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Formulated Composite Insoles Reduce Foot Pain and Fatigue and Increase Working Efficiency in Healthcare Workers: A Pilot Non-controlled Experimental Study

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Author's contribution

The sole author designed, analyzed and interpreted and prepared the manuscript.

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ABSTRACT

Aim: The aim was to evaluate self-assessed foot health status and working efficiency of healthcare workers when using composite insoles to treat foot problems.
Introduction: Foot pain and fatigue are two of the most common problems facing healthcare workers owing to many hours of walking and standing per day. Many choices of conservative treatment are available such as the use of insoles and orthotic support. Commercially prefabricated insoles are one of the most widely used treatments for foot pain and fatigue as they are easily accessible at reasonable prices. However, there is limited evidence supporting the effectiveness of these treatments.
Methodology: Test subjects included 49 volunteers from Tung Song Hospital screened by an

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orthopedist and physical therapist to meet predetermined criteria. Data collected included demographic data, validated foot function score of a Foot Health Status Questionnaire (FHSQ), and a synthetic working efficiency score generated using the Thai Questionnaire of Working Efficiency for Healthcare workers. A self-evaluation form was designed to record the efficacy of using Smile feet™ insoles before and after one month of treatment. Statistical analysis was performed using the Wilcoxon signed rank test.

Results: Responses to the Foot Heath Status Questionnaire showed a statistically significant change in several foot health metrics (p-value < 0.01) after using the composite insoles for 1 month: Improvement greater than the minimal important difference was achieved by 75.5% in foot pain, 44.9% in foot function, 89.8% in foot wear, and a 57.1% in general foot health. Respondents to the Thai Working Efficiency questionnaire reported improvement in sections of working, reducing muscle soreness and fatigue in 30 of the 49 volunteers (61.2%). Among those that experienced improvement, [self-reported] work productivity increased by 73%.

Conclusion: Healthcare workers reported improvements after using a commercially available composite insole in all criteria on a self assessment questionnaire, including muscle soreness, working efficiency, work productivity, fatigue, foot pain, foot function, foot wear, and general foot health.

Level of Evidence: Level IV, therapeutic case series.

Keywords: Foot pain; fatigue; healthcare workers; composite insoles; foot function score; working efficiency.

1. INTRODUCTION

Foot pain and fatigue are common problems for healthcare workers [1–3]. The symptoms affect daily activities to the extent that working efficiency may be compromised. Moreover, healthcare workers' duties often include a requirement to help patients move around, exacerbating any incipient foot pain and fatigue during work [6]. It is estimated that 10% to 75% of the general population experience foot pain, depending on varying factors such as: aging, walking activity, and body weight [4–10]. Chronic foot pain is also common within the general population; the first line of treatment before medication or surgery being the use of orthotic insoles [4,5]. Despite the amount of research showing different degrees of effectiveness of insoles in relieving foot pain [11–15], there is a dearth of research conducted specifically to examine solutions to foot pain in healthcare workers using insoles [3]. Some preliminary data examining the health status of healthcare workers in a Thai hospital (Siwawat, unpublished) indicate that more than 75% of the healthcare workers had complained of foot pain after walking and standing for longer than 4 hours per shift. Attempts to mitigate the effects of foot pain in those groups had employed medication alone (34.5%), insole alone (9.5%), combined medication and insole (19.2%) or other treatments (36.8%). The group treated using insoles had reported varying responses depending on the type of insoles used. There was some correlation between the use of certain commercially available brands of insoles and clinical improvement after commencing use. While it seems that using insoles can improve foot pain in healthcare workers, there is a need to demonstrate clear links between their use and improvement in terms of foot pain, foot health and working efficiency. This study focused on the health care worker group because it is a group that routinely spends long periods standing or walking, and reduction of their working efficiency is directly related to critical care of patients. Any treatable condition that deleteriously affects healthcare workers' capacity to appropriately care for patients should therefore be a priority for investigation.

Our study was concerned specifically with the foot pain and fatigue of healthcare workers. Our purpose was to conduct a one group pretest-post test study to investigate the effectiveness of a widely available composite insole in relieving foot pain, and improving foot health and working efficiency.

2. MATERIALS AND METHODS

2.1 Subjects

The study group comprised volunteers from amongst the healthcare workers of Tung Song Hospital, Nakorn Sri Thammarat, Thailand. All subjects were screened by an orthopedist and physical therapist to identify for inclusion those who had foot pain with maximum tenderness at

the medial calcaneal tuberosity or first step pain in the morning [5,16,17], and to exclude those not meeting the desired criteria, such as having wounds, wound scars, history of fractures, history of arthritis, or any deformity in their feet. Forty nine workers (46 females and 3 males) from Tung Song Hospital met the criteria to participate in this study; the strong bias towards female respondents mirrors the heavily skewed sex ratio amongst Thai healthcare facility workers. None of the volunteers had any history of significant foot or lower-limb injury or contusion during the 3 months prior to the commencement of the study. None of the volunteers had used any insole during the 3 months prior to study. All volunteers were provided with the same brand of fitted composite insoles (i.e. the low number of qualified candidates meant that there were insufficient numbers available to form a statistical control group that was to be denied treatment or to evaluate differences between brands of insoles). The study was approved by the Ethics Committee of Tung Song Hospital.

2.2 Data Collection

2.2.1 Demographic data

Demographic data for the study subjects are listed in Table 1. Data were recorded in the data record form on the date of the initial screening. The demographic data included age, gender, height, weight, body mass index (BMI) and number of hours of standing and walking per work shift.

2.2.2 Primary outcome measures

The Foot Health Status Questionnaire (FHSQ) [18–20] was used to measure foot health status. The FHSQ consists of thirteen key questions in four domains of foot health: foot pain, foot function, footwear and general foot health. Each question required a response using a five-point Likert scale. The “Foot pain” domain has four questions for evaluation of foot pain in terms of pain, severity and duration. The “Foot function” domain has four questions for evaluation of feet in terms of impact on physical function. The “Footwear” domain has three questions for evaluation of life-style issue related to and affected by footwear [20,21]. The “General foot health” domain has two questions related to the respondents’ own perception of the condition of their feet. FHSQ data analysis software© (Version 1.03) was used to convert the initial score for each domain to a score between 0 and 100 (worst to best condition). Self-report questionnaire of FHSQ was employed to record data prior to and after one month of use of the composite insoles. The basic unit of measurement in this study was the amount of change in each of the domains pertaining to foot health. The criteria for minimal improvement of the FHSQ according to Landorf et al. [22] were applied. These are: more than 13 points of improvement for foot pain; more than 7 points improvement for foot function; more than 2 points improvement for footwear, and any improvement at all in general foot health.

2.2.3 Secondary outcome measures

The minor purpose of our study was to investigate a possible increase in the working efficiency of the healthcare workers while using the composite insole [1,23,24]. The Thai Questionnaire of Working Efficiency for Healthcare workers [27], from Nursing Department, Prince of Songkla University, Hat Yai, Thailand, is a Thai language questionnaire with 88 questions. It was used to evaluate the working efficiency of using insoles after one month of use as an adjunct to the FHSQ. It consists of questions related to working time, completion of work, muscle soreness and fatigue. From the response group of The Thai Questionnaire of Working Efficiency for Healthcare workers, work productivity change attributable to the use of insoles was evaluated using the percentage of increase in work productivity between subsequent surveys.

2.3 Composite Insoles

Smile feet™ insoles are one of several commercially available insoles in the Thai market. They were developed in conjunction with medical and natural products researchers at Prince of Songkla University and Songklanagarind Hospital. They are manufactured by Health and Innovation Design Ltd., Thailand. This product was chosen for this study primarily because of the ready availability of sufficient insoles to treat the experimental group (other brands were available in limited numbers at the time of the study; because of the lack of control group, the treatment was required to be as homogeneous as possible) and also the willingness of the developers to submit their product to external trials. Insoles were obtained under existing worker healthcare augmentation procedures available to healthcare workers in Thai government healthcare facilities. The prefabricated composite insoles were provided in

different sizes to fit volunteers' shoes. Smile feet™ insoles (Fig. 1) consist of a prefabricated full-length 4 mm billet of specially formulated (BL-NEW) cushion foam with a top coating of (GR-SOFT) Microfiber fabric, superimposed on a special formulation (REBOUND G-GEL) of elastic gel (Fig. 2) for heel cushioning and additional support module to reduce heel impaction made of another special formula (OR-DOUBLE) cushion foam.

Fig. 1. Smile feet™ (Images and information from: http://www.smile-feet.com/)

Fig. 2. Special formula (REBOUND G-GEL) of elastic gel for heel cushioning inserted in a prefabricated cushion foam

2.4 Statistical Analysis

The distributions of participants' data were examined using mean and standard deviation (SD) and the FHSQ values in each domain before and after intervention compared using the Wilcoxon signed rank test. A p-value < 0.01 was considered significant.

3. RESULTS

All 49 volunteers (46 females and 3 males) completed a follow-up assessment and examination by an orthopedist and physical therapist one month after commencing use of the composite insoles. All subjects completed the self-evaluation questionnaire at either ends of the study, and all had a good compliance with 100% using the insoles consistently during work. The average age of participants was 39.2 years (SD 10.8) at the commencement of the study (Table 1). Workers who enrolled in this study were engaged in a wide variety of occupations at Tung Song Hospital (Table 2), but more than half of the respondents reported spending more than 8 hours per shift standing or walking (Table 1). The average work experience in the healthcare field of respondents was 17.5 years (SD 10.8).

Comparison of pre- and post-treatment scores on the Foot Heath Status Questionnaire [19,20] showed a significant difference ($p < 0.01$) before and after using composite insoles in all domains (Table 3). Average foot pain score improved from 50.7 (SD 17.2) to 75.0 (SD 13.2), average foot function score improved from 64.4 (SD 22.2) to 78.2 (SD 17.7), average foot wear improved score from 40.1 (SD 24.9) to 51.0 (SD 24.2), and average general foot health score improved from 45.2 (SD 20.4) to 60.1 (SD 17.9) (p-value <0.001 in each domain). Using the criteria for the minimal important improvement in the FHSQ advocated by Landorf et al. [22], important improvements in foot pain were recorded by 75.5%, in foot function by 44.9%, in foot wear by 55.1% and in general foot health by 95.9% (Table 4). Analysis of responses to the self evaluation section of the Thai Questionnaire of Working Efficiency for Healthcare workers indicated that 30 of the 49 respondents (61.2%) found improvement in the sections of working, muscle soreness and fatigue. For these 30 respondents, reported synthetic work productivity score increases averaged 73%. However, the average increase over all 49 respondents is 44.9%.

4. DISCUSSION

The results of this single group pre-test/post-test study suggest positive outcomes for the treatment of foot pain and fatigue in healthcare workers exposed to long hours on their feet through the use of simple, widely-available composite insoles to alleviate postural and impact-associated foot problems. The participants in this study reported decreases in worker fatigue and corresponding increases in productivity and working efficiency after exposure to remedial shoe insoles.

Table 1. Demographic data of subjects

Variable	Value
Age, years Mean (SD)	39.2 (10.8)
Male, number (%)	3 (6.1)
Female, number (%)	46 (93.9)
Height, cm. Mean (SD)	159.7 (6.3)
Weight, kg. Mean (SD)	57.6 (10.8)
BMI, kg/m2 Mean (SD)	22.5 (3.4)
Standing and walking hours per shift	
4-8 hr., number (%)	21 (42.8)
8-12 hr., number (%)	14 (28.6)
>12 hr., number (%)	14 (28.6)

Table 2. Occupations of health care workers in the study

Occupation	N (%)
Operating room nurse	11 (22)
Anesthesia nurse	3 (6)
Medical ward nurse	2 (4)
ENT nurse	2 (4)
Surgical ward nurse	1 (2)
OPD nurse	1 (2)
Emergency nurse	1 (2)
*Physical therapist	3 (6)
Nurse coordinator	18 (36)
*Transportation worker	1 (2)
*Medical officer	4 (8)
*Medical equipment cleaner	2 (4)

Table 3. Comparison of foot heath status questionnaire scores

Domain	Before using insole mean (SD)	After using insole mean (SD)	P-value
Foot pain	50.7 (17.2)	75.0 (13.2)	0.001**
Foot function	64.4 (22.2)	78.2 (17.7)	0.001**
Foot wear	40.1 (24.9)	51.0 (24.2)	0.001**
General foot health	45.2 (20.4)	60.1 (17.9)	0.001**

**=significant at α=0.05; **= significant at α=0.01*

Table 4. Number and percent of subjects showing at least minimal important improvement using FHSQ criteria

Domain	N	Percent (95%CI)
Foot pain	37	75.5 (61.1 – 86.7)
Foot function	22	44.9 (30.7 – 59.8)
Foot wear	27	55.1 (40.2 – 69.3)
General foot health	47	95.9 (86.0 – 99.5)

In general, patients who have foot pain seek doctors and pain relief medication [5,17,25]. This consumes resources within the medical system, such as the valuable time of healthcare providers, and the costs of patient medical care and medication [25]. Moreover, some patients also have a risk of drug allergies and experience side-effects to commonly prescribed medications. Footwear can be a contributor to foot pain. The long-term effects of poorly fitting shoes include misalignment of the toes, and microtrauma injuries to the foot. Micro-trauma injuries can be caused by surfaces that are too hard or too soft, or shoes that have poor force-absorption qualities. By augmenting the force-absorption properties of footwear, and remediating postural misalignments, composite insoles can be a treatment and a pro-active measure to alleviate plantar stress caused by prolonged standing. Composite insoles (such as the insoles manufactured by Smile feet™ used in this study) are an ideal alternative solution to reduce the cost on the medical system and reduce the need for side-effect causing medications [26,27]. The composite insoles can also be used for the amelioration of plantar stress in other groups of workers whose jobs require long hours of walking and standing. In fact, there is a standard recommendation to use insoles to reduce impaction force and to treat plantar fasciitis [6,14,28,29].

The primary limitation of our study is in the lack of a control group due to limited resources which limited our ability to attribute all improvements to the treatment. The lack of comprehensive medication records, the use of self-reported outcome measures and short-term intervention mean that the results of this study should be interpreted conservatively. Because our study was interested only in healthcare workers who were currently suffering from chronic foot pain, the pool of potential study participants in a small regional hospital may not represent the general population of Thai or overseas healthcare workers. A future study might benefit from location in a larger municipal facility; more insight could perhaps be obtained from a randomized study with one or more control groups. While this study did not make any comparison between the Smile feet™ product and other types of insoles, our focus was only to compare the efficiency of composite insoles in one group pre-test/post-test study.

5. CONCLUSION

We found a statistically significant short-term improvement in healthcare workers' foot pain, foot function, footwear, and general foot health after 1 month of using composite insoles. A large proportion of the respondents in this study

reported positive effects on their working efficiency attributable to the use of insoles, corresponding to 44.9% increases in work productivity in overall average. We therefore find that inexpensive, commercially available composite insoles represent a viable treatment for chronic foot pain and fatigue in healthcare workers, and have potential for broader acceptance in preventative and ameliorative treatment of chronic postural and impact-associated foot pain in the general population.

CONSENT

Author declares that written informed consent was obtained from the patient for publication of this case report and accompanying images.

ETHICAL APPROVAL

Author hereby declares that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki."

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COMPETING INTERESTS

The author has declared that he has no competing interest.

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