Home Monitoring of Foot Skin Temperatures to Prevent Ulceration

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OBJECTIVE — To evaluate the effectiveness of at-home infrared temperature monitoring as a preventative tool in individuals at high risk for diabetes-related lower-extremity ulceration and amputation.

RESEARCH DESIGN AND METHODS — Eighty-five patients who fit diabetic foot risk category 2 or 3 (neuropathy and foot deformity or previous history of ulceration or partial foot amputation) were randomized into a standard therapy group ($n = 41$) or an enhanced therapy group ($n = 44$). Standard therapy consisted of therapeutic footwear, diabetic foot education, and regular foot evaluation by a podiatrist. Enhanced therapy included the addition of a handheld infrared skin thermometer to measure temperatures on the sole of the foot in the morning and evening. Elevated temperatures (>4°F compared with the opposite foot) were considered to be "at risk" of ulceration due to inflammation at the site of measurement. When foot temperatures were elevated, subjects were instructed to reduce their activity and contact the study nurse. Study subjects were followed for 6 months.

RESULTS — The enhanced therapy group had significantly fewer diabetic foot complications (enhanced therapy group 2% vs. standard therapy group 20%, $P = 0.01$, odds ratio 10.3, 95% CI 1.2–85.3). There were seven ulcers and two Charcot fractures among standard therapy patients and one ulcer in the enhanced therapy group.

CONCLUSIONS — These results suggest that at-home patient self-monitoring with daily foot temperatures may be an effective adjunctive tool to prevent foot complications in individuals at high risk for lower-extremity ulceration and amputation.

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Foot ulcers are one of the most common precursors to diabetes-related amputations (1,2). Other factors that have been associated with amputation, such as infection, faulty wound healing, and ischemia, usually do not cause tissue loss or amputation in the absence of a wound. Therefore, ulcer prevention is one of the foci of any amputation prevention program.

One of the most common mechanisms in the development of neuropathic foot ulcerations involves a cumulative effect of unrecognized repetitive trauma at pressure points on the sole of the foot over the course of several days (3–5). The standard approach to prevent ulceration is to provide padded insoles and protective shoes, educate the patient and their family, and provide regular foot inspection by the patient's primary care physician or podiatrist.

Except for traumatic wounds, areas that are likely to ulcerate have been associated with increased local skin temperatures due to inflammation and enzymatic autolysis of tissue (6–8). Identifying areas of injury by the presence of inflammation would then allow patients or health care providers to take action to decrease the inflammation before a wound develops. Our rationale for evaluating skin temperatures involves the search for a quantifiable measurement of inflammation that can be used to identify pathologic processes before they result in ulcers. Inflammation is one of the earliest signs of foot ulceration. It is characterized by five cardinal signs: redness, pain, swelling, loss of function, and heat. Many of these signs are difficult to assess objectively. In the neuropathic extremity, pain and disturbance of function may be absent because of neuropathy and thus are poor indicators of inflammation. In addition, swelling and redness are difficult to objectively grade even among experienced clinicians. Most lay people will not be able to understand or accurately evaluate these subtle parameters. However, temperature measurements can be easily performed by patients or their spouses and provide quantitative information that has been shown (6,9–11) to be predictive of impending ulceration.

The objectives of the study were to evaluate the effectiveness of a novel infrared temperature instrument to improve clinical outcomes and functional status in diabetic patients at high risk for foot complications. The infrared skin temperature device was used to provide objective information to patients so they would have an "early warning sign" of inflammation and tissue injury because their innate ability to perceive pain and protect their feet from tissue injury was blocked by severe diabetic peripheral sensory neuropathy.

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Abbreviations: VPT, vibratory perception threshold.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—*Patient characteristics and clinical outcomes*

	Standard therapy	Enhanced therapy
Patient population	44	41
Age (years)	54.8 ± 9.6	55.0 ± 9.3
Sex (% men)	52.3	48.8
Duration of diabetes (years)	12.7 ± 10.0	14.8 ± 11.5
Risk category 2	26 (59)	24 (59)
Risk category 3	18 (41)	17 (41)
History of amputation	1 (fifth toe amputation)	1 (second toe amputation)
Risk category mean	2.41 ± 0.50	2.41 ± 0.50
VPT (left foot)	33.8 ± 10.4	35.9 ± 9.1
VPT (right foot)	35.9 ± 11.3	36.5 ± 8.6
Elective/voluntary dropouts from the study	4	3
Outcomes		
Foot ulceration	7*	1
Charcot fracture	2	0
Total	9*	1

Data are means ± SD or *n* (%). *$P < 0.05$.

RESEARCH DESIGN AND METHODS

— This study was a single-blinded, randomized clinical trial of 85 patients assigned to either a standard therapy group or an enhanced therapy group. Subjects were recruited from the high-risk diabetic foot clinics at the University of Texas Health Science Center at San Antonio. Study subjects were evaluated for 6 months. During the course of study, the treating physician was blinded as to whether the patient belonged to either the standard therapy or enhanced therapy group.

Both groups received standard care consisting of therapeutic footwear, diabetic foot education, and foot evaluation by a podiatrist every 10–12 weeks. In addition to the standard elements of diabetic foot care, the enhanced therapy group also used a handheld infrared skin thermometer (TempTouch; Xilas Medical, San Antonio, TX) to measure temperatures on the sole of the foot in the morning and evening. Fundamentally, this methodology used skin temperature measurements to forewarn the patient of impending inflammation and ulceration. Six predetermined sites were measured and recorded in a log book on each foot. The sites tested include first, third, and fifth metatarsal head, great toe, central midfoot, and heel. If a toe or toe and metatarsal had been previously amputated, an adjacent anatomic area was measured. For instance, if the great toe had been amputated, the second toe was used as a temperature assessment site. If a site had callus, it was still used as a temperature assessment site.

If there was a temperature difference >4°F (4.0°F ~ 2.2°C) between the left and right corresponding sites, the patients were advised to contact a nurse case manager and to significantly reduce the number of steps taken in the following days or until the temperature differences fell <4°. The clinical outcomes that were evaluated were incident foot ulcers, infections, Charcot fractures, and amputations.

Patients who were enrolled in the study met a high-risk profile for developing diabetic foot ulcerations. We defined high-risk patients as adult patients with diabetes with a history of foot ulceration or lower-extremity amputation or patients with peripheral sensory neuropathy with loss of protective sensation, with a foot deformity such as hallux valgus or claw toes. These criteria are based on previously identified risk factors for foot ulcerations and amputations (12,13).

Inclusion criteria included diagnosis of diabetes by World Health Organization criteria (14), ability to provide informed consent, age 18–80 years, and risk group 2 or 3 using the diabetic foot risk classification system as specified by the Interna-

Table 2—*SF-36 scores*

Pre- versus posttesting	Standard therapy	Enhanced therapy
Physical functioning		
Pre	44.7 ± 30.6	46.7 ± 32.1
Post	44.3 ± 36.5	45.3 ± 36.4
Role physical		
Pre	38.4 ± 41.7	37.2 ± 42.7
Post	36.3 ± 41.74	39.0 ± 44.1
Bodily pain		
Pre	62.1 ± 24.7	57.8 ± 26.2
Post	52.9 ± 32.1	53.2 ± 33.3
General health		
Pre	49.9 ± 21.3	48.1 ± 21.2
Post	42.7 ± 30.2	42.0 ± 28.5
Vitality		
Pre	51.2 ± 22.2	49.2 ± 22.4
Post	51.1 ± 28.9	49.0 ± 30.1
Social functioning		
Pre	64.8 ± 26.5	64.8 ± 26.3
Post	60.5 ± 35.2	60.8 ± 34.6
Role emotional		
Pre	52.0 ± 49.1	49.6 ± 50.0
Post	47.0 ± 43.3	52.7 ± 45.0
Mental health		
Pre	67.8 ± 22.4	67.3 ± 23.4
Post	64.5 ± 32.6	65.7 ± 30.7

Data are means ± SD. There was no significant difference in any of the measurements of the SF-36 when pre- and posttherapy measurements were compared.

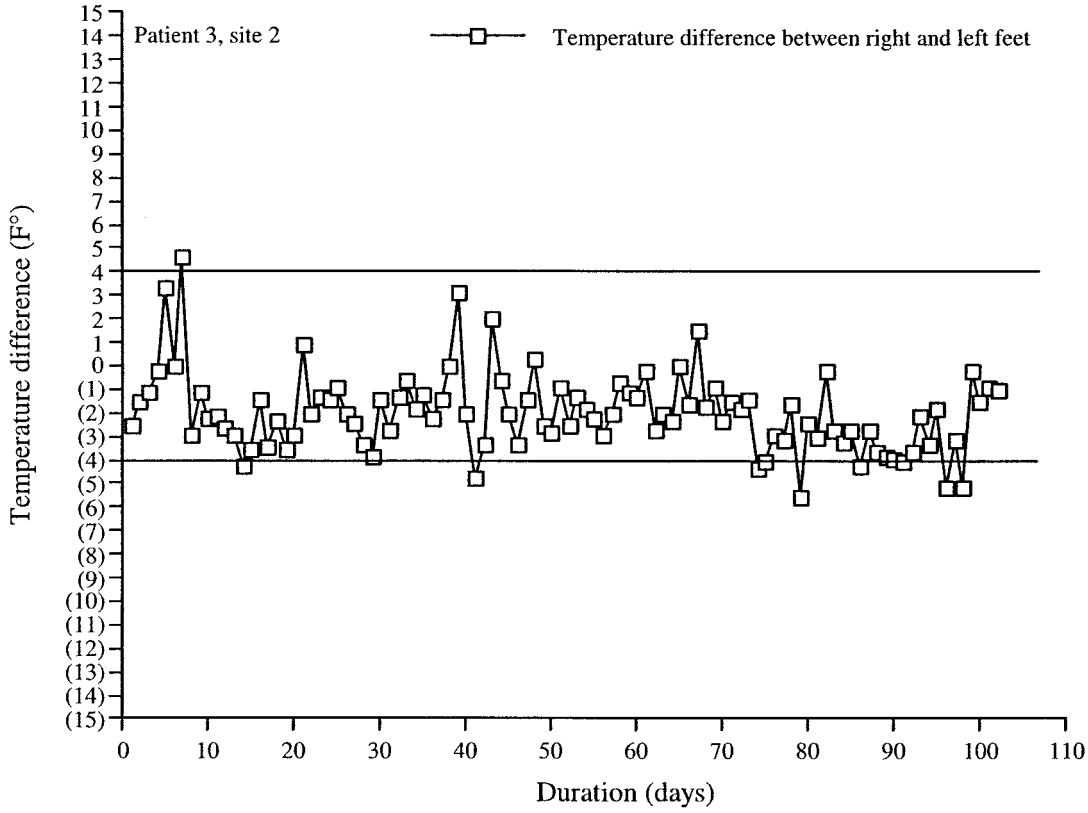

Figure 1—*This graph shows daily temperatures taken under the first metatarsal of patient 3. Patient 3 was a 56-year-old man with a 7-year history of diabetes and a history of amputation. This patient maintained a consistent temperature pattern throughout the monitoring period and did not experience any foot complication. Temperature differences on the y-axis were determined by comparing temperatures measured under the first metatarsal head on the right and left feet. Measurements that are above the 4°F "boundary" limit at the top of the graph represent higher temperatures on the right foot, and measurements beyond the lower "boundary" represent higher temperatures on the left foot.*

tional Working Group on the Diabetic Foot (13). Exclusion criteria included patients with open ulcers or open amputation sites, active Charcot arthropathy, peripheral vascular disease, active foot infection, dementia, impaired cognitive function, history of drug or alcohol abuse within 1 year of the study, or other conditions based on the principal investigator's clinical judgment.

Neurologic assessment consisted of testing vibratory perception threshold (VPT) (15,16). For the purpose of this study, we assessed VPT at the distal pulp of the great toe using the Xilas VPT meter (Xilas Medical, San Antonio, TX). The presence of sensory neuropathy was defined as VPT >25 V. The vascular assessment consisted of palpation of dorsalis pedis and posterior tibial arteries. If one or both arterial pulses were not palpable, the subject was excluded.

The Short-Form Health Survey (SF-36) (17) was used at the beginning and end of the study to evaluate functional impairment (18).

We used an ANOVA to evaluate all continuous variables between treatment groups. Dichotomous variables were evaluated with a Fisher's exact test with odds ratio and 95% CI. For all analyses we used an α of 0.05. Analysis was conducted on an intent-to-treat basis.

RESULTS

Foot complications

There were no significant differences in age, duration of diabetes, severity of neuropathy measured by VPT, or diabetic foot risk category among patients assigned to the standard therapy and enhanced therapy groups (Table 1). The most striking result of the study was the disparity in the number of foot complications between the two groups. Patients in the enhanced therapy group exhibited significantly fewer diabetic foot complications (Table 1). There were nine (20%) foot complications in the 44 patients in the standard therapy group and one (2%) complication in the 41 patients in the group that used home infrared temperature monitoring ($\chi^2 = 6.63$, $P = 0.01$). Patients in the standard therapy group were 10.3 times more likely to develop a foot complication compared with patients in the enhanced therapy group (95% CI 1.2–85.3). In the standard therapy group, there were seven ulcers and two Charcot fractures. Two of the patients developed infections and required local foot amputations. In the enhanced therapy group, one patient developed an ulcer. No infections, amputations, or Charcot fractures were identified in the enhanced therapy group. There were three patients in the standard therapy group who voluntarily dropped out of the study, and four patients in the enhanced therapy group dropped out of the study.

Quality of life

We used the SF-36 to evaluate functional status at the beginning and end of the study (Table 2). There were no statistical differences in the SF-36 scores (total or subcategory scores) either between

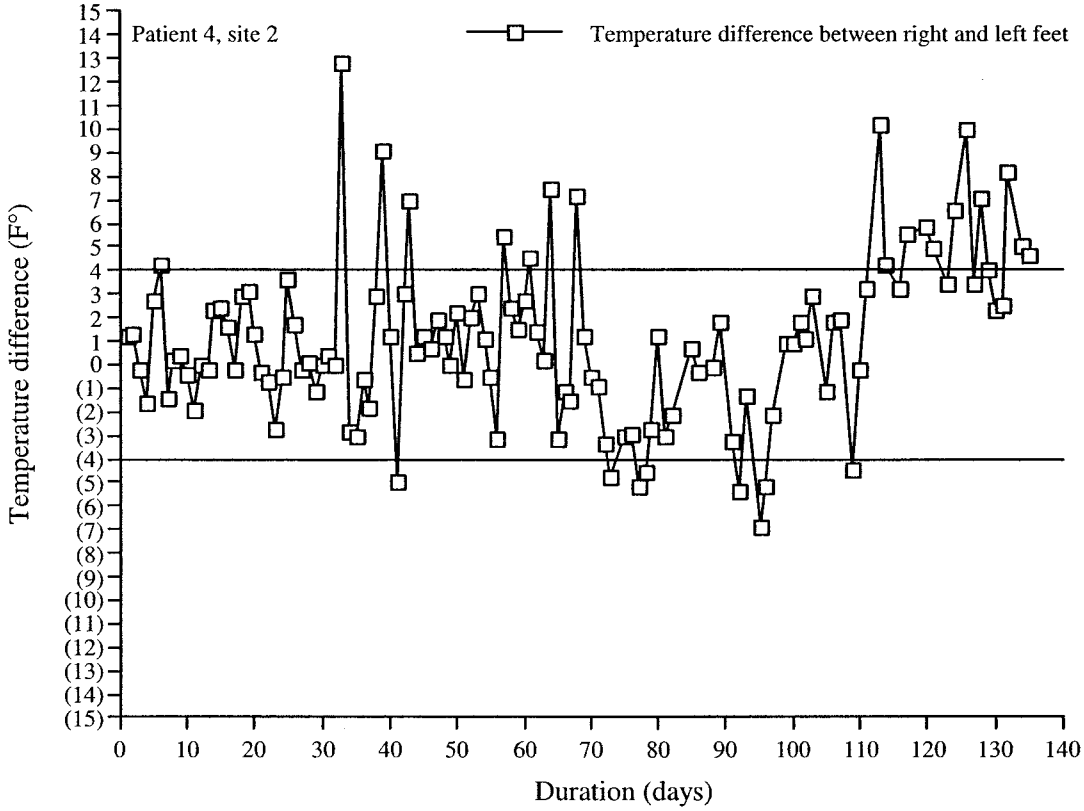

Figure 2—*The graph shows daily temperature measurements taken under the first metatarsal head of a study patient who developed a wound at this site.*

groups (unpaired *t* test) or, in the pre- and poststudy evaluations, within groups (paired *t* test).

Two examples of temperature variations are provided in Figs. 1 and 2. Figure 1 shows the foot temperature profile for a patient who suffered no complications during the study. The temperature difference did occasionally exceed the 4°F range, but did not stay at this level. Figure 2 shows the temperature profile for a 48-year-old woman with diabetes for 12 years, a history of severe sensory neuropathy, and a previous ulceration under the first metatarsal head. She had several episodes of temperatures above the 4°F range. She failed to call the study nurse as instructed when her temperatures spiked throughout the study. On day 138, she was seen in clinic, and a superficial wound under the first metatarsal head was identified. The patient failed to contact the health care provider upon recording a series of >4°F temperature differences on 21 consecutive days just before ulceration. This patient was the only subject in the enhanced therapy group who developed a wound.

CONCLUSIONS — The results of this pilot study suggest that home monitoring with daily foot temperatures could be an effective adjunctive modality to prevent foot complications. The clinical outcomes in the enhanced therapy group were significantly better than those in the standard therapy group. Patients were able to use the device and either modify their activity or contact the study nurse for advice or to schedule clinical evaluation. Previous studies (17,19–22) report ulcer recurrence in 1 year of 26–40% in subjects who use therapeutic footwear following ulcer healing. In our study, 16% of patients in the standard therapy group and 2.4% of patients in the enhanced therapy group reulcerated (16% ulcers and 4.5% Charcot fractures in standard therapy). The annualized rates observed in our standard therapy group are similar to reulceration rates in other studies. Patients in the home temperature-monitoring group had a very low rate of foot complications compared with our standard therapy group and reports using similar prevention practices.

The lower incidence of Charcot arthropathy in subjects with home monitoring was a logical clinical outcome but not an a priori study objective. We used a standard clinical approach to diagnose Charcot arthropathy. If patients had unilateral swelling, deformity, increased temperature, or any other concerns, they had access to study podiatrists for immediate clinical evaluation, radiographic assessment, and additional diagnostic imaging as deemed appropriate by the treating physician. We believe that the subjects using the home temperature-monitoring device had a lower threshold for a physician to diagnose Charcot because of the study's built-in referral pattern for elevated temperatures. We would have expected more subtle cases of Charcot's arthropathy to be diagnosed in the home monitoring group. Temperature measurements have been reported (23,24) as an assessment tool to diagnose and monitor treatment of Charcot's arthropathy. Because most patients at risk for ulceration are also at risk for Charcot, a longer study in the future may help provide more information on temperature as-

sessment to prevent fracture as well as ulceration.

Even among educated, well-informed, and highly motivated patients, there is a high rate of recidivism of diabetic foot complications. These patients almost uniformly have severe sensory loss. Often they are obese, have limited mobility of the hip and knee, or are visually impaired. These factors make self-inspection and identification of early signs of foot disease difficult. For instance, in an earlier study (3), we identified that 15% of diabetic patients with foot ulceration were legally blind, and 54% of these patients did not have adequate visually acuity and the ability to position their extremity to view the foot for self-care. In addition, visual cues probably occur late in the disease process. They are often subtle, and because pain is usually our primary trigger to provide self-care or seek professional care, a patient's ability to take action to avoid neuropathic foot ulceration is poor. As part of patient education, both treatment groups were instructed to inspect their feet on a daily basis. Most likely by the time there were visual signs of a foot problem, implementing prevention was too late. The simple home monitoring device used in this study allowed high-risk patients a self-assessment tool they could easily use and from which to obtain actionable information.

There are several issues that have been raised from this initial study that need further investigation and evaluation. Firstly, the outcomes may be a result of increased vigilance and enhanced foot inspection in the subjects who used the temperature device. Subsequent studies in this area should consider randomizing to a third patient cohort, in whom some form of active screening and reporting mechanism (such as a daily log form) would be used. Also future studies may consider the efficacy of once-daily temperature monitoring instead of the twice-daily protocol used in this study. Secondly, it is entirely possible that similar outcomes may not be enjoyed over a larger time frame. Subsequent studies should consider extending the follow-up period. It is possible that the subjects in the enhanced therapy group participated in their foot care more enthusiastically because they were using an inspection tool. It was not feasible to blind the study subjects or give them a sham temperature device. We felt that this might give them a false sense of safety and might in fact increase the risk of foot complications in a sham treatment arm. Finally, even if a modality such as thermometry proves able to serve as an early warning system for development of diabetic foot wounds, future studies should also consider whether this intervention is cost-effective over a wide-ranging population.

In summary, this pilot study suggests that early identification of preulcerative inflammation through the use of personal thermometers may be an effective means to further reduce risk for diabetic foot ulceration. We look forward to further studies in the literature that may either confirm or refute this suggestion. If positive, we believe that ultimately, thermometers may be used to allow patients to dose their activity (by checking their skin temperatures) just as many dose their insulin by checking their blood glucose.

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