

# Influence of pressure-relief insoles developed for loaded gait (backpackers and obese people) on plantar pressure distribution and ground reaction forces

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## A B S T R A C T

The aims of this study were to test the effects of two pressure relief insoles developed for backpackers and obese people on the ground reaction forces (GRF) and plantar pressure peaks during gait; and to compare the GRF and plantar pressures among normal-weight, backpackers, and obese participants. Based on GRF, plantar pressures, and finite element analysis two insoles were manufactured: flat cork-based insole with (i) corkgel in the rearfoot and forefoot (SLS1) and with (ii) poron foam in the great toe and lateral forefoot (SLS2). Gait data were recorded from 21 normal-weight/backpackers and 10 obese participants. The SLS1 did not influence the GRF, but it relieved the pressure peaks for both backpackers and obese participants. In SLS2 the load acceptance GRF peak was lower; however, it did not reduce the plantar pressure peaks. The GRF and plantar pressure gait pattern were different among the normal-weight, backpackers and obese participants.

*Keywords:* Orthoses Obesity Walking

(Birrell and Haslam, 2009), joint problems (Birrell and Haslam, 2009), and foot blisters (Knapik et al., 1992) found in backpackers; and the loss of mobility (Messier et al., 1996), higher risk of hip and knee osteoarthritis (Felson, 1990; Hochberg et al., 1995; Ko et al., 2010), foot ulceration (Vela et al., 1998), and heel pain (Prichasuk and Subhadrabandhu, 1994) described in obese people.

Foot orthoses is a general term to describe a broad range of devices including heel lifts, lateral/medial wedges, or insoles (custom-made or prefabricated) (Chevalier and Chockalingam, 2012). These devices have been shown to be effective for managing many foot problems (Bonanno et al., 2011; Colagiuri et al., 1995; Cronkwright et al., 2011; Lynch et al., 1998; Sasaki and Yasuda, 1987). They can reduce and redistribute plantar foot pressure and subsequently avoid or decrease foot pain (Burns et al., 2007). However, the exact mechanisms by which foot orthoses work are yet to be fully understood (Chevalier and Chockalingam, 2012), and the biomechanical effect of these devices is far from the simplistic model often proposed in a clinical context (Nester et al., 2003); also, there is a need to establish the most suitable shoe/foot orthoses across clinical or high-risk populations (Rao et al., 2012).

## 1. Introduction

The musculoskeletal system is often either permanently loaded, as in obese people, or occasionally loaded as in walkers that wear weighted backpacks (backpackers). In both cases (labeled as loaded populations), alterations in the biomechanical parameters of gait, such as in plantar pressure distribution (Castro et al., 2013; Castro et al., 2014; Hills et al., 2001) and ground reaction forces (GRF) (Birrell and Haslam, 2010; Birrell et al., 2007; Browning and Kram, 2007; Castro et al., 2013; Castro et al., 2014; Messier et al., 1996; Simpson et al., 2012) has been shown. Possibly, these biomechanical alterations may contribute to the higher incidence of low back pain (Grimmer and Williams, 2000; Skaggs et al., 2006), higher perceived exertion and shoulder discomfort (Simpson et al., 2011), second metatarsal stress fractures (Arndt et al., 2002), muscle strain

The comprehension of how the forces are distributed on the foot along the stance phase seems to be essential to detecting overloaded regions. The evaluation of the plantar pressures allows assessing the function of the ankle or foot while walking and other functional activities, as the foot and ankle are responsible for providing support and flexibility while weight transferring (Cavanagh and Ulbrecht, 1994). On the other hand, the plantar pressure systems do not provide any information regarding the shear forces. The analysis of the GRF provides global information about the vertical and shear stress forces during gait, whereas the plantar pressure analysis identifies the distribution of the vertical GRF over the plantar foot surface. The combination of both analyses offer more detailed information about specific features of forces acting on the foot during gait (Castro et al., 2013).

The knowledge of the different adaptations of the body when submitted to occasional or permanent load, and the development and testing of insoles developed specifically for these potential harmful situations may be helpful to further understand the mechanisms of foot orthoses to make physical exercise safe and to prevent injury. The primary aim of this study was to test the effects of two pressure relief insoles developed for loaded populations on GRF parameters and plantar pressure peaks during backpackers and obese' adults gait. The secondary aim was to compare the GRF and plantar pressures among normal-weight, backpackers and obese participants.

## 2. Methods

### 2.1. Participants

The participants were between 18 and 45 years old, had body mass index (BMI) either lower than 25 or higher than 30 and did not have any traumatic-orthopedic impairment or difficulty with independent gait. Twenty-one participants (10 men and 11 women; age =  $25.81 \pm 2.47$  yrs; body mass =  $63.62 \pm 6.96$  kg; height =  $1.68 \pm 0.07$  m; and BMI =  $21.56 \pm 3.65$  kg/m<sup>2</sup>) were selected as the normal-weight group. These participants wore loaded backpacks and they were also considered as backpackers group. Ten participants (five men and five women; ages =  $35.60 \pm 4.90$  yrs; body mass =  $101.80 \pm 20.31$  kg; height =  $1.66 \pm 0.10$  m; and BMI =  $36.50 \pm 4.51$  kg/m<sup>2</sup>) formed the obese group. This project was approved by the local ethical committee and all participants freely signed an informed consent term, based on Helsinki's declaration.

### 2.2. Instruments and data acquisition

A Bertec force plate, model 4060-15 (Bertec Corporation, Columbus, USA), operating at 1000 Hz, and the Acknowledge software (BIOPAC System, California, USA) were used to capture GRF. The F-Scan in-shoe pressure system (TekScan, South Boston, USA) operating at 300 Hz with about 960 pressure cells (depending on the size of the shoe) with 0.18 mm thick insole sensor, and the F-Scan Research 6.33 software (TekScan, South Boston, USA) were used to capture plantar pressure data.

### 2.3. Insoles

We aimed to develop and test two models of insoles for an averaged "general" foot—not custom-made insoles—to be used indistinctly by people walking under loaded conditions (backpackers and obese subjects). Peak pressure relief was the rationale for the development of the insoles. Thus, based on the analysis of previous in-shoe plantar pressure data from backpackers (Castro et al., 2013) and obese subjects (Castro et al., 2014) during

walking, as well as on simulations with a finite element model (FEM) which was adapted from a previous study (Pinto et al., 2011), the features of the insoles were selected for manufacturing and experimental testing.

#### 2.3.1. Finite element model (FEM) of the foot and insole

From computed tomography medical images of one of the obese participants (male, with body mass of 121 kg) was obtained a single file with the corresponding mesh clouds, using Mimics® v9.1 software (Materialise, Belgium). These mesh cloud were exported as STL files to Solidworks® 2009 (Dassault Systèmes SolidWorks Corporation, Massachusetts, USA), where they were edited and improved to generate a solid part for each 3D object (further information about the FEM in Appendix 1).

For the insole construction model, a combined method of optical techniques (laser scanning method) and CAD model adjustments were used to obtain its geometry. Each obtained 3D insole model, with geometrical and material adjustments, was computationally tested at midstance gait cycle by a static simulation with the insole between the foot and the ground in the Ansys Workbench Platform® v.11 (Ansys, Pennsylvania, USA). The data were analyzed qualitatively (based on pressure distribution along the plantar surface) and quantitatively (based on values extracted from eight foot regions – Appendix 1).

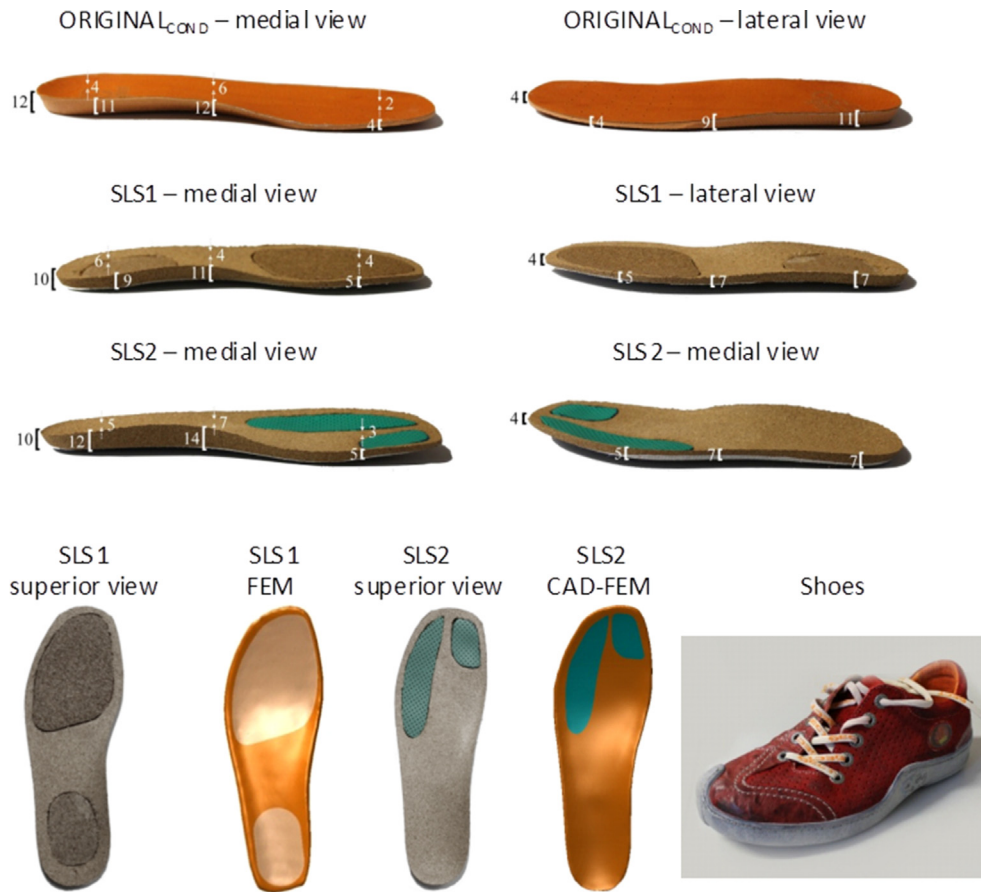
After analyzing the FEM static simulation data, and the experimental gait data from backpackers (Castro et al., 2013) and obese subjects (Castro et al., 2014), two insoles were considered the most appropriate to reduce the pressure peaks. Thus, they were selected for manufacturing by a specialized company of shoe components: 3DCork Lda (Passos de Brandão, Portugal).

Both insoles were full-length, dual-density prefabricated (not customized), and had similar geometry (Fig. 1). They were labeled as stress-less shoe insole 1 (SLS1): flat insole made of cork (Young's Modulus = 1060 kPa) with corkgel A30 (Young's Modulus = 7.5 kPa) in the forefoot and rearfoot regions (Fig. 1); and as stress-less shoe insole 2 (SLS2): made of cork with poron foam (Young's Modulus = 63 kPa) in the great toe and lateral forefoot regions (Fig. 1). Unisex casual shoes with rubber sole (sneaker) with cutting and lining leather (Eject Shoes, Felgueiras, Portugal – Fig. 1), and its original insole (unisex flat insole made of polystyrene and leather lining) were used. The original insoles were removed from the shoes when testing the manufactured insoles.

### 2.4. Tasks and procedures

The participants' body mass and height were recorded. A cuff unit (VersaTek hub, F-Scan system) measuring  $98 \times 64 \times 29$  mm with Velcro strap up was attached on the lateral malleolus region of both legs of each participant. The participants were given a pair of thin socks and a sneaker with the sensor-pressure insole inside. This sneaker was selected due to its regular flat sole and a wide internal space. The participants familiarized with the setup by walking at a pace of 100 steps per minute, controlled by a metronome (Wittner Maelzel Metronome, Germany), over a 6 m walkway in which a force plate was embedded in the middle. For the testing, the obese participants performed three valid right foot trials in four conditions:

- Shoe-only condition (SHOE-ONLY<sub>COND</sub>): wearing the sneakers without any insole;
- Original condition (ORIGINAL<sub>COND</sub>): wearing the sneaker with its original insole;
- SLS1: wearing the sneaker with the SLS1;
- SLS2: wearing the sneaker with the SLS2.



**Fig. 1.** Insoles and shoes used in the study. The numbers in the lateral and medial view figures are the thickness in millimeters. SLS1 and SLS2 = manufactured insoles; ORIGINAL<sub>COND</sub> = original condition; CAD = used to generate the finite element mesh.

The normal-weight group performed three valid right foot trials wearing the sneakers without any insole, which was labeled as unloaded condition (UNLOADED<sub>COND</sub>). After that, the mass to raise their BMI to 30 was calculated, and a backpack was filled with sand and fixed at the central area of the participants' back (making them as backpackers group). The mass of the backpack ranged from 19.04 to 25.61 kg (mean load  $22.26 \pm 1.44$  kg). As BMI = 30 is considered as a possible threshold for traumatic-orthopedic injuries (Class I obesity), we used it as load criterion to promote an occasional load (which is potentially harmful in the long-term) to assess load carriage during a standardized and substantially difficult (heavy) condition (Castro et al., 2013). Then they performed three right foot trial with the same four conditions as the obese participants. The order of the conditions was randomized.

## 2.5. Data analysis

The data from the force plate (three GRF components) and the in-shoe pressure system (values of each sensor in each frame) were exported to Matlab 7.0 software (MathWorks, Massachusetts, USA) and a program was developed for data processing and calculation of the variables.

Considering the absolute GRF data, the followed parameters were calculated:

- Duration of the stance phase;
- Fz1 (load acceptance peak): first peak from the vertical GRF;
- Fz2 (minimum between peaks): minimum value between the two peaks from vertical GRF.

- Fz3 (thrust peak): second peak from the vertical GRF;
- Fy1 (braking peak): first (negative) peak from the anterior-posterior GRF;
- Fy2 (propulsive peak): second peak (positive) of the anterior-posterior GRF;
- Fx (medial-lateral peak): peak from the medial-lateral GRF.

Regarding the pressure data, the program calculated the in-shoe pressure peak (sensor that showed the highest pressure value during the stance) for 10 foot regions: great toe, little toes, medial, central and lateral forefoot; medial and lateral midfoot; and medial, central and lateral rearfoot, as previously proposed (Castro et al., 2013).

## 2.6. Statistical analysis

Some variables were chosen arbitrarily to verify the intra-individual repeatability of the three trials. For this, the intra-class correlation coefficient (ICC) was calculated to the stance phase duration, Fz1, Fz3, and for the pressure peaks in the lateral forefoot and central rearfoot.

The mean of the three repetitions of each participant was computed and all the statistical procedures were performed with these mean values. To verify the influence of the insoles on the gait pattern, a repeated measures MANOVA was conducted with the groups (normal-weight/backpackers and obese participants) as between group factor, conditions (UNLOADED<sub>COND</sub>, SHOE-ONLY-<sub>COND</sub>, ORIGINAL<sub>COND</sub>, SLS1, and SLS2) as within group factor, and the set of variables (GRF: duration of stance phase, Fz1, Fz2, Fz3, Fy1,

Fy2, and Fx; or pressure peaks from the 10 regions) as dependent measures. The partial Eta square ( $\eta_p^2$ ) was used to measure the effect sizes considering that an  $\eta_p^2$  of 0.01 was considered small, of 0.06 medium, and above 0.14 large (Stevens, 2002). The statistical analyses were performed using the Statistica® v.8 software (Statsoft®, Tulsa, USA) with an  $\alpha$  value set as 0.05.

### 3. Results

Good to excellent data repeatability was found. All variables showed ICC higher than 0.89.

#### 3.1. Differences in GRF among groups

ANOVA interaction among conditions, groups and GRF variables ( $F(24, 696) = 25.498; p < 0.001; \eta_p^2 = 0.468$ ) with a large effect size was found. Similar stance phase durations ( $p > 0.05$ ) among normal-weight ( $0.74 \pm 0.03$  s), backpackers ( $0.78 \pm 0.03$  s), and obese participants ( $0.77 \pm 0.05$  s) were found. The obese participants showed higher Fz1, Fz2 and Fz3 compared to backpackers and normal-weight participants, and higher Fy1 and Fy2 than normal-weight participants. The backpackers showed higher Fz1, Fz2, Fz3, Fy1 and Fy2 than normal-weight subjects. Similar Fx were found among the groups (Fig. 2).

#### 3.2. Influence of insoles on the GRF

Differences among conditions were found in GRF parameters for both backpackers and obese participants. Obese individuals presented lower Fz1 and Fz2 in SLS2 than in the other conditions. Backpackers also showed lower Fz1 in SLS2 than in ORIGINAL<sub>COND</sub> and SLS1, and lower Fz2 in ORIGINAL<sub>COND</sub> than in the other conditions. Similar values were found for Fz3, Fy1, Fy2 and Fx among conditions during obese and backpackers' gait (Table 1).

#### 3.3. Differences in plantar pressure peaks among groups

ANOVA interaction among conditions, groups and pressure peaks ( $F(36, 1044) = 2.138; p < 0.001; \eta_p^2 = 0.068$ ) with a medium effect size was found. The obese participants showed higher pressure peaks in the central and lateral forefoot compared to normal-

weight (UNLOADED<sub>COND</sub>) and backpackers; and higher values in the medial forefoot, lateral midfoot and lateral rearfoot than normal-weight participants. The backpackers showed higher pressure peaks in the great toe, little toes, medial and central forefoot, and medial and central rearfoot than walking without a backpack (Fig. 3).

#### 3.4. Influence of insoles on plantar pressure peaks

Significant differences among conditions were found in backpackers' gait. In the great toe and medial forefoot regions the SHOE-ONLY<sub>COND</sub> showed lower pressure peaks than the other conditions (ORIGINAL<sub>COND</sub>, SLS1 and SLS2). The SLS1 showed lower values in the little toes and medial midfoot regions and a higher value in the medial rearfoot compared to SHOE-ONLY<sub>COND</sub> (Fig. 4A).

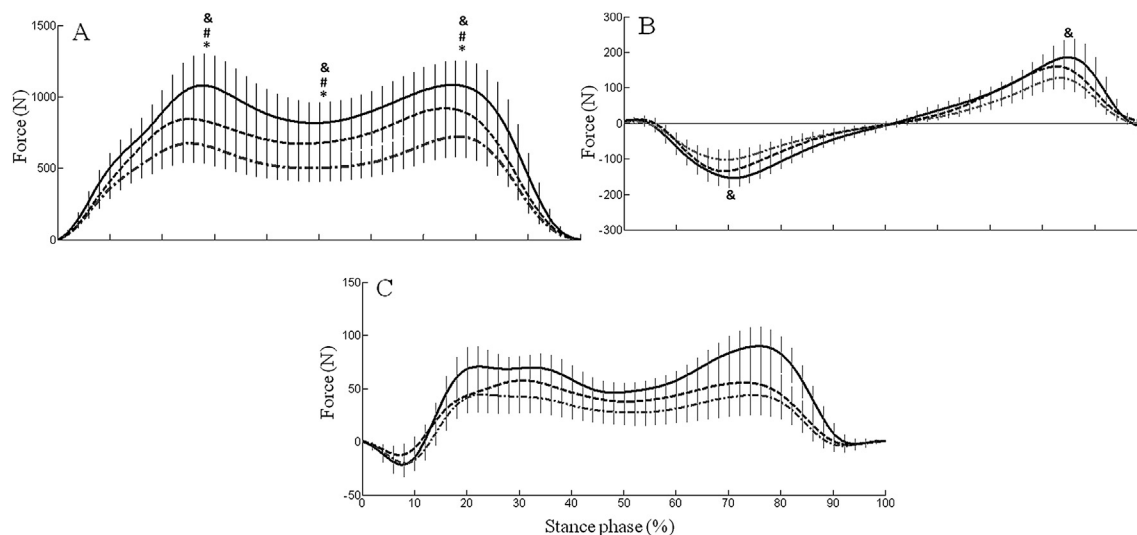
Differences among conditions in pressure peaks were also found for the obese participants. The SLS1 showed higher pressure peaks in the great toe, the SLS2 in the medial forefoot, and the SHOE-ONLY<sub>COND</sub> in the central forefoot compared to the other conditions. For the lateral forefoot and midfoot the pressure peaks in the SLS1 were lower than in the SHOE-ONLY<sub>COND</sub>. Similar pressure peaks in the rearfoot were found among conditions during obese' gait (Fig. 4B).

## 4. Discussion

The aims of this study were to compare the plantar pressure peaks and GRF among normal-weight, backpackers and obese participants, and to test the effects of two pressure relief insoles on these parameters during gait. The differences found among the groups (normal-weight, backpackers, and obese participants) and among conditions (SHOE-ONLY<sub>COND</sub>, ORIGINAL<sub>COND</sub>, SLS1, and SLS2) for the backpackers and obese individuals were not only statistical significant, but also appear to have a practical relevance as medium to large effect sizes were found.

#### 4.1. Differences in GRF among groups

All analyzed events of the vertical GRF (Fz1, Fz2, and Fz3) suggest a load-dependent behavior. As expected, the obese participants (mean weight: 102 kg) showed higher values than the



**Fig. 2.** Ground reaction forces (GRF). (A) Vertical GRF; (B) Anterior–posterior GRF; (C) Medial–lateral GRF of normal-weight group (UNLOADED<sub>COND</sub> = unloaded condition, dash-dotted gray line), backpackers (SHOE-ONLY<sub>COND</sub> = Shoe-only condition, dashed black line), and obese participants (SHOE-ONLY<sub>COND</sub>, continuous black line) during gait; \* Denotes a significant difference ( $p < 0.05$ ) between obese and normal weight group; # between obese and backpackers; and & between backpackers and normal-weight group.

**Table 1**  
Ground Reaction Forces during backpackers and obese' gait in different conditions.

Variables	SHOE-ONLY <sub>COND</sub>	ORIGINAL <sub>COND</sub>	SLS 1	SLS 2	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
Backpackers	Fz1 (N)	860.0 (118.6)	868.0 (113.7)*	863.3 (118.5) <sup>#</sup>	845.2 (105.5) <sup>**</sup>
	Fz2 (N)	664.4 (78.9)*	646.0 (64.3) <sup>**#&amp;</sup>	669.0 (76.2) <sup>#</sup>	665.5 (78.1) <sup>&amp;</sup>
	Fz3 (N)	928.35 (123.0)	931.4 (114.6)	928.4 (121.2)	919.7 (103.3)
	Fy1 (N)	-141.5 (11.9)	-145.5 (27.6)	-140.7 (23.9)	-145.6 (33.4)
	Fy2 (N)	157.8 (29.6)	159.0 (26.4)	153.7 (30.3)	151.1 (24.1)
	Fx (N)	63.0 (14.1)	64.7 (13.1)	61.9 (13.7)	58.8 (10.1)
	Obese	Fz1 (N)	1076.4 (226.0)*	1074.8 (233.8) <sup>#</sup>	1078.4 (227.3) <sup>&amp;</sup>
Fz2 (N)		777.1 (164.9)*	784.1 (167.9) <sup>#</sup>	777.8 (171.8) <sup>&amp;</sup>	749.3 (132.2) <sup>**#&amp;</sup>
Fz3 (N)		1052.2 (197.0)	1049.4 (202.4)	1060.0 (195.4)	1034.7 (187.0)
Fy1 (N)		-159.2 (24.1)	-166.8 (25.5)	-166.8 (26.2)	-165.0 (25.7)
Fy2 (N)		186.2 (50.7)	184.6 (46.8)	183.6 (42.7)	184.6 (44.1)
Fx (N)		91.5 (18.3)	94.9 (17.8)	95.2 (19.3)	94.0 (20.1)

SHOE-ONLY<sub>COND</sub> = Shoe-only condition; ORIGINAL<sub>COND</sub> = Original condition; SLS1 = stress-less shoe insole 1; SLS2 = stress-less shoe insole 2.

\* # & Equal symbols between conditions denote significant difference with  $p < 0.05$ .

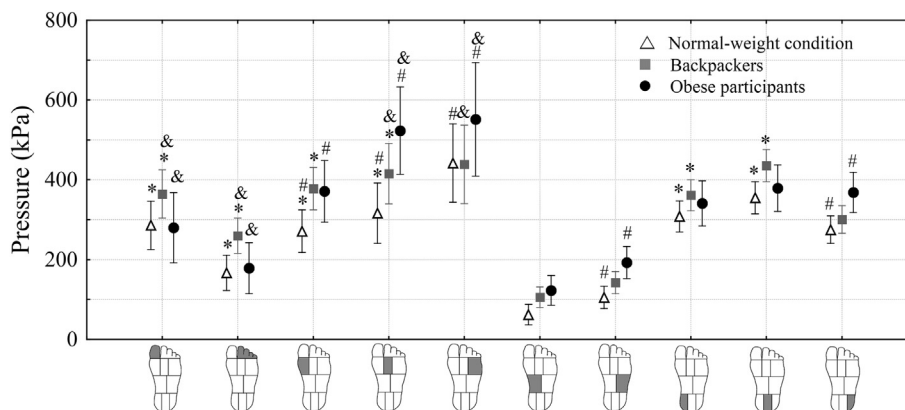
backpackers (86 kg) and normal-weight (64 kg) group, and the backpackers showed higher values than the normal-weight group. Other studies comparing backpackers (Birrell and Haslam, 2010; Birrell et al., 2007; Castro et al., 2013; Simpson et al., 2012) and obese subjects (Browning and Kram, 2007; Messier et al., 1996) with normal-weight individuals corroborate with these findings. Considering the anterior-posterior GRF and being aware that higher magnitudes in this component have been related to blister development (Knapik et al., 1997). Our data suggest the obese participants may have developed gait pattern adaptations for preventing this kind of injury; while the backpackers seem to be more likely to develop blisters compared to normal-weight group, as evidenced by their higher anterior-posterior GRF peaks. These findings are in accordance with other studies (Birrell and Haslam, 2010; Castro et al., 2013; Simpson et al., 2012). In terms of medial-lateral GRF, no differences were found among the groups. As the medial-lateral GRF is related with gait stability (Birrell et al., 2007), these results were surprising because other studies assessing the GRF component in backpackers (Birrell et al., 2007; Castro et al., 2013; Simpson et al., 2012) or obese people (Browning and Kram, 2007), and kinematic studies (Lai et al., 2008; Qu, 2013) found greater instability in the loaded population' gait. We assessed the gait during over-ground level walking under a controlled pace. The aforementioned studies assessed the gait either with a self-selected speed (Birrell et al., 2007; Castro et al., 2013; Qu, 2013; Simpson et al., 2012), or with a controlled speed on a treadmill (Browning and Kram, 2007). These methodological criteria might cause these

differences between the current study and others. Overall, our data support similar stability conditions among normal-weight group, backpackers and obese people walking over-ground at a controlled pace showed.

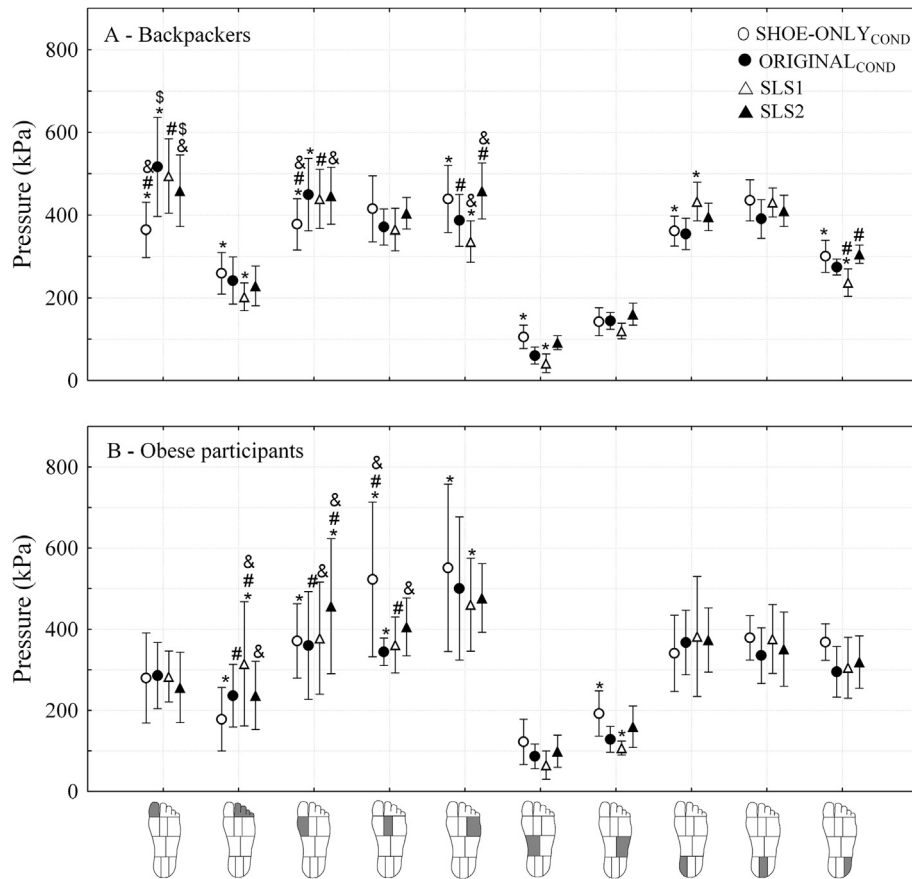
#### 4.2. Differences in plantar pressures among groups

Only few studies have investigated the plantar pressure distribution during loaded gait (Birtane and Tuna, 2004; Castro et al., 2013; Hills et al., 2001). A previous study (Castro et al., 2013) found higher pressure peaks in nine out of ten foot regions in backpackers compared to a normal-weight condition (only the lateral midfoot showed similar values). In the present study higher values were observed in six out of ten regions. This differences may occurred because of the different shoes used in the studies: casual shoes with rubber sole (present study) versus ballet sneakers (Castro et al., 2013).

The obese participants presented an overall increased in the pressure peaks while walking compared to the normal-weight subjects. Two studies (Birtane and Tuna, 2004; Hills et al., 2001) assessed the plantar pressures in obese adults; in both of them, the rearfoot and midfoot were each considered as one region. Higher (Hills et al., 2001) and similar (Birtane and Tuna, 2004) values were found in the rearfoot, and the midfoot showed higher values (Birtane and Tuna, 2004; Hills et al., 2001) when compared to lean individuals. The present study partially agrees with them. We find higher values for the lateral region in both areas (rearfoot and



**Fig. 3.** Mean and 95% confidence interval of pressure peaks for the normal-weight group, backpackers and obese participants (SHOE-ONLY<sub>COND</sub> = Shoe-only condition); \* # & Equal symbols denote significant differences ( $p < 0.05$ ) between groups.



**Fig. 4.** Mean and 95% confidence interval for (A) backpackers and (B) obese while walking in different conditions; \* # & Equal symbols denote significant differences ( $p < 0.05$ ) between groups.

midfoot), whereas similar values were found for the medial and central areas. The present study and a previous one (Hills et al., 2001) found increased pressure peaks in the three forefoot regions in obese participants compared to normal-weight peers. In contrary, another study (Birtane and Tuna, 2004) did not find any difference between these populations. The different levels of obesity may be the cause of these differences among the studies:  $36.5 \text{ kg/m}^2$  (present study),  $38.8 \text{ kg/m}^2$  (Hills et al., 2001), and  $32.2 \text{ kg/m}^2$  (Birtane and Tuna, 2004).

When both loaded gait groups were compared (obese vs. backpackers), different pressure peaks were found. These findings suggest that the load distribution (obese: abdominal – men; gluteofemoral – women vs. backpackers: mid back) and the duration of loading (permanent vs. occasional) may play an important role on the plantar pressure distribution pattern.

#### 4.3. Influence of SLS1 on gait

This insole did not influence the GRF parameters, but it did influence the pressure peaks. This condition caused different effects in the groups. In the backpackers: the rearfoot pressure in SLS1 shifted from the lateral to the medial region. This insole also showed an interesting effect in the lateral forefoot, in which it decreased the peaks compared to the other conditions. However, compared to the shoe-only condition, higher values were found in the great toe and medial forefoot. In the obese participants: it seems that the SLS1 is the most appropriated insole as it displayed the most consistent pressure-relieving in all forefoot (region in which the highest peaks were found) and lateral midfoot regions

with this orthosis. Thus, a homogenous application of lower-density material (in the rearfoot and forefoot regions) seems to have a positive effect for relieving pressure peaks during loaded gait.

#### 4.4. Influence of SLS2 on gait

The SLS2 promoted attenuation in Fz1 compared to the other conditions for both backpackers and obese participants. Thus, this insole appears to play a relevant role in helping the heel in shock absorption. One possible explanation is the different material applied in the rearfoot region. In this case, the higher density of SLS2 may be more effective in load-acceptance attenuation when compared to the lower-density material of SLS1. However, a positive influence of this condition was not identified in the plantar pressure peaks for both groups: no alterations in the rearfoot, midfoot, and great toe regions were found; whereas, in the forefoot, the SLS2 increased the pressure peaks in the lateral region for the backpackers and in the medial region for the obese participants.

#### 4.5. Limitations of this study

The findings of this study should be read considering several limitations. First, only the immediate biomechanical effects of the insoles were investigated; thus, the results may not reflect the long term changes such as the degradation of the insole material and the acclimatizing of the participants. Second, the participants wore standardized shoes which may not be representative of what they typically wear; however, as the shoes can influence the GRF and

pressure parameters, this approach was adopted in order to decrease other sources of influence on the data. Third, the FEM is a static model, analyzing the midstance gait, and it was based on only one of the participant's morphology; nevertheless, we also analyzed experimental data of both populations (backpackers and obese) for establishing the insoles' features. Overall, we believe the mentioned limitations were either needed to make the methods consistent or they were minimized and did not have relevant influence in the results. The good to excellent observed data repeatability hints and supports the good internal consistency for the present methods.

In conclusion, we noted that insoles developed for the loaded population (backpackers and obese participants) showed positive effects for either the plantar pressure distribution or GRF parameters. The medium to large effect sizes observed suggest that these findings can be generalized for the loaded population. The SLS1 did not influence the GRF parameters but did influence positively the pressure peaks; it seemed to be the most appropriate insole for loaded gait population (mainly for the obese). The SLS2 helped the heel in shock absorption during the heel strike (lowered Fz1); however it did not show any positive influence on the plantar pressure distribution. Several differences in GRF and plantar pressure peaks were found among the normal-weight group, backpackers and obese participants.

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