A Remote Thermometric System for the Early Detection of Diabetic Foot Ulcerations

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Introduction

Foot ulcers are often preceded by clinical/sub-clinical inflammation, for which increased temperature is a surrogate marker. Plantar temperature measurements in the diabetic foot primarily contribute to identifying abnormal values that increase risk for foot ulceration, and they are becoming increasingly more integrated in clinical practice and daily life of the patient. While plantar temperature measurements have long been present, only recent evidence shows their importance in ulcer prevention. Prevention by identifying people at higher risk is crucial for better clinical management of such patients.

Purpose and Hypothesis

Monitoring plantar foot temperatures to prompt timely pressure offloading has been demonstrated to be effective for preventing diabetic foot ulcers (DFU), which are known to be associated with increased morbidity, mortality, and resource utilization. In this study, we utilized an automated, cloud-based, thermometric floor mat for temperature asymmetry analysis (Figure 1). Primary outcomes of interest included the ability to detect plantar DFUs. Secondary outcomes included subject adherence to daily use of mat.

Materials and Methods

We completed a prospective, multicenter cohort study in 129 high-risk diabetic subjects each followed for 34 weeks. Enrollment criteria included history of plantar DFU and absence of active foot pathology. Subjects were instructed to use an in-home, telemedicine, temperature-monitoring mat once daily. Outcomes of interest included development of plantar DFU and adherence in the use of the mat. All subjects received the study device and were instructed to use it once per day. Subjects received preventative standard of care. All subjects and investigators were blinded to the thermometric data until study completion. Subjects were instructed to discontinue use of the device if acquire an open wound. Statistical analysis was performed evaluating sensitivity and specificity calculated over 2-month samples. ROC analysis was used to evaluate classification accuracy.

Subject demographics & comparison of subjects with and without DFU

	All Subjects	Without DFU	With DFU	Significance
Number	129	92	37	-
DFU episodes	53	0	53	-
Age	61.8 (+/- 10.5)	62.2 (+/- 11.0)	61 (+/- 9.3)	NS
Duration since last ulcer healed (months)	13.9 (+/- 39.2)	16.1 (+/-45.1)	8.2 (+/- 14.4)	NS
Duration since diabetes diagnosis (years)	17.6 (+/- 10.8)	16.9(+/- 10.9)	19.1(+/- 10.7)	NS
Percent requiring insulin	60.5% (78/129)	55.4%(51/92)	73.0% (27/37)	NS
Most recent HbA1c	8.3(+/- 2.0)	8.2(+/- 2.1)	8.6(+/- 1.8)	NS
BMI	33.4 (+/- 6.6)	32.7 (+/- 6.9)	34.8 (+/- 5.9)	NS

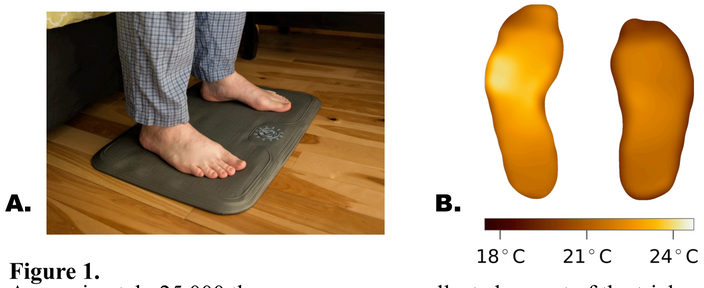
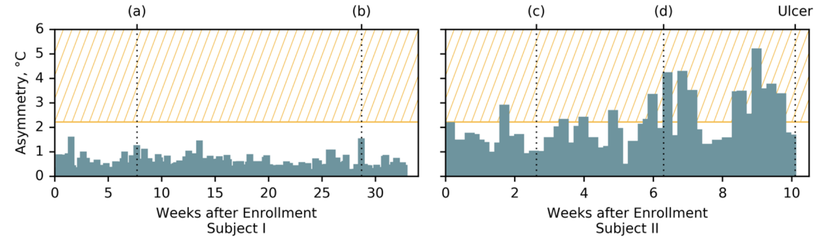
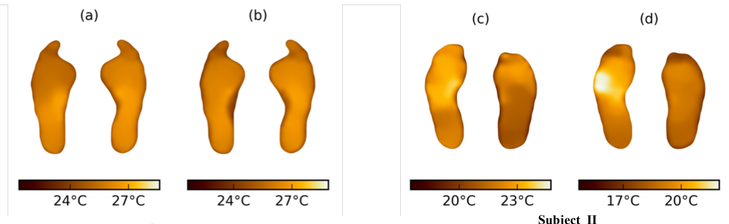


Figure 1.
Approximately 25,000 thermograms were collected as part of the trial.
A. Wireless foot mat with thermometric coverage across the plantar surface
B. B. High-resolution thermograms collected with each use.

Case Study Examples with Thermometric Data





Subject I
61 year old male with a history of DFU on the left hallux (closure 40 weeks prior to enrollment) and right hallux status post amputation (healed incision 42 weeks prior to enrollment). At no point during study participation did he exceed a temperature asymmetry of 2.2ºC or experience a new DFU.

Subject II
59 year old female subject with a history of DFU on her right hallux and right 5th metatarsal head, the latter of which closed approximately 11 weeks prior to enrollment. Temperature asymmetry exceeded 2.2ºC at multiple time periods during participation, and her right fifth metatarsal head DFU recurred by week 10.

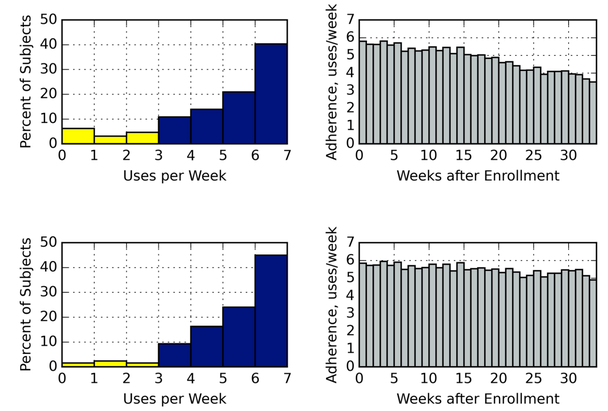
Adherence Results

ITT Analysis

Subjects with active consent, less those who acquired a clinical contraindication

Per-Protocol Analysis

Subjects with active consent, less those who acquired a clinical contraindication or became lost to follow-up



Results

Using a model based on the temperature asymmetry between the left foot and right foot at six plantar locations, we predicted the development of plantar DFU (Figure 2). We characterized the sensitivity, specificity, and lead time of the model's predictions for four different temperature asymmetry thresholds. A total of 53 non-acute plantar DFU occurred to 37 patients (0.63 DFU/subject/year). Under its current capabilities, the system was able to detect up to 97% of plantar DFU approximately 5 weeks before they occurred using 2.22 degrees Celsius as a threshold. Using an intention-to-treat approach, we calculated a mean adherence in the daily use of the mat of 5.0 uses/week. Approximately 86% of subjects used the mat more than three times per week on average.

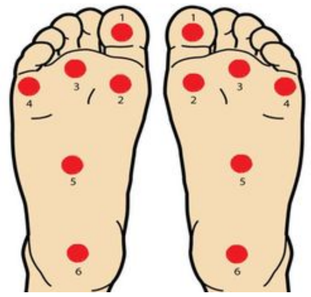


Figure 2. Temperature Guided Avoidance Therapy. The system recorded temperatures at the 12 locations. Asymmetry between each ordered pair was calculated. If any region's asymmetry exceeds 2.2 degrees Celsius for two consecutive days, subjects were contacted to reduce activity until temperatures normalized.

Conclusions

Use of the system may significantly reduce DFU-related morbidity, mortality, and resource utilization.

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