STUDY ON THE DESIGN OF PREVENTIVE PRODUCTS FOR DIABETIC FOOT ULCER

Guo Xiaohui, Donghua University, First year of Master's degree
Li Huifang, Donghua University, Second year of Master's degree
Tang Yingte, Donghua University, Fourth year of undergraduate
Shen Po, Donghua University, First year of undergraduate
Wang Xinyu, Donghua University, First year of undergraduate
Li Xuyi, Donghua University, First year of undergraduate

Advisor: Zhi Tang, Professor
Donghua University
Shanghai, China

Introduction. Diabetes mellitus (DM) is a chronic metabolic disease characterized by hyperglycemia, which is one of the major diseases threatening threaten human health. In recent years, the incidence of DM has shown a rapid growth trend. According to the Diabetes Atlas report provided by the International Diabetes Federation (IDF) in 2022, 10.5 % of the global population aged between 20-79 have been diagnosed with diabetes in 2021, and the number of diabetic patients in China reached the highest in the world in 2011 [1].

Diabetic foot ulcer (DFU) is the most common complication with varying recurrence rates. It is one of the most expensive chronic complications of diabetes treatment and can even lead to amputation and death in severe cases. In the face of a large number of diabetic patients, in order to reduce the social and economic burden brought by DFU, it is urgent to pay more attention to the prevention of diabetic foot ulcers, identify diabetic foot ulcers early, effectively reduce the risk of complications to patients, and prevent the occurrence of diabetic foot ulcers has important research significance.

Research status of diabetic foot pressure. The occurrence of diabetic foot ulcer is affected by peripheral neuropathy (DPN), peripheral arterial disease (PAD) and foot deformity. Patients with peripheral neuropathy, pain and sensory feedback of the distal limb subside, skin damage is not easily detected, the damaged area is susceptible to invasion by bacteria and other microorganisms, and the ulcer is difficult to heal in the high-sugar microenvironment. Meanwhile, the human body's ability to adjust gait according to pressure and pain degree is reduced, and the stress distribution on the plantar surface during the gait cycle is uneven, and the continuous effect leads to the occurrence of foot ulcers.

Abnormal increase of plantar pressure is an independent risk factor for foot ulcers in diabetic patients. Correcting abnormal high foot pressure in diabetic patients and evenly distributing plantar pressure are very important for preventing diabetic foot ulcers. Through the analysis of the foot pressure data, it provides effective experimental data and reference for the relevant design of effectively improving the distribution of plantar pressure and reducing the risk of ulcer, especially for the prevention of diabetic foot ulcer AIDS.

Caselli et al. [2] showed that one of the abnormalities in the early stage of diabetic foot ulcer was that the foot pressure could not evenly distribute the load throughout the foot, and the plantar pressure was higher. OWINGS et al. [3] found that plantar ulcers in diabetic patients were most common in the first metatarsal bone and thumb toe, followed by the second metatarsal bone, and took the average pressure in shoes of 200kPa as the safe limit to prevent the occurrence of diabetic foot ulcers. Jiang Ya et al. [4] found that the plantar pressure of people is manifested as forefoot > heel > arch, and the foot pressure of diabetic patients is most severe in the base of the third metatarsal, which is a common area for diabetic foot ulcers in clinical practice.

Therefore, the implementation of effective preventive measures during the walking process of diabetic patients, the reduction of foot pressure or foot pressure redistribution of patients, especially the decompression intervention of metatarsal bone, is very important for the prevention and treatment of diabetic foot ulcers.

Design and study on prevention of diabetic foot ulcer. Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update) proposes five key elements for preventing diabetic foot ulcers: Risk identification, regular examination, professional education, wearing comfortable footwear and treatment [5]. Timely monitoring and prevention of early abnormal plantar pressure in diabetic patients as well as correction of significant high pressure are crucial in preventing the occurrence of diabetic foot ulcers. Preventive decompression insoles and footwear are conservative treatment programs and effective preventive measures for diabetic foot ulcers. At present, the commonly used measurement indexes to evaluate the partial pressure effect of shoes include peak pressure, peak force and pressure time accumulation, etc. Good partial pressure effect can effectively predict the occurrence of diabetic foot ulcer.

With low cost and few side effects, orthopedic insoles can effectively regulate foot biomechanics, improve plantar pressure distribution and effectively prevent the occurrence of diabetic foot ulcers. Guldemond et al. [6] added different combinations of metatarsal dome, inner wedge, valgus wedge and arch support of different heights on the basic insole (Figure 1) to study plantar pressure during walking. The results showed that the combination of metatarsal dome and arch support could effectively reduce plantar pressure. Hellstrand et al. [7] showed that patients who used customized insoles had lower peak pressure than prefabricated insoles, and there was a significant difference in peak pressure in the heel region.

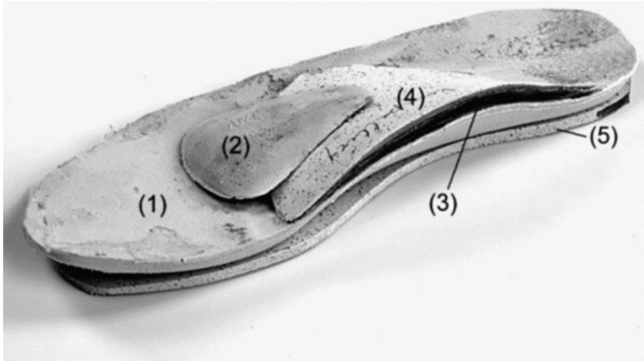

Figure 1. (1) Basic insole, (2) metatarsal dome, (3) ‘normal’ arch support, (4) ‘extra’ arch support, (5) wedge (medial)[6].

Aiming at the structure of the decompression insole, L.Tang et al. [8] applied the functional gradient structure characteristics to the insole according to the geometric structure and gait of the patient's foot, optimized the stress distribution of the contact surface, and reduced the peak pressure of the foot by about 33.67% (Figure 2). M. S. H. Leung et al. [9] proved that the concave-convex structure could effectively increase the contact area of the heel insole and reduce the peak value of plantar pressure by adjusting the relevant parameters of the concave honeycomb structure (Figure 3). Y.Thang et al. [10] studied and compared the stiffness of soles with different lattice topologies (Diamond, Cubic, X shape, Vintiles), and found that the soles designed with Diamond topology can reduce the maximum stress of the foot (Figure 4).

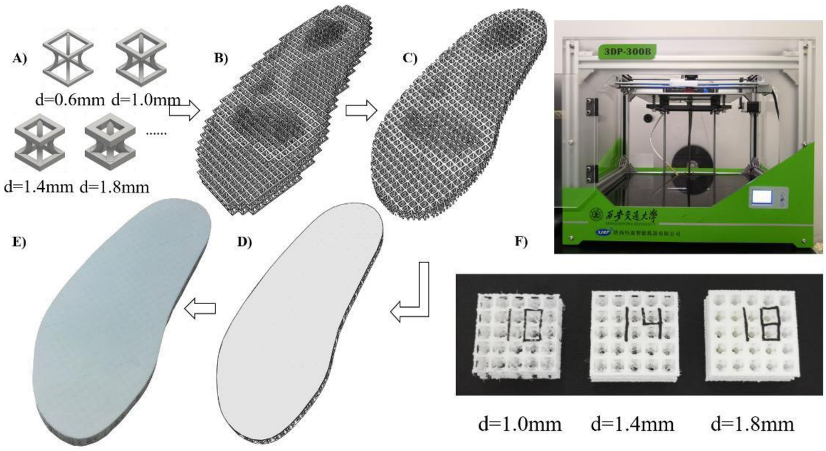

Figure 2 Full-contact insoles with functionally gradient Structure[8].

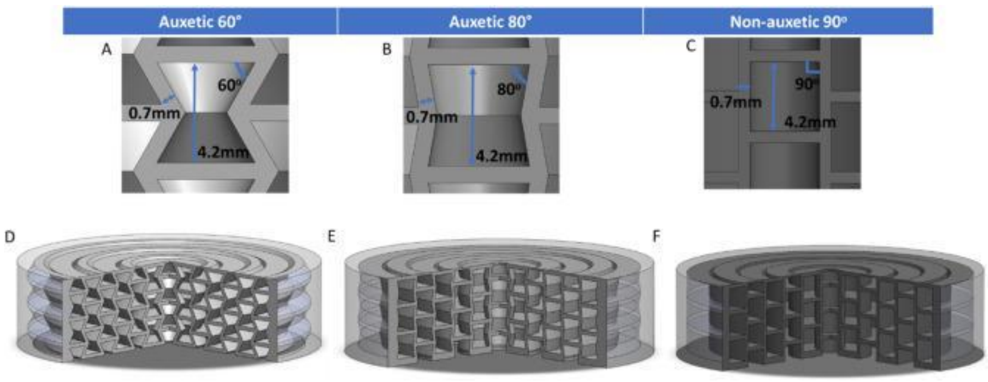

Figure 3 Heel pads with concave honeycomb structure: (A), (B), (C) internal angle, and (D), (E), (F) internal structure[9].

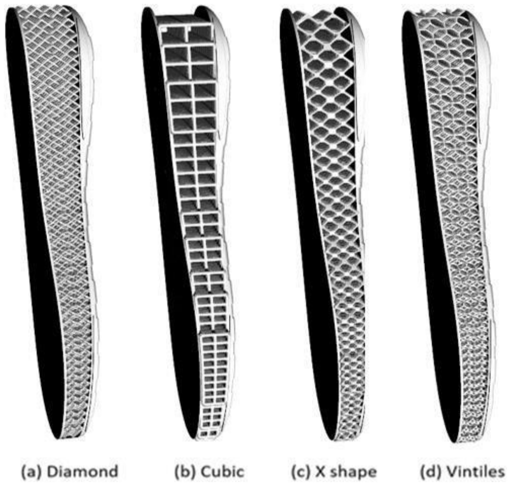

Figure 4 The shoe sole design with different topologies（Diamond、Cubic、X shape、Vintiles）[10].

Suitable diabetic shoes can adapt to foot deformities and prevent foot injury. At the same time, with orthopedic insole, they can effectively disperse foot peak pressure, correct abnormal plantar pressure distribution and prevent diabetic foot ulcers. Compared with current therapeutic footwear, the peak foot pressure of diabetic shoes during walking should be reduced by at least 30%, or the peak foot pressure should be less than 200kPa[11]. Rizzo et al. [12] conducted a long-term structured follow-up plan experiment on 298 patients with high-risk diabetic ulcers, and found that the incidence of DFU was significantly reduced in patients who used customized treatment shoes. Zwaferink[13] et al. compared the plantar pressure data of patients wearing data-driven customized shoes, sports shoes and non-treatment shoes during walking, and the results showed that wearing data-driven shoes could significantly reduce the peak pressure of metatarsal head, especially the hand-customized group had the best pressure reduction effect. Moral et al. [14] showed that compared with semi-rigid soles, patients using therapeutic footwear with rigid shaking soles (Figure 5) could reduce the activity of metatarsophalangeal joint, thereby reducing plantar pressure and effectively reducing the risk of recurrence of plantar ulcer [15].

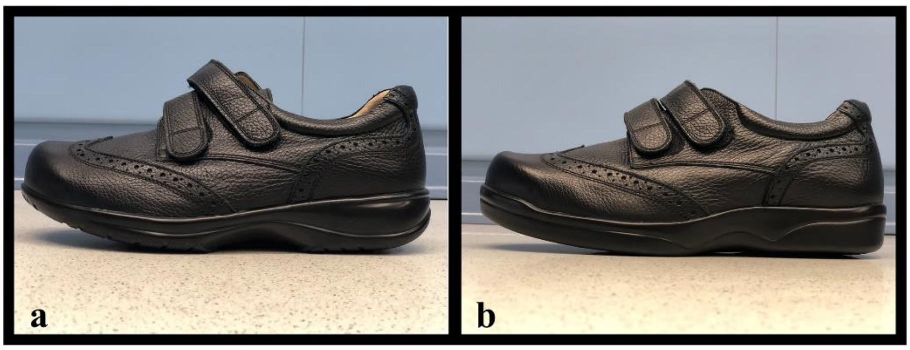

Figure 5 Sample of rigid and semi rigid sole footwear.(A) Rigid shoe (B). Semi-rigid shoe[14].

In recent years, three-dimensional finite element studies of diabetic feet have begun to appear. Finite element analysis (FEA) can calculate complex shapes and reconstruct and simulate complex boundary conditions, which can be effectively used to simulate various effective designs and combinations of materials. FEA is a practical tool for studying foot pressure, understanding foot biomechanics and different intervention effects, as well as applied to clinical research and footwear design related to prevention and treatment [16]. Nouman M et al. [17] simulated the influence of different material stiffness and design on the plantar pressure of diabetic patients through FEA, so as to design customized insoles (CMI). The results showed that the use of soft materials as heel, front foot pad and heel pad can effectively reduce the peak plantar pressure. Jafarzadeh E et al. [18] created a three-dimensional finite element model of the foot through CT scan images of diabetic patients, optimized the stiffness and shape of the insole, and reduced the plantar pressure by 40% and 25% respectively (Figure 5-7). Geiger F et al. [19] adjusted the insole stiffness through FEA and 3D printing technology, and reduced the plantar pressure through finite element analysis of parameters. The results showed that there was a certain deviation between the experimental and simulated peak plantar pressure, but the regional positioning of plantar pressure distribution was similar. FE provided a powerful tool for the development and research of diabetic foot 3D printing insole.

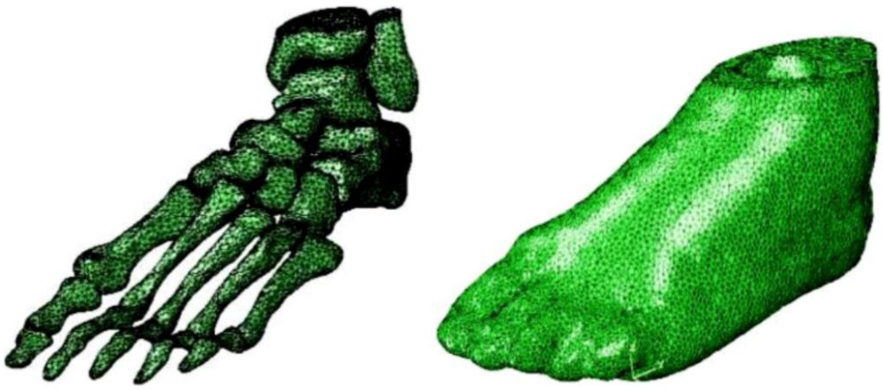

Figure 6 The finite element model of the bones and soft tissue of the foot and ankle[18].

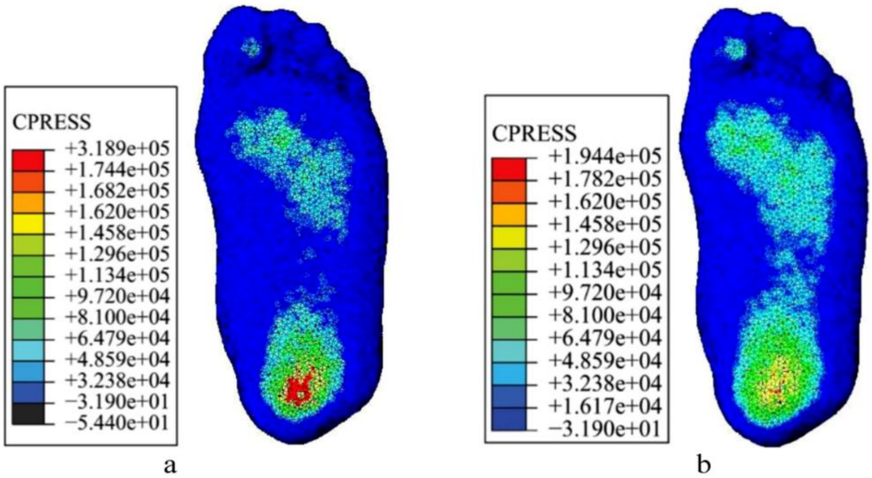

Figure 7 The contact pressure of the foot for the homogeneous flat insole with the stiffness of 74 MPa, (a) before, and (b) after stiffness optimization[18].

Summary. In recent years, the main complication of diabetic foot has become an important factor affecting the quality of life of diabetic patients, seriously affecting the physiology and psychology of diabetic patients. The key to prevent the occurrence of diabetic foot ulcer is to effectively reduce the peak foot pressure of diabetic patients and redistribute the foot pressure. At present, the research on the prevention of diabetic foot ulcers at home and abroad is still in-sufficient, and relevant domestic studies started late, and most of them are the verification of the effect of diabetic footwear produced abroad, and there is a lack of design products based on the characteristics of Chinese diabetic patients in the market. Moreover, the complexity of diabetic foot lesions leads to the lack of uniform standards and specifications for the design of diabetic foot ulcer prevention products.

The product design of diabetic foot prevention is changing from the method based on experience and skills to the more scientific and effective data-driven method, which has guiding significance for the design and transformation of diabetic foot ulcer prevention products. New technologies and methods need to be supported by more experiments and research data, and a large number of relevant experimental studies need to be carried out in the future to help patients effectively prevent the occurrence of diabetic foot ulcers.

Список литературы

1. International Diabetes Federation. IDF Diabetes Atlas 2022 Reports. https://diabetesatlas.org/2022-reports/.
2. CASELLI A, PHAM H, GIURINI J M, et al. The forefoot-to-rearfoot plantar pressure ratio is increased in severe diabetic neuropathy and can predict foot ulceration[J]. Diabetes Care,2002,25(6):1066-1071.
3. OWINGS TM, APELQVIST J, STENSTROM A, et al. Plantar pressures in diabetic patients with foot ulcers which have remained healed. Diabetic Med. 2009;26:1141-1146.
4. Jiang Ya. Analysis of the characteristics and influencing factors of barefoot plantar-pressure in Type 2 diabetes patients with natural gait [D]. Guangdong:

Southern Medical University, 2013.

5. Schaper NC, van Netten JJ, Apelqvist J, et al. Practical guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update). Diabetes Metab Res Rev 2020; 36(Suppl 1): e3266.

6. GULDEMOND N A, LEFFERS P, SCHAPER N C, et al. The effects of insole configurations on forefoot plantar pressure and walking convenience in diabetic patients with neuropathic feet[J]. Clinical Biomechanics（Bristol, Avon）, 2007, 22（1）: 81-87.

7. Hellstrand T U，Zügner R，Lisovskaja V，et al. Comparison of plantar pressure in three types of insole given to patients with diabetes at risk of developing foot ulcers - a two year，randomized trial [J]. J Clin Transl Endocrinol, 2014, 1(4): 121132.

8. L. Tang, L. Wang, W. N. Bao, S. Y. Zhu, D. C. Li, N. X. Zhao and C. Z. Liu, J. Mech. Behav. Biomed. Mater, 2019, 94, 279 —287.

9. M. S. H. Leung, K. L. Yick, Y. Sun, L. Chow and S. P. Ng, Comput. Biol. Med, 2022, 146, 105582.

10. Y. Tang, G. Dong, Y. Xiong, Q. Wang, Data-driven design of customized porous lattice sole fabricated by additive manufacturing, Procedia Manuf. 53 (2021) 318–326.

11. Bus SA, Lavery LA, Monteiro-Soares M, Rasmussen A, Raspovic A, Sacco ICN, et al. Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update). Diabetes Metab Res Rev. 2020;36(Suppl 1): e3269.

12. Rizzo, L, Tedeschi, A; Fallani, E; Coppelli, A; Vallini, V; Iacopi, E; Piaggesi, A. Custom-Made Orthesis and Shoes in a Structured Follow-Up Program Reduces the Incidence of Neuropathic Ulcers in High-Risk Diabetic Foot Patients. Int. J. Low. Extrem. Wounds 2012, 11, 59–64.

13. Zwaferink, J.B.J; Custers, W; Paardekooper, I; Berendsen, H.A; Bus, S.A, Optimizing footwear for the diabetic foot: Data-driven custom-made footwear concepts and their effect on pressure relief to prevent diabetic foot ulceration. PLoS ONE 2020, 15, e0224010.

14. López-Moral M, Lázaro-Martínez JL, García-Morales E, García-Álvarez Y, Álvaro-Afonso FJ, Molines-Barroso RJ. Clinical efficacy of therapeutic footwear with a rigid rocker sole in the prevention of recurrence in patients with diabetes mellitus and diabetic polineuropathy: a randomized clinical trial. PloS One. 2019;14:e0219537.

15. Gong Taisheng, Han Xuejing, Wan Bo-ming, Ni Liangchen, Wang Mengyuan, Wang Meng. Research status of foot AIDS for diabetic patients [J]. Journal of leather science and engineering, 2022, 32 (3): 42-47. DOI: 10.19677/j.issn. 1004-7964.2022.03.008.

16. Wang Zhanxing,Michael Roland, Chen Zhaoyu, Pang Xiaoyan,Stefan Diebels. Diabetes shoes functional research progress [J]. China leather, 2021, 50 (01): 1-8. DOI: 10.13536/j.cnki.issn1001-6813.2021-001-001.

17. Nouman M, Chong DYR, Srewaradachpisal S, Chatpun S. The Effect of

Customized Insole Pads on Plantar Pressure Distribution in a Diabetic Foot with Neuropathy: Material and Design Study Using Finite Element Analysis Approach. Applied Sciences. 2023; 13(1):399.

18. Jafarzadeh E, Soheilifard R, Ehsani-Seresht A, Design optimization procedure for an orthopedic insole having a continuously variable stiffness/shape to reduce the plantar pressure in the foot of a diabetic patient. Med. Eng. Phys, 98 (2021), pp. 44-49.

19. Geiger F, Kebbach M, Vogel D, Weissmann V, Bader R. Efficient Computer-Based Method for Adjusting the Stiffness of Subject-Specific 3D-Printed Insoles during Walking. Applied Sciences. 2023; 13(6):3854.