PSUMJ
PSU MEDICAL JOURNAL

Original Article

Finite Element Approach Towards Selection of Appropriate Materials to Redistribute Peak Plantar Pressure in Diabetic Foot with Neuropathy

Muhammad Nouman, M.Sc.[1], Desmond Y.R. Chong, Ph.D.[2], Surapong Chatpun, Ph.D.[1]

[1]Institute of Biomedical Engineering, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla 90110, Thailand.

[2]Engineering Cluster, Singapore Institute of Technology, 138683, Singapore.

ABSTRACT

Objective: The aim of this study was to assess the effect of customized insole (CMI) variations on plantar pressure in diabetic foot with neuropathy, using finite element analysis (FEA).

Material and Methods: A three-dimensional foot model was constructed using FEA to study the peak contact pressure between the foot and the CMI. Nora® Lunalastike, Ethylene Vinyl Acetate (EVA), Amfit® and TPU were chosen for insole materials; and from these eight CMI models were created. The top surface of the tibia and fibula were fixed, and a displacement of 3 mm was exerted from the ground along with upwards Achilles tendon force.

Results: The peak contact pressure contour showed that a softer material, CMI-A (E = 1.04 MPa), resulted in a better reduction of peak contact pressure compared to a stiffer material; CMI-D (E = 11 MPa). In addition, it was shown that the use of a single material to fabricate the CMI resulted in higher peak contact pressure; with the exception of CMI-A, in comparison to a dual-layer material of CMI-E and CMI-F. Using FEA, can effectively enhance the insole material selection process, without need of a trial and error practice in a clinical setting.

Conclusion: The use of dual materials to fabricate CMIs, with the softer material as a top layer, is beneficial compared to a stiffer top layer material in the reduction of peak plantar pressure for diabetic foot with neuropathy.

Keywords: custom made insole; diabetic foot; finite element analysis; insole materials; peak plantar pressure

Corresponding author: Assist.Prof. Surapong Chatpun, Ph.D.
Institute of Biomedical Engineering, Faculty of Medicine,
Prince of Songkla University, Hat Yai, Songkhla 90110, Thailand.
E-mail: surapong.c@psu.ac.th
doi: 10.31584/psumj.2021247166
https://he01.tci-thaijo.org/index.php/PSUMJ/

PSU Med J 2021;1(2):43-54
Received 15 January 2021
Revised 14 March 2021
Accepted 18 March 2021
Published online 1 July 2021

INTRODUCTION

Diabetic foot ulcer is a frequent complication found in diabetes mellitus, and it has been estimated that 85.0% of all amputations are preceded by foot ulceration and re-ulceration.[1] The lifetime risk of diabetic foot ulceration ranges from 15.0% to 25.0%.[2] Annually, 26 million people with diabetes are effected with diabetic foot ulcers, and its prevalence stands at 6.3% worldwide.[3] Diabetic foot ulceration is a severe, chronic complication resulting from abnormal plantar pressure distribution and neuropathy.[4] Limited joint mobility, foot deformities and previous ulcerations are identified as risk factors for ulcer development.[5] Without appropriate foot care, the lower limb has a higher risk of amputation, due to the prolonged complications of diabetes.[6]

Custom-made insoles (CMIs) are frequently prescribed to relieve peak plantar pressure under bony prominences, so as to prevent ulceration and re-ulceration in the diabetic foot with neuropathy.[7] The success rate of CMIs is associated with the reduction of peak plantar pressure.[8] To attain an ideal CMI, for the diabetic foot with neuropathy, it is important to explore the plantar pressure distribution under the foot. Plantar pressure distribution has been measured by experimental procedures to better understand the biomechanics of diabetic foot along with factors contributing to foot ulcers during gait. However, these experimental procedures are time consuming with varying, uncontrolled variables. Additionally, these varables have resulted in the difficulty of the studies in acquiring reliable results for diabetic foot with neuropathy.[9]

There are different effects of CMI materials on plantar pressure distribution depending on the material stiffness, insole thickness and CMI contour to the foot.[10, 11] Increasing the material stiffness and thickness of the insole enhances stability during gait; however, the cushioning is reduced when increasing the insole stiffness, and stiff insoles are contraindicated towards the diabetic foot.[12, 13] Cushioning is an important factor as it acts as a shock absorber and reduces the impact on joints; especially the ankle, knee and the lower back.[14,15] Ethylene Vinyl Acetate (EVA) is commonly used for the midsole in running shoes, due to the fact that it has good cushioning properties.[16] On the contrary, the stability during gait cannot be achieved by using insoles fabricated from EVA alone. Besides EVA, insoles fabricated from Poron® tend to reduce plantar pressure compared to the shod gait.[10,17] However, using Poron® increases the tendency of abrasion on the plantar surface of the foot. Whilst, there is a vast variety of commercial materials available that claim to reduce the peak plantar pressure, very few materials can be prescribe to the diabetic foot with neuropathy. This is bcause CMIs prescribed in real clinical scenarios are mostly fabricated from multi-density materials for dibetic foot withneuropathy. Finite element analysis (FEA), based on foot models, is potentially significant in understanding foot pathologies and for developing therapeutic interventions.[18] FEA enables an effective evaluation of therapeutic interventions to obtain clinical goals in the selection process of appropriate designs and materials of CMI for ideal performance.[19] Whilst, most researchers focused on single materials used to fabricate an insole with varying hardness, others have used materials selected for diabetic foot that are inappropriate. Additionally, in some cases the designs are not well controlled and are clinically inapplicable.[20]

To enhance the plantar pressure management for the diabetic foot with neuropathy, it is a necessity to select appropriate materials for fabricating CMIs. In addition, the effect of the combination of various materials, that reflect real clinical situations towards prescription of CMIs for the diabetic foot with neuropathy, also need to be studied. Therefore, this study focused on the material properties, by controlling the overall thickness of a custom-made insole for the diabetic foot with neuropathy. A three-dimensional finite element model of the foot was developed in contact with different custom made insoles and the ground. The influence of uniform and multi-layer custom-made insoles on plantar pressure at the loading response phase of the gait cycle were evaluated. The outcome of this analysis will help the researchers to design and select an appropriate material for a desirable plantar pressure distribution for the diabetic foot with neuropathy.

MATERIAL AND METHODS

Finite element model generation

A three-dimensional (3D) FEA model of the left foot was constructed to study the contact pressure between the foot and the CMI. This study was approved by the Human Research Ethics Committee (REC. 63-219-25-2), Faculty of Medicine, Prince of Songkla University, Thailand. Computerized tomography images of the unloaded, left foot (male subject, 57 years old, 84 kg) were imported to the image processing software Mimics version 20 (Materialise, Leuven, Belgium), and a 3D model of the foot bones and encapsulated soft tissue were developed. As, the foot is a complex structure; comprising of 28 bones, 33 joints, 107 ligaments, and 18 muscles[21], our FEA model was therefore simplified to reduce the modeling time and to improve the feasibility of optimization. In this study, 28 bones were fused together as one, whole object. The relative motion between the bone segments was neglected, and the effects of muscles and ligaments were also neglected. The foot model was assembled in Ansys Spaceclaim (Ansys Inc. Pennsylvania, USA). The CMI and the ground were created following the geometry of the foot, as shown in Figure 1.

Material properties

The reconstructed 3D model was imported to a finite element solver Ansys 2019 R1 (Ansys, Inc. Pennsylvania, USA) to predict the plantar pressure distribution with CMI. The foot bones and soft tissues were assumed to be isotropic, and assigned with linear elastic material properties.[22, 23] The selected materials, to design a custom made insole, were those most commonly used in a realistic clinical setup: their properties are listed in Table 1.

The combination of materials to make a dual layer CMI are as follows: CMI-E (Nora® Lunalastike and Amfit®), CMI-F (Nora® Lunalastike and TPU), CMI-G (EVA and Amfit®) and CMI-H (EVA and TPU): as shown in Table 2. Note that the first material in the bracket represents the top layer in contact with the foot, and the second material represents the base layer in contact with the ground.

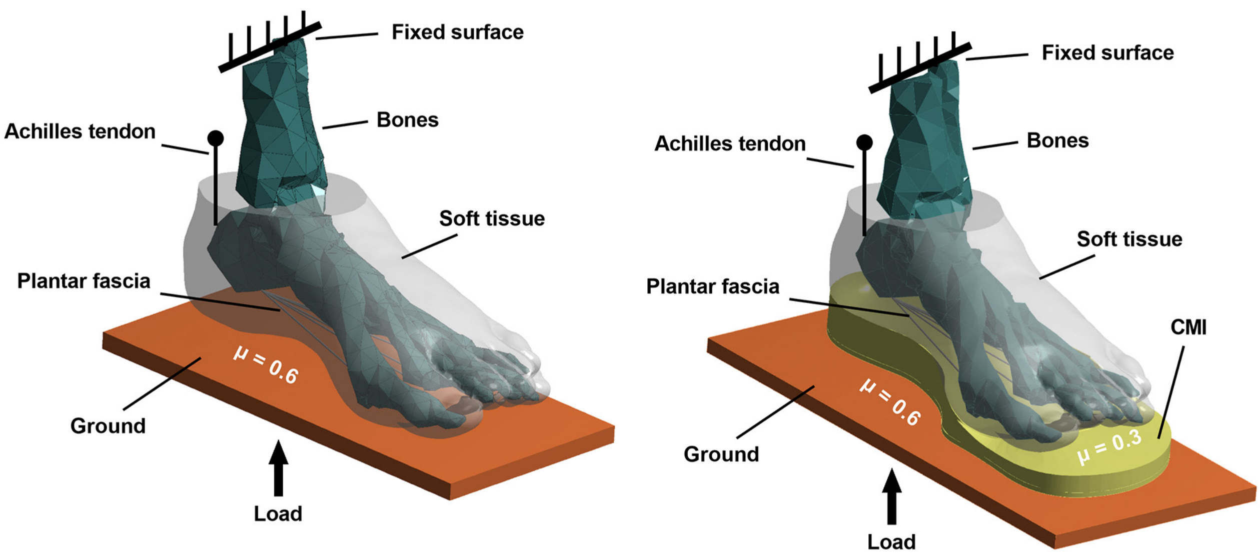


Figure 1 Finite element analysis model of the foot: showing the foot (A) without and (B) with the custom made insole (CMI) geometries, demonstrating the boundary and loading conditions used in the simulation

Loading and boundary conditions

Diabetic foot is prone to neuropathy, limited joint mobility, and most frequent ulcer formation. As the body weight transfers to the limb during loading response, the heel acts as a rocker with the flexed knee acting as a shock absorption. Ankle plantar flexion results in forefoot contact and progress to mid-stance of the gait cycle. With limited joint mobility, shock absorption can be achieved by the CMI from heel strike to mid-stance of the gait cycle. Therefore, the authors focused on the loading response of the gait phase.

Table 1 Material properties of bone, soft tissue, plantar fascia and custom-made insoles in the finite element model

Components	Young's modulus (MPa)	Poisson's ratio	References
Bone	7,300	0.30	Brilakis E et al.[43]
Soft tissue	0.19	0.49	Chen WP et al.[44]
Plantar fascia	350	0.35	Wright DG et al.[45]
CMI-A (Nora® Lunalastike)	1.04	0.25	Lo WT et al.[46]
CMI-B (EVA)	5	0.40	Lewis G et al.[47]
CMI-C (Amfit®)	8.97	0.39	Lo WT et al.[46]
CMI-D (TPU)	11	0.45	Frick A et al.[48]
Ground	21,000	0.30	Su S et al.[23]

EVA = Ethylene vinyl acetate; TPU =Thermoplastic polyurethane; CMI = custom-made insoled

Table 2 Combination of materials for custom-made insoles

Type	Top layer	Base layer
CMI-E	Nora® Lunalastike (3 mm)	Amfit® (3 mm)
CMI-F	Nora® Lunalastike (3 mm)	TPU (3 mm)
CMI-G	EVA (3 mm)	Amfit® (3 mm)
CMI-H	EVA (3 mm)	TPU (3 mm)

EVA = Ethylene vinyl acetate; TPU = Thermoplastic polyurethane; CMI = custom-made insoled

The bones and soft tissues were set to be bonded. Without the CMI the foot-ground interaction was set to be frictional; with a frictional coefficient of 0.6. In cases of the foot with the CMI, frictional coefficient of 0.6 was assigned between the CMI and the ground.[24] Interaction between the foot and the custom made insole was set to be frictional, with a frictional coefficient 0.3.[25] To simulate the plantar fascia we used 5 tension-only link elements, and the origin and insertion points were based on their anatomical location in regards to an anatomy atlas.[26]

The top surface of both the tibia and fibula were fixed, and displacement of 3 mm represented a load of 396 N was exerted beneath the ground:[27] as shown in Figure 1. Moreover, a vertically upward directed Achilles tendon force, approximately 50.0% of the load, during loading response was used in this FEA model; this was based on a previous study.[28] The peak contact pressure between the foot and the CMI was then evaluated.

Meshing

The complete 3D model of foot along with custom made insole and ground was meshed with linear tetrahedron elements. A mesh convergence analysis was performed to ensure that the predicted FEA results were insensitive of the element size and number. The mesh convergence study was conducted based on the peak contact pressure for five different element sizes (6 mm to 4 mm with an interval of 0.5 mm). A negligible difference (of less than 2.0%) in the peak contact pressure was observed from element sizes of 5 mm to 4.5 mm, and then further to 4.0 mm. Therefore, the element size of 5 mm (with 203,482 elements) was considered to be a computationally optimal mesh size for further analysis.

FEA model validation

Validation is one of the most important stages in FEA. This FEA foot model was validated by comparing the peak contact pressure with the experimental result of peak plantar pressure from neuropathic diabetic patients, measured by Pedar® system from shod gait without a CMI, at level ground from the author's previous study.[29]

RESULTS

This current work analyzed the effect of CMI materials, and its combinations on the plantar pressure distribution, using the FEA approach. With the use of a CMI, the contact area between the foot and the CMI increased when compared to without use of a CMI. Alternatively, the peak contact pressure was reduced with all the materials used in this study; with the exception of a CMI made from a stiffer material. Using CMI with soft materials tends to reduce the peak contact pressure effectively, when compared to stiffer materials. CMIs fabricated from a combination of soft and stiff materials resulted in a more evenly distribution of the contact pressure. The softer top layer provided a better distribution of peak contact pressure compared to the stiffer top layer with the same base layer.

Validation

In order to validate the accuracy of the current FEA foot model, the simulated peak contact pressure was compared with the experimental peak plantar pressure measured on diabetic subjects in Nouman et al.'s work.[29] It was found that the peak contact pressures at the heel and forefoot of the FEA foot model without a CMI were in similar magnitudes to the peak plantar pressure from the experiment (Figure 2A). The comparison also showed that there was a good agreement of the predicted FEA foot model, and the experimental peak plantar pressure mapping (Figure 2B); especially at the hind-foot which represented the initial stage of the gait cycle during the loading response phase (3.0-12.0% of the gait cycle).

Effect of using single materials on peak contact pressure

The FEA foot model predictions for peak contact pressure, corresponding to four CMIs from CMI-A to CMI-D, are shown in Figure 3. The contact pressure contour showed that CMI-A resulted in 78.0% reduction of peak contact pressure compared to CMI-B. The contact pressure increased with the use of stiffer CMIs. An increase in the stiffness of the CMIs, increased the contact pressure; especially at the mid-foot and hind-foot. With CMI-D the peak contact pressure was the highest; especially at the hind-foot compared to CMI-A, which resulted in minimum peak contact pressure.

Effect of using dual materials on peak contact pressure

Figure 4 shows the simulated contact pressure distribution from the combination of dual materials. The peak contact pressure was highest under the hind-foot with dual materials. With the stiffer material, as both top and bottom layers, this resulted in high peak contact pressure at both the mid-foot and hind-foot. However, there was not much difference in peak contact pressure, when keeping the top layer unchanged; as shown in CMI-E and CMI-F. The change of contact pressure occurred when the top layer material was changed, as shown in CMI-E and CMI-G. It was found that CMI-E resulted in the lowest peak contact pressure compared to CMI-G, with the same base layer; wherein, the reduction of peak contact pressure was 35.0% with CMI-E compared to CMI-G.

Effect of type of insole on peak contact pressure and regions of the foot

Three regions of the foot represented with cross-over lines, with a CMI and without a CMI, at the fore-foot and hind-foot are shown in Figure 5A and Figure 5C. However, there is no contact pressure at the mid-foot without a CMI (Figure 5B). The peak contact pressure

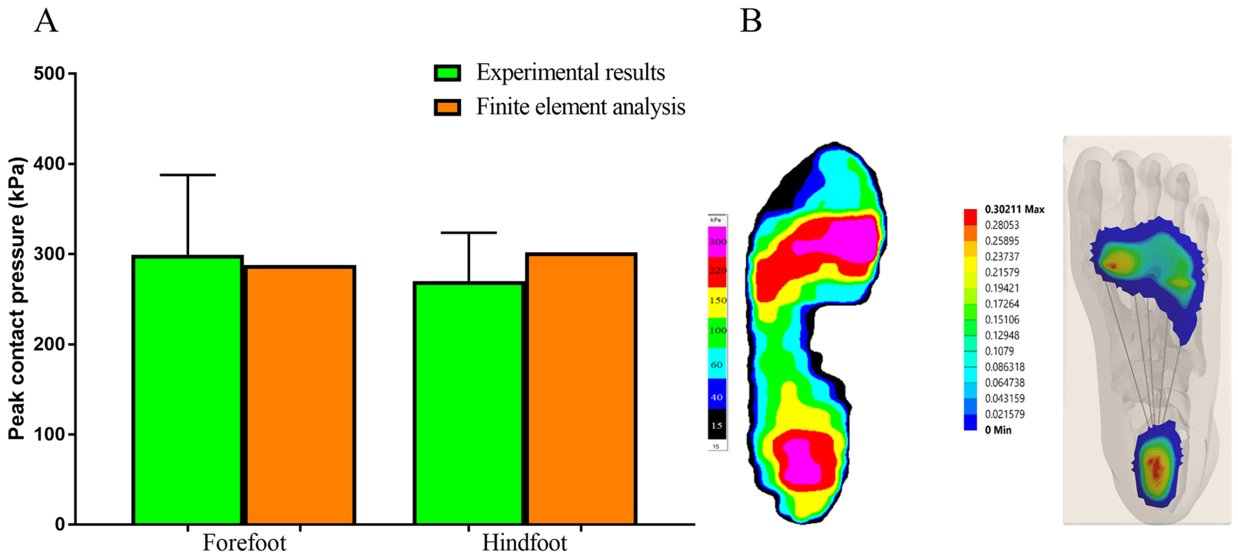
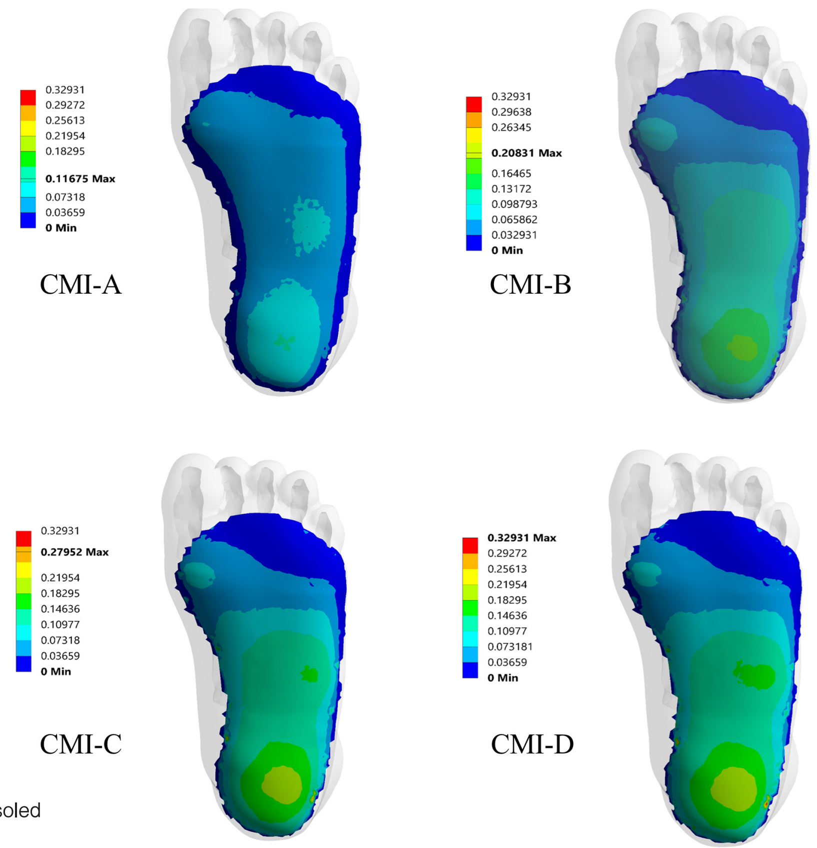


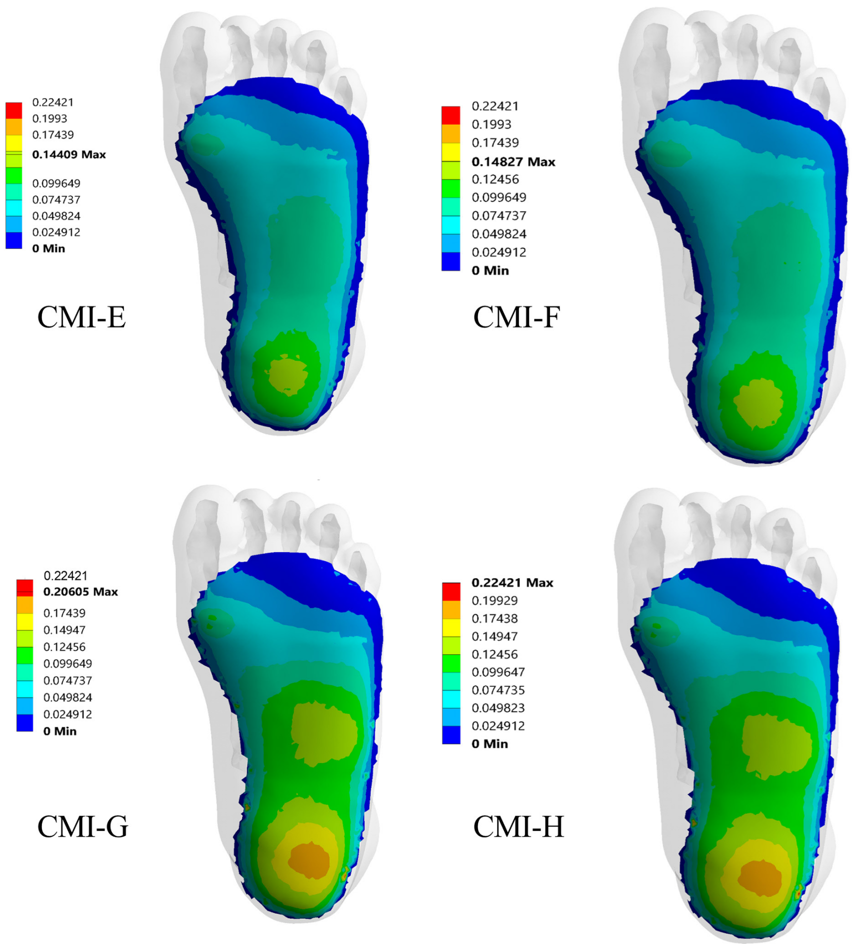
Figure 2 Validation of plantar pressure: (A) predicted peak contact pressure and experimental measurement during gait and (B) plantar pressure mapping from the previous study by Nouman et al. (2017); and finite element analysis without a CMI[29]



CMI = custom-made insoled

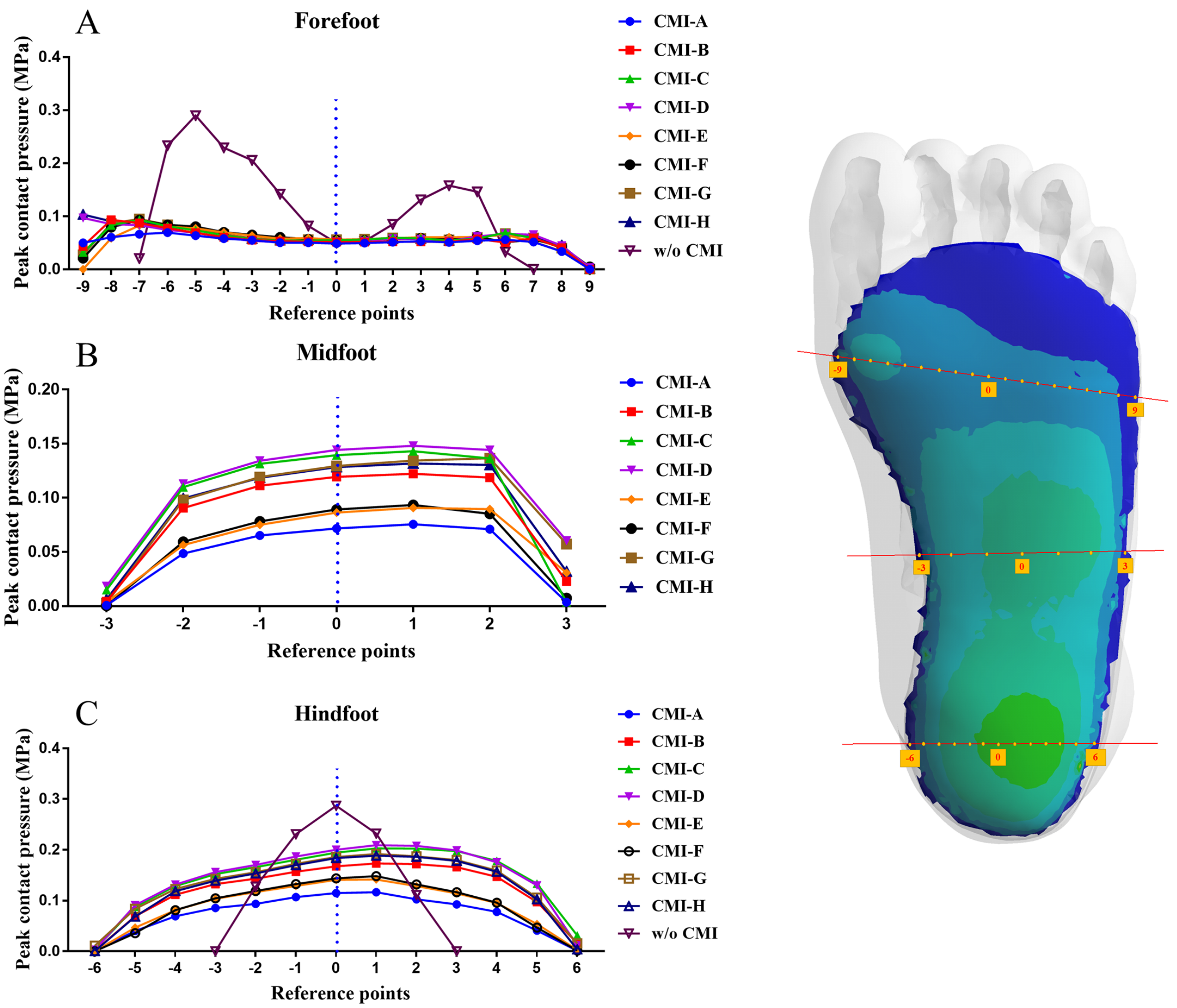
Figure 3 The plantar contact pressure obtained from four FEA models; using a single material. CMI variations, from soft to hard (CMI-A to CMI-D) was highest without a CMI; especially at the fore-foot and hind-foot. With the use of a CMI, more peak contact pressure was distributed to the medial and lateral sides, and it increased from softer to stiffer materials, as from CMI-A to CMI-D; especially at the hind-foot and mid-foot. However, with softer base layer materials (Nora® and EVA) the peak contact pressure dropped for all regions compared to that of stiffer single materials (Amfit® and TPU).

The contact pressure was highest at the medial and lateral of the fore-foot without a CMI. With the use of a CMI the peak plantar pressure from the medial and lateral of the foot dropped. The peak contact pressure at the fore-foot reduced from 78.0% and 68.0% from the medial and lateral of the foot, respectively. There is not much difference of peak contact pressure at the fore-foot with all types of CMIs; howbeit, the vulnerability can be seen at the medial fore-foot. CMI-E resulted in minimum peak contact pressure compared to all types of CMI at the medial fore-foot. However, there was a 24.0% increase in peak contact pressure compared to CMI-A. CMI- D, and CMI-H resulted in the maximum peak contact pressure at the medial fore-foot.



CMI = custom-made insoled

Figure 4 The plantar contact pressure obtained from four FEA models of dual-layer materials



CMI = custom-made insoled

Figure 5 Effect of CMIs on peak contact pressure at three regions of the foot: fore-foot, mid-foot and hind-foot. On the right figure the point at the middle of the line is the reference point "0"

The contact pressure was highest at the lateral mid-foot with all types of CMI, with the highest peak contact pressure being found with CMI-D; when compared to all other types of CMIs. In contrast, a similar pattern was found, as at the hind-foot, with the use of CMI-A resulting in minimum peak contact pressure; when compared to all other types of CMIs. Compared to CMI-A, there were 20.0% and 23.0% increments in peak contact pressure with CMI-E and CMI-F, respectively.

At the hind-foot, peak contact pressure was highest with a smaller area of contact without a CMI, compared to all types of CMIs. The peak contact pressure decreased by 59.0% with the use of CMI-A, when compared to without a CMI. The highest peak contact pressure occurred at the lateral hind-foot with all types of CMIs. CMI-D resulted in the highest peak contact pressure compared to all other types of CMIs; whereas, CMI-A resulted in minimum peak contact pressure, as compared to other CMIs. The second, most appropriate CMIs for hind-foot were CMI-E and CMI-F. There was a 21.0% increase of peak contact pressure with the use of CMI-E when compared to CMI-A. Moreover, CMI-F resulted in a 27.0% increase of peak contact pressure when compared to CMI-A.

DISCUSSION

The peak contact pressure with different types of custom made insoles, based on both single and dual materials, at the loading response of the gait cycle were examined in this study. The FEA models for the foot and CMIs were developed and validated with experimental data. Using FEA the key finding of these current results showed that: with the same base material, the top layer with a softer material (CMI-E), resulted in a significant reduction of peak contact pressure, compared to a stiffer material as a top layer (CMI-G). Moreover, the base layer has a minimal effect on peak contact pressure when the material is changed from soft to hard.

The foot without a CMI, the FEA model, and the results were validated by comparing the peak plantar pressure during gait, measured by the Pedar® system. Using this comparison, the FEA results were consistent with the experimental results. Therefore, the author's current FEA model was considered to be sufficiently accurate for use in further biomechanical investigations. The FEA model allows a systematic analysis of the effects of a CMI, made up of both uniform and a combination of materials, on peak plantar pressure in the diabetic foot with neuropathy. The unique aspect of this work, compared to previous works, is the investigation of multiple materials that are useful for clinical practice towards the diabetic foot with neuropathy.

The foot acts as a flexible body during initial contact, for shock absorption while also acting as a rigid body to push the body forward. The plantar pressure in the current FEA model was found to be higher at the hind-foot from initial contact to mid-stance, and at the fore-foot from mid-stance to terminal stance of the gait cycle.[30] This would be more relevant in the case of diabetic feet that frequently face ulceration and re-ulceration at the hind-foot and fore-foot.[31] Both the hind-foot and fore-foot peak plantar pressure increased in diabetic neuropathic foot; however, the fore-foot and hind-foot ratio increased only in severe diabetic neuropathy.[32] As the authors current FEA model focused on the initial stage of diabetes, the loading response phase condition would be a more realistic situation to consider as representing the first peak of the gait cycle. As expected, the present FEA model predicted that all the CMIs showed a reduction of peak contact pressure compared to those without a CMI. CMIs, fabricated either from single and soft materials or a combination of soft and stiff materials, resulted in 61.0% and 52.0% reduction of peak contact pressure compared to those without use of a CMI, respectively. Similar reduction of peak plantar pressure was found while using different cushioning materials, and conformity compared to flat insoles.[33] Other studies reported that using CMIs could reduce 30.0 to 40.0% of peak plantar pressure.[34, 35]

CMIs are strongly dependent on the mechanical characteristics of the material used to provide cushioning.[36] The use of a single and stiffer material of CMI-D tended to result in increased contact pressure, as compared to CMI-A (softer), that is commonly seen in FEA studies. In individuals with higher peak plantar pressure, the overall reduction of peak value is achieved by increasing the thickness of the insole[37] Moreover, peak plantar pressure with the use of prefabricated insoles, was reduced with the use of soft materials: 55 shore EVA and 35 shore EVA.[38] Similar reduction was observed in this current study, by changing the material and keeping the same thickness of the CMIs. Other studies claimed that the value of maximum stress remains nearly constant, due to the use of uniform materials to fabricate CMIs.[39] Howbeit, in a real clinical scenario, the combination of materials is used for the diabetic foot with neuropathy to relieve the pressure from the areas of high pressure, and to provide comfort.

Clinical trials have been conducted to evaluate the effect of different insole configurations on the fore-foot plantar pressure distribution. The plantar pressure reduced with both arch support and metatarsal dome, from the central (36.0%) and medial fore-foot (39.0%).[11] Based on our results, with the addition of a base layer of a stiffer material, the peak contact pressure was reduced; especially from the mid-foot and fore-foot, compared to flat insoles and optimal insoles.[28] By changing the base layer material, the peak contact pressure has a minimal effect on plantar pressure distribution. In contrast, changing the top layer from a soft material to a stiff material increased the peak contact pressure. Similar results were found while using varying materials, with the most effective material being used as a cushioning material. This resulted in a reduction of plantar pressure of up to 53.0% when compared to painful fore-foot.[40]

Modifications to the insole have an impact on different regions of the foot, compared to the basic insoles fabricated from Nora Lunalastike® and Nora Lunasoft®; as both the top and bottom layers, respectively, tend to have a peak pressure of 231 kPa.[41] From our results, in the loading response phase, the peak contact pressure reduced from 115 kPa to 78 kPa, when changing the material type and its combination. CMIs fabricated from softer materials resulted in the least peak contact pressure, compared to stiffer materials. However, the prescription of CMIs, towards the diabetic foot with neuropathy, has to provide comfort to the foot, cause a reduction of peak plantar pressure; especially from the fore-foot, and allow for the provision of stability during gait. These functions of CMIs can be achieved by a combination of materials in the fabrication of CMIs for the diabetic foot with neuropathy. The control mechanism of the combination of appropriate materials provides a better control of fore-foot, with an improvement in gait: which was similarly found in previous studies.[42]

Despite clinical evidence of the beneficial effects of CMIs, for prevention of ulcerations in the diabetic foot with neuropathy, there is still a need to explore further into CMI materials. Additionally, the design of any CMI also plays an important role in the correction or accommodation of foot deformities, and the prevention from ulceration and re-ulceration in the diabetic foot with neuropathy. Finite element analysis can provide a useful means for investigating plantar pressure distribution in the diabetic foot with neuropathy. This is achieved by varying the insole interventions (materials and designs) without the need to conduct the in vivo experiments, which are resource and time intensive.

Some limitations were presented in our study while investigating the use of CMI materials. At present, only one-foot model, without foot deformities, was simulated with different types of CMIs. Our foot model was also simplified with the bones being fused together, in addition to being assigned with linear elastic material properties. Furthermore, this study proposed a subject specific model. However, the validation was not performed on the same subject with the experimental study by plantar pressure measurement. The soft tissue properties of diabetic foot were not considered, and the relative motion between bones of the foot were neglected. The Achilles tendon was the only muscle force considered, while other intrinsic and extrinsic muscle forces were not simulated. Material combinations, with controlled overall insole thickness and insole designs during other phases of gait cycle; especially towards the diabetic foot with neuropathy, should be studied in the future.

CONCLUSION

For the diabetic foot with neuropathy, CMI materials and designs play an important role on the reduction of peak contact pressure during gait. Our study demonstrated how CMI materials and their combinations can dramatically alter peak contact pressure. Using dual materials to fabricate CMIs, and having a softer material as a top layer is beneficial compared to stiffer materials, in the reduction of peak plantar pressure in the diabetic foot with neuropathy.

ACKNOWLEDGEMENT

We would like to give thanks to the Graduate School, Prince of Songkla University for financial support. We also would like to thank Thailand's Education Hub for the Southern Region of ASEAN countries, TEH-AC scholarship, from the Graduate School, Prince of Songkla University. We also thank Mr. Andrew Jonathan Tait from the International Affairs Office of Faculty of Medicine for the English editing of this manuscript.

CONFLICT OF INTEREST STATEMENT

The authors declare no potential conflicts of interests.

REFERENCES

1. Moxey PW, Gogalniceanu P, Hinchliffe RJ, Loftus IM, Jones KJ, Thompson MM, et al. Lower extremity ampu tations--a review of global variability in incidence. Diabet Med 2011;28:1144-53.
2. Bartus CL, Margolis DJ. Reducing the incidence of foot ulceration and amputation in diabetes. Curr Diab Rep 2004; 4:413-8.
3. Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcersand Their Recurrence. New Engl J Med 2017;376:2367-75.
4. Grimm A, Kastenbauer T, Sauseng S, Sokol G, Irsigler K. Progression and distribution of plantar pressure in Type 2 diabetic patients. Diabetes Nutr Metab 2004;17:108-13.
5. Boulton AJ, Kirsner RS, Vileikyte L. Clinical practice. Neu-ropathic diabetic foot ulcers. N Engl J Med 2004;351:48-55.
6. Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J The global burden of diabetic foot disease. Lancet 2005;366: 1719-24.
7. Cavanagh PR. Therapeutic footwear for people with diabetes. Diabetes Metab Res Rev 2004;20(Suppl1):S51-5.
8. 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;19:629-38.
9. Praet SF, Louwerens JW. The influence of shoe design on plantar pressures in neuropathic feet. Diabetes Care 2003; 26:441-5.
10. Gerrard JM, Bonanno DR, Whittaker GA, Landorf KB. Effect of different orthotic materials on plantar pressures: a sys-tematic review. J Foot Ankle Res 2020;13:35.
11. Nouman M, Dissaneewate T, Leelasamran W, Chatpun S. The insole materials influence the plantar pressure distribu tions in diabetic foot with neuropathy during different walking activities. Gait Posture 2019;74:154-61.
12. Chatzistergos P, Gatt A, Formosa C, Farrugia K, Chockalin-gam N. Optimised cushioning in diabetic footwear can sig-nificantly enhance their capacity to reduce plantar pressure. Gait Posture 2020;79.
13. Ahmed S, Barwick A, Butterworth P, Nancarrow S. Footwear and insole design features that reduce neuropathic plantar forefoot ulcer risk in people with diabetes: a systematic literature review. J Foot Ankle Res 2020;13:30.
14. Turpin KM, De Vincenzo A, Apps AM, Cooney T, MacKenzie MD, Chang R, et al. Biomechanical and clinical outcomes with shock-absorbing insoles in patients with knee osteoar thritis: immediate effects and changes after 1 month of wear. Arch Phys Med Rehabil 2012;93:503-8.
15. Sun X, Lam WK, Zhang X, Wang J, Fu W. Systematic review of the role of footwear constructions in running biomechanics: Implications for running-related injury and performance. J Sports Sci Med 2020;19:20-37.
16. Wang L, Hong Y, Li JX. Durability of running shoes with ethylene vinyl acetate or polyurethane midsoles. J Sports Sci 2012;30:1787-92.
17. Lo WT, Wong DP, Yick KL, Ng SP, Yip J. Effects of custom-made textile insoles on plantar pressure distribution and lower limb EMG activity during turning. J Foot Ankle Res 2016;9:22.
18. Wang Y, Wong DW, Zhang M. Computational models of the foot and ankle for pathomechanics and clinical applica-tions: a review. Ann Biomed Eng 2016;44:213-21.
19. Luo GM, Houston VL, Garbarini MA, Beattie AC, Thongpop C. Finite element analysis of heel pad with insoles. J Biomech 2011;44:1559-65.
20. Ghassemi A, Mossayebi AR, Jamshidi N, Naemi R, Karimi MT. Manufacturing and finite element assessment of a novel pressure reducing insole for diabetic neuropathic patients. Australas Phys Eng Sci Med 2015;38:63-70.

21. Morton DJ. Evolution of the human foot. Am J Phys Anthropol 1922;5:305-36.
22. Cheung JT, Zhang M. A 3-dimensional finite element model of the human foot and ankle for insole design. Arch Phys Med Rehabil 2005;86:353-8.
23. Su S, Mo Z, Guo J, Fan Y. The effect of arch height and material hardness of personalized insole on correction and tissues of flatfoot. J Healthc Eng 2017;2017:8614341.
24. Zhang M, Mak AF. In vivo friction properties of human skin. Prosthet Orthot Int 1999;23:135-41.
25. Tang L, Wang L, Bao WN, Zhu SY, Li DC, Zhao NX, et al. Functional gradient structural design of customized diabetic insoles. J Mech Behav Biomed 2019;94:279-87.
26. Mates M. Atlas of anatomy: general anatomy and musculo-skeletal system. Occup Ther Health Care 2008;22:76-7.
27. Dian W, Ping C. Finite element analysis of the expression of plantar pressure distribution in the injury of the lateral Ligament of the Ankle. Nano Biomed Eng 2019;11:290-6.
28. Hsu YC, Gung YW, Shih SL, Feng CK, Wei SH, Yu CH, et al. Using an optimization approach to design an insole for lowering plantar fascia stress--a finite element study. Ann Biomed Eng 2008;36:1345-52.
29. Nouman M, Leelasamran W, Chatpun S. Effectiveness of total contact orthosis for plantar pressure redistribution in neuropathic diabetic patients during different walking activities. Foot Ankle Int 2017;38:901-8.
30. Wang Y, Wong DW, Tan Q, Li Z, Zhang M. Total ankle arthroplasty and ankle arthrodesis affect the biomechanics of the inner foot differently. Sci Rep 2019;9:13334.
31. Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. New Engl J of Med 2017;376:2367-75.
32. Guiotto A, Sawacha Z, Guarneri G, Avogaro A, Cobelli C. 3D finite element model of the diabetic neuropathic foot: a gait analysis driven approach. J Biomech 2014;47:3064-71.
33. Goske S, Erdemir A, Petre M, Budhabhatti S, Cavanagh PR. Reduction of plantar heel pressures: Insole design using finite element analysis. J Biomech 2006;39:2363-70.
34. Albert S, Rinoie C. Effect of custom orthotics on plantar pressure distribution in the pronated diabetic foot. J Foot Ankle Surg 1994;33:598-604.
35. Kitaoka HB, Luo ZP, Kura H, An KN. Effect of foot orthoses on 3-dimensional kinematics of flatfoot: a cadaveric study. Arch Phys Med Rehabil 2002;83:876-9.
36. Cheung JT, Zhang M. Parametric design of pressure-relieving foot orthosis using statistics-based finite element method. Med Eng Phys 2008;30:269-77.
37. Lemmon D, Shiang TY, Hashmi A, Ulbrecht JS, Cavanagh PR. The effect of insoles in therapeutic footwear--a finite element approach. J Biomech 1997;30:615-20.
38. Hellstrand Tang U, Zügner R, Lisovskaja V, Karlsson J, Hagberg K, Tranberg R. 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.
39. Sarikhani A, Motalebizadeh A, Asiaei S, Kamali Doost Azad B. Studying maximum plantar stress per insole design using foot CT-scan images of hyperelastic soft ti sues. Appl Bonics Biomech 2016;2016:8985690.
40. Davia-Aracil M, Hinojo-Pérez JJ, Jimeno-Morenilla A, Mora-Mora H. 3D printing of functional anatomical insoles. Comput Ind 2018;95:38-53.
41. Guldemond NA, Leffers P, Schaper NC, Sanders AP, Nieman F, Willems P, et al. The effects of insole configurations on fore foot plantar pressure and walking convenience in diabetic patients with neuropathic feet. Clin Biomech (Bristol, Avon) 2007;22:81-7.
42. Fauli AC, Andres CL, Rosas NP, Fernandez MJ, Parreno EM, Barcelo CO. Physical evaluation of insole materials used to treat the diabetic foot. J Am Podiat Med Assn 2008;98:229-38.
43. Brilakis E, Kaselouris E, Xypnitos F, Provatidis CG, Efstathopoulos N. Effects of foot posture on fifth metatarsal fracture healing: a fi nite elementstudy. J Foot Ankle Surg 2012;51:720-8.
44. 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:S17-24.
45. Wright DG, Rennels DC. A study of the elastic properties of plantar fascia. J Bone Joint Surg Am 1964;46:482-92.
46. Lo WT, Yick K, Ng Z, Yip J. Numerical simulation of orthotic insole deformation for diabetic foot. J Fiber Bioeng Inform 2015;8:401-11.
47. Lewis G. Finite element analysis of a model of a therapeutic shoe: effect of material selection for the outsole. Biomed Mater Eng 2003;13:75-81.
48. Frick A, Rochman A. Characterization of TPU-elastomers by thermal analysis (DSC). Polym Test 2004;23:413-7.