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The insole materials influence the plantar pressure distributions in diabetic foot with neuropathy during different walking activities

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ABSTRACT

Background: Abnormal peak plantar pressure in neuropathic diabetic foot during walking activities is well managed through the use of appropriate design and material selection for the fabrication of custom made insoles (CMI). The redistribution of plantar pressure is possible by selecting an appropriate material for the fabrication of CMI. The walking activities may alter the plantar pressure distribution; which may differ while using CMI with different materials.

Objective: The objective of the study was to evaluate the effectiveness of CMI's materials on plantar pressure distribution during different walking activities, in diabetic feet with neuropathy.

Methods: The study was conducted on sixteen diabetic neuropathic subjects. The subjects were provided with two types of CMI; CMI-A (Plastazote® and microcellular rubber) and CMI-B (Multifoam, Plastazote® and microcellular rubber). Maximum peak plantar pressure and plantar pressure distribution were determined by Pedar-X® sensor insole during level walking, ramp walking and stair walking.

Results: The CMI-B lessened the maximum peak plantar pressure from the forefoot throughout the walking activities compared to CMI-A. The contact area was observed as lower using CMI-A compared to CMI-B, while performing walking activities.

Conclusion: CMI-B, with multifoam as an additional top layer, provided more effective peak plantar pressure reduction at forefoot and it had better plantar pressure distribution compared to CMI-A during level walking and ramp ascending in diabetic foot with neuropathy.

1. Introduction

The most common complication of diabetes is neuropathic foot ulcerations, and re-ulceration [1]. About 15% of the diabetic population faces foot ulcerations throughout the passage of the disease, additionally more than 80% of them face recurrence of diabetic foot ulcers each year [2]. Abnormal plantar pressure distribution along with its effects on soft tissue under bony prominences cause a prolong high rate of ulceration due to neuropathy, limited joint mobility and foot deformities in diabetic neuropathic feet [3,4]. The big toe, metatarsal heads, midfoot and hindfoot are the most frequent sites prone to deformities as well as ulcers [5,6]. In clinical setup custom-made insoles are believed to be an effective solution for the management of diabetic neuropathic foot with proper prescription and evaluation of insoles [7].

Custom-made insoles (CMI) are designed to redistribute, and decrease the peak plantar pressure from regions that are susceptible to ulceration. Diabetic shoes and CMI have an optimistic outcome on

redistribution, and unloading of peak plantar pressure [8]. Both shoes and CMI offload the concerned areas of the foot; however, the production of CMI is simple compared to diabetic shoes production [9]. Even though there has been report on the effectiveness of foot orthosis in an avoidance of diabetic foot ulcers, there is limited research data on the comparison of orthotic material properties [10,11]. Previous research has shown that; soft foot orthotic materials and their combinations reduced the peak plantar pressure by adaptation to the foot shape, thus having a tendency to increase the contact area [12,13]. On the other hand, Aoife et al. found that using the medium density of polyurethane as a flat insole showed the distribution of load over a larger area, while the pressure is applied during treadmill walking [14]. Healy et al. compared a customized and a prefabricated foot orthosis, and found that CMI is expensive and less effective in decreasing the peak plantar pressure [15]. On the contrary, prefabricated insoles are the ideal prescription for a diabetic foot with neuropathy. As CMI offer proper arch support with additional pads if required to reduce the

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magnitude of pressure. Moreover, the selection of CMI materials are based on the expertise of the clinician.

Despite most of the CMI's being either fabricated from single material or dual, most of the CMI materials are tested individually on a bench top without considering activities that take place in real scenario. The evidence regarding the materials with different hardness and multiple layers to design CMI during different walking activities is still lacking. Due to the availability of a wide variety of materials to fabricate CMI, as well as to gain knowledge and understanding of plantar pressure distribution using CMI in diabetic foot with neuropathy; it was hypothesized that CMI with multiple layers and different hardness would have an influence on the peak plantar pressure and contact area. These are the main parameters observed in clinical setup during different walking activities. Therefore, this study examined the effectiveness of custom-made insole materials towards maximum peak plantar pressure distribution, pressure-time integral, pressure distribution, contact area and center of pressure during walking activities in diabetic foot with neuropathy.

2. Methods

2.1. Participants

Sixteen diabetic neuropathic patients were recruited from the primary care unit at Songklanagarind hospital, Faculty of Medicine, Prince of Songkla University. The sample size was calculated from the ground reaction force which was a variable available in literature [16], with standard deviation (0.1), for a two-tailed test with 80% power ($1 - \beta = 0.80$) and $\alpha = 0.05$. The inclusion criteria for participants were: (i) age range 40–60 years old; (ii) diabetes type II; (iii) callus at the forefoot; or forefoot deformity (hallux valgus, hammer toe or mallet toes); (iv) blood pressure in the range of 140/90 mmHg; (v) diminished, or insensate foot to 10 g monofilament; (vii) no assisted walker at least 10 m. We excluded those who had: foot ulcerations, lower limb joint surgery, ischemic heart disease, and partial or total amputation. To lessen the effect of footwear, all participants wore the same kind of shoes, with the same heel height. The project was approved by, the Research Ethics Committee of the Faculty of Medicine (No. 58-161-20-2). All participants signed the informed consent.

2.2. Custom-made insole

The material essential for the fabrication of custom-made insoles (CMI) included: multifoam 5 mm thick (30° Shore A hardness), Plastazote® 8 mm (25° Shore A hardness) and Microcellular rubber 10 mm (70° Shore A hardness). Two types of custom-made insoles were fabricated: a two-layer insole (Plastazote® and microcellular rubber) as CMI-A, and a three-layer insole (Multifoam, Plastazote® and microcellular rubber) as CMI-B, as shown in Fig. 1. A qualified orthotist acquired a foam imprint of the patient's feet. The specimens from the center of the anterior, middle and posterior of both insoles were tested with the compression mode according to ASTM D575 (Zwick Roell, Germany), with standard force at 0% strain load application, and standard force 20% strain load application for four cycles per insole type.

2.3. Evaluation of custom-made insoles

The plantar pressures were recorded from 3 walking activities: level walking (10 m), ramp walking (angled 8.04°) for 4 m, and 10 steps stair walking (step height 17.5 cm and 29 cm deep) for 3 rounds at self-selected speed with CMI-A and CMI-B. The plantar pressure data was collected using Pedar-X® mobile in-shoe system (Novel GmbH, Munich, Germany) to assess the two types of CMI. The zero calibration or unloading for insole was conducted according to the manufacture's instruction, by asking participants to stand on each leg for 6–9 seconds

before each trial. All data were managed by Novel-Win multi masking software (Novel GmbH, Munich, Germany). Results, including, maximum peak plantar pressure, pressure-time integral, pressure distribution, contact area and center of pressure were analyzed for three consecutive gait cycles. The foot plantar surface was divided into 3 main regions, these being: hindfoot, midfoot and forefoot. Moreover, the forefoot was subdivided into: hallux, medial forefoot, central forefoot and lateral forefoot, for more analysis (Fig. 1). Properly sized Pedar-X® sensors were positioned in the patient's shoes, and the data were sampled at 100 Hz. To minimize bias, the participants were unaware of the type of CMIs used while performing their walking activities.

2.4. Data and statistical analysis

The statistical analysis was performed with Prism 5.0 (GraphPad software, San Diego, USA). The percentage difference was calculated using an absolute difference value between CMIs, divided by CMI-A value. The paired- *t*-test was performed to test the significance of differences between two different insoles, for plantar regions of the foot. The statistical significance was set at $p < 0.05$.

3. Results

Sixteen participants (56% men and 44% women) participated in the study, with their duration of diabetes being 8.37 ± 4.50 years. Their body mass index specified the participants were in range of overweight (28.74 ± 4.75 kg/m²). The participants presented with: big toe callus (63%), metatarsal head callus (81%) and hallux valgus deformity (31%). There was no statistically significant difference among the peak pressure, contact area and pressure-time integral for left and right foot of each subject. Thus, all analyses were achieved from the left foot.

3.1. Compression testing of custom made insoles

Stress-strain curves of the insole materials (multifoam, Plastazote® and microcellular rubber) under loading, and unloading conditions are illustrated in Fig. 2A to Fig. 2C. The results revealed that all three materials had a viscoelastic property. Furthermore, Plastazote® was softer compared to multiform and microcellular rubber, due to less compressive force with same elongation. When the samples were taken from CMI (Fig. 2D to Fig. 2F), the initial portion of the CMI-A anterior of the insole curve demonstrates s-curve with moderate increase in stress, compared to CMI-B representing J-curve. CMI-A shows higher energy absorption for the anterior of the insole compared to CMI-B, in regards to a larger area between loading and unloading curves. However, CMI-B encompassed higher energy return compared to CMI-A, for the middle and posterior of the insole, due to a larger area under the unloading curve.

3.2. Influence on maximum peak plantar pressure

Table 1 shows maximum peak plantar pressure in each region of foot, using both types of CMI. The pressure increased during all activities with the CMI-A, when compared to CMI-B from the pressure mapping. There was a significant difference in maximum peak plantar pressure for the forefoot between CMI-A and CMI-B in performed activities. The CMI-B effectively reduced maximum peak plantar pressure, especially from the forefoot regions 14% ($p = 0.0002$) during level walking and 16% ($p = 0.0008$) during ramp ascending, compared to CMI-A. Peak pressure at midfoot showed a reduction of peak pressure 36% ($p = 0.04$) with CMI-B, during stair ascending, compared to CMI-A. There was no significant difference between CMIs in the hindfoot, however, with the CMI-B increased maximum peak plantar pressure occurred compared to CMI-A during stair ascending and stair descending. The metatarsal regions showed a significant difference with the CMI-B, with pressure reduction 11% ($p = 0.002$) during level

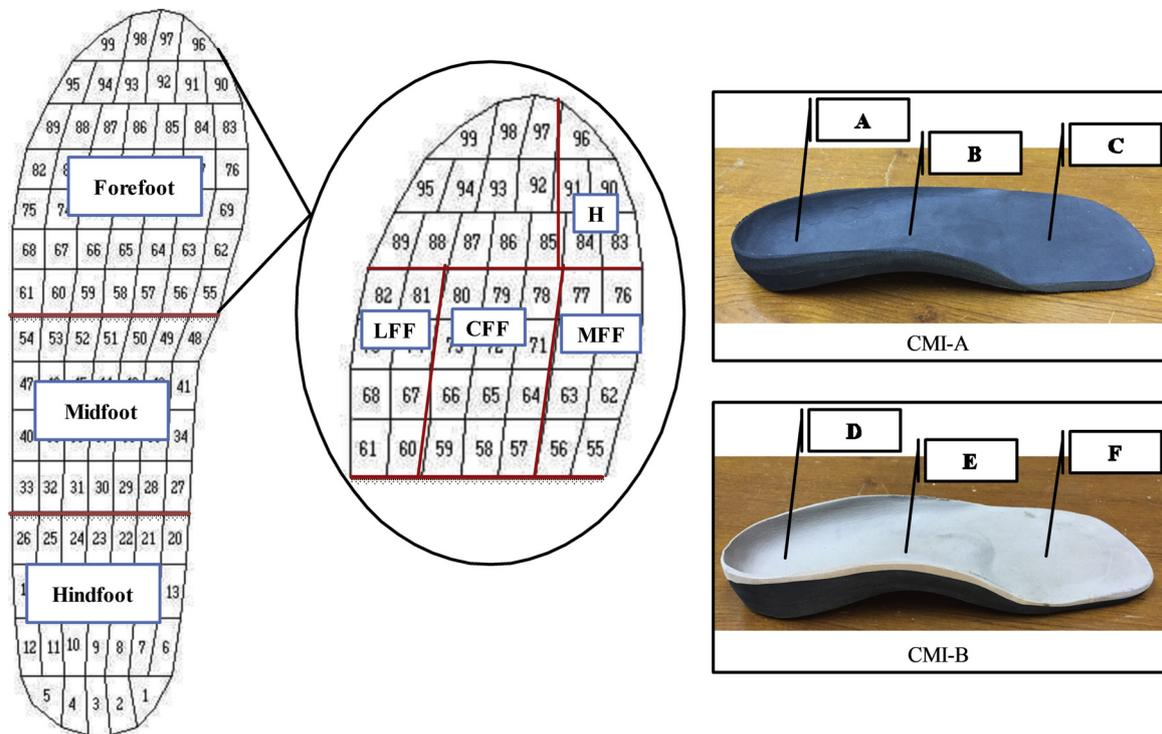


Fig. 1. Three main regions of foot as: hindfoot, midfoot, forefoot. The forefoot is subdivided into four regions as: LFF; lateral forefoot, CFF; central forefoot, MFF; medial forefoot and H; hallux using masking software. The CMI-A with A; posterior insole (Plastazote® and microcellular rubber), B; middle insole (Plastazote® and microcellular rubber) and C; anterior insole (Plastazote®) and CMI-B with D; posterior insole (Multifoam, Plastazote® and Microcellular rubber) and E; middle insole (Multifoam and Plastazote®).

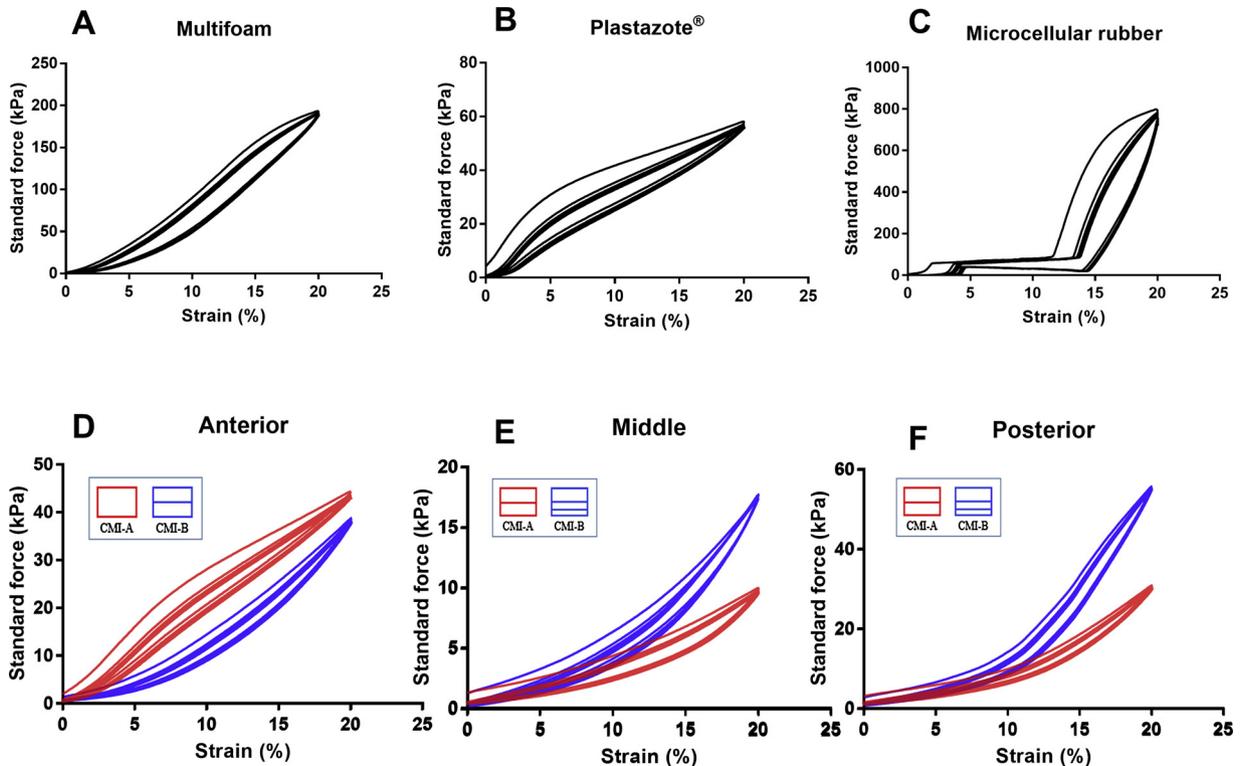


Fig. 2. The stress-strain curve as a single layer material for A; Multifoam, B; Plastazote®, C; Microcellular rubber and multilayer CMIs as D; anterior insole, E; middle insole, F; anterior insole for three regions of CMI-A and CMI-B.

Table 1
Mean and standard deviation of maximum peak plantar pressure with CMI-A and CMI-B, from three main regions of the foot and four subdivided regions of the forefoot, during walking activities (N = 16).

Variable	Activity	Type	Forefoot	Midfoot	Hindfoot	Hallux	Medial forefoot	Central forefoot	Lateral forefoot
Maximum peak plantar pressure (kPa)	Level walking	CMI-A	248.2 (61.92)	200.5 (130.57)	260.9 (129.58)	168.4 (72.16)	212.3 (52.58)	203.5 (57.16)	160.1 (30.04)
		CMI-B	211.6 (47.01)**	153.5 (42.92)	222.1 (74.92)	148.2 (60.24)	188.2 (47.67)**	182.3 (40.15)**	141.3 (22.81)*
			256.3 (76.29)	206.5 (128.26)	226.8 (149.1)	183 (77.59)	207.5 (68.27)	199.7 (77.88)	158.8 (35.85)
	Ramp ascending	CMI-A	212.9 (52.57)**	155.2 (43.37)	187.3 (71.35)	150.8 (66.95)**	175.8 (41.12)**	177.9 (49.02)	138.8 (28.99)*
		CMI-B	213.2 (71.67)	225.3 (166.02)	228.2 (157.1)	163.9 (85.33)	159.9 (53.04)	144.6 (48.76)	143.6 (38.36)
			188.1 (63.29)	147.8 (49.24)	189.6 (91.25)	146.1 (69.29)	150.7 (55.54)	142.7 (39.05)	122.1 (27.85)*
	Ramp descending	CMI-A	248.3 (87.19)	254.6 (178.01)	137.6 (70.82)	153.3 (68.05)	166.7 (40.75)	184.3 (83.51)	189.4 (71.24)
		CMI-B	208.2 (46.12)	163.4 (45.88)*	147.7 (63.82)	136.01 (57.36)	166.1 (38.69)	181.1 (54.53)	154.1 (39.57)*
			235.1 (92.53)	256.1 (190.77)	149.1 (74.61)	168.7 (64.04)	160.5 (48.68)	156.6 (81.71)	176.4 (78.33)
	Stair ascending	CMI-A	181.9 (41.77)*	171.5 (46.52)	152.9 (59.01)	131.6 (44.09)**	148.1 (36.74)	143.2 (54.76)	138.6 (25.02)
		CMI-B							
	Stair descending	CMI-A							
		CMI-B							

Significant differences are displayed with.
 * (p < 0.05).
 ** (p < 0.01) and.
 *** (p < 0.001).

walking and ramp ascending. However, hallux showed no significant difference, except during ramp ascending and stair descending 17% (p = 0.001) and 22% (p = 0.005), respectively.

3.3. Pressure-time integral (PTI)

In general, CMI-A resulted in higher values of PTI in all areas of the foot during walking, with the exception of the hindfoot during stair ascending and stair descending (Table 2). There was a significant difference for the forefoot during level walking 14% (p = 0.009) and 17% (p = 0.0005), while using CMI-B. Using CMI-B reduced the PTI, with the maximum percent reduction at midfoot 27% (p = 0.02) during ramp descending and stair ascending. However, the CMI-B slightly increased the PTI at the hindfoot, while stair ascending and stair descending 3%–7% (p > 0.05), compared to CMI-A. A significant difference with the reduction of PTI with CMI-B was found for the medial forefoot 16% (p = 0.0001), central forefoot 10% (p = 0.02) and lateral forefoot 16% (p = 0.02), and the hallux 20% (p = 0.006) during ramp ascending.

3.4. Pressure distribution and contact area

The plantar pressure distribution mapping during the gait, from initial contact to pre-swing varied with both types of CMI, for three walking activities is shown in Fig. 3A. The pressure was distributed well with the CMI-B during all activities. With CMI-A the plantar pressure is higher at the medial forefoot as well as hallux, whereas with CMI-B the plantar pressure was lesser in the metatarsal heads along with hallux.

The contact area significantly increased in most of the forefoot regions, except LFF, with the CMI-B with a maximum increase at the hallux 41% (p = 0.008), when compared to CMI-A during level walking (Fig. 3B). Using CMI-B, the forefoot showed a significant increase in contact area for all activities, especially during level walking 13% (p = 0.0007), compared to CMI-A. The medial and central forefoot contact areas significantly increased with CMI-B 7% (p = 0.001) during stair ascending and 6% (p = 0.04) during ramp descending. However, midfoot contact area showed a significant increase 6% (p = 0.019) only during level walking. The maximum increase of contact area occurred at the hindfoot 22% (p = 0.003), during stair ascending, followed by hallux with 41% (p < 0.008), for level walking.

3.5. Center of pressure (COP)

The trajectory of center of pressure (COP) presented variabilities with two insoles while performing activities (Fig. 4). The CMI-B restricted the trajectory of COP to the middle of the foot, compared to the CMI-A. The key alteration was observed during stair ascending and stair descending, with the CMI-B having even distribution of pressure, compared to CMI-A. With CMI-B, the trajectory of COP was limited to the middle of the foot, without allowing it to move the pressure concentration towards the medial forefoot.

4. Discussion

We examined the maximum peak plantar pressure during walking activities, then assessed the effects of CMIs on foot regions during gait. The key findings of the current study revealed that CMI-B, which had multifoam as an additional layer to CMI-A, altered the maximum peak plantar pressure, and presented effectiveness during walking activities in diabetic feet with neuropathy. The maximum peak plantar pressure is significantly reduced using CMI-B, compared to CMI-A at the forefoot region during level walking. For CMI-B, the pressure-time integral showed significant reduction during all activities; especially from the forefoot region of the foot. Moreover, the contact area increased with CMI-B during all performed walking activities.

Neuropathic diabetic feet showed higher plantar pressure,

Table 2
Mean and standard deviation of pressure-time integral with CMI-A and CMI-B, from three main regions of the foot and four subdivided regions of the forefoot, during walking activities.

Variable	Activity	Type	Forefoot	Midfoot	Hindfoot	Hallux	Medial forefoot	Central forefoot	Lateral forefoot
Pressure-time integral (kPa*s)	Level walking	CMI-A	86.05 (20.49)	89.11 (49.39)	103.71 (56.43)	40.78 (18.05)	63.35 (17.68)	63.53 (17.19)	66.89 (20.09)
		CMI-B	73.37 (10.75)**	76.03 (22.37)	96.09 (58.36)	36.26 (15.37)	54.84 (11.03)**	58.41 (11.21)	58.69 (11.33)
	Ramp ascending	CMI-A	87.77 (18.31)	89.77 (41.38)	97.21 (67.78)	47.18 (18.86)	60.08 (15.45)	62.64 (19.08)	67.11 (18.08)
		CMI-B	72.04 (13.46)***	76.79 (27.42)	88.04 (54.32)	37.61 (16.64)**	50.15 (12.01)***	56.27 (14.71) [†]	56.12 (13.19) [†]
	Ramp descending	CMI-A	92.16 (21.62)	90.62 (47.65)	84.64 (62.56)	58.98 (31.94)	62.09 (19.97)	60.37 (17.82)	72.14 (19.85)
		CMI-B	76.86 (23.81) [†]	65.75 (21.78)	72.71 (53.39) [†]	48.83 (26.02)	56.48 (20.41)	57.43 (17.82)	56.72 (14.23)*
	Stair ascending	CMI-A	111.2 (31.49)	137.4 (86.57)	81.11 (55.92)	55.32 (32.39)	63.71 (20.66)	75.78 (26.78)	95.72 (30.31)
		CMI-B	91.46 (18.01)**	99.21 (34.55)	87.01 (60.15)	47.32 (28.09)	62.08 (19.13)	73.22 (19.96)	77.17 (17.76)
	Stair descending	CMI-A	118.2 (28.78)	117.61 (65.59)	74.09 (51.03)	75.93 (35.66)	80.06 (28.94)	78.73 (25.44)	91.55 (24.12)
		CMI-B	98.37 (21.83)**	89.17 (30.27)	76.33 (56.09)	62.11 (30.22) [†]	75.27 (21.21)	76.56 (24.95)	75.34 (16.48) [†]

Significant differences are displayed with.

* (p < 0.05).

** (p < 0.01) and.

*** (p < 0.001).

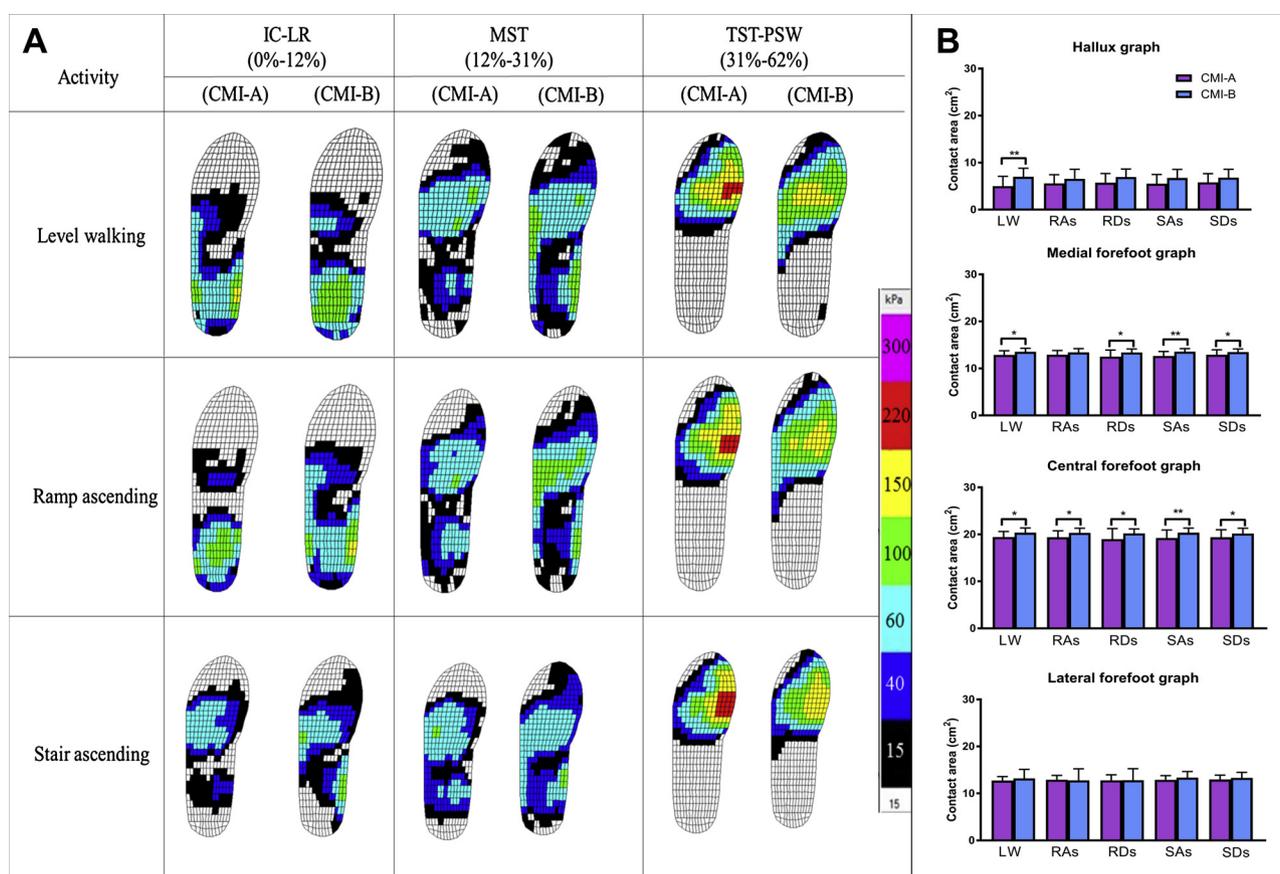


Fig. 3. Pressure mapping during walking activities with CMI-A and CMI-B, IC – LR; initial contact to loading response, MST; midstance and TST – PSW; terminal stance to pre-swing from a single representative subject. Contact area with CMI-A and CMI-B, from four regions of the forefoot, during walking activities. Significant differences are displayed with * (p < 0.05), ** (p < 0.01) and *** (p < 0.001).

compared to a non-neuropathic diabetic foot [17]. A CMI normally reduces the higher peak plantar pressure from the neuropathic diabetic feet, especially from the forefoot, even during the stair ascending and descending; as the initial contact changes from hindfoot to forefoot. Though, many patients obtain satisfactory peak plantar pressure reduction from CMI alone; others require greater pressure reduction due to ulcers. The metatarsal pads are believed to play a vital role in reduction of peak plantar pressure from the forefoot region; especially,

during level walking was found in our study [18]. It is, therefore, recommended that a mechanism of arch support deviated the load from forefoot and hindfoot towards midfoot, and increased pressure in the midfoot [19].

A CMI is normally fabricated from more than one single material, generally applied in layers, and the testing of combinations of CMI materials added greater clinical impact. Previous studies cannot be comparable as different methodology, materials tested and procedures

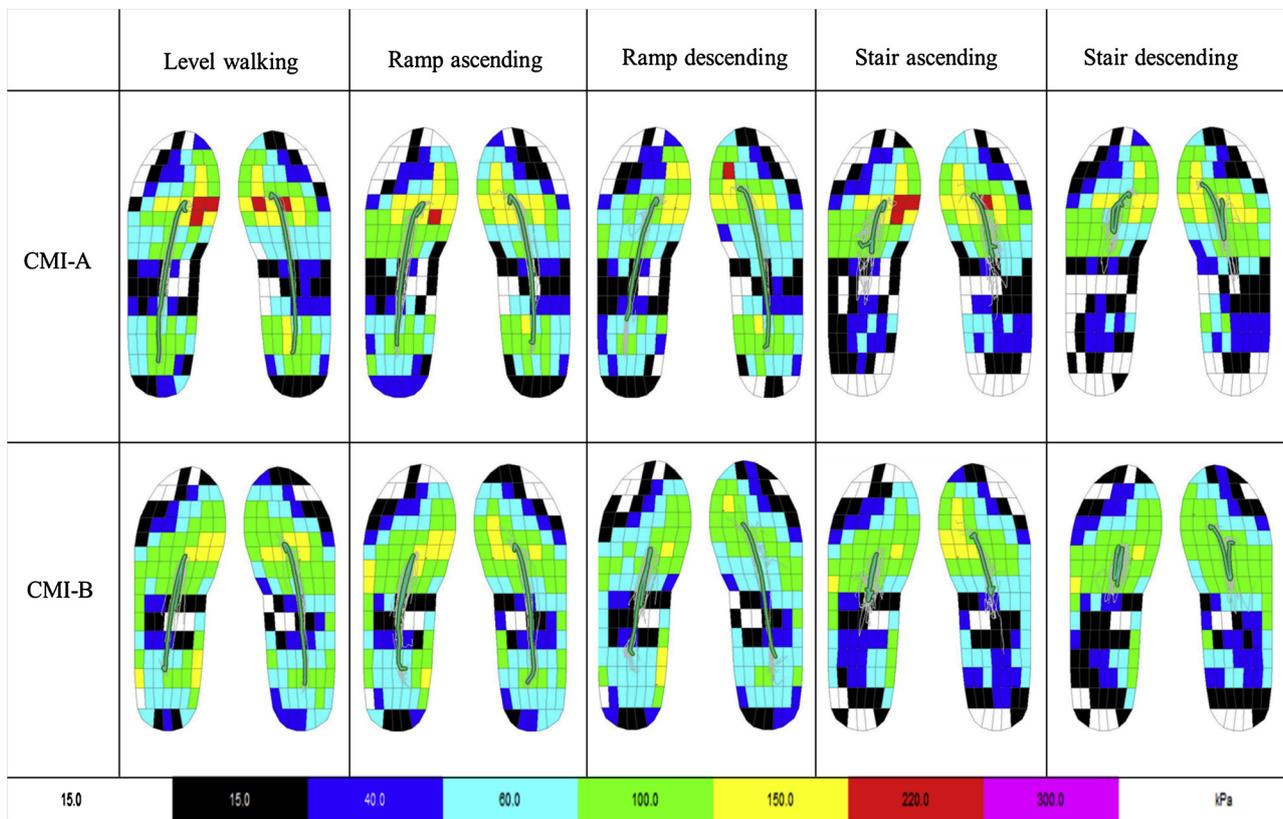


Fig. 4. Center of pressure with CMI-A and CMI-B, from whole foot during walking activities.

were followed without considering real situation [20,21]. Our study showed that the materials have a role as an extra layer of insole providing shock absorption, coupled with a combination of a more rigid insole, with soft insole materials can offer additional absorption, and more durability. The stress-strain curves of CMI-B presented an increase in energy retention, particularly at the middle and posterior of the insole. CMI-B is suitable for the diabetic population, from this study, as it requires greater compression forces compared to CMI-A. To maintain the CMI morphology, the additional top layer is beneficial, especially at the midfoot, to support both the arch and hindfoot stability. In our study, both CMIs resulted in the plantar pressure redistribution capability in the forefoot region, which is in agreement with the previously described results by Hellstrand Tang et al. [22]. We found that although the CMIs increased the contact area, significantly, the peak pressure was still high for CMI-A. As potential energy is stored in the deformed matrix it causes air to be drawn back when unloading, but prolonged loading causes cell foam damage, leading to a shortening of the shelf life of the material [23]. Therefore, it is advantageous to have an additional layer of insole to protect the overall structure from damage, which also increases its properties of shock absorption.

There is no much difference between the hysteresis loops of multifoam and Plastazote®, while testing individual materials. However, multifoam provided a shock absorption, and could endure higher forces, during the testing of individual materials in our study. When the materials are combined together, forming CMIs, as demonstrated from our material testing, the CMI-A showed a similar trend of shock absorption compared to CMI-B. However, the addition of multifoam made a difference; especially, while testing the middle and posterior of the insoles. The structure of the CMI-B can withstand higher forces compared to CMI-A, due to having a multifoam as a top layer covering the Plastazote®. Several research has shown that the soft foot orthotic materials, including Spenco® and low density Plastazote®, or a combination of Poron®/Plastazote® and Aliplast®/Plastazote® bottom out with prolonged use [24–26], which in turn reduced the peak plantar

pressure by adaptation to the foot shape, thus, this has a tendency to increase the contact area. However, when the Plastazote® was combined with a higher density material; such, as microcellular rubber the shape of CMI did not collapse, even under a heavy weight [27]. The results from our study presented that changing the type of material, during walking on different surfaces behaves differently, and the effect can be seen from initial contact to pre-swing of the gait cycle. During level walking, ramp ascending and descending the forefoot showed higher pressure with CMI-A, which is in similar fashion without CMI [28–30]. On the contrary, with CMI-B it tended to reduce the pressure from initial contact to pre-swing during level walking. Furthermore, the COP trajectory differs from level walking and ramp walking, as the COP initiates from forefoot towards midfoot, ending at the forefoot, for the push-off phase of the gait cycle, during stair ascending and stair descending. Moreover, the COP trajectory is centered with CMI-B to the midfoot, this is important towards the management of diabetic foot with neuropathy, when prevention of forefoot ulceration is the goal. The extra layer provides absorption of pressure in the middle layer, as the soft material sandwiched between stiffer materials. Thus, the CMI-B reduced the maximum peak plantar pressure while performing all walking activities.

The forefoot division, studied in our work, helps to understand more about plantar pressure occurrence. It shows that not all forefoot regions have high peak plantar pressure during walking activities. The maximum peak plantar pressure reduction in the heel region is possibly due to the additional stiffer top layer; that can grip well and follows the shape of the heel. With multifoam as an additional top layer, the CMI-B results in the reduction of maximum peak plantar pressure during walking activities. The pronation is controlled by the CMI-B, as clear from the pressure mapping (Fig. 3) during the terminal phase of the gait cycle. CMI-B may provide stable arch support, which increases the contact area during walking. The increase in the contact area does not only help to relieve the high peak plantar pressure, but also decreases the chances of overburden at a specific site; especially in diabetic feet

with neuropathy.

Considering that different activities, and different materials have an effect on plantar pressure appropriate selection of insole materials effectively reduces the plantar pressure from the sites of high pressure to other regions of the foot. Moreover, the contact increase enhances the foot function, especially at the forefoot region of the foot. Several limitations in our study need to be highlighted, for appropriate understanding and applications of our study. This study was not randomized, as all the participants were asked to try CMI-B and then CMI-A. Moreover, the sample size calculation was not based on plantar pressure and a range of insoles. This should be considered to determine from the relevant parameters [19,31]. Classifying subjects according to their arch index may give more details about foot behavior, and plantar pressure distribution during gait. Our study considered only three types of materials, other CMI materials need to be addressed to see further distribution of plantar pressure in diabetic feet with neuropathy.

5. Conclusions

With the CMI-B, maximum peak plantar pressure in the forefoot was reduced, when compared to CMI-A during level walking, ramp ascending, stair descending. Based on the results of our study, the addition of a multifoam layer on top of Plastazote® and microcellular rubber reduces maximum peak plantar pressure, and has better plantar pressure distribution in diabetic feet with neuropathy. Thus, the multilayer insoles, with moderate hardness material on top and softer material as a middle layer, provide an advantage on the plantar pressure distribution in diabetic feet with neuropathy.

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Declaration of Competing Interest

All authors have no conflicts of interest to declare.

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