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DEVELOPMENT AND TESTING OF A NOVEL DIABETIC ORTHOSIS FOR PLANTAR PRESSURE REDUCTION

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Abstract. *The prevalence of diabetes has been increasing worldwide, and this has resulted in a rise in diabetic foot ulcers. Several assistive devices, such as custom shoes, unloading orthoses, and insoles, have been developed to address these issues. A modular insole was developed to off-load the peak plantar pressures in diabetic patients. Plantar pressure values were measured using an indigenously fabricated pressure mapping insole integrated with high precision Force Sensitive Resistor (FSR) sensors. The performance of the modular insole was quantified quantitatively and qualitatively to assess its effectiveness. For the healthy participants, the results showed that the maximum average zonal pressure (AZP) was reduced by 97% from 122.39 ±3.62 kPa to 3.27 ±0.50 kPa during standing and by 98% from 195.71 ±3.19 kPa to 3.57 ±0.31 kPa during walking. Similarly, for the diabetic participants, AZP values were reduced by 96% from 67.92 ±12.45 kPa to 3.09 ±0.32 kPa for standing and by 97% from 130.96 ±4.27 kPa to 3.67 ±0.54 kPa for walking conditions, respectively. The results confirmed the effectiveness of the modular insole in off-loading the plantar pressure. The development of such devices holds great promise in improving the quality of life of diabetic patients and reducing the risk of complications such as diabetic ulceration*.

Key Words: *Diabetic Foot, Modular Insole, Pressure Off-loading, Intervention*

1. INTRODUCTION

Diabetes is a chronic illness that affects millions of people worldwide. In fact, there are currently 382 million cases of diabetes globally, and it's estimated that this number will increase to 592 million by 2035 [1–3]. One of the consequences of diabetes is diabetic foot ulceration, which is becoming more common as the population ages and obesity rates

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continue to rise [4]. Diabetic foot ulcers occur in around 5% of all patients with diabetes and can be the precursor to 80% of lower limb amputations due to diabetes [5–7]. These ulcers usually occur in areas of the foot that experience high levels of mechanical stress. If not treated promptly, foot ulcers can become infected and may ultimately require amputation [8].

Early diagnosis and timely medication can help prevent and mitigate ulceration in diabetic patients. However, when peripheral neuropathy occurs in the foot, which is a common occurrence in diabetic patients, diagnosing the condition becomes extremely complicated and difficult. When it comes to treating protruding diabetic ulcers, conventional interventions include using pressure off-loading techniques such as crutches, special foot orthotics, and custom pressure off-loading insoles [9–11]. The main objective of medical intervention is to redistribute the pressure exerted on the plantar fascia, which is the underlying cause of ulcers [12,13]. Customized foot orthoses are regarded as a better treatment because they provide complete contact with the plantar portion of the foot, unlike prefabricated orthoses [14]. However, effective treatment of diabetic ulcers requires a comprehensive approach, including wound care and glycemic control management, to prevent further complications. Therefore, diabetic patients are advised to seek medical attention immediately after they notice any signs of foot ulceration to prevent the condition from worsening [15,16].

Previous studies have shown that it is essential to lower plantar pressures in diabetic patients to reduce this risk [17–19]. In a study by Caselli et al. [20], they observed that the forefoot and heel areas were the most affected in the diabetic population, with the highest levels of plantar pressure. Furthermore, increased pressure was positively correlated with increased severity of neuropathic disease. A force-measuring device was used by Cock et al. [21] to determine the center of pressure and plantar pressure of the foot. They found significant variation in the results for different gait phases across all the participants. The recent development of sensor-based insoles has made it possible for patients to collect data outside of clinics, making it easier to monitor their progress and detect any potential issues early on [22,23]. Several studies have used shoe-based pressure-measuring devices while walking or running. These devices typically have numerous sensing sites (piezoresistive materials or force-sensitive resistors) and use wireless data transmission methods [24,25]. Force-sensitive resistors or piezoresistive materials are often used to provide flexibility to the sensors [26].

After conducting a thorough review of existing literature, it was observed that custom pressure off-loading insoles offer similar assistance to Total Contact Cast (TCC) but with fewer drawbacks. The fabrication of such customized insoles is a laborious and intricate procedure that demands detailed attention to every aspect [27,28]. Also, the process of traditional fabrication might be time-consuming, as it may need several days to effectively address the issue of isolating and relieving pressure from the area prone to ulceration [29–31]. To address these challenges, there is a need to develop a tailored and economical insole that is almost universally applicable and can efficiently alleviate pressure from any specific area on the sole of a diabetic foot. Additionally, the insole should possess both comfort and shock absorption characteristics, particularly at the heel, while also providing support to the whole plantar area of the foot. The reported work focuses on developing and validating a customized insole designed to off-load plantar pressure for diabetic patients. This particular insole can effectively intervene for ulceration during post-operative medical care and wound care.

2. Materials And Methods

The modular diabetic pressure off-loading insole was designed to alleviate pressure on ulcerated areas of the foot. Removable supporting segments were made to create a void under the affected area, which helps to distribute weight more evenly and reduce pressure on the ulcer. The fabrication process involves using high-quality materials and advanced manufacturing techniques to ensure that the insole is durable, comfortable, and effective. A pressure measurement device was used to measure the pressure distribution and off-loading capabilities of the insole. The testing process involves monitoring the results to verify that the insole is effective in reducing pressure in diabetic patients and corresponding on ulcerated areas (in future studies) and improving the overall comfort and mobility of the individual.

2.1. Designing and Modeling of Modular Insole

A standard UK-8 insole size was considered for designing and fabricating the modular insole. The outline of the insole's mid-frame was plotted as per the mondopoint system using SolidWorks 2021 (Dassault Systèmes, France). The modular insole comprised two main components: the mid-frame (Fig. 1b) and fourteen uniquely molded silicone rubber inserts (Fig. 1a). To accommodate the specific needs of each region, molded silicone inserts were designed to be individually removable and re-attachable. This segmentation was based on previous literature studies, which highlighted the most common areas where diabetic patients experience abnormal or peak plantar pressures [15,16].

Due to the significant stretching and bending strains experienced when walking, Thermoplastic Polyurethane (TPU) material with a shore hardness of 95A was chosen for the 3D printing of mid-frame (0.6mm thickness) to withstand these stress conditions [32,33]. The inserts were created with grooves of width and depth of 0.6mm and 3mm, respectively (Fig. 1c), to facilitate the proper attachment of the inserts to the matching segments in the mid-frame. These inserts (thickness of 6mm each) were designed to provide maximum comfort and support to the foot, making it easier to walk, run, and stand for prolonged periods of time. The focus of this work was to improve the cushioning properties of insoles; therefore, the cylindrical voids were strategically placed in a homogenous pattern, designed, and incorporated into the insoles (as shown in Fig. 1a). The inserts were made using a polymeric solution of shore hardness 10A (liquid silicone rubber), a bio-inert and wear-resistant material that was easy to mold.

Figure 2 shows the 3D-printed molds for fabricating the modular insole and the fabricated silicone inserts. Figure 3 illustrates the 3D-printed mid-frame of the insole and the assembled silicone inserts with the mid-frame. The final modular insole was then packed in the pouch for the participant's trial. The material used for the pouch was soft and stretchable, which means that the pouch will adjust itself according to the foot's movements, providing a smooth and comfortable experience for the individual. The assembled insole, designed specifically for diabetic patients, is a novel technology that aims to improve the individual's comfort while reducing the risk of ulceration.

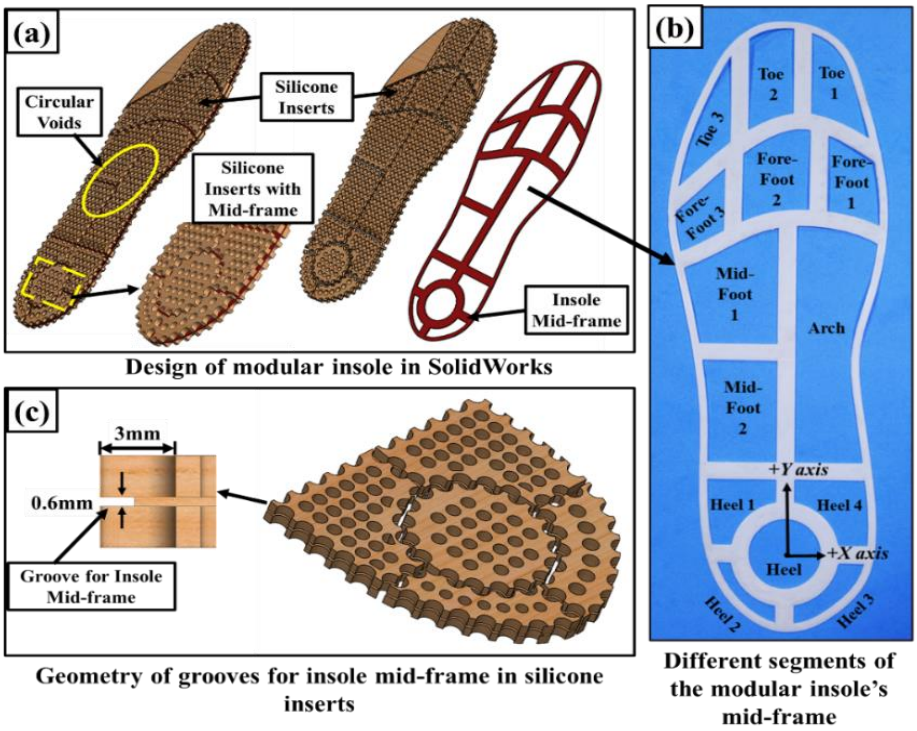

Fig. 1 (a) SolidWorks design of modular insole, (b) 3D-printed mid-frame for holding the inserts, (c) grooves geometry in inserts

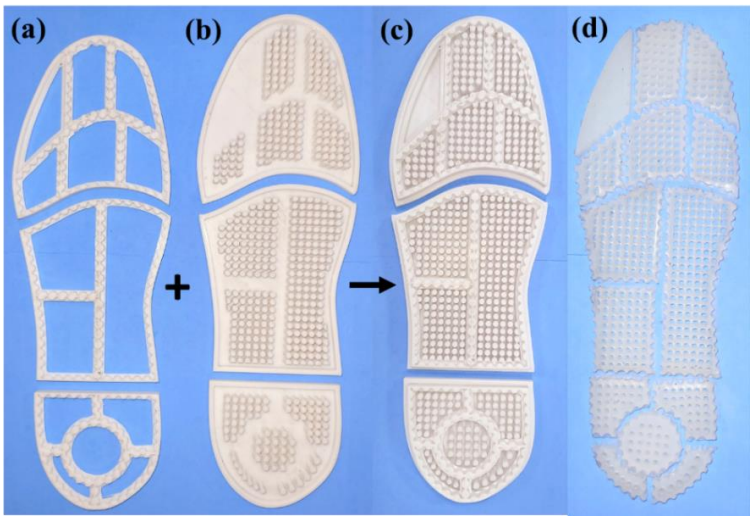

Fig. 2 (a) 3D-printed mold wall with grooves, (b) mold base with circular voids, (c) assembled mold for fabricating silicone inserts, (d) fabricated silicone inserts

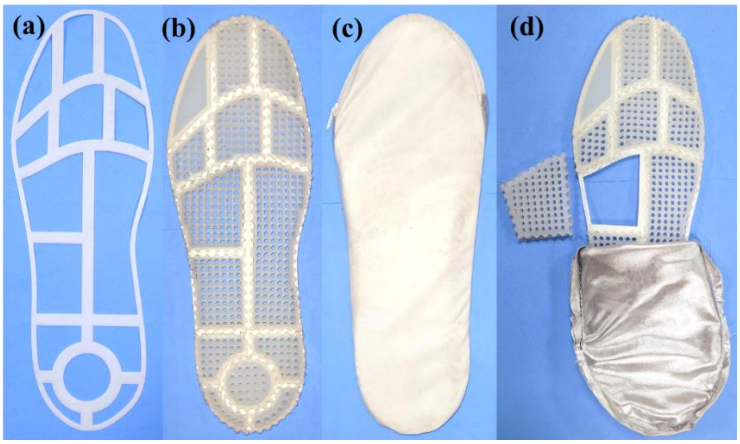

Fig. 3 (a) 3D printed mid-frame, (b) assembled silicone inserts and mid-frame, (c) modular insole in the pouch, (d) mid-foot 1 insert removed from the insole (for representation only)

2.2. Pressure Measurement of Plantar Fascia

A wearable pressure measurement insole was developed to quantify the pressure values at the foot plantar, with the aim of validating the effectiveness of modular insole in pressure off-loading. The insole was comprised of Force Sensitive Resistor (FSR) sensors manufactured by Interlink Electronics, Inc., California, United States. These FSR sensors (Ø12.5 mm) have proven to be highly effective in sensing variations in pressure levels, and they were placed in the centers of eleven different regions of the modular insole. However, three regions (Toe 3, Heel 2, and Heel 3) were not measured due to their small size or because they showed insignificant pressure levels that would not contribute to the occurrence or progression of ulceration [15,16,34]. Table 1 shows the location of each sensor with respect to the segment Heel as the origin point. The negative coordinates represent the lateral part, and the positive coordinates represent the medial part of the foot (Fig. 1b).

Table 1 Sensor location on the in-house fabricated pressure measuring insole

Sensor Location		**Coordinates (in mm)**	
Abbreviated word	*Abbreviation*	*X-axis*	*Y-axis*
Heel	Heel	0	0
Heel 4	Heel Medial Region	22.5	21
Heel 1	Heel Lateral Region	-22.5	21
Arch	Arch	14.5	86
Mid-Foot 2	Midfoot Region 2	-19	58
Mid-Foot 1	Midfoot Region 1	-22	110
Fore-Foot 3	Forefoot Region 3	-37	143
Fore-Foot 2	Forefoot Region 2	-6	161
Fore-Foot 1	Forefoot Region 1	25	158
Toe 2	Toe Region 2	-9	207
Toe 1	Toe Region 1 (Hallux)	16.5	203

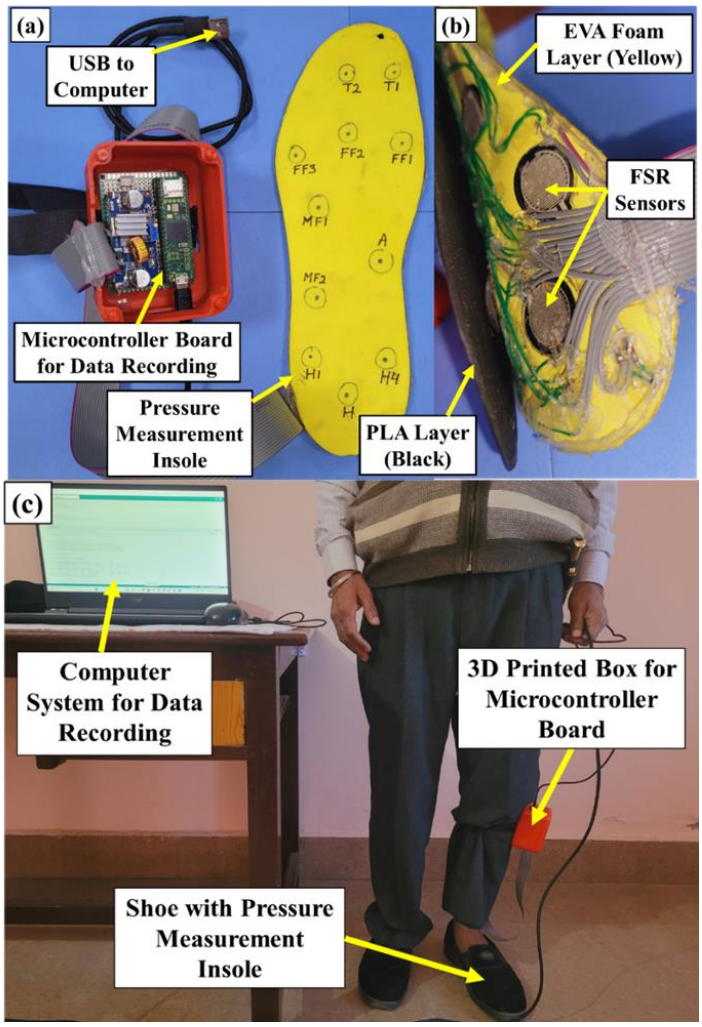

Fig. 4 (a) Pressure measuring insole with microcontroller board for data recording, (b) EVA-PLA sandwich with FSR sensors, (c) diabetic volunteer with the modular insole (inside the shoe)

Figure 4 shows a detailed view of the pressure-measuring insole, designed and fabricated to monitor the plantar pressure values of the foot. The FSR sensors were affixed to one side of a 2mm thick Ethylene-Vinyl Acetate (EVA) foam sheet, which was precisely shaped into the dimensions of a UK8-size insole, serving as the base for the FSR sensors. On the opposite side, a 3D-printed PLA sheet of 0.6mm thickness was used to cover the sensors, providing FSR sensors with a solid surface for the accurate recording of the data. A voltage divider circuit connected the sensors in the insole to the microcontroller board, which reduced the voltage from the sensors to a level that could be read by the microcontroller [35,36]. A box was 3D printed to fix the microcontroller board, which was

tied onto the volunteer's leg using a Velcro strap during all trials in this study to record the data via a 20-band flat ribbon cable (Fig. 4c). By keeping the microcontroller board in a fixed position, the data obtained from the sensors could be accurately recorded and analyzed.

2.3. Measurement of the Recorded Data

During the data collection, the pressure-measuring insole was positioned underneath the modular insole inside the shoe. Arduino Integrated Development Environment (IDE) was used to code pressure measuring insoles with complete scans of 5000 per second to collect sensor data. A complete scan was operationally defined as the time required for the microcontroller to execute one full loop of the whole code and display the processed values of each sensor. The study included the mean value of plantar pressures, calculated at a frequency of 20 milliseconds for each scan, as well as the highest pressure values recorded by each sensor at any point throughout the trial period. The recorded data values were shown on the laptop in the Arduino IDE program (Fig. 4c) and full computed datasets were saved from the microcontroller board to the laptop via a USB connection for each trial.

2.4. Performance of Modular Insole

The modular insole was tested quantitatively and qualitatively on a group of fifteen healthy and fifteen diabetic participants (all males) with a UK8 foot size under the approval of the Ethical Committee of the Indian Institute of Technology Delhi (IIT-Delhi). Table 2 listed the details for healthy participants (height, weight, age) and diabetic participants (height, weight, age, blood glucose) of the present study. The modular insole was tested using various performance parameters, including comfort, fit, durability, and pressure off-loading, to ensure that it meets the highest safety and efficacy standards for diabetic patients.

Table 2 Details of the healthy and participants with diabetes for the study

Sr. No.	**Healthy Participants**			**Participants with Diabetes**			
	Height (in cm)	Weight (in Kg)	Age (in years)	Height (in cm)	Weight (in Kg)	Age (in years)	Blood Glucose (mg/dL)
1	165.1	72	28	170.4	72	62	178.3
2	185.4	66	33	174.2	78	58	141.4
3	180.3	83	31	175.3	81	47	120.5
4	175.4	78	42	170.2	65	51	126.5
5	180.3	86	50	165.4	76	39	130.5
6	177.1	74	52	173.7	77	42	138.2
7	182.9	68	47	165.1	89	60	174.2
8	164.6	91	62	175.5	71	53	230.4
9	171.4	57	30	173.7	87	55	142.4
10	166.3	63	26	170.2	79	49	164.7
11	182.9	61	29	180.3	59	36	136.2
12	185.4	74	35	166.3	64	59	152.1
13	173.7	88	36	177.6	82	58	211.3
14	164.6	76	32	181.1	71	46	132.8
15	175.4	62	35	179.3	83	51	146.5

2.4.1 Qualitative Tests

The study aimed to evaluate the performance of a modular insole using the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) questionnaire [37,38]. This questionnaire measures the subjective parameters of an assistive device, such as comfort, ease of use, and effectiveness. The questionnaire has eight items, and each item was scored from 1 to 5, where 5 corresponds to completely satisfied and 1 means completely dissatisfied. The modular insole was tested for healthy participants (HP) and diabetic participants (DP) in two cases, i.e., with all inserts in the midframe in case 1 (Q1) and removal of inserts one by one in case 2 (Q2). In this way, there were two individual cases for healthy participants (HP-Q1 and HP-Q2) and diabetic participants (DP-Q1 and DP-Q2).

2.4.2 Quantitative Tests

The testing setup consists of a pair of shoes with a pressure-measuring insole under the modular insole in one of the shoes by replacing the original insole. The testing trials were carried out under two conditions: standing (stated as case CS) and walking (stated as case CW). Initially, each participant trial was conducted with all inserts connected to the modular insole, which is denoted as CS (full) and CW (full). Subsequently, nine out of the fourteen inserts (namely, Toe 1, Fore-Foot 1, Fore-Foot 2, Fore-Foot 3, Mid-Foot 1, Mid-Foot 2, Heel 1, Heel 4, and Heel) were individually removed to record the plantar pressure values for each sub-case per participant. Toe 2 and Arch were not included in the removal experiments due to their significantly low-pressure magnitudes in both CS and CW scenarios. However, pressure for these regions was recorded for the full insole during standing and walking. Each participant had a total of 10 trials, consisting of one trial with a complete insole and nine trials with the inserts removed for each instance (CS and CW). The AZP values were recorded using the running average algorithm with pressure measuring insole. During the trial in case CS, participants were instructed to maintain an upright posture, as they typically would, for a period of 5 seconds. For walking cases (i.e., CW), the participants were instructed to walk naturally and without any restrictions for a period of 20 seconds. The effectiveness of the modular insole was validated based on its AZP values for the off-loaded regions, confirming the efficient pressure off-loading in the desired region.

3. Results and Discussion

3.1. QUEST-based Qualitative Analysis

For healthy participants, the QUEST score was calculated to be 4.63 ±0.08 for the HP-Q1 case and 4.61 ±0.09 for the HP-Q2 case. For diabetic participants, the QUEST score for case DP-Q1 was 4.80 ±0.06, indicating high satisfaction with the insole's comfort and other features. Similarly, for case DP-Q2, the QUEST score was 4.81 ±0.17, demonstrating consistent user satisfaction. Figure 5 displays the QUEST scoring for the healthy participants (Fig. 5a) and diabetic participants (Fig. 5b), providing a detailed view of the individual’s satisfaction levels.

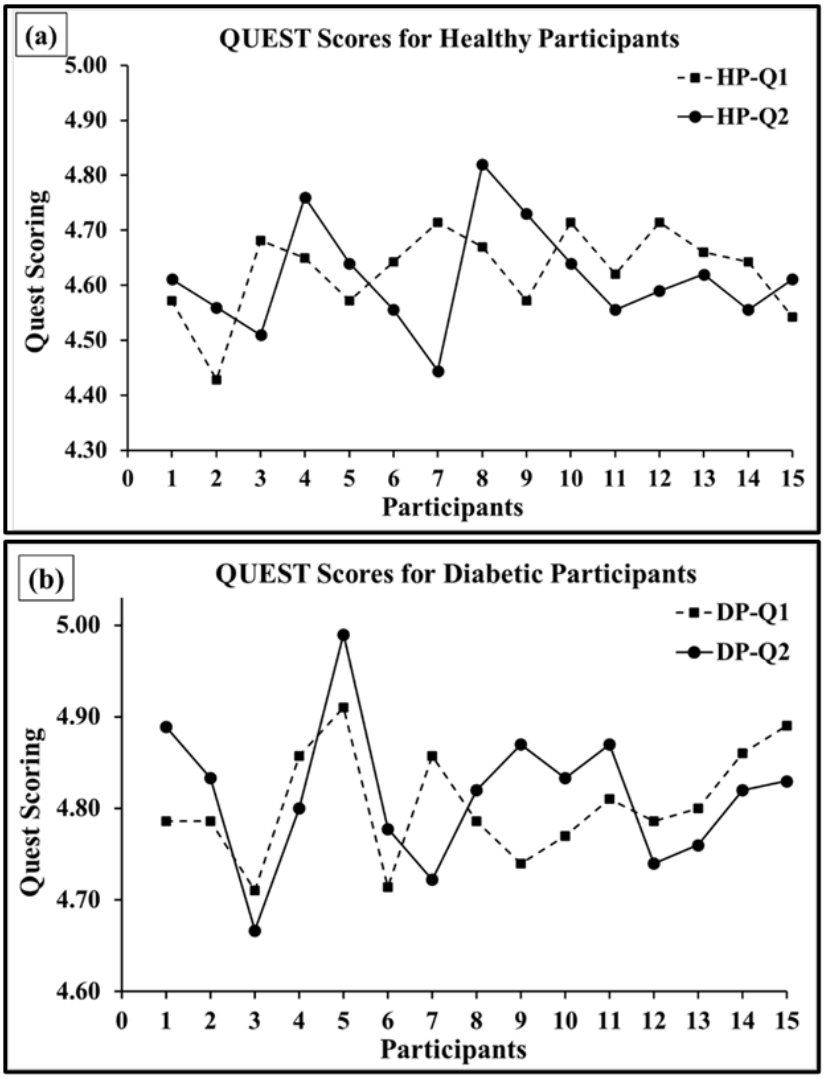

Fig. 5 QUEST scoring for: (a) healthy participants, (b) diabetic participants

According to the QUEST results, the participants were very satisfied with the performance of the insole, as it scored between 4 and 5 on the scale. During the Qualitative trials for healthy (HP-Q1, HP-Q2) and diabetic participants (DP-Q1, DP-Q2), certain feedback points regarding the modular diabetic insole were noted. The participants did not notice the truncated regions at Fore-Foot 1, Fore-Foot 2, Fore-Foot 3, Heel 1, and Heel 4 during Q2 (HP-Q2 and DP-Q2), probably due to support from the surrounding surface of the insole. The empty space left by inserts Toe 1 and Toe 2 in Q2 (HP-Q2 and DP-Q2) was only felt by participants when they lowered their toes voluntarily. The voids created by removing inserts Toe 3, Heel 2, and Heel 3 were entirely imperceptible due to their minimal

areas. The foot area at region Toe 3-5 did not add my significant contribution to the plantar pressure values and hence excluded from the design of circular voids for simplicity. The simplified insole design and fabrication made it easy for everyone to use, and participants were comfortable removing and reattaching any insert from the mid-frame. All participants acknowledged that the insole offered a substantial level of comfort to the foot. Moreover, the insole can be recommended as a comfort insole that can be used in cases of non-diabetic foot ulceration as well.

3.2. Evaluation of Pressure Off-loading

As discussed earlier, a pressure mapping insole was used for the measurement of plantar pressures under eleven segments of the modular insole for healthy and diabetic participants for standing and walking conditions, respectively. These values were then averaged (from the individual values of all participants) to calculate the values of Average Zonal Pressure (AZP). The AZP values provide a comprehensive understanding of the distribution of pressures across the different regions of the foot.

3.2.1 Pressure Off-loading for Healthy Participants

Table 3 comprehensively summarizes the AZP values (mean ±S.D.) for nine cases that were off-loaded during standing conditions for healthy participants. The values for full insole and no insole were also recorded to compare the effectiveness of the off-loading in different cases. Similarly, Table 4 corresponds to the summary of AZP values for plantar pressure off-loading during walking conditions for healthy patients. Figure 6 provides detailed information about the pressure values at various regions for healthy participants in standing and walking cases. The pressure values were recorded at eleven different locations (nine off-loaded), and the corresponding AZP values (in kPa) were noted for all fifteen participants. These values were then averaged to obtain a representative value (mean ±S.D.). To provide a more comprehensive understanding, Figs. 6a and 6c show AZP values for healthy participants in standing and walking cases with full modular insole, i.e., without removing any insert from the insole. In contrast, Figs. 6b and 6d illustrate the off-loaded AZP values obtained by removing one of the inserts and keeping the rest during trials during standing and walking conditions, respectively.

For standing condition with the full insole, the maximum value for average zonal pressure was observed at the heel region with a magnitude of 122.39±3.62 kPa (Fig. 6a). On the other hand, the minimum magnitude of average zonal pressure was observed at the arch region with a value of 3.86±3.66 kPa. The pressure magnitudes at inserts Toe 2 and Arch were quite low, accounting for only 1.83% and 0.76% of the total pressure recorded. Therefore, the AZP values for Toe 2 and Arch were not considered for the study. In the off-loaded case, as shown in Fig. 6b, the plantar pressure values decrease from 97.52% to 99.98% at Mid-Foot 1 and Heel 1, respectively. The maximum AZP value was quantified at Fore-Foot 1 (4.89±1.38 kPa), confirming the off-loading at other regions during standing conditions across all the participants.

Table 3 Average zonal pressure values (in kPa) for healthy participants (standing) in different off-loading conditions

Removed inserts ↓	**Toe 1**	**Toe 2**	**Fore-Foot 1**	**Fore-Foot 2**	**Fore-Foot 3**	**Mid-Foot 1**	**Mid-Foot 2**	**Arch**	**Heel 1**	**Heel 4**	**Heel**
No insole	63.52	7.40	98.34	24.35	78.66	32.27	25.73	3.09	116.64	17.77	133.44
Std. Dev.	4.40	5.88	4.06	5.27	5.59	6.78	6.50	3.11	3.41	4.98	3.54
Full insole	47.52	9.20	73.74	18.55	54.82	22.67	23.55	3.86	105.96	19.31	122.39
Std. Dev.	3.97	4.89	3.80	3.95	4.78	5.61	5.25	3.66	3.51	6.06	3.62
Toe 1 removed	**3.52**	10.53	74.78	31.87	42.41	21.26	24.45	3.17	95.50	12.08	82.82
Std. Dev.	**0.38**	3.51	4.01	3.60	4.76	6.29	5.46	3.14	4.03	4.36	4.25
Fore-Foot 1 removed	51.86	25.22	**4.89**	18.73	87.51	50.05	60.60	3.53	98.93	44.23	147.58
Std. Dev.	4.30	5.45	**1.38**	4.19	3.98	4.78	4.06	3.47	3.58	4.47	3.65
Fore-Foot 2 removed	34.71	9.19	53.13	**3.31**	66.95	22.47	40.72	3.59	115.28	30.70	148.95
Std. Dev.	3.86	5.48	4.77	**0.30**	3.79	5.62	4.89	3.39	3.30	6.06	3.56
Fore-Foot 3 removed	84.69	20.10	87.35	15.28	**3.82**	15.59	19.22	13.18	86.16	23.30	144.67
Std. Dev.	3.10	3.95	3.37	3.44	**0.34**	3.61	3.68	3.73	3.33	3.68	3.29
Mid-Foot 1 removed	67.52	21.29	88.78	16.40	47.05	**3.97**	34.81	4.06	109.65	42.74	141.72
Std. Dev.	3.26	3.56	3.38	3.50	3.94	**0.87**	5.98	3.41	3.57	4.69	3.47
Mid-Foot 2 removed	55.69	41.65	34.16	29.71	91.86	60.48	**4.41**	3.47	117.52	33.77	155.36
Std. Dev.	4.14	3.84	12.24	4.02	3.87	3.54	**1.96**	3.37	3.31	4.66	3.35
Heel 1 removed	46.71	5.97	111.58	40.03	89.06	29.83	27.35	10.85	**3.86**	58.52	115.08
Std. Dev.	3.31	3.29	3.19	3.41	3.52	3.68	4.19	3.48	**0.02**	3.69	3.38
Heel 4 removed	46.71	5.97	111.58	40.03	89.06	29.83	27.35	10.85	58.52	**3.09**	115.08
Std. Dev.	3.31	3.29	3.19	3.41	3.52	3.68	4.19	3.48	3.69	**0.09**	3.38
Heel removed	65.62	13.41	106.73	35.25	105.09	43.31	36.13	9.05	52.68	16.63	**3.27**
Std. Dev.	4.36	5.12	3.72	4.34	4.01	4.35	3.58	6.01	5.52	4.28	**0.50**

** Bold values represent the removed/off-loaded inserts.*

Figure 6c shows the AZP values for healthy participants with the full insole in walking condition. The highest value of average zonal pressure was observed at the heel region with a magnitude of 195.16±3.19 kPa, indicating the maximum pressure applied at that point. Conversely, the lowest average zonal pressure value was observed at the arch region with a magnitude of 22.32±6.28 kPa. The areas with high AZP values are considered to be at greater risk of skin breakdown and injury, while the areas with low AZP values are less susceptible to injury.

It should be noted that the AZP magnitudes at inserts Toe 2 and Arch were observed to be very low, contributing only 1.44% and 1.88% of the total recorded pressure. They were not considered for evaluation based on the fact that their impact on the overall pressure was insignificant, and removing these inserts would not have a significant effect on the outcome

of the trials. In Fig. 6d, the off-loaded cases showed a significant decrease in pressure, ranging from 92.71% to 98.17% at segments Heel 4 and Heel, respectively. The highest pressure value occurred at segment Fore-Foot 3, with an AZP value of 5.70±1.25 kPa. It was also observed that the Fore-Foot 1 and Fore-Foot 2 segments followed the highest pressure value after the Fore-Foot 3 segment with a magnitude of 4.36 ±0.48 kPa and 4.07±1.36 kPa, respectively. Although these values were minor in magnitude, evidence of similar contact during the heel strike was observed at segments Heel, Heel 4, and Heel 1. After considering the observed results and participant feedback, it was concluded that the modular insole provided sufficient pressure off-loading in all nine regions, with a range of 92.71% – 98.17%.

Table 4 Average zonal pressure values (in kPa) for healthy participants (walking) in different off-loading conditions

Removed inserts ↓	**Toe 1**	**Toe 2**	**Fore-Foot 1**	**Fore-Foot 2**	**Fore-Foot 3**	**Mid-Foot 1**	**Mid-Foot 2**	**Arch**	**Heel 1**	**Heel 4**	**Heel**
No insole	67.16	6.55	114.50	30.53	69.23	22.26	21.64	4.60	116.88	19.58	138.43
Std. Dev.	5.96	7.35	4.71	7.08	7.41	7.72	9.10	5.96	3.60	6.63	4.31
Full insole	128.10	17.06	171.69	93.98	201.21	78.32	80.87	22.32	143.63	48.66	195.16
Std. Dev.	3.91	5.42	3.42	3.29	3.52	3.44	3.58	6.28	3.23	3.93	3.19
Toe 1 removed	**3.33**	17.79	80.88	36.58	163.14	103.99	106.44	3.19	104.56	71.88	195.55
Std. Dev.	**0.34**	7.58	4.10	4.35	3.57	3.33	3.59	3.10	3.61	4.54	3.52
Fore-Foot 1 removed	77.12	21.64	**4.36**	52.35	192.36	85.48	102.29	10.03	130.71	71.09	186.05
Std. Dev.	4.85	5.74	**0.48**	4.55	4.14	3.42	3.48	11.02	3.75	4.01	3.52
Fore-Foot 2 removed	130.07	58.66	150.93	**4.07**	122.55	62.83	87.95	3.26	97.04	50.44	150.24
Std. Dev.	3.12	3.41	3.34	**1.36**	3.44	3.33	3.30	3.06	3.15	3.52	3.16
Fore-Foot 3 removed	132.77	40.54	32.36	57.86	**5.70**	45.55	63.84	15.02	123.82	55.21	171.36
Std. Dev.	4.66	3.97	15.62	4.08	**1.25**	3.62	3.76	14.89	3.75	3.43	3.97
Mid-Foot 1 removed	129.03	16.72	171.36	88.96	196.58	**3.51**	67.99	15.07	140.75	47.41	193.46
Std. Dev.	3.83	6.13	3.51	3.56	3.53	**0.23**	3.66	5.29	3.35	4.11	3.27
Mid-Foot 2 removed	92.42	25.12	118.24	27.95	71.85	55.48	**3.43**	11.89	128.78	59.29	170.78
Std. Dev.	4.90	3.88	4.39	6.22	5.22	3.52	**0.15**	13.09	3.45	3.51	3.64
Heel 1 removed	93.55	77.55	92.07	58.93	233.12	121.44	115.74	3.27	**3.83**	79.89	182.08
Std. Dev.	4.63	3.26	9.22	5.63	3.12	3.41	3.45	3.23	**0.45**	3.87	3.35
Heel 4 removed	75.79	15.84	159.45	85.37	167.68	69.96	73.07	12.21	133.69	**3.55**	193.68
Std. Dev.	3.38	4.02	3.13	3.13	3.08	3.32	3.25	3.36	3.13	**0.26**	3.11
Heel removed	68.02	22.30	125.31	50.83	132.90	71.30	44.75	6.58	28.67	11.93	**3.57**
Std. Dev.	4.52	7.71	4.15	4.58	4.12	4.22	4.56	7.10	3.50	4.03	**0.31**

** Bold values represent the removed/off-loaded inserts.*

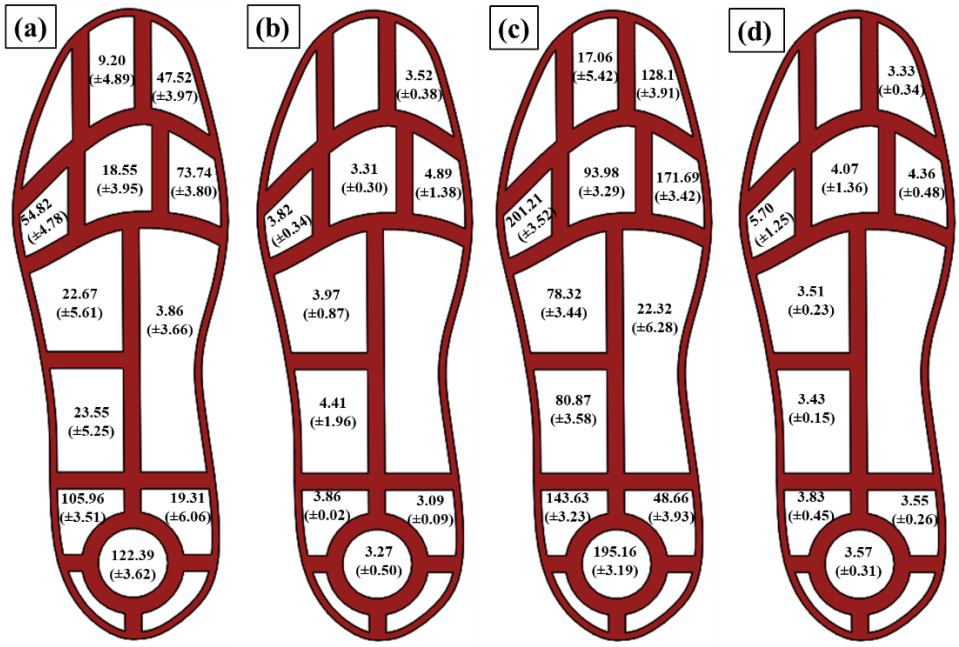

Fig. 6 AZP values (in kPa, mean ±S.D.) for healthy participants: (a) full insole with all inserts during standing, (b) off-loading of regions by removing their respective insert in standing position, (c) full insole with all inserts during walking, (d) off-loading of regions by removing their respective insert in walking condition

3.2.2 Pressure Off-loading for Diabetic Participants

The recorded AZP values (mean ±S.D.) for the fifteen diabetic participants during standing and walking conditions are tabulated in Tables 5 and 6, respectively. Additionally, the values were recorded for both the full insole and no insole cases to compare the off-loading results for both cases.

During the diabetic participants in standing condition with a full insole, the highest AZP was found at the heel region, reaching a magnitude of 40.92 ±12.45 kPa (Fig. 7a). Conversely, the lowest magnitude of AZP was recorded at the arch region, with a value of 4.88 ±4.53 kPa. Similar to the healthy participants, the pressure magnitudes at the inserts toe 2 and arch were relatively low, accounting for only 2.78% and 2.19%, and excluded from the off-loaded trials. For the off-loading case, the AZP values of plantar pressure were decreased, ranging from 87.11% to 97.82% at Fore-Foot 3 and Heel 1, respectively (Fig. 7b). The AZP values for the rest of the segments were lower than those at Fore-Foot 3, which confirmed the pressure off-loading across all the other regions.

The data presented in Fig. 7c shows the AZP values for diabetic participants with full insole while walking. The heel region showed the highest AZP value of 130.96 ±4.27 kPa, indicating the maximum pressure applied at that specific point. Conversely, the lowest average zonal pressure value was observed at the arch region with a magnitude of 12.45±9.51 kPa. For diabetic patients, the plantar region with high AZP values is more susceptible to skin breakdown and injury (ultimately the ulceration), while the areas with

low AZP values are less vulnerable to injury. Similar to the previous cases, it should be noted that the AZP magnitudes at inserts Toe 2 and Arch were observed to be very low, contributing only 2.21% and 2.06%. Therefore, these were excluded from off-loading cases during the trials. Figure 7d illustrates the results of the pressure off-loading trials, which showed a significant decrease in pressure ranging from 81.52% to 97.19% at segments Heel 4 and Heel, respectively.

Table 5 Average zonal pressure values (in kPa) for participants with diabetes (standing) in different off-loading conditions

Removed inserts ↓	**Toe 1**	**Toe 2**	**Fore-Foot 1**	**Fore-Foot 2**	**Fore-Foot 3**	**Mid-Foot 1**	**Mid-Foot 2**	**Arch**	**Heel 1**	**Heel 4**	**Heel**
No insole	26.07	3.26	40.00	16.83	41.78	10.40	8.64	3.09	29.26	5.10	57.77
Std. Dev.	9.64	3.33	16.48	7.74	9.37	6.34	6.50	3.06	6.62	4.21	7.17
Full insole	24.40	6.19	33.43	24.34	30.74	13.63	17.89	4.88	47.40	15.23	67.92
Std. Dev.	9.37	5.24	11.69	6.63	9.37	8.37	8.45	4.53	9.99	5.69	12.45
Toe 1 removed	**2.42**	14.88	90.12	37.40	80.62	24.33	26.39	4.23	118.69	12.53	104.10
Std. Dev.	**2.46**	4.18	7.63	5.25	6.03	7.43	8.26	4.63	5.73	5.74	10.12
Fore-Foot 1 removed	56.85	19.09	**3.74**	23.63	115.56	45.61	66.93	3.75	84.53	36.64	125.87
Std. Dev.	3.76	4.88	**1.66**	3.72	4.11	5.41	4.50	3.55	3.73	4.55	3.45
Fore-Foot 2 removed	38.24	8.43	14.39	**2.47**	76.49	16.93	32.95	3.68	102.99	16.25	123.96
Std. Dev.	3.33	3.21	3.38	**0.53**	3.28	3.38	3.41	3.19	3.12	3.62	3.28
Fore-Foot 3 removed	70.68	13.30	57.66	12.93	**3.96**	14.91	18.94	9.14	90.81	23.65	152.14
Std. Dev.	3.98	6.03	5.81	4.38	**0.38**	3.85	3.95	5.88	3.39	3.60	3.28
Mid-Foot 1 removed	62.18	18.64	84.40	16.59	57.46	**1.10**	51.84	3.95	118.96	56.87	153.89
Std. Dev.	3.14	3.22	3.24	3.17	3.30	**0.08**	3.11	3.17	3.26	3.23	3.14
Mid-Foot 2 removed	90.81	24.42	116.27	27.32	69.96	53.77	**2.26**	12.32	126.54	57.33	172.35
Std. Dev.	4.76	3.85	4.56	6.27	5.39	3.47	**0.06**	13.99	3.47	3.55	3.70
Heel 1 removed	67.83	3.60	122.84	18.34	73.24	16.82	16.53	3.14	**1.03**	7.72	83.44
Std. Dev.	4.16	3.57	3.92	4.47	4.30	4.37	4.25	3.11	**0.02**	4.11	4.27
Heel 4 removed	42.63	11.02	81.93	29.09	61.90	42.73	32.58	7.61	68.93	**1.58**	106.83
Std. Dev.	3.34	3.26	3.25	3.14	3.21	3.32	4.15	3.31	3.27	**0.37**	3.37
Heel removed	27.76	11.44	54.96	15.17	19.14	11.41	14.02	3.08	60.15	6.55	**3.09**
Std. Dev.	3.56	3.39	3.50	3.49	3.60	3.97	3.83	3.08	3.32	3.46	**0.32**

** Bold values represent the removed/off-loaded inserts.*

Table 6 Average zonal pressure values (in kPa) for participants with diabetes (walking) in different off-loading conditions

Removed inserts ↓	**Toe 1**	**Toe 2**	**Fore-Foot 1**	**Fore-Foot 2**	**Fore-Foot 3**	**Mid-Foot 1**	**Mid-Foot 2**	**Arch**	**Heel 1**	**Heel 4**	**Heel**
No insole	7.75	5.51	28.68	17.20	14.71	13.45	18.07	3.07	89.63	35.84	105.68
Std. Dev.	3.50	3.47	4.00	3.63	3.98	3.61	3.64	3.07	3.23	3.31	3.13
Full insole	55.76	13.35	66.20	37.13	72.20	49.66	40.25	12.45	98.84	27.07	130.96
Std. Dev.	6.74	5.26	9.01	6.73	8.18	4.84	6.38	9.51	4.25	6.40	4.27
Toe 1 removed	**3.44**	10.84	62.83	44.17	111.20	31.62	44.12	3.62	93.55	25.18	114.42
Std. Dev.	**0.27**	6.27	5.23	4.39	4.29	7.50	5.05	3.44	3.60	4.85	3.42
Fore-Foot 1 removed	88.05	23.22	**4.32**	61.19	216.91	87.55	105.50	12.18	138.52	78.71	188.00
Std. Dev.	4.35	5.88	**0.52**	3.42	3.29	3.39	3.42	11.06	3.58	3.41	3.55
Fore-Foot 2 removed	101.82	27.17	75.74	**6.86**	70.55	39.88	29.44	8.95	137.52	44.20	112.35
Std. Dev.	4.96	3.61	5.54	**1.44**	6.87	3.68	5.20	13.51	3.41	3.80	5.60
Fore-Foot 3 removed	90.17	17.42	70.66	24.43	**5.66**	23.10	21.88	8.51	111.64	31.09	114.06
Std. Dev.	4.53	5.67	5.30	4.86	**1.11**	4.15	3.51	6.38	3.69	4.27	4.37
Mid-Foot 1 removed	65.98	25.61	32.42	25.58	26.23	**4.32**	18.54	3.14	128.29	11.99	107.97
Std. Dev.	3.92	5.60	4.19	8.88	5.14	**0.57**	3.87	3.15	3.76	5.87	3.64
Mid-Foot 2 removed	163.14	35.49	176.90	77.94	127.77	76.46	**3.52**	23.70	139.88	71.48	180.34
Std. Dev.	3.45	3.46	3.51	3.25	3.57	3.75	**0.28**	16.23	3.36	3.21	3.84
Heel 1 removed	139.47	21.16	156.73	80.90	159.99	72.74	71.58	5.86	**3.58**	36.24	153.71
Std. Dev.	3.67	7.41	3.79	3.95	4.37	3.39	3.50	6.09	**0.31**	4.86	4.00
Heel 4 removed	113.38	28.53	122.55	41.19	92.60	43.17	38.77	7.45	97.71	**3.19**	110.94
Std. Dev.	3.59	5.24	3.84	4.82	3.49	4.25	3.61	3.78	3.41	**0.08**	3.32
Heel removed	48.68	8.43	131.26	50.21	139.47	54.02	39.03	17.64	32.80	16.05	**3.67**
Std. Dev.	3.60	3.39	3.45	3.59	3.35	3.61	3.63	4.05	3.55	3.70	**0.54**

** Bold values represent the removed/off-loaded inserts.*

After analyzing the results for both healthy and diabetic participants, certain important observations were made. First, diabetic patients have lower AZP values with full insole than healthy participants for both standing and walking conditions. For the standing case, the maximum AZP values were recorded at the Heel region. The calculated value for healthy participants was 122.39 ±3.62 kPa (mean ±S.D.) and 67.92 ±12.45 kPa for the diabetic participants. Similar to the standing case, the maximum AZP values were recorded at the Heel region for the walking. The AZP value for healthy participants was found to be 195.16 ±3.19 kPa (mean ±S.D.) and 130.96 ±4.27 kPa for the diabetic participants. The segments of the forefoot region, i.e., Fore-Foot 1, Fore-Foot 2, and Fore-Foot 3, also showed comparable results. This is due to the reason that diabetes affects the stiffness of the plantar fascia of diabetic patients, making it swollen and achy, hindering them from

placing the entire foot while standing and walking properly. Second, the AZP values closely resembled across all the nine off-loading cases for healthy and diabetic participants in both conditions, i.e., standing and walking, confirming the effectiveness of the modular insole. Third, based on the QUEST results, diabetic patients found the insole as a conformable solution for their walking and pressure off-loading. This statement can also be confirmed from the off-loading values during standing and walking in nine different cases for diabetic patients. Fourth, the heel region is most prone to ulceration occurrence, and the modular insole can be a preventive measure to off-load the pressure from the region, particularly for diabetic patients.

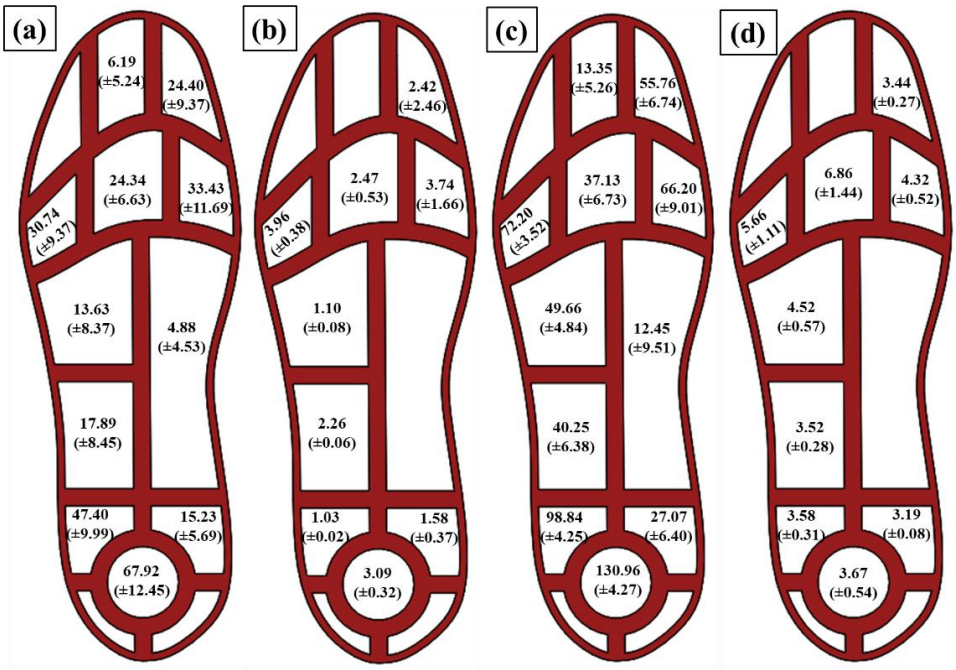

Fig. 7 AZP values (in kPa, mean ±S.D.) for diabetic participants: (a) full insole with all inserts during standing, (b) off-loading of regions by removing their respective insert in standing position, (c) full insole with all inserts during walking, (d) off-loading of regions by removing their respective insert in walking condition

4. CONCLUSIONS

The novel modular insole has proved to be an effective way of off-loading the pressure from the foot's plantar fascia. It has the potential to improve the quality of an individual's life suffering from diabetic ulcers by off-loading pressure from the plantar region of the foot, thus reducing pain and improving mobility. The findings of this study would be valuable for researchers and medical practitioners to better understand the progression of ulceration in the diabetic foot. The modular insole can help prevent the progression of ulceration, which can lead to serious complications if left untreated.

There are some limitations of the modular diabetic insole that should be acknowledged. First, it was observed from the AZP values of the heel region at the ball of the foot that the heel was mostly in contact with the shoe during the heel striking of the gait phase. To address the issue, the radius of the silicone insert of the heel region could be decreased and, subsequently, increase the insert areas of heel 1, heel 2, heel 3, and heel 4. Second, the insole trials (particularly walking) should be for longer duration to validate all nuances in the performance and comfort of the modular diabetic insole. In conclusion, this study will benefit diabetic patients by providing an analysis of plantar pressure, which can help prevent ulceration or re-occurrence. Overall, this study emphasizes the importance of accessible and innovative solutions for managing diabetic foot ulcers.

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