An active insole to normalise plantar pressure loading: using pre

dictive real time finite element driven soft hydraulic actuators to minimise plantar pressure and the pressure time integral for diabetic foot ulceration risk management.

J. Shuang, A. Haron, D. Crosby, G. J. Massey, C. Lin, F. L. Bowling, N. D. Reeves, H. Dawes, G. Cooper, and A. Weightman.

***Abstract*—537 million people have diabetes worldwide and 19-34% of this population will develop a diabetic foot ulcer in their lifetimes. Patient specific pressure offloading insoles are commonly used to prevent ulceration. However, static offloading insoles cannot adapt to dynamic plantar loading and be optimised for the different regions of the foot at risk of ulceration throughout stance. Furthermore, static offloading insoles can cause edge effect problems, and transfer higher loads to other areas of the foot negatively affecting the participant's gait and plantar loading. We present the design and evaluation of a novel soft robotic shape changing insole to normalize peak plantar pressure and loading timing to potentially reduce the risk of ulceration. Control is driven by an approximate finite element model of the participants' foot with a cost function to minimise plantar pressure loading and the pressure time integral. The system was evaluated with two diabetics and one healthy participant, measuring normal plantar stress in shoe both before and after shape changes. The results from the participants demonstrate an average reduced peak plantar pressure of 35% [9% - 52%] and average decreased pressure time integral of 31% [6% - 44%] at the high-risk plantar region, whilst minimizing edge effects and maintaining gait symmetry, regularity and cadence. The finite element driven controller was implemented when participants rested between walking periods and took less than six minutes to run. The results demonstrate the feasibility of a soft robotic shape changing insole for normalising plantar pressure and reducing the risk of diabetic foot ulceration without adversely affecting gait. Future work will focus on improved control and out of laboratory evaluation.**

***Index Terms*—Diabetes, Footwear, Soft robotics, Simulation, Ulceration.**

I. Introduction

WORLDWIDE the number of people living with diabetes rose to 537 million between 2000 and 2021, and this could increase further to 643 million by 2030 if there is no effective action taken [1]. Diabetic foot ulceration has been one of the most serious diabetic complications, with 19-34% of diabetics developing ulceration during their lifetime [2], [3]. The total worldwide cost for diabetes is approximated to be around one trillion US dollars by 2030 [1]. The prevention of diabetic foot ulceration is preferable for the individual and in terms of the economic costs [4]. Increased plantar pressure can indicate diabetic foot ulceration in people living with diabetes [5]. Armstrong et al. found that if the foot experienced peak plantar pressures greater than 700kPa this was a good predictor of ulceration [6]. In addition, the pressure-time integral can indicate potential diabetic foot ulceration risk [7], [8], [9].

One method used to prevent and manage diabetic foot ulceration is a patient specific offloading insole which changes insole shape to minimise the plantar pressure. These patient specific offloading insoles can decrease the plantar pressure at high-risk regions, for example the metatarsal heads, and therefore reduce diabetic foot ulceration risk [4], [10], [11], [12]. Penny et al. compared the effect of two different offloading insoles on healthy participants' plantar pressure, and observed a decrease of 40% and 24% respectively in the first metatarsal head plantar pressure by removing plugs under the first metatarsal head [10]. Lin et al. evaluated the effect of a foam insole with removable plugs on diabetic patients' plantar pressure, and observed a decrease of 32% in peak plantar pressure by removing plugs under the highest peak plantar pressure region [11]. Raspovic et al. tested the performance of a new offloading device (DH Offloading Post-op Shoe^{TM}, Ossur, CA) which removed plugs according to the patients foot condition [12]. It resulted in a 51% decrease in peak plantar pressure compared to a control shoe [12]. Total contact insole can decrease the average plantar pressure at third metatarsal head by 41% [13]. All these offloading insoles showed a capacity to reduce peak plantar pressure in high-risk foot regions.

However, offloading insoles can lead to a plantar pressure increase in other regions. The edge effect, which is described as the increased plantar pressure around the offloading aperture edge, was found during testing on healthy participants [14]. The tissue at the edge of the cutout section of the insole can cause higher plantar stresses around the hole which could damage the plantar tissue under repeated loading during walking. Furthermore, it has been observed that while the plantar pressure decreases in the offloaded regions of the foot, it may conversely increase in other regions [11]. Applying a soft plug to offload the second metatarsal head caused an increase in plantar pressure in the adjacent first metatarsal head for healthy participants, and in both the first metatarsal head and hallux for diabetic participants [15]. Unpublished previous work by the author observed that offloading the calcaneus region caused the average peak plantar pressure and peak pressure time integral increase in the metatarsal heads region, and vice versa supporting the need to move away from static offloading insole. Increases in plantar pressure, particularly when using static insoles, can lead to a rise in the pressure-time integral in these regions, which can indicate potential diabetic foot ulceration risk [7], [8], [9].

Finite element models have been applied to optimise offloading insoles to minimise the plantar pressure in existing research [2], [16], [17], [18], [19], [20], [21]. Shualian et al. developed a novel finite element model to improve the shape of the offloading hole, aiming to overcome the edge effect problem [2]. The results demonstrated that a larger offloading hole radius, greater hole depth, and either a large or small radius of curvature on the cutout edge can minimize the loads on the heel's soft tissue, particularly in and around regions at high risk for ulceration. A graded stiffness heel-offloading insole was evaluated, and the results showed that it can reduce the average peak plantar pressure in and around high-risk regions but also increases the average peak plantar pressure in the entire heel region [16], [22]. A simplified finite element model was evaluated, and found the difference between simulation and measurement was smaller than 16% when predicting for flat surface [19]. The simplified finite element model was improved and used to optimise standard insoles, and the optimised insoles showed a decrease of about 40 kPa in peak plantar pressure compared to a standard shape insole [20], [21]. Such finite element models have shown effective improvement for offloading insoles, but all of the simulations focus on static loading optimisation. Real world plantar loading is dynamic, and it is likely that these static optimisations will not reduce pressure time integrals or overall peak plantar loading from activities of daily living.

Dynamic shape changing offloading insoles could offer better diabetic foot ulceration prevention performance than static shape offloading insoles. However, the research on shape changing offloading insoles is limited; the authors identified a single study [23]. A pressure measurement system was combined with a shape changing component that automatically detected the high pressure region and adjusted insole shape to decrease the pressure [23]. Hemler et al. applied pressure-offloading modules that functioned through a magnetorheological fluid within a deformable bellow, enabling fluid flow into an auxiliary reservoir for increased compression, or solidifying the fluid for reduced compression by control of a magnetic field, which provided a maximum compression of 2.5 mm [23]. The system, comprising measurement and shape-change components, is straightforward to implement, but it has no capability to predict plantar pressure and dynamically adapt which could lead to unexpected high pressure after shape changing [23].

The aim of this paper is to present the design, development and evaluation of a novel active shape changing insole to normalise plantar tissue loading and potentially minimise the risk of diabetic foot ulceration for people living with diabetes. The effect of offloading insoles on balance was neglected despite the critical impact on mobility [24]. Therefore, the gait parameters were evaluated in this study. This is the first study to demonstrate active minimisation of plantar loading in people with diabetes and to research gait kinematics in both healthy and diabetic participants. Unlike traditional static offloading insoles and Hemler et al.'s insole concept [23], our innovative design aims to dynamically adapt its shape driven by a predictive finite element model and inputs from plantar pressure sensors. It is the first time that predictive finite element model is utilized to drive a novel active shape changing insole. Additionally, our active shape changing insole offers a wider range of shape adjustments and hence the potential to adapt and normalise plantar tissue pressure in multiple loading conditions. This could facilitate dynamic loading adjustment, mitigate the edge effect problem, and prevent the occurrence of diabetic foot ulceration. The objectives of this work are to: (1) create a simplified finite element model to predict and optimise plantar pressure distribution, (2) develop an active shape changing insole, (3) evaluate the impact on plantar pressure and gait of the prototype system with both healthy and diabetic participants during gait.

II. System Design

A. Active Shape Changing Insole Hardware Design

Design requirements for the active shape changing insole were determined by a multidisciplinary team of engineers, social scientists, therapists, and clinicians, as part of the 'Happier Feet' project, funded through the United Kingdom Engineering and Physical Sciences Research Council, see TABLE I.

The active shape changing insole was fabricated from Shore A 50 silicone (Smooth-Sil 950 Smooth-On, Inc., Macungie, Pennsylvania, US) (Fig. 1). The manufacturing process for this insole began with the use of a 3D printer to create moulds (polylactic acid) for two soft hydraulic actuators (46.0×4.0×32.5 mm). These soft hydraulic actuators were first cast in one integrated mould. After the silicone had cured for 24 hours, a second 3D-printed mould (polylactic acid) was utilised to integrate nylon tubing (2.5 mm inner diameter, 4.0 mm outer diameter, RS Pro Nylon Air Hose, RS, UK) and silicone tubing (1.0 mm inner diameter, 2.0 mm outer diameter, model A16090800ux0406, Amazon, UK) with the silicone soft hydraulic actuators by covering them in silicone. Next, a 10.0 mm thick EVA mould was made to match the contours of UK size 8 diabetic shoe insoles (97308, Finncomfort, Germany), and the silicone soft hydraulic actuators were located at the metatarsal heads region. The final silicone insole was manufacture in the EVA mould. To ensure the integrity of the entire structure, clamps were added at the junctions of the nylon and silicone tubing after silicone curing, ensuring leak-proof connections.

A linear actuator (Actuonix miniature electric linear actuator, 50.0 mm, 6V dc, 20.0 mm/s) was utilised to control the volume of fluid in the soft hydraulic actuators, controlled by an arduino board (Arduino Mega 2560 Rev 3) powered by a battery (RS PRO, 12V, AA, NiMH rechargeable battery, 1.3Ah), in combination with a voltage converter (Murata power solutions OKR-T/10-W12 DC-DC converter), a relay (Seeed 103030009 Relay Shield For Arduino V3.0), and two two-way valves (GEMS Sensors, Inc BG2005-01LC-B-G1-203). The actuator drove a syringe (B08H116BSJ, Amazon, UK) which moved water in and out of the shape changing region of the insole (soft hydraulic actuators). A custom arduino code was written to control the movement of the actuator. By changing the extension or compression of the syringe and the state of two valves, the soft hydraulic actuator shapes can both be changed to the required shape.

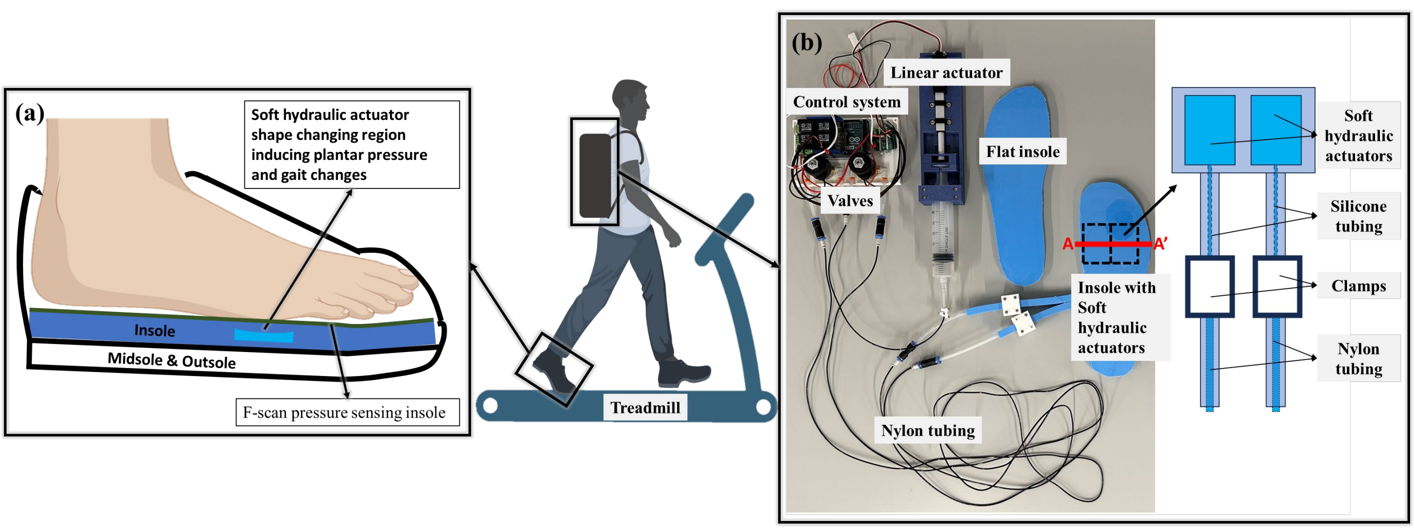


Fig. 1. The active shape changing insole, actuator and control system. (a) the location of the soft hydraulic actuators. (b) The black dashed line demonstrated the location of two soft hydraulic actuators, and the red solid line A-A' was the centre line of the two soft hydraulic actuators in the anterior-posterior direction which was defined as the high-risk region.

The active shape changing insole was placed in a right diabetic shoe and was then connected to the actuator by fittings

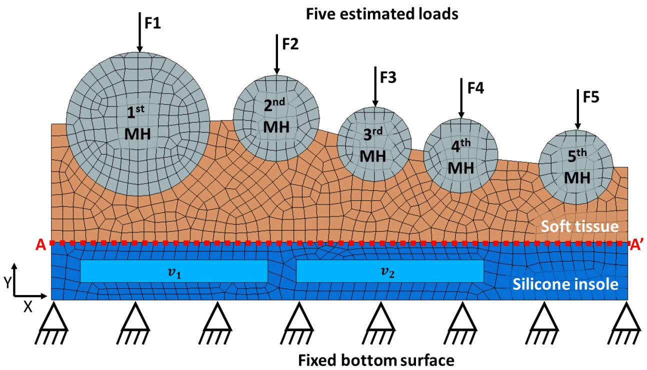


Fig. 2. The assembly view of the simplified 2D finite element model. F1, F2, F3, F4, and F5 are the five concentrated forces estimated from the plantar pressure data. v_1 and v_2 refer to the medial and lateral soft hydraulic actuators respectively. MH denotes the metatarsal heads and the red round dashed line A-A' indicates the path where the stress in the Y axis was exported.

TABLE I
DESIGN REQUIREMENTS FOR ACTIVE SHAPE CHANGING INSOLES

Requirements	Achieved	Future
Functionality requirements		
Ability to change insole shape in a controlled mannerr in metatarsal head region: 1. Maintain shape for more than 30 minutes; 2. Complete plantar pressure data analysis within six minutes; 3. Change insole shape within 60 seconds.	✓	
Enable plantar pressure optimisation while maintaining gait symmetry and regularity within 20% of participants normal gait.	✓	
Automatically change insole shape to minimise peak plantar pressure and pressure time integral.	✓	
Measure normal plantar pressure across the sole of the foot between 0-1 MPa.		✓
Usability requirements		
User comfort: 1. Insole thickness is less than 10mm; 2. Insole weight is less than 0.4 kg; 3. Plantar pressure is lower than that of normal gait.	✓	
Practicality: 1. Energy requirement for one shape changing is less than 100 J; 2. Fit within the shoe; 3. Suitable to use with different types of footwear; 4. Reliable to execute six plantar pressure optimisation processes without errors.	✓	
Safety: 1. No risk of electric shock; 2. No risk of harmful shape change; 3. No risk of loss of balance.	✓	

(Plug-in Reducer KQ2R, RS, UK) and a 2.0 mm tubing (Festo PUN-H Series Polyurethane Tubing, RS, UK). A solid silicone 10.0 mm thick insole without soft hydraulic actuators was inserted into the left shoe (passive insole). The whole control system was protected by a foam box and fixed to a backpack for the participant to carry while walking.

As shown in Fig. 1 (b), the black dashed line illustrates the location of two soft hydraulic actuators, and the red solid line A-A' was the centre line of the two soft hydraulic actuators in the anterior-posterior direction (Fig. 1). The centre line of the two soft hydraulic actuators was defined as the high-risk region, where the author optimised the plantar pressure distribution. By adjusting the volume of two soft hydraulic actuators, the insole's shape in the metatarsal heads region can be altered

TABLE II
THE SEARCH STRATEGY INFORMED BY THE FE MODEL AND THE NORMAL PLANTAR PRESSURE MEASUREMENTS DURING GAIT

First optimisation			Second optimisation				
Actuator volumes (mL)		Insole shape	Actuator volumes (mL)				Insole shape
Medial	Lateral		Medial		Lateral		
6	6		9	x	3	y	
6	9		9	x	4	y+1	
6	3		9	x	2	y-1	
9	6		10	x+1	4	y	
9	9		10	x+1	3	y+1	
9	3		10	x+1	2	y-1	
3	6		8	x-1	4	y	
3	9		8	x-1	3	y+1	
3	3		8	x-1	2	y-1	

Conditions for the first optimisation are the nine combinations of 3, 6, and 9 mL water for both two soft hydraulic actuators; Conditions for the second optimisation are the nine combinations of x-1, x, x+1 mL water for medial soft hydraulic actuator and y-1, y, y+1 mL water for lateral soft hydraulic actuator, where x and y are the soft hydraulic actuators volume determined according to the first optimization results. In this table, the second optimization is an example which assumes x and y are 9 and 3 respectively.

during two optimisations, thereby modifying both plantar pressure and pressure time integral.

B. Finite Element Model of the Metatarsal Heads

A simplified 2D finite element model consisting of five metatarsal heads, soft plantar tissue, and an active shape changing insole with soft hydraulic actuators was created in Abaqus as shown in Fig. 2 [19].

The geometry of the foot was simplified from the literature [19], and the geometry of the insole was measured from the prototype. No scaling was applied for different shoe size. The Young's Modulus of metatarsal heads were set to 7300 MPa with a Poisson's Ratio of 0.3 [25]. The soft tissue was set to be an Ogden hyperelastic material (μ=0.01645 MPa, α=6.82) [26]. The Young's Modulus of silicone was measured through a compressive mechanical test to be 6.18 MPa and the Poisson's ratio was assumed to be 0.49 for an incompressible material [27]. The element type was set to be CPS4R (a 4-node bilinear plane stress quadrilateral, reduced integration, hourglass control), and the mesh size was set to be 0.002 m. The mesh size in the simulation was refined, initially decreasing from 0.1 m to 0.001 m. Convergence was achieved at a mesh size of 0.002 m. This mesh design was validated by comparing the simulated plantar pressure along path A-A' (Fig. 2) with the actual plantar pressure data obtained from F-scan measurements (Fig. 1).

The soft hydraulic actuator volumes were adjustable from 2 ml to 10 ml by changing the shape of the medial and lateral soft hydraulic actuators (v_1 and v_2 in Fig. 2) as shown in TABLE II. Then the five metatarsal heads were constrained to move only on the Y axis. The medial and lateral edges of both the foot and insole were constrained to move only along the Y axis. The interaction between the foot and insole was hard contact with an estimated friction coefficient of 0.5 [28]. The bottom surface of the insole was fixed, and the two soft hydraulic actuators (v_1 and v_2 in Fig. 2) were set to be fluid cavities. The finite element model was solved in five load steps to simulate the plantar pressure distribution under different load conditions. The load conditions on the metatarsal heads were estimated from the F-scan plantar pressure data along the centre line of the two soft hydraulic actuators in the anterior-posterior direction (Fig. 1 (b)) at five uniform time points of one normal gait cycle.

As shown in Fig. 2, the interface pressure between insole and foot was exported through the path A-A' at the end of 1st – 5th load steps. Pressure time integral was estimated, as in (1).

$$PTI = \sum_{1}^{5} P_i \times t \div 5 \quad (1)$$

where PTI means the pressure time integral, i means the load steps, t means the gait cycle time.

C. Shape Changing Control Algorithm

The objective of the control algorithm was to minimise the diabetic foot ulceration risk considering both the peak plantar pressure and pressure time integral by adapting the shape of the active shape changing insole based on results from finite element simulations as shown in cost functions (2, 3, 4, 5). The process of the active shape changing insole optimisation are applied to improve the plantar pressure distribution recurrently (Fig. 3). Two optimisation processes are conducted in this study which are referred to as the first optimisation and the second optimisation.

$$PPP = f(v_1, v_2)\ subject\ to: v_1 \in 1,2:9, v_2 \in 1,2:9 \quad (2)$$

$$PPTI = f(v_1, v_2)\ subject\ to: v_1 \in 1,2:9, v_2 \in 1,2:9 \quad (3)$$

$$min(R) = f(PPP, PPTI) \quad (4)$$

$$R_i = \left(\frac{PPP_i - PPP_{min}}{PPP_{max} - PPP_{min}} + \frac{PPTI_i - PPTI_{min}}{PPTI_{max} - PPTI_{min}}\right) \div 2 \times 100 \quad (5)$$

where PPP is a matrix of peak plantar pressure of nine conditions in kPa, $PPTI$ is a matrix of peak pressure time integral of nine conditions in kPa·s, v_1 is the medial soft hydraulic actuator volume in mL, v_2 is the lateral soft hydraulic actuator volume in mL, R is the diabetic foot ulceration risk correlating with peak plantar pressure and peak pressure time integral, i is the condition number, max is the maximum value of the matrix, and min is the minimum value of the matrix.

The active shape changing insole starts from a neutral condition when the medial and lateral soft hydraulic actuators are filled with 6 mL of water (filling the volume, leaving the surface of the insole undeformed). The plantar pressure during walking was measured by an in-shoe measurement device (Tekscan Inc., Norwood, MA, USA). The authors reviewed the data and choose one typical whole gait cycle. Plantar pressure data at five uniform time points of this one gait cycle was exported to estimate five load conditions for finite element model. The plantar pressure data was then inputted to the MATLAB environment to estimate the metatarsal heads load by integrating the pressure at each metatarsal head's region. The five load conditions were input to the finite element model to simulate the predicted plantar pressure of nine conditions. Nine conditions for the first optimisation were the nine combinations of 3, 6, and 9 mL water for both two soft hydraulic actuators, while nine conditions for the second optimisation were the nine combinations of x-1, x, x+1 mL water for medial soft hydraulic actuator and y-1, y, y+1 mL water for lateral soft hydraulic actuator, where x and y are the soft hydraulic actuators volume determined according to the first optimisation results (TABLE II). Pressure time integral of nine conditions were calculated by customed MATLAB code,

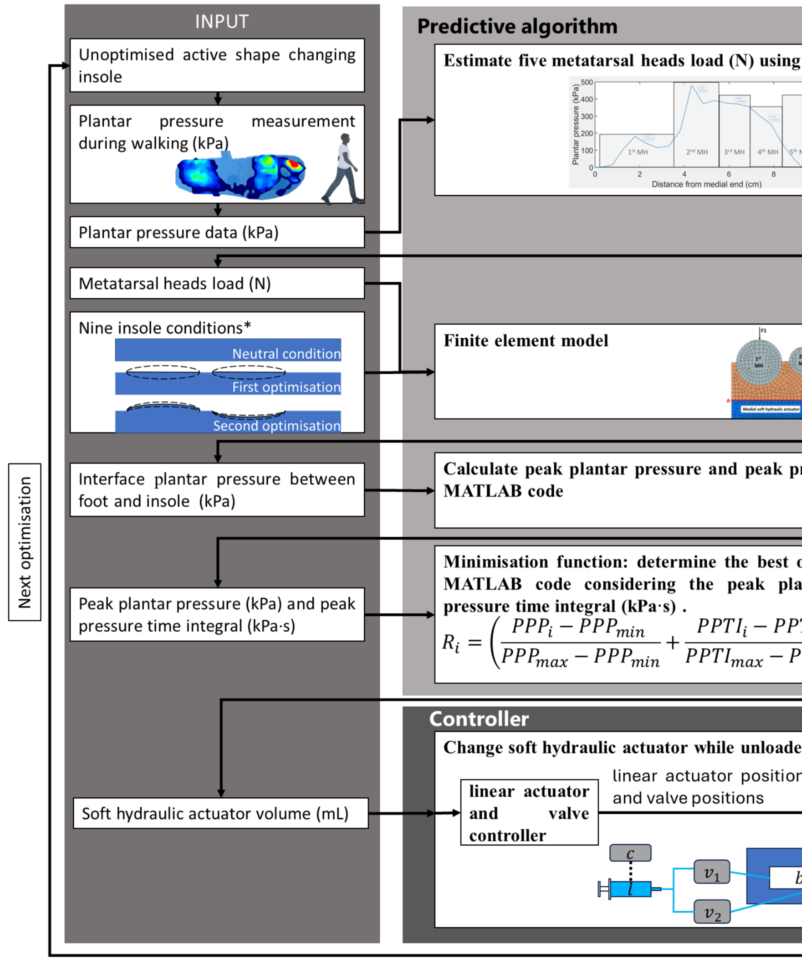


Fig. 3. The process of the active insole optimisation. c refers to the controller, l th hydraulic actuators. *Conditions for the first optimisation are the nine combinations Conditions for the second optimisation are the nine combinations of x-1, x, x+1 mL w for lateral soft hydraulic actuator, where x and y are the soft hydraulic actuators volu

as in (1). The peak plantar pressure and pressure time integral are evaluated by MATLAB to determine the best offloading condition (lowest diabetic foot ulceration risk), as in (5). The soft hydraulic actuator condition obtaining the smallest R value (diabetic foot ulceration risk) was chosen as the best offloading condition and the soft hydraulic actuator volumes are input to the actuator.

The soft hydraulic actuator volume data was input to the Arduino code by the researcher. The Arduino code controlled the state of the two valves and the position of the linear actuator to change the active shape changing insole shape. Then the second optimisation was conducted to refine the active shape changing insole further to reduce the R value (diabetic foot ulceration risk).

III. Methods For Gait Laboratory Validation

Ethical approval was granted for this study by the HRA and Health and Care Research Wales (HCRW) (reference 22/NW/0216) and the trial registration identifier was NCT05865353 (ClinicalTrials.gov). In this study, one healthy and two participants with diabetes were recruited for experimental trials at the University of Exeter. The mean and standard deviation of age, height and weight of the three male participants was 42.3 (14.6) years old, 171.3 (4.2) cm and 94.0

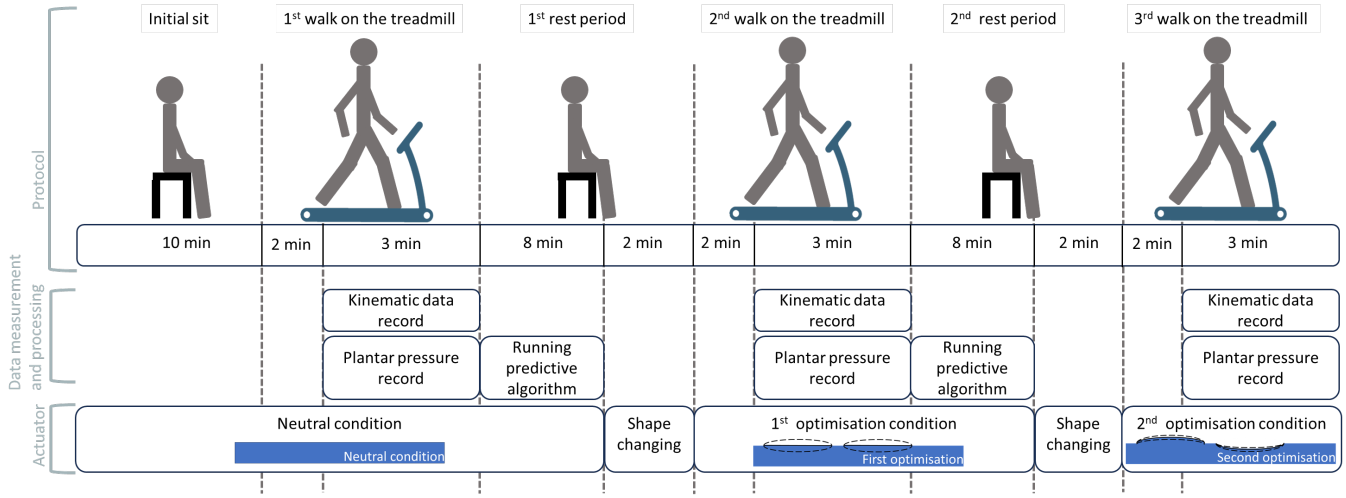


Fig. 4. An illustration of the experimental protocol combined with participant activities, data record and analysis, and actuator states.

(15.1) kg respectively. Before the experiment, health professionals examined the feet of all participants. Healthy participants were tested first to reduce the risk to diabetic participants.

A. Prediction of Plantar Pressure

Prior to conducting the experiment, participants were asked to wear socks (Silversock, Cuxson Gerrard & Co. Ltd., Oldbury, UK) and shorts (461069, SportsDirect.com Retail Ltd., UK) provided by the research team. The insole's soft hydraulic actuators were prepared by the experimenter, who evacuated any air before injecting 6 ml of water into each soft hydraulic actuator, ensuring the insole's surface was uniformly flat. For the experiment, the active shape changing insole was placed in the right shoe, and a standard flat silicone insole was inserted into the left shoe. Additionally, a pair of F-scan pressure sensing insoles (Tekscan Inc., Norwood, MA, USA), operating at a frequency of 100Hz, were positioned over the silicone insoles in each shoe (Fig. 1).

As shown in Fig. 4, this study involved two optimisation process aimed at minimising plantar pressure and pressure time integral in the high-risk region, i.e. the metatarsal heads (Fig. 3). The participant started from sitting on the chair to have a rest of ten minutes. In the first optimisation, the participant walked at a self-selected speed on a treadmill set to zero incline (Woodway PPS 55med-I) to acclimatise for two minutes. The participant kept walking for three more minutes. During this time, plantar pressure were recorded. Following this walking session, the participant took a ten-minute rest, allowing the experimenter to analyse the plantar pressure data. This involved using MATLAB code to approximate the load on the metatarsal heads, applying these loads to a finite element model, and then conducting simulations. The finite element model simulated nine different conditions, varying the water volume in the soft hydraulic actuators at 3, 6, and 9 mL, to assess their impact on plantar pressure. The results of these simulations were then analysed using MATLAB code to identify the condition which minimised both the plantar pressure and pressure time integral. The data analysis was finished within eight minutes. Based on the results, adjustments were made to the shape of the active shape changing insole within two minutes, and then the participant walked again to start the second optimisation process. The second optimisation process mirrored the first optimisation process, with the exception of the nine simulation conditions explained in Fig. 3. After completion of the second optimisation process, the participantwas asked to walk on the treadmill once more. This final walk was to record both the adjusted plantar pressure and gait kinematics data.

B. Gait Analysis Methods

A reflective marker was placed at the L3 location on the back of all three participants. Marker displacement data was collected during walking using a 12-camera motion capture system (Miqus M3, Qualisys AB, Gothenburg, Sweden) operating at 100 Hz (Fig. 4).

The gait analysis followed the method described by Moe-Nilssen and Helbostad [29]. In summary, the method involved filtering the marker displacement using a second-order 6 Hz

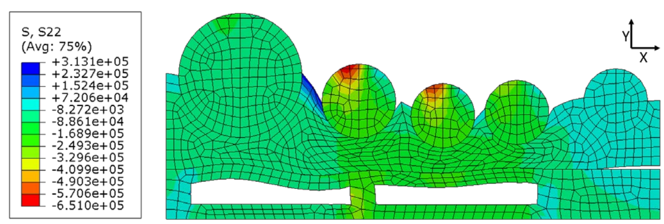


Fig. 5. Finite element results of stress in Y axis when applying neutral condition insole to diabetic participant 1 (Pa).

low-pass filter of the vertical and mediolateral displacement data from the L3 marker [30]. The filtered data was then differentiated twice with respect to time to obtain acceleration. The MATLAB function 'xcorr' was utilised to perform unbiased autocorrelation estimation on the acceleration data. This autocorrelation was normalised to ensure the coefficients at zero lag was 1.0. In analysing vertical acceleration autocorrelation, the first and second peak values to the right of zero lag were identified as step regularity (A_{d1}) and stride regularity (A_{d2}), respectively. In the case of mediolateral acceleration, the first valley and peak values to the right of zero

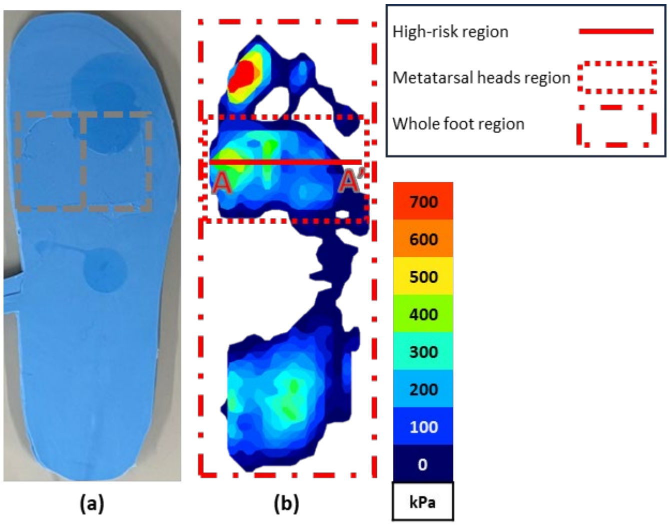
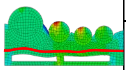
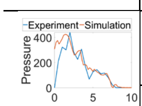


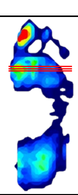
Fig. 6. The location of the two soft hydraulic actuators and the high-risk region. (a) Silicone insole with two soft hydraulic actuators: The dashed grey frame indicates the soft hydraulic actuators locations. (b) Average peak plantar pressure when applying neutral condition insole to diabetic participant 1. The red solid line A-A', dashed rectangle and dot-dashed rectangle are defined as the high-risk region, metatarsal heads region and whole foot region respectively.

lag on the Y-axis were step regularity (A_{d1}) and stride regularity (A_{d2}), respectively. Step asymmetry in both the vertical and mediolateral directions was quantified as the ratio of A_{d1} to A_{d2}. Additionally, cadence was calculated using the formula: $c = 60f/n$, where c represents cadence (steps/min), f is the sampling frequency, and n is the number of samples between zero lag and the first peak or valley.

TABLE IV
SIMULATION AND EXPERIMENT RESULT OF PLANTAR PRESSURE AT HIGH-RISK REGION







Participant	Neutral insoles	First optimisation	Second optimisation
Simulation result			
Average peak plantar pressure (kPa)			
H1	752	702	513
D1	198	160	138
D2	424	424	416
Peak pressure time integral (kPa·s)			
H1	225	212	109
D1	76	62	42
D2	186	186	186
Experiment result			
Average peak plantar pressure (kPa)			
H1	683	656	620
D1	359	234	172
D2	440	440	248
Peak pressure time integral (kPa·s)			
H1	135	132	127
D1	97	61	56
D2	207	207	117

H1 is the healthy participant 1, D1 is diabetic participant 1 and D2 is diabetic participant 2. The solid red line shows the high-risk region.

IV. Results For Gait Laboratory Validation

A. Prediction of Plantar pressure

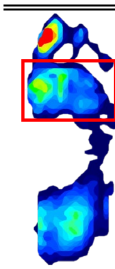
The finite element model achieved validation and convergence, and the normal plantar pressure was exported for analysis (Fig. 5).

The optimisation strategies advised for the three participants by the finite element model results are shown in Table III.

The experimental result of the plantar pressure distribution of diabetic participant 1 when applying neutral insole is shown in Fig. 6.

TABLE IV shows the simulation and experiment results of plantar pressure at high risk region respectively. The average peak plantar pressures of 10 gait cycles from both the experiment and simulation results were observed to decrease after the first and second optimisations except diabetic participant 2 whose first optimisation indicated the best coarse offloading condition is neutral condition. The peak pressure time integral of 10 gait cycles from both the experiment and simulation results decreased after the first and second optimisation except diabetic participant 2 who only observed the experiment result decrease after the second optimisation. Average peak plantar pressure decreases of 31.8%, 30.3%, and 1.9% in simulation results after the second optimisation were found in healthy participant 1, diabetic participant 1, and diabetic participant 2 respectively, while the pressure time integral decreases are 51.5%, 44.7% and 0 %. The experiment result of average peak plantar pressure observed a decrease of 9.2%, 52.1%, and 43.6% after the second optimisation in healthy participant 1, diabetic participant 1, and diabetic participant 2 respectively, while the decrease of pressure time integral are 5.9%, 42.3%, and 43.5%.

TABLE V
EXPERIMENT RESULT OF PLANTAR PRESSURE AT METATARSAL HEADS REGION



Participant	Neutral insoles	First optimisation	Second optimisation
Average peak plantar pressure (kPa)			
H1	1021	1029	1059
D1	388	413	383
D2	440	440	311
Peak pressure time integral (kPa·s)			
H1	224	226	213
D1	102	115	92
D2	214	214	136

H1 is the healthy participant 1, D1 is diabetic participant 1 and D2 is diabetic participant 2. The solid red frame shows the metatarsal heads region.

TABLE III
SOFT HYDRAULIC ACTUATORS VOLUMES CHANGE DURING TWO OPTIMISATION OF THREE PARTICIPANTS

Participant	Soft hydraulic actuators	Neutral insoles (mL)	First optimisation (mL)	Second optimisation (mL)
H1	Medial	6	9	10
	Lateral	6	6	5
D1	Medial	6	9	10
	Lateral	6	3	4
D2	Medial	6	6	5
	Lateral	6	6	6

H1 is the healthy participant 1, D1 is diabetic participant 1 and D2 is diabetic participant 2.

TABLE V demonstrates the experiment result of plantar pressure at the metatarsal heads region. The first optimisation increased the average peak plantar pressure and pressure time integral for healthy participant 1 by 0.8% and 0.9%, and for diabetic participant 1 by 6.4% and 12.7%. The second optimisation also increased the average peak plantar pressure but decreased the peak pressure time integral of healthy participant 1. Both diabetic participants observed a decrease in average peak plantar pressure and pressure time integral after the second optimisation. In conclusion, there is no great difference in both plantar pressure and pressure time integral at metatarsal heads region.

TABLE VI demonstrates the plantar pressure at the whole foot region. No clear trend was found for the average peak plantar pressure and the pressure time integral of the healthy participant. Both diabetic participants observed decrease in the average peak plantar pressure which are 27.6% and 13.0%, and peak pressure time integral which are 38.7% and 39.0% after the second optimisation.

TABLE VII
EXPERIMENTALLY DETERMINED GAIT PARAMETERS

D1	Neutral insoles	First optimisation	Second optimisation
Vertical			
Step regularity	0.83	0.93	0.79
Stride regularity	0.92	0.89	0.84
Step symmetry	0.90	0.93	0.94
Mediolateral			
Step regularity	-0.75	-0.77	-0.79
Stride regularity	0.82	0.77	0.79
Step symmetry	-0.91	-1.00	-1.00
Cadence	85.71	84.51	84.51
D2	Neutral insoles	First optimisation	Second optimisation
Vertical			
Step regularity	0.78	0.78	0.78
Stride regularity	0.84	0.84	0.73
Step symmetry	0.93	0.93	1.07
Mediolateral			
Step regularity	-0.85	-0.85	-0.89
Stride regularity	0.90	0.90	0.91
Step symmetry	-0.94	-0.94	-0.98
Cadence	82.19	82.19	84.51
H1	Neutral insoles	First optimisation	Second optimisation
Vertical			
Step regularity	0.89	0.92	0.90
Stride regularity	0.93	0.93	0.90
Step symmetry	0.96	0.99	1.00
Mediolateral			
Step regularity	-0.77	-0.77	-0.64
Stride regularity	0.87	0.87	0.75
Step symmetry	-0.89	-0.89	-0.85
Cadence	103.45	103.45	103.45

H1 is the healthy participant 1, D1 is diabetic participant 1 and D2 is diabetic participant 2. ADD units or is this SD

B. Gait Analysis Results

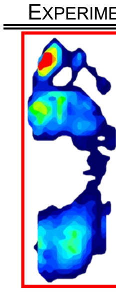
TABLE VII displays key gait parameters: step regularity, stride regularity, step symmetry, and cadence. The percentage changes in gait kinematics were observed below 16.8% from use of the active shape changing insoles. For diabetic participant 2, there was a 15.1% increase in vertical step symmetry and 13.1% decrease in vertical stride regularity following the second optimization. Healthy participant 1 observed a 16.8% decrease in mediolateral step regularity and a 13.8% decrease in mediolateral stride regularity after second optimisation. Aside from these specific changes, all other differences in parameters remained below 10.0% after first or second optimisation.

V. DISCUSSION

The aim of this paper was to present the development and evaluation of an active shape changing insole system to normalise plantar loading and hence reduce the risk of foot ulceration in people living with diabetes. The results of this study demonstrate the feasibility of the active shape changing insole to reduce the average peak plantar pressure at the high-risk region (Fig. 1 (b)), which is the centre line of the two soft hydraulic actuators in the anterior-posterior direction, by a mean of 35.0% [9.2% - 52.1%]. Furthermore, the pressure time integral at the high-risk region decreased by a mean of 30.6% [5.9% - 43.5%]. Importantly no average peak plantar pressure and pressure time integral increase were found at the metatarsal heads region in two diabetic participants after the second optimisation which means that the novel active shape changing insole can offload the high-risk region without increasing diabetic foot ulceration risk in metatarsal heads region.

No research has studied gait parameters in diabetic patients using the Moe-Nilssen and Helbostad methods [29]. However, these methods were applied to healthy young subjects, and the results showed a standard deviation of 0.7 in step regularity and 0.12 in stride regularity [31]. The step and stride regularity values for the two diabetic participants in this study were both smaller than 0.7 and 0.12, respectively, which indicates that we can reduce peak plantar pressure and pressure time integral of diabetic participants without large impact on gait kinematics. Compared to existing static offloading footwear, our system can adjust dynamically to changing gait and plantar loading normalising pressure, reducing the risk of ulceration without impacting on gait kinematics. The existing static footwear could affect the gait kinematics and therefore affect the plantar pressure distribution. The active shape changing insole can minimise the new peak plantar pressure caused by gait change through operating another optimization process. In the future, the combination with other predictive models and an accelerometer on the back could make the active shape changing insole keep improving the offloading strategy considering the effects of gait at the same time.

TABLE VI
EXPERIMENT RESULT OF PLANTAR PRESSURE AT WHOLE FOOT REGION



Participant	Neutral insoles	First optimisation	Second optimisation
Average peak plantar pressure (kPa)			
H1	1077	1059	1125
D1	605	413	438
D2	1194	1194	1039
Peak pressure time integral (kPa·s)			
H1	224	226	213
D1	150	115	92
D2	426	426	260

H1 is the healthy participant 1, D1 is diabetic participant 1 and D2 is diabetic participant 2. The solid red frame shows the whole foot region.

The active shape changing insole can determine the offloading level from 2 ml to 10 ml, which avoids insufficient or excessive offloading to overcome edge effect problems. Hemler et al. generated an intelligent footwear system consisting of pressure-offloading modules to change the insole shape when a high plantar pressure is measured, but the maximum compression length of the modules is 2.5 mm, which could be a limitation on the plantar pressure change possible [23]. Existing static offloading insole could reduce the plantar pressure by a mean of 32% [11]. Hemler et al.'s intelligent footwear observed a maximum plantar pressure reduction of 18-24% when testing on four healthy male participants [23], while the active shape changing insole in this study enabled changes of 9-43%. Consequently, our active shape changing insole may be better in decreasing plantar pressure.

In addition, unexpected high pressure could appear in other regions of the foot when changing the insole shape without prediction. By applying the finite elements model, we can normalise pressure across all regions to prevent excessive loading. The offloading strategy which could cause higher pressure can be avoided. The finite element models also shorten the time cost in obtaining the best offloading strategy. Currently, a simplified 2D model is applied in this study, which can only provide a coarse simulation result. However, compared with a 3D model, the 2D model enables running in an embedded system with limited computational power, and require fewer inputs. In the future, more powerful computation techniques could be introduced to improve the prediction of the offloading strategy.

The limitations of this study are the limited participants and F-scan plantar pressure measurement device. These insoles should be tested with a large sample of participants to gain deeper insights and prepare for the application of more powerful computation techniques. F-scan plantar pressure measurement device is not suitable for daily walking. A portable sensing insole system which can measure both pressure and shear stress was evaluated [32]. In the future, the active shape changing insole could be combined with this portable sensing insole system to measure plantar pressure during daily walking to make it practical.

VI. Conclusion

The active shape change insole driven by the finite elements model can minimise plantar pressure and pressure time integral without large plantar pressure and pressure time integral increasing in other regions and negatively affecting gait. A future combination of sensing insole can make daily plantar pressure optimisation feasible, and thereby prevent diabetic foot ulceration.

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J. Shuang is with School of Engineering, University of Manchester, Manchester, UK. (e-mail: jiawei.shuang@manchester.ac.uk).
A. Haron is with School of Engineering, University of Manchester, Manchester, UK. (e-mail: athia.haron@manchester.ac.uk).
D. Crosby is with School of Engineering, University of Manchester, Manchester, UK. (e-mail: damian.crosby@manchester.ac.uk).
G. J. Massey is with NIHR Exeter BRC, Exeter, UK, (e-mail: g.j.massey@exeter.ac.uk).
C. Lin is with School of Engineering, University of Manchester, Manchester, UK. (e-mail: chaofan.lin@manchester.ac.uk).
H. Dawes is with NIHR Exeter BRC, Exeter, UK, (e-mail: h.dawes@exeter.ac.uk).
F. L. Bowling is with School of Medical Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, UK, and Manchester Academic Health Science Centre, Manchester University NHS Foundation Trust, Manchester, UK.
N.D.Reeves is with Department of Life Sciences, Faculty of Science and Engineering, Manchester Metropolitan University, Manchester, United Kingdom, and Manchester Metropolitan University Institute of Sport, Manchester, United Kingdom
G. Cooper is with School of Engineering, University of Manchester, Manchester, UK. (e-mail: glen.cooper@manchester.ac.uk).
A. Weightman is with School of Engineering, University of Manchester, Manchester, UK. (e-mail: andrew.weightman@manchester.ac.uk).