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Original Article

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The Effect of Protective Socks with Functional Insoles on Plantar Foot Pressure in Diabetes Patients

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Purpose: The most common cause of plantar ulceration is an excessive plantar pressure in patients with peripheral neuropathy. Foot orthosis and therapeutic footwear have been used to decrease the plantar pressure and prevent the plantar ulceration in in diabetes patients. We investigated whether protective sock with functional insoles reduce plantar pressure while walking in 17 diabetes patients.
Methods: An in-shoe measurement device was used to measure the peak plantar pressure while walking. Peak plantar pressure data were collected while walking under two conditions: 1) wearing diabetic sock and 2) wearing the protective sock with functional insoles. Each subject walked 3 times in 10-m corridor under three conditions, and data were collected in 3 steps in the middle of corridor with in right and left feet, respectively. Pared t-test was used to compare the peak plantar pressures in three plantar areas under these two conditions.
Results: The protective sock with functional insoles significantly reduced the peak plantar pressure on the lateral rearfoot, but significantly increased the peak plantar pressure on the middle forefoot, and medial midfoot ($p < 0.05$). However, there were not significant in medial and lateral forefoot, lateral midfoot, and medial rearfoot between diabetic sock and the protective sock conditions ($p > 0.05$).
Conclusion: The protective sock with functional insoles reduced plantar pressures in the rearfoot and supported the medial longitudinal arch. However, it is necessary to change the position of metatarsal pad in the insole design of forefoot area to prevent diabetic foot ulceration.

Keywords: Diabetes mellitus, Insole, Plantar pressures, Sock

INTRODUCTION

Approximately one-third of diabetes patients are exposed to major risk factors for diabetic foot complications, such as peripheral neuropathy, vascular disease, deformity, and trauma.[1,2] It is estimated that 2-7% of the diabetic population has active foot ulcers due to a lack of diabetic foot care, with about 3% experiencing amputations.[3] To prevent foot complications in diabetes patients, various non-surgical methods, such as patient education, management of skin and toenails, proper shoes, and wearing protective sock, as well as general medical evaluation and treatment of the feet, are utilized.[4,5] Excessive foot pressure is the main factor that causes foot ulcerations in diabetes patients with peripheral neuropathy. Because it is important to redistribute the abnormally high plantar pressure that occurs during walking before foot ulcers form, many foot appliances, such as therapeutic footwear, extra-depth shoes, and custom-made foot orthoses are commonly recommended for diabetes patients with peripheral neuropathy.

Current trends indicate that Asians will eventually constitute more than 60% of the world's diabetic population.[6] In many Asian countries, it is customary to remove outdoor shoes before entering a house.[7] Sock are then the first line of defense for the diabetic foot, and are considered to be an important and modifiable risk factor for foot ulceration in Asians.[8-10] We developed protective sock combined with functional insoles that can be used both indoors and outdoors. In pilot study, it was investigated whether protective sock

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combined with functional insoles was effective to decrease the plantar pressure in healthy subjects.[11] However, it was no study to compare the plantar pressure between the protective sock combined with functional insoles and commercial diabetic sock in diabetic patients.

Previous studies have found that padded sock reduce plantar pressure and blistering in patients with rheumatoid feet and diabetic neuropathy. Although previous studies have evaluated padded or multilayered sock, no protective sock combined with insoles are yet available to effectively reduce plantar pressure both indoors and outdoors in patients with diabetes. Therefore, we investigated whether protective sock with functional insoles reduce plantar pressure while walking in diabetes patients.

METHODS

1. Subjects

Seventeen subjects (8 men, 9 women) with type 1 or type 2 diabetes, in whom diabetes onset more than 5 years previously, participated in this study. The general characteristics of the subjects are presented in Table 1. We recruited subjects from local hospitals and obtained informed consent from all participants after providing them with sufficient information on the study. The exclusion criteria were as follows: foot ulceration and amputation, foot pain and edema, foot deformity such as hammer and claw toes, and difficulty of gait. This study was conducted under the approval of the institutional review board (IRB) of Joongbu University (JIRB-2017111501-01-171218).

Table 1. Demographic data of subjects (N=17)

Sex (female/male)	Age (yr)	Height (cm)	Weight (kg)	BMI (kg/m^2)
9/8	70.35±10.12*	164.00±9.45	67.59±6.70	25.29±1.44

BMI: body mass index.
*mean±SD.

2. Experimental methods

1) Protective sock with functional insoles protective

In this study, we used protective sock with functional insoles made from cushioned urethane material, which support the longitudinal arch and transverse arch of the foot with metatarsal pads (Figure 1). This structure helps prevent diabetes ulcers in Charcot foot and forefoot including metatarsal head. The shape of the insole that enters the sock can help absorb shock by using a polyurethane material that is restored to its original shape when released after compression deformation. To maintain blood circulation, humidity and antibacterial properties, we used the silver yarn.

2) Instrumentations

Existing diabetic sock are thinly padded with silicone material on the soles (Softsock; Silipos, Niagara Falls, NY, USA). A dynamic pressure mapping system (DYNAFOOT 2; Techno Concept, Mane, France) was used to measure peak plantar pressure during walking. There were 58 pressure sensors inside the insole, and the foot pressure was measured at a data sampling rate of 100 Hz divided into the medial, middle, and lateral parts of the forefoot, the medial and lateral parts of the midfoot, and the medial and lateral parts of the rearfoot. The measured pressure distribution data were analyzed using the DYNAFOOT 2 analyzer.

3) Procedure and data analysis

A research assistant contributing to the project development con-

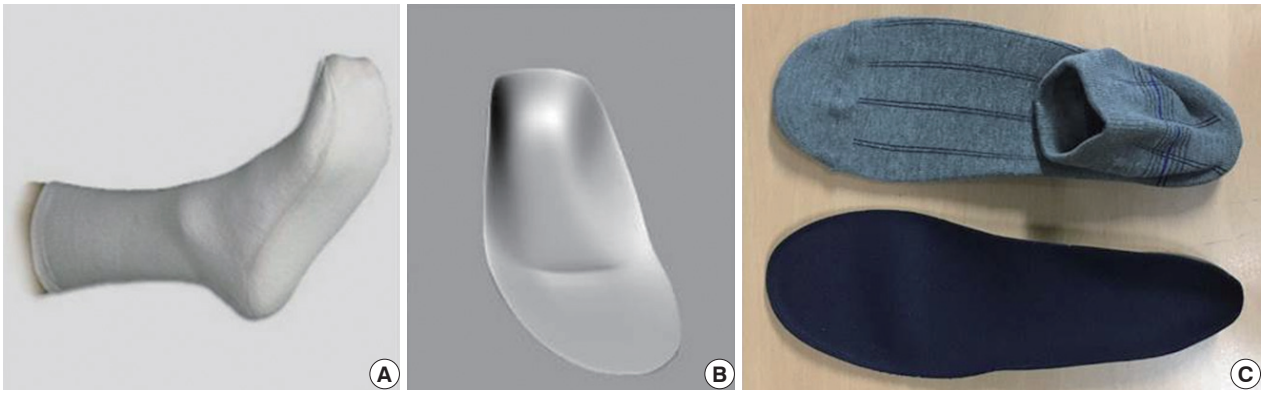

Figure 1. Commercial diabetic sock (A), design of functional insole (B), protective sock with insole (C).

ducted the experiments and data collection. Peak plantar pressure data were collected while walking under two conditions: 1) wearing commercial sock for diabetes patients and 2) wearing the protective sock with functional insoles. To ensure a constant walking speed was maintained during the tests, the average walking speed of each subject was calculated by measuring his/her comfortable walking speed three times. The subjects walked down a 15-m-long corridor five times to familiarize themselves with the calculated walking speed using a metronome. Insole-type pressure sensors were inserted in advance into the left and right sock and the wireless communication modules were firmly attached to the shoelaces. Each subject randomly selected cards numbered 1 (diabetic sock), or 2 (protective sock with functional insoles) for random assignment of the order of the three conditions. As each subject walked three times in time with the metronome, foot pressures were measured for three steps in the middle of the 15-m-long corridor.

The mean value of the peak plantar pressure at the middle step of the three was calculated for data analysis. Pared t-test was performed to compare the peak plantar pressures in three plantar areas under these two conditions. The significance level was set as $p = 0.05$. Data were processed using SPSS for windows software (ver. 19.0, SPSS Inc., Chicago, IL, USA).

Table 2. Mean values and standard deviation (kg/cm^2) of peak plantar pressures in each condition (Feet = 34)

Conditions	Forefoot			Midfoot		Rearfoot	
	Medial	Middle	Lateral	Medial	Lateral	Medial	Lateral
Diabetic sock	8.72 (1.44)*	11.35 (2.03)	11.18 (2.66)	9.49 (2.22)	11.48 (3.53)	10.86 (2.29)	10.57 (2.95)
Protective sock	9.10 (1.70)	12.03 (2.53)	10.96 (1.90)	11.01 (2.42)	11.83 (3.54)	10.41 (2.25)	9.26 (3.06)
p	0.09	0.01	0.65	0.00	0.50	0.23	0.00

*Mean (SD).

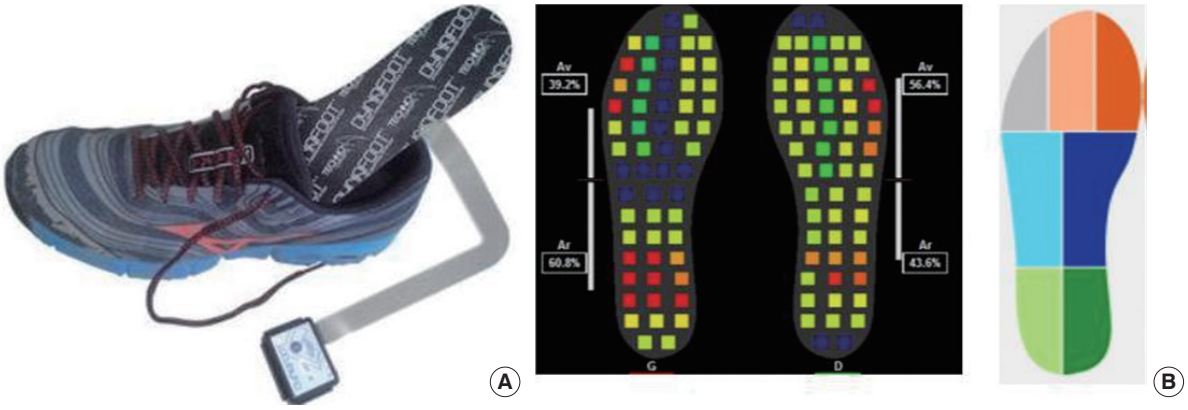

Figure 2 Dynamic pressure mapping system. (A) Insole sensor and module, (B) Measurement areas of pressure.

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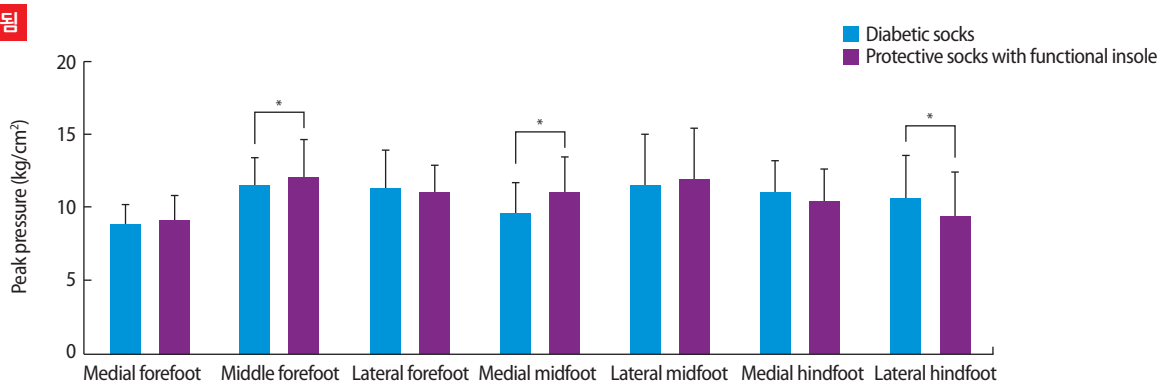

Figure 3. The comparison of peak plantar pressure between diabetic and protective sock (*$p < 0.05$).

RESULTS

Table 2 shows the mean values of peak plantar pressure for each part of the sole when walking under the two conditions. The protective sock with functional insoles significantly reduced the peak plantar pressure on the lateral rearfoot, but significantly increased the peak plantar pressure on the middle forefoot, and medial midfoot ($p < 0.05$). However, there were not significant in medial and lateral forefoot, lateral midfoot, and medial rearfoot between diabetic sock and the protective sock conditions ($p > 0.05$)(Table 2).

DISCUSSION

Many previous studies have reported the effectiveness of therapeutic shoes and foot orthoses to reduce plantar pressure in people with diabetes.[12,13] However, there have been few studies on diabetic sock. Only four previous studies used peak plantar pressure as a dependent variable to determine the effectiveness of diabetic sock. In most previous studies, padded sock decreased peak plantar pressure, then padded sock as well as proper shoes and insoles are recommended to prevent the occurrence of foot ulcers in diabetes patients.[6,10,14,15] Veves et al.[10] reported that the peak plantar pressure at the forefoot was significantly reduced in 10 diabetes patients wearing padded protective sock, by 15.5% after 3 months and 17.6% after 6 months. Garrow et al.[6] reported that multi-layered protective sock reduced the peak plantar pressure on the forefoot during walking by 10.2% compared to regular sock in 19 diabetes patients who did not have ulcers. Veves et al.[15] reported that the protective sock significantly reduced peak plantar pressure at the metatarsal heads by approximately 26% when compared to the subject's own sock or barefoot walking in 27 diabetic patients with peripheral neuropathy. However, in our study, when the diabetic sock was worn, the peak plantar pressure in middle forefoot area was significantly lower than when the protective sock with functional insoles were worn. Therefore, the design of the forefoot area of the insole, especially position of metatarsal pad, and the selection of the material should be changed, considering the common ulceration site of diabetic ulcers.

Neuropathic foot ulcers are common in the first, second, and third metatarsal heads, and ulceration may be caused by Charcot's foot deformity with collapsing of the midfoot arch due to limitation of ankle joint.[16] In previous studies on common sites of foot ulceration, protective sock with functional insoles were constructed with arch and metatarsal head supports to distribute the pressure over the foot during walking. The results of this study showed that the peak plantar pressure in the lateral rearfoot area was significantly decreased, because the cushioning of the heel area of the insole decreased the impact of heel strikes when walking. In contrast, the peak plantar pressure was significantly increased at the medial midfoot. In a study by Farzadi et al.[17] with similar results to this study, the peak plantar pressure on the medial part of the midfoot was significantly increased while wearing foot orthoses with arch support. They noted that the arch support reduced the effects of peak plantar pressure in the metatarsal head located at the forefoot. However, this study showed that protective sock with functional insoles significantly increased the peak plantar pressure on the forefoot at the metatarsal head compared to diabetic sock. Design changes are needed to reduce the peak plantar pressure on the forefoot by changing the height and angle of the arch support of the insole combined with the sock.

In previous studies, a metatarsal pad was placed at the proximal site of the metatarsal bone for each subject during running and walking, thus achieving a significant reduction of peak plantar pressure on the forefoot.[18-20] However, the peak plantar pressure on the middle forefoot in protective sock with functional insoles was increased by 5.65% compared to that in diabetic sock. These differences may be due to a variety of underlying differences, such as between subjects, shoes, and the position of the metatarsal head. Hsi et al.[19] reported that optimal plantar pressure reduction at the metatarsal head can be achieved by locating a metatarsal pad directly on the proximal site of the metatarsal head. In previous studies, metatarsal pads were adjusted according to the position of the metatarsal head of each subject, and attached to the existing insole. In this study, we placed the transverse arch support in the forefoot of the insole; however, this did not achieve optimal positioning owing to the diversity of the anatomical locations of the metatarsal heads among the subjects. Another reason is that, due to limitations of the measuring equipment, it was necessary to analyze the plantar pressure on the metatarsal heads, rather than on the full forefoot. Future studies are needed to measure the peak plantar pressure by attaching pressure sensors directly to the metatarsal heads, to measure the pressure on the actual metatarsal head when wearing sock with functional insoles.

Diabetic sock should have antibacterial effects, promote good blood circulation, prevent skin dryness, and use a seamless design. Previous studies have examined changes in skin moisture and temperature, as well as plantar pressure, to assess the efficacy of diabetic sock. In a 6-week randomized trial, to increase skin moisture content, a new nanotechnology-based sock design, consisting of synthetic polyamide fibers containing microcapsules of emollient, was introduced. Yick et al.[21] reported increased skin temperature and humidity with protective sock in two diabetic patients. Although we investigated peak plantar pressure in this study, which is the main cause of foot ulceration, it will be necessary in the future to investigate changes in skin moisture and temperature when wearing sock with functional insoles.

A limitation of our study was the brevity of the period during which the protective sock were worn. In this study, plantar pressure was measured immediately after wearing the protective sock with functional insoles, but the long-term effects were not assessed. In future studies, diabetes patients should be evaluated not only for changes in plantar pressure, but also for the incidence of diabetic ulcers after prolonged use compared to the use of conventional diabetic sock.

The purpose of this study was to compare peak plantar pressure while walking between two conditions: wearing diabetic sock, and wearing protective sock with functional insoles. The protective sock with functional insoles reduced plantar pressure in the rearfoot and supported the medial longitudinal arch; however, they significantly increased the peak plantar pressure of the middle forefoot. Therefore, it is necessary to change the position of metatarsal pad in the insole design of forefoot area to prevent diabetic foot ulceration.

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