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Research Paper

Comparison of plantar pressure in three types of insole given to patients with diabetes at risk of developing foot ulcers – A two-year, randomized trial☆

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ABSTRACT

Background: Special insoles and shoes designed to prevent foot ulcers caused by repetitive high pressures are recommended for patients with diabetes who have any of the following risk factors: neuropathy; peripheral vascular disease; foot deformities; previous ulcers; amputation; and skin pathologies. However, there is a need for increased knowledge regarding: a) differences in the peak pressure (PP) and pressure time integral (PTI) for different types of insoles; and b) the properties of the pressure distribution for insoles used over a period of several months. We present the results of a randomized trial to compare the plantar pressures of three commonly used insoles.
Objectives: The primary objective was to compare the PP and PTI between three types of insoles. The secondary objective was to explore the long-term pattern of peak plantar pressure distribution and variations in specific regions of interest (ROI). The tertiary objective was to investigate the impacts of insole adjustments, how much the insoles were used, and the levels of patient satisfaction.
Methods: In a 2-year trial, 114 patients with type 1 ($N = 31$) or type 2 ($N = 83$) diabetes (62 men and 52 women; mean age, 57.7 ± 15.4 years; duration of diabetes, 12.3 ± 11.2 years; neuropathy, 38%), were randomized to be supplied with one of three different insoles. The ethylene vinyl acetate (EVA) insoles were used in outdoor walking shoes. The 35 EVA group ($N = 39$) received soft custom-made insoles composed of EVA of 35 shore A hardness, the 55 EVA group ($N = 37$) received custom-made insoles composed of EVA of 55 shore hardness, and the control group ($N = 38$) received prefabricated insoles composed of a hard core with a top layer of soft 12 shore hardness microfiber. Using F-Scan®, the in-shoe plantar pressures were measured at seven ROI (hallux, metatarsal head 1, metatarsal head 2, metatarsal head 4, metatarsal head 5, lateral aspect of the mid-foot, heel) on five occasions during the study period. The plantar-pressure variables used were PP (main outcome) and PTI. The plantar patterns of load were explored, satisfaction and usage of the insoles were rated by the participants, and insole adjustments were recorded.
Results: A mixed model analysis estimated lower PP values in the heel regions for the 35 EVA and 55 EVA insoles (171 ± 13 and 161 ± 13 kPa, respectively) than for the prefabricated insoles (234 ± 10 kPa) ($p < 0.001$). Also for some of the other six ROI indications of difference in PP or PTI could be observed. The redistribution of peak plantar pressure for all of the insoles, was stable at the mid-foot, while the proportion of load on the distal area changed during the study period According to the self-reported answers (scale, 0–100), the average usage of the insoles was rated as 79 and satisfaction was rated as 85 ($N = 75$). Thirty-two percent of the subjects had not received foot care. Fourteen adjustments to insoles were made during the study period, and 86 pairs of insoles were exchanged due to wear, with 49% being exchanged in the 35 EVA group.

Abbreviations: EVA, ethylene vinyl acetate; 35 EVA, 35 shore EVA insoles; 55 EVA, 55 shore EVA insoles; ROI, region of interest; MTH1, metatarsal head 1; MTH2, metatarsal head 2; MTH4, metatarsal head 4; MTH5, metatarsal head 5; PP, peak pressure; PTI, pressure time integral.

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Conclusions: Custom-made insoles used in combination with stable walking shoes gave lower pressures at the heel region. The variation makes it difficult to detect a systematic difference in plantar pressure for the 6 ROI, if such a difference indeed exists. The levels of satisfaction and usage for all the insoles tested were high. The insoles maintained their pressure redistribution properties over long periods, and few adjustments were needed.

Introduction

The effective prevention of foot ulcers in the 347 million people around the world who are diagnosed with diabetes can be achieved with appropriate footwear [1]. Overall, 50%–86% of lower limb amputations in patients with diabetes are preceded by foot ulcers [2–4], which are often caused by ill-fitting footwear [5,6]. The prevalence of foot ulcers is 3%–10% [7–9], and neuropathy, peripheral vascular disease, previous ulcers or amputation, skin pathology, and high plantar pressure due to foot deformities have been identified as risk factors for the onset of foot ulcers [10–15]. The international recommendations for preventing diabetic foot ulcers includes the prescription of appropriate footwear (insoles and shoes), foot care, regular foot checks, and education [5]. These preventive steps have been proven to have positive effects on patient quality of life and in reducing healthcare expenditure [16–18]. However, there is a need for long-term studies in which the pressure redistribution capacities of different types of insoles are compared [19–21]. There is also a need for a global consensus on how to interpret the results from in-shoe pressure measurement devices [22].

Previous research has shown that high plantar pressure can be reduced through the use of custom-made or contoured insoles, in combination with special footwear [23–26]. It is widely debated among clinicians whether or not: (i) all patients with diabetes should have custom-made insoles; and (ii) custom-made insoles constructed from softer material are more effective in reducing the pressures in areas where there is a high risk of an ulcer development. Using an in-shoe pressure measurement technique, new insights may be obtained as to plantar pressure distribution, which will enable the formulation of recommendations related to the optimal prescription of insoles. This paper presents the results of a study in which patients with diabetes were given different types of insoles and the impacts on plantar pressure were evaluated. The patients were followed for 2 years with regard to differences in the peak pressure (PP) and pressure time integral (PTI) for different types of insoles, and additional information, e.g., levels of patient satisfaction with the insoles, was recorded at the end of the study.

Several studies on this topic have been performed in recent years. The first randomized trial, which was conducted by Paton and colleagues in 2012, included 119 patients with diabetes (96% with type 1) and neuropathy [27] and compared custom-made insoles with prefabricated insoles. The material used for both types of insoles consisted of a 3-mm-thick EVA base (medium density), with a top cover of 6-mm-thick Poron®. Their results showed no significant differences in peak plantar pressure between the different types of insoles, as measured with the F-Scan in-shoe measurement system. However, the PTI values during walking were lower for the custom-made insoles than for the prefabricated in the forefoot area.

Bus et al. [28] and Owings et al. [29] measured plantar pressure in cross-sectional studies using the Pedar® shoe-pressure measuring system. Bus et al. [28] studied 20 patients with diabetic neuropathy and foot deformities and showed that custom-made CAD-CAM manufactured insoles (composed of urethane foam over a 2-mm base with a 0.7-mm top cover) significantly reduced the PP and force-time integrals at the heel and first metatarsal head, as compared with a flat insole made of open-cell polyurethane 0.95 mm. These two types of insoles were tested in super-depth shoes.

Owing et al. [29] established a threshold value (207 kPa) for plantar pressure, and they recommended this value as the upper limit that should not be exceeded if ulcer recurrence was to be avoided. These results were obtained from a group of 49 patients with diabetes and neuropathy who used their own shoes during the study period. In the same study, the mean barefoot plantar peak pressure measured with the Emed® platform was 566 kPa.

The primary objective of the present study was to compare the peak pressures (PP), maximal peak pressures (maxPP) and pressure time integrals (PTI) for three types of commonly used insoles in a cohort of diabetic patients with or without neuropathy. The plantar pressure variables were studied for seven regions of interest (ROI). The secondary objective involved exploring the redistribution patterns of the average peak plantar pressures between the ROI, by studying the different sources of variations in the data and describing the insoles, adjustments, the frequencies of insole use, and the levels of patient satisfaction.

Subjects and methods

We performed a randomized, controlled trial that comprised patients with type 1 or type 2 diabetes who were referred to the Department of Prosthetics and Orthotics at Sahlgrenska University Hospital, Gothenburg, Sweden. The patients were supplied with insoles and shoes. Data collection and pressure measurements were performed in collaboration with the Gait Laboratory, Lundberg Laboratory for Orthopaedic Research, located at the same hospital. Recruitment took place between January 2008 and September 2009, and the patients were followed for 2 years, with examinations at approximately 6-month intervals. In line with regional guidelines and prevention strategies, the patients who were referred to be supplied with insoles and shoes were those who showed clinical signs of distal neuropathy or angiopathy, had a history of a previous ulcers or amputation, and had foot deformities or foot pathologies [30]. A total of 235 participants met the primary criteria for study eligibility, which were: $\geq$18 years of age; diagnosis of diabetes; ability to walk unaided; ability to understand the Swedish language; no present foot ulcers and being first-time visitors. Patients who were included in the study were randomly allocated to one of the following three interventions: (i) custom-made insoles composed of ethylene vinyl acetate (EVA) with a hardness of 35 shore A (35 EVA group; $N = 39$); (ii) custom-made insoles composed of EVA of 55 shore A hardness (55 EVA group; $N = 37$); and (iii) prefabricated insoles (control group; $N = 38$). The 35 shore A EVA is softer than the 55 shore EVA. A randomization with sealed envelopes (38 in each group) was performed prior study start prepared by the researchers at Lundberg Laboratory for Orthopaedic Research. The allocation was concealed until assignment occurred and the technician was informed of the assigned intervention. A mistake at the Department of Prosthetics and Orthotics at study start resulted that one