Evaluating the Impact of a Thermovisual Home Monitoring Solution to Detect Diabetic Foot Risk Factors for Early Intervention

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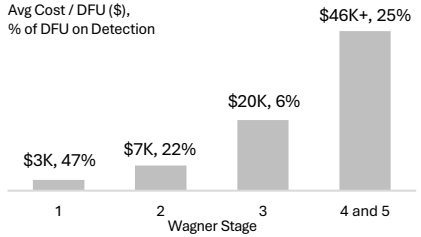
Background

Diabetic foot ulcers (DFUs) are a costly, burdensome problem. In the US, ~$17B in direct cost is associated with DFUs. Each ulcer costs on average $31,000[1]. A driver of these costs is amputation, which, if required can balloon episode costs to over $100,000[2]. However, not all ulcers are equal when it comes to cost and outcomes. DFUs are commonly graded using the Wagner Grading System which classifies ulcers from Stages 1-5. With Stage 1 being a superficial ulcer, and Stage 4-5 being deep DFUs with gangrene. Fig. 1 illustrates the current distribution and average cost associated with each Wagner DFU stage[3].

Fig. 1 Average Cost per Episode for Wager Stage 1-5 Ulcers



The data provided highlight an opportunity to lessen severity at time of DFU detection through remote pedal monitoring, using a thermovisual at-home foot scanner paired with a monitoring service. The scanner provides temperature analysis and high-resolution images for foot inspection.

Remote Thermovisual Foot Scanner and Representative Scan

Methods

Enrollment | Individuals with diabetes, peripheral neuropathy and a history of DFU (including varying levels of amputation) were referred by their physicians. A foot scanner was delivered to their home, and individuals received ≥ 1 onboarding call to set-up scanner and communicate program expectations (use 3 times / week or more). **Monitoring** | During the program, if individuals did not scan for 3 consecutive days, they were reminded by SMS or phone, depending upon their elected preference. As individuals scanned, we analyzed the image and temperature data to assess risk based on a pre-defined clinical policy and inspection protocol developed using generally accepted standards. Analysis resulted into risk classifications of ***Stable – Monitor and Document Change, Elevated – Preventative Remote Coaching According to Policy, and High – Notify Patient to Protect, Escalate to Provider for Clinical Intervention***.

Analysis (47 patients / 4,912 scans were analyzed, with exclusions only for patients monitored < 30 days)

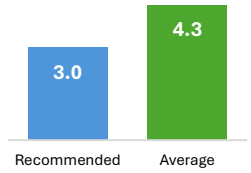
Patient Risk Assessment on Referral (First Scan)

Patients referred into the monitoring program represent those of highest risk[4,5], including individuals healing from a DFU, possessing known deformities or prior partial amputations, and even individuals with below the knee amputations where the remaining limb is unilaterally monitored. To illustrate the risk associated with individuals represented in the data, the table contains counts of patients experiencing visual risk factors at time of first scan. Future investigation planned to develop advanced Visual Risk Assessment Index (VRAI).

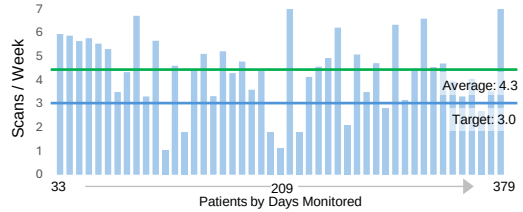
First / Enrollment Scan Observation Categories	Patients Affected
No Material Observations | Includes Light Dryness or Soiling	9/47 (19%)
Minor Observations | Scarring from Prior Ulcer, Callous, Excessive Dryness or Soiling	29/47 (62%)
Deformity | Non-Amputation, Non-Acute, (includes Charcot)	2/47 (4%)
Partial Amputation | Toe(s), Partial foot	4/47 (9%)
Active Risk | Active wound(s), Bandage(s), Offloading Boot	7/47 (15%)
Below the Knee Amputation	2/47 (4%)

All patients in this cohort meet the highest risk tier for diabetic foot complications (i.e. diabetes, peripheral neuropathy, and a history DFUs), qualifying them as "High Risk" per IWGDF guidelines[6]. The VRAI concept would build upon the IWGDF criteria, adding a time based assessment of risk based on a visual inspection associated with the categories listed in the table to the left. Aspirationally, this would further support management plans for individuals exhibiting early clinical or subclinical signs of increased foot stress or deterioration. As a preamble to a formal, validated VRAI, we have leveraged a basic classification scheme to emphasize the elevated risk levels associated with this cohort. Notably, 81% of patients analyzed were assessed to possess visual risk at their initial scan, revealing a level of foot health vulnerability that exceeds expectations, even for this high-risk group. This highlights a need for more routine foot inspections, likely dependent upon technology-enhanced foot surveillance.

Compliance (Scans per Week)



Patients Sorted by Days Monitored (Low to High)



Avg: 213, Max: 379, Min: 33

Compliance Insights

83% of monitored patients scan ≥ suggested 3 times per week

Endured compliance over duration of monitoring, with lower compliance attributed to specific patient challenges versus time such as:

- Environment | Moving to transitional housing, work schedule changes
- Health | Illness or injury not prohibitive to scanning but impacting motivation
- Motivation | Patient willingness to incorporate into routine, regardless of time in program. Despite this, minimum scans per week at least 1 for such individuals.

Risk Detection Rates by Patient and Scans

	% Patients	% Scans
Observed Abnormality	100.0%	65.3%
Preventative Remote Engagements	95.7%	6.8%
Physician / Clinical Visit for Escalated Risk	40.4%	0.7%

Typical Patient Experience Per Program Year

224 Scans / Year

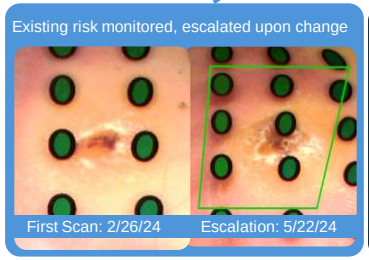
15 Remote Preventative Engagements

2 Elevated Risks Referred to Provider

Existing Risk v. New Risk Detection

64% of observations requiring clinical intervention were known issues at time of referral

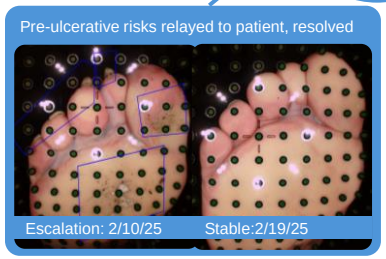
36% of observations requiring clinical intervention developed during monitoring

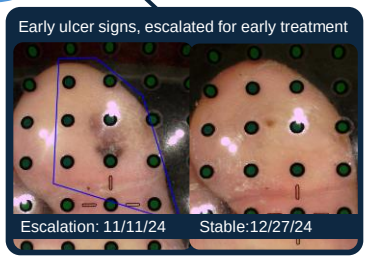


Pre-Ulcer v. Ulcer on Escalation to Physician

58% of escalations were "pre-ulcerative" risks that were persistent or worsening (callous, bruising, excessive soiling, etc)

42% of escalations were assessed as early Stage 1 at time of referral, regardless of prior ulcer severity

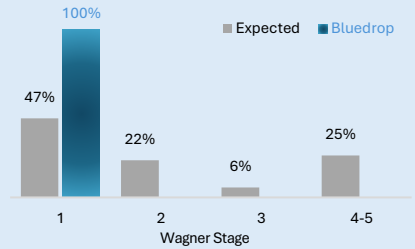




Implied Benefit of Thermovisual Monitoring

This data suggests remote pedal monitoring that **includes thermal and visual inspection**, paired with a patient-centric monitoring program may dramatically reduce severity of ulcers and may result in substantially lower cost, and improved patient quality of life for high-risk individuals.

National DFU Severity[3] v. Bluedrop



Due to the nature of risk associated with the cohort analyzed, **the estimated reduction in cost likely exceeds the modeled reduction against current national averages, which is estimated between 80-90% for lower severity alone**. Further analysis with a higher sample size and discrete cost data is required to validate the observational findings presented here and calculate the true reduction in costs.

Key Observations and Insights

Cohort Risk Level | The individuals presented in this analysis fall into the highest risk, including those with prior amputations. This should be considered in assessment of the results included herein.
Compliance | To deliver consistent value, patients must use the scanner consistently for potentially years. The data suggests an ongoing endurance to suggested compliance, with minimum use frequent enough (1 use per week) to identify issues much sooner than standard clinic visits, as reflected in the risk detection data. This may be attributed to the ease of use of the device, combined with a purposeful alert model that reduces unnecessary concern and burden to the user, made possible by the combination of thermal and visual analysis.
Risk Detection | The use of both thermal and image data to monitor patients supports a holistic understanding of risk associated with the plantar foot surface. Image data enables ability to remotely monitor emerging risk over time and initiate action with patients and / or providers when needed.
Action | A purposeful, proactive monitoring model ensures timely notification of meaningful risk to patients, without overburdening the patient and their provider with obscure or superfluous data that may cause unnecessary effort or lead to apathy. Clear, descriptive insights made possible through image data support effective communication to providers for early intervention when needed. The effectiveness of the model is supported by the fact that all escalated issues were acted upon by patients and providers, resulting in low severity grading upon detection.

1. Rice et. al (2014) "Burden of Diabetic Foot Ulcers for Medicare and Private Insurers"
2. Barsky (2024) "The diabetes dilemma: why amputations are rising in the US"
3. Stockl et. al (2004) "Costs of lower-extremity ulcers among patients with diabetes"
4. Lin et. al (2025) "Risk factors associated with the recurrence of diabetic foot ulcers: A meta-analysis"
5. Peters et. al (2007) "Risk Factors for Recurrent Diabetic Foot Ulcers: Site matters"
6. Schaper et. al (2019) "Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update)"