Thermovisual Home Monitoring in High-Risk Patients: Early Detection of Diabetic Foot Ulcers at Low Severity

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Introduction

Diabetic Foot Ulcers (DFUs) represent a major global health burden, contributing to high morbidity, mortality, and healthcare costs (1). The global prevalence of DFU is estimated at approximately 6.3%, with rates as high as 13% in North America (2).

The Clinical & Economic Problem
- DFUs are a leading cause of morbidity, amputation, and healthcare expenditure
- High recurrence rates:

Up to 40% within 12 months of healing (1)

Up to 65% within 5 years (1)

- Treatment cost escalates sharply with ulcer severity (3)
  - Advanced-stage ulcers and amputations drive disproportionate healthcare costs
- High-risk patients (prior DFU, neuropathy, deformity) remain persistently vulnerable

Rationale for Thermovisual Monitoring
- Combines **thermal + photographic imaging** for comprehensive surveillance
- Supports proactive intervention before progression by enabling detection of:

Foreign bodies	**Factors that impact the assessment of general foot hygiene**	**Localized hotspots**
Callous thickening and discoloration	**Fissures developing or worsening**	**Excessive dryness**
Blister formation	**New or worsening lesions**	**Early stage (low Wagner Grade) ulcers**

Remote Thermovisual Foot Scanner (4) and Representative Scan

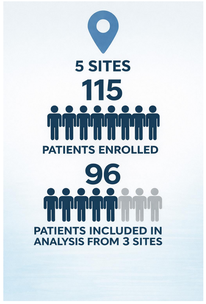
Methods

This retrospective, multi-site clinical investigation (NCT06782386) is underway at 5 sites to evaluate the performance and impact of the Bluedrop OneStep™ Foot Scanner (4) for remote monitoring of foot health in individuals with diabetes at risk for foot ulceration.

The primary endpoint is the ***incidence of Wagner grade 2 or higher diabetic foot ulcers (DFUs) at the time of first presentation*** in participants with a history of previously healed DFUs within the past five years.

115 participants have been initiated in this study to date. Participants use the device daily at home to capture thermal and visual images of both feet. Data are transmitted automatically for remote review by Bluedrop monitoring professionals. Scans that exceed predefined thresholds under the monitoring protocol and are identified as potential risk factors are escalated to the referring HCP/PI for review and appropriate clinical action.

For the interim analysis presented in this poster, data from **96** participants at three sites were included. These participants completed at least 90 days of home monitoring and had at least one quarterly clinical review of their podiatric health records.



Results

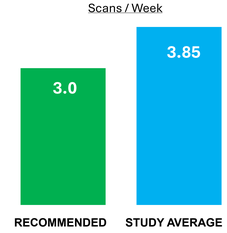
Patient Characteristics

Table 1 Demographics	N = 96
Age (years) - Mean - Range	 62.6 years 31-84 years
Gender - Male - Female	 68 (70.8%) 28 (29.2)
Ethnicity - Caucasian - African American / Hispanic / Latino - Native American	 77 (80.2%) 18 (18.8%) 1 (1%)
Diabetes Type - Type 1 - Type 2	 2 (2.1%) 94 (97.9%)
Duration of Diabetes (years) **n = 55; unknown for 41 patients*	20.0 (1–50)
Co-morbidities - Nephropathy - Retinopathy - Hypertension - Ischaemic Heart Disease - Congestive Heart Failure - Cancer	 53 (55.2%) 11 (11.5%) 79 (82.3%) 19 (19.8%) 1 (1%) 1 (1%)
Active ulcer (Wagner Grade 1) or high risk lesion on enrolment	59 (61.46%)
Prior ulcer history (number experienced) - 1 - 2+	 39 (40.6%) 57 (59.4%)

Compliance (Scans per Week)

Participants were instructed to perform foot scans at least three times per week to support consistent surveillance of foot health. This recommendation aligns with prior temperature-monitoring protocols while acknowledging potential physical, cognitive, and psychosocial barriers that may limit daily adherence.

Notably, even intermittent scanner use facilitated early identification of pre-ulcerative changes and incident DFUs that may otherwise have remained undetected between routine podiatric visits – **See Case Studies 1 & 2**.



Risk Detection and Management

96 patients met the inclusion criteria for this analysis, each monitored for ≥ 90 days and undergoing a minimum of one quarterly review of their podiatric records. In this analysis, 17 new diabetic foot ulcers (DFUs) developed on the plantar surface in 14 patients, with all classified as Wagner Grade 1 at the time of diagnosis and first presentation. The remote monitoring service identified early changes or flagged concerns prior to routine clinical review in 82.4% of these DFU cases, enabling earlier intervention – with the remaining cases displaying no visual data due to bandages/wrapping. Additionally, a further 16 cases were identified and escalated by the remote monitoring service at the pre-ulcerative stage.

Number of patients	96
Number of patients who developed a DFU	14
Total Number of new DFUs on the plantar surface	17
Grade 1 ***(first presentation)***	17
Grade 2+ ***(first presentation)***	0
Patient years of monitoring	65.53
DFU per patient year	0.26
Grade 1 (on initial presentation) per patient year	100%
Grade 2+ (on initial presentation) per patient year	0%
Escalations per patient year	2.61
% of patients who developed a new DFU	14.6%
Identified ahead of routine/scheduled clinic visit	82.4%

Key Observations and Insights

EARLY DETECTION | In 82.4% of DFU cases, the remote monitoring platform identified early changes or risks prior to scheduled clinical review, enabling earlier clinical intervention and management.

PRE-ULCERATIVE LESIONS |16 additional areas of localized inflammation, callus formation, or skin breakdown were detected and treated promptly in clinic, potentially preventing progression to ulceration.

ACTION AND OUTCOMES | Early detection through routine monitoring enabled rapid intervention for recurrent DFUs and effective remote management of minor lesions

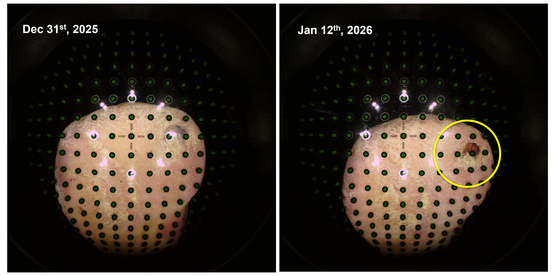
OVERALL INSIGHT | Continuous remote monitoring provides timely, clinically meaningful data that supports proactive care, early intervention, and improved healing outcomes in high-risk diabetic foot populations.

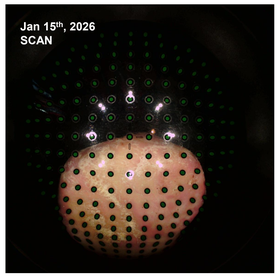
Case Studies

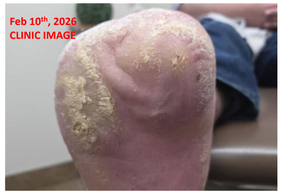
CASE STUDY 1:
Early Identification of Pre-Ulcerative Change in a High-Risk Amputee

Patient History:
45-year-old male with diabetes and prior right trans metatarsal amputation (TMA).
At enrollment (August 7, 2025), an active wound was present on the right medial forefoot. The wound was confirmed fully healed approximately August 19, 2025.
Average compliance to date: **1.52 scans per week**.

Episode Timeline:
08/07/2025 – Recruited to study and referred for monitoring program
~08/19/2025 – wound confirmed **closed**.
01/12/2026 - Escalation report sent to HCP: "Right medial forefoot **callus changes and blood noted**."
01/13/2026 – Patient attended clinic for assessment and prompt management.
02/10/2026 – Follow-up visit confirms full resolution with **no progression to ulceration**







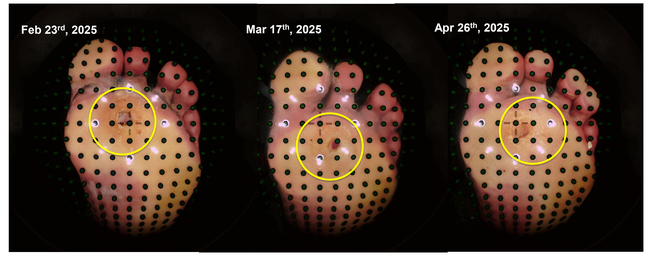
Key Insight:
In a patient with prior partial foot amputation and recently healed ulceration, remote thermovisual monitoring identified early structural and surface changes (callus progression with bleeding) before development of a recurrent ulcer.
Despite scanning below the recommended average frequency, monitoring enabled:
- **Early detection of tissue deterioration**: with remote image analysis identifying progressive callus changes and signs of localized bleeding at a previously healed high-risk site
- **Prompt clinical evaluation:** as the escalation alert enabled rapid communication with the treating provider and a clinic visit the following day.
- **Timely preventative intervention**: with targeted debridement performed to remove callus and relieve localized pressure before ulcer formation occurred.
- **Prevention of progression to recurrent DFU**: with follow-up confirming complete resolution of the pre-ulcerative lesion and no development of a new ulcer.

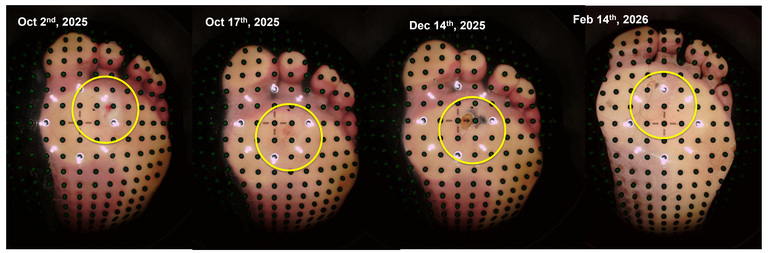
This case highlights the value of ongoing surveillance at previously healed sites in high-risk amputee patients and demonstrates how identification of pre-ulcerative changes can interrupt the recurrence cycle before breakdown occurs.

CASE STUDY 2:
Remote Monitoring Reduces Healing Time & Prevents Recurrence

Patient History:
57-year-old male with visual impairment preventing self-inspection of the feet. History of recurrent DFUs across both feet requiring prolonged treatment.
At study enrolment (Feb 23, 2025), a **Wagner Grade 1 DFU** was present on the left central forefoot at the site of a previous ulcer that required ~10 months to heal.
Average compliance to date: **2.43 scans per week**.

Episode Timeline:
02/23/2025 – Enrolled with active DFU (Grade 1) on left central forefoot
03/17/2025 Early monitoring – Increased redness flagged; interim review arranged (03/24) and offloading cast applied for a number of weeks.
0**4/14/2025** – DFU healed (**~2 months vs ~10 months previously**).
10/02/2025 – Recurrent lesion observed; pressure reduction advised with remote monitoring.
10/17/2025 – Lesion resolved without requiring in clinic intervention.
12/18/2025 – Discoloration observed; clinic visit next day for **callus paring**. Area stabilized during subsequent monitoring.





Key Insight:
In a patient with visual impairment who lacked the ability to check his own feet, remote monitoring reduced healing time in an already active ulcer and enabled subsequent early identification of inflammatory changes at this previously ulcerated site, allowing rapid intervention and pressure offloading before significant deterioration occurred. This supported early management of subsequent lesion episodes before progression to ulcer recurrence.
- **Timely offloading intervention**, resulting in wound closure in **~2 months versus ~10 months** during the prior episode.
- **Early identification of subsequent lesions**, allowing pressure reduction and remote observation without immediate clinical intervention.
- **Targeted clinical escalation when needed**, including callus paring to address emerging tissue stress.
- **Ongoing surveillance of a high-risk site**, supporting sustained healing and preventing progression to recurrent DFU.

1. Armstrong DG, Boulton AJM, Bus SA. *Diabetic Foot Ulcers and Their Recurrence.*
2. Zhang P, Lu J, Jing Y, et al. *Global epidemiology of diabetic foot ulceration: a systematic review and meta-analysis*.
3. Rice JB, et al. *Burden of diabetic foot ulcers for Medicare and private insurers.*
4. Bluedrop Medical. *OneStep™ Remote Foot Monitoring System*