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ORIGINAL STUDY

Diabetic Insole Design Using Finite Element Analysis

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Abstract

Diabetic patients frequently face complications such as foot ulcers which are the primary cause of lower-limb amputation. Recent research has found that reducing plantar pressure can dramatically minimize the chance of developing a diabetic foot ulcer. Using orthopedic insoles can lead to reducing and redistributing pressure on the foot's sole. The purpose of this study was to develop a technique using finite element analysis (FEA) for creating dedicated, low-cost insoles for diabetic patients to reduce maximal plantar pressure and to rapidly refine designs and assess their effectiveness in meeting a predefined pressure threshold for foot offloading in diabetic neuropathic patients. Initially, a three-dimensional model of the foot was created using computed tomography (CT) scan images. Subsequently, three customized insole designs are created: single-layer which divided into semi-porous and flat, and three-layer. Six different materials; Amit EVA, Nora Lunalastike, Plastazote PE, Thermoplastic polyurethane (TPU), Nora Lunairflex, and Poron were employed to create the proposed three customized insole models. Additionally, finite element analysis software was employed to compute foot plantar pressure distribution. The results indicated that, in comparison to the flat insole model, the semi-porous and three-layer customized insole models showed a significant reduction in foot contact stress. Employing Nora Lunairflex, Nora Lunalastike on Middle-layer, and Amfit EVA materials on the top layer of the middle-layer, and the base-layer of the three-layer custom-insole model, respectively, resulted in 12.88, 20.46, and 6.91% plantar pressure reduction compared with the other three material combinations used in this paper. Lastly, the semi-porous insole model with Nora Lunalastike material decreased peak contact stress by 29.09%, outperforming all simulated models and materials in our study.

Keywords: Custom-made insole, Finite element analysis, Plantar pressure, Semi-porous

1. Introduction

Diabetic foot, primarily caused by sensory neuropathy and excessive mechanical stress, is a prevalent complication often observed in individuals with type-2 diabetes (Singh et al., 2005). Neuropathy-induced loss of sensation makes individuals with diabetes susceptible to adverse consequences. Minor wounds or injuries, due to the inability to detect them, can quickly become infected, posing significant health risks. Failure to address ulceration promptly can result in necrosis, eventually requiring amputation of the foot or lower leg (Tsung et al., 2004). Diabetic foot ulcers afflict around 15% of patients diagnosed with diabetes (Boulton et al., 2004). Foot ulceration in type-2 diabetes is primarily caused by peripheral neuropathy, peripheral vascular disease, foot deformity, and limited joint mobility. This condition significantly increases the risk of nontraumatic lower limb amputation (Boulton et al., 2005; Peters et al., 2007; Waaijman et al., 2014).

Wearing inappropriate footwear can contribute to the development of ulcers (Andrew Boulton et al., 2000). Biomechanics researchers have demonstrated a strong association between diabetic foot ulcers and the pressure applied to the soles of the feet. Thus, effectively reducing plantar pressures is crucial in

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preventing the reoccurrence of ulcers (Ghanassia et al., 2008; Peters et al., 2007). However, measuring plantar pressure distribution and identifying areas of high pressure within the shoe is often a time-consuming process that involves prolonged trial-and-error procedures (Woolard et al., 2004). Additionally, the high cost of measuring instruments and evaluation procedures presents a challenge. However, the utilization of finite element analysis (FEA) offers a cost-effective solution for evaluating various protocols without the need for direct patient involvement (Sayed et al., 2020). Furthermore, FEA facilitates a comprehensive understanding of foot biomechanics and the effects of different interventions (Wang & Cai, 2019). Researchers (Cheung & Zhang, 2005; Ghassemi et al., 2015) have focused on studying the impact of insole stiffness and thickness on the distribution of plantar pressure, which is crucial for preventing ulcers in therapeutic footwear. By utilizing various design parameters, such as shoe design to distribute weight evenly and specialized insoles for cushioning and support, peak plantar pressure can be reduced in individuals with diabetic neuropathy (Anderson et al., 2020; Bus et al., 2017; Cavanagh, 2004). Additionally, selecting materials wisely, such as foam over hard materials, can further contribute to the reduction of peak plantar pressure by effectively absorbing shock (Ahmed et al., 2020). Consideration of all design parameters in combination is crucial when designing footwear or insoles for individuals with diabetic neuropathy, as the expertise of a pedorthist strongly influences the selection of insole shapes and materials. These design choices are effective in reducing plantar pressure and alleviating heel pain when compared with simulated flat insoles (Goske et al., 2006; Wibowo et al., 2019).

In this field, A study conducted in 2015 developed a new insole design with three layers, which was proven effective through a FEA, resulting in reduced stress concentration by 9% and decreased plantar pressure by 63% compared with barefoot (Ghassemi et al., 2015). Another study in 2015 analyzed the impact of various material combinations in insoles on the distribution of plantar pressure during balanced standing. It specifically identifies the hallux, metatarsal head, and heel as the most vulnerable areas experiencing higher compressive stress. Insoles composed of Plastazote and Poron demonstrate increased stress at the toes and medial heel due to their lower Young's modulus of compression, suggesting potential bottoming out over time. The application of FEA assists in predicting and measuring the deformation of insoles, thereby facilitating the selection of properly fitting insoles to enhance patient comfort and minimize complications such as ulceration (Lo et al., 2015). Later in 2017, a study highlighted the importance of selecting suitable materials for custom-made insoles (CMI) to relieve foot plantar pressure. It discussed the properties and effectiveness of various materials, such as foam, gel, cork, and carbon fiber, in offloading pressure. The study also used FEA to evaluate the mechanical behavior of the insole and predict its capacity to relieve pressure. Emphasizing individual patient factors such as foot type, weight, and activities, the study emphasized the need to consider these factors in material selection for optimal comfort and pressure relief (Mandolini et al., 2017). One Year later, in 2018, a study presented a novel custom insole design with arch support and ulcer isolations for diabetic foot conditions. FE modeling was used to test the stress reduction effects of the insole, revealing up to 91.5% peak stress reduction at the ulcers due to the ulcer isolation feature and the use of a synthetic skin-like material. The findings highlighted the importance of ulcer isolation and provided insights into material selection for custom insole design to improve post-ulcer conditions (Chanda & Unnikrishnan, 2018). Another study in 2019 introduced a novel design method for diabetic insoles, utilizing functional gradient structural properties and FEA to optimize stress distribution and reduce contact pressure. The designed insole increased foot contact area by approximately 30% and reduced peak contact pressure by 35%, showing potential for improved contact mechanics and mitigation of diabetic foot severity (Tang et al., 2019).

In 2020, a study proposed customized pressure-relieving insoles for diabetic foot and compared them to traditional insoles. These novel insoles consisted of layered modular insoles with eight layers of small cushions. They effectively reduced peak pressure from 208.86 to 160.02 kPa, ensuring that high pressure was not observed in sensitive locations of the diabetic foot. Furthermore, the novel insoles provided a better fit for the diabetic foot compared with the traditional insoles (Zeng et al., 2020). A year later, in 2021, FE methods were used to assess two models of footwear and develop a mathematical model for determining the thickness of an EVA insole to reduce plantar pressure and prevent diabetic foot ulcers. Results showed that incorporating the skeletal structure resulted in significant reductions of 1.35% in total deformation, 43.04% in insole deformation, 4.30% in plantar pressures, and 29.10% in insole stresses, highlighting the effectiveness of EVA insoles, especially when combined with the skeletal structure, in alleviating sole pressure and supporting cost-effective footwear production (Ghazali et al., 2021). By optimizing the insole stiffness, foot plantar pressure decreased by 40%, and the insole's elastic modulus decreased by 60%, with the minimum Young's modulus reaching 0.4 MPa. The variations in Young's modulus were primarily observed in the heel and metatarsal areas. Using an initial flat insole resulted in a 25% reduction in maximum foot plantar pressure, from 319 to 240 kPa. Evaluating different insole stiffness levels, a softer insole simulation resulted in a 23% reduction in maximum plantar pressure, from 220 to 170 kPa, with overall lower plantar pressure compared with the harder insole (Jafarzadeh et al., 2021). Recently in 2023, graded stiffness offloading insoles were developed to reduce and distribute plantar pressure, especially in the forefoot and hindfoot regions. Utilizing a softer material and incorporating a heel-forefoot void further decreased maximum frictional stresses compared with a heel-forefoot pad with softer materials, indicating that employing FEA during design and material selection for a CMI can minimize prolonged clinical trial and error in reducing abnormal peak contact pressure in a neuropathic diabetic foot (Nouman et al., 2023).

In this study, an accurate and simplified FE model for the foot was developed, along with three different insole models: a semi-porous, flat, and a three-layer CMI. Moreover, six different materials TPU, Nora Lunairflex, Nora Lunalastike, Amfit EVA, Plastazote PE and Poron were chosen from the literature for the FEA, in which a total of 12 different simulation runs were adopted, eight material selections and four material combinations were employed for the single-layered and three-layered insole models, respectively. The study aimed to employ FEA to avoid the need for extensive, costly, and prolonged clinical trials in refining insole designs for diabetic neuropathic foot. Second, the goal of this study was to assess the impact of the suggested insole designs, as well as material stiffness adjustment with respect to a predefined maximum pressure threshold that is considered acceptable in foot offloading in diabetic neuropathic patients using FEA.

2. Materials and methods

2.1. Solid body foot model preparation

A 26-year-old female with 60 kg weight was submitted to a CT scan. Medical images of both feet were imported into MIMICS v21.0 software (Materialise, Leuven, Belgium), where left foot was extracted by adopting manual segmentation procedures. At this stage, boundary surfaces were created in tessellated format, converted to STL format, and imported into the SolidWorks 2018 (SolidWorks Corporation, Concord, MA, USA) CAD system. Subsequentially, the model was simplified and smoothened for better convergence and accuracy of FE analysis. From this CAD model, the FE model was created in Ansys workbench (ANSYS Inc., Canonsburg, PA, USA) for analysis. Boundary conditions, contact, and identity relationships were established. Fig. 1 depicts the 3D foot model preparation workflow that was adopted in the present research.

2.2. Insole designs and materials

In this paper, three types of insoles were developed in Ansys SpaceClaim (ANSYS Inc., Canonsburg, PA, USA) according to the surface topography of the foot model (Fig. 2): a single-layer semi-porous CMI, a single-layer flat CMI, and a three-layer CMI labeled as CMI-I, CMI-II, and CMI-III, respectively. The initial design of the first insole (CMI-I) involved partitioning it into two distinct regions, each with unique structural characteristics tailored to specific needs.

A porous region was incorporated to effectively distribute weight, while a solid region served as a cushioning support area. The second insole (CMI-II)

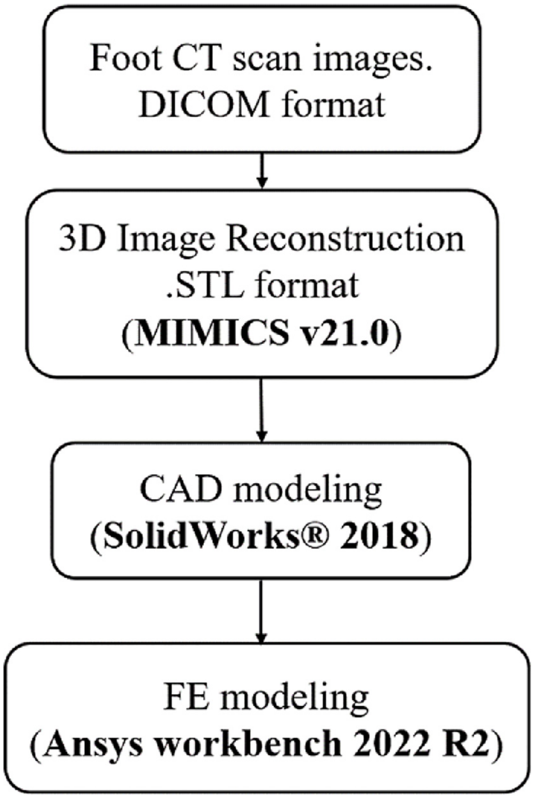

Fig. 1. Work-flow methodology.

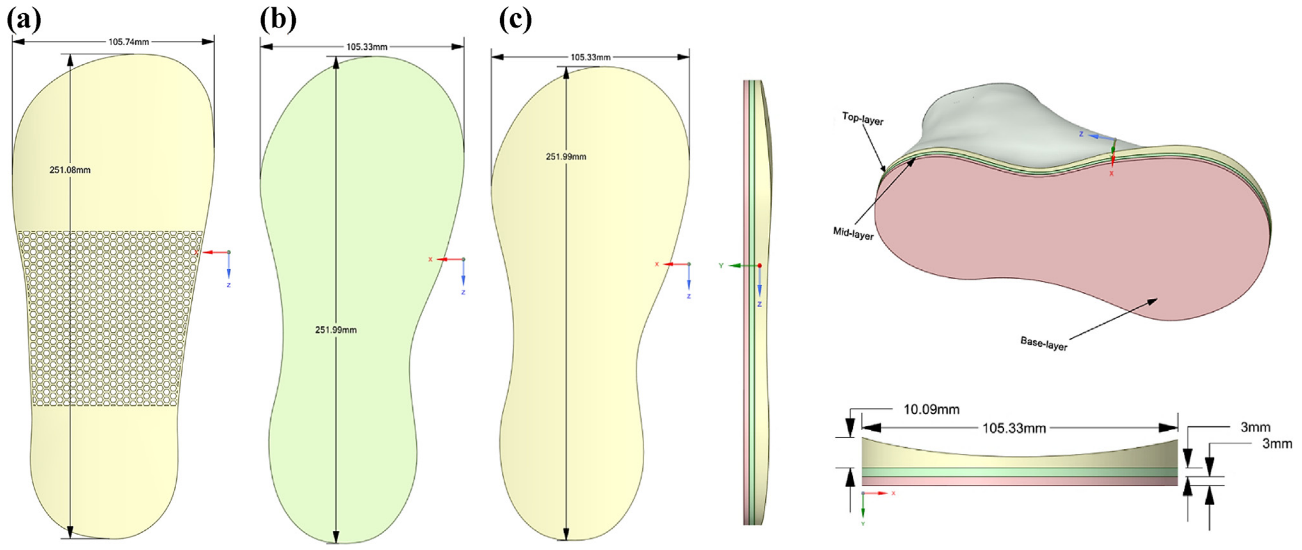

Fig. 2. Custom made insole design: (a) semi-porous insole design, (b) flat insole design, and (c) three-layer insole design (with isometric and its three planes).

was developed as a simple flat structure. In contrast, the third insole (CMI-III) comprised three layers, each 3 mm thickness, with varying material combinations, as detailed in (Table 1). All the three insole models' average thickness was set to 9 mm.

The current work, the focus was to study the effect of the developed CMI designs with the given materials on the diabetic foot plantar pressure distribution. Consequently, a simplified foot model was used that includes the average and material effects of the bones and soft tissues in diabetic foot condition (Cheung et al., 2005; Cheung and Zhang, 2005, 2008; Guiotto et al., 2014). This material model is based on literature values of the average modulus of elasticity and Poisson's ratio of diabetic foot (Table 2).

2.3. Boundary and loading conditions

A three-dimensional (3D)FE foot model with CMI was created in Ansys SpaceClaim. The whole model was meshed (3D-tetrahedra element type) in Ansys following virtual topology using the packages with a range of solid elements in the software (Fig. 3). The use of virtual topology allowed for efficient and precise surface subdivision of the model while preserving its underlying geometry. As a result, the simulation's efficiency and accuracy increased significantly. Individual variations in foot loads and boundary conditions result from factors such as body weight, height, and foot size, which are further influenced by daily physical activities (Rodgers, 1995). However, for individuals with diabetes,

Table 1. Summary of custom three-layer insole materials combinations.

Layer	Thickness (mm)	CMI-III A	CMI-III B	CMI-III C	CMI-III D
Top	3	Amfit ® EVA	Poron	Poron	Nora ® Lunairflex
Middle	3	Nora ® Lunalastike	Nora ® Lunalastike	Nora ® Lunalastike	Nora ® Lunalastike
Base	3	TPU	TPU	Amfit ® EVA	Amfit ® EVA

Table 2. Material properties of diabetic foot and custom insole models used in the FEA.

Material	Young's modulus (MPa)	Poisson's ratio	References
Encapsulated Foot Tissues	483.0	0.40	(Cheung et al., 2005; Cheung and Zhang, 2005, 2008; Guiotto et al., 2014)
TPU	11	0.45	Frick and Rochman (2004)
Nora ® Lunairflex	0.62	0.23	Lo et al. (2015)
Nora ® Lunalastike	1.04	0.25	Lo et al. (2015)
Amfit ® EVA	8.97	0.39	Lo et al. (2015)
Plastazote ® PE	0.45	0.38	Nouman et al. (2023)
Poron ®	0.23	0.48	Lo et al. (2015)

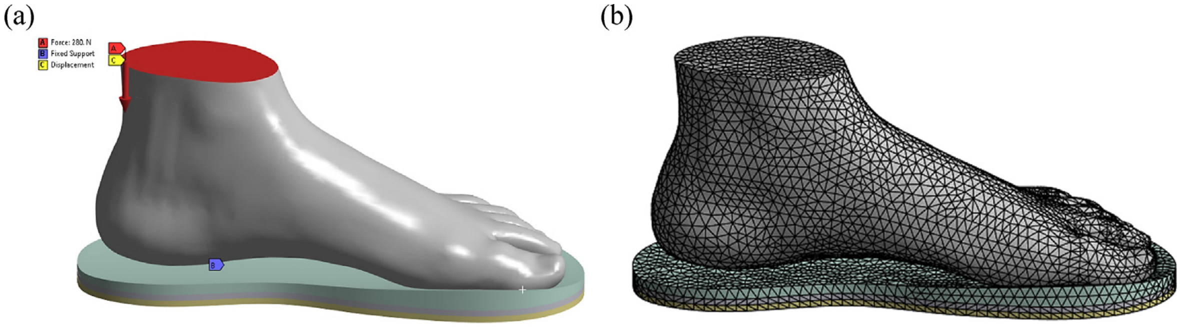

Fig. 3. (a) Loading definition of the FEA model, and (b) the three-dimensional foot model mesh with tetrahedral elements.

mobility is restricted due to neuropathy and the occurrence of skin cracks and ulcer formations on the feet (Boulton et al., 1983; Leung, 2007). Therefore, in the present study, only foot pressures in case of standing were simulated.

After assembling the model in Ansys SpaceClaim, loads and boundary conditions were applied to represent a static standing position. The foot-insole contact was set to rough. For a female patient weighing 60 kg, it was assumed that each foot supported half of her weight, resulting in a mass of 30 kg per foot. Therefore, a force of 300 N was applied to each foot (Fig. 3) (Bus et al., 2014).

3. Results and discussion

The main objective of this study was to analyze the effects of a CMI, designed to decrease pressure on diabetic foot, on various parts of the foot. A 3D FE model of the human foot was effectively created to capture its precise geometrical characteristics. This model demonstrated the ability to accurately predict the distribution of plantar pressure resulting from natural body weight, as well as the stress experienced by the foot's surface and insole. By examining the impact of both insole design and material on the stress and strain encountered by both the foot and footwear. Using these models, the research provides useful insights into material performance, adding to a better understanding of the problem. The next sections will cover the results of the stress and plantar pressure distributions in the presence of the proposed three CMI models with various material properties. To enhance our knowledge of insole performance, the effect of the design and materials selection of the CMI designs on the stresses developed at the foot was evaluated.

3.1. Plantar pressure distribution

To evaluate the plantar pressure data, the foot was split into three anatomical areas: hindfoot, midfoot, and forefoot (Fig. 4). The stress of the CMI in all areas was simulated using the FE model. The next three parts will cover the stress distribution simulation results for each of the three insole designs fabricated from six different materials. Subsequently, the effect of various insole designs and material properties on redistributing and reducing plantar pressure.

3.1.1. Plantar pressure distribution with the semi-porous insole design CMI-I

In order to simulate standing position, the diabetic foot material properties were estimated in the 'Materials and methods' section and the foot was originally placed in contact with CMI-I at an applied foot force of 300 N. As shown in Fig. 5, this initial

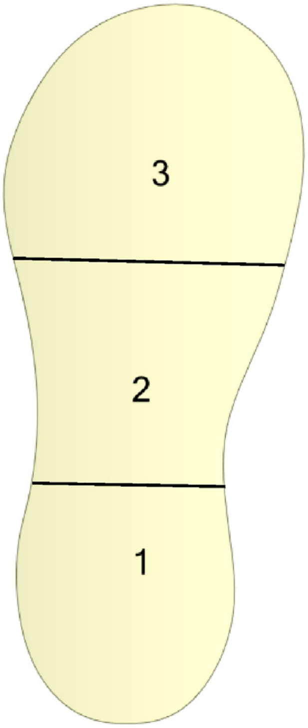

Fig. 4. Three subareas for left foot.

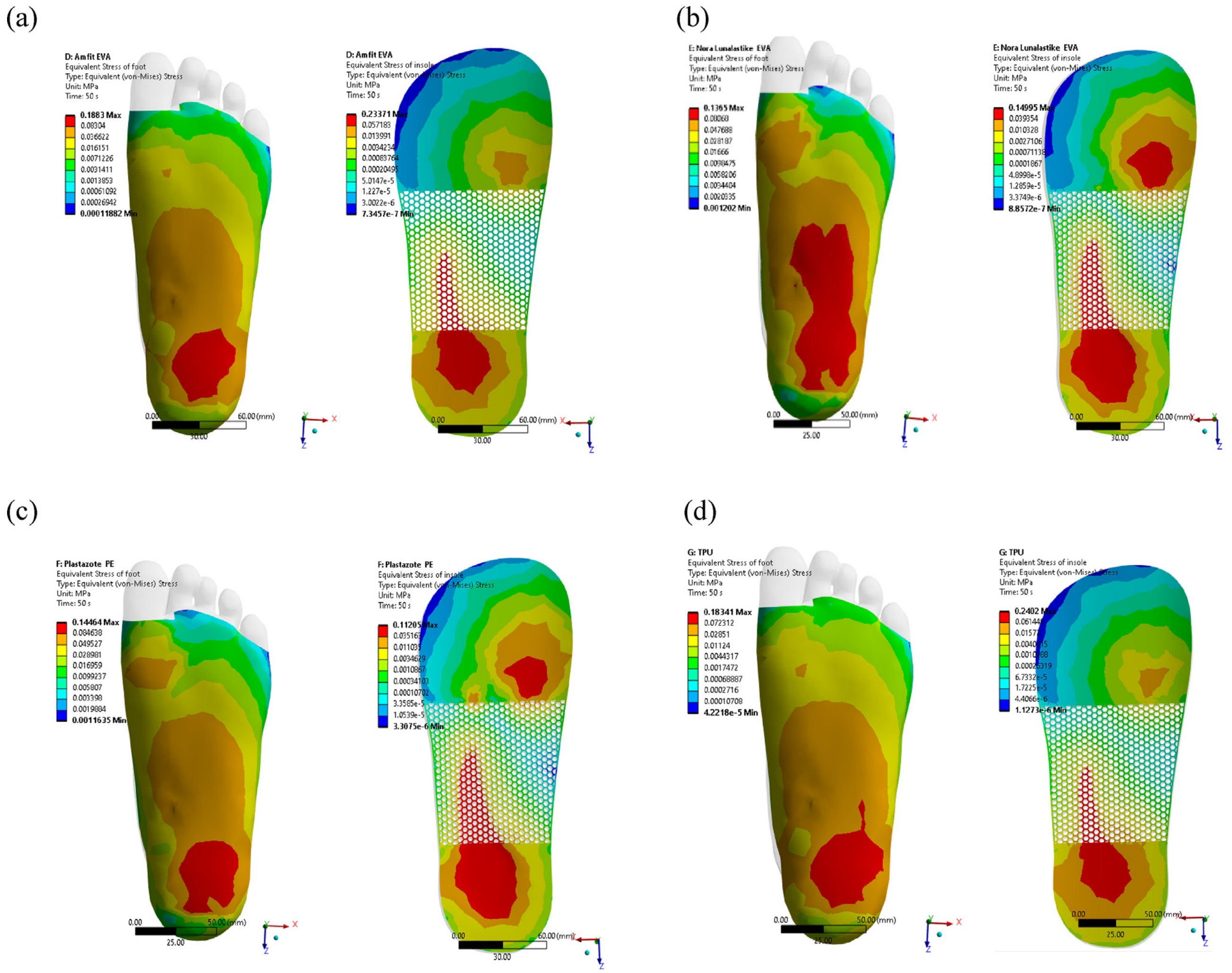

Fig. 5. Foot and CMI-I stresses for standing using four different insole materials: (a) Amfit® EVA (b) Nora® Lunalastike. (c) Plastazote® PE, and (d) TPU.

simulation provided a von Mises stress profile at the foot and the insole. The same boundary conditions are applied to the four individual insole materials. In a comparison of various insole materials when using the CMI-I insole model, considerable variations in induced plantar pressures were found. The study evaluated four materials: TPU, Plastazote PE, Nora Lunalastike, and Amfit ® EVA. The measured peak plantar pressures for these materials were 0.1834 × 10^6Pa, 0.1446 × 10^6Pa, 0.1365 × 10^6Pa, and 0.1883 × 10^6Pa under the hindfoot region, respectively. Furthermore, AmfitEVA displayed the highest plantar pressure among them, indicating the least effective pressure reduction, While Nora Lunalastike material demonstrated excellent performance, suggesting this material superior ability in CMI-I to reduce peak contact stress without additional structural support. These results highlighted the significance of material selection when constructing diabetic neuropathic insoles for effective plantar pressure reduction.

3.1.2. Plantar pressure distribution with the flat insole design CMI-II

The plantar pressure distribution and insole contact stress derived from the CMI-II under similar loading conditions as the CMI-I is shown in Fig. 6. TPU, Plastazote PE, NoraLunalastike, and AmfitEVA were the materials investigated; their corresponding plantar pressures were 0.3795 × 10^6Pa, 0.1381 × 10^6Pa, 0.1548 × 10^6Pa, and 0.3365 × 10^6Pa. With a plantar pressure of 0.1381 × 10^6Pa, Plastazote PE showed the lowest plantar pressure on the midfoot area, demonstrating its superior capacity

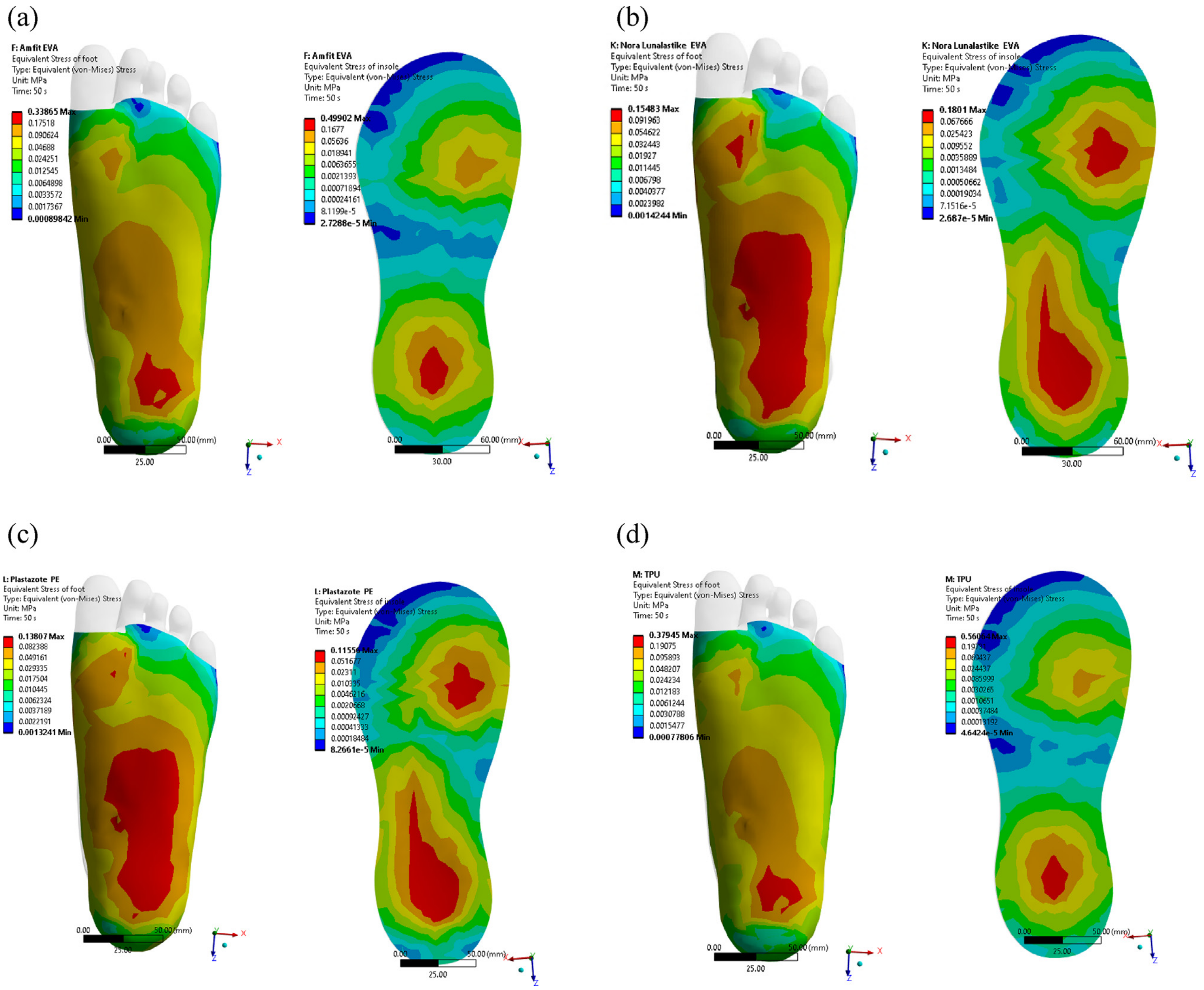

Fig. 6. Foot and CMI-II stresses for standing using four different insole materials: (a) Amfit® EVA (b) Nora® Lunalastike. (c) Plastazote® PE, and (d) TPU.

for pressure distribution. On the other hand, TPU showed the highest plantar pressure on the hindfoot region, indicating the least efficient distribution of the plantar pressure.

3.1.3. Plantar pressure distribution with the three-layer insole design CMI-III

Using the CMI-III insole model, the study analyzed the effects of the four material combinations mentioned in the 'Materials and Methods' section on the foot plantar pressure and the insole contact stress (Fig. 7). The plantar contact stresses for these combinations that were tested designated as CMI-III A, CMI-III B, CMI-III C, and CMI-III D were 0.1715×10^6Pa, 0.1878×10^6Pa, 0.1605×10^6Pa, and 0.1494×10^6Pa on the hindfoot region, according to that order. The CMI-III D combination experienced the lowest plantar contact stress of all of them, at 0.1494×10^6Pa, demonstrating its superior ability to reduce foot contact stress. Conversely, CMI-III B demonstrated the highest plantar contact stress (0.1878×10^6Pa), indicating that it is the least effective combination for reducing plantar pressure. These results demonstrated how using multiple layers made of different materials significantly affects the distribution of plantar contact stress, which is important for optimizing insole design to improve foot comfort and reduce the risk of pressure and diabetes-related foot ulcers.

3.2. The impact of insole design and materials selection on plantar pressure reduction

Using the CMI-I, CMI-II, and CMI-III insole models, a comparative study of the effects of different insole combinations and materials on the

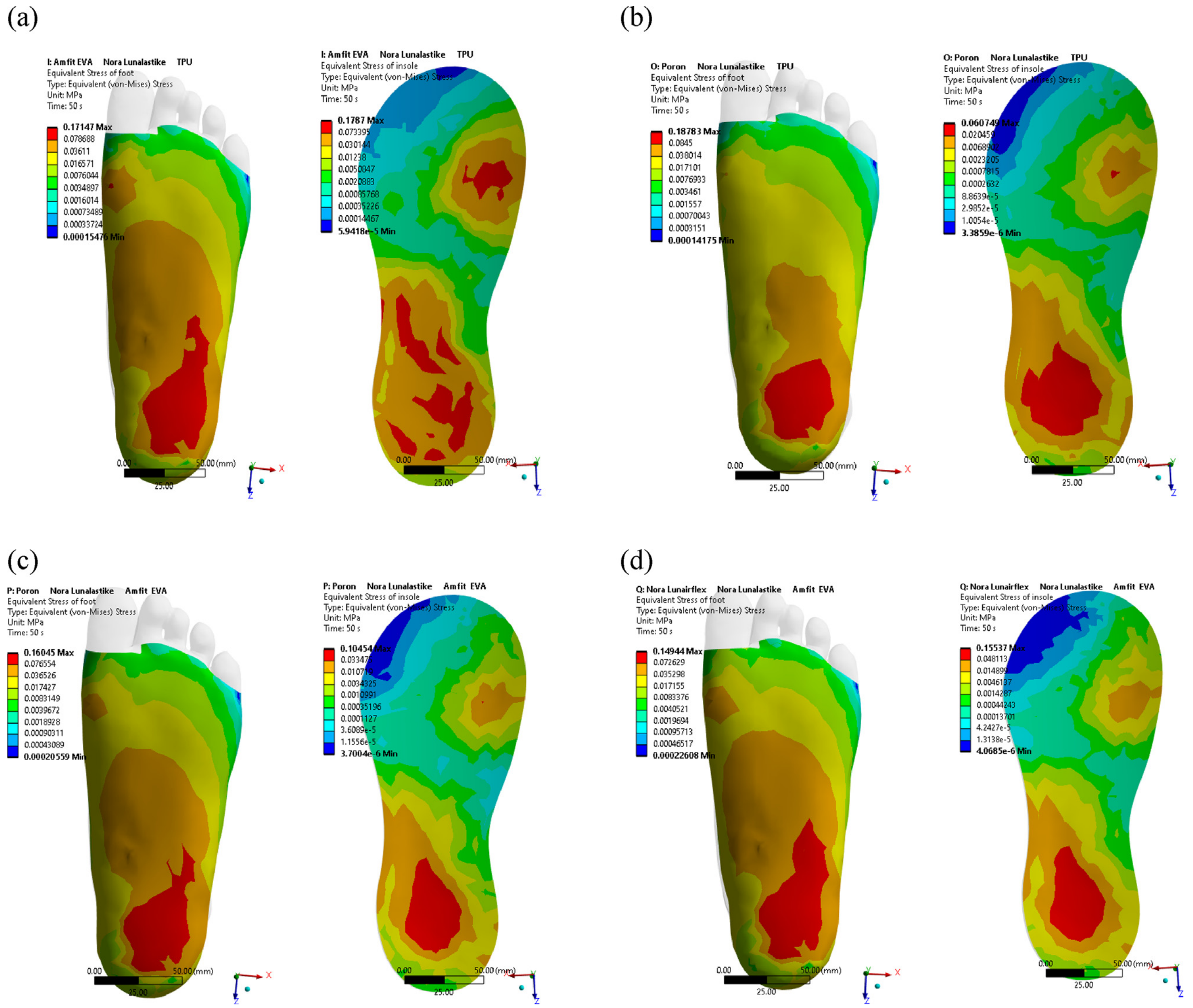

Fig. 7. Foot and CMI-III stresses for standing using four different insole material combinations: (a) CMI-III A. (b) CMI-III B. (c) CMI-III C, and (d) CMI-III D.

predicted foot peak contact stress has been carried out. The results of the comparison, which are illustrated in Fig. 8, showed substantial variations in performance between the three insole models and materials selections.

A comparison of insole materials on foot contact stresses demonstrated considerable differences in the performance between semi-porous (CMI-I) and flat (CMI-II) models. When compared with flat CMI-II model, the use of Amfit EVA, Nora Lunalastike, and TPU materials resulted in considerable reduction in maximum foot contact stresses of 44.04, 1.16, and 51.64%, respectively. This implies a significant improvement in pressure distribution for Amfit EVA and TPU materials with a semi-porous structure. In contrast, the Plastazote PE material increased foot contact stress by 4.71% when using the CMI-I insole as opposed to the CMI-II insole, indicating that the semi-porous design might not be effective with this material. As a result, as compared with material combinations III A, III B, and III C, respectively, the CMI-III created with the III D material combination decreased the maximum foot contact stress by 12.88, 20.46, and 6.91%. Finally, in comparison to the three-layer insole CMI-III D, the use of Nora Lunalastike material in the semi-porous insole (CMI-I) and Plastazote PE in the flat model (CMI-II) resulted in an 8.63% and 7.56% reduction in peak contact stress, respectively. This suggests that using Nora Lunalastike with the semi-porous insole model (CMI-I) performed better than all simulated insole models and materials in this study.

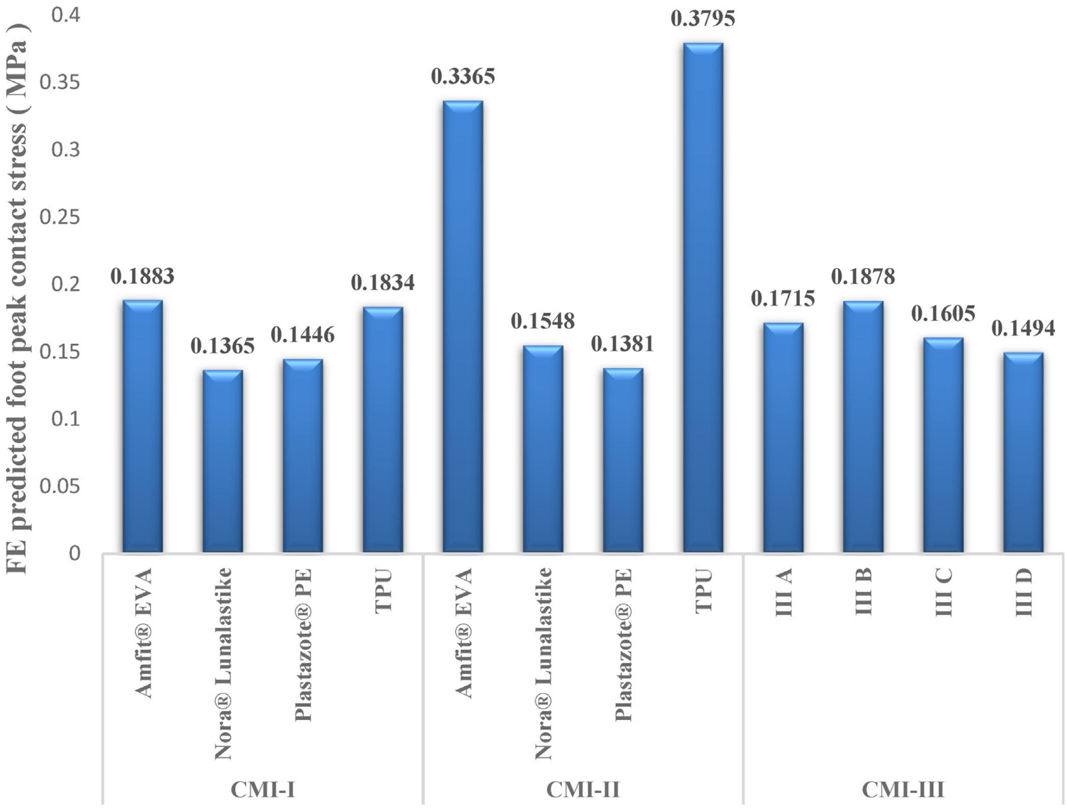

Fig. 8. FE predicted peak pressure of all insole designs.

The influence of the insole design and material properties on each region of the foot is summarized in Table 3. The table data particularly showed variances regarding predicted stress values and pressure reduction percentages at the hindfoot, midfoot, and forefoot regions. In general, the CMI-I insoles showed smaller stress values in the forefoot and midfoot areas when compared with the flat CMI-II insoles. These results highlighted how important material selection and insole design are for maximizing plantar pressure distribution and improving general foot comfort.

However, this study found that, except for CMI-II while using Nora Lunalastike and Plastazote PE materials, the hindfoot, and the forefoot areas for the three proposed insole models, had the highest, lowest plantar contact stresses, respectively. Furthermore, for TPU material, the CMI-II, hind foot region experienced the highest stress value of any of the models evaluated. Meanwhile, the CMI-I forefoot area demonstrated the smallest stress value as opposed to all other models. Additionally, based on the results of the first two insole models CMI-I and CMI-II, employing the softest material (i.e., Nora Lunalastike)

Table 3. Peak contact stress and pressure reduction percentage of plantar areas of the foot with varying materials.

	Peak Contact stress (MPa), red. (~%)															
	Amfit EVA				Nora Lunalastike				Plastazote PE				TPU			
Plantar Areas	CMI-I		CMI-II		CMI-I		CMI-II		CMI-I		CMI-II		CMI-I		CMI-II	
Hindfoot	0.1883	73	0.3365	61	0.1365	56	0.1381	46	0.1446	57	0.1184	47	0.1834	77	0.3795	59
Midfoot	0.0834	17	0.1245	19	0.0971	26	0.1548	35	0.0777	31	0.1381	35	0.0771	16	0.1211	20
Forefoot	0.0424	10	0.1233	20	0.0715	18	0.1095	19	0.0608	12	0.0888	18	0.0345	7	0.1201	21
Whole foot	0.1883	0.3365	0.1365	0.1548	0.1446	0.1381	0.1834	0.3795								
	CMI-III A				CMI-III B				CMI-III C				CMI-III D			
Hindfoot	0.1715		79		0.1878		76		0.1605		78		0.1494		72	
Midfoot	0.1216		15		0.0803		18		0.1019		18		0.1097		19	
Forefoot	0.0875		6		0.0401		6		0.0545		4		0.0609		9	
Whole foot	0.1715				0.1878				0.1605				0.1494			

Note: I—CMI-I, II—CMI-II, III A—CMI-III A, III B—CMI-III B, III C—CMI-III C, and III D—CMI-III D.

increased the area of the high plantar contact pressure regions, in other words, redistributed pressure. Furthermore, employing the highest stiffness material in CMI-II, TPU, induced the maximum peak contact stress in comparison to CMI-I.

A critical measure for evaluating the effectiveness of the suggested designs and materials selections is to compare the maximum plantar pressure value obtained to an assigned acceptable level. Many studies have identified 200 kPa as the top limit for successful foot offloading in diabetic patients (Bus et al., 2011; Hellstrand Tang et al., 2014; Lin et al., 2013; Martinez-Santos et al., 2019; Owings et al., 2009). When comparing CMI-I to CMI-II regarding the FE-predicted peak contact stress on the foot, CMI-II produced higher values for all materials used, except for Plastazote PE. Additionally, for CMI-III, the III D material combination provided the optimal result, with a stress value of 0.1494 MPa. Ultimately, the most effective combination of material selection and insole design was found to be using the Nora Lunalastike with the CMI-I design, resulting in the lowest maximum stress of 0.1365 MPa. As a result, porosity is a major factor in insole design, as demonstrated by the superior overall results obtained with the semi-porous insole design (CMI-I).

However, the findings indicate that the hindfoot region is primarily where peak plantar pressure is concentrated, suggesting that standing diabetic foot ulcers are more likely to develop in this area (Ghassemi et al., 2015; Ghazali et al., 2021; Raspovic et al., 2000). This agrees with what we experience on an everyday basis, which is that under pressure, insoles usually bottom out in this area. High-quality rubber materials such as Nora Lunalastike is an excellent choice for designing the due to its superior cushioning, shock absorption, flexibility, moisture management, skin-friendly properties, ease of customization, and consistent manufacturing quality. Its exceptional comfort, durability, and ability to mold to the foot's contours make it ideal for providing support and pressure relief, particularly in footwear applications where comfort and performance are critical. Additionally, Nora Lunalastike exhibits a balanced Young's modulus of compression, allowing for optimal support without sacrificing deformability, ensuring that the insole maintains its shape and support over time for lasting comfort. Nevertheless, because of its typically balanced Young's modulus of compression, Nora Lunalastike insoles could suggest comparatively rapid shape deformation, and therefore enhancing pressure reduction and redistribution. Consistent with our present study's discussion, material stiffness appears to be the primary factor controlling pressure reduction (Telfer et al., 2014).

The current study has significant limitations. To begin, the proposed procedure was only applied to one subject, emphasizing the importance of future analyses including numerous patients to ensure an accurate assessment of the presented results. Furthermore, the created FE foot model is simplified (i.e. partial FE model of the foot without bones). A study showed that adding the bone structure increased the simulation accuracy and led to a 4.30% reduction in plantar pressures compared with the simplified foot model (Ghazali et al., 2021). In addition, the study focused primarily on the patients' standing position, limiting the importance of the results to other patient situations, such as walking. Furthermore, the insole's shape was adjusted using a high beginning thickness value, which may not have been optimum. While altering this value could theoretically produce more precise outcomes, current literature suggests that differences in cushioning material thickness may not strongly affect pressure distribution, although topology does have an effect (Chatzistergos et al., 2017). Lastly, building the FE model from CT scan images of a normal foot is time-consuming, limiting the scalability of this method.

3.3. Conclusion

In conclusion, this study investigated and presented three insole models made of various materials to optimize stress distribution on contact surfaces between the foot and the insole, with the goal of decreasing peak plantar pressure and preventing foot ulcer incidences. Furthermore, employing 3D printing technology for the designed insoles will reduce costs, potentially allowing for greater adoption of personalized insoles. Accordingly, results indicated that semi-porous insole design (CMI-I) showed the best performance in reducing plantar foot pressure among all the models that were analyzed. In addition, this design Nora Lunalastike material combines overall cushioning and ventilation in the mid-foot region. Furthermore, the three-layer custom insole (CMI-III D) is the second best-performing design, with a significant redistribution and reduction in plantar pressure when compared with other presented insole models. This implies that insoles with variable shape structure or constantly varying stiffness might offer better pressure distribution than insoles with a solid structure and non-changing stiffness. In the future work, the durability, wear resistance, and material degradation over time of the proposed insoles should be considered and measured in case of manufacturing.

Ethical approval

The dataset was collected from the first author of this research paper with no need for ethical committee approval.

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Author contributions

In the development of this work, the authors contributed significantly to the application of Finite Element Analysis (FEA) by designing the methodology, implementing the computational models, and interpreting the results. Their combined efforts focused on refining the accuracy of the simulations, improving the convergence of the algorithms. Each author also played a role in reviewing relevant literature, drafting the manuscript, and providing critical revisions to ensure the quality and integrity of the research.

Data availability

All data and materials are the property of the authors. Corresponding authors may provide raw data upon reasonable request.

Conflict of interest

There are no conflicts of interest.

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