Use of a Remote Thermovisual Monitoring System in High-Risk Patients: A Pilot Study

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INTRODUCTION

- Diabetic Foot Ulcers (DFUs) are associated with high morbidity and mortality.
- Once healed, approximately 40% of patients will develop a subsequent ulcer in 12 months (1).
- Each year in the USA there are over 86,000 amputations as a result of DFUs (2).
- Remote temperature monitoring has been proposed to reduce the high rates of recurrence. Six points are assessed on each foot and compared. A hot spot is defined as a 2.2ºC temperature difference between similar points on opposite feet. (3, 4, 5). See Figure 2 for dashboard view of the software presenting temperature and visual information.
- The addition of remote visual monitoring may also offer advantages in identifying issues not identified by remote temperature monitoring alone – see Figure 1 for detail available in DFS scan image

The Delta Foot Scanner (DFS) (Figure 3) allows for combined thermal data and visual images of the feet to be taken in an easy-to-use device (Bluedrop Medical Ltd.). 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.

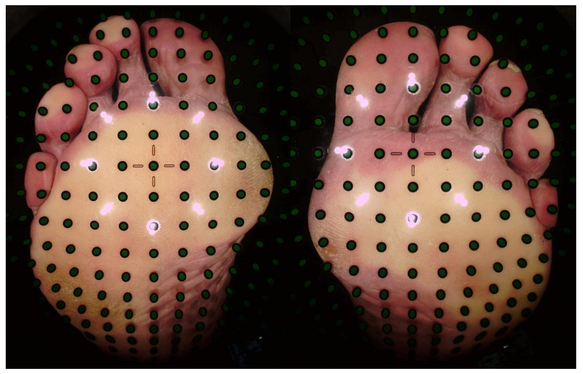


Figure 1. Close up Visual Monitoring Data from Sentinel Review Interface

Black dots are Bluedrop's patented temperature sensors

Figure 3. Delta Foot Scanner

AIM

The aim of this pilot (NCT05039645) was to understand the implications of using remote visual and thermal monitoring in a high-risk diabetic population. We hypothesized that at-home thermovisual monitoring would be beneficial to patients' standard podiatric care, and thus may ultimately reduce DFU rates.

METHODS AND MATERIALS

- In this single arm, open-label, pilot study in 2 countries (UK and Ireland), 27 patients with a DFU history were recruited to remote podiatric monitoring, alongside their routine podiatry care.
- Users were asked to stand on the investigational device daily at home, for up to 12 weeks.
- Plantar thermal and visual data were captured and transmitted to a cloud-based server for daily review by the Monitoring Service's blinded physician, independent of the clinical sites.
- Scans with abnormalities were reported to patients' healthcare provider (HCP) who then determined best course of intervention.
- Primary endpoint was mean patient adherence across the study. Likert scales assessed a) HCP reported utility of data to perform remote assessment, b) patient reported device usability.

RESULTS

- 1,547 daily scans were taken during 1,940 active study days.
- Baseline characteristics of the study patients are in Table 1
- 11 patients withdrew from the study (after 59.2±22.3 days) due to DFU development (n=7), other reasons (n=4).

Table 1 - Baseline Characteristics	Patients (n=27)
n, Galway site : Manchester site	17 (63%) : 10 (37%)
Age (years)	66·0 ± 10·4
Male	22 (81·5%)
Type 2 diabetes	18 (66·7%)
Diabetes duration (years)	15·4 (10.5-30.5)
HbA_{1c} (mmol/mol)	57.5 (47.0-68.5)
BMI (kg/m^2)	29·1 ± 4·2
Nephropathy	12 (44·4%)
Retinopathy	9 (33·3%)
Hypertension	17 (63·0%)
Ischaemic Heart Disease	5 (18·5%)
Neuropathy Disability Score	8·3 ± 2.2
Vibration Perception Threshold (mean of both feet)	39.9 ± 6.5
Claw toes	12 (44·4%)
Prominent metatarsal heads	11 (40·7%)
Bony prominences	11 (40·7%)
Plantar Callus	17 (63·0%)
Charcot	3 (11·1%)
Total previous DFU sites *(n=45)* (Toes/MTHs/Other)	21 (46·7%) / 17 (37·8%)/ 7 (15·6%)

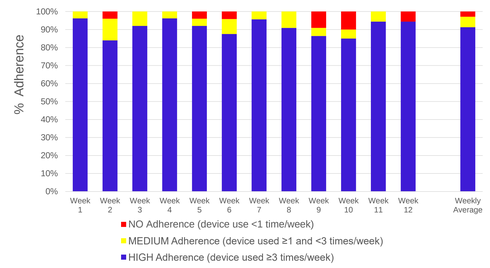
Data are n (%), mean ± SD or median (IQR)

Adherence / Patient Compliance

- 91% patients had 'high adherence' to using the device (≥3 scans taken per week) (Figure 4).
- Mean **patient adherence** to daily device use was 80% (± 19).

RESULTS

Figure 4: % Number of Patients with HIGH, MEDIUM or NO Adherence to using their foot scanner device, each study week.



Participant data: Week 1, n=26; week 2, n=25 ; week 3, n=25 ; week 4, n=26 ; week 5, n=25 ; week 6, n=24 ; week 7, n=23 ; week 8, n=22 ; week 9, n=22 ; week 10, n=20 ; week 11, n=18 ; week 12, n=18.

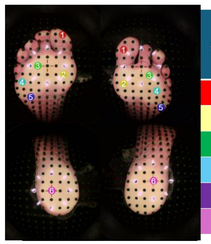
Flagged Reports / Remote Intervention

- Over the entire study, 73 scans were identified as **abnormal.**
- Reasons given for the abnormal scan **flagged reports,** sent to local HCP teams for review/action, are in Table 2.

Table 2: Primary reason for flagged report	*n*
Foreign body vs. Lesion	4 (5.5%)
New bandage	17 (23.3%)
Thermal 'hot spot'	6 (8.2%)
Reddened area	1 (1.4%)
Potential lesion/area for review	19 (26.0%)
Foreign body/Material to be removed	5 (6.8%)
Callous build up	15 (20.5%)
Incorrect foot placement, wearing socks	1 (1.4%)
Poor foot hygiene	4 (5.5%)
Escalation after no response	1 (1.4%)
	73

- The mean response time for the HCP team in providing an appropriate early intervention response for the patient after receiving a flagged report was 1.1 ± 1.9 days (mean ± SD).
- In 62% of cases the HCPs were able to remotely intervene (25%) or continue to monitor (37%). 10% of all flagged reports received by the HCP team resulted in the decision to bring the patient in for an emergency clinic appointment to address the area(s) of concern (See Table 3 for Interventions)

Table 3: Intervention by HCP team	*n*
Non-emergency follow-up appointment	21 (28.8%)
Emergency appointment	7 (9.6%)
Remote Intervention, i.e. phone the patient	18 (24.7%)
Wait and see approach	27 (37.0%)
	73



Temp assessment point	Right Foot	Left Foot	Delta
1	22.71	23.41	0.70
2	24.62	24.11	0.51
3	23.36	22.85	0.51
4	23.59	22.90	0.69
5	23.39	21.98	1.41
6	23.44	23.42	0.02

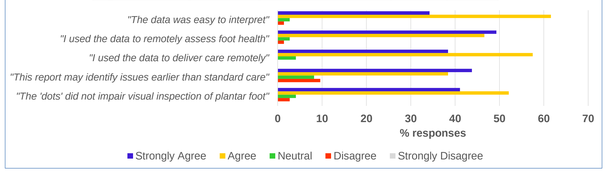
Figure 2.Information available from SRI (Visual & Thermal)

RESULTS

Report Utility Data

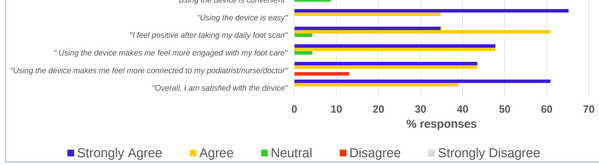
- In **Report Utility Statements** (n=73) HCPs reported that they **strongly agreed/agreed** that they could use the scan data to remotely assess patients' foot health in **96%** of cases (Figure 5)
- In **82%** of all flagged reports, HCPs reported that they **strongly agreed/agreed** that the scans helped identify issues earlier than standard care (Figure 5).
- HCPs found the **temperature scan data** useful in 12% of flagged reports versus 90% for the **visual scan data**.

Figure 5: Report Utility Statements completed by HCPs



100% of all study participants who completed a device usability statement at the end of study (n=23 (85%)) agreed that they were satisfied with the device and found it easy to use (Figure 6).

Figure 6: Device Usability Statement completed by Participants



CONCLUSIONS

- High risk patients with previous DFU showed very good adherence (91%) to using a home-based, diabetic foot thermal/visual scanning device over a 12-week study period.
- Our protocol of daily scanning, remote identification of abnormal daily scans, generation of flagged reports to local HCPs, followed by appropriate patient intervention showed very good clinical utility and patient satisfaction.
- Future studies are warranted to assess the impact on DFU prevention.
- Home-based daily thermal/visual monitoring using a system such as this may be beneficial to patients' standard podiatric care.

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