

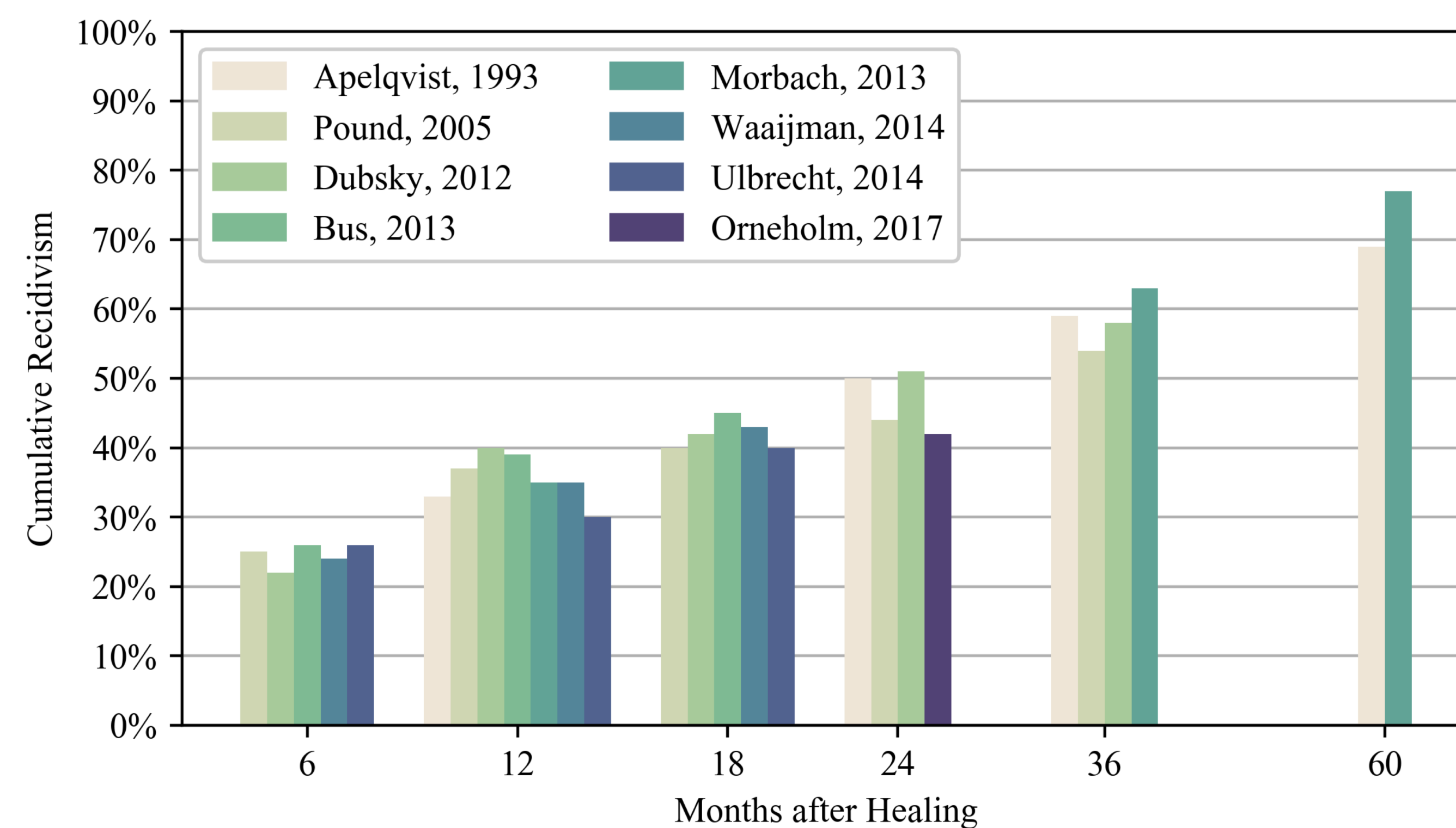
Investigating Right-Censoring of Diabetic Foot Ulcer Recidivism

A Case Series of Three Patients

Gary M. Rothenberg^{1,2}, DPM, CDE, CWS; Brian Petersen², MS, MBA; Jon Bloom², MD
[1] University of Michigan School of Medicine; [2] Podimetrix, Inc.

Introduction

Diabetic foot ulcers (DFU) are known to be associated with increased morbidity and mortality. This burden is borne disproportionately by those with history of previously-healed DFU. Several prospective studies report annual DFU recidivism rates of diabetic foot ulcers (DFU) between 20% and 40%, and within 5 years, the recidivism rate may exceed 75%. [1-3]



Although recidivism rates for diabetic foot ulcers (DFU) are well-established, existing studies are limited by incomplete characterization of incidence due to **right-censoring**. Right-censoring occurs when an outcome is interest (in this case, development of DFU) is not observed during the study. Two common sources of right-censoring include a participant completing or withdrawing from a study before developing a DFU. Techniques are available to handle these common scenarios. [4-5]

Most studies of DFU recidivism introduce two additional uncommon types of right-censoring which may not be well-appreciated:

1. disenrolling patients on initial DFU occurrence prior to the end of the study follow up
2. analyzing multiple distinct DFU presenting on the same date as a single occurrence

Methods

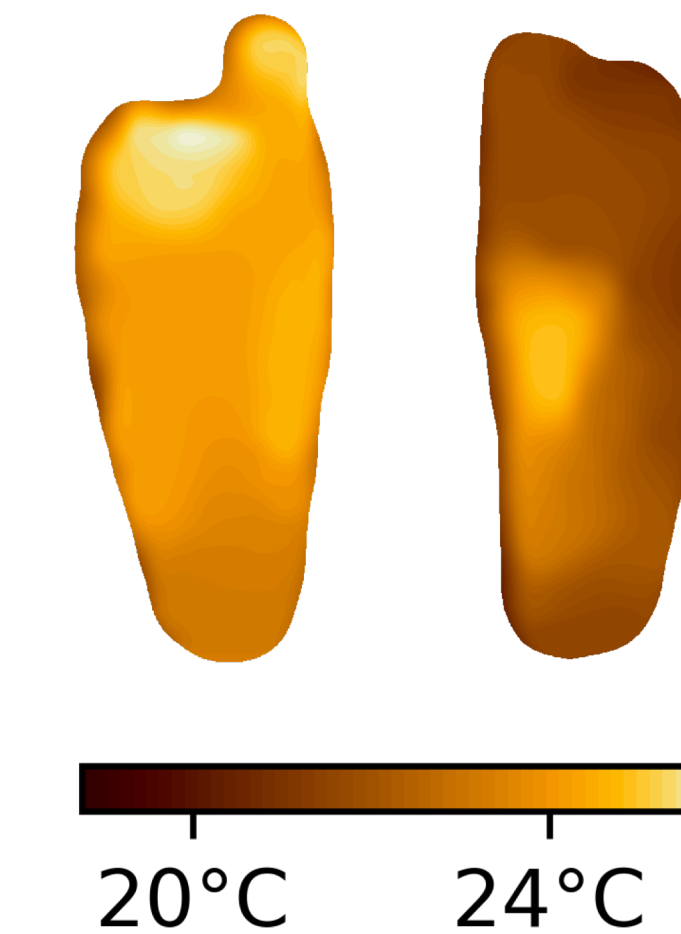
A recent multi-center investigation [6] studied the accuracy of a remote temperature monitoring mat (Podimetrix RTM System) in a cohort of 129 participants with history of plantar DFU. These patients were followed for 34 weeks or until withdrawing consent. Although participant outcomes were right-censored at the end of participation or death (consistent with all study designs), this study did not introduce additional sources of right-censoring and thus characterized all distinct DFU occurring during participation. We explored the possibility that right censoring results in underreporting of recidivism rates through a case series of three patients with multiple DFU during the study.

Case 1

- 47 year old male with h/o DM2 (HbA1c = 11.2%), obesity (BMI = 48.1), and PN.
- Patient has h/o DFU to left hallux and right third metatarsal head, both of which were healed for approximately one year prior to enrollment.
- During week 1 of participation, patient thermometry shows inflammation to the right forefoot and hallux which persisted during the remainder of the study.
- During week 17 of participation, patient presents with callus to right plantar hallux. Upon debridement of callus, a superficial DFU (UT1A) discovered. This DFU healed one week later during week 18 of participation.
- During week 20 of participation, patient presented with a new DFU (UT1A) to the plantar 3rd metatarsal head that healed during week 34 (at study completion).
- **This case has 1 additional DFU that would not be reported under Type 1 censoring.**



Enrollment



Week 3



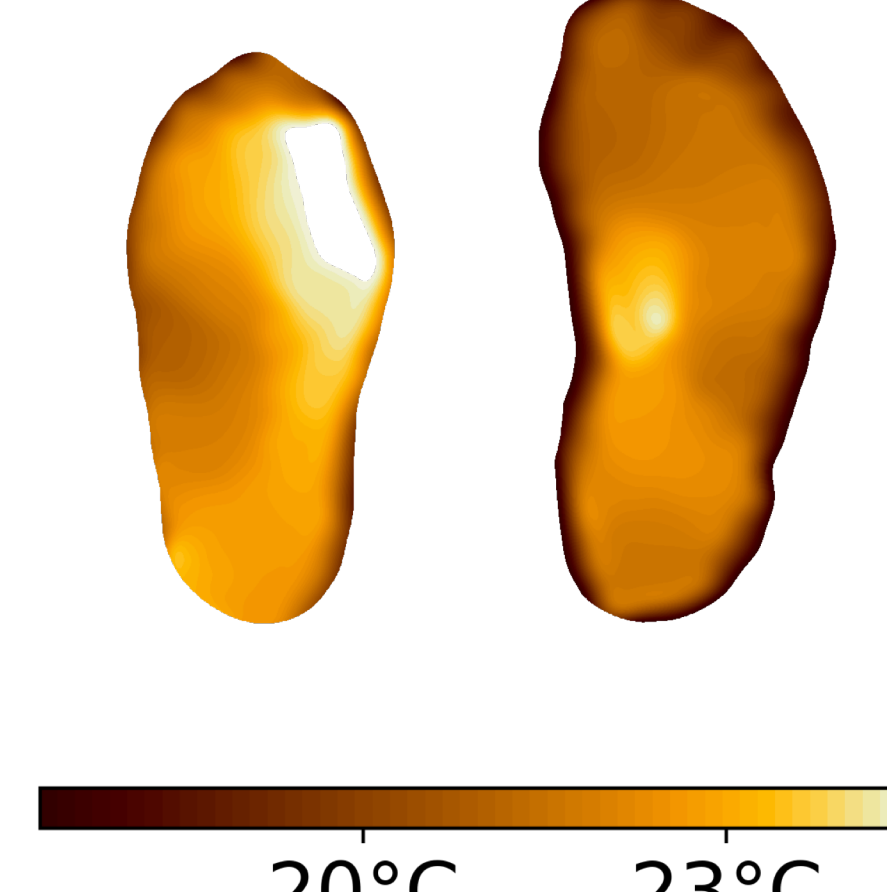
Week 20

Case 2

- 58 year old male with h/o well-controlled DM2 (HbA1c = 6%) and obesity (BMI = 36.6).
- Patient has h/o DFU on right hallux and right first metatarsal head, the latter of which required partial right ray amputation and was healed three months prior to enrollment.
- Patient thermometry suggests inflammation proximal to amputation at enrollment.
- Patient presents with dorsal wound proximal to amputation during week 2 and a subsequent plantar wound beginning in week 4.
- These wounds were resolved via resection of distal aspect of remaining first metatarsal head during week 5. Patient subsequently developed DFU along incision 1 month after amputation which remained unhealed during the remainder of the trial.
- Patient developed a subsequent left heel ulcer during week 18.
- **This case has 3 additional DFU that would not be reported under Type 1 censoring.**



Enrollment



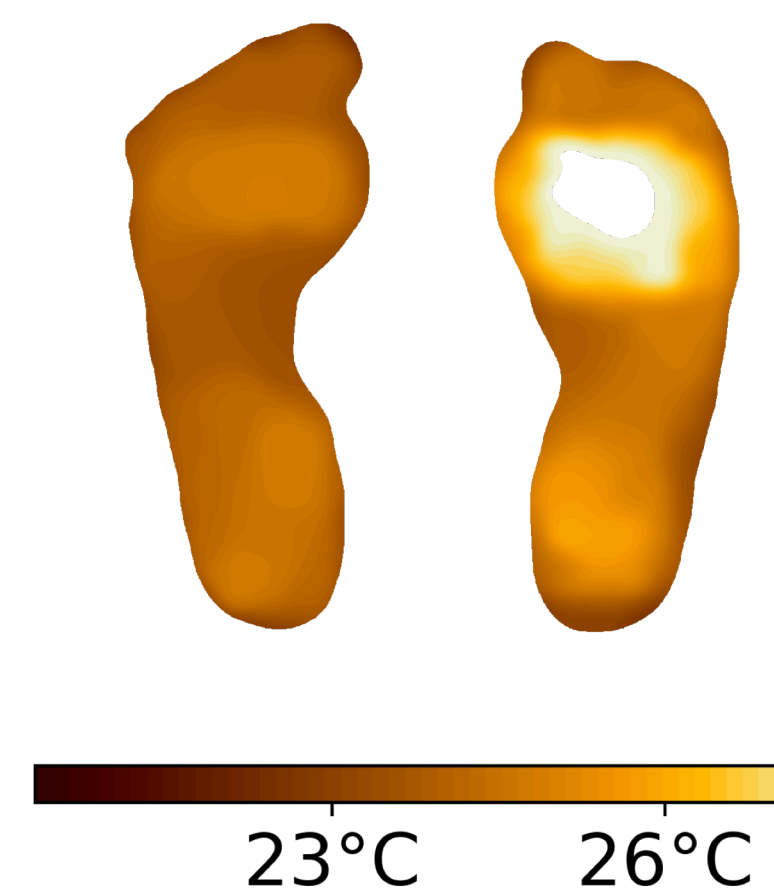
Week 1



Week 2

Case 3

- 50 year old male with h/o DM2 (HbA1c = 10.5%), obesity (BMI = 37.3), and PN.
- Patient has h/o right and left forefoot wounds healing approximately 1 month prior to enrollment.
- Thermometry indicates inflammation to left forefoot beginning during week 20.
- During week 25, the patient presented with two wounds to left forefoot (UT1A) which remained unhealed during the remainder of participation.
- **This case has 1 additional DFU that would not be reported under Type 2 censoring.**



Week 20



Week 25

Conclusion

These three cases illustrate five additional DFU that would not have been characterized in most previous studies of DFU recidivism due to right-censoring. These cases suggest that recidivism rates may be significantly underreported. In each case, the remote temperature monitoring mat detected inflammation associated with the DFU prior to presentation.

More research is needed to characterize the effect of right censoring on reported recidivism rates. This may enable improved allocation of resources and communication of prognosis, resulting in reduced DFU-related morbidity, mortality, and resource utilization.

References

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