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Original Article

Effects of thickness and length of custom made insole on plantar pressure for diabetic foot with neuropathy: A finite element approach♣

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Abstract

Custom made insole (CMI) effectively reduces the incidence of foot ulceration and re-ulceration in the diabetic foot with neuropathy. Several factors influence the effectiveness of CMI, which can be studied using the finite element analysis (FEA). This study investigated the effect of varying CMI thickness and length on the peak plantar pressure using FEA. A subject-specific 3D foot model was reconstructed with the CMI. The top surface of tibia and fibula were fixed and a displacement of 3 mm was exerted from the ground along with the upward Achilles tendon force. The peak contact pressure was reduced by 17.52% and 9.46% with an overall thickness of CMI of 9mm and 6mm compared to 3mm, respectively. Full-length CMI redistributed contact pressure at the midfoot better than half-length CMI. In conclusion, FEA provides more insight for the intervention of CMI on plantar pressure in the diabetic foot with neuropathy.

Keywords: finite element analysis, diabetic foot, custom made insole, insole characteristic, plantar pressure

1. Introduction

The abnormal peak plantar pressure is a strong prognostic indicator of plantar foot ulcerations and re-ulceration in the presence of diabetic foot with neuropathy (Lazzarini *et al.*, 2019). The orthotic intervention tends to prevent foot from injuries caused by abnormal plantar pressure and accommodate foot structural deformities. The effectiveness of foot orthotic interventions and ulcer healing strategies are usually evaluated by measuring the peak plantar pressure (Mueller *et al.*, 2006; Petre, Tokar, Kostar, & Cavanagh, 2005). Custom made insole (CMI) is frequently prescribed to redistribute the peak plantar pressure at high risk regions of the foot to reduce ulcerations and re-occurrence in a patient with diabetes (Armstrong, Peters, Athanasiou, & Lavery, 1998; Waaijman *et al.*, 2012). The most common technique used to offload is to remove materials from high pressure area and build-up at other areas of the foot.

The design of these CMIs is based on the foot morphology using conventional techniques after identification

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of abnormal foot pressure sites. Additionally, the design of intervention is based on the clinical expertise of an orthotist. However, the therapeutic footwear designed to reduce peak plantar pressures and the prevention of ulceration are still unsuccessful in severe cases of diabetic foot with neuropathy (Lavery, Armstrong, Wunderlich, Tredwell, & Boulton, 2003). Offloading procedure consists of selection of appropriate combination of softer materials under high pressure areas and stiffer material for the areas that can bear the pressure like metatarsals shaft (S. A. Bus, 2016). Unfortunately, current measuring techniques provide only information about the peak pressure under foot. These conventional fabrications of CMI and measuring techniques may lead to inconsistency in a prescription of CMI and a suitable design and material selection for diabetic foot (Actis *et al.*, 2008; Guldemond *et al.*, 2007; Paton, Stenhouse, Bruce, Zahra, & Jones, 2012).

Finite element (FE) modeling has significantly advanced benefits in the medical applications. As a useful tool for researchers and clinicians, successful works have been carried out on lower limb biomechanics, supporting the development and assessment of a range of treatments and interventions without prolonged trial and error procedures (Be'ery-Lipperman & Gefen, 2006; Fang, Jia, & Wang, 2007). FE was effective in the evaluation and optimization of the arch conforming insoles for high arch diabetic foot compared to fallen arch (Niu, Liu, Zheng, Ran, & Chang, 2020). Moreover, fully conforming insole design mostly highlighted the effective reduction of plantar pressure and reduction of heel pain compared to flat insole simulated in early phase of gait cycle (Goske, Erdemir, Petre, Budhabhatti, & Cavanagh, 2006; Wibowo, Widodo, Haryadi, Caesarendra, & Harahap, 2019). CMI design selection is effective in stress reduction from the ulcer sites and prevention from re-ulceration (Chanda & Unnikrishnan, 2018).

It is possible with the FE analysis to estimate plantar pressure distribution on the foot. The uses of FE model are to model the foot-insole structure and to analyze the effects of different insole material combinations and design on the plantar pressure distribution. However, very limited work has been done on overall and individual layer of CMI thickness along with the length of CMI. CMI is generally fabricated as full length from three layers of different materials for diabetic foot with neuropathy (Nouman, Dissaneewate, Leelasamran, & Chatpun, 2019). There is a challenge to obtain an optimized CMI design to redistribute the peak plantar pressure with a relatively quick and easy procedure for the insole fabrication. Therefore, the aim of this study was to investigate the effect of varying CMI thickness and length that can reduce the peak plantar pressure in the diabetic foot with neuropathy.

2. Materials and Methods

2.1 Finite element models construction

A simplified three dimensional (3D) FE foot model with CMI was constructed to study various insole thicknesses and lengths affecting plantar pressure distribution in diabetic foot with neuropathy. This study was approved by the research ethics committee (EC-63-219-25-2), Faculty of Medicine, Prince of Songkla University. The computerized tomography scan images of a left foot (male subject, 57 years old, 84 kg) were imported to the image processing software Mimics version 20 (Materialise, Leuven, Belgium) to construct a 3D model of the foot. The morphology of the foot was based on single male subject obtained from Digital Imaging and Communications in Medicine (DICOM) files. The contour of the bones and the soft tissues were segmented manually from computed tomography scan of the left foot to obtain a 3D model. To simplify and reduce the modeling cost and time, the model of the bones was fused together as one body and encapsulated by the soft tissue (Behforootan, Chatzistergos, Naemi, & Chockalingam, 2017). The 3D smoothed geometry was generated and exported as a binary stereo lithography (STL) format. The reconstructed 3D foot model was imported to the finite element solver Ansys, 2020 R2 (ANSYS, Inc., USA) to analyze plantar pressure distribution.

2.2 Boundary and loading conditions

The FE foot model with CMI was assembled in Ansys SpaceClaim (ANSYS Inc., USA) along with a ground. The foot bones and soft tissues were assumed to be isotropic and assigned with linear elastic material properties. The bones and encapsulated soft tissues were set to be bonded. The foot-insole interaction had a frictional coefficient 0.3 (Tang *et al.*, 2019) and the insole-ground interface has a frictional coefficient 0.6 (Zhang & Mak, 1999). The FE foot model was fixed at the tibia and fibula; however, upward displacement 3mm was applied from the ground (Figure 1A). Moreover, a vertically upward directed force by Achilles tendon about 50% of the load during balanced standing was used in this FE model, based on a previous study (Hsu *et al.*, 2008). To simulate the plantar fascia, 5 tension-only link elements were used and the origin and insertion sites were based on their anatomical location according to an anatomy atlas (Mates, 2008). The complete model of the foot along with CMI was meshed with tetrahedral elements of 5mm (Figure 1B).

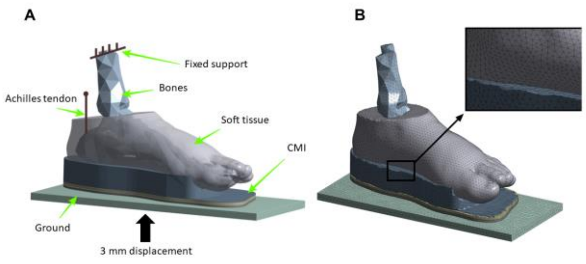

Figure 1. (A) Reconstructed geometry of the foot with bones, soft tissue, custom made insole (CMI) and ground under it; with the fixed support and applied displacement condition, and (B) The complete foot model along with CMI and ground meshed with tetrahedral elements

2.3 Evaluation of CMI thickness and length

The CMI is evaluated in three steps; overall thickness, individual layer thickness and length of CMI (Table 1). In this study, the overall thickness with the reference point from the lowest point of the heel to the ground were 3mm, 6mm and 9mm with material properties of EVA (Figure 2). To evaluate thickness of individual layer effect on

Table 1. Design and materials of custom made insoles

CMI	Layer	Length	Materials and layer thickness	
			Top layer	Base layer
A	single	uncovered MTH	EVA (3mm)	-
B	single	uncovered MTH	EVA (6mm)	-
C	single	uncovered MTH	EVA (9mm)	-
D	two	uncovered MTH	EVA (3mm)	TPU (6mm)
E	two	uncovered MTH	EVA (6mm)	TPU (3mm)
F	two	covered MTH	EVA (6mm)	TPU (3mm)

MTH – metatarsal heads; EVA – ethylene vinyl acetate; TPU – thermoplastic polyurethane

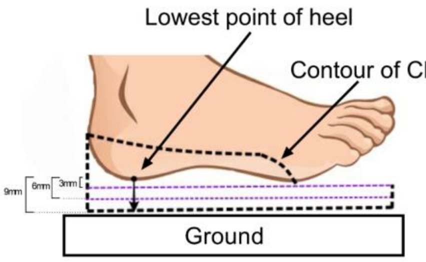

Figure 2. Defining the overall thickness of CMI from the lowest point of heel to the base layer of CMI

peak plantar pressure, top layer 3mm EVA and base layer 6 mm TPU versus top layer 6mm EVA and base layer 3mm TPU were compared. The half-length with the trim lines proximal to the metatarsal heads (MTH) and full-length covering MTH were selected for this study. The materials selected to design a CMI were most commonly used in a realistic clinical setup, and their properties are listed in Table 2. The FE model was validated by comparing the peak contact pressure from the hindfoot and forefoot with the published work in a balanced standing position.

3. Results and Discussion

The focus of current work was to investigate various design factors that alter plantar pressure distribution and to optimize the plantar pressure redistribution of CMI. The peak plantar pressure is affected by the major change of overall thickness of CMI with single material. The thickness of individual layer also plays an important role in reduction of peak contact pressure. Moreover, the length of CMI with 9mm also contributed to the reduction of peak plantar pressure especially at the forefoot by increasing the contact area. The contact area increases with the full-length CMI compared to half-length CMI.

3.1 Validation

The validation results showed that the predicted peak plantar pressure of FE models of bare foot were at a similar order of magnitude to the published measured data from the heel during balanced standing (Table 3). Furthermore, the plantar pressure distribution was more at the hindfoot compared to the forefoot during balanced standing that was similarly reported in previously published articles (Aguiar de Souza, 2008; Cheung & Zhang, 2005; Goske *et al.*, 2006). The peak contact pressures at hindfoot reported in previous published work and current study varied due to the differences in measuring technique, foot morphology and boundary conditions. However, the comparison showed that the FE model in this study was reliable showing similar trend of high pressure at the hindfoot followed by the forefoot (Akrami *et al.*, 2018; Cheung & Zhang, 2005; Costa *et al.*, 2020) and able to be modified for further study on the reduction of peak plantar pressure for diabetic foot with neuropathy.

3.2 Effect of overall and individual layer thickness of insole material on plantar pressure distribution

With varying overall thickness of EVA, the peak plantar pressure was lower with the thicker CMI (9mm) compared to the thinner CMI (3mm). There was 9.46% and 17.52% reduction of peak plantar pressure occur with the CMI-B and CMI-C compared to CMI-A respectively (Figure 3). Comparing CMI-A with other CMIs, there was no plantar pressure at the forefoot because the forefoot was not fully covered with the insole.

The use of CMI significantly reduced the peak plantar pressure compared to flat insole (Sicco A. Bus, Ulbrecht, & Cavanagh, 2004). The thickness of the insole has an impact on the postural stability and the risk of falling for older adults (Buyukturan, Demirci, Buyukturan, & Yakut, 2018). CMI with varying thickness is an important design parameter to study its effectiveness on peak plantar pressure (Lemmon, Shiang, Hashmi, Ulbrecht, & Cavanagh, 1997). The CMI with the thickness from 6.3mm to 12.7mm reduced the peak plantar pressure up to 12% (Goske *et al.*, 2006). Similar observations were found in our current study with an overall thickness of 3mm to 9mm.

Using CMI with varying top and base layer thickness while keeping the overall thickness 9mm, it was found that the plantar pressure distribution varied with varying individual layer thickness (Figure 4). With the thicker top layer 6mm and thinner base layer 3mm as CMI-E, the reduction of peak plantar pressure was 5.87% compared to CMI-D with the thinner top layer (3mm) and thicker base layer (6mm).

Table 2. Material properties for the finite element models

Components	Young's modulus (MPa)	Poisson's ratio	Reference
Bones	7,300	0.3	(Brilakis, Kaselouris, Xypnitos, Provatidis, & Efstathopoulos, 2012)
Soft tissue	0.15	0.49	(Chen, Ju, & Tang, 2003)
Plantar fascia	350	0.35	(Wright & Rennels, 1964)
EVA	5	0.40	(Lewis, 2003)
TPU	11	0.45	(Frick & Rochman, 2004)
Ground	2,100,000	0.30	(Su, Mo, Guo, & Fan, 2017)

Table 3. Peak plantar pressure at the heel with barefoot balanced standing in comparison with the previous published papers and each model of CMIs with varying thickness and length

Models	No. of elements	Peak plantar pressure (kPa)
Barefoot hindfoot (Cheung & Zhang, 2005)	54,188	266
Barefoot hindfoot (Aguiar de Souza, 2008)	-	274
Barefoot hindfoot (Goske *et al.*, 2006)	-	343
Barefoot hindfoot (Current FE model)	203,482	302
CMI-A	200,687	306
CMI-B	213,096	277
CMI-C	213,413	253
CMI-D	214,232	273
CMI-E	214,232	258
CMI-F	232,787	260

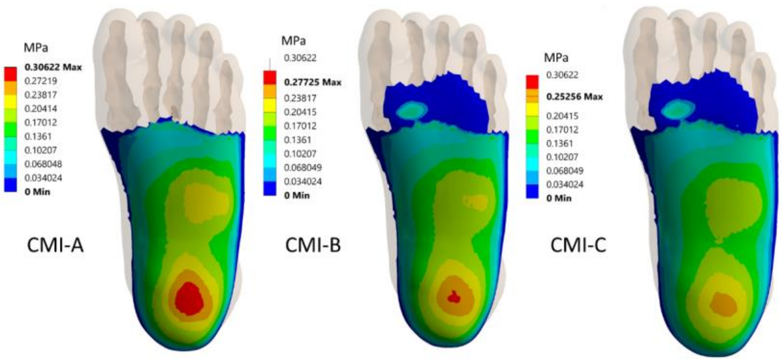

Figure 3. Peak plantar pressure distribution with three CMIs fabricated from EVA with overall thickness of 3mm (CMI-A), 6mm (CMI-B) and 9mm (CMI-C)

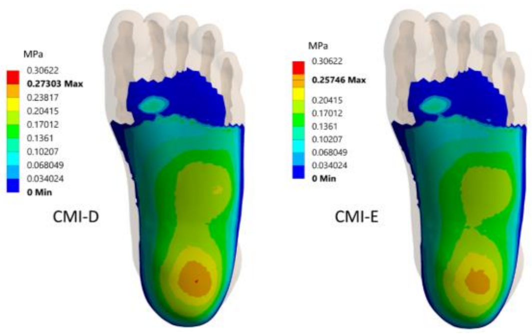

Figure 4. Peak plantar pressure with CMI-D (top EVA layer 3mm and base TPU layer 6mm) and CMI-E (top EVA layer 6mm and base TPU layer 3mm)

FE study revealed an interesting trend with minimum influence of individual top and base layer thickness on the plantar pressure reduction. The contribution to reduction of peak plantar pressure is less with the insole and midsole thickness compared to shape of CMI (Cheung & Zhang, 2008). This finding from our FE study may have an important implication for the fabrication of CMI for the diabetic foot. Even though the beneficial effects of CMI towards diabetic foot are clear, there is still a need to explore more about CMI designs and various pathologies of the foot because the design of CMI plays an important role in the correction or the accommodation of foot deformities and the prevention of ulceration and re-ulceration in the diabetic foot with neuropathy.

3.3 Influence of CMI length on plantar pressure distribution

Considering the same thickness of CMIs with two layers the peak plantar pressure has no effect at the heel; however, major change was observed at the forefoot. With the insole design with covered MTH (CMI-F), the plantar pressure at forefoot was reduced and the plantar pressure redistributed well by increasing the contact area at the forefoot. This reduction and increase in contact area also changes the plantar pressure distribution at the midfoot (Figure 5).

Full-length CMI while prescribing a lateral wedge provided a reduction of knee stress in osteoarthritic patients (Hinman, Bowles, Payne, & Bennell, 2008), although long-term clinical goals need to be evaluated. However, plantar pressure reduction will be more relevant in the case of the diabetic foot that faces frequent foot ulceration and re-ulceration (Gefen, 2003; Scarton *et al.*, 2018). CMI caused a shift in the peak plantar pressure in the diabetic foot from the distal central forefoot to the proximal central forefoot and midfoot (Postema, Burm, Zande, & Limbeek, 1998; Stolwijk, Louwerens, Nienhuis, Duysens, & Keijsers, 2011). Full-length CMI reduced the peak plantar pressure compared to sulcus length CMI but increased the dorsal pressure (Doty *et al.*, 2015). Similarly, in our study CMI with covered MTH (CMI-F), peak plantar pressure was reduced in the forefoot and midfoot with an increased contact area in the forefoot compared to CMI with uncovered MTH (CMI-E).

CMI design factor was found to be a more important factor to reduce peak plantar pressure in the diabetic foot with neuropathy. The peak plantar pressure was reduced with the CMI in combination with stable shoes, especially from the heel. The heel is one the most highlighted region of the foot especially in people with heel pain and diabetic patients with a high risk of foot ulceration (Hellstrand Tang *et al.*, 2014; Luo, Houston, Garbarini, Beattie, & Thongpop, 2011). The reduction of peak plantar pressure and uniform distribution of plantar pressure with CMI might be a good indicator of comfort (Actis *et al.*, 2008).

Though the use of CMI is well acknowledged in clinical settings, limited information is available for the selection of appropriate thickness and length for the diabetic foot with neuropathy. FEA provides useful information of plantar pressure and stress on internal structures with in the foot that are almost impossible to measure during clinical trials. FEA is widely used numerical technique to study different intervention including materials and implants (Ye *et al.*, 2017). These numerical techniques potentially assist the traditional clinical trials to reduce time consumption with the use of limited resources to effectively reduce the plantar pressure in diabetic foot with neuropathy.

There were some limitations present in the current FE study while investigating the use of CMI designs. Currently, only one-foot model, without foot deformities, was simulated with different types of CMIs. Several studies reported that the plantar pressure distribution differs for foot type, foot pathologies and footwear (Chuckpaiwong, Nunley, Mall, & Queen, 2008; Iaquinto & Wayne, 2010). The upward displacement condition was applied in the current study to represent the ground reaction force acting on the foot during standing. However, it is better that the application of ground reaction force should be applied at the center of pressure to be a more realistic situation. The bones were fused together to represent a single bone as the focus of this study was the plantar surface of the foot rather than bone. Moreover, balanced standing was considered in our FE study which might not represent other daily living activities in diabetic foot. Plantar pressure during gait with varying CMI stiffness might give an insight into foot using FE. The plantar fascia was represented with linked elements; however plantar fascia plays an important role in maintaining the medial longitudinal arch of the foot (Mei *et al.*, 2019). The reaction from the foot model with realistic plantar fascia with the CMI might be useful in the evolution of excessive pressure on the internal structure of the foot. The FE evaluation of CMI design affecting plantar pressure distribution during the gait cycle; especially towards the diabetic foot with neuropathy, could be studied in the future.

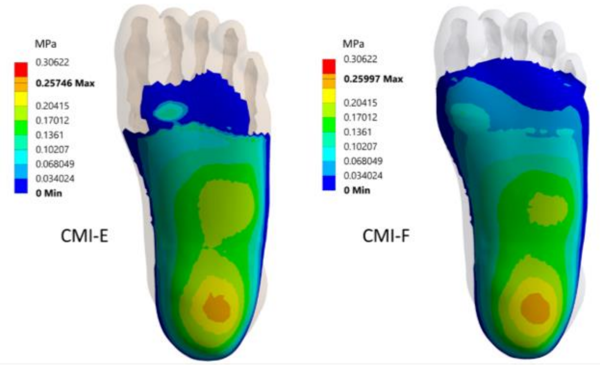

Figure 5. Peak plantar pressure distribution with uncovered metatarsal heads (CMI-E) and covered metatarsal heads (CMI-F) with overall thickness of 9mm and same fabricated materials (top EVA layer and base TPU layer)

4. Conclusions

In general, CMI designs have an impact on plantar pressure distribution. Our FE foot model showed that full-length with an overall 9mm CMI thickness tends to reduce the plantar pressure especially at the hindfoot and forefoot better than other CMI models. Increasing the thickness of CMI redistributes the plantar pressure at the midfoot and hindfoot. Moreover, the length of CMI also effected plantar pressure distribution especially at the forefoot and midfoot with full length CMI. The design of CMI plays a major role in the correction or accommodation of deformities and prevention from ulceration and re-ulceration in diabetic foot with neuropathy by reducing the peak plantar pressure from the hindfoot and forefoot. FEA can facilitate and provide unlimited trials of intervention with an indirect involvement of subjects. Furthermore, the finite element analysis can provide a useful means for investigating the plantar pressure distribution in diabetic foot with neuropathy, with the varying CMI designs without conducting experiments which require resources and are time intensive.

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