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Effectiveness of insoles on plantar pressure redistribution

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Abstract—For this study, we compared the effectiveness of different design insoles for redistributing pressure during walking for diabetic patients and for normal control subjects. Comparisons of dynamic plantar foot pressure patterns were made with different support, including shoe-only, flat insole, and three contoured insoles. We custom-molded the three contoured insoles by casting the plantar surface of the foot under the conditions of non-weight-bearing, semi-weight-bearing, and full-weight-bearing. With the F-Scan in-shoe system, the interfacial pressure distribution during walking with different plantar supports was measured at 50 Hz for 10 s. The use of insoles could significantly reduce local peak pressure and pressure-time integral and increase the contact area. Contoured insoles were significantly better than flat insoles with regard to the insole functions in reducing local peak pressures. The insole with the semi-weight-bearing foot shape can offer the greatest peak pressure reduction compared to other insole designs, especially for patients with peak pressure located at the second to third metatarsal heads.

Key words: diabetes mellitus, foot biomechanics, foot pathologies, foot shape, insole design, neuropathy, plantar pressure.

INTRODUCTION

Diabetes mellitus (DM) is one of the most common and rapidly increasing health problems worldwide. The number of people in the developing world with diabetes will increase by more than 2.5-fold, from 84 million in 1995 to 228 million in 2025 [1]. With the rise in prevalence of DM, the burden of this disease to society becomes progressively greater [2]. Pathologies of the foot due to DM are a significant contributor to the economic burden [3]. An estimated 25 percent of DM patients developed foot problems [4], and about 20 percent of diabetic patients entering the hospital are admitted because of foot problems [5].

Studies showed that complications of DM, such as changes in bony structures, limited joint mobility, callus formation, and arterial insufficiency, may cause locally elevated plantar pressures [6–8]. Repeated applications of such high pressures make the foot more susceptible to the development of ulcers [9].

Abbreviations: DM = diabetes mellitus, 4–5 MTH = fourth to fifth metatarsal heads, FWB = full-weight-bearing, MF = midfoot, NWB = non-weight-bearing, 1 MTH = first metatarsal head, PTI = pressure-time integral, RF = rear foot, SD = standard deviation, SWB = semi-weight-bearing, 2–3 MTH = second to third metatarsal heads, WF = whole foot.

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In routine clinical practice, DM patients are often given a special insole for ulcer prevention. Especially for those neuropathic patients who lose sensation in their feet, a proper insole support should help maximize the contact area and reduce locally high plantar pressure and pressure-time integral (PTI) when walking. If the prescribed insole is not properly shaped and the foot structure cannot be balanced, the foot plantar soft tissues will become overstressed and may develop ulcers with accumulative trauma disorders [10].

Currently, custom-molded insoles are made from a foot cast taken with full-weight-bearing (FWB), semi-weight-bearing (SWB), or non-weight-bearing (NWB) conditions. Since the foot shape is changed with loading [11–14], the benefit provided by the insole cast with different weight-bearing conditions may vary. We found that modifications of a custom-molded insole cast from an unloaded plantar shape were more effective for pressure relief [15–16]. This finding suggests that a custom-molded insole from an unloaded foot may not be the best shape to properly fit the flexible feet. A better cast can be made from other loading conditions for custom-molded insoles.

A lack of objective information exists in choosing an insole-casting condition for the needs of particular subject groups. Knowledge of the pressure redistribution with different insole shapes can offer guidance for the better design and construction of a comfortable and functional support. For this investigation, we compared the functions of different insoles cast under different loading conditions in redistributing the interfacial pressures during walking.

METHODS

Six DM subjects with sensory neuropathy, 48 to 62 years of age (mean 56.2 ± 6.2), voluntarily participated in this study. Their feet were free of gross deformity, such as Charcot joints or amputation, and major skin lesions. Their mean shoe size was 38.0 ± 3.5 (European size; equal to U.S. size 6). Eight normal subjects, 37 to 74 years of age (mean 46.5 ± 11.7), were studied as the control group. The age difference between the two groups was not statistically significant ($p = 0.092$). Their feet were free of foot deformities. Their mean shoe size was 39.3 ± 2.3 (European size; equal to U.S. size 7). The experimental protocol was set up in line with the Human Subject Ethics Committee at The Hong Kong Polytechnic University. Each subject signed a consent form before the experiment.

Insole Preparation

Five support conditions were studied, including three custom-molded insoles, flat insole, and shoe-only conditions. For the three custom-molded insoles, foot impression casts were taken under three weight-bearing conditions:

1. FWB—standing straight on the casting foot only.
2. SWB—standing straight with body weight evenly distributed on both feet.
3. NWB—sitting without load acting on the casting foot, with the knee flexed at 90°, and ankle neutral.

For all casting conditions, the axes of the casting foot were pointing forward. Foot impression casts were taken to the tip of the lateral malleolus of the foot with dental plaster. The nonmodified positive plaster casts were then made and digitized with a commercial optical 3-D (three-dimensional) digitizing system (COMET 100 Steinbichler, Germany), and used for insole fabrication.

A standard trimline was applied on all digitized foot models. We trimmed the foot models 10 mm horizontally above the weight-bearing plane to standardize the depth of the test insoles on the lateral and posterior aspects. We curved the medial aspect of the insole upward by projecting the tangent line, connecting the medial prominence of the first metatarsal head and the widest part of the medial heel on the side of the 30° inverted foot model. The anterior portion of the medial and lateral insole trimline was curved downward anteriorly to the metatarsal heads connecting with the flat forefoot surface. We designed the testing insoles as full-length insoles to avoid the potential risk of pressure concentration at the toe break area (**Figure 1**).

We used a computer numerical-controlled milling machine (Fanuc, Japan) for insole fabrication. The insoles were milled from the Nora Lunasoft AL insole material (hardness A50°) (Freudenberg, Germany), with a standard thickness of 3 mm at both forefoot surface and heel center region. The flat insole was made of the same material as the contoured insole, with a uniform thickness of 3 mm. For each support condition, a layer of 3 mm Poron flat insole material (hardness A25°) (Dr. Kong Footcare Ltd., Hong Kong) with a flexible cloth served as a soft cover.

Standard Shoe

A pair of extra-deep diabetic shoes (Dr. Kong Footcare Ltd.) was provided for each subject for the tests.

Figure 1.
Typical shape for contoured insole.

The extra-depth inlay and flexible Lycra upper of the shoe accommodate the volume of the inserts and are adaptable for diabetic patients with minor plantar and dorsal structural abnormalities. The shoe was fastened with a Velcro® Dacron-backed closure. A small hole was made on the end of the fastener, which provided an attachment point for the use of a hand-held force transducer. Tightness of the shoe closure was then measured and maintained for each trial. Shoe size was selected for each subject according to Tovey's principles [17]. The first metatarsophalangeal joint should be accommodated in the widest part of the shoe and the length should allow 1 to 1.25 cm between the end of shoe and the longest toe.

Pressure Measurement

Several in-shoe pressure measurement systems are available on the market, but most of them are limited with the relatively thick sensing insole, which is difficult to conform to the shape of a curved surface. We evaluated the pressure distributions of different insole designs with a flexible F-Scan® insole sensing system (Tekscan, Inc., Boston, MA). The sensing insole was relatively thin, 0.18 mm thick. Although studies pointed out that the sensor was sensitive to surface conditions, loading speed, and temperature, the system is recommended for relative comparisons of plantar pressure distributions under constant condition and calibration before use [18–21]. We used the same pair of sensors for each subject, allowing for relative comparisons. Following the manufacturer's instructions, we completed calibration with subjects standing on the sensor to minimize error caused by sensor deterioration.

Before we began recording, subjects practiced walking for 3 minutes to reduce temperature effects, which allowed temperatures to stabilize [22]. We collected data at a sampling rate of 50 Hz for 10 s, as the subject walked at the preferred pace along the 10 m walkway. To reduce the effect of walking speed, we instructed subjects to walk at their normal patterns. No statistical difference was found for the mean time of each step for all subjects among the support conditions ($p = 0.245$). For standardizing the experimental procedure and minimizing different examiner errors, the same orthotist performed all the tests. For the five conditions tested, we randomized the order of recording pressure.

DATA ANALYSIS

We studied three parameters:

1. Mean peak pressure—defined as the average value of the maximum pressures from each step recorded over the foot region studied.
2. PTI—defined as the amount of load maintained through a defined area multiplied by the time taken to complete the propulsion phase of gait.
3. Mean peak contact area—defined as average value of the peak contact area between foot support interfaces from each step recorded over the defined areas.

We obtained data from the whole foot (WF) and six regions: hallux (Hallux), first metatarsal head (1 MTH), second to third metatarsal heads (2–3 MTH), fourth to fifth metatarsal heads (4–5 MTH), midfoot (MF), and rear foot (RF), as shown in **Figure 2**.

For each trial, we evaluated only the middle five steps to avoid the variable steps associated with initiation and termination of gait. The results measured in the shoe-only condition served as reference for comparison with insole used conditions. A two-factor repeated measure analysis of variance (ANOVA) test determined whether or not the two intrasubject factors (left or right foot and support condition) were significantly associated with each other, and whether or not the support conditions had significant effects on the parameters. Pairwise comparison was made between normal subjects and DM subjects. The significance level was set at 5 percent ($p < 0.05$).

RESULTS

The statistical analyses showed that the foot side (left or right) does not have significant interaction with the support condition and the measured parameters. Therefore, all

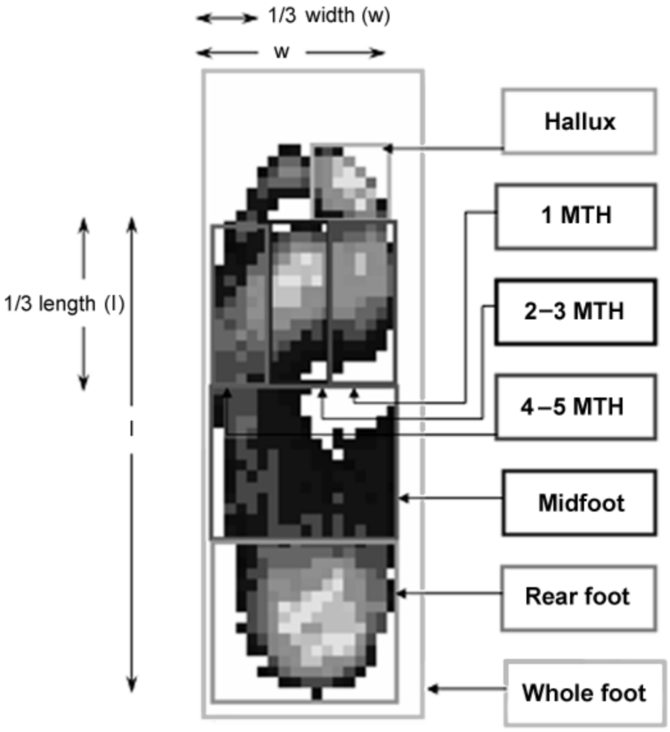

Figure 2.
Definitions of foot regions. MTH = metatarsal head.

results described hereafter were the average value of both feet. The results of the comparison between the normal and DM groups on the pressure and contact area are listed in **Table 1**. Peak pressure and PTI over the 2–3 MTH region in the DM group were significantly higher than the normal group ($p < 0.05$). We found no significant difference in other measured parameters. Because no significant interaction of subject group factor was found on the measured parameters, all results described hereafter include both groups.

Figure 3 shows typical peak pressure curves from one normal subject for which the peak value of pressure at each instant for the whole foot during stance phase was plotted against time, with the five support conditions. The SWB insole shows smallest peak pressure among the test conditions.

Figure 4 shows the mean and standard deviations (SDs) of peak pressure, PTI, and peak contact area over the whole foot and six foot regions with different support conditions during walking, averaged from both subject groups and both feet. According to **Figure 4(a)**, the shoe-only condition always exhibits the highest mean peak pressure among the conditions tested. The SWB condition provides the largest reduction of mean peak pressure when compared with the shoe-only condition in all foot regions.

Considering the mean value of PTI in different support conditions, as shown in **Figure 4(b)**, the NWB insole condition always produces the lowest value, followed by SWB insole, FWB insole, flat insole, and then the highest value in shoe-only condition for most of the foot regions, except the hallux and midfoot region. Considering the mean peak contact area under different support conditions, we found patterns for most of the whole foot measurement in the largest value with SWB insole; the lesser value with NWB insole, FWB insole, flat insole; and the smallest value in shoe-only condition (**Figure 4(c)**).

Table 2 shows the percentage reduction of pressure and area values measured from different insole conditions to the shoe-only conditions. We demonstrated that the contoured insoles were significantly better in increasing contact area and reducing local peak pressure than the flat insole. Comparing the immediate effectiveness of different support conditions on pressure distribution, the SWB insole was the most effective design in reducing the local peak pressure, especially the peak pressure located over the 1–3 MTH region. The NWB insole was the most effective design for subjects with pressure reduction needs over the hallux region, since the PTI was most reduced with the NWB insole. The shape of the insole cast from the NWB condition provided the highest arch support and a less flattened contour than that of the more weight-bearing design, such as the SWB and FWB.

DISCUSSION

We found that an insole could significantly affect the plantar pressure distribution by reducing local peak pressures and PTI, and maximizing contact area compared with shoe-only condition. Previous studies examined the effects of insole type and material on pressure redistribution, but few dealt specifically with the comparison of insole shapes cast under different loading conditions. Soft flat insoles have been found to reduce plantar pressure and increase contact area [23–25], but they were found less effective than the contoured insoles [15,22,26–27]. In the current study, soft flat insoles were found to reduce the mean peak pressure and to maximize contact area in the whole foot region, but significant change occurred in the PTI for all foot regions from the shoe-only condition.

Table 1.
Comparisons between normal ($n = 16$) and DM subject ($n = 12$) groups.

Region	Mean Peak Pressure (kPa) (Mean ± SD)			Pressure-Time Integral (kPa•s) (Mean ± SD)			Mean Peak Contact Area (cm^2) (Mean ± SD)		
	Normal*	DM*	Mean Diff†	Normal*	DM*	Mean Diff†	Normal*	DM*	Mean Diff†
Hallux	251.2 ± 48.1	241.0 ± 52.7	10.2 ± 71.4	147.9 ± 18.6	140.8 ± 20.3	7.2 ± 27.5	—	—	—
1 MTH	182.7 ± 21.5	221.2 ± 23.6	–38.4 ± 32.0	138.0 ± 15.4	157.3 ± 16.8	–19.3 ± 22.8	—	—	—
2–3 MTH	211.3 ± 19.9	337.4 ± 21.8	–126.1 ± 129.5‡	169.6 ± 18.1	234.5 ± 19.9	–64.9 ± 26.9‡	—	—	—
4–5 MTH	153.3 ± 17.5	199.3 ± 19.2	–46.0 ± 26.0	135.3 ± 15.8	149.1 ± 17.3	–13.8 ± 23.5	—	—	—
MF	115.6 ± 9.9	100.0 ± 10.8	15.6 ± 14.6	120.9 ± 11.0	97.9 ± 12.0	23.1 ± 16.3	—	—	—
RF	240.0 ± 20.2	256.8 ± 22.1	–16.9 ± 30.0	203.2 ± 12.4	210.1 ± 13.5	–6.9 ± 18.3	—	—	—
WF	315.5 ± 26.7	371.1 ± 29.3	–55.6 ± 39.6	211.6 ± 12.7	228.7 ± 13.9	–17.1 ± 18.9	109.5 ± 5.8	98.0 ± 6.3	11.5 ± 8.6

Note: Minus sign (–) indicates normal group has smaller mean value than DM group.
*Mean ± standard deviations (SDs) of data from all support conditions of same subject group.
†Average difference between normal and DM groups.
‡$p < 0.05$
DM = diabetes mellitus, MTH = metatarsal, MF = midfoot, RF = rear foot, WF = whole foot

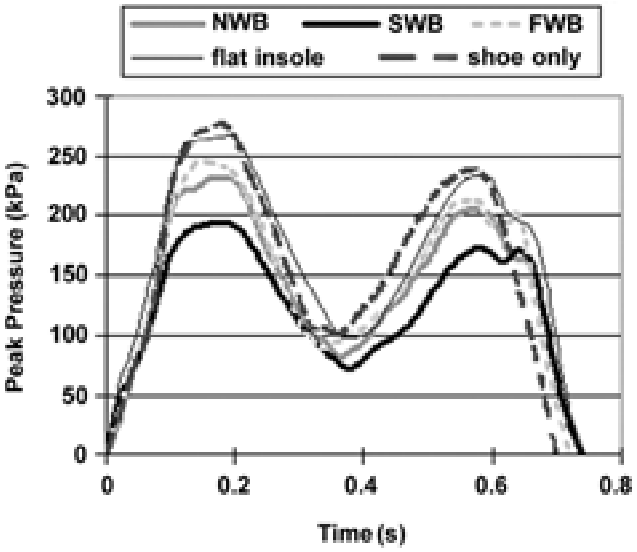

Figure 3.
Typical peak pressure curves during stance phase over whole foot for one normal subject with five support conditions. NWB = non-weight-bearing, SWB = semi-weight-bearing, and FWB = full-weight-bearing.

Custom-made insoles were found more effective than soft insoles. The significantly larger support area allowed a better distribution of pressure over the whole foot in the contoured insole rather than the flat one, especially over the medial arch.

Kato et al. demonstrated that the use of custom-molded polyurethane insole could provide a mean reduction of peak pressure of the whole foot by 56.3 percent, and increase the peak contact area by 62.7 percent [15]. Albert and Rinoie reported that custom-molded foot orthoses could reduce the peak plantar pressure by 30–40 percent and increase total contact area by 5–10 percent [26]. In the present study, we found similar results, but the percentage changes between "with" and "without" contour insoles varied among different cast loadings. For the mean peak pressure, the percentage change from shoe-only condition in the whole foot was similar for both the NWB insole and SWB insole conditions (about 20% reduction), but the FWB insole condition had a smaller reduction (14%), while the mean peak contact area was increased by 20 to 30 percent. The differences between the results of this study and those of the previous ones may be due to the insole materials, insole shapes, and shoes.

A properly shaped arch support should help prevent hyperpronation of the forefoot [28] and shift the pressure away from heel and metatarsal areas to the midfoot area [29]. However, if the arch support portion is too prominent, it may induce excessive localized pressure over the plantar arch and lead to discomfort. Previous research indicates that custom-molded orthosis with some modifications were more effective in the management of plantar pressure than the custom-molded orthosis alone without modifications [15–16]. In this study, we noted significant differences in pressure distribution between the three contoured insoles, which illustrated that an insole made of different casting conditions could provide different pressure redistribution function. In fact, the NWB insole that was cast from the

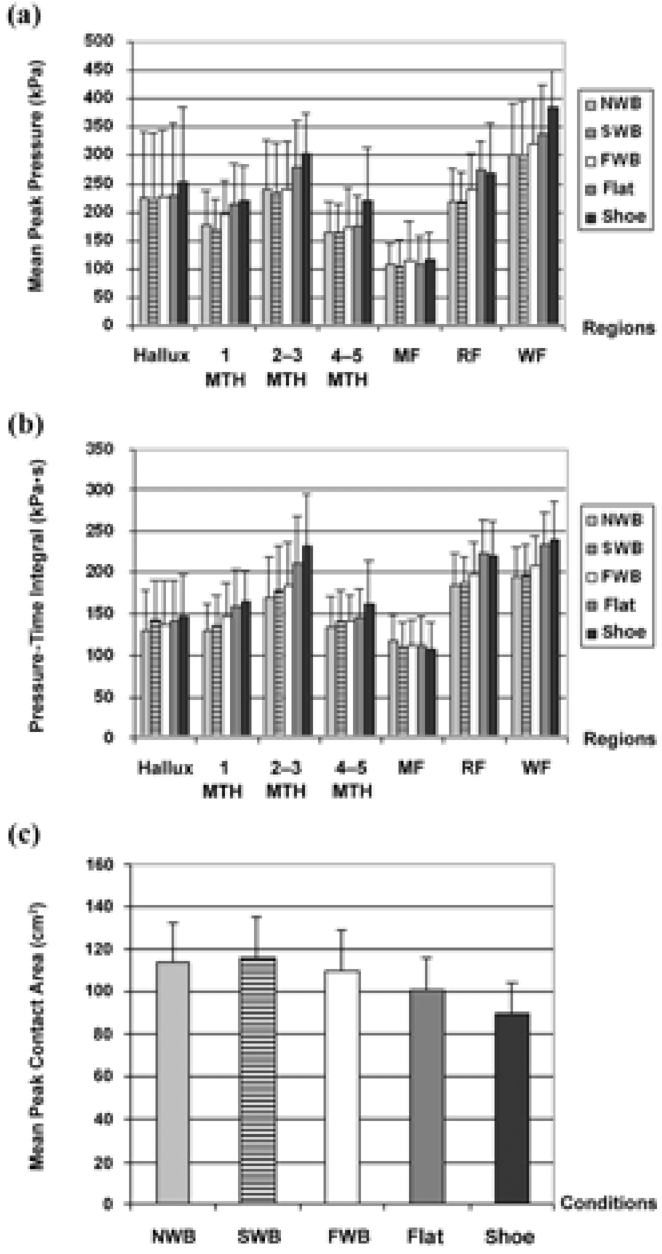

Figure 4.
Means and standard deviations of **(a)** mean peak pressure, **(b)** pressure-time integral of seven foot regions, and **(c)** mean peak contact area over whole foot with different support conditions during walking, averaged from all normal and diabetic subjects. MF = midfoot, RF = rear foot, WF = whole foot, NWB = non-weight-bearing, SWB = semi-weight-bearing, FWB = full-weight-bearing, flat = flat insole, and shoe = shoe-only.

NWB foot, had the highest arch support height and arch support angle in the midfoot region among the three contoured insoles [14]. The NWB formed a sharply curved medial arch support.

As presented in **Table 2** and **Figure 4**, the NWB insole produces the largest increase in PTI in the midfoot region, compared with the shoe-only condition. This increase may be explained by the localized pressure from the sharply curved arch support on the subject's feet. It may take longer to roll over the larger support surface in the arch region, and the combined effect of longer loading time and increased pressure induces the increase in PTI of the NWB insole condition. Although PTI is increased in the midfoot region, we noticed a large reduction in the other regions, especially in the hallux region. Therefore, the NWB insole may be useful to help prevent or heal ulcers over the hallux region, on the condition that pressures over other regions were acceptable. Such effects would need to be further examined.

The immediate benefit of using the SWB insole is to reduce the peak pressure over the 2–3 MTH regions, and the long-term effectiveness of the insole on preventing pressure ulcers needs to be further investigated. The shape of the SWB insole was found to be somewhat intermediate between the NWB and FWB insoles. This shape allowed satisfactory pressure redistribution without overloading the midfoot regions. The NWB insole could provide the most prominent arch support, the FWB insole the least support, and the SWB insole medium support. The effectiveness of the contoured insole may not depend directly on how much it supports the foot. The amount of arch support that is provided by the contoured insole may have a threshold value for the most effective and even distribution of pressure. Further study is recommended to increase the number of subjects and to test more specifically the effect of the amount of arch support on the insole function.

Because different casting conditions could provide different patterns of pressure redistribution, we suggest that clinicians prescribing insoles for patients at risk of foot ulcers may consider the location of peak pressure. We also suggest measuring the subject's ligamentous rigidity and metatarsal foot pad thickness to obtain additional information on the subject's condition, which may help in better selection of the insole casting conditions.

CONCLUSION

In this study, we compared the effectiveness of different insoles for redistributing pressure during walking for diabetic patients and normal control subjects. The results

Table 2.
Mean percentage differences of measuring parameter of listed support conditions from that of shoe-only from findings of all subjects. Values were calculated as (test condition – shoe-only condition)/shoe-only condition × 100.

Change (%)	Support Condition	Hallux	1 MTH	2–3 MTH	4–5 MTH	MF	RF	WF
Mean Peak Pressure	NWB	3.8	–13.2	–16.4	–14.8	4.5	–9.8	–13.4
	SWB	1.6	–17.9	–17.9	–13.8	6.0	–9.9	–13.8
	FWB	6.1	–2.6	–16.8	–12.9	15.2	5.1	–8.1
	Flat insole	–1.5	0.3	–2.0	–5.0	3.4	12.6	–2.4
Pressure-Time Integral	NWB	3.1	–15.8	–20.9	–9.4	23.7	–7.2	–11.2
	SWB	12.5	–11.8	–16.9	–3.1	14.6	–5.5	–9.7
	FWB	6.8	–5.7	–14.2	–4.6	15.5	–0.7	–4.5
	Flat insole	5.3	0.0	–1.7	2.6	14.1	11.6	5.1
Mean Peak Contact Area	NWB	—	—	—	—	—	—	37.3
	SWB	—	—	—	—	—	—	39.2
	FWB	—	—	—	—	—	—	31.0
	Flat insole	—	—	—	—	—	—	18.7

NWB = non-weight-bearing, SWB = semi-weight-bearing, FWB = full-weight-bearing, MF = midfoot, RF = rear foot, WF = whole foot, MTH = metatarsal head

show that the use of insoles could significantly reduce local peak pressure and increase the contact area. Contoured insoles were significantly better than flat insoles with regard to the insole functions in reducing local peak pressures. The insoles with the semi-weight-bearing foot shape can offer the greatest peak pressure reduction at the second to third metatarsal heads.

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