บทความวิจัย Original Article

การเปรียบเทียบการกระจายน้ำหนักที่ฝ่าเท้าระหว่างวัสดุที่นำเข้ากับวัสดุภายในประเทศที่ใช้สำหรับการผลิตแผ่นรองเท้าเฉพาะรายในผู้ป่วยเบาหวาน ประเภทที่ 2

วรญา ลายสนิทเสรีกุล[1] กุลภา ศรีสวัสดิ์[2] นวพร ชัชวาลพาณิชย์[2] ศศิธร สุขถมยา[1]

[1]โรงเรียนกายอุปกรณ์สิรินธร คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล

[2]ภาควิชาเวชศาสตร์ฟื้นฟู คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล

Received: November 14, 2021
Revised: December 27, 2021
Accepted: February 19, 2022

บทคัดย่อ

การป้องกันการเกิดแผลที่เท้าในผู้ป่วยเบาหวานทั่วโลกนั้นสามารถทำได้โดยการใช้แผ่นรองเท้าและรองเท้าที่เหมาะสม คำแนะนำสำหรับผู้ป่วยเบาหวานที่มีปัญหาเท้าสำหรับการป้องกันการเกิดแผล ประกอบด้วยการดูแลเท้า การตรวจเท้าอย่างสม่ำเสมอ และการใช้แผ่นรองเท้าร่วมกับรองเท้าที่เหมาะสม การศึกษาที่ผ่านมาแสดงให้เห็นว่า การมีแรงกดสูงที่ฝ่าเท้าสามารถลดลงได้ด้วยการใช้แผ่นรองเท้าแบบเฉพาะรายร่วมกับรองเท้าที่เหมาะสม ในคลินิกเท้าเบาหวานทั่วโลก การเลือกใช้วัสดุต่างๆ ในการผลิตแผ่นรองเท้าแบบเฉพาะราย ขึ้นอยู่กับประสบการณ์ของผู้รักษาและวัสดุที่มีในประเทศนั้นๆ มีการศึกษาจำนวนมากที่เกี่ยวข้องกับการกระจายน้ำหนักที่ฝ่าเท้า โดยการใช้วัสดุในการผลิตแผ่นรองเท้าที่แตกต่างกัน อย่างไรก็ตาม ราคาของวัสดุที่นำเข้ามีราคาที่สูงกว่าเมื่อเปรียบเทียบกับวัสดุในประเทศไทย จุดประสงค์ของงานวิจัยนี้เพื่อเปรียบเทียบการกระจายน้ำหนักที่ฝ่าเท้าระหว่างวัสดุที่นำเข้ากับวัสดุในประเทศที่ใช้สำหรับการผลิตแผ่นรองเท้าเฉพาะรายในผู้ป่วยเบาหวานที่มีความเสี่ยงในการเกิดแผลที่เท้าปานกลางจนถึงสูง การศึกษานี้ศึกษาโดยแบ่งเท้าออกเป็นสี่ส่วนคือ เท้าส่วนหลัง เท้าส่วนกลาง เท้าส่วนหน้า และนิ้วเท้า ซึ่งศึกษาในผู้ป่วยเบาหวานประเภทที่ 2 จำนวน 20 ราย ที่มีการสูญเสียการรับความรู้สึกที่เท้า (neuropathic foot) อาสาสมัครจะได้รับแผ่นรองเท้า 2 แบบ แบบที่หนึ่งคือ แผ่นรองเท้าที่ทำจากวัสดุนำเข้าเป็นชั้นบนสุด Insole P (Plastazote®, Poron and Microcock) และแบบที่สองคือ แผ่นรองเท้าที่ทำจากวัสดุในประเทศเป็นชั้นบนสุด Insole E (Ethylene Vinyl Acetate foam, Poron and Microcock) โดยวัดการกระจายน้ำหนักด้วยเครื่อง foot array scan สี่ส่วนของเท้าระหว่างยืนและเดิน ผลการศึกษาพบว่า ในขณะที่อาสาสมัครยืนบนแผ่นรองเท้าแบบที่หนึ่ง (Insole P) เปรียบเทียบกับแผ่นรองเท้าแบบที่สอง (Insole E) แผ่นรองเท้าแบบที่หนึ่ง (Insole P) มีแรงกดบนฝ่าเท้าน้อยกว่าในทุกๆ บริเวณของฝ่าเท้า ยกเว้นที่เท้าส่วนหลังเท่านั้น อย่างไรก็ตาม ในขณะที่อาสาสมัครยืนบนแผ่นรองเท้าทั้งสองแบบแรงกดที่ได้ไม่มีนัยสำคัญทางสถิติ แต่ในทางกลับกันในขณะที่อาสาสมัครเดินบนแผ่นรองเท้าแบบที่หนึ่ง (Insole P) พบว่าแรงกดบนฝ่าเท้าที่บริเวณเท้าส่วนหน้านั้น มีแรงกดน้อยกว่าแผ่นรองเท้าแบบที่สอง (Insole E) อย่างมีนัยสำคัญทางสถิติ (p=0.023) โดยสรุปแผ่นรองเท้าทั้งสองแบบนั้นสามารถลดแรงกดบนฝ่าเท้าในทุกๆ บริเวณของฝ่าเท้าและยังสามารถช่วยในการกระจายน้ำหนักทั้งขณะยืนและเดินได้ดีในผู้ป่วยเบาหวานประเภทที่ 2

<u>คำสำคัญ:</u> เบาหวานประเภทที่ 2 แผลกดทับที่เกิดจากโรคปลายประสาทเสื่อม แผ่นรองเท้าแบบเฉพาะราย การกระจายน้ำหนักที่ฝ่าเท้า วัสดุที่ใช้ในการผลิตแผ่นรองเท้า

<u>ผู้นิพนธ์ประสานงาน:</u>
กุลภา ศรีสวัสดิ์
ภาควิชาเวชศาสตร์ฟื้นฟู คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล
2 ถนนวังหลัง แขวงอรุณอมรินทร์ เขตบางกอกน้อย กรุงเทพฯ 10700
อีเมล: gulapar@yahoo.com

Comparison of the plantar pressure distribution between imported and local materials used for custom-made foot orthoses in patients with type 2 diabetes

Voraya Laisanitsalekul[1], Gulapar Srisawasdi[2], Navaporn Chadchavalpanichaya[2], Sasithon Sukthomya[1]

[1]Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Siriraj Hospital, Mahidol University

[2]Department of Rehabilitation, Faculty of Medicine Siriraj Hospital, Mahidol University

Abstract

The prevention of foot ulcers in diabetic patients around the world can be achieved by the use of appropriate footwear. The recommendations for diabetic patients who have problems with foot ulcers for the prevention of such ulcers include foot care, regular foot screening, and the use of appropriate footwear. Many previous research studies have shown that high pressure on the plantar surface of the foot can be reduced by the use of custom-made foot orthoses with appropriate shoes. In diabetic foot clinics around the world, the choices of materials used to fabricate custom-made foot orthoses depend on the experience of the therapist and the availability of the materials in that area. There are many studies related to plantar pressure distribution in terms of the different types of material used to fabricate custom-made foot orthoses. However, the cost of imported material is higher when compared to the cost of local materials in Thailand. Consequently, the purpose of this study was to compare the plantar pressure distribution patterns during standing and walking between imported and local materials used to fabricate custom-made foot orthoses in diabetic patients with a moderate to high risk of foot ulcers in four areas of the foot: the hind foot, midfoot, forefoot, and toes. The study was conducted with 20 type 2 diabetic neuropathic participants. The participants received two types of custom-made foot orthoses: Insole P (fabricated from Plastazote®, Poron, and micro-cork) and Insole E (fabricated from ethylene-vinyl acetate foam, Poron, and micro-cork). The maximum plantar pressure and distribution were measured using a foot scan array sensor at the hind foot, midfoot, forefoot, and toes during standing and walking. The results showed Insole P has a lower peak pressure than Insole E in all areas when participants were standing, except the hind foot. But Insole P and Insole E showed no statistically significant differences in all areas. While the participants were walking, Insole P had significantly lower peak plantar pressure in the forefoot as compared to Insole E (p=0.023). In conclusion, Insole P and Insole E could both reduce the peak plantar pressure in all areas of the foot and provide good pressure distribution during both standing and walking for participants with type 2 diabetes.

Keywords: type 2 diabetes, neuropathic foot ulcer, custom-made foot orthosis, plantar pressure, foot orthosis material

Corresponding Author:

Gulapar Srisawasdi

Department of Rehabilitation, Faculty of Medicine Siriraj Hospital, Mahidol University

2 Thanon Wang Lang, Khwaeng Arun Amarin, Bangkok Noi, Bangkok 10700, Thailand.

E-mail: gulapar@yahoo.com

Introduction

The prevention of foot ulcers in diabetic patients around the world can be achieved by the use of appropriate footwear[1]. A previous study about lower limb amputation in diabetic patients showed that peripheral artery disease, peripheral neuropathy, and foot ulcers are independent risk factors for lower limb amputation in diabetic patients[2]. Increasing plantar pressure on the foot can increase the risk of foot ulcers due to deformities of the foot[3]. The recommendations for diabetic patients who experience problems with foot ulcers regarding the prevention of such ulcers include foot care, regular foot screening, and the use of appropriate footwear[4]. Many previous research studies have shown that high pressure at the plantar surface of the foot can be reduced by the use of custom-made foot orthoses with appropriate shoes[5]. In diabetic foot clinics around the world, the choices of materials used to fabricate custom-made foot orthoses depend on the experience of the therapist and the availability of the materials in that area. There is a debate about the most appropriate material and whether soft material can reduce the plantar pressure at areas with a high risk of ulcer development. Data on the plantar pressure distribution can provide the therapist with information on the high-pressure areas where ulcers might form. Also, data on the plantar pressure distribution can help to determine the effects of custom-made orthoses. Hellstrand Tang et al. in 2014[6] studied the plantar pressure with three types of insoles for patients with diabetes, specifically the peak pressure (PP), pressure-time integral (PTI), and the properties of the pressure distribution pattern. After applying the insole interventions, they used mixed model analysis to estimate the lower peak pressure in the heel area with the use of 35 shore ethylene-vinyl acetate (EVA) insoles and 55 shore EVA insoles compared with the use of prefabricated insoles. The distribution of the peak pressure of all the insole types was stable at the midfoot. Also, they found that the load on the distal part changed within the study period according to the patient's self-reporting. There are many studies related to plantar pressure distribution with different types of materials that have been used to fabricate custom-made foot orthoses. Possible materials include local materials and imported materials. However, the cost of imported materials is high compared to the cost of local materials in many countries, such as Thailand. Consequently, this study aimed to evaluate the plantar pressure distribution pattern and ability of the materials to redistribute the plantar pressure to the areas that can tolerate the pressure between imported and local materials used to fabricate custom-made foot orthoses in diabetic patients at moderate to high risk of foot ulcers.

Objectives

The primary objective of this study was to compare the plantar pressure distribution patterns during standing and walking between imported and local materials used to fabricate custom-made foot orthoses in diabetic patients at a moderate to high risk of foot ulcers in four areas of the foot: the hind foot, midfoot, forefoot, and toes. A secondary objective was to compare the material properties of imported and local materials used to fabricate custom-made foot orthoses.

Materials and Methods

This study was an interventional quasi-experimental study. Locally sourced ethylene-vinyl acetate foam (EVA foam) was compared to Plastazote as the standard, but imported, material. In this study, participants received two types of insoles: an Insole cover made from an imported material (Plastazote®) and another insole cover made with a local material (EVA foam) on the top layer, while the other layers of both insoles were the same to control for further variations in the data. The study participants were diabetic type 2 patients at a moderate to high risk of foot ulcers recruited from the DM Foot Clinic, Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Siriraj Hospital. In total, there were 20 participants[7]. The study inclusion were the following criteria:

- Diagnosed with type 2 diabetes and
- Aged more than 18 years old and
- BMI from underweight to Class II obesity (BMI: <18 to 35.0–39.9) and
- Loss of protective sensation (tested by monofilament testing) and foot deformity or
- Peripheral artery disease and foot deformity and
- Can walk independently and
- Can walk following instructions and understand the Thai language

The exclusion criteria were:

- Have an active ulcer or
- Have a history of lower-extremity amputation (minor or major)
- Leg length discrepancy

The withdrawal criteria were:

- While using the interventions, the participant gets an ulcer at the plantar surface of the foot
- Participants have a high risk of falling during the interventions
- Participants want to quit the study

Instrumentation used for measuring the plantar pressure distribution

The study applied the FSA in-shoe system (Vista Medical, Canada)

The FSA in-shoe system comprises three essential parts:

- In-shoe measurement insole
- Monitor display
- Analyzer system

For this study, the in-shoe measurement insole was used to measure the peak pressure and pressure–time integral at the plantar surface of the foot. The in-shoe measurement insole contained 128 measurement sensors per one side operating at a measurement frequency of 100 Hz. The in-shoe measurement insole was placed inside the shoe to be used in the study. The analyzer system was used to analyze and store the data from the testing trials related to the peak pressure. In addition, data could be stored in the program system and printed out later.

Instrumentation used for the compression set

The compression set consisted of:

- Compression plates: comprising a pair of parallel, flat, chromium-plated steel or stainless-steel plates, with the test piece compressed between the faces of the plates.
- Steel spacers: used to provide the required compression; these were of such a size and shape to ensure that contact with the compressed test piece was avoided.
- Clamping device: comprising a simple screw device.

Compression testing

Compression tests were performed to determine the strength of the materials using a Universal Testing Machine (UTM) (Instron 4593), with the crosshead speed set at 5 mm/minute and load on the cell set at 1 kg·N. at 50% strain of the material thickness at baseline.

Cost of local materials (EVA foam)

The EVA foam materials were sourced from Bangkok and nearby provincial marketplaces at a variety of thicknesses and sizes. The material is typically sold in different thicknesses (3, 4, and 5 mm) in 1,000 mm x 2,000 mm sized pieces at a cost of 200 Thai baht (THB) for 3 mm thickness and 250 Thai baht for 4 and 5 mm thickness. The advantage of this material is its reasonable price and the good availability of the material.

Custom-made foot orthoses

The custom-made foot orthoses used in this study were made from imported material (Plastazote: shore A hardness 15–20) on the top layer with micro-cork as the base layer. In this study, the imported material was called "Insole P", see Figure 1, while the local material (EVA shore A hardness 15–20) with micro-cork as the base layer was called "Insole E", see Figure 2. The plantar surface of the participants' feet was captured by the foam impression method and a positive mold was used to form the custom-made foot orthoses, as shown in Figure 3 and Figure 4 .

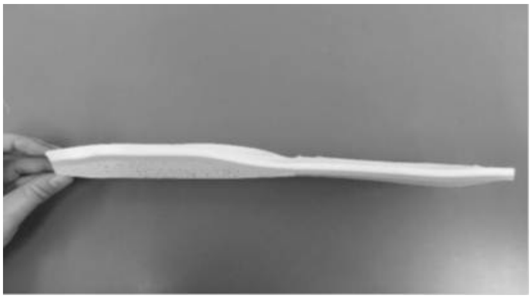

Figure 1 Insole P top layer with Plastazote

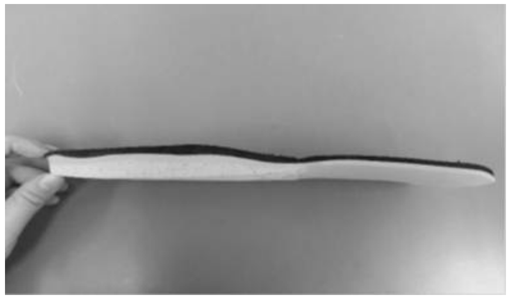

Figure 2 Insole E top layer with EVA foam

Figure 3 Capture of the plantar surface

Figure 4 Plaster mold of the plantar surface of the participant's foot of the participant's foot

Test procedure and data collection

The study participants were asked to stand on the in-shoe plantar pressure device and then walk straight on the walkway for 10 meters while wearing Insole P (Plastazote) or Insole E (EVA foam) inside the comfort shoe at their own self-selected speed of walking. They also had an opportunity to familiarize themselves with the devices and equipment. In the trials, the participants were asked to walk three times to obtain the average of three values for the peak pressure in kiloPascal (kPa). Data were collected during the trials for both the left and right foot while standing and walking. Data were analyzed by SPSS Microsoft Program Windows. Dependent two samples T-test, two tails, and the average of the mean peak pressure were used to analyze the data.

Data analysis

FSA 4.1 software was installed on the computer that was to be used to monitor the data. The four study areas of the foot (the hind foot, midfoot, forefoot, and toes) were divided up manually by the researcher in the program system after taking an image of the foot, in line with Hu et al., 2015[8].

Results

Participants

In total, 20 participants were recruited in the study (comprising 12 men (60%) and 8 women (40%), aged 70.45 ± 13.32 years old). Their body mass index (BMI) was within the normal to obese class II range (27.40 ± 4.84). All the analyses were performed on both left and right feet and there was no significant difference between both the left foot and right foot.

Testing of the material properties

Compression set

Compression set testing was performed using the spacer tool to compress (by 25%) the test materials to 75% of their normal state at 37 ^{0}C for 30 minutes. The materials were first cut into 12 x 12 x 25 mm^{3} pieces and then put into the appropriate sized tools for testing. The pieces were compressed by 25% to 75% of their starting thickness. Next, the test materials were taken out of the tool and then kept at room temperature for 30 minutes. The results showed that Plastazote was more flexible than the EVA foam with a lower compression set percentage (%), but this difference was not significant.

Compression test

After the compression testing was done, the results of the testing showed that when applying more force, the value was higher. Because both Plastazote and the EVA foam had the properties of softness and toughness, the graph of the compressive stress plotted against the compressive strain showed stress and strain curves for both (Figure 5). Regarding the Young's modulus and compressive stress at the maximum load, it was found that the EVA foam had a higher value, about 2 times that of the Plastazote. As a result, EVA foam had more strength compared to Plastazote.

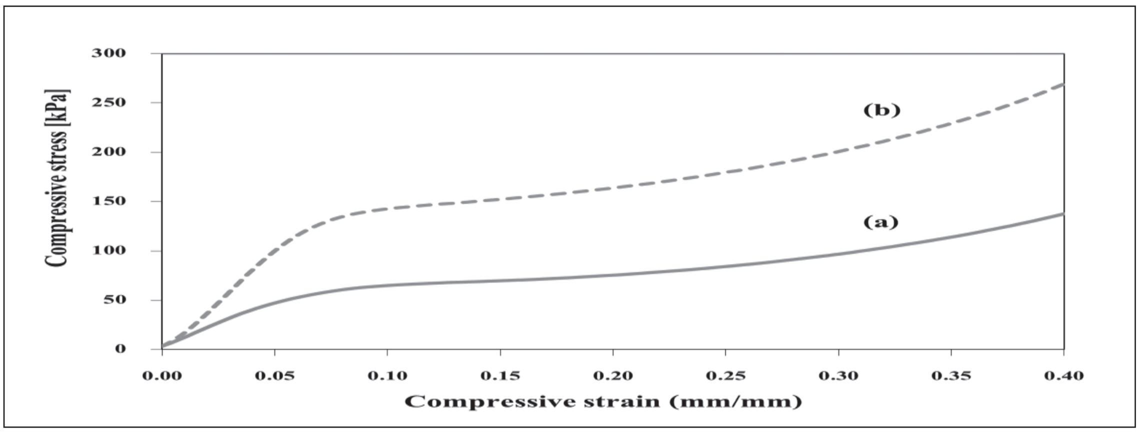

Figure 5 Graph showing the compressive stress and compressive strain curves of Plasazote (a) and EVA foam (b)

Plantar pressure distribution

The maximum peak plantar pressures in each area of the foot when using both Insole P and Insole E are shown in Table 1. When the participants were standing, Insole P had lower peak plantar pressure in all areas of the foot except at the hind foot. During walking when using Insole P, the hind foot, midfoot, and toe areas of the foot had lower peak plantar pressure when compared to Insole E. However, when the participants were walking, the peak plantar pressure with Insole P was significantly different (p=0.023) compared with Insole E at the forefoot area.

Table 1 Mean and standard deviation of the maximum peak plantar pressure in four areas of the foot for participants wearing either Insole P or Insole E during the walking and standing trials

Variable	Activity	Insole type	Hind foot	Midfoot	Forefoot	Toes
Maximum Pressure (kPa)	Standing	Insole P Insole E	68.26 ± 23.78 65.18 ± 24.31 (p=0.353)	62.95 ± 22.67 68.48 ± 27.19 (p=0.181)	46.36 ± 18.27 47.15 ± 15.90 (p=0.769)	20.71 ± 12.72 21.51 ± 13.67 (p=0.634)
Maximum Pressure (kPa)	Walking	Insole P Insole E	115.71 ± 30.85 121.38 ± 36.65 (p=0.230)	97.79 ± 35.54 105.34 ± 37.54 (p=0.222)	89.19 ± 29.78 109.55 ± 36.85 (p=0.023)	44.49 ± 25.25 47.94 ± 27.47 (p=0.427)

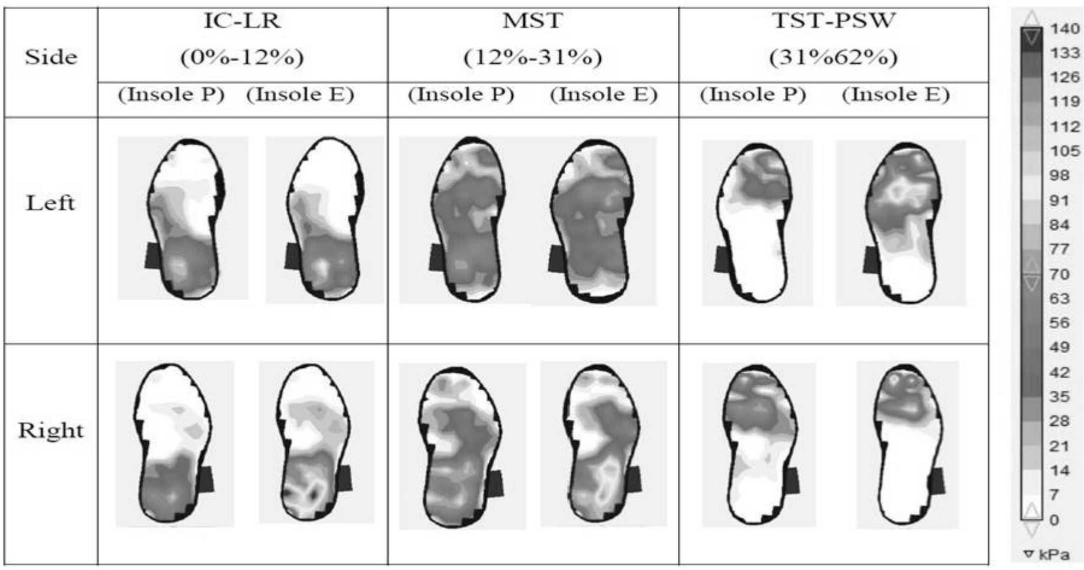

Figure 6 Pressure mapping from during the walking trials with Insole P and Insole E; IC-LR, initial contact to loading response; MST, midstance; and TSW-PSW, terminal stance to pre-swing from a single participant

The plantar pressure distribution mapping performed during the gait cycle with both Insole P and Insole E and for the left and right sides of the foot is shown in Figure 6. The pressure was well distributed with Insole P and Insole E for both the left and right foot (see the scale; where the maximum pressure was not more than 140 kPa). With Insole E, the pressure was higher at all periods of the gait cycle compared to with Insole P. However, both Insole P and Insole E showed no significant differences in pressure.

Discussion

Custom-made foot orthoses are used to reduce plantar pressure in people with a moderate to high ulcer risk and a neuropathic foot. Many studies have been done on such orthoses, including studies performing material testing, such as compression tests,[7] to evaluate the properties of the used materials and to compare which is the most appropriate to use with patients. Also, some studies have been done on the physical properties and have included mechanical testing[9,10]. This study aimed to find the most appropriate materials that have the right properties to distribute and reduce peak plantar pressure in patients with diabetes who also have a neuropathic foot problem. In this study, the researchers chose EVA foam (shore A hardness 15–20) because this material can easily be found in many markets in Thailand and as the cost of this material is cheap. Also, the physical properties of this EVA foam are similar to Plastazote, a commonly used imported but higher cost material. From the results of this study, the researchers found that the physical properties of the materials were quite similar and both could reduce the peak plantar pressure, with no significant differences seen, except in the forefoot area, where Insole P had significantly lower peak plantar pressure. Further study should be done with more participants to have a higher impact.

Conclusion

Both Insole P and Insole E showed no significant differences in maximum peak pressure in the standing trial. In the standing trial, Insole P had lower peak plantar pressure in all areas, except for in the heel area. In the walking trial, Insole P had lower peak plantar pressure in all areas, though a significant difference was only found at the forefoot area when compared to Insole E. EVA foam can be used as low cost alternative to the imported material. Thus, it was demonstrated that custom-made foot orthoses fabricated following the contour shape of the foot can provide and redistribute plantar pressure.

Recommendation

The researchers suggest more long-term experiments are needed to test the participants’ satisfaction level and to see how the plantar pressure distribution changes after long-term use of the devices. The hope is that diabetic foot care can be improved across the globe through better custom-made foot orthoses for patients with type 2 diabetes.

Acknowledgements

This research was financially supported by a Siriraj graduate scholarship, Faculty of Medicine Siriraj Hospital, Mahidol University. We would like to thank the Mtec Company for help evaluating and testing the mechanical properties of the materials. The authors would like to thank DM Foot Clinic at Sirindhorn School of Prosthetics and Orthotics for the participant recruitment and for use of their facilities. Finally, thanks to all participants for their good participation, and thanks to the Faculty of Medicine Siriraj Hospital, Mahidol University, for granting the authors the opportunity to do this research.

References

1. Danaei G, Finucane MM, Lu Y, et al. National, regional, and global trends in fasting plasma glucose and diabetes prevalence since 1980: Systematic analysis of health examination surveys and epidemiological studies with 370 country-years and 2·7 million participants. Lancet 2011;378:31-40.
2. Adler A, Boyko E, Ahroni J, et al. Lower-extremity amputation in diabetes. Diabetes Care 1999;22:1029-35.
3. Fernando ME, Crowther RG, Lazzarini PA, et al. Plantar pressures are higher in cases with diabetic foot ulcers compared to controls despite a longer stance phase duration. BMC Endocr Disord 2016;16.
4. Jakosz N. Book review - IWGDF Guidelines on the prevention and management of diabetic foot disease. Wound Pract Res 2019;27:144.
5. Arts MLJ, Waaijman R, de Haart M, et al. Offloading effect of therapeutic footwear in patients with diabetic neuropathy at high risk for plantar foot ulceration. Diabet Med 2012;29:1534-41.
6. Hellstrand Tang U, Zügner R, Lisovskaja V, et al. 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. J Clin Transl Endocrinol 2014;1:121-32.
7. Nouman M, Dissaneewate T, Leelasamran W, et al. The insole materials influence the plantar pressure distributions in diabetic foot with neuropathy during different walking activities. Gait Posture 2019;74:154-61.
8. Hu X, Li JX, Hong Y, et al. Characteristics of plantar loads in maximum forward lunge tasks in badminton. PLoS One 2015; 10:1-10.
9. Paton JS, Stenhouse EA, Bruce G, et al. A comparison of customised and prefabricated insoles to reduce risk factors for neuropathic diabetic foot ulceration: A participant-blinded randomised controlled trial. J Foot Ankle Res 2012;5:1-11.
10. Burns J, Begg L, Vicaretti M. Comparison of orthotic materials on foot pain, comfort, and plantar pressure in the neuroischemic diabetic foot: A case report. J Am Podiatr Med Assoc 2008;98:143-8.