A Pilot Study: Efficacy of Simple Customized Shoe-insert to Decrease Abnormal Plantar Pressure in Patients with Plantar Foot Pain

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ABSTRACT

Objective: To evaluate the efficacy of a simple customized shoe-insert in decreasing abnormal plantar pressure and in changing the pain score in patients with chronic plantar foot pain.

Methods: Ten patients with chronic plantar foot pain were initially recruited from the outpatient unit of the Department of Rehabilitation Medicine, Siriraj Hospital. The simple customized shoe-inserts were fabricated from 2 layers of EVA foam. Some pieces of foam were attached to the specific locations between the two layers by using the subjects' foot pressure graph as blueprint. The plantar pressures were measured during walking by digital foot scanning (Footscan™ insole system), with and without the customized shoe-inserts in. The average pain scores were altogether reported by the patients in terms of a visual analog scale. The same measurements were repeated again with the shoe-inserts in after 2 weeks of use.

Results: Nine participants (3 males, 6 females) were evaluated completely. The diagnoses were plantar fasciitis (all 9 subjects) and matatarsalgia (3 of the 9 subjects). Immediately after applying the shoe-inserts, foot pressures were significantly decreased ($p = 0.011$) when walking. However after 2 weeks, the pressures were no longer significantly reduced ($p = 0.859$, $p = 0.173$) compared to the baseline before fitting. Also, for the pain score change, most subjects initially reported pain relieved (7 in 9 subjects), but the second visit showed no significant difference ($p = 0.081$) compared to the first day before using.

Conclusion: The simple customized shoe-inserts could potentially decrease average plantar pressure as well as the average pain score in most cases. However the pain score reductions were not significantly different after 2 weeks of the device applications. Future investigations with an appropriate sample size are required to precisely conclude the efficacy of the shoe-inserts.

Keywords: Shoe-insert, insole, plantar foot pain, plantar pressure, orthosis

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Chronic foot pain has been a common problem found in general medical practice.[1] The area under a pathological foot usually shows abnormal distribution of plantar pressure when compared to the sound side and is usually related to the pain syndrome. Wearing et al, found that those patients diagnosed as having plantar fasciitis usually have thicker plantar fascias and have more pressure on the affected heels than on the other normal sides.[2]

One of the standard orthotic devices usually used for plantar foot pain management is the total contact insole (inlay) or total contact shoe-insert. According to the principle of plantar pressure redistribution, by increasing more contact surface between the foot and the shoe-insert and the use of soft materials to absorb impact from walking, this othosis has the ability to reduce the peak plantar pressure and thereby alleviate the pain symptom from walking.[3]

The most common type of shoe-insert material is foam[4] which is popularly used in diabetic feet[5] and in the management of foot pain such as plantar fasciitis[6] and callus, etc.

In practice, it takes time and labor to make a pair of foam insoles. After diagnosis and feet impressions are taken, the patients have to wait up to 2 weeks to get the shoe inserts. In the meantime, they usually suffer from walking difficulty. The application of temporary shoe inserts is, however, very important and necessary from the beginning of the treatment process.

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Accordingly, the research team had to invent new-design simple shoe inserts to be used whilst waiting for fabrication of the standard customized ones.

Actis and his team had conducted a study on peak plantar pressure by comparing customized insoles (total contact insert) with the special shoe inserts with soft plugs arranged under the metatarsal heads. It was found that such special shoe inserts with plugs could decrease the pressure on the plantar aspect of the forefeet better than the customized ones.[7] Kang and his team found that the peak plantar pressure decreased with metatarsal pad application and was related to the decrease of the plantar pain report in the patients with metatarsalgia.[8]

The shoe inserts in this study were fabricated from EVA (ethylene vinyl acetate) foam material, that is, the local-made foam sheet, which is cut and assembled with the same characteristics as that of the standard thermoformed shoe inserts. Thickness, configuration and location of pieces of foam arrangement were determined by using the information from the foot pressure graph as blueprint. Such steps of production can be put into practice easily and rapidly, so the patients can take such shoe inserts back home for use from the first visit. The present study aims primarily to evaluate plantar foot pressure reduction before and after application of the simple inserts as well as the pain score change.

MATERIALS AND METHODS

Patients

Between August to September 2008, 10 patients were initially recruited from the outpatient unit of Department of Rehabilitation Medicine, Siriraj Hospital, Mahidol University, by the criteria below. This study was approved by the Siriraj Ethics Committee. COA no. Si 352/2008.

Inclusion criteria

1) Age 18-65
2) Chronic plantar foot pain requiring shoe inserts

Exclusion criteria

1) Foot ulceration
2) Pain or deformity in the lower limb other than the foot
3) Diabetes, peripheral neuropathy, peripheral vascular disease

Before fabricating the inserts, a static foot pressure graph was performed by standing barefoot on the ink mat (Harris Mat™) to get the foot imprint with outline on a paper, which indicated plantar pressure distribution. Then EVA foam sheet (3 mm thick, 55° shore A) was prepared that fits the foot size of the patient. The blueprint was used for transferring the foot pressure pattern on the foam sheet. Various shapes of foam pieces (metatarsal pad, medial arch support, heel wedge) were cut to match the foot pattern, then put and glued on specific locations over the foam sheet in order to change the distribution of abnormal pressure. Then, glue was applied on top of the foam sheet with foam pieces and the overall surface covered with another thin EVA foam sheet of 1 mm thickness (40° shore A). Finally, the outer edge was trimmed to fit the inside surface of the shoe. For the other foot that had no pain, the same insert was done and applied in the same way to prevent leg length discrepancy. The complete step was demonstrated in Fig 1.

All participants met by the criteria were explained the research procedures and reasons and then signed the information letter and the consent form. The background recording and physical check up was then made on both feet of the participants with details including the imprint of the foot pressure graph. After that, the participants were asked about the average pain score in terms of a Visual Analogue Scale (VAS). VAS is a subjective pain measurement commonly used in research and practice estimated by patients themselves starting from score 0 (no pain at all) to score 10 (very severe pain) according to the increment of pain perception. The analysis was then made on the plantar pressure while walking by the digital Footscan™ insole system machine (Fig 2) before and after the insertion of the fabricated simple shoe inserts, and the VAS score was checked at the time of 5, 10 and 15 minutes on a continual walking. After finishing, the feet were checked for any irritative ulcers or blebs caused by the inserts. After 2 weeks, plantar pressure analysis was repeated and inquiries were made on the average pain score while wearing shoes with the inserts.

Statistical analysis

Statistical analysis by SPSS program version 11.5 was expressed in terms of mean and standard deviation for continuous data. The comparison of baseline and the experiment was made by Wilcoxon signed-rank test and the correlation between the value of plantar pressure and the VAS change was analyzed by the Pearson's correlation test. The criterion for statistical significance was p-value less than 0.05.

RESULTS

General information

There were initially 10 participants with 1 subject withdrawn from the research due to sickness. Therefore, a total of 9 subjects completely attended, comprising 3 men and 6 women at the average age of 48.4 ± 13.8 year old with the average body mass index (BMI)

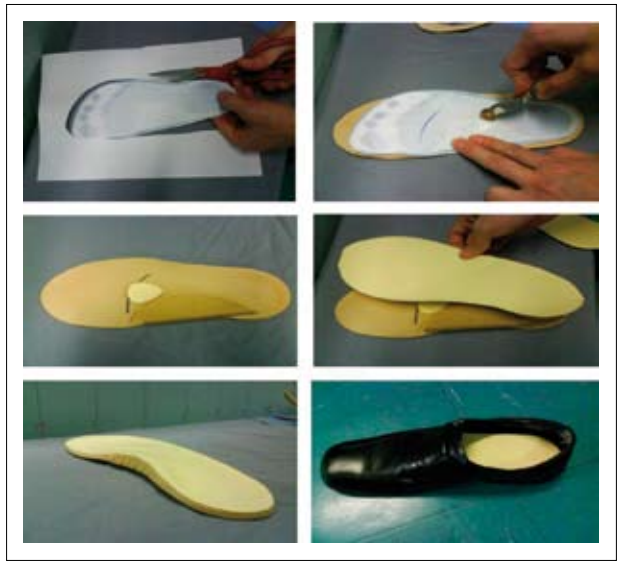

Fig 1. Step to fabricate the simple customized shoe-insert.

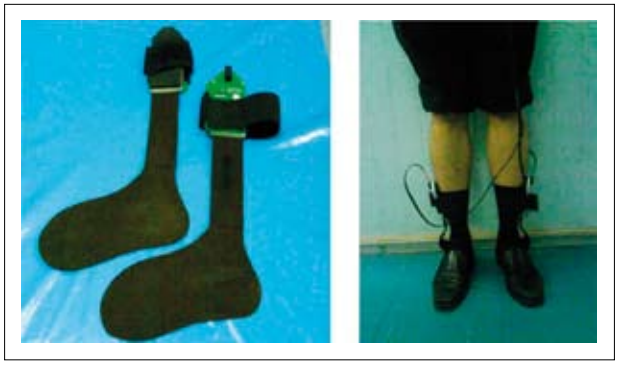

Fig 2 a. Digital foot scan (Footscan™ Insole System).

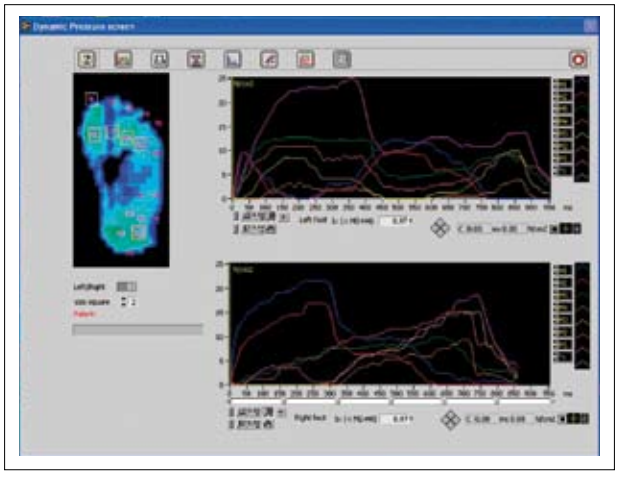

Fig 2 b. Digital foot pressure graph. (Left) higher plantar pressure areas are illustrated in green color while the lesser pressure areas are shown in blue-green and blue. Each specific location is presented in capital letter: H (Hallux), M (Metatarsal head), T1 (Great toe). (Right) the figure shows plantar pressure variation in different cycles of stance phase.

of 24.9 ± 4.5 kg/m^2. There were walking and standing activities of 4.3 ± 2.8 hours/day. While the duration varied from 4 months to 2 years, all 9 subjects were diagnosed as having plantar fasciitis and 3 of them were co-diagnosed metatarsalgia. Every participant had been treated with physical therapy and medications for pain and inflammation, but experienced just temporary relief.

Visual analogue score-VAS

Comparing the baseline before initial fitting to the wearing of the shoe inserts for 2 weeks, 7 out of 9 participants had the average VAS decrease from 5.3 ± 1.5 to 4 ± 1.7 (decrease by 1.3 ± 2.0). However, it had no statistical significance (p = 0.081). Individual VAS score changes were shown in Fig 3.

Plantar pressure value

At first visit, from the measurement comparing the plantar pressure values before and after initial fitting, it was found that the total plantar pressure (TPP) and the peak plantar pressure (PPP_H) at heels decreased with statistical significance (p = 0.011, p = 0.012) as in Table 1.

When comparing the data after 2 weeks of use and the data before first wearing, we found that the TPP value and the PPP_H decreased from the baseline; however, there was no statistical significance (p = 0.173, p = 0.193) as in Table 2. Each subject's plantar pressure changes were shown (Fig 4 and Fig 5).

The Correlation Coefficient between decrease in VAS change and the decrease in plantar pressure.

During the 2 weeks of wearing shoes with the inserts, the decrease of both TPP and PPP_H values had correlation in the same direction, but rather low (r = 0.215, r = 0.163) and had no significant statistical correlation (p = 0.676, p = 0.549).

Behavior in using shoe inserts

Eight of 9 participants were satisfied with the use of the shoe inserts. Seven persons reported wearing such shoe inserts outside of their houses with leather dress shoes at the average of 7.56 ± 3.81 hours per day, while 3 participants were wearing sneakers and 1 participant used both types of shoes. At home, 7 subjects used thong sandals or cloth slippers, while 2 participants walked barefoot. No one used the shoe inserts inside their houses.

DISCUSSION

It was found from the study that this type of the shoe inserts could potentially decrease the total plantar foot pressure and specifically pressure under the heels. Since it was a pilot study, the number of included

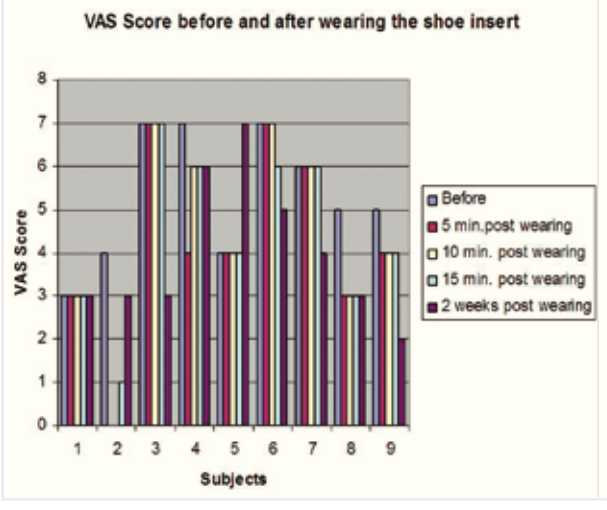

Fig 3. Visual analogue score (VAS) change before and after wearing the shoe insert in 9 subjects. VAS score increasingly reported, 0 (no pain at all) to 10 (very severe pain), regarding to higher in pain intensity.

TABLE 1. Patients' plantar pressure, at initial fitting of the insert. Total plantar pressure (TPP), Peak plantar pressure at heel (PPP_H).

Location	Average plantar pressure (N/ cm^2)			p value
	Before wearing	1st day, after wearing	Amount change	
TPP	137.4±38.4	120.89±26.4	16.6±15.9	0.011
PPP_H	36.9±12.2	29.2±8.3	7.7±6.5	0.012

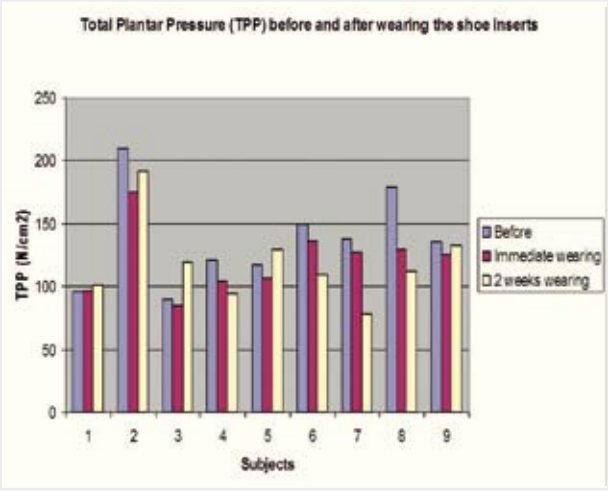

Fig 4. Total plantar pressure change before and after wearing the shoe insert in 9 subjects.

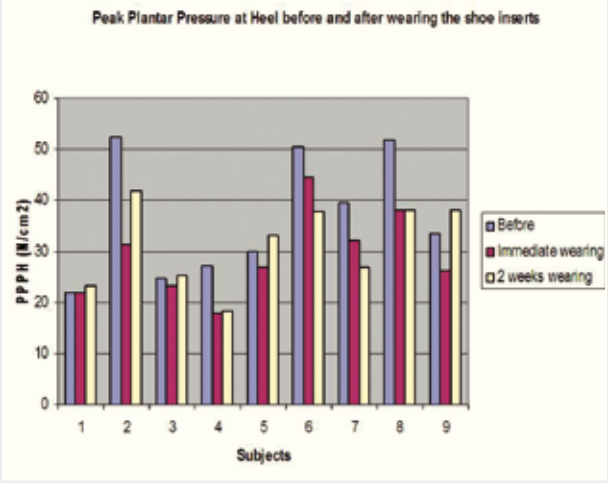

Fig 5. Peak plantar pressure change before and after wearing the shoe insert in 9 subjects.

participants was not calculated. Therefore, the efficacy of these shoe inserts could be underestimated until conducting further research. Besides, the subject recruitment was not confined to a single specific pain diagnosis of either forefoot or hind foot pain condition; thus, the pathological mechanism might be incomparable. In addition to the specific diagnosis, the participants included should be classified according to the severity of pain because the ones with minor symptoms would respond to this simple treatment better and quicker than the group with serious pain complaint. As a result, little reduction in VAS score can be explained by these factors and how much they walked. In addition the patients were advised to follow other protocols; for instances, activity modifications, and proper shoe wearing. From the interview, compliance to these recommendations was quite poor and it should take longer time to evaluate the pain reduction efficacy.

From a study by Cheung JT et al., done in healthy men to explore how much foot pressure reduction could be achieved by the customized total contact insoles, they found the peak plantar pressure decreased by up to 40.7% and 31.6% at the metatarsals and at heels respectively.[9] Compared to our study the average plantar pressure reduction were 12.08% (total plantar pressure) and 20.86% (at the heel). This might imply the lesser effectiveness in pressure reduction of the simple designs. However, the thickness of the materials seems to be too thin and impair all of the parameter outcomes in terms of pain score reduction and the plantar pressure. In reality the research should have been done to compare the standard insert and this simple new design with the same foam materials and to the same thickness before drawing a conclusion. Nevertheless, there was good potential for this design to be applicable in clinical practice due to its simplicity.

The study of medical equipment needs to be done for both short and long term results. Since it was a research on temporary shoe inserts, only short-term results were studied. As mentioned earlier, the fabrication of standard shoe inserts takes a lot of time and labor and not every person needs the customized ones, especially those with minor symptoms and those who have mild feet deformity. Unfortunately, the prefabricated inserts were totally imported and expensive; these simple-made inserts would be the good alternative for the Thai situation. From the calculation of the total cost, a pair of regular shoe inserts made by Siriraj Hospital, was about 2,400 baht. Further study on the efficacy of temporary shoe inserts among patients with mild severity of symptoms should be now seriously considered.

CONCLUSION

The simple shoe insert for temporary use could potentially decrease the plantar pressure and pain symptom for most of the patients. However, it was found that the decrease in plantar pressure value had no correlation with VAS score reduction. Regarding to the behavior in using these shoe inserts, we found that no one wears the shoe inserts while at home. Also, there was no adverse effect reported from the application of this orthosis.

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TABLE 2. Patients' plantar pressure, after 2 weeks. Total plantar pressure (TPP), Peak plantar pressure at heel (PPPH).

Location	Average plantar pressure (N/ cm^2)			p value
	Before wearing	After wearing for 2 weeks	Amount change	
TPP	137.4±38.4	118.8±32.4	18.6±33.2	0.173
PPPH	36.9±12.2	31.4±8.2	5.5±7.7	0.193

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