Watching the Foot Closely: Preliminary Observations from an Ongoing Study of Remote Monitoring in High-Risk Patients

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Background

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). Each year in the United States alone, more than 100,000 amputations occur as a result of DFUs, and the 10-year mortality risk for affected patients is nearly double that of individuals without ulceration (3). Beyond their personal impact, DFUs impose substantial economic strain, with an average treatment cost exceeding $16,000 per episode (4).

Despite advances in preventative foot care, recurrence remains common—30–50% of patients develop another ulcer within 12 months of healing, and up to 70% recur within five years (5). Preventing re-ulceration remains a critical challenge.

Remote temperature monitoring has been proposed as an evidence-based strategy to detect early signs of inflammation and prevent recurrence (6). This approach compares six anatomical points on each foot, identifying a "hot spot" when temperature differs by ≥ 2.2 °C between corresponding sites (7). Studies have shown this can reduce DFU recurrence when consistently applied (8).

However, temperature data alone may not identify all emerging foot issues. The addition of remote visual monitoring offers a complementary dimension—enabling detection of skin or structural changes that precede ulceration (9).

The Bluedrop OneStep™ Foot Scanner integrates these modalities, capturing both thermal and photographic images of the feet. The device is designed to look and behave like a standard home weight scale and takes the patient 30 seconds to use per day at home (10).

Remote Thermovisual Foot Scanner and Representative Scan
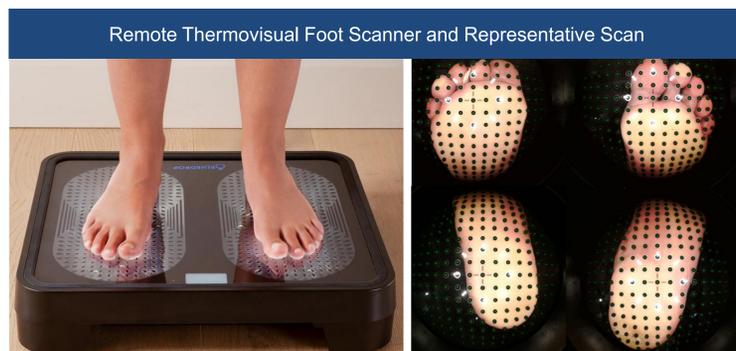
Methods

This retrospective, multi-site clinical investigation (NCT06782386) is underway at 4 sites to evaluate the performance and impact of the Bluedrop OneStep™ Foot Scanner 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 enrolled 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 62 participants at two 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.


4 SITES
115 PATIENTS ENROLLED
62 PATIENTS INCLUDED IN ANALYSIS FROM 2 SITES

Data and Analysis

Patient Characteristics

| Table 1 Demographics	N = 62
Age (years)	
- Mean	62.9 years
- Range	31-84 years
Gender	
- Male	44 (71%)
- Female	18 (29%)
Ethnicity	
- Caucasian	53 (85.5%)
- African American / Hispanic / Latino	8 (12.9%)
- Native American	1 (1.6%)
Diabetes Type	
- Type 1	3 (4.8%)
- Type 2	59 (95.2%)
Duration of Diabetes (years)	15.0 (1 – 38 years)
Co-morbidities	
- Nephropathy	8 (12.9%)
- Retinopathy	8 (12.9%)
- Hypertension	53 (85.5%)
- Ischaemic Heart Disease	18 (29%)
- Congestive Heart Failure	1 (1.6%)
- Cancer	1 (1.6%)
Active ulcer (Wagner Grade 1) on enrolment	39 (62.9%)
Prior ulcer history (number experienced)	
- 1	32 (51.6%)
- 2+	30 (48.4%)

Compliance (Scans per Week)

Patients in study are advised to scan 3 or more times per week to enable frequent surveillance of foot health. This follows protocols used in prior temperature analysis studies and considers the physical, cognitive, or psychosocial challenges that may prevent daily use. It is important to note that even intermittent use of the scanner enabled the early detection of pre-ulcerative lesions and incident DFUs that would have otherwise likely gone unnoticed between routine podiatry visits.
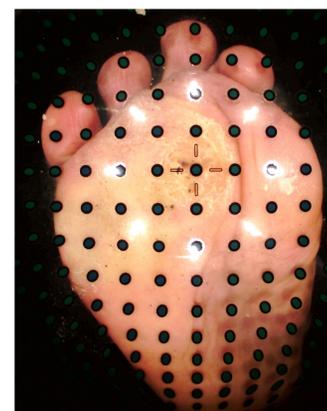

Scans / Week
RECOMMENDED 3.0
STUDY AVERAGE 3.9
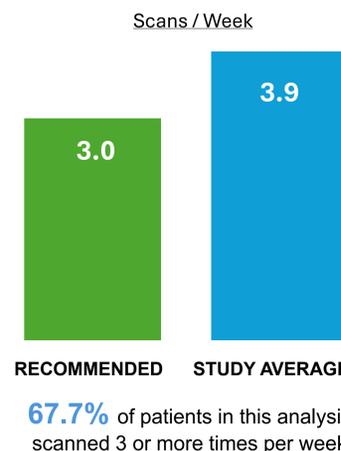
67.7% of patients in this analysis scanned 3 or more times per week

CASE STUDY 1:
Early Detection, Intervention Reduced Recurrence Duration
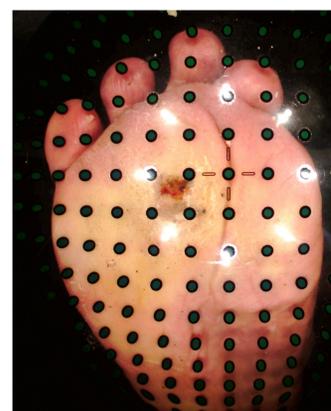
8/3/2025: Early signs of re-opening **8/22/2025: Complete epithelialization**

Patient History:
DFU present on the **right central forefoot**, persisting for > 4 months on **recurred twice during monitoring**.
Episode Timeline:
2/5/2025 – Recruited to study and referred for monitoring program
7/28/2025 – DFU noted as **closed and fully healed** by PI during clinic visit.
8/3/2025 – **Early signs of re-opening** were flagged through routine monitoring, **6 days after closure**.
8/7/2025 – Patient attended clinic for assessment and prompt management.
8/22/2025 – Wound achieved **complete epithelialization and healing**, significantly shorter than previous episodes.
Key Insight:
Because of **early detection** of wound re-opening and **timely intervention**, the wound healed within **3 weeks**, compared to **over 4 months** in previous occurrences. This demonstrates the **impact of proactive monitoring and rapid response** in preventing prolonged ulceration.

CASE STUDY 2:
Early Detection Enables Simple Remote Management

7/18/2025: No lesion **7/19/2025: New lesion** **8/17/2025: Lesion healed**

Patient History:
A **potential new lesion** was flagged on the **left 5th toe** during routine monitoring.
Episode Timeline:
4/2/2025 - Recruited to study and referred for monitoring program
7/19/2025 - Lesion identified through the system, prompting further investigation. Same day contact to determine patient had **accidentally ripped a toenail while putting on a sock.** The family was **unaware** of the incident.
7/19/2025: Following communication with the patient and family, a **home-based care plan** was initiated — the lesion was kept **clean and covered**, and its progress monitored remotely.
7/20/2025 - 8/17/2025 - The lesion remained **dry, uninflamed**, and was in a **healing state.**
8/17/2025- The lesion was **no longer visible on scans**, indicating **complete healing** without complications.
Key Insight:
Early flagging of the lesion enabled **timely intervention** through **remote management**, avoiding escalation and **preventing unnecessary clinic visits**, while achieving **full resolution**.

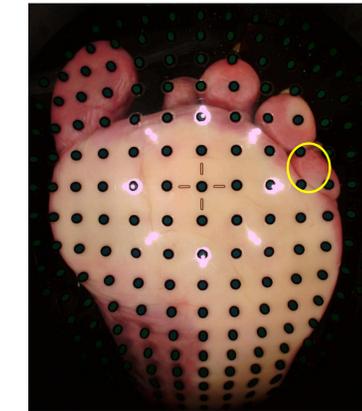### Risk Detection and Management

62 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, 12 new diabetic foot ulcers (DFUs) developed in 10 patients, 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 50% of these DFU cases, enabling earlier intervention.

In the remaining cases, no relevant visual or thermal data were available—for example, lesions located on non-plantar surfaces or covered by dressings, preventing signal detection. In addition to DFU detection, 8 pre-ulcerative lesions (e.g., areas of localized inflammation, callus, or skin breakdown) were identified through the remote monitoring program. These lesions were treated promptly, potentially preventing progression to full ulceration.
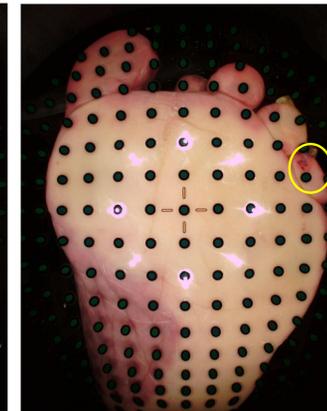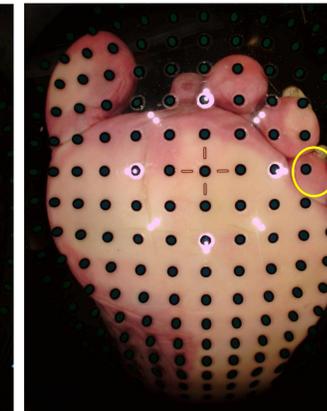
Number of patients	62
Number of patients who developed a DFU	10
Total Number of new DFUs	12
Grade 1 *(first presentation)*	12
Grade 2+ *(first presentation)*	0
Patient years of monitoring	26.3
DFU per patient year	0.38
Grade 1 (on initial presentation) per patient year	100%
Grade 2+ (on initial presentation) per patient year	0
Escalations per patient year	4.1
% of patients who developed a new DFU	15%
Identified ahead of routine/scheduled clinic visit	50%

Key Observations and Insights

EARLY DETECTION | In 50% 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 | 8 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 identification through monitoring supported accelerated healing in recurrent DFUs and enabled effective remote management of minor lesions, reducing the need for in-person visits. All escalations were addressed promptly, resulting in low severity grading at the time of clinical review.

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.

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. Armstrong DG, et al. *Five year mortality after non-traumatic lower extremity amputation*
4. Rice JB, et al. *Burden of diabetic foot ulcers for Medicare and private insurers.*
5. Bus SA, van Netten JJ. *A shift in the paradigm of preventive foot care for diabetes.*
6. Lavery LA, Higgins KR, Lanctot DR, et al. *Home monitoring of foot skin temperatures to prevent ulceration*
7. Armstrong DG, Holtz-Neiderer K, Wendel C, et al. *Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients.*
8. Frykberg RG, et al. *Role of temperature monitoring in wound healing and diabetic foot care*
9. Bowling FL, et al. *Remote monitoring of foot ulcers in diabetes: a review of technologies and evidence*
10. Bluedrop Medical. *OneStep™ Remote Foot Monitoring System*