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A cross sectional pilot study utilising STrain Analysis and Mapping of the Plantar Surface (STAMPS) to measure plantar load characteristics within a healthy population

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ABSTRACT

Background: No in-shoe systems, measuring both components of plantar load (plantar pressure and shear stress) are available for use in patients with diabetes. The STAMPS (STrain Analysis and Mapping of the Plantar Surface) system utilises digital image correlation (DIC) to determine the strain sustained by a deformable insole, providing a more complete understanding of plantar shear load at the foot-surface interface.
Research questions: What is the normal range and pattern of strain at the foot-surface interface within a healthy population as measured by the STAMPS system? Is STAMPS a valid tool to measure the effects of plantar load?
Methods: A cross-sectional study of healthy participants was undertaken. Healthy adults without foot pathology or diabetes were included. Participants walked 20 steps with the STAMPS insole in a standardised shoe. Participants also walked 10 m with the Novel Pedar® plantar pressure measurement insole within the standardised shoe. Both measurements were repeated three times. Outcomes of interest were global and regional values for peak resultant strain (S_{MAG}) and peak plantar pressure (PPP).
Results: In 18 participants, median peak S_{MAG} and PPP were 35.01 % and 410.6kPa respectively. The regions of the hallux and heel sustained the highest S_{MAG} (29.31 % (IQR 24.56–31.39) and 20.50 % (IQR 15.59–24.12) respectively) and PPP (344.8kPa (IQR 268.3 – 452.5) and 279.3kPa (IQR 231.3–302.1) respectively). S_{MAG} was moderately correlated with PPP ($r = 0.65$, $p < 0.001$). Peak S_{MAG} was located at the hallux in 55.6 % of participants, at the 1st metatarsal head (MTH) in 16.7 %, the heel in 16.7 %, toes 3–5 in 11.1 % and the MTH2 in 5.6 %.
Significance: The results demonstrate the STAMPS system is a valid tool to measure plantar strain. Further studies are required to investigate the effects of elevated strain and the relationship with diabetic foot ulcer formation.

1. Introduction

Diabetic foot disease places a significant burden upon patients and healthcare services. Up to one quarter of patients with diabetes will develop a diabetic foot ulcer (DFU) [1]. Following the first DFU presentation, 17 % of patients will undergo a minor amputation within one year, 5 % will undergo a major amputation, rising to 8 % in those with peripheral arterial disease [2]. For those that successfully heal, 40 % will have recurrence within one year, 65 % within five years and 90 % within ten years [1]. The financial cost is significant. Overall, the total cost to health care for DFUs and amputations is estimated at 0.8–0.9 % of the National Health Service's (NHS) total budget, and a reduction in prevalence of DFUs by one third would amount to a saving of in excess of £250 million [3].

Development of a DFU is a complex, multifactorial process. Underpinning this process are neuropathy and foot deformity, leading to pathological foot biomechanics and elevated plantar load. Plantar pressure comprises the vertical component of plantar load, with plantar shear stress acting tangentially to the plantar surface. Peak plantar pressure is elevated in patients with diabetes and is associated with DFU

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formation [4,5]. However, peak plantar pressure alone is a poor predictor of DFU development [5–8]. Plantar shear stress is recognised as a key component of decubitus pressure DFU formation, yet its association with DFU formation is poorly understood [9,10]. A recent systematic review, conducted by the author, identified 16 studies investigating shear stress in patients with diabetes [11] Meta-analysis found patients with a current or previous DFU exhibit elevated levels of shear stress compared with those without ulceration [11]. However, no systems have been developed that measure plantar pressure and shear stress, in-shoe, across the plantar surface.

A wide spectrum of sensing technologies have been trialled, though none have progressed beyond preliminary clinical studies. Given the challenges faced with traditional sensing techniques, we proposed an alternative process for plantar load analysis: the Strain Analysis and Mapping of the Plantar Surface (STAMPS) system. STAMPS comprises a multilaminar, plastically deformable insole combined with Digital Imaging Correlation (DIC) techniques to analyse plantar strain following a period of gait. A post-walking image of the insole is compared with a pre-walking image, and the pattern and magnitude of deformation is calculated using DIC software. The deformation is measured in the x and y axes, and the outcome of most interest is the resultant xy strain (S_{MAG}). The technique has been described previously [12], and experimental testing validated the method to measure the effects of both vertical pressure and tangential shear stress at the foot-surface interface [12]. In the context of an insole, following a period of gait, the magnitude of strain is the cumulative effect of pressure and shear stress at the foot-insole interface. Prior to investigating its use in patients with diabetes and the association between strain and DFU formation, investigating strain patterns in a healthy population is required to establish expected 'normal values'. The aim of this study is to report 'normal' values of strain within a healthy population and to investigate the validity and repeatability of the STAMPS system to measure plantar strain of the applied plantar load.

2. Methods

A cross sectional pilot study of healthy participants was conducted. Participants were recruited from the University of Leeds student and faculty. Ethical approval was obtained from the University of Leeds ethics committee to conduct the study (LTMECH-005), with participants providing written consent prior to assessment. Participants were included who were >18 years of age and capable of walking unaided for 50 m. Exclusion criteria were the presence of diabetes, major or minor lower limb amputation, or significant comorbidities associated with mobility or foot health (as assessed by the clinician conducting the study). Demographic and clinical data including weight and the presence and location of callus. The presence of callus was recorded by the clinician conducting the study and was not debrided prior to the walking assessments.

The development of the STAMPS system has been described previously however the technique will be reviewed here in brief [12]. The STAMPS system comprises a multi-layered, plastically deformable insole, the surface of which is covered with a stochastic speckle pattern. Pre and post walking images are taken with a custom built digital camera platform (Ultra HD IMX317 USB camera, ELP ltd) to obtain 4 K (3840×2160) images. Images are analysed using the DIC software GOM correlate (GOM Metrology Gmbh) before post-processing occurs (MATLAB, Mathworks) using custom-built analysis scripts. The plantar strain data is segmented into 11 regions which emulates that employed in commercial plantar analysis software (Pedar™, Novel GmbH, Munchen, Germany): Heel, medial and lateral midfoot, 1st Metatarsal Head (MTH), 2nd MTH, 3rd MTH, 4th MTH, 5th MTH, hallux, second toe, toes 3–5 [13]. The mask is scaled and rotated to fit the specific plantar data (i.e. to accommodate insole size variance) after which the strain data are allocated into each region. Strain metrics are calculated for each region and the overall plantar space; peak S_{MAG}, peak anterior and posterior strain (S_{ANT}, S_{POST}) and peak medial and lateral strain (S_{MED}, S_{LAT}). Strain is the change in size, or length of an object, relative to its original size following application of force. In this context, strain is measured by comparing small areas (subsets) of the stochastic speckle pattern on the surface of the insole. Therefore the strain metrics described are the percentage change, within the subsets, between the pre and post walking images, in the specified axes.

As optimised in the prior study, the STAMPS insoles were prepared >24 hours prior to use and maintained at a constant 15 degrees Celsius prior to use [12]. Participants shoe size was measured and the appropriately sized supportive neoprene boot (Ninewells Boot, Chaneco) was supplied for use. For consistency, the right shoe was used for each participant. A pre-walking image was taken of the insole, which was inserted into the right shoe of the participant. A similarly sized insole was inserted into the left shoe to prevent a discrepancy in insole depth. Participants were asked to walk 20 steps, along a flat surface, ensuring 10 steps were taken with the right foot at a self-selected normal walking speed. The insole was removed and a post-walking image was taken. This process was repeated three times, a new insole used for each assessment and each assessment timed. Following walking assessments with the STAMP insole, repeat assessments were performed using the Pedar™ (Novel GmbH, Munchen, Germany) in-shoe plantar pressure measurement system. Participants were required to walk along the same, flat surface, a distance of 10 m at their self-selected normal walking speed [14]. This process was repeated three times. Outcomes of interest were overall plantar aspect and regional values for S_{MAG}, S_{ANT}, S_{POST}, S_{MED}, S_{LAT} and peak plantar pressure (PPP).

3. Statistical analysis

Data were analysed using SPSS statistical software version 26 (IBM Corp, Chicago, USA). The peak S_{MAG},S_{ANT}, S_{POST} S_{MED}, S_{LAT}, for each region of interest and the total plantar surface was extracted. PPP for each region and of the total plantar surface were extracted via the multimask application (Novel, GmbH Munchen, Germany), using the previously described mask. The Shapiro-Wilk test was used to test for normality of continuous variables [15]. The Kruksal-Wallis test or ANOVA with the Bonferroni multiple comparisons correction were used as appropriate to compare S_{MAG} and PPP between regions. Pearson's correlation coefficient or Spearman's rho was used as appropriate to assess the relationship between S_{MAG} and PPP. A correlation coefficient of <0.4 is accepted as a weakly correlation, 0.4 – 0.69 a moderate correlation, 0.7 – 0.89 a strong correlation and 0.9 – 1.00 a very strong correlation [16]. A significant relationship was determined if a moderate, statistically significant correlation was present ($r > 0.4$ and $p < 0.05$). To establish repeatability, the coefficients of variation (CV) of PPP and S_{MAG} were calculated for each region, due to significant positive skew, median CV is reported [17].

4. Results

18 healthy participants were recruited and completed the walking assessments, 12 males and 6 females, baseline characteristics are shown in Table 1. The median weight was 70.7 kg (Interquartile range (IQR) 64.2 – 79.9 kg) with a median BMI of 23.8 (IQR 21.6 – 25.1).

The overall median peak S_{MAG} was 35.01 % (IQR 27.91 – 53.81 %), ranging from 17.12 % to 73.24 %. the median PPP was 410.6 kPa (IQR 320.6 – 454.5 kPa), ranging from 235kPa to 529 kPa. Representative S_{MAG} heat maps for a sample of the cohort are shown in Fig. 1. The figures show distinct patterns of strain between individuals. Regions of high strain varied between individuals. Peak S_{MAG} was located at the hallux in 10 (55.6 %) participants, at the MTH1 in 3 (16.7 %), the heel in 3 (16.7 %), toes 3–5 in 2 (11.1 %) and the MTH2 in 1 participant (5.6 %). The region of highest PPP was the hallux in 12 (66.7 %) participants, the 2nd MTH in 2 (11.1 %), the heel in 2 (11.1 %), the 4th and 5th MTHs in 1 (5.6 %) and the hallux and 2nd MTH in 1 (5.56 %) participant. Peak

Table 1
Participant baseline characteristics.

Participant	Gender	Height (cm)	Weight (kg)	Callus	Foot size
P01	M	185	87.0	Hallux callus	11
P02	M	175	82.1	Nil	9
P03	M	193	91.2	Nil	11
P04	M	173	63.4	Nil	9
P05	M	192	81.1	Nil	12
P06	M	184	78.6	Nil	11
P07	M	178	68.5	Hallux callus + 1st MTH callus	9
P08	M	182	70.7	Hallux callus	8
P09	M	172	62.8	Nil	8
P10	M	188	115.8	Callus across MTHs, lateral styloid and heel	11
P11	F	161	67.0	Nil	6
P12	F	158	65.0	Nil	6
P13	F	155	57.4	Nil	5
P14	F	162	56.6	Nil	6
P15	F	162	50.5	Nil	5
P16	M	175	75.0	Nil	10
P17	F	175	67.5	Hallux callus	8
P18	M	173	74.0	1st MTH callus	8
Median		175	70.7		

S_{MAG} and highest PPP occurred within the same regions in 50 % of participants.

The region of peak S_{MAG} was consistent across all trials in 10 of 18 participants, in 5 of 18 the region of peak S_{MAG} was consistent in 2 of three walking trials (Table 2). The median coefficient of variation of S_{MAG} for each participant, compared between the three trials was 23.9 %, the median coefficient of variation of PPP was 14.5 %. The mean coefficient of variation for overall peak plantar strain for each participant, compared between the three walking trials was 17.8 %.

Median regional values with IQR for S_{MAG} and PPP are shown in Table 2. The hallux and heel sustained the highest S_{MAG}, followed by the regions of the 2nd toe and toes 3–5. Across the MTHs, highest S_{MAG} was found at the 1st MTH, reducing moving laterally. The hallux region sustained significantly greater S_{MAG} compared with the 3rd, 4th and 5th MTHs and the medial and lateral midfoot. The heel region sustained significantly elevated S_{MAG} compared with the 3rd MTH and the medial midfoot. In addition, the medial and lateral midfoot sustained significantly lower S_{MAG} than the regions of the 2nd toe, toes 3–5, and 1st and 2nd MTHs (Fig. 2).

The regions of highest PPP were the hallux and heel, followed by the 2nd and 1st MTHs and the 2nd toe. Unlike S_{MAG}, the region of Toes 3–5 were an area of relatively low PPP. The regions of the hallux and heel sustained significantly elevated PPP compared with the 5th MTH, Toes 3–5 and medial and lateral midfoot. The region of the medial midfoot sustained lower PPP than all regions bar the lateral midfoot, 5th MTH and Toes 3–5. The 2nd MTH sustained significantly elevated PPP compared with the region of toes 3–5 (Fig. 3).

Increasing S_{MAG} was moderately associated with increased PPP, Spearman's correlation coefficient 0.65, $p < 0.001$ (Fig. 4). The relationship between PPP and S_{MAG} per region is demonstrated in Fig. 4.

Callus was reported in six patients, in five of the six patients (83.3 %), the region of peak S_{MAG} was within the region of callus. The region of PPP was within the region of callus in three patients (50 %) (Table 1).

No statistically significant relationships were identified between S_{MAG} and PPP and the covariates weight and walking time.

5. Discussion

This study has demonstrated successful application of the STAMPS system. Investigating values within a healthy cohort was the primary outcome of this study. The mean peak S_{MAG} was found to vary significantly within the population, ranging from 17.1 % to 73.24 %. The regions of highest strain were the hallux and heel, followed by the lesser toes and medial metatarsal heads. A similar pattern was found in the distribution of PPP. Significant variation in magnitude and pattern of strain was identified between individuals. Given the strong relationship between strain and PPP, it is likely similar participant characteristics that are known to affect PPP will affect strain. Factors known to influence plantar pressure include foot deformity, gait speed, weight and the presence of callus. In this current study, no association was found between S_{MAG} and either gait speed or weight. Additional insight pertaining to the pattern of strain associated with foot morphology would be gained with the assessment of the foot posture index, though this was not performed in the present study [18]. A further study involving healthy participants is investigating the effect of gait speed upon strain. Further insights into factors influencing strain patterns will be gained when analysing patients with diabetes and foot pathology.

Investigating validity to measure plantar load was a key outcome measure. As described, the STAMPS system measures the resultant effect of both shear stress and plantar pressure at the foot-surface interface. A true measure of validity to assess plantar load would require a comparison with plantar pressure and shear stress, measured using established systems. In the absence of a shear stress system, plantar pressure measurement alone was performed. A moderate correlation was found between peak plantar pressure and S_{MAG} ($r = 0.65$). This suggests the STAMPS system is a valid system to measure the effects of plantar pressure. However, there were regions that exhibited relatively high strain compared with PPP, and others, lower strain than expected. The biomechanical factors causing elevated strain at the lesser toes, compared with the MTHs, despite lower PPP are unclear. High strain, in the presence of low PPP suggests the region may experience elevated shear stress, therefore accounting for the deformation seen. Though, as direct measures of shear stress were not performed this cannot be confirmed. Evidence in the literature neither supports nor refutes this hypothesis as few studies describe the distribution of in-shoe shear stress and pressure across the plantar surface with which to compare the results. Yavuz et al., performed barefoot analysis of the forefoot in a cohort of healthy participants [19]. The central forefoot was the region of highest peak shear stress (61.1 kPa) and PPP (444.3 kPa). The hallux, medial forefoot and lateral forefoot sustained similar levels of peak shear stress (46 kPa, 44 kPa and 46 kPa respectively), whilst the toes experienced the lowest levels (28 kPa) [19]. Lord and Hosein measured in-shoe plantar shear stress and pressure within a healthy cohort. Peak shear stress at the 1st MTH was 34.9 kPa, compared with 86.5 kPa and 71.0 kPa at the 3rd and 4th MTH respectively. The peak shear stress at the heel was 48.5 kPa. Peak plantar pressure at these regions were 201 kPa, 228 kPa, 152 kPa and 169 kPa respectively [20]. To date, no studies have compared in-shoe plantar shear stress between the lesser toes and the metatarsals. The pressure distribution within this cohort are comparable to findings from previous studies. Fuchs et al., found the highest in-shoe mean PPP at 2nd-3rd MTHs (237.8 kPa), mean PPP at the heel, hallux and lesser toes were 233.9 kPa, 191.6 kPa and 124.3 kPa respectively [21]. The masking algorithm used was previously described by Putti et al., who investigated regional PPP in 53 healthy individuals using Pedar™ [13]. The region of highest PPP was the hallux (280.4 kPa), followed by the heel (264.3 kPa) and the 1st and 2nd MTHs (248.0 kPa and 246.5 kPa) respectively. Regional in-shoe PPP measurements vary within the literature, however the results of this study are comparable with the results of Putti et al., using Pedar™ with the same masking algorithm.

There are some limitations associated with this technique. The STAMPS system measures the cumulative shear strain sustained by a deformable insole during a period of gait, allowing inferences of plantar shear load, though does not directly assess load in its constituent parts. A relatively high mean coefficient of variation was identified, though this was lower when considering only variation in overall peak plantar strain. STAMPS uses DIC, which can be subject to systematic errors.

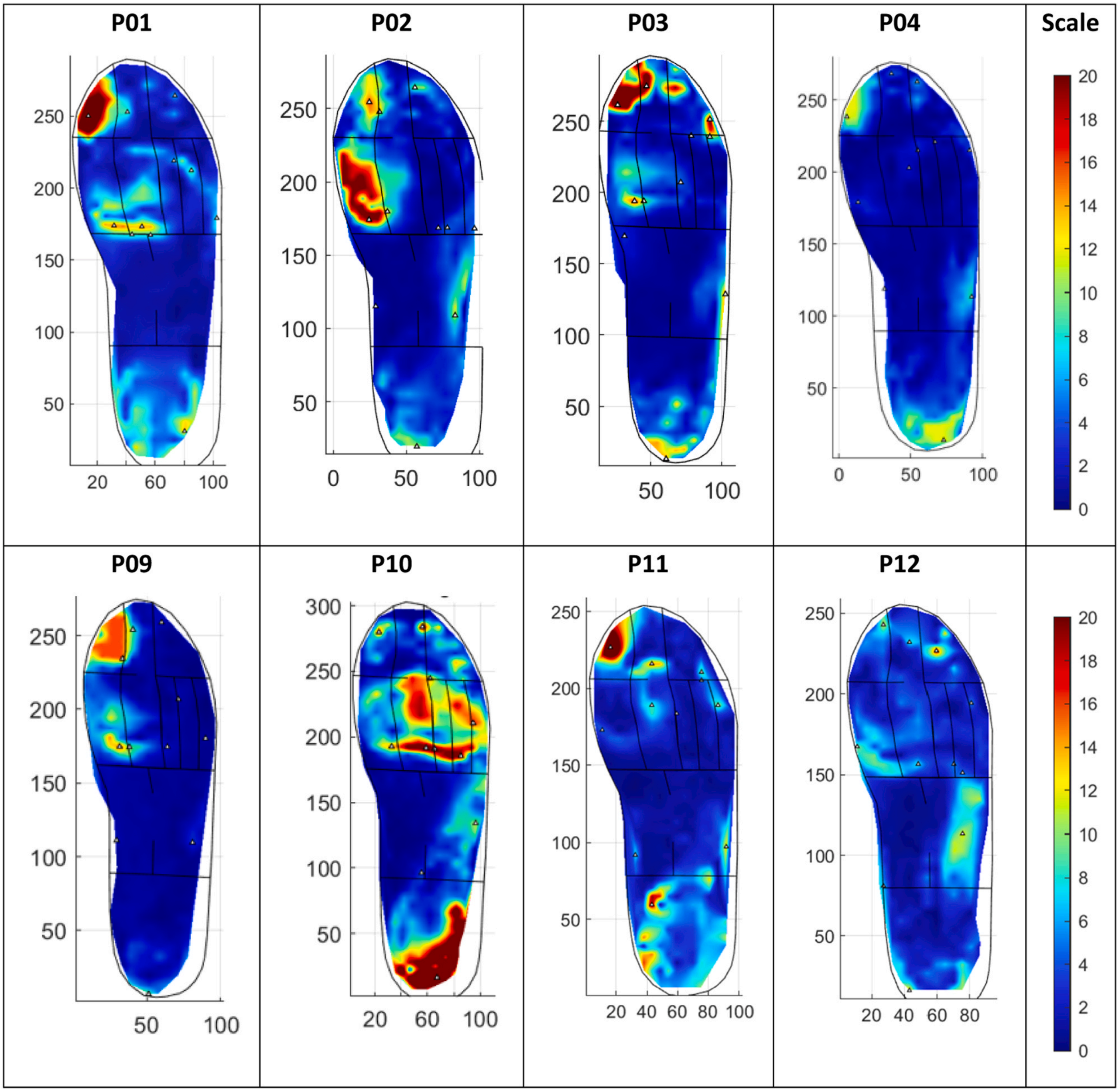

Fig. 1. Representative plantar strain characteristics for a sample of the cohort showing S_{MAG} measured using the STAMPS system. Legend shows percentage strain associated with colour map.

Table 2
Regional values of median S_{MAG}, PPP, IQR and the strain characteristics S_{ANT}, S_{POST}, S_{MED}, S_{LAT}.

	Median S_{MAG} (%)	IQR (%)	Mean PPP (kPa)	IQR (kPa)	S_{ANT} (%)	S_{POST} (%)	S_{LAT} (%)	S_{MED} (%)
Overall peak plantar strain	35.01	27.91–53.81	410.57	320.6–454.5	27.79	-21.84	24.57	-12.01
Hallux	29.31	24.56–31.39	344.76	268.3 – 452.5	17.78	-9.37	20.89	-4.45
2nd toe	15.42	10.09–23.38	171.77	114.2 – 291.6	11.02	-4.55	6.14	-3.47
Toes 3–5	16.44	8.02–22.46	109.20	78.2 – 130.6	9.95	-6.89	6.30	-4.32
MTH1	9.81	6.93–15.97	190.03	133.7 – 237.5	6.70	-9.28	5.20	-3.95
MTH2	9.64	6.85–17.06	227.91	174.8 – 234.9	6.65	-7.94	4.77	-2.43
MTH3	5.55	3.89–7.10	164.97	140.4 – 226.3	3.65	-3.88	3.11	-2.24
MTH4	5.47	4.51–11.41	162.47	146.3 – 212.9	3.31	-3.75	3.17	-2.42
MTH5	8.72	6.07–11.56	73.29	60.3 – 121.2	2.82	-4.53	3.66	-4.04
Midfoot (lateral)	6.50	4.62–12.70	107.59	82.1 – 118.8	2.14	-3.04	7.39	-1.33
Midfoot (medial)	4.77	3.62–6.33	45.10	32.2 – 49.8	1.00	-1.87	1.40	-2.59
Heel	20.50	15.59–24.12	279.32	231.3–302.1	10.18	-14.00	10.68	-7.50

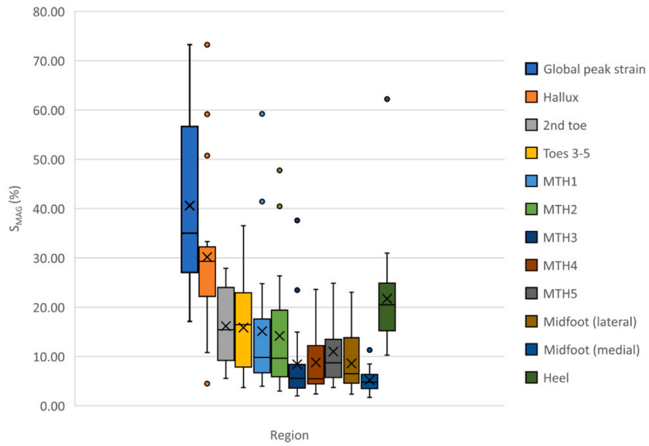

Fig. 2. boxplots demonstrating regional distribution of S_{MAG}.

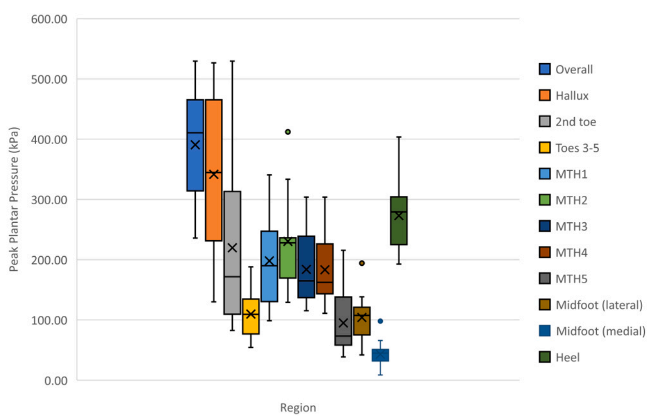

Fig. 3. Boxplots demonstrating regional distribution of PPP.

Several steps have been taken to ensure that the differences in strain patterns observed are a result of true variation rather than systematic errors. Patterning is consistent, with high contrast between speckle and background. The speckle size, density, variation, facet size and subset spacing has been optimised to reduce the likelihood of error [22]. Furthermore, variables affecting the material properties of the insole including temperature and 'cure time' were controlled. Experimental testing outlined in a prior publication, measured S_{MAG} with controlled application of normal pressure and shear stress [12]. The overall mean coefficient of variation between three repeats of identical loading cycles was 7.29 %. This suggests the relatively high coefficient of variation found within this study is representative of natural variation in gait, rather than instrument error.

Development of a low cost, time efficient plantar load system will aid risk stratification, guide offloading interventions specific to regions of increased load and improve approaches to management of active DFUs. Despite IWGDF recommendations, plantar pressure assessment is rarely performed in a clinical setting, in part due to the cost of sensing devices and the time and expertise required to use them. As such, there is a requirement for low cost, time efficient in-shoe systems, measuring both plantar pressure and plantar shear stress to determine how plantar load contributes to DFU development and deterioration. The STAMPS system is an innovative approach to the assessment of plantar load; utilising DIC to measure and quantify the cumulative degree of strain sustained by a deformable insole during a period of gait, and using this as the basis to infer plantar loading patterns [12]. The results of this study demonstrate successful application within a healthy cohort, producing valid results and a moderate correlation with the Pedar™ (Novel GmbH, Munchen, Germany) in-shoe plantar pressure measurement system.

6. Conclusion

The STAMPS system is an innovative tool to measure the effects of plantar load at the foot-surface interface. Development of such systems is vital to advance understanding of DFU development, guide custom-made offloading interventions and support management of active

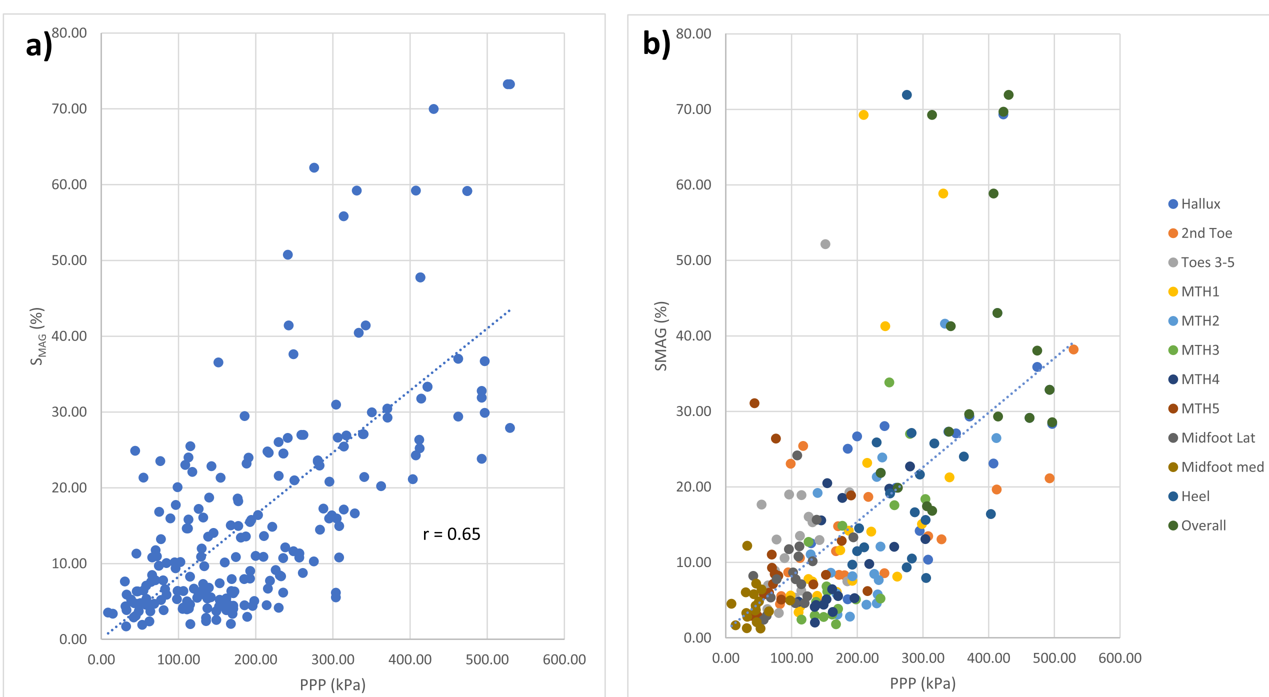

Fig. 4. a) Scatter plot demonstrating the relationship between SMAG and PPP b) Scatter plot demonstrating the relationship between SMAG and PPP divided into anatomical regions.

DFUs. This study has demonstrated successful application of the STAMPS system to measure plantar strain within a healthy cohort. It has identified a range of normal values within a healthy sample and suggests validity to measure the effects of plantar load at the foot-surface interface. Future work is aimed at its use in patients with diabetes, assessing elevated plantar strain as a risk factor for DFU formation.

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CRediT authorship contribution statement

Peter Culmer: Writing – review & editing, Supervision, Software, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Heidi Siddle:** Writing – review & editing, Supervision, Methodology. **David Alexander Russell:** Writing – review & editing, Supervision, Resources, Methodology, Investigation, Funding acquisition, Conceptualization. **Sarah Crossland:** Writing – review & editing, Software, Project administration, Methodology, Formal analysis, Data curation. **Alexander David Jones:** Writing – original draft, Validation, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Jane Nixon:** 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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