Eur Spine J (2005) 14: 546–550
DOI 10.1007/s00586-004-0824-z

ORIGINAL ARTICLE

S. Shabat
T. Gefen
M. Nyska
Y. Folman
R. Gepstein

The effect of insoles on the incidence and severity of low back pain among workers whose job involves long-distance walking

Received: 26 June 2004
Accepted: 16 September 2004
Published online: 25 January 2005

S. Shabat · T. Gefen · M. Nyska
R. Gepstein
The Orthopaedic Surgery Department,
Spine Unit, Sapir Medical Center,
Tel-Aviv Sackler Medical School,
Kfar-Saba, Israel

Y. Folman
Department of Orthopaedic Surgery,
Hillel-Yafe Medical Center,
Hadera, Israel

S. Shabat (✉)
The Orthopaedic Surgery Department,
Spine Unit, Sapir Medical Center,
Tel-Aviv Sackler Medical School, 48
Tchernichovsky Street,
Kfar-Saba, 44281, Israel
E-mail: drshabat@hotmail.com
Tel.: +972-9-7472549
Fax: +972-9-7410596

Abstract The prevalence and incidence of low back pain in general society is high. Workers whose job involves walking long distances have an even higher tendency to suffer from low back pain. A positive effect of insoles in reducing low back pain was found in professional sports players. This was not examined on people whose job involves walking long distances. In this double blind prospective study we examined the effectiveness of insoles constructed in a computerized method to placebo insoles in 58 employees whose work entailed extensive walking and who suffered from low back pain. The evaluation was performed by the MILLION questionnaire, which is considered as a valid questionnaire for evaluation of low back pain. We calculated the differences of the pain intensity before and after the intervention, in the employees using the insoles manufactured by computer in comparison to the users of the placebo insoles. In each group, the analysis was performed in comparison to the baseline. A total of 81% of the employees preferred the real insoles as effective and comfortable in comparison to 19% of the users of the placebo insoles ($P < 0.05$). The results of this study indicate a substantial improvement in the low back pain after the use of the true insoles. The average pain intensity according to the MILLION questionnaire before the use of the insoles was 5.46. However, after the use of the real insoles and the placebo insoles, the average pain intensity decreased to 3.96 and 5.11, respectively. The difference of the average pain intensity at the start of the study and after the use of the real insoles was significant: −1.49 ($P = 0.0001$), whereas this difference after the use of the placebo insoles was not significant: −0.31 ($P = 0.1189$). The reported severity of pain also decreased significantly: a level 5 pain and above was reported by 77% of the subjects at the start of the study. After the use of the real insoles only 37.9% of the subjects reported a similar degree of pain severity, and 50% of the subjects did so after the use of the placebo insoles ($P < 0.05$). We did not find a link between low back pain and other variables such as gender, age, number of offspring, work seniority, smoking, previous use of insoles and previous medication. This study demonstrates that the low back pain decreased significantly after the use of real insoles compared to placebo ones.

Keywords Low back pain · Workers · Insoles · Long distance walking

Introduction

The prevalence of low back pain in the general population is estimated to be between 60 and 80% [28]. Low back pain is considered to be the second complaint of patients arriving to their primary care physician, only following upper respiratory tract infection [7], and is one of the most common causes that every occupational physician faces each day in his/her daily practice [8]. The prevalence of low back pain is 25 times higher in the industrial countries [11], and it is common during the second and fifth decades, which means it creates a heavy financial burden on society [28].

One of the common causes for low back pain is walking long distances [5, 18]. This is common in some professional workers such as post-office deliverers, nurses, etc. It is assumed that there is a connection between the anatomical shape of the foot and foot pain or low back pain during walking. There is a physiological connection between the feet and the back muscles. The thoracolumbar fascia is a very important link between these two structures, and it transmits the loads from the upper extremities, to the back, and from the back to the lower extremities and the ground [29]. Therefore, the assumption is that unbalanced pressure over the feet will cause low back pain due to a compensatory spasm on the quadratus lumborum muscles. This assumption was not validated so far.

Insoles have been used for many years. They make the person feel more comfortable [2]. This phenomenon is achieved by decrease in the point pressure by 30–50% (depends on the material the insole is made of) [16]. It was also proven by electromyographic studies that insoles decrease the fatigability in the back muscles [14, 19, 27].

Not many studies have looked into the agronomic physiological aspects of insoles [4, 9, 12, 13, 20, 24]. Brown and co-workers concluded that more research is needed to explain the clinical success in using insoles [20].

The Foot Support Anterior Posterior (FSAP) (TekScan, Inc., Boston, Mass., USA) is one of the methods to make insoles. This is a computerized method, which shows an individual map of the foot with the various pressure points, and therefore enables to make insoles with maximal support to the foot. This method was used for searching pressure points in diabetic patients in order to prevent chronic ulcers [22]. After a comprehensive search in Medline, we found only one study that examined the relation between the use of insoles to low back pain during long distance walking in military recruits [15]. The purpose of this work was to examine if such a connection exists.

Materials and methods

A total of 105 postmen whose job includes walking long distances (walking for many hours a day) were asked if they suffered from low back pain. Of these 105 persons, 75 (71.4%) answered that they did. Out of these 75 (80%), 60 persons agreed to participate in this prospective double-blind study. The feet of these 60 subjects were fitted before the beginning of this study for the insoles, and after randomization they received, either a true FSAP insole or a placebo insole for 5 weeks, and then it was switched to the other insole for the next 5 weeks. Either the true or the placebo insoles were made from a commercially available and widely used viscoelastic polymeric material for shoe inserts (Sorbothane, Sorbothane Inc., Kent, Ohio, USA). Both the caregiver and the subjects were blinded and both shoe insoles looked the same when used. The participants were permitted to put the insoles during work time, or non-work time (including home use).

Demographical parameters which included age, sex, marital status, smoking habits, height and weight, number of years at work and number of children were recorded. Each patient filled a MILLION questionnaire [21] to assess his/her back pain intensity before receiving insoles and after each period of using either the true or placebo insoles. The questionnaire was distributed and collected by another person not connected with this study. This questionnaire is widely used in the spine literature for assessing the changes in the back pain after a certain procedure or treatment and is considered as valid [3, 21]. In addition, each patient filled a questionnaire after each period with questions regarding the use of insoles, timing of pain in relation to walking distance, feeling of being tired after work and if at all so and preference for one of the insoles.

Statistical analysis was done using the SAS statistical program. Due to a normal distribution we used the Student's *t*-test. A P value of less than 0.05 was considered as statistically significant.

Results

A total of 60 patients (25 men and 35 women) agreed to participate in this study. In the first round, 41 patients received the true insoles (FSAP) and 19 received the placebo. After the first period of 5 weeks, two patients (one from each group) dropped from the study. One patient from the true insoles group was hospitalized for a non-related reason, and another patient from the placebo group refused to continue in the study because the insoles were inconvenient for him. Therefore, in the second round 40 patients received placebo insoles and 18

patients received true insoles. A comparison between the groups in terms of the demographical parameters did not reveal statistical difference in any of the examined parameters ($P > 0.05$) (Table 1).

A constant use with the insoles was reported by 49 patients (84.5%) from the true insole group and by 45 (77.6%) of the placebo group. Of these patients, four (6.9%) and six (10.3%), respectively, reported that they used it often, while five patients from each group (8.6%) reported only part-time use. Two patients from the placebo group (3.5%) did not use it at all.

The frequency of low back pain that was found in relation to the type of insole is presented in Table 2. This frequency was found to be lower after the use of true insoles relative to placebo ($P < 0.05$). A total of 54 patients (93.1%) from the true insoles group and 46 (79.3%) from the placebo group would have liked to continue with the use of the insole ($P > 0.05$). However, 47 patients out of the 58 (81%) would have preferred the true insole ($P < 0.05$). This shows that the patients were satisfied with both insoles including the placebo (placebo effect), but were much satisfied with the true insoles.

The average back pain according to MILLION was 5.46 ± 1.8 before the study, 3.96 ± 1.74 after the use of the FSAP insoles and 5.11 ± 1.85 after use with the placebo insoles ($P < 0.05$). This led us to examine if there is an influence on the results according to the first insole that was used by the patients. Such an influence was not found (Table 3).

Table 2 Frequency of low back pain according to type of insole (MILLION questionnaire). *M0* "Basic" Million questionnaire (before enrollment), *M1* million questionnaire after use of true insoles, *M2* million questionnaire after use of placebo insoles

Frequency of LBP	M0	M1	M2
Never	0 (0%)	6 (10.3%)	2 (3.4%)
Seldom	15 (25.9%)	34 (58.6%)	26 (44.8%)
Often	37 (63.8%)	15 (25.9%)	24 (41.4%)
Every day	6 (10.3%)	3 (5.2%)	6 (10.3%)
Total	58 (100%)	58 (100%)	58 (100%)

Discussion

The relation between insoles, feet pain and low back pain was examined mainly on professional sports players [4, 9, 12, 16, 20] and on people whose their job involves a lot of standing [2, 19, 27]. In the latter, it was found that 74% of the examinees found the insoles to be comfortable and reported decrease in their feet and lower back pain [2]. However, none of these papers examined the relation between insoles and low back pain in patients whose job includes walking long distances. Only one study examined the relation between insoles and low back pain in military conscripts who are supposed to walk relatively long distances and found a positive relation between the use of insoles to reduction of low back pain [15].

There is evidence that the frequency and severity of low back pain is related to heavy loading of the spine [1, 25, 26]. It was also shown that walking, a regular daily activity produces heavier loads on the lumbar spine [6]. This increase in the loads is transferred from the foot during heel strike to the lower extremity and then to the spine.

The most crucial factor for the development of shock wave related injuries is not the absolute value of the force at heel strike but the loading rate [23]. Our study group consisted of postmen who used to walk regularly for long distances each day, which means a high loading rate. In this group of examinees, we could have anticipated a high rate of low back pain. The fact that the insoles reduced the low back pain rate proves its potential to absorb some of the force, which is generated by repetitive walking. Windle and co-workers have shown that the insoles placed in shoes would attenuate the peak pressure at heel strike during running and marching compared to a "no insole" condition [30]. A decrease in the shock-wave amplitude transferred to the tibia in subjects who had insoles was reported by Light et al. [17]. This decreased load, which in turn transfers less energy towards the upper part of the lower extremity and the lumbar spine, is probably the cause for the decrease in low back pain.

This study was designed as a double blind study. To our knowledge, this is the only study reported in this subject which utilizes a double-blind technique. This is

Table 1 Demographic data of the 60 patients

Parameters	Mean ± SD[a]	Mean ± SD[b], placebo first use	Mean ± SD[c], true first use	*P*-value
Age (years)	39.14	37.8 ± 9.07	39.7 ± 7.67	0.415
Weight (Kg)	69.74	69.2 ± 10.6	70.0 ± 12.1	0.494
Height (cm)	167.98	166.8 ± 7.7	168.5 ± 8.9	0.821
BMI (kg/cm^2)	24.67	24.8 ± 2.8	24.6 ± 3.6	0.857
No. of children	2.21	1.66 ± 1.8	2.45 ± 1.8	0.123
No. of years at work	8.59	8.3 ± 6.7	8.7 ± 6.6	0.847
Shoe size	40.71	40.5 ± 2.3	40.8 ± 2.6	0.675

[a] Total—58
[b] Eighteen subjects, 9 females, 9 males
[c] Forty subjects, 24 females, 16 males

Table 3 The efficiency of the insoles (according to MILLION questionnaire). *P–T* placebo insoles were used prior to the true, *T–P* true insoles were used prior to the placebo

Questionnaire	Delta D	P–T (18 patients)	*P* value	T–P (40 patients)	*P* value
M1–M2	Between true insoles and placebo	−1.30	0.0008	−1.16	0.0001
M1–M0	Between use of true insoles to "basic" MILLION	−1.91	0.0001	−1.31	0.0001
M2–M0	Between use of placebo insoles to "basic" MILLION	0.61	0.146	−0.17	0.4443

superior to other methodologies which do not use double blind techniques.

In this study, it was shown that the patients reported a greater reduction in their low pain when used the true insoles, in comparison to the period that they used the placebo insoles. It was found that the contribution of the true insoles to the improvement in the low back pain, after reducing the placebo effect, is 79.2%. We did not find any correlation between improvement of low back pain to other measured criteria such as age, sex and marital status.

Evaluation of back pain is a subjective evaluation. For this evaluation we used the MILLION questionnaire that was proven to be valid in this subject [3, 21]. This work also contributes to the validity of this questionnaire as there was a good correlation between the different times that the subjects filled out this questionnaire, in terms of their low back pain.

Reduction in pain intensity by about 2 points in a 10-point scale, or more than 30%, has been reported to represent a clinically important difference in pain between treatments [10]. In our study we found this reduction in the patients when they used the true insoles and not when they used the placebo.

In conclusion, it was proven that insoles causes improvement of low back pain for subjects with repetitive loading such as walking long distances every day.

References

1. Andersson GBJ, Herberts P, Ortengren R (1976) Myoelectric back muscle activity in standardized lifting postures. Biomechanics 5A: 520–529
2. Basford J, Smith M (1988) Shoe insoles in the workplace. Orthopedics 11(2):285–288
3. Beurskens AJ, de Vet HC, Koke AJ, van der Heijden GJ, Knipchild PG (1995) Measuring the functional status of patients with low back pain. Spine 20(9):1017–1028
4. Brown GP, Donatelli R, Catlin PA, Wooden MJ (1995) The effect of two types of foot orthoses on rearfoot mechanics. J Orthop Sports Phys Ther 21(5):258–267
5. Carson R (1994) Stand by your job. Occup Health Saf 63(4): 38–42
6. Cromwell R, Schultz AB, Beck R, Warwick D (1989) Loads on the lumbar trunk during level walking. J Orthop Res 7(3):371–377
7. Cypress BK (1983) Characteristics of physician visits for back symptoms: a national perspective. Am J Public Health 73(4): 389–395
8. Cypress BK (1978) Office visits to internists: the National Ambulatory Medical Care Survey, United States. 1975. Vital Health Stat 36(13):1–70
9. Dufek JS, Bates BT, Davis HP, Malone LA (1991) Dynamic performance assessment of selected sport shoes on impact forces. Med Sci Sport Exerc 23(9):1062–1067
10. Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM (2001) Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 94:149–158
11. Frymoyer JW, Cats-Baril W (1987) Predictors of low back pain and disability. Clin Orthop 221:89–98
12. Gross ML, Davlin LB, Evanski PM (1991) Effectiveness of orthotic shoe inserts in the long distance runner. Am J Sports Med 19(4):409–412
13. Hawes MR, Sovak D, Miyashita M, Kang SJ, Yoshihuku Y, Tanaka S (1994) Ethnic differences in forefoot shape and the determination of shoe comfort. Ergonomics 37(1):187–196
14. Konno S, Kikuchi S, Nagaosa Y (1994) The relationship between intramuscular pressure of the paraspinal muscles and low back pain. Spine 19(19):2186–2189
15. Larsen K, Weidich F, Leboeuf-Yde C (2002) Can custom-made biomechanic shoe orthoses prevent problems in the back and lower extremities? A randomized, controlled intervention trial of 146 military conscripts. J Manipulative Physiol Ther 25(5):326–331
16. Leber C, Evanski PM (1986) A comparsion of shoe insole materials in plantar pressure relief. Prosthet Orthot Int 10(3):135–138
17. Light LH, McLellan GE, Klenerman L (1980) Skeletal transients on heel strike in normal walking with different footwear. J Biomech 13:477–480
18. Manning DP, Shannon HS (1979) Injuries to the lumbosacral region in a gearbox factory. J Soc Occup Med 29(4):144–148
19. Mark S (1995) Influence of flooring on standing fatigue. Hum Fact 37(3):570–581
20. McCulloch MU, Brunt D, Vander Linden D (1993) The effect of foot orthotics and gait velocity on lower limb kinematics and temporal events of stance. J Orthop Sports Phys Ther 17(1):2–10
21. Million R, Hall W, Nilsen KH, Baker RD, Jayson MI (1982) Assessment of the progress of the back-pain patient 1981 Volvo Award in Clinical Science. Spine 7(3):204–212
22. Mueller MJ (1995) Use of in-shoe pressure measurement system in the management of patients with neuropathic ulcers or metatarsalgia. J Orthop Sports Phys Ther 21(6):328–336
23. Ogon M, Aleksiev AR, Pope MH, Wimmer C, Saltzman CL (1999) Does arch height affect impact loading at the lower back level in running? Foot Ankle Int 20(4):263–266

24. Robbins S, Gouw GJ, McClaran J (1992) Shoe sole thickness and hardness influence balance in older men. J Am Geriatr Soc 40(11):1089–1094
25. Schultz A, Andersson G, Ortengren R, Bjork R, Nordin M (1982) Analysis and quantitative myoelectric measurements of loads on the lumbar spine when holding weights in standing postures. Spine 7(4):390–397
26. Schultz AB, Andersson GB (1981) Analysis of loads on the lumbar spine. Spine 6(1):76–82
27. Stuart-Butle C, Marras WS, Kim JY (1993) The influence of anti-fatigue mats on back and leg fatigue. Proceedings of the Human Factors and Ergonomics Society 37th Annual Meeting
28. Svensson HO, Andersson GB, Johansson S, Wilhelmsson C, Vedin A (1988) A retrospective study of low-back pain in 38-64 year-old women. Frequency of occurrence and impact on medical services. Spine 13(5):548–552
29. Vleeming A, Pool-Goudzwaard AL, Stoeckart R, van Wingerden JP, Snijders CJ (1995) The posterior layer of the thoracolumbar fascia: its function in load transfer from spine to legs. Spine 20(7):753–758
30. Windle CM, Gregory SM, Dixon SJ (1999) The shock attenuation characteristics of four different insoles when worn in a military boot during running and marching. Gait Posture 9(1):31–37