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A Prospective, Randomised, Proof-of-Concept Study Examined the Recurrence of Diabetic Foot Ulcers at Plantar Locations

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Abstract

In this prospective, randomised, proof-of-concept study, patients with diabetes, and with peripheral neuropathy and a recent history of plantar foot ulceration were recruited from two multidisciplinary outpatient diabetic foot clinics in the UK, and were randomly assigned to either intervention or control. An insole system that continuously measured plantar pressure throughout the day was given to each patient. When abnormal pressures were found, the intervention group was given audiovisual notifications through a smartwatch connected to the insole system and offloading instructions, while the control group did not. Plantar foot ulcer development within 18 months was the main result. The ISRCTN number for this trial is ISRCTN05585501, and it is finished and closed to enrollment.

Keywords: Diabetic Foot; Ulcer

Introduction

The direct expense of treating diabetes can account for up to one-third of lower extremity complications, which are among the most frequent and expensive diabetes consequences. These complications include diabetic foot ulcers and lower limb amputations. Over the course of their illness, 25% of diabetics will acquire a diabetic foot ulcer, which is the most common reason for diabetes-related hospital admission. In addition, one in five ulcers will necessitate amputating the lower limb. Although there are several clinically recognised risk factors for diabetic foot ulcers, including a history of the condition, diabetic peripheral neuropathy, foot deformities, and elevated plantar pressures, there are currently no proven preventative strategies for both the initial and recurrent development of diabetic foot ulcers [**1**]. In the first year after developing a foot ulcer, a person's chances of a recurrence are 40%.This is the first potential, randomly selected, proof-of-concept study to examine the efficacy of an intelligent insole system (designed to continuously measure static plantar pressure during daily life activities and guide regular self-directed, dynamic offloading) in preventing diabetic foot ulcers in individuals with diabetes who are at high risk of developing ulcers and who have a recent history of a healed diabetic foot ulcer. This study is the first to describe how an intervention involving active feedback element (via a smartwatch) senses and enables self-directed adjustment according to the conditions experienced by the foot, thereby reducing foot ulcer recurrence, even though previous studies on the prevention of diabetic foot ulcers have shown variable efficacy using passive solutions [**2-7**]. Static pressure (i.e., a prolonged period of sustained plantar pressure, such as during prolonged sitting or standing >15 min.) is another significant variable used to quantify foot pressures and, consequently, potentially diabetic foot ulcer risk. It can be sampled at a lower frequency (8 Hz) for longer periods of time than can be measured in the laboratory setting. With the use of static pressure measurements, we have narrowed our attention to pressures that are consistently high but not at their highest during normal everyday activities over the course of many months. We hypothesise that relatively low-pressure thresholds (i.e., 35 mm Hg) might be regularly exceeded for a sustained length of time based on the results from research on pressure-related diabetic foot ulcers and cross-sectional data [**8**].

Material and Method

Proof-of-concept study

Patients were enlisted from two multidisciplinary outpatient diabetic foot clinics in the UK for this prospective, randomised, single-blinded (patient only), proof-of-concept study. The protocol for the study is published in the appendix, and it was approved by regional research ethics committees and other pertinent governmental agencies in the UK. Major inclusion criteria were age at least 18 years, type 1 or type 2 diabetes, history of previous ulceration on the weight-bearing surfaces of the foot, presence of diabetic peripheral neuropathy (as defined by any loss of sensation), and ability to walk independently for 30 steps [**9,10**]. Active foot ulceration, severe vascular disease, lower limb amputation above the ankle, in-shoe orthotics made of non-compressible materials, dementia, uncorrected visual or psychological impairment, and psychiatric diseases were the main exclusion criteria.

Procedure

Each location employed a straightforward randomization process that was based on a single series of randomly chosen positive and negative values produced in a spreadsheet. At the end of the screening visit, patients who passed screening were allocated to either the intervention group (if the next number in the list was below or equal to 0·5) or control group (if the following number in the list was above 0·5). Only the researcher at each site was aware of the grouping (single blinded). Internal podiatrists and physicians who were kept anonymous from the intervention provided all patients with podiatry evaluation and care throughout the research. After the 18-month follow-up or at any point prior to the 18-month follow-up, patients who discontinued the study for reasons other than a plantar ulcer did so. The pressure-feedback device was examined and calibrated using internal software at baseline and at each subsequent monthly visit. Every regular monthly appointment included the insole testing and calibration procedure. The patient's shoes had their insoles removed during this treatment.

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The sensor sites in the insoles were verified to be precisely detecting a range of standard static pressure 25-225 mm Hg using the in-house software on the research laptop. This was accomplished by physically applying increasing pressure increments to the insoles while reading the sensor responses from the computer programme. The insoles were then calibrated to make sure they could detect 50 mm Hg reliably.

Discussion

By using an innovative insole technology that continuously provides plantar pressure feedback and encouragement to offload during daily life, we have demonstrated a reduction in the recurrence of diabetic foot ulcer sites in our prospective, randomised, proof-of-concept trial. In an intention-to-treat analysis, the intervention group experienced a 71% decrease in the recurrence of diabetic foot ulcers over an 18-month follow-up period. When comparing groups that adhered to wearing the connected device every day, the intervention group's rate of diabetic foot ulcer recurrence was 86% lower than that of groups who did not. In compliant users of the active device, the time to ulceration was similarly prolonged. However, there was no discernible impact of the system on the proportion of patients who experienced re-ulceration. We had a strong control group because there was accessible diabetic foot care in the area. Also, by giving patients in the control group access to a non-alerting system rather than letting their diabetic foot ulcers progress naturally, we were able to demonstrate the effectiveness of audiovisual feedback alerts for reducing diabetic foot ulcers. Our study's design took into account characteristics including the frequency of patient interaction, the focus on foot health, and any potential placebo effects from the gadget. However it's possible that the intervention's positive effects were muted by the high drop-out rate and lower number of randomly assigned participants than anticipated.

Conclusion

As a result of our research, it has been demonstrated that high-risk diabetic patients can experience a reduction in the incidence of recurrent diabetic foot ulcers over a period of 18 months by using an innovative intelligent insole system that continuously monitors plantar pressure and encourages offloading throughout the day. The patients' compliance with using the device every day for at least six months and their proper instruction in the use of the intelligent insole technology have been crucial to the trial's success. For the purpose of preventing ulcers, we advise that future randomised controlled studies examine the efficacy and financial viability of this technology in a larger group of diabetics at risk for neuropathic conditions.

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