

INVESTIGATION OF THE EFFECTIVENESS OF PLANTAR PRESSURE REDISTRIBUTION OF CUSTOMIZED INSOLE STRUCTURE DESIGNED BASED ON PLANTAR STRUCTURE

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ABSTRACT. Although both fabricated insoles and customized insoles were designed with varied function components, current knowledge approved that customized insoles worked much better. However, how the customized insoles achieved a better performance in term of load re-distribution was still lacking quantitative assessment. The aim was to determine whether the customized insole structure based on a novel customization procedure proposed in this study performs better than the prefabricated insoles in terms of plantar pressure re-distribution efficiency. This study included ten healthy subjects, each wearing four types of insoles accordingly (control insoles; arch support insoles; orthotic insoles; customized insoles), and plantar pressure was collected in a walking state. The custom insoles are made by determining the subject's plantar surface and key plantar points, then following the customization procedure to finish them. The plantar area was divided into eight zones and then a pressure transfer algorithm was used to gain insight into the plantar pressure. Compared to the control group insoles, the arch support of the customized insoles reduced pressure in the hallux region and transferred pressure from the M4-5 to the MH and LH regions, while the metatarsal pad enhanced the pressure transfer in the mid-foot, and the anterior-posterior height difference of the insole plays a role in pressure transfer. Furthermore, the customized insoles performed close to the professional orthotic insoles. Design strategy with accurate insole's component location and reasonably plantar surface matching, our customized insole demonstrated advantages such as a better loading redistribution and significant pressure relieving on the forefoot.

KEY WORDS: customized insole, prefabricated insole, pressure transfer, metatarsal pad, arch support

INVESTIGAREA EFICIENȚEI REDISTRIBUȚIEI PRESIUNII PLANTARE LA UTILIZAREA UNUI BRANȚ CU STRUCTURĂ PERSONALIZATĂ PROIECTAT PE BAZA FORMEI PLANTARE

REZUMAT. Deși atât branțurile fabricate, cât și branțurile personalizate sunt proiectate cu variate componente funcționale, datele actuale confirmă că branțurile personalizate funcționează mult mai bine. Cu toate acestea, lipsește o evaluare cantitativă a modului în care branțurile personalizate ajung la o performanță mai bună în ceea ce privește redistribuirea încărcăturii. Obiectivul lucrării este de a determina dacă structura personalizată a branțului utilizând o nouă procedură de personalizare propusă în acest studiu funcționează mai bine decât branțurile prefabricate în ceea ce privește eficiența redistribuirii presiunii plantare. Acest studiu a inclus zece subiecți sănătoși, fiecare purtând patru tipuri de branțuri (branțuri martor; branțuri de susținere a boltei plantare; branțuri ortetice; branțuri personalizate), iar presiunea plantară a fost măsurată în timpul mersului normal. Branțurile personalizate sunt realizate prin determinarea suprafeței plantare a subiectului și a punctelor plantare cheie, urmând apoi procedura de personalizare pentru a le finisa. Zona plantară a fost împărțită în opt zone și apoi s-a folosit un algoritm de transfer al presiunii pentru a obține o perspectivă asupra presiunii plantare. În comparație cu branțurile martor, suportul plantar al branțurilor personalizate a redus presiunea în regiunea halucelui și a transferat presiunea din regiunile M4-5 în regiunile MH și LH, în timp ce suportul metatarsian a îmbunătățit transferul de presiune în zona mediană a piciorului, iar diferența de înălțime anteroposterioară a branțului joacă un rol în transferul presiunii. În plus, branțurile personalizate au avut o performanță asemănătoare cu branțurile ortetice profesionale. Fiind realizate pe baza unei strategii de proiectare cu localizarea precisă a componentelor branțului și o potrivire rezonabilă pe suprafața plantară, branțul personalizat realizat a demonstrat avantaje precum o redistribuire mai bună a încărcăturii și o reducere semnificativă a presiunii asupra antepiciorului.

CUVINTE CHEIE: branț personalizat, branț prefabricat, transfer de presiune, suport metatarsian, suport plantar

ÉTUDE DE L'EFFICACITÉ DE LA REDISTRIBUTION DE LA PRESSION PLANTAIRE LORS DE L'UTILISATION D'UNE SEMELLE INTÉRIEURE AVEC STRUCTURE PERSONNALISÉE CONÇUE À PARTIR DE LA FORME PLANTAIRE

RÉSUMÉ. Bien que les semelles fabriquées et les semelles personnalisées soient conçues avec divers composants fonctionnels, les données actuelles confirment que les semelles personnalisées fonctionnent bien mieux. Cependant, une évaluation quantitative de la façon dont les semelles personnalisées obtiennent de meilleures performances en termes de redistribution de la charge fait défaut. L'objectif de l'article est de déterminer si la structure de semelle personnalisée utilisant une nouvelle procédure de personnalisation proposée dans cette étude est plus performante que les semelles prefabricées en termes d'efficacité de redistribution de la pression plantaire. Cette étude a inclus dix sujets en bonne santé, chacun portant quatre types de semelles (semelles de contrôle, semelles de soutien de la voûte plantaire, semelles orthopédiques, semelles personnalisées), et la pression plantaire a été mesurée pendant la marche. Les semelles intérieures personnalisées sont fabriquées en déterminant la surface plantaire du sujet et les points plantaires clés, puis en suivant le processus de personnalisation pour les finir. La région plantaire a été divisée en huit zones, puis un algorithme de transfert de pression a été utilisé pour mieux comprendre la pression plantaire. Par rapport aux semelles de contrôle, le support plantaire des semelles personnalisées a réduit la pression dans la région de l'hallux et a transféré la pression des régions M4-5 vers les régions MH et LH, tandis que le support métatarsien a amélioré le

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transfert de pression dans la zone du milieu du pied, et la différence de hauteur de la semelle antéropostérieure joue un rôle dans le transfert de pression. De plus, les semelles intérieures personnalisées fonctionnaient de la même manière que les semelles orthopédiques professionnelles. Fabriquée à partir d'une stratégie de conception avec un emplacement précis des composants de la semelle intérieure et un ajustement raisonnable sur la surface plantaire, la semelle intérieure personnalisée a démontré des avantages tels qu'une meilleure redistribution de la charge et une réduction significative de la pression de l'avant-pied.

MOTS CLÉS : semelle intérieure personnalisée, semelle intérieure préfabriquée, transfert de pression, support métatarsien, support plantaire

INTRODUCTION

Plantar pressure distribution is a direct index which reflects the foot structure, posture, and function during walking; while wearing insoles is the direct approach to change the foot posture, then to affect its function performance. So, by adjusting and novel designing insole's structure, stiffness and shape, the target of plantar pressure distribution can be achieved. In terms of insole's structure, Tse *et al.* [1] explored the differences in plantar pressure distribution during walking between wedge-only insoles and wedge insoles with arch support, and their results showed that both wedge insoles reduced medial heel and forefoot pressure; further the reduction was more pronounced with supported wedge insoles than unsupported wedge insoles; Farzadi *et al.* [2] used orthotic insoles with medial arch support to reduce the pressure under the hallux and first metatarsal heads, where the load under these two regions shifted to the other regions; meanwhile, Partovifar *et al.* [3] utilized metatarsal pads and medial longitudinal arch support to significantly alleviate the maximum pressure in the heel and metatarsal (MTH) for rheumatoid arthritis patients. In terms of insole's stiffness, Meng *et al.* [4] evaluated the effectiveness of low and high stiffness insoles on plantar pressure during walking and the results showed that the insoles with high stiffness significantly increased plantar pressure of the medial forefoot, but the one with low stiffness increased the loading under mid-foot. In terms of insole's form, Jiang *et al.* [5] designed a plantar pressure redistribution insole based on the characteristic points of plantar pressure redistribution pressure for flat feet adults and they reported that the insole not only reduced the pressure of the second to third metatarsal and medial heel regions, but also it improved gait efficiency.

Most of the existing insoles were prefabricated insoles, which were designed according to the laws of the foot shape from a coherent population. However, foot shape varied through population, a customized design and made insole were considered as the most effective. Miguel Davia-Aracil *et al.* [6] proposed the use of additive manufacturing technology and fused deposition modeling to personalize the material and structure of insoles, while Jandova *et al.* [7] proposed a method that the insole form was 100% matching foot plantar surface to redistribute plantar pressure for patients with flat feet or high arched foot deformities. Korada *et al.* [8] manifested that the customized insoles designed based on plantar form and barefoot plantar pressure could significantly reduce maximum plantar pressure; meanwhile, Stolwijk *et al.* [9] combined the plantar pressure of 204 participants for their individual customized insole design, they observed the effectiveness of pressure redistribution of the customized insole; particularly a significant reduction under the 2nd-5th metatarsal and heel were found. Although positive plantar pressure redistribution was achieved by customized insole, this methodology was still disputed, since 100% of foot matching would ignore the fact that the arch region can change in height during movement, which in turn inhibits the foot's own cushioning capacity.

However, the above studies lack a method to gain insight into the role of insole structure, the pressure transfer algorithm is a method to evaluate the redistribution and transfer of plantar pressure, through this method we can have an insight into the transfer of pressure within foot structure zone, which would indirectly prove the effectiveness of insole structure and form. Bus *et al.* [10] proposed a pressure transfer approach in 2003 and they provided a perspective on changes in foot loading in patients with diabetic neuropathy and foot deformities. Bonanno *et*

al. [11] executed the pressure transfer analysis for asymptomatic adults wearing insoles with medial heel slopes of 2, 4 and 6 mm; then they disclosed that the insoles with a medial heel slope of 4 mm or 6 mm increased the peak pressure in the medial heel when the subject's foot was in a flat arch or rotated forward position; while plantar pressure in the mid-foot and forefoot did not change. Additionally, Hu *et al.* [12] had an insight into the transfer of plantar pressure in the foot with increasing age in 319 healthy children aged 2-6 years. Nevertheless, the above study assessed the plantar transfer, little literature was focusing on qualitatively assessing pressure transfer caused by customized insoles.

Therefore, the purpose of this study was first to propose a new set of ideas for customized insole design and then to quantitatively evaluate the pressure redistribution efficiency of customized insoles using pressure transfer algorithm. We hypothesize as follows: since the contact area of customized insole was relative larger and the structure design was reasonable and accurate, an optimal pressure distribution, for instance, more anterior and posterior foot pressure transfer, medial and lateral, as well as better forefoot pressure relief would be found.

EXPERIMENTAL

Methods

Participants

Ten participants, two males and eight females (age 22.2 ± 1.0 years, height 166.1 ± 7.8

cm, and weight 59.1 ± 8.7 kg) were recruited. Inclusion criteria were the following: normal BMI; no foot or leg disorders and no history of lower extremity surgery; no abnormal gait pattern. The purpose and procedures of this study were explained to the participants and their formal consent was obtained prior to conducting the test. In addition, the experiment was conducted based on the principles of the Declaration of Helsinki and was approved by the Ethics Committee of Sichuan University.

LuxScan Software Scanning and Modeling of the Foot

LuxScan (v1.1.25, LuxCreo, China) is an application based on the depth-of-field camera of iPhone phones (iPhone X and above) for easy scanning of foot models. The structure-based optical depth camera consists of a point projector, an IR camera and an RGB camera. During the scanning process, the point projector projects special structural patterns onto the object surface; the neural network algorithm in the phone's bionic chip calculates the 3D shape and depth information of the object based on the distortion of the structural light observed by the IR camera on the 3D physical surface, as shown in Figure 1. After obtaining the 3D structure of each subject's foot, the custom design of the insole is performed according to the corresponding algorithm.

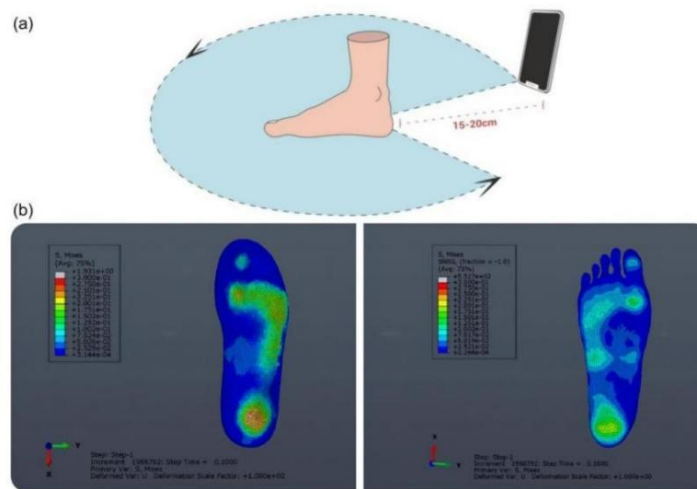


Figure 1. (a) Schematic of 3D scan of the foot (b) 3D plantar structure acquired by LuxScan

Insole Customization Procedure

The design of the key points of the customized insoles in this study followed the following steps, and the specific process is shown in Figure 2.

Insole plane and size design: through the first MTH area (72.5% of foot length), the fifth MTH area (63.5% of foot length) and the heel center key point (18% of foot length).

Arch length: make a medial tangent to the sole of the foot, and determine the arch length of the insole according to the intersection of the first MTH area and the medial heel area point with the medial tangent.

Arch width: determine the arch width according to the vertical distance from the midpoint of the arch (41% of the foot length) to the medial tangent line.

Arch height: divide the outline of the foot into three equal parts (forefoot A, mid-foot B, heel C), excluding the toes, determine

the arch height according to the relationship between the arch index x [$x=B/(A+B+C)$] and the standard navicular bone y ($y = -0.3x + 0.2$) [13], and adjust the arch height according to the foot type, increasing by 2 mm for high arched feet and decreasing by 2 mm for flat feet.

Metatarsal pad: determine the location of the metatarsal pad according to the intersection area of the line between the first MTH area and the fifth MTH area and the mid-axis of the foot, and adjust the range and height of the metatarsal pad to elevate the transverse arch area of the forefoot according to the sole of the foot.

Heel cup: design the heel bump height of 20mm for both men and women according to the foot survey data [14]. The insole is 3D printed with PLA material, which is a full lattice structure, as shown in Fig. 3, and the insole hardness relies on the lattice for personalized adjustment to the subject.

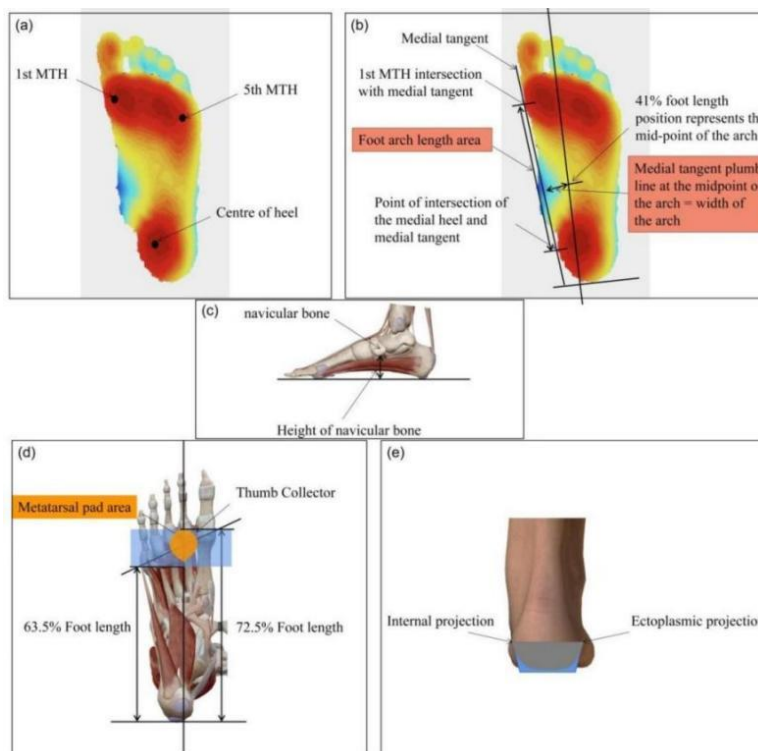


Figure 2. (a) Size design; (b) Arch support area location design; (c) Arch support height design; (d) Metatarsal pad design; (e) Heel cup design
















Figure 3. Customized insole structure diagram

Insole for Test

Four insoles with standard test shoes were tested in this study, their details are shown in Table 1.

Table 1: Pictures of shoes and insoles to be tested and their detailed parameters of structure

Insole Type	Front view	Back view	Side view	Arch support	Heel cup	Metatarsal pad	Anterior-posterior height difference	Insole hardness (average)	Remarks
Standard test shoes				x	x	x	x	x	No structure
Control insoles				x	x	x	0mm	46HC	No structure
Arch support insoles				√	√	x	1.8mm	46HC	Bulge
Orthotic Insoles				√	√	x	5.1mm	38HC	Hard support and uneven insole material
Customized insoles				√	√	√	6mm (average)	40HC	Lattice structure

Test Equipment and Test Procedure

The Pedar system (Pedar-X, Novel GmbHgmbh, Germany) was used for the tests. Ramanathan *et al.* [15], Price *et al.* [16] and Hurkmans *et al.* [17] approved good accuracy and repeatability for Pedar insole system. The sole of the foot was divided into eight subdivisions: the hallux (T1), toes 2-5 (T2-5), the 1st metatarsal (MTH1), the 2nd to 3rd metatarsal (MTH2-3), the 4th to 5th metatarsal (MTH4-5), the mid-foot (MF), medial heel (MH), and lateral heel (LH).

Participants warmed up for 3 to 5 minutes; then they wore uniform standardized socks and performed the test on a treadmill with sports shoes. Testing order was determined randomly for each participant. The slope is 0 and speed is 5 km/h for men and 4 km/h for women. Each trail lasted 3 minutes, and they repeated three times for each insole. Data was processed at the end of the experiment. At first, mean pressure (kPa) of each trail was calculated; then, the pressure data of the left and right feet were averaged; finally, the pressure percentage (PP, %) in each area was calculated.

Plantar Pressure Transfer Model

According to the plantar pressure partitioning, four regions were defined from the plantar region: the toe region (level 1), the forefoot region (level 2), the mid-foot region (level 3) and the hind region (level 4) (Fig. 4).

Next, the difference between insoles in each zone was calculated by subtracting the previous insole from the latter, the units of the figures are % (Fig. 4A1).

Then, the arrows from positive to negative marked the transfer of pressure within the level, which means that the loss of pressure in the positive region was transferred to the negative region. The final value of the pressure after the transfer was exhibited in the underlined red color (Fig. 4B1).

After that, the correlation of pressure transfer between adjacent levels was considered and the inter-level and pressure transfer was marked. When an area was faced with a pressure transfer situation to multiple areas, the inside-out and proximity principles need to be considered (Fig. 4C1). Finally, with the longitudinal arch, it was also possible for pressure transfer to occur across the levels (Fig. 4D1).

RESULT

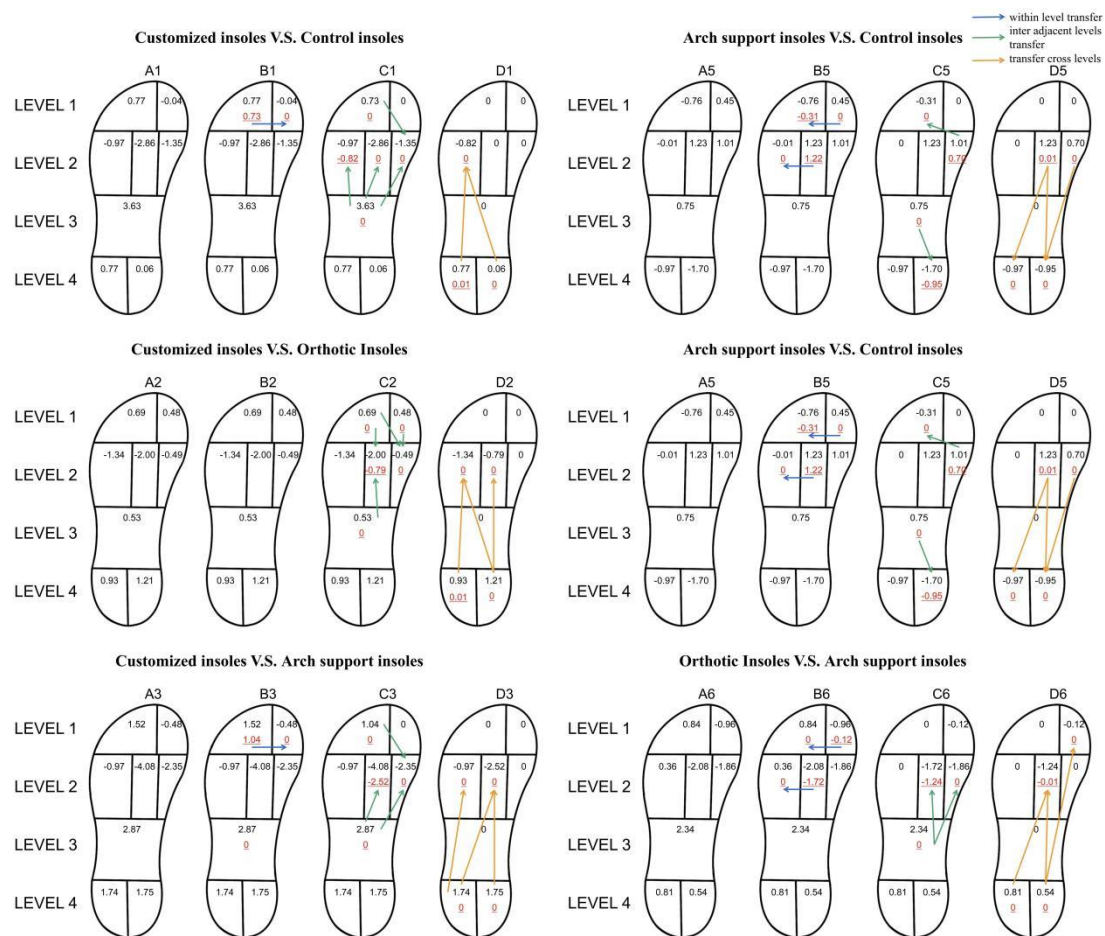


Figure 4. Pressure percentage transfer between insoles (A: PP difference between insoles; B: PP shift within a level I; C: PP transfer between adjacent levels; D: PP transference across levels)

According to Figure 4 we could directly observe what the different insole structures did. The role played by the customized insole in relation to the control group: the arch support adjusted the foot posture and reduced pressure in the T1 region; the metatarsal pad enhanced the transfer of pressure in the mid-foot; the arch support acted as a bridge to transfer pressure from the forefoot region to the mid-foot region on the one hand, and to transfer pressure from M4-5 to the MH and LH regions on the other. Similar results had been found in arch support insoles and orthotic insoles.

In contrast to the arch support insole, the customized insole’s metatarsal pad further enhanced the pressure transfer from the mid-foot to the M1-3; its arch support and 6.00mm anterior-posterior height difference further adjusted the foot posture and reduced

pressure in the T1 region; the metatarsal pad further enhanced the transfer of pressure from the forefoot to the heel.

The metatarsal pad of the customized insole further took over the pressure transfer in the toe area and mid-foot as opposed to the orthotic insole; personalized fit arch support and a greater anterior-posterior height difference further enhanced pressure transfer from the forefoot to the heel. With orthotic insoles and arch support insoles, there were differences in the role played by the structure: the mid-foot torsional support adjusted the foot posture and also took over the pressure transfer from the forefoot; the fore-and-aft height difference further contributed to the concentration from the forefoot and toe area to the heel area.

DISCUSSION

In this study, firstly, a customized insole design method based on the plantar surface was developed and custom-made insoles were made for ten healthy adults; then the ability of pressure redistribution of four insoles were assessed by the plantar pressure measure and pressure transfer algorithm; finally, the insoles was quantified using a pressure transfer algorithm to characterize the plantar pressure transfer, which not only bridged the anterior and posterior region, but also they apparently reduced load under MTH. Overall performance was similar but superior to that of professional orthotic insoles.

The present study served to reduce mid-foot pressure in terms of arch support. Song *et al.* [18] exhibited that the use of insoles with arch support reduced peak pressure and impact forces in the MTH and heel, and that peak forces of ground reaction were also reduced; Cheng *et al.* [19] conducted a crossover experiment with ten patients with flat feet and showed that the arch support structure significantly increased peak ankle dorsiflexion and peak pressure in the medial mid-foot region, while peak pressure in the heel region was significantly reduced; Abu-Faraj *et al.* [20] showed a significant increase in lateral peak pressure on the plantar aspect of the foot and a significant decrease in peak pressure in the toe and heel regions after the application of arch support. Our result is similar with these reports, but the orthotic insole in the present study did not reduce the pressure in the heel region, which may be related to the custom-made insole metatarsal pad and the 6 mm anterior-posterior height difference in the present study. In addition, the length and height of the arch support are also important factors affecting the plantar pressure, which also provides ideas for the improvement of the heel support structure.

Metatarsal pads usually distribute forefoot pressure and reduce pressure in the metatarsal area. Burgess *et al.* [21] indicated that metatarsal pads shift the peak plantar pressure from the medial forefoot to the lateral forefoot while reducing the peak plantar pressure; Baur *et al.* [22] found that the use of metatarsal pads or cushion pads can

achieve a reduction in peak forefoot pressure and that metatarsal pads can lead to an increase in mid-foot pressure; Chen *et al.* [23] demonstrated that the position of the metatarsal pad directly influenced the effect of pressure distribution, with the best results when the center of the toe pad was positioned 20 mm from the anterior point of the second metatarsal head and 6.5 mm or 13 mm from the anterior point of the second metatarsal head, which would lead to foot tissue damage. These reports are consistent with the findings of this paper that when the metatarsal pad is in the correct position, it can redistribute plantar pressure and transfer the pressure load under the metatarsal region to adjacent areas; however, due to insufficient thickness or improperly low position of the metatarsal pad, the pressure under the metatarsal region may not be reduced, and the proper position and size of the toe pad is important for successful pressure relief under the MH, which explains the importance of customized insoles.

In terms of anterior-posterior height difference, it mainly plays the role of pressure transfer. Shim *et al.* [24] showed that anterior-posterior height difference significantly increased plantar pressure in the metatarsal region and mid-foot region, but there was no significant difference in pressure between foot regions; Zhang *et al.* [25] indicated that after elevating the heel height, the peak pressure in the rear foot decreased, while the peak pressure in the forefoot and mid-foot regions did not increase, indicating an improved plantar pressure distribution. These reports and the results of this study are consistent, but the performance of each insole in this study is consistent, because the anterior-posterior height difference of the customized insole in this study is only 6 mm, and the main role is to cooperate with other structures of the insole to play the role of pressure transfer, while playing a secondary role for the redistribution of plantar pressure. And the study by Koenraadt *et al.* [26] indicated that metatarsal pads produce an increase in the width of the forefoot and an increase in the height of the second metatarsal head, which makes the critical part of the sole of the foot mainly affected by other insole structures in this study.

Our above finding approved the hypothesis, where an optimal pressure redistribution anterior and posterior foot pressure transfer, medial and lateral, as well as better forefoot pressure relief were obtained. However, limitations of this study include the small sample size, the study parameters were only analyzed based on plantar pressure, and the structure of the customized insoles was in a combined form that could not be analyzed against other insoles with a single variable. Future studies should use a larger sample size or even invite patients with flat feet or diabetes to perform the test in order to better analyze the effect of the insole structure; in addition, this study was tested in the walking condition, and future studies could try to analyze the pressure distribution of the customized insole in the exercise condition.

CONCLUSION

Overall, the pressure transfer model was used to insight the plantar pressure redistribution and its path of the customized insole which designed following the foot plantar surface, meanwhile reasonable and accurate insole structure design made our approach function similarly but superior to the professional prefabricated orthotic insole. Therefore, our strategy in custom-design insole would be further utilized orthotic or pressure relieving scenario, such as diabetic patients who need the accurate structure design.

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