

Comparison of Two Types of Insoles on Musculoskeletal Symptoms and Plantar Pressure Distribution in a Work Environment: A Randomized Clinical Trial

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ABSTRACT

Background: the aim of the present study was to assess plantar pressure distribution and musculoskeletal symptoms following the use of customized insoles among female assembly line workers. **Methods:** twenty-nine female assembly line workers (age: 29.76 ± 5.79 years; weight: 63.79 ± 12.11 kg) with musculoskeletal symptoms and who work predominantly while standing participated in the study. The Nordic Musculoskeletal Questionnaire was administered for the sample selection. Plantar pressure was determined using a computerized plantar pressure feedback system. A control group (13 individuals) used ethylvinylacetate insoles (Podally) that were individually heat-molded and heat-glued. The intervention group (14 individuals) also used the insoles and a strip of the same material was added to the site of greatest plantar pressure, as determined by the electronic feedback device. After five weeks, the plantar pressure data were collected again and the questionnaire was administered second time. **Results:** there was no significant difference between groups with regard to pain in any anatomic site. Within each group, however, the lumbar region exhibited a reduction in symptoms in the intervention group ($p < 0.05$) and the feet exhibited a reduction in symptoms in both groups ($p < 0.05$). Mean plantar pressure increased and plantar surface decreased in the intervention group ($p < 0.05$). **Conclusions:** insoles increased the feet comfort in both groups and added strip did not either significantly modified the plantar pressure or the other symptoms in female workers.

Keywords: Worker health, Orthopedic Devices, Foot.

INTRODUCTION

Plantar insoles are often used in the treatment of musculoskeletal pain and problems in the lower limbs^{1,2}. Specifically regarding the use of insoles, scientific findings report the prescription of this device in the field of sports^{3,4}, for pain in the lumbar region and lower limbs⁵⁻⁷, for alleviating plantar pressure⁸⁻¹⁰ and for improving foot ulcers caused by diabetes^{10,11}.

In the work environment, there are descriptions of the use of insoles as an ergonomic tool for reducing work-related symptoms, especially in subjects who predominantly remain in a standing position^{12,13}. This position affects venous blood flow, inter-vertebral stress and weight-bearing joints, thereby causing pain and discomfort as well as exacerbating musculoskeletal conditions^{14,15}. Despite the evident nature of the problem, there are few clinical trials addressing the use of and response to insoles in the work environment. An ergonomic approach to the issue is therefore important.

Few studies have examined the use of insoles order to verify the reduction of complaints, without, however, associate them with weight-bearing changes or other explanatory mechanical factor for its occurrence¹³. Within the workplace, appropriate scenario for manifestation of symptom of ergonomic nature, few studies evaluate the effectiveness of this intervention^{12,13} and no made comparison between different insoles in the national market in this environment. In this sense, it observe gaps for interventions aimed at the condition of standing and static position in symptomatic workers, mostly related to plant behavior and comparisons of insoles found in the national market.

The present study is justified based on a typical situation in the workplace characterized by biomechanical loads and a standing position associated to complaints of pain, with possible harm to worker health. The aim of this study was to assess plantar pressure distribution and

musculoskeletal symptoms following the use of customized insoles among female assembly line workers.

METHODS

Sample and study design

The sample was made up of 40 female workers at an assembling line industry in the northeastern portion of the state of São Paulo (Brazil). All the women remain standing throughout their daily work shift, wearing the same shoes and cutting leather for the confection of dog chew bones. Women over 18 years of age, with signs and symptoms of work-related musculoskeletal conditions in the lumbar region or lower limbs developed while performing the current bone-confection job were included in the study. Nine women were excluded for symptoms the onset of which occurred prior their work activities at the firm, systemic diseases, structural deformity or previous trauma; and two were transferred from the work sector. Thus, the final sample was made up of 29 female workers, with an average age of 29.76 ± 5.79 years and an average weight of 63.79 ± 12.11 kg. The choice of the female gender was based on epidemiological data that reveal women to be more affected by this type of injury¹⁶.

The study received approval from the Research Ethics Committee (process number n° 6032/2005) and authorization was obtained from the firm where the study was conducted. Participation of the individuals required the reading, comprehension and signing of a term of informed consent. This study was registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) under number ACTRN12609000922279.

Data collection and questionnaire

Participants were assessed before and after the protocols with the use of insoles. The plantar distribution (primary outcome) and musculoskeletal symptoms (secondary outcome) were assessed by means of a electronic plantar pressure plate (FootWork, AM3 -IST, France) connected to a microcomputer (Pentium III) and responses to the Nordic Musculoskeletal Questionnaire, respectively.

The study is characterized as a double-blind randomized clinical trial. The participants selected to participate in this study were randomly admitted and then randomly divided into two groups by means of a lottery: the control group (CG) and intervention group (IG). An opaque sealed envelope containing the groups studied was used for the randomization. The names "CONTROL" and "INTERVENTION" were used to ensure the confidentiality of the allocation of the participants. A researcher who was unaware of the objectives or purposes of the study carried out this procedure. The researcher was not aware of which group the participants to be analyzed belonged.

Data were collected at the work site during the first trimester of 2008, addressing questions on personal information such as age, weight, height, systemic disease, structural deformity and trauma prior to the analysis. The Nordic Musculoskeletal Questionnaire (NMQ) was used for the description of musculoskeletal complaints, employing the version validated for the Portuguese language¹⁷. This model is used internationally and was developed in order to standardize studies on the subject. The NMQ is of easy comprehension and contains simple, direct questions¹⁸. This questionnaire is based on multiple or binary choices regarding the occurrence of symptoms in different anatomical regions of the body over the last twelve months and in the last seven days, as well as withdrawal from their activities. Participants reported how often they felt the symptoms (pain, numbness or discomfort) considering the 12 months prior to

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completing the questionnaire¹⁷. However, for data analysis, the scale was broken into two parts, namely, the presence or absence of musculoskeletal symptoms. Questions were added regarding the severity of the complaint for each anatomical region, on a scale of one to four, in which one represented no symptoms, while index two was attributed to a mild symptom, index three to a moderate symptom, and finally index four to a severe symptom¹⁶. The questionnaire was administered by the researcher during the work shift on two separate occasions: prior to the intervention and five weeks after arch support use. The interview format was adopted in order to avoid biases stemming from participants with different degrees of schooling, as suggested by Pastre *et al.*¹⁶.

A digital scale was used to determine body weight (kg) and a metric tape attached to the wall was used to determine height (to an accuracy of 0.1 cm). Plantar pressure values were obtained using an electronic plantar pressure plate (*FootWork, AM3-IST, France*), connected to a microcomputer (Pentium III). The system has 2704 active surface sensors, with a frequency of 150 Hz, and emits a mathematical mean value of plantar pressure for each support as well as contact surface and maximal peak in kilogram-force/cm², which was measured in both phases of the experiment (T1 and T2).

The volunteers remained in a standing position, with eyes looking straight ahead, arms alongside the body, base free of support within the delimited space on the pressure plate. The automatic calibration of the equipment considered the body weight of the individual, which is an important factor in establishing the validity of the pressure measurements. The recording of the test then began, with the individual remaining on the pressure plate for ten seconds in bipodal support and barefoot. This procedure was repeated three consecutive times in each phase of the experiment (T1 and T2). All evaluations were performed in the morning period, following the work shift.

Description of insoles

Ethylvinylacetate (EVA) insoles (Podaly® Palmilhas do Brasil) were used (Figure 1). All participants had plantar measurements taken in order to facilitate the design of the insoles. The insoles were then individually heat-glued and heat-molded and placed in a press (Termoprensa Ortopédica) at approximately 100 °C. The insole was then inserted into a mold on which the individual stepped for 60 seconds, thereby giving shape to the insole, in compliance with the manufacturer's recommendations.

In the IG, an additional element consisting of a 2 mm strip of the same material was added to the site of greatest plantar pressure obtained from the plantar pressure analysis system.

Experiment

The participants were randomly divided into two groups. The CG (n=15) used the EVA insole and the IG (n=14) used the EVA insole with the additional element. The participants were instructed to use the insoles on a daily basis as part to their work clothing for a period of five weeks. A complementary visit to the work site confirmed that the participants made use of the insoles during their labor activities throughout the five-week period of the experiment. A total of 29 eligible subjects participated in this study. After randomization of the two groups no participants were excluded. Therefore, all 29 participants completed the trial and were included in subsequent analyzes (Figure 2). The experiment was divided into two evaluation times: one prior to the intervention (T1) and another at the end of the five-week period of insole use (T2). The NMQ and plantar pressure analysis system were administered on both occasions.

Data analysis

The parameters used for the evaluation of the data for both feet were peak contact pressure, mean plantar pressure and contact surface of the feet. Values from the positioning of the

volunteer are recorded continuously. However, as described above, the equipment offers the mean values recorded during the evaluation. In order to establish localization limits within the anatomic structure, the option was made to use the center of pressures as reference, which is indicated by the computational program, defining the anterior region as the forefoot and the posterior region as the hindfoot. From the plantar pressure values taken from the three 10-second collections, mean values were calculated for use in the data analysis. This procedure was adopted in order to correct possible interpretation biases related to the oscillation or disequilibrium of the volunteer throughout the test. This measure was adopted for all the variables at both evaluation times (prior to and following intervention). All data collected were entered on an electronic spreadsheet for the subsequent statistical analysis.

Statistical analysis

Statistical analysis involved descriptive measures of the anthropometric values using the Student's t-test and Mann-Whitney test for the comparison between groups. The Mann-Whitney test was used for the comparative study of variables related to anatomic site, pain intensity and evaluation time. Non-parametric analysis of variance for three way ANOVA was used for the analysis of plantar pressure distribution in relation to the evaluation times. Goodman's test was used to determine the association between group and pain in anatomic sites. The level of significance for all statistical tests was 5%.

RESULTS

The anthropometric data of both groups showed that it are homogeneous (Table 1). There was no statistically significant association for any anatomic site between groups before or after intervention. Within each group, however, a reduction in pain levels occurred between the initial and final evaluation times (T1 and T2) for the feet in both groups ($p < 0.05$) and for the lumbar region in the IG ($p < 0.05$) (Table 2).

Regarding the distribution of plantar pressure at the different evaluation times, there was a reduction in contact surface for both feet in both groups (Table 3). However, there was a significant difference for the intervention group as well as for the right foot in the control group ($p < 0.05$). There was a significant difference in the IG regarding mean plantar pressure distribution ($p < 0.05$). In lumbar region, knee and feet, an improvement in symptoms occurred in both groups when comparing evaluation times prior to and following the intervention ($p < 0.05$) (Table 4).

DISCUSSION

The choice of the sample population in the present study should first be discussed. According to Walsh *et al.*¹⁹ and Reis *et al.*²⁰, women between 20 and 39 years of age are affected by a greater frequency of musculoskeletal disorders. Andersen *et al.*²¹, Orlando *et al.*²², King²³ and Messing *et al.*²⁴ point out that the use of the standing position in the workplace has a significant impact on worker health, productivity and absenteeism. Thus, based on these issues related to gender, age and work, the sample selected for the present study offered excellent control conditions for the investigation.

The results of plantar pressure distribution in the present clinical trial revealed a reduction in contact surface in both groups as well as an increase in mean plantar pressure in the IG, which demonstrates that the inclusion of the additional element to the insoles did not have an effect on improving plantar pressure distribution. These findings corroborate those described by Raspovic *et al.*¹¹, who found no positive effects of the use of insoles with the placement of strips on areas of ulceration in patients with diabetes. The findings are also in agreement with Pawelka *et al.*²⁵, who found no improvement in plantar pressure distribution using insoles with no additional elements. However, the findings of the present study are in disagreement with those described by Guldmond *et al.*⁹, Tsung *et al.*¹⁰ and Kelly *et al.*²⁶, who demonstrated that the use of insoles

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without additional elements were able to reduce plantar pressure in diverse populations, especially in the forefoot. However, these authors did not make comparisons between insoles with and without additional strips. It must consider the lack of standardization in customization, the inclusion of instruments in the insoles, material type and thickness, factors that influence the absorption of shocks^{9,27}, therefore, it is understood then that any baropodometric data should be interpreted with caution, as well as suggested by Oliveira et al.²⁸

It should be stressed that there was no standardization in the aforementioned studies regarding the customization of the insoles, the inclusion of additional elements in the insoles or the type and thickness of the material employed, which are factors that influence shock absorption. This hinders the comparison of results, as pointed out by Chiu *et al.*²⁷ and Guldmond *et al.*⁹.

A positive response was expected in the present study in relation to the distribution of plantar pressure, however, such effects were not observed. One of the hypotheses that could be raised regarding this finding concerns the specificity of the intervention. The participants used the implements in a particular position and under the condition of repetitive activity. However, the initial and final evaluations were preformed obeying a predefined protocol using a static standing position, without the characteristic movements performed by the workers in the work environment. Thus, the expected adaptation processes may not have been identified by the proposed analysis, as the stimuli were given in a situation completely different from the initial and final analyses. In future studies, the possibility could be speculated of an evaluation in the work setting specific to a particular function as well as the indication of implements individually based on the kinematic and kinetic characteristics of the motor actions employed by the workers. Such considerations reinforce the need for caution in analyzing plantar pressure data, as suggested by Oliveira *et al.*²⁸.

With regard to the symptoms, on the other hand, the use of both types of insoles led to a reduction in pain levels. This result is similar to that described by Sobel *et al.*¹², who found an improvement in musculoskeletal discomfort among police officers. It should be pointed out, however, that the authors used elastomer insoles with the inclusion of various additional elements placed at different plantar pressure sites for five weeks. Although the intervention period was the same, the material was different and there was no comparison to a control group or standardization with regard to the placement of the additional elements. Another study used polyethylene viscoelastic insoles with no additional elements and found an improvement in symptoms after five weeks of use among workers who remained standing 75% of the time, which corroborates the findings of the present study¹³.

The feet had the greatest frequency of improved symptoms following insole use in both groups. This finding may be explained by the fact that the workers received a structure of comfort for the feet, which minimized the transmission of force with the hard surface on which the workers are placed in order to perform their work.

There was also an improvement in pain for the lumbar region, but only in the intervention group. A possible explanation would be directed toward biomechanical aspects. However, the findings of the present study do not support this statement, as there was no improvement in the distribution of plantar pressure. Furthermore, despite the improvement in foot symptoms, which one may expect to be reflected in an ascending fashion to the back, this finding was observed in both groups, which also limits this line of reasoning. Thus, excluding chance, the initial evaluation method and specificity of the prescription of the insoles merit special attention in future studies.

In a generic but supported analysis, it can be said that the use of insoles causes a sensation of comfort^{13,29}, which is a fundamental aspect to the success of the prescription. This, in turn,

causes a subjective sensation of improvement in symptoms triggered by the standing position. In an obvious conclusion, but pertinent to this discussion, the literature suggests the remaining standing on a soft surface is less fatiguing and more comfortable than standing on a hard surface²³. The results of the present study reveal that, although pressure levels were negative, benefits were demonstrated in terms of symptoms. Thus, it is undeniable that the condition of greater comfort is a positive factor in relation to a reduction in symptoms of less clinical importance.

Further pertinent issues regarding the present study should be addressed. As a limitation, the comparative aspect of this study with previously published investigations was rather weak. Although the method adopted in this trial was adequate, there is an absence of standardization in the data collection and greater specificity from the standpoint of the clinical intervention as well as the data collection and recording, which indeed limits the discussion between studies. Furthermore, the need for an individualized insole prescription should be addressed, considering foot type, ankle mobility, insole material and thickness, and standardization in the placement of additional elements. Attention to these aspects could provide different results from those encountered in the present study and thus facilitate the discussion of the results.

We believe that strategic actions that unite health and work should be encouraged to establish therapeutic proposals, such as the individualized prescription of insoles, which are designed to provide greater comfort and reduce physical loads and musculoskeletal symptoms imposed on the bodily structures of workers. Such actions can have a positive impact on worker health, in addition to consequences in the social sphere.

CONCLUSION

Insoles increased the feet comfort in both groups and added strip did not either significantly modified the plantar pressure or the other symptoms in female workers.

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Table 1. Mean and standard deviation of variables according to groups.

Variable	Groups	
	Control (n=15)	Intervention (n=14)
¹ Age	31.93 ± 6.33	28.29 ± 5.17
² Weight (kg)	63.53 ± 11.96	64.07 ± 12.16
² Height (m)	1.59.00 ± 6.94	1.61.93 ± 3.79
² BMI (kg.m ²)	25.39 ± 5.97	24.50 ± 5.08

Note: Student's t-test ¹ and Mann-Whitney test ².

Table 2. Median, minimal and maximal values of pain level according to group and evaluation time.

Local	Group	Evaluation time	
		Before	After
Lumbar region	Control	2.0(1.0-4.0)	1.0(1.0-4.0)
	Intervention	3.0(1.0-4.0)*	1.0(1.0-3.0)
Hip	Control	1.0(1.0-4.0)	1.0(1.0-4.0)
	Intervention	1.0(1.0-2.0)	1.0(1.0-2.0)
Knee	Control	1.0(1.0-4.0)	1.0(1.0-4.0)
	Intervention	1.0(1.0-4.0)	1.0(1.0-2.0)
Foot	Control	4.0(3.0-4.0)*	3.0(1.0-4.0)
	Intervention	4.0(2.0-4.0)*	1.0(1.0-4.0)

Note: *Statistically significant difference between the times ($p < 0.05$); Mann-Whitney test; Intervention Group (n=14) and Control Group (n=15).

Table 3. Mean, standard deviation and 95% confidence interval of variables according to plantar pressure distribution and evaluation time.

Variable	Group	Foot	Evaluation time		
			Before	After	
Mean of foot	Control	R	0.320 ± 0.036 [0.308 – 0.334]	0.329 ± 0.040 [0.316 – 0.340]	
		L	0.354 ± 0.049* [0.338 – 0.368]	0.353 ± 0.038 [0.341 – 0.365]	
	Intervention	R	0.304 ± 0.030 [0.294 – 0.313]	0.340 ± 0.034# [0.329 – 0.351]	
		L	0.331 ± 0.034* [0.321 – 0.342]	0.359 ± 0.038# [0.346 – 0.370]	
	Peak of foot	Control	R	0.855 ± 0.086 [0.828 – 0.880]	0.873 ± 0.116 [0.838 – 0.908]
			L	0.876 ± 0.090 [0.848 – 0.902]	0.893 ± 0.077 [0.869 – 0.915]
Intervention		R	0.852 ± 0.111 [0.817 – 0.887]	0.875 ± 0.115 [0.838 – 0.910]	
		L	0.891 ± 0.098 [0.860 – 0.921]	0.890 ± 0.099 [0.858 – 0.920]	
Plantar surface	Control	R	174.667 ± 26.765# [166.62 – 182.71]	162.311 ± 26.576 [154.32 – 170.30]	
		L	181.623 ± 28.181 [173.15 – 190.09]	176.600 ± 25.264 [169.00 – 184.20]	
	Intervention	R	179.546 ± 28.832# [170.56 – 188.53]	161.071 ± 31.081 [151.38 – 170.76]	
		L	181.643 ± 27.015# [173.22 – 190.06]	171.548 ± 30.202 [162.13 – 180.96]	

Note: *Significant difference ($p < 0.05$) in comparison between feet (D vs E) in the same group and time; #Significant difference ($p < 0.05$) in comparison between time (before vs after) in the same group and foot; Non-parametric analysis of variance for three way ANOVA; Intervention Group (n=14) and Control Group (n=15).

Table 4. Distribution of occurrence of pain according to group and evaluation time.

Local	Group	Before evaluation		After evaluation	
		Absence of pain	Presence of pain	Absence of pain	Presence of pain
Lumbar region	Control	4(26.67%)	11(73.33%)	8(53.33%)	7(46.67%)
	Intervention	2(14.29%)	12(85.71)	9(64.29%)	5(35.71%)
Hip	Control	11(73.33%)	4(26.67%)	11(73.33%)	4(26.67%)
	Intervention	13(92.86%)	1(7.14%)	13(92.86%)	1(7.14%)
Knee	Control	10(66.67%)	5(33.33%)	11(73.33%)	4(26.67%)
	Intervention	8(57.14%)	6(42.86%)	13(92.86%)	1(7.14%)
Foot	Control	0(0.0%)	15(100.0%)	4(26.67%)	11(73.33%)
	Intervention	0(0.0%)	14(100.0%)	8(57.14%)	6(42.86%)

Note: Goodman's test; Intervention Group (n=14) and Control Group (n=15).

FIGURES

Figure 1. Insole design.



Figure 2. Flow Chart of study based on CONSORT.