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Functional gradient structural design of customized diabetic insoles

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Abstract

Diabetic foot is a common and serious complication of diabetes, largely due to sensory neuropathy and excessive mechanical stresses. Studies have shown that reducing the contact pressure can effectively lower the incidence of diabetic foot. A new design method is proposed in this study for optimizing the stress distribution of the contact surfaces between the foot and the insole by applying functional gradient structural properties to the insole. Finite element analysis was employed for studying the contact mechanics, which laid the foundation for modulus readjustment during the optimization process. The moduli of the materials were correlated to the properties of the structural porous units. The customized insoles were manufactured using additive manufacturing technology and put into mechanical test. Results show that the designed insole helps in increasing the foot contact area by approximately 30% and reducing the peak contact pressure by 35%. Hence, the proposed method can be used to design customized insoles, particularly diabetic insoles, by offering better contact mechanics and good potential for reducing the severity of diabetic foot. The methodology is equally applicable to other designs involving optimization of material properties.

Keywords: Diabetic insoles; functional gradient structure; Porous structural units; Additive manufacturing

HIGHLIGHTS

- Innovative design of diabetic insole for optimized planter stress-distribution using functional gradient structure (FGS).
- Regional modulus of insole was adjusted based on contact mechanics of insole–foot interface.
- Relationship was built between equivalent modulus and structural parameters of porous structure.
- Customized insoles with regional gradient modulus are manufactured using additive manufacturing technology.

1 Introduction

Diabetic foot is one of the most common complications of type-2 diabetes, largely due to sensory neuropathy and excessive mechanical stress[1]. Studies have shown that reducing the planter contact pressure in diabetic patients helps in preventing diabetic foot [1]. It has been proved that compared to ordinary flat insoles, soft total contact insoles can effectively decrease the peak planter contact pressure and increase the contact area, thereby reducing the probability of foot ulcers in diabetic patients [2][3].

The main design factors of diabetic insoles include geometry contour, stiffness, thickness, and other types of variations such as that in metatarsal pads. Among them, the geometry contour was found to be the dominant factor in the determination of the peak contact pressure, and the stiffness was the secondary factor [4]. It has been well documented that the total contact insoles help in decreasing the peak contact pressures in the forefoot and rearfoot by 19.8–56.8% compared to flat insoles [5]. This reduced pressure will be reallocated to the midfoot and the newly increased contact area [7]. Moreover, using soft insole materials and increasing the thickness of insoles can help in expanding the foot contact area and decreasing the peak contact pressure; however, to a certain limitation. The combination of multiple design factors contributed more to the stress reduction of the interface than the single design factor[24]. It has been demonstrated that shape- and pressure-based insoles provide superior offloading of metatarsal head compared with conventional diabetic orthoses[19].

The main criteria in the design and development of the current insoles is to match the patient's foot contour [7][16][17]. These designs generally have homogenous material properties throughout the whole insole [21][22][23]. However, the physiological characteristics of human foot may result in a rather high level of pressures especially in the forefoot and rearfoot regions, which cannot be reduced ideally simply by adjusting the flexibility of the insole as a whole. Therefore, different areas of planter require individual material properties of insole materials. In comparison to the homogenous design, functionally gradient material is more conducive to adapting to subject-specific geometrical topology of foot, leading to better opportunities of reduced planter pressure. Meanwhile, with the development of 3D printing technology, it is possible to make use of the porous microstructures to adapt the mechanical properties of homogeneous materials.

The aim of this study was to develop a new design method for optimizing the planter pressure distribution by applying functional gradient structural properties to the insole to maximize the reduction in the peak planter pressures in the forefoot and rearfoot[6]. Finite element (FE) analysis was employed to study the contact mechanics, which laid the foundation for modulus readjustment during the optimization process. The moduli of the materials were correlated to the properties of the structural porous units. Finally, the customized insoles were manufactured using additive manufacturing technology and tested experimentally. The test results showed that customized insoles could effectively reduce the peak planter pressure compared to ordinary flat insoles.

2 Methods

In this study, a simplified three-dimensional FE model of a human foot was constructed to study the contact mechanics of the interface between the foot and the insole. An optimization method was proposed to apply functional gradient structural properties to the insole based on the FE analysis results.

The mechanical properties of the porous structural units were measured experimentally. These data were then used to lay the structural foundation for modeling the customized insole with porosity corresponding to the regional gradient modulus. The insole was then manufactured using 3D printing technology and tested. The same volunteer was selected for the FE model development, manufacturing process and testing.

2.1 FE model construction

A three-dimensional FE (Figure 1) model of a soft-tissue-skeletal foot complex was created based on the volume reconstruction of coronal computer tomography (CT) images of a human right foot. These computed tomography (CT) images of a healthy volunteer were scanned at Xijing Hospital in Xi'an, China. Model segmentation was carried out using Mimics (Materialise, Inc., Belgium). Geomagic Studio 2012 (Geomagic, Inc., USA) was used to simplify and smoothen the models for better convergence and accuracy of the FE analysis. Two different insole models, flat insole and total contact insole, were created using Inventor 2016 (Autodesk, Inc., USA) according to the surface topography of the foot model.

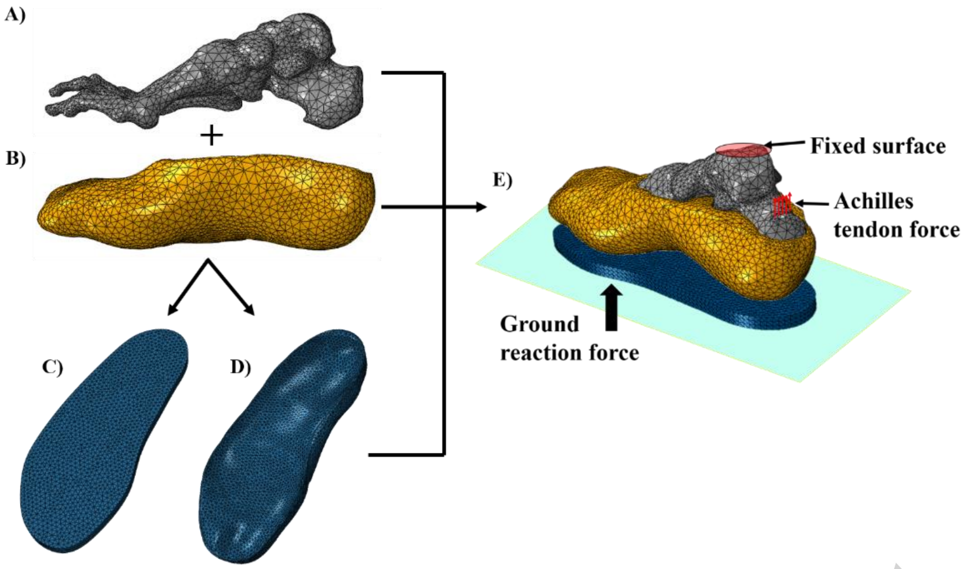


Figure 1 A) Foot bone B) Soft tissue C) Flat insole D) Total contact insole E) Load and boundary conditions of the FE model

The human foot is an extremely complex structure comprising 26 bones, 33 joints, 107 ligaments, and 18 muscles[11]. In this study, the FE model was simplified to reduce the modeling cost and to improve the feasibility of the optimization. The 26 bones were merged together as one whole body, in that case the relative motion between the segments was neglected, and the effects of ligaments and muscles associated with them were neglected. In addition to the bones, the residual soft tissue was incorporated as a whole for simplification. The foot skeleton and the soft tissue component were free-meshed by 32,651 and 88,445 ten-node tetrahedral elements (C3D10) with a characteristic length of 7mm and 7.5mm, respectively. Meshes for the bones and the soft-tissue component shared the same nodes at the interface. A mesh sensitivity analysis was performed to ensure that the mesh density used in the FE model was sufficient to reach the converged numerical results[8].

The bone and soft tissues were assumed to be continuous and linearly elastic. Due to these assumptions made above, the material properties of the bones as well as the soft tissue need to be adjusted for better representation of the real case scenario[7][12][13]. Thermoplastic polyurethane is commonly used to manufacture insoles given its mechanical properties. In this study, TPU, PolyFlex_TDS-v1 was selected for manufacturing of the insoles, and its material properties were employed in the modelling work as summarized in Table 1.

Table 1 Material properties of different parts used in the finite element model

Component	Young's modulus (MPa)	Poisson's ratio	Reference
Foot bone	5500	0.3	Cheung and Zhang[4]
Soft tissue	0.45	0.49	Chen et al.[5]
Insole	11.7	0.45	Frick et al.[20]

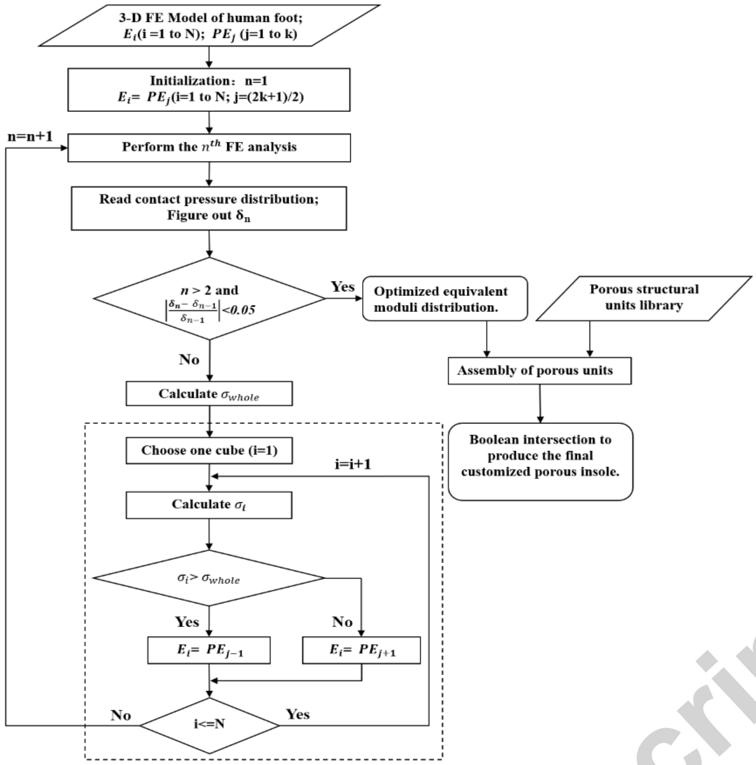
Figure 1 (A) shows the load and boundary conditions of the FE model. A vertical upward force was applied underneath the horizontal plate as the ground reaction force. The upper surface of the talus was fully constrained [4][7][10]. Another vertical force was applied upward to the Achilles tendon to maintain the balance of standing posture[12]. The inner surface of the soft tissue was tied to the outer surface of the bone part, with no relative

displacement at the interface. Frictional contact was set for the interface between the insole and the foot model, with a friction coefficient of 0.3[5]. The distal surface of the insole was fully constrained to the rigid ground.

For validation purposes, the predicted distribution of contact pressure was compared with the published data of experimental measurements obtained under the same boundary conditions.

2.2 Methodology developed to optimize the distribution of material properties

Figure 2 shows the detailed design and optimization process of the insole based on the stress analysis of the verified FE model, wherein the adjustment of the material properties of the insole is shown in the dotted box.



E_i	The Young's modulus of elements in one cube
N	The total number of cubes in the insole
PE_j	The equivalent Young's modulus of porous units, arranging from small to large
δ_n	The standard deviation of the contact stress value of all nodes of the insole in the n^{th} analysis result
σ_{whole}	Average contact stress of the whole insole
σ_i	Average contact stress of one cube

Figure 2 Flow chart for the procedure of design and optimization

As shown above, the main idea of this method was to modify the material properties of various regions of the insole according to the FE predicted contact pressure value, so as to reduce peak pressure value and uniform the pressure distribution. Before the optimization begins, the insole was divided into cubes with a side length of 6 mm and all elements inclusive in a cube were defined as one element set, in this case the insole was also divided by several element sets. The reason to select 6mm as the side length was due to the limitation of 3D printing processing of FDM for porous structure. The material properties of various regions of the insole were adjusted through these element sets. In each optimization, the effective stresses for individual cube was determined by the average value of the stresses associated with the involved elements in this cube predicted from FEA. Then the averaging stress was compared with that of the entire insole and the difference between them was used as the criterion for increasing or decreasing the Young's Modulus of the cube. In such a manner, the material properties of individual cube were then adjusted respectively throughout the complete insole model, and the detailed procedure is described in the dotted box in Figure 2. In this case, the cube associated with higher stress value would be re-assigned with relatively lower modulus and the cube associated with lower stress value would be re-assigned with increased modulus, led to a fairly homogenized stress distribution for the next round of FEA. For each iteration, all cubes could be examined and dealt in a surface by surface manner.

Each time after the modification of the material properties of the whole insole model, an FE analysis was carried out for calculation of the stress distribution, which would subsequently be used as the criterion for stopping or continuing the modification any further. As such, the optimization procedure was carried out in an iterated manner. The standard deviation of the pressure value for all the nodes of the insole model was served as convergence criteria, with the tolerance of 5%. The whole procedure was run in ABAQUS 6.14

(DASSAULT, Inc., France) software under the control of the Python language script.

2.3 Effective properties derived for porous structural unit

The thermoplastic polyurethane (TPU), which was used as the insole material in this study, is a homogeneous and isotropic elastic material with a Young's modulus of 11.7 MPa and a Poisson's ratio of 0.45. The mechanical properties could be adjusted by constructing porous structures with various characteristic parameters, such as the unit structure and cross-sectional size of the struts. The relationship between the mechanical properties of the porous units and their characteristic parameters was built through FE analysis and experimental measurement. The measured force and displacement of the units under compressive loading were used to determine their equivalent moduli by Hooke's Laws.

An assembly model with 50 porous units (5 × 5 × 2) was constructed using ABAQUS to calculate its equivalent moduli. Similarly, the stress–strain curve of the assembly was determined via mechanical tests and the elastic stage of the curve was used to calculate the equivalent moduli. Experimental measurements were used to verify the FE results. Mechanical compressive testing was carried out according to the ISO604-2002 standard using a universal mechanical testing machine (ETM 103A) operating at a compressive speed of 1mm/min, with a sample frequency of 50 Hz[18]. In this study, four different porous structure units were designed for various equivalent modulus in total. The equivalent Young's modulus of the four units were obtained by using the fore mentioned combined analysis method of FEA and mechanical testing, and the summary as shown in Figure 2 were then used later on as the database of selecting the porous structural unit for the assembly of the insole model.

2.4 Insole reconstruction and manufacturing

The insole reconstruction was also performed in foot FE model. The complete process is presented in Figure 3. After the optimization process, each cube had its corresponding position and Young's modulus information. And then, according to the relationship between the mechanical properties of the porous units and their characteristic parameters obtained in the previous section, a corresponding unit with the same Young's modulus was imported and assembled at the location of each cube to form a porous substrate during the assembly process in ABAQUS. The completed porous substrate was then intersected with the initial insole model to generate a porous customized insole model, which was later manufactured using fused deposition modeling (FDM). The printing machine and the 3D-printed testing samples are shown in Figure 3F. Table 2 lists the detailed manufacturing parameters.

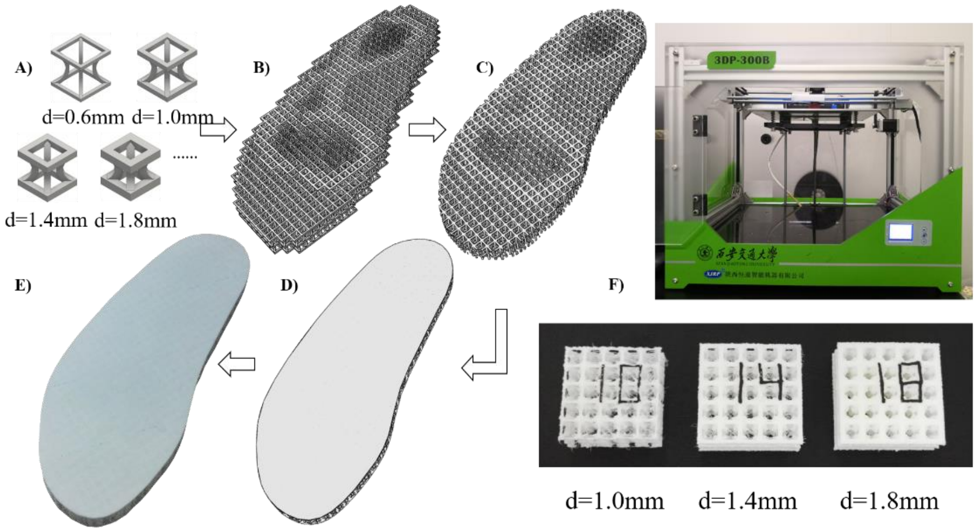


Figure 3 Assembly and manufacturing process of the customized porous insole A) Different porous units to be assembled B) Porous substrate C) Boolean intersection of the porous substrate and the original insole D) The complete customized porous insole model E) Manufactured porous customized flat insole and full contact insole F) The printing machine and the 3D-printed testing samples

Table 2 Printing parameters of FDM for the customized insole

Print Parameters	Value
Nozzle size (mm)	0.4
Print speed (mm/s)	30
Layer height (mm)	0.2
Shell thickness (mm)	0.4
Printing temperature (℃)	230
Fill density (%)	100

2.5 Experimental verification

Experiments for measuring the contact pressure between the foot and insole were carried out for validation purposes, via a Pedar-x insole pressure measurement system (Novel Pedar System, Germany). It contained an insole with 99 pressure sensors distributed uniformly across the surface area, which were thin enough to be placed in between the foot and the insole to measure the planter pressure in kPa accuracy. The sampling frequency was set at 100 Hz. These sensors have a range of 15 to 600kPa and the configuration of them is shown in Figure 8. There were four types of insoles being tested: ordinary flat insole, optimized flat insole, ordinary total contact insole and optimized total contact insole. The geometric model of the contact insole was obtained by subtracting the planter soft tissue model from the thick flat insole model. The plantar soft tissue model was reconstructed from CT data of volunteers. The volunteer weighed 54 kg and stood still with arms akimbo during measurement.

3 Results

3.1 Model validation

The validation results shows that the predicted contact pressure distribution of the FE model is similar to the measurements obtained in the literature [7][1215] under the same boundary conditions, some of them are shown in Figure 4. The relatively higher stresses are located in the rearfoot and forefoot.

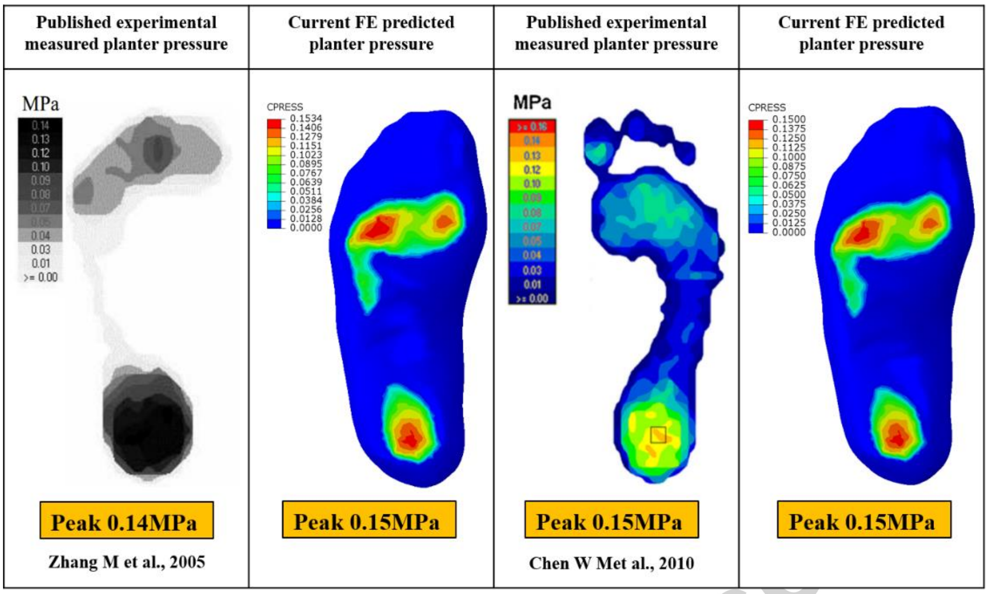


Figure 4 Comparison of predicted plantar pressure distribution with published experimental measurements under the same boundary conditions

The comparison showed that there was a good agreement in the overall patterns of the predicted and measured plantar pressure distributions during balanced standing, indicating that the FE model developed in this study was reliable.

3.2 Material properties optimization results

The contour plots of the contact pressure predicted for the insole before and after applying the optimized material properties are shown in

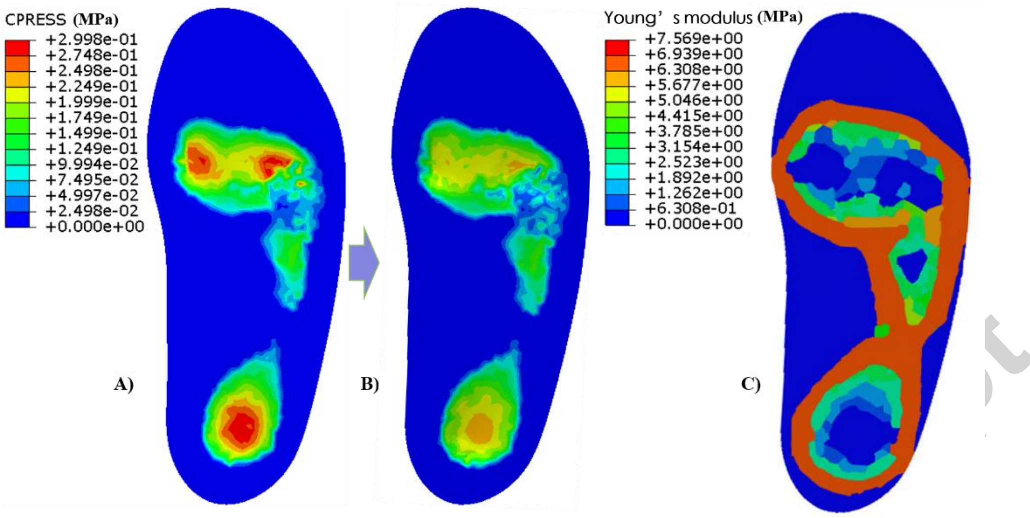


Figure 5. The optimized material properties help in decreasing the peak pressure for approximately 20% of the foot model. The optimized Young's modulus map smoothed by interpolation indicated that the material modulus in the high-pressure region such as rearfoot and forefoot have been decreased to the minimum. Meanwhile, there were some regions with high modulus at the boundaries of the contact region associated with low contact pressure.

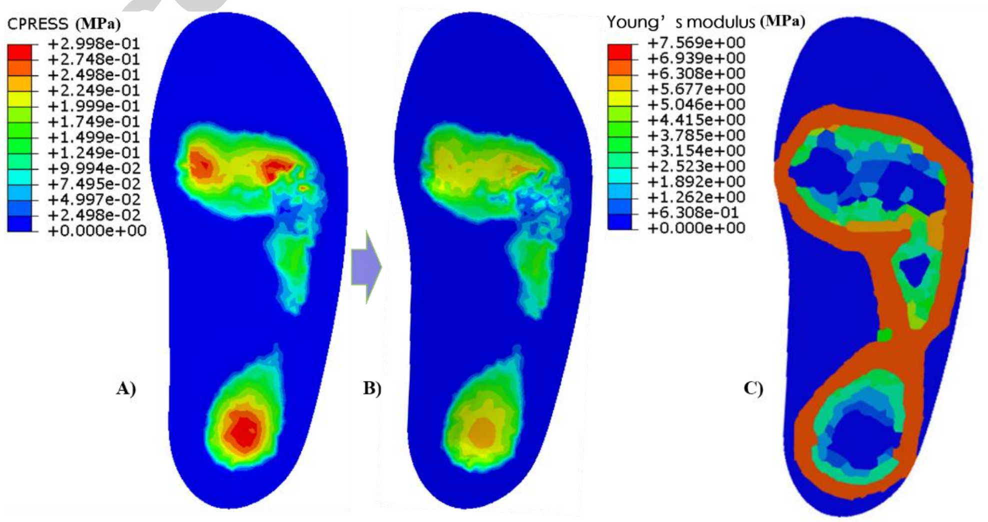


Figure 5 Comparison of foot contact pressure A) before and B) after optimization and C) optimized Young's moduli distribution

The area change of different contact pressures before and after optimization is shown in Figure 6. The area of contact pressure in the range of 0.25–0.30 MPa was reduced from 2.5% to 0.02% of the total area. Overall, the contact area was not significantly increased.

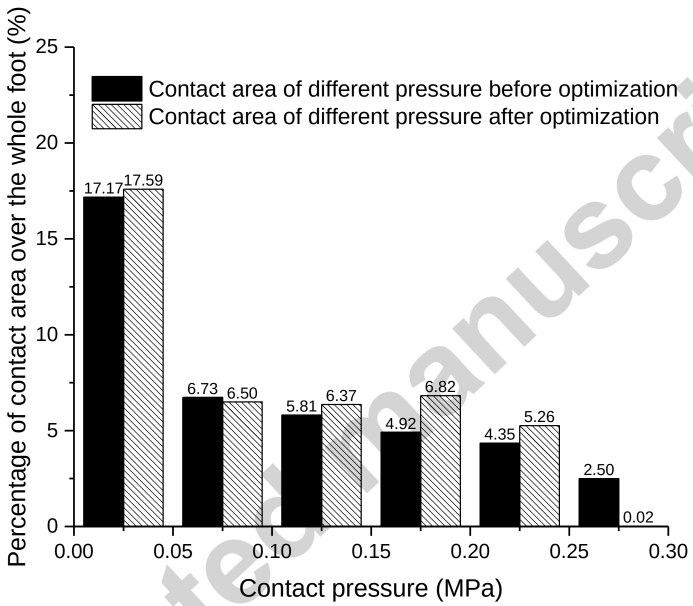


Figure 6 Percentage of contact area over the entire contact surface at different levels of pressure before and after optimization

3.3 Effective properties derived for porous structural unit

The equivalent modulus of the soft tissue of a human foot is only approximately 0.45 MPa[12], the insole material must be soft enough to generate a large deformation and decrease the peak value of the contact pressure. Therefore, four units with different structures were selected as the basis for research. The relationship between the equivalent modulus of porous units and their cross-section size of the struts is shown in Figure 7A. In terms of the equivalent modulus, unit D is associated with the highest value whereas unit B is associated with the lowest value. The forming quality of unit B is poor due to the large inclination angle of its struts. The structure for unit C tends to tilt toward one side when the deformation occurs.

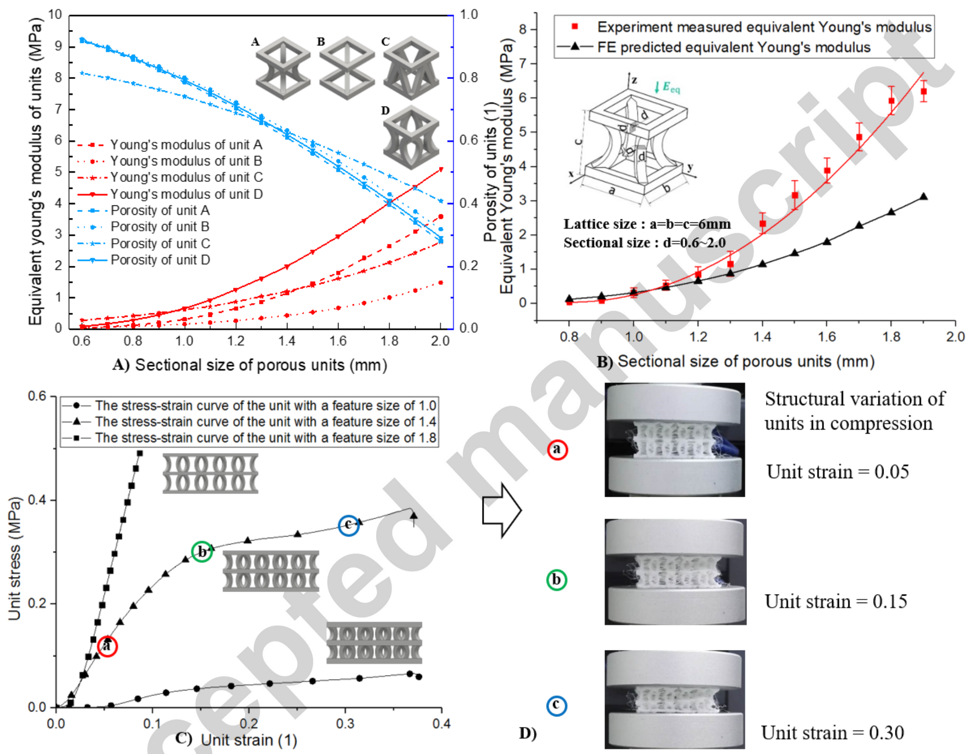


Figure 7 A) Variation in the mechanical properties of different porous units with respect to their cross-section sizes B) Experimentally measured and FE predicted equivalent moduli of the porous units with struts of different section sizes C) Stress–strain curve of the units during compression D) Structural variation in the units under compression

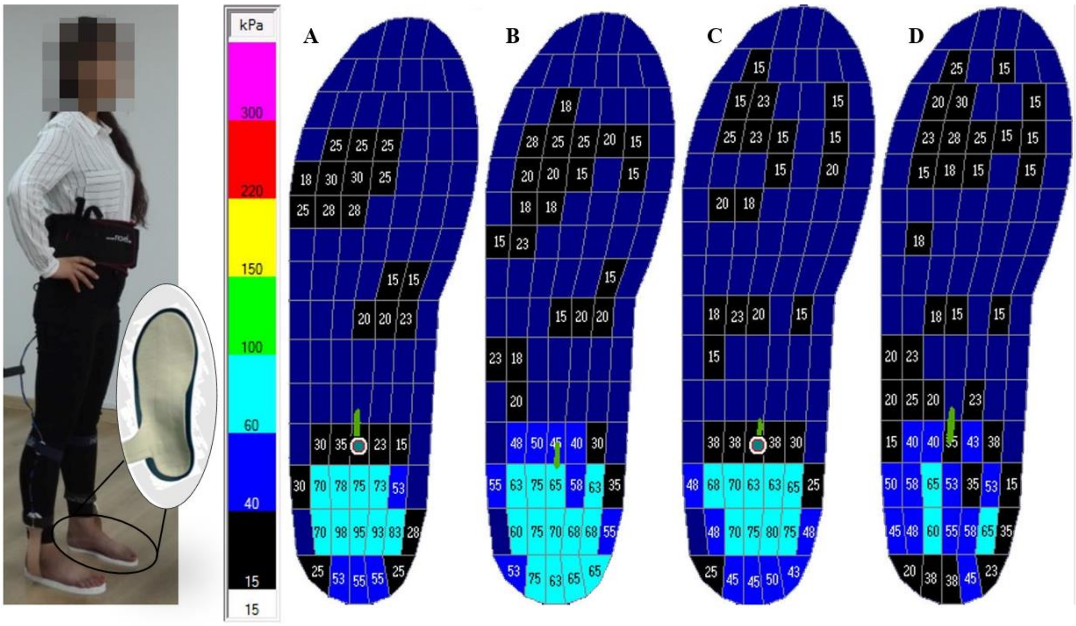
In summary, unit A was selected as the structural unit for designing the customized insole model for its low modulus and high forming quality for FDM.

Figure 7B shows the difference between the equivalent modulus measured in the experimental tests and those derived from the FE Analysis. The actual equivalent moduli were slightly lower than those predicted using the FE analysis for units with struts of small section sizes. However, for units with struts of larger section sizes, the actual equivalent moduli were greater than those predicted by modelling.

3.4 Construction and production of customized porous insole

As shown in Figure 3, the units with different moduli in the porous insole had distinct differences in color. The section sizes of the struts of the units in the forefoot and rearfoot were small, indicated in black. These units could deform significantly under compression to reduce the contact pressure. Moreover, there was a ring of high-modulus units at the periphery of the low-modulus units, indicated in white, to effectively support the load. A layer of 0.8 mm thickness was added to the upper and the bottom surfaces of the insole to prevent stress concentration and improve the surface quality, particularly because the shape corner generated after the porous base was Boolean intersected with the original insole. D and E showed the optimized insole model and manufactured object, respectively.

In the experimental verification, as shown in Figure 8, the planter pressures of the four different insoles were concentrated in the heel region. The peak contact pressure of the ordinary flat insole was the highest among the four types of insoles, whereas that of the optimized total contact insole was reduced by 33.67% compared to the ordinary flat insole. The contact area of the optimized total contact insole was increased by approximately 30% compared to that of the ordinary flat insole. The experimental results were in good agreement with those predicted using the FE analysis.



Experimental site	Ordinary flat insole	Optimized flat insole	Ordinary total contact insole	Optimized total contact insole
Peak contact pressure/MPa	98	75	80	65
Degree of declining/%	\	23.47	18.37	33.67

Figure 8 Experimental measurement results of A) ordinary flat insole B) optimized flat insole C) ordinary total contact insole and D) optimized total contact insole

4 Discussion

In this study, an iterative optimization method based on FE analysis was developed to construct customized diabetic insoles with inhomogeneous material properties. This study presented a new method to design diabetic insoles for tailoring the most appropriate insole for patients based on their planter geometry and stance. The final experimental results demonstrated the effectiveness and reliability of this method for homogenizing the contact pressures in the forefoot and rearfoot. The peak contact pressure could be reduced by 20% when the method was applied to ordinary flat insoles. The published FE analysis results showed that the total contact insole could decrease the peak contact pressure by 30–40% [7]. However, the experimental results showed that the total contact insoles could lower the peak pressure by only 18% compared to ordinary flat insoles, similar to that of the optimized flat insoles. That might result from the variance of the insole material and the testers. Furthermore, the optimized total contact insoles could reduce the peak pressure by 33% and increase the contact area by more than 40% based on the two design factors of gradient Young's modulus and geometry contour. The differences between the FE analysis and the experimental measurement were largely due to the discrepancies between the mechanical properties of the FE model and the actual human foot. Moreover, the soft tissue materials used in this model were simplified, making it difficult to represent the real soft tissue.

For each iteration during the optimization process, the program decreased the moduli of regions with high contact pressures to increase the deformation of those particular regions, and consequently reduces the contact pressure. At the same time, the moduli of low-pressure regions were increased to resist deformation and bear more load, thus preventing the pressure increasement in high pressure area. In fact, the optimization method mainly focused on the homogenization of the contact pressure distribution to reduce the peak pressure, which had no clear effect on the enlargement of the contact area. Therefore, the change in the contact area was not clear before and after the optimization (Figure 6).

There existed a clear inflection point on the stress–strain curve (Figure 7C), before and after which the equivalent modulus was a bit different. The inflection point implied that the structure of the porous unit started to twist here, which was shown in Figure 7D, leading to the sudden reduction in the equivalent modulus. The peak contact pressure of the planter was in the range of approximately 0.52–0.62 MPa, located in the forefoot and rearfoot during walking [13]. Therefore, for high-modulus units, the modulus before the inflection point was selected as the equivalent modulus, whereas the modulus after the inflection point was selected as the equivalent modulus for low-modulus units and then substituted them in the optimization process.

Compared to the FE prediction, the experimental measurement of the porous units showed that the equivalent moduli of the units with slender struts were slightly lower because of the defect generated in the manufacturing process of the porous structures. However, for units with struts of larger section sizes, the equivalent moduli were higher than those obtained from the prediction, largely because of the structural fusion between the neighboring structures caused by small gap during the FDM process.

There were some limitations in this study. Only a single stance of the gait cycle was considered instead of a complete gait cycle; this could have altered the load and boundary conditions of the FE model. Moreover, the geometry of the insole was determined using the surface morphology of the planter measured in static manner, whereas the regional gradient modulus of the insole was determined using the force state of the foot, which may vary over the entire gait cycle. Additionally, due to the porous structural characteristics, the insole printed via FDM manufacturing technology had some morphological defects in micro-level, which might cause shorter fatigue life. However, with the development of printing process, the printing quality and the service life of 3D printing insoles would be significantly improved.

Future research will be concentrated both on the improving of the FE model and the optimization method under multi-gait conditions. In parallel many efforts will be done to completely develop the totally automated design and optimization process and relative computer aided design software for customized diabetic insoles. In the future application, only the CT scanning data and the body weight are required to generate the FEA simulation model and the initial contact insoles, based on which the final customized insoles for printing can be obtained through an automated optimization procedure.

5 Conclusions

In this study, a new design method was proposed for optimizing the stress distribution of the contact surfaces between the foot and the insole by applying functional gradient structural properties to the insole, aiming to help reduce the peak planter pressure and prevent foot ulcers. 3D printing manufacturing technology was employed for the optimized insole, which had reduced the cost of the customized insoles. This would be beneficial for further popularization and application of customized insoles. Experimental results demonstrated that the optimized total contact insole could reduce the peak planter pressure by 33.67%. The methodology developed in this study could be equally applicable to other footwear and had a great potential of market for not only the diabetic patients but also other people with similar demands.

Acknowledgements

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