Temperature Monitoring to Assess, Predict, and Prevent Diabetic Foot Complications

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Preventing foot complications in high-risk patients with diabetes is often overlooked. Assessing risk factors and providing standard preventative care is low tech and relatively inexpensive. The objective of this article is to discuss standard screening and prevention practices and using temperature as a self-assessment and monitoring tool. There are a number of studies that demonstrate the impact of screening and prevention; three randomized clinical trials report a three- to 10-fold reduction in foot ulcerations among high-risk patients.

Introduction

Ideally, preventative care includes professional diabetes education that is repeated on a regular basis, therapeutic shoes and insoles, regular podiatry evaluation, and active involvement of the patient and their family members. Programs aimed at treatment and prevention have been shown to be effective at reducing complications [1–4]. However, even in specialty diabetes centers with dedicated staff and top-shelf resources, this is often not enough. The rate of ulcer recurrence is still very high.

There has been little innovation in preventative care for high-risk persons with diabetes. We have made considerable progress demonstrating the impact of proactive foot care to prevent and heal foot wounds in order to avoid amputation and reduce hospitalizations. However, we have not made much headway in advancing prevention. Unfortunately, there is still an "in-my-hands" approach to therapeutic shoes and insoles and little scientific evidence to direct the use of insole materials or material combinations and to identify effective shoe and insole designs.

Failure of Standard Prevention Therapies

Several studies support the effectiveness of standard prevention therapies to reduce the incidence of ulceration and amputation [5–14]. However, most patients do not receive the type of clinical evaluation and standard prevention therapies that are recommended by the American Diabetes Association, the International Working Group on the Diabetic Foot, and the American College of Foot and Ankle Surgeons [15,16]. For instance, Sugarman et al. [17] indicated that less than 3% of eligible diabetic patients receive therapeutic shoe and insoles in the United States.

Even at specialty centers, 26% to 41% of high-risk patients still re-ulcerated within 12 months after healing [5–14]. Ulcer recurrence has been linked to poor compliance with therapeutic shoes and insoles and ineffective therapeutic insoles (Table 1). Patients complain that shoes are hot, heavy, and unattractive. High-risk patients do not use them in the relative safety of their homes because they think their feet are protected by padded carpets or they simply do not understand the mechanism of injury. Ultimately, this is a disease process that does not hurt; thus, patients have no avoidance mechanism.

Unfortunately, there is very little information in the medical literature to help us understand if therapeutic shoes and insoles are effective in high-risk patients without a previous history of foot ulcer. The work by Reiber et al. [12] would suggest that there is not a reduction in new foot ulcers in a mixed risk group of subjects with a history of a foot lesion and subjects without sensory neuropathy. Most studies have evaluated patients with a previous history of foot ulceration or lesion. This is primarily because a relatively small (and affordable) group can be studied with a high enough rate of foot ulcers to show a realistic treatment effect.

Studies Evaluating Insoles in Persons with Diabetes

Limitations of self-inspection

There are a number of limitations to self-care and self-inspection in high-risk patients; they often have multiple diabetes-related complications. Many high-risk patients have not had formal education about the risk factors or

Table 1. Studies evaluating shoes and insoles in persons with diabetes

Study	Study design	Study population	Intervention	*n*	Ulcers per year, %
Reiber et al. [12]	RCT, 24 mo	Foot lesion history but only 58% with neuropathy	Custom cork-Neoprene*	121	8
			Prefabricated polyurethane	119	7
			Self-selected shoes	160	17
Uccioli et al. [13]	RCT	Foot ulcer history	Custom shoe and insole	33	28
			Self-selected shoes	36	58
Busch and Chantelau [6]	Cohort, up to 42 mo	Foot ulcer history	Rock shoe and standard insole	87	15
			Self-selected shoes	24	60
Dargis et al. [8]	Cohort, 24 mo	Foot ulcer history	Extra depth shoes: multilaminar Plastazote† insole	56	30
			Self-selected shoes	89	58
Chantelau et al. [7]	Cohort, 25 mo	Foot ulcer history	Therapeutic shoes-cushioned insoles: compliant	41	21
			Therapeutic shoes-cushioned insoles: not compliant	32	44

*DuPont Performance Elastomers, Wilmington, DE.
†Zotefoams plc, Surrey, UK.
RCT–random controlled trial.

mechanisms of injury that lead to ulcers and amputations. Self-treatment practices are frequently based on mythology and misinformation.

Education focuses on self-inspection, self-care, and foot hygiene issues. However, many patients cannot adequately perform the self-inspection task because they are obese, have limited joint mobility, or impaired vision. For instance, in a study of ulcer risk factors, a large proportion of patients with and without foot ulcers did not have the visual acuity, manual dexterity, or joint flexibility to perform simple self-examination checks of their feet. Among ulcer patients, 49% could not bend the hip, knee, and ankle adequately to see the bottom of the foot; or they lacked the visual acuity to see a 1-cm spot on the foot. Also, 15% of ulcer patients were legally blind in at least one eye. Even if a family member is available to visually inspect the foot, without an objective measure of injury, most laymen will only be able to identify ulcers once they have occurred [18]. Even when patients were educated and equipped with special mirrors to see the bottom of the foot, in the vast majority of patients an ulcer was already present by the time they observed visual signs of injury [19••].

Elevated temperatures predict foot complications

The rationale for evaluating skin temperatures involves the search for a quantifiable, reproducible 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. Five cardinal signs characterize inflammation: 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 from clinician to clinician or from visit to visit. Most health care professionals and high-risk patients and their family members will not be able to accurately evaluate these subtle parameters. However, temperature measurements can be used as an objective tool to detect subtle signs of inflammation. Local areas of inflammation would probably not be recognized as "symptomatic" when using "traditional" methods of visual inspection and physical examination.

Over the past four decades, several authors have suggested that skin temperature monitoring may be a valuable tool to detect sites at risk of ulceration in patients with neuropathy. As early as 1971, Goller et al. [20] reported an association between increased local foot temperatures and localized pressure leading to tissue injury. Sandrow et al. [21] subsequently used thermometry as a tool to diagnose occult neuropathic fractures in patients with diabetes in 1972. Stess et al. [22] and Clark et al. [23] described the use of infrared thermography to assess skin temperatures in diabetic control subjects with no foot pathology, diabetic patients with neuropathic fractures, diabetic patients with ulcers, patients with leprosy, and healthy control subjects. They found that neuropathic foot ulcers frequently had increased skin temperatures surrounding a central necrotic area and suggested that infrared thermometry may be a useful technique to identify patients at risk for ulceration.

Table 2. Trials determining if patients can effectively use a handheld temperature assessment tool to avoid foot ulcers

Study	Study population	Sample size and duration	Outcomes
Lavery et al. [26•]	1) Ulcer history; 2) neuropathy-deformity	*N* = 85; 6 mo	Temperature group, 2%; standard therapy, 20%
Lavery et al. [19••]	Ulcer history	*N* = 173; 15 mo	Temperature group, 8.5%; standard therapy, 29.3%, structured therapy, 30.4%
Armstrong and Lavery [25]	1) Ulcer history; 2) neuropathy-deformity	*N* = 225; 18 mo	Temperature group, 4.7%; standard therapy, 12.2%

Benbow et al. [24] took this work a step further and evaluated foot temperatures as a tool to identify complications in a cohort of diabetic patients. They suggested that thermographic patterns could be used to screen high-risk patients. They prospectively evaluated 50 patients with diabetes and sensory neuropathy for 3 to 4 years. Six patients developed a foot ulceration during the study period. These patients had significantly higher foot temperatures at baseline than patients who did not ulcerate.

There have been three randomized clinical trials to determine if patients can effectively use a handheld temperature assessment tool to avoid foot ulcers (Table 2) [19••,25,26•]. All three studies have demonstrated a three- to 10-fold reduction in incident foot ulcers in high-risk patients with a history of a foot ulcer or with sensory neuropathy and foot deformity. These studies used a similar basis for standard prevention therapy. Subjects in the control group were treated with therapeutic shoes and insoles and a standardized diabetic foot education program.

Lavery et al. [26•] evaluated the effectiveness of the TempTouch (Xilas Medical, San Antonio, TX), a handheld infrared temperature device, in a cohort of 180 high-risk diabetic patients with a history of foot ulceration or partial foot amputation. There were three treatment arms in the study. The standard therapy group received therapeutic shoes and insoles, patient education, and regular foot evaluations by a podiatrist every 10 to 12 weeks. The structured foot evaluation group performed a structured foot evaluation to identify local signs of tissue injury, redness, discoloration, swelling, and local warmth twice a day and recorded their findings in a log book in addition to receiving standard therapy. Subjects also used a hand mirror to visualize the bottom of their feet. The temperature therapy group received standard therapy plus the addition of the TempTouch. They measured temperatures on six sites on the sole of each foot once a day. If temperatures were elevated by more than 4°F compared with the same site on the contralateral foot, they reduced their activity until the temperatures normalized.

The incidence of foot ulceration during the 15-month evaluation period was essentially identical in the standard therapy (29.3%) and structure foot evaluation (30.4%) treatment arms. However, there was more than a fourfold decrease in the risk of developing foot ulceration in subjects in the temperature therapy group (8.5%) compared with the standard therapy group (OR = 4.37, $P = 0.005$) and the structured foot evaluation group (OR = 4.71, $P < 0.003$).

Temperature as a Tool for Health Care Providers

Temperature monitoring has also been advocated as a clinical tool to monitor compliance with off-loading, to identify Charcot fractures, and to evaluate therapeutic responses to antibiotics, bisphosphonates, and immobilization. Armstrong and Lavery [25] used an infrared temperature device to evaluate a cohort of diabetic patients with neuropathic fractures. They tracked a cohort of subjects treated for Charcot foot fractures with serial total contact casting, who then progressively transferred to removable cast boots, and finally to therapeutic shoes and insoles. They suggested that patients should be immobilized until their temperatures are the same as the contralateral extremity. In a cohort of subjects with foot ulcers, the difference in temperature at the site of neuropathic foot ulcerations, compared with the corresponding contralateral site, decreases as the surface area of the wound decreased when subjects were off-loaded with total contact casts.

Unfortunately, this relatively new monitoring tool does not lend itself to the kind of gold standard for normal temperatures that we are accustomed to when we evaluate oral temperatures or core body temperatures. Because autonomic neuropathy and peripheral vascular disease affect foot temperatures, temperatures can vary widely from person to person. The three randomized clinical trials that focused on ulcer prevention asked patients to match the temperature on the contralateral extremity. These studies used a 4°F (2.2°C) difference to identify an area that was inflamed and prone to ulceration.

Temperature monitoring to assess the diabetic foot is not a new concept. The technology has been available and many centers of excellence have incorporated it into their treatment algorithms. Various products exist that are inexpensive and easy to use. Using a home monitoring device is novel and there are now a large number of randomized trials that demonstrate its effectiveness.

Conclusions

A focused program to identify patients who fit a high-risk profile for developing foot complications can be very effective.

Standard prevention that consists of foot-specific education, protective shoes and insoles, and regular foot examinations can reduce the incidence of foot ulcers by 50%. Daily self-assessment using an infrared temperature device can reduce ulceration by an additional three- to 10-fold.

References and Recommended Reading

Papers of particular interest, published recently, have been highlighted as:

- • Of importance
- •• Of major importance

1. Armstrong DG, Harkless LB: **Outcomes of preventative care in a diabetic foot specialty clinic.** *J Foot Ankle Surg* 1998, **37:**460–466.
2. Lavery LA, Wunderlich RP, Tredwell J: **Disease management for the diabetic foot: effectiveness of a diabetic foot prevention program to reduce amputations and hospitalizations.** *Diabetes Res Clin Pract* 2005, **70:**31–37.
3. Rith-Najarian SJ, Reiber GE: **Prevention of foot problems in persons with diabetes.** *J Fam Pract* 2000, **49(11 suppl):** S30–S39.
4. Armstrong DG, Lavery LA, eds: *Clinical Care of the Diabetic Foot*. Alexandria, VA: American Diabetes Association; 2005.
5. Ronnemaa T, Hämäläinen H, Toikka T, Liukkonen I: **Evaluation of the impact of podiatrist care in the primary prevention of foot problems in diabetic subjects.** *Diabetes Care* 1997, **20:**1833–1837.
6. 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* 2003, **20:**665–669.
7. Chantelau E, Breuer U, Leisch AC, et al.: **Outpatient treatment of unilateral diabetic foot ulcers with "half shoes".** *Diabet Med* 1993, **10:**267–270.
8. Dargis V, Pantelejeva O, Jonushaite A, et al.: **Benefits of a multidisciplinary approach in the management of recurrent diabetic foot ulceration in Lithuania: a prospective study.** *Diabetes Care* 1999, **22:**1428–1431.
9. Edmonds ME: **Experience in a multidisciplinary diabetic foot clinic.** In *The Foot in Diabetes*. Edited by Connor H, Boulton AJM, Ward JD. Chichester: John Wiley and Sons; 1987:121–131.
10. Edmonds ME, Blundell MP, Morris ME, et al.: **Improved survival of the diabetic foot: the role of a specialized foot clinic.** *Q J Med* 1986, **60:**763–771.
11. 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, **85A:**1436–1445.
12. Reiber GE, Smith DG, Wallace C, et al.: **Effect of therapeutic footwear on foot reulceration in patients with diabetes: a randomized controlled trial.** *JAMA* 2002, **287:**2552–2558.
13. Uccioli L, Faglia E, Monticone G, et al.: **Manufactured shoes in the prevention of diabetic foot ulcers.** *Diabetes Care* 1995, **18:**1376–1378.
14. Walker SC, Helm PA, Pullium G: **Total-contact casting, sandals, and insoles. Construction and applications in a total foot-care program.** *Clin Podiatr Med Surg* 1995, **12:**63–73.
15. Frykberg RG, Armstrong DG, Giurini J, et al.: **Diabetic foot disorders: a clinical practice guideline. American College of Foot and Ankle Surgeons.** *J Foot Ankle Surg* 2000, **39(5 suppl):**S1–S60.
16. Apelqvist J, Bakker K, Van Houtum WH, et al.: **International consensus on the diabetic foot.** In *International Working Group on the Diabetic Foot*. Amsterdam, The Netherlands: International Diabetes Federation; 1999:67–72.
17. Sugarman JR, Reiber GE, Baumgardner G, et al.: **Use of the therapeutic footwear benefit among diabetic Medicare beneficiaries in three states, 1995.** *Diabetes Care* 1998, **21:**777–781.
18. Lavery LA, Armstrong DG, Vela S, Fleishli JG: **Practical criteria to screen patients at risk for diabetic foot ulceration.** *Arch Intern Med* 1998, **158:**157–162.
19.•• Lavery LA, Higgins KR, Lanctot DR, et al.: **Preventing diabetic foot ulcer recurrence in high-risk patients: use of temperature monitoring as a self-assessment tool.** *Diabetes Care* 2007, **30:**14–20.

This paper reports the results of a randomized clinical trial in which patients with a history of a foot ulceration were assigned to use a temperature device to evaluate their foot temperatures, a visual self-inspection protocol, or usual care. There was a fourfold reduction in foot ulcers with temperature monitoring compared with the other two study groups.

20. Goller H, Lewis DW, McLaughlin RE: **Thermographic studies of human skin subjected to localized pressure.** *Am J Roentgenol Radium Ther Nucl Med* 1971, **113:**749–754.
21. Sandrow RE, Torg JS, Lapayowker MS, Resnik EJ: **Use of thermography in the early diagnosis of neuropathic arthropathy of the feet in diabetics.** *Clin Orthop* 1972, **88:**31–33.
22. 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.
23. 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.
24. 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:**835–839.
25. Armstrong DG, Lavery LA: **Advanced foot surveillance with skin temperature monitoring reduces the risk for diabetic foot ulceration in high risk patients.** *Am J Med* 2007, In Press.
26.• Lavery LA, Higgins KR, Lanctot DR, et al.: **Home monitoring of foot skin temperatures to prevent ulceration.** *Diabetes Care* 2004, **27:**2642–2647.

This randomized clinical trial compared home temperature assessment with a handheld thermometer to standard prevention therapies in a cohort of high-risk patients for foot ulceration. There was a 10-fold reduction in foot complications in the group that used the thermometer for self-evaluation.