Preventative Sensor-Based Remote Monitoring of the Diabetic Foot

Integrating RPM technologies into clinical practice is a promising strategy in improving diabetic foot care.

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Remote patient monitoring (RPM) has been discussed as a promising strategy in the prevention of diabetic foot ulcers (DFU). RPM can help to facilitate a more integrated care pathway to improve early symptom detection, treatment efficacy and clinical outcomes in this high-risk patient population. RPM enables biometric data to be collected, recorded, and contextualized by qualified healthcare professionals, typically nurses, empowering early intervention and reducing escalations to acute care.[1,2] The technological evolution and availability of digital technologies has enabled RPM to grow exponentially, with sensor-based RPM now providing healthcare professionals with continuous, data-driven, actionable insights to improve patient care. For individuals at risk of developing a DFU, sensor-based RPM has been proposed as a possible solution to overcome many of the challenges with existing footcare best practices, offering the opportunity for early intervention and proactive prevention.

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Diabetes affects approximately 550 million people worldwide (9.3% of the population).[3,4] Of those with diabetes, 34% develop a diabetic foot ulcer (DFU) during their lifetime.[3,5] DFU recurrence rates are high, with an estimated 40% of ulcers recurring within the first year after healing.[5]

Fortunately, at least 75% of DFUs are preventable using established foot care methods and are treatable when detected early.[6,7] The current standard (SOC) of care for DFU prevention includes appropriate fitting footwear, custom diabetic insoles, and education around foot care and daily self-checks for redness, callus, and wounds. This SOC has historically been the same regardless of the patient's baseline risk profile. Detection and prevention of DFUs can pose numerous challenges including difficulty performing foot self-exams due to limited mobility or vision, limited at-home support, and limited retention of medical information when not reinforced. Utilizing sensor-based technologies to monitor physiologic parameters, such as plantar pressure and temperature, may offer insights into DFU development and support the early detection of foot complications.[8-13]

Clinical use of sensor-based RPM for DFU prevention is relatively novel and limited resources exist to help support the successful implementation of remote monitoring programs into clinical practice. 'Preventative Sensor-Based Remote Monitoring of the Diabetic Foot in Clinical Practice'[14] was developed to help answer many of the questions that healthcare professionals have around successfully introducing RPM into their practices in a way that remains synergistic to patient care. This paper is fundamentally based on established standards of care, such as those written by the International Working Group on the Diabetic Foot (IWGDF)[6] and Prevention of Amputation in Veterans Everywhere (PAVE).[15] The insights and knowledge in this paper stem from clinical leaders in diabetic foot care and

Continued on page 124

New Concepts and Studies

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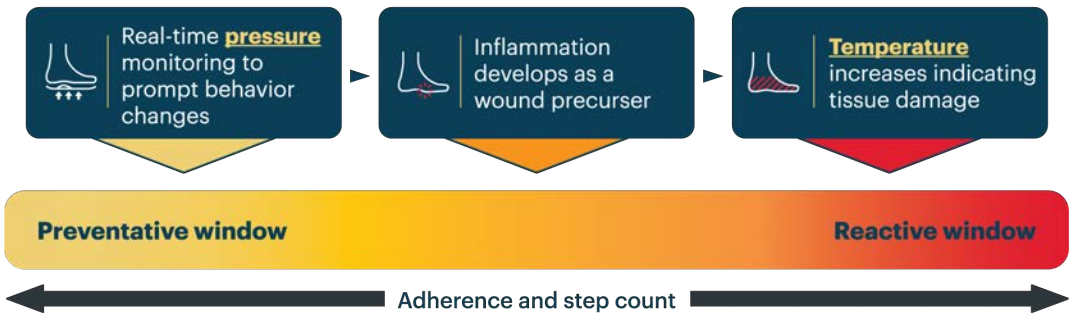

Figure 1: Physiologic parameters contributing to tissue damage on a preventative spectrum.[14]

deployment of RPM programs: Dr. David Armstrong is a professor of surgery and director of the Southwestern Academic Limb Salvage Alliance at the Keck School of Medicine, University of Southern California; Dr. Brock Liden is an office-based podiatric surgeon specializing in limb salvage and reconstruction in Ohio; and Dr. Evan Minty is an Internal Medicine physician and clinical assistant professor at the University of Calgary. This has been further expanded based on insights gained from using a sensor-based RPM technology (Orpyx® Sensory Insoles) to help address the gap in knowledge between standard patient care and the addition of sensor-based RPM care.

RPM programs should be part of a comprehensive disease management approach and should be complementary to existing patient care.

The sensory insoles offer tracking and monitoring of plantar pressure, temperature, step-count, and daily usage, providing clinicians with a robust set of data for their at-risk patients. The importance of all these parameters in DFU development has been well studied and documented, and monitoring multiple physiologic parameters in these patient populations offers clinicians a more detailed view of a patient's foot health.

RPM programs should be part of a comprehensive disease management approach and should be complementary to existing patient care. The RPM device form factor should be selected based on patient-specific needs and circumstance.

Patient Selection and Data Collection for RPM Programs

Patient selection is an important component of any remote monitoring program to ensure that it is effective for both the patient and the healthcare provider. When identifying potential patient candidates for an RPM program designed to prevent DFUs, it is recommended that patients have the following characteristics:

- Patients with Type 1 or Type 2 Diabetes with established peripheral neuropathy (PN) and loss of protective sensation (LOPS)
- Patients with a previously healed DFU (no active wound present)
- Patients who are willing and open to engaging in their diabetic foot health through digital prevention and RPM
- Patients with the cognitive capacity and technological fluency to understand the digital device and its operation
- A supportive care environment is also an asset

These patient selection criteria are based on factors that deem a patient to be at risk of DFU development and generally align with risk levels established by international clinical practice guidelines such as PAVE and those written by the IWGDF.

A thorough patient history and physical exam, especially focused on the feet, is important prior to patient enrolment in an RPM program to help contextualize physiologic data and facilitate informed care decisions.

The Importance of Multimodal Sensing in DFU Prevention

There is a continuum of physiologic parameters that evolve alongside the progression pathway of DFU development. Sensor-based DFU prevention paired with RPM can be considered preventative of tissue injury or reactive to tissue injury, as illustrated in Figure 1.

Patient selection is an important component of any remote monitoring program to ensure that it is effective for both the patient and the healthcare provider.

There are numerous causal factors that can contribute to DFU risk. Progression of neuropathy, gait/load imbalances, marked changes in activity levels, or contributions of these can lead to a state of pressure overload. This pressure overload can lead to tissue degradation, and in cases of tissue injury, an inflammatory state, which can ultimately lead to wound precursor lesions or early wounds. This DFU pathogenesis pathway is illustrated in Figure 2, alongside intervention opportunities using sensor-based RPM.

Continued on page 125

Remote monitoring of multiple physiologic parameters that contribute to DFU development can offer more opportunities for early intervention and prevention of foot complications. Adherence analysis offers the opportunity to promote patient engagement in both the RPM program and in the broader preventative and therapeutic care plan.

Utilizing RPM technologies that monitor multiple physiologic parameters provides the opportunity to intervene as early upstream as possible.

Pressure-based monitoring aims to detect elevated, repetitive, and undetected pressures that can cause cumulative tissue mechanical stress or exceed capillary perfusion pressures over a certain time integral.[10,16] Monitoring plantar pressure can offer opportunities for upstream intervention prior to the development of tissue injury. This can be patient-facing to promote immediate patient-directed offloading and/or RPM-facing to be integrated into patient assessment decisions. Dynamic, patient-directed pressure offloading has demonstrated a 71% risk reduction of DFU recurrence, which was further increased to 86% in users who wore smart insoles >4.5 hours per day.[9]

Temperature-based monitoring aims to detect an inflammatory response as a sign of tissue damage.[11-13] Foot temperature monitoring has been shown to effectively detect high temperature asymmetries between feet and predict the onset of DFUs, with the accepted threshold of concern looking at contralateral asymmetries of +/- 2.2C (4F).[11-13]

The desired impact of RPM intervention is to interdict DFU development and promote tissue and patient wellbeing. Utilizing RPM technologies that monitor multiple physiologic parameters provides the opportunity to intervene as early upstream as possible. There are many comorbidities common to patients with diabetes that may confound plantar temperature monitoring. Immunocompromised patients may present with a partially suppressed inflammatory response resulting in minimal skin temperature difference following tissue injury.[6,17] Alternative-

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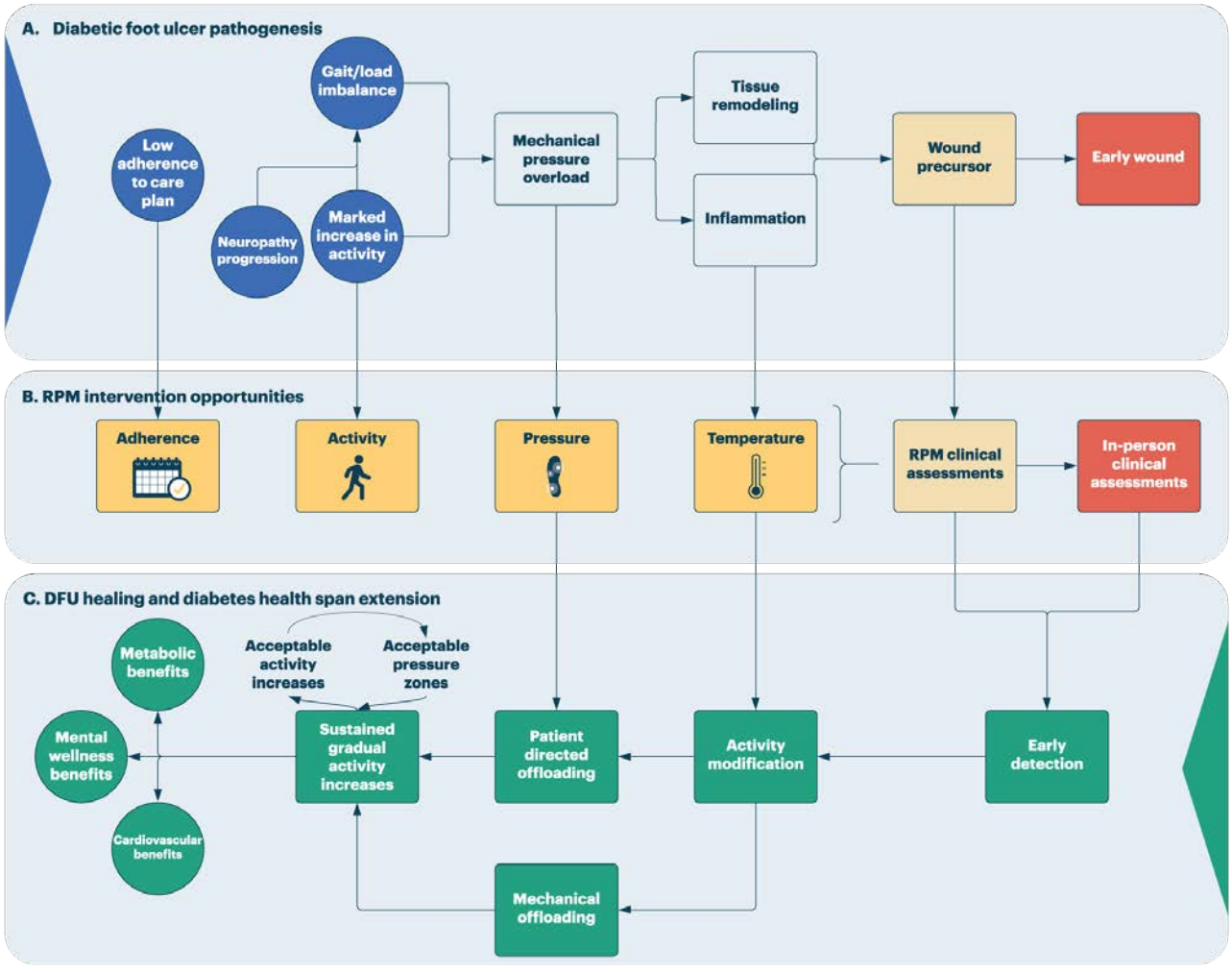


Figure 2: Simplified DFU causal pathway and RPM intervention opportunities.[14]

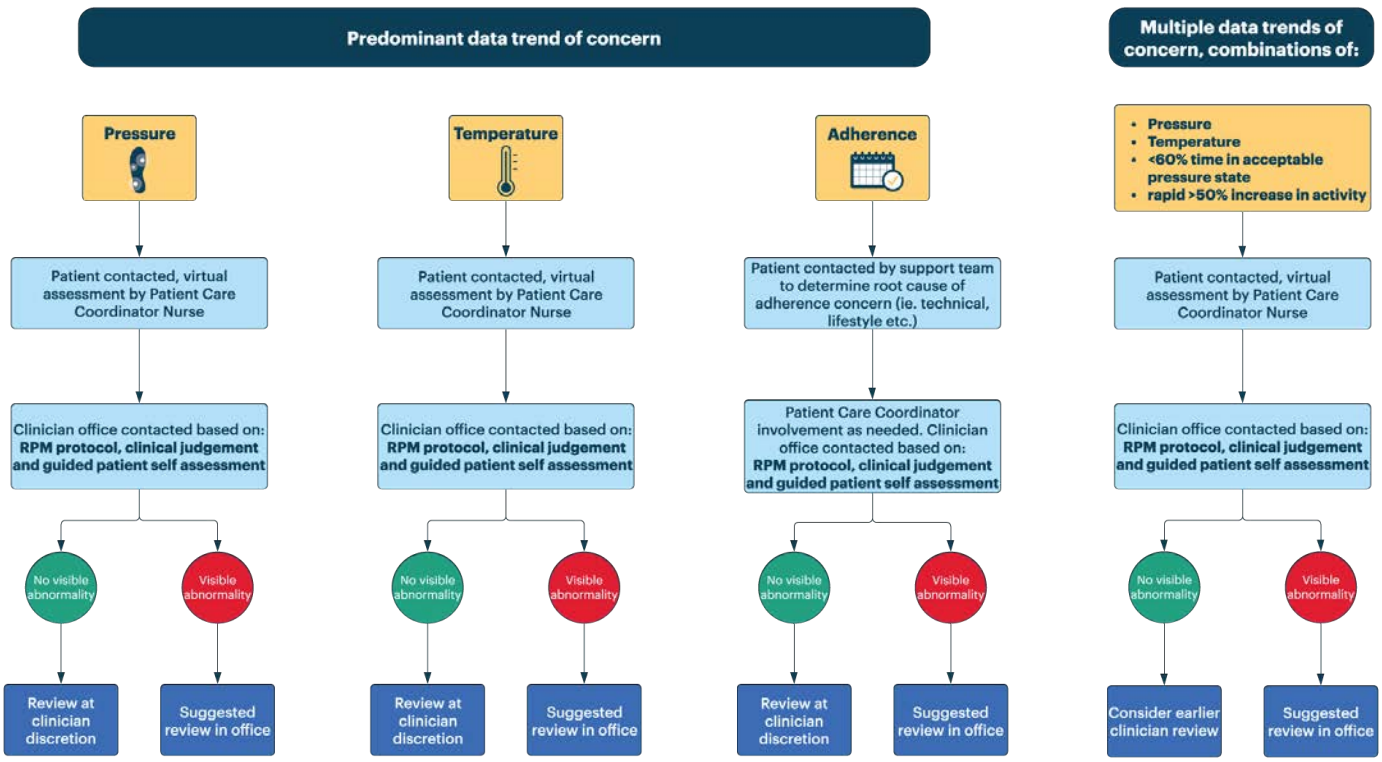
ly, patients with PVD or PAD may exhibit baseline limb temperature differences, and adjustments to temperature monitoring may be required to account for this baseline variant to typical physiology.[18] Conversely, not all patients will see elevated plantar pressures contributing to pre-ulcer development, and it is possible that temperature warnings alone, or a combination of pressure and temperature warnings contribute to wound development. Given the complex comorbidities that are present in patients with diabetes, monitoring multiple physiologic parameters can provide more robust predictive analytics to inform care.

Activity and adherence related data provide additional context to physiologic data (pressure and temperature) and can provide insights into the root cause of DFU precursors. One advantage of RPM technologies is the insights that can be generated around patient adherence to preventative care regimens. Limited patient adherence is often complex, as chronic disease can be exhausting and overwhelming for many patients. An additional benefit of RPM programs is that through consistent, recurrent engagement with RPM nurses, preventative care can be tailored to the patient's specific preferences and goals. In addition to DFU prevention, RPM programs should also focus on promoting sustained, gradual increases (as appropriate) in activity and overall wellbeing. Activity monitoring via step-count is a valuable tool in understanding baseline patient activity levels, providing activity/exercise recommendations, and signifying any acute changes to activity levels that may put the patient at risk for foot complications.

Remote Patient Assessment and Communication

Remote monitoring communication pathways should be established between the RPM service provider and the treating clinician prior to commencement of an RPM program. These protocols will detail how, and when, patient communication occurs and when patient data should be escalated for clinician review.

Continued on page 127



Pressure predominant data trend of concern

Examine both feet

Increase patient-directed offloading.

If persistent alerts to the same biomechanical region, consider mechanical offloading:
- custom insole prescription
- insole offloading modifications
- modified weight bearing activity (e.g. peddler)

Temperature predominant data trend of concern

Examine both feet

Diagnostic considerations:
- environment / artifact
- inflammation
- chronic physiologic asymmetries

If chronic, **vascular assessment** (ABI with segmental pressures and waveform analysis) at intervals consistent with local/international guidelines.

Low adherence data trend of concern

Aim for evidence-based target adherence (e.g. >4.5h / day for smart insoles that detect sustained plantar pressures).

Explore reasons for limited adherence to see if there are adjustments that allow continued engagement in a preventative care plan.

Combinations of multiple data trends of concern may indicate a higher risk profile

Multiple recurrent alerts, across different domains, to the same biomechanical regions may be at higher risk.

Rapid increases in activity in a previously sedentary patient may increase their risk.

Consider earlier evaluation in a high risk patient.

Figure 3: Suggested clinical actions for patients with concerning data trends in pressure, temperature, and adherence domains, or across multiple domains.[14]

Remote assessment of the patient should include an assessment of the physiologic data trend generating the concern, a self-guided assessment of the patient's feet, and education and reinforcement of foot care best practices. Health coaching and motivational interview techniques can also be incorporated into patient assessment and engagement with an RPM provider. Patients can also be provided with ongoing education and coaching on diet, exercise, medication, and integrative foot care.

Clinical Response to RPM Escalation

Sensor-based RPM programs designed for DFU prevention provide clinicians with a novel, robust set of data to help inform clinical decisions. Through RPM, patients can be continuously monitored outside of their standard care visits providing the healthcare provider with greater insights to the patient's real-world behaviors that impact their foot health. If a patient presents with concerning trends in their physiologic data, the RPM nurse may escalate this patient to their treating clinician for review and medical intervention, as required. These escalation pathways are created and mutually agreed upon by the RPM service provider and clinician.

Case escalations will involve alert triage by an RPM team and virtual patient assessment. Remote intervention by the RPM nurse should be guided by escalation protocols specific to the RPM device and the RPM nurses' clinical judgment, accompanied by a guided patient self-assessment. If no visible abnormalities are detected, the RPM nurse will provide a note to the clinician indicating patient review at their discretion. If there are visible abnormalities notes, the RPM nurse will escalate the patient to their clinician for review in-person.

Once a patient has been escalated from remote to in-person care, the treating clinician can utilize their clinical training to assess the patient in the context of the physiologic data generating the concerning trend. This may involve mechanical intervention, such as insole modifications, prescription footwear or offloading devices, activity modification interventions, or other clinical treatments. Suggested clinical actions for patients with concerning data trends in pressure, temperature, and adherence domains, or across multiple domains are highlighted in Figure 3.

Summary

Among the many complications associated with diabetes, DFUs are one of the most devasting and costly. DFUs lead to severe consequences such as lower extremi-

Continued on page 128

ty amputations and increased mortality rates. The current standard of care methods has limitations in early detection and treatment, making prevention efforts difficult and resulting in little improvement of overall DFU and amputation rates over time. Sensor-based RPM programs can help to overcome those limitations, encouraging adherence to established foot care best practices and complementing them with early warning and patient self-management strategies.

Diabetic foot complications are influenced by several factors, highlighting the importance of sensor-based RPM programs to collect physiologic and behavioral data across multiple domains. Monitoring pressure, temperature, activity, and adherence offer opportunities for intervention across different stages of the disease process and increase the possibility of DFU prevention.

RPM programs for DFU prevention should be integrated into a comprehensive disease management strategy and should seek to complement existing standards of care.

RPM programs for DFU prevention should be integrated into a comprehensive disease management strategy and should seek to complement existing standards of care. The overall goal for these programs should not only be to prevent DFUs, but also to promote sustained, gradual increases in activity and overall wellbeing. In doing so, these RPM programs can provide more than just DFU prevention but can provide potential benefits that impact the overall diabetes disease trajectory.

The full publication can be found at https://www.orpyx.com/resources/preventative-sensor-based-remote-monitoring-of-the-diabetic-foot-in-clinical-practice. **PM**

References

[1] Smith-Strøm H, Iversen MM, Graue M, Skeie S, Kirkevold M. An integrated wound-care pathway, supported by telemedicine, and competent wound management—Essential in follow-up care of adults with diabetic foot ulcers. Int J Med Inf. 2016;94:59-66. doi:10.1016/j.ijmedinf.2016.06.020

[2] De Guzman KR, Snoswell CL, Taylor ML, Gray LC, Caffery LJ. Economic Evaluations of Remote Patient Monitoring for Chronic Disease: A Systematic Review. Value Health J Int Soc Pharmacoeconomics Outcomes Res. 2022;25(6):897-913. doi:10.1016/j.jval.2021.12.001

[3] Armstrong DG, Tan T, Boulton AJM, Bus SA. Diabetic Foot Ulcers: A Review. J Am Med Assoc JAMA. 2023;330(1):1-13. doi:-doi:10.1001/jama.2023.10578

[4] Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9th edition—PubMed. Accessed March 30, 2023. https://pubmed.ncbi.nlm.nih.gov/31518657/

[5] Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. N Engl J Med. 2017;376(24):2367-2375. doi:10.1056/NEJMra1615439

[6] Schaper NC, van Netten JJ, Apelqvist J, et al. Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update). Diabetes Metab Res Rev. 2020;36(S1):e3266. doi:10.1002/dmrr.3266

[7] Bus SA, van Netten JJ. A shift in priority in diabetic foot care and research: 75% of foot ulcers are preventable. Diabetes Metab Res Rev. 2016;32(S1):195-200. doi:10.1002/dmrr.2738

[8] Frykberg RG, Gordon IL, Reyzelman AM, et al. Feasibility and Efficacy of a Smart Mat Technology to Predict Development of Diabetic Plantar Ulcers. Diabetes Care. 2017;40(7):973-980. doi:10.2337/dc16-2294

[9] Abbott CA, Chatwin KE, Foden P, et al. Innovative intelligent insole system reduces diabetic foot ulcer recurrence at plantar sites: a prospective, randomised, proof-of-concept study. Lancet Digit Health. 2019;1(6):e308-e318. doi:10.1016/S2589-7500(19)30128-1

[10] Chatwin KE, Abbott CA, Boulton AJM, Bowling FL, Reeves ND. The role of foot pressure measurement in the prediction and prevention of diabetic foot ulceration—A comprehensive review. Diabetes Metab Res Rev. 2020;36(4):e3258. doi:10.1002/dmrr.3258

[11] Lavery LA, Higgins KR, Lanctot DR, et al. Preventing diabetic foot ulcer recurrence in high-risk patients: use of temperature monitoring as a self-assessment tool. Diabetes Care. 2007;30(1):14-20. doi:10.2337/dc06-1600

[12] Lavery LA, Higgins KR, Lanctot DR, et al. Home monitoring of foot skin temperatures to prevent ulceration. Diabetes Care. 2004;27(11):2642-2647. doi:10.2337/diacare.27.11.2642

[13] Armstrong DG, Holtz-Neiderer K, Wendel C, Mohler MJ, Kimbriel HR, Lavery LA. Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. Am J Med. 2007;120(12):1042-1046. doi:10.1016/j.amjmed.2007.06.028

[14] Minty E, Bray E, Bachus CB, et al. Preventative Sensor-Based Remote Monitoring of the Diabetic Foot in Clinical Practice. Sensors. 2023;23(15):6712. doi:10.3390/s23156712

[15] Prevention of Amputation in Veterans Everywhere Program. Published online 2022. Accessed August 1, 2023. https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=9852#:~:text=PURPOSE-,This%20Veterans%20Health%20Administration%20(VHA)%20directive%20states%20policy%20and%20requirements,%C2%A7%207301(b)

[16] Bus SA. The Role of Pressure Offloading on Diabetic Foot Ulcer Healing and Prevention of Recurrence. Plast Reconstr Surg. 2016;138(3S):179S. doi:10.1097/PRS.0000000000002686

[17] Kato S, Chmielewski M, Honda H, et al. Aspects of Immune Dysfunction in End-stage Renal Disease. Clin J Am Soc Nephrol. 2008;3(5):1526. doi:10.2215/CJN.00950208

[18] Ilo A, Romsi P, Mäkelä J. Infrared Thermography and Vascular Disorders in Diabetic Feet. J Diabetes Sci Technol. 2020;14(1):28-36. doi:10.1177/1932296819871270

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