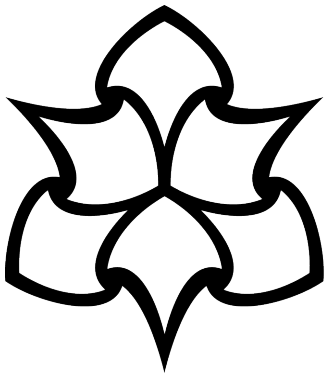

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An intelligent insole system with personalised digital feedback reduces foot pressures during daily life: An 18-month randomised controlled trial

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ABSTRACT

Aims: High plantar pressure is a major risk factor in the development of diabetic foot ulcers (DFUs) and recent evidence shows plantar pressure feedback reduces DFU recurrence. This study investigated whether continued use of an intelligent insole system by patients at high-risk of DFUs causes a reduction in plantar pressures.

Methods: Forty-six patients with diabetic peripheral neuropathy and previous DFU were randomised to intervention (IG) or control groups (CG). Patients received an intelligent insole system, consisting of pressure-sensing insoles and digital watch. Patients wore the device during all daily activity for 18-months or until ulceration, and integrated pressure was recorded continuously. The device provided high-pressure feedback to IG only via audio-visual-vibrational alerts. High-pressure parameters at the whole foot, forefoot and rearfoot were compared between groups, with multilevel binary logistic regression analysis.

Results: CG experienced more high-pressure bouts over time than IG across all areas of the foot ($P < 0.05$). Differences between groups became apparent >16 weeks of wearing the device.

Conclusions: Continuous plantar pressure feedback via an intelligent insole system reduces number of bouts of high-pressure in patients at high-risk of DFU. These findings suggest that patients were learning which activities generated high-pressure, and pre-emptively offloading to avoid further alerts.

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1. Introduction

There is consensus across the literature on the key role of high plantar pressures in the development of diabetic foot ulcers (DFUs). High plantar pressure on the diabetic foot is the result of a multitude of risk factors, including diabetic peripheral neuropathy (DPN) and foot deformities[1–3]. DPN results in a loss of protective sensation and is the predominant risk factor for DFU development as it limits the ability for self-regulation of foot pressures.

The primary aim of DFU prevention strategies is to reduce high plantar pressures. Current prevention strategies, centred around prescription footwear and orthotics, are only effective when worn, however are often associated with low adherence[4–8].

Providing personalised feedback on high plantar pressures offers an alternative strategy for the patient to reduce their plantar pressures, with the potential for a learning effect over time. A small number of laboratory-based studies have investigated this concept, with the majority providing visual feedback for a single 'at-risk' area of peak pressure, identified following a walking trial[9–11]. Studies have shown that a single laboratory visit with this feedback significantly reduced pressure to the at-risk area, with the effects lasting for up to 10 days[10,11]. However, no longer-term reductions to plantar pressure were reported in high-risk patients following two feedback sessions, suggesting the need for more frequent pressure feedback to achieve meaningful reductions towards DFU prevention[9].

A few biofeedback studies have also monitored pressure across all areas of the foot[9,11,12]. This is particularly relevant considering that after successful offloading of an at-risk area, a significant increase in plantar pressure to the contralateral mid-foot was identified in one study[11]. These studies, however, were small-scale and laboratory-based, and further investigation through a randomised control trial of a continuous monitoring system over a sustained follow-up period is required.

Advancements in intelligent technologies have seen the development of pressure-feedback systems that are able to continuously analyse and provide feedback to the patient [13,14]. The development of such intelligent systems in DFU prevention, however, is an emerging area.

The aim of the current study was to investigate whether daily use of an intelligent insole system, providing continuous, personalised high-pressure feedback, can reduce pressure to the at-risk diabetic foot over an 18-month period. The current study was part of a randomised controlled trial of an intelligent insole system for reducing DFU in high-risk patients, for which we have recently reported efficacy[15]. We hypothesise that DFU prevention seen in the previous study, was due to reduced plantar pressure resulting from pressure feedback. Although the current study involves the same patient cohort as in our previously published study of DFU incidence, this represents a separate aspect and, in contrast, examines a new dataset of novel plantar pressure data.

2. Materials and methods

2.1. Subjects

Patients were recruited from two hospital sites in the UK. Eligibility criteria have been previously described in detail by Abbott [15]. Inclusion criteria included: Type 1 or Type 2 diabetes; DPN; age > 18 years; previous DFU on the weight-bearing surfaces of the foot. Exclusion criteria included: active DFU; severe vascular disease; Body Mass Index > 40 kg/m^2. Patients provided written consent in accordance with study procedures approved by local research ethics committees and governance bodies in the UK (clinical trial registration number: ISRCTN05585501; NHS REC reference number: 13/NW/0649).

2.2. Study design

In this prospective, randomised controlled trial, all recruited patients were required to undergo initial screening to confirm eligibility. Presence and severity of DPN were assessed with the modified neuropathy disability score; testing pain, vibration and temperature sensation, and ankle reflexes, with any loss of sensation classified as DPN[16,17]. Additional assessments included: cutaneous pressure perception at the great toe, first, third and fifth metatarsal heads, using a 10 g monofilament; vibration perception threshold at the great toe using a Biothesiometer (Medical Instruments, Newbury, OH, USA); the Neuropad™ test (Trigocare, Wiehl, Germany) identifying presence of sudomotor dysfunction.

Following a successful screening visit, patients were randomised using a single-blinded design to the Intervention Group (IG) or Control Group (CG). Patients were monitored on a monthly basis for 18-months, or until a plantar DFU developed. All patients continued with their standard podiatry and diabetes-related foot care throughout the study.

At each monthly visit, a foot examination took place to identify any new plantar DFUs or any areas that appeared to be at risk of ulceration[18].

2.3. Intelligent insole system

All recruited patients were provided with their own intelligent insole system (SurroSense Rx, Orpyx Medical Technologies Inc., Calgary, AB, Canada), which consisted of a pair of pressure-sensing 0.6 mm flexible insoles and a digital display watch, all of which were worn for the duration of the study, throughout daily life (Fig. 1.A). Only patients in the IG had an intelligent system that provided feedback on their foot pressures via their watch; the CG did not receive any feedback. Patients were required to select a pair of shoes for insole placement, which were worn for most daily life activities; shoes ranged from off-the-shelf to custom-made. Only researchers were permitted to remove and fit the pressure-sensing insoles to ensure proper placement and prevent damage. The pressure-sensing insoles were placed underneath patient's own orthotics/insoles; in rare cases where patients did not have their own, a standard, non-customised insole (3 mm Poron) was provided. Pressure-sensing insole calibration took place at device set-up and each monthly visit; this accounted for the low pressure exerted by the patient's own insole covering the pressure-sensing insole.

Plantar pressure was collected from the intelligent insoles at a sampling rate of 8 Hz from eight sensors located on the plantar surface (Fig. 1.B). Pressure data were analysed and categorised by the device as being either above or below

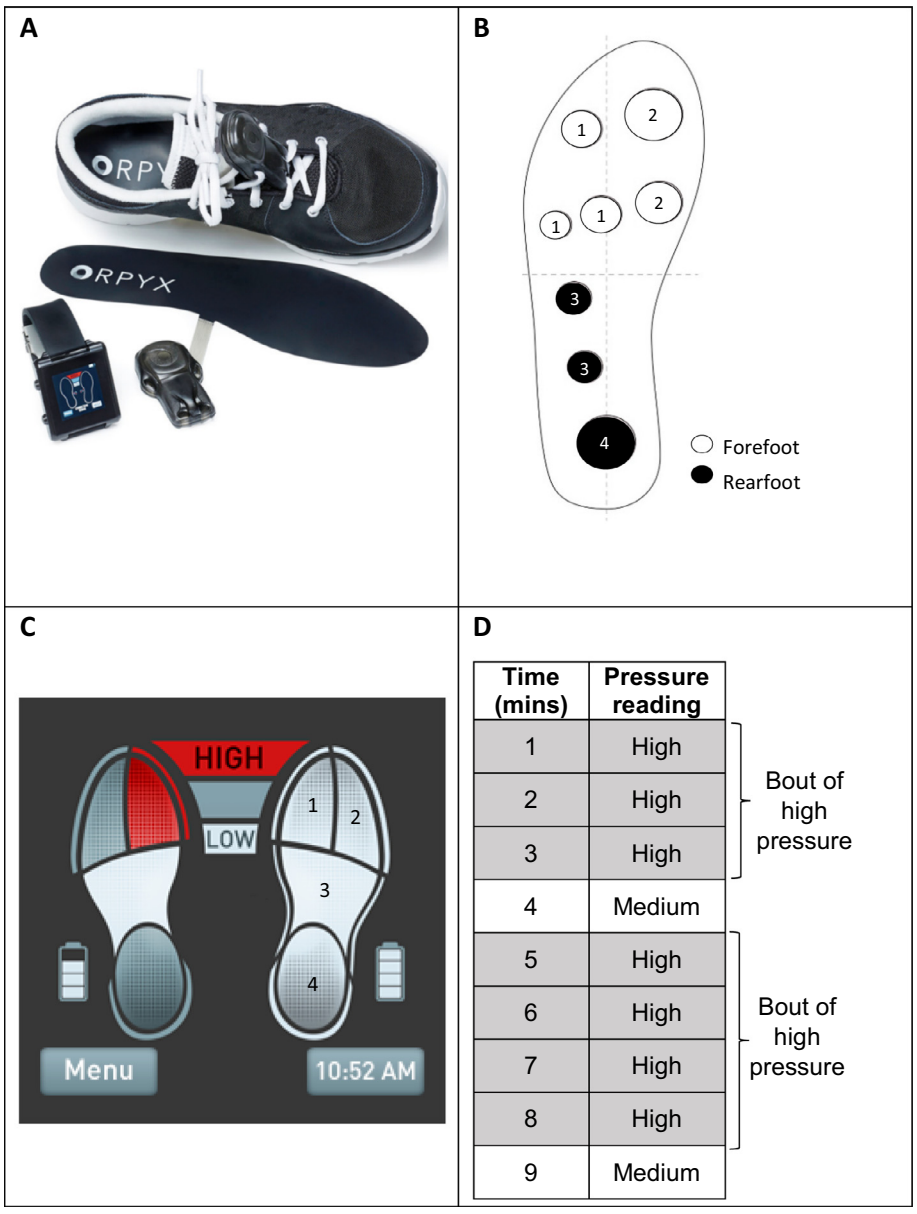

Fig. 1 – Intelligent insole system (SurroSense Rx, Orpyx Medical Technologies, Alberta, Canada). (A) Intelligent insole system including digital display watch and pressure-sensing insoles worn in patients' own shoes, only Velcro or laced shoes were permitted to ensure secure attachment of the sensor pod to the shoe exterior. NB figure does not show patient's own insoles that were required to be worn on top of the pressure-sensing insoles. (B) Locations of the eight sensor sites on the pressure-sensing insole, indicating forefoot and rearfoot. Numbers indicate which of the four foot-map areas each sensor corresponds to. (C) Digital watch display showing the foot map where areas of sustained high pressure were highlighted in red for IG only. (D) Visual representation of bouts of high pressure. For every new bout of high pressure, the IG received an alert on the smartwatch in addition to standard off-loading guidance, which encouraged patients to 1) walk around for 2 min; if the alert was not removed then: 2) actively off-load the affected foot by sitting down, if still not effective: 3) check for over-tightness of the shoe and any foreign bodies.

plantar tissue capillary perfusion pressure (35 mmHg)[19]. For each sensor, the insole system integrated pressure data collected over the previous 15 min into 'high', 'medium' or 'low' categories based on the percentage of data which exceeded capillary pressure ('high' = 95–100% readings $\geq$ 35 mmHg, 'medium' = 35–94% $\geq$35 mmHg, 'low' = 0–34% $\geq$35 mmHg). Categorisation was completed every minute of wear and was wirelessly transmitted to the digital watch where data was stored.

Following screening, all recruited patients began with a two-week familiarisation period, which involved wearing the insole system with a non-alerting (no pressure-feedback) watch. Following familiarisation, the IG had their non-alerting watch replaced with an alerting watch. When a

new bout of sustained high pressure was detected at any sensor site, the watch (IG only) provided a vibrational and audio-visual alert, highlighting areas of high pressure in red on the watch display's 'foot-map' (Fig. 1.C), in addition to standard off-loading guidance. The watch provided reminder alerts until successful offloading occurred, clearing the alert. The watch display's foot-map separated the plantar surface into four areas; however, raw data was specific to each of the eight sensors.

All patients in IG and CG wore the same intelligent insole system, which recorded plantar pressure data throughout daily life when shoes were worn. Patients were encouraged to wear the insole system as often as possible throughout the follow-up, with adherence monitored at each monthly visit. The important difference between the groups was that only the IG received pressure feedback; in contrast, the CG had a device that did NOT provide any pressure feedback.

2.4. *Data analysis*

A reading of 'high' (95–100% ≥35 mmHg), 'medium' or 'low' integrated pressure was recorded for each of the eight sensors on each insole, every minute of wear, for the duration of the follow-up period (18 months). Occurrences of sustained high pressure were the primary focus of this study. Due to the large volume of data, custom scripts were developed in MATLAB to enable data processing. Pressure data were analysed for each patient-foot independently, rather than combining left and right feet. High plantar pressure is a precursor for DFU development and DFUs do not always develop on both feet, but when they do, the locations of such are not often identical for both feet, highlighting the independence of these events. Therefore, this provides evidence to suggest that plantar pressures not only differ across the foot, but also between feet. Furthermore, IG patients within this study received pressure feedback that was independent to each foot and so authors treated them as such. A similar approach was adopted in previous studies[20,21].

The following parameters were derived for each sensor: number of bouts of sustained high pressure (where a bout was a group of continuous high pressure readings, for each new bout, IG received an alert (Fig. 1.D)), minutes of sustained high pressure, bout duration of sustained high pressure (the length of time sustained pressure readings persisted). All parameters were normalised per hours of wear. Averages over 4-week periods were calculated for each individual sensor. Whole foot totals were calculated using the sum of all eight sensors. The forefoot region was defined as the five sensors covering the toes and metatarsal head regions, whereas the rearfoot covered the remaining three sensors (Fig. 1.B). Four-week periods were specific to each patient-foot and the patient's study start date due to the staggered nature of patient recruitment. Four-weekly periods that contained zero pressure data for both patient's feet were removed.

Low compliance was assessed by calculating the time in study (hours) from the number of days each patient was enrolled onto the study, divided by total hours the device was worn. Distribution of results was plotted via scatter and boxplots to identify negative outliers as low compliers, which were subsequently removed from further analyses.

2.5. *Statistical analysis*

Baseline patient demographics and other study outcomes were compared between treatment groups. Variables were compared with an Independent Student's *t*-test, Mann-Whitney *U* test, or Chi-squared (X^2) test of independence where appropriate.

Multilevel binary logistic regression was performed to investigate the effect of the intervention on pressure variables over the study period, accounting for months with missing data and patients withdrawing. For each parameter, two multilevel models were performed, both included using group and month as fixed effects; the IG was the reference group. In addition, one model included the nested interaction term 'group*month' to investigate whether the change in pressure variables over the study period differed between IG and CG. As described, analysis was grouped by individual feet. All analyses were run using SPSS version 25 (IBM Corporation, Armonk, NY) with a significance level of $P < 0.05$ and 95% CI.

3. Results

Fifty-eight people were randomised to the study, as previously described[15]. Four patients' devices did not provide sufficient pressure data during their time in study and these patients were subsequently excluded from pressure analyses. Following analysis of hours of wear data, an additional eight patients were identified as low compliers and were also removed from analyses.

The baseline patient demographics of the remaining patients (n = 46) are summarised in Table 1. The IG was significantly younger (59.5 ± 9.1 vs 66.4 ± 9.1 years, $P = 0.014$); however, all other characteristics were similar between IG and CG.

The average follow-up period was 12.0 ± 6.8 months and did not differ between groups (median 12(1–22) months CG, 13(1–22) months IG $P = 0.479$). Twenty-five patients did not complete the full study follow-up due to development of a plantar DFU (n = 10), loss of contact (n = 1) and withdrawal before completion (n = 14); however, such patients' pressure data was included in the analyses as it fit within the study objectives and ethical permissions.

3.1. *High pressure results*

The number of 4-week periods for which pressure data was available did not differ between groups (median 13(1–23) 4-weeks CG, 12(2–24) 4-weeks IG $P = 0.635$). The average hours the intelligent insole system was worn per day, was also similar between groups (6.78 ± 2.2 h CG, 6.01 ± 2.02 h IG $P = 0.192$). The results of the sustained high-pressure parameters: number of bouts and minutes, for individual feet (n = 92) are presented below and in Figs. 2 and 3, respectively. Results for bout duration of pressure failed to reach significance and were highly variable.

3.1.1. *Bouts of pressure*

On average, holding time in study (weeks) constant, the CG experienced 0.08(95% CI, −0.40 to 0.57, $P = 0.73$) more bouts of high-pressure per hour than the IG for the whole foot,

Table 1 – Baseline patient characteristics.

	Control (n = 21)	Intervention (n = 25)
Male	18 (86%)	23 (92%)
Age (years)*	66.4 (9.13)	59.5 (9.07)
BMI (kg/m^2)	31.5 (4.74)	31.8 (5.73)
Type 2 diabetes	18 (86%)	17 (68%)
Duration of diabetes (years)	22.8 (11.0)	23.6 (15.2)
Ethnicity		
White	17 (81%)	21 (84%)
Black	1 (4.8%)	1 (4%)
Asian	3 (14%)	1 (4%)
Mixed	0	1 (4%)
Other	0	1 (4%)
Study site 1	15 (71%)	18 (72%)
Hba1c (%)†	7.6 (5.9–9.7)	8.3 (5.8–13)
(mmol/mol)	60 (41–83)	67 (40–122)
NDS score	9 (1–10)	8 (2–10)
NDS category		
Minimal (NDS 0–2)	1 (4.8%)	1 (4%)
Mild (NDS 3–5)	4 (19%)	1 (4%)
Moderate (NDS 6–8)	5 (24%)	11 (44%)
Severe (NDS 8–10)	11 (52%)	12 (48%)
Abnormal 10 g monofilament‡		
Left	17 (85%)	24 (96%)
Right	16 (80%)	25 (100%)
Previous amputations, left foot		
None	19 (90%)	22 (88%)
Great toe	0	2 (8%)
2nd – 5th toes	2 (9.5%)	1 (4%)
Previous amputations, right foot		
None	21 (100%)	23 (92%)
Great toe	0	0
2nd – 5th toes	0	2 (8%)
Neuropad, abnormal result§	18 (95%)	19 (95%)
Foot deformity score¶		
Left	2 (0–5)	2 (0–5)
Right	2 (0–5)	2 (0–6)

Data are mean (SD), n (%) or median (range). Study site 1 = Manchester. NDS = Neuropathy Disability Score, scored out of 10 with 10 being most severe. An abnormal 10 g monofilament result was defined as the inability to detect the 10 g monofilament at any one of the tested plantar sites (great toe, first, third and fifth metatarsal head). Foot deformity score, scored from 0 to 6, a score of 1 for each of the following deformities identified per foot: hammer or claw toes, prominent metatarsal heads, small muscle wasting, bony prominences, Charcot, or limited joint ability as determined by prayer sign. *Significantly different ($P < 0.05$) between control (CG) and intervention (IG). †CG n = 20, IG n = 22. ‡CG n = 20, IG n = 25. §CG n = 19, IG n = 20. ¶CG n = 18, IG n = 23.

although this did not reach significance (Fig. 2). The number of bouts of high pressure at the forefoot and rearfoot also showed no significant differences between groups when time in study was held constant. However, the interaction effect of group and time in study showed the number of bouts of high pressure were significantly greater over time for the CG compared to the IG for whole foot '0.053(0.018 to 0.088, $P = 0.003$)', forefoot '0.022(0.0002 to 0.044, $P = 0.048$)', and rearfoot '0.029 (0.011 to 0.047, $P = 0.001$)'.

3.1.2. *Minutes of pressure*

On average, holding time in study (weeks) constant, the CG experienced 6.9(-7.4 to 21, $P = 0.34$) more minutes of high pressure per hour than the IG for the whole foot (Fig. 3). In addition, on average, more minutes of high pressure per hour were evident in the CG when separating the foot into forefoot '3.5(-6.9 to 14.0, $P = 0.51$)' and rearfoot '3.5(-2.7 to 9.6, $P = 0.26$)'. However, such differences did not reach significance. Furthermore, the interaction effect of group and time in study indicated that over time, minutes of high pressure per hour remained higher for the CG compared to IG, however such result was non-significant (whole foot '0.6(-0.56 to 1.8, $P = 0.31$)', forefoot '0.12(-0.69 to 0.93, $P = 0.77$)', rearfoot '0.47 (-0.11 to 1.1, $P = 0.11$)').

4. Discussion

For the first time, we have shown that providing continuous, high-pressure, personalised feedback during daily activities over a prolonged time-period, has reduced plantar pressure in patients at high-risk of DFU. Importantly, IG patients displayed a learning response following approximately four months of receiving pressure-feedback.

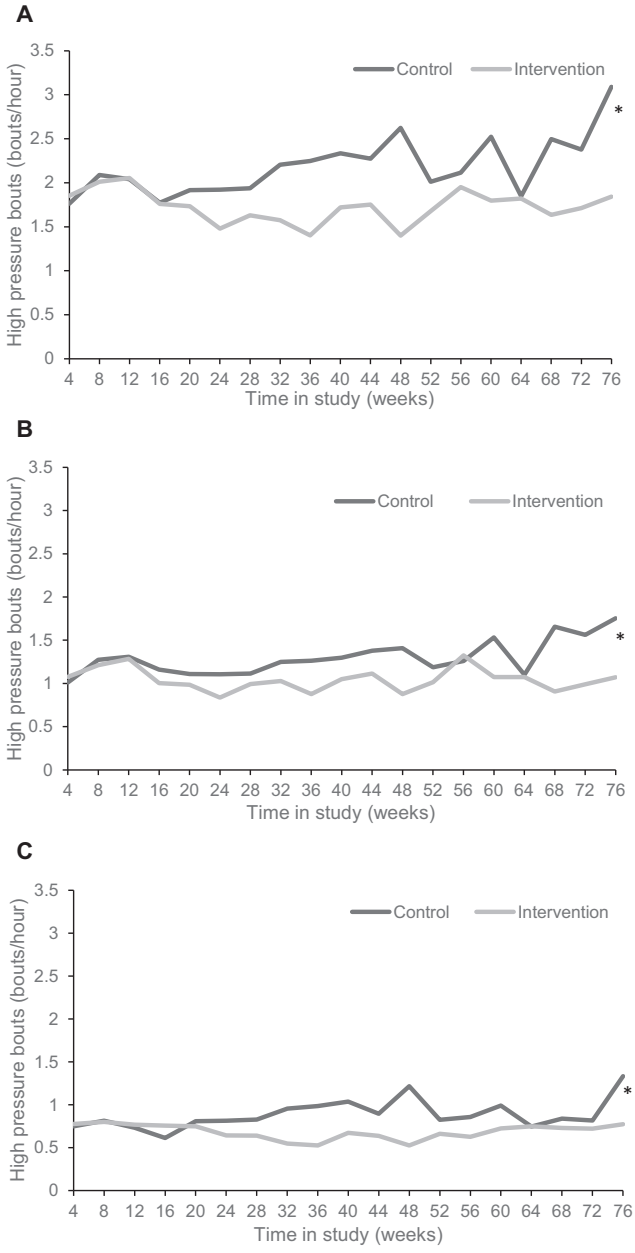

Fig. 2 – Average number of bouts of sustained high pressure per hour of wear at the (A) Whole foot, (B) Forefoot and (C) Rearfoot regions, comparing IG to CG. Averages were calculated for every 4-week period worn, see results for 95% CI as an indication of variation. *The interaction effect of group and time in study (weeks) was significantly greater for the CG ($P < 0.05$). Due to withdrawals and in-study DFUs throughout the follow-up period, the number of patients reduced over time, the number of feet every third 4-week period for figures A, B and C were as follows: weeks 9–12 n = 84 (36 CG, 48 IG); weeks 21–24 n = 74 (32 CG, 42 IG), weeks 33–36 n = 60 (26 CG, 34 IG); weeks 45–48 n = 52 (22 CG, 30 IG); weeks 57–60 n = 36 (18 CG, 18 IG); weeks 69–72 n = 34 (16 CG, 18 IG).

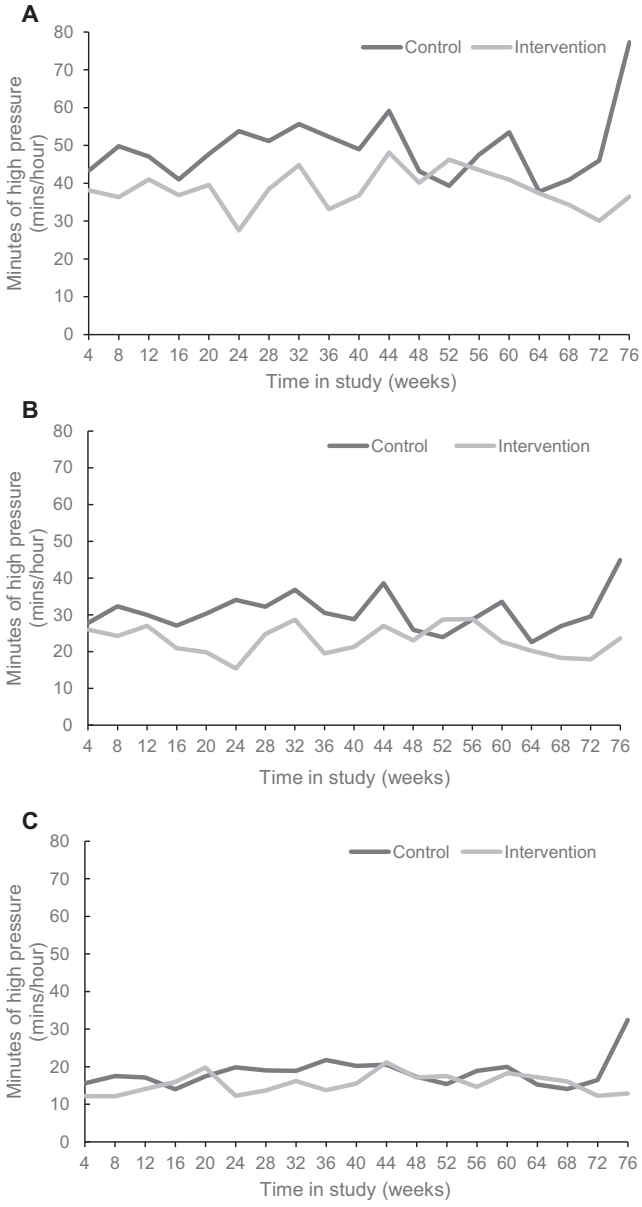

Fig. 3 – Average minutes of sustained high pressure per hour of wear at the (A) Whole foot, (B) Forefoot sensors and (C) Rearfoot sensors, comparing the IG, who were alerted when in a high-pressure state, to the CG who did not receive any pressure-feedback. Averages were calculated every 4 weeks, see results for 95% CI as an indication of variation. N.B For each region, the sum of the corresponding sensors was used; therefore, it is possible for a total reading above 60 min/hour, as all sensors could in theory read high pressure at the same time. Due to withdrawals and in-study DFUs throughout the follow-up period, the number of patients reduced over time, the number of feet every third 4-week period were as follows: weeks 9–12 n = 84 (36 CG, 48 IG);weeks 21–24 n = 74 (32 CG, 42 IG), weeks 33–36 n = 60 (26 CG, 34 IG); weeks 45–48 n = 52 (22 CG, 30 IG); weeks 57–60 n = 36 (18 CG, 18 IG); weeks 69–72 n = 34 (16 CG, 18 IG).

When analysing the whole foot (Fig. 3), the number of bouts of sustained high pressure (group of continuous high-pressure readings, alerting the IG) were similar for IG and CG during the first 16 weeks of the study. However, after 16 weeks of wearing the intelligent insole system, the number of bouts of high-pressure became significantly lower for the IG compared to CG and remained lower for the duration of the study. This suggests a learning response in the IG, where during the first 16 weeks of receiving continuous high-pressure feedback, the IG began to learn which activities/foot positions resulted in high-pressure alerts and were able to pre-empt and largely avoid these bouts of high pressure from this point and for the remaining duration of the study. Similar results were recorded when the forefoot and rearfoot pressures were examined separately. The forefoot, where most DFUs occur[22], had a shorter learning response, with the number of bouts remaining lower for the IG following just 12 weeks of wear, whereas the rearfoot, showed a positive learning response following 20 weeks of receiving pressure-feedback.

Events triggering high-pressure alerts were likely to have been specific to each individual. However, commonly patient-reported events included; driving or standing still for prolonged periods, sitting down with feet in a fixed position e.g. tucked under a chair, with actually very few reports of alerts during walking[15]. Despite the significantly reduced bouts of high-pressure in the IG, from week to week the number of high-pressure bouts fluctuated and did not necessarily show a continual decrease over time (Fig. 2). Nevertheless, the average number of high-pressure bouts for the whole foot reached its peak at the 12th week whilst IG patients were still 'learning' from feedback, and although results did fluctuate, the average number of bouts remained below this level for the duration of the follow-up. In contrast, the CG recorded the highest number of bouts at the final 4-week period (week 76), indicating a different pattern where plantar pressures continued to rise in the absence of any intervention. The fluctuations in the data evident in both groups are highly likely to be the result of recording such large volumes of pressure continuously over a very long period, during which patient's activity levels and pressure would be expected to vary, in addition to the gradual decline in the number of patients remaining in the study. However, despite the variation, a positive effect from receiving high-pressure feedback is still evident when looking at changes over the 18-month follow-up period.

Although the CG generally experienced more high pressure for all parameters, the bout duration and number of minutes of high pressure failed to yield any significant differences and results again did fluctuate. Nevertheless, any small differences should be considered potentially important as they have the potential to accumulate to larger differences over time, which could be clinically meaningful in terms of DFU prevention. As the intelligent insole system used in the current study involves a unique method of measuring pressure continuously, it is unknown how much of a reduction in high pressure could result in a positive DFU prevention response. This trial has recently reported a 71% reduction in DFU incidence to the IG, therefore this present study provides evidence of the underpinning mechanism enabling the reduction in DFU occurrence, which we suggest relates to a reduction in plantar pressure, specifically the number of high-pressure bouts[15].

The current study is unique compared to previous laboratory-based studies providing pressure feedback to patients with diabetes, as feedback here was provided continuously throughout daily activities over a prolonged period (18 months). Previous research has provided visual pressure-feedback on walking only, following standardised trials inside a laboratory, mostly on a single occasion[10,11]. Such conditions are more controllable and therefore more likely to produce less variable results with perhaps more notable differences; however, it is not fully clear how applicable such results are to plantar pressure experienced throughout daily life. Whilst significant reductions in plantar pressure were reported in studies with relatively low-risk diabetes patients using pressure-feedback, no significant reductions were reported in a high-risk cohort[9]. These findings suggest continuous, personalised feedback may be favourable for diabetes patients at a higher risk of DFU, such as those included in the present study. Furthermore, previous studies identified a single at-risk area and provided feedback specific to that area only. As identified in previous literature, focusing on only one at-risk area has the potential to overlook the development of other at-risk areas due to a shift in pressure distribution[9,11,12]. However, if such studies were to provide feedback on more than one at-risk area, this would have perhaps overloaded the patients due to the feedback methodology used. The intelligent insole system used in this study allows the patient to continually receive feedback from eight sensors positioned across the whole plantar surface of the foot, via the watch display's foot-map and audio-vibrational alerts (Fig. 1). The nature of the feedback provided is arguably easier and quicker to process than looking at a target range on a figure on a computer screen, therefore prevents patients from being overloaded with information. Furthermore, the device used in this study, measures plantar pressure and provides high-pressure feedback throughout all daily activities; therefore, it has the potential to reduce accumulated plantar pressures in activities such as standing and sitting as well as walking, potentially preventing more DFUs, than feedback provided on walking alone. To the authors' knowledge, no previous research exists measuring plantar pressure of patients with diabetes whilst completing other daily activities, with previous laboratory-based studies limited to walking.

The insole system used in this study had a 8 Hz sampling rate, considerably lower than pressure analysis in previous studies, where the minimum rate is often 50 Hz[9,11]. However, rather than this being a limitation, 8 Hz is believed to be adequate for recording an accumulation of high plantar pressure over time, in addition to being a compromise for the amount of data stored over the prolonged period. Unlike the present study, most studies measuring diabetic plantar pressure analyse peak pressure. Although the difference in pressure parameters limits how much we can compare the current study's findings to previous results, an accumulation of high, but not peak pressure, represents a risk for DFU development[19].

The current study was limited by high withdrawal rates both pre- and post-randomisation. However, due to the

nature of the study we were able to include data from withdrawals post-randomisation in the analysis up until the point of withdrawal. In addition, the follow-up period was similar for IG and CG and statistical analyses were not affected by a continual reduction in patient numbers over the follow-up; nevertheless, this likely contributed to high variation within the data. Anecdotal reports indicated possible reasons for withdrawal included difficulty in using the touchscreen and intelligent technology. In addition, the high-risk nature of the patients meant that many had comorbidities and so participation in this study for some meant too many appointments, resulting in withdrawal. Further reasons for withdrawal included reluctance to wearing only laced or Velcro shoes and custom-made footwear not being suitable for intelligent insole placement. Future updates to the insole system, or new interventions, can utilise this anecdotal feedback on withdrawals to improve adherence.

The current study was part of a randomised controlled trial with the primary outcome being DFU incidence. Therefore, the study sample size calculation was primarily designed to investigate differences in ulcer incidence between groups, rather than plantar pressure changes, which carries the risk of the present study being underpowered. However, due to the lack of previous research assessing plantar pressure in the same way as the current study and over such a long follow-up period, there was no available comparable data and an accurate sample size calculation was therefore difficult to determine. Although some plantar pressure parameters were non-significant and could have been under-powered, there was a significant difference for the interaction effect of the number of bouts of high pressure, indicating adequate statistical power for this parameter.

Despite randomisation to groups, the IG was significantly younger than the CG, however, it is unlikely this has influenced the differences in plantar pressure shown between groups. There is little evidence for the effect of age *per se* on plantar pressures in diabetes, therefore, it is unlikely that the younger age of IG contributed to fewer high-pressure bouts recorded over time. Plantar pressure for this cohort is more likely to have been influenced by factors such as BMI, ulcer history, foot deformity, DPN and duration of diabetes for which IG and CG were similar.

In summary, continuous pressure feedback over 18-months via an intelligent insole system reduced high plantar pressure in high-risk diabetes patients, by inducing a learning response. The learning response was identified as early as the 12th week of wear, with the positive reduction in pressure remaining for the duration of the 18-month study. This unique insole system was able to provide feedback throughout daily activities (not confined to laboratory) and the resultant pressure reduction is assumed to be the mechanism for reduced DFU incidence.

CRediT authorship contribution statement

Caroline A. Abbott: Methodology, Project administration, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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