in groups 1 and 2 (no or minor problems, according to the standard examination), the instrument indicated that 26% may be at risk of foot complications. The study was, however, not designed to answer whether any of these were false-positives or not.

Analysis of groups 3–5 (several and/or large problem areas) gave an indication of the extent to which the foot indicator could detect already identified foot problems. These groups comprise 27 examinations, of which 74% were identified by the foot indicator. A visible problem area is not always associated with a temperature difference, which can explain some discrepancy, and the true identification of warm areas may therefore be higher.

An examination with the SpectraSole Pro 1000 was considered easy and quick to perform even if some thermographs may be diffuse and somewhat difficult to interpret. The instrument was also perceived as useful in communication between caregiver and patient. The investigators in primary care were of the opinion that it could motivate patients to greater compliance with therapeutic advice, as it clearly visualizes and indicates problem areas.

Discussion and Conclusions

The literature shows that monitoring of foot temperature could be used for preventive purposes. Studies of at-home monitoring of foot temperature have indicated that the incidence of foot ulcers in a risk group may be reduced by more than 60%. This, however, requires a relatively large effort by the patients, which can be hard to maintain in an everyday situation. A regular healthcare-induced monitoring might therefore be a feasible alternative. The SpectraSole Pro 1000 offers an alternative to temperature scanning as it maps the entire sole of the foot in one measurement procedure. It will probably benefit most in primary care as a tool for prevention of foot problems. Our study indicates that the instrument has a clinical value, but the number of patients is too small to draw certain conclusions. To be able to assess how thermography could affect the incidence of ulcers and amputations, a larger trial must be performed in the primary care setting, preferably with a long-term follow-up to assess the outcome of avoided foot complications.

The instrument identified 74% of the foot problems among the patients with the worst foot status, and among all patients in the study the instrument detected six cases that had not been detected in the preceding ordinary examination. This leads to the conclusion that the foot indicator gives additional information, but, as in every case of imaging, the thermographs must be interpreted in consideration of other findings from the foot status examination.

The six hot spots that were only detected by the foot indicator had all normalized at follow-up. It is not clear whether this was a normal course of the disease or if better off-loading was a factor in this. Compliance with therapeutic advice is often a problem in diabetes care, and an aspect that was discussed among the foot specialists was that the instrument might motivate patients to greater compliance.

Temperature monitoring should be a complement and cannot replace any of the current steps in a standard foot examination. Adoption of the foot indicator may lead to a more frequent referral of patients from primary care to specialists. Further imaging studies will be needed to determine the cause of an increased temperature, and, as early treatment is crucial for the healing of foot lesions due to diabetes, resources for early interventions must be available to take care of a higher number of suspected foot complications.

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Author Disclosure Statement

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