

Preventing Diabetic Foot Re-Ulceration Through an Innovative Pressure and Temperature Monitoring Clinical Device

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Abstract

This study compared the outcome of an innovative in-shoe pressure and temperature measuring device as an adjunct to standard clinical care for diabetic foot versus standard clinical care alone. It included 88 participants with Type 2 diabetes mellitus with a history of one or more plantar foot ulceration who were already using prescription orthoses. These were randomly divided into the control group ($n = 44$, standard care only) and the experimental group ($n = 44$, standard care plus the innovative device). Both groups were monitored for re-ulceration for one year. Overall, the control group exhibited a higher number of re-ulcerations ($n = 14$) with 2 amputations in comparison with the experimental group (only 2 ulcerations and no amputations) at the end of the study. In conclusion, this innovative in-shoe pressure and temperature measuring device appears to reduce re-ulcerations by offering objective data for clinical decision making in the management of the diabetic high-risk foot.

Keywords

in-shoe temperature, in-shoe pressure mapping, diabetic foot, ulceration, diabetes mellitus, wearable sensors

Lower-extremity complications of diabetes constitute a substantial burden for people with diabetes as once healed, foot ulcerations frequently recur. Notwithstanding the advances in medicine, amputation rates are still very high and have not reduced significantly.¹ This may suggest that current management of the diabetic foot may not be as effective as desired, clearly demonstrating the need for the implementation of new and effective strategies aimed primarily at prevention of ulceration. The time to referral will determine the number of ulcerations and re-ulcerations or alternatively ulcer free days—in other words “Time is Tissue! We need to act now without further delay!”⁷

The overall prevalence of diabetic foot ulcerations and their recurrence differs from one country to another as apart from variation in population characteristics and general definitions, there is a variation in diagnostic methods and patient management.² In most countries diabetic foot care management focuses on the monitoring of the vascular and/or dermatological complications. Moreover, the effectiveness of devices prescribed to off-load areas at-risk of ulceration or re-ulceration, is often determined through visual observation and clinical experience of the clinician.³

To date, in-shoe technologies can only be used to measure either pressures or temperatures separately and

are known to be very costly and time-consuming to use.^{4,5} Furthermore, the current subjective method of asserting the effectiveness of an off-loading device may not be sufficient. In view of this, an innovative, low-cost, single-sensor, in-shoe pressure and temperature measuring device was developed and validated in a healthy population.⁶

In this context, the aim of the study was to evaluate if this innovative device could be used as an adjunct objective measurement of temperature and pressure to standard foot care in the prevention and management of diabetic foot ulceration/re-ulceration.

Materials and methods

This study, conducted between June 2021 and August 2022, obtained institutional ethical approval and followed all principles of the Declaration of Helsinki (Registration Number:

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