The Impact of Custom Made Insoles on the Plantar Pressure of Diabetic Foot

Saleh S. Altayyar*1

*For correspondence stayyar@ksu.edu.sa

1Biomedical Technology Department, College of Applied Medical Sciences, King Saud University, Riyadh, Saudi Arabia

Abstract

Diabetes mellitus is a common disease that effect many organs of the body and can also cause serious adverse effect on the foot. Diabetic foot complications range from atrophy and weakness of foot intrinsic muscles, abnormal walking pattern, neuropathy and foot ulcers. Severe cases of diabetic foot ulcers can result in amputation. Custom-made insoles are one of the foot care recommendations for patients with diabetic foot, as they help to distribute the plantar pressure and reduce the risk of ulceration.

The objective of this study is to examine the impact of custom made insoles on the plantar pressure in 64 diabetic subjects (32 females and 32 males without any foot ulceration) by comparing the peak plantar pressure during bare foot walking with that while using custom made insoles.

The statistical analyses indicate a significant impact of custom made insoles on the plantar pressure of both female and male subjects. The female subjects showed 84.7% and 84.5% reduction in the right and left foot average peak plantar pressure respectively, and the male subjects experienced a reduction of 77.6% and 76.5% in the average peak plantar pressure of the right and left foot, respectively. Custom made insoles can reduce the plantar pressure of diabetic foot and thus, can reduce the risk of diabetic foot ulcers related to uneven distribution of plantar pressure.

Keywords: Plantar Pressure, Custom made insoles, diabetic foot

الملخص

يعتبر مرض السكري احد الأمراض الشائعة وله تاثير على العديد من اعضاء الجسم. لمرض السكري تاثير بالغ على القدم حيث تتباين مشاكل القدم السكرية من ضمور وضعف العضلات الداخلية ، وخلل في المشي ،وألإعتلال العصبي ، وتقرحات في القدم قد تؤدي إلى البتر. قد تؤدي تقرحات القدم السكرية الحادة إلى البتر. تعتبر الحشوات الطبية من احد اهم نصائح التوعية الصحية بالقدم السكرية ، حيث انها تساعد على إعادة توزيع ضغط الوزن على باطن القدم مما يساهم في خفض نسبة خطر الإصابة بتقرحات القدم السكرية.

تهدف هذه الدراسة إلى دراسة أثر الحشوات الطبية المصنعة خصيصا للمريض على ضغط الوزن على باطن القدم على ٦٤ عينة من مرضى السكري (٣٢ إمراة و٣٢ رجل ممن ليس لديهم تقرحات بالقدم) من خلال مقارنة ضغط الوزن على باطن القدم خلال المشي حافي القدمين مع الضغط على باطن القدم خلال المشي باستخدام الحشوات الطبية المصنعة خصيصا لكل شخص.

أكدت التحايل الإحصائية وجود علاقة وتاثير قوي للحشوات الطبية على ضغط الوزن على باطن القدم لدى العينتين من النساء والرجال ، حيث ساهمت الحشوات الطبية في خفض متوسط ضغط الوزن على باطن القدم لدى النساء بنسبة ٪84.7 في القدم اليمنى و ٪84.5 في القدم االيسرى في حين كانت النسبة لدى الرجال ٪77.6 في القدم اليمنى و ٪76.5في القدم اليسرى.

قد تساعد الحشوات الطبية على خفض ضغط الوزن على باطن القدم السكرية والذي سيساهم في خفض خطر الإصابة بتقرحات القدم السكرية الناتج من االخلل في توزيع الضغط على باطن القدم

الكلمات الدلالية: ضغط الوزن على باطن القدم ، الحشوات الطبية المصنعة خصيصا للمريض، القدم السكرية

Introduction

Diabetes mellitus is a common disease that can develop either from the lack of insulin production in the body or due to the body's insulin inability to perform its normal function. Diabetes Mellitus affects approximately 15% of the population over the age of 65 in developed countries[1]. Twenty to fifty percent of individuals with diabetes of more than 10 years will have symmetrical distal sensory neuropathy resulting in impaired sensation in lower extremity[2]. This can lead to abnormal weight bearing pattern on the planter surface of the foot, which in the long run can result in ulceration[3]. Foot constitutes 5% of the body surface, supports 95% of the body weight and absorbs the ground impact force during gait [4, 5]. Neuropathic ulcerations result from repetitive stress over areas of high pressure on the planter surface of the foot [6]. Foot ulceration is the most common cause of amputation in diabetic patients[7]. It has been reported that 85% of diabetes related lower extremity amputations are preceded by ulceration[8]. An increased dynamic foot pressure is among the identified risk factors in the formation of diabetic foot ulcer [9-16]. Foot care and proper shoes are the initial standard treatment protocol for diabetic feet at risk[17].

Diabetic neuropathy usually leads to a biomechanical abnormalities resulting in abnormal plantar foot pressure[18]. The risk of foot ulcer increases in patients who have a combination of foot deformity and neuropathy[18]. Most of the foot ulcers and injuries occur through a foot deformity such as prominent metatarsal heads or clawed toes subjected to repetitive elevated plantar pressure and shear stress in the presence of neuropathy[19]. Foot pathologies can alter foot function, resulting impaired gait during daily activity, and severely affecting quality of life[18]. These pathologies are usually painful due to high or abnormal plantar pressure, which can causes asymmetrical pressure distribution between the two feet[20]. Motor neuropathy affects the muscles, causing abnormal force distribution during walking resulting reactive thickening of skin (callus) at sites of abnormal load, the callus leads to breakdown of skin and subcutaneous tissue, resulting in a neuropathic ulcer[18]. The risk of a diabetic person developing a foot ulcer is as high as 25% [17].

Objective

The objective of this study is to assess the impact of custom made insoles on the plantar pressure of diabetic subjects without any foot ulceration.

Methodology

A total of 64 diabetic subjects (32 female subjects; age 50.5 ± 13.26 years, weight 76.79 ± 15.6 kg) and 32 male subjects; age 45.84 ± 10.88 years, weight 87.14 ± 18.73 kg) participated in this study. They were randomly selected from Albusmah Center (Riyadh, Saudi Arabia). Each subject provided an informed consent.

Procedures

Each subject's height and weight (without shoes & socks and in light clothing) was measured using mechanical scale. Dynamic plantar pressure, force, and contact area were measured using a portable platform NOVEL E-med ST (2 sensors / cm^2), as shown in Figure 1. While looking straight, the subjects were asked to walk in a straight line without targeting the pressure platform. Each subject stepped onto the pressure platform with their first step landing in the centre of the pressure platform and to ensure repeatability, continued to walk for 10 steps (5 steps each foot "Right and Left"). Each subject was fitted with a custom made insoles, especially designed after detailed assessment of her/his plantar pressure profile and foot biomechanics. Later in shoe plantar pressure was measured for each subject while walking with custom made insoles using Pedar Inshoe System, as shown in Figure 2.

Data analysis

Descriptive analysis was done to calculate mean and standard deviation. Paired t-test was used to compare the plantar pressure during barefoot and while using custom made insoles. In addition, regression analysis was performed for estimating the relationships among the studied variables. Level of significance was taken at $p<0.05$.

Results

Dynamic peak plantar pressure of 32 female and 32 male diabetic subjects was obtained for both (bare foot and insole measurements), and was analysed, as shown in Table 1. The average peak plantar pressure significantly decreased when using custom made insoles compared to bare foot. For the female subjects, the average peak plantar pressure of the right foot when walking bare foot was 640.26 Kpa. Whereas the corresponding value while walking with custom made insoles was 98.22 Kpa. Thus, there was 84.7% reduction in the average peak plantar pressure with the use of custom made insoles. Similarly, the left foot average peak plantar pressure dropped from 671.82 Kpa when walking bare foot to 104.4 Kpa while using the custom made insoles (84.5% reduction). The male subjects showed less reduction that those of females. The right foot average peak plantar pressure when walking bare foot was reduced from 621.56 Kpa to 139.52 Kpa when walking using custom made insoles (77.6% reduction), and left foot average peak plantar pressure dropped from 555.47 Kpa when walking bare foot to 130.38 Kpa while using the custom made insoles (76.5% reduction), as shown in Table 2.

Figure 3, 4, 5, and 6 showed a comparison of peak plantar pressure during barefoot and using custom made insoles, for all female (n=32) and male (n=32) subjects. The results clearly showed a consistency in the reduction of plantar pressure when using custom made insoles for all subjects. Results of paired samples t-test indicated highly significant relationship between the peak plantar pressure when walking bare foot and the peak plantar

pressure when walking using custom made insoles. Table 3 showed the summary output of the statistical analysis for male subjects showing a p-value of 0.0019, similarly Table 4 showed the summary output of the statistical analysis for female subjects which indicate a p-value of 0.0316. This clearly demonstrates a strong positive relation between the uses of custom made insoles and reduction in the peak plantar pressure.

Discussion

Neuropathy is one of the serious complications of diabetic foot, resulting in the loss of sensory feedback[18]. In this study, the impact of custom made insoles on the plantar pressure of diabetic female and male subjects was examined, by analysing the dynamic peak plantar pressure when walking bare foot and also walking with custom made insoles. The statistical analysis indicated a strong significant impact of custom made insoles on the plantar pressure of both female and male subjects. There was a significant reduction in the peak plantar pressure for both female and male subject, which constitutes 84.7% and 84.5 % for female right and left foot respectively. Similarly for the male subjects, the corresponding values for the right and left foot were 77.6% and 76.5%, respectively.

The results in the present study were in agreement with previous studies. Jung et al.[21] reported significantly increased contacting foot surfaces and significantly reduced highest peak pressure and the mean pressure when insole was used. Similarly, Chen et al.[22] reported that the total contact insoles was able to reduce high pressures at regions such as heel and metatarsal heads and can redistribute the pressure to the midfoot region. In addition, Choi et al.[23] reported that the plantar foot pressure concentrated in certain parts was reduced by custom-made insoles. Furthermore, Bus et al.[24] reported that the custom-made insoles were more effective compared to flat insoles in reducing the pressure at first metatarsal head region.

In conclusion, custom made insoles help

Table 1: Average Peak Plantar Pressure (Kpa)

	Right Barefoot	Left Barefoot	Right In-shoe	Left In-shoe
Female	640.26	671.82	98.22	104.4
Male	621.56	555.47	139.52	130.38

Table 2: Percentage Reduction in Peak Plantar Pressure due to Custom Made Insoles

	Right Foot	Left Foot
Female	84.7%	84.5%
Male	77.6%	76.5%



Figure1: E-Med Platform system



Figure 2: Pedar Inshoe System

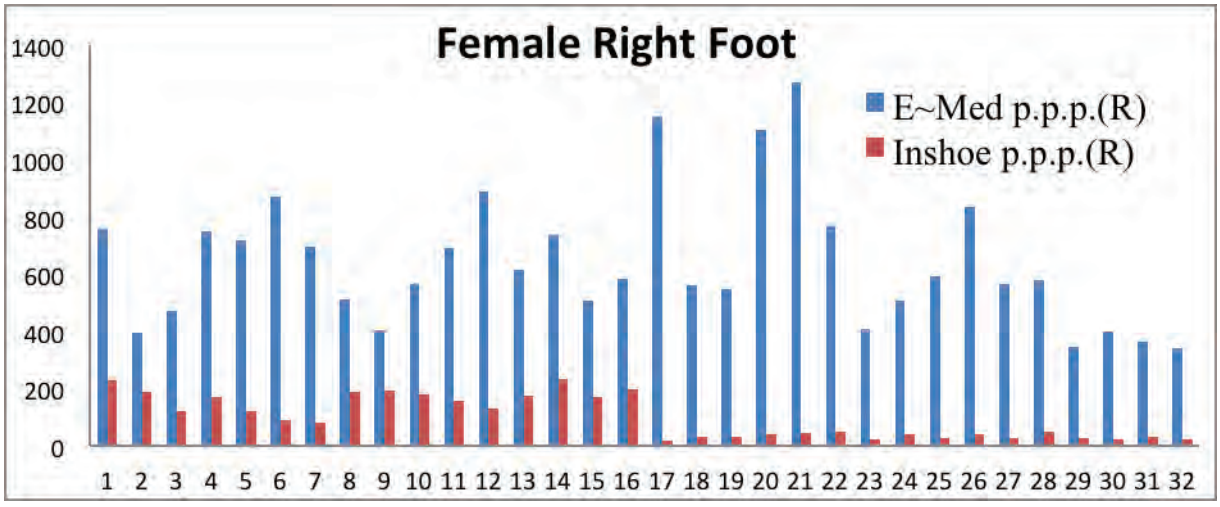


Figure 3: Comparison of barefoot (e-med) and in-shoe peak plantar pressure for the female right foot

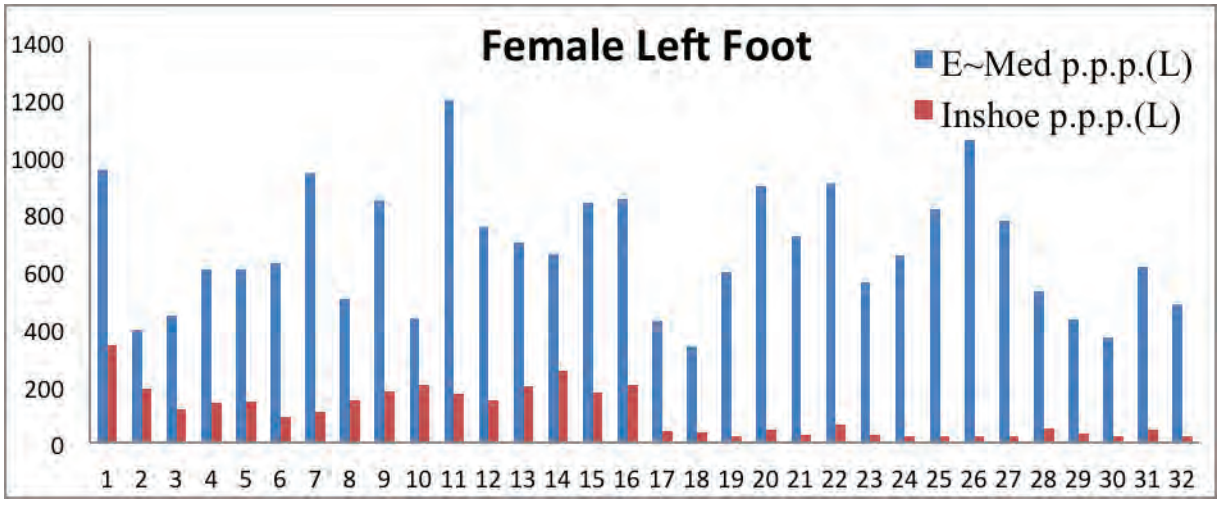


Figure 4: Comparison of barefoot (e-med) and in-shoe peak plantar pressure for the female left foot

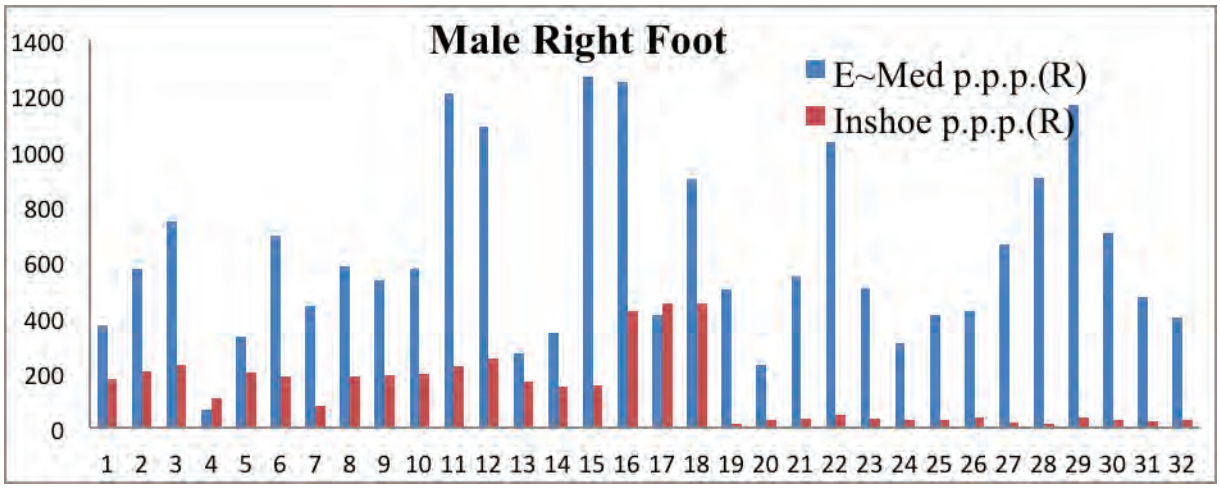


Figure 5: Comparison of barefoot (e-med) and in-shoe peak plantar pressure for the male right foot

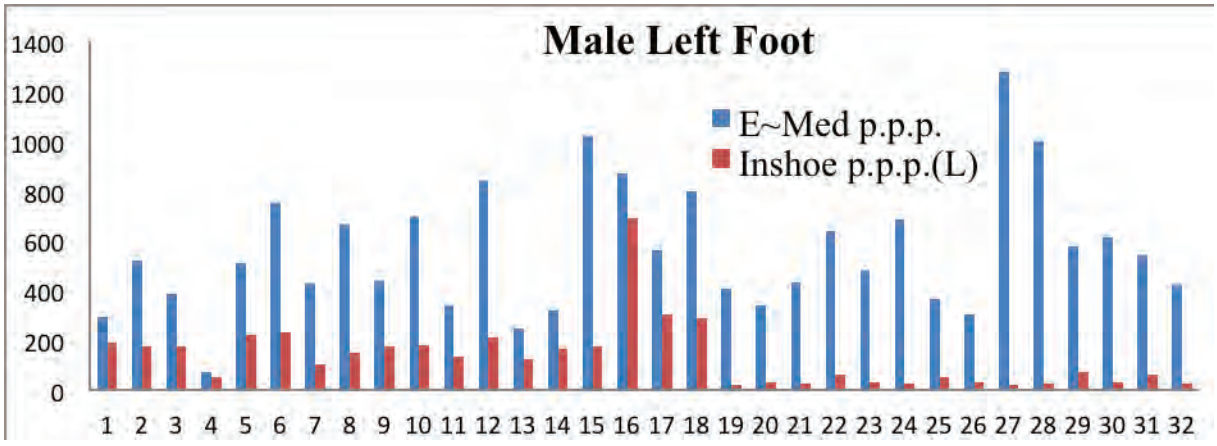


Figure 6: Comparison of barefoot (e-med) and in-shoe peak plantar pressure for the male left foot

reduce the average peak plantar pressure and therefore, reduce the risk of diabetic foot ulceration related to elevated plantar pressure in diabetic patients in general and those with neuropathy in particular. The custom-made insoles can help to protect the foot from elevated planter pressure and thus improve the quality of life of diabetic patients by helping them walk safely with reduced risk of foot ulceration.

Recommendations

Based on the findings of this study, it is highly recommended that diabetic patients be provided with custom-made insoles to protect their feet from ulceration and reduce the possible risk of amputation. This practice can provide them with better quality of life, and at the same time can reduce the burden on healthcare system by reducing hospitalization time and amputation rate.

References:

[1].Albert SF, Chen WY. Rigid Foot Orthoses in the Treatment of the Neuropathic Diabetic Foot. Lower Extremity 1996;3(2):97 – 105.

[2].Cavanagh PR, Simoneau GG, Ulbrecht JS. Ulceration, unsteadiness, and uncertainty: The biomechanical consequence of diabetes mellitus. J Biochech 1992;26(Suppl 1):23 – 40.

[3].Boulton AJ, Kirsner RS, Vileikyte L. Clinical practice. Neuropathic diabetic foot ulcers. N Engl J Med 2004;351:48–55.

[4].Ramanathan AK, Kiran P, Arnold GP, Wang E, Abboud RJ. Repeatability of the pedar-X in-shoe pressure measuring system. Foot and Ankle Surg 2010; 16:70 – 73.

[5].Kim Y, Kim S, Son J, Jeong B. Kinetic role of the metatarsophalangeal joint in normal walking: Joint moment and power. Int J Precis Eng Manuf. 2012;13:1481–5.

[6].Reiber GE, Vileikyte L, Boyko EJ, del Aguila M, Smith DG, Lavery LA, et al. Causal pathways for incident lower-extremity ulcers in patients with diabetes from two settings. Diabetes Care 1999;22:157–62.

[7].Catanzariti AR, Haverstock BD, Grossman JP, Mendicino RW. Off-loading techniques in the treatment of diabetic plantar neuropathic foot ulceration. Adv Wound Care. 1999;12(9):452-8.

[8].Moxey PW, Gog)alniceanu P, Hinchliffe RJ, Loftus IM, Jones KJ, Thompson MM, et al. Lower extremity amputations--a review of global variability in incidence. Diabet Med. 2011; 28(10):1144-53.

[9].Armstrong DG, Lavery LA, Vela SA, Quebedeaux TL, Fleischli JG. choosing a practical screening instrument to identify patients at risk for diabetic foot ulceration. Arch Intern Med 1998; 158:289-92.

[10]. LoGerfo FW. Vascular disease, matrix abnormalities, and neuropathy; implications for limb salvage in diabetes mellitus. J Vasc Surg 1987;5:793-6.

[11]. Payne CB. Biomechanics of the foot in diabetes mellitus: some theoretical considerations. J Am Podiatr Med Assoc 1998; 88:285-9.

[12]. Veves A. Sarnow MR, Giurini JM, Rosenblum BI, Lyons TE, Chrzan JS, et al. Differences in joint mobility and foot pressures between black and white diabetic patients. Diabet. Med 1995; 12:585-9.

[13]. Stess RM, Jensen SR, Mirmiran R. The role of dynamic plantar pressures in diabetic foot ulcers. Diabetes Care 1997; 20:855-8.

[14]. Hill MN, Feldman HI, Hilton SC, Holechek MJ, Ylitalo M, Benedict GW. Risk of foot complications in long term diabetic patients with and without ESRD: a preliminary study. ANNA J 1996; 23:381-6.

[15]. Helm PA, Walker SC, Pulliam GF. Recurrence of neuropathic ulceration following healing in a total contact cast.

Arch Phys Med Rehabil 1991; 72:967-70.

[16]. Moss SE, Klein R, Klein BEK. The prevalence and incidence of lower extremity amputation in a diabetic population. Arch Intern Med 1992;152:610-6.

[17]. Vuorisalo S, Venermo M, Lepantalo M. Treatment of diabetic foot ulcers. J Cardiovasc Surg (Torino). 2009;50(3):275-91.

[18]. Alexiadou K, Doupis J. Management of diabetic foot ulcers. Diabetes Ther. 2012;3(1):4. doi: 10.1007/s13300-012-0004-9.

[19]. Apelqvist J, Bakker K, van Houtum WH, Nabuurs-Franssen MH, Schaper NC. International consensus and practical guidelines on the management and the prevention of the diabetic foot. International Working Group on the Diabetic Foot. Diabetes Metab Res Rev. 2000;16 Suppl 1:S84-92.

[20]. Apelqvist J, Bakker K, van Houtum WH, Schaper NC; International Working Group on the Diabetic Foot (IWGDF) Editorial Board. Practical guidelines on the management and prevention of the diabetic foot: based upon the International Consensus on the Diabetic Foot (2007) Prepared by the International Working Group on the Diabetic Foot. Diabetes Metab Res Rev. 2008 May-Jun;24 Suppl 1:S181-7. doi: 10.1002/dmrr.848.

[21]. Jung JY, Kim JH, Kim K, Trieu PH, Won YG, Kwon DK, Kim JJ. Evaluation of Insole-equipped Ankle Foot Orthosis for Effect on Gait based on Biomechanical Analysis. Korean Journal of Sport Biomechanics 2010; 20:469-477.

[22]. Chen WP, Ju CW, Tang FT. Effects of total contact insoles on the plantar stress redistribution: a finite element analysis. Clin Biomech (Bristol, Avon). 2003;18(6):S17-24.

[23]. Choi JK, Cha EJ, Kim KA, Won Y, Kim JJ. Effects of custom-made insoles on idiopathic pes cavus foot during walking. Biomed Mater Eng. 2015;26 Suppl 1:S705-15. doi: 10.3233/BME-151362.

[24]. Bus SA, Ulbrecht JS, Cavanagh PR. Pressure relief and load redistribution by custom-made insoles in diabetic patients with neuropathy and foot deformity. Clin Biomech (Bristol, Avon). 2004;19(6):629-38.