Use of Thermovisual Monitoring for Prevention of Recurrence of DFU: Case Reports

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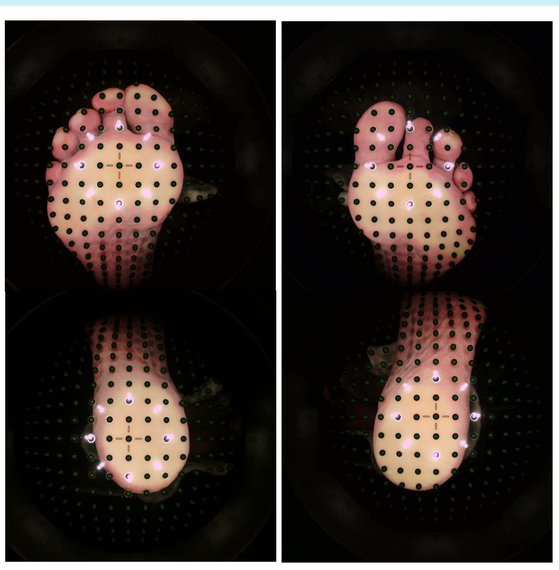
Introduction

- 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 (RTM) 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 2.2°C temperature difference between similar points on opposite feet. (3, 4, 5). See Figure 1 for dashboard view of the software presenting temperature and visual information.
- The addition of remote visual monitoring (RVM) may also offer advantages in identifying issues not identified by RTM alone – see Figure 2 for detail available in DFS scan image

Bluedrop Medical have developed the Delta Foot Scanner (DFS) – see Figure 3 -, which allows for combined thermal data and visual images of the feet to be taken in an easy to use device. The device is designed to look and behave like a standard home weight scale and takes 30 seconds to use per day.



Patient Right Foot Patient Left Foot

Black dots = patented temperature sensors

FIGURE 1: RVM Data from Sentinel Review Interface

	Patient Right	Patient Left	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: RTM Data from Sentinel Review Interface

FIGURE 3: Delta Foot Scanner

Aim

The aim of this pilot (NCT05039645) is to understand the implications of using RVM with RTM in reducing the onset and severity of DFUs in a high-risk population.

Methods

In the ongoing study, participants use the device in their homes daily and collected data is remotely reviewed for signs of skin damage. If an issue is identified the patient is contacted for remote care or to schedule an in-person appointment.

30 patients in total, with a history of DFU will be recruited from high-risk podiatry care clinics and consent to be remotely monitored for a 3 month follow-up period.

Results

Case Study 1: Self inflicted abrasions from filing calloused areas

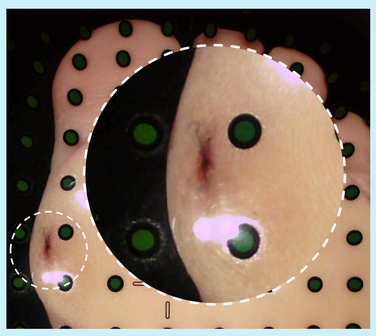


FIGURE 4: 3RD NOV 2022

Lesion noted on left foot with no corresponding hotspot.

While there was no temperature differential recorded the lesions appearance was worrying enough for the reviewing Clinician to signal that the site team review was required.

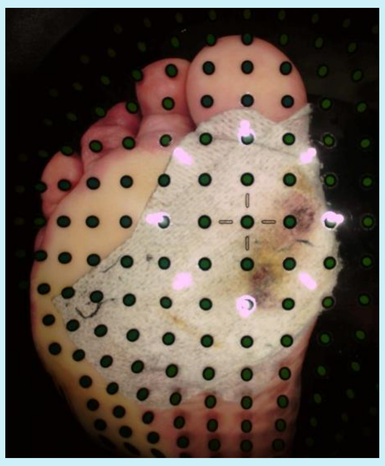


FIGURE 5: 7th NOV 2022

FIGURE 6: 8th NOV 2022

A scan from the same participant later appeared with a soiled bandage but no hot spots on scan day or days preceding. The visual analysis prompted clinical review and an appointment with the participants clinician. The bandage concealed a full thickness skin break caused by acute trauma - participant had used a scalpel to remove plantar callus. RTM alone did not detect this issue.

Case Study 2: Fissure bleed monitored through healing

FIGURE 7: 18th SEPT 2022

RVM identifies minor lesion without hot spot. Protocol indicates continued monitoring for change versus immediate escalation.

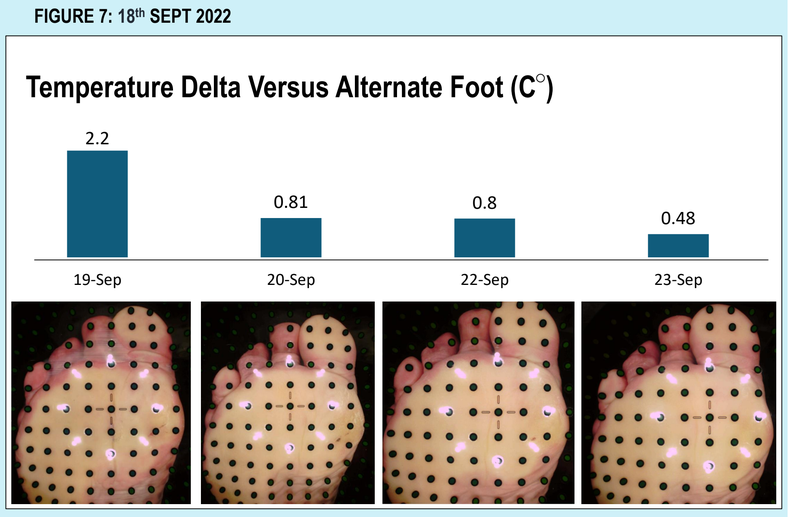


FIGURE 8: RTM and RVM Data for 19 Sep – 25 Sep

A hot spot was noted on 19 Sep but not escalated as per the approved study protocol as no subsequent hot spot detected. Continued monitoring revealed no further hotspots and visual confirmation of healing.

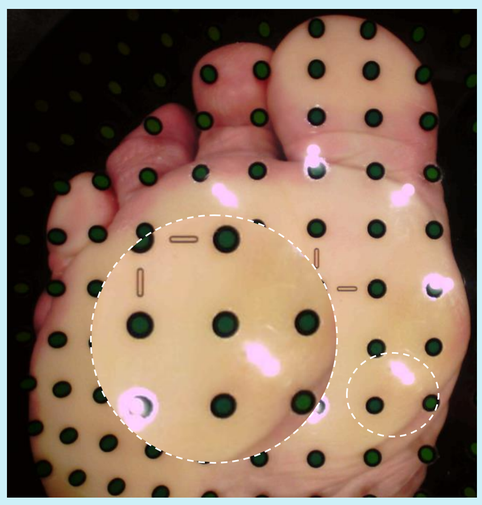


FIGURE 9: 17h OCT 2022

On 17 Oct the area appears completely healed and no concerns are raised during the daily temperature assessments.

Results Continued

Case Study 3: Foreign body detection prompting lifestyle coaching

FIGURE 10: 28TH APR 2023

A foreign substance, known to contribute to development of an ulcer, noted on scan, however, no evidence of the material the following day. Observation indicates that this participant may engage in high-risk behavior by walking barefoot. Continued monitoring combined with coaching to patient may reduce risk of foreign substance causing a future ulcer.

Conclusion

Compliance at Home

85% of participants in the study **are 100% compliant** to recommended use of system daily for monitoring and study protocol (n=7).

Combined Impact of RTM with RVM

Daily monitoring of this specific cohort has shown:

1) The addition of RVM with RTM allows for:
   a) Identification of issues that require clinical intervention that may not present with a temperature Hot Spot and,
   b) Remote monitoring of less serious breaks in the skin with a corresponding Hot Spot to ensure no exacerbation, reducing unnecessary clinical visits.
2) Timely action alerting of clinical staff at the earliest stages of issues ensures clinical intervention is most efficacious.
3) Remote intervention with participants is effective in influencing reduction in high-risk activities such as walking around barefoot.

The case reports so far are demonstrating the value of RTM and RVM as a cost-effective, preventative strategy for prevention of re-ulceration in this high-risk population

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