A Portable Insole System to Simultaneously Measure Plantar Pressure and Shear Stress

Lefan Wang*, Dominic Jones*, Alexander Jones, Graham J. Chapman, Heidi J. Siddle, David Russell, Ali Alazmani, Peter R. Culmer

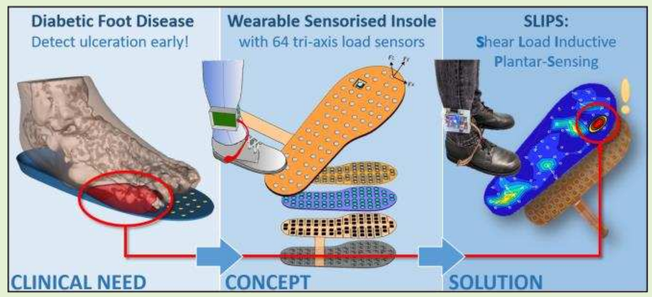
***Abstract*— Objective: This work aims to develop an integrated in-shoe measurement system to fully record plantar loading, including both pressure and shear stresses, across the full contact surface. These data are vital to help understand and prevent the development of complex conditions such as Diabetic Foot Ulcers (DFUs), a worldwide healthcare challenge. Currently no systems exist to reliably record these data.**

Methods: In this paper we report development of the SLIPS ('Shear Load Inductive Plantar Sensing') system which integrates 64 tri-axial force sensors into a flexible insole to measure plantar loading. SLIPS translates our multi-axis inductive load sensing technology into a full sensory array embedded within an insole and complete with communication and power bus. A pilot study evaluates the system in three healthy participants during walking.

Results: Testing shows that the SLIPS system is well tolerated by participants and can operate under dynamic gait loading regimes. The pilot study reveals the complex nature of plantar loading. Regions of peak pressure loading align with anatomical landmarks and shear loading forms a significant component of the overall load. Notably, regions of peak shear and pressure are not necessarily collocated or present in unison.

Conclusion: This work highlights the need for in-shoe plantar measurement systems like SLIPS capable of mapping both pressure and shear load, and their use to improve understanding of how these factors relate to clinical conditions like DFU.

Significance: SLIPS represents the first in-shoe measurement system capable of measuring both pressure and shear across the whole plantar surface in unison.



***Index Terms*— Diabetic foot ulcers, Insole system, Plantar pressure and shear stress, Tri-axial force sensor.**

I. Introduction

FOOT ulcers are among the most common and severe complications of diabetes. Each year, approximately 2-3% of people living with diabetes will develop diabetic foot ulcers (DFU) [1]–[4]. DFUs are often difficult to heal and tend to recur, with about 40% of patients experiencing recurrence within one year and 60% within three years [5]. DFUs can lead to infection, amputation, and other complications, significantly

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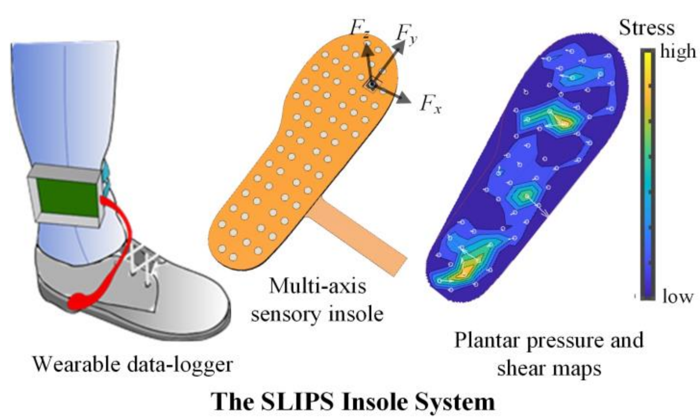

Fig. 1. The proposed SLIPS insole system to measure plantar load

affecting quality of life of the individuals and increasing hospital admissions. It is reported that DFUs bring patients a 2.5-fold increased risk of mortality within 5 years [6]. The economic cost is significant, with NHS England spending approximately £0.97-1.13 billion in 2014-15 [7] and the US spending $9-13billion each year on the treatment of DFUs [8] Expenditure is approximately 5 times higher in patients with a DFU compared to those without diabetes [9]. Therefore, prevention of DFUs is considered to be of paramount importance for reducing risks to patients and the resultant economic and societal impact [10], [11].

Elevated plantar pressure (perpendicular to plantar surface) is considered a key causative factor in the formation of DFUs. However, recent studies indicate that plantar pressure alone may be ineffective for predicting DFU development [12], [13] and the importance of plantar shear stress (parallel to plantar surface) has been underestimated [14]. Accordingly, assessment of shear stress has been suggested as a potential adjunct to plantar pressure for risk assessment of DFUs, and to guide offloading for healing and prevention of DFUs [15], [16].

Various sensing systems have been developed to measure plantar load, which can be mainly categorized into measurement plate and wearable sensing footwear [3]. Plate-based systems are usually fixed/placed onto the floor and only allow static and limited dynamic measurements of 1-2 stance phases. In contrast, footwear-based devices (mainly in the form of instrumented insoles) potentially allow users to move unconstrained during activities of daily living and enable researchers to study plantar load distribution over multiple stance phases, which is essential to advance our knowledge of ulcer development and improve the prevention of DFUs. Due to these advantages, both commercial and academic research groups have been developing wearable insole systems to measure plantar load distribution. Examples of the commercially available insole systems include Pedar®, F-Scan™, BioFoot®, the medilogic WLAN® insole, W-INSHOE and MoveSole®, examined in detail in a recent review [3]. All these systems are limited to plantar pressure measurement, without the capacity of monitoring plantar shear stress. Additionally, they are typically developed for general-purpose applications, e.g. sport biomechanics, footwear evaluation, and gait analysis, although some of these systems (e.g. Pedar® and F-Scan™) have been widely used for research and clinical applications. The majority of academic research groups have also focused on plantar pressure measurements [3], [17]–[21], but in recent years several began to explore simultaneous measurements of plantar pressure and shear stress. For instance, Mori *et al*. [22] implemented a sensing insole by integrating three shear sensors with the commercial pressure sensing insole F-Scan™. Two uniaxial shear sensors (35 mm × 35 mm × 1.2 mm) were placed in the region of the metatarsal head, another biaxial shear sensor (40 mm × 40 mm × 3 mm) at the heel. The additional sensing elements increased the insole thickness significantly to 7 mm and had low spatial resolution for plantar shear stress measurement. Later, Amemiya *et al*. [23] attached four triaxial piezoelectric sensors directly onto the plantar surface of the 1st, 2nd, and 5th metatarsal heads for pressure and shear stress measurements. This approach might induce skin damage and precipitate ulceration. Tavares *et al*. [24] incorporated five biaxial FBG-based sensing cells into an insole to monitor plantar pressure and shear stress under hallux, metatarsals, midfoot, and heel. This system is currently limited to single-axis shear stress measurements.

TABLE I

TABLE 1. MAIN REQUIREMENTS FOR MEASURING PLANTAR LOAD UNDER DIABETIC FOOT. SUMMARISED FROM [3].

Measuring capability	Pressure	>740 kPa
	Shear stress	> 140 kPa
Spatial resolution / sensor's active surface	<= 10 mm × 10 mm	
Sampling rate	>= 50 Hz to cover walking activities	
Sensor coverage	To cover the entire plantar surface	
Sensor location	As close to the plantar surface as possible	

Despite progress, research is required to develop a system capable of mapping shear stresses across the entire plantar surface, to assist in clinical applications such as the prevention and management of DFUs.

Our research aims to address these clinical needs, and here we present the design, development and evaluation of the 'Shear Load Inductive Plantar Sensing system' (SLIPS); an in-shoe plantar pressure and shear stress measurement system. The concept of SLIPS is to integrate an array of tri-axis load sensors into a flexible insole by utilizing our thin inductance-based load-sensing technology [25], [26], as shown in Fig. 1. This sensing technology has been developed specifically for the measurement of plantar load and thus provides a strong basis for the development of the core sensing system. In this paper, Section II details the system design, encompassing sensing electronics, hardware and software development. Section III then reports on the evaluation of the system in laboratory testing and a pilot study with human participants. Findings are discussed in Section IV, and conclusions drawn in Section V.

II. INSOLE SYSTEM DESIGN

Our development of SLIPS was informed through a set of clinical, technical and personal requirements for clinically orientated in-shoe measurement systems, focused on walking activities [3]. Key aspects related to the sensing system are summarized in TABLE I

. The SLIPS system comprises 1) a sensory insole, 2) a wearable data logger, and 3) software tools for calibration, analysis and visualization; as detailed in the following sections.

A. Sensory Insole Configuration

The foundation of the SLIPS insole is the inductive sensing technology we previously developed and demonstrated as an individual tri-axial load sensor [25]–[27]. This forms the repeat sensing unit, referred to hereafter as a 'node', from which the SLIPS sensing array is formed. Each node comprises three layers; at the base a set of planar inductive coils, followed by a thin elastomeric layer and topped with a conductive target. In brief, the operating principle is based on the eddy-current effect, as illustrated in Fig. 2a. When a vertical force (F_z) is applied, the target is brought closer to the coils via the deformation of the elastomer, leading to an increased magnetic coupling between the target and each coil and thus causing the inductances of all four coils to decrease. When a load is applied along the y-axis (F_y), L_1 and L_2 decrease whilst L_0 and L_3 increase, with the same principle applying for F_x. The coil inductances are measured by using an external capacitor to form an L-C resonator, energized by the four-channel 28-bit inductance-to-digital converter (LDC1614, Texas Instruments). To minimize the effect of parasitic impedances (e.g. from the wire traces) the measurement circuitry and sensing coils were collocated via a multi-layer flexible printed circuit board (FPCB). Our prior work identified the optimal configuration for this application as having four-square coils with maximal turns in a 10 mm × 10 mm sensing area, coupled with a circular conductive target and an elastomer layer (thickness < 2 mm) [26].

The SLIPS sensing insole integrates 64 of these tri-axial force sensors to map the load across the entire plantar surface, as shown in **Error! Reference source not found.**(b). Although this approach requires more sensors than focusing only on specific anatomical locations, it allows the system to capture the full range of load experienced and to observe the spatial distribution of loading over time, aspects which have potential clinical relevance in diabetic ulceration, for example identifying concentrated regions of loading [16]. As highlighted in TABLE I

, the SLIPS system is focused on walking activities for clinical assessment, hence a sampling rate of ≥50Hz is recommended from literature [3].

For this proof-of-feasibility stage of research, the SLIPS insole was sized for the average UK male (UK size 10, ca. 285 mm (L) × 101 mm (W)). The sensing nodes were distributed across 15 rows with 2-6 nodes per row, as shown in Fig. 2. Similar to the single sensing node, the SLIPS insole comprises four flexible sheets (see Fig. 2c): the conductive target sheet, the elastomer sheet, the FPCB coil layer and a sheet with cavities to support electronic components located on the underside of the FPCB, each of which are introduced below.

1) *Target Sheet*

The target layer must centrally position a conductive target above the coils of each sensing node. It comprises an array of circular copper discs, each of which has a diameter of 7.2 mm (to intersect the inductive coil centres). As shown in Fig. 2(c), the layer was designed for fabrication using standard FPCB processes such that each disc is composed of thin-film copper (thickness 0.07 mm) on a 25 μm Kapton polyimide film. Around each disc, the film was partially removed via laser-cutting to create flexible 'S' shaped support scaffolds that facilitate positioning and alignment of the target array while enabling localized movement of each target relative to the overall insole.

2) *Elastomer sheet*

The function of the elastomer layer is to modulate the movement of the sensing targets occurring due to external load, dictated by the mechanical properties of the layer. Based on our prior work [26], a prefabricated silicon rubber sheet with 40A shore hardness and a thickness of 1.5 mm (Silex Silicones Ltd., Bordon, UK) was chosen. The material can be readily bonded with other materials (e.g. Kapton film). A laser cutting machine (VLS3.50, Universal Laser Systems) was used to cut the silicon rubber sheet into the desired insole shape. For each sensing target position, a circular slot (see the purple area in Fig. 2c) was etched to create a raised elastomer disc (ϕ9.2 mm). This process acts twofold; it provides the raised disc with appropriate mechanical compliance in shear and normal axes to accommodate the load regime defined in Table 1 within a movement volume of ±1 mm for shear axes and 1 mm normal axis. In conjunction, it provides mechanical decoupling between sensing nodes and enables each to function

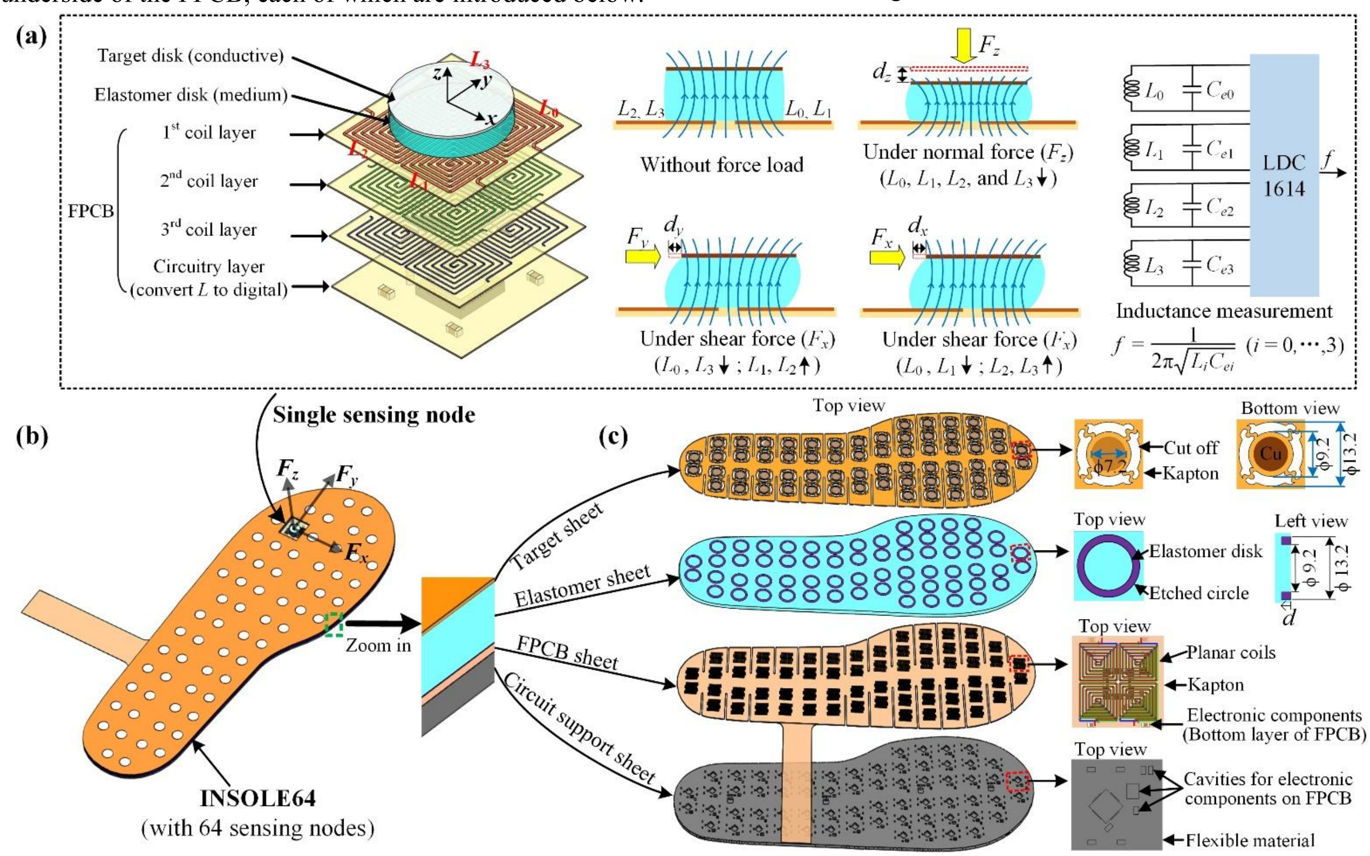

Fig. 2. Sensing principle and configuration of the integrated SLIPS insole system.

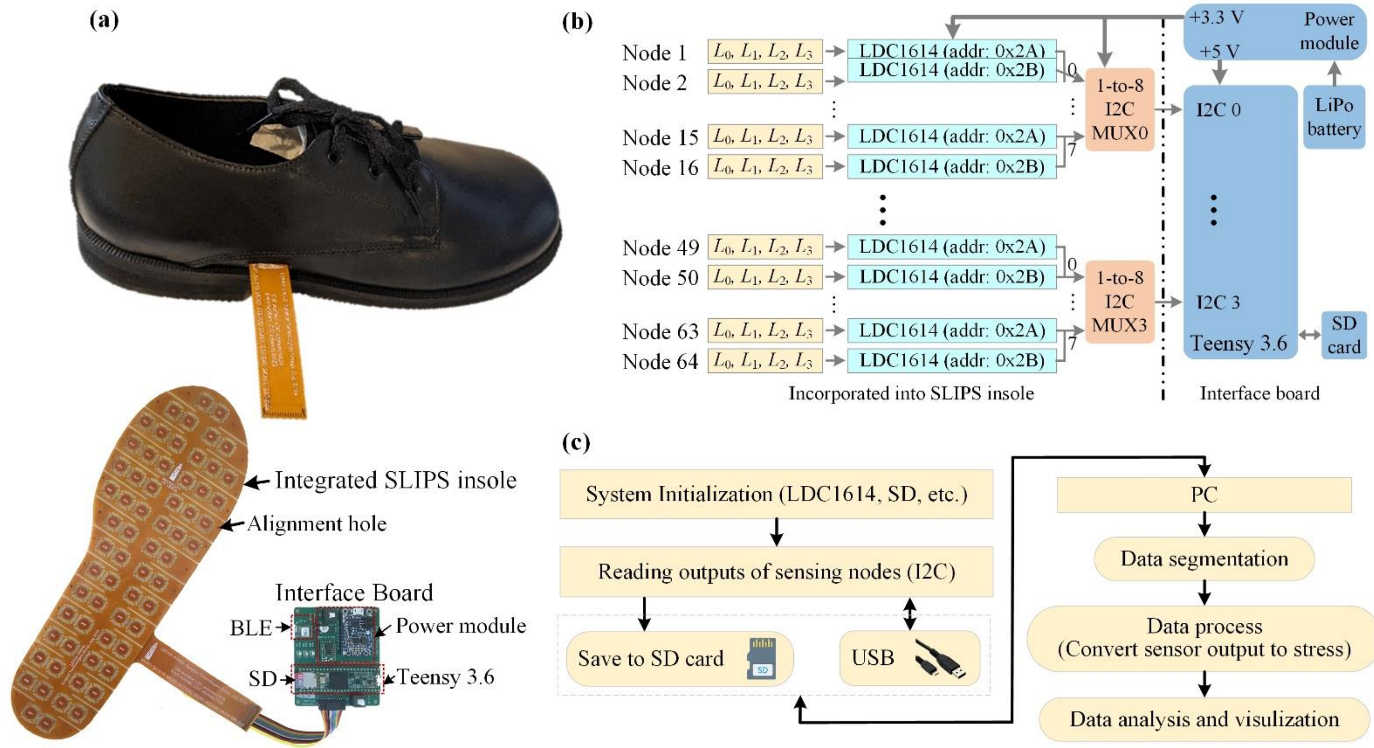

Fig. 3. The SLIPS system showing a) hardware and prototype, b) electronics and c) software sub-systems.

independently with negligible mechanical cross-talk.

3) *FPCB Sensing Sheet*

The FPCB sensing sheet holds the array of sensing nodes (each composed of four inductive sensory coils), together with interface and connectivity circuitry. The FPCB has four layers, with a thickness of 0.3 mm in total. As per the single node illustrated in Fig. 2a, the sensory coils were arranged on the top three layers of the FPCB, and the measurement circuitry was located on the bottom layer. The sensing coils were fabricated with a trace width of 0.1 mm, a pitch width of 0.1 mm and a copper thickness of 0.035 mm. Interface circuitry was realized using a communication 'spine' comprising four I2C buses and power (3.3V), branching to the 64 individual nodes through a series of four eight-channel I2C switches (TCA9548A, Texas Instruments), as shown in Fig. 3b. This configuration overcomes I2C address limitations of the LDC1614 measurement chips (which have two possible address states) and enables effective coverage of the entire insole area. The I2C and power lines of the spine are terminated in an FPCB interface lead, and connected to the datalogger using a 16-way connector (Micro-Lock Plus – 1.25 mm; MOLEX).

4) *Circuitry support sheet*

The support sheet performs a crucial role in protecting the electronic components located on the underside of the FPCB and providing a bottom surface to the overall insole. This was achieved by designing a flexible support sheet in which cavities are placed to accommodate the shape of each electronic component. The layer should be flexible (to permit bending of the insole) while mechanically hard in comparison to the elastomer layer (to minimize deformation under load which would reduce measurement sensitivity). Accordingly, the sheet was manufactured using a 3D printer (Objet1000 Plus, Stratasys Ltd.) using a flexible polymer (TangoPLUS FLX930), based on experimental evaluation to achieve shore 50A hardness.

5) *Assembly*

Accurate alignment and bonding of the various insole layers are vital for the effective functioning of the SLIPS insole. A series of small alignment holes (ϕ1.0 mm) were added to each layer to achieve this, which could then be collocated using a jig with metal rods. The sheets were bonded together using a thermally-activated bonding film (583 Thermal Bonding Film, 3M PLC). This provided an ideal solution because it allows free positioning of layers during assembly, cures at relatively low temperatures tolerated by all materials within the insole (here we used 120 °C at 15 kPa), is provided as a thin regular sheet (0.05 mm) and achieves a high bond-strength while remaining robust to bending. The resultant integrated SLIPS insole is shown in Fig. 3a.

B. Data Logging System

The SLIPS datalogger was developed to configure and control the acquisition of measurements from the insole system and enable recording and communication of the resultant data with external devices. As shown in Fig. 3b&c, an open-source Arduino-compatible microcontroller (Teensy 3.6, PJRC, USA) forms the basis of the datalogger, providing the requisite connectivity of four I2C ports and an integrated microSD port. The microcontroller is mounted onto a custom PCB interface board to integrate voltage regulator and BLE communications chips, together with a socket for the SLIPS insole interface. A LiPo battery (3.7V, rated capacity 2 AH) powers the system.

Using the Arduino software platform, code was developed for the microcontroller to control the system. As shown in Fig. 3c), the system begins by initialization of the LDC1614 chips to configure measurement parameters of the inductance digitization process) and initiates the SD card. The system then waits for a button press to initiate measurement for an activity. An asynchronous approach is used to obtain measurements from the sensor array by sequentially requesting measures from each node first then later returning to retrieve the resultant data. This minimizes overall wait times in the measurement cycle to achieve a maximum sampling frequency of 65 Hz. Each node returns a 4x28bit data packet representing the coil inductances which are collated with the elapsed time, and formatted into a 1024 byte message (including padding) to facilitate efficient file I/O to the microcontroller flash memory file system (a mounted SD-card using 512 byte sector size), as follows:

Time (ms)	$L^{\{Node1Coil1\}}$	…	$L^{\{Node1Coil4\}}$	…	$L^{\{Node64Coil4\}}$

These data are recorded as a binary stream to a pre-allocated file each cycle, concatenating the message from each cycle until a button press on the data logger terminates the activity and the file is closed with a unique name. Files are transferred to a host PC for post-processing via serial-over-USB.

A casing was 3D printed to house and protect the datalogger components (88×78×31.5mm). The casing integrates a compliant 'hook and loop' strap to secure it to the leg during use.

C. Measurement Calibration

Calibration methods were developed for SLIPS to transform the raw insole sensor measurements into multi-axis load measures. A concise summary is provided here based on our prior single-node work [26]. A single-stage approach was used to directly transform the measured coil inductances into an associated load. This enables nullification of inter-node variation in inductances which can occur due to manufacturing variability [25]. Referring to Fig. 2(a), the calibration approach finds a function to directly transform the coil inductances $L_{0\text{-}3}$ into the associated applied load vector F_{xyz}, see equation 1.

$$\boldsymbol{F} = \{F_x, F_y, F_z\} = f_{load}(\boldsymbol{L_0}, \boldsymbol{L_1}, \boldsymbol{L_2}, \boldsymbol{L_3}) \tag{1}$$

This approach requires specific calibration sets to be obtained for each sensor node, totaling 64 measurement sets for the overall SLIPS system. A two-layer feed-forward neural network was used to map the non-linear relationship between the coil inductances ($\mathbf{L_{1\text{-}4}}$) and the applied load vector F_{xyz}. Training and validation data were generated using a custom 3 axis micro-positioning system [26] and a 20 mm diameter planar circular indenter centered over the node target. For each sensor node, a multi-axis loading process moved the target through a 1 mm × 1 mm × 1.5 mm volume (equivalent to the anticipated working range of each sensing node). The system recorded the sensor inductances, stage position and reference load (Nano25, ATI)) to form individual calibration data sets (comprising >31K data points) for each of the 64 sensor nodes. A neural network was then trained for each sensor node using the MATLAB Neural Network toolbox (r2019a, Mathworks Inc., MA, USA), as reported in [25], to generate 64 unique NNs.

D. Data Analysis and Visualisation

After recording a walk with the SLIPS system, the data are uploaded to a PC, calibrated (as per Section IIc), after which the load data are processed and segmented to identify and isolate critical temporal and spatial aspects associated with gait.

Firstly, for each sensor, the time-series force data was processed to determine the vertical, shear and overall magnitude components of stress, based on the active sensing area of each sensor node during calibration:

$$\sigma_z(s) = P = \frac{f_z(s)}{A_s} \qquad \vec{\sigma}_{shear}(s) = \frac{\langle f_x(s) | f_y(s) \rangle}{A_s} \tag{3}$$

where s denotes the sensing node from 1-64

The temporal response of each recorded activity was analysed to identify the ground-contact phases (e.g. the 'steps') using MATLAB (r2019a, Mathworks Inc., MA, USA). These periods were segmented through a peak-trough detection algorithm using the summed force magnitude across the insole:

$$F_T = |\sigma_{insole}| = \sum_{s=1}^{64} |\sigma(s)| \tag{4}$$

Each individual step was identified by finding local load peaks (F_T^{Max}), and from this the corresponding troughs which demark the start and end of the ground contact phase. The algorithm advances through the activity, sequentially identifying and numerically labelling each ground-contact phase for subsequent analysis (e.g. step 1…N). To more readily inspect spatial characteristics, the SLIPS insole was partitioned into three anatomical regions. Groups of nodes were defined corresponding to the forefoot (s1:30), midfoot (s31:46), and rearfoot (s47:64), as shown in Fig 4a.

III. Experimental Testing

Testing was conducted to validate the measurements obtained from the SLIPS insole and to evaluate its performance in typical usage conditions with healthy participants.

A. System Validation

The electrical properties of the SLIPS FPCB was evaluated prior to load calibration. Testing showed variability up to 4 % full scale inductance across the sensor nodes.

For the load validation, the manufactured insole was loaded using a cylindrical indenter (20mm diameter) at each of the 64 node positions using the same multi-axis load employed for calibration. For validation of the normal force, the nodes were indented vertically to a depth of 1mm. For validation of shear force, sensors were indented vertically by 0.7 mm, then sheared horizontally 0.7 mm. These movement ranges were selected from preliminary testing to provide appropriate load ranges.

A summary of key performance characterestics determined through experimental testing is provided here for brevity. These results are typical of the SLIPS system and consistent with the response of the individual sensor nodes that we previously examined and reported in detail [25] to document the temporal and dynamic properties of these elements. For the SLIPS system we determined a Root Mean Square error (RMSe) for the calibrated output values during multi-axis loading. The RMSe for F_x (medial-lateral shear) was 0.99N (14.89 kPa, 6.3% full scale), for F_y (anterior posterior shear) was 0.49N (7.37 kPa, 4.8% full scale) and for F_z (plantar pressure) was 1.19N (17.90 kPa, 2.1% full scale). The measurement sensitivity in each axis was F_z = +- 0.08N (1.2 kPa) and F_x / F_y = +- 0.02N (0.30 kPa). No measureable cross-talk was observed between sensor nodes during validation.

B. Pilot Study

A pilot study was conducted to evaluate the efficacy of using the SLIPS system to record in-shoe plantar load maps in healthy participants. Accordingly, the objectives of the study were:

1. to demonstrate that the SLIPS was tolerated in normal gait by the participants (e.g. it did not impede walking)
2. to demonstrate that the SLIPS system could function

within a typical in-shoe environment
3. to record representative plantar loading data from the system to inform future development of such systems

1) *Method*

A study was designed to address the objectives across an initial target of three participants. Ethical approval was obtained from the University of Leeds ethics committee (LTMECH-005) to conduct the study with healthy participants from university staff. Inclusion criteria were that participants should be over 21 years of age, wear a UK size 10 or 11 shoe (to fit the measurement area of the SLIPS insole), and be capable of unaided walking. Exclusion criteria were any comorbidities associated with mobility or foot health.

The study protocol was defined around participants performing a standardized 10m walk activity, comparable to clinical practice and research literature. Prior to data collection, each participant read the participant information sheet and provided written informed consent. Participants were required to wear a pair of custom shoes (UK size 11), with the instrumented SLIPS insole fitted within the right shoe and a non-instrumented insole (with identical dimensions and mechanical properties) in the contralateral side. The SLIPS datalogger was positioned above the ankle of the right leg using a compliant strap to the left foot, together with the SLIPS datalogger located above the ankle using the compliant strap. Each shoe was laced to a comfortable fit as self-reported by the participant. The datalogger was then set to record data, and the participant asked to walk 10m between clearly marked location on a level floor at a self-selected pace. The process was repeated ten times with a short pause between each repetition.

After each participant had completed the activity, they were asked to evaluate their experience of using SLIPS using a 5-point Likert scale to rate a) comfort b) awareness of the system c) ability to walk unimpeded. Data from the system were uploaded to a PC for processing to extract the contact phase (as per Section IIc-d) for further analysis. The first and last gait cycle were removed from the data to reduce the effect of gait initiation and termination. Data were then manipulated to investigate their temporal and spatial characteristics. The time-series response of the insole sensing array and anatomical regions (forefoot, midfoot and rearfoot) were extracted to show how shear and pressure changed during the contact phase. Time-Series Integrals (TSIs) were then calculated for the normal (σ_z) and shear stress (σ_{xy}) response. TSIs highlight the overall spatial aspects of the plantar load response and provide clinically relevant insight into regions which may be subject to extended durations of elevated pressure which could lead to tissue ischaemia [28], [29]. Finally, the TSIs were summarized by finding the mean for each anatomical region, thus indicating the load distribution across the plantar surface.

2) *Results*

Three participants were recruited for the study, sumarised in Table 2. Each met all inclusion criteria, provided informed consent and completed the walking activities. Data were recorded for the first two of the three participants. Unfortunately, during testing of the third participant, a period of rapid gait (approximately twice the speed reported here) caused a fault to develop in the SLIPS insole, precluding further data collection. Consequently here we report plantar loading data collected from participants 1 and 2.

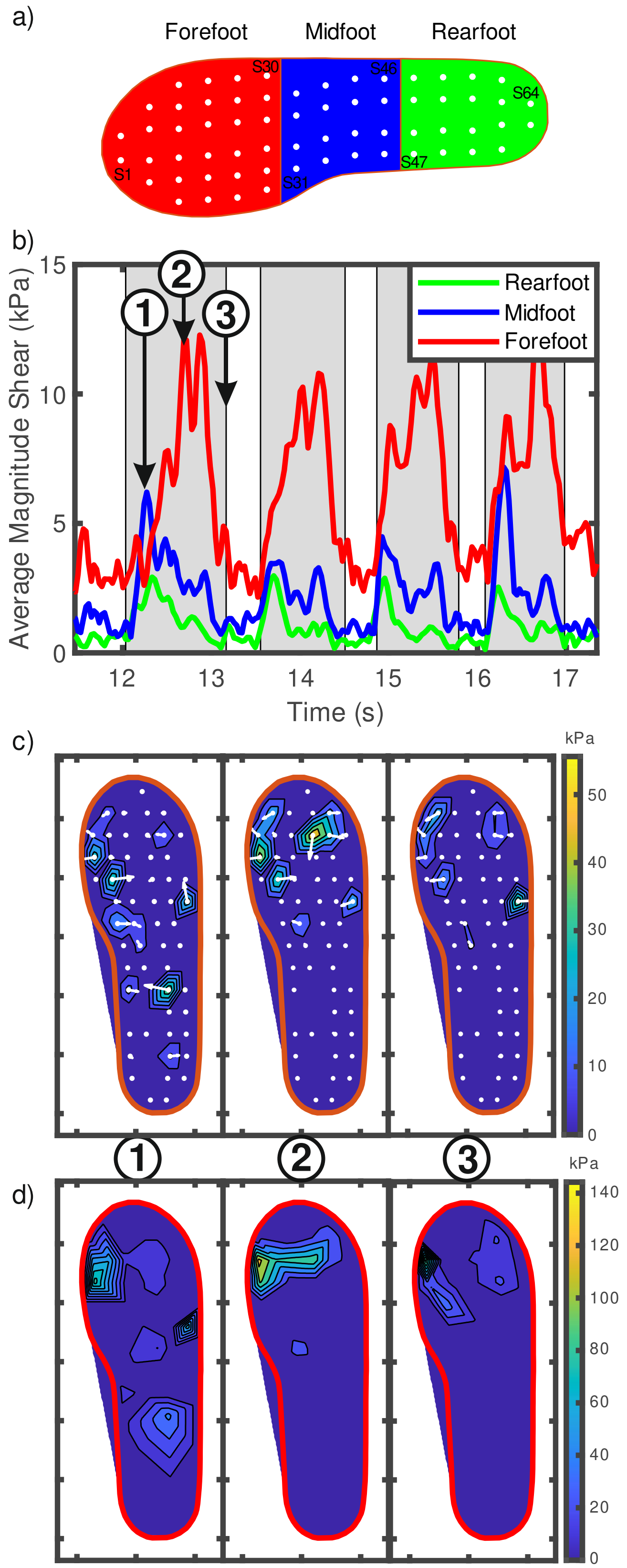

Fig. 4. An example of typical temporal and spatial load characteristics recorded by the SLIPS system, shown here for participant 2 providing a) definition of anatomical regions b) the mean shear magnitude over time in each anatomical region c-d) the distribution of shear load and pressure at key time points of the contact phase (arrows show the direction of shear, scale bars show load magnitude)

Feedback from the participants revealed that the SLIPS insoles were considered comfortable (mean score = 4.3/5), caused some awareness of the insole (mean score = 2) but that this did not impede natural gait (mean score = 4.3). The SLIPS insole was easily located and removed within the shoe with no discernible relative movement during gait. The SLIPS datalogger was located immediately superior to the ankle on each participant and remained securely located. The FPCB interface between the SLIPS insole and datalogger enabled free movement of the foot and ankle during gait.

A typical example of the plantar loading data recorded by SLIPS is shown in Fig. 4. Key time points in the ground contact phase were defined, as shown in Fig. 4b, and correspond to heel-strike, peak load and toe-off. The temporal characteristics of the shear in each anatomical region show a typical gait cycle, with load initiating in the rearfoot region, then transferring through the midfoot and onto the forefoot at the end of the contact phase. Considering the relative magnitude, shear in the forefoot region dominates the response and peaks at 12.5 kPa average for the second half (terminal stance) of the ground contact phase (point 2). In contrast shear is lowest in the rearfoot region which peaks early at 3.2 kPa (point 1). The midfoot response shows higher shear than the rearfoot, peaking at 6.1 kPa just after point 1. Toe-off (point 3) represents the low minima for all regions. The associated spatial characteristics of plantar load at these time points are presented in Fig 4c-d. The shear load is initially distributed along the medial aspect of the foot (point 1) before focusing toward the front of the foot, along the metatarsal heads and hallux with a peak of 53 kPa (point 2) before decaying in magnitude at toe-off (point 3). The pressure response (Fig. 4d) shows spatial distribution focused toward the mid and forefoot. Pressure load in the rear foot region is low, peaking at 8.8 kPa and exceeded by the midfoot region which peaks at 52.6 kPa. The forefoot region yields the highest pressure ranging from 80-140kPa along the metatarsal heads.

Fig. 5 shows the Time Series Integral of the plantar load response for participant 1 and 2. The overall magitude of shear in each region is comparable between participants, although participant 1 records a particularly low level of shear at the rearfoot. Consistent with the temporal response shown in Fig. 4, the forefoot region records the highest levels of shear in both participants. The hallux and metatarsal heads are prominent, together with the medial midfoot region. The direction of shear is more challenging to interpret. Some commonality is evident in peak regions such as the hallux in which shear loading is directed laterally, while other regions show disparity between participants, likely as a result of individual gait characteristics.

IV. Discussion

Our focus has been to harness our advances in innovative load sensing technology [32] to develop an integrated system for recording in-shoe plantar shear and pressure loads. The concept of making such a sensory array by tiling individual sensing elements is deceptively simple. However, realizing sensor networks to achieve this ambition brings a series of noteworthy engineering challenges. Firstly, the electronics system (Fig. 2) requires careful design to route power and communications to multiple sensing nodes within the spatial constraints of the insole. Our approach of using sensor nodes branched from a central spine provides a pragmatic solution which is achievable with commercially available PCB techniques. However, the limitation of approach is that it result in a monolithic design that couples sensor node arrangement with the electronics design. Thus, the electronics subsystem must be designed to suit each particular shape/size of insole.

Following design, careful fabrication and calibration of the

TABLE 2.
SUMMARY OF PARTICIPANTS IN THE PILOT STUDY

Participant Number	Age (Yrs)	Weight (Kg)	Height (m)	Shoe Size (UK)	Steps Taken
1	40	75	1.80m	10.5	76
2	27	77	1.85m	11	57
3	35	82	1.82m	10	75

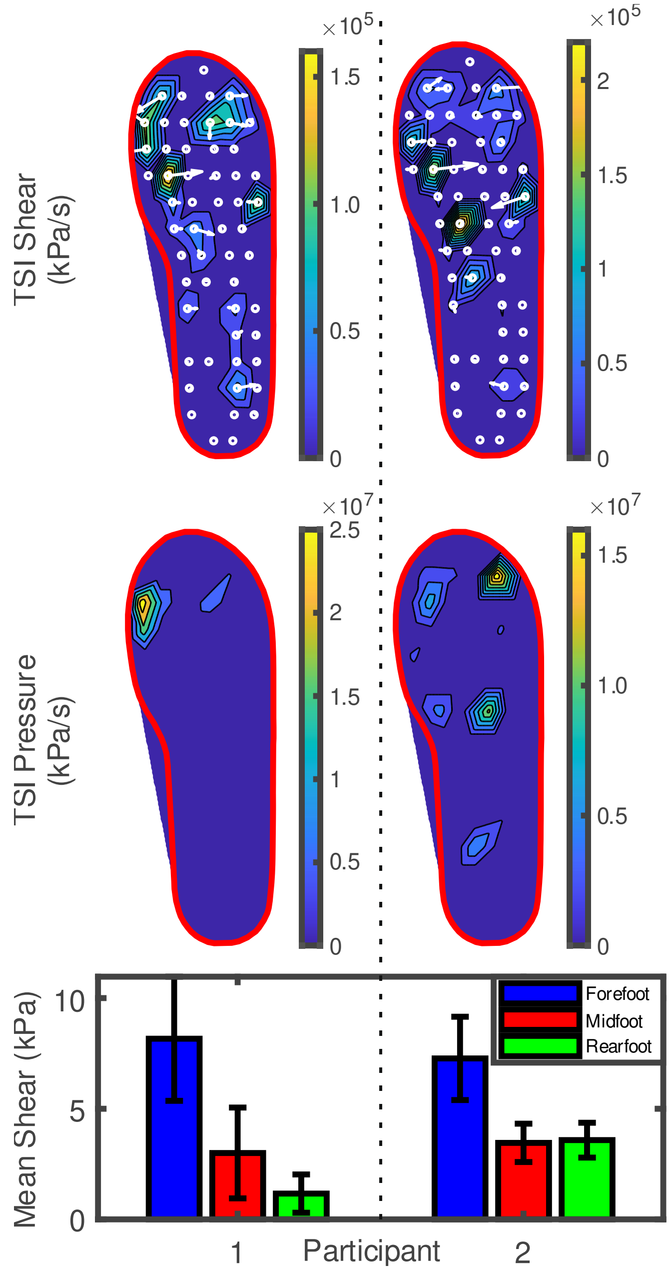

Fig. 5. The Time-Series Integral (TSI) of plantar loading for each participant over the 10m walk activity, showing plots for shear, pressure and associated summary metrics of the mean shear over each anatomical region (error bars show STD).

integrated SLIPS insole is critical for consistent sensing performance across the sensing array. This encompasses FPCB fabrication and assembly of the insole (to align and uniformly bond the multiple layers of the insole). Despite modern FPCB manufacture methods and careful fabrication, some variability inevitably occurs during manufacture. Consequently, the calibration process was designed to compensate for variability between sensors in the array. At this stage of development, this approach has the merit of reducing individual sensor error. Lab validation showed an RMS error of 4.8-6.3% in shear and 2.1% in plantar pressure across the SLIPS sensor array, comparable with other in-shoe measurement systems (e.g. PEDAR [30]). Similarly, it shares measurement constraints in the assumption that all sensor nodes have full coverage during loading, partial coverage would result in mis-estimation of pressure and shear. It should be noted individual sensor calibration is a time-consuming process that may be impractical outside a lab environment, thus future research will explore alternative methods suited for clinical application.

The pilot study evaluated the efficacy of using the SLIPS system for in-shoe measurement of dynamic loading. Firstly, the study demonstrated that the SLIPS insole was perceived to be comfortable whilst not impeding gait. Secondly, it demonstrated that the system can capture and record data both pressure and shear data during natural gait. However, the electrical fault which developed during the latter part of the study highlights the harsh environmental challenges posed by in shoe plantar load measurement. Investigation revealed the fault was caused by a solder stress-fracture at a surface-mount chip in the heel area, a common failure mode when FPCBs are not adequately supported. Future work will improve system robustness by refining the circuit support layer (see Fig. 2) to better distribute loading around vulnerable regions. Similarly, our prior work shows that the core inductive sensing technology used in SLIPS has good robustness and insensitivity to temperature and humidity variation [27], but these aspects merit further investigation as integrated into the SLIPS system and within a representative in-shoe environment.

The outcomes of the pilot study provide insights into both the performance of the SLIPS system and preliminary indications of the shear characteristics of plantar in-shoe loading. The magnitude of plantar pressure recorded in this pilot study are lower than those reported for comparable activities with participants of comparable body mass [31]. Investigation revealed that the orthotic shoe's base layer (onto which the SLIPS insole was placed) had greater mechanical compliance than anticipated. Consequently it acted to attenuate the pressure recorded by the SLIPs insole. However, shear measures were unaffected since the insole was firmly located to prevent shear slip with respect to the shoe surface. This highlights how the choice of footwear, encompassing both sock and shoe, can influence the output of plantar load measurement systems such as SLIPS. For example, the properties of the sock effects the tribological interaction between foot, sock and insole which in turn influence transmitted shear, with higher friction associated with improved measurement quality [32]. Similarly, the shape and mechanical properties of footwear are influential; shoe sole stiffness effects the magnitude of plantar loading [33] while heel height shifts pressure distribution [34]. In practical terms, SLIPS could be used to monitor and provide feedback on different configurations of sock and shoe type, if the data are to be used for comparative purposes (e.g. between participants in a clinical study), controlling sock and shoe type would be an important factor to consider. It is also important to note that in a clinical situation, the outcome would be interpreted in the context of many complex factors which lead to ulceration [2].

Our preliminary results in this area show that the forefoot region experienced significantly higher levels of shear than the rearfoot, in agreement with other studies in healthy participants [35]. The peak shear ranged up to 140 kPa, higher than that reported in other studies for healthy participants (e.g. Stucke et al found a peak of 37.7 kPa) and those with diabetic foot neuropathy (e.g. seminal work by Yavuz et al suggest peak shear magnitudes of ca. 130 kPa [14], [36]). Caution must be taken with direct comparison as these were made barefoot using custom load platforms and further research is required to investigate these aspects in more detail. Although these data are limited, they support the notion that shear loading on the plantar surface is a significant factor during gait. Furthermore, our data support the notion that regions of elevated shear do not necessarily coincide with regions of high plantar pressure and thus shear patterns cannot be directly inferred from pressure characteristics [35], [37]. Accordingly, studies employing direct measurement of in-shoe shear are vital to investigate the pathomechanics of DFUs.

Having demonstrated the efficacy of using the SLIPS system for in-shoe measurement of plantar shear loading, our future research will seek to refine this towards clinical use. The preliminary data reported here will enable optimization of the sensing system, particularly in the composition of the elastomeric and electronics layers, to ensure robustness and appropriate sensitivity, together with the development of techniques to facilitate multi-sensor calibration. Further testing is also critical, firstly to investigate potential failure modes in the higher plantar load regimes associated with DFU, and secondly to expand the evidence base on in-shoe plantar shear loading across a range of activities, demographics and foot health conditions like DFU.

V. Conclusion

This work reports the development and preliminary evaluation of SLIPS; an in-shoe measurement system for complete measurement of plantar loading. This translates our multi-axis inductive load sensing technology into an integrated in-sole system capable of measuring pressure and shear stress across the entire plantar surface. A pilot study shows that SLIPS is well tolerated by participants and can effectively capture the spatial and temporal characteristics of plantar pressure and shear during gait. The resultant data reveal the complex nature of plantar loading in which peak shear and pressure are not necessarily collocated or present in unison. Overall, this work highlights the potential, and need for, in-shoe plantar measurement systems capable of mapping pressure and shear.

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