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.

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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.

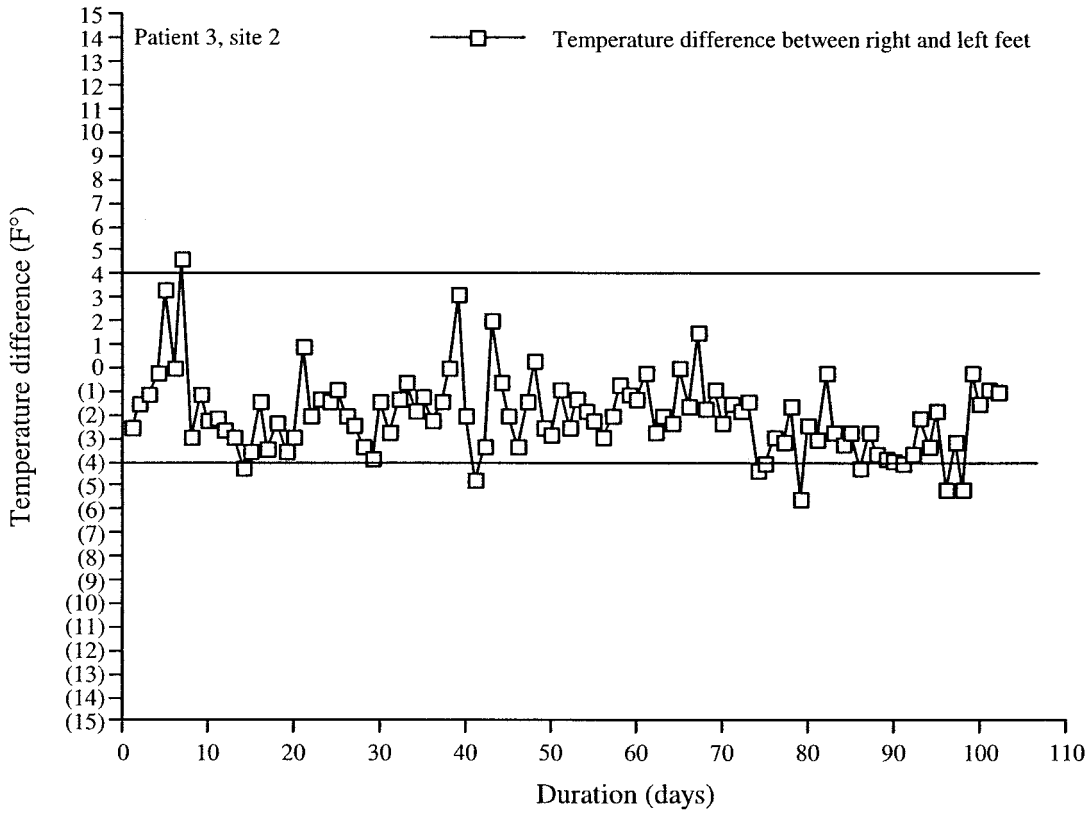

Figure 1—*This graph shows daily temperatures taken under the first metatarsal of patient 3. Patient 3 was a 56-year-old man with a 7-year history of diabetes and a history of amputation. This patient maintained a consistent temperature pattern throughout the monitoring period and did not experience 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

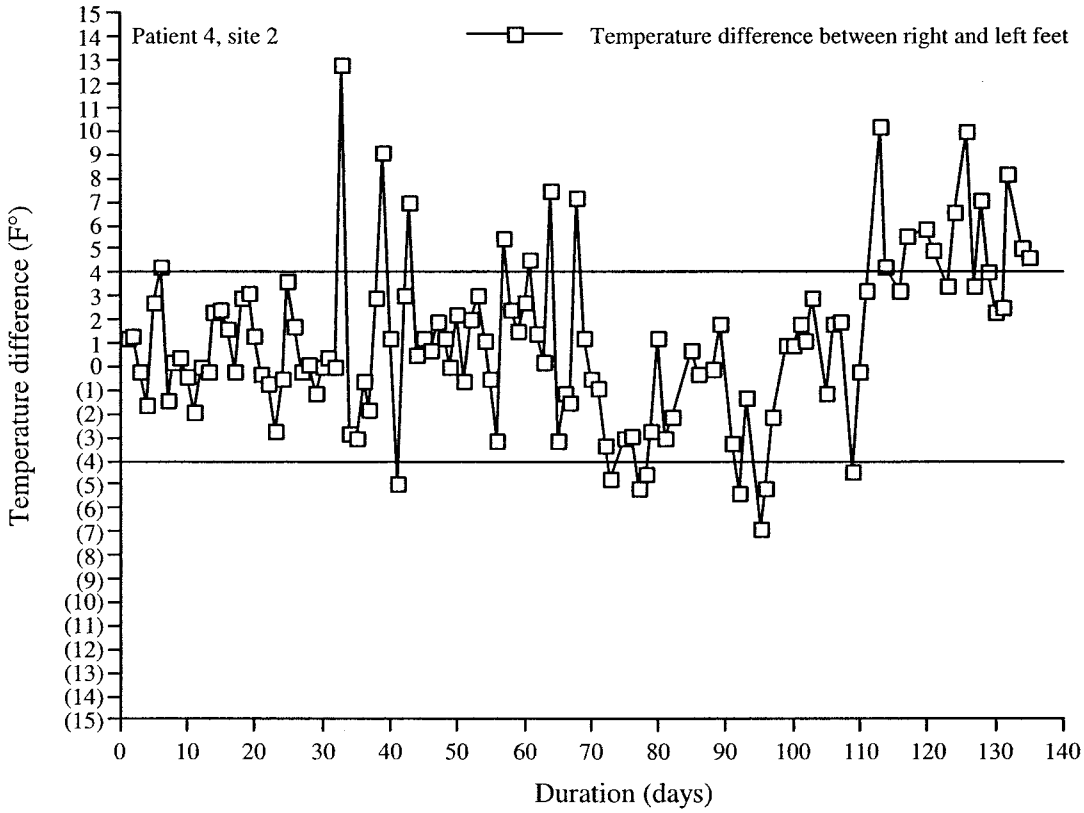

Figure 2—*The graph shows daily temperature measurements taken under the first metatarsal head of a study patient who developed a wound at this site.*

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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References

1. Pecoraro RE, Reiber GE, Burgess EM: Causal pathways to amputation: basis for prevention. *Diabetes Care* 13:513–521, 1990
2. Pecoraro RE: Chronology and determinants of tissue repair in diabetic lower-extremity ulcers. *Diabetes* 40:1305–1313, 1991
3. Lavery LA, Armstrong DG, Vela S, Fleishli JG: Practical criteria to screen patients at risk for diabetic foot ulceration. *Arch Int Med* 158:157–162, 1998
4. Reiber GE, Vileikyte L, Boyko EJ, del Aguila M, Smith DG, Lavery LA, Boulton AJ: Causal pathways for incident lower-extremity ulcers in patients with diabetes from two settings. *Diabetes Care* 22:157–162, 1999
5. Frykberg RG, Lavery LA, Pham H, Harvey C, Harkless L, Veves A: Role of neuropathy and high foot pressures in diabetic foot ulceration. *Diabetes Care* 21:1714–1719, 1998
6. Armstrong DG, Lavery LA, Liswood PJ, Todd WF, Tredwell J: Infrared dermal thermometry of the high-risk diabetic foot. *Phys Ther* 77:169–177, 1997
7. Brand PW: The insensitive foot (including leprosy). In *Disorders of the Foot and Ankle*. Jahss M, Ed. Philadelphia, Saunders, 1991, p. 2173–2175
8. Clark RP, Goff MR, Hughes J, Klenerman L: Thermography and pedobarography in the assessment of tissue damage in neuropathic and atherosclerotic feet. *Thermology* 3:15–20, 1988
9. Schubert V, Fagrell B: Local skin pressure and its effect on skin microcirculation as evaluated by laser Doppler fluxmetry. *Clin Physiol* 9:535–545, 1989
10. Schubert V, Fagrell B: Evaluation of the dynamic cutaneous post-ischaemic hyperaemia and thermal response in elderly subjects and in an area at risk for pressure sores. *Clin Physiol* 11:169–182, 1991
11. Armstrong DG, Lavery LA: Predicting neuropathic ulceration with infrared dermal thermometry. *J Am Podiatr Med Assoc* 87:336–337, 1997
12. Lavery LA, Armstrong DG, Wunderlich RP, Tredwell J, Boulton AJM: Diabetic foot syndrome: evaluating the prevalence and incidence of foot pathology in Mexican Americans and non-Hispanic whites from a diabetes disease management cohort. *Diabetes Care* 26:5–12, 2003
13. Peters EJ, Lavery LA: Effectiveness of the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. *Diabetes Care* 24:1442–1447, 2001
14. World Health Organization: *WHO Expert Committee on Diabetes Mellitus. Second Report*. Geneva, World Health Org., 1980 (Tech Rep. Ser., no. 646)
15. Young MJ, Breddy JL, Veves A, Boulton AJM: The prediction of diabetic neuropathic foot ulceration using vibration perception thresholds. *Diabetes Care* 16:557–560, 1994
16. Armstrong DG, Lavery LA, Vela SA, Quebedeaux TL, Fleischli JG: Choosing a practical screening instrument to identify patients at risk for diabetic foot ulceration. *Arch Int Med* 158:289–292, 1998
17. Uccioli L, Faglia E, Monticone G, Favales F, Durola L, Aldeghi A, Quarantiello A, Calia P, Menzinger G: Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care* 18:1376–1378, 1995
18. Stewart AL, Ware JE: *Measuring Functional Well-Being*. Durham, NC, Duke University Press, 1992
19. Chantelau E, Haage P: An audit of cushioned diabetic footwear: relation to patient compliance. *Diabet Med* 11:114–116, 1994
20. Edmonds ME, Blundell MP, Morns ME, Thomas EM, Cotton LT, Watkins PJ: Improved survival of the diabetic foot: the role of a specialized foot clinic. *Q J Med* 60:763–771, 1986
21. Mueller MJ, Sinacore DR, Hastings MK,

Strube MJ, Johnson JE: Effect of Achilles tendon lengthening on neuropathic plantar ulcers: a randomized clinical trial. *J Bone Joint Surg Am* 85:1436–1445, 2003
22. Busch K, Chantelau E: Effectiveness of brand new stock diabetic's shoes to protect against diabetic foot ulcer relapse. *Diabet Med* 20:665–669, 2003
23. Armstrong DG, Lavery LA: Acute Charcot's arthropathy of the foot and ankle. *Phys Ther* 78:74–80, 1998
24. Armstrong DG, Lavery LA: Monitoring healing of acute Charcot's arthropathy with infrared dermal thermometry. *J Rehabil Res Dev* 34:317–321, 1997

Preventing Diabetic Foot Ulcer Recurrence in High-Risk Patients

Use of temperature monitoring as a self-assessment tool

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OBJECTIVE — The purpose of this study was to evaluate the effectiveness of a temperature monitoring instrument to reduce the incidence of foot ulcers in individuals with diabetes who have a high risk for lower extremity complications.

RESEARCH DESIGN AND METHODS — In this physician-blinded, randomized, 15-month, multicenter trial, 173 subjects with a previous history of diabetic foot ulceration were assigned to standard therapy, structured foot examination, or enhanced therapy groups. Each group received therapeutic footwear, diabetic foot education, and regular foot care. Subjects in the structured foot examination group performed a structured foot inspection daily and recorded their findings in a logbook. If standard therapy or structured foot examinations identified any foot abnormalities, subjects were instructed to contact the study nurse immediately. Subjects in the enhanced therapy group used an infrared skin thermometer to measure temperatures on six foot sites each day. Temperature differences >4°F (>2.2°C) between left and right corresponding sites triggered patients to contact the study nurse and reduce activity until temperatures normalized.

RESULTS — The enhanced therapy group had fewer foot ulcers than the standard therapy and structured foot examination groups (enhanced therapy 8.5 vs. standard therapy 29.3%, $P = 0.0046$ and enhanced therapy vs. structured foot examination 30.4%, $P = 0.0029$). Patients in the standard therapy and structured foot examination groups were 4.37 and 4.71 times more likely to develop ulcers than patients in the enhanced therapy group.

CONCLUSIONS — Infrared temperature home monitoring, in serving as an "early warning sign," appears to be a simple and useful adjunct in the prevention of diabetic foot ulcerations.

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Foot ulcers are among the most common complications of diabetes (1,2). Sensory neuropathy is often a major component in the critical pathway for the development of diabetic ulcers and amputations. Pain is one of the primary natural warning systems that alerts individuals to take action and seek medical care (3). Because this early warning system is faulty, individuals with diabetic neuropathy can sustain injuries that are not recognized until they are so severe that full-thickness wounds result (4). In the "diabetic foot" patient, involvement to identify early warning signs of the disease process is imperative to reduce the incidence of complications.

Inflammation is one of the earliest signs of tissue injury and ulceration (5–8). However, the clinical signs of inflammation are usually too subtle to be detected by patients or even by trained health care providers (9). We hypothesized that skin temperatures could be used as a surrogate measure of injury and localized inflammation. Skin temperature measurements can be easily performed and assessed by the lay public and have been used as a diagnostic tool for diabetic foot ulcerations, decubitus wounds, and Charcot arthropathy (10–20). Pilot work in this area suggests that high-risk patients can effectively use an infrared thermometer as a home monitoring tool to identify inflamed tissue and take action to prevent foot ulceration (21). The aim of the present study was to evaluate a home temperature monitoring tool to help high-risk individuals identify areas on their feet that are inflamed and prone to ulceration before a wound develops.

RESEARCH DESIGN AND METHODS

— This was a single (physician) blinded, multicenter, randomized trial with a 15-month evaluation period. We randomly assigned 173 individuals at high risk for diabetic foot ulceration to three treatment groups (Fig. 1). The three treatment arms involved a standard therapy group, a structured foot examination group, and an enhanced therapy group. The study was approved by the hospital institutional review board. We used a computer generated randomization list. The information was sealed in opaque envelopes and opened after randomization and verification that the subject met all of the inclusion criteria and had none of the exclusion criteria. Subjects were instructed not to discuss their group assignment with the treating physician.

Standard therapy

Standard therapy consisted of lower extremity evaluation by a physician every 8 weeks, an education program that fo-

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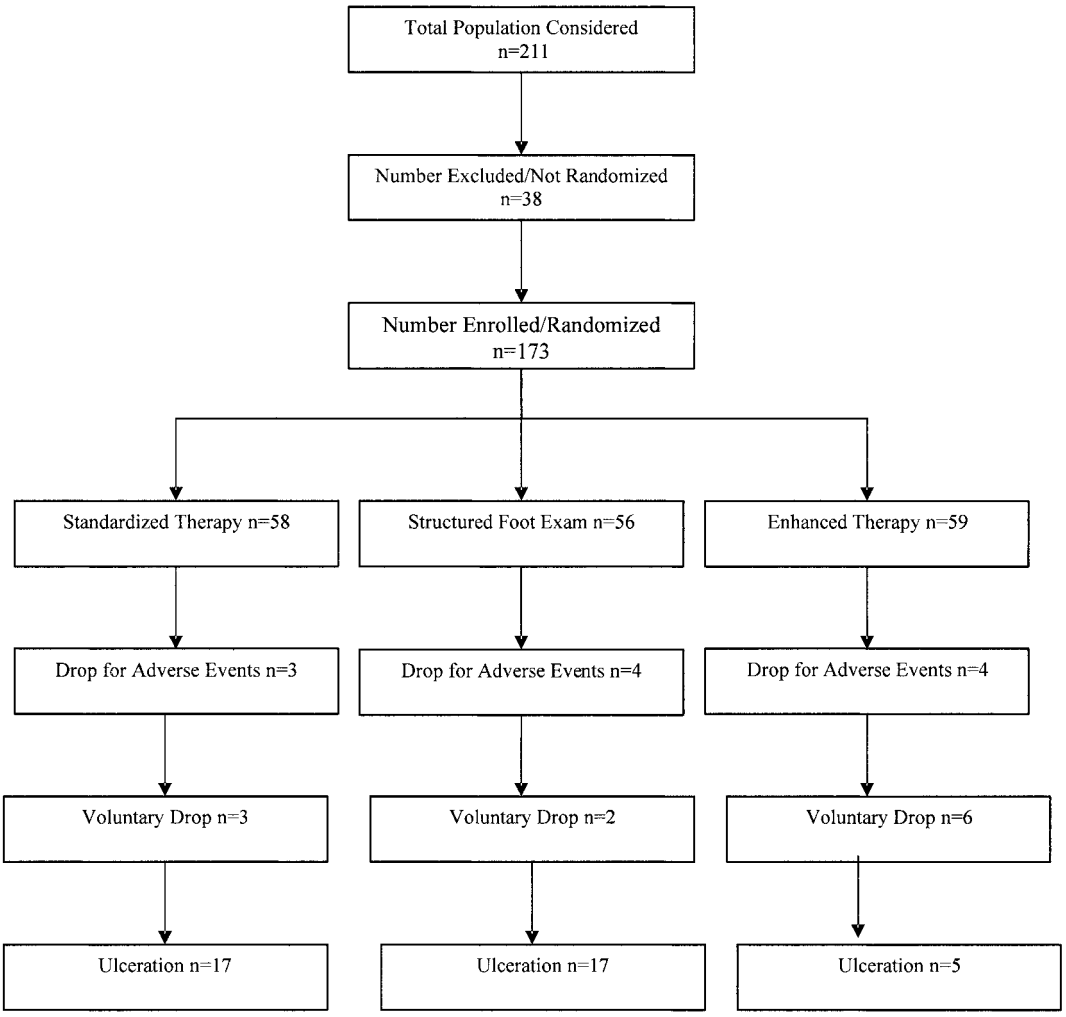

Figure 1—*Study enrollment schematic.*

cused on foot complications and self-care practices, and therapeutic insoles and footwear. The treating podiatrist evaluated the shoes and insoles during regularly scheduled clinic visits and determined whether any components of the shoes or insoles needed to be replaced or repaired. The education segment of training was provided by a videotape that addressed the etiology of diabetic foot ulcers, risk factors, self-care practices, and early warning signs of diabetic foot disease. In addition, all study participants were provided with a pedometer to record their daily activity in a logbook.

Patients were advised to inspect their feet daily. If patients identified an area of concern on their foot, they were instructed to contact the study nurse. The nurse then scheduled an appointment with a study investigator without divulging the treatment group assignment. Patients were asked not to discuss their treatment group assignment with the treating physician.

Structured foot examination

Patients assigned to this treatment group received standard therapy in addition to training to conduct a structured foot inspection twice a day with the assistance of a mirror to see the bottom of the foot. The objective of the examination was to identify redness, discoloration, swelling, and local warmth by palpation. Patients recorded normal and abnormal observations in a logbook with pictorial representations of both feet and a checklist of the elements to be included in the self-examination. The intent of the logbook was to go beyond customary education and recommendations for self-inspection and provide a structured protocol for evaluation. In addition, the logbook provided verification that the examination was performed. If the patient identified any abnormalities, he or she was instructed to contact the study nurse.

Enhanced therapy

In addition to measures implemented in the standard therapy group, patients assigned to the enhanced therapy group were taught to use a digital infrared thermometer (TempTouch; Xilas Medical, San Antonio, TX) to measure and record temperatures on each foot. To standardize training, a videotape was used to teach subjects how to use the infrared thermometer. The study nurse had each subject demonstrate the correct use of the temperature device. Subjects recorded foot temperatures in a logbook with pictorial representations of the top and bottom of both feet and six sites to measure temperatures: the great toe, the first, third, and fifth metatarsal head region, the midfoot, and the heel. Subjects who had undergone amputation at the standard evaluation sites were given alternative sites on the basis of the site of their previous amputation. If skin temperatures were elevated by >4°F (2.2°C) compared with the corresponding site on the

opposite foot for two consecutive days, subjects were instructed to contact the research nurse and decrease their activity until temperatures normalized.

Infrared dermal thermometer

The thermometer is equipped with a "touch sensor" tip that detects contact with skin. Thus, to operate the device, the user places the tip of the device on the skin, which then automatically triggers a temperature measurement and displays it on a liquid crystal display screen. The thermometer has a gooseneck design, which allows the user to reach any point on the bottom or sides of the foot.

Inclusion and exclusion criteria

To be included in the study, subjects were required to be 18–80 years of and to have a history of foot ulceration, a diagnosis of diabetes, the ability to provide informed consent, and ankle-brachial indexes ≥0.70. Subjects were excluded if they had open ulcers or open amputation sites, active osteoarthropathy, severe peripheral vascular disease, foot infection, dementia, or other conditions that would preclude active participation based on the investigator's judgment.

Outcomes and clinical assessment

The primary outcome was foot ulceration, which was defined using previously established criteria (22,23). A questionnaire was administered at the conclusion of the study to evaluate self-reported daily use of prescribed shoes and insoles. An ordinal scale was used to determine whether patients wore therapeutic shoes <4 h, 4–8 h, >8–12 h, or >12 h each day. The neurological assessment consisted of vibratory perception threshold and 10-g monofilament testing using previously described methods (24–26). When assessing monofilament results, we recorded the number of sites missed of 10 sites tested on each foot. The vascular assessment consisted of palpation of foot pulses, noninvasive Doppler, and ankle-brachial indexes.

Sample size justification

Sample size was calculated on the basis of the proportion of study patients we expected to develop ulcers during the 15-month treatment period. These reulceration estimates are based on a previous randomized trial (20) and reports of reulceration in high-risk patients (3–5). We expected that 9% of subjects in the enhanced treatment group would develop ulcers during the evaluation period ($P_o = 0.09$) and that 30% of subjects who received standard therapy would develop foot ulcers. A power of 0.8 was chosen to yield a sample size of 55. We expected a 10% dropout rate. Therefore, we planned to enroll 60 subjects in each group to have 55 subjects complete the study in each treatment arm.

Analysis plan

To make between-group comparisons on continuous-type variables, we used ANOVA for independent samples. For all exposures, an odds ratio (OR) with a 95% CI was identified. For all analyses, we used $\alpha = 0.05$. We evaluated the data using a last observed carried forward intent-to-treat approach (27).

We used a Kaplan-Meier survival analysis to compare the time to develop a foot ulcer by treatment group. We used three statistical tests to examine whether the three treatments were different. First, an overall test was done. Then we used a pairwise comparison, and finally a test for trend was performed. We used the log-rank test, provided in SPSS 10 in the analysis. We used the Pearson χ^2 statistic based on the cell counts of ulcer status versus treatment (standard therapy, structured foot examination, and enhanced therapy) to evaluate the effect of the interventions on incident foot ulceration.

RESULTS — All of the study participants had a history of a foot wound and sensory neuropathy with loss of protective sensation. There were no significant differences in age, duration of diabetes, history of partial foot amputation, severity of sensory neuropathy, or activity level among the three treatment groups. Descriptive characteristics of this population are detailed in Table 1. Data are reported as means ± SD.

A Kaplan-Meier survival analysis was performed to evaluate the time to ulcerate by treatment group (Fig. 2). Subjects were censored when an ulcer developed or if they left the study for other reasons. There was a statistically significant overall difference between the times to develop ulcers by treatment groups using the log-rank test ($P = 0.011$). Simultaneous pairwise comparisons using the log-rank test showed no difference between standard therapy and structured foot examination ($P = 0.910$). However, enhanced therapy was significantly different from both standard therapy ($P = 0.0059$) and structured foot examination ($P = 0.0055$). From the test for trend, there was a statistically significant trend of survival with the enhanced therapy being superior over the standard therapy or structured foot examination ($P = 0.0107$).

The incidence of foot ulceration during the 15-month evaluation period was essentially identical in the standard therapy (29.3%) and structured foot examination (30.4%) treatment arms. There was a >4-fold decrease in the risk of developing foot ulceration in subjects in the enhanced therapy group (8.5%) compared with the standard therapy group (OR 4.48[95% CI 1.53–13.14], $P = 0.008$) and structured foot examination group (4.71 [1.60–13.85], $P = 0.0061$).

Not surprisingly, adherence to prevention practices was a pivotal factor in ulcer prevention. In the enhanced therapy group, patients who were compliant with recording foot temperatures at least 50% of the time were significantly less likely to develop a foot ulcer (OR 50.0, $P < 0.001$). Of patients in the enhanced therapy group who developed foot ulcers, 80% did not comply with temperature assessment. However, of patients who did not develop an ulcer in the enhanced therapy group, 92% recorded their foot temperatures at least half the time. Among patients in the structured foot examination group, there was no difference in compliance with recording daily foot inspections in patients who developed ulcers (47.1%) and those who did not (43.6%; $P = 0.81$).

In addition, self-reported adherence with wearing therapeutic shoes and insoles was high in all three treatment arms (Table 1). There was no significant difference in subjects who wore therapeutic shoes and insoles at least 8 h/day among treatment groups (standard therapy 89.5%, enhanced therapy 83.0%, and structured foot examination 73.2%; $P > 0.071$) (Table 1)

Enhanced therapy patients used the temperature monitoring device as a trigger to contact the study nurse, and they identified "areas of concern" more frequently than patients in other treatments arms who relied on visual signs. Significantly more patients in the enhanced therapy group contacted the study nurse for concerns of foot problems than patients in the standard therapy ($P = 0.030$) or structured foot examination groups ($P = 0.026$) (Table 2). Thirty-one subjects in the enhanced therapy group contacted the study nurse. In addition, 7 more patients did not contact the study

Table 1—*Patient characteristics*

Subject population	Standard therapy	Enhanced therapy	Structured foot examination
n	58	59	56
Age (years)	65.0 ± 9.6 (41–80)	65.4 ± 9.3 (42–80)	64.2 ± 8.6 (40–80)
Sex (% male)	53.4	55.9	51.7
Race			
Non-Hispanic white	31 (53.4)	32 (54.2)	31 (55)
Mexican American	24 (41.4)	22 (37.3)	25 (45)
African American	3 (5.2)	3 (5.1)	2 (4)
Type 2 diabetes	56 (97)	55 (93)	53 (95)
Duration of diabetes (years)	13.7 ± 10.3 (2–22)	12.7 ± 9.7 (4–25)	13.8 ± 11.5 (5–31)
Diabetes medication			
Oral	31 (53.4)	32 (54.2)	30 (53.6)
Insulin	13 (22.4)	15 (25.4)	10 (17.9)
Combination	10 (17.2)	11 (18.6)	12 (21.4)
Diet	4 (6.9)	1 (1.7)	4 (7.1)
Ulcer history and locations			
Hallux	7 (12.1)	4 (6.8)	8 (14.3)
Toes	29 (50.0)	35 (59.4)	30 (53.5)
Submetatarsal	21 (36.2)	17 (28.8)	21 (37.5)
Midfoot to heel	3 (5.1)	7 (11.9)	5 (8.9)
Patients with a history of previous amputation	18 (31.0)	13 (22.0)	14 (25.0)
Amputation sites			
Toe	12 (20.7)	11 (18.6)	12 (21.4)
Toe and metatarsal	8 (13.8)	4 (6.8)	4 (7.1)
Midfoot	0	2 (3.4)	2 (3.6)
History of vascular surgery			
Lower extremity bypass	3 (5.2)	0	0
Lower extremity angioplasty	0	0	1 (1.8)
Coronary artery bypass surgery	2 (3.4)	1 (1.7)	0
Cardiac angioplasty	0	0	2 (3.6)
Lower extremity examination			
Neuropathy evaluation			
Semmes-Weinstein 10-g monofilament right	5.2 ± 4.8	5.3 ± 4.7	5.2 ± 4.7
Semmes-Weinstein 10-g monofilament left	4.7 ± 4.3	4.7 ± 4.3	4.7 ± 4.3
Vibration perception threshold right	41.8 ± 9.8 (14–50)	40.6 ± 9.6 (12–50)	40.6 ± 8.6 (14–50)
Vibration perception threshold left	39.3 ± 8.6 (12–50)	38.6 ± 8.1 (11–50)	39.0 ± 8.0 (12–50)
Foot deformity			
Hallux rigidus	50 (86.2)	51 (86.4)	46 (82.1)
Hallux valgus	23 (39.0)	33 (55.0)	12 (21.0)
Claw toe/hammer toe	33 (56.0)	41 (69.0)	41 (73.0)
Vascular examination			
Ankle-brachial index right	1.1 ± 0.4 (0.7–1.5)	1.1 ± 0.4 (0.7–1.5)	1.1 ± 0.6 (0.8–2.0)
Ankle-brachial index left	1.2 ± 0.5 (0.7–1.7)	1.1 ± 0.6 (0.7–1.9)	1.2 ± 0.6 (0.7–1.9)
Activity (steps per day)	3,817 ± 3,364	3,489 ± 2,706	3,963 ± 2,363
Footwear compliance			
Time prescribed shoes were worn (h)			
<4	1 (1.7)	2 (3.4)	0
4–8	5 (8.6)	8 (13.6)	15 (26.8)
>8–12	33 (56.9)	31 (52.5)	19 (33.9)
>12	19 (32.6)	18 (30.5)	22 (39.3)

Data are means ± SD (range) or *n* (%).

nurse when they observed elevated foot temperatures but decreased their activity based on pedometer activity data. When we compared the number of steps per day for the 3 days before and 3 days after an elevated temperature was identified, on average, there was a 51.2% decrease in activity, representing an average reduction of 1,725 ± 1,784 steps/day.

Based on inspection of their feet, subjects in the structured foot examination group contacted the study nurse 18 times, and subjects in the standard therapy group contacted the study nurse 17 times. However, by the time patients in the stan-

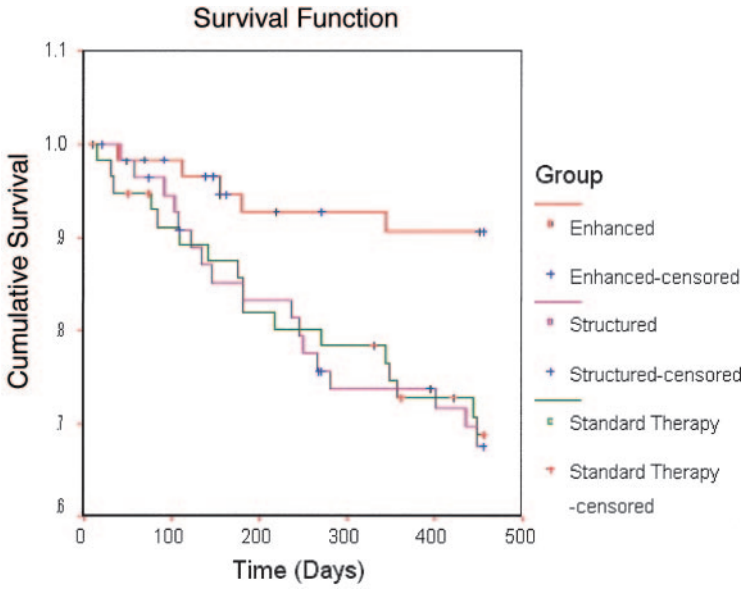

Figure 2—*Kaplan-Meier survival analysis of time to ulceration by treatment group. Kaplan-Meier survival analysis demonstrated a significantly longer time to ulcerate in the enhanced therapy group compared with the structured foot examination and standard therapy groups. The mean time to ulcerate was 429.5 ± 11.9 in the enhanced therapy group, 377.3 ± 18.4 in the structured foot examination group, and 378.5 ± 18.6 in the standard therapy group.*

dard therapy and structured foot examination groups contacted the study nurse, usually a foot ulceration had already developed (structured therapy group 94.4%; structured foot examination group 100%).

CONCLUSIONS— Specialty diabetic foot clinics have been shown to reduce the incidence of ulceration and amputation in high-risk patients (2,28,29). Often these foot clinics provide protective shoes and insoles, foot-specific education, and advanced clinical care. These clinics usually deliver services that are well above the local community standard. However, even in specialty foot clinics, recurrence of diabetic foot ulcers is often very high, generally ranging from 25 to 80% per annum (30–33). In ideal circumstances, high-risk patients can only be evaluated in specialty clinics four to six times a year. Patients and their families must bridge the gap between examinations. Therefore, self-monitoring to identify areas on the foot that are injured is critical to prevent ulceration and lower extremity amputation.

Self-care may be the single most important factor in preventing complications in individuals with a high risk for diabetic foot ulceration (34–36). Patients and their families must be able to monitor the lower extremities to identify signs of disease and precursors to injury. The medical community has, to date, failed to provide any practical, efficacious tool to help in this process. At most, clinicians encourage self-inspection and occasionally suggest that patients use a mirror to evaluate the bottom of the foot. Unfortunately, many diabetic patients with a high risk for ulceration cannot see their feet because of obesity, limited joint mobility, or visual impairment (37). As demonstrated in this study, most of the time, self-inspection skills are not effective in identifying the subtle precursors to ulceration. By the time patients in this study were able to visualize areas of concern, it was too late, and an ulceration had already developed. The results of this study surprisingly suggested that structured self-inspection with the aid of a mirror provided no overt risk reduction compared with general diabetic foot education. The incidence of foot ulceration in the standard therapy and structured foot examination groups was similar to that in studies using "standard" prevention practices as described in this project (2,31,33).

The intervention in this study, namely home temperature monitoring, proved to be an effective approach to provide objective feedback, so patients could modify their activity and protect their foot before ulceration developed. The majority of study subjects were able to use the device as an early warning system and reduce their activity until temperatures normalized. Enhanced therapy patients used the temperature device to identify abnormalities more often than the other groups (standard therapy and structured foot examination patients) could by visual inspection or palpation alone. Overall, 88% of patients in the enhanced therapy group recorded their temperatures >50% of the time during the 15-month study period. Patients who developed ulcers did not comply with measuring their foot temperatures; four of five (80%) subjects who were assigned to use the temperature device and developed ulcerations did not

Table 2—*Clinical outcomes, adverse events, and voluntary withdrawals*

Outcomes	Standard therapy	Enhanced therapy	Structured foot examination
n	58	59	56
Patients who contacted study nurse after self-examination	18 (31.0)	31 (52.5)	17 (30.4)
Foot ulceration	17 (29.3)	5 (8.5)	17 (30.4)
Withdrawal from study because of adverse events			
Foot trauma	1 (1.7)	1 (1.7)	0
Fracture	0	1 (1.7)	2 (3.6)
Death	2 (3.4)	1 (1.7)	0
Osteomyelitis: no ulcer	0	0	1 (1.8)
Motor vehicle accident	0	0	1 (1.8)
Myocardial infarction	0	1 (1.7)	0
Voluntary withdrawal from study			
Too much to do	2 (3.4)	6 (10.2)	2 (3.6)
Moved out of town	1 (1.7)	0	0

Data are *n* (%).

adhere to their prescribed assessment regimen.

This study was successful in amalgamating observations from previous studies and putting them in the hands of high-risk subjects in the form of a simple, easy to use device. The vast majority of participants were able to comply with instructions and subsequently prevent foot ulcerations. The rates of compliance with this program seemed to be much higher than those for home blood glucose monitoring, for which the prevalence of noncompliance can be as high as two-thirds (38,39). Thus, the results of this study suggest that equipping individuals with diabetes at highest risk for foot ulceration with simple skin temperature devices may significantly reduce the risk for foot ulcers. In fact, just as with comprehensive general programs aimed to facilitate good glucose control (40), a regimen incorporating home temperature monitoring may allow individuals to monitor their "dose" of activity by checking their skin temperatures just as they might monitor their dose of insulin by checking their glucose. It seems likely that the cost benefit of home temperature monitoring might be much better than that for using glucose strips for home monitoring. In addition, a tool to adjust activity could help with the dilemma of exercising for better health versus the need to rest and protect the foot to avoid foot ulcers.

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References

1. Lavery LA, Armstrong DG, Wunderlich RP, Boulton AJM, Tredwell JL: Diabetic foot syndrome: evaluating the prevalence and incidence of foot pathology in Mexican Americans and non-Hispanic whites from a diabetes disease management cohort. *Diabetes Care* 26:1435–1438, 2003
2. Singh N, Armstrong DG, Lipsky BA: Preventing foot ulcers in patients with diabetes. *JAMA* 293:217–228, 2005
3. Brand PW: The insensitive foot (including leprosy). In *Disorders of the Foot and Ankle,* 2nd ed. Jahss M, Ed. Philadelphia, Saunders, 1991, p. 2170–2175
4. Armstrong DG, Lavery LA, Quebedeaux TL, Walker SC: Surgical morbidity and the risk of amputation due to infected puncture wounds in diabetic versus nondiabetic adults. *South Med J* 90:384–389, 1997
5. Brand PW: The diabetic foot. In *Diabetes Mellitus, Theory and Practice,* 3rd ed. Ellenberg M, Rifkin H, Eds. New York, Medical Examination Publishing, 1983, p. 803–828
6. Benbow SJ, Chan AW, Bowsher DR, Williams G, Macfarlane IA: The prediction of diabetic neuropathic plantar foot ulceration by liquid crystal contact thermography. *Diabetes Care* 17:835–839, 1994
7. Manley MT, Darby T: Repetitive mechanical stress and denervation in plantar ulcer pathogenesis in rats. *Arch Phys Med Rehabil* 51:171–175, 1980
8. Stess RM, Sisney PC, Koss KM, Graf PM, Louie KS, Gooding GAW, Grunfield C: Use of liquid crystal thermography in the evaluation of the diabetic foot. *Diabetes Care* 9:267–272, 1986
9. Murff RT, Armstrong DG, Lanctot D, Lavery LA, Athanasiou KA: How effective is manual palpation in detecting subtle temperature differences? *Clin Podiatr Med Surg* 15:151–154, 1998
10. Frykberg RG, Armstrong DG, Giurini J, Edwards A, Kravette M, Kravitz S, Ross C, Stavosky J, Stuck R, Vanore J: Diabetic foot disorders: a clinical practice guideline: for the American College of Foot and Ankle Surgeons and the American College of Foot and Ankle Orthopedics and Medicine. *J Foot Ankle Surg* 39 (5 Suppl.):S1–S60, 2000
11. Armstrong DG, Lavery LA: Monitoring healing of acute Charcot's arthropathy with infrared dermal thermometry. *J Rehabil Res Dev* 34:317–321, 1997
12. Armstrong DG, Todd WF, Lavery LA, Harkless LB: The natural history of acute Charcot's arthropathy in a diabetic foot specialty clinic. *Diabet Med* 14:357–363, 1997
13. Wienert V, Sick H, zur Muhlen J: Local thermal stress tolerance of human skin. *Anasth Intensivther Notfallmed* 18:88–90, 1983 [article in German]
14. Jarcuskova D, Uhrik J: Evaluation of thermal conductivity and skin temperature in the treatment of leg ulcers. *Bratisl Lek Listy* 89:519–523, 1988 [article in Slovak]
15. Schubert V, Fagrell B: Postocclusive reactive hyperemia and thermal response in the skin microcirculation of subjects with spinal cord injury. *Scand J Rehabil Med* 23: 33–40, 1991
16. Schubert V, Perbeck L, Schubert PA: Skin microcirculatory and thermal changes in elderly subjects with early stage of pressure sores. *Clin Physiol* 14:1–13, 1994
17. Seymour RJ, Lacefield WE: Wheelchair cushion effect on pressure and skin temperature. *Arch Phys Med Rehabil* 66:103–108, 1985
18. Kokate JY, Leland KJ, Held AM, G.L. H, Kveen GL, Johnson BA, Wilke MS, Sparrow EM, Iaizzo PA: Temperature-modulated pressure ulcers: a porcine model. *Arch Phys Med Rehabil* 76:666–673, 1995
19. Knox DM: Core body temperature, skin temperature, and interface pressure: relationship to skin integrity in nursing home residents. *Adv Wound Care* 12:246–252, 1999
20. Patel S, Knapp CF, Donofrio JC, Salcido R: Temperature effects on surface pressure-induced changes in rat skin perfusion: implications in pressure ulcer development. *J Rehabil Res Dev* 36:189–201, 1999
21. Lavery LA, Higgins KR, Lanctot DR, Constantinides GP, Zamorano RG, Armstrong DG, Athanasiou KA, Agrawal CM: Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes Care* 27: 2642–2647, 2004
22. American Diabetes Association: Consensus Development Conference on Diabetic Foot Wound Care, 7–8 April 1999, Boston, Massachusetts (Position Statement). *Diabetes Care* 22:1354, 1999
23. Armstrong DG, Lavery LA, Harkless LB: Validation of a diabetic wound classification system: the contribution of depth, infection, and ischemia to risk of amputation. *Diabetes Care* 21:855–859, 1998 [see comments]
24. Young MJ, Breddy JL, Veves A, Boulton AJ: The prediction of diabetic neuropathic foot ulceration using vibration perception thresholds: a prospective study. *Diabetes Care* 17:557–560, 1994
25. Young MJ, Boulton AJ, MacLeod AF, Williams DR, Sonksen PH: A multicentre study of the prevalence of diabetic peripheral neuropathy in the United Kingdom hospital clinic population. *Diabetologia* 36:150–154, 1993
26. Armstrong DG, Lavery LA, Vela SA, Quebedeaux TL, Fleischli JG: Choosing a practical screening instrument to identify patients at risk for diabetic foot ulceration. *Arch Intern Med* 158:289–292, 1998
27. Armitage P, Berry G, Matthews JNS: *Statistical Methods in Clinical Research.* Oxford, U.K., Blackwell, 2002
28. Edmonds ME: Experience in a multidisciplinary diabetic foot clinic. In *The Foot in Diabetes.* Connor H, Boulton AJM, Ward JD, Eds. Chichester, John Wiley, 1987, p. 121–131
29. Edmonds ME, Blundell MP, Morns ME, Thomas EM, Cotton LT, Watkins PJ: Improved survival of the diabetic foot: the role of a specialized foot clinic. *Q J Med* 60:763–771, 1986
30. Uccioli L, Faglia E, Monticone G, Favales F, Durola L, Aldeghi A, Quarantiello A, Calia P, Menzinger G: Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care* 18:1376–1378, 1995
31. Mueller MJ, Sinacore DR, Hastings MK, Strube MJ, Johnson JE: Effect of Achilles tendon lengthening on neuropathic plantar ulcers: a randomized clinical trial. *J Bone Joint Surg* 85A:1436–1445, 2003
32. Chantelau E, Kushner T, Spraul M: How

effective is cushioned therapeutic footwear in protecting diabetic feet? A clinical study. *Diabet Med* 7:335–339, 1990
33. Busch K, Chantelau E: Effectiveness of a new brand of stock 'diabetic' shoes to protect against diabetic foot ulcer relapse: a prospective cohort study. *Diabet Med* 20: 665–669, 2003
34. Assal JP, Mehnert H, Tritschler HJ, Sidorenko A, Keen H: On your feet! Workshop on the diabetic foot. *J Diabetes Complications* 16:183–194, 2002
35. Crausaz FM, Clavel S, Liniger C, Albenau A, Assal JP: Additional factors associated with plantar ulcers in diabetic neuropathy. *Diabet Med* 5:771–775, 1988
36. Assal JP, Mulhauser I, Pernat A: Patient education as the basis for diabetes care in clinical practice. *Diabetologia* 28:602, 1985
37. Lavery LA, Armstrong DG, Vela SA, Quebedeaux TL, Fleischli JG: Practical criteria for screening patients at high risk for diabetic foot ulceration. *Arch Intern Med* 158:158–162, 1998
38. Dorchy H, Roggemans MP: Improvement of the compliance with blood glucose monitoring in young insulin-dependent diabetes mellitus patients by the Sensorlink system. *Diabetes Res Clin Pract* 36: 77–82, 1997
39. Shobhana R, Begum R, Snehalatha C, Vijay V, Ramachandran A: Patients' adherence to diabetes treatment. *J Assoc Physicians India* 47:1173–1175, 1999
40. de Sonnaville JJ, Bouma M, Colly LP, Deville W, Wijkel D, Heine RJ: Sustained good glycaemic control in NIDDM patients by implementation of structured care in general practice: 2-year follow-up study. *Diabetologia* 40:1334–1340, 1997

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CLINICAL RESEARCH STUDY

Skin Temperature Monitoring Reduces the Risk for Diabetic Foot Ulceration in High-risk Patients

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ABSTRACT

PURPOSE: To evaluate the effectiveness of home temperature monitoring to reduce the incidence of foot ulcers in high-risk patients with diabetes.

METHODS: In this physician-blinded, 18-month randomized controlled trial, 225 subjects with diabetes at high risk for ulceration were assigned to standard therapy (Standard Therapy Group) or dermal thermometry (Dermal Thermometry Group) groups. Both groups received therapeutic footwear, diabetic foot education, regular foot care, and performed a structured foot inspection daily. Dermal Thermometry Group subjects used an infrared skin thermometer to measure temperatures on 6 foot sites twice daily. Temperature differences >4°F between left and right corresponding sites triggered patients to contact the study nurse and reduce activity until temperatures normalized.

RESULTS: A total of 8.4% (n = 19) subjects ulcerated over the study period. Subjects were one third as likely to ulcerate in the Dermal Thermometry Group compared with the Standard Therapy Group (12.2% vs 4.7%, odds ratio 3.0, 95% confidence interval, 1.0 to 8.5, $P = .038$). Proportional hazards regression analysis suggested that thermometry intervention was associated with a significantly longer time to ulceration ($P = .04$), adjusted for elevated foot ulcer classification (International Working Group Risk Factor 3), age, and minority status. Patients that ulcerated had a temperature difference that was 4.8 times greater at the site of ulceration in the week before ulceration than did a random 7 consecutive-day sample of 50 other subjects that did not ulcerate (3.50 ± 1.0 vs 0.74 ± 0.05, $P = .001$).

CONCLUSIONS: High temperature gradients between feet may predict the onset of neuropathic ulceration and self-monitoring may reduce the risk of ulceration. © 2007 Elsevier Inc. All rights reserved.

KEYWORDS: Diabetes; Foot; Thermometry; Ulcer; Wound

In diabetes, as in other chronic diseases, self-care is an essential element of disease management and prevention. Most diabetic lower extremity complications involve sensory neuropathy; patients do not recognize that their feet are being injured until a wound develops.[1,2] Wounds are invariably preceded by inflammation.[3-6] Therefore, it would stand to reason that identifying preulcerative inflammation might predict foot ulceration. Temperature assessment seems to be a likely surrogate to measure inflammation.

Studies of dermal thermometry have suggested that variations in temperature >4°F (2.2°C) could be helpful in skin

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surveillance.[7-12] More recently, 2 randomized trials appeared to confirm that dispensing simple "personal thermometers" to neuropathic patients might serve as useful prevention tools.[13,14] The second of these studies appeared to suggest that this preventative effect is independent of simply increasing visual surveillance of the foot.[14] Previous studies using temperature as a self-assessment and monitoring tool appear promising; however, they were either conducted over rather short time frames (6 months)[13] or they studied very specific patient populations.[14] Therefore, the purpose of this study was to evaluate the effectiveness of an infrared home temperature monitoring instrument to reduce the incidence of foot complications in patients at high risk for diabetic foot ulceration.

CLINICAL SIGNIFICANCE

- Diabetic foot wounds are common, complex and costly. They are frequently caused by repetitive stress to the foot, causing inflammation and skin breakdown.
- The results of this study suggest that a simple device used by the patient can identify potentially damaging inflammation and allow the patient to modify activity before ulceration.
- In this manner, patients may modify their activity by checking their skin temperatures much as they dose their insulin by checking their glucose.

METHODS

In this physician-blinded, 18-month randomized controlled trial, 225 United States veterans with diabetes at high risk for ulceration (neuropathy and deformity or previous history of ulceration) were assigned to standard therapy or dermal thermometry groups. Both groups received therapeutic footwear, diabetic foot education, and regular foot care. All subjects were instructed to perform a structured foot inspection daily and record their findings in a logbook. If Standard Therapy Group subjects identified any foot abnormalities, they were to contact the study coordinator immediately. Dermal Thermometry Group subjects used an infrared skin thermometer (TempTouch, Xilas Medical, San Antonio, Tex) to measure temperatures on 6 sites on the foot twice a day. Temperature differences >4°F (>2.2°C) between left and right corresponding sites triggered patients to contact the study coordinator and reduce activity until their temperatures normalized. As a practical measure, the opposite extremity was used as a control because both feet are exposed to the same repetitive stresses during walking and therefore represented a built-in comparison source. Because the disease processes of neuropathic ulceration involves multiple factors that affect lower extremity perfusion and temperature regulation, we felt that it would be difficult to identify an absolute skin temperature level that could be considered normal or one that could be used as a universal reference.

Participants

All patients with type 2 diabetes receiving foot care at the Southern Arizona VA Health Care System, aged 18-80 years, who fit category 2 or 3 of the International Diabetic Foot Risk Classification System,[15] were candidates for inclusion in the study. Risk Group 3 included patients with a history of either a foot ulcer or of a partial foot amputation. Risk Group 2 included patients with neuropathy and structural foot deformity or limited joint mobility.[15] There were approximately 4800 patients with type 2 diabetes receiving care at the Southern Arizona VA Health Care System. Of these, 1942 were identified as high risk for development of foot ulcers (neuropathy and deformity), and at least 300 had been treated for a foot ulcer or a partial foot amputation in 1999.

Candidates were not admitted to the study if any of the following criteria were present: active open ulcers, amputation sites, or foot infections; active Charcot arthropathy; severe peripheral vascular disease, as evidenced by nonpalpable foot pulses or an ankle-brachial index <0.8 on either extremity; dementia or impaired cognitive function; active drug abuse or history of drug or alcohol abuse within 1 year of the study; sight impaired (ie, unable to read the large (2.5 cm) digital display characters on the dermal thermometer); or unable to walk without the assistance of a wheelchair or crutches.

Interventions

The TempTouch thermometer (Xilas Medical) is equipped with a "touch sensor" that detects tip contact with skin, which allows the user to just simply touch the end of the probe to the skin to take a measurement. To operate the device, the user would place the tip of the device on the skin, which would then automatically trigger a temperature measurement and display it on an LCD (liquid crystal display) screen. The thermometer utilized incorporates a gooseneck design, which allows the user to reach any point on the bottom or sides of the foot.

Objectives

We evaluated the effectiveness of self-administered in-home infrared temperature probe monitoring to reduce the incidence of diabetic foot ulcers in high-risk veterans with type 2 diabetes. Secondary objectives were to measure the effect of the intervention on type of ulcer, health-related quality of life, self-efficacy, satisfaction with care, and modulation of activity. We tested the hypothesis that self-monitored temperatures would: reduce the rate of foot ulcers and positively influence health-related quality of life, self-efficacy and satisfaction with care, and modulation of activity. This article addresses the primary outcome of foot ulcer

incidence; subsequent articles will present secondary outcomes.

Outcomes

Primary measures were collected at baseline and every 3 months thereafter (months 0, 3, 6, 9, 12, and 15), with a final visit at month 18. The primary endpoint (and focus of this article) with respect to effectiveness in reducing the incidence of diabetic foot ulcers, was the proportion of patients in each group developing a foot ulcer of any type. An ulceration was defined as the full thickness loss of epidermis and dermis or involvement of deeper structures. Additional outcomes, to be reported in future articles, included health-related quality of life, self-efficacy, and satisfaction with care, activity titration, and program costs.

Sample Size

Up to 70% of patients with a history of foot ulcers experience recurrence within 1 year. We believed that the incidence of ulceration would be 70% in the usual care group and from 30% to 45% in the thermometry self-monitoring group based on the work of Uccioli and coworkers and Walker and coworkers.[16,17] For a sample size of 70 per group, a log-rank test (2-sided $\alpha = .05$) for equality of survival curves would have 99% power to detect a 40% difference, 93% power to detect a 30% difference, and 83% power to detect a 25% difference. Interim analyses were not performed. There was no evidence that enhanced monitoring would result in worsened outcomes, thus, stopping rules were not established.

Randomization: Allocation Concealment and Implementation

Our study biostatistician generated a randomized assignment list. Once potential subjects were screened and consented, the coordinator used this list to sequentially assign patients to the intervention or usual care group; no exceptions were made.

Blinding (Masking)

The attending physician was blinded to the use of the TempTouch thermometer throughout the entire course of the study. When evaluating study patients, the subjects were instructed not to discuss their treatment group assignment. The treating physician did not use temperature assessment as part of their diagnostic examination.

Statistical Methods

The Cox proportional hazard model was used to evaluate the dependent outcome differences between groups (time to incident foot ulcers), producing a relative risk controlling for covariates such as history of amputation, diabetes complications index, and glucose control (HbA1c). Selection of covariates was performed using stepwise modeling procedures, supplemented by evidence from pilot studies and the literature. We used a chi-squared test with Yates correction to evaluate potential univariate dichotomous associations. We used a Mann-Whitney *U* test to evaluate skin temperature differences (compared with the contralateral foot) at the site of ulceration in the week preceding the reulceration and compared that with a 1-week sample of 50 randomly sampled subjects that did not ulcerate. For all evaluations, we used an alpha of 5%.

Table Descriptive Characteristics

	Thermometry	Control	*P*-value
Age (years)	68.2 (9.6)	69.7 (10.4)	.26
Sex %	98.2	94.7	.16
Duration diabetes	13.6 (11.6)	12.6 (9.1)	.47
Hemoglobin A1c	8.1 (1.9)	7.4 (1.4)	.29
Non-Hispanic white	72.97	71.05	
African American	4.50	8.77	
Hispanic	20.72	17.54	
Asian	0.00	1.75	
Native American	1.80	0.88	.383
Retinopathy (%)	23.4	34.2	.074
Diabetic foot risk classification			
Risk 2	84.7%	82.5%	
Risk 3	15.3%	17.5%	
VPT (volts)	42.6 (21.0)	50.1 (85.4)	.39
Neuropathy with loss of protective sensation	100%	100%	

All values are mean (SD) unless stated otherwise.

RESULTS

Descriptive characteristics of this population are illustrated in the Table. There was not a significant difference in characteristics based on treatment group assignment ($P > .05$ for all).

A total of 8.4% (n = 19) of all subjects ulcerated over the 18-month follow-up period. In the Standard Therapy Group, 12.2% (n = 14) of patients ulcerated compared with 4.7% (n = 5) of those in the Dermal Thermometry Group (OR 3.0, CI, 1.0 to 8.5, $P = .038$).

Proportional hazards regression analysis suggested that Standard Therapy Treatment, elevated foot ulcer classification (International Working Group Risk Factor 3), age, and minority status were significantly associated with a shorter time to ulceration. Standard Therapy Treatment (adjusted hazard ratio [HR] 2.9; 95% CI, 1.03 to 8.4; $P = .04$), Risk Group 3 status (adjusted HR 16.5; 95% CI, 4.5 to 31.7; $P = .001$), age (adjusted HR 0.93; 95% CI, 0.89 to 0.98; $P = .02$), and minority status (adjusted HR 0.40; 95% CI, 0.12 to 1.3; $P = .1$) were associated with ulceration. The cumulative survival curve comparing Dermal Thermometry Group treatment with standard therapy is illustrated in Figure 1.

Patients that ulcerated had a temperature difference (between the affected foot and the same site contralaterally) that was 4.8 times greater in the region of ulceration in the

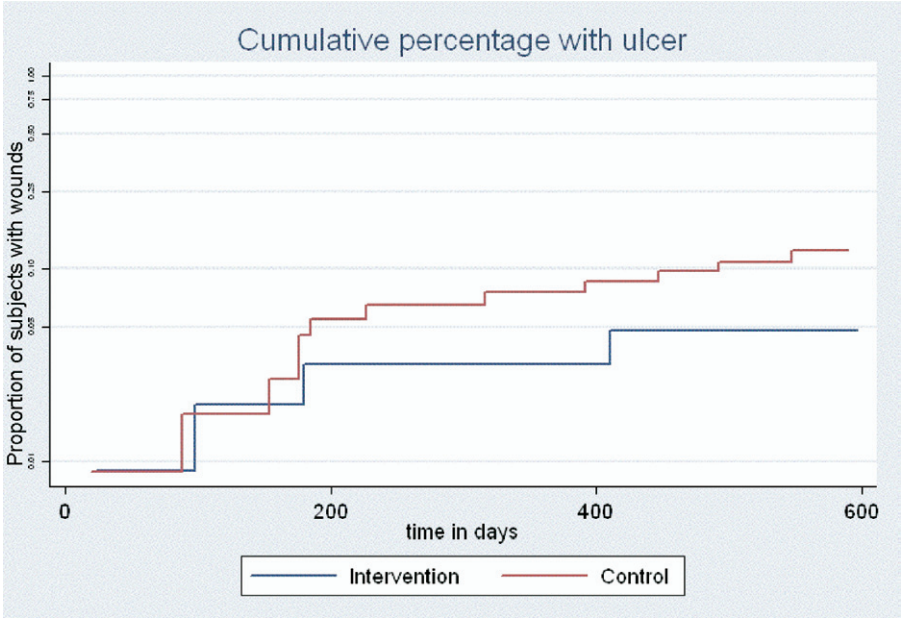

Figure 1 Prevention of ulceration: dermal thermometry vs. standard therapy. There were 12.2% patients ulcerated in the Standard Therapy Group compared with 4.7% in the Dermal Thermometry Group (OR 3.0; 95% CI, 1.0 to 8.5; $P = .038$). Additionally, thermometry was associated with a longer time to ulceration than control ($P = .04$).

week before the event than did a random 7-consecutive-day sample of 50 subjects that did not ulcerate (3.50 ± 1.0 vs 0.74 ± 0.05, $P = .001$). These data are illustrated in Figure 2.

DISCUSSION

There are few effective therapies to help high-risk patients with diabetes prevent foot ulcerations. Under the best circumstances, high-risk patients will receive a few hours of education a year concerning the complications of diabetes, regular foot evaluation by their primary care physician or specialty care by a podiatrist, and protective shoes and insoles. Unfortunately, standard prevention therapies usually are not provided. And, even when patients are treated in centers of excellence with aggressive medical and surgical intervention, between one third and two thirds of subjects with a prior history of diabetic foot ulcers will reulcerate in 12-24 months.[2,16,18] Lavery and coworkers have reported 2 randomized clinical trials using a temperature home monitoring device with similar results to this study.[13,19] This study substantively augments those previous studies in a larger, potentially higher-risk population and is the first, to our knowledge, to suggest that thermometry used by patients themselves can identify areas of inflammation before skin breakdown.

Self-monitoring is necessary to identify early warning signs to reduce the incidence of diabetic foot complications and the associated decrements in quality of life and high resource costs. Sadly, the ability of the most motivated patients with diabetes, their family members, and even health care professionals to identify "early warning signs" is limited. The precursors to ulceration are subtle, especially in a neuropathic foot. Self-evaluation of temperature seems to offer a mechanism to identify an early sign of injury, when there is still time to avert a wound. The results of this study suggest that a simple, inexpensive temperature device can be used effectively by high-risk patients to reduce foot ulceration. This offers a significant advantage over traditional prevention practices and therapies.

The concept of measuring skin temperature as a marker for tissue inflammation and injury in the insensate foot has been addressed by several authors. As early as 1971, Goller et al reported an association between increased local temperature and localized pressure leading to tissue injury.[7]

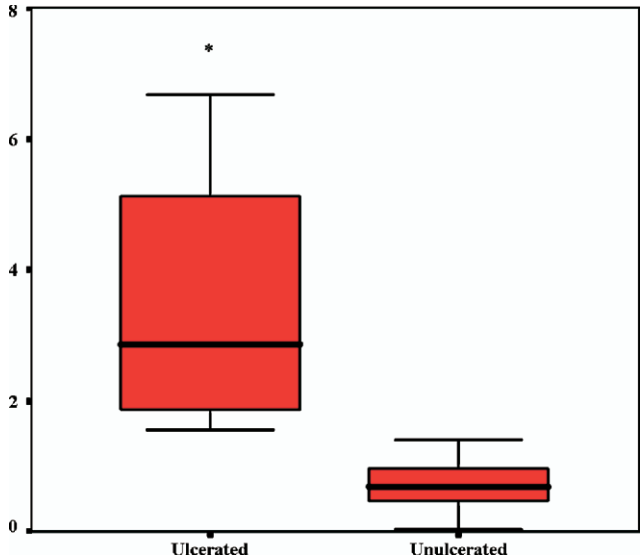

Figure 2 Temperature difference at 1 week before ulceration. *$P = .001$.

Sandrow and coworkers subsequently used thermometry as a tool to diagnosis occult neuropathic fractures in patients with diabetes in 1972.[20] Stess and colleagues described the use of infrared thermography to assess skin temperatures in patients with diabetes, patients with diabetes with neuropathic fractures, patients with diabetes with ulcers, patients with leprosy, and controls.[21] They found that neuropathic foot ulcers frequently had increased skin temperatures surrounding a central necrotic area, and suggested that temperature assessment may be a useful technique to identify patients at risk for ulceration. Similar findings were revealed in a larger study by Armstrong et al using standard thermometers.[22] The concept is elegant in its simplicity, and even challenging patient populations appear to have been able to successfully use the device.

Veterans treated in the Department of Veterans Affairs are older, poorer, and have more comorbidities than general community dwellers. However, they are not appreciably different from the disproportionately low income and minority population with diabetes in regards to ulcer outcomes.[23,24] Therefore, the results of this study should be applicable to both veteran and nonveteran populations alike. In fact, a less challenged population might realize better preventative outcomes.

In this study we evaluated 2 risk groups: patients with a history of previous diabetic foot ulceration or amputation (Risk Group 3) and those with sensory neuropathy and loss of protective sensation with structural foot deformities (Risk Group 2). The majority of subjects enrolled were in the latter group, and this group had a lower incidence of ulceration than expected. Our sample size estimate was based on published outcomes using "standard prevention" in diabetics with a history of pathology (Risk Group 3). Therefore, we underestimated the sample size needed to evaluate Diabetic Foot Risk Group 2 subjects, and we disproportionably enrolled fewer Diabetic Foot Risk Group 3 subjects. Despite these errors, the smaller patient sample was sufficient to show a significant impact when home temperature monitoring was used.

Quality of life, functional status, self-efficacy, satisfaction with care, and cost outcomes from this study will be addressed in future articles. While smaller studies in this area have mirrored the current project,[13,19] it is unknown if the same outcomes and compliance would be observed in a multicenter clinical trial over an extended period of evaluation. We look forward to work that might continue to refine this method's usefulness in a variety of settings.

References

1. Pecoraro RE, Reiber GE, Burgess EM. Pathways to diabetic limb amputation: basis for prevention. *Diabetes Care*. 1990;13:513-521.
2. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA*. 2005;293(2):217-228.
3. Armstrong DG, Abu-Rumman PL, Nixon BP, Boulton AJ. Continuous activity monitoring in persons at high risk for diabetes-related lower-extremity amputation. *J Am Podiatr Med Assoc*. 2001;91(9):451-455.
4. Armstrong DG, Lavery LA, Holtz-Neiderer K, et al. Variability in activity may precede diabetic foot ulceration. *Diabetes Care*. 2004; 27(8):1980-1984.
5. Maluf KS, Morley RE, Richter EJ, et al. Foot pressures during level walking are strongly associated with pressures during other ambulatory activities in subjects with diabetic neuropathy. *Arch Phys Med Rehabil*. 2004;85(2):253-260.
6. Maluf KS, Mueller MJ. Novel Award 2002. Comparison of physical activity and cumulative plantar tissue stress among subjects with and without diabetes mellitus and a history of recurrent plantar ulcers. *Clin Biomech (Bristol, Avon)*. 2003;18(7):567-575.
7. Goller H, Lewis DW, McLaughlin RE. Thermographic studies of human skin subjected to localized pressure. *Am J Roentgenol Radium Ther Nucl Med*. 1971;113(4):749-754.
8. Stess RM, Sisney PC, Moss KM, et al. Use of liquid crystal thermography in the evaluation of the diabetic foot. *Diabetes Care*. 1986;9(3): 267-272.
9. Armstrong DG, Lavery LA, Liswood PJ, et al. Infrared dermal thermometry for the high-risk diabetic foot. *Phys Ther*. 1997;77(2):169-175.
10. Benbow SJ, Chan AW, Bowsher DR, et al. The prediction of diabetic neuropathic plantar foot ulceration by liquid-crystal contact thermography. *Diabetes Care*. 1994;17(8):835-839.
11. Bergtholdt HT, Brand PW. Thermography: an aid in the management of insensitive feet and stumps. *Arch Phys Med Rehabil*. 1975;56(5): 205-209.
12. Clark RP, Goff MR, Hughes J, Klenerman L. Thermography and pedobarography in the assessment of tissue damage in neuropathic and atherosclerotic feet. *Thermology*. 1988;3:15-20.
13. Lavery LA, Higgins KR, Lanctot DR, et al. Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes Care*. 2004;27(11): 2642-2647.
14. Lavery LA, Higgins KR, Lanctot D, et al. Preventing diabetic foot ulcer recurrence in high-risk patients: the use of temperature monitoring as a self-assessment tool. *Diabetes Care*. 2007;30(1):14-20.
15. Peters EJ, Lavery LA. International Working Group on the Diabetic Foot. Effectiveness of the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. *Diabetes Care*. 2001;24(8):1442-1447.
16. Uccioli L, Faglia E, Monticone G, et al. Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care*. 1995;18(10):1376-1378.
17. Walker SC, Helm PA, Pulliam G. Total contact casting and chronic diabetic neuropathic foot ulcerations: healing rates by wound location. *Arch Phys Med Rehabil.* 1987;68:217-221.
18. Mueller MJ, Sinacore DR, Hastings MK, et al. Effect of achilles tendon lengthening on neuropathic plantar ulcers. A randomized clinical trial. *J Bone Joint Surg Am*. 2003;85-A(8):1436-1445.
19. Lavery LA, Higgins KR, Armstrong DG, et al. Randomized clinical trial to evaluate a novel home temperature monitoring device to reduce the incidence of diabetic foot complications (Abstract). *Diabetologia*. 2002;45(Suppl 2):A342.
20. Sandrow RE, Torg JS, Lapayowker MS, Resnick EJ. The use of thermography in the early diagnosis of neuropathic arthropathy in the feet of diabetics. *Clin Orthop*. 1972;88:31-33.
21. Stess RM, Sisney PC, Koss KM, et al. Use of liquid crystal thermography in the evaluation of the diabetic foot. *Diabetes Care*. 1986;9: 267-272.
22. Armstrong DG, Lavery LA, Liswood PJ, et al. Infrared dermal thermometry for the high-risk diabetic foot. *Phys Ther*. 1997;77(2):169-175; discussion 176-177.
23. Reiber GE, Koepsell TD, Maynard C, et al. Diabetes in nonveterans, veterans, and veterans receiving Department of Veterans Affairs health care. *Diabetes Care*. 2004;27(Suppl 2):B3-B9.
24. Reiber GE, Boyko EJ. Diabetes research in the Department of Veterans Affairs. *Diabetes Care*. 2004;27(Suppl 2):B95-B98.