

Remote home monitoring to identify and prevent diabetic foot ulceration

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The formation of a foot ulceration is an end-stage complication of diabetes. Given that a diabetic foot ulceration has a 50% chance of becoming infected and the subsequent risk of a moderate to severe diabetic foot infection requiring amputation is approximately 15%, the need for aggressive prevention is great (1-3). The current standard of care for diabetic foot prevention includes diabetic foot education, regular diabetic foot evaluation, and therapeutic shoes and bespoke insoles. The current standard of care has been shown to decrease the re-ulceration rate by half (4-11).

The recurrence rate of a diabetic foot ulceration depends on access to and compliance with the standard of care for prevention. Diabetic education programs have been shown to be beneficial in reducing diabetic foot ulceration and amputation. Malone *et al.* (12) in a prospective randomized study showed a diabetic foot education program could reduce the ulceration and amputation rate to 1/3 that of the non-education arm (8 *vs.* 26 ulcerations and 7 *vs.* 21 amputations). Litzelman *et al.* (13) reports the results of a diabetic education program in a randomized controlled trial that focused not just on the patient but also on the clinician and compared this to the standard of care. A 41% decrease in diabetic foot ulcers was shown in the education group compared to standard of care. The education group patients were more likely to perform self-foot examinations, receive educational materials, and have their feet examined in office visits. While diabetic education and home preventative measures such as self-foot inspection have been shown to be useful, diabetics can have comorbidities making self-

inspection difficult. Lavery and colleagues have previously shown that half of diabetic patients have impaired vision and 40% of patients do not have the mobility to flex their hips, knees, and ankles so the sole of their feet can be inspected (14). Locking-Cusolito and colleagues (15) evaluated similar limitations in the diabetic population noting 25% vision impairment and 40% with mobility impairment. These types of impairments hinder daily self-examination. These comorbid limitations are minimized with methods such as automated foot temperature monitoring, where their only requirement is to stand on the mat.

Therapeutic shoes and insoles, when compared to self-selected shoes, have been shown in several studies to reduce re-ulceration by 30% to 50% (4-11). Busch and Chantelau (5) evaluated 92 neuropathic diabetics with a history of ulceration and showed a 45% absolute risk reduction in re-ulceration rate the first year by using off-the-shelf diabetic shoes and insoles compared to self-selected shoes. Uccioli and colleagues (10) reported the results of a randomized controlled trial that evaluated diabetic patients with a history of foot ulceration that were assigned to custom-made shoes and insoles or self-selected shoes. Among patients with self-selected shoes, 58.3% re-ulcerated compared to 27.7% of patients with custom shoes. While therapeutic shoes and insoles, education, and regular foot care reduces the rate of re-ulceration by half, the incidence of ulceration is still very high (30%).

Investigators have tried to improve on the results of standard of care therapies by using advances in insole design and temperature as a self-assessment tool. In a randomized

controlled trial, Lavery and colleagues studied 299 patients that were treated with standard diabetic insoles or shear-reducing insoles. The standard therapy group showed a 3.5 fold higher risk of ulceration compared to the shear-reducing insole (16). Others have sought to improve outcomes by optimizing the design and pressure reduction of therapeutic insoles. Bus *et al.* (17) in a multicenter randomized controlled trial compared standard diabetic insoles to enhanced customized insoles which provided further offloading via additional measurements and modifications with a goal to reduce peak pressure point measurements by 20%. While there was no statistical significance in an intent to treat analysis, there was a significant reduction in re-ulceration in patients that were adherent and used enhanced insoles compared to patients with standard of care insoles (25.7% vs. 47.8% respectively). Ulbrecht *et al.* (18) in a single-blinded multicenter randomized controlled trial compared standard offloading diabetic insoles to orthoses that were altered to better offload high pressure areas in neuropathic diabetics with history of ulceration. The experimental orthoses were manufactured by obtaining a general shape with a foam molding box and were then modified with a computer-aided design process using defined algorithms based on peak barefoot plantar pressure distribution. Patients that received “computer-designed” insoles had fewer ulcers or non-ulcerative foot lesions (ex. hemorrhagic callus) than patients that received the standard of care (37.9% and 45.3% respectively).

Perhaps one of the most promising prevention tools is home temperature assessment. Foot temperature monitoring has been advocated for 45 years as a means to identify injured tissue. The idea of increased foot temperature being related to tissue injury was first reported by Goller *et al.* in 1971 (19) and was later proposed as a tool to predict diabetic foot complications by Benbow *et al.* (20). Temperature monitoring has been shown to be an effective prevention tool in three randomized controlled trials and has continued to grow as a topic of interest for diabetic foot ulcer prevention. In three randomized controlled trials, the incidence of re-ulceration was reduced by 3–10-fold when patients used self-temperature assessment and standard of care compared to standard of care alone (8,21,22). These randomized controlled trials used a simple, inexpensive, handheld infrared thermometer. The device was designed with a “goose neck” type extension to allow for easy plantar foot readings and a touch sensor that only took temperature readings when applied to the patient’s skin. While the device was technically easy to use, it had limitations. The

device took a temperature from a single point with each application, requiring multiple measurements per foot, and then the patient had to manually record the temperatures in a log. The patient was responsible for recognizing the increased temperature and acting on it by reducing their activity until their foot temperatures returned to a normal range. One of the main limitations was that non-compliant patients could not be identified until they reported for evaluation every 10 weeks. Eighty percent of the participating subjects who ulcerated (4/5) were non-compliant with the monitoring regimen (8).

Frykberg and colleagues recently performed a multicenter cohort trial evaluating a novel method of foot temperature monitoring (23). This involved a prospective cohort of 132 diabetic patients with a history of diabetic foot ulceration and occurred over a 34-week period. The studied device was a novel temperature monitoring unit that used a wireless floor mat with a reported accuracy of ± 0.6 °C and a precision of 0.1 °C. The mat has 2,000 embedded thermistor sensors (Podometrics Mat, www.podometrics.com) and collected data on both feet in about 20 seconds. The temperature mat and the data from the prospective cohort study fill important voids in our knowledge about home temperature monitoring and its role in diabetic foot ulcer prevention. First, the temperature mat can collect data on the entire plantar foot surface and send it through the internet to be analyzed and reported almost instantaneously. It requires very little effort on the part of the patient.

The objectives of Frykberg’s study were to determine if this novel method of temperature monitoring was effective in predicting diabetic foot ulceration, identifying the time to re-ulceration, and to evaluate ease of use and compliance. This study expanded our understanding of the threshold of temperature that might predict ulceration and the time frame that a site could show abnormal temperatures before an ulcer developed. The mat provided an impressive 37-day lead time to ulceration when set to alert with a temperature difference of 2.22 °C (97% sensitivity, 57% false positive). Alternatively, it was also found that there was a 35-day lead time to ulceration with a 3.2 °C difference (70% sensitivity, 32% false positive). Although there is a high false positive rate at 2.22 °C, the potential to arrest re-ulceration is worth the perceived inconvenience to the patient required by the need to decrease activity until the temperature returns to within 2.22 °C of the contralateral foot. It was noted that the mat would amount to approximately 3 notifications per user, per year on average (23). Should the patient receive an alert, their initial instructions would be as unobtrusive as

decreasing activity until the temperatures normalized.

The preliminary compliance data from this study are encouraging. Eighty-eight percent of subjects rated the device very easy to use (maximum ease of use score) and 98% could set up the product for home use without difficulty. An admirable 86% of the subjects used the device at least 3 days per week for the 34 study weeks (23). Although daily use would be optimum, weekly use would likely provide valuable data and allow for a decrease in the re-ulceration rate of diabetics.

This data is especially encouraging given that compliance with bespoke shoes and insoles is often poor (24,25). The effectiveness of diabetic shoes and insoles, like any other preventative measure or treatment, depends on compliance. Unfortunately, patient compliance with diabetic shoes and insoles can vary widely from 15% (24) to 67% (25). However, patients may only need to use the temperature mat every few days since the window to identify a spike in temperature is 37 days prior to ulceration. Given the data for adherence to the Remote Temperature Monitoring system is high (86%) and the need for daily compliance is low, even poorly compliant patients should benefit. Widespread implementation of a device like this should be considered for patients with a history of diabetic foot ulceration or diabetes related amputation. In addition to the objective data provided, this technology can identify patients with poor compliance or even patients that stop using the system. These patients can be contacted for further follow up, evaluation, and in depth personal education allowing for immediate correction.

Remote temperature monitoring is a much-anticipated intervention for high risk diabetic patients. Frykberg and colleagues (23) have provided novel data to advance our understanding of the etiology and prevention of diabetic foot ulcerations.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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