



Turning Up the Heat on Remote Temperature Monitoring Mats and Shoe Insoles

These devices can accurately predict future DFUs, and the technology continues to evolve.

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The field of wearable technology continues to advance with inroads being made into the health sector. The technology and mobile industries continue to innovate and improve on what is possible. “Smart” watches, glasses, beds, and rings are only the start of such devices that are able to monitor our health and activity. These devices can communicate findings with the user, letting us know when we achieve a goal, and when concerns present. With the integration of these technologies into our health and well-being, these devices provide the opportunity to communicate valuable information to medical experts (Figure 1).

A National Initiative

In 2019, the Veteran’s Administration implemented a national initiative to offer a remote foot-temperature monitoring system (aka “smart mat”) to veterans deemed high-risk for the development of foot ulcerations and amputations. Diabetic foot ulcers are responsible for more hospital admissions than any other diabetic complication and diabetes mellitus is the leading cause of non-traumatic amputation in the United States.¹ The technology functions by measuring the temperature of the plantar surface of the feet,



Figure 1: Modern smart watch providing a user with his/her heart rate

and if concerning measurements occur, provides an automatic alert to the patient’s healthcare provider. The lofty goals of this initiative were to reduce

prospective, multicenter cohort study evaluated a total of 132 participants, all with a history of prior diabetic foot ulceration that were currently deemed healed at the onset of the study. The 34-week study required participants to stand on the smart mat for a 20-second duration each day. At the conclusion of the study, it was determined that the smart mats were able to impressively predict, with a sensitivity of 97%, the future occurrence of non-traumatic diabetic foot ulceration. Even more impressively, it could predict the occurrence approximately five weeks before clinical presentation.

A Series of Studies

The creation of this novel remote foot-temperature monitoring system was based on years of previous research. It was well-established in 1979

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hospital admissions and non-traumatic lower-extremity amputations.

This national initiative was introduced after a Veteran’s Administration-led study in 2017² evaluated this novel smart mat (Figure 2). This

that temperature assessment was important in the detection of inflammation when a presented case study³ offered that temperature assessment could be used to reduce the incidence

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of injury and ulceration in the insensate foot. Following this, Armstrong, D., et al.⁴ compiled a retrospective review of patients with sensory neuropathy after monitoring their skin temperature in the clinical setting. The findings demonstrated that sites of neuropathic ulceration were associated with an average increase in temperature of approximately 5.6 °F.

This study also identified that temperature increases could also be noted on clinical exams of patients immediately preceding their clinical occurrence of ulceration. In 2004, a single-blinded, randomized clinical trial was completed at the University of Texas Health Science Center at San Antonio⁵ with the utilization of at-home temperature monitoring devices for six months. This expanded the use of temperature monitoring beyond the clinic exam room and into the patient's homes. When foot temperatures were elevated greater than 4 °F, participants were provided education and follow-up until temperature levels normalized. The temperature monitoring and intervention resulted in significantly fewer diabetic foot complications (2% vs. 20%) in the monitored group vs. the control group.

Results from the 2019 VA initiative have returned and have been reported. The retrospective cohort study⁶ which included 924 at-risk patients evaluated between 2019 and 2021 were compared to 2,757 non-enrolled patients

deemed to be of the same at-risk category. Unfortunately, the primary goals of the VA initiative—reducing hospital admissions and lower-extremity amputations—were not reached. There was no significant decrease in either the occurrence of hospital admissions or lower-extremity amputation in the patients monitored with the smart mats.

Questions

The disappointing results of this newly released 2023 VA study leads to many questions. First, why would a device that has been shown to reliably predict the occurrence of diabetic foot ulcerations not reduce the occurrence of hospital admissions and lower-extremity amputations? The presence of the diabetic foot ulceration is not a reason for hospital admission; however, infection of the foot ulceration is. Infections lead to hospital admissions, and potentially, lower-extremity amputations.⁷ The assumption is that early detection of ulcerations should effectively reduce the risk for infection and thus reduce the rate of hospital admission and lower-extremity amputation. However, it should be stated clearly that smart mats are not a treatment—they are a monitoring device. That statement is important. The 2017 Frykberg, R., et

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al.² study which acted as a pilot for the novel smart mat technology was used to determine the viability of the technology. The limitation of this study is that it offered the device only as a means to monitor and provide alerts.

When we review the newly released 2023 VA study, we know that it was based on a research-backed smart mat that provides critical alerts in the early detection of diabetic foot ulcerations. However, what we do not know is what was done after a critical alert occurred. When you take a closer look at the 2017 pilot study,² temperature increases at the threshold of 2.22 °C predicted 97% of future observed diabetic foot ulcers. Using this temperature threshold also presented a false-positive rate of 57%. This resulted in an average of 3.1 alerts per participant per year. However, the pilot study noted that the 86% of the enrolled participants used the device at the benchmark of least three days per week with “modest decay” in participation over time. This raises the next question, was adherence to use and the amount of alerts provided enough to make a difference? Alerts should prompt education to the patient which includes the importance of daily foot examination, their use of off-loading accommodative shoes, and follow-up with their podiatrist.

Guidance and Explication

The previously discussed 2004 UTSA study⁵ offered some guidance. When foot temperatures were elevated

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ed, participants were provided follow-up with education and intervention every day until temperature levels normalized. The result was significant: the group with regular monitoring of their pedal temperature had significantly fewer diabetic foot complications. However, even daily may not be enough to optimize care. A 2017 study⁸ suggested that alerts may need to occur every two hours for optimal offloading cues. This study came to the aggressive conclusion utilizing true wearable tech—smart shoe insoles. This prospective study used novel devices implanted in shoes which monitored pressures. When foot pressures were deemed unsafe, an immediate alert was sent to a wearable smart watch, triggering a change in activity.

Another important note is that these modalities offer monitoring only for the prevention of ulcerations. Both smart mats and smart shoe insoles are to be discontinued in the presence of an active open ulceration. As previously mentioned, it is not the ulceration that causes the hospital admission or the lower extremity amputation; ulcerations are only the conduit that leads to this. Ultimately preventing ulcerations is only half of the equation. When ulcerations occur, quick and efficient healing will also be required to drive down hospital admission and lower extremity amputations. Monitoring the progress of treatment is also gaining traction in wearable technology. The standard of wound care demands off-loading of diabetic foot ulcerations,⁹ and a critical factor is patient adherence to off-loading devices.^{9,10} As the compliance to the use of offloading devices is a known issue, the use of non-removable devices is recommended.⁹

In addition, the use of “surgical off-loading,”—surgical procedures designed to permanently reduce pressure from an area of ulceration—has also grown.¹¹ However, non-removable devices and surgical intervention carry their own shortcomings and risk factors. A smart offloading boot, designed for use with active foot ulceration, was tested and results were released in 2022.¹⁰ This device enables remote patient monitoring and real-time adherence and activity reporting.

The Podiatrist’s Role

Ultimately, these studies reinforce the need for and the role of a podiatrist in the medical care of high-risk patients with diabetes mellitus. Podiatrists will continue to serve as the experts who identify at-risk patients and prescribe these new smart devices that monitor risk factors. When ulcerations occur, podiatrists will remain the experts in healing ulcerations and preventing infections that lead to lower extremity amputation, whether by wound care and offloading expertise or surgical intervention.

Wearable technology will only continue to evolve and improve. Telehealth and communication devices will continue to integrate into medicine and while current ver-



Figure 2: Utilization of a smart mat to provide temperature measurement of the foot

sions may have some shortcomings, the future will bring innovations and potential. **PM**

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