Insoles Use: The Effect on Pain and Daily Activities and the relation between Satisfaction and use

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Abstract

**Introduction:** Pain in the Lower Extremities (LE) decreases person’s ability to perform daily activities. Shoe insoles are recommended in some cases to reduce the pain. This study aimed to evaluate insoles’ effect on pain and daily activities and to describe the relationship between persons’ satisfaction with insoles and actual time for using them.

**Methods:** This is an uncontrolled study, with a 4 weeks follow-up period. Brief Pain Inventory (BPI), International Physical Activity Questionnaire (IPAQ), and Orthotics and Prosthetics Users’ Survey (OPUS) module Lower Extremities Functional Status (LEFS) were used as outcome measures. A modified OPUS Client Satisfaction with Device (CSD-14) module was used in the follow-up. The datasets were analyzed according to three grouping variables; Gender, Pain cause, and History of using insoles (Fitting).

**Results:** Totally, 89 participants provided data in the study (74% females). Significant reduction in pain and pain interference with daily activities and mood were reported among Females (pain severity; \( p = 0.001 \), pain interference; \( p = 0.006 \)). In Males, significant reduction in pain severity was reported \( (p=0.045) \). There were no significant changes in daily activities as measured by IPAQ and LEFS; (IPAQ Walking; \( p = 0.912 \), IPAQ Total PA; \( p = 0.947 \), LEFS; \( p = 0.853 \)). There was a significant relation between CSD-14 and use of insoles; however the effect of CSD-14 on use of insoles was low \( (R^2 = 0.069, p=0.017 \, [95\% \, CI= 0.013-0.135]) \).

**Conclusion:** Insoles reduces pain severity and pain interference with daily activities and mood in most clients. There are no effects from insoles using on PA or functional status of the LE in a 4 week follow-up period. Users’ satisfaction with the device can affect using time of insoles. Further studies are recommended to investigate insoles effect on pain interference in males, and the insoles effect on persons with pain causes other than structural or work-related.

**Keywords:** Pain, Orthotic Devices, Physical Activity, Satisfaction, Activities of Daily Living, Questionnaires, Lower Extremities.
Background

Pain in weight-bearing joints limits persons’ function and ability to perform Activities of Daily Living (ADL) [1,2] and causes a negative effect on productivity and increases the costs for social insurance [3,4]. This pain is often the outcome of structural deformities such as flat foot, cavus foot, or hammer toe, or the results of deformities that are caused by systemic diseases like rheumatoid arthritis, osteoarthritis, or diabetes. In addition to the structural deformities, work-related foot pain often occurs in workers when their occupations include standing or walking for a long time, e.g. in nurses, postmen, assembly line workers, aviation workers, and hairdressers. Discomfort, fatigue and edema are considered as consequences of prolonged standing work or walking [3-5]. Hence, such workers often complain of pain in Lower Extremities (LE) joints, i.e. hip, knee, ankle or foot and pain reduction is therefore an important goal for these persons [6].

A shoe insole is a mechanical device that is used inside the shoe to prevent, correct, or accommodate excessive pressure on the foot. It can also redistribute weight-bearing stress over the entire planter surface of the foot by supporting the foot and keeping it in an appropriate alignment [7]. The insoles can be prescribed by a number of clinical reasons, such as joint instability, healing of diabetic ulcers, etc. However, the most common reason for prescribing insoles are to prevent deformity and enhance functioning by reducing nonspecific pain in foot, leg or back. Reduction of pain is expected to increase enjoyment in daily activities such as work, physical activities, house keeping and gardening [8,9]. Hence, fitting of insoles is a common intervention for individuals with LE pain.

There are many studies performed that have focused on the biomechanical and physiological responses to insoles in patients with low back pain [10], rheumatoid arthritis [11], or osteoarthritis [12]. However, although it seems to be an inverse effect between pain and daily activities, insoles’ effect on pain and daily activities is not clear. Winemiller et al. concluded in their study that nonspecific foot pain affects patients’ enjoyment in work and that insoles improve work satisfaction [13]. Furthermore, foot pain may reduce a person’s ability to perform physical activities (PA). To avoid more pain, reduction in walking is expected to be the major effect of foot pain on PA. Hence, assessment of PA in persons with insoles may help in evaluation of the effect of insoles on these activities [14-16].

As use of the insoles is a prerequisite for any effect of them, evaluation of users’ satisfaction with the insoles is of interest to the evaluation of the effect of the devices. Satisfaction relates to the
comfort, acceptability of use, and attitudes to using the device (e.g. how do users feel about the appearance of their insoles or the amount of foot perspiration?) [17]. Some studies have concluded that frequent use of insoles may be associated with usability of the device (including satisfaction) [18,19]. However, the relation between satisfaction and use of insoles is seldom investigated.

Thus, the aims of this study were i) to evaluate the effect of insoles on pain and daily activities; and ii) to investigate the relation between satisfaction with the insoles and the actual use of them; in persons with pain in the LE.

The specific research questions were: 1) Does the use of insoles affect pain severity and pain interference with daily activities; 2) Does the use of insoles affect physical activity and the performance of daily tasks involving the lower extremities; 3) Is there a difference in effect on pain and physical activity based on gender, cause of pain, or history of fitting of insoles?, and 4) Is there a relation between satisfaction with the insoles and the actual use of them and in what way does the satisfaction affect the use?

Methods

For this study, an uncontrolled pre- and post-intervention survey design was chosen. The data was collected when the participants came to the clinic, before First time fitting or, in previous users Re-fitting, of insoles and after four weeks of use.

The study was approved by the Regional Ethical Review Board in Uppsala, Sweden; document number 2010/285.

Participants and Procedure

In this study, data which was collected prospectively from 30th of August 2010 to 31st of January 2011 was analyzed. The participants were persons referred to the Dept. of Prosthetics and Orthotics at Örebro University Hospital, Örebro city, Sweden. Inclusion criteria were pain in LE, age 18 years or older, and speaking Swedish. Exclusion criteria were: 1) pain due to a systemic or progressive disease (e.g. Rheumatoid arthritis), 2) use of orthosis of other type than insoles, or 3) earlier foot surgery or current use of prosthesis. These exclusion criteria helped to concentrate on the evaluation of insoles’ effect on LEs’ pain that were not related to systemic diseases or surgery.
During the data collection period, 143 persons agreed to participate in the study. However, 43 of them were excluded due to pain in other locations than the LE, due to a progressive disease, use of another orthosis (e.g. heel cup), or due to failure of completing the initial questionnaires. One hundred persons completed the first part of the data collection. At the follow-up, 11 persons did not return the questionnaires. Hence, 89 participants completed the first and follow up questionnaires; females were 74% of the participants (n= 66). Mean age of the participants were 53 (SD= 15); females mean age= 53.3 (SD= 14.9) and males= 51.9 (SD= 15.5) (Table 1). The participants were prescribed four types of insoles; most of them were made of Ethylene vinyl acetate (EVA), produced from casting (n=39), foot print (n= 11), or off-the-shelf, i.e., Standard (n= 32) and carbon fiber insoles (n=1), missing data (n= 6). Based on the inclusion criteria, the questionnaires were prepared and placed in the patient’s folder before he/she came to the clinic. At the time of the visit he/she was given oral and written information and was asked to participate in the study. After having received the persons’ written agreement to participate in the study, they were asked to answer three standardized questionnaires and a study specific questionnaire. At the same time, eight Certified Prosthetist and Orthotist’s (CPO) at the department filled in a checklist for each participant they were seeing. Four weeks from starting using the insoles, the participants received the same three questionnaires and one new questionnaire by mail, and were asked to answer and send them back in the included prepaid envelope. A reminding letter was sent if the questionnaires were not returned after two weeks.

**Questionnaires**

The questionnaires that were used in this study were:

**Brief Pain Inventory-Short Form (BPI):** This questionnaire has shown validity to be used in the evaluation of chronic pain [20,21]. The BPI is a multidimensional pain scale including two dimensions; 1) Pain severity (4 items), which assesses pain variability in its worst, least, average, and current, and 2) Pain interference (7 items), which assesses the pain interference with 7 daily activities; walking, general activity, work (including job, home keeping, gardening, etc.), relation with others, enjoyment, mood, and sleep. All questions in these two dimensions are rated on a numerical scale from 0 = no pain/no interference to 10 = pain as bad as you can imagine/interference completely.

The data was handled and scored as the BPI developers recommend [22]. The BPI data was analyzed according to the three-factor-model which includes the Pain severity dimension and two
subdimensions of the *Pain interference* dimension: *Activity* (4 items) and *Affective* (3 items). This model was chosen as it represents the pain better than the two-factor model where *Pain interference* is treated as one factor [23].

The first question in BPI, "Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today? Yes/No" was omitted as well as the medication effect question because there is no psychometric evaluation for them [22].

**International Physical Activity Questionnaire-short format (IPAQ):** The IPAQ is recommended to be used for population monitoring [24]. It was developed for studying PA in adults aged from 15 to 69 years [25], and re-validated to be used for elderly as well [26]. This questionnaire assesses frequency and duration of PA by dividing it into three categories; *Vigorous, Moderate,* and *Walking.* Further information about IPAQ is available at [www.ipaq.ki.se](http://www.ipaq.ki.se). The most important category in IPAQ in this study was *Walking,* therefore this category was analyzed separately. The *Walking* category has been investigated in isolation for its reliability and validity by Van der Ploeg HP, et al. [27]. *Total PA* level was assessed as well to investigate if there were changes in *Total PA.* The data was processed according to IPAQ protocol with one exception: if the participant didn’t answer one or two items of IPAQ or answered “I don’t know”, this/these item/s would be considered as missing instead of excluding the participant as it is recommended in the protocol [25]. This way of analyzing the data was used previously for the Swedish reference data [26]. The output unit of the PA level was Metabolic Equivalent Turnover (MET).minutes/week. MET is a unit used to classify PA intensity; 1 MET is the rate of energy expenditure during sitting at rest [28]. METs were as the following: *Vigorous = 8, Moderate = 4 and Walking = 3.3* [25]. The statistical analyses for the IPAQ were conducted according to its guidelines and analysis protocol [25].

**Orthotics and Prosthetics Users' Survey (OPUS):** The OPUS is a self-report instrument developed to be used with protheses and orthosis users [29]. Two OPUS modules modified in a previous study [30] were used in this study; Lower Extremity Functional Status (LEFS) and Client Satisfaction with Device (CSD). The LEFS consists of 27 items rated on a 4-level Likert scale varying from “Very easy” to “Cannot perform activity.” The CSD consists of 9 items rated on a 4-level Likert scale varying from “Strongly agree” to “Strongly disagree” [30]. Based on earlier results from validating the CSD, six new items were added to raise the ceiling of the
module [30]. Three items were adopted from existing instruments; “My device is effective (corresponds to my needs)” [31], “I can use my device without being bothered by perspiration”, and “My device is easy to use” [32]. Three items were constructed based on clinical experience; “I can use the shoes and clothes I want to when I use my device”, “I am satisfied with the size of my device”, and “I can use my device in all contexts I want to”. The six new items were analyzed according to Rasch-analysis using the rating scale model. The results showed that only one item (I can use my device without being bothered by perspiration) misfit the model, that is, had an information-weighted (infit) or outlier-sensitive (oufit) mean square > 1.4 in combination with an infit or oufit z standardized ≥2.0 [33-35]. The results shows that all items except one (I can use my device without being bothered by perspiration) are valid. The final CSD-14 items version was, thus, used in this study.

In addition to these standardized questionnaires, a study-specific questionnaire was administered to the participants at the first data collection. This questionnaire included demographic variables, e.g., age, gender, weight and length to calculate Body Mass Index (BMI), and pain cause. Besides this, the CPO at the clinic answered a checklist for each participant; this checklist included information about type of insole and History of using insoles (First time or a Re-fitting of insoles). Pain cause was categorized under three groups; 1) Structural cause, including deformities such as flat foot, cavus foot, hallux valgus, leg length difference, etc., 2) Work related cause, including overload, strains caused by work or activity, standing or walking for long time, etc., and 3) Other cause, including pain causes that cannot be categorized in the previous categories, e.g. fracture or residual conditions after car accidents, etc.

Statistical analysis

Statistical analyses were conducted by using SPSS 15. Two-sided p-values < 0.05 were considered as statically significant. The BPI datasets were ordinal and the IPAQ datasets were skewed; therefore these data were analyzed as non-parametric and differences between groups were tested with Wilcoxon signed ranked test. Descriptive data were presented with median and 25th -75th quartiles. The LEFS raw scores were converted to OPUS units on a scale from 0-100 by using WINSTEPS Rasch-analysis software, version 3.70.0.3, with the item difficulties and rating scale structures anchored based on the results from a previous study [30] Similarly, the CSD-14
raw scores were converted to OPUS units from the validity analysis made in this study. These data were analyzed as parametric and tested by using paired samples t-test.

For detailed results, the data was analyzed separately by using Wilcoxon signed ranked test based on three grouping variables (each group alone): Gender, Pain cause and History of using the insoles. The result from each group was further compared within the subgroups by using Mann-Whitney or Kruskal-Wallis tests.

Linear regression analysis was performed to describe the relation between participant’s satisfaction with insoles (independent factor) and using time (dependent factor) according to CSD-14.

**Results**

Eighty-nine participants with pain in LE were included in this study. Their descriptive data according to Gender, Pain cause, and History of using insoles are presented in Table 1. Based on the BMI calculations, 64% of the participants were under the Overweight category (BMI $\geq$ 25). This results is somewhat different from the national BMI for adult Swedish population 2009; Normal category was 52%, and Overweight was 45% [36]. Most of the participants were Females (n=66, 74 % $p < 0.001$). Ages of the two Genders were close to each other ($p= 0.691$). Body Mass Indexes (BMI) of both genders were close to each other (females n= 64, males n= 22, $p= 0.676$). Most of the participants had Structural pain cause (61%, $p <0.001$) and most of them received insoles for the First time (72%, $p< 0.001$) (Table 1).

(Insert Table 1)

Overall, there was a significant improvement (i.e. lower scores) on all three factors (Pain severity and Pain interference; Activity subdimension, and Affective subdimension) of the BPI (Table 2).

The results showed that there was a difference based on Gender; the Females demonstrated significant improvement on all BPI factors except “Worst pain” item; $p=0.051$. The Males showed improvement on the Pain severity factor as a general and “Worst pain” (Table 2). When comparing the data sets according to Gender, significant differences were found between Males and Females in all factors, the Females scored higher than Males on all BPI factors both before ($p 0.006$- 0.045) and after ($p <0.001$-0.024) using insoles.

(Insert Table 2)
When looking at the results from BPI based on *Pain cause* (Table 3), participants with *Structural* cause showed significant decrease in *Pain severity* and *Affective* subdimension, whereas participants with *Work-related* cause demonstrated significant decrease in *Pain severity* and *Activity* subdimension. There were no significant effects of insoles in the subjects with *Other* pain cause. When comparing the data sets based on subgroups by using Kruskal-Wallis test, there were no statistically significant differences between them, neither before (*p* 0.156-0.801) nor after using the insoles (*p* 0.243-0.908).

(Insert Table 3)

By dividing the participants according to their *History of using insoles* (*First time* or *Re-fitting*), generally, there were significant differences for both subgroups on all three BPI factors (Table 4). When comparing the data sets according to *History of using insoles* by using Mann-Whitney test, there were no significant differences between *First time* and *Refitting* either before (*p* 0.094-0.887) or after (*p* 0.059-0.383).

(Insert Table 4)

There were no statistically significant changes in *Total PA* or *Walking* as measured by IPAQ. As a whole, the participants demonstrated reduction in *Total PA*; median 1975 before and 1440 MET.min/week after using the insoles (*p* = 0.947), while the Walking was at the same median value; 693 MET.min/week both before and after using the insoles (*p* = 0.912). By separating the participants according to *Gender*, the *Females* showed a reduction in *Total PA*; median 2079 vs. 1386 MET.min/week, (*p* = 0.577), the median of *Walking* level was decreased from 891 to 693 MET.min/week, but this reduction was not significant (*p* = 0.640). In contrast, *Males* reported an increase in *Total PA*; median 1638 vs. 2373 MET.min/week (*p* = 0.370) and very little increase in *Walking*; 676 vs. 693 (*p* = 0.938), however not significant. No significant differences were found on the IPAQ categories between *Males* and *Females* (*p* 0.376-0.905). No significant changes were detected when comparing IPAQ according to *Pain cause*; *Total PA* (*p* 0.241-0.638) and *Walking* (*p* 0.423-0.798), or *History of using the insoles*; *Total PA* (*First time* *p* = 0.407 and *Refitting* *p* = 0.230) and *Walking* (*First time* *p* = 0.330 and *Refitting* *p* = 0.206).

(Insert Figure 1)

In LEFS, no significant improvements were detected among the participants by comparing functional status before and after using the insoles (mean 58.8 vs. 59.0; *p* = 0.853). However,
Males showed a higher ability to perform daily activities than Females when they were compared under "before start using the insoles" (mean 64.1 vs. 56.8; \(p = 0.019\)), while after using them (mean 63.5 vs. 57.4; \(p = 0.101\)). Comparisons of LEFS results based on Pain cause (Structural \(p = 0.538\), Work-related \(p = 0.929\), and Other causes \(p = 0.348\)), or History of using insoles (First time \(p = 0.787\) and Refitting \(p = 0.910\)) did not show any significant changes. In addition, no significant changes were detected when comparing subgroups of each grouping variables; Pain cause (one-way ANOVA; before \(p = 0.830\) and after \(p = 0.838\)) and History of using insoles (t-test before \(p = 0.737\) and after \(p = 0.902\)).

When comparing CSD-14 within each grouping variable, i.e., Gender, Pain cause, or History of using the insoles, no significant differences were detected between subgroups. The mean time of using the insoles (6.8 hours/day) was positively correlated (Pearson’s \(r = 0.262\)) with the mean CSD-14 (65.4 units). Time of using insoles was somewhat dependent on the satisfaction with the device. Linear regression of using time on CSD-14 demonstrated a significant relation between them (\(p = 0.017\); R Sq = 0.069 [CI 95% 0.013-0.135]) (Figure 2).

(Insert Figure 2)

Discussion

This study shows that the use of insoles reduces pain severity in most subjects. Overall, the use of insoles also reduces pain interference with daily activities and mood but this varies mainly depending on gender and cause of pain. There were no statistically significant effects on physical activity or performance of daily activities involving the lower extremities from the use of insoles. Satisfaction with insoles has a somewhat positive effect on the use of them. The only group of participants in this study that did not show any effect from fitting of insoles was those with ‘Other’ cause of pain. However, in this study this group was small in numbers and this may have had an effect on the results. Further studies are needed to confirm this.

The difference in Gender showing that Females had a significant reduction in all three BPI factors whereas Males only had an effect on one factor, Pain severity, may be due to the fact that Females experience pain differently than Males. In this study Males scored pain level lower than Females in all BPI dimensions, especially in Least and Current pain where the Males had very low initial values. Many studies report that Females represent higher prevalence in musculoskeletal pain and report higher pain intensity comparing with Males [37,38].
The *Pain cause* seemed to affect the way the participants experienced the interference of pain on daily activities. The participants with *Structural* cause of pain had an effect on the *Affective* subdimension of pain interference whereas participants with *Work-related* cause of pain had a significant decrease in pain interference with the *Activity* subdimension. There was, however, no significant difference between the two groups but the result may indicate that cause of pain interferes differently with peoples’ daily activities. Further studies are needed to confirm this. A difference in insoles effect on pain had been expected depending on the *History of using the insoles*. In persons who already had insoles, the pain was expected to be lower and have less impact on daily activities. However, the results show that they all had significant reduction in both pain severity and pain interference with daily activities. This is a clinically important result as it supports the fact that both subgroups benefitted from the insoles.

*Walking* and *Total PA* were used in this study as being part of daily activities to evaluate the effect of insoles. Walking was expected to give more information about insoles effect since it concentrates on PAs that are executed by LE mainly and could show the effect of insoles on PA level in general [27]. In this study, an indication of this was shown in males. The IPAQ analyses did not show statistically significant increase in PA level in any of the *Gender*. It is well known that there is a significant difference in PA level between *Females* and *Males* [39,40]. However, surprisingly, in this study the PA results showed no significant differences in PA level between *Females* and *Males*. This is something that needs to be confirmed in future studies.

The World Health Organization (WHO) recommends 150 minutes of *Moderate* intensity OR 75 minutes of *Vigorous* intensity PAs to be performed weekly, which equals to 600 MET.min/week [28]. The participants in this study exceeded this recommended PA level (Figure 1). In a previous thesis the estimated median PA level among Swedish adults was 1699 (693-3600) MET.min/week with males reporting significantly higher than females; 1836 vs. 1554 MET.min/week respectively [41]. In the same study, walking proportion was 45% of Total PA among females and 35% among males [41]. The results from this study give an indication of somewhat different proportions between walking and total PA. Perhaps people with LE pain adjust their PA to a higher proportion of walking because it is less painfull? This is something that needs to be studied further.

In this study the LEFS assessed participants’ ability (functional status) to perform daily activities whereas IPAQ estimated their PA level. The result from LEFS shows that *Males* reported higher ability to perform daily activities than *Females* under the same period of time. However, the
ability of all participants was above average (57) on the 0-100 LEFS unit scale [24]. Likewise, the PA level was close to the results of the IPAQ population study [41]. Overall, this indicates an average ability in the study sample.

The level of PA can be changed according to the season; PA would be decreased during the winter (cold months) [42,43]. According to meteorology factor, the weather was getting colder during the period of data collection and this may have played as a barrier to make a significant increase in PA.

The regression analysis of the relation between CSD-14 and using time of insoles indicated that 6.9% of the proportion of participants’ satisfaction with the insoles was related to the time it was used. However, this goodness of fit (i.e. 6.9%) suggested that the variability in using time cannot be explained by users’ satisfaction only. As can be seen in Figure 2, there were subjects who were quite satisfied with the insoles (e.g., CSD-14 50) but did not use them at all (wearing time 0). Similarly, there were subjects who used the insoles more than 15 hours/day but were not really satisfied with them (CSD-14 40). This indicates that people use the insoles because they provide them with something useful, e.g. pain relief, but that the person still is not happy with the insoles. This should be an indication for the clinicians to improve the comfort or other aspects of the insoles and hopefully increase the client satisfaction.

**Limitations**

The major limitation in this study is the size and distribution of subgroups in the sample. More participants would have increased the power to the study and, hence, may have resulted in significant results in Pain interference with activity in Males and overall in the group with “Other” pain cause. Thus, we recommend further studies with larger samples to investigate this.

A controlled design would have increased the strength of the study. However, due to ethical reasons, therefore the decision was not to leave patients without intervention or with a placebo intervention. These participants might have complained from increased pain or deformities due to the longer waiting time before fitting of insoles.

Use of subjective methods to evaluate PA level and LE functional status may face the probability of overestimation [44-46], and the recall may pose another limitation [24]. However, by using repeated measures from the same sample these limitations may be present in both data collections and, thus, reduce the impact of the limitations on the results.
This study has shown a trend towards increase in PA level from the use of insoles in males. However, besides a larger sample, other factors influencing daily activities, such as e.g. weather condition, should be taken into consideration in future studies on the impact of insoles on daily activities. Also, a longer follow-up period with repeated measures may give a better view of the effect of insoles on daily activities.

**Conclusion**

In conclusion, fitting of insoles in persons with structural or work related pain in lower extremities leads to reduction in pain severity and pain interference with daily activities. The reduction is present in both *First time* and *Re-fitting* of insoles. Changes in using time cannot be predicted by users’ satisfaction only. The insoles effect on performance of daily activities needs to be studied further with larger samples and longer follow-up period.

**Conflict of interests:**

The authors have no conflicts of interest.

**Acknowledgement:**

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References:


Table 1: Demographic data for the respondents.

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th>Males</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Mean (SD)</td>
<td>53.3 (14.9)</td>
<td>51.9 (15.5)</td>
</tr>
<tr>
<td>BMI*</td>
<td>Mean (SD)</td>
<td>27.9 (5.4)</td>
<td>26.6 (4.7)</td>
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<td></td>
<td>Normal (25&gt;BMI&gt;=18.5)</td>
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<td>8</td>
</tr>
<tr>
<td></td>
<td>Pre-obese (30&gt;BMI&gt;=25)</td>
<td>23</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Obese (BMI &gt;= 30)</td>
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<td>6</td>
</tr>
<tr>
<td>Fitting</td>
<td>First time</td>
<td>55</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Refitting</td>
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<td>14</td>
</tr>
<tr>
<td>Pain cause</td>
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<td></td>
<td>Work-related</td>
<td>22</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Total (%)</td>
<td>66 (74%)</td>
<td>23 (26%)</td>
<td>89</td>
</tr>
</tbody>
</table>

* BMI: Body Mass Index = Weight (kg)/[Length (m)]^2 [36]. Females n = 64, Males n = 22.
Table 2: Median (inter-quartile range) of pain severity and pain interference before and after fitting of insoles in persons with nonspecific pain in lower extremities, measured by the Brief Pain Inventory (BPI).

<table>
<thead>
<tr>
<th>BPI Items</th>
<th>All participants (n= 89)</th>
<th>Females (n=66)</th>
<th>Males (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>After</td>
<td>p value&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>I- Pain severity</td>
<td>4.0 (1.0-5.0)</td>
<td>2.0 (0.0-5.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1- Worst pain</td>
<td>5.0 (2.5-7.0)</td>
<td>4.0 (0.0-6.0)</td>
<td>0.006</td>
</tr>
<tr>
<td>2- Least pain</td>
<td>1.0 (0.0-3.0)</td>
<td>0.0 (0.0-2.0)</td>
<td>0.003</td>
</tr>
<tr>
<td>3- Average pain</td>
<td>4.0 (1.5-6.0)</td>
<td>2.0 (0.0-5.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>4- Current pain</td>
<td>3.0 (0.0-5.0)</td>
<td>1.0 (0.0-4.0)</td>
<td>0.002</td>
</tr>
<tr>
<td>II- Pain interference</td>
<td>3.0 (0.1-5.6)</td>
<td>1.7 (0.0-4.8)</td>
<td>0.003</td>
</tr>
<tr>
<td>1- Activity subdimension</td>
<td>3.5 (0.2-6.3)</td>
<td>1.5 (0.0-5.0)</td>
<td>0.004</td>
</tr>
<tr>
<td>2- Affective subdimension</td>
<td>2.0 (0.0-5.3)</td>
<td>1.0 (0.0-3.5)</td>
<td>0.004</td>
</tr>
</tbody>
</table>

<sup>a</sup>Wilcoxon signed rank test, p-values <0.05 written in bold text.
Table 3: Median (inter-quartile range) of pain severity and pain interference before and after fitting of insoles in persons with nonspecific pain in lower extremities according to pain cause, measured by the Brief Pain Inventory (BPI).

<table>
<thead>
<tr>
<th>BPI Items</th>
<th>Structural (n=54)</th>
<th></th>
<th>Work-related (n=25)</th>
<th></th>
<th>Other (n=10)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>After</td>
<td>$P$ value&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Before</td>
<td>After</td>
<td>$P$ value&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>I- Pain severity</td>
<td>4.0 (0.8-5.0)</td>
<td>2.0 (0.0-5.0)</td>
<td><strong>0.002</strong></td>
<td>4.0 (2.0-5.5)</td>
<td>2.0 (0.5-5.0)</td>
<td><strong>0.004</strong></td>
</tr>
<tr>
<td>1- Worst pain</td>
<td>6 (0.0-7.0)</td>
<td>2.5 (0.0-6.0)</td>
<td><strong>0.005</strong></td>
<td>5.0 (3.0-7.0)</td>
<td>3.0 (1.0-6.5)</td>
<td><strong>0.038</strong></td>
</tr>
<tr>
<td>2- Least pain</td>
<td>1.0 (0.0-3.3)</td>
<td>0.0 (0.0-2.5)</td>
<td><strong>0.104</strong></td>
<td>2.0 (0.0-4.5)</td>
<td>1.0 (0.0-2.0)</td>
<td><strong>0.003</strong></td>
</tr>
<tr>
<td>3- Average pain</td>
<td>4.0 (0.8-6.0)</td>
<td>2.0 (0.0-5.0)</td>
<td><strong>0.002</strong></td>
<td>5.0 (3.0-6.0)</td>
<td>2.0 (0.5-5.0)</td>
<td>&lt;<strong>0.001</strong></td>
</tr>
<tr>
<td>4- Current pain</td>
<td>3.0 (0.0-5.0)</td>
<td>1.0 (0.0-5.0)</td>
<td><strong>0.012</strong></td>
<td>4.0 (1.5-5.0)</td>
<td>2.0 (0.0-4.5)</td>
<td>0.065</td>
</tr>
<tr>
<td>II- Pain interference</td>
<td>2.9 (0.0-6.1)</td>
<td>1.0 (0.0-4.4)</td>
<td>0.071</td>
<td>3.0 (1.7-5.6)</td>
<td>1.9 (0.0-5.2)</td>
<td><strong>0.006</strong></td>
</tr>
<tr>
<td>1- Activity subdimension</td>
<td>3.6 (0.0-6.5)</td>
<td>1.5 (0.0-5.0)</td>
<td><strong>0.111</strong></td>
<td>3.5 (2.3-6.2)</td>
<td>2.0 (0.0-4.7)</td>
<td><strong>0.002</strong></td>
</tr>
<tr>
<td>2- Affective subdimension</td>
<td>2.0 (0.0-5.7)</td>
<td>0.7 (0.0-3.6)</td>
<td><strong>0.012</strong></td>
<td>3.0 (0.7-5.2)</td>
<td>1.3 (0.0-4.5)</td>
<td>0.080</td>
</tr>
</tbody>
</table>

<sup>a</sup> Wilcoxon signed rank test, p-values <0.05 written in bold text.
Table 4: Median (inter-quartile range) of pain severity and pain interference before and after fitting of insoles in persons with nonspecific pain in lower extremities according to fitting history, measured by the Brief Pain Inventory (BPI).

<table>
<thead>
<tr>
<th>BPI Items</th>
<th>1st time fitting (n=64)</th>
<th>Refitting (n=25)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>After</td>
<td>p value&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Before</td>
</tr>
<tr>
<td>I- Pain severity</td>
<td>4.0 (2.0-5.0)</td>
<td>3.0 (0.0-5.0)</td>
<td><strong>0.003</strong></td>
<td>3.0 (0.5-5.0)</td>
</tr>
<tr>
<td>1- Worst pain</td>
<td>5.0 (3.0-7.0)</td>
<td>4.0 (0.0-7.0)</td>
<td><strong>0.044</strong></td>
<td>6.0 (0.5-7.0)</td>
</tr>
<tr>
<td>2- Least pain</td>
<td>1.0 (0.0-3.0)</td>
<td>1.0 (0.0-3.0)</td>
<td><strong>0.024</strong></td>
<td>0.0 (0.0-3.0)</td>
</tr>
<tr>
<td>3- Average pain</td>
<td>5.0 (2.0-6.0)</td>
<td>3.0 (0.0-5.0)</td>
<td><strong>0.002</strong></td>
<td>3.0 (0.5-5.0)</td>
</tr>
<tr>
<td>4- Current pain</td>
<td>3.0 (1.0-5.0)</td>
<td>2.0 (0.0-5.0)</td>
<td><strong>0.025</strong></td>
<td>1.0 (0.0-5.0)</td>
</tr>
<tr>
<td>II- Pain interference</td>
<td>3.0 (0.3-5.7)</td>
<td>2.0 (0.0-5.0)</td>
<td><strong>0.026</strong></td>
<td>3.0 (0.0-5.4)</td>
</tr>
<tr>
<td>1- Activity subdimension</td>
<td>3.5 (0.4-6.3)</td>
<td>2.4 (0.0-5.2)</td>
<td><strong>0.035</strong></td>
<td>3.3 (0.0-6.5)</td>
</tr>
<tr>
<td>2- Affective subdimension</td>
<td>2.5 (0.0-5.3)</td>
<td>1.3 (0.0-4.5)</td>
<td><strong>0.043</strong></td>
<td>2.0 (0.0-4.9)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Wilcoxon signed rank test, p-values <0.05 written in bold text.
Figure 1: Median of Physical Activity (PA) in females and males with non-specific pain in lower extremities before and after fitting of insoles measured by the International Physical Activity Questionnaire (IPAQ); percentages of Walking out of Total PA are shown.

* Walk + Vigorous & Moderate PA = Total PA; according to IPAQ [25]

1 = Minimum recommended PA; 600 MET.min/week. 2 = PA level among Swedish females; 1554 MET.min/week. 3 = PA level among Swedish population; 1699 MET.min/week. 4 = PA level among Swedish males; 1836 MET.min/week [47,48]
Figure 2: The relation between Client Satisfaction with Device (CSD-14) and using time in hours/day (n=80). Goodness of fit = 0.069 (Sig. = 0.017; 95% CI 0.013-0.135). Pearson's r = 0.202