

1 **Results**

2 Eighty-nine participants with LE pain were included in this study (Table 1). Most of the
3 participants were women (74 %, $p < 0.001$). Men and women were of similar age ($p = 0.720$) and
4 BMI (women 27.7, men 27.1, $p = 0.676$). Most of the participants had structural pain causes
5 (61%, $p < 0.001$) and most of them had received insoles for the first time (72%, $p < 0.001$) (Table
6 1).

7 *(Insert Table 1)*

8 Overall, there was a significant improvement (i.e. lower scores) on all three factors (*Pain severity*
9 and the *Activity* and *Affective* subdimensions of *Pain interference*) of the BPI (Table 2). There
10 was a difference based on sex; women demonstrated significant improvement on all BPI factors
11 except on the “*Worst pain*” subitem ($p = 0.051$). Men showed improvement on the *Pain severity*
12 factor overall and on the “*Worst pain*” subitem (Table 2). Women scored higher than men on all
13 BPI factors, both before ($p = 0.006$ – 0.045) and after ($p < 0.001$ – 0.024) using the insoles.

14 *(Insert Table 2)*

15 Participants with structural pain causes showed significant decrease in *Pain severity* and the
16 *Affective* subdimension of *Pain interference*, whereas participants with work-related causes
17 demonstrated significant decrease in *Pain severity* and the *Activity* subdimension of *Pain*
18 *interference* (Table 3). There were no significant effects of insoles on BPI scores in the
19 participants with other pain causes and no statistically significant differences in BPI scores
20 between the pain cause subgroups, either before ($p = 0.156$ – 0.801) or after ($p = 0.243$ – 0.908)
21 using the insoles.

22 *(Insert Table 3)*

23 Participants of both *First time* and *Refitting* subgroups reported a significant effect of insoles on
24 all three BPI factors (Table 4) and there were no significant differences between the subgroups,
25 either before ($p = 0.094\text{--}0.887$) or after ($p = 0.059\text{--}0.383$) using the insoles.

26 *(Insert Table 4)*

27 There were no statistically significant effects on *Total PA* or the subcategory *Walking*, as
28 measured by IPAQ (Figure 1). *Walking* was unchanged: median 693 MET.min/week both before
29 and after using the insoles ($p = 0.912$). Women reported a non-significant reduction in *Total PA*
30 (median 2079 vs. 1386 MET.min/week, $p = 0.577$) and *Walking* (median 891 vs. 693
31 MET.min/week, $p = 0.640$). In contrast, men reported an increase in *Total PA* (median 1638 vs.
32 2373 MET.min/week, $p = 0.370$) and a small increase in *Walking* (676 vs. 693, $p = 0.938$), but
33 neither these differences were statistically significant. No significant differences were found on
34 the IPAQ categories between men and women ($p = 0.376\text{--}0.905$), either before or after using the
35 insoles. No significant changes were detected in IPAQ scores after four weeks of insoles use in
36 the *Pain cause* subgroups (*Total PA*: $p = 0.241\text{--}0.638$; *Walking*: $p = 0.423\text{--}0.798$) or *Insole fitting*
37 *history* subgroups (*Total PA*: *First time* $p = 0.407$, *Refitting* $p = 0.230$; *Walking*: *First time* $p =$
38 0.330 , *Refitting* $p = 0.206$).

39 *(Insert Figure 1)*

40 There was no significant effect of insole use on ease of performance of daily activities as
41 measured by the LEFS (mean scores before 58.8 vs. after 59.0, $p = 0.853$). However, an initial
42 difference in sex was shown, indicating that men had a higher ability than women before using
43 the insoles (mean 64.1 vs. 56.8, $p = 0.019$), but this difference decreased and was not statistically
44 significant at follow-up (mean 63.5 vs. 57.4, $p = 0.101$). There were no significant changes of
45 LEFS scores at follow-up for the subgroups according to *Pain cause* (*Structural* $p = 0.538$, *Work-*
46 *related* $p = 0.929$, and *Other* causes $p = 0.348$), or *Insole fitting history* (*First time* $p = 0.787$ and

47 *Refitting* $p = 0.910$). In addition, no significant differences were detected between the subgroups;
48 either for *Pain cause* (before $p = 0.830$, after $p = 0.838$) or for *Insole fitting history* (before $p =$
49 0.737 , after $p = 0.902$).

50 The mean insole use duration was 6.8 hours/day and the CSD mean score was 65.4 units. There
51 were no significant differences in CSD mean score between the subgroups (*Sex* $p = 0.173$, *Pain*
52 *cause* $p = 0.876$, or *Insole fitting history* $p = 0.359$). The insole use duration and CSD scores
53 were positively correlated (Pearson's $r = 0.262$). Insole use duration was somewhat dependent on
54 the user's satisfaction with them. Linear regression of insole use duration on CSD demonstrated a
55 significant relation ($p = 0.017$, R Sq = 0.069 [CI 95% 0.013– 0.135], Figure 2).

56 *(Insert Figure 2)*

57

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Table 1: Participants' demographic data.

		Women	Men	Total
Age	Mean (SD)	52.6 (14.1)	51.3 (16.6)	52.3 (14.8)
BMI*	Mean (SD)	27.7 (5.4)	27.1 (4.5)	27.5 (5.2)
BMI* Categories	Normal (25 > BMI ≥ 18.5)	23	8	31
	Pre-obese (30 > BMI ≥ 25)	23	8	31
	Obese (BMI ≥ 30)	18	6	24
Fitting	First time	55	9	64 (72%)
	Refitting	11	14	25 (28%)
Pain cause	Structural	37	17	54 (61%)
	Work-related	22	3	25 (28%)
	Other	7	3	10 (11%)
Total (%)		66 (74%)	23 (26%)	89

59 * n= 86 (missing BMI data: 2 women, 1 man). BMI: Body Mass Index = Weight (kg)/ [Length (m)]².

Table 2: Median (inter-quartile range) of pain severity and pain interference before and after fitting of insoles for clients with nonspecific pain in lower extremities, measured by the Brief Pain Inventory (BPI).

BPI Items	All participants (n=89)			Women (n=66)			Men (n=23)		
	Before	After	<i>p</i> value ^a	Before	After	<i>p</i> value ^a	Before	After	<i>p</i> value ^a
I- Pain severity	4.0 (1.0-5.0)	2.0 (0.0-5.0)	<0.001	4.0 (2.0-5.3)	3.0 (1.0-5.0)	0.001	3.0 (0.0-4.0)	0.0 (0.0-2.0)	0.045
1- Worst pain	5.0 (2.5-7.0)	4.0 (0.0-6.0)	0.006	5.5 (3.0-7.0)	5.0 (1.0-7.0)	0.051	4.0 (0.0-7.0)	0.0 (0.0- 4.0)	0.046
2- Least pain	1.0 (0.0-3.0)	0.0 (0.0-2.0)	0.003	1.5 (0.0- 4.0)	1.0 (0.0-3.0)	0.010	0.0 (0.0-2.0)	0.0 (0.0- 1.0)	0.147
3- Average pain	4.0 (1.5-6.0)	2.0 (0.0-5.0)	<0.001	5.0 (2.0- 6.0)	3.0 (1.0-5.0)	0.001	2.0 (0.0-5.0)	0.0 (0.0- 2.0)	0.082
4- Current pain	3.0 (0.0-5.0)	1.0 (0.0-4.0)	0.002	3.0 (1.0- 5.3)	2.0 (0.0-5.0)	0.016	1.0 (0.0-5.0)	0.0 (0.0- 2.0)	0.063
II- Pain interference	3.0 (0.1- 5.6)	1.7 (0.0-4.8)	0.003	3.7 (0.6- 6.3)	2.2 (0.0-5.0)	0.006	0.7 (0.0-5.0)	0.0 (0.0- 2.0)	0.244
1- Activity subdimension	3.5 (0.2-6.3)	1.5 (0.0-5.0)	0.004	4.0 (0.8- 6.5)	2.9 (0.0-5.9)	0.009	1.0 (0.0-5.0)	0.0 (0.0- 2.5)	0.179
2- Affective subdimension	2.0 (0.0-5.3)	1.0 (0.0-3.5)	0.004	3.0 (0.3- 5.7)	1.7 (0.0-4.4)	0.006	0.0 (0.0-3.3)	0.0 (0.0- 1.3)	0.432

^a 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 for clients with nonspecific pain in lower extremities according to pain cause, measured by the Brief Pain Inventory (BPI).

BPI Items	Structural (n=54)			Work-related (n=25)			Other (n=10)		
	Before	After	<i>P</i> value [□]	Before	After	<i>P</i> value [□]	Before	After	<i>P</i> value [□]
I- Pain severity	4.0 (0.8-5.0)	2.0 (0.0-5.0)	0.002	4.0 (2.0-5.5)	2.0 (0.5-5.0)	0.004	3.0 (0.8-5.0)	3.5 (1.5-4.5)	0.380
1- Worst pain	6 (0.0-7.0)	2.5 (0.0-6.0)	0.005	5.0 (3.0-7.0)	3.0 (1.0-6.5)	0.038	3.5 (1.5-5.5)	5.5 (3.-7.3)	0.167
2- Least pain	1.0 (0.0-3.3)	0.0 (0.0-2.5)	0.104	2.0 (0.0-4.5)	1.0 (0.0-2.0)	0.003	0.0 (0.0-2.3)	0.0 (0.0-1.8)	0.680
3- Average pain	4.0 (0.8-6.0)	2.0 (0.0-5.0)	0.002	5.0 (3.0-6.0)	2.0 (0.5-5.0)	<0.001	3.0 (0.0-5.5)	3.0 (1.5-6.3)	0.864
4- Current pain	3.0 (0.0-5.0)	1.0 (0.0-5.0)	0.012	4.0 (1.5-5.0)	2.0 (0.0-4.5)	0.065	2.5 (0.0-3.8)	3.0 (0.0-4.0)	0.916
II- Pain interference	2.9 (0.0-6.1)	1.0 (0.0-4.4)	0.071	3.0 (1.7-5.6)	1.9 (0.0-5.2)	0.006	2.9 (0.0-5.4)	2.2 (0.0-5.3)	0.889
1- Activity subdimension	3.6 (0.0-6.5)	1.5 (0.0-5.0)	0.111	3.5 (2.3-6.2)	2.0 (0.0-4.7)	0.002	3.2 (0.0-6.5)	2.7 (0.0-6.1)	0.779
2- Affective subdimension	2.0 (0.0-5.7)	0.7 (0.0-3.6)	0.012	3.0 (0.7-5.2)	1.3 (0.0-4.5)	0.080	2.4 (0.0-4.3)	1.5 (0.0-3.9)	0.999

[□] 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 for clients with nonspecific pain in lower extremities according to insole fitting history, measured by the Brief Pain Inventory (BPI).

BPI Items	First-time fitting (n=64)			Refitting (n=25)		
	Before	After	<i>p</i> value ^α	Before	After	<i>p</i> value ^α
I. Pain severity	4.0 (2.0-5.0)	3.0 (0.0-5.0)	0.003	3.0 (0.5-5.0)	2.0(0.0-2.5)	0.011
1- Worst pain	5.0 (3.0-7.0)	4.0 (0.0-7.0)	0.044	6.0 (0.5-7.0)	2.0 (0.0-5.5)	0.057
2- Least pain	1.0 (0.0-3.0)	1.0 (0.0-3.0)	0.024	0.0 (0.0-3.0)	0.0 (0.0-1.0)	0.055
3- Average pain	5.0 (2.0-6.0)	3.0 (0.0-5.0)	0.002	3.0 (0.0-5.0)	2.0 (0.0-3.0)	0.035
4- Current pain	3.0 (1.0-5.0)	2.0 (0.0-5.0)	0.025	1.0 (0.0-5.0)	1.0 (0.0-3.0)	0.032
II- Pain interference	3.0 (0.3-5.7)	2.0 (0.0-5.0)	0.026	3.0 (0.0-5.4)	0.9 (0.0-3.7)	0.042
1- Activity subdimension	3.5 (0.4-6.3)	2.4 (0.0-5.2)	0.035	3.3 (0.0-6.5)	0.8 (0.0-3.9)	0.035
2- Affective subdimension	2.5 (0.0-5.3)	1.3 (0.0-4.5)	0.043	2.0 (0.0-4.9)	0.3 (0.0-3.3)	0.027

^α Wilcoxon signed rank test, p-values <0.05 written in bold text.



