Novel plantar pressure-sensing smart insoles reduce foot ulcer incidence in 'high-risk' diabetic patients: a longitudinal study

C.A. Abbott[1], K.E. Chatwin[1], A.N.B. Hasan[1], S.M. Rajbhandari[2], C. Sange[2], N. Musa[2], P. Foden[3], K. Stocking[3], L. Vileikyte[4], F.L. Bowling[4], A.J.M. Boulton[4], N.D. Reeves[1];
[1]Manchester Metropolitan University, Manchester, [2]Lancashire Teaching Hospitals NHS Foundation Trust, Chorley, [3]Wythenshawe Hospital, Manchester, UK, [4]University of Manchester, Manchester, UK.

Background and aims: The lifetime risk of diabetic, neuropathic, plantar first foot ulceration is 25%, whereas ulcer recurrence rates for patients with ulcer history are 50-70% within 5 years. To date, effective ulcer prevention strategies remain elusive. Foot ulcer development in the insensate foot is intimately linked to high peak plantar pressures and high pressure-time integrals during gait as patients with diabetic neuropathy cannot detect aberrant pressures and do not adjust their walking strategy appropriately. We hypothesize that an intervention providing plantar pressure feedback would reduce aberrant high pressures developed during daily activities. We aimed to test efficacy of a novel plantar pressure-sensing smart insole system, the SurroSense Rx® (Orpyx Medical Technologies Inc., Canada) in reducing DFU occurrence in 'high risk' diabetic patients. This system comprises pressure-sensing inserts worn inside patients' footwear, recording continuous plantar pressure at eight sensor locations, during day-to-day life. When critical pressure thresholds are detected, a smartwatch feeds back to the patient via an alert and encourages off-loading, to modify aberrant plantar pressures developed during daily activities.
Materials and methods: In this randomised controlled trial, patients with recent history of DFU, peripheral neuropathy, no peripheral vascular disease, and no current DFU were recruited from two hospital sites within Greater Manchester, UK. Ninety participants were consented, 58 were randomized, all being set-up with the pressure-sensing inserts and smartwatch. Intervention group (IG) received feedback alerts from the smartwatch when pressures were 'high', whereas Control group (CG) did not receive alerts. At baseline, participants received device training and a detailed foot check. Patients were reviewed monthly for a foot check and system calibration. Follow-up was for 18 months or until plantar ulceration occurred.
Results: At follow-up, there were 10 ulcers from 8,638 person-days in CG and 4 ulcers from 11,835 person-days in IG. A Poisson regression model compared the two groups on incidence of ulceration with log exposure days as offset and showed a 71% reduction in ulcer incidence in IG (Incidence Rate Ratio = 0.29, 95% CI: 0.09-0.93) relative to the CG (p=0.037). Characteristics of CG (n=26) vs. IG (n=32) were: age, 67.1(9.6) vs. 59.1(8.5) [mean (SD)]; Type 1 diabetes, n=4 (15.4%) vs. n=9 (28.1%); duration diabetes, 21.2(10.7) vs. 22.2(14.3) years; HbA1c, 58(41-83) vs. 65.5(38-122) [median (range)] mmol/mol. In survival analysis, the Kaplan-Meier graph and log-rank test suggested no significant difference in treatment groups in time to ulceration (18 month ulcer-free proportion: CG - 68.4%, IG - 77.5%; p=0.30). Self-reported hours of wearing the device were: CG, 4.6 (2.9) vs. IG, 5.1 (3.0) hours/day, p=0.63.
Conclusion: Plantar pressure feedback and encouragement to offload throughout daily life via smartwatch alerts resulted in 71% lower DFU incidence after 18 months follow-up. We conclude that there has been a significant, positive impact of this plantar pressure feedback intervention on reducing DFU incidence in 'high risk' diabetic patients.
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