Accuracy of Daily Foot Temperature Monitoring for Patients with Recently Healed Diabetic Foot Ulcers or History of Amputation

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Introduction

Diabetic foot ulcers (DFU) result in significant morbidity, mortality, and healthcare costs. Fortunately, recent data suggest as many as 75% of DFU [1] may be preventable. This implies significant potential for reduction in rates of partial lower extremity amputations (PLEA) as well because as many as 84% of PLEA are preceded by DFU [2].

Clinical practice guidelines recommend evidence-based foot temperature monitoring (thermometry) for preventing DFU and its complications in high-risk patients [3-5]. Despite this, several authors have noted that thermometry is not commonly practiced [6, 7]. This is potentially due to lack of evidence on the accuracy of thermometry in some of the highest-risk cohorts, including those with a recently-healed DFU or with history of PLEA. The former may present with ipsilateral inflammation as part of normal healing, while the latter may lack the anatomy required for direct contralateral comparison of temperatures between the feet. Whether these concerns affect the accuracy of thermometry needs to be assessed.

Methods

A recent multi-center investigation [8] studied the accuracy of a remote temperature monitoring mat in a cohort of 129 participants with history of plantar DFU. These patients were followed for 34 weeks or until withdrawing consent. The results of the study suggest that the thermometric mat may address some barriers to adoption. The mat was found to predict as many as 97% of non-traumatic plantar DFU with an average lead time of five weeks in a cohort with history of DFU.

In the current investigation, we hypothesized no difference in the predictive accuracy of thermometry in two subgroups: those who healed from a DFU fewer than three months before enrolling, and those with a history of partial LEA (Syme amputation or more distal). We assessed the accuracy in each subcohort compared to compare the ROCs of the recently-healed subgroup and the amputation subgroup to entire cohort using Delong's approach [9].

Results

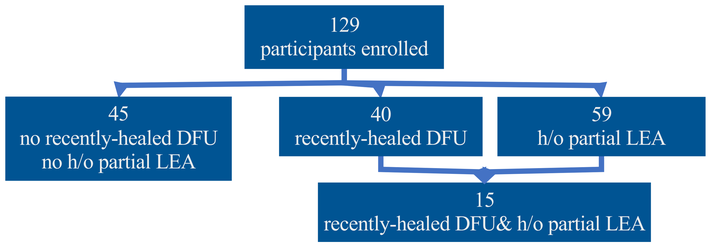
Of the 129 subjects studied, 31% had recently-healed DFU and 56% had history of LEA. Although no difference in DFU incidence was found in the LEA subgroup, we found significantly higher incidence in those with recently-healed DFU (0.88 vs 0.63 DFU/subject/year).

	Entire Cohort	Neither RH-DFU or P-LEA	RH-DFU	P-LEA
Number of Participants	129	35%	39%	56%
Age	61.8 ± 10.5	58.3 ± 9.2	62.7 ± 11.3	66.5 ± 7.5
Male	86%	73%	95%	92%
Number of DFU	53 (0.63 ppy)	18 (0.57 ppy)	23 (0.88 ppy)	24 (0.62 ppy)
VHA Participant	45%	26%	45%	73%
Adherence (days/week)	5.5 ± 1.2	5.6 ± 1.3	5.4 ± 1.2	5.5 ± 1.2
Months from Healing	13.9 ± 39.2	11.0 ± 12.3	1.0 ± 0.9	15.9 ± 26.9

Delong's method allows for comparison of ROCs derived from dependent samples. Two comparison are made:

1. 40 with recently-healed DFU to entire 129 participant cohort
2. 59 with h/o partial LEA to entire 129 participant cohort

Results



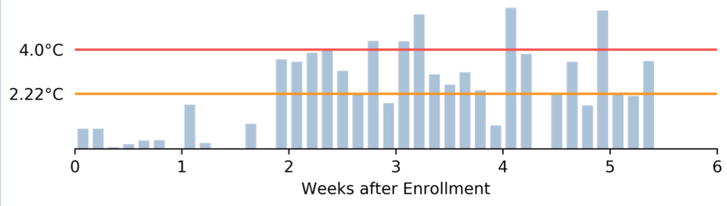
Applying the DeLong method to these data, we reject the alternative hypothesis that the ROC curve from each subgroup differs from the ROC curve from the entire cohort. However, we do note that the temperature threshold required to obtain a given sensitivity/specificity combination does change depending on the cohort, as shown in the table below.

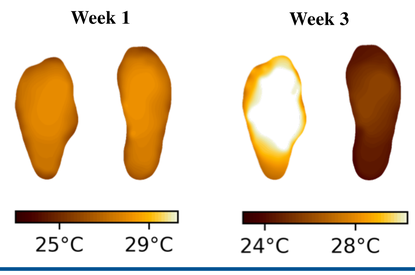
Diagnostic Accuracy at 2.2°C Threshold

	Entire Cohort	RH-DFU	P-LEA
Sensitivity	97%	100%	100%
Specificity	43%	45%	36%
Alert lead time (days)	37 (± 18)	40 (± 17)	45 (± 16)

Case 1

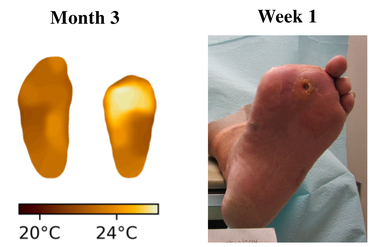
- 65 year old male with peripheral neuropathy and DM (HbA1c = 8.9%)
- History of R Charcot arthropathy and recurrent DFU to R sub 1st metatarsal head and R hallux.
- Enrolled upon epithelialization of most recent R 1st metatarsal head DFU.
- Thermometry showed no inflammation for two weeks, but then elevated inflammation in the next three weeks culminates in recurrent DFU.
- **Thermometry initially indicated no inflammation after healing from DFU, but risk increased during week three and patient ultimately developed recurrent DFU.**





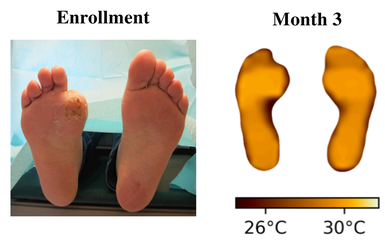
Case 2

- 54 year old female with peripheral neuropathy and poorly-controlled DM (HbA1c = 9.7%)
- History of DFU to left hallux and second digit requiring amputation of both digits
- Enrolled two months after hallux DFU resolved via amputation
- Thermometry suggests high risk during first week of participation, and patient presented with wound during month 3.
- **Despite recent amputation to resolve past DFU to hallux, thermometry correctly classified patient at risk for DFU to a location without prior DFU history.**



Case 3

- 57 year old female with peripheral neuropathy and poorly-controlled DM (HbA1c = 12.9%)
- History of DFU to R sub 1st metatarsal head & hallux requiring hallux amputation
- Enrolled upon epithelialization of prior 1st metatarsal head DFU
- Thermometry suggests low risk throughout 34 week participation and no DFU developed
- **Despite amputation history and recently-healed DFU, patient was correctly classified as low-risk for recurrence by thermometry.**



Conclusion

These data suggest thermometry is appropriate for monitoring both recently-healed DFU or partial LEA patients. Utilization of thermometry in these high-risk patients may significantly reduce morbidity, mortality, and resource utilization. In addition, future algorithm development for DFU prediction should account for elevated risk of recently-healed DFU as well as explore improved techniques for LEA.

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