Abstract

High plantar pressure as a result of diabetic peripheral neuropathy is often reported as a major risk factor for ulceration. However, previous studies are confined to laboratories with equipment limited by cables, reducing the validity of measurements to daily-life. The participant concerned in this case report was wearing an innovative plantar pressure feedback system as part of a wider study. The system allows for continuous plantar pressure monitoring and provides feedback throughout all activities of daily living. The participant concerned was a 59-year-old male with type 2 diabetes who presented with severe peripheral neuropathy. In addition, the right ankle had previously undergone fusion. Between monthly study appointments, the participant unknowingly had a screw embedded in his right shoe, whilst pressure was being recorded. Although no significant differences in pressure were present for the right foot with the embedded screw, the contralateral foot showed significantly higher pressure when the screw was embedded, compared to pre and post time-periods. The increase in pressure on the contralateral foot is expected to result from the protrusion of the screw in the right shoe, causing a perturbation to balance and a shift in the centre of pressure towards the contralateral side. This compensatory effect is likely to have been magnified by the limited mobility of the fused right ankle. These findings highlight the importance of checking both feet for ulcer risk, in the event of receiving high-pressure feedback. This innovative technology may improve our understanding of diabetic plantar foot ulcer development.

Loss of sensation due to diabetic peripheral neuropathy plays a major role in the multi-factorial pathway leading to the development of high plantar pressure and represents a major risk factor for ulceration [1,2]. Although previous studies have been able to quantify plantar pressures in diabetes patients, these studies are confined to walking in the laboratory, with participants tethered to cables, limiting the validity of measurements to daily-life [3,4,5,6]. The participant concerned in this case report is part of a wider study in which participants with diabetic neuropathy wear a plantar pressure feedback system (SurroSense Rx, Orpyx Medical Technologies, Canada). The system requires participants to wear a pair of pressure-sensing inserts within their footwear, throughout day-to-day life. The insert version used, records plantar pressure at eight sensor locations at a sampling rate of 8Hz. Participants receive high-pressure alerts from a smartwatch, to notify them and encourage offloading. To our knowledge, this is the first system that records plantar pressure and provides continuous pressure feedback throughout daily life. Furthermore, previous research has been limited to quantifying plantar pressures during walking, whereas the system used in the present case report allows pressure assessment of all activities of daily living (standing, sitting et cetera), thus giving a more comprehensive pressure analysis [7,8]. The system aims to prevent plantar ulcerations in people with diabetic peripheral neuropathy, through the provision of pressure feedback. Initial work exists looking at the adherence of this device and the effects of plantar pressure feedback in people with diabetic peripheral neuropathy [9].

In this case study, we report a particularly unique and interesting case where a participant accidently and unknowingly had a screw through his shoe, whilst pressure was being recorded.

Methods

Participant information

The study gained approval from Health Research Authority, National Research Ethics Service Committee North West - Greater Manchester East (approval number: 13/NW/0649). The participant, who provided written informed consent, was a 59-year-old Caucasian male who had type 2 diabetes for five years. He was insensate to 50 Volts during the vibration perception threshold test using a Biothesiometer (Medical Instruments, Newbury, OH, USA) and had a modified neuropathy disability score of 7 (maximum of 10), therefore, indicating severe peripheral neuropathy [10]. The participant had a history of plantar ulceration, but was ulcer-free at the time of study entry. In addition, the participant's right ankle was fused and small muscle wasting existed on both feet, however, no other foot deformities were present.

Case report

The participant was being seen on a monthly basis as part of the larger study. On one particular visit, he reported that since his previous visit he had unknowingly stepped on a screw, which had remained embedded in his right shoe for up to approximately 4 weeks. Although retrospectively the participant reflected receiving a greater number of high pressure alerts during this period, he only realised he had a screw embedded in his shoe by chance when his shoe rolled over after removing, revealing the bottom of the shoe and the embedded screw. The participant removed the screw from his shoe at this point. On inspection at his following podiatric appointment, the screw had resulted in a small superficial puncture wound at the right, lateral mid-foot region. The study visit followed two days later, at this point the wound was visible but healed. In addition, the experimenters discovered the screw had also pierced through the right pressure insert. The pressure-sensing insert sits between the sole of the shoe and the participant's own insole. On inspection, the screw had not pierced directly through a sensor site, but the material in between the lateral mid-foot sensors. The sensors continued to function normally and so the participant continued to wear the insert following the study visit.

Data analysis

Both pre- and post-screw time periods represent 10 days of data collection before and immediately after the screw was embedded (Fig. 1). A similar period during which the screw was thought to be embedded ('during' period Fig. 1), was selected between known appointments when the screw was absent.

Pressure data was categorical, with occurrences of high pressure being the primary focus of this case study. The systems' definition of high pressure was based on pressure-time integral data exceeding plantar tissue capillary perfusion pressure, reported as ~35 mmHg [11]. Categorisation of pressure was completed every minute of wear for each sensor and data was processed through MATLAB.

A three-way ANOVA was conducted on hours of wear data. Whereas, statistical analysis of the high-pressure measurements took the form of a multi-variate ANOVA, with hours of wear as a covariate. When appropriate, a post-hoc with Bonferroni correction was applied and data were considered significant if $p \leq 0.05$.

Results

There were no significant differences in the hours of wear for the device between the three time periods: pre, during and post-screw event (Fig. 1).

Despite the embedded screw, no significant differences were evident in the pressure analysis for the right insert. However, the total minutes of high pressure per hour for the left insert significantly

increased ($p<0.001$) during the screw event, compared to both pre and post time-periods (Fig. 2a). The number of bouts of high pressure per hour (defined in Fig. 3) also showed a significant increase in the left foot ($p<0.001$), during the time the screw was embedded in the shoe (Fig. 2b).

Discussion

In this case study, we captured the effects of a foreign object penetrating the sole of the shoe of a person with severe diabetic neuropathy. Although the object was removed before sufficient trauma leading to neuropathic ulceration could occur, plantar pressures increased concurrently on the contralateral foot, increasing the risk of contralateral ulceration during this period.

Using an innovative plantar pressure feedback system, we were able to describe its effect on plantar pressures in both feet. A screw had penetrated through the participant's right shoe and was estimated to be in situ for just under 4 weeks. Although no changes in high pressure were evident for this right foot (where the screw was embedded), the pressure on the left foot increased over this ~4-week period compared to periods before and after the 'screw event' (Fig. 2a,b).

The presence of severe diabetic peripheral neuropathy meant that the participant could not have felt the embedded screw. The increase in pressure on the contralateral foot is expected to have resulted from the protrusion of the screw causing a perturbation to balance and shifting the body's centre of mass and therefore the centre of pressure towards the contralateral side. With this innovative device, these findings may highlight the importance of checking both feet for increased risk of foot ulceration in the event of receiving high-pressure feedback from the device. Indeed, our data match the participant's reports of an unusually high number of high-pressure alerts that he received to his watch during this period.

The participant's right ankle had previously undergone fusion, which as studies suggest, will have resulted in a decrease in ankle joint range of motion [12]. In addition, previous research identified the contralateral, un-operated foot to have an overall increase in plantar pressure compared to both the operated and control feet [13]. Such results provide evidence of bilateral asymmetry and compensatory gait, in response to ankle fusion and particularly of the inability to accommodate and adapt to a perturbation to gait. A reduction in ankle mobility is also a common contributory factor along with diabetic peripheral neuropathy, for increased plantar pressure and risk of ulceration in the diabetes cohort [14]. However, there is limited research on gait analysis of participants with both ankle fusion and peripheral neuropathy due to diabetes. Furthermore, no research exists on the effects of a screw in a shoe.

Bilateral asymmetry is evident in the case study participant, with pressure variables consistently higher for the left insert (Fig. 2a,b). The asymmetry appears to increase during the period when the screw is in the shoe. The screw embedded in the lateral mid-foot area, likely resulted in a small mechanical perturbation and tendency to evert the right foot. The limited mobility in the right fused ankle may have restricted such movement, resulting in a greater effect of the perturbation in causing a compensatory shift in the centre of pressure observed as increased pressure in the contralateral foot.

As stated in section 1, the plantar pressure feedback system (SurroSense Rx, Orpyx Medical Technologies, Canada) is the first of its kind, allowing for continual pressure analysis and feedback throughout daily-life. The system was designed to provide a high pressure alert when pressure exceeded capillary perfusion pressure. Alerting sensitivity is a crucial factor in avoiding over- or under alerting, which would affect adherence and device efficacy, respectively. The system was designed to take into account pressure-time integrals, rather than peak pressures that would be more reactive and perhaps too sensitive. Previous studies have been limited to pressure assessment within a laboratory, reducing the validity to activities of daily living [3,4,5,6]. Further analysis of daily-life plantar pressure in participants with diabetes will improve our understanding of ulcer development.

Due to no significant differences identified between the individual sites across the right insert and for the purpose of the case study, individual sensors sites were grouped for the whole foot. An unavoidable limitation is the exact duration of the screw in the shoe is unknown, due to the participant being unaware of its presence. The 'during' time period is estimated based on the participant's known podiatry and study appointment dates, where the screw was not in-shoe, of which there were 15 days of data collection.

This case study provides an interesting insight into biomechanical alterations due to a foreign object in the shoe of a diabetes participant with peripheral neuropathy and ankle fusion. The unknown presence of the screw resulted in significant increases in plantar pressure to the contralateral foot, thus increasing its risk of ulceration.

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The Authors declare that there is no conflict of interest

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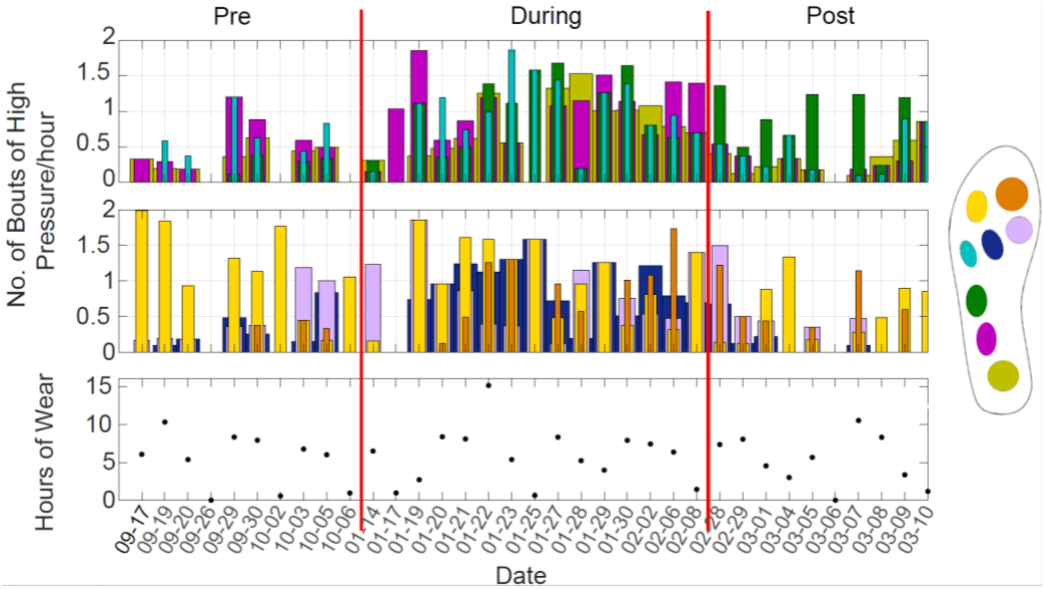
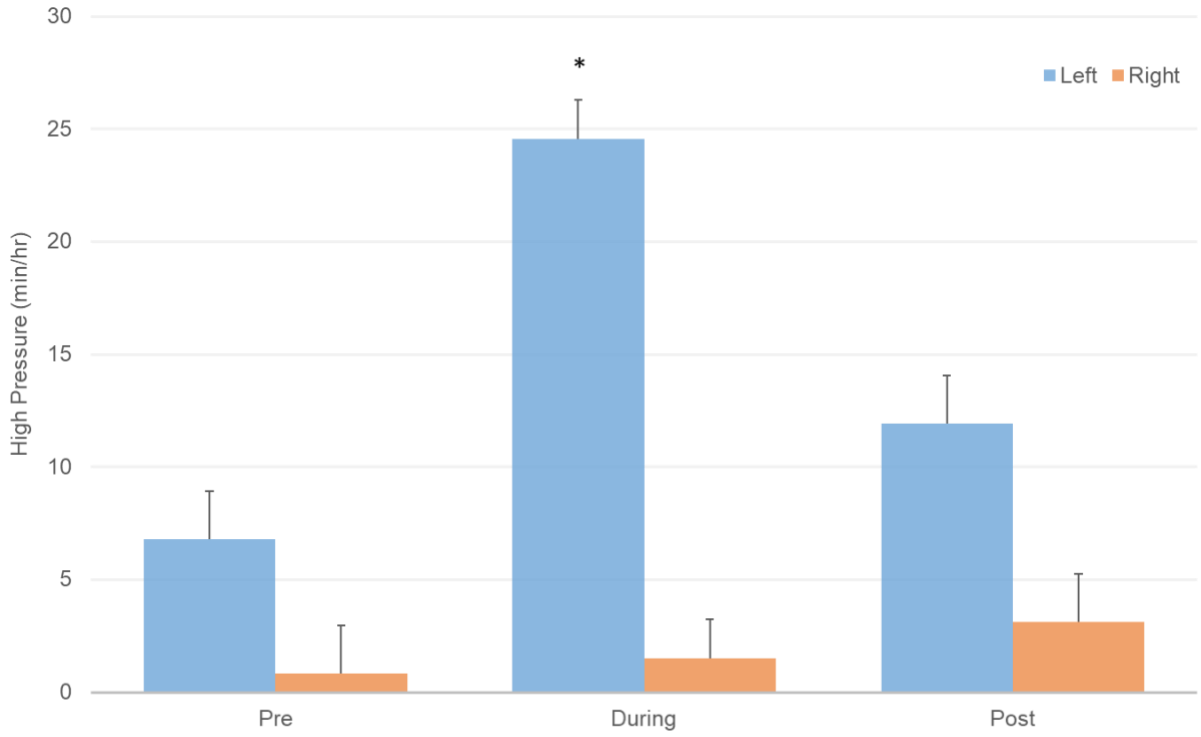


Figure 1. Number of bouts of high pressure for individual sensor locations (the different coloured bars correspond to the sensor locations on the insert diagram) on the left foot (top two panels) and hours of wear (bottom panel). Calendar dates are shown on the x-axis and vertical lines are used to delineate the pre (left), during (middle) and post (right) time periods.

(a)



(b)

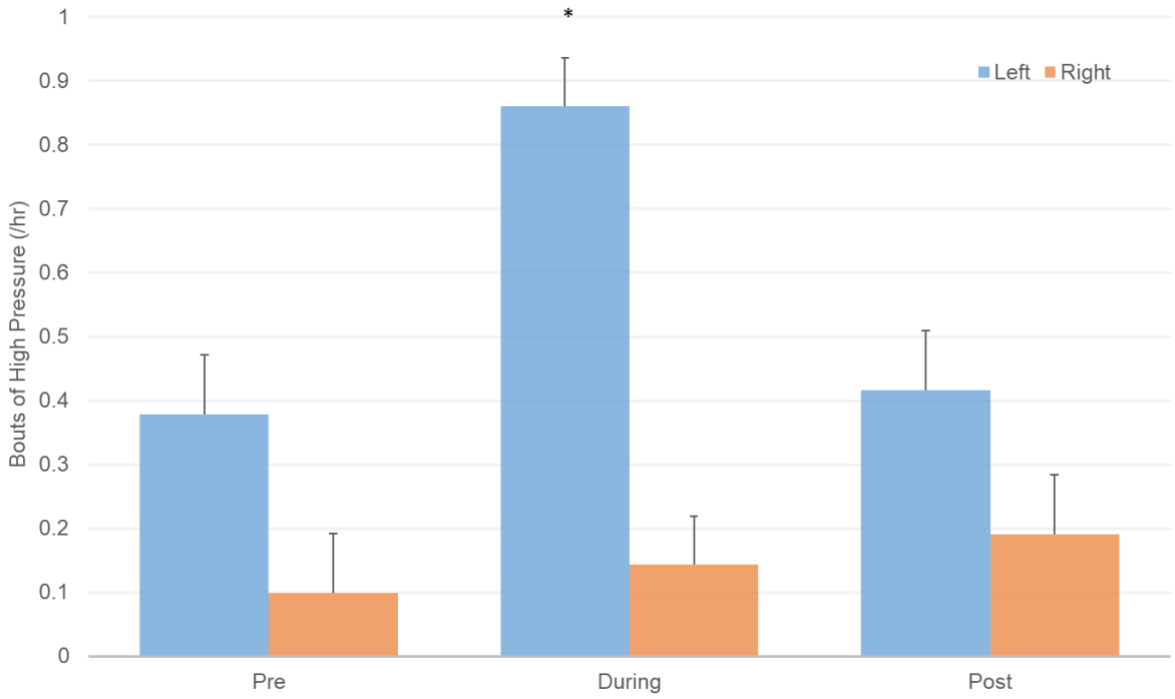


Figure 2. (**a**) Total minutes of high pressure per hour and (**b**) bouts of high pressure per hour, for left and right feet pre-, during and post-screw event. Data show means and standard errors for each period of time (pre / during / post). * denotes a significant ($p \leq 0.05$) difference compared to pre and post-screw periods for the left foot.

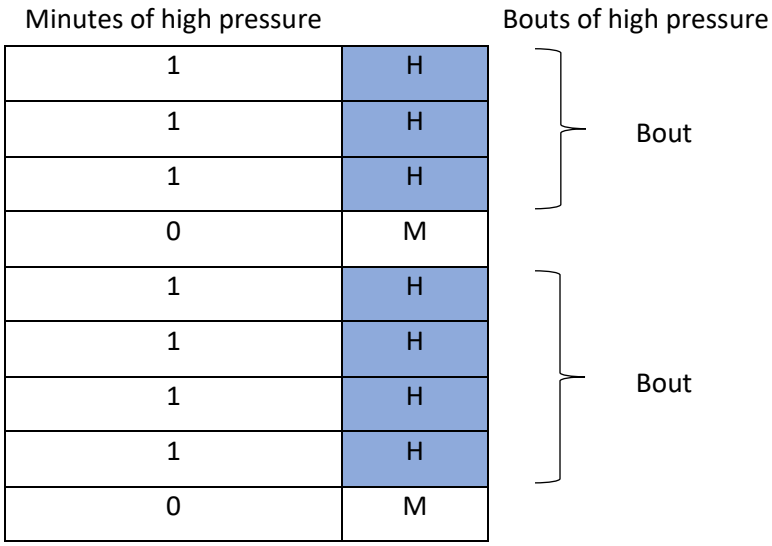


Figure 3. A schematic diagram to illustrate the definition of bouts of high pressure (H) and minutes of high pressure (M = medium).