

# Comparison of plantar pressure and musculoskeletal symptoms with the use of custom and prefabricated insoles in the work environment

## Comparaç o da press o plantar e dos sintomas osteomusculares por meio do uso de palmilhas customizadas e pr -fabricadas no ambiente de trabalho

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### Abstract

**Objectives:** To compare the effect of the use of custom and prefabricated insoles on the behavior of plantar weight load and musculoskeletal symptoms in assembly line workers. **Methods:** A randomized trial was carried out with 27 women who worked in a static standing position and had musculoskeletal symptoms. The mean age was 30.3±7.09 years and the weight 64.85±13.65 Kg. The Nordic Musculoskeletal Questionnaire was administered, and plantar pressure was determined using a computerized baropodometric system (FootWork). The sample was then divided into control group, which wore pre-fabricated insoles, and intervention group, which wore ethylvinylacetate insoles for eight weeks. Baropodometric data were collected and the questionnaire was administered once again. **Results:** There was no statistically significant difference in the comparison between groups and baropodometric data. However, a change was noted in the behavior of the load variables between evaluations, with an increase in mean load pressure and maximal plantar pressure ( $p<0.05$ ). No statistically significant difference was found between groups for any anatomical site in the different evaluations. Within each group, there was a reduction in foot pain and back pain between evaluations ( $p<0.05$ ). **Conclusions:** Both types of insole reduced pain symptoms in the lumbar region and feet. After eight weeks of use, there was an increase in maximal and mean plantar pressure and a reduction in plantar surface area with both types of insole. Article registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) under the number ACTRN 12609000922279.

**Key words:** occupational health; orthotic devices; foot.

### Resumo

**Objetivos:** Comparar os efeitos do uso de dois tipos de palmilhas, customizadas e pr -fabricadas, sobre a descarga plantar de peso e o comportamento de sintomas osteomusculares em trabalhadoras de linha de montagem. **M todos:** Ensaio randomizado com 27 mulheres que trabalhavam em postura ortost tica est tica, com m dia de idade de 30,3±7,09 e massa de 64,85±13,65 e que apresentavam sintomas osteomusculares. Inicialmente, aplicou-se o Question rio N rdico de Sintomas Osteomusculares e coletaram-se as press es plantares pelo sistema de baropodometria computadorizada (*FootWork*). Posteriormente, a casu stica foi dividida em grupo controle (GC), que utilizou palmilha pr -fabricada e grupo interven o (GI), que usou palmilha customizada de etilvinilacetato (EVA) durante oito semanas. Dados baropodom tricos foram novamente coletados assim como a reaplica o do question rio. **Resultados:** N o houve diferen a estat stica significativa na compara o entre grupos e dados baropodom tricos. Notou-se, entretanto, mudan a de comportamento nas vari veis de descarga em cada momento avaliado, assim como o aumento para as vari veis de m dia press o de descarga e press o plantar m xima ( $p<0,05$ ). T m tamb m n o foi mostrada diferen a estat stica significativa para qualquer local anat mico entre os grupos nos diferentes momentos de avalia o. Observou-se que, dentro de cada grupo, houve redu o dos n veis dolorosos na regi o dos p s e da coluna lombar, quando comparado momento inicial e final da interven o ( $p<0,05$ ). **Conclus es:** Ambas as palmilhas reduziram os n veis dos sintomas na coluna lombar e p . Ap s oito semanas, houve aumento da press o m xima e m dia das press es nos p s e redu o de  rea de superf cie plantar, observados nas duas palmilhas. Artigo registrado no Australian New Zealand Clinical Trials Registry (ANZCTR) sob o n mero ACTRN12609000922279.

**Palavras-chave:** sa de do trabalhador; aparelhos ortop dicos; p .

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## Introduction

Repetitive strain injuries (RSI) or work-related musculoskeletal disorders (WMSDs) are characterized by pain in the anatomical sites most used during occupational functions<sup>1-4</sup>. This condition has been shown to be associated with inadequate body postures, including prolonged periods of time in the standing position at work that affect particularly the spine and lower limbs and generate absenteeism and reduction in production, as suggested by Laperrière et al.<sup>5</sup> and Sobel et al.<sup>6</sup>. The maintenance of the described posture and musculoskeletal discomfort has been addressed in the scientific literature<sup>7-10</sup>. However, only Basford and Smith<sup>11</sup> studied the use of insoles to verify the reduction in complaints, but without associating them with changes in weight load or other mechanical explanations. Sobel et al.<sup>6</sup> and Shabat et al.<sup>12</sup> examined the use of insoles in the workplace, but in populations who walked during work. In this sense, there are gaps for interventions aimed at standing and static positions in symptomatic workers, especially those related to plantar performance and comparisons of insoles found in the national market.

The use of plantar orthoses has been recommended to reduce painful conditions related to the feet<sup>13-15</sup> and spine<sup>12,16</sup>. It is suggested that these devices may affect the distribution of plantar loads in contact with rigid surfaces, thus reducing the absorption of shocks and minimizing pain in the lower limbs and lumbar spine<sup>6</sup> because a better distribution of body weight on the plantar area provides proper alignment to the pelvis and, therefore, to the spine<sup>17</sup>. Hodge, Bach and Carter<sup>13</sup> investigated the effectiveness of plantar orthoses in subjects with rheumatoid arthritis and metatarsalgia and showed reductions in pain and pressure in the first and second metatarsals. Jannink et al.<sup>14</sup> evaluated the effectiveness of customized insoles in patients with degenerative foot problems and concluded that they were effective in reducing symptoms and plantar pressure. Shabat et al.<sup>12</sup> found positive effects of the use of insoles on the painful conditions of the lumbar spine in people whose work involved long-distance walking. In contrast, Sahar et al.<sup>16</sup> concluded that there was a need for better tests to confirm the associations between insoles and back pain prevention.

Few studies have evaluated the effectiveness of insole use<sup>6,11,12</sup> within the work environment, an appropriate setting for the manifestation of ergonomic symptoms. Furthermore, no studies have compared different types of insole materials in the work environment. The present study is justified because it shows a well-defined, common problem in the occupational environment, characterized by biomechanical overload and standing posture. This posture is associated with complaints of pain and with possible harm to the health of workers. Thus, this study aimed to compare the effects

of two types of insoles, custom made and prefabricated, on plantar weight loads and musculoskeletal symptoms in assembly line workers.

## Methods

### Study type and population

Fifty female workers of an industrial assembly line in the state of São Paulo who worked in a static standing position wearing uniform shoes participated in the study. All participants worked in the leather cutting section of a dog bone manufacturing company. They had eight hours of work a day, with a one hour lunch break; they worked the same shift and did not perform any physical activity during the working hours. Female participants were chosen because epidemiological data have shown that this gender was the most affected by injuries of this nature<sup>2</sup>.

An initial interview was conducted at the work site to collect personal data such as age, weight, height, systemic diseases and the presence of trauma prior to the analyses. A physical therapy evaluation was included to verify the presence of congenital deformities or limitations in the range of motion of the joints. Women over 18 years who had work-related musculoskeletal symptoms in the lumbar spine or lower limb were selected. Twenty-three participants were excluded, 13 of whom had musculoskeletal signs and symptoms prior to working in this section. The remainder had systemic diseases, structural deformities or previous trauma. Thus, the sample of the study consisted of 27 female workers with a mean age of 30.30±7.09 yrs and weight of 64.85±13.65 kg.

The study was designed as a randomized, double-blind trial, with blinding of the assessor to group allocation. The participants were randomly allocated by draw to one of two groups, intervention group (IG) or control group (CG). The CG (n=13) wore prefabricated insoles, and the IG (n=14) wore custom insoles. The anthropometric characteristics of both groups are shown in Table 1; the groups were homogeneous regarding these characteristics.

### Procedures for collection and description of the questionnaire

The Nordic Musculoskeletal Questionnaire (NMQ), validated in the Portuguese language, was used to identify the musculoskeletal problems<sup>18</sup>. This questionnaire is used internationally and was developed to standardize research on this subject. It is also easy to understand, with simple and direct questions<sup>19</sup>. The questionnaire was used by Pastre et al.<sup>2</sup>, who included questions about the severity of the complaints for

each anatomical region, ranging from one to four, where one represents no symptoms; two, mild symptoms; three, moderate symptoms; and four, severe symptoms. The same authors also included the arms and calves as symptom sites in the body map of the original questionnaire.

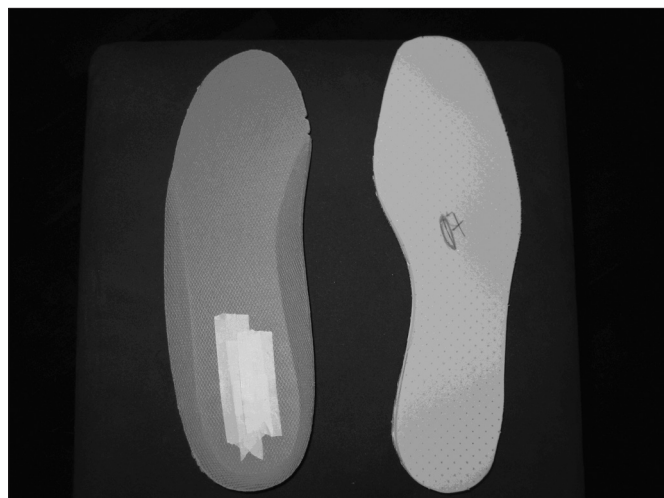
To obtain the data, the questionnaire was administered by the researcher during the workday. This procedure was adopted to avoid bias, as suggested by Pastre et al.<sup>2</sup> for participants with different levels of education. A digital scale was used to measure body weight in kilograms, and a tape measure with a precision of 0.1 cm was attached to the wall to measure height.

To obtain the values for plantar pressure, a force platform was used (electronic baropodometry, FootWork electronic model, IST Informatique, France). It was connected to a Pentium III personal computer. The force platform consists of a rigid base (645x520x25 mm) with 2704 pressure sensors (7.62x7.62 mm), which individually records up to 100 N/cm<sup>2</sup> of pressure. These sensors are spread across a 40x40 cm active area that allows baropodometry analyses of pressure loads in kilogram-force/cm<sup>2</sup> (kgf/cm<sup>2</sup>) and time of foot contact with the ground (plantar surface - cm<sup>2</sup>) in the static standing position. This equipment consisted of a 16-bit A/D converter with sampling frequency of 150 Hz.

**Table 1.** Descriptive measures of variables according to groups.

Variable	Descriptive measures	Group		p-value
		Control (n=13)	Intervention (n=14)	
*Age	Median	30	32	p>0.05
	Mean±SD	30.69±7.34	29.93±7.10	
** Weight (kg)	Median	65.00	63.00	p>0.05
	Mean±SD	66.54±16.77	63.29±10.37	
** Height (cm)	Median	165.00	164.00	p>0.05
	Mean±SD	164.77±6.26	163.28±3.29	

\* Mann-Whitney test; \*\* Student's t-test; SD=standard deviation.



**Figure 1.** Prefabricated insole (Left) and custom-made EVA insole (Right).

The participants remained in the standing position, looking straight ahead, arms along the body, with their base free of support within the marked area on the platform. The body weight was used for the automatic calibration of the equipment. Calibration is important to establish the validity of the pressure measurements. The participants remained on the platform for 60 seconds in double-leg stance and bare feet. All evaluations were performed during the participants' break from activities, prior to the lunch break.

The experiment was divided into three times of evaluation: the first was the pre-intervention (T1), the second after four weeks of insole use (T2) and the third after eight weeks of insole use (T3). Each evaluation included the application of the NMQ questionnaire and the foot examination by electronic baropodometry as described above. The body mass was also measured in all evaluations and used for new calibrations of the equipment. There were no significant changes in body mass during each phase of the trial.

## Description of insoles

To perform the experiment, two different types of insoles were used (Figure 1). The first consisted of a simple, prefabricated insole similar to that used in footwear and considered a placebo for the purposes of the study. The other insole was composed of ethylvinylacetate (EVA) (Comfort model, Podaly® Palmilhas do Brasil) which was individually customized, heat-glued and molded in a heat press (Termoprensa Ortopédica) at approximately 100° C. The orthoses were then inserted into a mold, and the worker stepped on it for 60 seconds to shape the insole, according to manufacturer recommendations. The participants were instructed to use the insoles daily with the work uniform for eight weeks. During a visit to the work site, it was observed and confirmed by enquiry that all participants made use of the insoles at work in the proposed time period.

## Data analyses

The parameters used for the data analysis were: maximal plantar pressure for both feet, characterized by the highest value recorded by a pressure sensor during the evaluation; mean plantar pressure of the right and left foot, corresponding to the sum of the pressure values divided by the number of sensors triggered during the test; and plantar surface, defined as the total area of sensors triggered during the test. These data were selected for the comparisons because they were analyzed and calculated by the software and were related to the biomechanical adaptation of the feet to the constant oscillations. Any change in stance interferes with the biomechanics of the body, and this is reflected on the feet and other segments<sup>20</sup>. Thus, the study of plantar

pressures is an important element in the investigation of certain impairments associated with musculoskeletal disorders<sup>21</sup>.

The body's center of gravity was chosen as a reference to define locations within the anatomical structure, as indicated by the device software. Thus, the anterior region of the foot was defined as forefoot and the posterior, as rearfoot. These data were transferred to Excel (Microsoft Windows®) for later analyses.

## Statistical procedures

Verification of the homogeneous variables of age, weight and height in the two studied groups was performed (Table 1). The Student's *t*-test for independent samples was used when there were normal probability distributions (weight and height) and the non-parametric Mann-Whitney test when normal probability distribution was not present (age).

To compare the study groups (IG and CG), considering the response category (T1, T2 and T3), we used parametric (Table 2) and non-parametric analysis of variance (Table 3) for repeated measures with independent groups. We also used multiple comparison tests for group evaluation at specific times and for comparison among assessment times within group. The choice of parametric or non-parametric procedures was established according to the Gaussian distribution of the variables. The significance of the multiple comparisons is indicated in these tables by lower case letters (group comparison at specific times) and uppercase letters (comparison between times within the group). For all analysis the level of significance was established at 0.05.

## Ethical considerations

The research began after approval by the Research Ethics Committee of Faculdade de Medicina de São José do Rio Preto, Protocol 6032/2005, and authorization from the company where the study was conducted. All participants read, understood and signed an informed consent form.

## Results

Maximal plantar pressures were obtained from the rearfoot region in all evaluations. Table 2 shows the mean and standard deviation values for the baropodometric variables at each time of evaluation. There were no significant differences between the two groups, however, within each group, there were changes in the load variables at each evaluated time, i.e. mean plantar pressure and maximal pressure increased and plantar surface decreased ( $p < 0.05$ ).

Table 3 shows the level of pain according to the time of evaluation and anatomical site. There were no significant

differences for any anatomical site between both groups at the different times of evaluation. There was a reduction in pain within each group when comparing the initial and final times for foot segment and lumbar spine in both groups ( $p < 0.05$ ).

## Discussion

The choice to perform the present study was based on the facts that the use of insoles can be considered a simple intervention that is commonly prescribed, and that industrial workers are part of a population well known to suffer with musculoskeletal injuries. Therefore, both facts help to characterize a well-defined problem. Concerning the target population, there is a greater prevalence of musculoskeletal injuries in young women between 20 and 39 years of age, according to the reports of Walsh et al.<sup>3</sup> and Reis et al.<sup>22</sup>. These characteristics were similar to those of the present study, resulting in excellent control conditions for this investigation. Another particular characteristic of the participants in this study was related to the ergonomic conditions. Working in the standing position interferes with venous reflux and causes intervertebral stress, joint overload, pain and discomfort, which have been shown to have a major impact on worker's health, productivity and absenteeism<sup>8,9,23-25</sup>.

The results of plantar load indicated an increase in the mean load and maximal pressure values and a reduction in the plantar surface area for both groups after eight weeks. These findings corroborated the claims of Rasovic, Newcombe and Dalton<sup>26</sup>, who did not find positive effects of the use of insoles in all diabetic patients. In contrast, the present results disagreed with the findings reported by Tsung et al.<sup>27</sup>, Guldmond<sup>28</sup> and Kelly and Winson<sup>29</sup> who showed that the use of insoles could reduce plantar pressures, especially in the forefoot region of different populations. It should be emphasized that the previously mentioned studies had no standardized customization process, type of material or insole thickness, factors which could influence shock absorption<sup>28,30</sup>, thus hampering the comparison of results. It is understood, then, that any baropodometric data should be interpreted with caution, as suggested by Oliveira et al.<sup>20</sup>.

In the present trial, positive responses were expected in relation to the distribution of plantar loads. These effects were not observed, and a possible explanation for that is the specificity of the intervention. The participants used the insoles in a certain position and in a particular condition of movement repeatability. However, the initial and final evaluations followed a pre-defined protocol, i.e. full static position, but without the movement characteristics adopted by workers in their work environment. Thus, the expected processes of adaptation might not have been identified by the proposed analysis because the

**Table 2.** Mean values and SD of baropodometric variables according to groups and time of evaluation.

Variables	Groups	Time of evaluation		
		T1	T2	T3
Right foot mean pressure	Control	0.40±0.15 aA	0.56±0.10 aB	0.70±0.19 aC
	Intervention	0.35±0.08 aA	0.57±0.15 aB	0.60±0.13 aB
Left foot mean pressure	Control	0.55±0.13 aA	0.73±0.12 aB	0.81±0.19 aC
	Intervention	0.52±0.11 aA	0.76±0.12 aB	0.79±0.14 aB
Right foot maximal pressure	Control	2.43±0.73 aA	2.83±0.63 aB	3.21±0.91 aC
	Intervention	2.22±0.57 aA	2.76±0.73 aB	3.01±0.66 aB
Left foot maximal pressure	Control	2.53±0.58 aA	3.17±0.94 aB	3.67±0.93 aC
	Intervention	2.56±0.54 aA	3.53±0.63 aB	3.36±0.62 aB
Right plantar surface	Control	191.03±23.01 aB	143.97±24.31 aA	147.59±17.09 aA
	Intervention	186.62±16.38 aB	143.37±20.64 aA	152.17±25.56 aA
Left plantar surface	Control	164.35±14.32 aB	150.38±19.45 aA	145.76±19.50 aA
	Intervention	165.41±16.23 aB	142.73±13.88 aA	145.32±19.70 aA

Parametric Analysis of variance; letters are used for comparisons between values. Letters are different when there are significant statistical differences; when there are no differences, letters are equal. Lower case letters indicate group comparisons, in each column, with a fixed response category and a<b. Uppercase letters indicate the comparison between response categories (T1, T2 and T3), in each row (within each group), with A<B<C. Plantar pressure values are expressed in Kg/cm<sup>2</sup> and plantar surface values in cm<sup>2</sup>.

**Table 3.** Median, minimum and maximum values of pain levels according to groups and time of evaluation.

Variables	Groups	Time of evaluation		
		T1	T2	T3
Lumbar spine	Control	3.0 (1.0-4.0) aB	1.0 (1.0-3.0) aAB	1.0 (1.0-2.0) aA
	Intervention	2.0 (1.0-4.0) aB	1.5 (1.0-2.0) aAB	1.0 (1.0-2.0) aA
Knee	Control	1.0 (1.0-3.0) aA	1.0 (1.0-3.0) aA	1.0 (1.0-2.0) aA
	Intervention	1.0 (1.0-2.0) aA	1.0 (1.0-2.0) aA	1.0 (1.0-2.0) aA
Foot	Control	3.0 (1.0-4.0) aB	3.0 (1.0-4.0) aB	1.0 (1.0-3.0) aA
	Intervention	3.0 (1.0-4.0) aB	2.0 (1.0-3.0) aAB	1.0 (1.0-2.0) aA

Non-Parametric Analysis of Variance; letters are used for comparison between values. Letters are different when there are significant statistical differences; when there are no differences, letters are equal. Lower case letters indicate group comparisons, in each column, with a<b. Uppercase letters indicate the comparison between response categories (T1, T2 and T3), in each row (within each group), with A<B.

stimuli were provided in a very different situation from the initial and final analyses.

In the context of these symptoms, there were reductions in pain levels when comparing the initial and final times of evaluation for each of the groups. These findings agreed with those of Basford and Smith<sup>11</sup>. It should be noted, however, that the viscoelastic polyurethane insoles were used for five weeks, an intervention time similar to that of the present study but with a different material. Despite this divergence and based on the present group comparison results, it might be assumed that the use of any insole that brings comfort to the feet should relieve work-related pain symptoms.

As a hypothesis for this condition, the following chain of events could be used. It was understood that the prolonged standing position led to an increased sensitivity in the plantar region<sup>23,31</sup>. According to Shabat et al.<sup>12</sup> and King<sup>9</sup>, the use of insoles provided a greater sense of comfort to the feet, which, in turn, led to a subjective feeling of improvement in complaints triggered by standing postures. This is an obvious but relevant

conclusion in this discussion, and the literature suggests that standing on a soft surface is less fatiguing and more comfortable than on a hard surface<sup>8,9</sup>. In a more generic analysis based on loads and body symptoms, the possibility of a placebo effect in both groups must be considered because technically the changes in weight load were negative for both groups even with the improvement in symptoms. Nevertheless, it cannot be denied that the condition of greater comfort is a positive factor that is associated with the reduction of symptoms of minor clinical importance, as suggested by Shabat et al.<sup>12</sup>.

Finally, it is necessary to consider the limitations of the present study and the implications of its repercussions and conclusions. The comparative aspects were weak compared with previously published studies. The main factor is the lack of methodological standardization of data collection. Although the method adopted for this trial was considered appropriate, the lack of information, on the part of the device manufacturer, about the process of collection of pressure and calibration measurements could raise questions about the

accuracy of the data. As a contribution to the scientific and clinical fields, it is suggested that such data be included in the device manual.

Regarding the repercussions of this research, it should be noted that there is a need for a more individualized prescription of orthoses, considering foot type, ankle mobility, and insole thickness and materials<sup>32</sup>. Attention to these aspects could provide different results from those found in the present study and, to ensure a better understanding of the topic. Based on the present results, it was concluded that both insoles reduced

the levels of the lumbar spine and foot symptoms. After eight weeks, there was an increase in the maximal pressure and mean plantar pressures and a reduction in the plantar surface. These findings were observed for both insoles.

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