

Diabetic Foot Self Examination with the Tempstat™ as an Integral Component of a Comprehensive Prevention Program

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Abstract: Foot ulcers and amputations are major lower extremity complications of diabetes mellitus and account for expenditures of hundreds of millions of dollars annually. More importantly, these complications also are associated with an increased morbidity and mortality. Their prevention, therefore, becomes critically important in the overall care of persons with diabetes. Daily foot self-examination has consequently been recognized as a key component in diabetes amputation prevention programs. We herein introduce a novel self - assessment device that assists patients in examining the soles of their feet with a combination mirror and liquid crystal temperature sensitive pads. Areas of inflammation and increased skin temperatures can be easily visualized by patients, thus prompting them to seek early intervention for impending problems. Preliminary experience indicates that this modality has been favorably accepted by high risk patients. Nonetheless, longitudinal studies will be required to determine its overall effectiveness in preventing limb-threatening diabetic foot disorders.

Key words: Diabetes, Tempstat™, diabetic foot infection.

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Introduction

Diabetes-related foot disorders such as ulceration, infection, and gangrene are leading causes of hospitalization for patients with this disease in the United States and abroad.^{1-3,4} Unfortunately, of the estimated 24 million persons in the U.S. with diabetes, many will require amputation of the foot or above the ankle as a consequence of severe infection or peripheral ischemia.

The diabetic foot and its long-term sequelae account for direct medical expenditures of hundreds of millions of dollars annually, long hospital lengths of stay, and lengthy periods of disability.^{5, 6} The most characteristic lesion of the diabetic foot is, of course, the foot ulceration which consequently is one of the major risk factors for amputation. Diabetic peripheral neuropathy, including sensory, motor and autonomic neuropathy, is likely the most common lower extremity complication of this disease.^{3,7,8} Neuropathy can predispose the lower extremity not only to ulceration, but also to infection, gangrene, and amputation. Although the triad of neuropathy, deformity, and trauma are the primary component causes in its pathogenesis, the diabetic foot ulcer can further be attributed to other important risk factors.⁹⁻¹¹

Some of these include age, gender, peripheral arterial disease, hyperglycemia, callus, high plantar foot pressures, and renal insufficiency.



Figure 1 Photograph of TempStat™ Device.

Early detection of these risk factors as well as of foot ulcers themselves are key components in the overall management of diabetic foot disorders and amputation prevention programs.¹²⁻¹⁴

Prompt and aggressive management of diabetic foot ulcers can often prevent infection and diabetic foot complications that include the potential risk of amputation. The aim of therapy, therefore, should be early intervention to allow prompt healing of the lesion, and once healed, to prevent recurrence.¹⁴ Optimal care for foot ulcerations depend upon the treating clinicians' understanding of the pathophysiology involved, familiarity with accepted principles of treatment, and the knowledge that a coordinated multidisciplinary team approach will best accomplish the goal of limb salvage. Above all else, prevention of foot lesions should be the ultimate aim.^{2, 9, 15, 16}

Prevention

Diabetic patients with neuropathy and especially those with a prior history of ulceration or amputation are at the greatest risk for subsequent ulceration.^{10,11,17,18} Prevention is considered a key element in avoiding ulcer occurrence, recidivism and diabetic lower extremity amputation.^{13,16, 19-22} This is best accomplished with a multidisciplinary approach consisting of a team of

dedicated professionals committed to this ideal.^{13, 14, 22-26} Patient education assumes a primary role in this scheme and encompasses instruction in foot hygiene, the need for daily inspection, proper footwear, and the necessity for prompt treatment of new lesions. Daily inspection of one's feet not only fosters appropriate self-care behavior, but also promotes early detection of new or impending foot problems. By seeking care earlier in the natural history of foot injuries or ulcerations, especially in the incipient stages, patients themselves can facilitate earlier treatment and avoid more serious complications.^{2,27,28} Several recent studies have highlighted the effectiveness of daily foot temperature assessments in reducing the incidence of diabetic foot ulcerations.²⁹⁻³¹

Daily monitoring of foot temperatures not only engages the patient in his or her own care, but also prompts them to call their health care provider to seek prompt care at the onset of open foot lesions or sores.

A novel self-assessment device has recently become available to diabetic patients that provides them with an easy way to inspect the soles of their feet as well as to assess temperature changes associated with focal areas of inflammation (thought to be a common precursor to foot ulceration). TempStat™ (Visual Footcare Technologies, LLC, South Salem, N.Y.) is a personal home care device that is intended to enable patients to visualize the image and condition of the soles of their feet as part of their daily self-examination routine. Visual signs of irritation, abrasions, cuts, bruises, swelling or inflammation can therefore be detected by the patient at their earliest onset. This prescription device is intended to be used as an adjunct to, and not in replacement of, periodic foot care and examinations conducted by a health care professional. The TempStat™ is designed to make the examination of the plantar surface of the foot simple and easy to perform, providing that they do not have significant coexisting visual impairment. The TempStat™ consists of a plastic panel that has a 2X convex mirror in the center third section, with two polycarbonate plastic pads on either side of the mirror. The plastic pads are constructed primarily of

liquid crystalline cholesteric esters that react to skin surface temperature and change to a specific color relative to that level of temperature. The science and technology utilized by these pads is identical to the forehead strip thermometers currently available over the counter. With this device, the patient can visually examine his foot and also see a graphical representation of the heat pattern on the plantar sole of his foot. The device is designed to sit on the floor in front of the patient, who is seated in a chair. The patient leans over and raises his foot to see the bottom of his foot in the mirror, and then places them on the polycarbonate pads. After 60 seconds, the patient can remove his feet and can visualize the pattern of skin temperature from the plantar surface of his foot. (Fig. 1) Under normal circumstances, the temperatures (and therefore the images) of the two feet should be very similar.

If differences are noted in the thermal images (or differ from their usual appearances), further professional examination is warranted to determine the reason for the differences. In this way, the patients themselves become actively involved in their own ulcer prevention program.

Clinical Survey

We conducted a patient preference survey using the TempStat™ device. The purpose of this study was to obtain a realistic estimate of the ability of the TempStat™ device to provide assistance to the subject in visualizing the plantar surface of his foot. The subject conducted a visual inspection of his/her feet with and without the TempStat™ device. Afterwards, a podiatric physician conducted a similar examination on the subject's feet. Both of these inspections were recorded. Furthermore, an infrared thermometer was used to determine the skin temperature on the subject's foot at various locations. Finally, the patient utilized the liquid crystal pads of the TempStat™ device to provide a graphic representation of the plantar surface of his feet. The temperature differences taken on the patient's foot with in IR thermometer were reflected by color differences in the TempStat™ images of their feet.

The survey was conducted at two sites: one site was a podiatrist's office, and the other site was a retail shoe store. In the podiatric clinic both patients with Type 2 diabetes and those without diabetes were examined and photographed. Subjects who were healthy and engaged in moderate amounts of exercise were seen at the shoe store. A total of 35 study subjects were seen in the podiatric office, and 8 subjects at the shoe store, for a total of 43 subjects in all. Between examinations, the contact surfaces were wiped with a surface disinfectant to prevent transmission of biologic pathogens from one patient to another.

At the podiatric location, the patient questionnaire was modified to allow medical personnel to administer the questionnaire, rather than having the patient read and respond to the questions in writing.

Results

Of particular note in the study is the comparison of the various temperatures of the plantar surface of the foot in several areas taken with an infrared (IR) dermal thermometer and then comparing the TempStat™ prints to those temperature readings. The results of the IR thermometer demonstrated a qualitative correlation with the colors of the TempStat™ liquid crystal pads. In most cases where there were no open or impending lesions (areas of inflammation) the color was noted to be uniform throughout the soles of both feet. In those subjects where there were notably higher focal areas of temperature, the TempStat™ pads were able to highlight those areas with expressions of colors different from other areas of the same foot and the contralateral foot. Two such examples are presented below.

In the first case (Fig. 2), the subject's right foot shows the presence of a chronic ulcer with mild inflammation. The temperature reading for his right foot at the ulcer site taken by the IR thermometer indicated that it was 89°F and the surrounding areas were also in the mid-80°F range. The subject's left foot, which has no ulcer or appreciable inflammation, registered temperatures in the high



Figure 2 Clinical photograph of the feet (Case 1). There is an ulcer under the right first metatarsal head.

70°F and low 80°F ranges. As seen in the TempStat™ images (Fig. 3) the image of the right foot shows a generally dark blue color, with a higher temperature red spot at the ulcer site and looks very different from the contralateral image. When comparing the pictures of the patient's feet with the images on the TempStat™ pads, one can see the differences between the two feet corresponding to the inflammation (increased temperature).

In the second case (Fig. 4), the subject's heels measured temperatures of 92°F and the other areas of the foot registered in the mid-80°F range. The corresponding TempStat™ image (Fig. 5) shows that the images are generally dark blue in color, but the heels have a red tint. From a patient's perspective, only a quick glance is required to notice the color differences between the heel and the rest of the foot. This color difference corresponds to the temperature differences detected by the IR thermometer. As has been previously shown, areas showing increased cutaneous temperatures (inflammation) can indicate areas of impending ulceration.²⁹⁻³¹

All 43 of the study subjects felt that the TempStat™ device enhanced their ability to visualize the plantar surface of their feet and was easy to use.



Figure 3 Photograph of TempStat™ device image. (Case 1)

All of the study subjects indicated that if given the device to take home, that they would use it daily to examine their feet.

Conclusions

Prevention strategies are critically important in reducing the incidence of primary or secondary foot ulcerations in patients with diabetes mellitus. By reducing the frequency of foot ulcers we can also anticipate a reduction in the number of diabetes – related lower extremity amputations. In addition to periodic comprehensive foot examinations, patient self-examination and daily foot care assume an equally important role in the prevention of potentially limb-threatening lesions. In this pilot feasibility study we have introduced the TempStat™ device that patients can easily use to detect temperature elevations on the soles of their feet when used for daily assessment. Such abnormalities can then prompt these patients to seek early evaluation by their health care providers. This pilot investigation of a new self-examination device obviously requires an independent longitudinal evaluation of its effectiveness to determine its true value in reducing the incidence limb-threatening lesions in high-risk patients.



Figure 4 Clinical photograph of the feet. (Case 2)

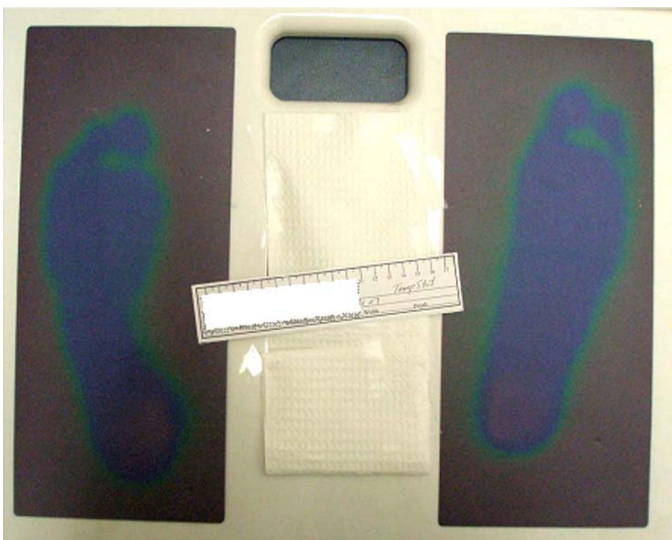


Figure 5 Photograph of TempStat™ device image. (Case 2)

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