A feasibility study to assess use of a pressure mat to obtain diabetes plantar foot pressure measurements in individuals with low risk of foot complications

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Key words
- Diabetes
- Pressure mat
- Plantar Pressure
- Screening

Article points
1. Diabetes foot pathologies are associated with raised plantar pressures and increased plantar pressure contributes to foot ulceration, which can lead to amputation and increased mortality. Identification of raised plantar pressure in diabetes facilities individualised intervention and prevention of ulceration.
2. A portable pressure mat can be used in a routine clinic setting to aid diabetes barefoot plantar pressure screening. Barefoot plantar pressures in individuals with diabetes and low-risk foot scores are comparable to those of individuals without diabetes.
3. Integration of longitudinal foot pressure measurement to diabetes foot screening programmes has the potential for identification of pressure thresholds that enable earlier intervention and prevention.

Author
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Background: Foot problems related to diabetes are associated with significant morbidity and mortality and are costly to the health service. Studies suggest that increased plantar pressure is a risk factor for ulceration in susceptible individuals. This feasibility study explored the use of a pressure sensing mat in a clinic setting to identify any patterns that could indicate early risk of foot disease in a diabetes cohort with designated low foot risk. Methods: Static and dynamic pressure measurements were obtained from 54 individuals (27 with, and 27 without diabetes) using a footscan® pressure sensing mat (Gait and Motion Technology Ltd.). Bare foot mid-stride dynamic foot pressure measurements were obtained. Maximum pressure was recorded for 10 anatomical regions of the foot. Results: Left medial heel, left lateral heel and right medial heel measurements in the diabetes group during walking were significantly lower than those in the control group (left medial heel: median 23.2, vs 28.8, *P*<0.006; left lateral heel: median 21.4, vs 25.1, *P*<0.021; right medial heel: median 22.8, vs 28.7), *s*< 0.017. This related to lower pressures in females compared to females without diabetes at these sites. Conclusions: A pressure sensing mat is a portable, simple and time-efficient method to obtain plantar pressure measurements in a clinic setting. The reasons for lower heel pressure values in the diabetes population are unclear although pressure measurements remained in the acceptable range across all areas assessed. More research is required into whether longitudinal plantar pressure measurements could be utilised in routine foot screening in predicting and preventing foot ulceration in diabetes.

Diabetes is a common chronic medical condition which is associated with significant morbidity and mortality. The prevalence of diabetes is increasing and by 2045, it is estimated that globally around 783 million people will have a diagnosis of diabetes (International Diabetes Federation [IDF], 2021). The 2020 Scottish Diabetes Survey reported that 5.8% of the population was recorded as having a diagnosis of diabetes. Some 87.7% of these people had type 2 diabetes and 10.7% had type 1 (NHS Scotland, 2022). The local NHS health board had 19,431 people on the diabetes register at the end of 2020. The crude prevalence of diabetes in this region has increased from 5.3% to 6.0% within 4 years (NHS Scotland, 2022).

People with diabetes are at increased risk of foot complications due to peripheral neuropathy and/or peripheral arterial disease (NICE, 2015). Lower-limb ulcers often precede infection and amputation and up to 17% of infected foot ulcers will require an amputation (Armstrong et al, 2020). Furthermore, it has been recognised that a diabetes foot ulcer and a lower-extremity amputation are independent risk factors for premature death (Kerr et al, 2019).

Averages of 7.9% of people with type 1 diabetes and 3.9% of those with type 2 in Scotland has a record of having had a foot ulcer (NHS Scotland, 2022).

Management of foot problems related to diabetes presents significant financial cost to the NHS through primary and community care, outpatient costs, inpatient bed occupancy and prolonged hospital stays. It has been estimated that upward of £800 million is spent by the NHS in England (Health and Social Care Information Centre, 2016), equating to about £80 million in Scotland, on foot ulcers and amputations per year.

To detect problems early and prevent foot ulceration, foot care screening programmes for people with diabetes are common practice. It is recommended that people are screened at diagnosis and annually thereafter by examining for neuropathy using a 10g monofilament, peripheral pulses and observing for ulceration, callus, or deformity (IDF, 2021). A person is then assigned a low, moderate, high or active risk category allowing referral of appropriate people for multidisciplinary foot care or protection (IDF, 2021).

Rationale for current study

Recommendations around foot screening exist: But there is considerable variation in practice (Dros et al, 2009). Systematic reviews have shown problems with monofilament testing, reporting limited sensitivity due to variability in number of anatomical foot sites tested (Deschamps et al, 2013).

Elevated plantar pressure measurements in susceptible individuals while walking have been increasingly recognised as a risk factor for foot ulceration. This may be due to alterations in gait in combination with bio-mechanical changes of soft tissues. Early research on the neuropathic foot in leprosy in the 1960s, reported increased barefoot pressure in neuropathic feet (Slim et al, 2012). Since then, studies using emerging technologies have shown that dynamic plantar pressures are generally higher at the ulcer or previous ulcer location in people with diabetes; but a pressure threshold that predicts foot ulceration has not yet been identified (Bus, 2016).

A systematic review explored the role of high plantar pressures in the prediction and prevention of foot disease in diabetes. Studies using pressure sensing platforms showed that people with diabetes had higher plantar pressures than those without, particularly within those with a history of diabetic foot ulceration (Chatwin et al, 2020). Furthermore, a 30-month prospective study reported that measuring dynamic forefoot peak pressure was able to accurately predict foot ulceration in people with diabetes (Caselli et al, 2002). Potentially, foot pressure measurements could act as a more accurate, standardised screening method for foot complications in diabetes and utilised in the production of individualised offloading insoles or footwear aiming to prevent ulcer development.

Materials and methods

A study of healthy people with no foot problems showed that using the footscan platform to measure plantar pressure is reliable and repeatable and it is, therefore, possible to use it in assessment of plantar pressure distribution (Xu et al, 2017). This device produces pressure measurements which can be viewed on a laptop with the potential to link up with existing diabetes databases. This feasibility study aimed to explore whether the footscan device could be used by a single operator in a clinic setting to measure plantar pressures measurements of people with diabetes to detect if there was a difference in pattern of pressures measurements compared with people without diabetes that might indicate early risk of diabetes foot disease.

Participants

A total of 54 participants were recruited. The sample consisted of 27 people with diabetes attending the routine hospital outpatient diabetes clinics and 27 people without diabetes for comparison, including individuals recruited from an outpatient clinic to age match the diabetes group and younger individuals with no health problems. People with diabetes self-reported low risk for diabetes foot problems and any individuals from either group unable to walk unaided, with lower-limb amputations, previous or current foot ulcers, injuries or operations were excluded.

The study was undertaken in compliance with the Helsinki agreement and related principles.

Study procedures

Plantar pressures measurements

A footscan pressure mat was utilised for assessing plantar pressure measurements. This was a 1,048mm x 418mm x 12mm platform with 8,192

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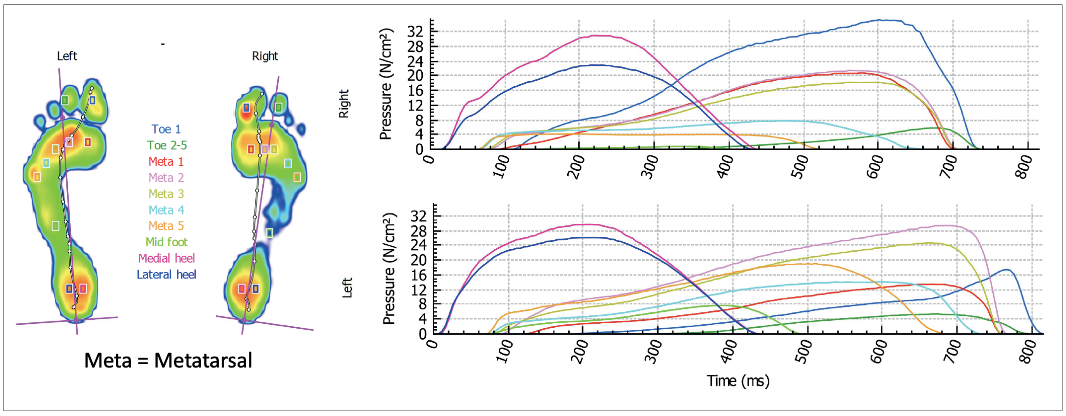


Figure 1. *Study sample patient data demonstrating 10 anatomical regions of foot assessed with associated graphic display of colour coded pressure ranges for each area.*

sensors designed to be placed on the floor to provide static or dynamic plantar pressure data as the person stands on or walks across the plate. The footscan software produces a colour map of average pressure distribution (N/cm^2) for 10 anatomical regions of each foot, represented by coloured boxes as well as a graphic display of pressure curves at each site (*Figure 1*).

The participant stood in the centre of the footscan® platform without shoes to record the static pressure measurement. This position was maintained for a further 20 seconds to assess balance. They then walked across the platform in a series of standardised walks to obtain dynamic recordings of each foot. This approach was used to allow data collection mid stride, rather than during the acceleration or deceleration in the early and late phases of walking. This was repeated three times, with the option of sitting down for 1 minute between walks if required. As per the manufacturer's manual, the footscan system was calibrated prior to each measurement. The platform was cleaned with hard surface wipes in between each participant. Participation took 15 to 30 minutes.

Data recording and storage

Pressure data were recorded and saved on the footscan computer software in anonymised personal folders for each participant. The maximum pressure was recorded for 10 anatomical regions of the foot, outlined in *Figure 1*.

Statistical Analysis

Descriptive analyses were performed using SPSS software (IBM SPSS Statistics 25). Results are presented as median and interquartile range on the population data. To assess correlations in the plantar pressure data, Pearson correlations were calculated. Independent samples tests allowed comparison of the medians of the plantar pressure data. The significance level was set at 0.05.

Results

Participant characteristics

Of the individuals with diabetes there were 17 with type 1, 7 with type 2 and 3 classified as another type). The group with diabetes was significantly older, with a mean age 55.4 ± 14.8 years and BMI 27.8 ± 5.7 kg/m^2 compared with control group, 36.7 ± 14.8 years (P< 0.001), and BMI 26.5 ± 4.1 kg/m^2 (P=0.325)(*Table 1*). For the participants with diabetes, the mean duration of diabetes was 17.4 ± 13.3 years and mean HbA_{1c} was 65 ± 11.8 mmol/mol.

Plantar pressure results

There was no discernible correlation between plantar pressure measurements and age, height or BMI within any groups of the total study population.

Compared with the whole control group, left medial heel (LHM), left lateral heel (LHL) and right medial heel (RHM) measurements in the diabetes group during walking were significantly lower (LHM: median 23.2, IQR 11.1 vs median 28.8, IQR 9.0, P<0.006; LHL: median 21.4, IQR 7.8 vs median 25.1, IQR 7.82, P<0.021; RHM: median 22.8, IQR 8.7 vs median 28.7, IQR 2.6), P<0.017. Results for right and left medial heel pressure and right and left first metatarsal head pressure (RM1 and LM1) in the diabetes and non-

Table 2. Switching from gabapentin to pregabalin.

	Diabetes whole group	Non-diabetes whole group	Significance
Age (years)	55.4 ± 14.8	36.7 ±14.7	*P*<0.001
BMI (kg/m²)	27.8 ± 5.7	26.5 ± 4.1	NS
HbA_{1c} (mmol/mol)	65.0 ± 11.8	-	-
Duration of diabetes (years)	17.4 ± 13.3	-	-
	Diabetes males	**Non-diabetes males**	
Age (years)	51.0 ±13.0	37.0 ± 17.0	*P*=0.020
BMI (kg/m²)	28.3 ± 5.7	25.6 ± 3.2	NS
HbA_{1c} (mmol/mol)	65.2 ± 12.2	-	-
Duration of diabetes (years)	15.6 ± 14.2	-	-
	Diabetes females	**Non-diabetes females**	
AGE (years)	61.7 ± 15.6	36.5 ± 13.3	*P*<0.001
BMI (kg/m²)	27.0 ± 5.9	27.2 ± 4.7	NS
HbA_{1c} (mmol/mol)	64.7 ± 11.9	-	-
Duration of diabetes (years)	20.0 ± 11.8	-	-

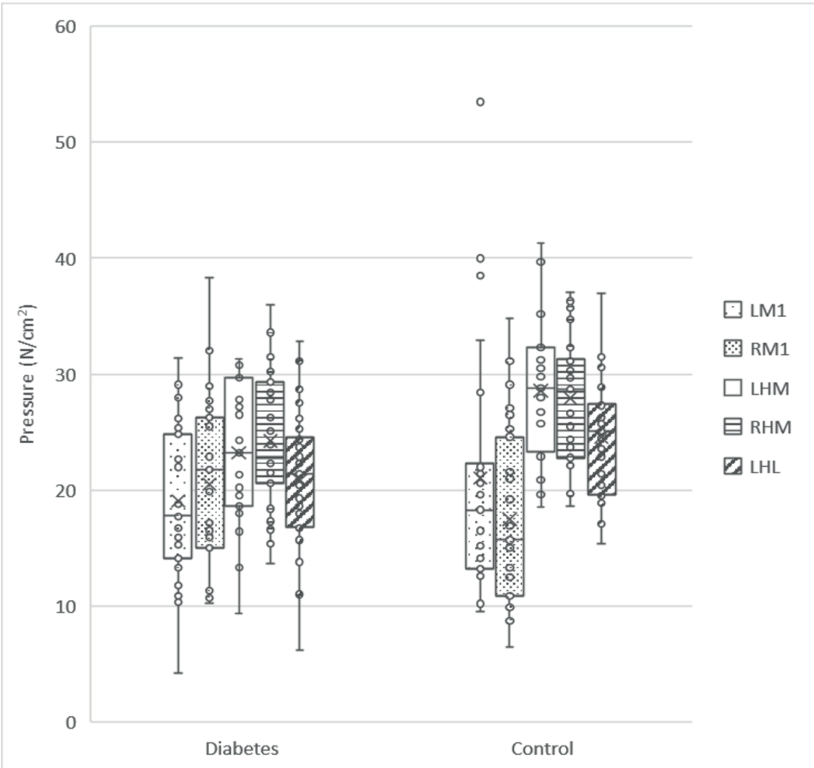
NS = Not significant

diabetes (control) groups are shown in *Figure 2*. This appeared to be accounted for mainly by lower pressures in females with diabetes compared to females without diabetes. (LHM: median 20.2, IQR 13.3, vs median 30.0, IQR 9.3, *P*<0.018; LHL: median 18.0, IQR 8.5 vs median 22.9, IQR 4.4, *P*<0.045 RHM: median 20.6, IQR 11.7 vs median 28.7, IQR 7.9, *P*<0.004). There was no difference between males and females in either group, and all other measurements were comparable between diabetes and non-diabetes individuals.

Discussion

This study aimed to assess the feasibility of this system being used in a diabetes clinic setting for measuring plantar pressure as an additional screening tool to help in the prediction of diabetic foot disease. The footscan platform system has previously been shown to accurately test plantar pressure and is being used more frequently in research and clinical practice (Xu et al, 2017). In other studies, it has been shown to help distinguish between normal and pathological gait (Chang et al, 2012), in the design of orthoses (Hähni et al, 2016) and in predicting risk of lower-limb injuries (Franklyn-Miller et al, 2014).

Our analysis has shown only one significant



Median and Interquartile range
LM1 = Left First Metatarsal Head; RM1 = Right First Metatarsal head; RHM = Right Medial Heel; LHM = Left Medial Heel; LHL= Left Lateral Heel

Figure 2. *Median and range for right and left metatarsal head, right and left medial heal and left lateral heel pressures in individuals with diabetes and those without (Control). LM1 = Left First Metatarsal Head; RM1 = Right First Metatarsal head; RHM = Right Medial Heel; LHM = Left Medial Heel; LHL= Left Lateral Heel*

difference between the plantar pressures measured in people with diabetes and low foot risk and those without diabetes, namely in the medial heel area. The reasons for the lower heel pressure values in the diabetes population are unclear. Bio-mechanical changes in gait related to alterations in anatomical structures and musculoskeletal function over time are well described in diabetes (Labovitz and Day, 2020) and structural changes associated with Achilles tendinopathy which could be hypothesised to reduce heel pressure have been demonstrated in women with diabetes (Papanas et al, 2019), however, there was no evidence that lower pressures in the heel area were associated with increased pressure on any other plantar area.

A further study has confirmed increased barefoot peak pressures in people with diabetes and two or more associated biomechanical pathologies (Chuter et al, 2021) as may be anticipated but there is limited data to date, relating to people with diabetes and low foot risk scores when utilising pressure mats for foot pressure screening in routine clinical settings. It is important to acknowledge that foot pressure measurements obtained at all sites within both the diabetes and non-diabetes groups in this study were within the acceptable pressure range as defined by the manufacture across all sites assessed.

Deschamps et al (2016) discussed a plantar pressure-based classification system for people with diabetes: In their retrospective analysis they described the development of foot ulcers in the study group since their initial gait analysis with eight out of eleven of these ulcers developing in a region of the foot with the highest forces (Deschamps et al, 2016). In a move away from defining plantar pressures as normal or abnormal, they describe “clusters” of patients with particular patterns of plantar pressures. Enabling classification of foot risk according to the individual’s bio-mechanical profile in addition to current screening methods, at an early stage would aid in communication, diagnosis, clinical decision making and intervention between the multidisciplinary foot team and people with diabetes (Deschamps et al, 2013).

Plantar pressure data can be used in the production of 3D printed insoles customised to individual patients. In people with symptomatic flatfoot, 3D printed insoles were more effective than prefabricated insoles (Xu et al, 2019). A study by Telfer, et al (2017) showed that in patients with diabetes who were classified as having at risk feet, personalised offloading insoles based on a design derived from shape, pressure and ultrasound data significantly reduced peak pressures compared to insoles based on shape data only (Telfer et al, 2017).

Footwear and offloading techniques are already commonly used once a diabetic foot ulcer is identified to aid healing and to prevent recurrence. A systematic review by Bus et al (2016) identified that evidence for offloading interventions to prevent a first foot ulcer is “practically non-existent”. This is likely due to the lack of current strategies to predict foot ulcers. More research into plantar pressure data is required and could take the form of a longitudinal observational study by measuring trends in plantar pressures over time. It may be possible to detect early changes which could predict areas at risk of ulceration before becoming clinically apparent and allow personalised interventions including lifestyle and customised off-loading to be implemented. More widespread use of the platform in routine clinical settings would also determine reproducibility and significance or impact of any gender differences in specific plantar pressures measurements.

Limitations

The non-diabetes group were younger and had a lower BMI, however, the study results would suggest that this is unlikely to have had any influence on outcomes.

Conclusions

This study has shown that the footscan system provides a portable, simple and time efficient method for measuring plantar pressures in a clinic setting. More research is required into the prospect of utilising longitudinal plantar pressure measurements in predicting and preventing foot ulceration in diabetes. In addition, further studies comparing foot pressures in individuals with moderate and high foot risk would be important in assessing their role in contributing to foot ulcer prediction algorithms. ■

Declaration of Interest: The authors declare no conflict of interest.

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